

# **Establishment of an ISO-Accredited PPE Testing Laboratory During a Global Pandemic**

### Provincial Infection Control Network Lunch and Learn Series 2021

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Be Kind Be Calm Be Safe Dr. Bonnie Henry



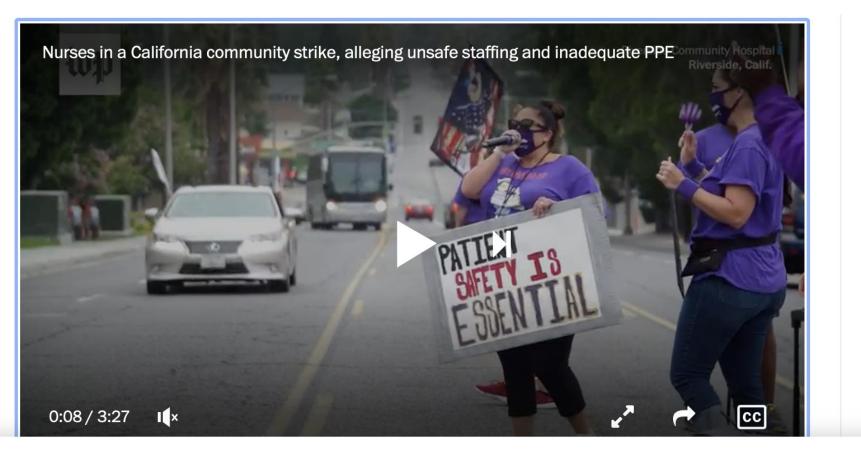
# PPE Supply Chain Is Important



Health

# America is running short on masks, gowns and gloves. Again.

Health-care workers are scrambling for supplies and reusing equipment as the coronavirus pandemic surges



# **Collaborative PPE Assessment and Testing**



# **Factors Contributing to PPE Shortage**

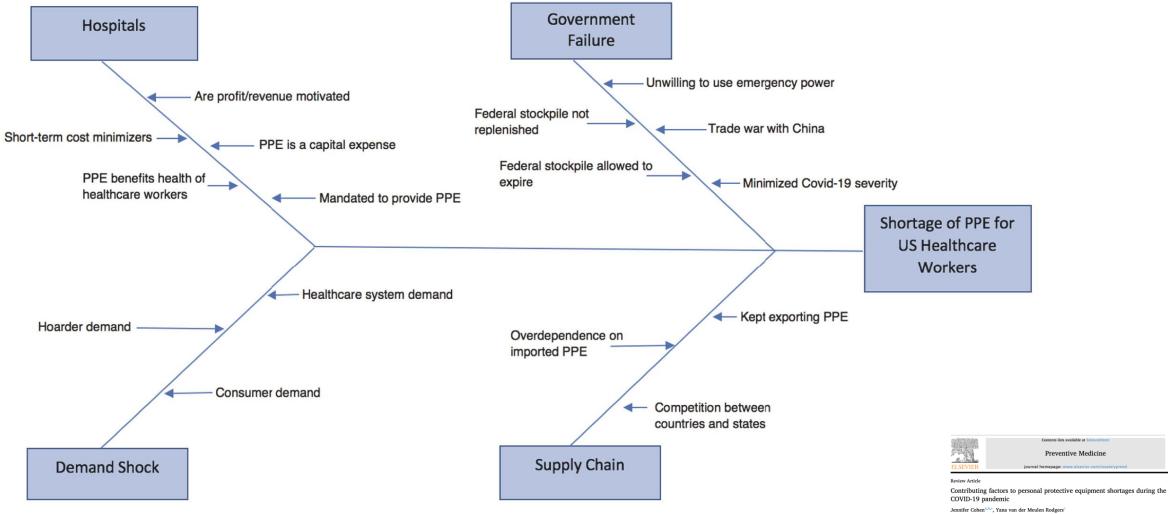


Fig. 2. Factors contributing PPE shortage.

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#### Flowchart to Determine if an N95 FFR Crisis Capacity Strategy Is Needed

# **PPE Crisis Capacity Strategy**

# How do we ensure we don't run out of a PPE item?

Evaluate Adequacy of Current N95 FFR Inventory and Supply Chain Is your current N95 FFR inventory and supply chain equal to or greater than your PPE needs?

