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Evidence, values, and masks for control of COVID-19

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Ethics, to a large extent, represents navigating group and societal with individual and personal interests. Public health decisions are paradigmatic of this tension. In 1902, during a smallpox epidemic in the state of Massachusetts, Reverend Henning Jacobson refused to receive vaccination against smallpox [1]. He invoked his individual rights against ''arbitrary and oppressive'' laws, his religious beliefs, concerns about civil liberties, and safety records of the vaccines (apparently, he and his son had serious adverse reactions to earlier vaccinations). In 1905, the US Supreme Court ruled that the Board of Health Authority of Massachusetts had the right to require vaccination against smallpox during a smallpox epidemic [1]. The threat to the group was simply too large to accommodate personal beliefs.

In 1918, the influenza pandemic devastated the United States. Masks, typically made of gauze and cheesecloth, were the only recourse against the spread of the deadly virus. But, then, as now, during the current coronavirus disease 2019 (COVID-19) pandemic, some people resisted wearing masks, perceiving direction to do so as a threat to personal liberty [2].

Here, we argue that the tension between public and individual values, while inevitable, can be substantially reduced by clear communication of evidence, even imperfect evidence. In fact, perfect evidence indicating the absolute ''truth'' is theoretically impossible [3]. Nevertheless, in the best tradition of evidence-based medicine, evidence can narrow the difference between competing views [4]. It may even be that varying understanding of the evidence might explain alternative positions that appear to be driven by value differences [5]. For instance, some who advocate for legislated enforcement of mask use may temper their position if they are aware that risks of infection are extremely low even without mask use; those resisting mask use may temper their position if they believe mask use will result in an important reduction in risks to themselves and their loved ones. Knowing evidence—with all associated uncertainties—can narrow gaps in our disagreements seemingly driven by incompatible values [5].

We focus on the effects of masks, possibly one of the most important yet controversial tools currently available for controlling the COVID-19 pandemic. Evidence on the efficacy of masks for the prevention of COVID-19 is based on observational studies and was rated as ''low certainty'' by the authors of most comprehensive systematic review on the topic to date [6]. However, the authors also stated, ''The effect was very large [adjusted odds ratio (OR): 0.15; 95%CI: 0.07 to 0.34); unadjusted relative risk (RR): 0.34; 95%CI: 0.26 to 0.45], and the certainty of evidence could be rated up, but we made a conservative decision not to because of some inconsistency and risk of bias; hence, although the effect is qualitatively highly certain, the precise quantitative effect is low certainty.'' [6] The authors are making the point that when the effect size is very large (say relative risk reduction over 50%), such an effect can typically override combined effects of random error and biases [7−9]. Therefore, although existing evidence is insufficient to be certain of the magnitude of benefit, we can be confident that these interventions do result in some reduction in coronavirus transmission [6,10,11]. The effect is likely magnified when wearing masks is combined with physical distancing; evidence for the latter is judged to be of moderate certainty [6]. Because it is not known if the combined effects of masks and physical distancing are dependent or independent, additive or multiplicative, in this article, we focus only on the effect of masks on the prevention of COVID-19 cases and deaths. Thus, the results shown represent minimal projected effects—they may be much larger. Even so, these results appear convincing regarding the acceptable course of action.

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What is new?

Key findings

- Ethics, to the large extent, represents navigating group and societal with individual and personal interests.
- During COVID-19 pandemics, some people resisted wearing masks, perceiving direction to do so as a threat to personal liberty.
- It is well known that people pay attention to what others do. When the tradeoff between benefits and harms of a given intervention are uncertain, comparing the effects to some commonly accepted benchmarks may aid decision-making.
- Given that millions of people routinely use statins for primary prevention of heart disease even though effects are very small (NNT = 500), it is reasonable to suggest NNT of 500 as a reference point below which most people would accept intervention for low-frequency event.

What this adds to what was known?

- Based on NNT = 500 as a reference point, we calculated that people living in 96% counties (3,103) in the continental United States would readily accept wearing masks.

What is the implication and what should change now?

