

## Philippine COVID-19 Living Clinical Practice Guidelines

Institute of Clinical Epidemiology, National Institutes of Health, UP Manila In cooperation with the Philippine Society for Microbiology and Infectious Diseases Funded by the Department of Health

## EVIDENCE SUMMARY

# Should cloth masks be used to prevent COVID-19 infection caused by Variants of Concern (VoC)?

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## RECOMMENDATION

We recommend the proper use of either a well-fitted cloth mask or a medical mask in the community setting. If a cloth mask will be used, we suggest that it should be made of at least two layers of cotton (e.g., t-shirt fabric) or non-woven nylon with aluminum nose bridge. (Very low certainty of evidence; Strong recommendation)

#### **Consensus Issues**

The panel unanimously recommended the proper use of either a well-fitted cloth or a medical mask in a community setting. Whether to add qualifiers or not (regarding, for instance, the type of fabric and the particular setting) to this updated recommendation, as was done in the previous one, weighed heavily on the consensus panel and was discussed extensively. Eventually, it was highlighted that regardless of the community area or situation (e.g., crowded places, close-contact settings, confined and enclosed spaces, indoors or outdoors), proper wearing of a well-fitted mask must be emphasized and is still strongly recommended.

#### **Key Findings**

At the time of writing, there were no published nor preprint studies that directly investigated the efficacy or effectiveness of cloth masks in preventing COVID-19 infection caused by specific SARS-CoV-2 variants of concern (VoC). There was indirect evidence from two studies that investigated cloth masks for the prevention of COVID-19 in general: one was a case-control study that showed no significant difference between cloth mask and medical mask, and the other was a cluster-randomized trial which showed that both cloth and surgical mask reduced the proportion of people with COVID-19-like symptoms in the community. The indirect evidence from these two studies suggested that cloth masks can reduce symptomatic COVID-19 cases at the community level, albeit at a lesser degree compared to medical masks. It also suggested that the community use of both surgical and cloth masks can reduce symptomatic COVID-19 cases at the community level.

#### Introduction

SARS-CoV-2 can be transmitted via direct, indirect, or close contact with an infected person through infected respiratory droplets (>5-10  $\mu$ m), respiratory secretions, saliva, or through aerosols especially in poorly-ventilated and/or crowded indoor settings.[1] The World Health Organization uses the "3Cs" concept ((1) crowded places; (2) close contact settings, especially



when people have conversations very near each other; (3) confined and enclosed spaces with poor ventilation) to illustrate settings where COVID-19 is more readily transmitted.[1]

The use of face masks was one of the consistently recommended non-pharmacologic interventions to prevent COVID-19 transmission when COVID-19 vaccines were not yet available, and remains to be so. Israel stopped the mandatory use of face masks when it was able to vaccinate 80% of its adult population, which corresponded to 50% of its total population.[2] However, the resurgence of COVID-19 cases despite the high vaccination rate prompted the country to reimpose its nationwide mask mandate.[3] The rise in COVID-19 cases was attibuted to the presence of the Delta variant in the said country.[4] In other countries, the use of face masks has been reemphasized in the presence of the more transmissible SARS-CoV-2 variants.

Just like other viruses, SARS-CoV-2 evolves over time. Persistent circulation of a virus in the community increases its likelihood to mutate.[5] The first SARS-CoV-2 VoC was identified in the United Kingdom in September 2020 and was designated as a VoC later in December 2020.[6]

This review was undertaken to determine the efficacy or effectiveness of cloth mask in preventing COVID-19 infection due to Variants of Concern.

WHO Label	Pango lineage	Location of first known outbreak	Date earliest samples were documented	Designation date	Description
Alpha	B.1.1.7	United Kingdom	September 2020	18 December 2020	Easier to transmit, associated with more severe COVID-19, and possibly more transmissible than the original strain.
Beta	B.1.351	South Africa	May 2020	18 December 2020	Known to have some resistance to certain SARS-CoV-2 vaccines.
Gamma	P.1	Brazil	November 2020	11 January 2021	May reduce the protective effect of antibodies.
Delta	B.1617.2	India	October 2020	11 May 2021	Has increased transmissibility and makes vaccines less efficacious.

Table 1. SARS-CoV-2 Variants of Concern as of 05 October 2021 [6–9]

## **Review Methods**

The team conducted a systematic search of published articles in PubMed for MEDLINE, the Cochrane Library, SCOPUS, Google Scholar, Clinical Key (Elsevier), and HERDIN Plus. Preprints in MedRxiv and BioRxiv were also searched for any study related to the research question. The team also looked at *Clinicaltrials.gov* and Epistemonikos for any ongoing studies related to cloth mask use against any VoC. The team used the keywords and mesh terms "cloth mask", "nonmedical mask", "disposable mask", "nonwoven mask", "face mask", "medical mask", and "surgical mask" to search for both cloth mask and other masks. To search for COVID-19, the team



used some COVID-related search strings.[10] The team searched for systematic reviews, randomized controlled trials, and observational studies until October 5, 2021.

