Court File No. CV-22-00682682-0000

Courts of Justice Act

ONTARIO
SUPERIOR COURT OF JUSTICE

BETWEEN:

RANDY HILLIER

Applicant

-and-

HER MAJESTY THE QUEEN IN RIGHT OF THE PROVINCE OF ONTARIO

Respondent

AFFIDAVIT OF DR. THOMAS WARREN
SWORN THE 8th DAY OF SEPTEMBER, 2022

I, Dr. Thomas Warren, of the Town of Oakville, in the Province of Ontario, MAKE OATH AND SAY AS FOLLOWS:

1. I have personal knowledge of the facts and matters hereinafter deposed to by me, except where same are stated to be based upon information and belief, and those I do verily believe to be true.

2. I am a full time Infectious Diseases Consultant and Medical Microbiologist with Halton Healthcare in Oakville, Ontario.

3. In 2013, I was appointed Assistant Clinical Professor (Adjunct) at McMaster University Department of Medicine, Faculty of Health and Sciences and I still hold such appointment as of the date of this my Affidavit.

4. From 2012 to 2021, I was a supervisor for physician assistant students, medical students, residents and infectious disease fellows from the University of Toronto and McMaster University for Infection Diseases clinical rotations.

5. In 2008 and 2009 I taught microbiology to second year medical students with the University of Toronto.

6. I am in good standing as a member with the Association of Medical Microbiology and Infectious Diseases Canada, the Canadian Medical Association, Canadian Medical Protective Association, the College of Physicians and Surgeons of Ontario, Ontario Medical Association and the Royal College of Physicians and Surgeons of Canada.

7. My qualifications are set out in the attached Curriculum Vitae ("CV") and marked as **Exhibit "A"** to this my Affidavit.

8. I have reviewed studies relevant to transmission of the SARS-CoV-2 virus and have broad experience with the issues of infectious diseases and virus transmission and have over 10 years of practice as an Infectious Diseases Consultant and Microbiologist.

9. I have been asked by counsel for the Applicants to prepare a report as an expert witness to provide my professional opinions on the following questions:

   a) What is the risk of COVID-19 transmission in outside settings?

   b) How does community disease rate change after a large outdoor gathering?

   c) What is the risk of COVID-19 transmission in outside settings where there are no or limited a) masking; and b) social distancing?

10. My signed Acknowledgement of Expert's Duty to this Honourable Court as an expert is attached as **Exhibit "B"** to this my Affidavit.

11. I acknowledge that in preparing this report and providing expert evidence, the Applicants' counsel explained that my role is to assist the court to determine the matters in issue. I further acknowledge that it is my duty to provide evidence that is fair, objective and non-partisan and to opine only on matters that are within my areas of expertise. This duty prevails over any obligations that I may owe to any party on whose behalf I am engaged.

12. Attached hereto and marked as **Exhibit "C"** to this my Affidavit is a copy of my report which I adopt and sets out the information and assumptions on which my opinion is based and a summary of my opinion.

13. Where I have relied on a document or data in forming my opinion, I have set out the citation to that document or data in the endnotes

SWORN REMOTELY by videoconference by)
Dr. Thomas Warren at the Town of Oakville,)
Ontario, before me at the City of Brampton,)
this 2 day of September, 2022 in accordance)
with O.Reg. 431/20 Administering Oath or)
Declaration Remotely)

Henna Parmar

HENNA PARMAR
Barrister & Solicitor

DR. THOMAS WARREN

This is **Exhibit "A"** referred to in the

Affidavit of **Dr. Thomas Warren** sworn

before me virtually this 8 day of

September, 2022.

