



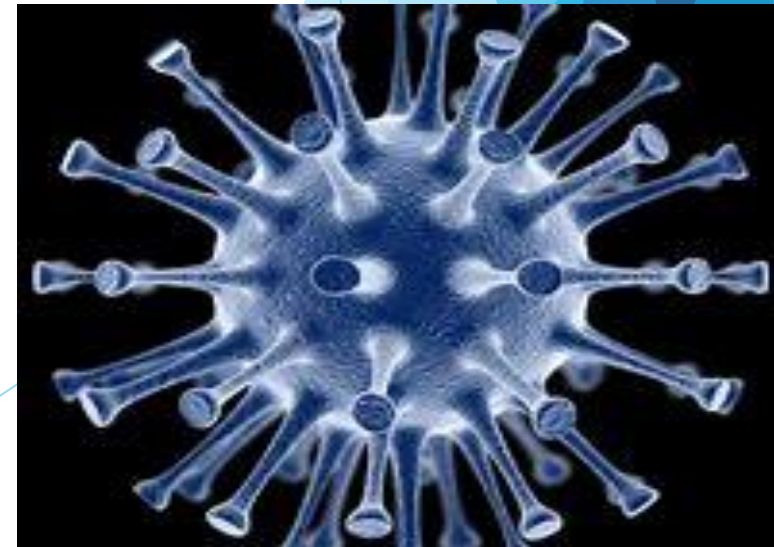
Safety in the Medical Device Reprocessing Department during COVID-19

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Disclosures/Acknowledgements

- Images in this presentation were obtained from Google Images unless otherwise identified
- This presentation is for information as of the day of this presentation; ensure to review current National Standards and recommendations for COVID-19
- Views and opinions expressed in this presentation are those of the presenter and may not represent official policy of other organizations
- Not for general circulation due to ever changing information
- Thanks to Clare Barry (IPAC Consultant) for her support

Objectives

- Is there any 'special' PPE required for MDR staff who reprocess, or transport devices used on positive COVID-19 patients?
- Discuss Coronavirus and COVID-19
- Provide an overview of Infection Prevention and Control Routine Practices in the Medical Device Reprocessing (MDR)
- Provide a refresher of donning and doffing personal protective equipment (PPE)
- Discuss PPE required to be worn in the Decontam area of MDR Department (MDRD).
- Discuss reprocessing single use N95 (PPE) risks and considerations to ensure quality when not available

Is there anything 'special' required for MDR staff who reprocess, or transport devices used on positive COVID-19 patients?

Answer :

- **No...** MDR staff wear PPE according to Canadian Standards Association (CSA)- Z314-18 (medical device reprocessing) and appropriate for the task
- Instruments and devices including those that have been used in procedures for patients with known or suspect COVID-19 should be handled the same as other instruments
 - *this also includes the equipment used in aerosol generated procedures

What is the Coronavirus?

- Coronaviruses are a large family of viruses (such as common cold)
- **COVID-19** is the name of the **illness** caused by this newly discovered (novel) coronavirus
- COVID-19 is the most recent virus of the 7 known strains of Coronavirus that are known to cause illness in humans
- 4 cause minor respiratory symptoms like a cold
- 3 have more serious outcomes
 - ❖ Severe Acute Respiratory Syndrome (SARS)
 - ❖ Middle East Respiratory Syndrome (MERS-CoV)
 - ❖ COVID-19
- First reported in December 2019

COVID-19- Transmission

- Spread from a infected person through: respiratory droplets, close prolonged personal contact, and touching nose, mouth, or eyes before washing hands
- Virus can persist on surface hours to a few days depending on temperature, surface and humidity. Clean surfaces frequently
- Spread by Droplet and Contact
- Therefore do not touch eyes, nose, and mouth before performing hand washing
- May take up to 14 days for symptoms to appear after exposure¹ “Hence why self isolation for 14 days”

