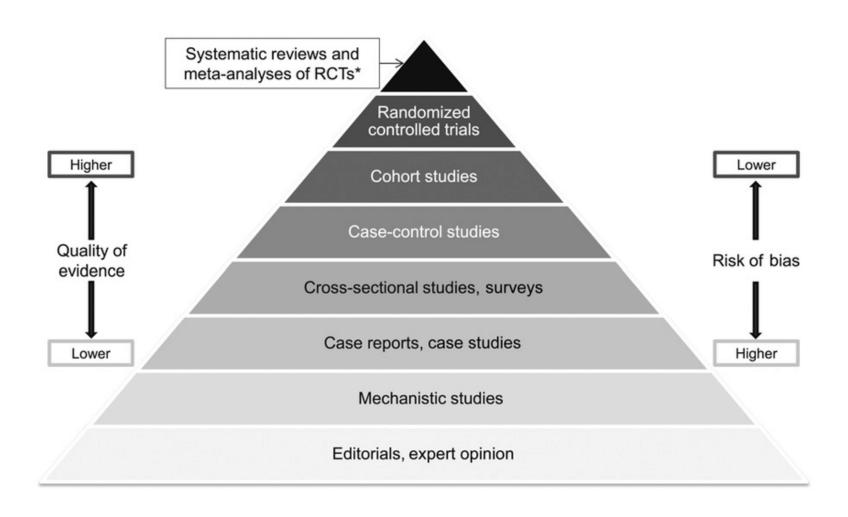
# Mask Research

## Hierarchy of Scientific Evidence



#### Meta Analyses

- 1 Xiao J, et al. Nonpharmaceutical Measures for Pandemic Influenza in Nonhealthcare Settings—Personal Protective and Environmental Measures. Emerg Infect Dis. 2020;26(5):967–975. <a href="https://dx.doi.org/10.3201/eid2605.190994">https://dx.doi.org/10.3201/eid2605.190994</a>
- 2 Wang MX, et al. Effectiveness of Surgical Face Masks in Reducing Acute Respiratory Infections in Non-Healthcare Settings: A Systematic Review and Meta-Analysis. Front Med (Lausanne). 2020;7:564280. Published 2020 Sep 25. doi:10.3389/fmed.2020.564280
- 3 Jefferson, T et al. 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. MedRxiv April 2020. doi: https://doi.org/10.1101/2020.03.30.20047217
- 4 Brainard J, et al. Facemasks and similar barriers to prevent respiratory illness such as COVID-19: A rapid systematic review. MedRxiv April 2020. doi: <a href="https://doi.org/10.1101/2020.04.01.20049528">https://doi.org/10.1101/2020.04.01.20049528</a>
- 5 Jefferson T, et al. Physical interventions to interrupt or reduce the spread of respiratory viruses. Cochrane Database of Systematic Reviews 2020, Issue 11. Art. No.: CD006207. DOI: 10.1002/14651858.CD006207.pub5. https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD006207.pub5/full
- 6 Does the use of face masks in the general population make a difference to spread of infection? The University of Edinburgh, Usher Institute; Usher Network for Covid19 Evidence Reviews. May 2020. https://www.ed.ac.uk/files/atoms/files/uncover\_003-03\_summary\_-\_facemasks\_community\_anon.pdf

## Meta Analyses (1 of 6)

"We did not find evidence that surgical-type face masks are effective in reducing laboratory-confirmed influenza transmission, either when worn by infected persons (source control) or by persons in the general community to reduce their susceptibility."

Xiao J, et al. Nonpharmaceutical Measures for Pandemic Influenza in Nonhealthcare Settings—Personal Protective and Environmental Measures. Emerg Infect Dis. 2020;26(5):967–975. https://dx.doi.org/10.3201/eid2605.190994

## Meta Analyses (2 of 6)

"Surgical mask wearing among individuals in non-healthcare settings is not significantly associated with reduction in [acute respiratory illness] incidence in this meta-review."