Are there N95 FFRs available from local healthcare coalitions and federal, state, and local public health partners (e.g., public health emergency preparedness and response staff) that can cover your PPE needs based on your burn rate and ability to procure more PPE when needed?

Use the Personal Protective Equipment (PPE) Burn Rate Calculator to help you plan and optimize the use of PPE during the response to coronavirus disease 2019 (COVID-19).



Evaluate Availability of Other Respirators in Your Inventory Are there NIOSH-approved respirators that meet or exceed the level of protection of N95 FFRs available in your inventory or from the supply chain to cover your PPE needs?

Are there NIOSH-approved respirators available from local healthcare coalitions and federal, state, and local public health partners (e.g., public health emergency preparedness and response staff) that can cover your PPE needs?

Other devices that can be used include N99, N100, P95, P99, P100, R95, R99, and R100 FFRs, elastomeric respirators, and powered air-purifying respirators (PAPRs).

The use of these devices is included in the conventional capacity strategies to conserve the supply of N95 FFRs. More information on other NIOSH-approved respiratory protective devices can be found here.



pply chai

Evaluate Extended Use of N95 FFRs

Can extended use of N95 FFRs (using the same N95 FFR for more than one patient contact) cover your PPE needs based on your burn rate and ability to procure more PPE when needed?

More information on extended FFR use and other contingency capacity strategies can be found here.



Apply crisis capacity strategies. More information can be found at here.

Check supply chain and other resources frequently (e.g. daily).





Follow conventional capacity strategies or if shortages are expected, contingency capacity strategies. Continue to monitor current respiratory protection needs and usage. More information on optimization strategies can be found here.

Yes

Yes

Yes





Contents lists available at ScienceDirect

## American Journal of Infection Control

journal homepage: www.ajicjournal.org

American Journal of Infection Control

State of the Science Review

Safety in the practice of decontaminating filtering facepiece respirators: A systematic review

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> Moist Heat, Microwavegenerated steam &UV-C and Vaporized Hydrogen Peroxide most effective



# **Provincial N95 Reprocessing Project – A Contingency Plan**



Technical Bulletin

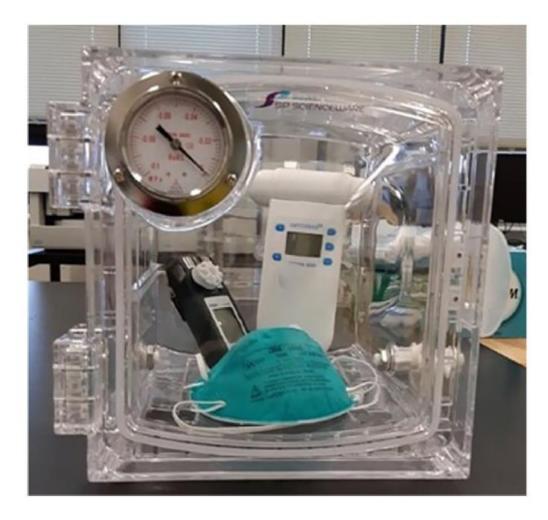
March 2021 Revision 13

Decontamination of 3M Filtering Facepiece Respirators, such as N95 Respirators, in the United States - Considerations

Over 150,000 N95 FFRs reprocessed at 38 healthcare facilities across BC



# **Does Reprocessing/Decontamination Respirators leave residues?**





### Evaluation of hydrogen peroxide and ozone residue levels on N95 masks following chemical decontamination

P. Kumkrong<sup>a,\*</sup>, L. Scoles<sup>a</sup>, Y. Brunet<sup>a</sup>, S. Baker<sup>a</sup>, P.H.J. Mercier<sup>a,b</sup>, D. Poirier<sup>a</sup> <sup>a</sup>National Research Council Canada, Ottawa, Ontario, Canada <sup>b</sup>Corem, Québec, Canada

