

PERSONAL PROTECTIVE EQUIPMENT- FOCUS ON MASKS AND GLOVES

INTRODUCTION

The coronavirus (COVID-19) has posed significant challenges to Dentistry around the world. The role of dental professionals in preventing the transmission of COVID-19 is critically important. While routine dental care has been suspended during the period of pandemic, the need for organised urgent care delivered by teams using appropriate personal protective equipment remains.

The New York Times reminded the world that dentistry had the most risk of any profession in relation to COVID-19. Dental drills cause aerosol and splatter commonly contaminated with bacteria, viruses, fungi and blood. Aerosols are liquid and solid particles (<50 µm diameter) suspended in air for prolonged periods. Splatter is a mixture of air, water and/or solid substances (50 µm to several millimetres diameter). Both poses health risks to the dental team. According to Genome Research (2009), over 600 different types of bacteria can be detected in the human oral cavity, and 1 ml saliva contains about 10 million bacteria. Bennet et al (2000) proved that during a 15-minute treatment without protective measures, approx. 0.014–0.12 µl of saliva is inhaled via the aerosol.

Personal protective equipment, commonly referred to as "PPE", must be worn to minimize exposure of the dental team to body fluids or from droplet or airborne pathogens. Personal protective equipment includes items such as masks, respirators, gloves, safety glasses/ goggles, surgical gowns, shoe covers, face shields and caps. In this article we will discuss masks and gloves in more detail.



FACEMASKS

Facemasks are intended to protect the patient and/or working environment from droplets coming from the nose and mouth of the wearer's face and are also worn as a barrier to protect the wearer's face from large droplets and splashes of blood or other body fluids. The WHO recommends that healthcare workers should wear a medical mask in any situation of care provided where a risk of contamination exist.

Surgical masks and surgical respirators vary in intended use, fit against the face, required testing and approval standards. Note that not all facemasks are regulated as surgical/ medical masks.

COTTON MASKS FOR HEALTHCARE WORKERS

Non-medical cotton masks are not indicated for healthcare workers because there is no filtration or protection against droplets or splashes. There is also the "wicking effect" which refers to the attraction of fabrics to moisture that increases the risk of contamination.

SURGICAL MASKS

Surgical Masks are widely used in healthcare. It creates a physical barrier between potential contaminants in the environment and the wearer. A surgical mask is meant to provide protection by reducing the risk of splashes, sprays, or splatter of blood, body fluids, and other secretions from reaching your mouth and nose. There is a common misperception that they will provide complete protection against small particles in the air that may be transmitted by coughs, sneezes, or aerosol generating medical procedures. Whilst surgical masks when worn correctly offers effective protection against splashes and large-particle droplets, the level of protection they offer against a residual aerosol risk is poorly understood. It is important to remember that surgical masks are not designed, or certified, as respiratory protective devices.

Surgical masks are classified as class 1 Medical Devices under the Medical Devices Directive 93/42/EEC and are regulated.

SURGICAL MASK TESTING

In Europe, surgical masks must bear a CE-mark and comply with the requirements defined in EN 14683. The version of EN 14683:2014 includes 4 tests.

1. Bacterial Filtration Efficiency (BFE)

Measures the efficiency at which the face mask filters bacteria passing through the mask.

2. Breathing Resistance (Delta P) or the Differential Pressure

Determines the air permeability of the mask (breathability). It is measured by determining the difference of pressure across the mask under specific conditions of air flow, temperature and humidity. The lower the delta P of the medical face mask, easier it is for the wearer to breathe in it.

3. Splash Resistance (ISO 22609)

Measures the fluid resistance of the mask.

4. Microbial Cleanliness (EN ISO 11737)

Determines the total number of viable microorganisms on the face mask using an extraction method. Based on the weight of the mask, the results are reported as the total bioburden per gram tested for each mask. According to EN 14683, in order to meet the performance requirements of Type I, Type II, and Type IIR, the bioburden of the face mask must be less than 30 cfu/g.

Other optional tests include Flammability and Biocompatibility testing.

