Questions for OSHA from Rational Ground

Agenda

- Questions
- Knowing Your Enemy: Virus-Carrying Respiratory Aerosol Size
- Alert to Potential, Unstudied Harms
- Deep-dive: Concerns on Filtration and Safety

What is Goal and Scope?

- Which pathogens?
 - COVID, Flu, all Respiratory illnesses?
- **Time frame?** Until? Every Respiratory virus season?
- Protection?
 - Vulnerable workers, all workers, can workers electing not to be "protected" opt-out?
- Would protection include a requirement to stop transmission in a workers' environment?
 - E.g., children in schools masked to protect teachers, patrons masks to protect performers, shoppers masked to protect shop workers?
- To which industries would this apply? White collar, too? What exceptions?
- What happens when an employee contracts a viral illness at work, despite the employer following the rules. Mightn't this presumption of protection expose employers?
- Have standards been considered to clearly define the vulnerable population, and develop stronger standards to protect them?
 Rather than all workers?

The First Rule of Defense: Know Your Enemy

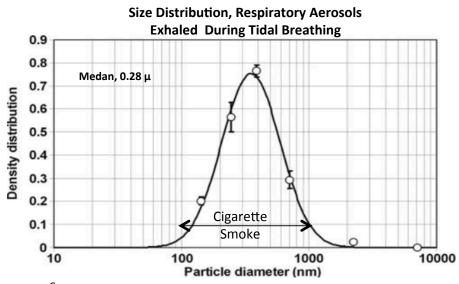
Airborne transmission arises through the inhalation of aerosol droplets exhaled by an infected person and is now thought to be the primary transmission route of COVID-19. By

Source: https://www.pnas.org/content/118/17/e2018995118

Significance

Lack of human data on influenza virus aerosol shedding fuels debate over the importance of airborne transmission. We provide overwhelming evidence that humans generate infectious aerosols and quantitative data to improve mathematical models of transmission and public health interventions. We show that sneezing is rare and not important for—and that coughing is not required for—influenza virus aerosolization. Our findings, that upper and lower airway infection are independent and that fine-particle exhaled aerosols reflect infection in the lung, opened a pathway for a deeper understanding of the human biology of influenza infection and transmission. Our observation of an association between repeated vaccination and increased viral aerosol generation demonstrated the power of our method, but needs confirmation.

<u>Yan et al, 2017: Infectious virus in exhaled breath of symptomatic</u> seasonal influenza cases from a college community.



Sources:

Respiratory aerosols https://www.liebertpub.com/doi/10.1089/jamp.2009.0809 Cigarette smoke particle distribution:

https://www.sciencedirect.com/science/article/abs/pii/0095852260900374

It is now widely thought that respiratory aerosols generated during normal breathing—the majority of which are less than 0.3 microns (the same size as cigarette smoke)—are the primary method of transmission for respiratory viruses.

The First Rule of Defense: Know Your Enemy (cont.)

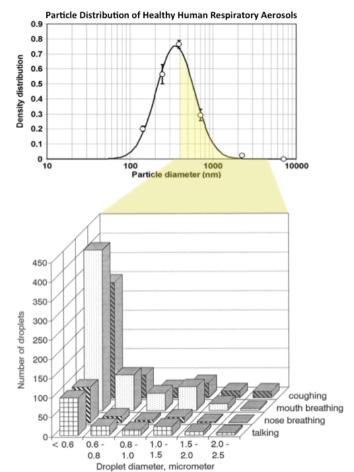
tidal breathe and patients did not cough during sample collection. The data also suggest that influenza virus RNA is contained in fine particles because over 87% of the exhaled particles were under 1 μ m and less than 0.1% were larger than 5 μ m. This distribution of particle sizes is consistent with previous studies showing that 98% of particles produced during normal breathing are under 1 μ m [6]–[8]. Thus, based on the particle size distribution, it is unlikely that

 μ m and <5 μ m), and 0 to 9 L⁻¹ (\geq 5 μ m). Figure 1 presents the averaged size distribution of the particles measured from all 10 subjects. On average 70% of the particles measured were between 0.3 μ m and <0.5 μ m, 17% between 0.5 μ m and <1 μ m, and 13% between 1 μ m and <5 μ m. Particles larger than 5 μ m were rarely recorded (<0.1%). Of the 10 subjects, 50%