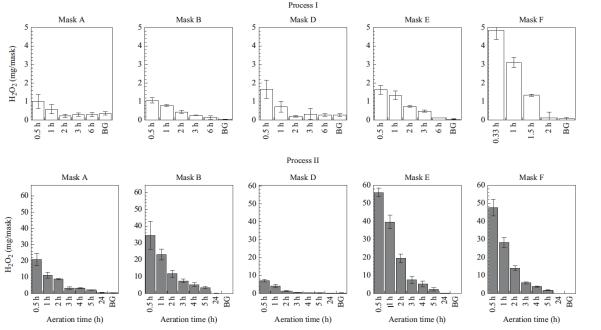


Figure 4. Residual hydrogen peroxide concentration and associated standard deviation (mg/mask) after aeration of N95 masks (A, B, D, E, and F) from decontamination process I and process II compared to untreated masks (BG).

Description	Fil	tratio	n va	ue (	%)	Pressure (max accepta value set at 0.7)
	0.3	0.5	1	3	5	(mbar) <sup>c</sup>
	μm	μm	μm	μm	μm	
IIR-surgical mask <sup>a</sup>	59	75	84	100	100	0.15
3M 1862 + <sup>a</sup>	96	98	99	99	100	0.20
ePM1 60% <sup>b</sup>	40	60	73	99	95	0.23
ePM <sub>1</sub> 60% <sup>b</sup> between quilt fabric	56	78	87	97	99	0 47

wear a

#### able ePM<sub>1</sub> 60%<sup>o</sup> between quilt fabric 78 8/ 9/ 99 0.4/ 56 ePM₁ 85%<sup>b</sup> 0.31 90 96 98 100 100 ePM<sub>1</sub> 85%<sup>b</sup> between quilt fabric 98 99 97 97 0.72 94 F7<sup>b</sup> 65 99 100 0.07 55 41 F7<sup>b</sup> between quilt fabric 72 82 97 97 0.43 55 F9<sup>b</sup> 78 88 92 100 99 0.15 F9<sup>b</sup> between quilt fabric 97 97 0.50 77 89 94 M5<sup>b</sup> 90 0.05 3 11 96 M5<sup>b</sup> between quilt fabric 38 96 97 0.39 19 54 Cleaning cloth between guilt fabric 21 54 92 93 0.39 40 Coffee filter (double) between guilt 90 99 99 98 98 2.18 fabric 0.36 Felt 155 g between quilt fabric 39 55 96 97 20 Leather 100 100 99 2.92 100 99 Microfibre fabric 88 95 99 1.50 59 99 82 95 94 0.64 Household paper towel (1 layer) 42 70 between quilt fabric Household paper towel (2 layers) 1.01 65 90 96 98 98 between quilt fabric Polypropelene fabric 1 0.41 10 27 41 65 75 Polypropelene fabric 2 28 55 0.18 18 5 61 Quilt fabric (2 layers) 55 94 95 0.31 37 16 Quilt fabric (4 layers) 69 0.66 59 63 34 71 Quilt fabric (6 layers) 74 88 98 0.97 46 98 Static dust cloth between quilt fabric 40 57 94 96 0.35 21 Tea towel (1 layer) 0.05 5 15 14 35 36 Tea towel (2 layers) 0.10 5 23 84 88 13

# **Filtration Efficiency is not** the only variable to consider. Breathability is important!



Is there an adequate alternative to commercially manufactured face masks? A comparison of various materials and forms

Healthcar Infection Society

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# PPE Laboratory Testing is Important



### **BUSINESS | HEALTH CARE | HEALTH Low-Quality Masks Infiltrate U.S. Coronavirus Supply**

Many imported masks fall short of N95 standards, tests show, putting workers on the front lines of battling the virus at risk



Workers on a production line for masks in Shanghai. PHOTO: ALY SONG/REUTERS

# Millions of counterfeit N95 masks distributed to health care workers in the U.S.

Masks imitating the real thing are flooding U.S. ports, and authorities can hardly keep pace.

