

## FOCUS ON

# Medical Isolation Gowns for COVID-19 in Health Care Settings



1<sup>st</sup> Revision: February 2021

## Introduction

This document provides information about gowns and gown use as part of personal protective equipment (PPE) in health care. It is intended to provide a summary of current guidance on the effectiveness of and considerations for gown use to help mitigate the spread of COVID-19.

Highlights include:

- A description of the types of medical gowns used in health care and how they are classified
- The standards and textiles used in the production of approved medical gowns
- Current guidance on safe approaches to conservation of medical gowns

## Background

When Additional Precautions are in place due to an infectious disease, a gown must be worn if skin or clothing will come in contact with the patient/resident or the patient/resident's environment. Also, as part of Routine Practices and a Personal Risk Assessment, a gown is worn when it is anticipated that a procedure or care activity is likely to generate splashes or sprays of blood, body fluids, secretions, or excretions. In Canada, all medical gowns are Class I medical devices which present the lowest potential body fluid exposure risk (Class I lowest risk, Class IV highest risk).<sup>1</sup> Medical gowns are used in a variety of health care settings and their selection depends on the anticipated use and needs of the health care professionals and client/patient/resident.

There are two main types of medical gowns: isolation gowns and surgical gowns. They are both Class I medical devices. It is important to note that the product names of gowns are not standardized. These products may also be called procedural gowns, operating room gowns, or non-surgical gowns. Typically the gowns used for Additional Precautions are isolation gowns.

## Methods

A review of current guidance from Public Health Ontario (PHO), Health Canada (HC), the Public Health Agency of Canada (PHAC), the Canadian Standards Association Group (CSA), the US Center for Disease Control and Prevention (CDC), the World Health Organization (WHO) and a limited literature scan was completed to summarize information regarding the appropriate usage and conservation of gowns in health care, worn as part of PPE.

## Summary of Findings

### Types of Gown

**Isolation gowns:** protective apparel used to protect the clothing of health care professionals, visitors, and clients/patients/residents from the transfer of microorganisms and body fluids.

**Surgical gowns:** sterile textile gowns worn by health care professionals who are performing activities in a sterile environment.<sup>2</sup>

### Levels of Risk

Regardless of how the product is named, the product labeling describes the intended use, and it is necessary to identify the desired level of protection based on the level of risk of exposure to blood and body fluids (see Table 1). There are four levels of risk that can be broken down into two categories: Low Risk (Level 1 and Level 2) and High Risk (Level 3 and Level 4). For more information refer to HC's [Important Regulatory Considerations for the Supply of Medical Gowns: Guidance to Industry](#).<sup>3</sup>

**Table 1. Exposure Risk levels to blood and body fluids and gown classification**

Gown classification	Level of risk	Examples of work
Level 1	Minimal	Standard precautions; Simple procedures
Level 2	Low	Minimally invasive surgery
Level 3	Moderate	Open gastrointestinal surgeries
Level 4	High	Open cardiovascular procedures; Trauma procedures

Source: [Important regulatory considerations for the supply of medical gowns: Guidance to industry](#)<sup>3</sup>

## Standards for Medical Gowns

There are standards for both the material integrity of gowns (HC accepts conformance with the [American Society for Testing and Materials \(ASTM\) F2407](#)), as well as for the protective nature they provide:<sup>4</sup>

- [Canadian Standards Association \(CSA\): CSA Z314](#),<sup>5</sup>
- [American National Standards Institute \(ANSI\) and the Association of the Advancement of Medical Instrumentation \(AAMI\): ANSI/AAMI PB70](#),<sup>6</sup>
- [The European Standards EN: \(EN 13795\)](#).<sup>7</sup>

[The World Health Organization](#) also recognizes the [EU Personal Protective Equipment \(PPE\) Regulation 2016/425](#) and [EU MDD Directive 93/42/EEC](#) for single use gowns.<sup>8-10</sup>

Note: These standards are not open access and require purchase to view full documents.

Table 2 summarizes the standards for gowns as identified by HC in [Important Regulatory Considerations for the Supply of Medical Gowns: Guidance to industry](#).<sup>3</sup> European equivalencies for these standards are also on that website.

**Table 2. North American Standards**

CSA Z314 (Canada) and ANSI PB70 (USA)

Classification	Standard/Testing
<b>Level 1</b> Minimal water resistance (some resistance to water spray)	AATCC 42: Water penetration $\leq$ 4.5 g AATCC 127: Hydrostatic pressure N/A
<b>Level 2</b> Low water resistance (resistant to water spray and some resistance to water penetration under constant contact with increasing pressure)	AATCC 42: Water penetration $\leq$ 1.0 g AATCC 127: Hydrostatic pressure $\geq$ 20cm water column
<b>Level 3</b> Moderate water resistance (resistant to water spray and some resistance to water penetration under constant contact with increasing pressure)	AATCC 42: Water penetration $\leq$ 1.0 g AATCC 127: Hydrostatic pressure $\geq$ 50cm water column
<b>Level 4</b> Blood and viral penetration resistance (2psi)	ASTM F167 (Blood) and F1671 (Viral): No penetration at 2 psi (13.8kPa)

