

# Patient Safety Begins with You

**Medical Device Reprocessing**

**Sandra Comand, Clinical Manager / Microbiology  
Consultant**

***Dedicated to preventing infections acquired within  
health-care facilities***



## Objective of Presentation

***Provide an over view of the role of Infection Prevention & Control as it pertains to the Medical Device Reprocessing Departments.***



- The control of microorganisms cannot be accomplished unless there is an understanding of the basics of microbiology and infection control.
- Microorganisms are everywhere: in the air, on surfaces, on people, animals, plants, in the soil, and in water. They are not visible to the naked eye.



# Clinical Microbiology

- Microorganisms help to maintain the balance of living organisms and chemical in our environment.
- Most human microorganisms are harmless and make up our normal flora.
- Some microorganism are pathogens, these are microorganisms that have the potential to cause an infection

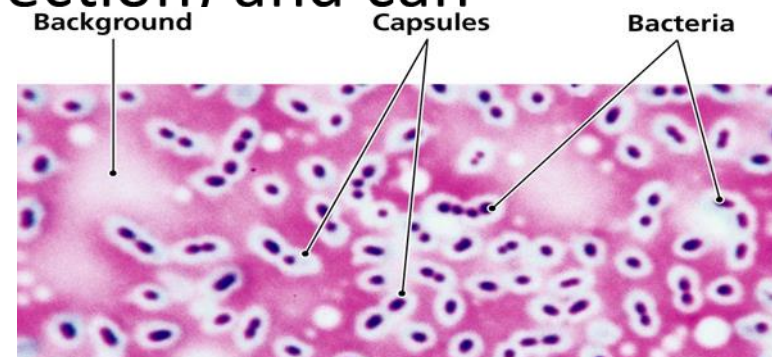


# Clinical Microbiology

Microorganisms are divided into the following:  
bacteria, fungi, viruses, parasites and prions

## **Bacteria:**

- Some bacteria when they are in their vegetative (actively growing) phase are relatively easy to kill.
- Some bacteria have the ability to produce a capsule or spore which gives it increased virulence (ability to cause an infection) and can be more difficult to kill.



# Clinical Microbiology

- Spore Stain: spores are metabolically dormant forms of bacteria that are resistant to heat (boiling), cold, drying and chemical agents. Spores form when there is a shortage of nutrients and can lie dormant for years.



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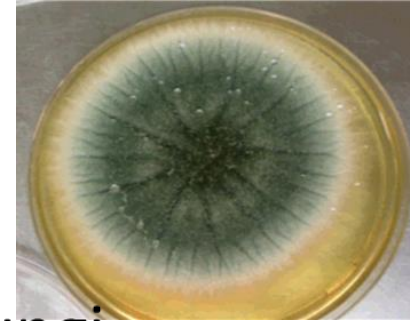
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# Clinical Microbiology



## Fungi:

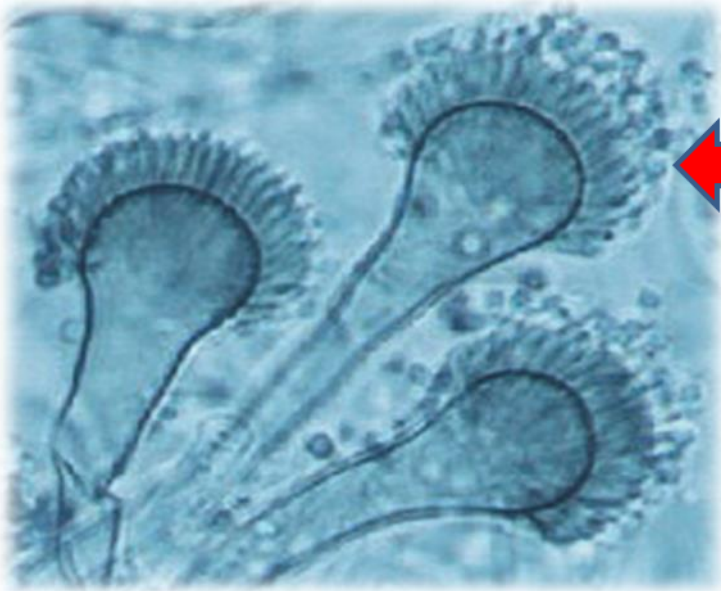
- Molds and yeasts are only two examples of fungi
- Fungi require organic matter as sources of energy and carbon
- Immunocompromised patients are susceptible to fungal infections
- Fungi can cause superficial infections of the skin, nails, or hair, such as ringworm or athletes foot to serious and system infections, often resulting in death.

