Good Microbiological and Aseptic Technique

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BIO

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Patrick Conley is a Senior Scientist within the Science and Technology division of Merrick and Company. In his role, Patrick is the primary healthcare liaison for Merrick's healthcare services platform designed to assist healthcare institutions manage the environment care, hazardous materials and waste, hazardous drugs and hazardous biologics, and infection prevention services, as well as to support clinical laboratories and therapeutic productions facilities operate at their best.

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Abstract

The intent of this presentation is to engage the audience in a discussion on the matters of aseptic technique and good microbiological practices in the healthcare setting.

Through this discussion, we will use the hierarchy of controls to demonstrate how aseptic technique is interconnected to each level of this hierarchy. As we explore this interconnection, we will discuss the application of these techniques and good microbiological practices and their importance in critical areas of the healthcare and biopharma enterprises.

Impact Statement

The development and use of techniques designed to prevent the contamination of sterile products, equipment, surfaces, and facilities is critically important to the assurance of safe and effective patient care. However, the techniques and their application do not exist in a silo and must be interconnected to other controls utilized in healthcare operations. Communication and training on these interconnection and their application in healthcare departments responsible for preparing sterile medications and equipment cannot be understated. Additionally, in the clinical laboratory, the role of aseptic technique and good microbiological practices is paramount not only to control of exposure to potential pathogens in human specimens and samples, but to the quality and accuracy of diagnostic test and data.

We must also consider that the sterility of some products, drugs, biologics, and sealed disposables begins with the manufacturer. Once these sterile products are received in healthcare facilities, the continuity of sterility defaults to the healthcare personnel who are responsible for storing and eventually preparing these materials for use in patient care. Thus, everyone involved in the chain of custody of sterile products must understand the important of asepsis, hygiene, and the practices encompassing both of these terms.

Learning Objectives

After attending this presentation, learners will be able to:

- Define aseptic techniques and good laboratory practices
- Describe the hierarchy of controls and their utility in healthcare
- Recognize the interconnections between these controls and aseptic technique
- Evaluate healthcare areas where these interconnections are critically important
- Identify healthcare personnel who have a role in the continuity of sterility and clean products, equipment, facilities, and practices
- Apply this knowledge through infection control outreach and education.

Discussion Topics

- Cover pertinent term and definitions
- Review the hierarchy of controls
- Establish the interconnection of the hierarchy of controls and aseptic techniques
- Identify and evaluate healthcare areas where this interconnection is important
- Discuss the role healthcare personnel play in maintaining this interconnection
- Apply this interconnection through healthcare operations

Pertinent Terms and Definitions

- Asepsis is defined as the process for keeping away disease-producing microorganisms. It is implemented to protect the patient by minimizing contamination to reduce the risk for infection.[2]

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- Hand hygiene refers to a variety of practices aimed at reducing the microbial flora on the hands. Examples include hand washing, antiseptic hand wash, antiseptic hand rub, or surgical hand antisepsis, maintenance of skin condition and fingernails, and wearing of jewerly.[2]

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- An antiseptic agent is defined as a antimicrobial substance applied to the skin to reduce the number of microbial flora.[2]

Pertinent Terms and Definitions

- Clean technique is a set of practices to reduce the overall number of microorganisms present and to minimize the risk of transmission from the environment or health care personnel to the patient. In clean technique, hand hygiene is performed, and clean (rather than sterile) gloves are used. Efforts are made to prevent direct contamination of supplies and materials. Routine cleaning of the patient's environment is done. **Clean technique does not eliminate all microorganisms or spores.**[1]

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- Aseptic technique refers to practices designed to render and maintain objects and areas maximally free from microorganisms and aid in the prevention of surgical site, urinary tract, bloodstream, and pneumonia infections that may be device- or procedure-related, including those associated with intravascular devices, urinary catheters, and indwelling drains or devices.[2]

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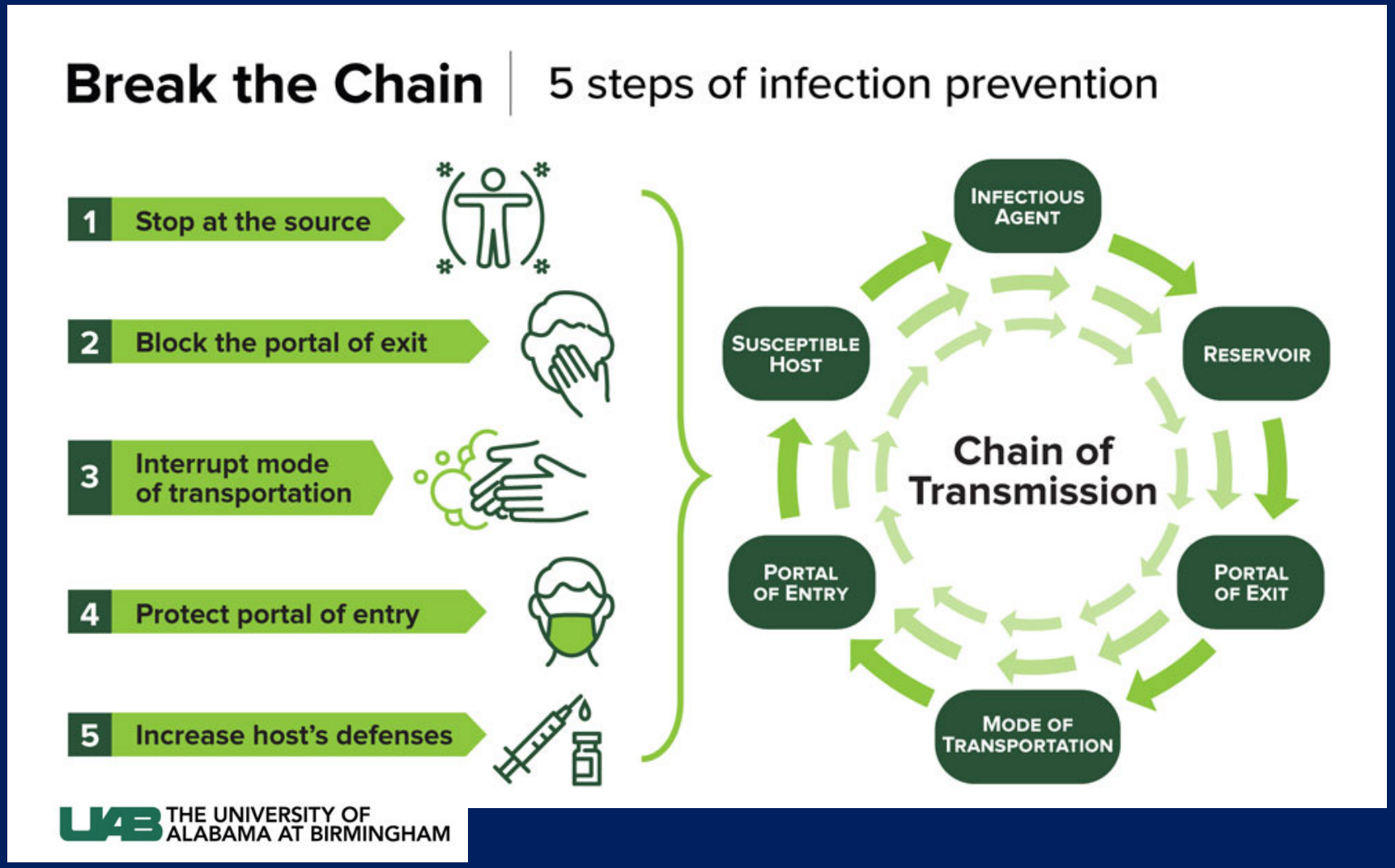
- Sterile technique, is used to prevent the transfer of any microorganism, regardless of whether it can cause disease. Sterile technique requires surgical scrub hand washing, which involves using antimicrobial soap on the hands and forearms for a longer period of time.

Pertinent Terms and Definitions

Aseptic Technique



Pertinent Terms and Definitions

Aseptic Technique

- Protects patients from getting healthcare-associated infections. It also protects patients from their own microorganisms that could cause infection.

- Protects healthcare worker from contact with blood, body fluids, and body tissue.

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- Protects healthcare worker from contact with blood, body fluids, and body tissue.
- Protects diagnostic quality and accuracy.
- Protects critical research by ensuring clean to sterile surfaces for prepping and manipulating cultures.

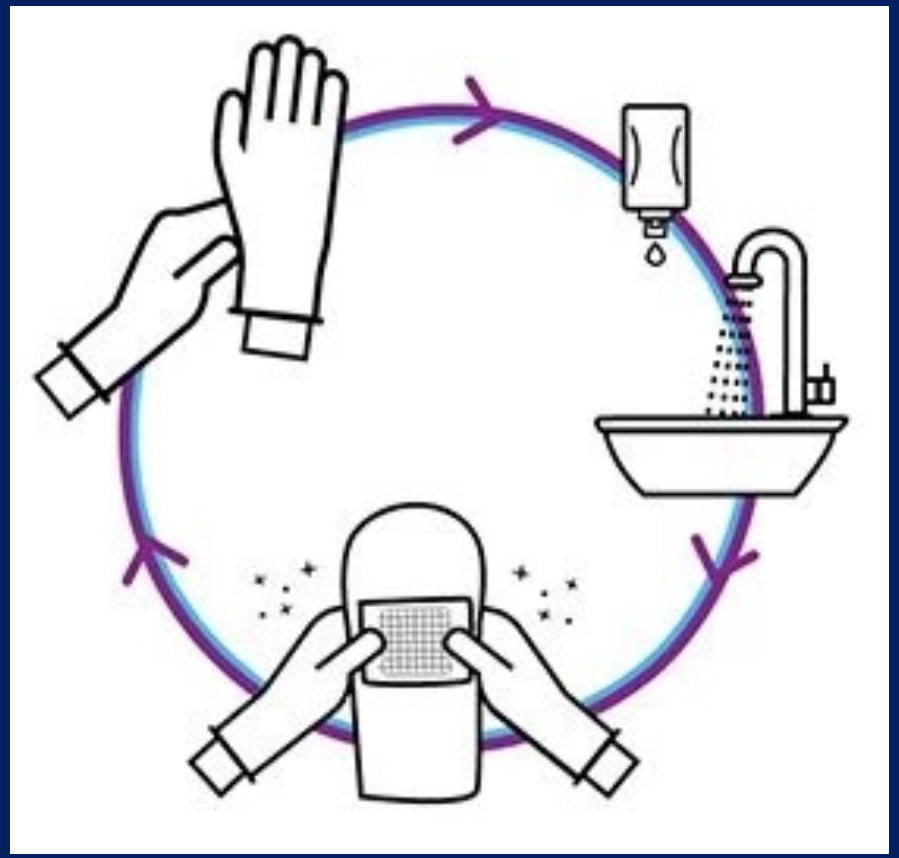
Pertinent Terms and Definitions

What are the common practices:

- Using barriers: Sterile gloves, gowns, drapes, and masks are used to prevent the transfer of microorganisms from the environment and healthcare personnel to the patient.

- Maintaining a sterile field: Equipment and key parts used for aseptic procedures are kept sterile.

- Practicing good hand hygiene: Healthcare workers should practice appropriate hand hygiene.



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What are the common practices:

- Disposing of contaminated waste: Contaminated waste should be disposed of appropriately.
- Environmental control: Healthcare providers should ensure there are no environmental risks to the procedure, such as open windows, bedside curtains, or nearby air conditioners.
- Aseptic technique also involves developing manual dexterity and mental dexterity.

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  - Set of basic practices in the laboratory to prevent the contamination of surfaces, equipment, and cultures.