Source: [Important regulatory considerations for the supply of medical gowns: Guidance to industry](#)<sup>3</sup>

## Textiles Used for Medical Gowns

Microorganisms' movement through medical gown fabrics depends on several factors, including the physical and chemical properties of the fabric, specific characteristics of the microorganisms, and the characteristics of carriers, and other factors such as physical and chemical stresses. A number of fabric and design characteristics also contribute to the effectiveness of medical gowns such as fabric and seam strength, pore size, repellency, size, fit, thermal comfort and mobility.<sup>11,12</sup>

Isolation gowns can be reusable or disposable. They should have long-sleeves, cover the body front and back from the neck to the thighs, overlap in the back, fasten at the neck and back and be easy to put on and take off.<sup>1</sup> All Health Care Workers (HCWs) require training on [how to put on properly and take off PPE safely, including the isolation gown](#).<sup>13</sup>

Disposable isolation gowns are typically fabricated with nonwoven materials or in combination with materials that offer increased protection from liquid penetration, such as plastic films. Various forms of synthetic fibers (e.g., polypropylene, polyester, polyethylene) are used for the construction of disposable isolation gowns.<sup>11</sup>

Reusable (multiuse) isolation gowns are laundered after each use and typically made of tightly woven 100% cotton, 100% polyester, or polyester-cotton blends.<sup>11</sup> They are usually chemically finished and may be pressed through rollers to enhance the liquid barrier properties.<sup>14</sup> It is important to remember that

reusable isolation gowns must be removed after care of a client/patient/resident and placed into an appropriate container for laundering, between client/patient/resident.

For both reusable and disposable gowns, a consistent finding is that, although impermeable materials are effective in reducing transfer of microorganisms, the thermal comfort of the wearer is compromised.

## Conservation of Gowns

Current PHO IPAC recommendations are to remove gowns when moving between patients/residents. Practices that extend the use of personal protective equipment (PPE) could potentially place health care workers and their residents at increased risk of transmission of COVID-19 or other pathogens<sup>15,16,17</sup>. IPAC best practices recommend that PPE should be put on immediately before use and removed immediately after use, followed by hand hygiene. The extended use of specific PPE such as gowns should only be implemented when supplies are limited, and should only be considered in consultation with the IPAC professional and/or the outbreak management team in order to mitigate the risk of transmission that may occur with extended use.

There are a number of strategies that can be used when faced with a low or critically low supply of gowns in health care during the current COVID-19 pandemic. Gowns are recommended for the care of suspected or confirmed COVID-19 client/patient/resident by the CDC<sup>18</sup>, the WHO<sup>19</sup>, and PHAC<sup>1</sup> as part of Contact Precautions.

Gowns used as PPE should be approved by Health Canada and be available in several sizes to ensure appropriate coverage for staff. Clinical and laboratory coats or jackets are not an adequate substitute for gowns where an isolation gown is indicated.

Before considering a reusable gown, CAN/CSA-Z314-18<sup>5</sup> indicates that the health care setting should ensure that it is supplied with validated written manufacturer's instructions for use for:

- the intended applications and limitations
- storage
- maintenance of sterility and package integrity
- environmental conditions for transport and storage (i.e., temperature and humidity)
- the measures to be taken if these limits are exceeded

Of note, it is recommended that anti-static agents not be used when laundering reusable gowns, and flammability performance requirements for gown fabrics must be met.

PHO<sup>20</sup>, CDC<sup>18</sup>, HC<sup>1</sup> and WHO<sup>19</sup> provide guidance regarding conservation of PPE during pandemic shortages.

Health Canada<sup>1</sup> indicates that, if a shortage of isolation gowns occurs in a healthcare setting, the following strategies should be considered:

- save existing supplies of gowns by decreasing the need for their use, such as:
  - placing a physical barrier between HCWs and individuals at screening points
  - reducing, postponing or cancelling non-essential procedures that may require a gown
  - bundling activities to reduce the need to change a gown

- increase the frequency of laundering of reusable gowns
- use other types of approved gowns such as:
  - operating room (or surgical) gowns
- change uniforms more frequently
- use expired disposable gowns for training of HCWs

Identify other apparel or combination of apparel that could provide similar protection, including:

- coveralls
- laboratory coats
- aprons
- sleeve covers
- if no alternatives are available, then, after discussions with staff, the use of expired gowns that are physically intact and show no visible wear could be considered in the strategies to address a shortage.

Other apparel such as coveralls, laboratory coats and aprons are not normally used by HCWs when caring for a client/patient/resident and are not equivalent to gowns. It is important to train HCWs on how to put on and safely take off these apparel, to minimize the risk of self-contamination.

## Coveralls

Coveralls (reusable or disposable) provide full body protection. They open at the front and can cover the head and feet as well. They are more complicated to put on and take off and sizing may be an issue for some HCWs. They might have to be worn in combination with an apron if the clothing is not fully protected at the front.