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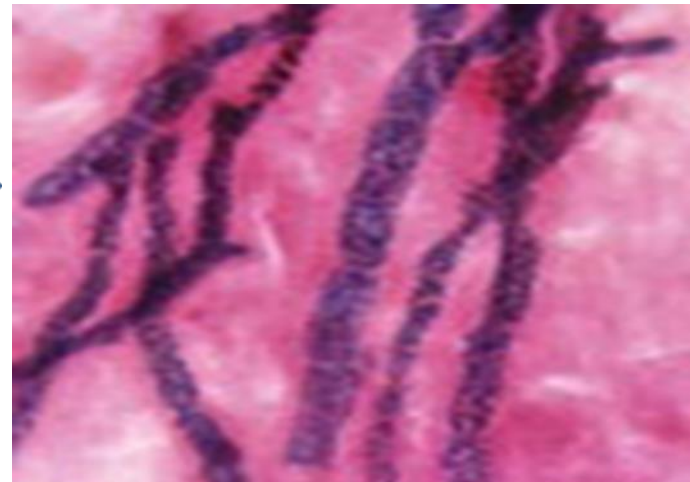
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*Aspergillus lactophenol*  
cotton blue prep – spores on  
the conidial head are  
responsible for the colour of  
the fungus that is visible to  
the naked eye

*Aspergillus* gram stain –  
hyphal strands –  
dichotomous branching

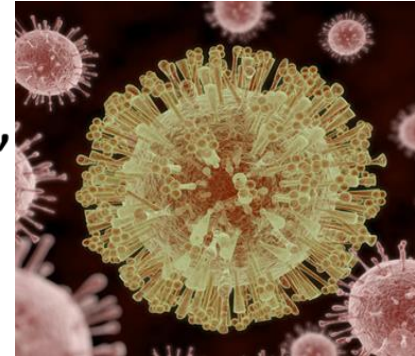




# Clinical Microbiology

## Viruses:

- Require a host cell of nutrients in order to grow
- Pathogens that are specific to the part of the body that they infect. E.g. the virus responsible for influenza, and the common cold, infect the cells lining the respiratory system and digestive system.
- Other diseases caused by viruses are chicken pox, measles, rabies, hepatitis, and herpes.
- After exposure to a virus, the immune system “remembers” how to fight the virus and produces antibodies against additional exposures. These antibodies are the basis of vaccinations against viral infections. E.g. influenza vaccine



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## Prions:

- Non-living pathogens made up of only protein
- Disease-causing prion protein is in an altered and distorted state
- Prions cause several human diseases, include Creutzfeldt-Jakob disease (CJD).
- Although prion diseases are very rare, it should be noted that prions are extremely resistant to conventional method of inactivation by sterilization



# Clinical Microbiology

	
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<b>Title:</b> Creutzfeldt-Jakob (CJD) / Transmissible Spongiform Encephalopathy (TSE) Disease	
<b>Manual:</b> Infection Control	<b>Section:</b> Infection Prevention & Control
<b>Document Number:</b> ICMAN.1101	<b>Issuing Authority:</b> Infection Control
<b>Date Issued:</b> January 2011	<b>Date Revised:</b> October 2014

## PURPOSE:

This policy provides the process that is followed to protect health care workers and patients from potential iatrogenic and nosocomial transmission of CJD/TSE from specimens collected from or items used on patients with *known, suspected or a differential diagnosis of CJD/TSE*.

## POLICY STATEMENT:

The most effective, safe, and efficient means of preventing iatrogenic transmission of CJD/TSE are to identify high-risk patients before an invasive procedure, in order to implement the required infection prevention and control measures, and to have a system for instrument tracking.