Wang MX, et al. Effectiveness of Surgical Face Masks in Reducing Acute Respiratory Infections in Non-Healthcare Settings: A Systematic Review and Meta-Analysis. Front Med (Lausanne). 2020;7:564280. Published 2020 Sep 25. doi:10.3389/fmed.2020.564280

## Meta Analyses (3 of 6)

"Compared to no masks there was no reduction of influenza-like illness (ILI) cases (Risk Ratio 0.93, 95%CI 0.83 to 1.05) or influenza (Risk Ratio 0.84, 95%CI 0.61-1.17) for masks in the general population, nor in healthcare workers (Risk Ratio 0.37, 95%CI 0.05 to 2.50)."

Jefferson, T et al. 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. MedRxiv April 2020. doi: <a href="https://doi.org/10.1101/2020.03.30.20047217">https://doi.org/10.1101/2020.03.30.20047217</a>

## Meta Analyses (4 of 6)

"The evidence is not sufficiently strong to support widespread use of facemasks as a protective measure against COVID-19."

Brainard J, et al. Facemasks and similar barriers to prevent respiratory illness such as COVID-19: A rapid systematic review. MedRxiv April 2020. doi: <a href="https://doi.org/10.1101/2020.04.01.20049528">https://doi.org/10.1101/2020.04.01.20049528</a>

## Meta Analyses (5 of 6)

"Pooled results from randomized trials did not show a clear reduction in respiratory viral infection with the use of medical / surgical masks during seasonal influenza. There were no clear differences between the use of medical / surgical masks compared to N95 / P2 respirators in healthcare workers when used in routine care to reduce respiratory viral infection."

Jefferson T, et al. Physical interventions to interrupt or reduce the spread of respiratory viruses. Cochrane Database of Systematic Reviews 2020, Issue 11. Art. No.: CD006207. DOI: 10.1002/14651858.CD006207.pub5. https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD006207.pub5/full

## Meta Analyses (6 of 6)

"This review found mixed and low quality epidemiological evidence on the use of face masks to prevent community transmission of respiratory illness," and, "Based on the epidemiological evidence, the effectiveness of face masks has not been demonstrated."

Does the use of face masks in the general population make a difference to spread of infection? The University of Edinburgh, Usher Institute; Usher Network for Covid19 Evidence Reviews. May 2020. <a href="https://www.ed.ac.uk/files/atoms/files/uncover\_003-03\_summary\_-">https://www.ed.ac.uk/files/atoms/files/uncover\_003-03\_summary\_-</a>
\_facemasks\_community\_anon.pdf

#### Danish RCT

No significant protective effect from wearing a mask in the first randomized controlled trial with masks and covid19.

"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 between-group difference was -0.3 percentage point (95% CI, -1.2 to 0.4 percentage point; P = 0.38) (odds ratio, 0.82 [CI, 0.54 to 1.23]; P = 0.33)."

Bundgaard H, et al. Effectiveness of Adding a Mask Recommendation to Other Public Health Measures to Prevent SARS-CoV-2 Infection in Danish Mask Wearers. 18 November 2020. Annals of Internal Medicine. https://doi.org/10.7326/M20-6817

#### Pro Mask Research

The evidence to support masking is lower quality and fraught with methodological issues like confounding factors, inconsistent testing, incomplete data, and timing.

- Case reports (hairdressers, cruises)
- Modeling
- Experiments (rats in cages, blowing into a tube)
- Observational
- Opinion pieces
- Flurry of papers that promote the above, while ignoring the higher quality evidence (including an NAS paper)

