

FW: Health Canada Application for P100 Respirator - Private, Confidential and Commercially Sensitive Advice to Cabinet

Morgado, David (OPO) <David.Morgado2@ontario.ca>

Mon 2020-06-29 11:21 AM

To: smitnicolas@hotmail.com <smitnicolas@hotmail.com>

Please see below response.

P100 Respirators – Background and Current Status

Ontario does not prohibit the use of P100 respirators. Clinical guidance in Ontario, from the Chief Medical Officer of Health, is that the P100 is an alternative, equivalent product to the N95 respirator.

Health Guidance for alternative equivalent product to the N95 Masks:

[Health Canada guidance](#) lists P100 respirators as an alternative, equivalent product to the N95 masks. Specifically, Health Canada advises the following:

“During the COVID-19 outbreak when medical-grade N95 or equivalent respirators aren't available, health care institutions may, at their discretion, purchase and use:

- commercial-grade N95 (or P95 and similar) respirators
- equivalents such as commercial-grade KN95 (or KP95) respirators
- **other alternative, equivalent commercial-grade filtering facepiece respirators that are at least as protective as the commercial-grade N95, such as the N99, N100, P95, P99, P100, R95, R99, and R100 respirators.**
 - P100 respirators are filtering, oil-resistant industrial respirators. These are similar to the N95 respirators, but their filter performance of airborne particles is greater than 95% (99.97%).
 - N100 respirators have the same filtration performance as the P100 but are not oil resistant (similar to the N95).” **(emphasis added)**

[Ontario's Chief Medical Officer of Health guidance](#) for COVID+ and airborne precautions in acute care settings states “**N95 fit tested respirator, or approved or equivalent or better protection.**”

Use of 7500 series Half-Faced Elastomeric Respirators with P100 filters in Ontario:

During the course of the COVID-19 pandemic, the Ontario Government has looked towards sourcing alternative models to traditional N95 respirators.

This pursuit has included alternative NIOSH approved disposable models and reusable formats such as Elastomeric and Power Air Purifying Respirators (PAPR).

To date, the Province has purchased 100,000 units of **7500 series Half-Faced Elastomeric Respirators with 100,000 P100 filters**. A first shipment of 25,000 units arrived in Toronto and are in the MOEC warehouse week. The remainder of these respirators are expected to arrive by the end of July 2020. Ontario Health is in the process of determining how to allocate these shipments to hospitals. Several Ontario hospitals have been using these Elastomeric respirators as an alternative and they have developed safe usage and sanitization guidance.

Health sector organizations will determine the appropriate setting for how and where these respirators can be used from a clinical workflow and patient safety perspective

Thanks,

David Morgado

*Executive Assistant to the Premier of Ontario
Office of the Premier of Ontario*

From: Shamoon, Rana (OPO) <Rana.Shamoon@ontario.ca>
Sent: June 29, 2020 12:12 AM
To: Morgado, David (OPO) <David.Morgado2@ontario.ca>
Subject: FW: Health Canada Application for P100 Respirator - Private, Confidential and Commercially Sensitive Advice to Cabinet

See below.

Rana Shamoon

Director, Health Policy | Office of the Premier

From: Sackville, Patrick (OPO) <Patrick.Sackville@ontario.ca>
Sent: June 26, 2020 10:24 PM
To: Silva, David (MGCS) <David.Silva@ontario.ca>; MacDonald, Allan (CAB) <Allan.MacDonald@ontario.ca>; Shamoon, Rana (OPO) <Rana.Shamoon@ontario.ca>
Cc: Francis, Heidi (MGCS) <Heidi.Francis@ontario.ca>; Fraser, Melanie (MOH) <Melanie.Fraser@ontario.ca>; Longo, Peter <peter.longo@unityhealth.to>
Subject: Re: Health Canada Application for P100 Respirator - Private, Confidential and Commercially Sensitive Advice to Cabinet

Thank you very much, David.

Adding Rana Shamoon for her awareness.

P

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From: Silva, David (MGCS) <David.Silva@ontario.ca>
Sent: Friday, June 26, 2020 6:53:28 PM
To: MacDonald, Allan (CAB) <Allan.MacDonald@ontario.ca>; Sackville, Patrick (OPO) <Patrick.Sackville@ontario.ca>
Cc: Francis, Heidi (MGCS) <Heidi.Francis@ontario.ca>; Fraser, Melanie (MOH) <Melanie.Fraser@ontario.ca>; Longo, Peter <peter.longo@unityhealth.to>
Subject: RE: Health Canada Application for P100 Respirator - Private, Confidential and Commercially Sensitive Advice to Cabinet

Good Evening Allan and Patrick,

Responding on Heidi's behalf with the following update provided by the teams at MGCS, MOH and OH. Please let us know if you have any questions.

David

P100 Respirators – Background and Current Status

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Health sector organizations will determine the appropriate setting for how and where these respirators can be used from a clinical workflow and patient safety perspective

From: MacDonald, Allan (CAB) <Allan.MacDonald@ontario.ca>

Sent: June 26, 2020 9:15 AM

To: Sackville, Patrick (OPO) <Patrick.Sackville@ontario.ca>; Francis, Heidi (MGCS) <Heidi.Francis@ontario.ca>; Fraser, Melanie (MOH) <Melanie.Fraser@ontario.ca>; Longo, Peter <peter.longo@unityhealth.to>

Subject: RE: Health Canada Application for P100 Respirator - Private, Confidential and Commercially Sensitive Advice to Cabinet

Morning Patrick,

This is news to me. Let me ask the team for an update for us both.

Heidi - Can you coordinate an update w Mel and Peter?

A

From: Sackville, Patrick (OPO) <Patrick.Sackville@ontario.ca>

Sent: June 24, 2020 11:06 AM

To: MacDonald, Allan (CAB) <Allan.MacDonald@ontario.ca>

Cc: Shamoan, Rana (OPO) <Rana.Shamoan@ontario.ca>

Subject: Health Canada Application for P100 Respirator - Private, Confidential and Commercially Sensitive Advice to Cabinet

Hi Allan,

Rana Shamoon and I have received outreach regarding HC review of the P100 Respirator (please see attached).

The outreach suggests that Ontario has prohibited the use of this mask type, further suggesting that Ontario hospitals have abundant inventories of this type of mask. The issue HC is raising is that no application has been received to review/approve this product.

Are you able to help bring clarity to this?

Thank you for your help.

P

Patrick Sackville
Executive Director of Policy
Office of the Premier of Ontario
Patrick.Sackville@Ontario.ca

----- Forwarded message -----

From: **Nicolas Smit** <smitnicolas@hotmail.com>
Date: Tue, Jun 16, 2020 at 9:50 AM
Subject: Health Canada Approval of P100 Respirators

Hi XXXXXXXX,

There is a serious issue in regards to PPE for health care workers which have just been approved by Health Canada that should get Doug Ford's immediate attention. I am forwarding this email from Health Canada which indicates why they have decided to approve P100 respirators 10 weeks after the Ontario government started saying they were dangerous and told hospitals they should not use their inventory of P100s under any circumstance.

This is a New York Time articles explaining P100 respirators in detail and why the US has used them for so long.

<https://www.nytimes.com/2020/05/27/us/coronavirus-masks-elastomeric-respirators.html>

This is a Northern Ontario Business article where Ontario Health Critic France Gelinas explains that Ontario hospitals have a lot of P100 respirators in their inventories but that the government has decided to not allow hospital staff to use them.

<https://www.northernontariobusiness.com/regional-news/sudbury/sudbury-engineer-urging-mining-industry-to-donate-respirators-2273156>

Here is an article that just came out about a month long test using thousands of P100s in Pittsburg hospitals.

<https://www.mcknights.com/news/clinical-news/use-of-elastomeric-respirators-could-reduce-providers-need-for-n95-masks/>

I am hoping Doug Ford and his team can look into this, talk to Health Canada and France Gelinas. I believe Doug Ford needs to hold a press conference to announce this new option for health care workers in hospitals and long term homes because there has been a lot of misinformation accidentally spread by the government and this needs to be addressed so that P100 are not feared.

Hospitals already have 10,000s of P100 respirators available so with a mandate from Doug Ford, front line workers could immediately have access to enough PPE to reduce the pressure on the system and lessen the worries of many Canadians. This will give Doug a huge win and give the province a boost of confidence that the virus is now under more control.

Kind Regards,

Nicolas Smit
[46 Mary Ave](#)
[Naughton, On](#)
[P0M 2M0](#)

Cell: 7056269863

Sent from my iPhone

Begin forwarded message:

From: "Boudreau, David (HC/SC)" <david.boudreau@canada.ca>
Date: June 12, 2020 at 10:28:32 AM EDT
To: "smitnicolas@hotmail.com" <smitnicolas@hotmail.com>
Subject: 20-108252-127 Response from the Medical Devices Directorate, Health Canada /
Réponse de la Direction des instruments médicaux, Santé Canada

Hello, Bonjour, Mr. Smit,

Please see my attached response in regards to your June 8th correspondence.

Best regards,

David Boudreau, ing.

A Director General, Medical Devices Directorate
Health Products and Food Branch
Health Canada / Government of Canada
david.boudreau@canada.ca / Tel: 819-639-4117

Directeur général int., Direction des instruments médicaux
Direction générale des produits de santé et des aliments
Santé Canada / Gouvernement du Canada
david.boudreau@canada.ca / Tél: 819-639-4117

Coronavirus Disease 2019 (COVID-19)

Elastomeric Respirators: Strategies During Conventional and Surge Demand Situations

Conventional, Contingency, and Crisis Strategies

Updated April 20, 2020

[Print Page](#)

Who this guidance is for: Federal, state, and local public health officials, respiratory protection program managers, occupational health service leaders, infection prevention and control program leaders, and other leaders in healthcare settings who are responsible for developing and implementing policies and procedures for preventing pathogen transmission in healthcare settings.

Purpose: This webpage offers guidance for the use of reusable elastomeric particulate respirators to provide respiratory protection to healthcare practitioners (HCP) against pathogens as a component of a formally developed and implemented written respiratory protection program.

This guidance is based on what is currently known about the transmission and severity of coronavirus disease 2019 (COVID-19).

The US Centers for Disease Control and Prevention (CDC) will update this guidance as needed and as additional information becomes available. Please check the [CDC COVID-19 website](#) periodically for updated guidance.



Conventional guidance is not applicable during the COVID-19 response when supplies are short. HCP should follow the contingency and crisis strategies.

Conventional Strategies During Non-Surge Demand Situations

Elastomeric Respirators

Elastomeric respirators, such as half facepiece or full facepiece tight-fitting respirators where the facepieces are made of synthetic or natural rubber material, can be repeatedly used, cleaned, disinfected, stored, and re-used. They are available as alternatives to disposable half mask filtering facepiece respirators (FFRs), such as N95 FFRs, for augmenting the total supply of respirators available for use by HCP. While elastomeric respirators are not cleared by FDA for fluid resistance, based on their NIOSH approval, they can provide at least equivalent protection to N95 FFRs. Some types of elastomeric respirators can offer higher assigned protection factors (APFs) than N95 FFRs. They are equipped with replaceable filter cartridges or flexible, disc or pancake-style filters, which are not housed in a cartridge body. All elastomeric respirators equipped with the proper air-purification filters, cartridges, or canisters would also have utility in this application. Elastomerics may also have sealing surfaces and adjustable straps that accommodate a better fit.

Because they can be re-used, elastomeric particulate respirators provide an alternative respiratory protection option to FFRs for protection against pathogens. While this document focuses on respiratory protection for exposure to pathogens, these respirators may also serve as protection against other airborne hazards in healthcare settings. However, they require maintenance and a supply of replaceable components including straps, inhalation and exhalation valves, valve covers, and filters, cartridges, or canisters.

Elastomeric respirators have the same basic requirements for an OSHA-approved respiratory protection program as filtering

TYPES OF RESPIRATORY PROTECTION



Elastomeric Half Facepiece Respirators are reusable and have replaceable cartridges or filters. They cover the nose and mouth and provide protection against gases, vapors, or particles when equipped with the appropriate cartridge or filter.



Elastomeric Full Facepiece Respirators are reusable and have replaceable canisters, cartridges, or filters. The facepiece covers the face and eyes, which offers eye protection.



Filtering Facepiece Respirators are disposable half facepiece respirators that filter out particles such as dusts, mists, and fumes. They do NOT provide protection against gases and vapors.



Powered Air-Purifying Respirators (PAPRs) have a battery-powered blower that pulls air through attached filters, canisters, or cartridges. They provide protection against gases, vapors, or particles, when equipped with the appropriate cartridge, canister, or filter. Loose-fitting PAPRs do not require fit testing and can be used with facial hair.



Supplied-Air Respirators are connected to a separate source that supplies clean compressed air through a hose. They can be lightweight and used while working for long hours in environments not immediately dangerous to life and health (IDLH).



Example of an open-circuit SCBA

Self-Contained Breathing Apparatus (SCBAs) are used for entry into or escape from environments considered to be IDLH. They contain their own breathing air supply and can be either open circuit or closed circuit.



Example of an SAR/SCBA

Combination Respirators can be either a supplied-air/SCBA respirator or supplied-air/air-purifying respirator. The SCBA type has a self-contained air supply if primary airline fails and can be used in IDLH environments. The air-purifying type offers protection using both a supplied-air hose & an air-purifying component and cannot be used for entry into IDLH environments.



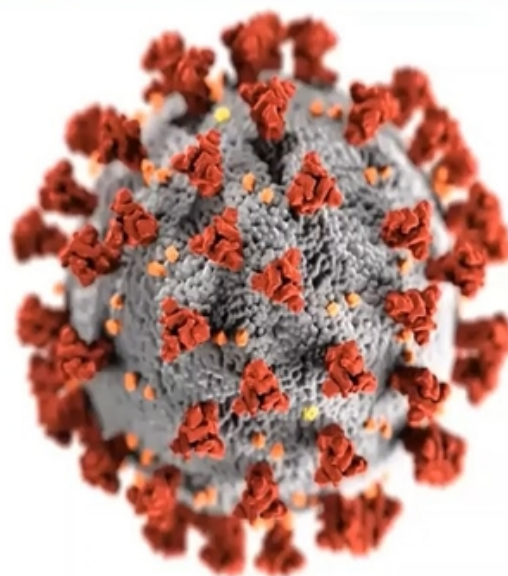
Centers for Disease Control
and Prevention
National Institute for Occupational
Safety and Health

September 2019

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Elastomeric Respirators for U.S. Healthcare Delivery

Key Considerations



For more information: www.cdc.gov/COVID19

This webinar provides an overview of respiratory protection and guidance surrounding supply shortages. This webinar also provides information on infection prevention measures, strategies for optimizing the supply of N95 respirators, and a broad overview of the use of elastomeric respirators in healthcare. Guidance on elastomeric respirators is currently in development.

facepiece respirators, including medical evaluation, training, and fit testing. However, they have additional maintenance

requirements which also include cleaning and disinfection of the facepiece components such as straps, valves, and valve covers. While it is often possible to decontaminate the hard outer casing of filters, the filter material itself typically cannot be cleaned or disinfected for reuse. Instead, filter components should be discarded when they become damaged, soiled, or clogged.

There are several types of elastomeric respirators, half-facepiece or half mask (APF = 10)¹ and full facepiece (APF = 50). The specific cautions, limitations, and restrictions of use should be understood when determining whether to use these respirators in healthcare facilities. Respirators with full facepieces have the same filter considerations but provide greater protection because of better sealing characteristics and less face seal leakage and also provide protection to more of the face and very importantly, the eyes. Elastomeric respirators with exhalation valves should not be used in surgical settings due to concerns that unfiltered air coming out of the exhalation valve may contaminate the surgical field.

OSHA-Compliant Written Respiratory Protection Program Requirements

When respirators are used to protect against hazardous airborne exposures in the workplace, OSHA requires employers to develop and implement a written respiratory protection program that conforms to OSHA 29CFR1910.134 including initial and annual fit testing.¹ The use of a NIOSH-approved respirator is required by OSHA. OSHA also requires that respirators be used in conformance with the conditions of their NIOSH certification. Hence, a NIOSH-approved respirator assembly cannot be modified, and only those replacement parts specified and provided by the manufacturer must be used. The manufacturer's instructions are specific to its respirator materials and specifications. Manufacturer instructions are generally provided with the respirator facepiece packaging.

Appendix B-2 to OSHA's Respiratory Protection standard ([29CFR1910.134](#) [↗](#)) provides general procedures for employers to use when cleaning respirators. OSHA also permits employers to use the cleaning recommendations provided by the respirator manufacturer, if such procedures are as effective as those listed in Appendix B- 2, meaning that the respirator is properly cleaned and disinfected in a manner that prevents damage to the respirator and does not cause harm such as skin irritation to the user.

Cleaning, Disinfection, and Use

Generally, it is recommended that respirators be cleaned and disinfected immediately after doffing (i.e., removing). To avoid contact transmission, precautions should be taken during doffing and use. Training on appropriate donning and doffing procedures should be provided to all employees expected to wear respirators. Both CDC and OSHA have videos illustrating proper donning and doffing of the respirator.¹⁶ Elastomeric components vary among manufacturers and react differently to cleaning and disinfection solutions and procedures. The respirator facepiece components such as facepiece, valves, and straps require maintenance including cleaning, disinfection and inspection prior to reuse. OSHA only requires replacing filters "where necessary," for example, when soiled, contaminated, or clogged.