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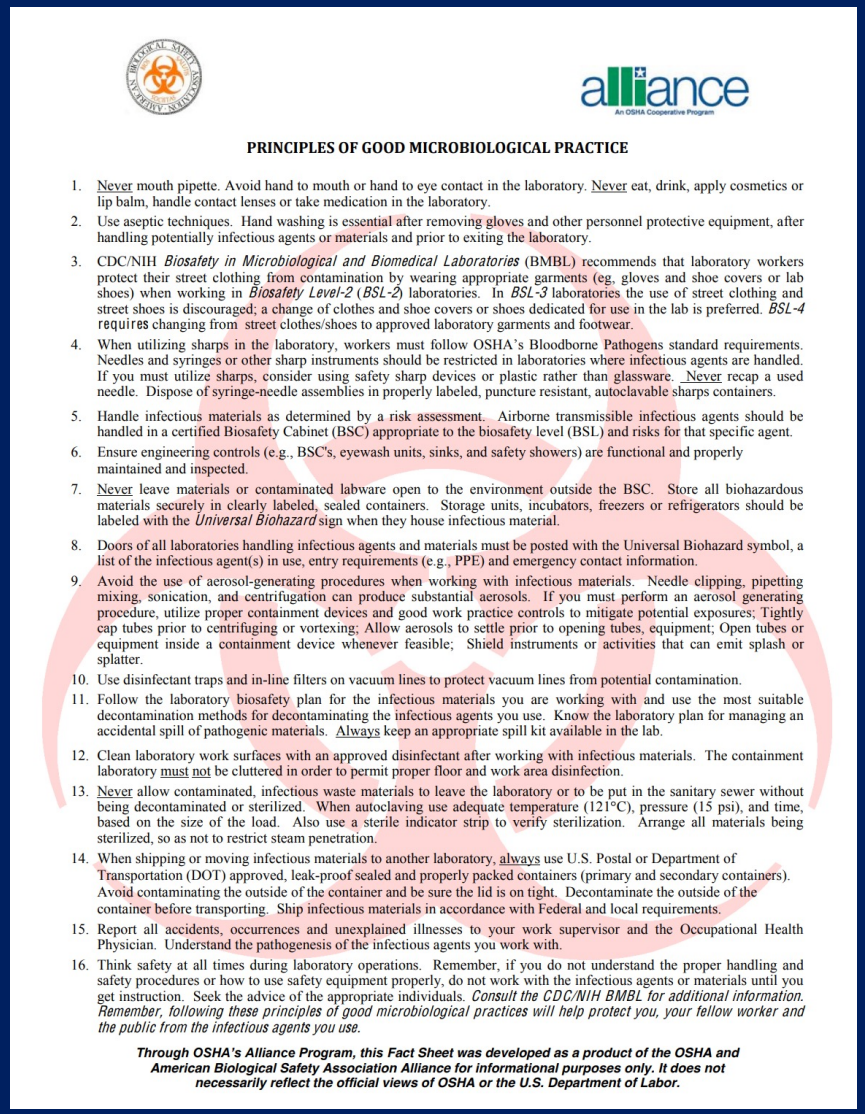
  - Set of techniques designed to control and contain the manipulation of microorganisms to prevent exposure to these biological agents.



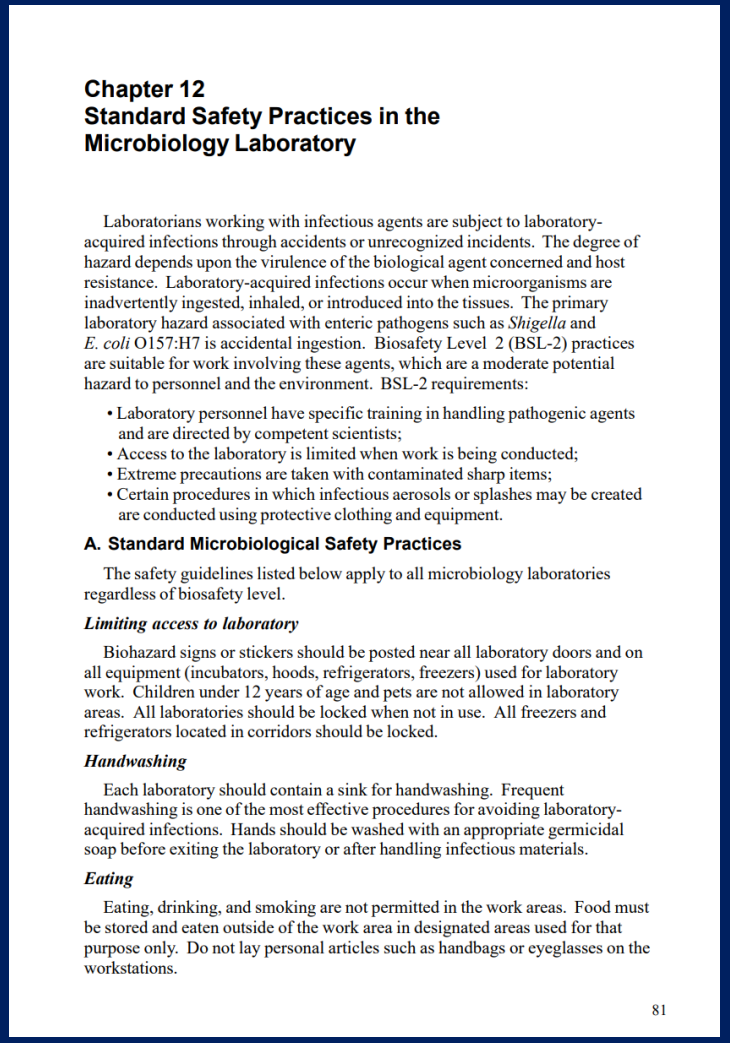
PRINCIPLES OF GOOD MICROBIOLOGICAL PRACTICE

1. Never mouth pipette. Avoid hand to mouth or hand to eye contact in the laboratory. Never eat, drink, apply cosmetics or lip balm, handle contact lenses or take medication in the laboratory.
2. Use aseptic techniques. Hand washing is essential after removing gloves and other personnel protective equipment, after handling potentially infectious agents or materials and prior to exiting the laboratory.
3. CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) recommends that laboratory workers protect their street clothing from contamination by wearing appropriate garments (eg, gloves and shoe covers or lab shoes) when working in *Biosafety Level-2* (*BSL-2*) laboratories. In *BSL-3* laboratories the use of street clothing and street shoes is discouraged; a change of clothes and shoe covers or shoes dedicated for use in the lab is preferred. *BSL-4* requires changing from street clothes/shoes to approved laboratory garments and footwear.
4. When utilizing sharps in the laboratory, workers must follow OSHA's Bloodborne Pathogens standard requirements. Needles and syringes or other sharp instruments should be restricted in laboratories where infectious agents are handled. If you must utilize sharps, consider using safety sharp devices or plastic rather than glassware. Never recap a used needle. Dispose of syringe-needle assemblies in properly labeled, puncture resistant, autoclavable sharps containers.
5. Handle infectious materials as determined by a risk assessment. Airborne transmissible infectious agents should be handled in a certified Biosafety Cabinet (BSC) appropriate to the biosafety level (BSL) and risks for that specific agent.
6. Ensure engineering controls (e.g., BSC's, eyewash units, sinks, and safety showers) are functional and properly maintained and inspected.
7. Never leave materials or contaminated labware open to the environment outside the BSC. Store all biohazardous materials securely in clearly labeled, sealed containers. Storage units, incubators, freezers or refrigerators should be labeled with the *Universal Biohazard* sign when they house infectious material.
8. Doors of all laboratories handling infectious agents and materials must be posted with the Universal Biohazard symbol, a list of the infectious agent(s) in use, entry requirements (e.g., PPE) and emergency contact information.
9. Avoid the use of aerosol-generating procedures when working with infectious materials. Needle clipping, pipetting mixing, sonication, and centrifugation can produce substantial aerosols. If you must perform an aerosol generating procedure, utilize proper containment devices and good work practice controls to mitigate potential exposures; Tightly cap tubes prior to centrifuging or vortexing; Allow aerosols to settle prior to opening tubes, equipment; Open tubes or equipment inside a containment device whenever feasible; Shield instruments or activities that can emit splash or splatter.
10. Use disinfectant traps and in-line filters on vacuum lines to protect vacuum lines from potential contamination.
11. Follow the laboratory biosafety plan for the infectious materials you are working with and use the most suitable decontamination methods for decontaminating the infectious agents you use. Know the laboratory plan for managing an accidental spill of pathogenic materials. Always keep an appropriate spill kit available in the lab.
12. Clean laboratory work surfaces with an approved disinfectant after working with infectious materials. The containment laboratory must not be cluttered in order to permit proper floor and work area disinfection.
13. Never allow contaminated, infectious waste materials to leave the laboratory or to be put in the sanitary sewer without being decontaminated or sterilized. When autoclaving use adequate temperature (121°C), pressure (15 psi), and time, based on the size of the load. Also use a sterile indicator strip to verify sterilization. Arrange all materials being sterilized, so as not to restrict steam penetration.
14. When shipping or moving infectious materials to another laboratory, always use U.S. Postal or Department of Transportation (DOT) approved, leak-proof sealed and properly packed containers (primary and secondary containers). Avoid contaminating the outside of the container and be sure the lid is on tight. Decontaminate the outside of the container before transporting. Ship infectious materials in accordance with Federal and local requirements.
15. Report all accidents, occurrences and unexplained illnesses to your work supervisor and the Occupational Health Physician. Understand the pathogenesis of the infectious agents you work with.
16. Think safety at all times during laboratory operations. Remember, if you do not understand the proper handling and safety procedures or how to use safety equipment properly, do not work with the infectious agents or materials until you get instruction. Seek the advice of the appropriate individuals. *Consult the CDC/NIH BMBL for additional information. Remember, following these principles of good microbiological practices will help protect you, your fellow worker and the public from the infectious agents you use.*

Through OSHA's Alliance Program, this Fact Sheet was developed as a product of the OSHA and American Biological Safety Association Alliance for informational purposes only. It does not necessarily reflect the official views of OSHA or the U.S. Department of Labor.

Pertinent Terms and Definitions

- Good Microbiological Practices and Procedures:
  - Set of basic practices in the laboratory to prevent the contamination of surfaces, equipment, and cultures.
  - Set of techniques designed to control and contain the manipulation of microorganisms to prevent exposure to these biological agents.
  - The equipment utilized to separate the user from infectious agent



Chapter 12
Standard Safety Practices in the Microbiology Laboratory

Laboratorians working with infectious agents are subject to laboratory-acquired infections through accidents or unrecognized incidents. The degree of hazard depends upon the virulence of the biological agent concerned and host resistance. Laboratory-acquired infections occur when microorganisms are inadvertently ingested, inhaled, or introduced into the tissues. The primary laboratory hazard associated with enteric pathogens such as *Shigella* and *E. coli* O157:H7 is accidental ingestion. Biosafety Level 2 (BSL-2) practices are suitable for work involving these agents, which are a moderate potential hazard to personnel and the environment. BSL-2 requirements:

- Laboratory personnel have specific training in handling pathogenic agents and are directed by competent scientists;
- Access to the laboratory is limited when work is being conducted;
- Extreme precautions are taken with contaminated sharp items;
- Certain procedures in which infectious aerosols or splashes may be created are conducted using protective clothing and equipment.

A. Standard Microbiological Safety Practices

The safety guidelines listed below apply to all microbiology laboratories regardless of biosafety level.

Limiting access to laboratory

Biohazard signs or stickers should be posted near all laboratory doors and on all equipment (incubators, hoods, refrigerators, freezers) used for laboratory work. Children under 12 years of age and pets are not allowed in laboratory areas. All laboratories should be locked when not in use. All freezers and refrigerators located in corridors should be locked.

