A Seat at the Table: The Key Role of Biostatistics and Data Science during the Pandemic

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May 27, 2021

DEPARTMENT of BIOSTATISTICS EPIDEMIOLOGY & INFORMATICS

Perelman School of Medicine University of Pennsylvania

CENTER FOR CLINICAL EPIDEMIOLOGY AND BIOSTATISTICS

Centrality of Statistics in the Pandemic

- **Biomedical Data Science**: emerging field including computer science, computational biology, informatics, statistics that together is involved in extracting knowledge from ever more complex and abundant data in biomedical research

- **Statistics** plays a central role in data science given expertise
  - Experimental design and reproducibility of research
  - Deep understanding of variability, measurement error, missing data, correlated data, and causal inference.
  - Fundamental understanding of inferential thinking
  - Quantification of uncertainty
  - Modeling frameworks for integrative learning across studies

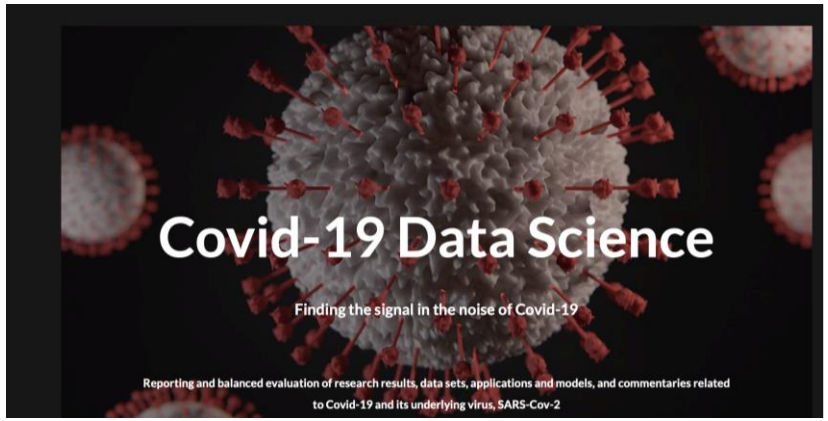
Centrality of Statistics in the Pandemic

- **Statistical thinking crucial to evaluate emerging knowledge**
  - Properly interpret various types of data: testing/case/hospitalization/death
  - Evaluate strength of evidence of emerging insights from papers/preprints
  - Cut through political and other narratives to identify what the data say
  - Synthesize information across different types of studies to identify knowledge
  - Clearly communicate results and their limitations and uncertainties
- **Engagement/Impact on Broader Society: Efforts during Pandemic**
  - **Covid-datascience.com** blog page
  - ***COVID-Lab county-level modeling and projections***
  - Summary of key emerging evidence re: mitigation, spread, reinfections, vaccines and variants, and the misunderstandings that have led to confusion/division (often fueled by failure to understand or communicate quantitative nuances)
  - Need for statisticians' greater visibility and engagement with policymakers, the media, and in scientific communication to the general public

Covid-datascience.com Website/Blog page

- **Early Pandemic Experience:** novel virus, uncertainty, false information
  - Tried to pass on ”good information” via Facebook to my friends, liberal and conservative
  - Started website/blog to provide more permanent and broadly impactful venue.

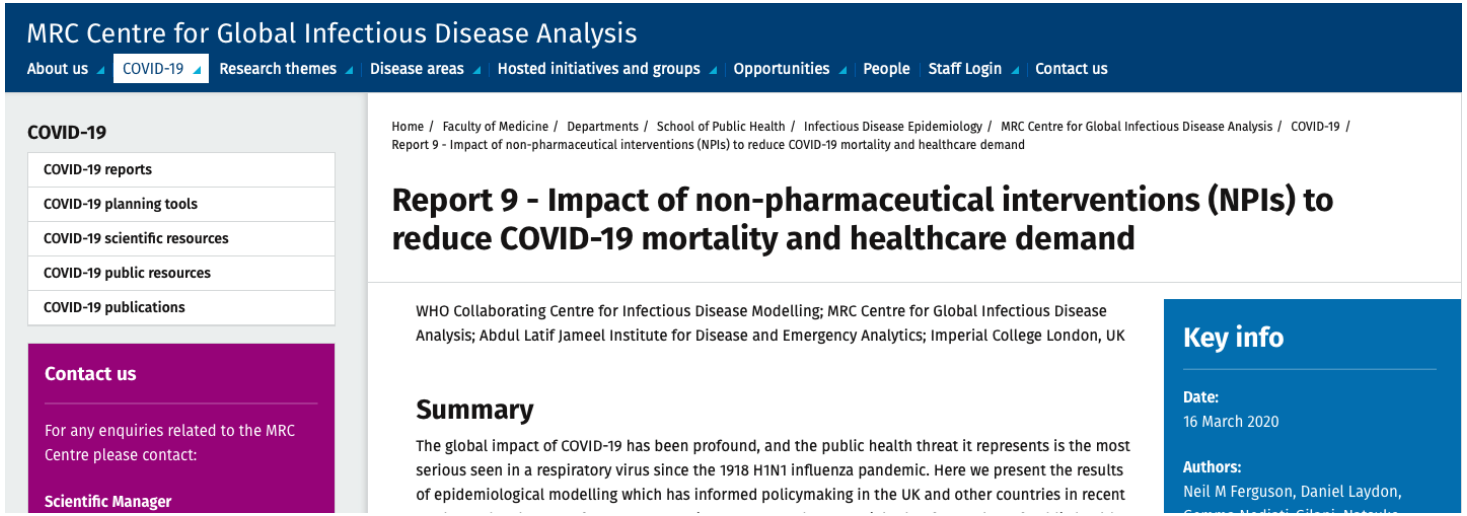
http://covid-datascience.com

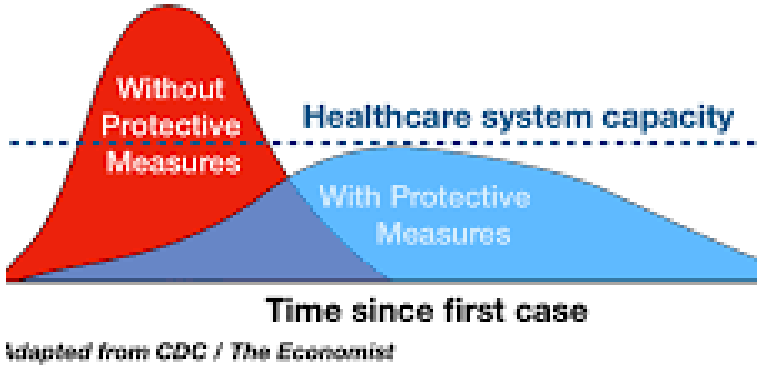


- **Goal:** Use my perspective as statistical data scientist to evaluate constantly emerging COVID-19 information, filter out biases, aggregate data together, identify key insights and uncertainty, and communicate them in accessible, balanced way.
- >215 blog posts (>100k unique visitors) on various topics; some brief commentaries while others are longer posts on key misunderstood or unappreciated topics, some debunking conspiracy theories/false experts (Mikovits/Cummins/GBD/Doshi/Northrup)

