

In my letter to you of 21 July 2020, I use five pages, detailing *some* of the truth about the absurd notion, vigorously promoted by you and others of your agenda and ilk, that masks are effective at reducing the transmission of viral particles.

As you are fully aware . . . masks do no such thing.

On Pages 12 through 16 of Attachment 2 above, I discuss the vileness necessarily associated with the process of convincing the ignorant and the fearful; **that vileness is censorship.**

That is Dr. Fauci, you are knowingly associated with the criminality of censoring the truth about the ineffective stature of face masks versus viral particles that measure orders-of-magnitude less-in-size than the best filtering offered by a face mask.

You are directly connectable to the process of 'lying by omission.' You are not merely aware of the increasingly widespread Marxist practices of censorship, currently deployed in-behalf of your "surprise outbreak," you are participating-in and supportive of the process of 'lying by omission.'

In this regard, and others, you are connected to the likes pictured next:



In stark comparison, others prefer to be connectable to the following types of public servants :



On Saturday, 12 December 2020, Cardinal Burke [explained in-part to the faithful](#) :

“The world-wide spread of Marxist materialism which has already brought destruction and death to the lives of so many, and which has threatened the foundations of our nation for decades, and now seems to seize the governing power over our nation . . .

To attain economic gains, we as a nation have permitted ourselves to become dependent upon the Chinese Communist Party, an ideology totally opposed to the Christian foundations upon which families and our nation remain safe and prosper. I speak of the United States of America, but evidently many other nations are in the throes of a similar, most alarming crisis.

Then there is the mysterious Wuhan virus about whose nature and prevention the mass media daily give us conflicting information. What is clear, however, is that it has been used by certain forces, inimical to families and to the freedom of nations, to advance their evil agenda. These forces tell us that **we are now the subjects of the so-called ‘Great Reset,’ the ‘new normal,’ which is dictated to us by their manipulation of citizens and nations through ignorance and fear.**

(quote continued on next page)

(quote continued from previous page)

Now we are supposed to find in a disease and its prevention the way to understand and direct our lives, rather than in God and in His plan for our salvation.

The response of many bishops and priests, and of many faithful, has manifested a woeful lack of sound catechesis. So many in the Church seem to have no understanding of how Christ continues his saving work in times of plague and of other disasters.

What is more, our holy mother Church, the spotless bride of Christ, in which Christ is ever at work for our eternal redemption, is beset by reports of moral corruption, **especially in matters of the sixth and seventh commandments, which seem to increase by the day . . .**

. . . In encountering the world, the Church falsely wants to accommodate herself to the world instead of calling the world to conversion in obedience to the divine law written on every human heart and revealed in its fullness in the redemptive incarnation of God the Son.”

As I discussed on Pages 12 – 16 of Attachment 2 above, even the reverse type of information regarding the ‘mask mandates’ are censored by Marxist materialists (censorship deployed by you and your comrades; exemplified on Page 1 of 3 to this Attachment 4).

That is . . . what of the known harm caused by the wearing of “face diapers”? Even *that* type of information **is censored under your approval.**

Even videos uploaded by public servants, such as Ohio State Representative A. Nino Vitale, are censored by your comrades at YouTube.



A link to his blocked video is

here: http://pvsheridan.com/CongressmanVitale_Tests_low_oxygen-DANGER_caused_by_mask.mp4

In overleaf, the very good, lay-person [oriented paper](#) by Professor Denis G. Rancourt entitled:

**Face masks, lies, damn lies, and public health officials:
"A growing body of evidence"**

As you are fully aware Dr. Fauci, the “growing body of evidence” rant is a lie. There is no such thing, hence Dr. Rancourt’s use of quotation marks. This is *another* falsification deployed against the well-being of a public that is manipulated, as Cardinal Burke explained, **“through ignorance and fear.”** All a far cry from the oath you took . . . the Hippocratic Oath.

See discussions, stats, and author profiles for this publication at: <https://www.researchgate.net/publication/343399832>

Face masks, lies, damn lies, and public health officials: "A growing body of evidence"

Technical Report · August 2020

DOI: 10.13140/RG.2.2.25042.58569

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Face masks, lies, damn lies, and public health officials: “A growing body of evidence”

Denis G. Rancourt, PhD
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Working report (not submitted for journal publication), published at Research Gate
(https://www.researchgate.net/profile/D_Rancourt)

3 August 2020

Summary

A vile new mantra is on the lips of every public health official and politician in the global campaign to force universal masking on the general public: “there is a growing body of evidence”.

This propagandistic phrase is a vector designed to achieve five main goals:

- Give the false impression that a balance of evidence now proves that masks reduce the transmission of COVID-19
- Falsely assimilate commentary made in scientific venues with “evidence”

- Hide the fact that a decade's worth of policy-grade evidence proves the opposite: that masks are ineffective with viral respiratory diseases
- Hide the fact that there is now direct observational proof that cloth masks do not prevent exhalation of clouds of suspended aerosol particles; above, below and through the masks
- Deter attention away from the considerable known harms and risks due to face masks, applied to entire populations

The said harms and risks include that a cloth mask becomes a culture medium for a large variety of bacterial pathogens, and a collector of viral pathogens; given the hot and humid environment and the constant source, where home fabrics are hydrophilic whereas medical masks are hydrophobic.

In short, I argue: op-eds are not “evidence”, irrelevance does not help, and more bias does not remove bias. Their mantra of “a growing body of evidence” is a self-serving contrivance that impedes good science and threatens public safety.