Handwashing

Each laboratory should contain a sink for handwashing. Frequent handwashing is one of the most effective procedures for avoiding laboratory-acquired infections. Hands should be washed with an appropriate germicidal soap before exiting the laboratory or after handling infectious materials.

Eating

Eating, drinking, and smoking are not permitted in the work areas. Food must be stored and eaten outside of the work area in designated areas used for that purpose only. Do not lay personal articles such as handbags or eyeglasses on the workstations.

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  - Set of techniques designed to control and contain the manipulation of microorganisms to prevent exposure to these biological agents.
  - The equipment utilized to separate the user from infectious agent
  - Barriers used to protect pertinent routes of exposure

CHAPTER

LABORATORY BIOSAFETY AND GOOD LABORATORY PRACTICES

11

Risk comes from not knowing what you're doing.
-Warren Buffett, American business magnate, investor, philanthropist.

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Paul Berg opening a jar under a protective hood.

Photo courtesy: Stanford University Archives.

An Introduction to Ethical, Safety and Intellectual Property Rights Issues in Biotechnology.
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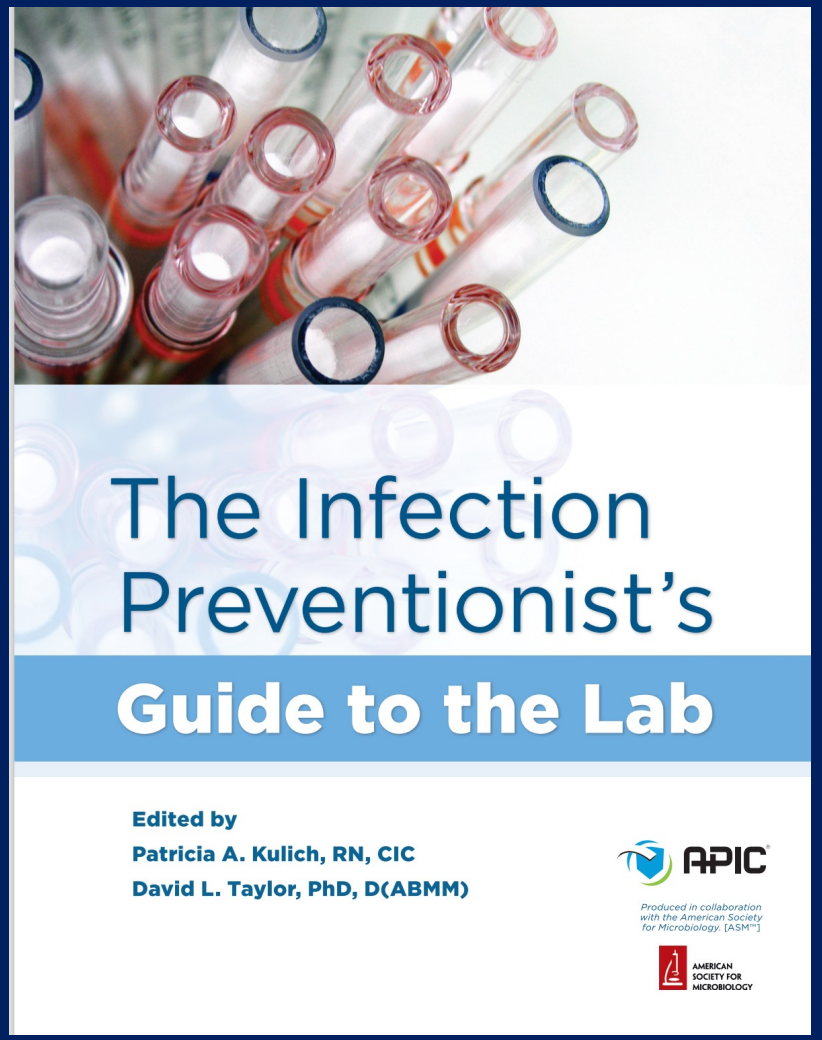
  - Laboratory hygiene designed to prevent contamination of clothing and the skin



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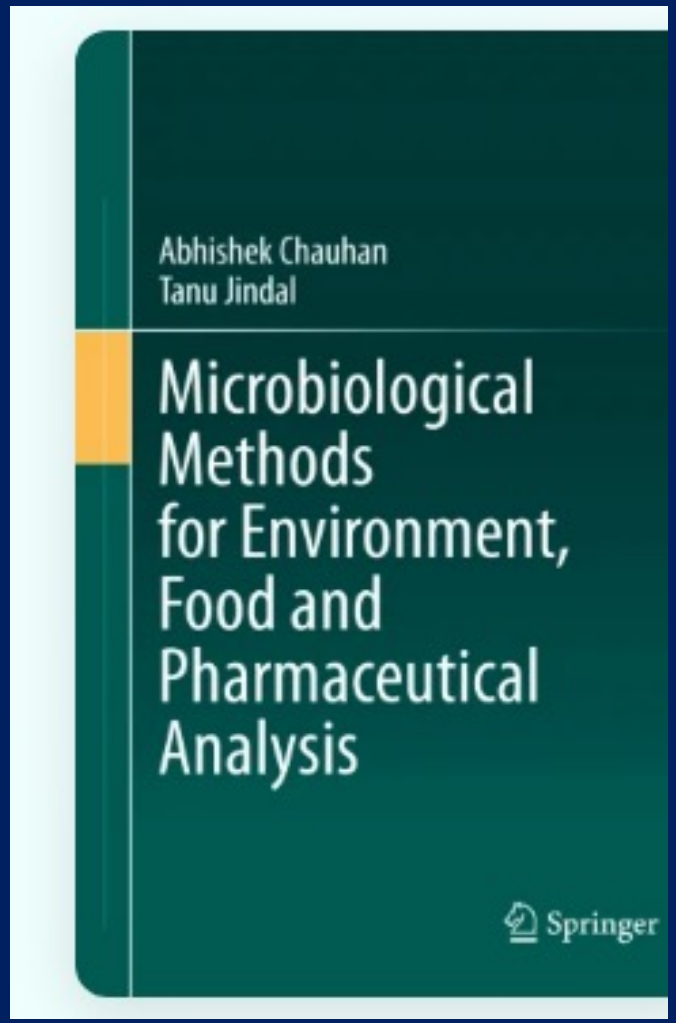
  - The equipment utilized to separate the user from infectious agent
  - Barriers used to protect pertinent routes of exposure
  - Laboratory hygiene designed to prevent contamination of clothing and the skin
  - Personal hygiene practices designed to remove biological burdens on the skin as a standard practice, when exposure occurs or is suspected.



Pertinent Terms and Definitions

Good Microbiological Practices and Procedures:

1. When in the lab, don't touch your face
2. Don't eat or drink in the lab
3. Use aseptic techniques, use PPE, and always use good hygiene practices, wash your dang hands
4. Good sharps practices
5. Do a risk assessment/job hazard analysis for all laboratory task involving hazards.
6. If you anticipate aerosol generation (vortexing, pipetting, sonication, centrifugation), use a functional BSC
7. **Don't pop your tubes open**
8. Label and put away your work in the required areas.
9. If infectious materials are used, Warning Postings on doors is required

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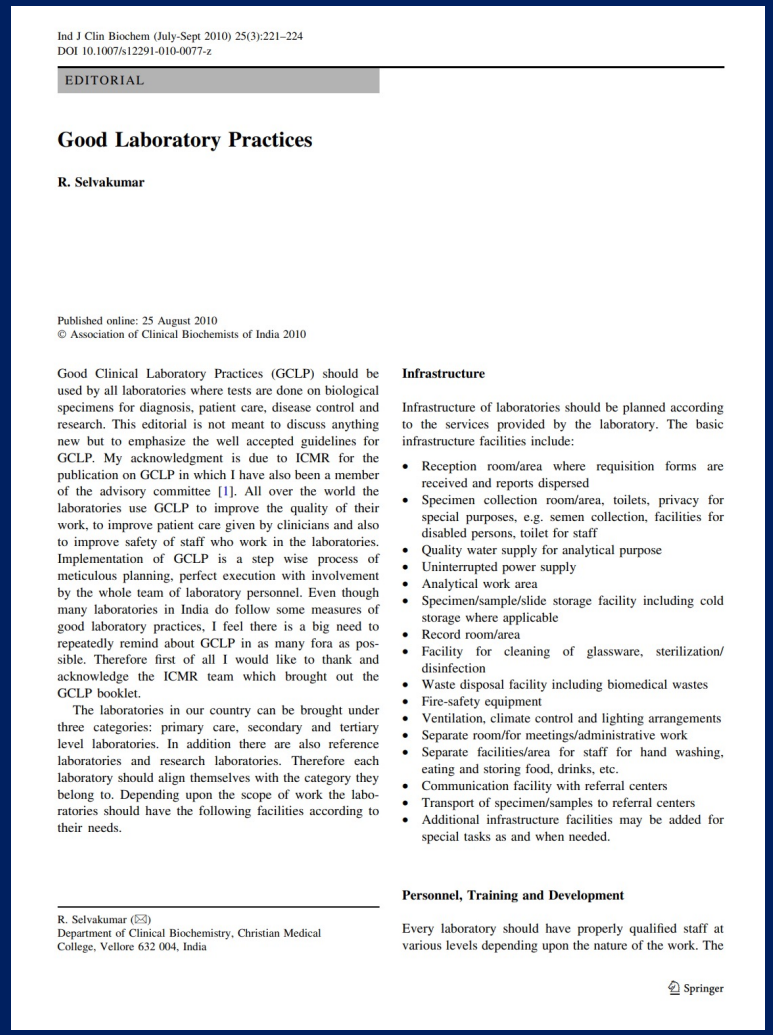
7. **Don't pop your tubes open**
8. Label and put away your work in the required areas.
9. If infectious materials are used, Warning Postings on doors is required
10. Identify the right disinfectant for the agents you are using, decontamination often, and ensure surfaces are fully decontaminated when you are done.
11. Have a plan and kits for spills and exposures.
12. Organize your laboratory and make cleaning and laboratory hygiene a uniform responsibility
13. Make sure all waste containers are covered when not in use.
14. Follow all policies on waste segregation, storage, and disposal.
15. Develop and follow hazard and infectious substances transport procedures to include using triple containment packaging.
16. Encourage reporting of all incidents and near misses and ensure exposures and injuries are promptly addressed
17. Think Safe, Be Safe

Pertinent Terms and Definitions

- Good Clinical Laboratory Practices (GCLP)
  - Used by all laboratories where tests are done on biological specimens for diagnosis, patient care, disease control and research.
  - Includes
    - Infrastructure
    - Sample Management and Quality Control
    - Laboratory SOPs
    - Laboratory Equipment
    - Practices
    - Training and Competencies
    - Laboratory Safety



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EDITORIAL

Good Laboratory Practices

R. Selvakumar

Published online: 25 August 2010

Good Clinical Laboratory Practices (GCLP) should be used by all laboratories where tests are done on biological specimens for diagnosis, patient care, disease control and research. This editorial is not meant to discuss anything new but to emphasize the well accepted guidelines for GCLP. My acknowledgment is due to ICMR for the publication on GCLP in which I have also been a member of the advisory committee [1]. All over the world the laboratories use GCLP to improve the quality of their work, to improve patient care given by clinicians and also to improve safety of staff who work in the laboratories. Implementation of GCLP is a step wise process of meticulous planning, perfect execution with involvement by the whole team of laboratory personnel. Even though many laboratories in India do follow some measures of good laboratory practices, I feel there is a big need to repeatedly remind about GCLP in as many fora as possible. Therefore first of all I would like to thank and acknowledge the ICMR team which brought out the GCLP booklet.

The laboratories in our country can be brought under three categories: primary care, secondary and tertiary level laboratories. In addition there are also reference laboratories and research laboratories. Therefore each laboratory should align themselves with the category they belong to. Depending upon the scope of work the laboratories should have the following facilities according to their needs.