The procedures recommended for managing instruments used on high-risk patients depend on the potential infectivity of the tissue contacted. Public Health Agency of Canada has provided a risk classification that categorizes the human tissue into three categories: high-infectivity, low-infectivity and no detected infectivity.

## DEFINITION (S):

**CJD:** Creutzfeldt - Jakob disease – A rare, fatal brain disorder, which typically causes a rapid progressive dementia, cerebella ataxia and myoclonus (twitching of muscles).  
CJD is one of a group of related disorders collectively known as Transmissible Spongiform Encephalopathies (TSE). Other TSEs include: Gerstman-Straussler-Scheinker disease (GSS) & Fatal Familial Insomnia (FFI), which are inherited.

**CJD Confirmed:** Examination of brain biopsy using standard neuropathological technique and/or immunocytochemically; and/or Western blot confirmed protease-resistant prion; and presence of scrapie-associated fibrils

**CJD Excluded Interpretation:** A proven alternate diagnosis is made that accounts for clinical symptoms.

**CJD Possible Diagnosis:** Progressive dementia; and at least two out of the following four clinical features:

- I Myoclonus
- II Visual or cerebellar signs
- III Pyramidal / extrapyramidal signs
- IV Akinetic mutism

AND the absence of a positive result for any of the three laboratory tests that would classify a case as "probable" (refer to tests a-c above)

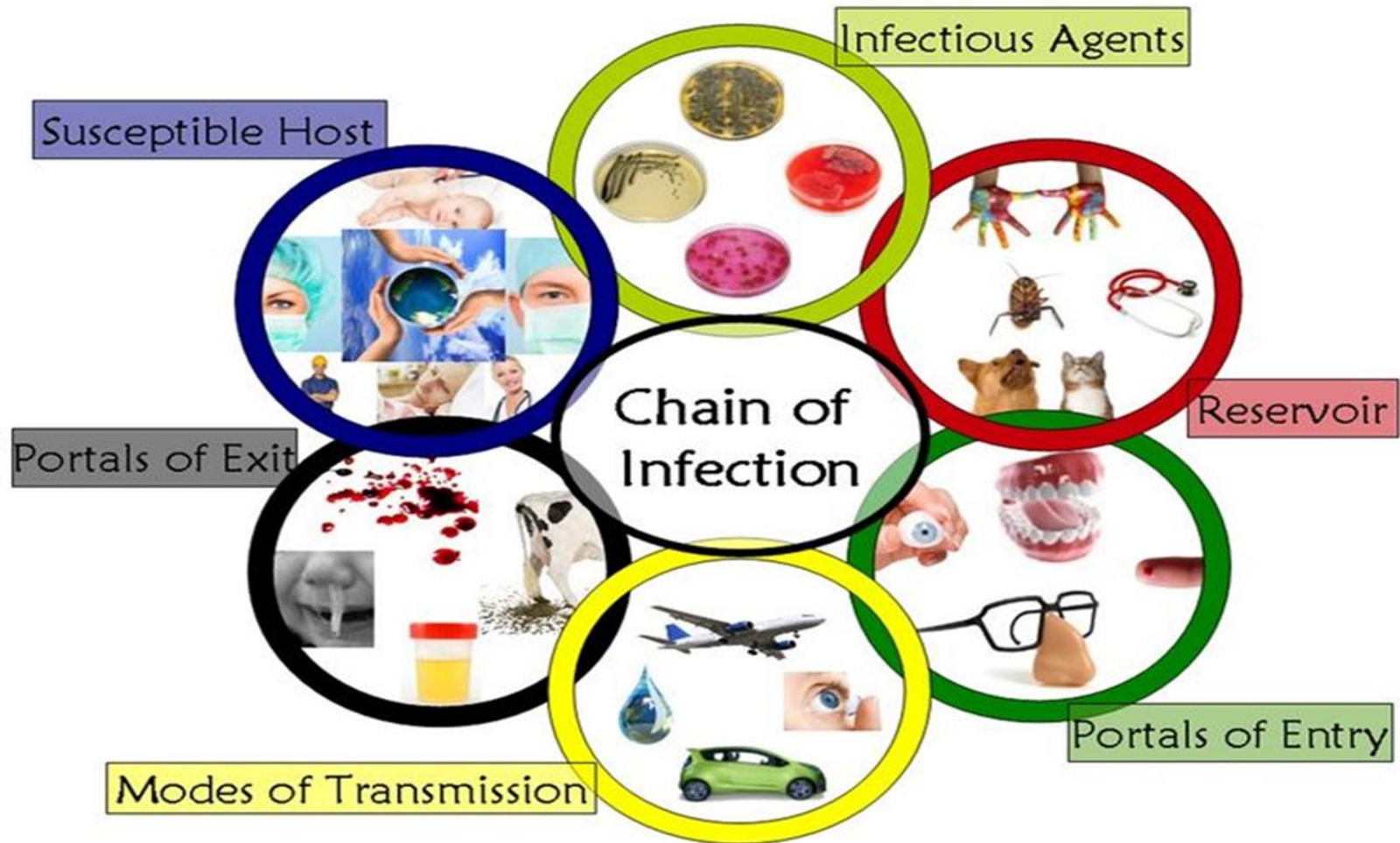
AND duration of illness less than two years