Viruses and bacteria that cause acute respiratory infections can survive on respirator components for variable periods of time, from hours to weeks. Consequently, contaminated respirators must be handled, cleaned, and disinfected carefully and properly to reduce the possibility of the device carrying infection and contributing to disease transmission.² Manufacturers recommend cleaning and disinfection procedures for their elastomeric respirator components such as facepiece, valve covers, valves, and straps. The materials that comprise the elastomeric components of NIOSH-approved respirators vary among manufacturers; consequently, cleaning and disinfection solutions and procedures recommended by manufacturers may also vary. Manufacturers typically recommend that filter cartridges be discarded after each use when cleaning an elastomeric respirator. Following manufacturer recommendations may be possible for some employers, but others may find discarding the filter component with each cleaning of an elastomeric respirator to be a cost factor when selecting between FFRs and elastomeric respirators, but especially in times of shortage, users may find it difficult to replace the filter cartridges due to supply difficulties. OSHA only requires replacing filters "where necessary," for example, when soiled, contaminated, or clogged. Additionally, cleaning and disinfecting respirators can damage or deteriorate respirator facepiece component materials and adversely affect their performance when re-using after disinfection.

Filter Types

Three types or series of filters are available for use with reusable elastomeric respirators. Filters are classified by their resistance to degradation by oil-based aerosols.

- N-Series filters are not oil-resistant.
- R-Series are somewhat oil-resistant, and, in industrial use, typically have an 8-hour time-use limitation.
- P-Series are oil-resistant and rarely have use-time limitations.

Manufacturers provide use-time limitations and other limitations or restrictions depending on the respirator's intended use. If the healthcare setting does not have any oil-based aerosols present, any filter series can be used. Filters are available in three efficiency levels – 95, 99, 100. Thus, a wide selection is potentially available for use to augment the overall supply of respirators in healthcare settings. The half mask or facepiece type respirator with N-Series 95% efficiency level filters (N-95) has been determined to provide adequate protection in combination with other healthcare practice interventions such as hand washing, isolation, and spatial distance for the risks associated with the transmission of tuberculosis, influenza, and novel coronaviruses.^{3 4}

Generally, in industrial settings, filters are replaced when soiled or contaminated, damaged, and when breathing resistance increases. However, in healthcare settings breathing resistance will unlikely be a reason for filter replacement since filters should seldom if ever become loaded with heavy concentrations of dust. Depending on use, one manufacturer recommends the filter be discarded after each use, while another recommends the filter cartridge be disposed no later than 30 days after the first use if no oil mists are present.^{5 6} The respirator's other elastomeric components should not be cleaned with solvents (e.g., acetone, ethanol) or exposed to temperatures greater than 50°C (122°F).

Disinfection Procedures

Cleaning and disinfection must be done using either the procedures in OSHA's Respiratory Protection Standard or the procedures recommended by the respirator manufacturer, provided they are at least as effective as OSHA's procedures. The employer must consult with the manufacturer for the proper disinfectants/procedures and their potential impact upon its respirator facepiece components.

If it is determined that the disinfection solution and procedures do not degrade the facepiece components, it is possible the components can be re-used, subject to inspection by a qualified individual to determine whether the components need to be repaired or replaced.

Filter cartridges should be removed from the facepiece prior to cleaning and disinfecting the elastomeric facepiece components. Generally, the facepiece components are removed from the facepiece to be cleaned and disinfected. There are several basic steps to clean and disinfect a respirator – remove, clean, disinfect, rinse and dry, inspect and repair or replace, and store. The order and details of each step are important. And it is very important that respirators are *thoroughly* air dried prior to storage.

Some disinfectants are powerful germicides and their use requires special precautions such as adequate ventilation, use of clean non-sterile gloves, gowns, and/or face shields. Therefore, cleaning and disinfection must be done by competent, trained individuals. Centralizing this activity might help ensure that it is being properly executed.

Maintenance must be performed only by those individuals who have been trained in the task and are knowledgeable of the models being serviced. Specially trained individuals (ideally the same people who clean and disinfect respirators) should also be employed to carefully inspect respirators after cleaning with attention to valves and straps. Inspections should follow the manufacturer's recommendations. Only the original respirator manufacturer's component parts should be stocked and available to replace damaged components when necessary.

Contingency Capacity Strategies During Surge Demand Situations

Who this guidance is for: Those responsible for developing and implementing policies and procedures for preventing pathogen transmission in healthcare settings. This includes federal, state, and local public health officials, respiratory protection program managers, occupational health service leaders, and infection prevention and control program leaders.

Purpose: This webpage describes options for deploying air-purifying reusable elastomeric particulate respirators to provide respiratory protection to healthcare practitioners (HCP) when supplies of N95 filtering facepiece respirators (FFRs), including surgical N95s, are limited or not available.

Strategies for reusable elastomeric respirator use in healthcare settings in conventional, non-surge demand situations, are discussed in [Conventional Strategies](#). Conventional use should adhere to OSHA requirements and manufacturer-specific recommended instructions.

Contingency capacity strategies are for emergency situations in which each elastomeric respirator is issued for the exclusive use of an individual employee. The respirators are cleaned and disinfected as often as necessary to remain unsoiled and sanitary. Their description and use should be part of a written OSHA respiratory protection program (RPP). If there is deviation from the standard RPP, it should be authorized and documented by the program's administrator.

Crisis capacity strategies are for emergency use, limited respirator and/or respirator component supplies such as filters, cartridges, or canisters, and valves, and situations in which it is impossible for individual HCP to have a dedicated elastomeric respirator, for example when the same respirator must be used by multiple HCP. When used by more than one HCP, respirators must be cleaned and disinfected before being worn by different individuals. The use of elastomeric respirators should be part of a written OSHA RPP. If there is any deviation from the conventional RPP, it should be authorized and documented by the program's administrator.

Elastomeric Respirators as an alternative to NIOSH-approved N95 respirators

NIOSH-certified reusable elastomeric particulate respirators provide at least the same level of protection as N95 FFRs, and some types of elastomeric respirators can offer higher assigned protection factors than N95 FFRs.

The most significant difference between reusable elastomeric respirators and disposable FFRs is that reusable respirators must be maintained and inspected after each use, including cleaning and disinfection of the elastomeric components such as facepiece valves, valve covers, and straps. When used in conventional workplace conditions, the filter, cartridge, or canister of a reusable elastomeric respirator is not cleaned or disinfected; it is discarded once damaged, soiled, or clogged. Elastomeric respirators are equipped with replaceable filters. Some replaceable filters are cartridge style in which the filtration media is housed inside of a cartridge. Others consist of flexible, disc or pancake-style filters, in which the filter media are not housed within a cartridge body.

This document provides considerations for disinfecting the outside of a filter cartridge during contingency and crisis scenarios to increase the supply of respirators for protection during the Coronavirus Disease 2019 (COVID-19) pandemic. However, there is an increased risk of contact transmission or damage to the filter cartridge that must be considered.

General Reusable Elastomeric Respirator Considerations

Reusable respirators described in this document include tight-fitting half-facepiece or full-facepiece elastomeric respirators that use replaceable filters, cartridges, or canisters and have facepieces made of synthetic or natural rubber material permitting repeated cleaning, disinfection, storage, and reuse. They contain an exhalation valve and should not be used in surgical settings when there is concern that unfiltered air coming out of the exhalation valve may contaminate the surgical field. As with N95 FFRs, reusable respirators require an RPP including, but not limited to, initial and annual fit testing, and a user seal check each time the respirator is used. However, on March 14, 2020 OSHA issued [Temporary Enforcement Guidance](#) [\[7\]](#) permitting OSHA field offices to exercise enforcement discretion regarding the annual fit testing requirements until further notice.⁷

NIOSH-approved, elastomeric respirators provide an alternative respiratory protection option capable of decreasing the total number of respirators required because they may be cleaned, disinfected, and reused numerous times, which should reduce the number of respirators needed when supplies are limited.⁸ However, a supply of elastomeric respirator facepiece components should be held in reserve to replace damaged or deteriorated parts, and supplies of replacement filters, cartridges, or canisters are also needed. The filters of these respirators are at least as protective as the N95 FFRs and surgical N95 FFRs typically used in healthcare settings. They are not cleared by FDA for fluid resistance and require maintenance including cleaning, disinfection, and inspection.

There are several types of filter media for use with NIOSH-approved reusable, half -facepiece elastomeric respirators. All are sufficient at removing droplet and viral size particles when worn correctly for the duration of the exposure. Filters are available in three efficiency levels – 95, 99, 100. Thus, a wide selection is potentially available for use to augment the overall supply of respirators in healthcare settings.

- On an emergency basis during contingency and crisis emergency use,

- Filters (except for unprotected disc type, i.e., pancake style) may be used for an extended period, if the filter housing of cartridge types is disinfected after each patient interaction provided the disinfectant or cleaning agent does not come in contact with the filter media.
 - Filters, even cartridge types, must not be dipped or immersed in a cleaning or disinfection solution because this may damage or render the filter material ineffective. When using a cleaning or disinfectant wipe on the external surface of a filter cartridge, users should avoid contact with the filter media on the inside of the cartridge.
- The specific cautions, limitations, and restrictions of use should be understood when determining whether to use these respirators in healthcare facilities.
 - Respirators with full facepieces have the same filter considerations but provide greater protection because of better sealing characteristics and less face seal leakage and also provide protection to more of the face and very importantly, the eyes.
 - Elastomeric respirators with exhalation valves should not be used in surgical settings due to concerns that unfiltered air coming out of the exhalation valve may contaminate the surgical field.

Half-facepiece or half mask (APF = 10)¹ and full facepiece (APF = 50) elastomeric respirators have specific cautions, limitations, and restrictions of use that need to be understood when determining whether to use these respirators in a healthcare facility. Respirators with full facepieces have the same filter considerations but provide greater protection because of better sealing characteristics and less face seal leakage and also provide protection to more of the face and very importantly, the eyes.

Effective Elastomeric Respirator Use

During contingency and crisis capacity strategies, when shortages are predicted, but supplies are still available, each elastomeric respirator is issued for the exclusive use of an individual employee. Elastomeric respirators must be cleaned as often as necessary to remain unsoiled and sanitary.

- As with N95 FFRs, achieving an adequate seal to the face is essential. OSHA regulations require a written respiratory protection program requiring workers to undergo an initial and annual fit test and conduct a user seal check each time the respirator is donned (put on). Workers must pass an initial and annual fit test to confirm a proper seal before using a tight-fitting respirator in the workplace. Any exception to the program during emergency use should be authorized and documented by the program administrator. On March 14, 2020 OSHA issued [Temporary Enforcement Guidance](#)  permitting OSHA field offices to exercise enforcement discretion regarding the annual fit testing requirements until further notice.⁷
- When properly fitted and worn, minimal leakage occurs around the edges of the tight-fitting respirator where it seals to the user's face when the user inhales. This means almost all the air is directed through the filter media.
- A respirator with an exhalation valve provides the same level of protection to the wearer as one that does not have a valve. The presence of an exhalation valve reduces exhalation resistance, which makes it easier to breathe (exhale). Some users feel that a respirator with an exhalation valve keeps the face cooler and reduces moisture build up inside the facepiece. However, respirators with exhalation valves are generally not be used in situations when a sterile field must be maintained, such as during an invasive procedure in a surgical or procedural setting, because the exhalation valve allows unfiltered air exhaled by the wearer, potentially contaminated with microbes, to escape and possibly contaminate the sterile field. There may be other healthcare activities where respirators with exhalation valves are appropriate.
- During contingency or crisis scenarios, HCPs may receive elastomeric respirators they are not accustomed to using. The JETFIT Study provides information about how quickly the healthcare workers can be trained on using elastomeric respirators when switching from N95 FFRs to elastomerics.⁹
- The Bessesen et al. protocol describes a simple approach to cleaning and disinfecting elastomeric respirators in healthcare settings.¹⁰ The CDC webinar on *Elastomeric Respirators for U.S. Healthcare Delivery* describes the Bessesen protocol and additional information about the use of elastomeric respirators in healthcare settings.¹¹

General Cleaning and Disinfection Information

Viruses and bacteria that cause acute respiratory infections can survive on respirator components for variable periods of time, from hours to weeks. Consequently, contaminated elastomeric respirators must be handled, cleaned, and disinfected properly to reduce the possibility of the device carrying infectious particles and contributing to disease transmission.²

Each respirator manufacturer identifies the appropriate cleaning procedures, which typically involves 1) using soap and warm water or chemical disinfectants authorized for use with their specific elastomeric facepiece components and 2) discarding the filter cartridge.

For conventional use: Employers must consult with the manufacturer concerning the effectiveness and uncertainties of alternative cleaning and disinfectant solutions and procedures used for reuse of the facepiece, straps, and filter components.

- The solutions and procedures must be effective for disinfection but 1) not damage the respirator, including causing damage to the filter media, which conventionally is discarded and 2) not cause harm such as skin irritation to the wearer.
- Prolonged or repeated use of disinfectants may damage or degrade respirator elastomeric components (facepiece, valves, valve covers, straps), causing components to discolor, swell, harden, and crack.

For contingency and crisis use: Because of necessity, elastomeric facepiece components and filter cartridges may be treated differently for their cleaning and disinfection. Whereas conventional practice is to discard the filter component, contingency practices may necessitate cleaning and disinfecting the filter housing, but care must be taken to not expose the filter media to any cleaning solutions. The performance of filter media can be degraded by contact with the disinfectant.

- During surge situations, when manufacturer instructions are not available, and supply shortages exist, interim cleaning and disinfection procedures may be necessary and effective to reuse scarce or unavailable replacement components. However, interim procedures could increase the risk of contact transmission or damage to the filter media if not done properly. Alternate procedures and risks must be considered to protect HCP and meet healthcare needs.
- First clean the surface of each component except for the filter media after each use. Removing organic and inorganic materials from the component surfaces will help achieve maximally effective disinfection.¹²
- Some disinfectants are powerful germicides, so their use requires special precautions such as adequate ventilation, use of clean non-sterile gloves, gowns, and face shields. As such, cleaning and disinfection must be done by competent, trained individuals.
- Additional guidelines for cleaning and disinfecting elastomeric respirators are available from the CDC/NIOSH-sponsored JETFIT study, conducted in 2019-2020 at two academic medical centers to better understand the feasibility of rapidly fit testing and training HCP to use elastomeric respirators.⁹
- Care needs to be taken during cleaning and disinfection to ensure the trained respirator cleaning staff does not contaminate or injure themselves. Centralizing this activity might be helpful for ensuring that it is being properly executed. Recent studies demonstrate that some elastomeric respirators continue to function and perform as expected after 150 cleaning and disinfection cycles.¹³

Basic Steps to Clean and Disinfect an Elastomeric Respirator

There are several basic steps to clean and disinfect an elastomeric respirator – remove, clean, disinfect, rinse and dry, inspect and repair or replace, and store. Bessesen et al. provide useful guidelines for cleaning and disinfecting elastomeric respirators in healthcare environments.¹⁰ These methods have been used successfully in several healthcare settings in the United States. The order and details of each step are important.

If available and appropriate, the respirator facepiece components should be cleaned using OSHA or manufacturer protocols.^{7 14–15} Filter cartridge components would conventionally be discarded. However, during periods of surge capacity, a careful wipe of the filter cartridge, avoiding contact with the filter media, and using a common hospital disinfectant wipe has low risk of damaging the filter. The filter cartridge should never be dipped or submerged in disinfectant or excessively wetted with disinfectant.

Generally, it is recommended that respirators be cleaned and disinfected immediately after doffing (i.e., removing). To avoid contact transmission, precautions should be taken during doffing and use. Training on appropriate donning and doffing procedures should be provided to all employees expected to wear respirators. Both CDC and OSHA have videos illustrating proper donning and doffing of the respirator.¹⁶ Elastomeric components vary among manufacturers and react differently to cleaning and disinfection solutions and procedures. The respirator facepiece components such as facepiece, valves, and straps require maintenance including cleaning, disinfection and inspection prior to reuse. OSHA only requires replacing filters “where necessary,” for example, when soiled, contaminated, or clogged. The alternate cleaning and disinfection method, described by Bessesen et al. for use in healthcare when conventional practices are not practical, has been used successfully.¹⁰

Cleaning

- When removing organic and inorganic matter from the respirator, trained personnel should wear nitrile gloves to protect their hands and limit the potential for self-infection. Additional protective equipment such as gowns and face shields, as well as ventilation, may be required during cleaning and disinfection procedures. Cleaning solution contact with the filter media must be avoided.
- A detergent or soap and warm water could be used to clean the surface of the filter cartridge prior to disinfection. Carefully avoid contact with the filter media. Cleaning can be done using a clean, soft cloth dampened with warm water approximately 49°C (120°F) containing a mild pH neutral (pH 6-8) detergent and using a mechanical wiping action. Other elastomeric facepiece components may be cleaned using the manufacturer's recommended procedures.

Disinfecting

The effectiveness of an alternate filter cartridge disinfection solution and procedure may be uncertain:

- All crevices of many filter cartridge housings may not be reached with sufficient disinfection solution or be contacted for the period of time required to be effective.
- The filter media may be degraded from contact with the disinfectant.

Some elastomeric respirators have filter cartridges that prevent disinfectant contact with the filter media. If available, these filter cartridges should be used in the contingency capacity strategies approach. These filter cartridges provide added assurance that the filter media will not be contacted with the cleaning and disinfectant solutions. These cartridges may be wiped down repeatedly.

NOTE: P-series filters can generally be re-used until they are soiled, damaged, or difficult to breathe through. Caution should be used when using the filter for a live virus, and thorough disinfection of the filter cartridge should be completed.

Practices not approved by the manufacturer can increase the risk and uncertainty of re-using damaged or degraded components. This must be balanced against other available HCP protection options to sustain effective HCP protection and patient care.

Modified procedures used during emergencies should be assessed and documented in the written RPP, including alternate cleaning and disinfection practices.

For disinfection, diluted household bleach solutions, alcohol solutions with at least 70% ethyl alcohol, and EPA-registered household disinfectants should be effective against coronaviruses.

For use of diluted household bleach solutions, follow disinfectant manufacturer's instructions for proper disinfectant application, PPE, and ventilation.