LIMITATIONS OF SURGICAL MASKS

- One time use i.e., one patient encounter
- Use for procedures to a maximum of 2-3 hours
- Should be discarded when it becomes contaminated with blood or other bodily fluids
- Surgical masks are designed to cover the mouth and nose loosely and are not sized for individual fit and therefore will not pass a fit test.

N95 RESPIRATORS

N95 Respirators (FFP2, FFP3) are specifically designed for efficient filtration of smaller airborne particles. The edges of the N95 respirator is designed to form a seal around the mouth and nose to achieve a tight facial fit. Given a proper fit, the filtration capabilities of N95 respirators exceed those of surgical face masks. 'N95' means that when subjected to testing, the respirator blocks at least 95 percent of tiny (0.3 micron) test particles.

Back in 2008, the Health and Safety Executive evaluated the protection offered by different types of masks against influenza bioaerosols and recommended the wearing of respiratory personal protective equipment, such as a surgical respirator (FFP3) when carrying out aerosol generating procedures such as dental drilling.

N95 RESPIRATOR GUIDELINES

- Dentists may use the same N95 respirator per session (i.e. changed once per day). Apron and gloves should be changed between patients.
- Discard N95 respirator immediately when it:
 - Becomes wet or visibly dirty;
 - Damaged or deformed;
 - No longer forms an effective seal to the face;
 - Breathing through it becomes more difficult; or
 - It is contaminated with blood, respiratory secretions, or other bodily fluids
- Use of the same respirator between a patient with COVID-19 and a healthy patient is not recommended.
- Never attempt to disinfect a N95 respirator as this destroys its integrity
- The N95 respirator can make it more difficult for the wearer to breathe. Those with respiratory, cardiac, or other medical conditions that make breathing difficult should check with their health care provider before using an N95 respirator or use a valved respirator (see limitation below).
- Seal tests should be performed each time a N95 respirator is used
- Because a proper fit cannot be achieved on children and persons with facial hair, the N95 respirator may not provide full protection and are not recommended.

N95 RESPIRATOR TESTING

Surgical N95 respirators are class II medical devices regulated by the FDA, under 21 CFR 878.4040, and CDC NIOSH under 42 CFR Part 84. The following tests are done to classify respirators (EN 149:2001+A1:2009)

1. *Filtration Efficiency*: The higher the FFP number, the more protection the respirator can provide if it is used properly.
2. *Breathing Resistance*: These masks are also tested to determine their total inward leakage, based on their filtration.
3. *Fit Test*: Respirators must seal to the wearer's face in order to provide expected protection. There are two types of fit tests:
 - Qualitative fit testing is a pass/fail and relies on the user's senses using one of four accepted test agents.
 - Quantitative fit testing uses an instrument to measure leakage around the face seal and produces a numerical result called a "fit factor."

VALVED VS NON-VALVED RESPIRATORS

Valved respirators can make it easier to breathe compared to non-valved respirators and may be more comfortable to wear. However, because the valve opens when exhaling, small particles may escape from the wearer into the air making it unsuitable for situations where sterility is required.



GENERAL MASK MANAGEMENT

For any type of mask, appropriate use and disposal are essential to ensure that they are effective and to avoid contamination.

- Extended use of a mask may increase risk of contamination of the mask with COVID-19 virus and other pathogens.
- Place the mask carefully over your mouth and nose and tie it securely. Ensure that there are no gaps between the face and the mask.
- Do not touch your mask while wearing it.
- Remove the mask using the appropriate technique. Avoid touching the front of the mask. Untie and remove by the strings or earloops.
- After removal or whenever a used mask is accidentally touched, clean hands by washing or rubbing with alcohol.
- When a mask becomes damp or visibly soiled, replace with a new mask as soon as possible.
- Refrain from re-using or sharing any single-use mask.
- No quality evidence is available to date on medical mask reprocessing and is not advised
- Discard single-use masks immediately after each use in an appropriate biohazard container.

CONCLUSION

The FDA regulates surgical masks and surgical N95 respirators differently based on their intended use. No head to head trial of these masks in COVID-19 has yet been published, and neither type of mask prevents all infection. Both types of mask need to be used in combination with other PPE measures.

