Technical Report

January 15, 2023

Prepared by:
Roy T. McKay, Ph.D.
University of Cincinnati
Occupational Pulmonary Services
160 Panzeca Way
Cincinnati, OH 45267-0056

513-558-1234 (voice mail)
roy@drmckay.com

Preventing COVID in HCWs: Study Claims Medical Masks Equivalent to N95 FFRs?
Several readers asked for my thoughts regarding the highly publicized study by Mark Loeb and colleagues published in the December 2022 issue of the *Annals of Internal Medicine*. The study evaluated COVID-19 infections among 1,009 Health Care Workers (HCW) having direct care for infected patients at 29 hospitals in Canada, Israel, Pakistan, and Egypt between May 4, 2020, to March 29, 2022.

Major news media outlets quickly summarized the study and reported medical masks were equally effective as N95 Filtering Facepiece Respirators (FFRs) in protecting healthcare workers (HCWs) exposed to COVID-19 patients. I've read the 11-page publication and 63-page supplement several times. At this time, I won't comment on the statistical analysis and study issues which include:

- Very wide confidence intervals that limit the ability to identify differences in the performance between medical masks and N95 FFRs.
- Inability to distinguish between infections that occur at the workplace versus home, community, or other non-patient care activities.
- Differences in background community transmission rates, and on the differences in the vaccination rates, type of vaccine, treatment, or type of SARS-CoV-2 variants present among the various global sites during the 2-year study period.

Instead I'll focus on the primary objective, which is the comparison of medical masks to fit tested N95 FFRs.

First, let's clarify what the news media reported and what the authors concluded in their publication. The authors didn't say medical masks and N95 Filtering Facepiece Respirators (FFRs) were equally effective. The authors concluded that among HCWs who provided routine care to patients with COVID-19, the overall estimates rule out a doubling in hazard of confirmed COVID-19 for medical masks compared to fit tested N95 FFRs. In essence, the N95 FFRs did not achieve the study threshold of being at least twice as effective as medical masks. The authors acknowledge results varied by country and overall estimates may not be applicable to individual countries because of "treatment effect heterogeneity". Missing from the conclusion, is

recognition of a general trend for N95 FFRs to perform better than medical masks at all sites, except Egypt. And, Egypt represented more than 50% of the study population. In Canada, which represented the 2nd largest group, N95 FFRs did exceed the doubling requirement, but lacked statistical significance due to very large confidence intervals.

A critical question is whether or not the N95 FFRs were properly fit tested and worn correctly at all locations? **I seriously doubt it**. Poorly fitting respirators can pass fit testing, if the test is administered incorrectly. This is true for both quantitative and qualitative fit testing. As mentioned in my previous newsletter, when photographs of respirator fit testing at healthcare facilities are included in published studies, they often document incorrect fit testing procedures not recognized by the authors. It's important to point out, **no** information in the 11-page publication or the 63-page supplement provides **any details** about the fit testing performed. If fit testing wasn't administered correctly or if the N95 FFRs were not properly worn, or used consistently, then the ability to distinguish protective effects between medical masks and N95 FFRs is obscured. It's easy to get an answer, it just might not be the correct answer.

The Loeb study doesn't mention what fit test methods were used at the various sites. Did they all use the same method or were different fit test methods used? Using different methods or different protocols would influence the reported results. There's no mention in the published paper or the 63-page supplement of the following words: quantitative, qualitative, fit factor, TSI, PortaCount, or AccuFIT. With respect to qualitative fit testing, none of the following words appear: sweet, sweetener, saccharin, bitter, Bitrex, or **QualFit**. When qualitative fit testing is used to fit test filtering facepiece respirators (FFRs), it's critical to maintain a proper challenge concentration for the duration of the test. This concentration is dependent upon the results of a threshold screening procedure when no respirator is worn. There's no mention in this study of threshold screening, the number of exercises conducted, the length of time for each exercise, the number of aerosol-generated squeezes, or the order of exercises. **QualFit™** Software© (www.qualfit.net) is designed to overcome these common errors and improve fit testing accuracy, but was not used.

This study doesn't mention anything regarding formal training or experience for the persons who administered the fit test. How many years of fit testing experience did they have? Did the fit test operators pass a practicum and written exam specific to the fit test method used? If yes, the reader would feel more confident in the quality of the fit test results. The absence of these data raises concerns, since the skill, experience, and training of the fit test operator can have a significant impact of the fit and selection of the respirator assigned to the worker.

