Clinical studies and meta-analyses of clinical studies of masks vs. no masks.

by Creon Levit

The questions addressed by this document are:

- 1) Do masks slow the spread or severity of influenza?
- 2) Do masks slow the spread or severity of covid-19?
- 3) Do masks reduce operating room infections?

I do not reference in-vitro studies (Petri dishes, mannequins, etc), fluid-dynamics studies, materials science studies, mathematical models, or simulations (though there is a link to a collection of such studies - without criticisms - near the end of the covid-19 section).

I only reference clinical studies, where one sub-population wears masks and another doesn't wear masks, or meta-analyses (summaries) of such clinical studies.

Do masks slow the spread of influenza?

Influenza is a human respiratory virus similar in many ways to SARS-CoV-2: it is transmitted the same way, is about the same size, and often has similar health consequences. But in contrast to covid it has been studied extensively for many decades.

All of the following influenza studies (even those from 2020) were published before masks became political. Once masks became political (after early 2020) I suspect many subsequent studies were politically biased.

Excerpt from: "The use of masks and respirators to prevent transmission of influenza: a systematic review of the scientific evidence" (2011). *Influenza Journal*.

"None of the studies established a conclusive relationship between mask/respirator use and protection against influenza infection."

Excerpt from: "Non-pharmaceutical public health measures for mitigating the risk and impact of epidemic and pandemic influenza. Annex: Report of systematic literature reviews" (2019). World Health Organization.

"Our review identified a lack of compelling evidence for the effectiveness of hand hygiene, respiratory etiquette and face masks against influenza transmission in the

community... there was no evidence that face masks are effective in reducing transmission of laboratory-confirmed influenza."

Excerpt from: "Non-pharmaceutical Measures for Pandemic Influenza in Non-healthcare Settings—Personal Protective and Environmental Measures" (2020). Emerging Infectious Diseases. www.cdc.gov/eid Vol. 26, No. 5, May 2020

"We identified 10 RCTs [randomized controlled trials] that reported estimates of the effectiveness of face masks in reducing laboratory-confirmed influenza virus infections in the community from literature published during 1946—July 27, 2018. In pooled analysis, we found no significant reduction in influenza transmission with the use of face masks"

Excerpt from: "Masks for prevention of viral respiratory infections among health care workers and the public - PEER umbrella systematic review" (2020). Canadian Family Physician Vol 66: July, 2020.

"Of the 6 RCTs examining the use of masks by health care workers, only 2 had a control group assigned to 'no mask.' In these trials, masks did not reduce influenza-like illness..., any clinical respiratory infection..., confirmed influenza, or confirmed viral respiratory infection compared with no masks."

Excerpt from: "Physical interventions to interrupt or reduce the spread of respiratory viruses" (2020). Cochrane Database of Systematic Reviews 2020, Issue 11. Art.No.CD006207.

"The pooled results of randomised trials did not show a clear reduction in respiratory viral infection with the use of medical/surgical masks during seasonal influenza... wearing a mask may make little or no difference to the outcome of influenza-like illness (ILI) compared to not wearing a mask... There is moderate certainty evidence that wearing a mask probably makes little or no difference to the outcome of laboratory-confirmed influenza compared to not wearing a mask"

Excerpt from: "Medical Masks" (2020). Journal of the American Medical Association (JAMA) 2020 Volume 323, Number 15 pp1517-8.

"Face masks should not be worn by healthy individuals to protect themselves from acquiring respiratory infection because there is no evidence to suggest that face masks worn by healthy individuals are effective in preventing people from becoming ill...

Because N95 respirators require special fit testing, they are not recommended for use by the general public."

Excerpt from: "Physical interventions to interrupt or reduce the spread of respiratory viruses.

Part 1 - Face masks, eye protection and person distancing: systematic review and meta-analysis" (2020). medRxiv preprint (not peer reviewed).

"There was no reduction of influenza-like illness (ILI)... or influenza ... for masks compared to no masks in the general population, nor in healthcare workers."

Excerpt from: "N95 Respirators vs Medical Masks for Preventing Influenza Among Health Care Personnel: A Randomized Clinical Trial". JAMA September 3, 2019 Volume 322, Number 9

"there was no significant difference in the incidence of laboratory-confirmed influenza among health care personnel with the use of N95 respirators (8.2%) vs medical masks (7.2%)."

Do masks slow the spread of Covid-19?

Excerpt from: "Advice on the use of masks in the context of COVID-19". World Health Organization (2020).

"[medical] staff who do not work in clinical areas do not need to use a medical mask during routine activities... At present, there is no direct evidence... on the effectiveness of universal masking of healthy people in the community to prevent infection with respiratory viruses, including COVID-19... the widespread use of masks by healthy people in the community setting is not yet supported by high quality or direct scientific evidence"

Excerpt from: "Facemasks and similar barriers to prevent respiratory illness such as COVID-19: A rapid systematic review" (2020) medRxiv preprint.

"The evidence is not sufficiently strong to support widespread use of facemasks as a protective measure against COVID-19. However, there is enough evidence to support the use of facemasks for short periods of time by particularly vulnerable individuals when in transient higher risk situations"

Excerpt from: "Effectiveness of Adding a Mask Recommendation to Other Public Health Measures to Prevent SARS-CoV-2 Infection in Danish Mask Wearers" (2020) [DANMASK]. Annals of Internal Medicine.

"A total of 3030 participants were randomly assigned to the recommendation to wear masks, and 2994 were assigned to control; 4862 completed the study. Infection with SARS-CoV- 2 occurred in 42 participants recommended masks (1.8%) and 53 control participants (2.1%)... the difference observed was not statistically significant..."

