



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 DOH AHEAD Program through the PCHRD

EVIDENCE SUMMARY

Among healthcare workers in the outpatient setting of communities with sustained COVID-19 transmission, does the use of personal protective equipment reduce risk of transmission?

Evidence Reviewers: Frangelo Conrad P. Tampus MD, Christopher G. Manalo MD, DPBEM, Howell Bayona, CSP-PASP

RECOMMENDATION

We recommend the use of at least surgical face mask and face shield for protection against COVID-19 infection among healthcare workers in the outpatient setting not performing aerosol generating procedures. Additional PPEs such as medical gowns and gloves should be worn as part of standard precautions during the performance of other procedures. (*Very low quality of evidence; Strong recommendation*)

Consensus Issues

The superiority of N95 over medical face masks cannot be established based on the imprecise effects noted from the evidence. The high likelihood of dermatosis or skin infections while using N95 respirators was also noted. Considering these issues, the panel deemed that medical face masks would be more cost-effective as long as only non-aerosol generating procedures are done in the outpatient setting. The use of additional PPEs may be required depending on the procedure that will be performed, consistent with the recommendation of the US Centers for Disease Control (CDC). Face shields are preferred over goggles as it offers a greater level of protection from droplets.

Despite the very low quality of evidence, a strong recommendation was formulated as the listed PPEs are already considered the minimum standard protection needed by the healthcare workers. Strict adherence to appropriate use of these PPEs is emphasized.

Key Findings

There are no available direct evidence comparing the effectiveness of N95 versus surgical mask in COVID-19 infection among healthcare workers in the outpatient setting. Meta-analysis comparing the two among healthcare workers in general showed no significant difference in their effectiveness in preventing clinical and laboratory viral infection. One RCT investigated the difference of N95 and surgical mask in protecting healthcare workers in different outpatient setting



Philippine COVID-19 Living Clinical Practice Guidelines

from viral respiratory infection and noted no significant difference between the two. Indirect evidence also shows more adverse skin reactions for those wearing N95 respirators as compared to surgical masks. The use of face shield on the other hand in addition to face mask provided added protection from acquiring COVID-19 among community healthcare workers in India based on a before and after study. The use of gowns and gloves are standards of care in medicine whenever handling patient's body fluids and this recommendation is still applicable in the current setting.

Introduction

In communities with moderate to high risk of transmission, a large part of COVID-19 cases would be coming from the people who are asymptomatic or with mild symptoms. As these individuals typically present in outpatient settings, it is important that healthcare workers who interact with them use personal protective equipment (PPE) that confer adequate safety against COVID-19 infections. The effectiveness of various PPEs in preventing COVID-19 infections among healthcare workers in outpatient settings needs to be determined as supply of PPE is also limited.

Different guidelines have advocated the use of PPE, most especially masks, to prevent droplet transmission [1]. In terms of different masks, N95 respirators and regular surgical face masks were not found to differ significantly in their protection against other respiratory infections [2,3]. Face shields have been proposed as an alternative to face masks in preventing aerosol transmission of respiratory infections [4]. Although face shields offer some advantages over masks in terms of reusability, breathability, and ease of communication, they have been shown to be less effective in blocking smaller aerosols that are able to flow around the edges of the shield [5].

Review Methods

We searched for articles that investigated on the transmissibility and incidence of COVID-19 infections among healthcare workers in the outpatient setting who used various PPE (e.g., mask, face shield, gown, gloves). We performed a systematic literature search up to 08 April 2021 using online databases such as MEDLINE, Cochrane, and Google Scholar, using combination of free text and subject headings for "COVID-19 or SARS-CoV2", "healthcare workers," "personal protective equipment," "face mask," "face shield", "eye protection" and "transmission". Additional searches in MedRxiv, BioRxiv, clinicaltrials.gov, and WHO ICTRP were also done to look for articles awaiting publication and ongoing clinical trials, respectively. References from systematic reviews and meta-analyses were also manually searched for additional articles. Letters, narrative reviews, and case reports, single-arm studies were excluded. Investigations involving healthcare workers working inside the hospital wards or intensive care units or exposed to aerosol generating procedures were also excluded.

Results

Characteristics of included studies

Two studies were included in this review. Evidence for face masks came from one indirect randomized controlled trial [6], while evidence for face shields came from one before and after



Philippine COVID-19 Living Clinical Practice Guidelines

study [9]. No direct evidence was found for gloves, gowns, N95 or surgical masks. Appendix 1 shows the summary of included studies.

Face masks

One randomized controlled trial (RCT) [6] deemed to have low risk of bias investigated N95 respirators versus surgical mask in preventing the influenza virus among 4051 healthcare personnel (5180 observations) in outpatient departments of six different medical centers via a clustered randomization method. The study spanned a period of 48 weeks.