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Infrastructure

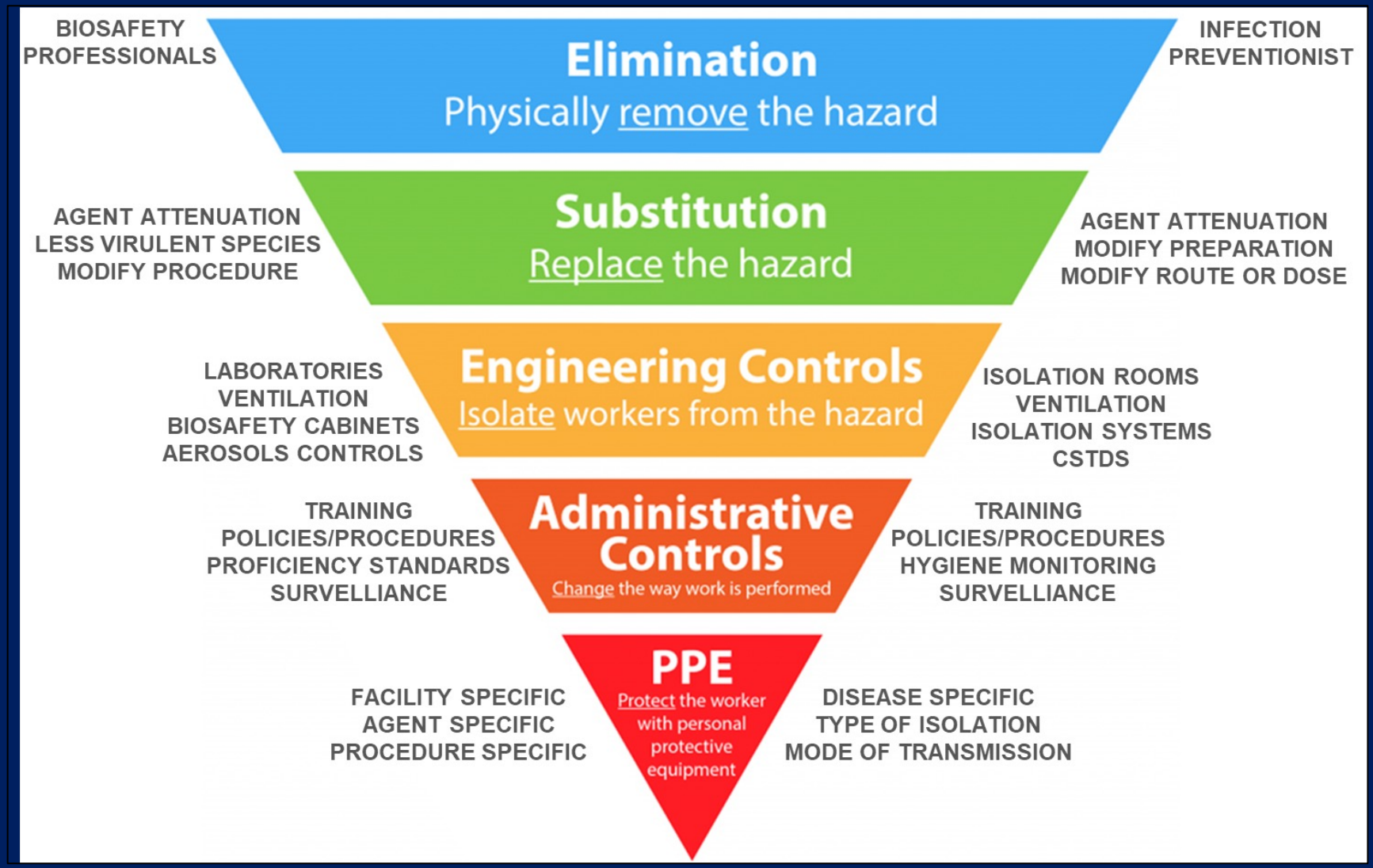
Infrastructure of laboratories should be planned according to the services provided by the laboratory. The basic infrastructure facilities include:

- Reception room/area where requisition forms are received and reports dispersed
- Specimen collection room/area, toilets, privacy for special purposes, e.g. semen collection, facilities for disabled persons, toilet for staff
- Quality water supply for analytical purpose
- Uninterrupted power supply
- Analytical work area
- Specimen/sample/slide storage facility including cold storage where applicable
- Record room/area
- Facility for cleaning of glassware, sterilization/disinfection
- Waste disposal facility including biomedical wastes
- Fire-safety equipment
- Ventilation, climate control and lighting arrangements
- Separate room/for meetings/administrative work
- Separate facilities/area for staff for hand washing, eating and storing food, drinks, etc.
- Communication facility with referral centers
- Transport of specimen/samples to referral centers
- Additional infrastructure facilities may be added for special tasks as and when needed.

Personnel, Training and Development

Every laboratory should have properly qualified staff at various levels depending upon the nature of the work. The

Hierarchy of Controls



Hierarchy of Controls

Elimination

Substitution

- **CAN’T DENY CARE**
- **Don’t know what the patient is harboring**
- **Is the patient receiving something that can be shed**

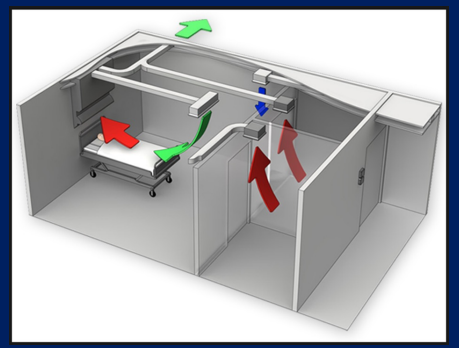
Hierarchy of Controls

Elimination
Substitution

- CAN'T DENY CARE
- Don't know what the patient is harboring
- Is the patient receiving something that can be shed

Engineering Controls

- Isolation Room
- Ventilation (HVAC and Exhaust)
- Safety Equipment (BSC)
- Laboratory Splash Guards



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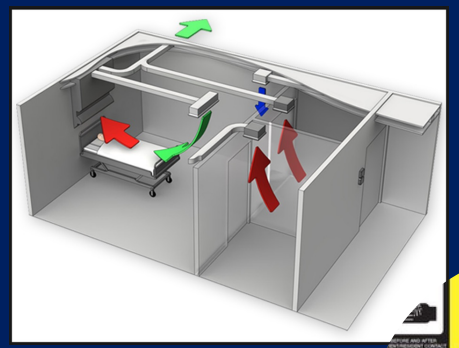

Administrative Controls

- Standard Operating Procedures
- Standard Precautions
- Transmission Precautions
- Training
- Personal Hygiene Practices

Hierarchy of Controls

Elimination
Substitution

- CAN'T DENY CARE
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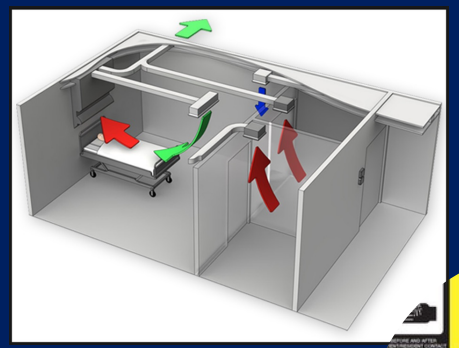


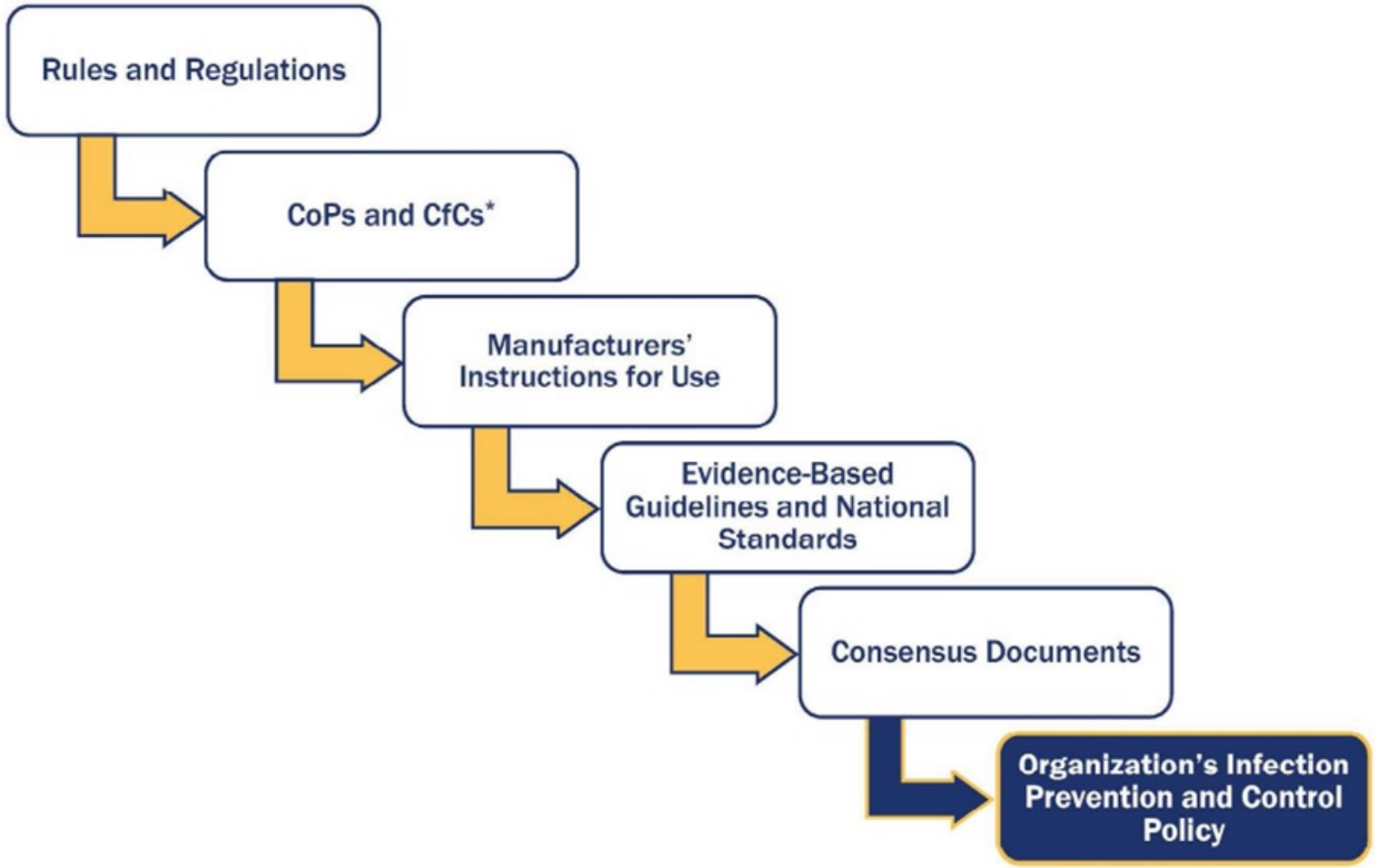
Administrative Controls

- Standard Operating Procedures
- Standard Precautions
- Transmission Precautions
- Training
- Personal Hygiene Practices