I prove that there is no policy-grade evidence to support forced masking on the general population, and that all the latest-decade's policy-grade evidence points to the opposite: NOT recommending forced masking of the general population. Therefore, the politicians and health authorities are acting without legitimacy and recklessly.

The article is organized into the following sections:

- ❖ Summary
- ❖ Introduction
- ❖ Competence to talk about face masks and COVID-19
- ❖ Government responses have been a public-health and safety catastrophe
- ❖ The “growing body of evidence” mantra needs to stop
- ❖ So, what actually is the “growing body of evidence”?

Introduction

On 5 June 2020, the World Health Organization (WHO) reversed more than a decade of public health bodies around the world expressly not recommending face masks for the general population. [1]

The WHO made its recommendation of the preventative medical intervention of face masks for the entire global population while stating: [2]

“At the present time, the widespread use of masks by healthy people in the community setting is not yet supported by high quality or direct scientific evidence and there are potential benefits and harms to consider (see below).” (p. 6)

The pretext used by the WHO was:

“a growing compendium of observational evidence on the use of masks by the general public in several countries”. (p. 6)

Therefore, in its recommendation that could have devastating civil, social and medical consequences, when enforced on the scale of the world population, the WHO violated the Golden Rule of medical ethics: “You don’t recommend an intervention without policy-grade evidence for both harms and benefits”.

Regarding the said Golden Rule of medical ethics, allow me to quote the most authoritative voices of Califf, Hernandez and Landray, discussing medical-treatment-protocol assessment during COVID-19, and writing in the prestigious *Journal of the American Medical Association (JAMA)* on 31 July 2020: [3]

[...] However, there is growing concern about whether attempts to infer causation about the benefits and risks of potential therapeutics from nonrandomized studies are providing insights that improve clinical knowledge and accelerate the search for needed answers, or whether these reports just add noise, confusion, and false confidence. Most of these studies include a caveat indicating that “randomized clinical trials are needed.” But disclaimers aside, does this approach help make the case for well-designed randomized clinical trials (RCTs) and accelerate their delivery? Or do observational studies reduce the likelihood of a properly designed trial being performed, thereby delaying the discovery of reliable truth?

[...]

Anxious, frightened patients, as well as clinicians and health systems with a strong desire to prevent morbidity and mortality, are all susceptible to cognitive biases. Furthermore, profit motives in the medical products industry, academic hubris, interests related to increasing the valuation of data platforms, and revenue generated by billing for these products in care delivery can all tempt investigators to make claims their methods cannot fully support, and these claims often are taken up by traditional media and further amplified on social media. Politicians have been directly involved in discourse about treatments they assert are effective. The natural desire of all elements of society to find effective therapies can obscure the difference between a proven fact and an exaggerated guess. Nefarious motives are not necessary for these problems to occur.

[...] But if leaders, commentators, academics, and clinicians cannot restrain the rush to judgment in the absence of reliable evidence, the proliferation of observational treatment comparisons will hinder the goal of finding effective treatments for COVID-19—and a great many other diseases.

Thus, we see that the WHO and local public health officials are hindering advancement, by promoting non-RCT “observational studies”, rather than protecting public health.

It should be of great concern to all that the WHO pretext of “a growing compendium of observational evidence on the use of masks by the general public in several countries” has morphed into the mantra “a growing body of evidence”, which finds itself on the lips of virtually all public health officers and city mayors in the country.

This mantra of “a growing body of evidence” is advanced as the false silver bullet justification for draconian masking laws, in actual circumstances in which:

- There have been NO new RCT studies that support masking
- All the many past RCT studies conclusively do not support masking
- None of the known harms of masking have been studied

(re: enforcement on the entire general population)

This is the opposite of science-based policy. The politicians and public health officers are actuating the worst decisional model that can be applied in a rational and democratic society: forced preventative measures without a scientific basis, while recklessly ignoring consequences.

In this article, I prove that there is no policy-grade evidence to support forced masking on the general population, and that all the latest decade's policy-grade evidence points to the opposite: NOT recommending forced masking of the general population.

Therefore, the politicians and health authorities are acting without legitimacy and recklessly.

Competence to talk about face masks and COVID-19

I am retired and a former tenured Full Professor of Physics, University of Ottawa. Full Professor is the highest academic rank. During my 23-year career as a university professor, I developed new courses and taught over 2000 university students, at all levels, and in three different faculties (Science, Engineering, Arts). I supervised more than 80 junior research terms or degrees at all levels from post-doctoral fellow to graduate students to NSERC undergraduate researchers. I headed an internationally recognized interdisciplinary research laboratory, and attracted significant research funding for two decades.

I have been an invited plenary, keynote, or special session speaker at major scientific conferences some 40 times. I have published over 100 research papers in leading peer-reviewed scientific journals, in the areas of physics, chemistry, geology, materials

science, soil science, and environmental science. I have made fundamental scientific discoveries in the areas of environmental science, measurement science, soil science, bio-geochemistry, theoretical physics, alloy physics, magnetism, and planetary science.

My scientific h-index impact factor is 39 (84% of Nobel Prize winners in physics had h-indexes of at least 30), and my articles have been cited more than 5,000 times in peer-reviewed scientific journals. My publication record, citations statistics, and impact factors are publicly available at Google Scholar, at the URL <https://scholar.google.ca/citations?user=1ChsRsQAAAAJ> .

My recent non-committee-reviewed articles about the science of the COVID-19 epidemic and the science of masks for preventing viral respiratory diseases have been read more than 0.5 million times on *ResearchGate*, and more times on other venues. My recent video interviews and reporting videos about the science of COVID-19 and face masks have been viewed more than 1 million times.