Source: https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0002691

Particle Volumes (μ^3) & Time to Settle 2 m (hrs) for Various Particle Sizes

	0.2 μ	0.5 μ	1 μ	2 μ	5 μ	7 μ	10 μ
Volume	0.03	0.5	4.2	33	523	1,436	4,187
Settling Time	456	66	18	4.5	0.75	0.33	0.2



Source: Papieni & Rosenthal, 1997:

https://www.liebertpub.com/doi/10.1089/jam.1997.10.105

While there are some respiratory aerosols generated above 1 micron, and specifically above 5 microns, these larger, easier-to-contain aerosols contain only a tiny fraction of the virus.

Mechanistic Studies Showing Promise of Masks, not Borne Out Empirically or via RCTs

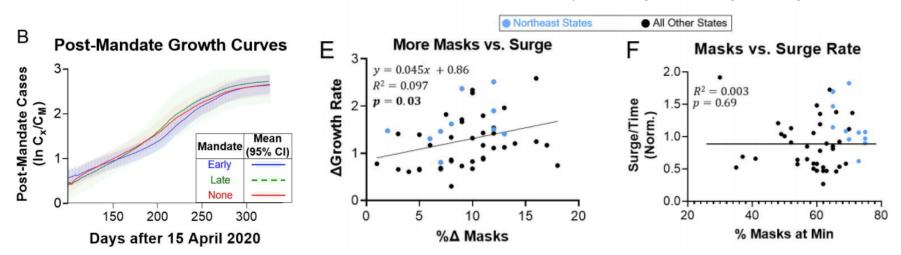
CDC Meta-Analysis of Mask and other NPI RCTs (May 2020)

Abstract

There were 3 influenza pandemics in the 20th century, and there has been 1 so far in the 21st century. Local, national, and international health authorities regularly update their plans for mitigating the next influenza pandemic in light of the latest available evidence on the effectiveness of various control measures in reducing transmission. Here, we review the evidence base on the effectiveness of nonpharmaceutical personal protective measures and environmental hygiene measures in nonhealthcare settings and discuss their potential inclusion in pandemic plans. 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.

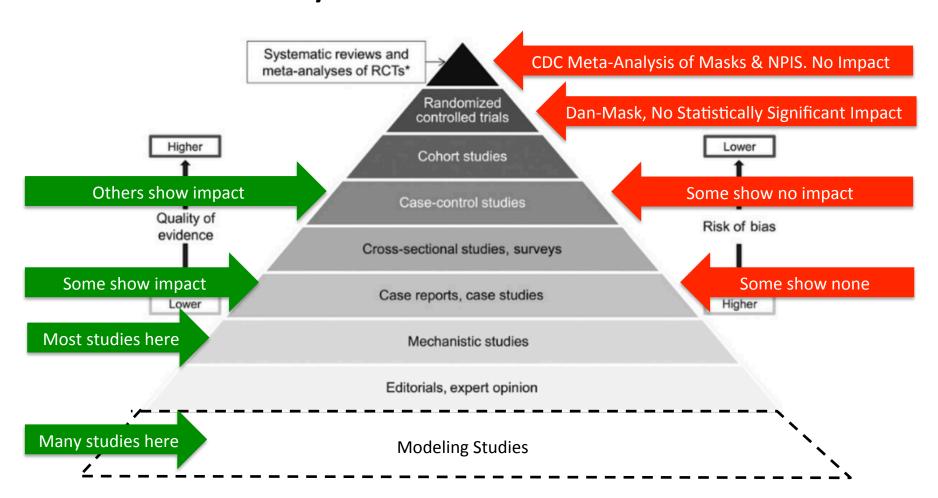
Source: https://wwwnc.cdc.gov/eid/article/26/5/19-0994 article

Conclusions: Mask mandates and use are not associated with slower state-level COVID-19 spread during COVID25 19 growth surges.