- We also found that dynamic of spread of SARS-CoV-2 virus in the continental United States indicate that few jurisdictions have remained free of infections, further suggesting that wearing masks may be acceptable to most Americans.

We first start with highlighting an important but often not fully appreciated fact: different communities have widely varying *incidence* and *prevalence* of COVID-19. The impact of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus on morbidity and mortality will be vastly different between high vs. low prevalence jurisdictions.

As a consequence, in low prevalence areas, we might be appropriately more tolerant of individuals electing not to adopt personal protection: failure to do so is unlikely to affect others. For example, the estimate in Oslo, Norway, in May 2020, put the infection rate at 10 cases per 100,000 people per week [12]. This would mean to prevent 6 COVID-19 cases per week, 1 million people would need to wear facemasks [12]. The authors of the report documenting the risk judged it too low to warrant imposing the burden of universal mask implementation [12].

To illustrate the potential impact of prevalence on COVID-19 in the United States, we estimated the effects of masks across the US counties included in the New York Times database using data on the effectiveness of masks cited earlier [6]. Taking a public health perspective on mask wearing, we estimated the impact of different compliance rates of wearing masks on COVID-19 infection and mortality.

Figure 1 illustrates the effects of wearing masks in high-prevalent areas of Winnebago, WI, and low-prevalent setting in Penobscot, Maine. (We only considered counties with a population of at least 100,000 and a history of at least 30 days of reported data.) Because COVID-19 is considered infectious for about 14 days, we calculated moving sums of active new COVID-19 cases and deaths in 15 days intervals from March 10 to October 22, 2020 (see Supplement for details). Note, however, that number of cases and deaths have changed over time. Penobscot, ME, remained one of the counties least affected by the pandemic throughout the period we analyzed. However, New York City, which was the leading COVID-19 ‘‘hot spot’’ in the United States until August 2020 has now been overtaken by Winnebago, WI, as the county with the highest percentage of cases and deaths because of COVID-19. Figure 2 shows that by October 22, 2020, the SARS-CoV-2 virus has substantially covered the entire continental United States. Thus, the lower risk areas, which may at one time have warranted lower vigilance, may no longer do so.

When the tradeoff between benefits and harms of a given intervention are uncertain, as is the case for the clinical and public health interventions and their associated social and economic costs for COVID-19, comparing the effects to some commonly accepted benchmarks may aid decision-making. Comparing the NNT for wearing masks (number of people who would need to wear the mask to prevent one COVID-19 infection or death, on average) with NNTs of commonly accepted medical interventions may provide guidance. Table 1 shows NNT for a number of widely accepted medical treatments compared with no interventions when there existed a low risk of serious adverse outcomes without treatment. The NNTs ranges from 36 (β-blockers for treatment of congestive heart failure) to 500 (statins for primary prevention of heart disease) [13].

Given that millions of people routinely use statins, it is reasonable to suggest NNT of 500 as a reference point below, which most people would accept intervention for low-frequency event. In our analysis, performed on October 22, 2020, almost 95% (561/591) of counties that have at least 30 days of reported data with more than 100,000 population had a prevalence that converts into NNT $\leq$500 for the effects of masks on preventing a new case of COVID-19. If this metrics is used for all (n = 3,103) continental US counties (Fig 2; total number of counties in the New York Times was 3,134. Fig 2 was based on data from