Henna Parmar

Barrister and Solicitor in the
Province on Ontario

Thomas A. Warren, MD

[redacted]

Employment

2011 - **Infectious Diseases consultant & Medical Microbiologist**
Halton Healthcare, Oakville ON

2010-2011 **Internal Medicine specialist – locum coverage**
St. Michael's Hospital, Toronto ON
Hamilton Health Sciences, Hamilton ON
Lakeridge Health, Oshawa ON

2010-2011 **University of Toronto**
Department of Laboratory Medicine & Pathobiology, Toronto ON
Resident, Medical Microbiology

2008-2010 **University of Toronto**
Department of Medicine, Division of Infectious Diseases, Toronto ON
Fellow, Infectious Diseases

2005-2008 **University of Ottawa**
Department of Medicine, Ottawa ON
Resident, Internal Medicine

1997-2003 **University of Western Ontario**
Department of Medicine, London ON
Computer Programmer & Web Developer

Education

2018 - **London School of Hygiene and Tropical Medicine, University of London**
Master's of Science (Epidemiology)
Expected Completion 2022

2010-2011 **Royal College of Physicians & Surgeons of Canada**
Residency in Medical Microbiology

2008-2010 **Royal College of Physicians & Surgeons of Canada**
Fellowship in Infectious Diseases

2005-2008 **Royal College of Physicians & Surgeons of Canada**
Residency in Internal Medicine

2001-2005 **University of Western Ontario**
Schulich School of Medicine & Dentistry
Doctor of Medicine

1997-2001 **University of Western Ontario**
Bachelor of Science - Honors Microbiology & Immunology
(Scholar's Electives Program)
Graduated With Distinction

Continuing Medical Education

2018 **IDEAS Foundations of Quality Improvement Program**
May 30
McMaster University
Hamilton, ON

2018 **Clinical Teaching Fundamentals**
January – March
McMaster University
Hamilton, ON

Peer-Reviewed Publications

2015 **Warren T**, Lau R, Ralevski F, Rau N, Boggild AK.
Fever in a visitor to Canada: a case of mistaken identity.
J Clin Microbiol. 53:1783-1785.

2012 **Warren TA**, Yau Y, Ratjen F, Tullis E, Waters V.
Serum galactomannan in cystic fibrosis patients colonized with Aspergillus species.
Medical Mycology. 2012; 50: 658-660.

2010 **Warren TA**, McTaggart L, Richardson SE, Zhang SX.
Candida bracarensis Bloodstream Infection in an Immunocompromised Patient.
Journal of Clinical Microbiology. 2010; 48: 4677–4679.

Abstracts & Conference Presentations

2011 **Warren TA**, Yau Y, Waters V.
Serum galactomannan in cystic fibrosis patients colonized with Aspergillus species.
Poster session presented at: Association of Medical Microbiology and Infectious Disease (AMMI) Canada 2011 Annual Conference
2011 April 7-9; Montreal, QC.

2010 **Warren TA**, Yau Y, Waters V.
Serum galactomannan in cystic fibrosis patients colonized with Aspergillus species.
Poster session presented at: North American Cystic Fibrosis Conference
2010 October 21-23; Baltimore, MD.

2010 **Warren TA,** Govindapillai S, Tullis E, Devlin HR, Ferris W, Matukas LM.
Evaluation of Etest Combination Testing of Antibiotics Against Isolates from Patients with Cystic Fibrosis.
Poster session presented at: 50th Interscience Conference on Antimicrobial Agents and Chemotherapy
2010 September 12-15; Boston, MA.

2010 **Warren TA**, Rotstein C, Cole EH, Singer LG, Keshavjee S4, Husain S.
Posaconazole therapy in solid organ transplant recipients refractory to or intolerant of standard therapy.
Poster session presented at: Canadian Society for Transplantation Annual Conference
2010 August 12-15; Vancouver, BC.

2010 **Warren TA**, McTaggart L, Zhang S. Candida bracarensis Blood Stream Infection in an Immunocompromised Patient: Case Report.
Poster session presented at: Focus on Fungal Infections
2010 March 3-5; New Orleans, LA.

2007 **Warren TA**, McCarthy AE.
A Ten-Year Retrospective Study of Vaccination Rates, Prophylactic Antibiotic Use, Serious Infection and Overwhelming Postsplenectomy Sepsis Rates in Splenectomized Patients.
Poster session presented at: Annual Meeting of the Infectious Diseases Society of America
2007 October 4-7; San Diego, CA.