Early Denial and Alarmism about Pandemic

- **Early on, seriousness of the pandemic was underestimated in USA (like past epidemics)**

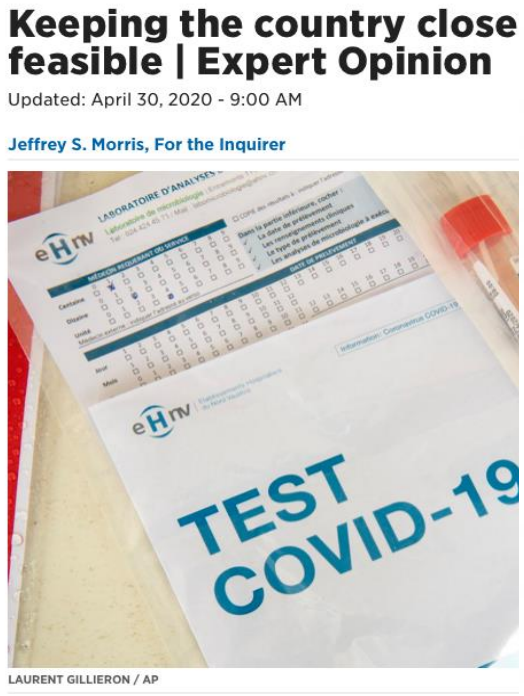




- **March 16th Report by MRC Centre for Global Infectious Disease Analysis at Imperial College London sounded the alarm of potential damage caused by pandemic**
  - **Highly publicized result:** If left unconstrained, the virus would affect 80% of USA, and assuming IFR of 0.8%, would kill 2.2 million Americans: raised the alarm bells, motivated lockdowns throughout USA
  - Note that the 2.2 million deaths was never intended to be the counterfactual to lockdowns – reflected the assumption of oblivious society with no immunity doing nothing to limit the spread of the virus
  - Focus of paper was assessing mitigation strategies – note that their model suggested with effective case isolation and social distancing measures there would be ~400k deaths

How long to keep lockdowns in place?

- **Report by Edmond Safra Center for Ethics at Harvard University:**
  - Called for near-universal testing “5 million tests/day by early June to deliver safe social reopening”
  - “20 million tests per day (ideally by late July) to fully remobilize the economy”
  - Essentially, suggested indefinite lockdowns (200k/day in April, ~1m/day July, 1.7m/day by January 2021)
  - First example of ***safetyism*** – not realistic, underestimates downsides/collateral damage, unnecessary
  - This motivated my focus on identifying “targeted mitigation” strategies that, if followed, could yield most of benefit of lockdowns with far less collateral damage to society, and finding middle ground
  - Other examples of well-intentioned alarmism (safetyism), such as push by groups for zero covid to open



Key Themes of Blog: Denial vs. Alarmism

- Find balance between two extreme viewpoints on pandemic

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- Bo)
- Important to consider ALL evidence and find middle ground between extremes
- Lack of respect, common ground, and discourse has prevented cooperation
- Statistical data scientists can serve as objective arbiters of what the data say

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  - Motivated focus on avoiding large gatherings and large crowds (especially indoors)
- **Indoor vs. Outdoor**: **Spreads 20x more efficiently indoors** (underappreciated)
- **Aerosol spread: WHO/CDC reluctant to acknowledge "airborne transmission"**
  - Conventional thinking of infectious disease scientists ruled out airborne transmission
  - July 2020: letter from environmental engineers to WHO to reconsider
  - May 7, 2021: CDC acknowledge (1) in enclosed spaces (2) with poor ventilation

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Masks: Hazards of "Wartime Science"

- **Utility of masks downplayed early**
  - Worry about hoarding from HCW
  - Emerging understanding of spread
    - Early: fomites from cough/sneeze
    - Later: exhaled from asymptomatic
- **Early 4/6/20 study suggested surgical and cotton masks did not effectively filter SARS-CoV-2**
  - Based on … 4 patients.
  - Retracted on July 7, but too late: created confusion on mask wearing
  - Later studies showed benefit of masks
- **Hazards of "Wartime Science"**
  - How do do rapid high quality science?

Annals of Internal Medicine®

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LATEST ISSUES IN THE CLINIC JOURNAL CLUB MULTIMEDIA CME / MOC AUTHORS / SUBMIT

Letters | 7 July 2020

Effectiveness of Surgical and Cotton Masks in Blocking SARS–CoV-2: A Controlled Comparison in 4 Patients FREE

Seongman Bae, MD, Min-Chul Kim, MD, Ji Yeun Kim, PhD, Hye-Hee Cha, BS, Joon Seo Lim, PhD, … View all authors +

Author, Article and Disclosure Information

https://doi.org/10.7326/M20-1342

This article has been retracted and there are 4 comments on PubPeer (by: Draba Oreades, Schistidium Canadense, Arachnothera Longirostra, Coprinellus Heterothrix)

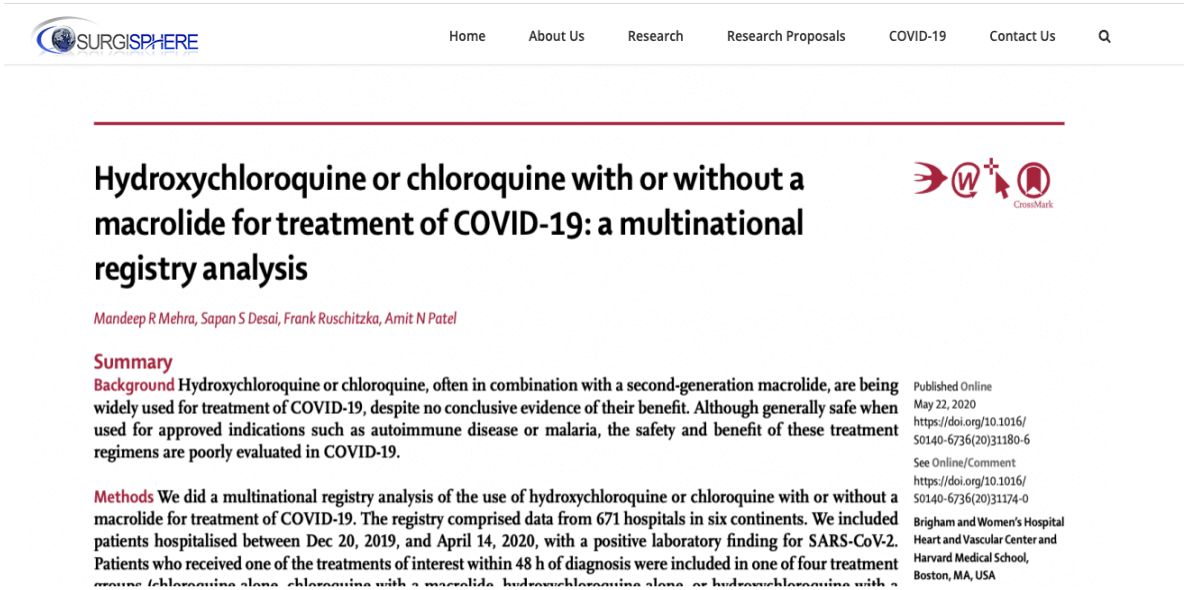
Table. SARS-CoV-2 Viral Load in Patient Samples, Petri Dishes, and Mask Surfaces