- Check to ensure the bleach is not past its expiration date.
- Never mix household bleach with ammonia or any other cleanser. Unexpired household bleach will be effective against coronaviruses when properly diluted.
- Most Household bleach solutions vary in concentration from 5.25% sodium hypochlorite (~50,000 ppm available chlorine) to up to 12.5% sodium hypochlorite (~125,000 ppm). It is important to check the product label and follow the disinfection directions for use, dilution, and contact time. Adjust the ratio of bleach to water as needed to achieve appropriate concentration of sodium hypochlorite.
 - Based on the EPA List N: Disinfectants for Use Against SARS-CoV-2 products, 2500 ppm (0.25%) for 5 minutes is effective. Most readily available bleach is approximately 6% so 2/3 cup of bleach per gallon of cold tap water (1:24 dilution) for 5 minutes is appropriate.
 - For bleach preparations containing 5.25% sodium hypochlorite, use ¾ cup of bleach per 1 gallon of cold tap water for 5 minutes.
 - If a lower concentration of bleach is desired, the EPA standard disinfection rate for hypochlorite products is 600 ppm for 10 minutes. That is, use 3 tablespoons of bleach per 1 gallon of cold tap water for 10 minutes.
- Prepare a fresh bleach solution each day in a well-ventilated area. Always add bleach to cold water, not water to bleach.

CAUTION: The following may degrade or damage the respirator components.

- Strong solutions such as hypochlorite, iodine, and high concentrations of alcohol may degrade, deteriorate or extract chemical additives from certain respirator materials.
- Healthcare sterilization processes including ethylene oxide should not be used unless authorized by the respirator manufacturer, as they may degrade and alter the shape of the facepiece.
- Steam sterilization equipment should not be used unless authorized by the respirator manufacturer.

Some EPA-approved disinfectants are also available as ready to use at 2700 ppm for 1 minute; however, these strong solutions could impact the integrity of the respirator components. [Products with EPA-approved emerging viral pathogens claims](#)  are expected to be effective against SARS-CoV-2. Follow the manufacturer's instructions for all cleaning and disinfection products (e.g., concentration, application method and contact time, etc.).

Disinfectants listed on the EPA's Registered Antimicrobial Products for Use Against Novel Coronavirus SARS-CoV-2, the virus that causes COVID-19, could be used to inactivate the virus.¹⁸ Those intended for use with soft surfaces may be preferred.

Inspection

All respirators used in routine situations must be inspected by properly trained individuals before each use and during cleaning. This includes a check of respirator function, tightness of connections, and the condition of the various parts, such as the facepiece, head straps, valves, cartridges, and canisters or filters.

Inspect elastomeric parts for pliability and signs of deterioration. Respirators that fail an inspection or are otherwise found to be defective should be removed from service and discarded, repaired, or adjusted in accordance with the following procedures:

- Repairs or adjustments to respirators must be made only by persons appropriately trained to perform such operations, and only using the respirator manufacturer's NIOSH-approved parts designed for the respirator.
- Repairs must be made according to the manufacturer's recommendations and specifications for the type and extent of repairs to be performed.
- Reducing and admission valves, regulators, and alarms must be adjusted or repaired only by the manufacturer or a technician trained by the manufacturer.

Particulate Filter Replacement

Discard filter cartridges if they become visibly soiled or wet, if they are visibly damaged, or if the respirator becomes notably harder to breathe through. Otherwise, change out the filters periodically. Provided the cartridge integrity and filter have not been compromised, current practice shows that conservatively, the filters could be used for at least one year.¹⁸

Training

Workers must be educated and trained on how to safely use their elastomeric respirator. Employers should follow the respirator manufacturer's instructions and OSHA guidance to the greatest extent possible; and consider training recommendations described in the Bessesen protocol. The NIOSH JETFIT study provides excellent training for contingency situations.

To ensure respirator maintenance is conducted properly, employers should establish disinfection and cleaning procedures and train staff to perform the required maintenance including storage, inspection, distribution, repair or replacement, cleaning, disinfection, and disposal. Employers may identify a central location for disinfection or train individual users to clean and disinfect their respirators. Initial surface cleaning should be done at point of use before moving to a central location for disinfection. ^{19, 20, 21}

Respirator storage

Respirators must be stored in a clean, non-contaminated location in a manner that does not distort the facepiece or straps. Respirators need to be thoroughly air dried prior to storage.

Crisis Capacity Strategies During Surge Demand Situations

Surge Capacity Strategies During Surge Demand Situations

During periods of crisis surge capacity, several strategies in addition to the contingency strategies may be followed.

Sharing elastomeric respirators

If it is impossible for individual HCP to have dedicated elastomeric respirators, the same elastomeric respirator may be used by multiple HCP. Elastomeric respirators issued to more than one employee should be cleaned, disinfected, and inspected before being worn by different individuals. One option is to label the respirator, conduct surface cleaning at the point of use, and return to a central location to be disinfected by central staff before reissuing the respirator to a different user.

Machines may be used to expedite the cleaning, sanitizing, rinsing, and drying of large numbers of elastomeric respirators. In general, the respirator's elastomeric components should not be cleaned with solvents (e.g., acetone, ethanol) or exposed to temperatures greater than 50°C (122°F). Post-cleaning inspection by personnel trained in the necessary maintenance tasks should still be conducted to assure respirator functionality has not been degraded.

Extreme care should be taken to limit tumbling, agitation, or exposure to temperatures above those recommended by the manufacturer, as these conditions may result in damage to the respirators.

Ultrasonic cleaners, clothes washing machines, dishwashers, and clothes dryers have been specially adapted and successfully used for cleaning and drying elastomeric respirators. ²²

Waiving the fit testing requirements

OSHA has issued temporary enforcement guidance about switching from quantitative to qualitative fit testing, and OSHA is waiving the annual fit testing requirements as described above.⁷ If fit testing is not possible, leakage at the face seal could occur and the protection provided to the wearer may be significantly reduced. For any tight-fitting respirator, such as FFRs and elastomeric respirators, a successful user seal check must be performed with each donning.

Under serious outbreak conditions in which respirator supplies are severely limited, HCP may not have the opportunity to ever be fit tested on a respirator before needing to use it. While this is not ideal, in this scenario, HCP should work with their employers to choose the respirator that fits them best, as, even without fit testing, a respirator will provide better protection than using no respirator at all or using a surgical mask.

If possible, the HCP should start with the size used previously for fit testing, but as size can vary by manufacturer and model, a different size may be needed to achieve a good fit.

If fit testing has never been done, the following recommendations are still useful.

- If using a half facepiece respirator, it should fit over the nose and under the chin. If a good face seal cannot be achieved when performing a user seal check, try a different model or size.
- OSHA has developed videos in English and Spanish to assist users with donning, doffing, and user seal checks.^{23, 24}
- If respirators are received during a crisis, and they need to be used right away without fit testing, ask the employer for additional product training videos and literature on proper donning (putting on) and doffing (taking off), and content on how to conduct a [user seal check](#) .²⁵
- Practice putting on the respirator and doing a [user seal check](#) at least several times.
- Check the fit in a mirror or ask a colleague to look to be sure the respirator is touching your face and appears to be on properly.

Fit testing is necessary to confirm if a respirator does or does not fit. During a crisis, however, when conventional requirements cannot be implemented, healthcare professionals should be able to determine if they have obtained a reasonable fit if they have had training and they perform a successful user seal check prior to each use of the respirator.

Considerations for Users of Corrective Lenses

- Conventionally, workers who wear a full facepiece respirator and need corrective lenses would have prescription inserts. In a surge situation, where multiple employees share respirators, the use of prescription inserts might not be feasible.
- Employees who use glasses could wear half facepiece respirators, with glasses worn over the respirator to avoid a situation where the arms of the glasses interfere with the respirator seal

where the arms of the glasses interfere with the respirator seal.

- The risks of contamination by solvent vapors do not apply in most healthcare settings. Therefore, individuals who wear contact lenses should be able to wear either full facepiece or half facepiece respirators. However, the use of contact lenses in general could present additional risks where SARS-CoV-2 exposures are known or suspected.

Footnotes

¹ An Assigned Protection Factor (APF) is the workplace level of respiratory protection that a respirator is expected to provide to employees when used in conjunction with an effective RPP.

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France Gélinas**Nicolas Smit**

Had you spoken out like a health critic should have, the government could have spent 15 million dollars to protect every health care worker in Canada yet the manufacturers still have yet to be asked for PPE.

A 5 minute video interview with national news on your part and \$15 million dollars from the government would have saved 20,000 health care workers from catching Covid yet you still won't come forward to ask Ford to do anything and you sit back and watch all the health care workers die and then criticize Ford for not doing enough yet it is you that has not done enough.

Jul 6, 2020, 1:20 PM

Nicolas Smit

I had begged you to talk to hold a press conference about p100 respirators for months and have told you for months neglecting to do so would force this problem in the food industry and not that is another thing the NDP will be blamed for.

The longer you wait to let the public know that you failed to criticize Ford, to let the public know about these respirators, to let food plants know like I had begged you in April to do, the more the NDP will end up being blamed for.

Jul 6, 2020, 1:15 PM

Nicolas Smit

You sent an attachment.

<https://www.facebook.com/businessinsider/posts/10157832270589071>

Jul 6, 2020, 1:07 PM

Nicolas Smit

Besides the blood of health care workers politicians will have the blood of prisoners, farmers and food producers on their hands and will also have to spend more money fighting the food supply shortage and legal issues then they would have to buy every health care worker in Ontario a respirator.

Jul 3, 2020, 11:00 AM

Nicolas Smit

<https://www.cbc.ca/news/canada/toronto/covid-19-coronavirus-ontario-july-2-update-1.5634774>
<https://www.cbc.ca/news/canada/toronto/covid-19-coronavirus-ontario-july-2-update-1.5634774>



Nicolas Smit

This is another effect of no politician being transparent and open with the public about these respirators. No one knows to use these so until a politician lets the public know about them, they will continue to accumulate blood on their hands.

Jul 3, 2020, 10:59 AM

Nicolas Smit

If that makes it to Canada or the US, this could cripple porc farmers.

If it doesn't make it to Canada, Canada can use this to help export porc to China in return for help with PPE manufacturing. This could help reduce tensions between our countries at such an important time.

Jun 30, 2020, 9:51 PM

Nicolas Smit

Also, I'm not sure if your aware but there's potentially another large epidemic coming and the experts are saying it is a swine flu similiar to H1N1 and the 1918 flu.

<https://www.bbc.com/news/health-53218704>

<https://www.bbc.com/news/health-53218704>

Jun 30, 2020, 9:48 PM

France Gélinas



Jun 30, 2020, 9:46 PM

Nicolas Smit

Besides reducing community spread, it would have reduced the spread in police officers and since less officers would have been needed to respond, the resources could have been used elsewhere.

Jun 30, 2020, 9:39 PM

Nicolas Smit

I have trouble having anyone in the government to listen to my ideas so I'm stuck doing everything on my own and hope people listen and take me seriously.

One of the solutions I tried to get the government to listen to in early April to help reduce the community spread was to use the same LRAD devices they use for protests to break up large public



The LRAD was a tool police already had so would not cost anything and could have been deployed immediately. It would have reduced the need for several officers to attend an area and give out tickets and warn thousands of people individually.

The police could have used the megaphone function to warn everyone to leave the area from a distance and if the crowd would not listen, the officers could use the noise disturbance function which releases a nuisance sound at 90db which would cause all the individuals to quickly leave.

Jun 30, 2020, 9:37 PM

Nicolas Smit

I've been an advocate of some sort since I was young. Since my mom was blind and such a big advocate for others, I had a great role model to learn from and learned to think outside the box on how to solve problems.

Jun 30, 2020, 9:28 PM

Nicolas Smit

Thank you. When I gave Carol my idea to incentivize PPE donations using tax credits, she was able to get the finance minister to get several committees set up and they figured out how to add my idea to the tax regulation so that will help a lot getting a lot of sponsorships from major companies.

Jun 30, 2020, 9:27 PM

Nicolas Smit

The reality is these respirators don't cost very much and once philanthropists or billionaire team owners realize how little they need to invest to be able make a big difference globally, they would likely jump at the chance even if it's purely to profit from the situation. The world will not be able to reopen as usual until everyone is vaccinated and that will not happen unless individuals or companies get involved to make sure third world countries also get vaccinated so that the disease would get eradicated like polio.

I also got a PPE company that has a p100 without the valve or communication issue to approach Air Canada and West Jet to see if they can offer their respirator to passengers. For \$20 extra a ticket, passengers would be fully protected for the whole flight and in airport and for an extra \$10, they could keep it. If they don't keep it, they get disinfected and reused and every future reuse, Air Canada would make Money from the surcharge.

I'm also trying to get these into food plants like the one in Alberta where over 1500 employees tested positive and around at least 8 died and this cause a food shortage which continues to happen at many plants where outbreaks are occurring. This will help reduce the looming food shortage.

Jun 30, 2020, 9:25 PM

France Gélinas

You have some good idea



Nicolas Smit

I'm now connected directly with Francis Bouillon, Doug Gilmor, Nick Eaves and a lot of other well know nhl figures and Thursday or Friday I will be trying to organize group discussions with them and PPE companies to make this kind of partnership.

"NHL players donate money for global vaccinations. NHL teams match amount and then so does NHL.

Ex: If Leaf Players raise \$1 Million, Leafs organization matches another \$1 million and NHL matches as well so \$3 Million would be raised thanks to Leafs. Repeat with every club and with a modest \$1 Million in player pooled donations on average means \$93 million would be raised for global vaccination.

PPE manufacturer would team up with NHL and for every \$75 raised, 1 P100 is donated to North American health care workers, 1 P100 is donated to charities that need them to continue normal operations like Big Brother Big Sister and 1 P100 is donated to a health care worker in a third world country.

The government would give a tax break to PPE manufacturer so that for all P100 donated, the company can claim that amount as a tax break in future years.

NHL players, teams and league would get tax break for donations toward vaccination.

NHL could take all credit in public and media for vaccine funding and PPE donations and in return, the PPE manufacturer would get to be named as a NHL partner and be able to market their partnership in the media as well.

I would get the government to sign off on confirming tax breaks. Carol Hughes, NDP MP has already worked hard and gotten new tax incentives for PPE donations added to the tax code in April.

PPE manufacturer would become instant brand recognition, a bigger player in PPE industry, closer ties to NHL and have great publicity out of it. It all comes down to Money so it would be made so that manufacturer and the NHL would profit from this.

This would also be such an impactful project that the stock market would rise because there would be less uncertainty knowing more health care workers would be protected around the world and more people will be vaccinated. Team owners would profit off of the stock market and make a lot of money from the turnaround in the market and make strategic stock purchases.

The problem can easily be broken down for businessmen to understand.

4 million P100 respirators in the right places would make a greater impact than most other initiatives and would cost only 93 million to buy and would be shared among a large group of individuals. Besides a large economic return in the stock market, there would be large tax deductibles to use in future years and this would bring unparalleled publicity for NHL and manufacturer.

Waiting on the government is not feasible since they do not know what they are doing and by the time they act, it is usually too late and they still don't act enough.

If Doug Ford's office would not have investigated the problem because I reached the right person on June 16th, hospitals would still be in limbo with p100s and there would never have been such a large purchase to protect health care workers. It still does not make sense these were never sent to



After NHL I will approach NBA, MLB, NFL, World Cup Soccer with different manufacturers.

I spoke with a PPE manufacturer President about my idea and since he already works with the NHL, he was going to approach them today.

Jun 30, 2020, 9:16 PM

France Gélinas

Well done

Jun 30, 2020, 9:01 PM

France Gélinas

Jun 30, 2020, 9:01 PM

Nicolas Smit

I forwarded the email to your government email account so Damien could look at it but in the chain of emails, the government admits these should have been used all along and that they didn't know hospitals were prevented from using them. Also, you will notice that the internal government investigation and the purchase of the 100,000 was as a direct result of the email I sent Doug Ford's office on June 16th.

Jun 29, 2020, 2:01 PM

Nicolas Smit

I received an email from Doug Ford's executive assistant,

This was sent out to cabinet members as well.

"To date, the Province has purchased 100,000 units of 7500 series Half-Faced Elastomeric Respirators with 100,000 P100 filters. A first shipment of 25,000 units arrived in Toronto and are in the MOEC warehouse week. The remainder of these respirators are expected to arrive by the end of July 2020. Ontario Health is in the process of determining how to allocate these shipments to hospitals.

Several Ontario hospitals have been using these Elastomeric respirators as an alternative and they have developed safe usage and sanitization guidance.

Health sector organizations will determine the appropriate setting for how and where these respirators can be used from a clinical workflow and patient safety perspective"

Jun 29, 2020, 1:37 PM

France Gélinas



Jun 29, 2020, 12:45 PM

Nicolas Smit

Sorry Andrew Sisnett is his name

Jun 29, 2020, 12:28 PM

Nicolas Smit

Thanks, the New York Times will likely be releasing a feature article about everything once the government officially makes the announcement. Also, if the government is having trouble reaching a specific p100 manufacture, let me know and I could get the company in direct contact with the government.

Andre Sisnet, President of Dorma might reach out to you as well. His company is one that does not have a valve or communication issue and they are based in Toronto and Montreal and are a Canadian company promoted by Navdeep Bains at one of the governments press conference a few weeks ago. His company already works with the NHL.

Jun 29, 2020, 12:27 PM

France Gélinas

I will continue to keep you posted as soon as I find out more. Good work on your part.

Jun 29, 2020, 12:23 PM

Nicolas Smit

Hi France,

I just wanted to let you know that once the government makes the announcement of buying the respirators, I will use the momentum from that announcement to get partnership/ between large organizations like the NHL and P100 manufacturers.

Over the last few months, I have gathered quiet a few powerful people including heads of the big p100 manufactures which I have been speaking and built closer ties to them. I have also used the last few months to gather powerful people in the NHL, NBA, famous singers and Hollywood celebrities to help with the cause.