Source: https://www.medrxiv.org/content/10.1101/2021.05.18.21257385v1.full.pdf

High-Quality Evidence Indicates No Effect, Low Quality Evidence Indicates Effect.



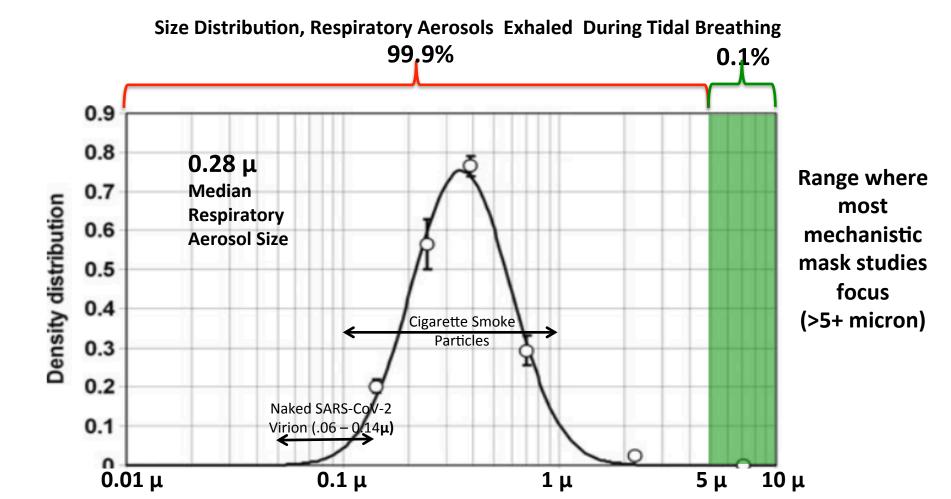
Why the disconnect?

3 Reasons Studies ≠ Reality 1: Mechanistic Studies Look at Wrong Size

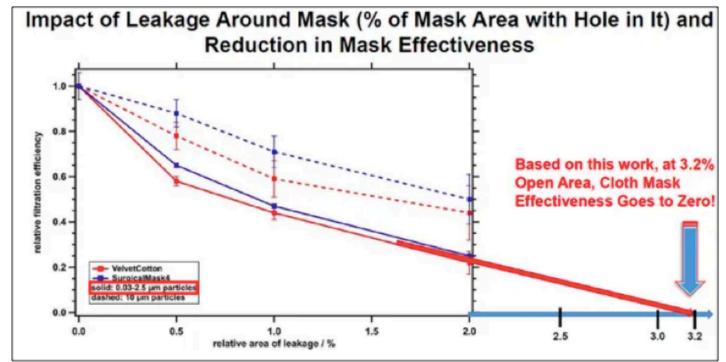
0.3 Microns

The majority of respiratory aerosols are this size or smaller.

The lower limit of most instrumentation used to measure aerosols, and how much virus they carry.



3 Reasons Studies ≠ Reality 2: They Ignore the Importance of Gaps



Source:

https://www.tandfonline.com/doi/full/10.1080/02786826.2020.1817846

1% gap in N-95, < and > 300 nm

Table 1. Filtration Efficiencies of Various Test Specimens at a Flow Rate of 1.2 CFM and the Corresponding Differential Pressure (ΔP) across the Specimen<u>a</u>

	flow rate: 1.2 CFM				
sample/fabric	<300 nm average ± error	>300 nm average ± er			
N95 (no gap)	85 ± 15	99.9 ± 0.1			
N95 (with gap)	34 ± 15	12 ± 3			

Source: https://pubs.acs.org/doi/10.1021/acsnano.0c0325212

3 Reasons Studies ≠ Reality 3: They Use Mass/Volume to Evaluate

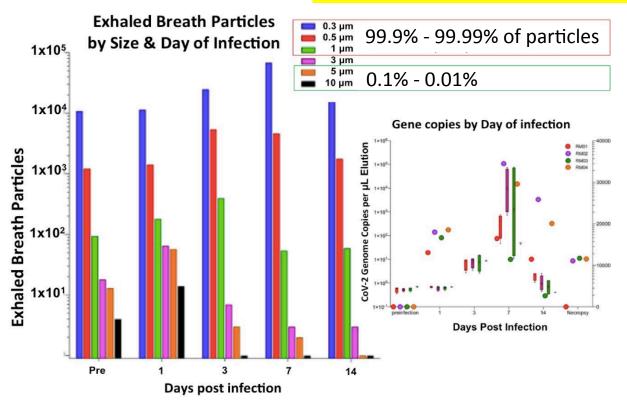
Particle Volumes (µ³) & Time to Settle 2 m (hrs) for Various Particle Sizes