Face shields

One before and after study [9] evaluated the effect of wearing face shields among community healthcare workers (CHCWs) in India from 03 May to 30 June 2020. These CHCWs were tasked to interview and counsel family contacts of COVID-19 confirmed patients in a locality with COVID-19 community transmission. The CHCWs were housed in a hostel and were not allowed to go out in public thus limiting their exposure. Before adding face shields, the standard PPE worn by the participants were 3 layered surgical masks, gloves, and a shoe cover. They did frequent alcohol hand rub and maintained a minimum of 6 ft all throughout their interviews with the family members. Weekly RT-PCR testing was done.

Outcomes

Prevention of COVID-19

N95 and surgical masks offered similar levels of protection against viral influenza. No significant difference for positive viral influenza culture (adjusted odds ratio 1.18, 95% CI 0.95-1.45) between the N95 group and surgical mask group. Likewise, there was also no significant difference in acute respiratory illness events (mean difference (MD) -21.9 events, 95% CI -48.2 to 4.4, $p=0.10$). Compliance in wearing masks were comparable between control and intervention groups. This RCT was assigned a GRADE quality of very low due to issues on indirectness of evidence and imprecision.

The addition of face shields was associated with significantly lower odds of getting COVID-19 (OR 0.05, 95% CI 0.003 to 0.86, $P = 0.04$). Before the addition of face shields, 62 CHCWs interviewed a total of 31,164 persons, of whom 222 (0.71%) eventually tested positive for COVID-19. After 2 weeks, two CHCWs developed symptoms prompting testing and addition of face shields. From the 62 CHCWs, 12 eventually tested positive (19%) with 8 eventually developed symptoms while 4 remained asymptomatic. None of the remaining 50 CHCWs who used face shields while visiting 118,428 people (2682 or 2.3% tested positive for COVID-19) contracted COVID-19. This study had the advantage of isolating the CHCWs, limiting their exposure to only the families they interviewed and thus making the result more likely due to the intervention. The quality of evidence for face shields for this outcome is low. The quality of evidence was downgraded due to risk of bias in terms of study design and small sample size. Risk of bias was deemed significant as the study design utilized was a before-and-after study rather than a randomized trial or a large cohort study. Furthermore, there was some degree of indirectness in the activities and patient encounter as described in the study and in the clinical question. The



Philippine COVID-19 Living Clinical Practice Guidelines

activities of health care workers in the study did mainly interviews rather than assessing and physically examining COVID-19 patients.

Appendix 2a shows the GRADE Evidence Table for N95 respirator versus medical mask for outpatient healthcare workers in places with sustained community transmission.

Appendix 2b shows the GRADE Evidence Table for no face shield versus use of face shield for outpatient healthcare workers in places with sustained community transmission.

Adverse reactions

In a cross-sectional survey, healthcare workers were reported to have increased events of skin reactions due to wearing of either N95 or surgical masks as part of their PPE during the COVID-19 pandemic [7]. Of the 390 participants, 96% reported experiencing some form of skin irritation while 61.7% of those with previous skin conditions experienced worsening. Similar findings regarding adverse reactions related to PPE use were reported in one observational study done during the SARS-COV-1 outbreak in Singapore [8]. Among the 307 participants who wore N95 masks, 35.5% experienced skin problems while no one wearing face mask reported any skin problems. The most common reported skin problems were acne, itch and rash.

Recommendations from Other Groups

The World Health Organization recommends healthcare workers to do targeted continuous masking whenever they are in their respective clinical areas. In non-aerosol-generating procedures, surgical masks (together with other PPE) are recommended over N95 respirators [11]. Face shields were recommended to be used only with a surgical mask or N95 respirator [11].

The CDC also recommends against the use of face shields alone for source control and should be used as part of other PPE, which include N95 respirators when handling aerosol generating procedures, surgical mask if respirator is not available and no AGPs, gowns, and gloves. These should be recommended among healthcare workers whenever they are handling confirmed and suspected cases in communities with at least moderate transmission risk [12]. Gloves and gowns are included as standard precaution in caring for all patients in all settings depending on the activities that will be performed, especially when there is a possible exposure to blood or body fluids of the patient [10].

Research Gaps

Only 1 ongoing clinical trial was found related to this topic. This is a cluster-randomized trial (NCT04823351) in Switzerland that aims to compare the protective effects of surgical mask versus FFP2 masks among health care workers in low-risk settings (i.e., nursing homes).