When worn correctly and frequently changed, regular surgical face masks used in dentistry offer around 80% filtration rate. This is enough protection for elective dentistry in normal circumstances, knowing that most patients are healthy. The COVID-19 virus measures around 120 nm (0.12 μm) and aerosol particle sizes range from 3-100 nm. The use of a FFP3 respirator offers a filtration rate of 99% of all particles measuring up to 0.6 μm and is therefore recommended for protection during aerosol generating procedures.

MEDICAL GLOVES

Medical gloves are examples of personal protective equipment that are used to protect the DHCP and the patient from the spread of infection or illness during dental procedures and examinations. Glove usage is often identified as being "the first line of PPE defence."

Medical gloves are defined as disposable gloves used during medical procedures and include examination gloves (non-sterile or sterile), surgical gloves, and chemotherapy gloves. These gloves are regulated as Class I reserved medical devices. Regulatory bodies review these devices to ensure that performance criteria such as leak resistance, tear resistance and biocompatibility are met.

Occupational Safety and Health Administration (OSHA) mandates that gloves should be used during all patient-care activities that may involve exposure to someone else's body fluids (such as blood, respiratory secretions, vomit, urine or faeces), mucous membrane or non-intact skin. Saliva has always been considered a potentially infectious material in dental infection control.

GLOVE EFFECTIVENESS

The efficacy of gloves in preventing hand contamination of healthcare workers during direct patient contact has been confirmed in several clinical studies. One study indicated that glove usage reduced the number of bacteria on healthcare workers' hands by more than 80%. Gloves also minimize the hazards of handling instruments, equipment, appliance/prostheses, and impressions contaminated with patient body fluids. Gloves has been shown to reduce the incidence of nosocomial infections. They also inhibit contamination of patient tissues by organisms present on practitioner hands.

However, medical gloves have limitations and are only but a part of an efficient infection-control strategy. DHCP's should keep in mind that wearing gloves does not eliminate the need for appropriate hand hygiene by rubbing or washing. Wearing gloves cannot completely prevent occupational acquisition of serious pathogens through exposure such as needlesticks, cuts, punctures, glove defects, or incorrect doffing procedures.



TESTING OF GLOVES

The Food and Drug Administration (FDA) sets guidelines by enforcing a set of test methods called American Society for Testing and Materials (ASTM). All medical gloves must meet certain Acceptable Quality Level (AQL) standards.

AQL is used by manufacturers to identify the maximum number of allowable defects per 100 gloves. The lower the AQL score, the higher the quality of the gloves. The current FDA AQL requirement is 2.5, which means for every 100 gloves tested, fewer than 2.5 gloves may be defective. Stricter standards apply to surgeon's than to examination gloves.

Water Testing is one way to measure the AQL for gloves. This test is conducted by filling the glove with 1,000 ml of water, suspending the glove for two minutes, and then looking for leaks. Each leak is counted as a defect. Another method is called the Air Inflation test. The glove is inflated with air and visually inspected for holes.

Although the FDA has identified acceptable quality levels, any glove may fail with exposure to mechanical (e.g. sharps, fingernails, or jewellery) and chemical hazards.

Also be aware that counterfeit medical gloves may be on the market, especially during this time of increased demand.



GUIDELINES TO GLOVE USE

- Differentiate between specific clinical situations when gloves should be worn and those where their use is not required. The use of gloves when not indicated represents a waste of resources and does not contribute to a reduction of cross-transmission.
- Wear gloves when it can be reasonably anticipated that contact with blood or other body fluids, mucous membranes, non-intact skin or potentially infectious material will occur.
- Wear sterile surgeons' gloves when performing oral surgical procedures.
- It's important to know the right size gloves to use. Gloves that are too big can easily be pulled off or liquids can make its way inside the glove. A glove that is too tight can cause fatigue and decrease dexterity. Choose gloves that fit well.
- Wash or rub your hands before putting on sterile gloves.
- Wear a new pair of medical gloves for each patient and remove them promptly after use.
- After removing gloves, wash your hands thoroughly with soap and water or alcohol-based hand rub to avoid transfer of microorganisms to other patients or the environment.
- Use the correct technique for donning and removing gloves that prevents hands becoming contaminated.
- Be aware that sharp objects can puncture medical gloves.
- Remove and change gloves that are ripped, torn, cut, or punctured as soon as feasible and wash/ rub hands before putting on new gloves.
- Washing, disinfecting, or sterilizing of gloves for reuse is not recommended.
- Never share medical gloves with other users.
- Ensure that appropriate gloves in the correct size are readily accessible.
- Consult with glove manufacturers regarding the chemical compatibility of glove materials with hand hygiene products as well as the dental materials being used. Use of petroleum-based hand lotions or creams may adversely affect the integrity of latex gloves and some alcohol-based hand-rub may interact with residual powder on hands.
- Beware of allergies to the natural rubber latex used in some medical gloves. Check package labelling to identify the materials used to make the gloves. If you or your patient is allergic to latex, you should choose gloves made from other synthetic materials (such as polyvinyl chloride (PVC), nitrile, or polyurethane).