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Settling Velocities: https://www.liebertpub.com/doi/full/10.1089/jamp.2020.1616

In this study, on the same day viral load peaks (NP), aerosols <0.3 microns increase by 7-fold, to almost 70K. Those over 1 micron decrease to fewer than 10.

Even on day 7,
when there are
more than 80K
particles <1
micron, those over
1 micron (fewer
than 10) make up
more than 90% OF
THE VOLUME.



Source: https://www.pnas.org/content/118/8/e2021830118

Limited Efficacy in Stopping Least Numerous

% of Respiratory Aerosols

% of Aerosols Observed

Mean Viral RNA copies /

Multiple of Viral Copies

Estimated Surgical Mask

Estimated Surgical Mask

efficacy (protection)

Efficacy, 3% Gap

N-95 (Protection)

(Transmission)

N-95, 1% gap

(Transmission)

30" sample (Yan et al, 2017)

Size Range (μ)

Settling Times

w/viral RNA

observed

(Yan et al, 2017)

Particles, Which Settle Fastest

.0 - 0.3

~ 50%

19 days

 (0.2μ)

Below

Observation

Threshold

Below

Observation

Threshold

0%

0%

60 - 80%

35%

0.3 - 0.5

~ 35%

66 hrs (0.5 μ)

0%

0%

100%

12%

0.5 - 1

~ 13%

18 hours

 (1.0μ)

76%

(40% infectious)

38,000

8.8

(not split out)

20 - 50%

0%

100%

12%

1 - 5

~ 1.9%

45 "

 (5μ)

50 - 70%

20%

100%

12%

5+

<0.1%

45 " (5 μ)

12 " (10 μ)

40%

(0 infectious)

12,000

1

70%

0-50%

100%

12%

38,000 Viral Copies of RNA Generated in 30 Minutes. Estimates of Infectious dose is 10 – 300 copies

	0.3-0.5 micron	0.5 - 1 micron	1-5 micron	Total	% Of infectious virus removed
% Of particles between 0.3 and 5 micron	70%	26%	4%	100%	-
# Of Viral Copies (30")	26,600	9,880	1,520	38,000	-
# Of Viral Copies Infectious (40%)	10,640	3,952	608	15,200	-
# Of Infectious Viral Copies Kept out by Surgical Mask	-	790	304	1,094	7.2%
# Of Infectious Viral Copies Stopped From Via Surgical Masks	-	-	122	122	0.8%

	0-3-0.5 microns	0.5-1 micron	1-5 microns	Total	% Effectiveness, Infectiousness
Time to Settle	66 hours	18 hours	45"		
% of Infectious Virus	70%	26%	4%		
Infectiousness (# of particles w/infectious RNA * Hours aloft)	702,240	71,136	456	773,832	
Protection from Infectiousness by Surgical Mask	0	14,227	228	14,455	1.9%
Reducing Infectiousness by containing infectious virus	0	0	91	91	0.012%

In a given 30" period, 15,000 copies of infectious viral RNA can be generated via breathing. The infectious dose is 10-300—Less than 2% of the virus generated. Masks filter ~7% of those, the least infectious, that settle fastest. They stop transmission of <1%

Despite a raft of studies of low evidence-quality, including mechanistic, ecological and modeling studies suggesting masks might work to reduce transmission or provide protection from respiratory viruses, higher quality evidence and the past years' worth of empirical data continue to argue the opposite.

The reason for this disconnect is almost certainly due to these mechanistic and modeling studies to focus their efforts on the aerosols that are easiest to measure—those over 5 microns (but which make up less than 0.1% of all respiratory aerosols)—but ignore those aerosols making up the other 99.99%.