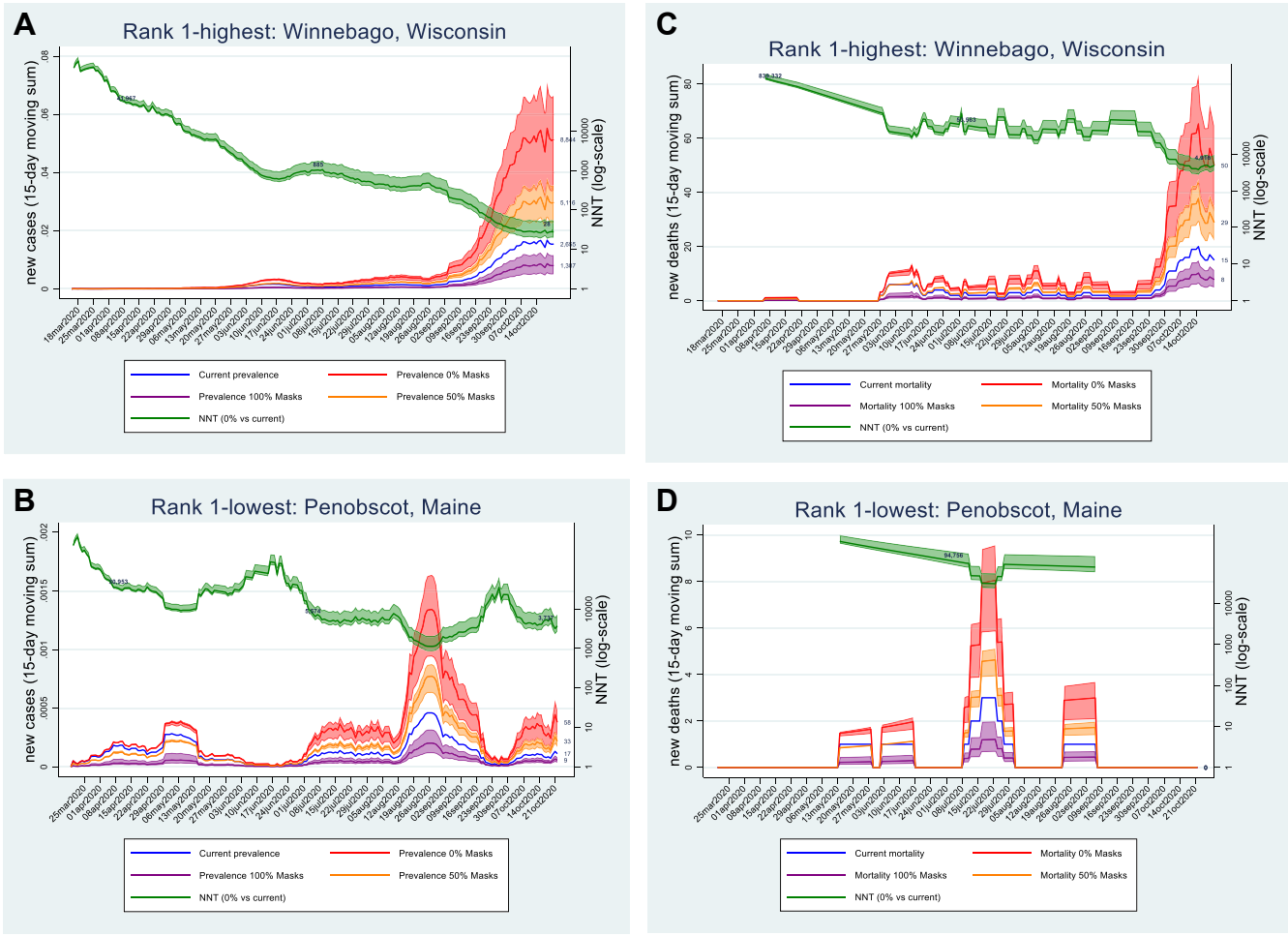

Fig. 1. Effect of wearing masks on the probability of getting COVID-19 and mortality because of COVID-19 in high (A, C) and low (B, D) prevalence area; the results expressed in terms of moving sum of the number of new cases and deaths in 15 days intervals from March 10 to October 22, 2020. (A, B): New cases (left Y-axis) and NNT (number of people who need to wear masks to prevent one new COVID-19 infection; right Y-axis). (C, D) Mortality (left Y-axis) and NNT (number of people who would need to wear the mask to prevent one COVID-19 death, on average; right Y-axis). Green line: NNT in high (A) or low (B) prevalence setting or deaths (C, D). Red line: assuming zero compliance with wearing masks and physical distancing. Purple line: assuming 100% compliance with wearing masks and physical distancing. Blue line: under best empirical estimate of compliance. Orange line: assuming 50% compliance throughout the study period. (Supplement provides details how the graphs were created). (For interpretation of the references to color in this figure legend, the reader is referred to the Web version of this article.)