Since these respirators do not cost very much, it will be easy for these organizations to work together with the PPE manufacturers to work out a deal to help front line workers and non profit charities get these respirators to where they need to go.

100,000 p100 respirators is the largest single purchase of these respirators in Canadian history and at average of \$20 a piece, it would have likely only cost about 2-2.5 Million dollars.

My goal is to have players donate their own money which would be matched by their team and matched by their league.



team and matched by the 31 teams and the NHL, that would bring in over 90 million dollars which would buy over 4.5 million p100 respirators which would be enough to help cover every weak spot in the North American health care system.

It all comes down to money and if the NHL and the owners jump on board, for the pennies they would invest, the stock market would go up by several percentage points since there would suddenly be hope for everyone and that amount of PPE would lower the forecasts on death tolls and Economic damage and this would boost the stock market and the owners would make money of their contribution.

This would spare the government resources and would speed things up, also, since pro sport leagues would be involved, countries like China would be more likely to help with sourcing materials and helping PPE manufacturers mass produce these.

Jun 29, 2020, 12:18 PM

France Gélinas



Jun 26, 2020, 9:28 PM

Nicolas Smit

I also forgot to mention, there is a company called Dorma based in Montreal and Quebec that created a P100 respirator that can be printed using a 3D printer and I spoke with their president and not only do they not have the issue with the valve but it is lighter and communication is not a problem. The president said he tested the respirator on phone calls and no one could tell he was using a respirator.

Navdeep Bains mentioned Dorma and their respirator in a press conference a couple weeks ago.

Jun 26, 2020, 9:22 PM

Nicolas Smit

Sorry, I had my ringer off. You can try again whenever you would like. I took my parents to camp for my fathers birthday this weekend so I'm available anytime. I'm not sure if you remember my mother Evelynne Smit but she says hi. She says she worked with you on a committee in Elliot Lake years ago and she says she remembers having lunch with you and her close friend Christine Twiddle as well.

Jun 26, 2020, 8:30 PM

Nicolas Smit

France missed your video chat.

Jun 26, 2020, 8:28 PM



You missed a video chat with France.

Jun 26, 2020, 8:18 PM

Nicolas Smit

A lot of businesses have closed down and laid off staff because they can no longer find p100 so I hope someone in the government will be able to do something for those companies so the economy could recover and they can rehire everyone they let go.

Jun 26, 2020, 3:41 PM

Nicolas Smit

That is great news, Canada has currently triple the amount of cases among health care workers compared to the rest of the country. We're sitting at 19% on average of cases but in Quebec and BC, health care workers make up 24% of all cases.

Jun 26, 2020, 3:36 PM

France Gélinas

Good news.. Here is what I just received from the Ministry of Health. I will keep you posted as soon as they are received and the distribution plan is finalized. Ontario Health has purchased 100,000 reusable P100 masks, also known as elastomeric masks; the order has not yet been received and the distribution plan is in progress. Mainly used in other sectors, like industry and mining, the P100 is increasingly in use in health care. These respirator masks are considered a sustainable alternative when there is high demand for the N95s. The mask is typically used when there is no requirement to don and doff regularly and there is no patient interaction (e.g. chemo treatment preparation), since the bulkiness makes conversation difficult. In Ontario, a number of hospitals are using the masks and some have established mechanisms to re-process them.

Jun 26, 2020, 3:23 PM

Nicolas Smit

It has been 10 days since Health Canada decided to actually approve P100 respirators and they updated their website yet not a single politician including yourself have made any public statements so hospitals still do not know these are no longer considered dangerous. Since the NDP is still refusing to do the right thing and apologize for past mistakes with this approval process including lengthy delays and making sure the public was kept in the dark instead of being transparent, I will have to continue to work on this on my own. During any future media interview, I will have to let the public know that you and the NDP were a great help to get these looked at by the government but that you and continue to stay silent when frontline workers are dying and catching covid and you will not even make statements so that health care workers know not to be afraid of these anymore and that Health Canada has decided to let them use these respirators in certain circumstances.

During any future media interview, I'll will have to admit the you and the NDP admitted you knew these respirators were safe to use and would save lives but instead letting the public know that the government made continued to make serious mistakes and came to dangerous conclusions, instead



In April. I asked dozens and dozens of times to be contacted by phone by the government or the approval team which should have been a simple thing to do, yet you refused and told me to wait for the process to finish.

When CBC investigated and found that the process had failed and that the government made terrible decisions, instead of admitting to mistakes, the government said they would begin approving P100 respirators if the CBC did not talk about the failures.

I begged you to come forward after seeing the news article and Angie's LinkedIn messages explaining the direction she took with her article and you told me to wait again for the process to finish before you would make any effort. You even refused to let hospitals or the public know that hospitals had 10,000 of these in stock which they cannot use even when nurses and doctors are dying due to the lack of PPE. You told me you would wait for the directive from Health Canada to come out before putting any effort yet when that directive failed to come, you still stayed silent and refused to be transparent or open with the public.

I asked again to be put in touch with the approval team and you again refused and said you could not get in touch with them so it was impossible for me to get in touch with them.

Because I know how lazy and bad politicians are, I found the team on my own. Within a few days of getting in touch with the actual Health Canada team, they sent me a letter which said that the government had never sent these respirators to the right departments for approval (shocking considering you were adamant these were in the right hands all along). Health Canada also said that because of the data I sent them and the panel of experts I got for them, they finally decided to approve these respirators and immediately updated their websites to reflect this change because of how important these respirators are in protecting health care workers. Health Canada also said they decided to fast track the approval because of all the evidence and the media inquiries they received.

The NDP handled this so badly even though they were the ones with the most knowledge about these respirators. The NDP did not even bother to ask the government to lift the ban they put on P100 manufacturers so while the government has been saying for months that P100 could not be used under any circumstance, businesses were still prevented from buying these filters and respirators because they were still being kept for health care workers.

<https://montrealgazette.com/news/local-news/we-need-to-protect-ourselves-construction-workers-need-dust-masks-visors>

This shows that the you and the NDP continue to act negligently even though thousands of lives are at risk and the economy is losing jobs because of you and the failure to listen to me and take this seriously.

I have already been contacted by Darryl Singer, lawyer for the class action lawsuit against long term care homes and I will be providing the media the emails and messages I received from the you and everyone in the NDP who kept refusing to act on the matter.

I'm sorry it had to come to this but I repeatedly begged you to do something so that I did not have to force anyone's hand.

<https://montrealgazette.com/news/local-news/we-need-to-protect-ourselves-construction-workers-need-dust-masks-visors>

Jun 22, 2020, 3:22 PM

Nicolas Smit



Jun 18, 2020, 5:00 PM

Nicolas Smit

A simple public criticism of Doug Ford for not being transparent or open in the P100 approval process would help let the public know that there are things that can help them stay safe that they do not know about.

Jun 18, 2020, 4:52 PM

Nicolas Smit

Firefighters in Ontario do not know P100 respirators can help protect them from the virus since the government has not made any effort to be open or transparent about them.

<https://www.cbc.ca/news/canada/toronto/mississauga-firefighters-ppe-n95-respirator-masks-iaff-local-1212-1.5615088>

In Manitoba, Firefighters switched two months ago to P100 because of how valuable they were.

This is why it so important to be more vocal about P100 because they continue to be overlooked.

<https://www.cbc.ca/news/canada/toronto/mississauga-firefighters-ppe-n95-respirator-masks-iaff-local-1212-1.5615088>

Jun 18, 2020, 4:48 PM

Nicolas Smit

That was from the Facebook message thread with CBC Sudbury, I told Kate Rutherford you were a great help and that you should be interviewed as part of the story.

Jun 17, 2020, 10:16 PM

Nicolas Smit

Markus--just so we don't get our wires crossed...Fiona asked me to follow this story and I am working on it. Thanks

Jun 17, 2020, 8:19 PM

Nicolas Smit



Jun 17, 2020, 2:05 PM

Nicolas Smit



Jun 17, 2020, 2:05 PM

Nicolas Smit

I did a taped interview for CBC Sudbury about P100 and I told them it was thanks to you the government looked into these and that you were a big help with the process. Kate Rutherford said she might call you for an interview and that Markus Shwabe will likely call me for a live interview.

I'm not sure if you read the letter Health Canada sent me but they said that P100s were never sent to the right department to get approved but that thanks to the data and panel of experts I sent them, they decided to change their guidelines and have already updated this on their website.

They said in the letter that "As of June 10, Health Canada has not received any application for P100 respirators under the Interim Order process."

They say "Health Canada has expressed the view that the P100, P99, P95, N100, N99, R100, R99, and R95 respirators are at least as protective or more against the inhalation of respiratory particles and are a suitable alternative when medical N95 respirators are not available."

Since Health Canada says "The decision to use respirators with exhalation valves may be made on a case by case basis based on provincial guidance." That is a chance for you to ask Doug Ford to provide provincial guidance and let hospitals know about P100 and how to use them.

Since these were never sent to the right teams for approval, this is your chance to ask how come the government never made sure that it made it to the right teams and this is your chance to criticize the process and how you relied on it but eventually realized the process was not done properly like with Doug Ford's so called experts that Andrea Horwath has already called him out for.

David Morgado and Nico Fidani-Diker, Doug Ford's personal assistants told me yesterday they were looking into P100s and if Doug Ford should do anything.

You can criticize Ford for forcing politicians to stay silent during this PPE approval process and that I had to find the actually team myself and had to get them the information and experts they should have had since March.

If I wouldn't have found the team on my own when the politicians told me it was impossible to get ahold of them, we would both still be thinking that the right team had been looking into this and that eventually something with P100 would be done.

Jun 17, 2020, 2:05 PM

Nicolas Smit



Jun 17, 2020, 2:03 PM

Nicolas Smit

Download file:

messages/inbox/FranceGelinass_3mCbEM1P0w/files/P100Letter_611_MDD_DGO_3001953310007

**Nicolas Smit**

The Montreal Gazette article says companies are forced to vacuum their filters to get try and get the asbestos out so they can reuse their filters passed what they are supposed to be used.

Isn't this a major health issue that should be raised? Have experts looked at what effects vacuuming a filter has on the seal that would protect these workers from breathing in asbestos?

Construction companies are known for short cuts and now that work sites are being shut down because workers don't have P100, don't you think more dangerous short cuts will not take place? And all this because of a ban left in place by the government so that hospitals can be the ones that get p100 at the same time they are told they can't use them and to hope for the best with what PPE they do have.

Jun 11, 2020, 6:52 PM

Nicolas Smit

Because the ndp refuses to criticize the failed process, try and fix it or even bring any public attention to it, hospital staff and long term care homes cannot use PPE they have available and continue to catch the virus since they do not have enough PPE to keep them safe. Like I have warned you about for a while, businesses have been forced to close, lay off staff because they can no longer buy P100 because of the ban that was put in place so hospitals could get them instead.

Until I read the Montreal Gazette article, I did not know that businesses are also forced to use unsafe techniques like vacuuming filters so they could be reused.

What is it going to take for the ndp to come public with these problems that you see are not being fixed. You said to wait for the experts and the process and then you saw the process failed and the experts were not experts. Then you said you would wait for the Health Canada directive and a month later that is still not out.

Why do you refuse to stand up for health care workers to be able to get immediate access to P100 when you know the experts were wrong and should be investigated not praised.

Why do you say to wait to act when your role is to act when you notice something is wrong.

How is letting people die because they don't have access to PPE not wrong? How is letting businesses close because you refused to talk about the failed government ban that is still in place not wrong? How is using experts that came to false conclusions that anyone who googled p100 could have known was wrong. How can a government stand by experts that don't even search the internet when they are deciding on something that would protect 100,000s of health care workers when they continue to get sick and die not wrong.

If you cannot go public with any of this, you could at least get someone from your church, group of friends or family members to go forward if you are more worried about your career. Taking 30 minutes of your time to go on CBC tv and raise any of these issues will save lives you know are being lost because of this. Steps should be taken to start saving health care workers but everyone wants to wait and see and only act once the media confronts them.



Jun 11, 2020, 6:13 PM

Nicolas Smit

Why has the ban on p100 sales to the general public remained in place since hospitals are not able to use them especially since the ban was put into place specifically for hospitals to be able to get them. Why is P100 safe in Manitoba, the number 1 recommended breathing PPE in the US but in Ontario it is somehow dangerous?

Jun 11, 2020, 5:25 PM

Nicolas Smit

<https://montrealgazette.com/news/local-news/we-need-to-protect-ourselves-construction-workers-need-dust-masks-visors>

<https://montrealgazette.com/news/local-news/we-need-to-protect-ourselves-construction-workers-need-dust-masks-visors>

Jun 11, 2020, 5:22 PM

Nicolas Smit

<https://winnipeg.ctvnews.ca/winnipeg-firefighters-paramedics-now-wearing-reusable-respirator-masks-while-on-call-1.4891533>

<https://winnipeg.ctvnews.ca/winnipeg-firefighters-paramedics-now-wearing-reusable-respirator-masks-while-on-call-1.4891533>

Jun 11, 2020, 5:21 PM

Nicolas Smit

Now that the NDP has come forward to criticize the government's so called experts and why there has not been any transparency or real experts used, the window of opportunity for the NDP to look good has passed.

You and the NDP should hold a press conference today or tomorrow to explain why you and the NDP refused to look into the p100 process that experts failed miserably on and which you were constantly warned about.

I have been telling you since the start of April the process was broken yet instead of looking into the issue, trying to fix it or even contain the damage that continues to be done by holding a press conference and clear up misinformation the so called experts kept spreading, you told me the process was fine, nothing needed to be looked at, I had to have faith and it was a process that's hard to endure but that it takes time.

How many families have had to see their loved ones complain about the lack of PPE they have access too in their hospitals and then watch those family members suffer an agonizing and preventable death because you refused to believe the process could be broken or that the experts did not know they were doing. You could have saved a lot of lives instead of staying quiet and



The same problem with experts that Andrea Norwan is now complaining about happened right under your nose. The longer you continue to refuse to help front line staff finally have access to the PPE they should have been able to use since early April, the more damage will be done to your political career and the NDP credibility.

At least publicly share the evidence you continue to try and get the experts to see but which they obviously continue to not get since none of the misinformation has been corrected.

If you will not fight for health care workers than fight for the businesses that have had to close and lay off staff because the government will not allow P100 manufacturers to sell them to business or individuals and only the hospitals that are banned from using them can purchase them.

Why have you stayed silent while this ban was kept in place that only created chaos and hurt people.

I have an American journalist from one of the biggest news empires on the world investigating this failure and the failure to do anything even when presented with undisputed evidence and the CBC is also looking into this more closely.

How could an expert claim there is no evidence P100s could be used in a hospital setting when a basic google search proves this has been happening for decades. How can experts say that P100 are too dangerous to use in any circumstance while the CDC says it is the top respirator hospitals can use and the one they have been recommending for hospitals to use during pandemics since 2018. How come these experts did not find the 15 page document the CDC released explaining online in detail why P100 is the best choice for front line workers which has now been out for over 7 weeks?

If a University student had worked on this project and made the same dangerous conclusions that your experts have made they would fail the project since the information could have been easily fact checked by doing their due diligence and researching the issue online.

Jun 10, 2020, 12:30 PM

Nicolas Smit

Is this not proof enough that you should stop relying on the process and start personally doing more or if you do not have the time, make sure your party comes out right away to explain why the NDP kept saying to trust the experts even though they themselves could not talk to them or to make sure evidence actually made it to the experts so that they could stop spreading misinformation.

When will the NDP act. The Liberals are now calling out the issue with the so called experts you keep having faith in and refuse to accept the fact that they continue to do more harm than good.

Jun 9, 2020, 9:31 PM

Nicolas Smit

<https://www.cbc.ca/news/canada/toronto/ford-experts-covid-1.5603327>

<https://www.cbc.ca/news/canada/toronto/ford-experts-covid-1.5603327>

Jun 9, 2020, 9:27 PM



It's not been a month since health Canada said they would approve p100 because they were confronted by the CBC with evidence of their previous failure. Why has nothing changed since then, and why has the government not removed the ban for their sale to the general public and businesses since hospitals are not an option? Why is there still no public outcry or criticism when people have lost their jobs and businesses because of this ban? Why is the NDP still refusing to talk publicly about this approval process that continues to be stalled, broken and continues to cost the lives of frontline workers?

Have all the lives lost and damage done over the last 10 weeks due to the lack of PPE not done anything in regards to the NDP raising this as an issue?

How many more weeks or months will this have to go on and how many more people will have to die before the NDP takes this seriously and get the government to fix the process?

What are the benefits of staying quiet, not trying to fix the process or confront Ford and Trudeau for stepping in when they should have known that the US has approved these decades ago.

Why not go outside the normal process since this is not a normal situation. Why not make sure the process is taking seriously? Why not make sure that hospitals can use P100 while Health Canada works on the process? Why not make sure the approval process is done within a week since all the evidence that is needed already exists and is easy to find? Why not bring this up to the media? Why is the NDP refusing to do anything except for sitting on their hands and watch this process continue to fail and people continue to die? What will it take for you or the NDP to start an inquiry or at least do media interviews to raise attention so that people know there is a problem that needs to be fixed.

When I first came to you, there was only 5000 cases and a handful of deaths. If you would have stayed on top of the situation and gotten Health Canada to act quickly back at the start of April, Canada would not have had 100,000 cases, 8000 people would not have died.

Jun 9, 2020, 11:24 AM

Nicolas Smit

It's been over 10 weeks and no one from Health Canada has gotten in touch with me, nobody in government has tried to address the broken process, no one has followed through to make sure Health Canada received the evidence you gave them.