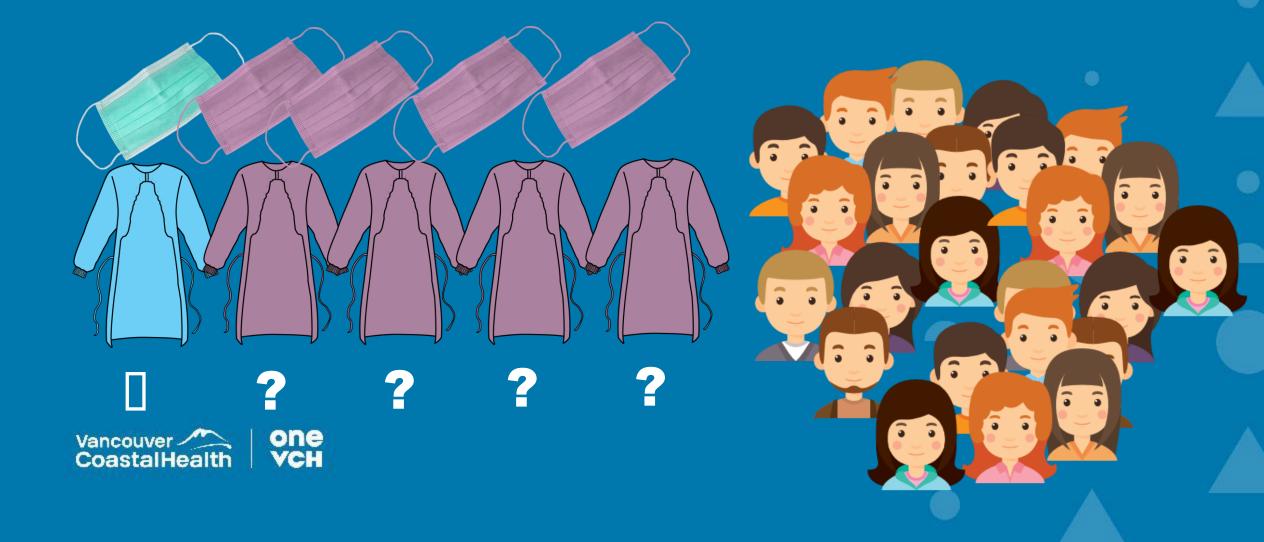


# During COVID, PPE supply from trusted vendors was challenged, while demand increased

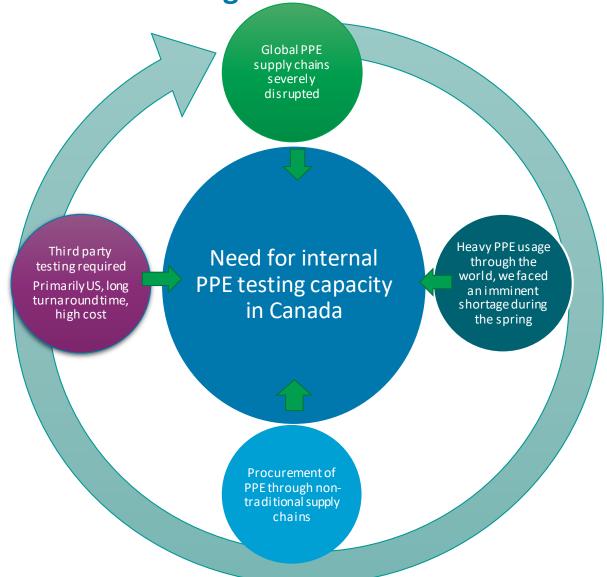




### Therefore, we needed to source