My personal knowledge and ability to evaluate the facts in this article are grounded in my education, research, training and experience, as follows:

- i. *Regarding environmental nanoparticles.* Viral respiratory diseases are transmitted by the smallest size-fraction of virion-laden aerosol particles, which are reactive environmental nanoparticles. Therefore, the chemical and physical stabilities and transport properties of these aerosol particles are the foundation of the dominant

contagion mechanism through air. My extensive work on reactive environmental nanoparticles is internationally recognized, and includes: precipitation and growth, surface reactivity, agglomeration, surface charging, phase transformation, settling and sedimentation, and reactive dissolution. In addition, I have taught the relevant fluid dynamics (air is a compressible fluid), and gravitational settling at the university level, and I have done industrial-application research on the technology of filtration (face masks are filters).

- ii. *Regarding molecular science, molecular dynamics, and surface complexation.* I am an expert in molecular structures, reactions, and dynamics, including molecular complexation to biotic and abiotic surfaces. These processes are the basis of viral attachment, antigen attachment, molecular replication, attachment to mask fibers, particle charging, loss and growth in aerosol particles, and all such phenomena involved in viral transmission and infection, and in protection measures. I taught quantum mechanics at the advanced university level for many years, which is the fundamental theory of atoms, molecules and substances; and in my published research I developed X-ray diffraction theory and methodology for characterizing small material particles.
- iii. *Regarding statistical analysis methods.* Statistical analysis of scientific studies, including robust error propagation analysis and robust estimates of bias, sets the limit of what reliably can be inferred from any observational study, including randomized controlled trials in medicine, and including field measurements during

epidemics. I am an expert in error analysis and statistical analysis of complex data, at the research level in many areas of science. Statistical analysis methods are the basis of medical research.

- iv. *Regarding mathematical modelling.* Much of epidemiology is based on mathematical models of disease transmission and evolution in the population. I have research-level knowledge and experience with predictive and exploratory mathematical models and simulation methods. I have expert knowledge related to parameter uncertainties and parameter dependencies in such models. Recently, in collaboration, I have examined the instantaneous reproductive rate of COVID-19 infections in response to government masking impositions, in U.S. States.

- v. *Regarding measurement methods.* In science there are five main categories of measurement methods: (1) spectroscopy (including nuclear, electronic and vibrational spectroscopies), (2) imaging (including optical and electron microscopies, and resonance imaging), (3) diffraction (including X-ray and neutron diffractions, used to elaborate molecular, defect and magnetic structures), (4) transport measurements (including reaction rates, energy transfers, and conductivities), and (5) physical property measurements (including specific density, thermal capacities, stress response, material fatigue...). I have taught these measurement methods in an interdisciplinary graduate course that I developed and gave to graduate (M.Sc. and Ph.D.) students of physics, biology, chemistry, geology, and engineering for many years. I have made fundamental discoveries and advances in areas of

spectroscopy, diffraction, magnetometry, and microscopy, which have been published in leading scientific journals and presented at international conferences. I know measurement science, the basis of all sciences, at the highest level.

It would be insufficient for me to be a simple medical doctor (MD) or public health officer. My relevant knowledge and ability stems from my broad multi-disciplinary knowledge, in light of the recognized difficulty of the question. For example, recently, 239 scientists put it this way:

Understanding the transmission of respiratory infections indoors requires expertise in many distinctly different areas of science and engineering, including virology, aerosol physics, flow dynamics, exposure and epidemiology, medicine, and building engineering, to name the most significant. No one person has expertise in all these areas. However, collectively, the community of the signatories to the Comment understands the characteristics and mechanisms behind the generation of respiratory microdroplets, survival of viruses in the microdroplets, transport of the microdroplets and human exposure to them, and the airflow patterns that carry microdroplets in buildings. We have dedicated our careers working in this multidisciplinary field, and our statement stems from our collective expertise spanning the entire field.

(First paragraph on page 1 of the Supplementary data, for: Morawska and Milton et al. (239 signatories) (6 July 2020) "**It is Time to Address Airborne Transmission of COVID-19**", in *Clinical Infectious Diseases*. [4])

Government responses have been a public-health and safety catastrophe

The forced masking laws are being recommended and enacted in a declared-pandemic context in which government responses to COVID have been disastrous, both in terms of response-induced deaths and permanent societal damage:

- a. In my 2 June 2020 article “**All-cause mortality during COVID-19: No plague and a likely signature of mass homicide by government response**”, I showed that an unnatural sharp “COVID-peak” in the all-cause mortality by week occurred across the world synchronously initiated by the 11 March 2020 WHO declaration of the pandemic and recommendation for States to empty their critical care units in preparation, which corresponded to a large acceleration of deaths of immunevulnerable elderly. [5]
- b. Since my article, at least two published scientific papers have arrived at the same conclusion regarding accelerated or excess non-COVID-19 deaths occurring within the said “COVID-peak”, as follows.
- c. The 1 July 2020 article “**Excess Deaths From COVID-19 and Other Causes, March-April 2020**”, by Woolf SH et al. in *JAMA* reports large numbers of said “COVID-peak” coincidence excess deaths actually caused by ●heart disease, ●diabetes, ●cerebrovascular disease, and ●Alzheimer disease, reported in their

Figure. [6] This means that the government responses caused these large numbers of non-COVID-19 excess deaths, unless one believes in supernatural coincidences.