AND without routine investigations indicating an alternative diagnosis.





# Chain of Infection



# Chain of Infection

- **Infectious agent** is the microorganism (bacteria, virus, fungus etc.) that causes the disease.

For example, hepatitis c, CRE

- **Reservoir** (source) is the host which allows the germ to live, and possibly grow, and multiply.

Humans, animals and the environment can all be reservoirs for microorganisms.

For example, hepatitis c thrives within the blood, CRE within the bowels





# Chain of Infection

- **Portal of Exit** is the path for the microorganism to escape from the host. The blood, respiratory tract, skin and mucous membranes, genitourinary tract, gastrointestinal tract, and transplacental route from mother to her unborn infant are some examples.

For example, patient has a surgical procedure and the blood which contains the hepatitis c exits the body, patient has a scope and the CRE leaves body via the scope



# Chain of Infection

• **Mode of Transmission** – since microorganism cannot travel on their own; they require a vehicle to carry them to other people and places. For example, blood with hepatitis c travels on the medical device used in the procedure



• **Methods of Transmission-**

**Contact Transmission:** a) direct contact – skin to skin

b) Indirect contact – contaminated surgical equipment



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# Chain of Infection

•**Droplet Transmission:** small droplets entering the mucous membranes such as eyes, nose and mouth. The droplets are from a person coughing and the pathogen is found in droplets.



•**Airborne Transmission:**  
Inhalation or breathing in of small droplet nuclei that remain suspended in air for a long period of time for example TB



# Chain of Infection

- **Ingestion:** Eating or ingesting the pathogen through contaminated food or water.

- **Parenteral:** Pathogen enters the body in a manner other than through the digestive canal. E.g. sharps exposure

- **Vector:** Vectors are living things that carry pathogens from one host to another. Examples of vectors are mosquitos, fleas, flies, and rats. Vectors are not usually harmed by the pathogens that they carry. E.g. zika



# Chain of Infection

- **Portal of Entry** is the path for the microorganism to get into a new host, similar to the portal of exit.

For example, the medical device was not reprocessed by a MDR technician / aide and the contaminated device was used in a subsequent procedure thus infecting a new patient with hepatitis c





Brooklyn

**DISEASE A**  
Hepatitis C is a  
blood-borne virus.  
The Centers for  
Disease Control  
estimate that  
about 4 million  
people in the  
United States  
have the virus.

# Hepatitis C outbreak among clinic patients

Patients of Brooklyn Clinic Are Sought

After Outbreak of Hepatitis C

A patient says a clinic is so clean that 'even the magazines are new.'

Some other way in which contamination introduced blood or other fluids into the scopes or the scopes themselves. There have been no sterilization problems in the years since the outbreak began.

By DIANE CARDWELL

Health officials are trying to contact 2,000 patients who underwent endoscopy exams at a Brooklyn medical center. Eight patients tested positive for hepatitis C. The outbreak may have occurred in the time such as an outbreak had occurred in the past.

Post that she and her husband were referred for routine colonoscopies last time by their doctor and "I was worried."