Awards

2011 **Best Student Poster Award – 2011 Annual Conference**
Association of Medical Microbiology and Infectious Disease (AMMI) Canada
Montreal, QC

2010 **ASM ICAAC Infectious Diseases Fellows Grant**
2010 Interscience Conference on Antimicrobial Agents and Chemotherapy
Boston, MA

2008 **Internal Medicine CanMeds Award for Communication**
University of Ottawa, Department of Medicine
Ottawa, ON

2006 **Resident Research Day Award of Excellence – PGY1**
University of Ottawa, Department of Medicine
Ottawa, ON

2001 **Laurene Paterson scholarship**
University of Western Ontario
London, ON

1997-2001 **Dean's Honor List**
University of Western Ontario, Faculty of Science
London, ON

1997 **Western Scholarship of Excellence**
University of Western Ontario
London, ON

Appointments

2013 - **McMaster University**
Assistant Clinical Professor (Adjunct)
Department of Medicine, Faculty of Health Sciences
Hamilton, ON

Teaching

2012-2021 **Infectious Diseases – Clinical Rotations**
Supervised physician assistant students, medical students, residents and infectious diseases fellows from the University of Toronto and McMaster University
Oakville, ON

2009 **Pathobiology of Disease**
Taught microbiology to second year medical students
University of Toronto
Toronto, ON

2008 **Pathobiology of Disease**
Taught microbiology to second year medical students
University of Toronto
Toronto, ON

2008 **Physical Skills Development Course**
Taught physical exam skills to first year medical students
University of Ottawa
Ottawa, ON

Memberships

Association of Medical Microbiology and Infectious Diseases Canada

Canadian Medical Association

Canadian Medical Protective Association

College of Physicians and Surgeons of Ontario

Ontario Medical Association

Royal College of Physicians and Surgeons of Canada

This is **Exhibit "B"** referred to in the

Affidavit of **Dr. Thomas Warren** sworn

before me virtually this 8 day of

September, 2022.

Henna Parmar

Barrister and Solicitor in the
Province on Ontario

Court File No. CV-22-00682682-0000

FORM 53
Courts of Justice Act

ONTARIO
SUPERIOR COURT OF JUSTICE

BETWEEN:

RANDY HILLIER

Applicant

-and-

HER MAJESTY THE QUEEN IN RIGHT OF THE PROVINCE OF ONTARIO

Respondent

ACKNOWLEDGMENT OF EXPERT'S DUTY

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1. My name is Dr. Thomas Warren. I live at the Town of Oakville, in the Province of Ontario.
2. I have been engaged by or on behalf of Randy Hillier, the Applicant, to provide evidence in relation to the above-noted court proceeding.
3. I acknowledge that it is my duty to provide evidence in relation to this proceeding as follows:
   (a) to provide opinion evidence that is fair, objective and non-partisan;
   (b) to provide opinion evidence that is related only to matters that are within my area of expertise; and
   (c) to provide such additional assistance as the court may reasonably require, to determine a matter in issue.
4. I acknowledge that the duty referred to above prevails over any obligation which I may owe to any party by whom or on whose behalf I am engaged.

Date: September 8 2022

Signature

NOTE: This form must be attached to any expert report under subrules 53.03(1) or (2) and any opinion evidence provided by an expert witness on a motion or application.

This is **Exhibit "C"** referred to in the

Affidavit of **Dr. Thomas Warren** sworn

before me virtually this 8 day of

September, 2022.

Henna Parmar

Barrister and Solicitor in the
Province on Ontario

SARS-CoV-2 and COVID-19

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a novel coronavirus. There are six other coronaviruses that are known to infect humans. Four coronaviruses, HCoV-NL63, HCoV-HKU1, HCoV-229E, and HCoV-OC43 circulate worldwide and together are the second most common cause of the common cold[1]. Severe acute respiratory syndrome coronavirus 1 (SARS-CoV-1) infected 8096 people in 2003 resulting in 774 deaths[2]. After 2003 there has not been any further human to human transmission. Middle East respiratory syndrome coronavirus (MERS-CoV) was first identified in humans in 2012[3]. MERS-CoV continues to cause sporadic infection and outbreaks in the Arabian peninsula, as well as occasional other cases and outbreaks in other parts of the world linked to travelers to the Arabian peninsula[4].