- d. The 2 July 2020 (date posted) article “**An Improved Measure of Deaths Due to COVID-19 in England and Wales**”, by Williams, S et al., available at SSRN reports that more than half of the deaths in the said “COVID-peak” are non-COVID-19 deaths, and concludes: [7]

Three key findings from our empirical analysis are as follows. First, although it has been widely reported that COVID-19 has been highly concentrated in the elderly, we find that it has been particularly concentrated in the very elderly (75-84 and 85+ years), and less so in the 65-74 age category. Second, using two sets of COVID identifiers, we find from the beginning of the two periods when we assume the lockdown was having an impact, through to the end of our study period (week ending 17th or 24th April 2020 - week ending 8th May 2020), that our weekly estimates of COVID deaths for five cases (the total; the 75-84 and 85+ age categories; males; and females) diverge from the corresponding 5 year average excess deaths measure. Over these periods, we find that, on average per week, our estimates of COVID deaths for these five cases were (in absolute 6 terms) considerably below the corresponding 5 year average excess deaths measure. For example, on average per week, our estimate of total COVID deaths over these periods was lower than the corresponding 5 year average excess deaths measure by 4670-4727 deaths (54%-63%). For the above five cases, and in line with our hypothesis, we posit that the 5 year average excess deaths contains a large number of non-COVID deaths. Third, and relatedly, our analysis suggests that the UK's lockdown has had a net positive impact on mortalities. That is to say, it resulted in more, not less, deaths.

- e. This means that government responses in many jurisdictions caused more deaths than the virus itself.

- f. The mechanism for the deaths caused by government response are manifold, and from my reading of the scientific and policy literature include:
- reduced access to care for chronic conditions,
 - the direct impact of psychological stress,
 - the practice of exporting ill patients from chronic care facilities to long-term care facilities, and
 - the practice of locking in and isolating long-term care facility residents.
- g. The direct impacts of fear and psychological stress on immunevulnerable elderly persons have most certainly been underestimated. Psychological stress is proven to be a factor that can measurably depress the immune system and induce diseases, including: immune response dysfunction, depression, cardiovascular disease and cancer: **“Psychological Stress and Disease”**, by Cohen, S et al., in *JAMA*. [8]
- h. Furthermore, it is established since 1991 that psychological stress dramatically increases susceptibility to viral respiratory diseases, even in young healthy college-age subjects: **“Psychological Stress and Susceptibility to the Common Cold”**, by Cohen, S et al., in *The New England Journal of Medicine*. [9]

- i. Additionally, it is known that social isolation increases susceptibility to viral respiratory diseases: **“Social ties and susceptibility to the common cold”**, by Cohen, S et al. in *JAMA*. [10]

- j. Thus, government responses that induced fear, psychological stress, and isolation, including face masking impositions, were diametrically opposite to known science and had the predictable effect, given their scale, of directly in themselves causing large numbers of deaths.

- k. This does not count the harm from restructuring the economy, corporate activity, and institutional networks. In a letter dated 19 May 2020, more than 500 USA physicians wrote to President Trump that **“In medical terms, the shutdown was a mass casualty incident.”** [11] In their letter, they concluded:

The millions of casualties of a continued shutdown will be hiding in plain sight, but they will be called alcoholism, homelessness, suicide, heart attack, stroke, or kidney failure. In youths it will be called financial instability, unemployment, despair, drug addiction, unplanned pregnancies, poverty, and abuse.

- l. There can be little doubt that governments have made fatal errors in responding to COVID-19, causing widespread harm and death.

- m. Imposing face masks on the healthy general population is another such disastrous blunder:

- Repeated large randomized controlled trials (RCT) with verified outcome (lab-confirmed infection) and several systematic reviews of RCTs have proven that face masks have no detectable benefit for reducing the risk of person to person transmission of a viral respiratory disease.
- Recent laser visualization of simulated coughs has proven that cloth masks do not prevent exhalation of clouds of suspended aerosol particles, above, below and through the masks. [12]
- The known significant potential harms of face masks, and cloth face masks in particular, have neither been studied nor ruled out nor been the subject of harm mitigation trials.
- For example, home fabrics are hydrophilic, whereas medical masks are hydrophobic, the many harmful consequences of which have not been studied, and are virtually never mentioned.
- All-population face mask impositions increase fear and psychological stress.
- All-population face mask impositions cause:
 - widespread discomfort,
 - impaired breathing,
 - impaired vision (e.g., fogging of glasses),
 - impaired communication,
 - psychological social distancing,
 - skin irritation and infections,

- impaired self-expression,
- prolonged exposure to bacterial cultures near the eyes, nose and mouth,
- possible collection and delivery of viral pathogens that would otherwise not be inhaled, and
- possible amplification of the exhaled aerosol size-fraction of infectious particles.

The “growing body of evidence” mantra needs to stop

I gave my review of the scientific literature regarding the measured (in)efficacy of masks to reduce the risk of transmission of viral respiratory diseases in my article published on 11 April 2020 at *ResearchGate*, entitled “**Masks Don’t Work: a Review of Science Relevant to Covid-19 Social Policy**”. [13]

The said article [13] was read some 400 K times on *ResearchGate*, was published in several venues, and has been the subject of many commentary articles and interviews. It was critiqued by an incompetent academic and columnist at *Phycology Today*, who was spectacularly exposed in a live debate with me: “**Digi-Debates. The Face Mask Debate**”, Digi Debates YouTube Channel, 25 July 2020, <https://youtu.be/AQyLFdoeUNk>, and see: <https://www.digi-debates.com/> .

My conclusion in the said article [13] is that the policy-grade science of the recent decade conclusively shows that any benefit from masks is too small to be detected in trials designed to detect a benefit in this application.