#### Pro Mask Research Examples

- Bangladesh Mask Study<sup>1</sup> only tested 10K subjects out of 300K, neglected to test those with symptoms, analysis should have been done by village, not individual. Difference in seropositivity was only 1 person in 1000. Oddly, seropositivity of cloth mask group was lower than the surgical mask group, yet one of the conclusions was that cloth masks don't work.
- Massachusetts schools<sup>2</sup> widely criticized due to inconsistent testing policy, timing, not accounting for seroprevalence, vaccination rates. Totally ignores the higher quality Spanish school study<sup>3</sup> that found no difference in infection rates in grades that masked and those that didn't and analysis of CDC data<sup>4</sup> that included more data over longer time period.
- 1 Abaluck J, et al. The Impact of Community Masking on COVID-19: A Cluster-Randomized Trial in Bangladesh. 2021 Aug 31.
- 2 Cowger TL, et al. Lifting Universal Masking in Schools Covid-19 Incidence among Students and Staff List of authors. New England Journal of Medicine. November 9, 2022 doi: 10.1056/NEJMoa2211029
- 3 Coma E, et al. 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)Archives of Disease in Childhood Published Online First: 23 August 2022. doi: 10.1136/archdischild-2022-324172
- 4 Chandra, Ambarish and Høeg, Tracy Beth, Revisiting Pediatric COVID-19 Cases in Counties With and Without School Mask Requirements—United States, July 1—October 20 2021. Available at SSRN: <a href="https://ssrn.com/abstract=4118566">https://ssrn.com/abstract=4118566</a> or <a href="https://dx.doi.org/10.2139/ssrn.4118566">https://dx.doi.org/10.2139/ssrn.4118566</a>

#### Major Issue - Leakage Jets

Masks without a tight seal simply redirect airflow. No seal, no protection.

"Surgical and handmade masks, and face shields, generate significant backward leakage jets that have the potential to disperse virus-laden fluid particles by several metres."

Viola I, et al. Face Coverings, Aerosol Dispersion and Mitigation of Virus Transmission Risk. Engineering in Medicine and Biology. 2021. doi: 10.1109/OJEMB.2021.3053215

#### Major Issue - Leakage Jets

"Surgical masks are not designed for use as particulate respirators and do not provide as much protection as an N-95 respirator. Most surgical masks do not effectively filter small particles from air and do not prevent leakage around the edge of the mask when the user inhales."

CDC Respirator Fact Sheet

https://www.cdc.gov/niosh/npptl/topics/respirators/factsheets/respsars.html

#### **N95**

- N95s have better filtering capacity and ability to reduce leakage jets, however they have not been found to be superior to surgical masks<sup>1</sup>.
- CFR1910.134 stipulates that people need to be medically cleared to wear an N95, professionally fit tested, and trained in proper use.
- In a community setting, only 12.6% of subjects properly fitted their N95 mask<sup>2</sup> despite written and visual instructions.
- Extrapolating data from Aerosol Science and Technology<sup>3</sup> indicates that a 3.2% leakage area brings mask efficacy down to zero.

1 Smith JD, et al. Effectiveness of N95 respirators versus surgical masks in protecting health care workers from acute respiratory infection: a systematic review and meta-analysis CMAJ May 17, 2016 188 (8) 567-574; DOI: <a href="https://doi.org/10.1503/cmaj.150835">https://doi.org/10.1503/cmaj.150835</a>

2 Yeung W, et al. Assessment of Proficiency of N95 Mask Donning Among the General Public in Singapore. JAMA Netw Open. 2020;3(5):e209670. doi:10.1001/jamanetworkopen.2020.9670

3 Drewnick F, et al. Aerosol filtration efficiency of household materials for homemade face masks: Influence of material properties, particle size, particle electrical charge, face velocity, and leaks, Aerosol Science and Technology, 55:1, 63–79, doi: 10.1080/02786826.2020.1817846

Ritter MA, et al. The operating room environment as affected by people and the surgical face mask. Clin Orthop Relat Res. 1975 Sep;(111):147–50. doi: 10.1097/00003086-197509000-00020. PMID: 1157412.

Laslett LJ, et al. Wearing of caps and masks not necessary during cardiac catheterization. Cathet Cardiovasc Diagn. 1989 Jul;17(3):158–60. doi: 10.1002/ccd.1810170306. PMID: 2766345

Tunevall TG. Postoperative wound infections and surgical face masks: a controlled study. World J Surg. 1991 May–Jun;15(3):383–7; discussion 387–8. doi: 10.1007/BF01658736. PMID: 1853618.