3,103 counties in the continental US after excluding Alaska and Hawaii), then 2,993 (96%) counties could be expected to readily accept wearing masks.

The State of California [14] suggests an alternative benchmarks: ≤1 case/day/100,000 people (0–15 cases/15 days/100,000) as minimal risk, 1–3.9 cases/day/100,000 people (15–60 cases/15 days/100,000) as moderate, 4–7 cases/day/100,000 people (61–105 cases/15 days/100,000) as substantial, >7 cases/day/100,000 people (105–300 cases/15 days/100,000) as widespread risk. Using these thresholds, only three counties in the continental US are at minimal risk, and 27 at moderate risk. That is, more than 99% of counties in the continental US have at some point proved at substantial or widespread risk for the transmission of the SARS-CoV-2 virus.

Accepting NNT = 500 as a reference point, one can argue that with the proper public health messaging [15], most people would accept wearing mask. Thus, the findings that (1) interventions with NNT <500 are commonly accepted and (2) dynamic of spread of SARS-CoV-2 virus in the continental US indicate that few jurisdictions have remained free of infections suggest that wearing masks may be acceptable to most Americans. The findings also highlight that local control may not be sufficient without coordinated federal response across the country. One can further glean understanding of the impact of mask wearing from the calculation of its effects on cumulative number of cases or deaths if 100% vs. 0% of the population were compliant with these measures. Under these conditions, by October 2020, almost 26 million people would have

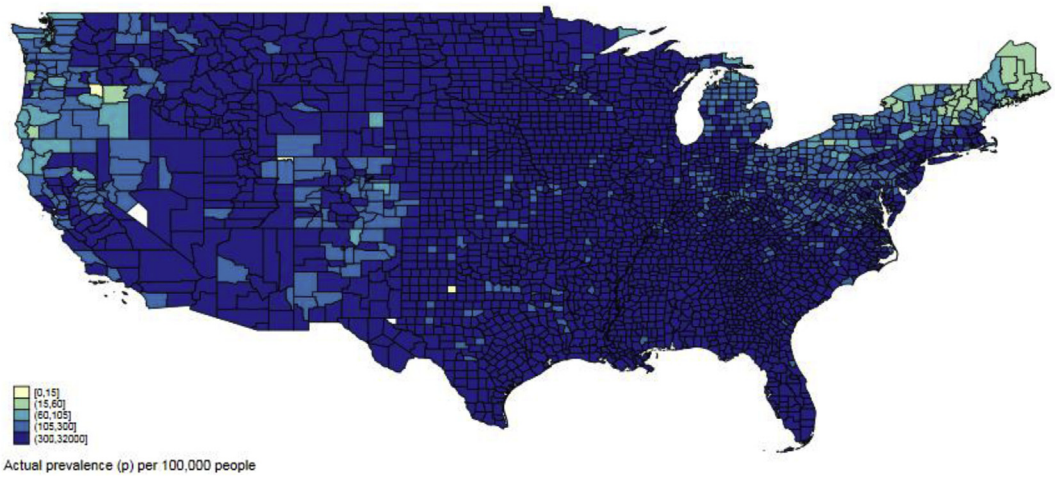

Fig. 2. Prevalence of COVID-19 in continental US across 3,103 counties. The colors indicate maximum number of cases that reached risk level according to the State of California guidelines at least once throughout the pandemic from March 10 to October 22, 2020. Yellow (*minimal risk*): 1 case/day/100,000 people (0–15 cases/15 days/100,000; *three counties)*; light blue (*moderate risk*): 1–3.9 cases/day/100,000 people (15–60 cases/15 days/100,000; *27 counties*); green (*substantial risk*) 4–7 cases/day/100,000 people (61–105 cases/15 days/100,000; *59 counties*); blue (*widespread risk*) > 7 cases/day/100,000 people split here in two categories: high risk: 105–300 cases/15 days/100,000; *530 counties*); and 300–32,000 cases/15 days/100,000; *2,484 counties*). *White*: presumably no data or no cases were reported in NYT database as of October 21, 2020). (For interpretation of the references to color in this figure legend, the reader is referred to the Web version of this article.)