My conclusions in the said article [13] regarding the RCT-with-verified-outcome studies are robust, and have again been corroborated by the very latest systematic reviews of RCTs, and by the most recently published expert assessments [14] [15] [16] [17] [18], as shown below.

In contrast, politicians of all jurisdictions, city mayors and local public health officers claim by mantra that this decade's worth of policy-grade research is being overturned by "emerging" evidence. Well, if it is "emerging", then it has not yet arrived.

Dr. Eileen de Villa, Medical Officer of Health, Toronto Public Health (TPH), announced her recommendation to the Toronto City Council on twitter as: Dr. Eileen de Villa @epdevilla "Since the beginning of this pandemic I've asked residents to take care of each other. Today I'm asking for this again & this is why I'm asking City Council to require masks or face covering in all public settings to help stop the spread of #COVID19: bit.ly/38cYlu8" 10:46 AM · June 30, 2020 · Twitter for iPhone.

The link provided in this tweet is to a TPH document (the "Recommendation") dated "June 30, 2020 at 9 a.m." entitled "**Update on COVID-19, Dr. Eileen de Villa, Medical Officer of Health**". [19]

The Recommendation contains ten (10) paragraphs as “bullets”. At the 2nd bullet, Dr. de Villa has **“there is a growing body of emerging evidence that shows that non-medical masks can help prevent the spread of COVID-19”**. This is squarely false.

There is not a single published scientific study “that shows that non-medical masks can help prevent the spread of COVID-19”, let alone “a growing body”. In order to measure “the spread of COVID-19”, one has to actually measure “the spread of COVID-19”. In fact, there is a growing body solely of spin and of false statements about the scientific research literature. For comparison, see the sober recent Public Health Ontario (PHO) synopsis. [20]

As another of a multitude of such examples of the use of the said mantra, mayor Jim Watson of the City of Ottawa, Canada, in a well-crafted statement put it this way, in answering a recent demand by the Ontario Civil Liberties Association, while ignoring all the points raised by OCLA: [21] [22]

“Increasing evidence supports wearing a mask when in enclosed public spaces as an important measure in reducing COVID-19 transmission, while the risk of rising rates of infection continues. The scientific community and public health organizations around the world have concluded that the cumulative weight of evidence supports that face masks lessen the rates of transmission of COVID-19 from wearers. Most agree that face masks work best by reducing the amount of virus that is projected into the air in respiratory micro-droplets from someone who is infected with the virus. Additionally, other community level measures such as physical distancing and hand hygiene should continue to be employed to decrease transmission of COVID-19.

While we respect that you may not necessarily agree with this public health initiative, we trust that you will understand the basis that prompted OPH to recommend that Council enact a by-law.”

Basically, the mayor is relying on “we are all saying it”.

Here is why “what they are all saying” is simply worthless. The new mantra is pure propaganda that is diametrically contrary to all the authoritative science reports, as follows:

- a. In medical research, the only scientifically valid way to test a medical intervention, such as wearing a face mask or prescribing any preventative treatment, is to use the universally accepted comparative study (e.g., face mask versus no face mask) specifically designed to remove selection and observational bias from the study. This is called a “randomized controlled trial” (RCT).

- b. Arguably the world’s leading medical standards and medical statistician expert, **Dr. Janus Christian Jakobsen**, author of the highly cited “Thresholds for statistical and clinical significance in systematic reviews with meta-analytic methods” (Jakobsen, JC et al., in *BMC Med Res Methodol* [23], has emphatically stated: [24]

Clinical experience or observational studies should never be used as the sole basis for assessment of intervention effects — randomized clinical trials are always needed. Therefore, always randomize the first patient as Thomas C Chalmers suggested in 1977. Observational studies should primarily be used for quality control after treatments are included in clinical practice.

Abstracted Conclusion (p. 1) in: “**The Necessity of Randomized Clinical Trials**”, by Jakobsen and Gluud, in the *British Journal of Medicine & Medical Research*. [24]

- c. Meldrum in her “**A Brief History of the Randomized Controlled Trial: From Oranges and Lemons to the Gold Standard**” (Meldrum, Marcia L., in Hematology/Oncology Clinics of North America) [25], puts it this way (p. 746):

Nevertheless, the RCT remains the “gold standard.” Its power as a model for good practice rests on its imposition of experimental order on the clinical setting and its production of numerical results that may not be absolutely accurate but that are unquestionably precise. As Theodore Porter has argued, the value of the precise quantitative result is that it is readily translated outside its original experimental setting, for replication, comparison, and adaptation elsewhere.[ref]

The inferential authority of the RCT has been such that it is accepted as a standard for “rational therapeutics” by physicians and regulatory authorities and also by patients and populations at risk.

- d. It appears that “regulatory authorities” in Ontario, Canada, are not up to speed on modern medical-practice standards.
- e. Recent medical history has shown that non-RCT comparative or observational studies can be egregiously wrong, with devastating negative public health consequences. Two examples are particularly well known, among many more:

- (i) Non-RCT studies of the antiarrhythmic agents flecainide and encainide were glowing when the drugs were put onto the market in the late 1980s, then a RCT showed that these drugs increased mortality rather than had any benefit.
 - (ii) Decades of non-RCT “observational studies” were the basis for widespread hormone replacement therapy for post-menopausal women, until 2002 and later when published RCTs showed that these treatments actually increased myocardial infarctions (heart attacks) rather than decreased them as intended. The RCTs also found that the treatment increased the risk of incident breast cancer, which had not previously been detected in the decades of use. See: **“Risks and benefits of estrogen plus progestin in healthy postmenopausal women: principal results From the Women's Health Initiative randomized controlled trial”** (Writing Group for the Women's Health Initiative Investigators, in *JAMA*.) [26]
- f. In my article **“Masks Don’t Work: a Review of Science Relevant to Covid-19 Social Policy”** [13], I concluded (p. 4):

No RCT study with verified outcome shows a benefit for HCW or community members in households to wearing a mask or respirator. There is no such study. There are no exceptions.