Lahme T, et al. Patientenmundschutz bei Regionalanästhesien. Hygienische Notwendigkeit oder entbehrliches Ritual? [Patient surgical masks during regional anesthesia. Hygenic necessity or dispensable ritual?]. Anaesthesist. 2001 Nov;50(11):846–51. German. doi: 10.1007/s00101-001-0229-x. PMID: 11760479.

Tunevall TG, et al. Influence of wearing masks on the density of airborne bacteria in the vicinity of the surgical wound. Eur J Surg. 1992 May;158(5):263–6. PMID: 1354489.

Bahli ZM. Does evidence based medicine support the effectiveness of surgical facemasks in preventing postoperative wound infections in elective surgery? J Ayub Med Coll Abbottabad. 2009 Apr–Jun;21(2):166–70. PMID: 20524498.

Ha'eri GB, et al. The efficacy of standard surgical face masks: an investigation using "tracer particles". Clinical Orthopaedics and Related Research. 1980 May(148):160–162. PMID: 7379387.

Skinner, et al. (2001). Do Anaesthetists Need to Wear Surgical Masks in the Operating Theatre? A Literature Review with Evidence-Based Recommendations. Anaesthesia and intensive care. doi: 10.1177/0310057X0102900402. PMID: 11512642.

Vincent M, et al. Disposable surgical face masks for preventing surgical wound infection in clean surgery. Cochrane Database Syst Rev. 2016 Apr 26;4(4):CD002929. doi: 10.1002/14651858.CD002929.pub3. PMID: 27115326; PMCID: PMC7138271.

Ritter called it way back in 1975:

"The wearing of a surgical face mask had no effect upon the overall operating room environmental contamination and probably work only to redirect the projectile effect of talking and breathing."

Ritter MA, et al. The operating room environment as affected by people and the surgical face mask. Clin Orthop Relat Res. 1975 Sep;(111):147–50. doi: 10.1097/00003086-197509000-00020. PMID: 1157412.

"To examine the efficacy of currently used synthetic-fiber disposable face masks in protecting wounds from contamination, human albumin microspheres were employed as 'tracer particles,' and applied to the interior of the fact mask during 20 operations. At the termination of each operation, wound irrigates were examined under the microscope. Particle contamination of the wound was demonstrated in all experiments. Since the microspheres were not identified on the exterior of these face masks, they must have escaped around the mask edges and found their way into the wound."

Ha'eri GB, et al. The efficacy of standard surgical face masks: an investigation using "tracer particles". Clinical Orthopaedics and Related Research. 1980 May(148):160–162. PMID: 7379387.

"From the limited results it is unclear whether the wearing of surgical face masks by members of the surgical team has any impact on surgical wound infection rates for patients undergoing clean surgery."

Vincent M, et al. Disposable surgical face masks for preventing surgical wound infection in clean surgery. Cochrane Database Syst Rev. 2016 Apr 26;4(4):CD002929. doi: 10.1002/14651858.CD002929.pub3. PMID: 27115326; PMCID: PMC7138271.

If masks don't work even for larger particles like the ones in the surgeon mask studies, how can they work for tiny, smoke-like respiratory aerosols?

#### Harms of Masks – More Lethal Infections

Masks may make infections more lethal.

"A parallelization analysis based on county-level data showed that in Kansas, counties with mask mandate had significantly higher case fatality rates than counties without mask mandate, with a risk ratio of 1.85 (95% confidence interval [95% CI]: 1.51–2.10) for COVID-19-related deaths."

"These findings suggest that mask use might pose a yet unknown threat to the user instead of protecting them, making mask mandates a debatable epidemiologic intervention. The cause of this trend is explained herein using the "Foegen effect" theory; that is, deep re-inhalation of hypercondensed droplets or pure virions caught in facemasks as droplets can worsen prognosis and might be linked to long-term effects of COVID-19 infection."