With Department is trying to find 2,000 people who had the clinic data from 2000 for a procedure in which the lining of the stomach or bowel is examined with a flexible lighted instrument. Such procedures can be part of the routine screening for colon cancer. Blood samples of the infected patients have been forwarded to the Centers for Disease Control and Prevention to try to identify the outbreak. Hepatitis C is a blood-borne virus that may be spread by sharing needles or other equipment that may have blood on them.

Drug-resistant superbug may be more widespread than previously known

## MEDICAL MYSTERY

# Hepatitis C outbreak Strikes 8 endoscopy patients of B'klyn clinic

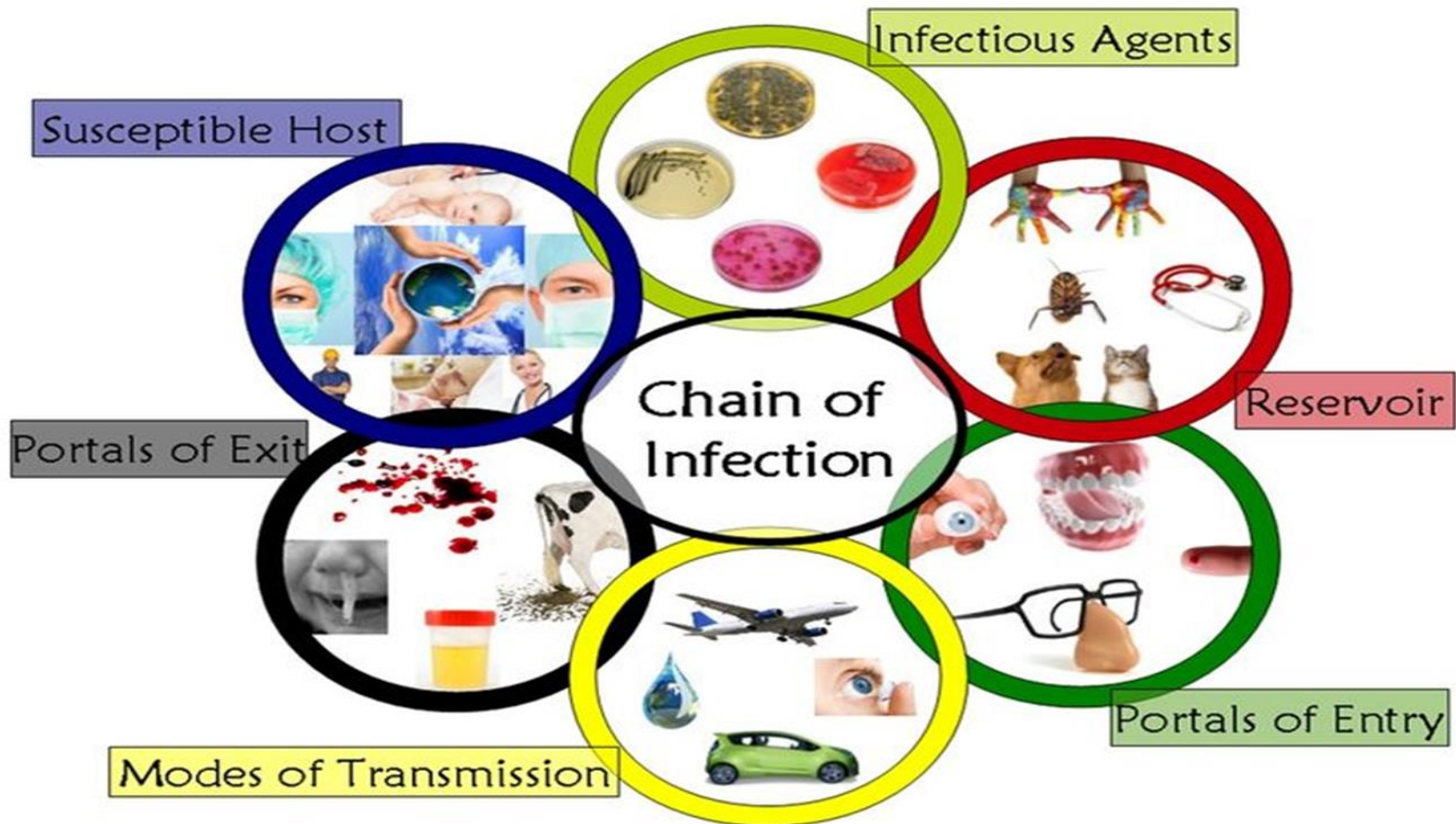
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# Breaking the Chain of Infection