Likewise, no study exists that shows a benefit from a broad policy to wear masks in public (more on this below).

Furthermore, if there were any benefit to wearing a mask, because of the blocking power against droplets and aerosol particles, then there should be more benefit from wearing a respirator (N95) compared to a surgical mask, yet several large meta-analyses, and all the RCT, prove that there is no such relative benefit.

- g. In my co-signed **21 June 2020 letter to the Executive Director of the WHO** [1], we (the Ontario Civil Liberties Association) put it this way:

Second, more importantly, you fail to mention that several randomized controlled trials with verified outcomes (infections) were specifically designed to detect a benefit, and did not find any measurable benefit, for any viral respiratory disease. This includes the many randomized controlled trials that find no difference between open-sided surgical masks and respirators. [Footnote-2: citing and quoting from ten (10) scientific studies.]

You failed to mention that such results set a probabilistic upper limit on mask effectiveness, and you failed to calculate this upper limit. Instead, you repeat the misleading notion that reliable evidence has “not yet” been found to confirm your adopted bias.

In other words, if masks were even moderately effective at reducing the risk of infection, then a benefit would have been statistically detected in one or more of the many reliable trials that have already been made.

More fundamentally, a major problem with your document is that you wrongly rely on substandard scientific reports as constituting usable “evidence”. With public policy, especially health policy having draconian consequences, there must be a standards threshold below which a given report cannot be used as an indicator of reality. The reason that science requires randomized controlled trials with verified outcomes is precisely because other study designs are susceptible to bias.

The context of a new disease and of a publicized pandemic is one in which all reporting (media, political, and scientific) is susceptible to large bias. The mechanisms of the biases are well known and anticipated, such as: political posturing, partisan conflicts, career advancement, publication-record padding, “discovery” recognition, public-interest and public-support mining, institutional and personal reputational enhancement, funding opportunities, corporate interests, and so on.

Group bias is not an uncommon phenomenon. Large numbers of bias-susceptible studies that agree are of little value. Any study that does not apply the established scientific tools for avoiding observational bias should be presumed to be biased, in any draconian policy context.

That is why the WHO cannot collect and rely on potentially biased studies to make recommendations that can have devastating effects (see below) on the lives of literally billions. Rather, the WHO must apply a stringent standards threshold, and accept only randomized controlled trials with verified outcomes. In this application, the mere fact that several such quality studies have not ever confirmed the positive effects reported in bias-susceptible reports should be a red flag.

For example, two amply promoted recent studies that do not satisfy the standards threshold, and that, in our opinion, have a palpable risk of large bias are the following. [...]

- h. My statements about the scientific evidence regarding masks are corroborated by all the concurrent and subsequent publications of leading experts on this question of reliable bias-free studies, as follows.
- i. >>> “**Rapid Expert Consultation on the Effectiveness of Fabric Masks for the COVID-19 Pandemic**” (National Academies of Sciences, Engineering, and Medicine, 8 April 2020): [17]

(p.2) In considering the evidence about the potential effectiveness of homemade fabric masks, it is important to bear in mind how a respiratory virus such as SARS-CoV-2 spreads from person to person. Current research supports the possibility that, in addition to being spread by respiratory droplets that one can see and feel, SARS-CoV-2 can also be spread by invisible droplets, as small as 5 microns (or micrometers), and by even smaller bioaerosol particles.[ref] Such tiny bioaerosol particles may be found in an infected person’s normal exhalation.[ref] The relative contribution of each particle size in disease transmission is unknown.

There is limited research on the efficacy of fabric masks for influenza and specifically for SARSCoV-2. As we describe below, the few available experimental studies have important limitations in their relevance and methods. Any type of mask will have its own capacity to arrest particles of different sizes. Even if the filtering capacity of a mask were well understood,

however, the degree to which it could in practice reduce disease spread depends on the unknown role of each particle size in transmission.

Asymptomatic but infected individuals are of special concern, and the particles they would emit from breathing are predominantly bioaerosols. [...]

(p. 3) An additional consideration in the effectiveness of any mask is how well it fits the user.[ref] Even with the best material, if a mask does not fit, virus-containing particles can escape through creases and gaps between the mask and face. Leakage can also occur if the holding mechanism (e.g., straps, Velcro®) is weak. We found no studies of non-expert individuals' ability to produce properly fitting masks. Nor did we find any studies of the effectiveness of masks produced by professionals, when following instructions available to the general public (e.g., online). [...]

(p. 6) **CONCLUSIONS** [...] The current level of benefit, if any, is not possible to assess.

- j. >>> "**Nonpharmaceutical Measures for Pandemic Influenza in Nonhealthcare Settings—Personal Protective and Environmental Measures**" (Xiao, J et al., in *Emerging Infectious Diseases*, 5 May 2020): [14]

(p. 967: Abstract) Although mechanistic studies support the potential effect of hand hygiene or face masks, evidence from 14 randomized controlled trials of these measures did not support a substantial effect on transmission of laboratory-confirmed influenza. We similarly found limited evidence on the effectiveness of improved hygiene and environmental cleaning. We identified several major knowledge gaps requiring further research, most fundamentally an improved characterization of the modes of person-to-person transmission.