COVID-19 (www.Canada.ca/coronavirus)

- Recent studies identified that COVID-19 may be spread by people who are not showing symptoms (asymptomatic)
- Symptoms may include: cough, headache, fever, difficulty breathing, pneumonia in both lungs, some have experienced other symptoms
- Highest number of deaths have been in the over 65 year population, anyone with chronic medical conditions and/or weakened immune systems; however people between the ages of 30-60 years have also been hospitalized
- Severe cases of infection can lead to death

Prevention and Treatment

- Respiratory (cough and sneeze) etiquette is extremely important
- Wearing a medical mask correctly in healthcare may limit the spread
- Wash your hands often, during and after removing PPE
- Use alcohol-based hand sanitizer if soap and water not available
- Imperative to stay 2 meters apart, avoid crowded places- stay home as much as possible
- At this time, a vaccine or therapy to treat or prevent this disease has not yet been developed. However, the COVID-19 pandemic has resulted in a global review of therapies that may be used to treat or prevent the disease¹.
- Think about performing a 'buddy system' to ensure PPE is donned and doffed correctly

Infection Prevention and Control (IPAC)- Routine Practices in MDR

- Consistent use of Routine practices is the basic practice to protect health care providers and patients therefore MDRD handles all equipment as potentially contaminated
- Applies to all body fluids, non intact skin, equipment contaminated with blood, body fluid or tissue whether visible or not

Personal Protective Equipment in Decontam

- **ALL PPE shall** be worn in the MDR shall be appropriate for the task(s).²
(fluid resistant facemask with eye protection or (full)face shield, gown, gloves and head covering)
- Shoe coverings as per hospital policy
- When the integrity of gloves, liquid- or chemical-resistant garments, face shields, or protective eyewear is compromised, they shall be replaced immediately²
- Hand hygiene shall be performed before donning fresh PPE²
- Care should be taken in putting on or taking off PPE, as PPE can be a source of contamination²
- Change PPE when or if it becomes grossly soiled, visibly contaminated with blood or body fluids

Donning (Putting on) PPE- In Decontamination

In This order of sequence:

- Wash hands and wrists, do not wear jewellery
- Don head covering (recommended for all areas of MDR) *hair coverings are worn in all areas of SPD as part of dress code;*
- Don fluid-protective shoe covers if worn – *not required but often worn in decontam area of MDR to protect from splashing. Follow your facilities policies; should be slip resistant*
- Wash hands

GOWN:

- Don long sleeve fluid-resistant gown (should be Level 3 at a minimum, Level 4 recommended for decontam area) – opening is at the back (not a apron)
- **N.B.**-*Typical isolation gowns have very limited protection against fluids*
- Secure gown at neck and waist



Don Fluid resistant Medical Mask Next

- Risk of exposure
- Secure ties or elastic bands at the crown of your head and neck
(or fit loops over ears)
- Fit to face and chin
- Form the flexible band at the nose bridge



Don Eye Protection Next

- Goggles, full face shield, or visor attached to mask are all accepted methods of eye protection
- If using a face shield/visor, it should fit over the brow
- Prescription or fashion eye glasses DO NOT offer sufficient eye protection
- Place over face and eyes, adjust to fit



Gloves Next

- Long fitted protective (consider dexterity, cut resistance, non latex)
- Insert each hand into appropriate glove and extend over the cuffs of the gown for barrier
- Keep gloved hands away from face and limit touching surfaces
- Change gloves and clean hands as needed (e.g. visibly soiled, between contaminated and clean tasks)



Doffing (Taking off) PPE

Things to consider!