Characteristic	Patient 1 (Hospital A)	Patient 2 (Hospital A)	Patient 3 (Hospital B)	Patient 4 (Hospital B)
Age, *y*	61	62	35	82
Sex	Male	Female	Male	Female
Clinical diagnosis	Pneumonia	Upper respiratory infection	Upper respiratory infection	Pneumonia with ARDS
Symptom onset before admission, *d*	24*	4	5	10
Timing of the mask test, *hospital days*	8	4	2	14
Viral load, *log copies/mL*				
Nasopharyngeal swab	7.68	5.42	5.98	3.57
Saliva	4.29	2.59	5.91	3.51
Petri dish				
Coughing without a mask (before control)	3.53	2.14	2.52	ND
Coughing with a surgical mask	3.26	1.80	2.21	ND
Coughing with a cotton mask	2.27	ND	1.42	ND
Coughing without a mask (after control)	3.23	2.06	2.64	2.44
Mask surface				
Outer surface of surgical mask	2.21	2.11	2.63	2.59
Inner surface of surgical mask	ND	ND	2.00	ND
Outer surface of cotton mask	2.76	2.66	3.61	2.58
Inner surface of cotton mask	ND	ND	3.70	ND

ARDS = acute respiratory distress syndrome; ND = not detected; SARS-CoV-2 = severe acute respiratory syndrome-coronavirus 2.
* Transferred from the other hospital.

Wartime Science

- **Another example:** May 21 *Lancet* paper
- **Results:**
  - HCQ arms were associated with higher in-hospital mortality, ventricular arrhythmias.
  - Risk factors matched other literature
  - Fit the prevailing negative narrative of HCQ and seemed to be final nail in its coffin.
  - WHO and others stopped HCQ studies, France even made treatment illegal.
- **Study Design**
  - N=96,032 COVID-19 patients from 671 hospitals from all continents of the world (except Antarctica): EHRs at work!!
  - All customers of Quartzclinical, machine learning/data management platform by Surgisphere, company by Sapan Desai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Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis

Mandeep R Mehra, Sapan S Desai, Frank Ruschitzka, Amit N Patel

Summary

Background Hydroxychloroquine or chloroquine, often in combination with a second-generation macrolide, are being widely used for treatment of COVID-19, despite no conclusive evidence of their benefit. Although generally safe when used for approved indications such as autoimmune disease or malaria, the safety and benefit of these treatment regimens are poorly evaluated in COVID-19.

Methods We did a multinational registry analysis of the use of hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19. The registry comprised data from 671 hospitals in six continents. We included patients hospitalised between Dec 20, 2019, and April 14, 2020, with a positive laboratory finding for SARS-CoV-2. Patients who received one of the treatments of interest within 48 h of diagnosis were included in one of four treatment

Published Online May 22, 2020 https://doi.org/10.1016/S0140-6736(20)31180-6

See Online/Comment https://doi.org/10.1016/S0140-6736(20)31174-0

Brigham and Women's Hospital Heart and Vascular Center and Harvard Medical School, Boston, MA, USA

Response to Widespread Reaction to Recent Lancet Article on Hydroxychloroquine

- **A Few Preliminary Questions:**
  - How could 4 authors assemble this cohort, analyze data, and write paper in 2 weeks?
  - If this product is all over the world, why hasn't anyone heard of this company or product?
- **Andrew Gelman blogged on this**

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Wartime Science

Diabetes/Hypertension rates constant across world?

ALL of Africa uses Surgisphere EMR and captures all COVID-19 cases?

Table S3. Unadjusted Summary Data by Continent

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Brigham and Women's Hospital Heart and Vascular Center and Harvard Medical School, Boston, MA, USA

ponse to Widespread Reaction to Recent Lancet icle on Hydroxychloroquine

Jeffrey S. Morris
May 30, 2020 · 9 min

Can't we even trust top journals? Evaluating and processing information in "Wartime Science"

This covid pandemic has brought the whole world to its knees, and stimulated an unprecedented level of focus and urgency to quickly...

326 views 0 comments 1

19 an

Australia

SPO_2 < 94%	6,244 (9.9)	401 (11.2)	1,477 (8.9)	483 (11.0)	703 (8.7)	9 (14.3)
Outcomes						
Ventricular arrhythmia	792 (1.3)	89 (2.5)	187 (1.1)	66 (1.5)	104 (1.3)	1 (1.6)
Hospital LOS	9.6 +/- 7.2	9.1 +/- 4.4	8.4 +/- 3.7	5.5 +/- 3.2	8.0 +/- 5.9	8.3 +/- 7.0
ICU LOS	3.1 +/- 6.0	2.3 +/- 5.0	2.9 +/- 4.8	2.1 +/- 5.2	2.5 +/- 4.0	2.0 +/- 3.7
Total LOS	12.7 +/- 9.5	11.4 +/- 6.8	11.3 +/- 6.3	7.6 +/- 6.3	10.5 +/- 7.4	10.3 +/- 7.7
Mechanical Ventilation	6,250 (9.9)	305 (8.5)	1,674 (10.1)	302 (6.9)	816 (10.1)	7 (11.1)
Mortality	7,417 (11.7)	437 (12.2)	1,573 (9.5)	561 (12.7)	707 (8.7)	3 (4.8)
Ventilator use or Mortality	10,435 (16.5)	586 (16.4)	2,674 (16.1)	713 (16.2)	1,103 (13.6)	8 (12.7)

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COVID-LAB: Mapping COVID-19 in Your Community