- k. >>> "**Masks for prevention of viral respiratory infections among health care workers and the public: PEER umbrella systematic review**" (Dugré et al., in *Canadian Family Physician*, July 2020): [15]

(p. 509, Abstract) **Synthesis** In total, 11 systematic reviews were included and 18 RCTs of 26 444 participants were found, 12 in the community and 6 in health care workers. Included studies had limitations and were deemed at high risk of bias. Overall, the use of masks in the community did not reduce the risk of influenza, confirmed viral respiratory infection, influenzalike illness, or any clinical respiratory infection. [...]

Conclusion This systematic review found limited evidence that the use of masks might reduce the risk of viral respiratory infections. [...]

- i. >>> Moe et al. summarized the detailed study of Dugré et al. [15] in their praxis article for medical practitioners: **“PEER simplified tool: mask use by the general public and by health care workers”** (Moe et al., in *Canadian Family Physician*, July 2020) [16]. Their Figure 1 (p. 506) has:

MASKS FOR THE GENERAL PUBLIC

Based on evidence from randomized controlled trials

If I wear a surgical mask while out in public, will it protect me from flu-like illness?

- 2 trials 1683 people
- The reduction in flu-like illness may be 4% (range: 0-8%) over 6 weeks.
- But no difference in lab-confirmed influenza

What about wearing a surgical mask at home after a household member becomes sick?

- Sick person wears mask: 2 trials, 903 people
- Healthy household members wear masks: 1 trial, 290 people
- Healthy and sick people wear masks: 4 trials, 2750 people
- In all three scenarios, wearing a mask did NOT reduce the risk of getting flu-like illness or confirmed influenza.

- m. Here, note that, as always, “flu-like illness” or “influenza-like illness” (ILI) means non-laboratory-confirmed infection, based on reported symptoms or clinical observation. Such determinations are not “verified outcomes” and are thus more susceptible to bias.

- n. >>> **“Masking lack of evidence with politics”** (Jefferson and Heneghan, in *Centre for Evidence Based Medicine (CEBM)*, Oxford University, 23 July 2020): [18]

(p. 1) The increasing polarised and politicised views [ref] on whether to wear masks in public during the current COVID-19 crisis hides a bitter truth on the state of contemporary research and the value we pose on clinical evidence to guide our decisions.

In 2010, at the end of the last influenza pandemic, there were six published randomised controlled trials with 4,147 participants focusing on the benefits of different types of masks.[ref] Two were done in healthcare workers and four in family or student clusters. The face mask trials for influenza-like illness (ILI) reported poor compliance, rarely reported harms and revealed the pressing need for future trials.

Despite the clear requirement to carry out further large, pragmatic trials a decade later, only six had been published: five in healthcare workers and one in pilgrims.[ref] This recent crop of trials added 9,112 participants to the total randomised denominator of 13,259 and showed that masks alone have no significant effect in interrupting the spread of ILI or influenza in the general population, nor in healthcare workers.

(p. 2) What do scientists do in the face of uncertainty on the value of global interventions? Usually, they seek an answer with adequately designed and swiftly implemented clinical studies as has been partly achieved with pharmaceuticals. We consider it is unwise to infer causation based on regional geographical observations as several proponents of masks have done. Spikes in cases can easily refute correlations, compliance with masks and other measures is often variable, and confounders cannot be accounted for in such observational research. [...]

The small number of trials and lateness in the pandemic cycle is unlikely to give us reasonably clear answers and guide decision-makers. This abandonment of the scientific modus operandi and lack of foresight has left the field wide open for the play of opinions, radical views and political influence.

So, what actually is the “growing body of evidence”?

Given the above-documented contradiction between the claimed “growing body of evidence” and the actual “all RCTs say the opposite of what is claimed”, one can reasonably ask: What are Ontario public health officers thinking of when they assert “there is a growing body of emerging evidence that shows that non-medical masks can help prevent the spread of COVID-19”?

One answer comes from the Simcoe-Muskoka District Health Unit (Ontario, Canada) webpage entitled “FAQ’s- Wearing a Face Covering in Indoor Public Spaces”, updated 24 July 2020. The latter webpage has the section: [27]

What is the evidence that supports the use of masks?

There is a growing body of scientific evidence that indicates the widespread use of face coverings by all persons decreases the spread of respiratory droplets. Public health experts also support the widespread use of face coverings to decrease transmission of COVID-19.

At this link you will find a collection of expert opinions and studies on face coverings. This list is for informational purposes only and is not representative of all articles and studies available on the subject, nor does this list cover all articles and studies that are reviewed by our staff and our Medical Officer of Health.

The said “link” is to a webpage of the Wellington-Dufferin-Guelph public health unit, entitled “Your Health / COVID-19 Information for the Public / Reliable Information Sources”, accessed on 28 July 2020. [28] The latter webpage has a section entitled

“EXPERT OPINIONS”, having eight (8) entries, and a section entitled “EVIDENCE AND STUDIES ON FACE COVERINGS (UPDATED ON JULY 23)”, having thirty (30) entries.

The eight (8) so-called “expert opinions” are merely “op-ed” type commentaries not providing any new data, evidence, or perspectives. These do not constitute “a growing body of emerging evidence”, nor do they add any evidence whatsoever.

The thirty (30) so-called “evidence and studies” (ES) can be described as follows, numbering them ES-1 through ES-30 in the order given (alphabetical order of first-author):

ES-1 through ES-30: None of these studies are RCTs, irrespective of whether any outcomes (infections) are “verified” (lab-confirmed) or not. Some are actually “op-ed” style opinions. Some are tentative modelling studies. Some are population studies. Some are physical mask-filtering studies. A few are overview reports. A few purport to be “meta-analyses” or “systematic reviews” of old RCT and non-RCT studies (see below). None can be considered additions to “a growing body of emerging evidence”, at least not usable policy-grade evidence. All are susceptible to large bias.