from alternative vendors, with unknown quality



## The Need for Canadian PPE Testing





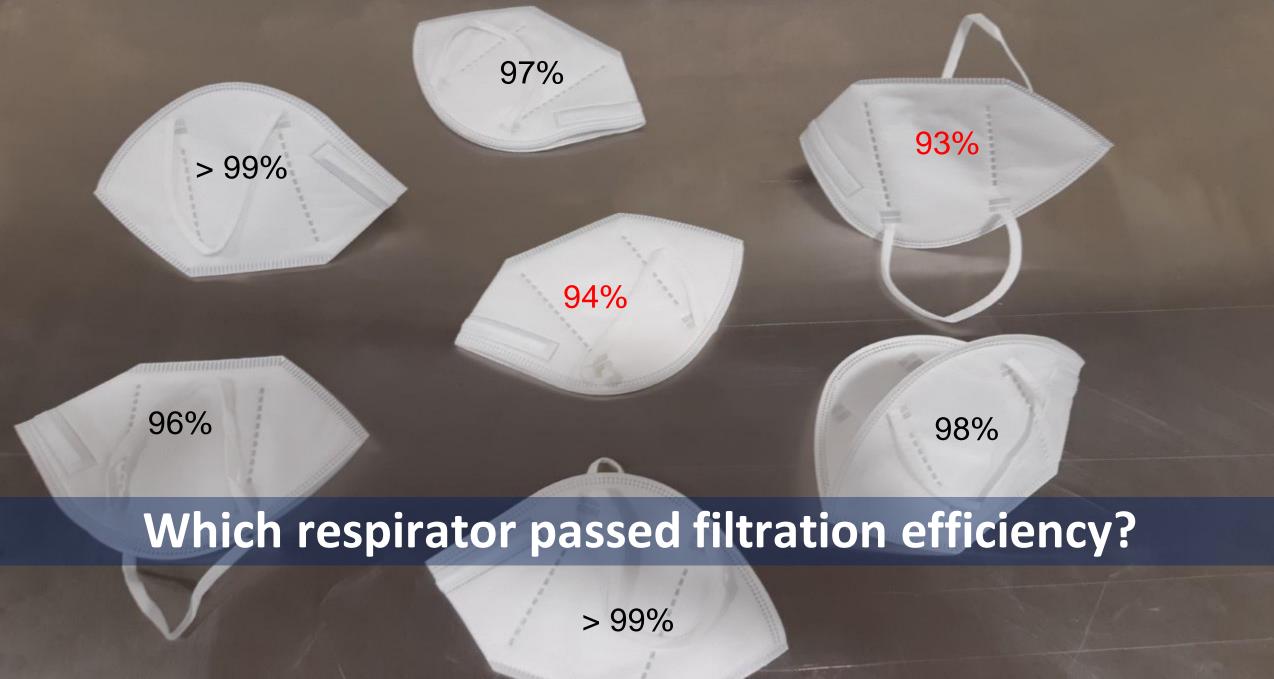
## A Multidisciplinary Team Built an ISO-accredited PPE Testing Laboratory