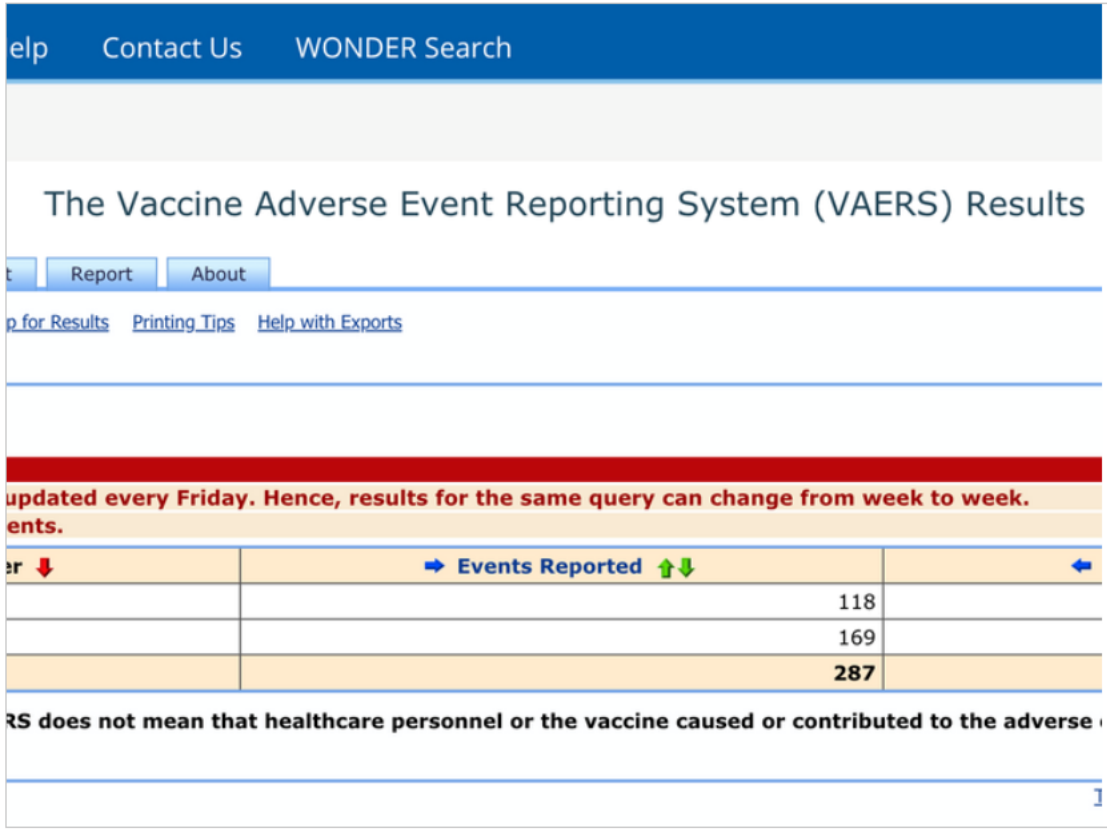
- **PolicyLab Investigators at CHOP and UPenn, led by David Rubin, set out to model and project COVID-19 incidence at county level**
  - Jing Huang (Assistant Professor) led statistical development.
  - I joined team late April as collaborator to help provide additional statistical ideas, insights, and perspective

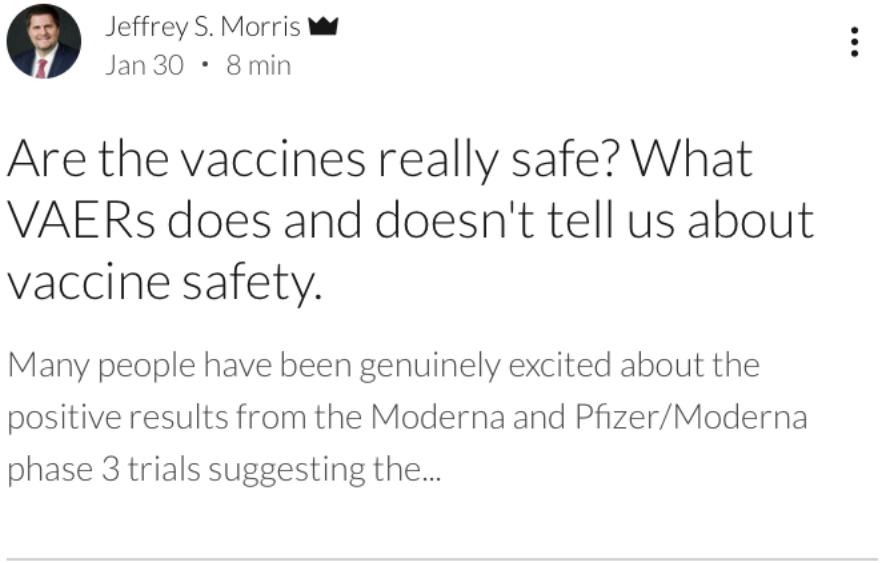

- **Basic idea:** Hybrid Statistical-Epi model to identify factors predicting cases, and to generate county-level projections to identify emerging hotspots.
- **Sources of data**:
  - Covid-19 incidence (http://usafacts.org/issues/coronavirus/),
  - Social distancing (https://www.unacast.com/covid19/),
  - Temperature (https://www.ncdc.noaa.gov/)
  - Demographics (US Census)
  - Testing (https://covidtracking.com), testing positivity rate (HHS – WH pandemic team)

PolicyLab Modeling

- Initial paper published *JAMA Network Open* (7/23/20)
- Model 700+ counties around country, weekly projections
- Used by policy makers to set standards and track surge
  - Governor of PA, local city/county leaders, numerous school districts; Deborah Birx and White House pandemic response team
  - Successfully predicted outbreaks (Houston example)
- Garnered substantial media attention
  - Newspaper/magazine interviews
  - Local/national television interviews
- Exceptionally impactful, but not perfect
  - Weekly data updates/model runs/refine & validate
  - ”Perfect is enemy of the good”
  - ***Dissemination*** and ***timeliness*** key to impact.
- Paper assessing impact of mask mandates

Are vaccines safe? Tracking vaccine-related SAEs





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  - Population-level vaccination, certain to see many deaths and SAEs in days of week after vaccination that are completely unrelated to the vaccine – would be seen even if placebo given; baseline rate
  - Public sees coincidence, assumes causation, enters into VAERs; some compelling enough for media
- **Active monitoring systems:** Vaccine Safety Datalink/Clinical Immunization Safety Assessment
  - These can be used to follow up on reports to assess relation to vaccine; worked for anaphylactic/VITT
  - Would still be a good idea to do matched vaccinated/not analyses in countries with good EMR (Israel/UK)

Do Vaccines protect against infection?

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Jeffrey S. Morris
Feb 6 · 15 min

Why it is all but certain the SARS-CoV-2 vaccines are protecting against infection and transmission

Do the SARS-CoV-2 vaccines protect against infection and prevent transmission of the virus, or do they simply reduce symptoms of...

2,719 views 0 comments 6

DEPART

FOR EPIDEMIOLOGY

Reinfections and Immune Protection After Recovery

- How long after recovery from SARS-CoV-2 infection does immune protection last?
- **Fall 2020**: Anecdotal reports of confirmed reinfections emerged raising concern


NEWS EXPLAINER · 04 SEPTEMBER 2020

nature

Coronavirus reinfections: three questions scientists are asking

Second infections raise questions about long-term immunity to COVID-19 and the prospects for a vaccine


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CORONAVIRUS

COVID-19 reinfection reported in Nevada patient, researchers say

The report comes several days after the first confirmed coronavirus reinfection in the world was identified in Hong Kong.