I have done my own investigation and found the team looking into P100s and have sent them a detailed email. I sent the email to your ndp email address so that you can now be part of the process that you can clearly see is broken but which no one has fixed, address publicly in an open setting, or bothered to keep track of.

In the email there is a list of experts including their contact info so that you and the team can talk to them and get all the evidence you need.

There is no excuse now for politicians to let this go on any longer. Business have had to close since they can no longer buy P100 for their staff to continue their normal operations. Businesses and individuals are banned from buying them because the government is only allowing their sale to hospitals even though hospitals are banned from using them.

Jun 8, 2020, 4:53 PM



I like the way you think but I will not give you false hope

Jun 5, 2020, 6:02 PM

Nicolas Smit

With this crisis, the province should give you more power to deal with any health issues you see and not stick to what was traditionally done. You have so much experience dealing with the health system and problems that you would make a great person to be in charge of a new provincial health unit set up to deal with covid issues.

This would relieve pressure on Health Canada and allow Ontario to act more quickly and within days when they find a problem. Instead of sitting and waiting for months for Health Canada to do something, Ontario could be proactive and slow the spread themselves.

Jun 5, 2020, 9:17 AM

France Gélinas

I am a provincial politician I do not get to talk to Health Canada. They are a federal agency.... I deal with provincial ministries.

Jun 5, 2020, 9:08 AM

Nicolas Smit

Next time you talk to Health Canada, you can let them know that ex CDC director Tom Frieden, who was the original CDC director to recommend P100 as the top respirator for pandemics, could speak with them to clear up any confusion the Health Canada team may have about P100s.

I have spoken to him several times and he is confused as to why Canada has made statements about them not being safe and he said it was a dangerous move for hospital to ban them.

Jun 4, 2020, 9:51 PM

France Gélinas

Jun 4, 2020, 9:44 PM

Nicolas Smit

That's great, thanks for letting me know. I think last time you tried to give them info that they did not bother to look at it or they would have never told hospitals and the public that they were dangerous and had no history or being used in a hospital setting.

Now that they have the info, hopefully they will act a quick knowing they were originally wrong. Once they approve P100, it'll immediately increase the stockpile of PPE so long term care homes could



I wonder when Health Canada will start thinking of using PPE like P100s at meat packing plants since thousands of workers are getting infected in those spots and if PPE were used, it would prevent 1000s of people spreading the virus from those plants to their communities and families. It would also prevent the looming food shortage which would continue to cripple the Canadian economy and people who lost their jobs. If food plants had the proper PPE, they would not have to close for two weeks every time there was an outbreak at one.

Thanks again for everything. Sorry for pushing so hard but as an advocate, you know the importance of not giving up and making your voice heard and I hope that this scandal helps the NDP get more power in government so that this does not happen again.

Jun 4, 2020, 9:43 PM

France Gélinas

I wanted you to know that a representative from the Ministry of health got back to me today to tell me he is sharing the information I have provided. Thank you for sharing those articles with me.

Jun 4, 2020, 9:17 PM

Nicolas Smit

Ontario has special powers with this crisis so you can criticize Doug Ford for not giving Ontario more power to protect front line workers by enabling Ontario Health to decide on any PPE by creating panel of Ontario PPE decision makers that clearly understand the situation to decide on any additional PPE they deem safe. Health Canada and the current process was not built for time sensitive issues like this crisis. The process itself was not built with proper safe guards in place to ensure a timely outcome to make sure that as many lives could be saved as soon as it was proven beyond a reasonable doubt like the P100 has without decades of use by the CDC as well as the tons of data the CDC released as to why they recommended in 2018 that P100 be the respirator of choice for pandemics. They also approved P100 with no one at Health Canada working on this project noticing. Sloppy work cannot continue with so much at stake.

I believe you should ask for special rights to get Ontario their own control over PPE since Ontario cannot tolerate losing any more lives just because a flawed and broken process has taken place where no one has taken the necessary steps to see it through properly.

I believe you would be perfect to lead the panel that decides PPE because you have brought so much to the government yet they clearly do not listen to you or the advice you give them which would have prevented many lives being lost by front line workers which the PC government says they want. Why continue to let people die knowing there are 10,000s - 100,000 of safe and reusable PPE that are made to protect them 100% from the virus which the surgical masks they are forced to wear do not. N95 are in such dangerously low supply that front line workers are sometimes forced to wear the same one for several days if they are lucky enough to have one. The majority of hospitals operate in a way to use 1-2 N95 per shift but the recommended protocol typically require 6-7 N95 mask per shift. The nurses sounded the alarm about not following the recommended number of N95 masks for the most dangerous situation they have ever been put in and they continue to see horrific deaths of their coworkers due to not being provided the recommended amount of PPE. They sounded alarm bells for that and Health Canada did not listen. P100 sat on shelves not being used but would have prevented this crisis every politician says they would love to have been able to prevent.



respirator hospitals should use for Covid 19 which also happened to be what they recommended originally in 2018. Health Canada did not listen to those alarm bells or bother to read the evidence you provided them proving p100 to be safe. Many people died during this time and politicians say they did everything they could and wished they could do more yet no one spoke out about P100 or health Canada and their massive failure.

Front line workers are sounding the alarm bell because they are forced to wear surgical masks around covid patients because not enough N95 are around that could protect them. Many nurses knew surgical masks was not effective as stopping them from catching the virus so they bought their own p100. They could not use p100 like they begged to because Health Canada said they were dangerous so although surgical masks posed a high risk of letting the droplets get through they were not dangerous like a P100 so the assumed risk was necessary . Ontario could have stepped in and said the P100 were proven effective in labs to protect the wearer and could be used around covid patients because the problem raised was not an issue around people that already are positive. Ontario could have stepped in and said they realized Health Canada was not listening to that alarm bell either and more people keep dying due to a process that is clearly broken and making things worse in a crisis. You could even say that Health Canada should have known that putting a surgical mask they provided front line workers dealing with covid patients over the valve of the P100 would have removed the risk completely instead of leaving a dangerously high level of exposure in place.

You can say it is time Ontario put its emergency powers for good use and let Ontario make their own PPE decisions if they feel it would save a single life let alone the 100,000 front line workers it would give 100% protection for at least 3 months. Or Ontario can stay silent and wait for the next alarm bell to ring that they could see Health Canada not act upon but that that Ontario not act upon either because a "process" has to take place.

Since the process is broken, the least Ontario can do if they don't make a public statement to prevent misinformation from continuing, the NDP could make sure that I become a bigger part of this process to make sure that due diligence is being followed, no short cuts are taken, this becomes a priority and not just taken lightly and given to someone as a project to do if they find spare time in their hectic schedule. The NDP should make sure I can become a big part of the process by asking the team or person in charge to call me as sound as they find a problem with P100 since I have had the solutions to the problems they say are unsolvable but that information does not make it to them. It is like a game of telephone tag where the people that lose are the front line workers that don't have enough PPE and are developing PTSD because they know they are likely to catch the virus if they are exposed long enough with their patient. They know they could die, they know how painful it is, they know how horrible it is once you get on the ventilator and how a lot of people wish they would die because the pain and suffering was intolerable. They know that because all they have is a surgical mask or a N95 they must reuse that there could be a good chance they could expose their family sick and feel responsible if one of the die or suffers from a life long mental health issue.

I hope I have shown to you that I know what I am talking about with P100 and I hope you took the time to read the articles I sent you explaining how P100 have already saved a lot of lives at American hospitals and that without them, many lives would have been lost.

Ontario front line workers do not have to lose any lives and they should not spend their day in fear of being exposed and their horrible effects that came with it.

Doug Ford could enact powers by the afternoon to make sure that any front line worker in a hospital or long term care home that does not have the recommended PPE in the recommended amount for their shift/situation should be given the option to use the 10,000-100,000 P100 hospitals already have in their inventory.

In good faith, no one should be forced to wear a mask that does not completely protect you from



Jun 3, 2020, 11:56 PM

Nicolas Smit

Here is an article that came out this afternoon about p100 saving lives in hospitals and preventing another crisis

https://curated.tncontentexchange.com/states/pennsylvania/ahn-partners-with-msa-safety-to-provide-p100-protective-masks-to-clinical-staff-on-frontlines/article_f69844a4-f1c2-5476-9a4c-7ff689b4e2c8.html

https://curated.tncontentexchange.com/states/pennsylvania/ahn-partners-with-msa-safety-to-provide-p100-protective-masks-to-clinical-staff-on-frontlines/article_f69844a4-f1c2-5476-9a4c-7ff689b4e2c8.html

Jun 3, 2020, 4:11 PM

France Gélinas

Hello Mr Smit, as you know I am a provincial politician, I have no contact with the federal government or its agencies. I shared your info with the provincial government. I will keep you posted if they get back to me but they do not have to get back to me and often don't. I have read your suggestions about criticizing the government...

Jun 3, 2020, 2:32 PM

Nicolas Smit

I still have not received a call from Health Canada. You do an amazing job getting the info to the people that should get it but after you hand it off, that info is not taken seriously.

I have been talking to the CDC director from 2009-2018 Tom Frieden and I believe it would be a great benefit for our government to talk to him and listen to him since he ran the worlds most respected organization on disease control.

Since you cannot talk about P100 as a pollution, can you talk criticize the governments handling or the process that clearly does not work and should have been done by early April, not in limbo going into June.

You can criticize the time line, you can criticize that they have not taken the evidence you provided because they are still saying there is no evidence it could be used in hospitals but you have provided them decades worth of evidence, you can criticize the process that took place because once they ran into a problem instead of trying to come up with a solution or look online/at the evidence you provided them that proved the problem not to be an issue and could be easily solved they declared P100 dangerous and prevented front line workers from having the option to protect themselves with it. You can also criticize the government for the fact that it is taking a private individual to get all the info and force the government to do the right thing.

You could explain that normally you would wait for the process to finish because you are not a scientist and are just a politician but that since you seen the CDC guidelines and all the other evidence, you felt coming forward and at least preventing the evidence to the general public was the



instead of staying silent, you had to come forward to make sure you could at least try and save as many people as possible by making sure they had enough PPE. You could criticize the government for not allowing them to be used since the beginning of April around covid patients because it would not endanger the patient but it would protect the front line worker dealing with the covid positive patient. You could criticize the fact that there are not enough PPE to fully protect everyone so that the people that don't have enough protection could at least use P100 While the process is taking place.

Jun 3, 2020, 2:03 PM

Nicolas Smit

Chris Hamby, the New York Times journalist that wrote that article is now investigating Health Canada and the Ontario government. I have been speaking with him this evening and he has asked me numerous questions about the governments mishandling of the p100 and he is pretty stunned with what happened and the answers people have been giving me. Angie Bonenfant the Radio Canada journaliste told me she was writing a story to confront health Canada as well but when she approached health Canada they said they would approve them so she had to remove 2/3 of her story (I forwarded that message to you on the 27th). Health Canada did not call me today and it seems like all they did was say they would approve them to stop being investigated.

Jun 2, 2020, 8:41 PM

Nicolas Smit

You sent an attachment.

<https://www.nytimes.com/2020/06/01/health/masks-surgical-N95-coronavirus.html>

Jun 2, 2020, 2:07 PM

France Gélinas

I will pass your information and cell number...

Jun 2, 2020, 8:27 AM

Nicolas Smit

Sorry, I forgot to give my cell number. It's 7056269863.

Jun 1, 2020, 9:45 PM

Nicolas Smit

I would like to be part of the team of "experts" involved in the decision process because I have done hundreds of hours of research on P100 and have known from the start how to fix the problems. If I would have been listened to and taken seriously, P100 could have been used in April and less people would have died in long term care homes and less people would have been exposed in hospitals because of the lack of PPE. If I was involved, I could also have helped to make sure P100 were produced in higher numbers instead of having lost all this valuable time where that process



I said waiting for Health Canada was a bad idea and because of this, a week of action has already been lost.

Jun 1, 2020, 9:34 PM

Nicolas Smit

This is part of an email is sent the liberals to explain that the experts the government has relied on for this should be fired for their major incompetence.

When the EXPERTS the NDP got to look at the P100 discovered that P100s were more effective than an N95 at protecting someone from the virus but that the air leaving the valve was not filtered they declared that it was not safe to use in any circumstance. An expert would have:

A) known that P100s are made by different manufacturers and only some have this problem.

B) known that since it protects the person wearing it that it could be used by front line workers treating known positive cases in places like an ICU since it would protect health care staff in the most dangerous of environments while not adding any risk to the patient. This would have also lessened the impact of the N95 shortage since N95s could have been given to more staff and so workers would be able to follow proper protocol and not be forced to reuse N95 due to a lack of PPE.

B)done their DUE DILIGENCE and checked online for a solution which is easy to find. There are easily accessible CDC guidelines explaining P100 respirators and how hospitals have solved that problem over 2 decades ago by putting a surgical mask over the exit valve. There are also many news article explaining how to solve that problem.

C) done their DUE DILIGENCE and checked for any solution to that problem with organizations and research firms. The non profit Quebec research company IRRST developed a membrane filter that clips onto the valve to give it complete protection on both sides of the respirator and they did this 2 months ago yet the EXPERTS still do not realize this

D) when these so called EXPERTS you are waiting for advise said that they did not know how or if P100 could be ever used in a hospital setting because they are industrial respirators not meant for the healthcare setting that should have set off alarm bells because:

- how did they not know P100 had been used since 1996 by American hospitals
- how did they not know they were used by hospitals for H1N1 in 2009
- how did they not know that in 2018 the CDC and NIOSH recommended countries stockpile P100 INSTEAD of the N95 because it offered better protection, was made to be reused and cost a fraction of what a years supply of N95 would cost
- how did they not know hospitals in the US started stockpiling them in January to prepare for when the virus would hit the US
- how did they not know these were used by doctors treating patients on the Diamond Princess Cruise Line
- how did they not know the CDC official approved for Covid 19
- how did they not know that these are recommended over the N95 by the CDC
- how come nothing was done by Health Canada until they were contacted by an investigative journalist
- how come Health Canada still does not list P100 even though they said it would now be approved



- how come your EXPERTS are saying that nothing can be done to prevent outbreaks at meat packing plants when outbreaks would not occur if staff had proper PPE

- how come your EXPERTS are saying nothing else can be done to save the lives of people in long term care homes when making sure PPE were supposed and used would prevent outbreaks

- how come your EXPERTS are not saying that providing prisons with PPE would prevent outbreaks, low moral and help return more rights to prisoners that were lost due to the virus

- how come your EXPERTS did not know Health Canada decided to approve P100

Jun 1, 2020, 9:29 PM

Nicolas Smit

I think you should have them call me. I have the answers they have been looking for two months but did not know of until I got the CBC to confront them. I also have experts like the CDC director from 2009-2017 who recommended p100 be stockpiled for pandemics who are willing to talk to them.

You can call me as well so I could help easier. I have solutions to all the problems you have told me and the government has mentioned publicly. I also have many examples of these solutions being used in hospitals. I also know the long history of their use and how to best use them.

Jun 1, 2020, 9:20 PM

France Gélinas

Well the Ministry of health got back to me today and want more info. What do you think I should send them?

Jun 1, 2020, 8:51 PM

Nicolas Smit

I posted that New York Times article on LinkedIn and Twitter along with the fact that the Ontario Liberals are now investing the NDP and the PCs because of their massive mishandling of P100 that is still going on.

Hopefully the investigation only takes a few days so that they can hold a press conference to let everyone in Ontario know p100 are safe, should be used, should have been used since April and also holding the NDP and PCs accountable for not bothering to put effort into anything except making sure people thought p100 were dangerous and did not get used.

May 30, 2020, 4:42 PM

Nicolas Smit

<https://www.dshs.texas.gov/tcid/respiratory-protection-faqs.pdf>
<https://www.dshs.texas.gov/tcid/respiratory-protection-faqs.pdf>

May 30, 2020, 4:38 PM

Nicolas Smit



May 30, 2020, 4:38 PM

Nicolas Smit

I received this email from Ian Hall, an Executive Director with the Ontario Liberal Party.

"Hi Nicolas,

Thanks for reaching out on this - I've read through and am connecting you to Damien O'Brien, the VP Policy of the party. If you can please send him what you have sent me, I've given him a brief synopsis of what you have provided, but I feel as though you will be able to convey it more accurately and in greater detail than I could do justice.

Hope you are keeping well, and if you can please send to Damien all you have sent me as well as any new materials you think would be useful, that would be great.

All the best,

Ian"

It is not too late for the NDP to minimize the damage that has been done due to their inaction by doing the a big press conference today or tomorrow. I am writing Damien the email now so if your lucky, the NDP might still have a day or two to get ahead and do what I've been begging them to do for months.

The NDP can't say I did not warn them that this would happen. I've been voting NDP my whole life and I'll be voting for you anytime your on the ballot but besides you and Carol, I cannot vote NDP in the future since they put politics over people and cannot be reasoned with.

It's too late for the NDP too look good but at least by acting quick, they won't look like hypocrites and will have more traction when they are criticizing the government for their inaction.

May 29, 2020, 1:22 PM

Nicolas Smit

Health Canada does not seem like they did much research because the CDC recommends a surgical mask over p100 valves that do let unfiltered air out but health Canada does not mention this at all. Health Canada still does not list p100s on their website either. You should have been one of the first people that Health Canada should have told p100 would get approved since your the health critic and on the covid task force so it would be important for you to know these things.

This is so mishandled by the government and they do not know what they are doing or how to research problems they run into.

All the problems they have had so far, I had answers too because I took the time to do my due diligence and do over 100 hours of online research. These so called scientists or researchers should have noticed P100 had already been researched and they should definitely have known once the CDC approved them on April 20th.

There is no date for health Canada to announce anything so front line staff will keep being unprotected due not having enough PPE. Who knows if it'll be another 8 weeks or 8 months before someone gets of their ass and finally does something.



up along because no one cares enough to make sure they can have access to the P100 in their inventory.