Philippine COVID-19 Living Clinical Practice Guidelines

References

- [1] WHO. Transmission of SARS-CoV-2: implications for infection prevention precautions [Internet]. [cited 2021 Apr 2]. Available from: <https://www.who.int/news-room/commentaries/detail/transmission-of-sars-cov-2-implications-for-infection-prevention-precautions>
- [2] Long Y, Hu T, Liu L, Chen R, Guo Q, Yang L, et al. Effectiveness of N95 respirators versus surgical masks against influenza: A systematic review and meta-analysis.
- [3] Smith JD, MacDougall CC, Johnstone J, Copes RA, Schwartz B, Garber GE. Effectiveness of N95 respirators versus surgical masks in protecting health care workers from acute respiratory infection: A systematic review and meta-analysis. CMAJ [Internet]. 2016 May 17 [cited 2021 Apr 2];188(8):567–74. Available from: <https://pubmed.ncbi.nlm.nih.gov/26952529/>
- [4] Perencevich EN, Diekema DJ, Edmond MB. Moving Personal Protective Equipment Into the Community. JAMA [Internet]. 2020 Jun 9 [cited 2021 Apr 7];323(22):2252. Available from: <https://jamanetwork.com/journals/jama/fullarticle/2765525>
- [5] Lindsley WG, Blachere FM, Law BF, Beezhold DH, Noti JD. Efficacy of face masks, neck gaiters and face shields for reducing the expulsion of simulated cough-generated aerosols. [cited 2021 Apr 7]; Available from: <https://www.tandfonline.com/action/journalInformation?journalCode=ust20>
- [6] Radonovich LJ, Simberkoff MS, Bessesen MT, Brown AC, Cummings DAT, Gaydos CA, et al. N95 respirators vs medical masks for preventing influenza among health care personnel: A randomized clinical trial. JAMA - J Am Med Assoc. 2019;322(9):824–33.
- [7] Trepanowski N, Larson AR, Evers-Meltzer R. Occupational dermatoses among front-line health care workers during the COVID-19 pandemic: A cross-sectional survey. J Am Acad Dermatol. 2021 Jan 1;84(1):223–5.
- [8] Foo CCI, Goon ATJ, Leow Y-H, Goh C-L. Adverse skin reactions to personal protective equipment against severe acute respiratory syndrome-a descriptive study in Singapore.
- [9] Bhaskar ME, Arun S. SARS-CoV-2 Infection among Community Health Workers in India before and after Use of Face Shields. Vol. 324, JAMA - Journal of the American Medical Association. American Medical Association; 2020. p. 1348–9.
- [10] Center for Disease Control. Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings-Recommendations of the Healthcare Infection Control Practices Advisory Committee. CDC [Internet]. 2017. Available from: <https://www.cdc.gov/hicpac/recommendations/core-practices.html>
- [11] WHO. Mask use in the context of COVID-19: Interim guidance. Who [Internet]. 2020;(December):1–10. Available from:



Philippine COVID-19 Living Clinical Practice Guidelines

[https://www.who.int/publications/i/item/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novel-coronavirus-\(2019-ncov\)-outbreak](https://www.who.int/publications/i/item/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novel-coronavirus-(2019-ncov)-outbreak)

- [12] CDC. Infection Control: Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) | CDC [Internet]. [cited 2021 Apr 7]. Available from: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html>



Philippine COVID-19 Living Clinical Practice Guidelines

Appendix 1. Summary of included studies

Study Author	Study Design	Population	Intervention n=2512	Comparator n=2668	Outcome
Radonovich 2019	Randomized pragmatic effectiveness trial	Healthcare workers working in outpatient settings of 7 US medical centers from Sept 2011 to May 2015	Wearing of N95 respirators	Wearing of medical mask	Laboratory confirmed influenza infection Acute respiratory illness events Laboratory-detected respiratory infections Laboratory-confirmed respiratory illness
Bhaskar 2020	Before and After Study	Community health workers in India assigned to counsel asymptomatic family contacts of laboratory confirmed COVID-19 patients	Face shield plus baseline PPE (3 layered surgical mask, gloves, shoe cover)	Baseline PPE (3 layered surgical mask, gloves, shoe cover)	RT-PCR test Development of symptoms



Philippine COVID-19 Living Clinical Practice Guidelines

Appendix 2a. GRADE Evidence Table for N95 respirator versus medical mask for outpatient healthcare workers in places with sustained community transmission

Author(s): Christopher G. Manalo, MD & Frangelo Conrad P. Tampus, MD

Question: N95 mask compared to medical mask for outpatient healthcare workers in places with sustained community transmission

Setting: Outpatient Setting

Bibliography: Radonovich LJ, Simberkoff MS, Bessesen MT, Brown AC, Cummings DAT, Gaydos CA, et al. N95 respirators vs medical masks for preventing influenza among health care personnel: A randomized clinical trial. JAMA - J Am Med Assoc. 2019;322(9):824–33.

Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	N95 mask	surgical mask	Relative (95% CI)	Absolute (95% CI)		

Laboratory-confirmed Influenza

1	randomised trials	not serious	not serious	serious ^a	serious ^b	none	207/251 2 (8.2%)	193/266 8 (7.2%)	OR 1.18 (0.95 to 1.45)	12 more per 1,000 (from 3 fewer to 29 more)	VERY LOW	CRITICAL
---	-------------------	-------------	-------------	----------------------	----------------------	------	---------------------	---------------------	------------------------------	---	----------	----------

Acute Respiratory Illness

1	randomised trials	not serious	not serious	serious ^a	serious ^b	none	1556/2512 (61.9%)	1711/2668 (64.1%)	OR 0.99 (0.92 to 1.06)	22 fewer per 1,000 (from 48 fewer to 4 more)	VERY LOW	
---	-------------------	-------------	-------------	----------------------	----------------------	------	----------------------	----------------------	------------------------------	--	----------	--

Laboratory-Detected Respiratory Infections

1	randomised trials	not serious	not serious	serious ^a	serious ^b	none	679/2512 (27.0%)	745/2668 (27.9%)	OR 0.99 (0.89 to 1.09)	9 fewer per 1,000 (from 33 fewer to 15 more)	VERY LOW	
---	-------------------	-------------	-------------	----------------------	----------------------	------	---------------------	---------------------	------------------------------	--	----------	--

Laboratory-confirmed Respiratory Illness


1	randomised trials	not serious	not serious	serious ^a	serious ^b	none	371/2512 (14.8%)	417/2668 (15.6%)	OR 0.97 (0.85 to 1.09)	9 fewer per 1,000 (from 28 fewer to 11 more)	VERY LOW	
---	-------------------	-------------	-------------	----------------------	----------------------	------	---------------------	---------------------	------------------------------	--	----------	--



Philippine COVID-19 Living Clinical Practice Guidelines

Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	N95 mask	surgical mask	Relative (95% CI)	Absolute (95% CI)		

Influenza-like Illness

1	randomised trials	not serious	not serious	serious ^a	serious ^b	none	128/2512 (5.1%)	166/2668 (6.2%)	OR 0.86 (0.68 to 1.10)	11 fewer per 1,000 (from 24 fewer to 1 more)	 VERY LOW	
---	-------------------	-------------	-------------	----------------------	----------------------	------	-----------------	-----------------	------------------------	--	---	--

CI: Confidence interval; OR: Odds ratio

Explanations

- The study included coronavirus subtypes HKU1, NL63, OC43, and 229E but not SARS-CoV-2
- Confidence interval of treatment effect and/or rate ratios crosses the line of no effect

Appendix 2b. GRADE Evidence Table for No face shield versus use of face shield for outpatient healthcare workers in places with sustained community transmission

Author(s): Christopher G. Manalo, MD & Frangelo Conrad P. Tampus, MD


Question: No face shield compared to face shield for outpatient healthcare workers in places with sustained community transmission

Setting: Outpatient Setting

Bibliography: Bhaskar ME, Arun S. SARS-CoV-2 Infection among Community Health Workers in India before and after Use of Face Shields. Vol. 324, JAMA - Journal of the American Medical Association. American Medical Association; 2020. p. 1348–9.

Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	no face shield	face shield	Relative (95% CI)	Absolute (95% CI)		

RT-PCR confirmed COVID-19 infection

1	observational studies	very serious ^a	not serious	not serious	not serious	none	12/62 (19.4%)	0/50 (0.0%)	OR 0.040 (0.002 to 0.850)	0 fewer per 1,000 (from 0 fewer to 0 fewer)	 LOW	CRITICAL
---	-----------------------	---------------------------	-------------	-------------	-------------	------	---------------	-------------	---------------------------	---	--	----------

CI: Confidence interval; OR: Odds ratio

Explanations

- Issues on study design and small sample size



Philippine COVID-19 Living Clinical Practice Guidelines

Appendix 3. Registered study protocol

	Clinical Trial ID / Title	Status	Start and estimated primary completion date	Study design	Country	Population	Intervention Group(s)	Comparison Group(s)	Outcomes
1	Clinical Efficiency of Surgical Masks and Filtering face-piece 2 masks NCT04823351	Not yet recruiting	Study start: April 8, 2021 Estimated primary completion: July 8, 2021	Allocation: Randomized Intervention Model: Crossover Assignment Design: cluster-randomized, parallel, controlled, non-inferiority study Masking: None (Open Label) Primary Purpose: Prevention	Switzerland	Health care workers in nursing homes Subgrouped into vaccinated and unvaccinated	FFP2 mask Surgical Mask	Surgical Mask FFP2 mask	SARS-CoV-2 infection