Aug. 28, 2020, 11:46 AM EDT / Updated Aug. 28, 2020, 3:52 PM EDT

- This fear reinforced by series of papers suggesting antibodies wane in months


CORRESPONDENCE

Rapid Decay of Anti–SARS-CoV-2 Antibodies in Persons with Mild Covid-19

September 10, 2020
N Engl J Med 2020; 383:1085-1087
DOI: 10.1056/NEJMc2025179
Metrics

34 subjects
2 timepoints


Article | Published: 26 October 2020

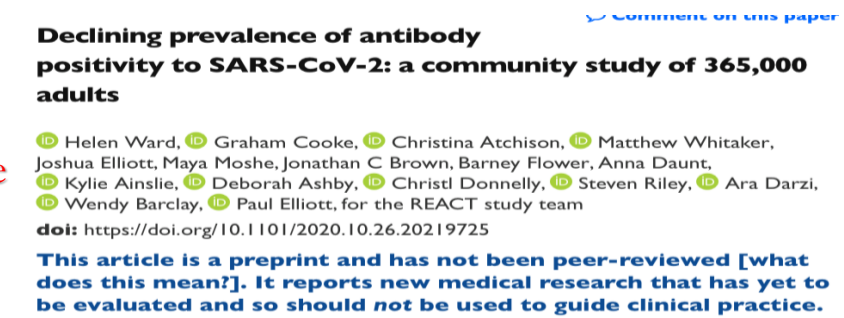
Longitudinal observation and decline of neutralizing antibody responses in the three months following SARS-CoV-2 infection in humans

Jeffrey Seow, Carl Graham, [...] Katie J. Doores

Nature Microbiology 5, 1598–1607(2020) | Cite this article

48k Accesses | 134 Citations | 1018 Altmetric | Metrics

65 subjects: "some decreased near baseline by 2m"

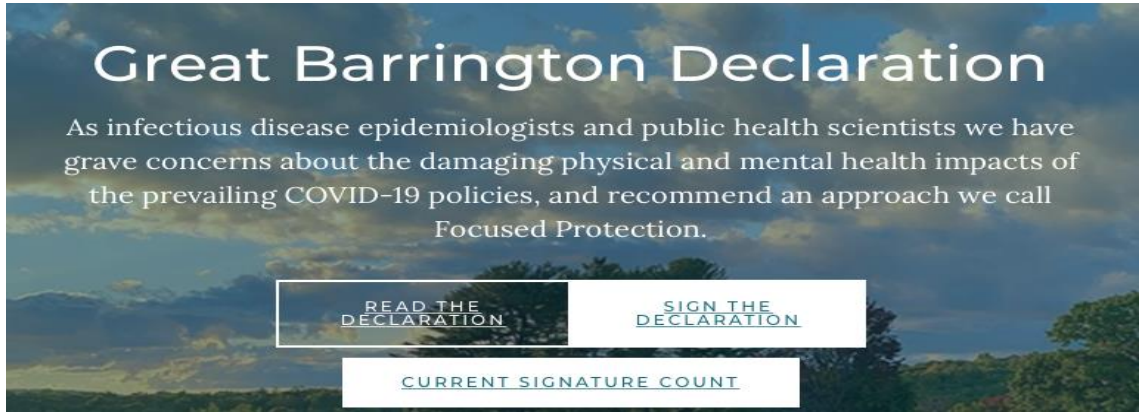

Declining prevalence of antibody positivity to SARS-CoV-2: a community study of 365,000 adults

Helen Ward, Graham Cooke, Christina Atchison, Matthew Whitaker, Joshua Elliott, Maya Moshe, Jonathan C Brown, Barney Flower, Anna Daunt, Kylie Ainslie, Deborah Ashby, Christl Donnelly, Steven Riley, Ara Darzi, Wendy Barclay, Paul Elliott, for the REACT study team

doi: https://doi.org/10.1101/2020.10.26.20219725

This article is a preprint and has not been peer-reviewed [what does this mean?]. It reports new medical research that has yet to be evaluated and so should *not* be used to guide clinical practice.

- **Political context of these discoveries**
  - **Great Barrington Declaration (10/2/20)**
  - **Scott Atlas hired as WH advisor (8/20)**
- How common are reinfections?


Great Barrington Declaration

As infectious disease epidemiologists and public health scientists we have grave concerns about the damaging physical and mental health impacts of the prevailing COVID-19 policies, and recommend an approach we call Focused Protection.

READ THE DECLARATION

SIGN THE DECLARATION

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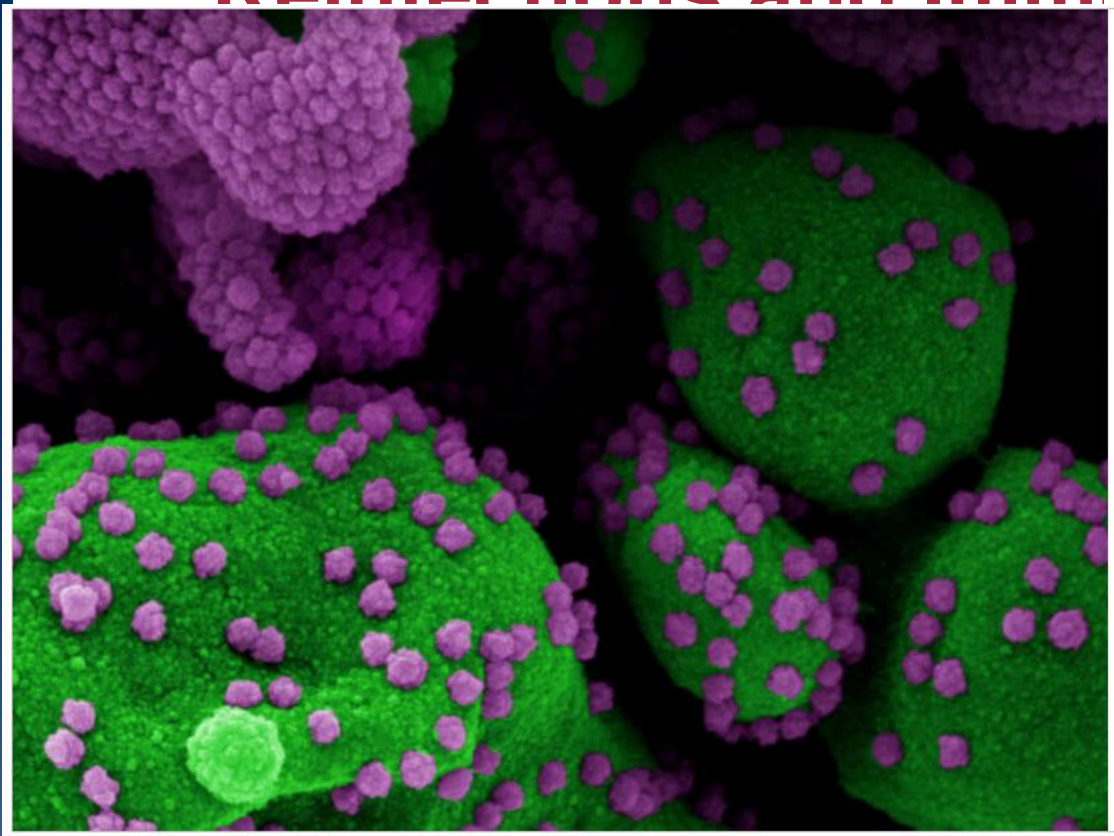
Perelman School of Medicine University of Pennsylvania