Why are problems like the outbreaks at food processing plants not fixed by giving them access to P100 respirators?

When will everyone stop saying they are doing everything they can to help front line staff and actually do something that would help? It would only take a 15 minute interview tomorrow morning for the NDP to explain the government was wrong about p100s and that hospitals should use them right away to fix the biggest problem hospitals are facing. The NDP can admit that the government made a huge mistake by not coming forward sooner and there is nothing they could do to fix that but that at least now they are doing something about it.

There is no reason not to come forward, all you need to do is weight the advantages and disadvantages.

The advantage, you can saves lives and look good doing it.

The disadvantage is people die, you get blamed for not doing anything because you should have known p100 should be used and that the government was not acting in the best interest of the front line staff.

If the NDP does not get their act together and come out with a big press conference to prevent more deaths and unecessart delays, I will be letting people know that the NDP knew for a long time that p100s were safe and should be used but due to a bureaucratic "process" they decided to stay quiet and do absolutely nothing to prevent it from happening even though they knew that continuing to stay silent would have deadly consequences and make it harder for the country to recover from the virus.

May 28, 2020, 9:29 PM

France Gélinas

Well done, you and I both know that filters exist that filter the air coming in and going out. So is it true that health Canada only look at the protection of the person who wears the mask not the people around them?

May 28, 2020, 8:57 PM

Nicolas Smit

<https://ici.radio-canada.ca/nouvelle/1706817/masque-cartouche-filtre-p100-covid-19-solution-rechange-n95-coronavirus>
<https://ici.radio-canada.ca/nouvelle/1706817/masque-cartouche-filtre-p100-covid-19-solution-rechange-n95-coronavirus>

May 28, 2020, 11:00 AM

France Gélinas

Well said



Nicolas Smit

I don't care about the credit credit, I just want to sleep at night knowing the PPE is going to get used and that people aren't dying because they don't have access to it. I feel partially responsible for it taking so long to get done. and I feel bad every time I read a story in the news about people in long term care homes dying because they didn't have access to PPE or when the government says that there is nothing they can do to stop the spread of the disease at meat packing plants when I know that p100 would prevent it but that no one is listening. I will sleep better once I know p100 is common knowledge and that people are not afraid of it and that they start to get used to reduce the rate of transmission and prevent a preventable food shortage where I know more people will die.

May 27, 2020, 6:18 PM

France Gélinas

I will be happy to give you credit for all your hard work. Let's keep an eye out of the federal directive...

May 27, 2020, 6:12 PM

Nicolas Smit

I still think the NDP should come out and do a press conference and get the credit for their part instead of getting blamed for not making sure it happened sooner. I forwarded that to Ian hall the liberal party guy so that if the NDP still delays the press conference, the Liberals can take the credit for getting the government to allow p100 to be used and confronting Ford and the ndp for not making sure such an important issue was taken seriously.

May 27, 2020, 6:02 PM

France Gélinas

You did it congratulations! I will look for the directive as soon as it comes out.

May 27, 2020, 5:58 PM

Nicolas Smit

Forwarded from Angie Bonenfant ([linkedin.com/in/angie-bonenfant-b3988a50](https://ca.linkedin.com/in/angie-bonenfant-b3988a50)):

Yes I do. I was about to write to you, later today. I received an answer from Health Canada saying that they are now recommending the use of P100 (and others industrial masks) in health facilities like hospital when the medicals N95 are not available. They will make changes to their directives very soon. It seems they will do like in the US. I've wrote something about it and it will be published tomorrow. I was going to write something about HC not letting hospitals use respirators but turned out they will. So there is a lot of material I can't use for my article. And my plan to do a small interview with you has been stopped. I'll send you a link of my article when it will be published. I would like to know what you think...

<https://ca.linkedin.com/in/angie-bonenfant-b3988a50>

May 27, 2020, 5:52 PM



It's more than just hard to endure. This is a crisis that our province has never had to experience before and There is no reason for bureaucratic process to cause delays or to do things the "tradional" way. P100 are proven safe and effective beyond a reasonable doubt so the only thing delaying doing such a simple thing as a press conference is going to do is:

1. Cost needles lives because they do not have any protection right now like the staff you've been fighting for
2. Cause people to fear P100 because our government is telling them it is not safe which will:
 - A)make it harder for hospitals to adopt later on because of how long health Canada has been saying not to use them due to their safety concerns
 - B) since hospitals cannot use p100, some might get rid of their stock to make room for PPE they can use
 - C)Cause organizations like the Ontario Centre for Excellence to stop looking at ways to get more P100s to everyone. This has already happened, they had a team working with me to help get p100s to hospitals and they were going to start getting companies to mass produce p100 but since Ontario health and health Canada kept saying p100 were not safe to use. The OCE is no longer working on P100s.
3. Delay the manufacturing process of P100s which 3M and other companies could start producing more of.
4. Cost more time/lives before long term care staff can all have PPE they need.
5. Cost more time/lives before prisons could protect staff and inmates with reusable PPE.
6. Cost more time/lives before meat packing plants are able to let their staff use P100 to prevent more deaths and disasterous food supply chain issues.
7. Since p100 are not being used and a lot of people are getting sick because they don't have any PPE at all due to the shortage, the spread of the virus will keep getting out of control.

It's a simple press conference where you and the NDP can state that the US is now recommending hospitals use P100 instead of N95 and that you have just become aware of it. You can say that the government has been researching it since March thanks to you and that so far it showed the person wearing it would be protected. You can say that P100 let unfiltered air out and that until you read the news articles or the CDC website, our government did not realize that a simple solution existed that has been used since 1996 and that was use a surgical mask over the filter to offer complete protection in areas where patients were not known to have covid. You can say that the government has found that it is hard to communicate but that hospitals across the US have been using them since the H1N1 virus and communication problems have not prevented them from using P100. You can say that although there is a normal process that takes place where P100 is researched and the data is analyzed and that this process takes time but that because lives are at stake and there is a lot of information easily accessible to anyone with a computer that you and the NDP needed to come forward with the information to bypass the delay since it's already been 8 weeks since the government proved it effective and 5 weeks since the CDC officially approved it and recommended it over the N95 but that the government since that time has only made things worse by pretending they did not know it could be used in hospitals. You could share any of the 50 news articles about hospitals using p100 in the states for covid 19. You can share the 15 page CDC document that explains in detail why p100/elastomeric respirators are now recommended over N95. You can share the CDC webpage on N95 alternatives which ranks N95 at the bottom and P100 at the top. You can mention that I've had to do all this fighting on my own because not a single person in the government has taken the time to call me or have a back and forth conversation except for Ian Hall



come forward due to the governments inaction which is what you want to do with your press conference. You can mention that Hospitals already have 10,000s of P100 in their inventory that if used, would prevent their staff from getting infected. You can say that by using p100 alongside N95 masks, the PPE supply issue will be so much better that extra PPE can be given to psw and home workers. You can say that P100 could be used in hot spots like meat packing plants so that things like 1500 staff getting sick at one plant in Alberta never happens again. You can say that by providing staff at hot spots like meat packing plants a p100, the food supply chain will not be as impacted by the virus and less Canadians will have to suffer from future food shortages. You can say that by providing p100s to prisons, prisoners will be able to move more freely and some of their regular rights like the right to a fair trial restored. You can say that by providing high risk individuals with a p100, the amount of people that will die will be significantly reduced. You can say that by making sure p100 get used, less staff get ptsd or severe mental health issues because they are afraid of dying due to the current lack of PPE. You can say that you did you due diligence and looked into p100 and found that there is so much information available, it was criminal not to come forward with that information. You can say that although there is normally a process that takes place, that the process has been severely mishandled and that in good faith, you could not sit back and remain silent. You could say that the benefits of coming forward with a press conference outweighed the negatives of waiting another 2 months for that process to continue down a path you knew was not working.

You could say something instead of letting people hear from the government that p100 are not safe to use and that they do not know if they can be used in a hospital setting.

May 27, 2020, 5:41 PM

France Gélinas

Hello Mr Smit, I know the speed of this issue is hard to endure. I congratulate you for continuing to push. I will keep you posted if I hear of any possibilities to move P100 forward.

May 27, 2020, 4:34 PM

Nicolas Smit

Hi France,

I wanted to let you know I was successful in getting in touch with the Ontario Liberals and they have asked me for a lot of information relating to the P100 and how the NDP and PCs have not bothered to take it seriously and continue to spread misinformation to prevent their use.

The Liberals were the first political party to have follow up questions about P100 when I approached them and they are now in the process of investigating the NDP and the Ford government over their negligence and inaction which has likely already cost the lives of front line workers and will continue to do so until the Liberals finally make this issue public.

I explained how the US government officially recommended P100 over N95, how they have been used by hospitals for 24 years, how our government showed they could protect anyone wearing it and yet how instead of making sure they get used properly, the government is actively preventing people from using them. The government is spreading misinformation by saying they are unsafe and that they do not know if they can be used in a hospital setting.

I don't understand why the NDP will not allow you to make a public interview so that people can at least learn about P100s. Since they are a valuable asset the government already has and would



How can the NDP continue to look nurses in the eye and say they did not know P100 would have been useful when all it takes to see its incredible significance is to google "CDC P100" or google "CDC elastomeric respirator" to see the CDC documents which explain how come hospitals in the US have been using them for the coronavirus.

I really like the NDP and have voted for them my entire life but I will be throwing the party under the bus since they continue to not take this seriously and continue to turn a blind eye to something that would significantly reduce the spread of the virus while protecting thousands of front line staff.

I know you are busy but I created a group message on LinkedIn with a lot of people that are deeply involved in P100 or the governments process and I even included Rick Bright, the famous American whistleblower that testified in congress last week about the inaction that is going on in the US with PPE. It's been available since Monday for you to ask any questions so that there is no more reason to say the NDP does not know enough either.

I have been begging the government to call me or email me for over 8 weeks so I could make sure P100s were understood and properly looked at but I have yet to receive a single call and the Liberals getting back to me and asking questions was the first time I was asked questions. I will be spending my time in the next couple weeks talking to as many liberals as possible since the NDP does not care about action except for making statements about the inaction from others.

May 27, 2020, 2:13 PM

Nicolas Smit

I have created a LinkedIn message group which will soon have all the information the government should have found on their own but are clearly not putting the effort at doing.

If there is a way you could include me in a group conversation next time you talk to the part of the government researching P100s, I could explain to them everything they are saying they no knowing about even though the information is easily accessible to anyone with an internet connection.

May 25, 2020, 5:19 PM

Nicolas Smit

The link I sent you also explains how to properly use, clean and maintain a P100 after exposure to the coronavirus. Here is another link with other approved N95 alternatives the government should have looked at months ago.

https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/default.html

Here is a news paper article written by New York cardiologist explaining the decades long history of P100 being used by CDC hospitals, why they are still overlooked and why they should have been used since January.

https://www.medicinenet.com/elastomeric_respirator_masks_for_covid-19_nurses-news.htm

I have forwarded you the contact of the doctor that wrote this article so that any question you or our government has on P100 can be answered by someone who knows what they are doing.



and information I have because even though the government are using experts, they lack common sense and cannot even bother to use the internet to see what information is already available.

Everyone seems to think work and research is being done on P100, but since there is clearly lack of any kind of effort except to prevent them from being used, more needs to be done and it can't wait months or weeks or even days.

There is enough info out there that the NDP can craft their own statement about the delay so that the government does not drag their feet any longer.

If the NDP keeps refusing to make public statement knowing everything they do, I will be forced to partner with the Liberal government in Ontario and the PC government in Canada and throw the NDP under the bus and have them shamed for not coming forward sooner. I cannot in good conscious let this delay go any longer knowing that 8 weeks have already passed since the government knew it was an effective source of PPE and 5 weeks since it was approved by the CDC.

The Ford and Trudeau government should be held to account but so does the NDP and I will be very supportive of the liberals in making sure this happens if they happen to be the party that actually makes sure P100 are understood, used and donated.

The government keeps talking about how they would love to be able to prevent the food shortage and outbreaks all over Canada at meat packing plants and these would not have happened if the government would have come forward at the start of April to share publicly what they knew from the start.

The next excuse the government will have once P100 are talked about publicly is that not enough of them are available for everyone and that they will have to start looking at ways to mass produce the P100z

Mass producing P100 since April would have prevented a lot of the things you have been fighting for yet it's not on anyone's radar since the government is still 24 years behind on P100s use in hospitals.

https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/default.html

May 25, 2020, 4:50 PM

Nicolas Smit

It seems like you're the only one in the NDP that is keeping the government accountable.

Since the government is still saying that they do not know if P100s are safe to use in hospitals. Here is documentation from the Center for Disease Control, CDC, that the government should have read and shared with the public months ago.

The government does not seem to know anything at all about P100 so you can let them know that they can also be called elastomeric respirators.

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/elastomeric-respirators-strategy/index.html>

Here is a webinar that the CDC created to explain to hospitals why P100s should be used, the different styles, how they were tested in US hospitals, how they are recommended over N95 and it includes the hospitals and research staff involved with their contact info that the Ontario government



<https://youtu.be/0Wd3BXZIVDI>

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/elastomeric-respirators-strategy/index.html>

May 25, 2020, 4:32 PM

Nicolas Smit

Thank you, can you let them know that they should contact the CDC to get the data about P100 because the "expert table" has yet to realize that P100 are already being used.

If the Ontario Health does not get back to you quickly or say P100 should be used, you could make a public statement indicating that P100s have been recommended to be used by CDC for years and explain to the public how they are well known and that there is a lot of data available on their effectiveness yet the government of Ontario is pretending like that information does not exist.

The longer it takes to make a statement that focuses on P100, the less confidence people will have in them because all they hear right now is misinformation and that they should not be used, and the less likely they will get used.

It takes less time to read the CDC, FDA, and NIOSH recommendations on P100 than it does to watch a tv show so there is no excuse for the government not to be acting quicker knowing the unnecessary delay is costing lives.

May 25, 2020, 4:16 PM

France Gélinas

Hello Mr. Smit, I understand your frustrations with the slow speed of decision making, believe me I face it every day. I have asked many times about the P100 mask. I am told that Ontario Health has an expert table dedicated to the supply of PPE. They are the one who make decisions on what can be used. I will ask again and let you know what I receive as an answer.

May 25, 2020, 3:46 PM

Nicolas Smit

Hi France,

Great interview and push for getting PPE to everyone with supplies being so low.

I am very confused as to why you and the government have still not made public comments on P100 besides to say that not enough information is known to allow their use.

Hospitals have 10,000s already in their stockpile and are not allowed to use them even though you say that PPE supply is at a dangerously low level and a lot needs to be done.

Why have you or the NDP not come out and specially made comments on P100 and the negligence the Ontario government has shown to make sure they get used.

The CDC, FDA and NIOSH have all recommended P100 be used by hospitals over the N95 against the coronavirus. The CDC has been using P100 to protect staff against deadly viruses since 1996, used them in 2009 for H1N1 and recommend in 2018 they be stockpiled over the N95 for future



The government and Health Canada are actively preventing hospitals from using their P100 stock and telling people it is because not enough information is known about P100 to make sure they are safe to use in hospitals. Why is the government turning a blind eye to the information that proves they should be used and spreading misinformation which would prevent more of these from being donated to hospitals, long term care homes or the groups you are pushing to help supply with PPE?

I have been trying to help the NDP so that they could be seen as the party that cares about protecting people. It's been a month since the P100 we're officially approved and recommended and NDP has had enough information to at least make a public statement to raise awareness at a general level but nothing has been done.

I am going to start sending messages to Ontario Liberals MP, their commutation people and their Health Care Critic in hopes that they can come out and do what's right and let people know about P100 and why they SHOULD have been used for months. While thousands of front line staff have been exposed to the virus due to dangerous levels of PPE, the NDP and PC party stood buy and did nothing knowing that there was PPE that could have prevented this all along.

Hopefully once the Liberals come out and make public statements shaming the NDP and PC and finally bringing awareness to P100s, these could finally start to be used in long term care homes, prisons and meat packing plants to reduce the spread of the virus. These could also start to be mass manufactured like the US has started to do so that PPE supply no longer becomes a significant problem.

May 25, 2020, 1:30 PM

France Gélinas

Hello Nicolas, it is truly unfortunate that sometimes it takes a tribunal to tell the government to do the right thing. You have a lot of courage...Bonne chance!

May 13, 2020, 12:35 PM

Nicolas Smit

Hi France,

I wanted to give you and Carol a heads up that I am going to try and get the nurses union, doctors union, dental union, prison union and meat packers union to join a class action lawsuit against the Ontario and Canadian government for negligence causing death which resulted due to the inaction by both governments.

It has been over 6 weeks since government labs have proven that P100 protect better than an N95, 3 weeks since the CDC officially approved P100 and promoted them as a superior to the N95 on their website. During this time, dozens of articles have also come out about P100s being recommended as having better protection than an N95 and used for years by hospitals dealing with viruses so this is not even new information.

Health Canada is still advising hospitals and associations that they do not know enough about P100s to make recommendations so hospitals are not allowing their staff to use them. Health Canada told the Manitoba dental association last week that they would have to do their own research on P100s because Health Canada would not approve them and they did not know enough about them to offer guidance.



February.

The CDC director from 2009-2017, Tom Friedman, recommended years ago that P100 be used as the main respirator for pandemics because it has better protection than N95, can be reused for months and cost less money to protect staff than the N95s.

For any Canadian politician or government employee to remain silent or still say not enough information is known about P100 to let hospitals use them is criminal negligence and every one of the front line workers that have died or lost a love one after giving them the virus will be part of a class action lawsuit.

I will be doing the same in the states although the government in the states admits P100 as the best choice for hospitals during the pandemic but are still saving their stock of P100 for future waves instead of protecting nurses that are currently dying due to the lack of PPE.