Bats were the source of SARS-CoV-1[5] and are known to be a natural reservoir for related coronaviruses[6]. In late 2019, SARS-CoV-2 was first detected in humans and is established as the cause of the disease now designated coronavirus disease 2019 (COVID-19). Approximately 30-40% of persons with SARS-CoV-2 infection are asymptomatic[7]. In those who are symptomatic, there is a wide range of illness from those with mild symptoms such as runny nose to those with severe disease affecting particularly the respiratory tract with high mortality[8]. Most people with SARS-CoV-2 infection are asymptomatic or have mild-moderate symptoms not requiring hospitalization. In one study of a relatively healthy population, those with COVID-19 requiring hospital care was < 2%, and the mortality rate was < 0.1%[9]. Infection with the Omicron variant has resulted in lower rates of hospitalization, less severe illness, and lower mortality compared to previous variants such as Alpha and Delta[10].

Transmission and mortality

The timing of peak SARS-CoV-2 transmission is primarily affected by seasonal patterns (i). The scale of SARS-CoV-2 transmission in a susceptible population is primarily determined by population density (ii). The mortality of COVID-19 is primarily determined by the age structure of the population (iii). Each of these important factors for SARS-CoV-2 transmission and mortality is non-modifiable.

(i) The timing of peak SARS-CoV-2 transmission is primarily affected by seasonal patterns.

The four human coronaviruses (OC43, 229E, NL63, HKU1) are known to have a seasonal pattern of increased transmission[11]. The peak of the transmission wave in the United States is in the coldest months of the year, usually January. SARS-CoV-2 transmission appears to have a similar seasonal pattern of transmission to the other seasonal human coronaviruses[12]. There are numerous studies that show climate (season) is one of the most important factors for SARS-CoV-2 transmission[13]. In general, colder temperatures are associated with increased SARS-CoV-2 transmission.

(ii) The scale of SARS-CoV-2 transmission is primarily determined by population density.

The transmission of SARS-CoV-2 is strongly associated with population density, particularly population-weighted density[14]. In the United States, incidence and mortality are ten times higher in the most densely populated areas compared to the least densely populated areas[15]. The association between population density and SARS-CoV-2 transmission has been identified in Europe[16], Italy[17], India[18], Argentina[19], Turkey[20], Algeria[21], Brazil[22], Japan[23], and China[24].

This is also evident in Canada. Provinces with the highest population density (e.g. Ontario) have the highest number of cases. Within provinces (e.g. Ontario), regions with the highest population density have the highest number of cases (e.g. Toronto).

(iii) The mortality of COVID-19 is primarily determined by the age structure of the population.

Age is the most important risk factor for COVID-19 mortality. Compared to persons under age 40, persons over the age of 80 have a greater than 300 times chance of dying from COVID-19[25]. The infection fatality ratio (IFR) in persons over 80 is approximately 1000 times the IFR in those under 20[26]. In Canada, 61% of deaths are in persons over 80, 82% of deaths are in persons over 70, and 93% of deaths are in persons over 60[27].

The risk of death due to COVID-19 in persons under 50 is very small[28]. In Canada, the risk of death due to COVID-19 in persons < 50 is less than the risk of death due to a motor vehicle fatality[29]. Globally, excess mortality related to COVID-19 is concentrated in persons over age 60, and particularly in persons over age 75; excess mortality related to COVID-19 was generally not seen in age groups less than age 60[30]. The attributable mortality due to COVID-19 is similar to influenza in persons aged less than 60[31].

1. What is the risk of COVID-19 transmission in outside settings?

A. Outdoor transmission of respiratory infections

It has been known for centuries that transmission of respiratory tract infections occurs much less frequently outdoors[32]. Tuberculosis (TB) and influenza are very important respiratory infections and have killed (cumulatively) hundreds of millions of people over centuries and millennia. The risk of outdoor transmission is considered very low for these very important human infections, as it is for all other respiratory tract infections.