Month	Confirmed Monthly cases	Percent infected	Confirmed reinfections by 3/31/21 (3m immunity)	Confirmed reinfections by 3/31/21 (6m Immunity)
March	192,177	0.06%	16,786	14,314
April	884,067	0.27%	74,974	62,612
May	718,221	0.22%	56,702	46,676
June	834,359	0.25%	62,147	43,017
July	1,922,730	0.59%	136,174	60,940
August	1,464,676	0.45%	95,187	19,080
September	1,201,822	0.37%	61,962	6,641
October	1,915,046	0.58%	60,696	
November	4,408,082	1.34%	57,424	
December	6,518,925	1.99%	36,020	
January	6,126,675	1.87%		
February	2,461,960	0.75%		
March	1,813,470	0.55%		
TOTAL	**30,462,210**	**9.28%**	**658,072**	**253,280**

Reinfections and Immu



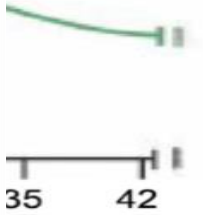
Antibody Detection | IgM | IgM + IgG

Jeffrey S. Morris
Apr 26 · 20 min

Overwhelming evidence now that previously infected have robust immune protection against reinfection

Key points of this article: An article was published in Israel demonstrating those previously infected with PCR confirmed SARS-CoV-2...

4,595 views 1 comment 7



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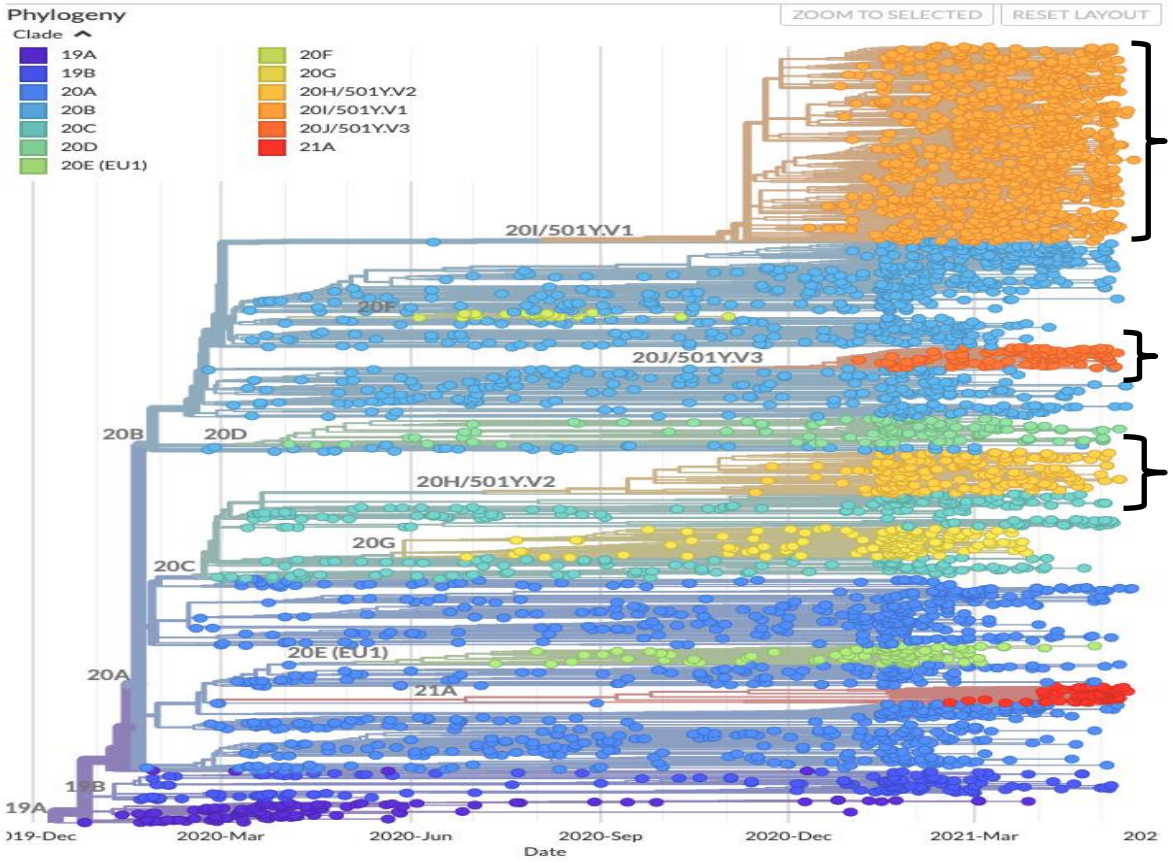
- Johnson&Johnson study (FDA): Placebo group (10% seropositive): **92.4% reduced risk**
- Hansen (3/17/21 Lancet): Denmark N=11k; **80.5% reduced risk** (47.1% >65yrs)]
- Goldberg (4/20/21 medRXiv): Israel N=6.3m+; **94.8% reduced risk**