- The effectiveness of double gloving in preventing disease transmission during oral surgical procedures has not been demonstrated, however, studies among healthcare personnel and DHCP have demonstrated a lower frequency of inner glove perforation and visible blood on the surgeon's hands when double gloves are worn. For procedures with contact with large amounts of blood or body fluids, double gloving is considered an appropriate practice.

RE-USE/REPROCESSING OF GLOVES

Medical gloves are single-use items, glove decontamination and reprocessing are not recommended and should be avoided, even if it is common practice in many health-care settings with low resources and where glove supply is limited.

At present no standardized, validated and affordable procedure for safe glove reprocessing exists.

Every possible effort should be made to prevent glove reuse in health-care settings, such as educational activities to reduce inappropriate glove use, purchasing good quality disposable gloves and replenishing stock in a timely manner.

DO MEDICAL GLOVES PROVIDE PROTECTION FROM CORONAVIRUS?

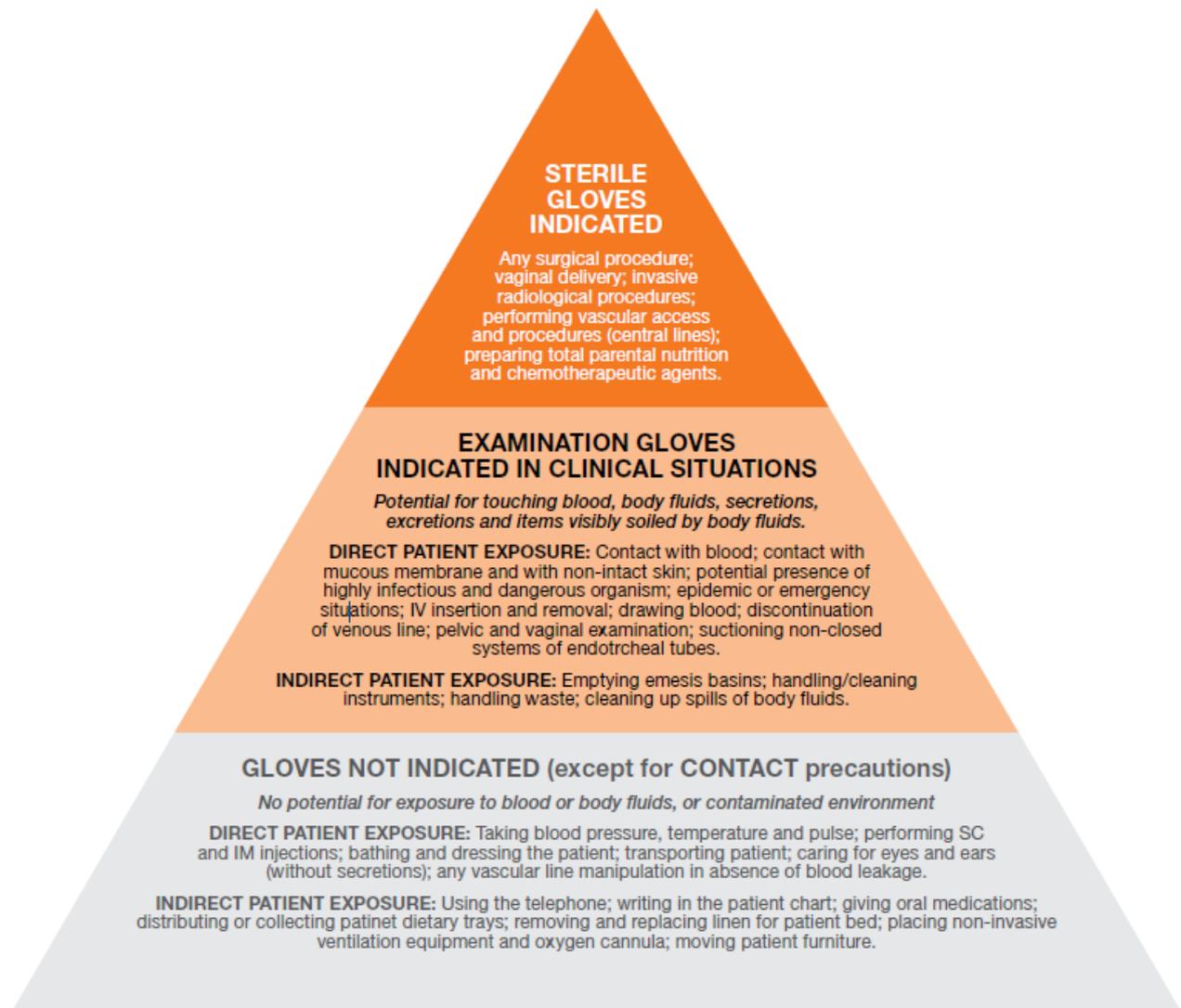
Medical gloves are intended to provide broad barrier protection. Please see current recommendations from Centre for Disease Control and Prevention (CDC) for patients with suspected or confirmed COVID-19. At this time, FDA has not cleared, approved, or authorized any medical gloves for specific protection against the virus that causes COVID-19 or prevention of COVID-19 infection.