We included articles with the following PICO:

Population	People with no COVID-19 or suspected to be at risk from COVID-19 Healthcare Workers Essential frontliners Household and occupational contacts General public People who are vaccinated (partially or fully)
Intervention	Cloth mask
Comparator	Basic surgical mask
Outcome	Proportion of people with confirmed COVID-19 infection caused by any VoC

## Results

We found no articles that directly compared cloth masks to basic surgical masks in preventing COVID-19 transmission caused by any VoC. The two studies included in this review (one cluster-randomized trial and one case-control study) investigated cloth masks for the prevention of COVID-19 transmission in general, without considering any VoC.

The case-control study done in Thailand evaluated the effectiveness of various personal protective measures against COVID-19 in 211 asymptomatic cases and 839 asymptomatic controls.[11] Using their data, we analyzed the subset of participants who used either a cloth mask (n=102) or a medical mask (n=281). Among those who wore a cloth mask, 25 developed COVID-19; in the medical mask group, 72 had COVID-19. There was no significant difference between the two groups (OR 0.94, 95% CI 0.56 – 1.59).

The cluster-randomized trial was done in a rural area in Bangladesh to ascertain strategies to increase mask-wearing (subclassified into cloth mask and surgical mask users) and to learn the impact of increasing mask use on symptomatic COVID-19. Two outcomes were used to determine the impact of mask-wearing on community COVID-19 cases. The first outcome involved getting the symptomatic seroprevalence of all participants from the intervention and control groups, while the other outcome used the WHO-defined COVID-19 symptomatic status.

The study showed that general mask use can reduce symptomatic seroprevalence of COVID-19 in the community by 9.3% (p = 0.043), given a 29-percentage point increase in mask wearing over 8 weeks. When segregated by type of face mask, the use of surgical masks led to a relative seroprevalence reduction of 11.2% (p = 0.043), while the use of cloth masks resulted in a relative seroprevalence reduction of 5.0% (p = 0.540).[12] The study also demonstrated that mask use can reduce the proportion of individuals in the community with COVID-19-like symptoms by 11.9% (p = 0.000). Both surgical and cloth mask use can reduce the proportion of people with COVID-19-like symptoms in the community by 13.6% (p = 0.000) and 8.5% (p = 0.048), respectively [12]. This also supports the finding of one study that cloth masks can be used as an alternative to medical masks especially when there is a low supply of the latter.[13]



## Evidence to Decision

#### Economic Impact of a Mask Mandate in a Community

Cloth masks are available in online stores in the Philippines for P15.00 per piece [14] and used by a person for up to 4 times per day [15]. One study done in Luzon, Philippines suggested that face mask use, together with other interventions like healthy lifestyle, social distancing, face mask, proper hygiene, and lockdown seemed to enhance the perceived effectiveness of COVID-19 preventive measures [16].

- No cost-effectiveness study found on use of cloth mask vs. medical mask.
- Costing
  - Cloth mask P15.00/ piece, to be used by a person for up to 4 times per day [15]
  - Disposable surgical mask, 3 ply: Php 35-140/ 50pcs (Shopee shipping fee not included)
- In a study conducted in Metro Manila, regarding the attitude towards mask use in general, majority of the respondents believe that mask use is an effective preventive measure against COVID-19 transmission, are comfortable when other people wear masks, and believe that mask wearing does not lead to non-compliance to social distancing [22]

#### Recommendations from Other Groups

The World Health Organization still recommends the use of non-medical, fabric masks by the general public below 60 years of age and who do not have comorbidities even in settings where VoC are present in the community.[17, 18]

The United Kingdom's Scientific Advisory Group for Emergencies – Environmental and Modelling group (SAGE-EMG) recommends more consistent and effective use of fabric face coverings and physical distancing, alongside other interventions to mitigate transmission of the B117 (Alpha) variant. Despite the uncertainties as to the increased transmissibility of the Alpha variant, the behavior of the respiratory particle is likely unchanged.[19] Fabric masks in conjunction with physical distancing are important mitigation strategies against the Alpha variant, albeit in a more consistent and effective manner.