ES-1: “Alberta Health Services COVID-19 Scientific Advisory Group. **Rapid Response Report: What is the effectiveness of wearing medical masks, including home-made masks, to reduce the spread of COVID-19 in the community?** Updated 2020 June.” [29] →

The first two bullets in the section entitled “Key Messages from the Evidence Summary” are (page 1):

- As medical masks are often bundled with other IPC interventions and have variable compliance, clinical trials on the effectiveness of medical masks have been challenging. Systematic reviews of randomized controlled trials in health care settings have not demonstrated a significant reduction in acute respiratory infections, (ARIs), ILIs or laboratory confirmed viral infections with medical mask use although it is acknowledged there were methodological flaws and smaller underpowered studies in the data analyzed.
- There is a paucity of clinical evidence in favor of using medical masks in the community, with multiple randomized trials demonstrating mixed results which when pooled demonstrate no significant reduction in acute respiratory infections (ARIs), ILIs or laboratory confirmed viral infections. There are some lower quality studies showing a reduction in viral infection rates in households, in transmission of viral respiratory infections in the context of mass gatherings, and in university residences when combined with hand hygiene interventions.

The third-last bullet is:

- There is limited evidence of harms related to community mask wearing with no studies identified that have systematically looked at potential harms. Such harms could include behavioral modifications such as risk compensation/non-adherence to social distancing or optimal hand hygiene practices, self-contamination, induction of facial rashes, and increasing real or perceived breathing difficulties. There are also concerns about poor compliance or tolerance of masks in children or those with cognitive challenges and communication difficulties.

The last bullet is:

- Pre-symptomatic transmission and asymptomatic transmission of SARS-CoV-2 have been described but the degree to which they contribute to community spread is unclear, At this point, there is no direct evidence that the use of a medical or homemade cloth mask or the wider use of masks in the community significantly reduces this risk. For more information, refer to the Asymptomatic Transmission of SARS-CoV-2 rapid review.

ES-7: “Chu DK, Akl EA, Duda S et al. **Physical distancing, face masks, and eye protection to prevent person-to-person transmission of SARS-CoV-2 and COVID-19: a systematic review and meta-analysis.** *Lancet.* 2020 [30] →

The DK Chu article has many problems. It was described in our letter to the WHO [1] as (pp. 5-6):

The Chu study was funded by the WHO. It contains no randomized controlled trials, but rather uses a hodgepodge of data about associations of ill-defined factors. DK Chu et al.’s own appraisal of “certainty” regarding their conclusion about masks is “LOW” meaning “our confidence in the effect estimate is limited; the true effect could be substantially different from the estimate of the effect” (their Table 2), yet such a result is a basis for your recommendation to governments.

ES-18: “Liang M, Gao L, Cheng C, et al. **Efficacy of face mask in preventing respiratory virus transmission: a systematic review and meta-analysis.** *Travel Med Infect Dis.* 2020 May 28.” [31] →

The Liang study purports to be a systematic review and meta-analysis yet it does not apply **PRISMA-P [Preferred reporting items for systematic review and meta-analysis protocols]** [32], nor does it perform **GRADE [Grading of Recommendations, Assessment, Development and Evaluations] reliability analysis** [33], which are the established standard in such medical research intended to be used for policy guidance. If Liang did apply GRADE, it would fail, because its included studies are mostly non-RCT “case-control studies”, and because its confidence intervals encompass outcomes leading to the oppose recommendation of masks:

“**GRADE guidelines 6. Rating the quality of evidence—imprecision**, by Guyatta et al., in *Journal of Clinical Epidemiology*. [34]

ES-21: “MacIntyre CR, Chughtai AA. **A rapid systematic review of the efficacy of face masks and respirators against coronaviruses and other respiratory transmissible viruses for the community, healthcare workers and sick patients.** *Int J Nurs Stud.* 2020. [35] →

The co-authors, MacIntyre and Chughtai, have both worked for or with 3M (a major proprietary mask and respirator manufacturer) and now work together; as they admit in the required “Conflict of Interest” statement. MacIntyre has made an industry or writing spin-laden articles about masks in scientific journals, which repeatedly have recast old RCT studies. This is one more in that pattern.

The authors MacIntyre and Chughtai claim “Results were reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) criteria (Moher et al., 2015).” (their “2. Methods” section, last sentence). In fact, this is false. The following numbered directives of PRISMA were not followed by MacIntyre and Chughtai (Table 3, [32]):

#13 List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale

#14 Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis

#15a Describe criteria under which study data will be quantitatively synthesized

#15b If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data, and methods of combining data from studies, including any planned exploration of consistency (e.g., I², Kendall’s tau)

#15c Describe any proposed additional analyses (e.g., sensitivity or subgroup analyses, meta-regression)

#15d If quantitative synthesis is not appropriate, describe the type of summary planned

#16 Specify any planned assessment of meta-bias(es) (e.g., publication bias across studies, selective reporting within studies)

#17 Describe how the strength of the body of evidence will be assessed (e.g., GRADE)

Not having introduced one iota of new evidence, MacIntyre and Chughtai conclude

(p. 5):

In summary, there is a growing body of evidence supporting all three indications for respiratory protection – community, healthcare workers and sick patients (source control).

The work of MacIntyre and Chughtai is not science that can be used to guide public policy. It is substandard and misleading.

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