I hope with this warning, the both of you will have enough time to protect yourselves from any fall back that may happen. I also hope the two of you will go on tv or talk to reporters in the next couple of days to make a big statement on their use because I do have to tell people that you were the ones that brought P100 to be tested by the government so there is a chance the 2 of you are used as scapegoats by the government.

May 13, 2020, 11:51 AM

France Gélinas

Well said

May 11, 2020, 6:22 PM

Nicolas Smit

Hi France,

P100s have been used to protect people from catching this virus since the Diamond Princess Cruise ship landed in San Antonio in February. They are safer than an N95, reusable, cost significantly less and take up less space in inventory. There is no reason not to be using these in every hospital. These should be the focus of every manufacturer instead of mass producing disposable N95s.

Unfortunately unless hospitals administrations hear about P100 through word of mouth or a local news paper article, they are oblivious to their potential use. Hospitals do not know they were officially approved for use by the CDC and FDA on April 20. They are even less likely to know that the CDC highlights the fact that they offer superior protection to an N95 and are reusable for months.

Hospitals are more likely than not to hear common P100 misconceptions and then not let their staff use any P100 donated or even ones they bought themselves. Because of this major problem, hundreds of front line staff are needlessly dying after catching the virus from their patients.

There is a nurse that just died 14 days after treating a known covid patient in a code blue because she rushed in using only a surgical mask and she didn't make it for Mother's Day. The N95s at her hospital were in such needlessly low supply, that when nurses weren't reusing the same N95 for several days at a time instead of the recommended disposal between patients or hours, they were under lock and key.



making a big public statement so that every Canadian hospital starts using and allowing the use of P100s in their hospitals. There is a CBC article from a couple days ago saying dentists in Manitoba are using P100s against the advice of Health Canada.

Holly Caruk, the reporter, emailed me and said "I found it bizarre that Health Canada would not comment on their use as an alternative. Instead, they said it's up to medical associations to determine what they feel comfortable with, but associations don't have the capacity to test these masks to be able to officially recommend them"

P100 would be especially useful in the meat packing plants so that outbreaks stop happening and our food supply isn't constantly threatened.

May 11, 2020, 10:26 AM

Nicolas Smit

You sent an attachment.

<https://www.kens5.com/article/news/health/san-antonio-hospital-could-have-an-answer-to-the-ppe-crisis-elastomeric-masks/273-882e7ea3-e377-4776-906c-33ce89e193cc>

May 11, 2020, 10:26 AM

France Gélinas

Apr 23, 2020, 7:40 PM

Nicolas Smit

The CDC finally released an approved list of N95 alternatives and it features the P100

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/elastomeric-respirators-strategy/index.html>
<https://www.cdc.gov/coronavirus/2019-ncov/hcp/elastomeric-respirators-strategy/index.html>

Apr 23, 2020, 7:38 PM

Nicolas Smit

Hi Carol and France,

There is an army of mining executives at the Canadian Institute of Mining including the president Samantha Espley, on stand-by waiting for word on the P100 and how it could protect doctors and nurses from the virus. Could you either of you get in touch immediately with Sam, either through her email which is attached or by calling her at (705) 690-8829 so that Sam and her wonderful team could secure the PPE needed before doctors and nurses run out of N95s in less than a week. Once Samantha gets confirmation from the government, Sam, myself and others can then talk to industry leaders and get more people involved to help and get massive amounts of P100 directly to hospitals. Sam's email explaining the CIM and their offer of assistance is attached to this email.



Nick

Can you please let me know when you hear back from the fed govt via Carol. The CIM national is keen to spread the word. Just waiting to know the health minister's response. Thanks.

Samantha Espley, P.Eng., MASc, FCAE
President-Elect
Canadian Institute of Mining, Metallurgy and Petroleum
Institut canadien des mines, de la métallurgie et du pétrole
Tel.: (705) 690-8829
Email: samantha_espley@hotmail.com

Apr 9, 2020, 7:50 AM

Nicolas Smit

Hi France,

I've been watching the news and I hear a lot of mention of being a week away from not having enough PPE in Ontario. The supply for N95 masks is causing severe diplomatic relations with the US so why is the current research on P100 immediately released so other governments could also work on and help their Canadian counterparts. I also think a major public announcement would help get the P100 stock at least looked at by industry while they wait for the confirmation of their effects. Since it is proven that it protects the wearer. These should immediately be sent to icus around Canada and to areas where nurses and doctors have only positive patients as case loads since being re-exposed to the virus has already been determined not to be an issue but not having the proper PPE or none at all has proven to be a severe issue. Getting P100s moving right away will ensure N95 masks go further and will help with the bureaucratic delays that would cause PPE to be delayed getting to hospitals.

Cheers,

Nick

Apr 6, 2020, 2:57 PM

Nicolas Smit

They are too busy trying to save lives that they often don't have time to deal with the stress, anxiety, pain, ptsd and other issues they are facing because of this crisis. The least we can do is make sure they can do their jobs safely and without having to worry about getting sick.

Mar 28, 2020, 11:32 AM

Nicolas Smit

Dear France Gélinas,

I am writing to respectfully request your help in getting Personal Protective Equipment ("PPE") to hospitals and front line workers as quickly as possible with the governments assistance.



medical staff. Doctors and nurses in Toronto and other virus hotspots in Canada are working without the necessary PPE to protect them and are being put at risk of catching the virus, which they can then pass on to patients, staff and their families at home. Nurses working in Covid 19 ICU units in Toronto do not even know if they will have enough face masks to properly protect themselves. The medical staff are being rationed to just two masks per 12 hour shift and are told they cannot get tested for the virus. At this time, they are only receiving free coffee on Thursdays and a \$10 parking subsidy which all would happily forego for PPE.

In addition to the medical staff, police are also catching it in large numbers. In New York, 500 police officers have tested positive and 11% of their workforce is off sick. The problem is also compounded by the fact that a lot of people spread the virus without showing any symptoms. In some studies, up to 50% of positive cases were asymptomatic. The individuals that are infected are spreading it to the front line workers because they do not know they have the virus and the medical staff cannot protect themselves properly.

The most essential service right now is the one that doctors, nurses police and fire fighters, are sacrificing themselves to do. We need to urgently prioritize their protection in order to protect the rest of the population.

I would respectfully submit that if the hospitals cannot find the supplies they need on the market, the government should step in to work with industry so that they can receive immediate donations for masks, respirators (that could be properly and safely re-used), goggles and other protective equipment. As a worst case scenario, Canada may need to secure supplies from non-essential businesses which have large supplies of PPE and are shutting down operations. This would include, notably, the mining sector.

A possible mechanism to incentivize businesses to donate PPE may be to offer a tax deductible credit (e.g. 1.05-1.25x of wholesale cost). This would help get PPE in the hospitals quicker and at a low wholesale cost to the government. Companies would also benefit from the positive marketing.

If we act now, we could reduce the spread of the virus and give Canada a much needed reprieve to help find ventilators, develop a vaccine, and hopefully a cure.

Thank you for your time.

If you are able to assist in any way, it would be greatly appreciated.

I look forward to hearing from you.

Nicolas Smit

Mar 28, 2020, 11:28 AM

Generated by Nicolas Smit on Monday, July 6, 2020 at 1:56 PM UTC-04:00
Contains data from March 24, 2020 to July 6, 2020



Santé

Le masque respiratoire P100 en voie de devenir une solution de rechange au N95

Lorsqu'il n'y a pas de masques N95 de qualité médicale, Santé Canada est d'avis que les respirateurs P100 représentent une bonne solution de rechange.



Lorsqu'il n'y a pas de masques N95 de qualité médicale, Santé Canada est d'avis que les respirateurs P100 représentent une bonne solution de rechange.

PHOTO : RADIO-CANADA

Angie Bonenfant

Publié le 28 mai 2020

Longtemps associés au secteur de la construction, les masques à cartouches remplaçables P100 sont devenus les alliés inespérés des travailleurs de la santé dans leur combat contre la COVID-19. Même s'ils ne sont pas conçus pour un usage médical, les respirateurs P100 seront bientôt recommandés par Santé Canada comme solution de remplacement aux masques N95.

Ce changement est peut-être la bouée de sauvetage qu'attendaient certains travailleurs de la santé aux prises avec un manque de matériel de protection et particulièrement anxieux à la perspective de devoir faire face à une deuxième vague de la pandémie.

Certains n'ont cependant pas attendu que Santé Canada change son fusil d'épaule.



Des ambulanciers paramédicaux en action.

PHOTO : RADIO-CANADA / DANIEL COULOMBE

« La COVID, c'est du jamais-vu! » lance Pierre-Alexandre Bisson, chef d'équipe à la Coopérative des paramédics de l'Outaouais. « Tout ce qu'on a appris au niveau de l'ambulance, il faut mettre ça de côté. On pourrait appeler ça ambulance COVID! »

M. Bisson, qui travaille à la Coop depuis 2010, préfère en rire, mais la réalité de son métier est loin d'être drôle. « Tout a changé », relate-t-il. « Le travail a beaucoup changé, la façon d'intervenir aussi. Plus rien n'est pareil! »

Ce changement, on le remarque aussi dans le matériel de protection que transportent les ambulanciers paramédicaux à chacune de leurs interventions sur le terrain. Tous les ambulanciers de la Coopérative sont désormais équipés d'un appareil de protection respiratoire (APR) — un demi-masque en élastomère muni d'un filtre P100.

« Depuis qu'ils sont arrivés, c'est vraiment apprécié des paramédics en général. »

— Pierre-Alexandre Bisson, Coopérative des paramédics de l'Outaouais

Des chantiers aux ambulances

Les masques en élastomère sont davantage associés aux travailleurs de la construction. De prime abord, on ne les penserait pas utiles dans un milieu de soins. Pourtant, lorsqu'ils sont équipés du bon filtre, ils se révèlent encore plus efficaces que les masques N95 pour protéger l'utilisateur des aérosols infectieux.

Les filtres P100 stoppent 99,97 % des particules en suspension dans l'air contrairement aux filtres N95, qui n'en retiennent que 95 %. De plus, le masque est très hermétique, soutient Pierre-Alexandre Bisson, ajoutant qu'il adhère bien au visage.

« Certains masques peuvent faire de la buée dans les lunettes. Ça, ça veut dire qu'il y a de l'air qui s'échappe. Mais avec ceux-là, vraiment, il n'y a aucune buée. On sent qu'ils sont plus étanches », explique l'ambulancier.



Agrandir l'image  

L'ambulancier Pierre Alexandre Bisson avec un masque P100 au visage.

PHOTO : RADIO-CANADA / RAPHAEL TREMBLAY

C'est ce haut niveau de protection qui a incité la Coopérative des paramédics de l'Outaouais à se tourner vers les masques en élastomère.

« Nos paramédics sont au front quotidiennement. On se devait de trouver une pièce d'équipement qui allait les mettre en sécurité à 100 % », explique à son tour Marie-Ève Daoust, chef aux opérations et aux communications.

« On veut leur donner la meilleure pièce d'équipement qu'il soit pour qu'ils se sentent en sécurité et qu'ils n'aient pas peur de faire leur travail. »

— Marie-Ève Daoust, Coopérative des paramédics de l'Outaouais

« Avec cet équipement », clame-t-elle, « nos paramédics savent qu'il n'y a pas de chance qu'ils puissent ramener [la COVID-19] chez eux et [infecter] leur famille [...] Parce que je vous mentirais si je vous disais qu'il n'y a pas eu d'inquiétude. »

Une utilité éprouvée

À l'Institut de recherche Robert-Sauvé en santé et en sécurité du travail (IRSST), un organisme qui mène des recherches pour éliminer les risques d'atteinte à la santé et à la sécurité des travailleurs, la réputation des demi-masques en élastomère n'est plus à faire.

En plus de leur étanchéité et de leur capacité de filtration, ils sont réutilisables. C'est là un autre avantage de taille, selon Geneviève Marchand, chercheuse spécialisée en microbiologie dans les bioaérosols.

Dans la mesure où un travailleur peut l'utiliser pendant plusieurs semaines, « tu ne tombes plus en pénurie parce que tu peux l'utiliser à plusieurs occasions », soutient la spécialiste. « Ce n'est pas comme le N95, qui est un masque jetable. »

QUELQUES CARACTÉRISTIQUES D'UN MASQUE EN ÉLASTOMÈRE MUNI D'UN FILTRE P100

**Le masque est d'une
très bonne étanchéité**



**Les filtres P100 captent 99,97 %
des particules dans l'air**



Le masque et les filtres P100 sont **réutilisables**



**Ils protègent celui qui le porte,
pas son entourage!**

C'est une solution de rechange également retenue par d'autres corps ambulanciers au Québec, en Ontario et en Nouvelle-Écosse, et même par certains dentistes au Manitoba. Aux États-Unis, les Centres pour le contrôle et la prévention des maladies (CDC) en recommandent l'utilisation dans les hôpitaux.

La décision d'utiliser ou non des instruments non médicaux comme les respirateurs P100 relève de la pratique clinique et dentaire, laquelle est du ressort des gouvernements provinciaux et territoriaux.

Même s'ils offrent une protection contre la COVID-19, les respirateurs P100 n'ont pas réussi à s'imposer comme solution de remplacement aux masques N95.

« Malheureusement, dans la majorité des milieux de soins, les APR sont peu utilisés et surtout très peu connus. Il y a très peu de connaissances par rapport à ça, » remarque Mme Marchand.



Santé Canada se positionne

Même s'ils ne sont pas des instruments médicaux, les respirateurs P100 seront bientôt reconnus par Santé Canada, dans une mise à jour de ses lignes directrices publiques, comme une option de rechange aux N95.

« Santé Canada est d'avis que les respirateurs P100 représentent une bonne solution de rechange lorsqu'il n'y a pas de masques N95 de qualité médicale, car ils offrent une protection au moins équivalente. »

— Santé Canada

« Au Canada, les établissements de santé qui n'ont pas accès à des respirateurs N95 de qualité médicale peuvent, s'ils le jugent approprié, acheter et utiliser des respirateurs de qualité commerciale, comme des masques N95, P95 ou P100 (ou des masques équivalents, comme KN95 ou KP95) pendant la pandémie de COVID-19 », affirme le ministère dans une note envoyée à Radio-Canada.

Toutefois, en raison du risque que l'air non filtré sortant de la soupape d'expiration contamine le champ chirurgical, ces types de masques ne pourront pas être utilisés dans un milieu stérile.

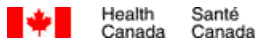
Reste maintenant à voir comment les masques en élastomère avec un filtre P100 vont s'inscrire dans les habitudes des travailleurs de la santé. « Ce qui va être intéressant de voir, c'est si ça va perdurer dans le temps après la pandémie », juge Geneviève Marchand.

À lire aussi:

[Du N95 au P100 : comprendre l'utilité des masques contre le coronavirus](#)

Angie Bonenfant





Medical Devices Directorate
11 Holland Ave.
Ottawa, Ontario K1A 0K9
Address Locator: 3005B

June 11, 2020

Nicolas Smit
46 Mary Ave,
Naughton, Ontario
P0M 2M0
smitnicolas@hotmail.com

Dear Mr. Smit,

Thank you for your email dated June 8, 2020 concerning Health Canada's oversight of P100 respirators. I have taken note of your comments and I can assure you that the Department is taking this matter seriously. We are striving to ensure, when regulatory requirements are met, that protective medical devices, including filtering respirators, are authorized for sale on the Canadian market in a timely manner and also that proper guidance about COVID-19 medical devices is available to Canadians during the pandemic.

As the federal regulator for medical devices, Health Canada is committed to protecting the health of Canadians by validating that the medical devices sold in Canada meet safety and effectiveness regulatory requirements, even during this health crisis. Health Canada regulates the sale and importation for sale of medical devices under the *Food and Drugs Act* and the *Medical Devices Regulations*. On March 18, the Minister of Health signed an [Interim Order](#) (IO) respecting the importation and sale of medical devices for use in relation to COVID-19. This Interim Order is intended to expedite access to medical devices related to COVID-19. The Medical Devices Directorate of Health Canada is actively expediting reviews of medical device to address urgent public health needs. Health Canada is also expediting the review and issuance of MDEL applications for companies applying to manufacture Class I medical devices, such as P100, or import or distribute Class I-IV medical devices in support of COVID-19 response efforts.

As of June 10, Health Canada has not received any application for P100 respirators under the Interim Order process. Should the department receive an application for P100 respirators intended for use against the spread of COVID, we would review it under the streamline regulatory process established under the IO and in a very timely manner. Our experts understand the similarities with medical respirators (N95) and technical features of the P100 and would review any application received on its own merit, with the same scrutiny as they would for other respirators.

While Health Canada has not authorized P100 respirators specifically for use in the context of the pandemic under the IO, the Department understands that there is a need for greater clarity and guidance surrounding the use of alternate respirators to those typically used in medical settings such as N95 respirators. Back in March, the department was already providing guidance as to the effect that considerations should be given to using some alternative devices but was not specifically referring to P100 respirators. In light of your previous correspondence and media inquiries received, the Department recently updated the guidance available on [our website](#). We specifically added a reference to the use of non-medical N95 and equivalent respirators such as P100 when HC authorized or licensed devices are not available.

That being said, I would like to highlight the fact that Health Canada does not have oversight or a role to play in procurement decisions by the Healthcare system nor on business decisions to submit application for authorizations. The decision to procure and use medical devices or alternative options, such as the P100, is not within Health Canada's mandate.

Our guidance indicates that healthcare institutions may, at their discretion, purchase and use commercial-grade respirators, such as the P100, in a health care setting during the COVID-19 outbreak when medical N95 (or equivalent) respirators are not available (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/masks-respirators-covid19/health-professionals.html#a33>). Furthermore, Health Canada has expressed the view that the P100, P99, P95, N100, N99, R100, R99, and R95 respirators are at least as protective or more against the inhalation of respiratory particles and are a suitable alternative when medical N95 respirators are not available. In its role of providing guidance, Health Canada takes into account various safety, public health, regulatory, and other considerations.