Excerpt from: "Mask mandate and use efficacy in state-level COVID-19 containment" (2021) medRxiv preprint.

"Conclusions: Mask mandates and use are not associated with slower state-level COVID-19 spread during COVID-19 growth surges."

Excerpt from: "The Impact of Community Masking on COVID-19: A Cluster-Randomized Trial in Bangladesh". Yale University (2021). This was widely reported in the media as "proof that masks work" - which it isn't by a simple look at the results quoted in the abstract below. That claim is unsupported by the raw data collected for the study (also this), and that the data are so biased that concluding anything other than the null result is unjustified.]

"The proportion of individuals with COVID-like symptoms was 7.62% (N=13,273) in the intervention arm and 8.62% (N=13,893) in the control arm"

Excerpt from <u>Physical interventions to interrupt or reduce the spread of respiratory viruses</u> Cochrane Database of Systematic Reviews 2023 Jan 30;1(1):CD006207.

"We included 11 new RCTs and cluster-RCTs (610,872 participants) in this update, bringing the total number of RCTs to 78. Six of the new trials were conducted during the COVID-19 pandemic...The pooled estimates of effect from randomised controlled trials (RCTs) and cluster-RCTs for wearing medical/surgical masks compared to no masks in the community suggests probably little or no difference in interrupting the spread of influenza-like illness... or laboratory-confirmed influenza/SARS-CoV-2..."

The lead author of the above review was <u>interviewed here</u>. It is pretty powerful. Among other things he states: "There is just no evidence that they [masks] make any difference. Full stop."

Excerpt from Unravelling the role of the mandatory use of face covering masks for the control of SARS-CoV-2 in schools: a quasi-experimental study nested in a population-based cohort in Catalonia (Spain)

"We found no significant differences in SARS-CoV-2 transmission due to FCM [face covering mask] mandates in Catalonian schools. Instead, age was the most important factor in explaining the transmission risk for children attending school."

From: "Child mask mandates for COVID-19: a systematic review" (2024):

"Conclusions: Real-world effectiveness of child mask mandates against SARS-CoV-2 transmission or infection has not been demonstrated with high-quality evidence. The current body of scientific data does not support masking children for protection against COVID-19.

On the other hand (well, not really): for a list of models, simulations, observational, and in vitro ("Petri dish") studies supportive of masks, see <u>this annotated bibliography</u>. I have still not found

any clinical studies that support masking against covid, nor have I found any supporting clinical evidence for masks against influenza (above) or surgical site infections (below).

Do masks reduce operating room infections?

People ask: "if masks don't work, then why do medical personnel wear them in operating rooms?". The "answer" is not what most people think:

Excerpt from: "Is a mask necessary in the operating theatre?" (1981). Annals of the Royal College of Surgeons of England (1981) vol. 63 pp. 390-392

"No masks were worn in one operating theatre for 6 months. There was no increase in the incidence of wound infection... there was an appreciable fall in the wound infection rate when masks were not worn [which] certainly warrants further investigation... The conclusion is that the wearing of a mask has very little relevance to the wellbeing of patients undergoing routine general surgery and it is a standard practice that could be abandoned."

Excerpt from: "Postoperative Wound Infections and Surgical Face Masks: A Controlled Study" (1991). World Journal of Surgery 15, 383-388, 1991

"It has never been shown that wearing surgical face masks decreases postoperative wound infections. On the contrary, a 50% decrease has been reported after omitting face masks."

Excerpt from: "Surgical face masks in modern operating rooms-a costly and unnecessary ritual?" (1991). *Journal of Hospital Infection* (1991) 18, 239-242.

"The routine wearing of masks by all staff working in a modern operating room with forced ventilation is a costly and unnecessary ritual."

Excerpt from: "Does Evidence Based Medicine Support The Effectiveness Of Surgical Facemasks In Preventing Postoperative Wound Infections In Elective Surgery?" (2009). Journal of Ayub Medical College Abbottabad 2009;21(2)

"Conclusion: From the limited randomized trials it is still not clear that whether wearing surgical face masks harms or benefits the patients undergoing elective surgery."

Excerpt from: "Surgeon's garb and infection control: What's the evidence?" (2011). Journal of the American Academy of Dermatology, v 64, n 5

"Masks have not been shown to reduce overall bacterial counts within the operatory. Several studies have failed to show reductions in SSIs [surgical site infections] with the use of masks."

Excerpt from: "Current Concepts Review - Surgical Attire and the Operating Room: Role in Infection Prevention" (2014). The Journal of Bone and Joint Surgery. 2014;96:1485-92

"In conclusion, current literature has been unable to support the use of surgical masks in reducing rates of surgical site infection in the operating room"

Excerpt from: "Surgical Attire: Proceedings of International Consensus on Orthopedic Infections" (2019). The Journal of Arthroplasty general assembly section, prevention, volume 34, issue 2, supplement, \$97-\$104, 2019

"The use of face masks and surgical caps by inhabitants in the operating room (OR) has not been shown to impact SSI [surgical site infection] rates..."

<u>Here is a document</u> with links to about a dozen studies showing that masks probably do nothing to prevent operating room infections.

Books

Unmasked: The Global Failure of COVID Mask Mandates. (2022) by Ian Miller.

<u>Unreported Truths About Covid-19 and Lockdowns: Part 3: Masks</u>. (2020) by Alex Berenson (former NYT science writer). Amazon deplatformed (=removed=censored) this book, but re-listed it after Elon Musk made a fuss. This book has 3548 reviews on Amazon, 95% with four or five stars.

Additional references

An even more exhaustive annotated bibliography on the ineffectiveness (and downright *harmfulness*) of masks <u>can be found here</u>.