#### Cochrane Review About Face Masks – Scientifically Irrelevant and Invalid

Saeed A. Qureshi, Ph.D. (principal@pharmacomechanics.com)

I read a recent article by Dr. Maryanne Demasi, "Did Cochrane's study on masks get it wrong?" which analyzes two views about the effectiveness or ineffectiveness of face masks in protecting from viruses and their infection (link).

There is no doubt that both views are presented by parties with high credentials emphasizing their expertise and experience in a write-up. Below are the two views in a nutshell:

- (1) Physical interventions to interrupt or reduce the spread of respiratory viruses (Cochrane Review, <u>link</u>) is " ... 2023 Cochrane review which concluded that wearing a face mask "probably makes little or no difference" in preventing SARS-CoV-2 transmission."
- (2) What Went Wrong with a Highly Publicized COVID Mask Analysis? (link)

Criticizes the above by stating, "The Cochrane Library, a trusted source of health information, misled the public by prioritizing rigor over reality" by Naomi Oreskes (Professor of the History of Science at Harvard University)

Reading the articles and having a background in science, especially in research, while working at Health Canada as a research scientist for 30 years, I am quite concerned about the poor quality of scientific research and reasoning provided in the publication (Cochrane Review) and follow-up discussions.

Therefore, through this article, I would like to provide my critical analysis with the hope that the presented science and its interpellation will be

reconsidered as it has seriously misrepresented the underlying science, i.e., the science of testing or analytical chemistry.

Let us start with analyzing the Cochrane Review, which is supposedly a scientific study, to see its weaknesses, followed by some short comments about the relevancy and validity of Professor Oreskes's argument.

Cochrane Review describes the study's objective as

"To assess the effectiveness of physical interventions to interrupt or reduce the spread of acute respiratory viruses." It is mainly about the use of face masks.

The study design is described as follows:

"We included randomised controlled trials (RCTs) and cluster-RCTs investigating physical interventions (screening at entry ports, isolation, quarantine, physical distancing, personal protection, hand hygiene, face masks, glasses, and gargling) to prevent respiratory virus transmission."

The reported results are as follows (for brevity, the focus is on the mask aspect only, the central part of the Review, and the description has been truncated)

#### "Medical/surgical masks compared to no masks"

"We included 12 trials (10 cluster-RCTs) comparing medical/surgical masks versus no masks to prevent the spread of viral respiratory illness (two trials with healthcare workers and 10 in the community)."

"Wearing masks in the community probably makes little or no difference to the outcome of influenza-

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like illness (ILI)/COVID-19 like illness compared to not wearing."

"Wearing masks in the community probably makes little or no difference to the outcome of laboratory-confirmed influenza/SARS-CoV-2 compared to not wearing masks. Harms were rarely measured and poorly reported (very low-certainty evidence)."

### "N95/P2 respirators compared to medical/surgical masks"

We pooled trials comparing N95/P2 respirators with medical/surgical masks (four in healthcare settings and one in a household setting). We are very uncertain on the effects of N95/P2 respirators compared with medical/surgical masks on the outcome of clinical respiratory illness."

"N95/P2 respirators compared with medical/surgical masks may be effective for ILI."

"Evidence is limited by imprecision and heterogeneity for these subjective outcomes."

"The use of a N95/P2 respirators compared to medical/surgical masks probably makes little or no difference for the objective and more precise outcome of laboratory-confirmed influenza infection."

"One previously reported ongoing RCT has now been published and observed that medical/surgical masks were non-inferior to N95 respirators in a large study of 1009 healthcare workers in four countries providing direct care to COVID-19 patients."

#### **Authors' conclusions**

"The high risk of bias in the trials, variation in outcome measurement, and relatively low adherence with the interventions during the studies hampers drawing firm conclusions." "There is uncertainty about the effects of face masks. The low to moderate certainty of evidence means our confidence in the effect estimate is limited, and that the true effect may be different from the observed estimate of the effect."

"The pooled results of RCTs did not show a clear reduction in respiratory viral infection with the use of medical/surgical masks. There were no clear differences between the use of medical/surgical masks compared with N95/P2 respirators in healthcare workers when used in routine care to reduce respiratory viral infection."

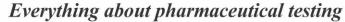
First, it is not a study per se but observations from pooled data from multiple studies. It may not be considered a valid or controlled scientific/experimental study from the perspective of physical science. The article notes that it is an observational survey, which would hugely impact the interpretation.

My main objection to such a study is that the approach or methodology has not been validated to see or detect the infection or the virus. Then, how can it be used to detect the differences, i.e., between the effects (mask vs no mask)?

Observing and relating the symptoms to masks could hardly be considered a scientific approach. The presence or absence of symptoms could be from several factors, such as individual body variations or unassigned variables. The question is, how has the link between illness and virus been established? I have not seen any study in which a virus has been isolated from an ill patient or any healthy person injected with it to produce an illness.

It could be argued that illness or virus may have been (indirectly) tested using PCR or antigen tests. However, these tests have never been validated to detect viruses or related illnesses (link). As a

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scientist who worked in testing (development, validation, and application) for 40+ years, I can categorically assert that no valid test exists or can detect the virus or its illness.