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# Breaking the Chain of Infection



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- Infection is a major risk of surgery and infections related to improper equipment reprocessing still occur, despite modern technologies and procedures.
- Achieving effective disinfection and sterilization is essential for ensuring that medical and surgical equipment / devices do not transmit infectious pathogens to patients, residents or staff.
- MDR can stop the spread of infection by interfering or breaking the chain of transmission required for pathogen transmission

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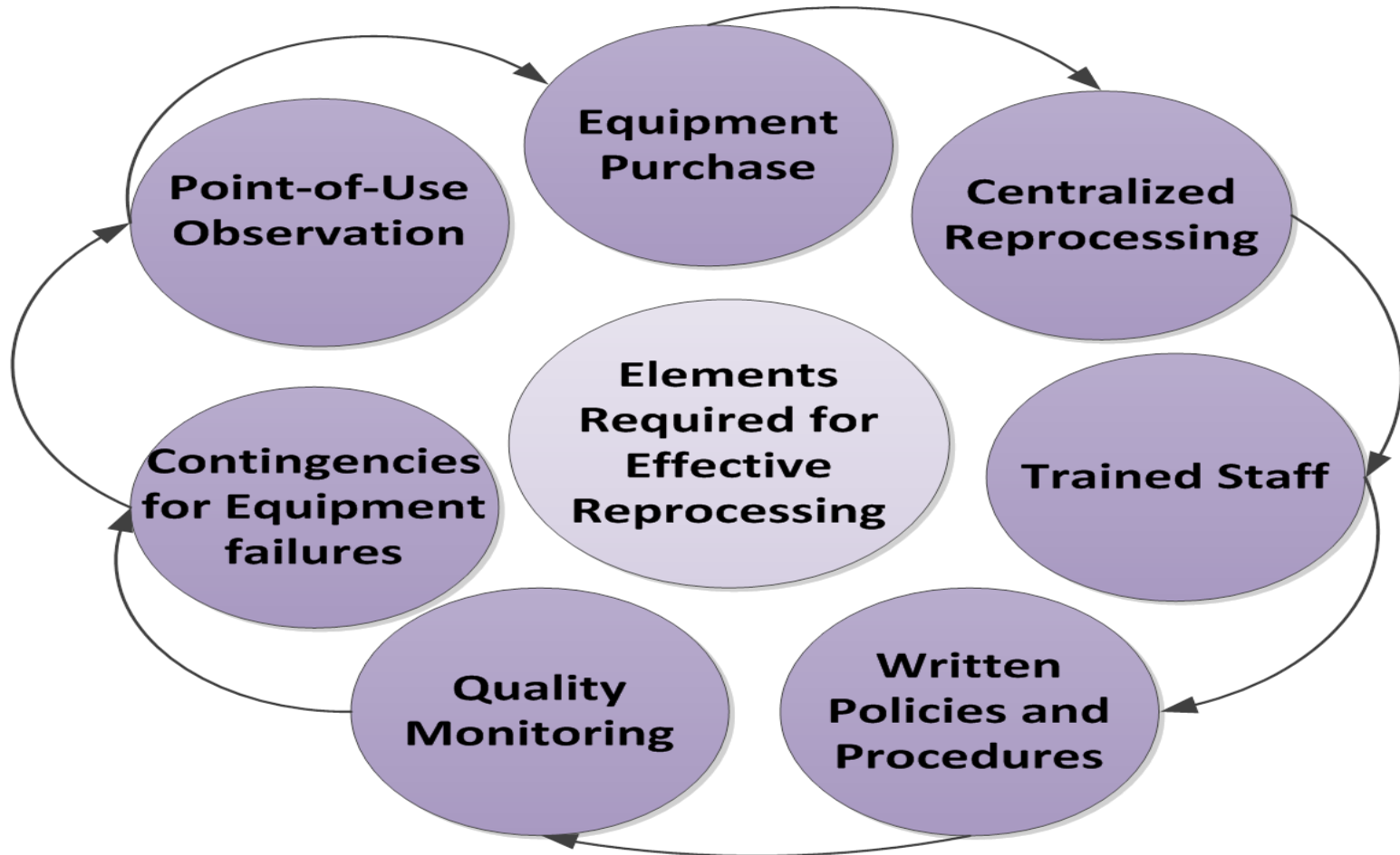