PPE

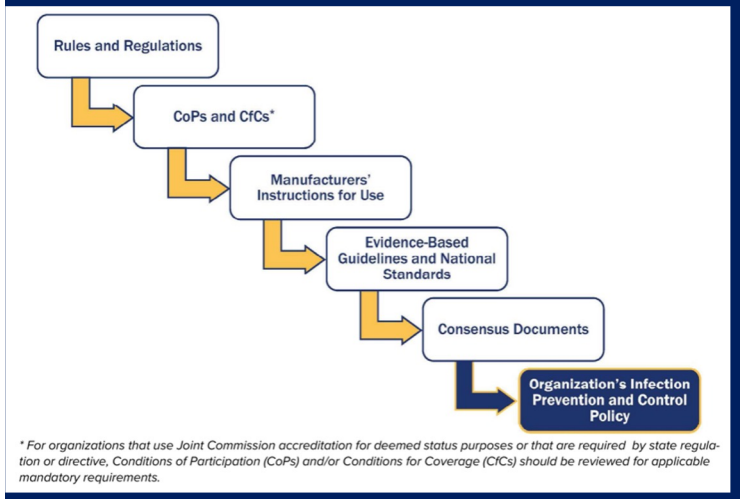
- Gloves
- Eye Protection
- Gowning
- Respirator

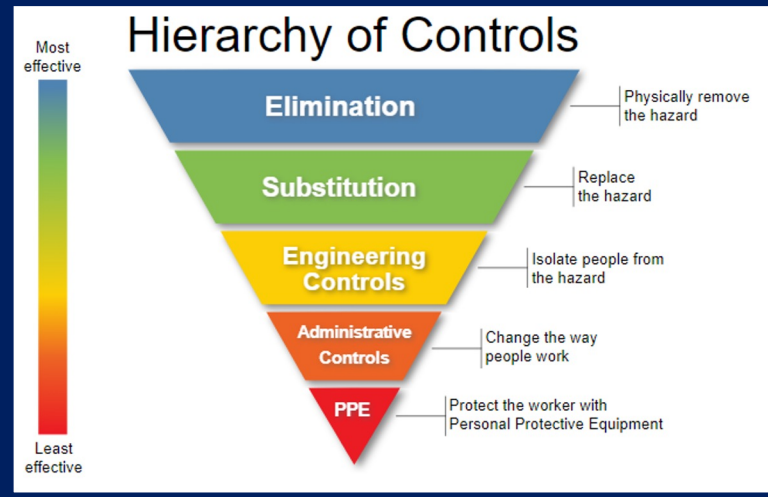
Hierarchy of Controls



** For organizations that use Joint Commission accreditation for deemed status purposes or that are required by state regulation or directive, Conditions of Participation (CoPs) and/or Conditions for Coverage (CfCs) should be reviewed for applicable mandatory requirements.*

The Interconnection





The Interconnection

The Interconnection

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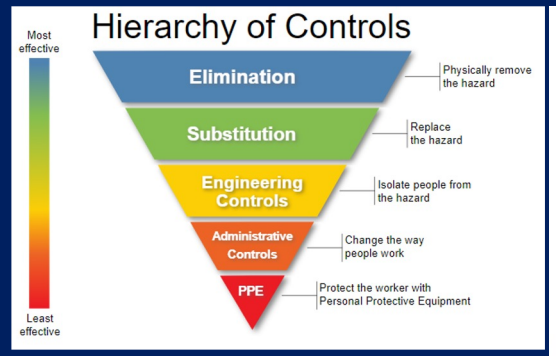

THE PROBLEM

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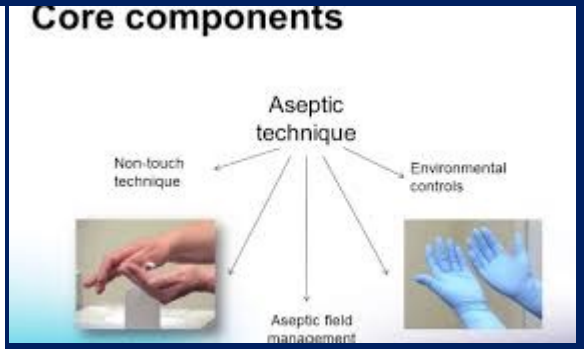

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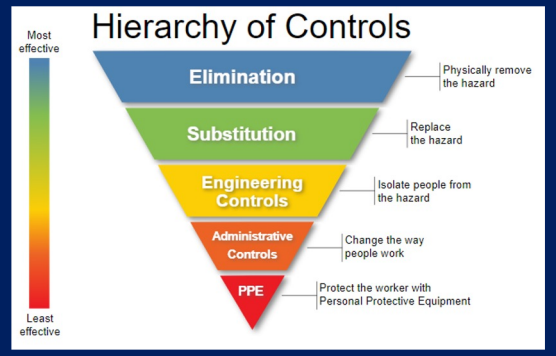

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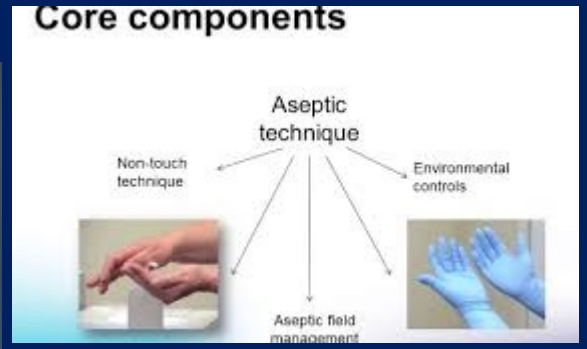

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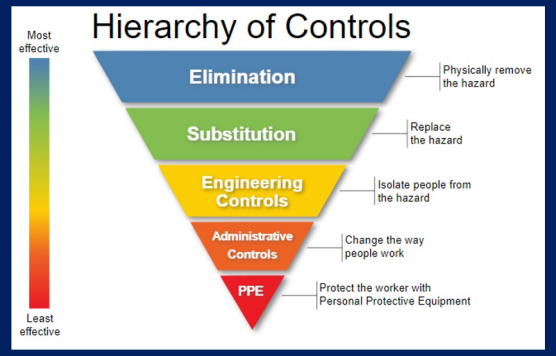

OPERATING ROOM

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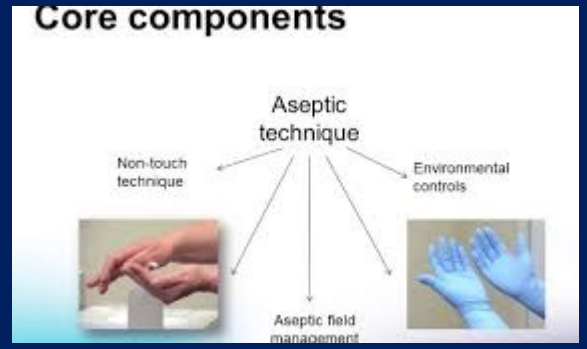

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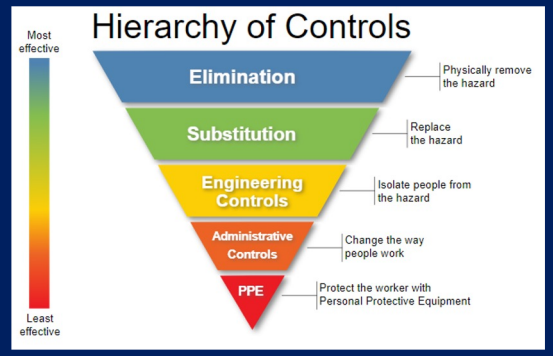

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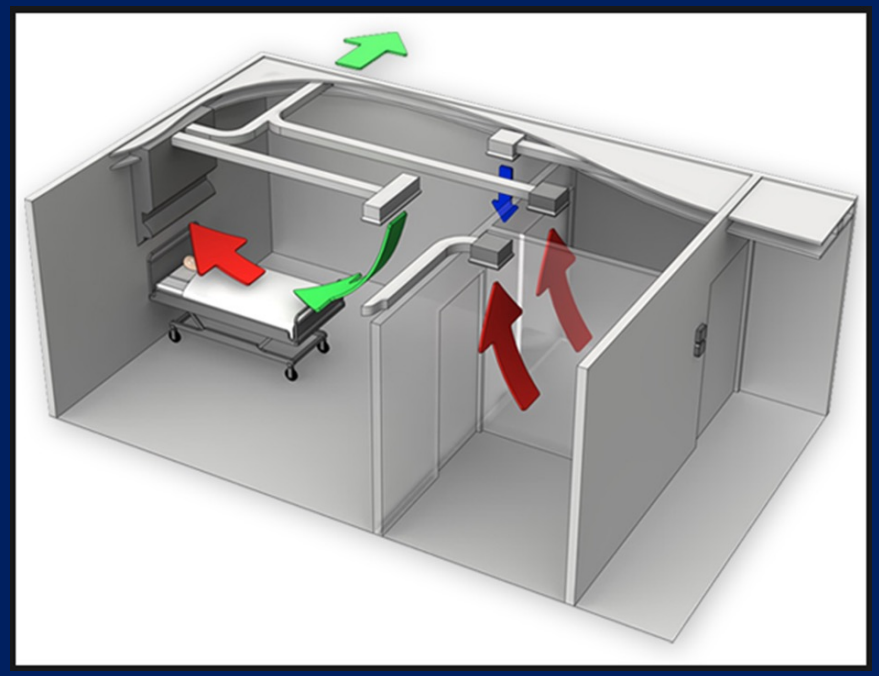

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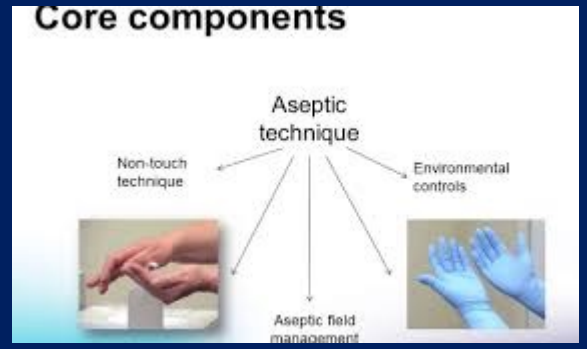

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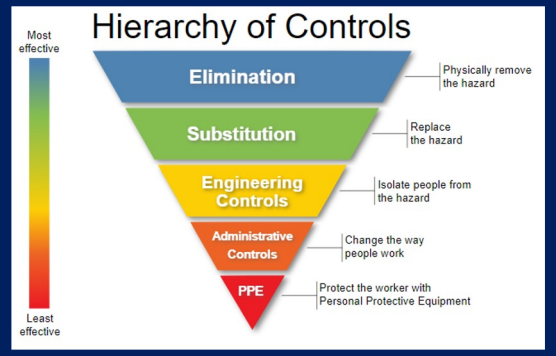
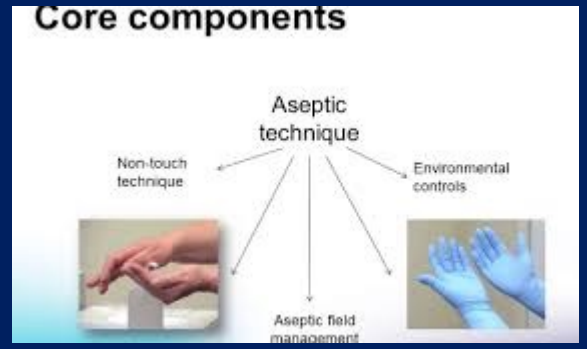


STERILE COMPOUNDING

AST and GMP



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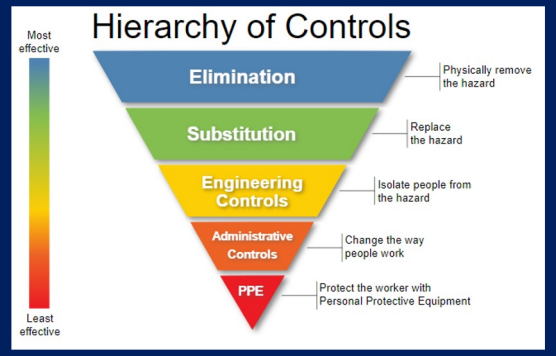
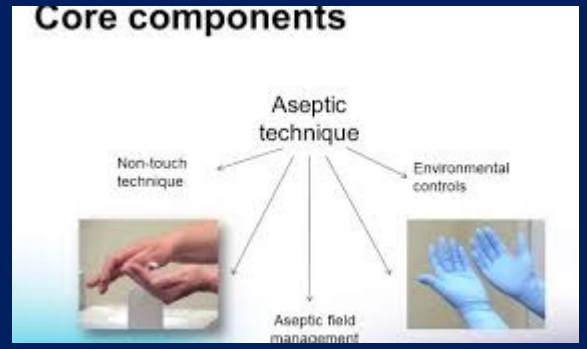