As OSHA considers a standard to require employers to provide protection from respiratory viruses, it must rectify these errors.

There is significant evidence suggesting that the majority of virus is also carried in the smallest aerosols—those less than 0.3 microns. Given that these are by far the most numerous, this would follow logically. But the challenge of measurement has made this challenging to confirm.

If OSHA is to provide a meaningful standard of protection, these knowledge gaps must be filled. Otherwise, vulnerable workers may be made to feel safe by PPE which provides no meaningful protection. Depending on the pathogen, this would put these workers at significant risk—risk which would have been sanctioned by OSHA.

A False Sense of Security

Respiratory Aerosols Carrying the Majority of Infectious Respiratory Viruses

Are the same size & Distribution as Cigarette Smoke



Double-Layer Fabric

Surgical

KN-95

Double-mask KN-95 + Fabric

Triple-mask KN-95 + Fabric + Gaitor

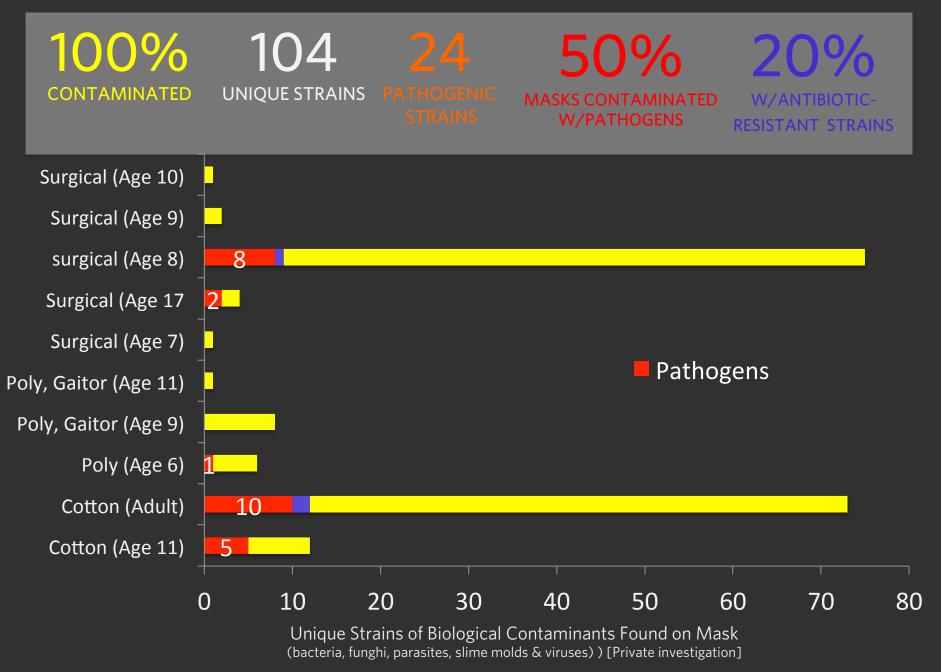
Videos available here: https://youtu.be/gK40iqHD6qQ

At-risk people have been given a dangerous false sense of security by wearing, and seeing others wear these kinds of masks. If they can smell cigarette smoke, they are not protected from COVID or other respiratory viruses