# Breaking the Chain of Infection



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- MDR needs to be engaged in the purchase of medical devices – consideration as to the way a device will be reprocessed and whether or not staff require training, visual aides must be considered
- Medical devices should be reprocessed in a centralized area by trained staff with monitoring and quality control measures in place
- Written policies and procedures that reflect current standards must be available to staff to ensure standardization of processes







- Equipment Service Contracts in place to ensure instrumentation is operating as intended
- Tracking system wherever possible in order to achieve a recall in the unlikely event of a QC failure
- MDR needs to be involved if not leading a multi-disciplinary “Reprocessing Committee” that includes the individuals responsible for purchasing the equipment/devices, maintaining the equipment/devices, infection control, organizational health and safety.



Classification	Definition	Level of Processing/Reprocessing	Examples
Critical Equipment/Device	Equipment/device that enters sterile tissues, including the vascular system	Cleaning followed by Sterilization	<ul style="list-style-type: none"> <li>• Surgical instruments</li> <li>• Implants</li> <li>• Biopsy instruments</li> <li>• Foot care equipment</li> <li>• Eye and dental equipment</li> </ul>
Semicritical Equipment/Device	Equipment/Device that comes in contact with non-intact skin or mucous membranes but does not penetrate them	Cleaning followed by high-level disinfection (as a minimum) Sterilization is preferred	<ul style="list-style-type: none"> <li>• Respiratory therapy equipment</li> <li>• Anaesthesia equipment</li> <li>• tonometer</li> </ul>
Noncritical Equipment/Device	Equipment/Device that touches only intact skin and not mucous membranes, or does not directly touch the client/patient/resident	Cleaning followed by Low-level Disinfection (in some cases, cleaning alone is acceptable)	<ul style="list-style-type: none"> <li>• ECG machines</li> <li>• Oximeters</li> <li>• Bedpans, urinals, commodes</li> </ul>



# Routine Practices

- All reusable medical equipment/devices must be reprocessed using procedures that are effective against all human pathogens, including blood borne pathogens.
- Special procedures, including labelling, for specific microorganisms (e.g. MRSA, VRE, CRE, TB, hepatitis) are not required.
- The exception is equipment/devices potentially exposed to CJD.



# How does MDR define Routine Practice



- Applying consistent practice that is defined in the policies and procedures in all areas of the department.
- The practices have been defined by performing a risk assessment on the specific tasks being performed within the department. Current standards provide the basis for the risk assessment.

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# How does MDR define Routine Practice: Dress code

Action	Rationale
All staff who works within MDR designated areas is required to wear freshly laundered operating greens upon entry to the department.	The uniform should confine skin cell and microbe shedding and promote infection control. Shedding is increased by movement and friction. Pants confine bacterial shedding.
Operating greens should be changed daily, and whenever it becomes visibly soiled, contaminated, or wet.	Soiled clothing increases the risk of cross-contamination to patients, staff, and the public.
Upon removal of operating greens, it is placed in a designated container for washing or disposal. OR greens shall not be hung in a locker to worn later.	
OR greens shall be laundered by the laundry facilities used by the health care facility for other surgical textiles.	Approved laundering facilities use recommended detergent and temperature settings to launder linen.
Long sleeved operating greens jackets (provided by hospital) may be worn within the restricted areas of MDR.	