TB is transmitted through airborne particles. The *Canadian Tuberculosis Standards* published by the Public Health Agency of Canada state that TB “transmission is rarely thought to occur outdoors”[33] and the “risk of [outdoor] transmission is negligible provided they are not in very close contact with susceptible individuals for prolonged periods of time”[34]. The result is that “outdoor exposures are not investigated during a contact tracing exercise”[35].

Influenza is another important respiratory tract infection. In a systematic review of outdoor mass gatherings and respiratory disease (mostly influenza) performed by the United States Centers for Disease Control and Prevention, “no single-day mass gathering-related outbreaks were identified in our review”[36]. Similarly, a global review of outbreaks (including influenza outbreaks) at outdoor large gatherings from 1980 to July 2012 did not identify any outbreaks associated with single day gatherings[37]. These studies and others were included in a systematic review of outdoor transmission of SARS-CoV-2 and other respiratory viruses; influenza outbreaks only occurred in the context of multiday outdoor events or communal housing[38].

In the absence of definitive evidence to the contrary, it can be assumed that the risk of outdoor transmission of SARS-CoV-2 is very low, like influenza and TB. The burden of proof requires evidence to the contrary, showing that outdoor transmission of SARS-CoV-2 is significant. In the absence of that evidence, the default assumption remains that the risk of outdoor transmission of SARS-CoV-2 is low. It would be remarkable if SARS-CoV-2 was the first respiratory tract infection in history to have significant outdoor transmission.

B. Where SARS-CoV-2 is known to be transmitted

The most common place for SARS-CoV-2 transmission is within households[39]; a Canadian study showed that odds of SARS-CoV-2 transmission in households was 44 times higher than in schools[40]. A study of households in Utah found that the household secondary attack rate was 36%, but the likelihood of a person in the study acquiring SARS-CoV-2 infection outside their household was only 0.41%[41]. A study performed in Switzerland estimated that a person was more than three times more likely to be infected with COVID-19 from a household member than from someone outside their household[42]. Household transmission accounted for 78%-85% of all SARS-CoV-2 transmission in China in one report from the World Health Organization[43]. Household contacts and travel together were the most important sources of SARS-CoV-2 transmission in another study[44]. Outbreaks in other indoor contexts where people live/sleep - such as long-term care facilities, hospitals, jails, and shelters - have also been established as an important source of indoor transmission in the Canadian context[45].

C. Transmission of SARS-CoV-2 outdoors

Increased time spent outdoors lowers the odds of acquiring SARS-CoV-2[46]. Using anonymized mobility flows derived from global mobile phone tracking data between February 2020 and February 2021 there was no evidence that increased visits to outdoor spaces increased COVID-19 transmission[47]. In one comprehensive study from China[48], only one outdoor outbreak involving two cases occurred out of 7324 identified cases. The reason for the very low risk of outdoor transmission is that “outdoor concentration of the exhaled droplets can be safely assumed to be zero in almost all situations”[49], and airflow outdoors rapidly dilutes any SARS-CoV-2 virus present to negligible amounts[50].

D. Conclusion

The transmission of any respiratory tract infection outdoors is low. SARS-CoV-2 is known to be transmitted primarily indoors, particularly in households and other places of residence (hospitals, jails, long-term care homes, shelters). The risk of SARS-CoV-2 transmission outdoors is very low.

2. How does community disease rate change after a large outdoor gathering?

Large outdoor gatherings vary substantially in several factors known to be important to SARS-CoV-2 transmission. First, multi-day outdoor events such as music festivals should not be considered outdoor events because there are overnight components that occur indoors, and (as shown above) the risk of SARS-CoV-2 transmission is much higher indoors. Second, the duration of outdoor events is an important factor. Transmission at large outdoor gatherings with a long duration does result in increased SARS-CoV-2 transmission. An outdoor music festival lasting 16.5 hours (2:00 pm to 6:30 am) resulted in increased SARS-CoV-2 transmission[51].