GLOVE TYPES AND USES

GLOVE	INDICATION	COMMENTS
EXAMINATION GLOVES	Patient care, examinations and other non-surgical procedures involving contact with mucous membranes.	*Regulated Medical device
		* Nonsterile and Sterile
		* Single-use disposable
SURGICAL GLOVES	Surgical Procedures	*Regulated Medical device
		*Sterile and single-use disposable
NON-MEDICAL GLOVES	Cleaning, Disinfecting, Handling of contaminated sharps or chemicals. Not for use during patient care.	* Not Regulated
		* Referred to as utility or general purpose gloves
		* Can Sanitize after use
		* Should be puncture and chemical resistant

THE GLOVE PYRAMID- WHO

Aids decision making on when to wear (and not wear) gloves. The pyramid details some clinical examples in which gloves are not indicated, and others in which examination or sterile gloves are indicated.



Available from: www.who.int/gpsc/en/index.html

Additional information on the use of gloves is available at the OSAP Website: osap.org.

DONNING AND REMOVING GLOVES- PROCEDURE

Technique for donning and removing non-sterile examination gloves

When the hand hygiene indication occurs before a contact requiring glove use, perform hand hygiene by rubbing with an alcohol-based handrub or by washing with soap and water.

I. HOW TO DON GLOVES:



1. Take out a glove from its original box



2. Touch only a restricted surface of the glove corresponding to the wrist (at the top edge of the cuff)



3. Don the first glove



4. Take the second glove with the bare hand and touch only a restricted surface of glove corresponding to the wrist



5. To avoid touching the skin of the forearm with the gloved hand, turn the external surface of the glove to be donned on the folded fingers of the gloved hand, thus permitting to glove the second hand



6. Once gloved, hands should not touch anything else that is not defined by indications and conditions for glove use

II. HOW TO REMOVE GLOVES:



1. Pinch one glove at the wrist level to remove it, without touching the skin of the forearm, and peel away from the hand, thus allowing the glove to turn inside out



2. Hold the removed glove in the gloved hand and slide the fingers of the ungloved hand inside between the glove and the wrist. Remove the second glove by rolling it down the hand and fold into the first glove



3. Discard the removed gloves

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QUESTIONS

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