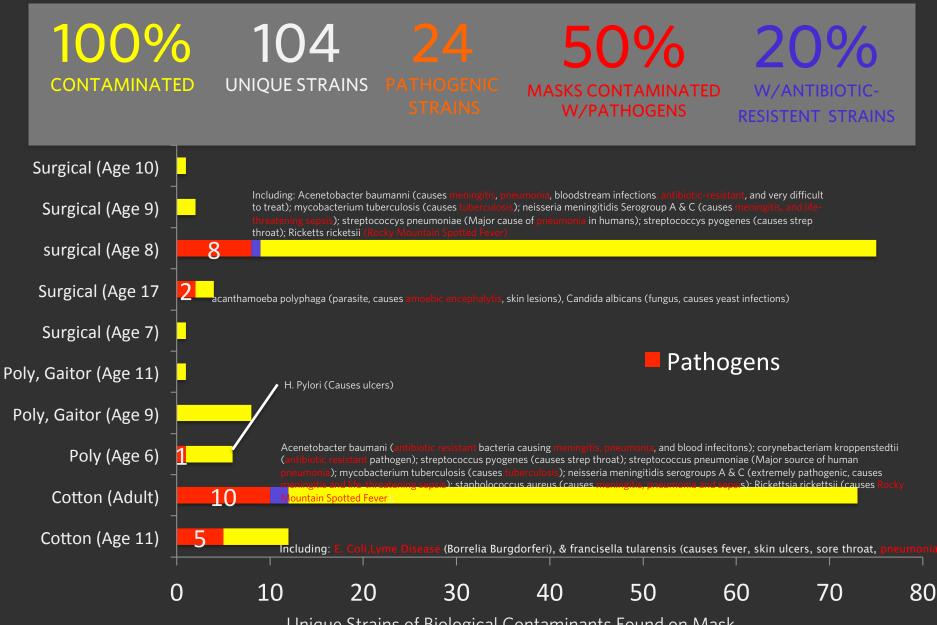
Current standards developed for wear for minutes, not hours at a time

- Potential for bacterial infection, see next slides, for examples of science that isn't being done, and can't get published.
- Impact on cognition, well-being, airflow for long-term wear.
- For children, impact on social and emotional growth.
- Fear cues, etc., etc..

10 MASKS, WORN FOR AN AVERAGE OF 7.9 HOURS/DAY

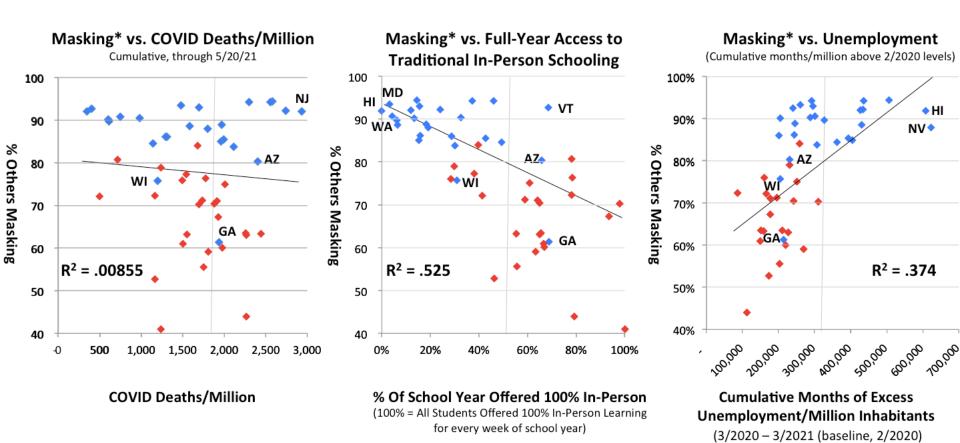


10 MASKS, WORN FOR AN AVERAGE OF 7.9 HOURS/DAY



Unique Strains of Biological Contaminants Found on Mask (bacteria, funghi, parasites, slime molds & viruses) [Private investigation]

Masking is not tied to decreased deaths, but is tied to low-levels of access to in-person education, and high unemployment



Sources:

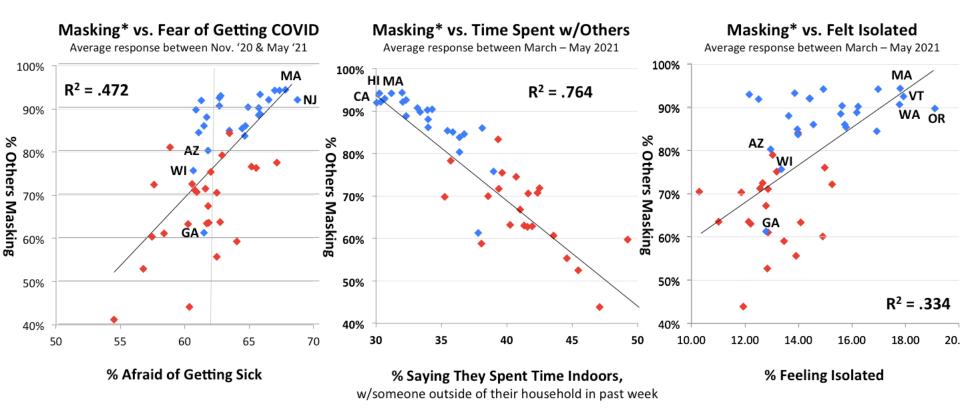
Masking: The Delphi Group at CMU, https://delphi.cmu.edu/covidcast/export/ Daily survey of 225K people, *Data represents daily average for each state between 11/29/20 and 5/20/21 "What portion of people around you are wearing masks?"