Large outdoor gatherings of a relatively short duration such as professional soccer[52] and football[53] matches do not result in an increased risk of COVID-19. Outdoor gatherings of a similarly short duration, such as political protests or religious gatherings, should be expected to have a similar risk of COVID-19.

3. What is the risk of COVID-19 transmission in outside settings where there are no or limited a) masking b) social distancing

There is scant direct evidence for the benefit of masking or physical distancing outdoors. The effect of masking outdoors and social distancing outdoors can be extrapolated from the risk of outdoor transmission (sections 1 and 2 above), the benefit of masking in general (section 3.A below), and the benefit of social distancing in general (section 3.B below).

A. Masking

i. Evidence for the masking of healthy people in the community to prevent infection with respiratory viruses prior to COVID-19

The best evidence for any medical intervention comes from large randomized controlled trials or meta-analysis of randomized trials. Prior to 2020, there were no randomized controlled trials or meta-analysis of randomized controlled trials that supported the effectiveness of masking of healthy people in the community to prevent infection with respiratory viruses.

A meta-analysis by the World Health Organization (WHO) in 2019 failed to show a substantial protective effect of face masks[54]. Similarly, another meta-analysis published in early 2020 showed that masks make no difference in preventing pandemic influenza in nonhealthcare settings[55]. A 2020 Cochrane meta-analysis of masks versus no masks in preventing viral respiratory illness found no difference in preventing influenza-like illness or laboratory confirmed illness[56]. Therefore, when the analysis is limited to the strongest types of evidence (randomized trials and meta-analyses of randomized trials), there was no evidence prior to COVID-19 that healthy persons wearing masks in non-healthcare settings prevented the spread of respiratory tract infections.

ii. Evidence for cloth masks to prevent infection with respiratory viruses prior to COVID-19

There was one randomized-controlled trial prior to 2020 comparing cloth masks to medical masks to prevent infection with respiratory viruses[57]. That study showed that risk of respiratory tract infection was significantly higher in hospital healthcare workers who wore cloth masks compared to hospital healthcare workers who wore medical masks.

iii. The rationale for masking healthy people in the community to prevent COVID-19

Masks were recommended or mandated during the COVID-19 pandemic, not based on the evidence, but based on the precautionary principle. The WHO admitted in a December 2020 report that "there is only limited and inconsistent scientific evidence to support the effectiveness of masking of healthy people in the community to prevent infection with respiratory viruses, including SARS-CoV-2"[58]. That report recommends masking healthy people in the community to prevent COVID-19 based on the precautionary principle, that masks *might* prevent infection.

To justify its recommendation for masking healthy people in the community to prevent COVID-19 the WHO report cites many poor-quality studies. The poor-quality studies cited by the WHO have significant limitations that need to be considered. Many of the studies referenced by the WHO are ecological studies[59], also called correlational studies. The ecological studies referenced by WHO compare mask use and COVID- 19 rates between geographic region, such as country, state, or city. The descriptive analysis of these rates does not provide an evidentiary base for concluding causation. Ecological studies have "many methodologic problems that severely limit causal inference, including ecologic and cross-level bias, problems of confounder control, within-group misclassification, lack of adequate data, temporal ambiguity, collinearity, and migration across groups."[60] The WHO report also acknowledges those studies "have important limitations to consider"[61].

Cohort studies[62], case control[63], and case series[64] are all referenced in the WHO document, but these study types are considered much weaker than randomized controlled trials or meta-analysis. Due to the limitation of the study designs, particularly bias and confounding, the true effect of masking is uncertain. Many of these studies also have limited generalizability. For example, a study looking at secondary transmission of SARS-CoV-2 in households[65] has limited generalizability to universal masking in the wider general public. The findings from case series of persons who traveled on the same flight[66] cannot be generalized to universal masking.