On July 27, 2021, a guidance specific to the Delta variant was released by the United States Centers for Disease Control and Prevention (CDC). It reiterated the use of masks in public indoor spaces, including those who are fully vaccinated.[20] Cloth masks are recommended to be used in this setting, provided it has (1) proper fit over the wearer's nose and mouth to prevent leaks, (2) has multiple layers of tightly woven, breathable fabric, (3) with a nose wire, and (4) made up of fabric that blocks light when held up to a bright light source.[21]

#### Research Gaps

Currently, there are no ongoing or completed studies looking into the efficacy or effectiveness of cloth masks in reducing infections caused specifically by SARS-CoV-2 variants. There is a need to investigate what fabrics of cloth mask, or how many layers of cloth, are required to effectively prevent infection with the more transmissible variants. Evidence would be needed for the efficacy of cloth masks against transmission of new variants, as they are identified and named to be of variants of concern. There is also necessity to guide public health measures among fully vaccinated individuals compared to non- or partially vaccinated ones, with regard to cloth mask use.



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# Appendix 1. Evidence to Decision

Table 1. Summary of initial judgments prior to the actual panel meeting (n = 9)

FACTORS			JUDGMEI	NT			RESEARCH EVIDENCE/ADDITIONAL CONSIDERATIONS FROM PANEL MEMBERS
Problem	No	Yes (9)					<ul> <li>In other countries, the use of face masks has been reemphasized in the presence of the more transmissible SARS-CoV-2 variants</li> </ul>
Benefits	Large (2)	Moderate (4)	Small (1)	Uncertain (2)			<ul> <li>Outcome 1: Proportion of people with confirmed There was an inconclusive result with regard to COVID-19 infection caused by any VoC</li> <li>Outcome 2: Seropositivity from COVID-19 Results were inconclusive.</li> <li>Outcome 3: Presence of COVID-19-like symptoms Results showed a 5% reduction in the presence of COVID-19-like symptoms.</li> <li>Benefits depend also on proper wearing of masks, quality of masks and other hygienic practices</li> </ul>
Harm	Large (2)	Small (3)	Uncertain (4)	Varies			None reported.
Certainty of Evidence	High	Moderate	Low (4)	Very low (5)			• The overall certainty of evidence is very low due to risk of bias, indirectness and imprecision.
Balance of effects	Favors cloth mask (3)	Does not favor cloth mask (2)	Uncertain (4)	Varies			<ul> <li>Outcome 1: Proportion of people with confirmed There was an inconclusive result with regard to COVID-19 infection caused by any VoC</li> <li>Outcome 2: Seropositivity from COVID-19 Results were inconclusive.</li> <li>Outcome 3: Presence of COVID-19-like symptoms Results showed a 5% reduction in the presence of COVID-19-like symptoms.</li> <li>No harms were reported.</li> </ul>
Values	Important uncertainty or variability (2)	Possibly important uncertainty or variability (2)	Possibly NO important uncertainty or variability (4)	No important uncertainty or variability (1)			
Resources Required	Uncertain	Large cost (1)	Moderate Cost (2)	Negligible cost or savings (4)	Moderate savings (2)	Large savings	<ul> <li>Cloth mask - P15.00/ piece, to be used by a person for up to 4 times per day Disposable surgical mask, 3 ply: Php 35-140/ 50pcs (Shopee – shipping fee not included)</li> </ul>



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FACTORS			JUDGMEI	NT		RESEARCH EVIDENCE/ADDITIONAL CONSIDERATIONS FROM PANEL MEMBERS
						Cloth masks are cheaper.
Certainty of evidence of required resources	No included studies (5)	Very low	Low (2)	Moderate (1)	High (1)	<ul> <li>No cost-effectiveness study found on use of cloth mask vs. medical mask. Cloth mask - P15.00/ piece, to be used by a person for up to 4 times per day [15]Disposable surgical mask, 3 ply: Php 35-140/ 50pcs (Shopee – shipping fee not included)</li> </ul>
Cost effectiveness	No included studies (7)	Favors the comparison	Does not favor either the intervention or the comparison (1)	Favors the intervention (1)		<ul> <li>No cost-effectiveness study found on use of cloth mask vs. medical mask.</li> </ul>
Equity	Uncertain (6)	Reduced (1)	Probably no impact (1)	Increased (1)		No research evidence found.
Acceptability	Uncertain (2)	No	Yes (7)	Varies		<ul> <li>In a study conducted in Metro Manila, as regards the attitude towards mask use in general, majority of the respondents believe that mask use is an effective preventive measure against COVID-19 transmission, are comfortable when other people wear masks, and mask wearing does not lead to non-compliance to social distancing</li> <li>Cloth masks are cheaper and cause less environmental pollution because of reuse. Poor disposal of medical mask is a problem.</li> </ul>
Feasibility	Uncertain	No (1)	Yes (8)	Varies		<ul> <li>In a study conducted in Metro Manila, sociodemographic profile of the respondents does not correspond to their knowledge and attitudes towards the proper use of PPEs amidst the pandemic. Economic status and sex do not show any significant association with the practice of Filipinos towards the COVID-19 pandemic. Age and educational attainment has association with their practices.</li> </ul>