## **PPE Testing Laboratory Test Menu**

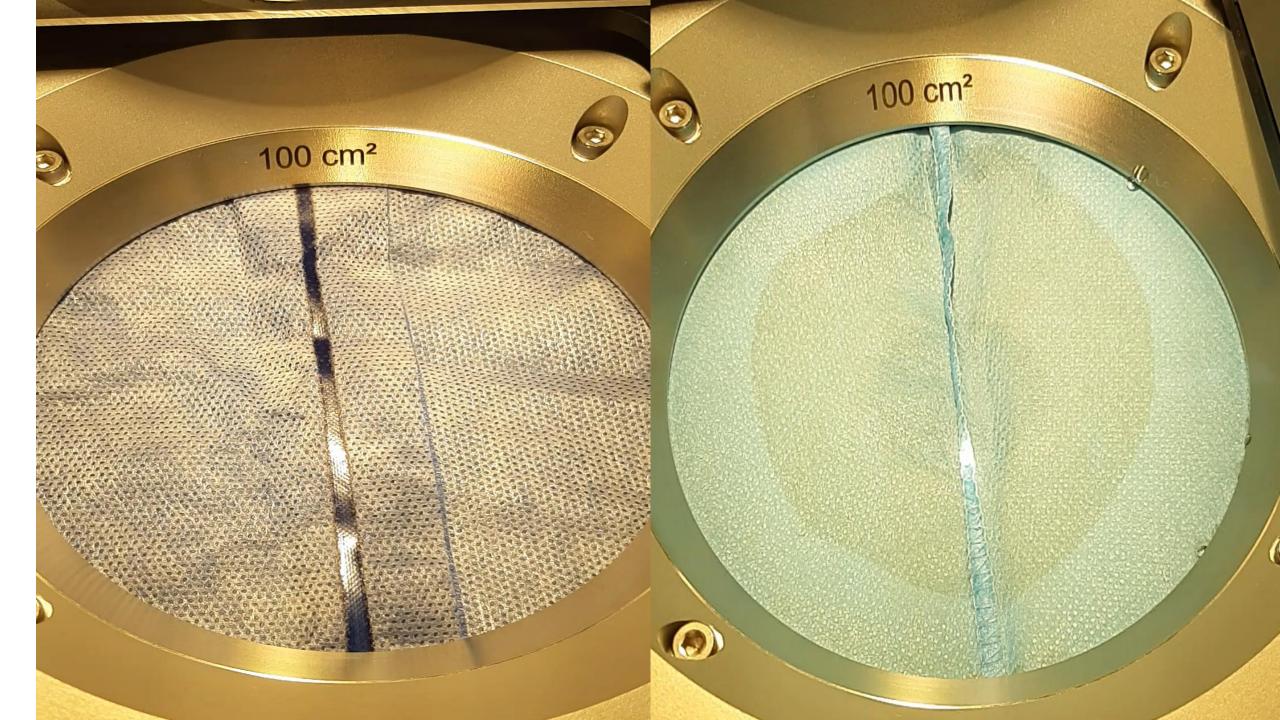
PPEfl	Test	Description				
	NaCl Filter Efficiency (TEB-APR-STP-0059)	This test measures the filtration efficiency of respirators using NaCl aeroso				
N95 respirator	Quantitative fit testing (CSA Z94.4-18 Section 9, Annex C)	This test measures the fit of respirators to ensure a good seal on the user face based on particle counting technology in the PortaCount machine				
	N95 inhalation and exhalation efficiency (STP-007, STP-003)	Measures the inhalation and exhalation breathing resistance for air- purifying respirators, including N95 filtering face-piece respirators.				
N95 respirator and Proc/Surg Masks	Fluid Resistance (ASTM – F1862)	Evaluates resistance of medical face masks to penetration by the impact of a small volume (~2 mL) of a high-velocity stream of synthetic blood.				
	Breathability (differential pressure)	Measures the differential pressure required to draw air through a medical face mask.				
Procedural/Surgical Mask	Bacterial Filtration and Particulate Filtration efficiency (ASTM F2101 – BFE, F2299 – PFE).	Measures filtration efficiency of medical masks using a viable bacterial test organism and a 0.1 micron latex particle				
	Flame Spread	Measures the flammability of the mask material				
Surgical/Isolation Gown	Water impact testing (AATCC TM42-2017e)	This test measures the resistance of fabrics to the penetration of water by impact, predicting the fluid resistance of fabrics and PPE items				
	Hydrostatic Water Pressure Test (AATCC - 0127)	Measures the resistance of a gown or fabric to the penetration of water under a constantly increasing pressure.				











# Laboratory Testing of PPE Identifies PPE that are Unsafe for Use

PPE Item	Sample	Test	Number Tested	Total Number of PPE Items	Test Result
	N95 "A"	Filtration Efficiency	1141	156,000	Fail
	KN95 "A"	Filtration Efficiency	167	1,200,000	Fail
N95 Respirator	KN95 "B"	Filtration Efficiency	301	1,300,000	Safe for use
	KN95 "C"	Filtration Efficiency	32	450,000	Safe for use
	KN95 "D"	Filtration Efficiency	50	1,000,000	Fail
Gowns	$(\gamma()) \wedge (N) \cdots \Delta''$	Spray Impact and Hydrostatic Pressure	50	250,000	Safe for use (AAMI Level 2)
	$(\gamma())(V/N) "B"$	Spray Impact and Hydrostatic Pressure	32	100,000	Fail
	(n())(N/N) = ("	Spray Impact and Hydrostatic Pressure	32	1,00,000	Fail
	$(\neg())(1/(N + 1))''$	Spray Impact and Hydrostatic Pressure	20	14,000	Safe for use (AAMI Level 2)