Finally, a comment should be made on the study[67] by Chu et al. as that study is referenced by the WHO and has been widely cited in the media. That study putatively showed a large reduction in risk of infection with face mask use. As noted in a 2020 Cochrane review, the Chu et al. study "has been criticised for several reasons: use of an outdated 'Risk of bias' tool; inaccuracy of distance measures; and not adequately addressing multiple sources of bias, including recall and classification bias and in particular confounding. Confounding is very likely, as preventive behaviours such as mask use, social distancing, and hand hygiene are correlated behaviours, and hence any effect estimates are likely to be overly optimistic."[68]

iv. Randomized controlled trials evaluating the benefit of masking of healthy people in the community to prevent SARS-CoV-2 infection

Only two randomized controlled trials have been published during the COVID-19 pandemic evaluating the benefit of masking of healthy people in the community to prevent SARS-CoV-2 infection. The first study, conducted in Denmark in April and May 2020, was published in November 2020[69]. That study found there was no significant difference in SARS-CoV-2 infection rates between those who wore masks and those who did not wear masks.

A second study was conducted in Bangladesh between November 2020 and March 2021, and published in January 2022[70].

> Cloth masks: The study showed that cloth masks do not have any statistical effect on COVID-19 infection.
>
> Medical (surgical) masks: The benefit of wearing a medical mask was very small. Based on the reported relative risk reduction of 11.1% with surgical masks and a symptomatic seropositivity in the control group of 0.76%, the number needed to treat (NNT) can be calculated to be 1,185. That means that 1,185 people need to wear a surgical mask for 8 weeks (the duration of the study) to prevent one infection. Alternatively, 182 people need to wear a surgical mask for one year to prevent one infection.
>
> The NNT should be put in context. A NNT greater than 50 to prevent a symptomatic condition is considered very high, so a NNT of 182 (to prevent one COVID-19 case per year) is very high. The case fatality rate for COVID-19 is approximately 1%, so the NNT to prevent one COVID-19 death per year could be roughly estimated to be 18,200. A NNT > 1000 to prevent one death is considered very high, so a NNT of 18,200 (to prevent one COVID-19 death per year) is very high.
>
> Hospitalizations and deaths: The study did not measure hospitalizations and deaths, so the effect of medical mask wearing to prevent COVID-19 deaths can only be estimated, as above. The study authors did their own estimates of the effect of medical mask wearing to prevent COVID-19 deaths and assumed that mask wearing would have no effect on mortality in those under age 50.
>
> Vaccination: The study was performed before COVID-19 vaccinations were widely available, so it is expected that the effects of mask use in a vaccinated population would be even lower.

v. Adverse effects of mask wearing

Healthy people in the community wearing cloth masks has no effect on COVID-19 transmission, and healthy people in the community wearing medical masks has a very small effect on COVID-19 transmission, so the potential adverse effects of wearing masks needs to be considered.

Wearing a face mask can cause retroauricular dermatitis[71], ear deformities in children[72], worsen acne[73], cause itch[74], jeopardises the ability of healthcare staff to successfully communicate with patients[75]. Wearing a mask in healthcare settings can limit empathy, trust and understanding between healthcare workers and patients[76] as well as increase cognitive load and listening effort for both patients and providers[77]. Wearing a face mask can increase blood carbon dioxide levels and decrease blood oxygen levels[78]. Face masks can compromise the capability to recognize the emotion on the basis of facial cues[79], undermines trust in others[80], impacts audiovisual word recognition in young children with hearing loss[81], affect emotion recognition in individuals with autistic traits[82], and reduce emotion-recognition accuracy and perceived closeness[83].

It is well established that healthcare workers improperly removing (doffing) personal protective equipment (including masks) can be one of the highest risks for infectious disease transmission[84]. A person who is not a healthcare worker likely does not know how to properly wear and take off masks so there is a reasonable possibility that any (small) benefit of masking is negated by self-contamination by improper use and removal; however, there are no studies on the topic[85].

vi. Conclusions

Cloth masks: Before the COVID-19, it was known that cloth masks were inferior to medical masks in protecting healthcare workers from respiratory tract infections. The RCT performed in Bangladesh confirmed with a high degree of certainty that cloth masks are useless for preventing COVID-19 transmission. Despite this evidence, mask mandates in many jurisdictions in Canada have recommended cloth masks, essentially mandating a futile intervention.