# Appendix 2. Search Yield and Results

#### Search date: 11 September 2021

Search	Query	Results
#1	"COVID-19" AND (("cloth mask" OR "non-medical	17
	mask") AND ("medical mask" OR "surgical	
	mask"))	

#### Other databases searched:

- Published: Scopus, Google Scholar, Clinical Key (Elsevier), and HERDIN Plus.
- Preprints: *MedRxiv and BioRxiv*
- Ongoing studies: *Clinicaltrials.gov and Epistemonikos*

## Appendix 3. Characteristics of Included Studies

Author	Population	Intervention	Comparator	Outcome	n
Doung- Ngern et al, 2020	Asymptomatic Thai individuals who reported mask use	Cloth mask	Medical mask	Proportion of persons who turned out to be asymptomatic positive for COVID-19	Case = 211 Control = 839 n = 1050
Abaluck et al, 2021	Residents of selected rural villages in Bangladesh	Cloth mask	Medical mask	<ul> <li>(1) Prevalence ratio of symptomatic seropositive individuals from COVID-19</li> </ul>	(1) Cloth mask = 400; Medical mask = 7115 n = 146783
				<ul> <li>(2) Prevalence ratio of persons with COVID- 19_like symptoms as defined by the WHO</li> </ul>	(2) Cloth mask = 4487; Medical mask = 8364 n = 155268



## Appendix 4. Study Appraisal

A. Observational studies (Newcastle Ottawa Scale)

Study	Selection	Comparability	Exposure
Doung-ngern et al, 2020	***	**	*

B. Cluster-Randomized Trial (Cochrane ROB 2 for Cluser-Randomized Trials)

		Risk of bias domains											
	D1	D1b	D2	D3	D4	D5	Overall						
Data         Data <thdata< th="">         Data         Data         <thd< th=""></thd<></thdata<>													
Domains: D1 : Bias arising from the randomization process.													
	D1b: Bias a and re- relatior D2 : Bias d D3 : Bias d D4 : Bias ir	rising from th cruitment of li n to timing of	e timing of id ndividual part randomizatio ons from inter outcome da nt of the outco	entification ticipants in n. nded intervent ta. come.	ion.		+ Low						

# Appendix 5. GRADE Evidence Profile

Question: Cloth mask compared to Medical mask against COVID-19 for COVID-19 Variants of Concern

#### Bibliography:

Doung-Ngern P, Suphanchaimat R, Panjangampatthana A, et al. Case-Control Study of Use of Personal Protective Measures and Risk for SARS-CoV 2 Infection, Thailand. Emerg Infect Dis 2020; 26: 2607–2616.

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	Certainty assessment						Nº of p	patients	Ef	fect			
Nº o stuo s	die	Study design	Risk of bias	Inconsisten cy	Indirectne ss	Imprecisio n	Other consideratio ns	Cloth mask	Medical mask	Relativ e (95% Cl)	Absolut e (95% CI)	Certainty	Importanc e

Proportion of people with confirmed COVID-19 infection

1	observation al studies	seriou	not serious	serious <sup>a</sup>	serious <sup>b</sup>	none			OR 0.94	-	⊕00 0	
		s					25/102	72/281	(0.56 to 1.59)	<b>5 fewer</b> <b>per</b> <b>1,000</b> (from 38 fewer to 47 more)	Very low	



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	Certainty assessment						Nºof∣	patients	Ef	fect		
№ of studie s	Study design	Risk of bias	Inconsisten cy	Indirectne ss	Imprecisio n	Other consideratio ns	Cloth mask	Medical mask	Relativ e (95% Cl)	Absolut e (95% CI)	Certainty	Importanc e

Seropositivity from COVID-19 (assessed with: Prevalence Ratio)

0 fewer)		1	randomised trials	not seriou s	not serious	serious <sup>a</sup>	serious <sup>c</sup>	none	401/54112 (0.7%)	712/106201 (0.7%)	<b>RR 0.91</b> (0.80 to 1.02)	1 fewer per 1,000 (from 1 fewer to 0 fewer)	⊕⊕⊖ ⊖ Low	
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Presence of COVID-19-like symptoms (assessed with: Prevalence Ratio)

thats         seriod         s         (1.5%)         S (7.5%)         (0.92 to         per         O           s         s         s         1,000         Low         (from 6)         fewer to         2 fewer)         2 fewer)         2 fewer)	1	randomised trials	not seriou s	not serious	seriousª	serious⁰	none	4488/5680 3 (7.9%)	8365/11152 5 (7.5%)	(0.92 to	per 1,000 (from 6 fewer to	⊕⊕⊖ ⊖ Low		
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CI: confidence interval; OR: odds ratio; RR: risk ratio

#### Explanations

a. Study does not take into account the presence of SARS-CoV-2 variants of concern.

b. The confidence interval is wide

c. Some values, like the number of people with COVID-19 on each study arm, were not given in the paper.