# How does MDR define Routine Practice: PPE

Action	Rationale
<b>Decontamination Areas:</b> Hair covering Face shield Gloves Impermeable / waterproof barrier gown	PPE worn for cleaning and handling contaminated equipment/devices includes gloves appropriate to the task, face protection (e.g. full face shield or fluid impervious face mask and protective eyewear) and impermeable gown or waterproof apron.
<b>Removal of PPE:</b> a)remove gloves and discard b)wash hands c) Carefully break away or untie neck ties of protective gown, taking care to avoid touching uniform or neck. d) Remove face shield - careful to avoid touching the front of the face shield. e) Remove protective gown, turning gown inside out; immediately place in laundry. f) wash hands	Upon leaving the decontamination areas, remove all PPE and deposit into yellow biohazardous bags, or laundry as appropriate.  Removing PPE in this order and performing hand hygiene when specified provides optimal protection to the team member.



# How does MDR define Routine Practice

## Hair Covering

Action	Rationale
All hair (including facial hair) shall be completely confined by a clean hair net / cloth hat.	Shedding of squamous cells and hair has been shown to affect surgical wound infection; therefore, complete coverage is necessary.
Hair covers / cloth hat are to be changed daily and when visibly soiled.	

## Footwear

Action	Rationale
Shoes should have closed toes and backs, low heels, non-skid soles and should be easy to clean. Socks are to be worn at all times.	Occupational Health and Safety mandates appropriate footwear.
Shoes are to be kept clean. Shoes are not to be worn outside of the hospital.	



# How does MDR define Routine Practice

## Safe Handling of Sharps

Action	Rationale
Place disposable sharp objects in puncture-resistant containers.	To prevent a blood or body fluid exposure.
Take care when handling glass and other fragile objects.	
Discard chipped or broken glass devices arrange to have them repaired.	
Sharps shall not be recapped or manually bent.	



# How does MDR define Routine Practice

## Jewellery

Action	Rationale
Dangly jewellery is not permitted within the departments, this includes but is not limited to bracelets, necklaces and dangly earrings. Only a plain wedding band, stud earring, small closed hoop earring and/or medical alert jewellery are permitted. Watches are not permitted within the designated work areas.	Rings harbour microorganisms and could result in a glove tear. Several studies have demonstrated that skin underneath rings is more heavily colonized than skin on fingers without rings. Necklaces increase desquamation.





# How does MDR define Routine Practice

## Fingernails

Action	Rationale
Fingernails shall be clean and short.	The subungual region harbors the majority of microorganisms on the hand. Damaged nails may provide a harbor for microorganism.
Artificial nails, extenders or artificial enhancers shall not be worn.	Long nails, natural and/or artificial can tear gloves.  Artificial nails and tips harbour higher numbers of organism, artificial nails are know to promote the growth of Staphylococcus aureus, gram negative bacilli and yeast as moisture becomes trapped between the natural and artificial nail
Nail polish if worn must not be chipped.	Chipped or peeling polish may provide a harbour for microorganisms.



# How does MDR define Routine Practice: Hand Hygiene

Action	Rationale
Hand hygiene shall be performed; upon entering and exiting the department, when hands are visibly soiled, and between procedures involving “clean” and “dirty” equipment.	<p>Alcohol based hand rub is the “gold standard” for hand hygiene. Hand wash is preferred when hands are visibly soiled.</p> <p>The main reason for performing hand hygiene is to cleanse the hands of pathogens and chemicals which can cause personal harm or disease.</p>
ABHR Method (hand rub):	Soap & Water (hand wash):
<ol style="list-style-type: none"><li>1. Dispense hand rub onto palm of hand</li><li>2. Rub vigorously, applying friction. Cover all skin surfaces, paying particular attention to; finger webs, nail beds and finger tips.</li><li>3. Rub hand surfaces together until the agent has completely dried.</li></ol>	<ol style="list-style-type: none"><li>1. Turn on water, wet hands and wrists.</li><li>2. Apply soap, lather well and apply friction covering all skin surfaces paying particular attention to webbing between fingers, palms, back, nail beds and each finger</li><li>3. Wash vigorously for AT LEAST 15 seconds. Rinse thoroughly with running water.</li><li>5. Pat hands dry with paper towel. Do not rub, because this encourages chapping.</li><li>6. Use the paper towel to turn the taps off, so as not to recontaminate your hands.</li></ol>



**Medical Device Reprocessing  
teams are an integral member  
of the healthcare team that  
ensure that all medical devices /  
equipment are reprocessed in a  
timely manner to meet the  
needs of the patient.**

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