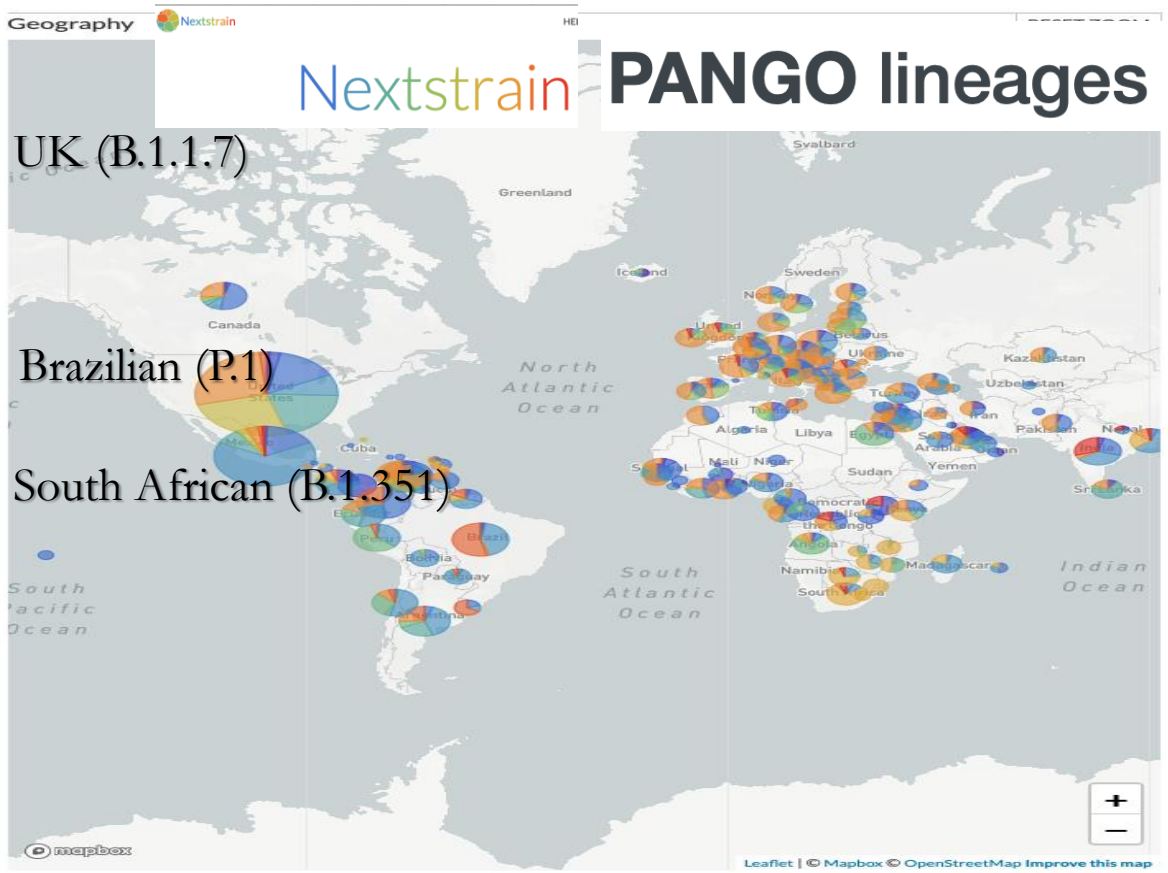
Implications

- Vaccinate previously infected? Israel no, USA yes; 5 recent papers suggest single dose
- Friedman, Krammer (6/1/2021 Lancet Letter): suggest single dose for previously infected
- Population/herd immunity considerations should include previously infected

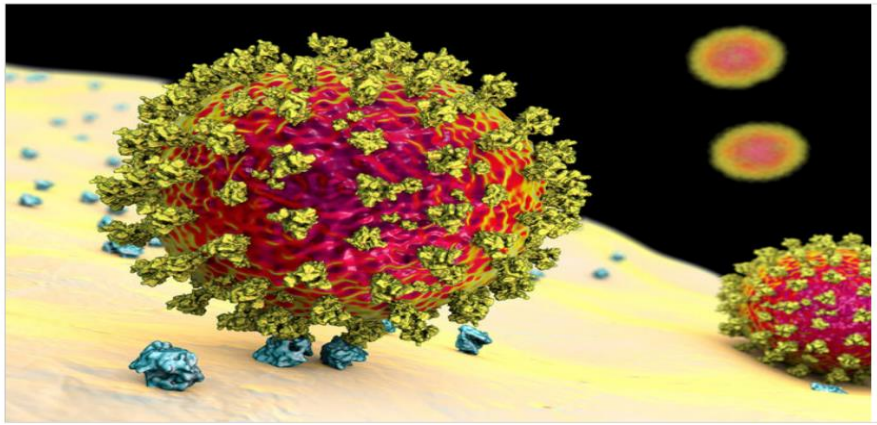
SARS-CoV-2 Variants

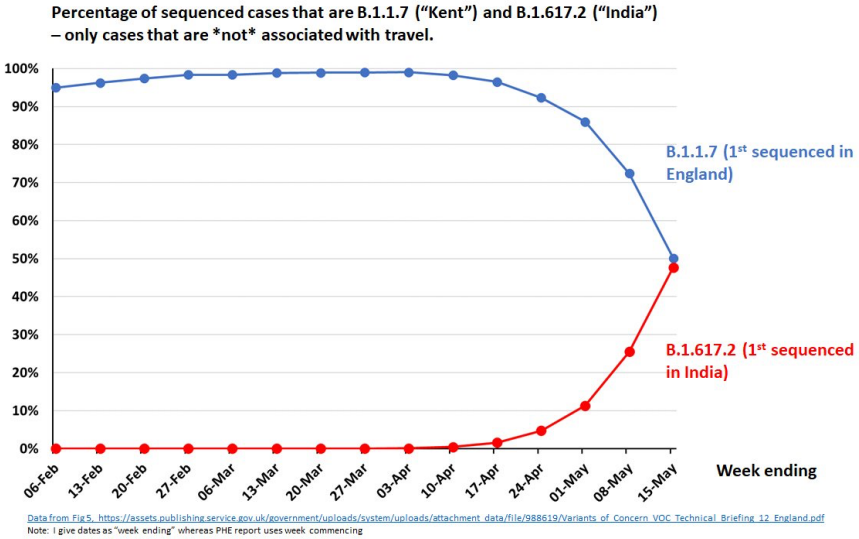
- **Viruses are always mutating/evolving, producing new "variants"**
  - Why influenza shots have low efficacy and need constant updating
- **SARS-CoV2:** much less genetic diversity, much slower mutation rate (1-2/mo)
  - BUT evolution can accelerate in immunocompromised long-haulers
- Most mutations docile, but some could increase spread/severity/immune escape





Key variants of con





- **UK Variar**
  - Strong
  - Higher
  - Not esc
- **Immune escape variants (E484K): B.1.351 So**
  - Appears more transmissible – not as many strong studies to characterize rate
  - **Immune escape**: evade monoclonal antibody response, 6-12x reduction in nAbs
  - Reduced vaccine efficacy (AZ 22% (70%); NV 60% (89%); J&J 56% (66%); Pfizer 75% (89%) - Qatar, NEJM letter 5/5/21, **97.4% vs. severe, critical, fatal**
- **Indian "double mutant" variants: B.1.617.1, B.1.617.2**
  - UK study: 50% more transmissible than B.1.1.7 (2-2.25x more than wild type)
  - Dominating B.1.1.7 in UK, also here now in the USA
  - UK report (4/5-5/16 sym inf): Pfizer 88%(93%), AZ 60%(66%), 1 dose 33%(50%)

Relating nAbs to Vaccine Efficacy

Article | Published: 17 May 2021

Neutralizing antibody levels are highly predictive of immune protection from symptomatic SARS-CoV-2 infection

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Nature Medicine (2021) | Cite this article