# N95's, KN95's and Medical Masks are Tested Differently

	Filtration Efficiency of N95, KN95, and Medical Masks							
Standard Test Method	TEB-APR-STP-0059 (NIOSH)	GB 19083-2010 (Medical KN95)	GB2626-2006 (KN95)	ASTM F2299 (Particulate Filtration Efficiency for Medical Masks)				
Aerosol Type	NaCl	NaCl	NaCl	Latex Bead				
Aerosol Size - count median diameter (nm)	75	75	75	100 - 5000				
Aerosol Charge Neutralization	Yes	No	Yes	Yes				
Flow Rate (LPM)	85	85	85	Not specified				
Face Velocity (cm/s)	5-10	~32	~32	0.5-25				
Filtration Efficiency (%)	95	95	95	95-98				
Inhalation Resistance (Pa)	≤343	≤343	≤350	≤240				
Exhalation Resistance (Pa)	≤245	NaCl	≤250	NA				
Fit Test Requirement	Covered under CSA Z94.4	Yes - overall fit factor >100	No	No				
Fluid Resistance (mm Hg)	80 - 160 (surgical N95 respirators under ASTM F1862)	80	No	80 - 160 (under ASTM F1862)				



# Different International Standards have Varying Thresholds for Mask Acceptability

	ASTM F2100-11			EN 14683				YY 0469-2011	YY/T0969-2013
	Level 1	Level 2	Level 3	Type I	Type IR	Type ll	Type IIR	Surgical mask	Medical mask
BFE (3.0 microns)	≥ 95	≥ 98	≥ 98	≥ 95	≥ 95	≥ 98	≥ 98	≥ 95	≥ 95
PFE (0.1 microns)	≥ 95	≥ 98	≥ 98	/	/	/	/	≥ 30	/
Fluid Resistance (mmHg)	80	120	160	/	120	/	120	120	/
Breathability (H2O/cm2)	< 4.0	< 5.0	< 5.0	< 3.0	< 5.0	< 3.0	< 5.0	< 5.0	< 5.0
Flame Spread	Class 1	Class 1	Class 1	/	/	/	/	Class 1	/



# Do different standards impact how we interpret studies?

	Study	Year	Country	Virus	Mask group		Control group		Mask type
					Infections*	Mask <sup>†</sup>	Infections <sup>‡</sup>	Control <sup>§</sup>	
1	Chen et al.	2021	China	2019-nCoV	10	78	8	27	Mask¶
2	Doung-ngern et al.	2020	Thailand	2019-nCoV	29	227	102	602	Mask¶
3	Guo et al.	2020	China	2019-nCoV	7	40	17	32	Mask¶
4	Heinzerling et al.	2020	USA	2019-nCoV	0	3	3	34	Mask¶
5	Khalil et al.	2020	Bangladesh	2019-nCoV	36	92	62	98	N95
6	Wang et al.	2020	China	2019-nCoV	0	278	10	215	N95

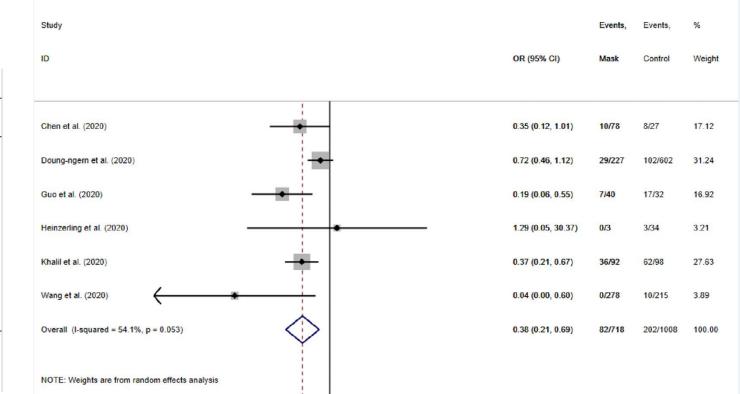
<sup>\*</sup>Infections in the mask group.

<sup>†</sup>Total sample in the mask group.

<sup>‡</sup>Infections in the control group.

<sup>§</sup>Total sample in the control group.

<sup>¶</sup>Specific type of mask was not reported.





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Major Article

Face masks to prevent transmission of COVID-19: A systematic review and meta-analysis

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Be Kind Be Calm Be Safe Dr. Bonnie Henry



# Thank you