CLINICAL LABORATORY

AST and GMP



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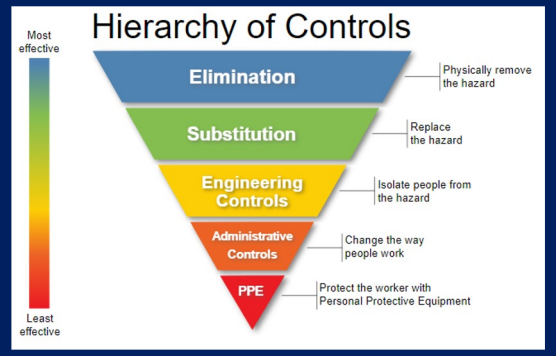
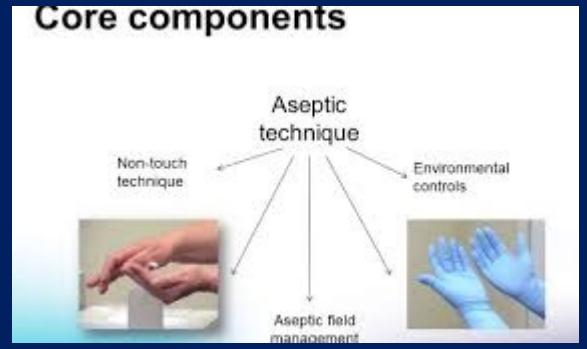


SOILED UTILITY ROOM

AST and GMP



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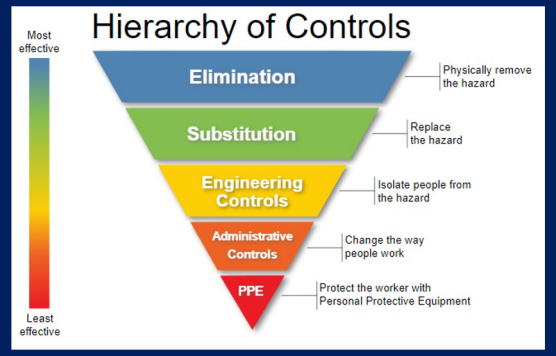

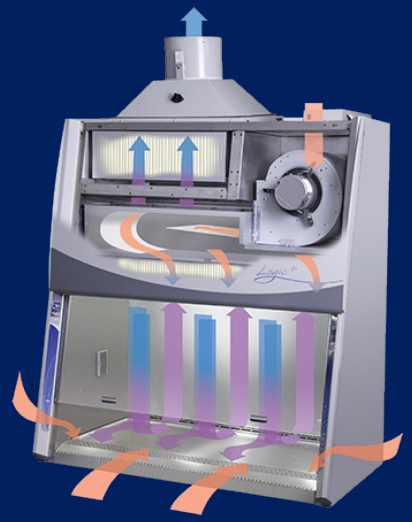

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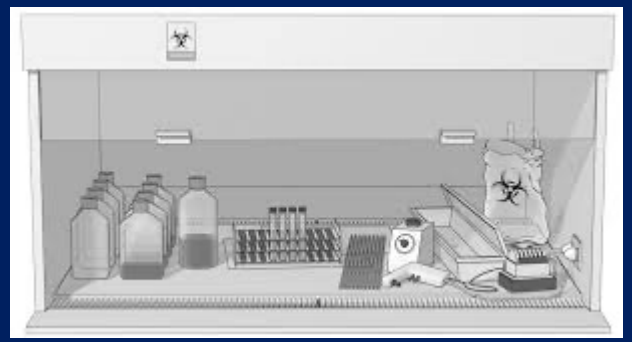

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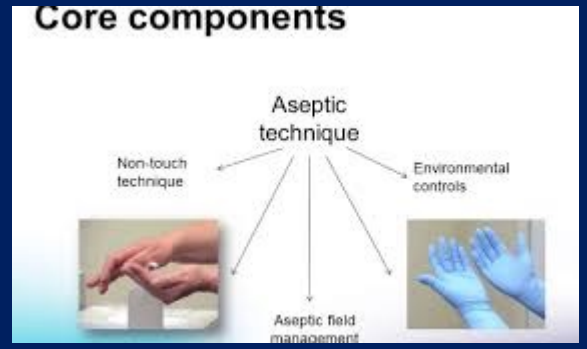

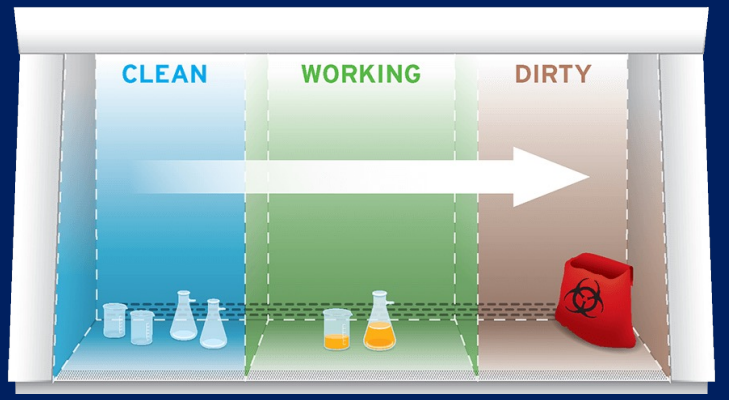

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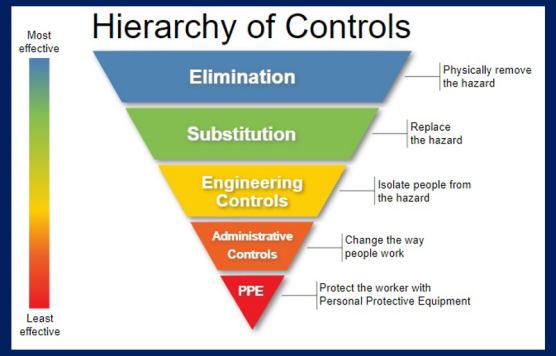

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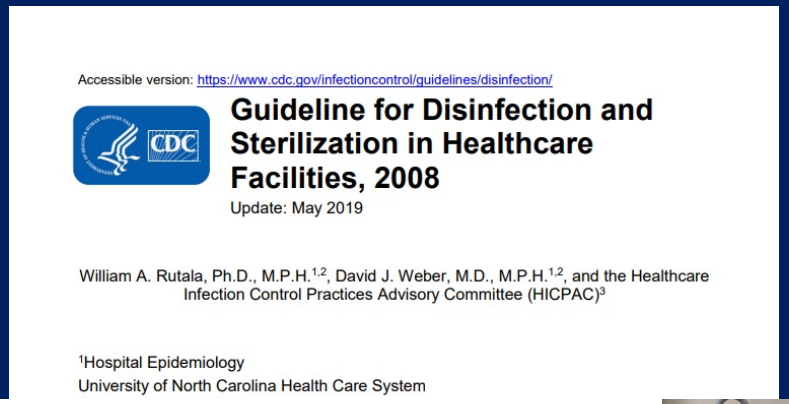


Accessible version: https://www.cdc.gov/infectioncontrol/guidelines/disinfection/

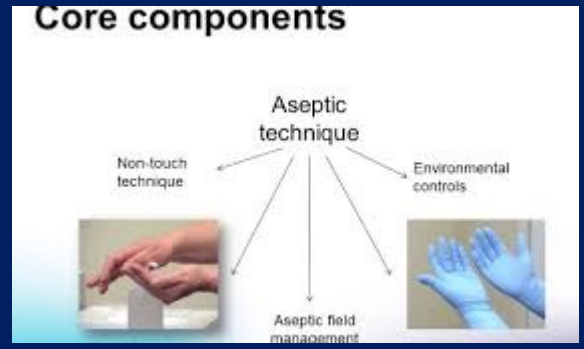
Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

Update: May 2019

William A. Rutala, Ph.D., M.P.H.[1,2], David J. Weber, M.D., M.P.H.[1,2], and the Healthcare Infection Control Practices Advisory Committee (HICPAC)[3]

[1]Hospital Epidemiology
University of North Carolina Health Care System

AST and GMP



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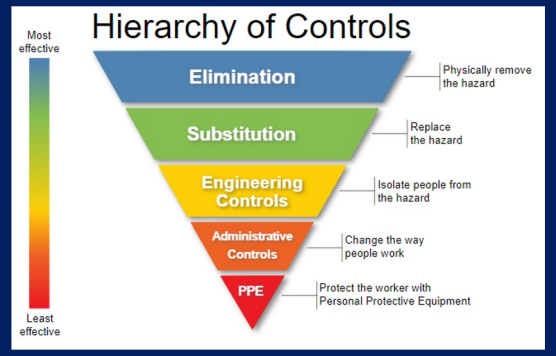

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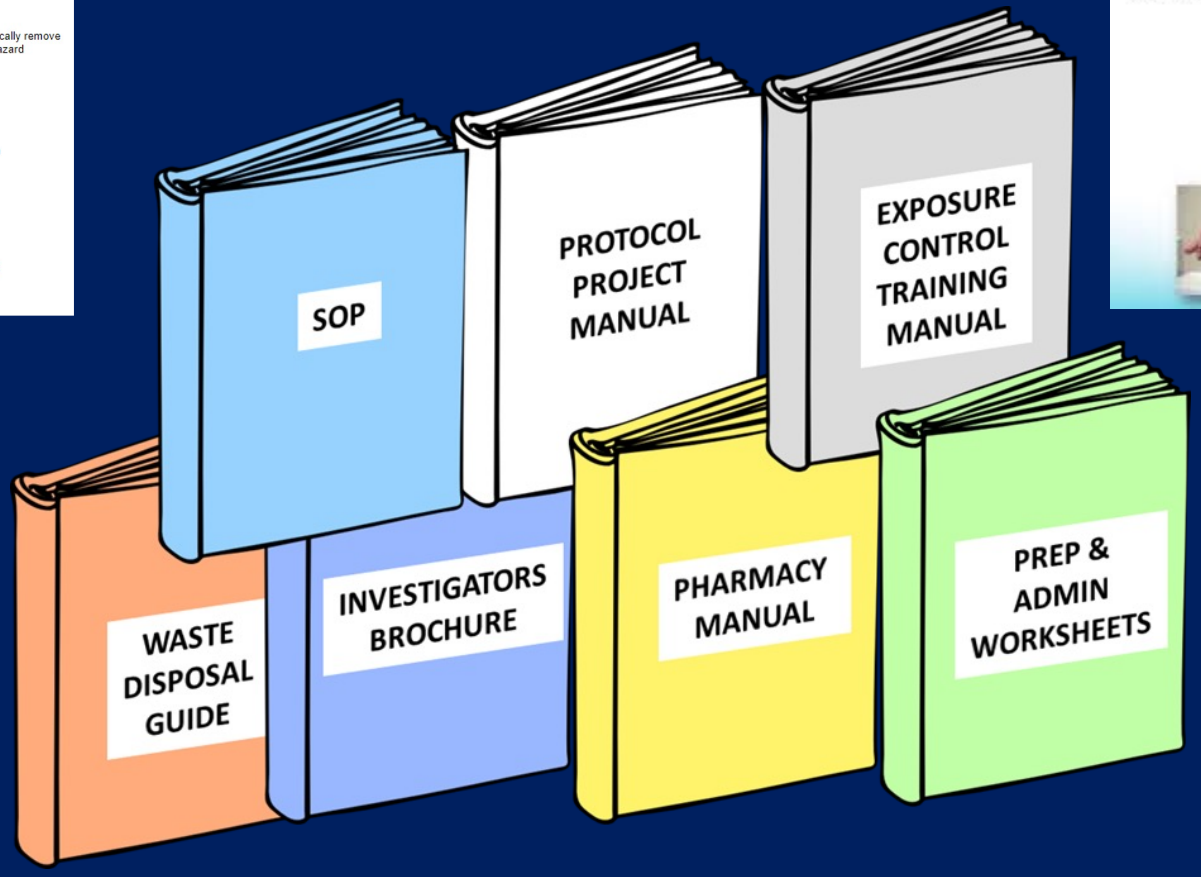