Which areas of the PPE are clean and contaminated:

- The outside of the face protection and glove is contaminated
- The front of the gown, sleeves are contaminated
- The inside and back of the PPE is considered clean

Doffing- Removing PPE

In this Sequence:

- Shoe covers if worn, are most contaminated; remove first
- Removing Gloves: do not touch the outer area of the glove as may be contaminated
- Pinch the outer glove surface at the wrist and remove the first glove; hold this in your opposite gloved hand.
- Slide finger of ungloved hand under the other glove at the wrist
- Peel glove over wrist and discard



Hand Hygiene

- Wash hands and wrists using soap and water or alcohol hand sanitizer after removing gloves



Removing Gowns



- Gown front and sleeves are contaminated!
- Unfasten gown ties, taking care sleeves do not contact your body when reaching for ties
- Pull the gown away from your neck and shoulders, touching inside of gown only
- Turn the gown inside out and fold or roll the gown into a bundle and discard in regular waste (disposable)
- *(some of you may be wearing the Level 3 or 4 'OR gowns' –place in linen cart)*
- **Perform hand hygiene after removal of gown**
****be informed about your facilities protocols****

Removing Goggles or Face Shield

- Outside of goggles or face shield are contaminated!
- If your hands become contaminated during goggle or face shield removal; immediately wash your hands or use alcohol hand sanitizer
- Remove goggles or face shield carefully from the back by lifting head band or ear pieces
- If the item is reusable, place in designated receptacle for reprocessing. Otherwise discard in waste



Removing Mask & Head Covering

- Front of mask is contaminated – DO NOT TOUCH!
- If your hands get contaminated during removal; immediately wash them
- Grasp bottom of ties or elastics of the mask, then the ones at the top, and lean forward slightly and remove without touching the front, lift off the mask
- Discard in waste container
- **Remove head covering** by lifting the head covering off of the head by grasping it in the center and lifting upward, discard it into a waste container
- **Wash hands or use alcohol hand sanitizer** immediately after removing PPE & before leaving decontam area
- Do not take MDR PPE home to launder.

What about Masks?

- There are different 'types' of masks with or without a shield
- Medical grade fluid resistant (fluid barrier rating) mask is required for decontamination area

Facial Protection

- A barrier that prevents droplets from an infected source from contaminating the skin, mucous membranes of the eyes, nose, and mouth from splashes or sprays of body fluids or blood of the wearer, or to trap droplets expelled by wearer, depending on the use; require eye protection
- A standard surgical mask is a fluid resistant mask is designed to provide a barrier and droplets asks
- Should be changed if the mask becomes moistened or damaged
- Removed carefully to not contaminate yourself



What is the N95 Respirator?

- N95 is a 'disposable' device worn on the face and covers nose and mouth to reduce the wearer from inhaling airborne particles
- The 'N' indicates that it is not oil-resistant or oil-proof
- Certified by the National Institute for Occupational Health and Safety (NIOSH) based out of USA
- Also hold a Medical Device Establishment License (MDEL) authorized by Health Canada to be imported into Canada

N95 Respirator

- Different styles, cup-style, flatfold or duckbill & may or may not have an exhalation valve
- Used when viruses or bacteria is spread via airborne route
- Today, there are only 3 viruses spread via airborne route (Measles, TB, Chickenpox)
- Must be properly fitted and tested for leaks before considered safe and provides efficient filtration of airborne particles (user performs a seal check each time put on)
- Worn in clinical settings when there are aerosol generating medical procedures on a person under investigation for COVID-19



What Facial/Eye Protection is required in Decontam?

- Mask with a fluid barrier rating with eye covering; full face shield is recommended
- N95 not needed in MDR because there should be no aerosol generating procedures
- Risk of cleaning soiled instruments is same for all; no different protocols; follow Canadian Standards Association (CSA)- Z314-18
- Ensure to practice good hand hygiene practices