fallen sick from COVID-19 in the continental US if no one had worn the mask (as opposed to 7.8 million by late October under current patchwork of compliance with masks and other public health measures such as keeping adequate physical distancing). On the other hand, this number could have been reduced by about half (to 4.1 million people infected by October 22, 2002) if everyone had worn the mask (Fig. 3A). The graphs also show estimates if we assume a 50% compliance rate. Similarly, if no one had worn the mask, more than 708,000 people would have died because of COVID19 by the end of October 2020 (as opposed to about 215,000 people recorded by this time). Had everyone worn the mask, this number would have fallen to about 114,000 (Fig. 3B).

Despite the associated uncertainties (effectiveness, number of and nature of contacts per person, and prevalence estimates), a message is clear: with the exception of a few low prevalence areas, data indicate that one could aggressively defend universal masking legal mandates [15] in the continental US. Such a risk-adapted approach would likely result in a large decrease in the number of COVID-19 cases and deaths across the United States without imposing undue violation of individual values. The prevalence data can be further combined with information regarding setting (indoors vs. outdoors), number and duration of contacts, and adequacy of ventilation to generate more nuanced, tailored approaches with respect to wearing face covering and physical distancing [16].

We conclude that the debate about wearing masks and observing physical distancing suffers from an insufficiently clear presentation of the evidence regarding the impact of these interventions on morbidity and mortality because of COVID-19. A focus on the evidence, along with encouragement to reflect on the implications, could potentially reduce the extent, or at least the intensity, of differences between opposing parties. Moreover, a focus on the evidence would improve the quality of decisions by those charged with balancing issues of safeguarding the health of the community vs. individual autonomy.

Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jclinepi.2020.11.020.

Table 1. Examples of numbers needed to treat (NNT) for common medical interventions[a] vs. COVID-19[b]

Condition or disorder	Intervention vs. no intervention	Risk without intervention[c]	NNT	Outcome[d]
COVID-19 (e.g., Winnebago, Wisconsin)	Mask vs. no masks	5.1%	28	Cases (9 counties $0 \leq$ NNT ≤ 36)
Congestive heart failure	β-blocker vs. placebo	8%	36	Overall mortality
History of coronary event	Implantation of cardioverter/defibrillator	5%	38	Risk of sudden death
Congestive heart failure	Spironolactone vs. placebo	8%	42	Overall mortality
Congestive heart failure	ACE inhibitor vs. placebo	8%	54	Overall mortality
COVID-19 (e.g., New York City, New York)	Mask vs. no masks	1.8%	80	Cases (203 counties $36 <$ NNT ≤ 150])
Nonvalvular atrial fibrillation	Warfarin vs. placebo	1.90%	85	Stroke
Survivors of myocardial infarction	ACE inhibitor therapy vs. placebo	4%	147	Overall mortality
COVID-19 (e.g., Los Angeles, California)	Mask vs. no masks	0.6%	253	Cases (226 counties $150 <$ NNT ≤ 300)
Survivors of curative resection for colorectal cancer	Intensive follow-up vs. usual care	2%	263	Overall mortality
Hypertension	ACE inhibitor vs. placebo	<1.5%	303	Fatal or nonfatal stroke or myocardial infarction
Survivors of curative resection for colorectal cancer	Adjuvant chemotherapy with fluorouracil and folinic acid vs. usual care	2%	312	Overall mortality
Rheumatoid arthritis treated with nonsteroidal anti-inflammatory drugs	Concurrent misoprostol vs. placebo	0.80%	312	Gastrointestinal complications
Persons without diagnosed cardiovascular disease	Aspirin vs. placebo	<2%	333	Any cardiovascular event[e]
HIV infection	Ritonavir vs. placebo	0.70%	340	AIDS-defining illness
Hypertension	Calcium antagonist vs. placebo	<1.5%	370	Fatal or nonfatal stroke or myocardial infarction
COVID-19 (e.g., Honolulu, Hawaii)	Mask vs. no masks	0.3%	419	Cases (105 counties $300 <$ NNT ≤ 500)
Persons without diagnosed cardiovascular disease	Statin therapy vs. placebo	<2%	500	Major cardiovascular event
COVID-19 (e.g., Penobscot, Maine)	Mask vs. no masks	0.04%	3,737	Cases (53 counties with NNT >500)