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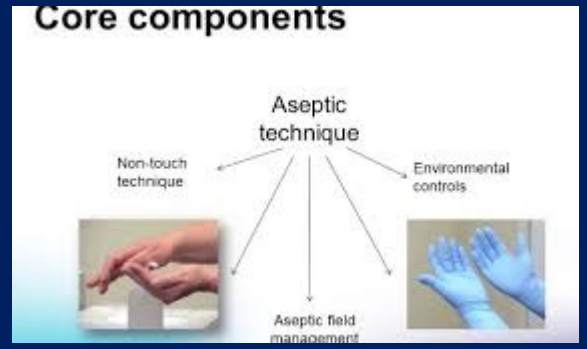

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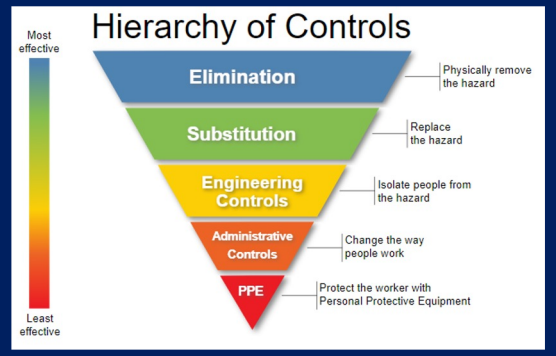

TRAINING

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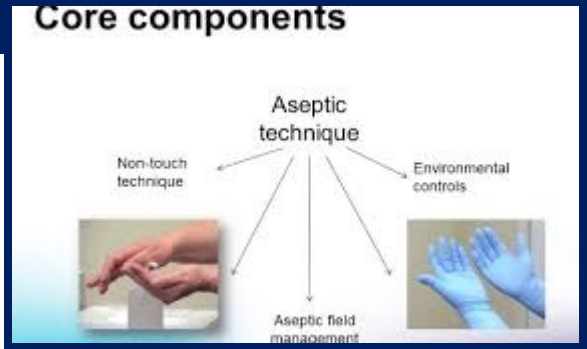

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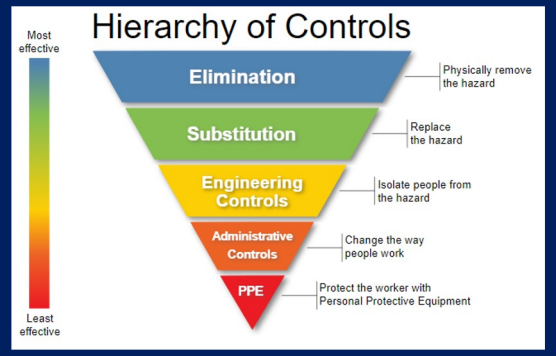
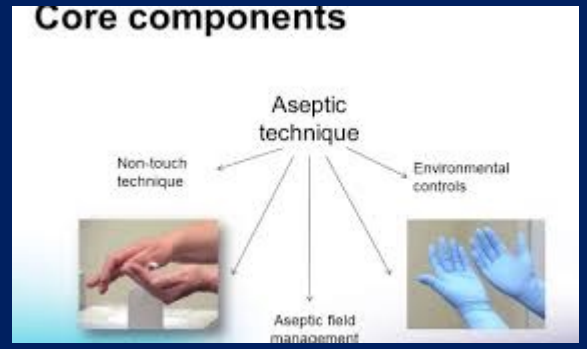


AWARENESS

AST and GMP



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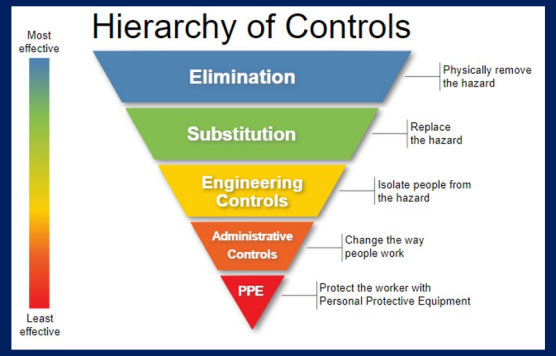
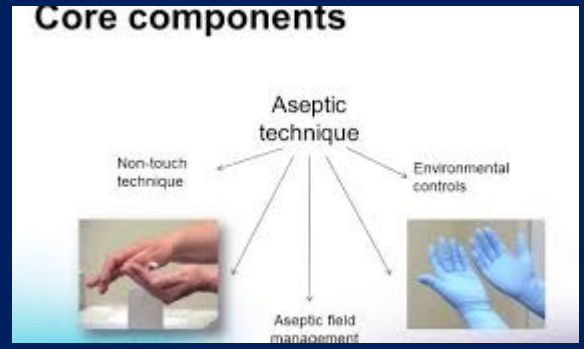


PRACTICES

AST and GMP



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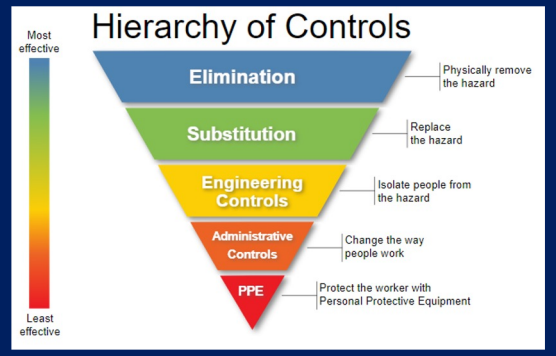

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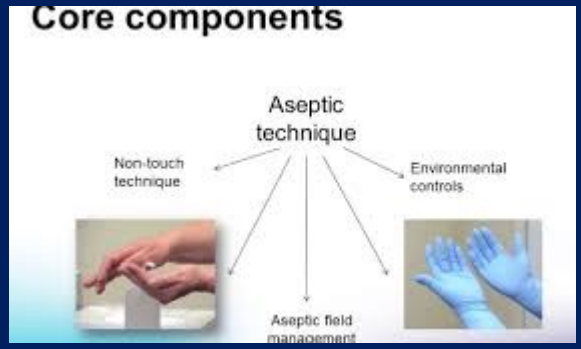

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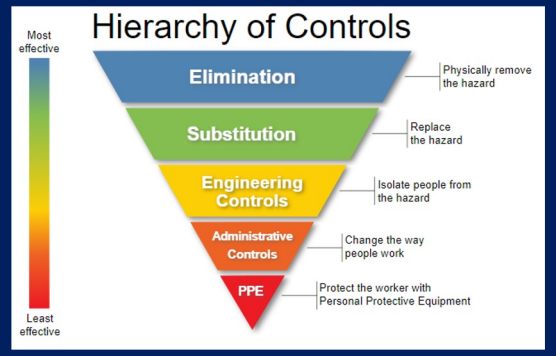

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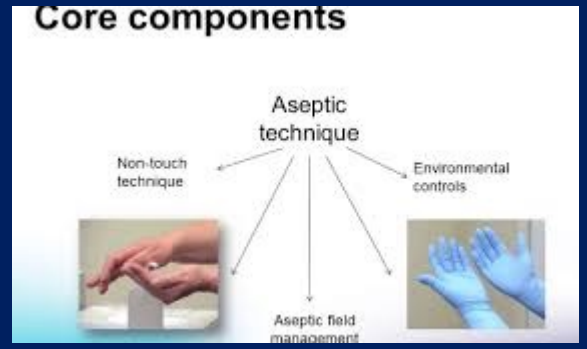

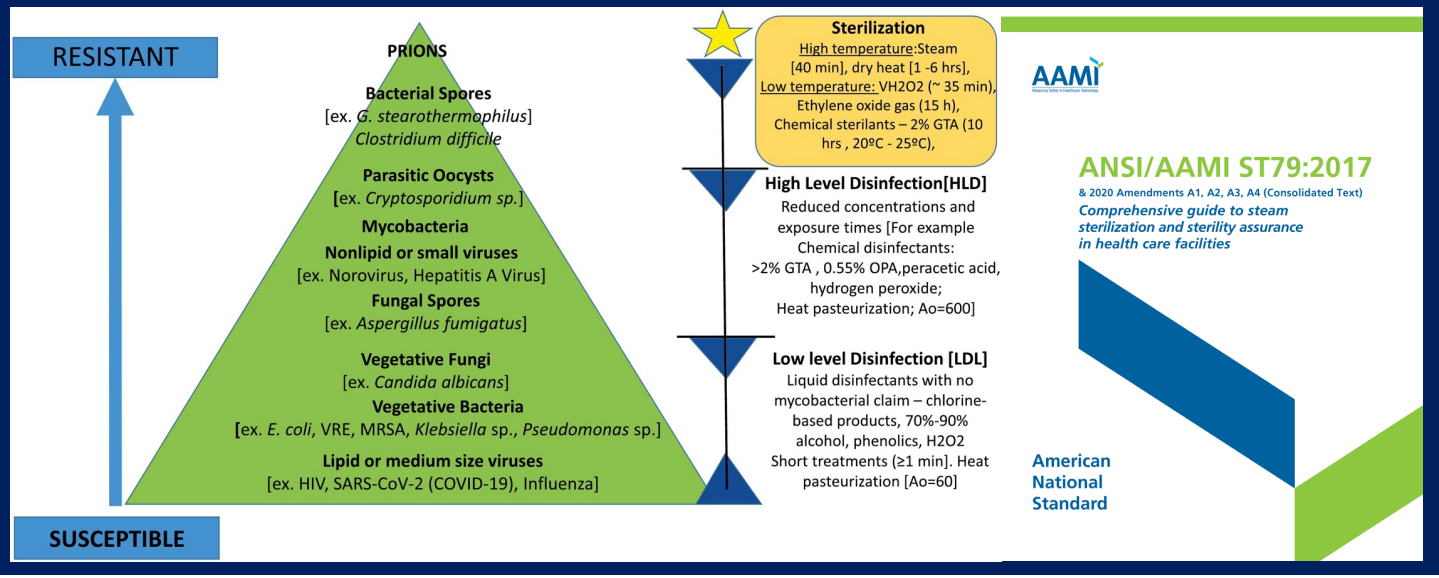

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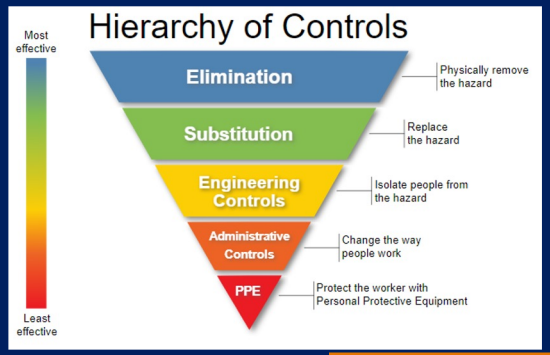