Deaths/Million: www.Worldometers.info, 05/20/21

Unemployment: www.bls.gov. Monthly data by state, 2/2020 - 3/2021. Excess defined as the amount of unemployed / month / million above the baseline level of 2/2020.

Access to In-Person Education: www.burbio.com, calculated weekly, the % of children in each state, each week with access to 100% in-person schooling, relative to the expected number of in-person school weeks that would have been offered.

High levels of mask-induced fear may contribute to hesitancy to teach in-person, have children attend school, or disinclination to patronize businesses.



Sources:

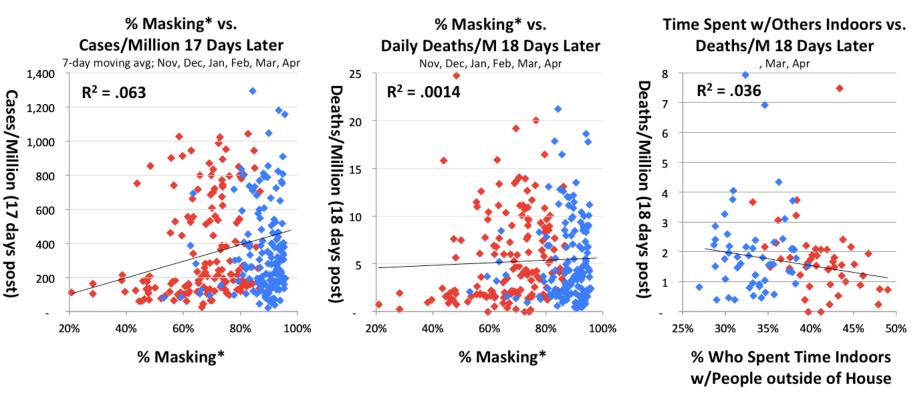
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Fear of Getting COVID: : The Delphi Group at CMU, https://delphi.cmu.edu/covidcast/export/ Daily survey of 225K people, *Data represents daily average for each state between Mar 21 and May 21 "Are you afraid of becoming ill with COVID?"

Time Spent with Others: The Delphi Group at CMU, https://delphi.cmu.edu/covidcast/export/ Daily survey of 225K people, *Data represents daily average for each state between Mar 21 and May 21 "Have you spent time indoors w/someone outside of your household in the past week?"

Have you felt Isolated: The Delphi Group at CMU, https://delphi.cmu.edu/covidcast/export/ Daily survey of 225K people, *Data represents daily average for each state between Mar 21 and May 21 "Do you feel isolated?"

None of these behaviors—masking or isolating from others is tied to reduced long- or short-term cases or deaths