## Laboratory Coats

Laboratory (lab) coats (reusable or disposable) provide a cover over clothing similar to a gown, except that they open in the front and may not be as long as a gown. Gloves may not fit well over the cuff of the lab coat, possibly exposing the wrist. Sizing may also be an issue for some HCWs.

For example:

- to increase effectiveness, lab coats should be buttoned up
- lab coats may need to be worn in combination with other items, such as an apron

## Aprons

Aprons (reusable or disposable) provide protection to the front of the body. They can tie at the neck or have an overhead strap. This type increases the chance of touching the face and self-contaminating when taking them off. They can be long-sleeved or without sleeves and can be made of different kinds of material, such as plastic or fabric. Aprons should be used in combination with other apparel, such as a lab coat and sleeve covers, since aprons may not cover the back and arms.

## Sleeve Covers

Sleeve covers protect the forearms and are available in different kinds of material. Sleeve covers need to be used in combination with other apparel such as aprons.

## Reprocessing of Gowns: Disposable<sup>20</sup>

- Reprocessing of disposable gowns is impractical due to the inability to launder, remove contamination and maintain integrity.
- A scoping literature search was completed by PHO and no studies were found on decontamination and reuse of disposable gowns.
- The CDC cites easy breakage of disposable gown ties and fasteners, making them less amenable to washing and reuse than reusable gowns.<sup>18</sup>

## Reprocessing of Gowns: Reusable<sup>20</sup>

- HC indicates that reusable (washable) medical gowns may be laundered after each use and safely reused.<sup>2</sup>
- Reusable gowns are required to meet manufacturer's instructions with respect to laundering requirements for healthcare settings. This includes the number of times gowns can be laundered to maintain performance, safety, and effectiveness. If there is no date available on the gown label or packaging to indicate a manufacturer-designed shelf life, facilities should contact the manufacturer.
- The CDC also recommends cloth gowns be laundered as per facility/supplier recommendations after each use.<sup>18</sup> A combination of mechanical, thermal, and chemical factors results in the antimicrobial action of the laundering process – protocols may vary.
- Laundry operations and personnel may need to be augmented to facilitate additional washing loads and cycles.
- Systems are established to routinely inspect, maintain (e.g., mend a small hole in a gown, replace missing fastening ties) and replace reusable gowns when needed (e.g., when they are thin or ripped).

## Extended Use of Gowns

- When disposable gowns are in short supply, extended use of gowns (disposable or cloth) may be considered in consultation with the IPAC professional and/or the outbreak management team in order to mitigate the risk of transmission that may occur with extended use.<sup>15,16,17</sup>
- A gown's use may be extended by wearing it for repeated encounters within a cohorted unit of COVID-19 positive clients/patients/residents, and without removing the gown between the clients/patients/residents within the cohort unless visibly soiled. For more see [Cohorting in Outbreaks in Congregate Living Settings](#).<sup>21</sup>

- The gown is to be removed after the last client/patient/resident encounter within the cohort and placed into an appropriate receptacle (hamper or waste receptacle) ideally foot operated to reduce hand contamination and followed by hand hygiene.

## Expired Gowns

- It is not recommended to use expired disposable medical gowns without confirming that they are still fluid resistant according to AATCC Test Method 42 for gowns of Level 1.
- HC states that reusable gowns can be used beyond their recommended life span provided they are free of damage.<sup>2</sup>
- Expired gowns should be visibly inspected for damage prior to use. Indications of damage may include odours or noticeable/heavy soiling, staining, or spotting (for example, signs of mould).
- Expired gowns, whether disposable or reusable, can also be used for training and demonstration purposes in cases where protective barriers are not needed.

## When No Gowns Are Available

The [CDC](#) provides some guidance on consideration that may be given to using gown alternatives that have not been evaluated as effective during times when medical gowns are not available.<sup>18</sup> It is important to keep in mind that **those options cannot be considered PPE, since their capability to protect HCWs is unknown**. Homemade gowns would fall into this category. Homemade gowns do not typically have HC approval and cannot be considered adequate PPE. Efficacy may vary based on the fabrics, construction, features and use of the gowns.

## Conclusion

There are several resources that can be used to help guide the choice and safe use following best practices. The use of gowns as part of PPE for COVID-19 helps protect the wearer's skin and clothing from contamination. When there is a shortage, strategies can be used for conservation of medical gowns in health care. This document offers some approved options to help inform choices about gown use during times of shortages.



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## Summary of Revisions

This document is current to August 2020. New material in this revision is highlighted in the table below.

Page	Revision	Implementation Date
1	Clarification on indications for use of a gown	January 29, 2020
5	Emphasis on best practices for use of PPE and that conservation or extended use of PPE should only occur during supply shortages.	January 29, 2020
7	Extended use of PPE should only be considered in consultation with the IPAC professional and/or outbreak management team.	January 29, 2020

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