Decontam area Protection²

- Completely submerge devices that require brushing/ cleaning below water line to minimize splashing as per CAN/CSA- Z314-18
- Aerosolized water faucet sprays increases splashing/aerosolization of microorganisms, pre-cleaning should occur at point of use, fully submerge devices for cleaning and rinsing
- Wear PPE as per CAN/CSA Standards–Z314-18 –medical device reprocessing. (including shoe covers(optional in some depts.) however possible risk of contaminating shoes, head covering –part of uniform, fluid resistant gowns, facial and eye protection, gloves)
- Ensure to clean environmental surfaces regularly with hospital grade cleaners and disinfectants ; as the COVID-19 virus may survive up to 72 hours on hard surfaces and 24 hours on cardboard but they do not survive without a host to grow¹

Additional comments

- Ensure staff are aware of hospital policy for transportation of clean and contaminated devices
- No special PPE required for transportation of soiled carts; follow CAN/CSA-Z314-18 (however, *your facility may be requiring masking for all staff due to community spread therefore follow hospital policy when outside of the MDR department*)
- Do not reuse single use 'PPE'
- Ensure to wear all PPE correctly required for the task
- Instruments and devices that have been used in procedures for patients with known or suspected COVID-19 are handled the same as other instruments
- Follow Manufacturers instructions for use for reprocessing and CSA Standard
- Wash your hands after removing PPE and before leaving the department

Can we Reprocess N95 Respirators as a Crisis Capacity Strategy during COVID-19?

- Unprecedented demand for certain supplies, including PPE during COVID-19
- Follow Health Canada and Provincial **emergency** approved guidelines and standards
- Health Canada invites manufacturers to submit innovative solutions with data for consideration and interim approval of normally disposable N95 respirators to meet current needs¹ and increasing domestic production
- Much of literature that is available on the reprocessing of Used Single Use N95 respirators are laboratory studies
- Laboratory studies may not reflect risks and outcomes in actual clinical settings (ECRI-March 2020)
- Health Canada evaluated the guidance of the FDA for optimizing reuse of respirators¹ and introduced interim regulatory measures
- Manufacturers must provide decontamination and reprocessing instructions¹

Reprocessing Used N95

- If deciding to reprocess N95, must meet approved statements put out by Health Canada
- Review the most current science based-published literature
- Current information:
 - ❖ Cellulose based respirators cannot be reprocessed
 - ❖ Ethylene Oxide (off-gassing) not recommended
 - ❖ Ionizing radiation not recommended(performance degradation)
 - ❖ Microwave not recommended (melting near metal components designed to fit the face)

Completed Interim Order applications for the re-processing of N95 respirators-April 24, 2020- slide courtesy –Health Canada

Device (method)	3M N95 models evaluated (throughput)	Max Number of Process Cycles	Filtration Efficiency	Fit Evaluation	IO authorization
Stryker Sterizone VP4 (VHP, Ozone)	1860 (480 masks/24h)	2	Pass	Pass	April 5, 2020
ASP Sterrad 100S, NX, 100NX (VHP, low temperature)	8210, 1860, 1860S (620 masks/24h)	2	Pass	Pass	April 9, 2020
Clean Works Medical Clean Flow Healthcare Mini (VHP, UVC, Ozone)	8210 1870 (1200 masks/hr)	10	Pass	Pass	April 13, 2020
Steris V-Pro 1 Plus, maX, maX2 Non-lumen cycle (VHP)	1860 8210	10	Pass	Pass	April 15, 2020
Ecolab Bioquell HPV generator (VHP)	1860	20	Pass	Pass	April 20, 2020

On-going reviews of IO applications for the re-processing of N95 respirators-April 24, 2020

Device (method)	3M N95 models evaluated (throughput)	Max Number of Process Cycles	Filtration Efficiency	Fit Evaluation	IO authorization
Daavlin 1 Series (UVGI)	Data pending	Data pending	Data pending	Data pending	Under review
CDR Acute Decontamination System	Data pending	Data pending	Data pending	Data pending	Under review
Clean Sleep Technology	Data pending	Data pending	Data pending	Data pending	Under review
Data maybe changing daily as processes approved					<i>Slides 30 & 31 - Courtesy-Health Canada</i>

What about reprocessing other devices that are unavailable or in extreme short supply?