I have explained this view from different perspectives in numerous articles on my <u>site</u> and the <u>book</u>, i.e., no test is available and/or can be developed. Please consider looking at them. Therefore, from a scientific perspective, PCR and antigen test results, positive or negative, must be ignored and discarded.

This will leave only the symptom aspect/testing, which is subjective and does not provide a link to the virus or its illness. So, checking the masks' effectiveness based on symptoms is invalid and should be ignored.

A clinical trial (random clinical trial or RCT) is also a test like any other scale or tester used to monitor an effect/parameter. Before its use, a test/tester must be validated to establish if it is valid and relevant to its intended purpose. Have the clinical trials been validated to monitor or establish protection from viruses using masks? Anyone, please share an example, as I do not find one. It is not a trick question but an indirect question, indicating that they (clinical trials) cannot be used or validated for such purposes. I will explain the reason for this with the following analogy.

Let us assume that a concern has been raised that some cars have started running rough (ill). Experts assume and declare that the cause is the fuel (gas/petrol), which has been contaminated. Before confirming or fixing the issue, it was decided that a filter should be used to clean or filter the fuel. To convince the public that it is the fuel issue and that filters are effective in eliminating the problem, at least temporarily, testing has started to establish the effectiveness of the filters.

Multiple countries and numerous brands of cars, selected randomly, were used with various statistical designs ("clinical trials") to assess the filter's effectiveness using endpoints/parameters to evaluate the performance of the cars.

It means that cars and their performance become a tester and performance indicator for evaluating filter effectiveness. It is to be noted that there are numerous variables between the filter and engine performance outcome (engines misfiring, fuel lines blockage, loose connections, even road surfaces, etc.), including the drivers' driving habits, which may, individually or collectively, cause the rough performance of the cars. It is impossible to differentiate between the impact of so many other variables between fuel and the car. How could cars be used for assessing filter/fuel issues by isolation from other mentioned issues? The point is that body or clinical trials cannot be used to detect or test its problem, having numerous coexisting variables in human populations.

Medical experts, including epidemiologists, do not realize this limitation or the fatal flaw in conducting and analyzing clinical trials. Clinical trials are considered flawless and "gold standards" for such evaluation, which is incorrect. They should realize that clinical trials are analytical tests like any other. These must be validated before their use. Therefore, clinical trial practice and its applications seriously violate science and its principles, making the Cochrane Review invalid and irrelevant – at least scientifically.

If the filters or masks are to be tested, they must be tested separately or independent of cars. For example, as I have explained in an article (link), the mask could be or should be tested independently. If the issue is that masks can protect or filter viruses, then this can easily be tested by passing the air contaminated with the virus through a tube

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with a filter/mask and measuring the virus on both sides of the filter/mask. The difference will quickly, accurately, and without bias show if masks work or filter the virus particles. It is a standard scientific approach for the job and is far less expensive and without any involvement of human subjects.

The question is, why has such an experiment not been done? The reason is that such testing requires a specimen of the virus and a validated test to measure the virus. As no virus specimen and virus test is available anywhere, such a valid and relevant test cannot be done. Therefore, endless so-called studies (clinical trials) are done without any success, which is bound to fail to provide any valid conclusion like other studies such as the origin of the virus, gain of function research, etc.

The review concludes,

"The high risk of bias in the trials, variation in outcome measurement, and relatively low adherence with the interventions during the studies hampers drawing firm conclusions."

As explained above, this is correct and should be expected from clinical trials. It is impossible to achieve a valid and unbiased conclusion, no matter how large the sample size is used. From the scientific perspective, it is so because such a study requires a virus sample and a test for measuring the virus. As they are unavailable, no study can show the effectiveness of masks or lack thereof.

Regarding Prof. Naomi Oreskes's article, it is difficult to consider scientific criticism, but it appears to be a judgemental and preformed view to discredit the "anti-mask view." By saying that, they

" ... misled the public by prioritizing rigor over reality,"

indicating Cochrance's analysis is rigorous but did not conclude what the public or experts like to hear ("reality"). Indeed, the Cochrane Review dealt with the real data but did not provide the desired outcome, at least for some.

According to Dr. Demasi, in her article, "Oreskes concludes that Cochrane got it wrong because its methods are too rigorous and that, stating;

"it's time those standard procedures were changed."

Oreskes criticizes the Cochrane Review for basing its findings "on randomized controlled trials, often called the 'gold standard' of scientific evidence" and said the analysis ignored "epidemiological evidence because it didn't meet its rigid standard."

That is, Cochrane got it wrong because its methods are too rigorous; hence, "it's time those standard procedures were changed." Therefore, change in the clinical trial standards is needed because they presumably failed to provide the desired outcome. Wow, that is interesting!

Indeed, I would agree, as stated above, that the practice of clinical trials is scientifically poor and needs to change or adjust, but not because it fails to provide the desired outcome.

In short, the Review mentioned above or its follow-up evaluation by Drs. Oreskes and Demasi may not be considered valid scientific studies or assessments. This study and its analyses are without controls and validation of testing approaches for viruses or their illnesses. It is an observational survey rather than a valid scientific study with controls. Hence, its conclusions could easily be ignored, and caution should be used in supporting or conducting such studies in the future.

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