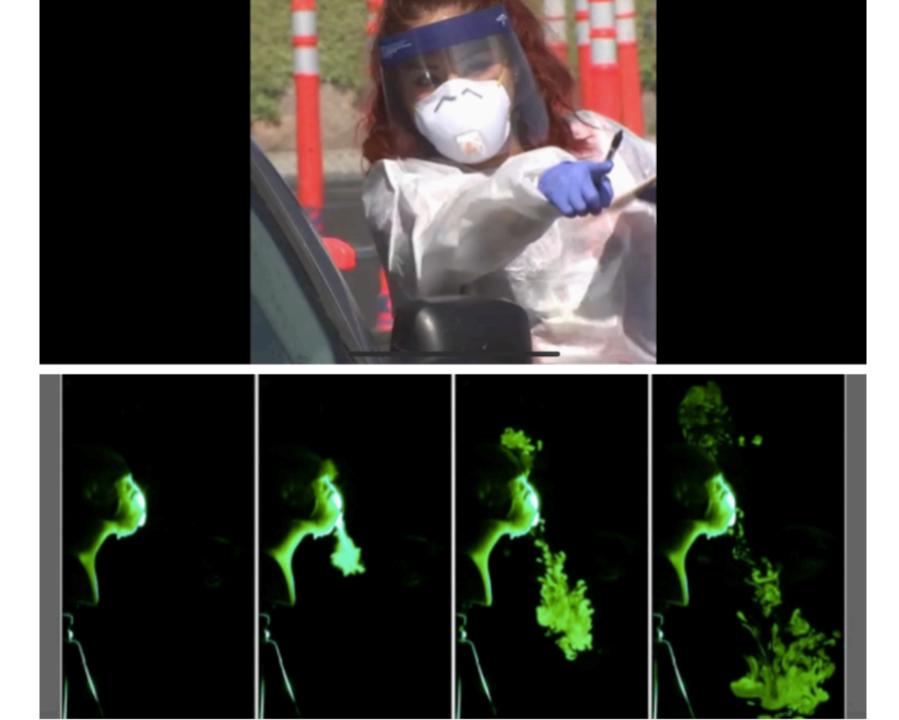
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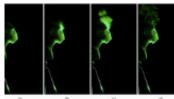
Time Spent with Others: The Delphi Group at CMU, https://delphi.cmu.edu/covidcast/export/ Daily survey of 225K people, *Data represents daily average for each state between Mar 21 and May 21 "Have you spent time indoors w/someone outside of your household in the past week?"

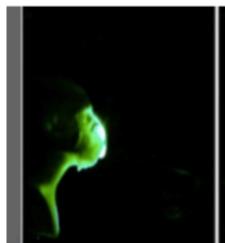
Cases and Deaths by day (7-day average) www.usafacts.org Masking or "time indoors responses were taken", for a given date of each month (the 29th*) of each month), the 7-day average for daily cases and deaths/million was then taken for 17 days after for cases, and 18 days after for deaths. These days were taken, because COVIDCast noted showed a statistically significant association. Analysis was done for all months with available data for each question.

Turning it Over to Megan Mansell

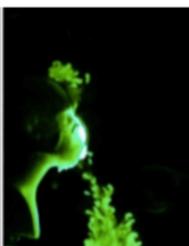


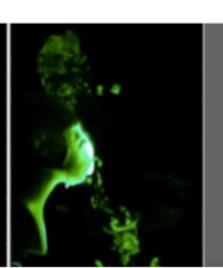


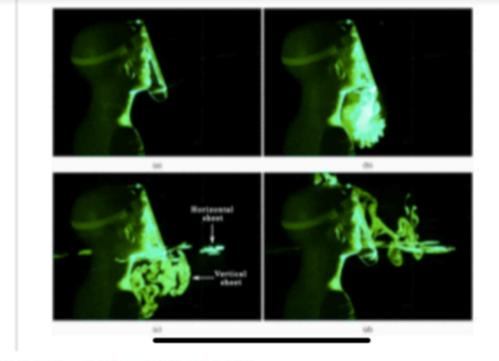


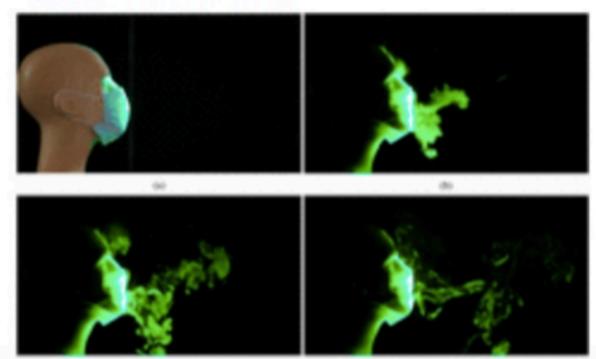














water vapor