Abbreviations: ACE, angiotensin-converting enzyme; COVID-19, coronavirus disease 2019.

[a] Modified from ref #13 (restricted to placebo or no treatment as a comparator).

[b] Only counties ($n = 596$) with a population of at least 100,000 and a history of at least 30 days of reported data were considered (calculation refers to the assessment performed on October 22, 2020).

[c] All risk refers to what is considered a low risk of developing outcome without treatment.

[d] Unless otherwise specified, outcomes refer to 1 year time frame.

[e] During 5 years of treatment. Note that we restricted analyses to common and noncontroversial treatments. Some interventions in wide use such as use of screening mammography have NNT >500 but they are not without controversy.

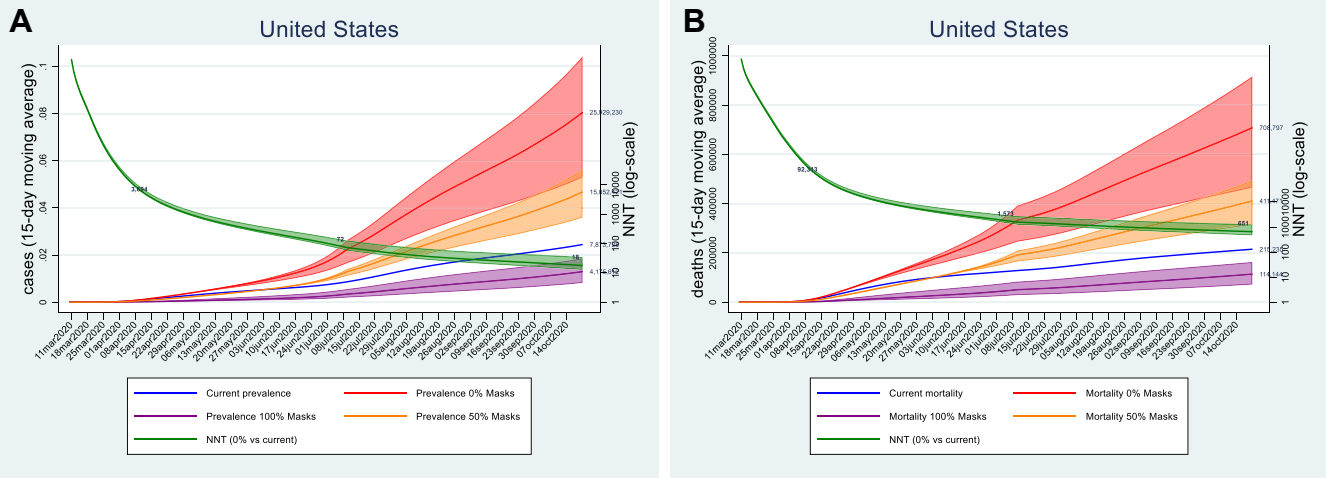

Fig. 3. Effect of wearing masks on the probability of getting COVID-19 in the US (left) (A) and mortality (right) (B). (see also text). (A): Prevalence (left Y-axis) and NNT (number of people who would need to wear the mask to prevent one COVID-19 infection or death (B), on average; right Y-axis). Green line: change of NNT over time as infection spreads (see also Fig. 2). Red line: assuming zero compliance. Purple line: assuming 100% compliance. Blue line: under best empirical estimate of compliance; see also Supplement). Orange line: assuming 50% compliance throughout the study period. (For interpretation of the references to color in this figure legend, the reader is referred to the Web version of this article.)

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