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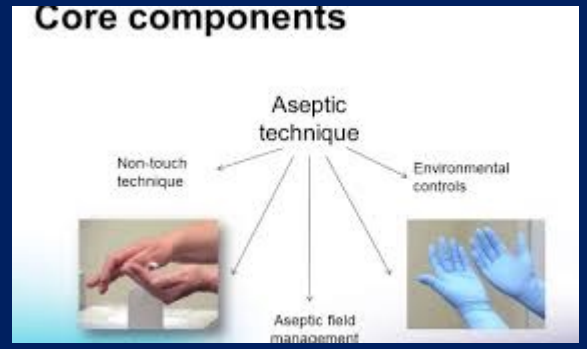

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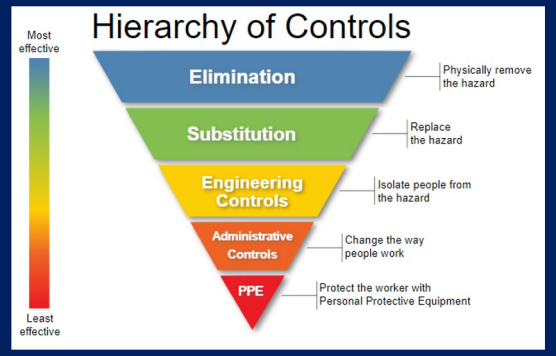

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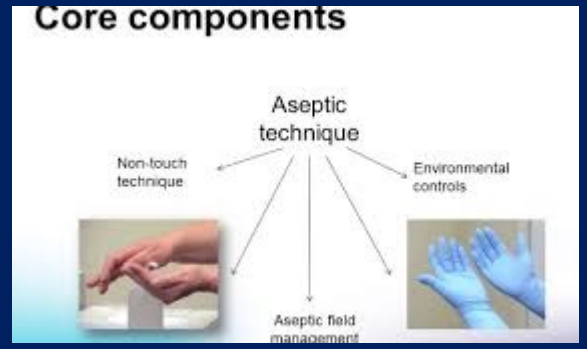

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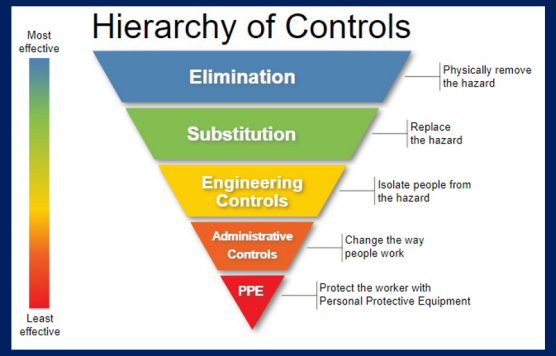

PRACTICES

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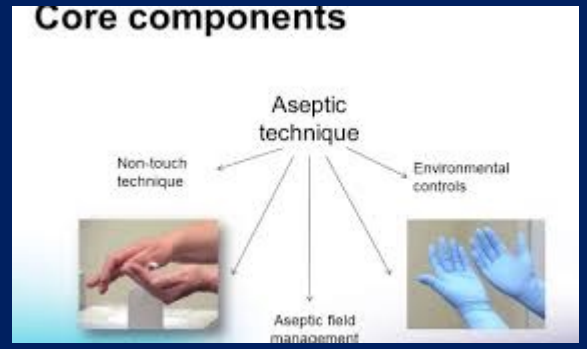

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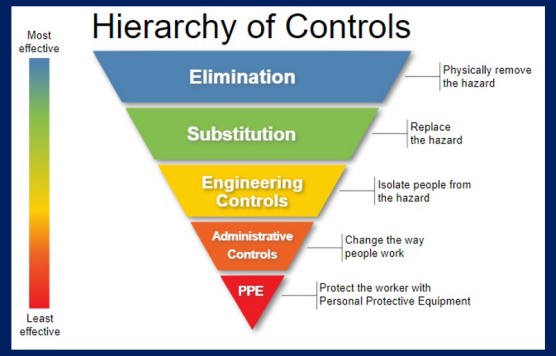

SPECIAL CONSIDERATION

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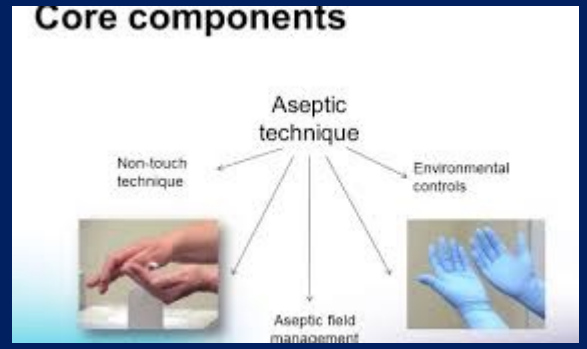

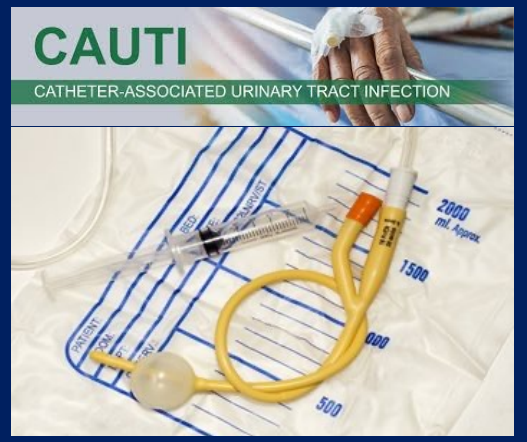

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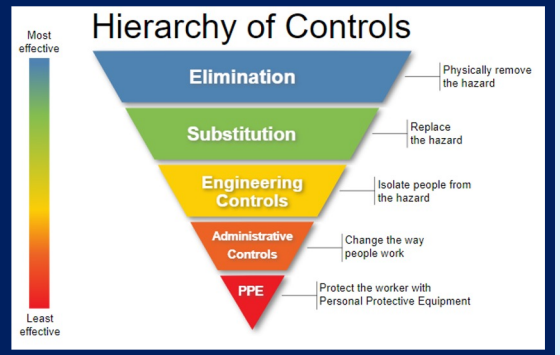
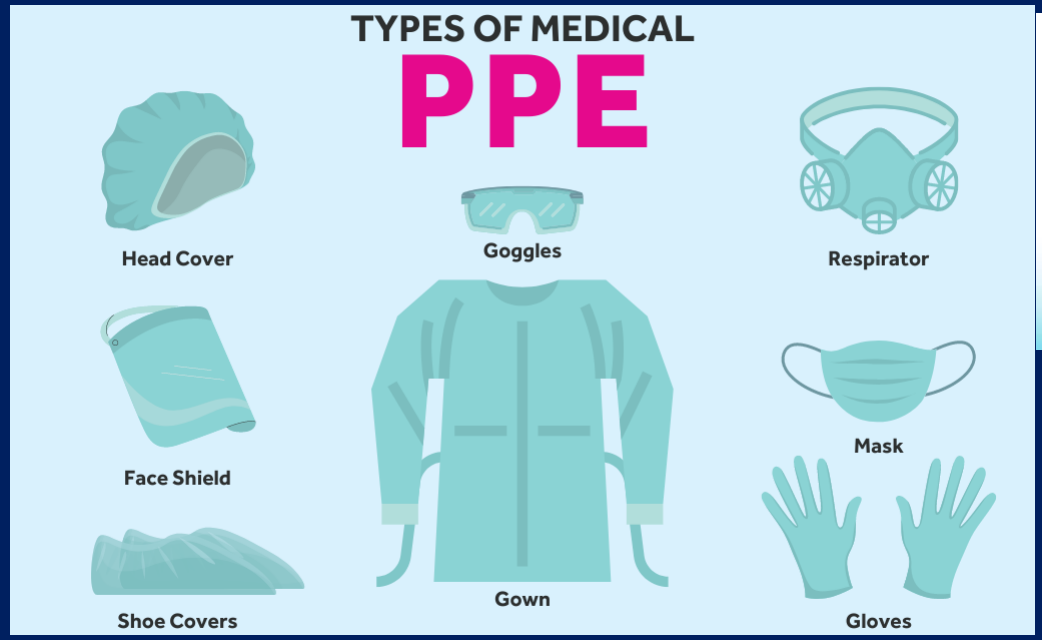


PPE



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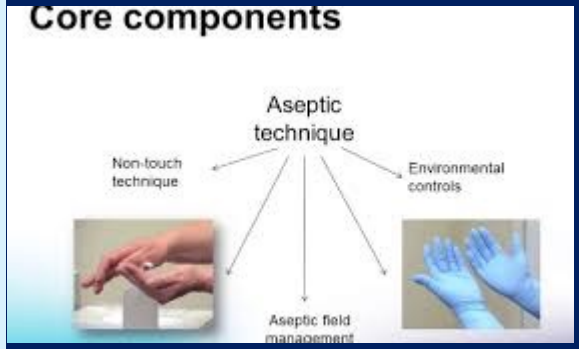

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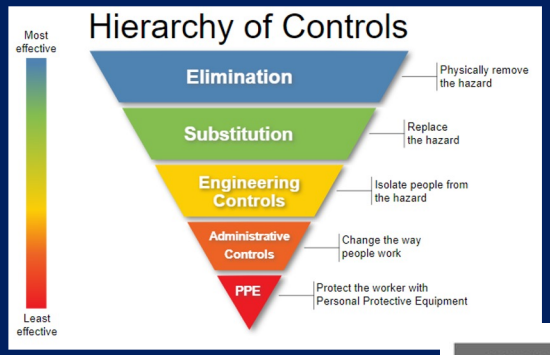
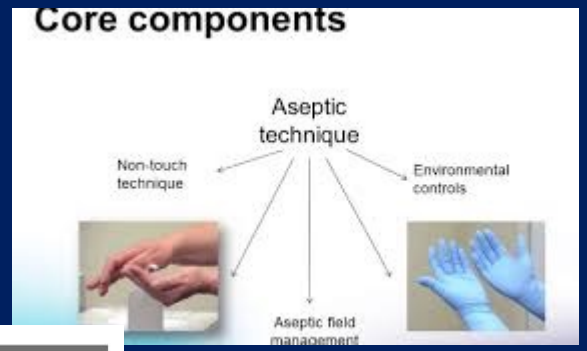


PPE

ANSI/AAMI PB70 Barrier Performance	Test Method	Test Definition	Requirement
Level 1	Water Resistance: Impact Penetration AATCC 42	AATCC 42 Measures the resistance of fabrics to the liquid penetration of water by impact.	Water Impact </= 4.5 g
Level 2	Water Resistance: Impact Penetration AATCC 42 Water Resistance: Hydrostatic Pressure AATCC 127	AATCC 42 Measures the resistance of fabrics to the liquid penetration of water by impact. AATCC 127 Measures the resistance of fabrics to the liquid penetration of water by impact under constant and increasing hydrostatic pressure.	Spray Impact </= 1.0 g Hydrostatic Pressure >/= 20 cm
Level 3	Water Resistance: Impact Penetration AATCC 42 Water Resistance: Hydrostatic Pressure AATCC 127	AATCC 42 Measures the resistance of fabrics to the liquid penetration of water by impact. AATCC 127 Measures the resistance of fabrics to the liquid penetration of water by impact under constant and increasing hydrostatic pressure.	Spray Impact </= 1.0 g Hydrostatic Pressure >/= 50 cm
Level 4	Viral Penetration ASTM F1671	ASTM F1671 Measures the resistance of fabrics to bloodborne pathogens using viral penetration at 2psi and ambient pressure.	Total Impervious

AST and GMP



The Interconnection and Healthcare Workers

The Interconnection and Operations

The Interconnection and The Importance

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References

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