Here's the only statement about fit testing in the publication:

> "Health care workers were excluded if they did not have a valid fit test within the past 24 months"

24 months is a long time between fit testing and use of respiratory protection in the workplace. A research study designed to compare medical masks to fitted N95 FFRs, should have fit testing & training conducted in close proximity to the study period. There's no statement indicating if the same make, model, and size respirator used for fit testing was always worn by HCWs at the workplace. The authors wrote: "Participants were required to use the same type of device they were allocated to, either a medical mask or an N95 respirator, for 10 weeks.". But did they? The supplement reveals multiple make and models were available. For example, in Canada, at least 8 different medical masks and 9 different N95 FFRs are listed in the supplement. There is no data confirming the worker consistently selected the assigned device. Respirator research clearly

shows workers don't always remember respirator training content, in particular proper donning, use and seal check procedures. An effective respirator program requires at least annual training. For a research study evaluating respirator performance, fit testing and training should be conducted shortly before the study period and monitored for compliance.

The only other reference to fit testing was found in the supplement which said:

> "Healthcare workers are excluded if they do not have a fit test within the last 24 months, could not pass a fit test (e.g., because of stubble beard growth, beard, mustache or sideburns which cross the respirator sealing surface)".

Notice, they did **not** specifically say that persons with facial hair at the sealing surface (i.e., beards, stubble, etc.), where excluded from fit testing or respirator use. This implies a person with a beard could be included if they passed the fit test. Bearded workers can pass fit testing when administered incorrectly or if the employee falsely denies tasting the challenge agent during qualitative fit testing. In addition, days, weeks, or 24 months later, this person's beard shape, length and style could be dramatically different. In these cases, it's improper to compare a medical mask to a "fitted" N95 FFR, when it may no longer fit.

There's no mention of user seal check procedures. It's unknown if seal checks were routinely conducted prior to each donning and prior to each patient encounter. If the HCW failed a seal check, was another fit test administered? Was another facepiece provided? Among the hundreds of HCWs wearing N95 FFRs on a daily basis, clearly some must have failed a seal check procedure at some point in time. The authors don't explain how a failed seal check was handled and/or analyzed. For that matter, it's unclear if all 29 hospitals followed the same guidelines.

Workers wearing N95 FFRs must be trained on proper donning technique. This includes, positioning on the face, adjustment of a metal nose band, if so equipped, and strap adjustment, when appropriate. A good respirator program conducts audits and evaluations to ensure the respirator is properly worn and maintained. In the respirator community, Workplace Protection Factor (WPF) studies are used to evaluate the performance of respirators. For these studies to be published, trained observers are used to monitor proper donning and use when respiratory protection is worn. The Loeb study goes beyond a typical WPF study, as it not only evaluates the performance of respirators, but compares it to another device. Nothing in the Loeb publication or supplemental information mentions respirator audits, proper use, or observations by trained observers. The Loeb study doesn't provide any evidence the N95 FFRs were properly worn throughout the study period? Think of facial hair. In addition, the study doesn't identify if a new N95 FFR was used each day or if it was used up until the point of failure (e.g., visual observation of damage, such as stretched out straps, etc.). Rather; "Participants were **asked** to discard the medical mask or N95 respirator if it became soiled or damaged or if breathing through the device became difficult.". The supplement reveals extended and re-use of the same N95 FFR was permitted. Cleaning, disinfection, and maintenance of respirators and medical masks was not reported.

In summary, until details about respirator use and fit testing become available, I don't believe it's appropriate to make any conclusion regarding the difference in protection between a medical mask and a fitted N95 FFR. We know the SARS-CoV-2 virus is primarily transmitted by inhalation of very small aerosols suspended in air. Direct exposure to large droplets is not the primary mode of transmission. Since the 2022 Loeb study doesn't report anything about fit

testing, proper donning, or proper respirator use, including seal checks, it's difficult to believe a medical mask with lower filtration efficiency and ear loops is equivalent to a properly fitted and properly worn respirator. Until respirator fit and performance data become available, I believe the Loeb study simply verifies that an ineffective respirator program diminishes the effectiveness of respiratory protection. The expected protection of a respirator, doesn't change by moving it from one location to another. Canada and Egypt used similar make and model N95 FFRs. The differences in effectiveness between these two locations is most likely related to respirator program effectiveness, fit testing, proper use, or other factors.

If interested in reading the 2022 Loeb article, go to the source:
https://doi.org/10.7326/M22-1966
Loeb M, Bartholomew A, Hashmi M, et.al. Medical Masks Versus N95 Respirators for Preventing COVID-19 Among Health Care Workers - A Randomized Trial. *Annals of Internal Medicine*, December 2022, Volume 175, Issue 12, pages 1-11.