- Health Canada will continue to respect the current oversight provided at the provincial and territorial level and guidance provided by the Public Health Agency of Canada

Health Canada advises that during a state of emergency, such as for a crisis capacity strategy:

- “Individual hospitals can develop and conduct their own testing and validation of reprocessed devices, as long as this is done internally and for internal purpose”
- “No sale of the reprocessed devices to another institution”

Can Reusable Face Shields and Goggles be Cleaned?

- Follow Manufacturers instructions for cleaning and disinfection if reusable
- Should be reprocessed as per facility Infection Prevention and Control approval and Occupational Health and Safety guidance

What about Single Use Face Shields

- Any reprocessing approved by facility should be performed in the MDRD
- Discuss with IPAC, MDR, Biomedical Engineering & Quality and Risk to decide on a process that can be performed safely

▶ <https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/eye-protection.html>

Considerations

- ▶ Decontamination processes may compromise the filter depending on the process decided on, therefore, ensure consider loss of fit and filtration effectiveness
- ▶ Consider the N95 Volumes required
- ▶ Initiate good Quality Controls & to ensure the number of times the N95 can be reprocessed recommended by reprocessing manufacturer There is really no way to clean these once used
- ▶ Identify and document a tracking method
- ▶ Develop the method of collection and ensure excellent communication
- ▶ Ensure consistency and identify a team member responsible to oversee any reuse protocols

Considerations

- ▶ Expired N95 stocks- Devices beyond their labelled shelf life may retain adequate filtration if stored properly, bands and other elastic parts may not ensure a proper fit.¹
- ▶ Heat and humidity can compromise the filter material. Inspect closely for damage and fit test before use (ECRI-March 2020).
- ▶ Follow Manufacturers Instructions

Considerations

- ▶ Store used N95 in designated area
- ▶ Follow the Interim Order provided to the manufacturer (refer to Health Canada slide)
- ▶ Ensure once this crisis is over, destroy the reprocessed N95 stock and resort back to the current Canadian standards and manufacturers recommendations as Single Use Device

Summary

- There is no change in the MDR PPE
- Reprocessing of the Single Use N95 is a crisis contingency plan ONLY to be used by staff as a last resort under the Emergency Plan; i.e. when and if there are no new N95 respirators available
 - ❖ MDR, IPAC, Biomedical Engineering, Quality and Risk should be involved in approval and development of the facility plan on how the process will take place (collection, transportation & reprocessing plans)
 - ❖ The processing should be performed in MDRD
 - ❖ Education and a communication plan is critical for those staff assigned designated staff assigned to the task

Resources & Contact Information/ Ressources et coordonnées

- Applications for medical devices under the Interim Order for use in relation to COVID-19 – Guidance document
<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/announcements/interim-order-importation-sale-medical-devices-covid-19/guidance-medical-device-applications.html>
- Products authorized under the Interim Order:
<https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/products-authorized-interim-orde.html>
- Email:
hc.devicelicensing-homologationinstruments.sc@canada.ca
- Demandes relatives aux instruments médicaux visés par l'arrêté d'urgence pour leur utilisation à l'égard de la COVID-19 - Ligne directrice
<https://www.canada.ca/fr/sante-canada/services/medicaments-produits-sante/medicaments/annonces/arrete-urgence-importation-vente-instruments-medicaux-covid-19/document-applications-dispositifs-medicaux.html>
- Instruments autorisés en vertu de l'arrêté d'urgence:
<https://www.canada.ca/fr/sante-canada/services/medicaments-produits-sante/covid19-industrie/instruments-medicaux/instruments-autorises-arrete-urgence.html>
- Adresse courriel:
hc.devicelicensing-homologationinstruments.sc@canada.ca

Slide Courtesy of Health Canada

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Thank-you!

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Dispositifs Médicaux