Medical masks: Before the COVID-19, masking of healthy people in the community to prevent infection with respiratory viruses was known to be ineffective. Until the publication of the Bangladesh RCT, there was only “limited and inconsistent scientific evidence to support the effectiveness of masking of healthy people in the community to prevent”[86] COVID-19. The results of the Bangladesh RCT have showed that the benefit of medical masks is very small and likely limited to those over age 50. When considered in the context of possible harms of mask wearing as well as the inevitability of SARS-CoV-2 infection, the benefit of mask wearing can reasonably be considered transient and very small in the short term, and negligible in the long term.

B. Social distancing

Almost all of the research done prior to 2020 examining the effectiveness of interventions such as avoiding crowding to control respiratory tract infections was done with influenza. Prior to 2020, social distancing was a term that included quarantine, school closures, work closures as well as avoiding crowding[87].

As noted in a recent systemic review, "clear biological and epidemiologic rationale supports the potential effectiveness of social distancing measures"[88] in the control of viral respiratory tract infections; however, the actual evidence for avoiding crowding by the general public for the control of viral respiratory tract infections is negligible.

A 2019 WHO review[89] of non-pharmaceutical public health measures for mitigating the risk and impact of epidemic and pandemic influenza found only three studies[90] relevant to "avoiding crowding". In all three studies the quality of evidence was rated as very low. Two of those studies were retrospective analysis of the 1918 pandemic[91], both published in 2007. The limitations of studies done almost a century after an event should be self-evident, and hence the quality of that evidence is rated as very low. Importantly, in reference to "avoiding crowding" the WHO document notes[92]:

> Ethical considerations
> In urban locations it can be difficult to avoid crowding without considerable social costs.
> Modification, postponement or cancellation of mass gatherings may have cultural or religious considerations, in addition to public health aspects.
>
> Knowledge gaps
> There are still major gaps in our understanding of person-to-person transmission dynamics. Reducing mass gatherings is likely to reduce transmission in the community, but the potential effects are difficult to predict with accuracy. Large-scale RCTs [randomized controlled trials] are unlikely to be feasible.

A 2020 Cochrane systematic review[93] "found only one RCT [randomized controlled trial] of quarantine, and no trials of screening at entry ports or physical distancing [emphasis added]." Since there is a complete absence of high-quality evidence regarding physical distancing, the authors state: "Physical distancing represents another major research gap which needs to be addressed expediently, especially within the context of the COVID-19 pandemic setting as well as in future epidemic settings."[93]

It is estimated that 50% of Canadians were infected with SARS-CoV-2 during five months of the Omicron wave in early 2022[94]. Similarly, 66% of the Danish population aged 17-72 were estimated to have been infected between November 1, 2021, and March 15, 2022[95]. This means SARS-CoV-2 infection is pervasive and possibly inevitable.

In summary, while there is clear biological and epidemiological rationale for avoiding crowding, there is an absence of high-quality evidence, such as randomized-controlled trials, that prove the effectiveness of avoiding crowding in particular groups or contexts, such as in outdoors settings. Like masking, the effect of social distancing on SARS-CoV-2 transmission can reasonably be considered transient and small in the short term, and negligible in the long term.

C. Conclusion

The effect of masking or social distancing on the risk of COVID-19 transmission in outside settings needs to be considered in the following context, as detailed above but summarized here. SARS-CoV-2 infection is pervasive and can reasonably be considered inevitable. Over 50% of the populations of Canada and Denmark were infected with SARS-CoV-2 in a 4-5 month period. The transmission of any respiratory tract infection outdoors, including SARS-CoV-2, is low, and SARS-CoV-2 is known to be transmitted primarily indoors. Large outdoor gatherings of a relatively short duration do not result in an increased risk of COVID-19. The effect of mask wearing and social distancing on SARS-CoV-2 transmission, in general, is small and transient. In this context, it is reasonable to conclude that SARS-CoV-2 transmission in outside settings is not materially affected by masking or social distancing.

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