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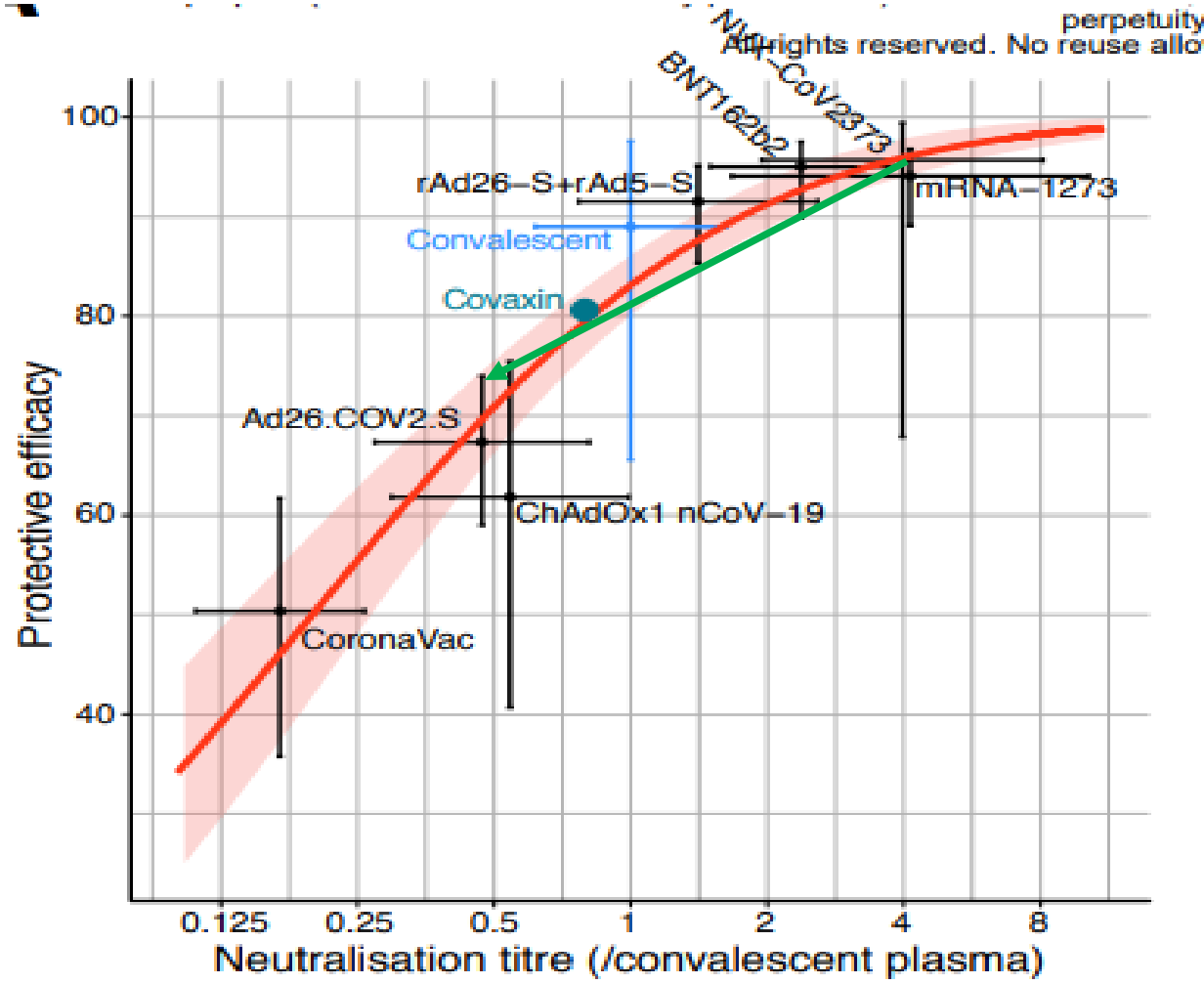
- **Nature Medicine paper fit smooth curve to protective efficacy vs. nAbs levels**
- **Provides useful function to predict efficacy of vaccines for new emerging variants without efficacy studies**
  - nAbs levels easily measured in laboratory
- **Accurately predicted Pfizer efficacy vs. B.1.351: 8-fold reduction ←→ 75% efficacy (Qatar)**



DEPARTMENT of BIOSTATISTICS EPIDEMIOLOGY & INFORMATICS

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Fact-Checking and Information Censoring in a Pandemic

- **Fact checking and social media censoring/tagging of scientific information is tricky in a fluid situation like a pandemic**
- **The public misunderstands science as a repository of incontrovertible truths ("follow the science"), when it is really a gradual accruing of knowledge that can have twists and turns**
- **Certain expert claims were later proven to be false or at least more uncertain**
  - Lack of utility of masks in mitigating viral spread
  - Lack of aerosol spread of the virus (i.e. "not airborne")
  - Degree of risk of reinfection and durability of immunity after recovery
  - Natural origin of virus via intermediate species (lab accident conspiracy theory)
- **Propagation of demonstrably false information online major problem, but danger of interfering with open discourse and knowledge discovery.**
- **Statistical data scientists can help assess degree of uncertainty**

Role of Biostatisticians in pandemic (and society)

- **Statistical skill set essential to society in navigating pandemic**
  - Evaluating bias, data integration, adjusting for measurement error and informative missing data, quantifying and communicating degree of evidence/uncertainty of scientific results.
- Recognize the scarcity of our skill set and importance to engage at societal level
  - Have a ”***seat at the table***” with policy and decision makers
  - Be visible to ***media*** members to clarify subtle quantitative nuances in science
  - Be involved in ***fact checking/scientific communication***, relay uncertainty
- **Natalie Dean** (Asst Prof Biostat, University of Florida, >100k Twitter followers): “We are able to bring nuance and insight to an often oversimplified public discussion, where an out of context point estimate can turn into a headline and then into a media frenzy.”
- ***Define impact broadly***, looking outward and not just inward; Reward biostatisticians for societally impactful work.
- Not just during the pandemic … these same quantitative nuances affect public understanding of science in other settings

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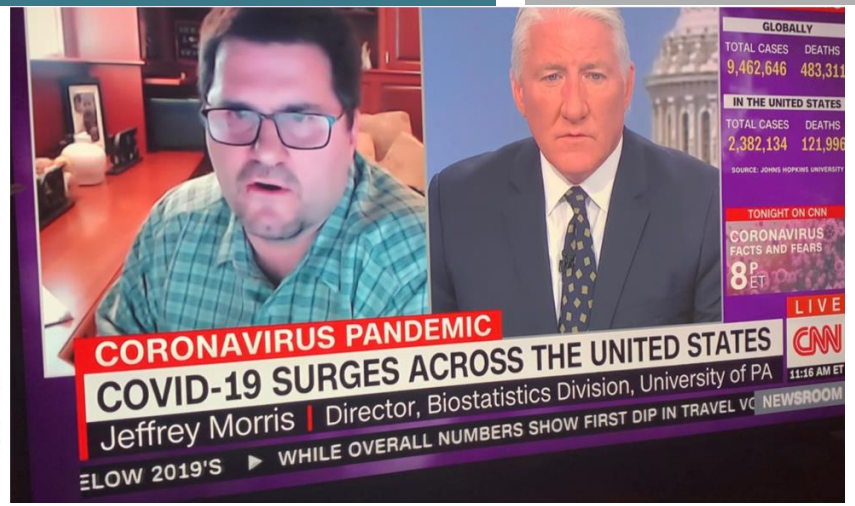

KHN
KAISER HEALTH NEWS

Received: 20 December 2020 | Revised: 26 January 2021 | Accepted: 13 February 2021
DOI: 10.1002/sim.8936

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Susan S. Ellenberg | Jeffrey S. Morris

Television/Radio Interviews: CNN, ABC, CBS, NBC, FOX, Arirang TV (Korean), KCBS (radio)
Podcast Interviews: The Gist (Mike Pesca), The COVAX Files, Biomedical Informatics Roundtable
Quoted in: Wall Street Journal, Time, Bloomberg Health, Kaiser Health News, The Washington Post, The Philadelphia Inquirer, The Seattle Times, The Denver Post, Wired

Questions
&
Discussion