Fögen, Zacharias MD\* The Foegen effect, Medicine: February 18, 2022 - Volume 101 - Issue 7 - p e28924 doi: 10.1097/MD.000000000028924

## Harms of Masks – Nano/Micro Particles

Researchers have found respirable plastic and fibrous debris on the inside of masks in the micron and sub micron range. Inhaling these fibers can cause:

"...stress and inflammation in the human respiratory tract and exacerbate vulnerability to viral infection."

"Respirable hazards such as micro(nano)plastics present in these may escalate from once an occupational hazard to a public health issue."

Han J, et al. Need for assessing the inhalation of micro(nano)plastic debris shed from masks, respirators, and home-made face coverings during the COVID-19 pandemic. Environ Pollut. 2021;268(Pt B):115728. doi:10.1016/j.envpol.2020.115728

#### Harms of Masks – Nano/Micro Particles

Jenner et al have identified a number of microplastic particles in human lung tissue. (This isn't a mask study, I just included it to show that we can inhale significant microplastics even when the source of microplastics isn't directly covering the nose and mouth.)

"These results support inhalation as a route of exposure for environmental MPs [micro plastics]."

Jenner LC, et al. Detection of microplastics in human lung tissue using  $\mu$ FTIR spectroscopy. Science of The Total Environment Volume 831, 20 July 2022, 154907.

#### Harms of Masks - Carcinogens

We inhale suspected human carcinogens from the mask.

"Although titanium dioxide (TiO2) is a suspected human carcinogen when inhaled, fiber-grade TiO2 (nano)particles were demonstrated in synthetic textile fibers of face masks intended for the general public."

Verleysen E, et al. Titanium dioxide particles frequently present in face masks intended for general use require regulatory control. Sci Rep 12, 2529 (2022). <a href="https://doi.org/10.1038/s41598-022-06605-w">https://doi.org/10.1038/s41598-022-06605-w</a>

#### Harms of Masks - Toxins

"The toxicity of some of the chemicals found and the postulated risks of the rest of the present particles and molecules, raises the question of whether [disposable plastic face masks] are safe to be used on a daily basis and what consequences are to be expected after their disposal into the environment."

Sullivan GL, et al. An investigation into the leaching of micro and nano particles and chemical pollutants from disposable face masks - linked to the COVID-19 pandemic, Water Research, Volume 196, 2021, 117033, ISSN 0043-1354, https://doi.org/10.1016/j.watres.2021.117033.

#### Harms of Masks - Microbes

Masks are filthy. People were forced to breath through these contaminated masks for 8 hours a day, including during exercise.

- Blachere FM, et al. Assessment of influenza virus exposure and recovery from contaminated surgical masks and N95 respirators. J Virol Methods. 2018 Oct;260:98–106. doi: 10.1016/j.jviromet.2018.05.009. Epub 2018 Jul 17. PMID: 30029810; PMCID: PMC6482848.
- Zhiqing L, et al. Surgical masks as source of bacterial contamination during operative procedures. J Orthop Translat. 2018 Jun 27;14:57–62. doi: 10.1016/j.jot.2018.06.002. PMID: 30035033; PMCID: PMC6037910.
- Chughtai AA, et al. Contamination by respiratory viruses on outer surface of medical masks used by hospital healthcare workers. BMC Infect Dis. 2019 Jun 3;19(1):491. doi: 10.1186/s12879-019-4109-x. PMID: 31159777; PMCID: PMC6547584.
- Park AM, et al. Bacterial and fungal isolation from face masks under the COVID-19 pandemic. Sci Rep 12, 11361 (2022). https://doi.org/10.1038/s41598-022-15409-x

#### Conclusion

Based on this data (and more), it's fair to question the efficacy and safety of masks. Any public health measure, especially when coerced, should rely on the highest quality of evidence.

## Thank you!

I deeply appreciate that you have spent your valuable time investigating this controversial topic.