With regards to using respirators with exhalation valves, Health Canada advises that these should not be used to prevent the spread COVID-19. The reason for this is that exhaust valves may allow infectious respiratory droplets to be released outside the respirator, and the use of respirators with exhaust valves will not protect others from COVID-19. We are aware that exhalation valves may be needed to balance higher filtration rates in some cases. The decision to use respirators with exhalation valves may be made on a case by case basis based on provincial guidance.

I share your views that in the context of the pandemic, innovative solutions and safe alternative options, such as the use of P100, should be considered by the healthcare system in the fight of COVID-19. However, as indicated above, Health Canada is not in position to influence procurement decisions by the healthcare system, nor dictate the use of specific personal protection equipment as this is not within its mandate.

I would like to thank you for providing a list of experts that could provide additional support on this issue. We have consulted some organizations in our research, such as the Critical Care Society and the Canadian Thoracic Society, and received valuable feedback on the technical information that informed the guidance that we published.

For additional information on the use of masks and respirators during the COVID outbreak, please refer to Health Canada's guidance which is updated on a regular basis as new information is made available at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/masks-respirators-covid19.html#a5>

Thank you again for your email.

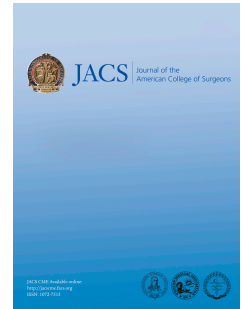
Sincerely,

A handwritten signature in black ink that reads "David Boudreau" with a stylized flourish at the end.

David Boudreau

A/ Director General
Medical Devices Directorate
Health Canada

Journal Pre-proof



Implementation of an Elastomeric Mask Program as a Strategy to Eliminate Disposable N95 Mask Use and Resterilization: Results from a Large Academic Medical Center

Sricharan Chalikonda, MD, MHA, FACS, Hope Waltenbaugh, MSN, RN, CNOR, NE-BC, Sara Angelilli, MSN, RN, CNOR, Tiffany Dumont, DO, Curt Kvasager, MBA, Timothy Sauber, MD, Nino Servello, CRNA, Anil Singh, MD, Rafael Diaz-Garcia, MD, FACS

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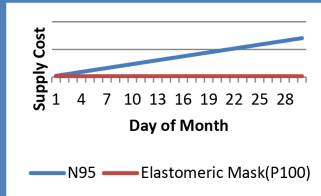
Please cite this article as: Chalikonda S, Waltenbaugh H, Angelilli S, Dumont T, Kvasager C, Sauber T, Servello N, Singh A, Diaz-Garcia R, Implementation of an Elastomeric Mask Program as a Strategy to Eliminate Disposable N95 Mask Use and Resterilization: Results from a Large Academic Medical Center, *Journal of the American College of Surgeons* (2020), doi: <https://doi.org/10.1016/j.jamcollsurg.2020.05.022>.

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Implementation of an Elastomeric Mask Program as a Strategy to Eliminate Disposable N95 Mask use and Resterilization: Results from a Large Academic Medical Center

Lower Cost



10x cheaper than disposable N95s after one month of use



Operational Efficiency



94% successful in fit testing
Multiple users with single mask

Sustainability



No limit to number of uses.
Ready for next surge.

Chalikonda et al. J Am Coll Surg, September 2020



Implementation of an Elastomeric Mask Program as a Strategy to Eliminate Disposable N95 Mask Use and Resterilization: Results from a Large Academic Medical Center

Sricharan Chalikonda, MD, MHA, FACS, Hope Waltenbaugh, MSN, RN, CNOR, NE-BC, Sara Angelilli, MSN, RN, CNOR, Tiffany Dumont, DO, Curt Kvasager, MBA, Timothy Sauber, MD, Nino Servello, CRNA, Anil Singh, MD, Rafael Diaz-Garcia, MD, FACS

From the Allegheny Health Network Clinical Operations, Pittsburgh, PA

Disclosure Information: Nothing to disclose.

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Short title: Elastomeric Mask Program

Background: The COVID-19 global pandemic has placed a large demand on personal protective equipment for healthcare workers. N-95 respirators, required to perform aerosolizing procedures, are in short supply and have increased significantly in cost. The lack of a clear end to the pandemic requires that hospitals need to create a long-term, cost effective solution to the N95 shortage. We initially used previously described methods to reuse and resterilize N95 masks however we found they did not solve the issues related to just in time fit-testing and cost.

Methods: We initiated a program with the aim to reduce our dependence on N95 masks by initiating a phased program to acquire industrial style elastomeric P100 masks as a substitute for reuse and resterilization of disposable N95s. We created an allocation strategy based on availability of the masks, as well as an operational plan to fit test, educate, and disinfect the masks.

Results: Within 1 month we were able to reduce the number of N95s needed by our network by 95%. We also found that the cost was conservatively 10 times less per month than purchasing disposable N95s and the cost benefit increases the longer that they are needed.

Conclusion: Establishing an elastomeric mask program is feasible and less expensive than programs focused on reusing and disinfecting disposable N95 masks. A well thought out elastomeric distribution and disinfection program does not pose greater operational challenges than an N95 reuse and resterilization program. In addition, elastomeric masks can be stored for future surges and should be considered an essential part of all healthcare facilities' supply of personal protective equipment. Implementation of the program has eliminated our dependence on disposable N95s to maintain normal operations during the global pandemic.

Introduction

The worldwide COVID-19 crisis has brought to light the importance of having a reliable supply of respirators for our healthcare providers. The N95 shortage has led the Centers for Disease Control (CDC) to create guidelines for extending the use of N95 beyond what is conventionally recommended by the manufacturer. In addition, the CDC has also recommended that fit testing of N95s be suspended to help reduce the number of N95s normally used during this process.[1] The cost of N95 masks has skyrocketed related to the increase in worldwide demand combined with the limited availability due to supply chain constraints. The unknown duration of the current pandemic requires healthcare organizations to create a long term solution to disposable N95s that can be achieved in a cost effective manner and scalable across large organizations. Many innovative methods for reusing and sterilizing masks have been introduced with early success in reducing the amount of N95s that are required for an organization to source.[2][3]. We, like other healthcare networks operationalized a mask reuse and sterilization protocol. However, implementing a sterilization and reuse program created an equally intensive operational plan and does not allow for use beyond a set number of reesterilizations.[4] The introduction of numerous types and brands of N95 and N95 equivalents also poses challenges related to fit testing and supply availability. For clinical efficacy, there must be consistency of the types of masks available in order to ensure that individuals have access to the masks for which they were fit tested. We implemented a widespread program to replace the majority of our N95 usage with reusable P100 elastomeric half mask respirators (Figure 1) and PAPRs to help alleviate the issues with N95 reuse and reesterilization.

Allotment Process

The Allegheny Health Network is a 9-hospital system comprising approximately 2200 licensed beds with sites in Pennsylvania and Western NY, employing 21000 individuals. The distribution of a limited protective resource within a 9-hospital network can be a controversial and stressful process. Every new patient contact brings some risk to the individual provider, and thus all providers can argue that they should be given priority to the limited resource. We felt that a utilitarian approach towards distribution was best suited to weigh risks and benefits to both our staff and patients. A panel of clinical personnel was assembled, with participation from institutional leadership amongst nursing, anesthesia, critical care medicine, surgery and supply chain. We prioritized clinical units and personnel based on their inherent risk to COVID-19 exposure. Greatest priority was given to those clinical staff with direct airway manipulation and those dealing with high acuity COVID-19 patients. (Table 1)

Initially, emergency rooms, intensive care units and anesthesia providers were targeted for conversion of disposable N95 usage to reusable P100 half-mask respirators.[1] Staffing per shift was broken down across the 9 hospitals, and a sufficient number of respirators were assigned to each unit for a 24hr period to provide protection for physicians, physician-extenders, nursing, and respiratory therapy in the first wave of distribution. Those devices were assigned to the specific clinical units rather than providers, with the assumption that they would be turned in for cleaning and processing after shift completion. System-wide fit testing was scheduled by nursing leadership. As additional shipments were made available, that initial disbursement was supplemented to expand device availability to phase 2 and 3 caregivers. Proceduralist physicians were included based on practice exposure to the airway or lung tissue.[5–7]

Finally, as more devices were delivered from the manufacturer, we transitioned from a high turnover unit-assigned, shared-device model to assigning devices to specific providers to use and maintain. This transition was necessary to maintain efficiency as we utilized individuals from our central sterile processing to disinfect the masks. We wanted to ensure that this was sustainable when those individuals would be redeployed for elective operative case volume once it returned.

Training and Education

To prepare for the launch and distribution of the masks, we engaged the director of education and the chief Certified Registered Nurse Anesthetist (CRNA) for each network hospital. Each site identified 1-2 site coordinators and multiple super users to perform the real time education, fit testing, and return demonstration with distribution of each mask. Super users were trained via an electronic module from the manufacturer and an in person demonstration session.

A multimodal approach to staff education was selected. This included electronic/ printed directions, in person demonstration, and video support. Super users completed one on one mask demonstrations with each staff member to ensure user safety and create a record of training activities. We filmed a real time video demonstration of mask donning, seal checks, and doffing accessible through QR codes to provide staff with access to directions at all times. During the time period when the supply of masks did not allow for individuals to have their own masks, we initiated a system of collection and disinfection. (Figure 2)

The sterile processing departments were trained in a similar fashion for the disassembly, disinfection and reassembly of the masks. A super user completed an onsite overview at each

facility. The site managers signed each staff member off on their knowledge of the disinfectant solution, cleaning process, and return demonstration of mask disassembly and reassembly.

Fit testing

In the first wave of distribution, 1,962 staff members were fit tested with 1,840 staff members passing. Staff members were required to remove make-up and report for fit testing clean shaven as applicable. Fit testing was performed via hood and sensitivity solution testing or using quantitative methods only after the staff member successfully donned the mask and passed positive and negative seal checks. If the staff member did not initially pass the seal checks, the mask would be adjusted or a different size would be selected. If the staff member could not successfully pass the seal checks, we did not proceed to fit testing. Staff members that failed P100 fit testing were offered an N95 mask if applicable or a powered air purifying respirator (PAPR) to use in clinical situations.

N95 usage

We measured N95 usage in the Medical Intensive Care Unit (MICU). The MICU is an 18 bed negative pressure ICU where the majority of COVID-19 patients were cared for. We recorded the number of individuals caring for the patients in a 24hour period. We also measured the number of room entries per individual/day. This would correlate with the number of N95 masks that would be used without extended reuse interventions.

Room entries (individuals multiplied by number of room entries) ranged from 41-133 entries in one patient room in a 24 hour period; with a mean room entry of 87 times per patient in a 24 hour period. (Table 2). At the beginning of the study we had not employed a policy to re-

use N-95s, therefore 87 N-95 masks were being used per patient per 24-hour time period.

Approximately 1,566 N-95 would be used per day in the MICU. We re-structured who could enter the room, as well to further decrease the usage of PPE. This eliminated consultants, dietary, environmental health services, and nursing assistants from entering the room.

Following institution of the Elastomeric N-100 masks our usage of N-95s masks has decreased to 0. Those staff members that failed fit testing for the Elastomeric N-100 masks were allocated PAPRs effectively reducing our disposable N95 usage to zero. After greater than one month of utilization no healthcare workers chose to return to N95 usage.

Cost

We utilized a cost ratio methodology to evaluate the economics of the program. We found that 116 P100 respirator and cartridges replaced 2088 disposable N95s/day. After more than one month of usage we have found that filters have not needed to be changed more frequently than once a month. Given that the cartridges are able to be used until they are visibly soiled and/or there is difficulty with airflow we set a time period of one month of use for routine replacement. Part of the education included proper replacement of the filter cartridges to prevent inadvertent soilage and contamination. We included the replacement of the filter monthly in the cost analysis. In order to calculate the current savings we utilized a price paid of approximately \$3.00/ N95 which is well below the current market rate compared to approximately \$20 for an elastomeric mask and \$10 per cartridge. We also reduced the usage of disposable N95 masks by 75% to take in to account the aggressive reuse and sterilization programs that would have been employed had we not purchased the elastomeric. The cost of an elastomeric mask programs is conservatively 10 times cheaper per month and the cost benefit continues to increase the longer they are in use. (Figure 3)

Discussion

The global impact of COVID 19 has revealed several weaknesses in our ability to secure critical PPE such as respirators. The utilization of disposable N95s during a global pandemic has several key limitations including supply, cost and the inability to adequately fit test healthcare workers without utilizing masks in the process. Resuming elective procedures requires that facilities demonstrate and adequate amount of resources including PPE. In order for hospitals to protect staff and patients in our procedural areas, the ability to provide respiratory protection is paramount. The implementation of elastomeric masks has allowed us to create an environment where universal respiratory precautions for all intubations and other aerosolizing procedures can be adopted without any noticeable impact on our supply of disposable N95 respirators. In addition, the advantage of implementing an elastomeric respirator program is that it does not require any additional hospital resources as compared to an N95 reuse and resterilization programs. The ability to disinfect and store these devices in healthcare has proven to be feasible.[8] The elastomeric masks have also been found to be well tolerated for use by healthcare workers during long periods of patient care.[9] In addition, the utilization of standardized type of mask eliminates the need for multiple fit testings related to the different brands and styles of masks that are acquired during a pandemic.[10]

Conclusion

Elastomeric masks with disposable P100 filters were found to be superior to disposable N95s for protection of healthcare workers at a large academic medical center. They do not have the waste associated with fit testing disposable N95s so there is no barrier to fit testing all front line caregivers. A return and disinfection program does not pose a greater operational challenge

than previously described disposable N95 resterilization programs. The nature of the elastomerics and their ability to be disinfected allows for multiple caregivers to share the same mask. The one time cost and storage aspects related to the program lend to a significant cost benefit when compared to disposable N95s. The financial impact that many hospitals are facing related to the pandemic requires long-term cost effective solutions and the implementation of an elastomeric respirator program will obviate many of the current issues that are being faced with disposable mask usage and allow for health systems to eliminate their dependence on a continual supply of disposable N95s. In order to resume operations, hospitals would benefit by using the time between surges to create and operationalize a reusable elastomeric mask program.

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Table 1. Calculation of Number of Room Entries by Team Taking Care of Critically Ill COVID-19 Patients in Medical Intensive Care Unit

Staff	Room entry (24-hour period)	
	Minimum	Maximum
Nursing; assessment every 2 hours repositioning, titration of drips, hygiene	12	40
Nursing assistant; blood sugar repositioning, stocking of supplies	7	28
Respiratory therapy; assessment every 4 hours, ventilator changes, arterial blood gases	5	15
MICU physician team; attending, fellow, resident, intern	8	18
Consultant; per service attending, fellow, resident	0	9
Dietary	0	6
Environmental services	1	2
Physical and occupational therapy	0	3
X-ray	0	6
IV team; IV access, PICC, midline, blood cultures, blood draws	0	3
Pharmacy; discuss with nursing, assessment of level of sedation	0	2
Total	41	133

MICU, medical intensive care unit; PICC, peripherally inserted central catheter

Table 2. Phased Approach to Distributing Elastomeric Masks

First wave, high risk, front line	Second wave, moderate risk	Third wave, at risk
Anesthesia CRNA, physicians, extenders	EP nurses, physicians, extenders	OR staff for at risk cases
ED nurses, physicians, extenders	Cath lab nurses, physicians, extenders	PACU staff for at risk cases
EMS, life flight nurses, physicians	TEE nurses, physicians, extenders	Preop nurses
Pulmonary and respiratory techs	Trauma OR nurses, physicians, extenders	Transplant surgery nurses, physicians, extenders
Pulmonary nurses, physicians, extenders	OR staff for moderate risk cases	SICU nurses, physicians, extenders
GI Nurses, physicians, extenders	PACU staff for moderate risk cases	CCU nurses, physicians, extenders
Critical care nurses, physicians, extenders	Ophthalmology nurses, physicians, extenders	Orthopaedic nurses, physicians, extenders
PACU nurses, physicians, extenders	Cardiovascular nurses, physicians, extenders	Others as deemed necessary by PPE committee
ENT, OMFS nurses, physicians, extenders	Dental nurses, physicians, extenders	-
Colorectal nurses, physicians, extenders	Hospitalist physicians, extenders	-
Thoracic nurses, physicians, extenders	Urology nurses, physicians, extenders	-
Plastics nurses, physicians, extenders	CT techs	-
Neurosurgery nurses, physicians, extenders (<i>performing endo access procedures</i>)	-	-
IR techs, nurses, physicians, extenders	-	-

As masks were procured, they were distributed to the caregivers in Phases as listed.

CCU, cardiac care unit; CRNA, certified registered nurse anesthetist; CT, computerized tomography; ED, emergency department; EMS, emergency medical services; ENT, ear, nose, and throat; EP, electrophysiology; GI, gastrointestinal; IR, interventional radiology; OMFS, oral and maxillofacial surgery; OR, operating room; PACU, post-anesthesia care unit; SICU, surgical intensive care unit; TEE, transesophageal echocardiogram.

Figure Legend

Figure 1. Photograph of elastomeric half mask respirator with disposable P100 filter.

Figure 2. Flowchart of mask disinfection and redistribution to caregivers. AHN, Allegheny Health Network; EPA, Environmental Protection Agency; PPE, personal protective equipment.

Figure 3. Cost ratio of disposable N95s to reusable elastomeric masks with filters. Price assumptions were made of \$3.00/disposable N95, \$20 for elastomeric mask and \$10 for disposable filters, assuming filters were replaced monthly.

Precis

Implementation of a reusable elastomeric mask program is feasible, cost effective, and eliminates dependence on disposable N95 masks and N95 mask disinfection programs at large medical centers.



P100 Mask Chart

