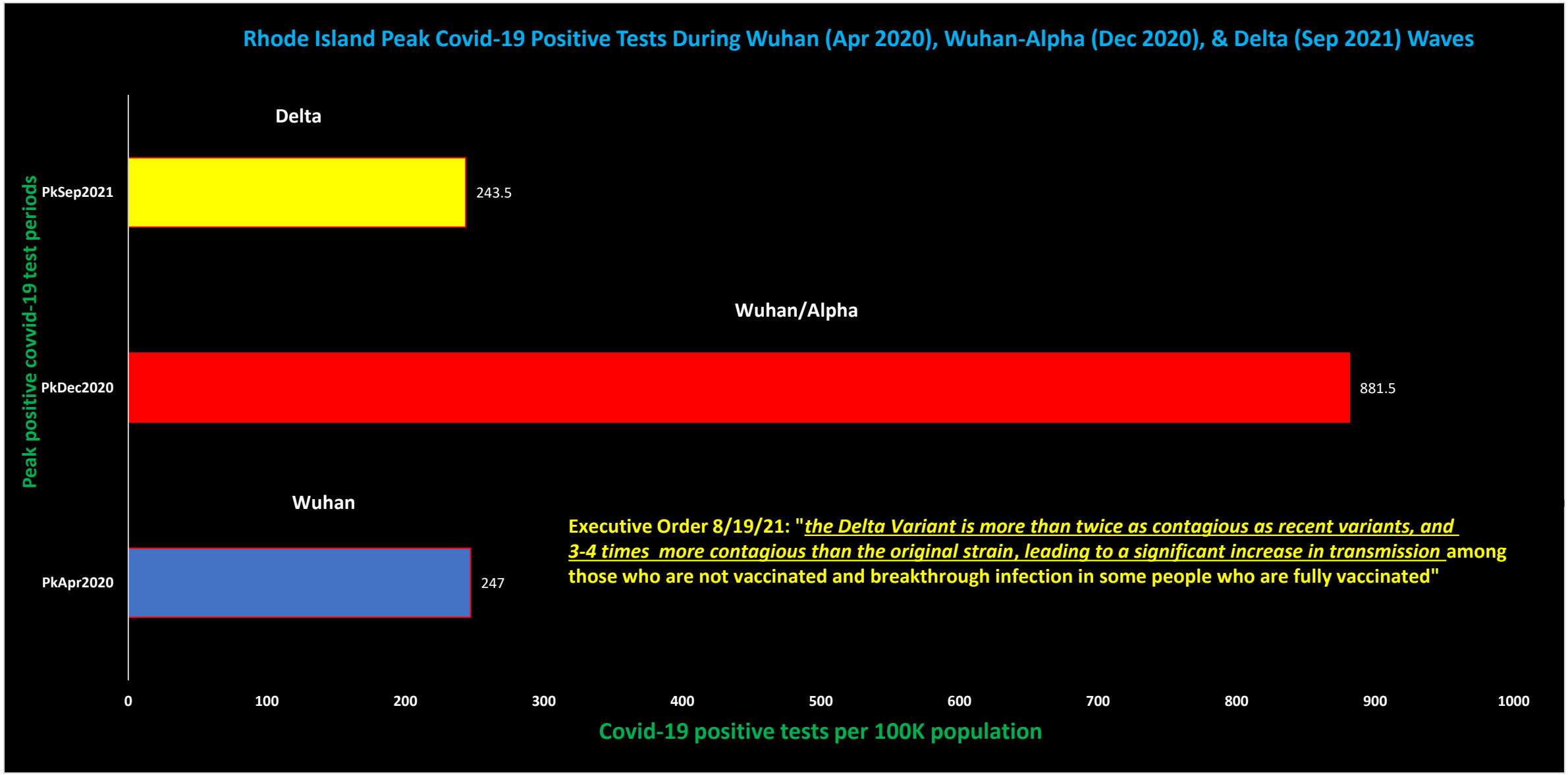
Andrew G. Bostom, MD, MS

Expert testimony on behalf of the plaintiffs, in Southwell et al., vs. McKee

(Begun October 5, 2021)

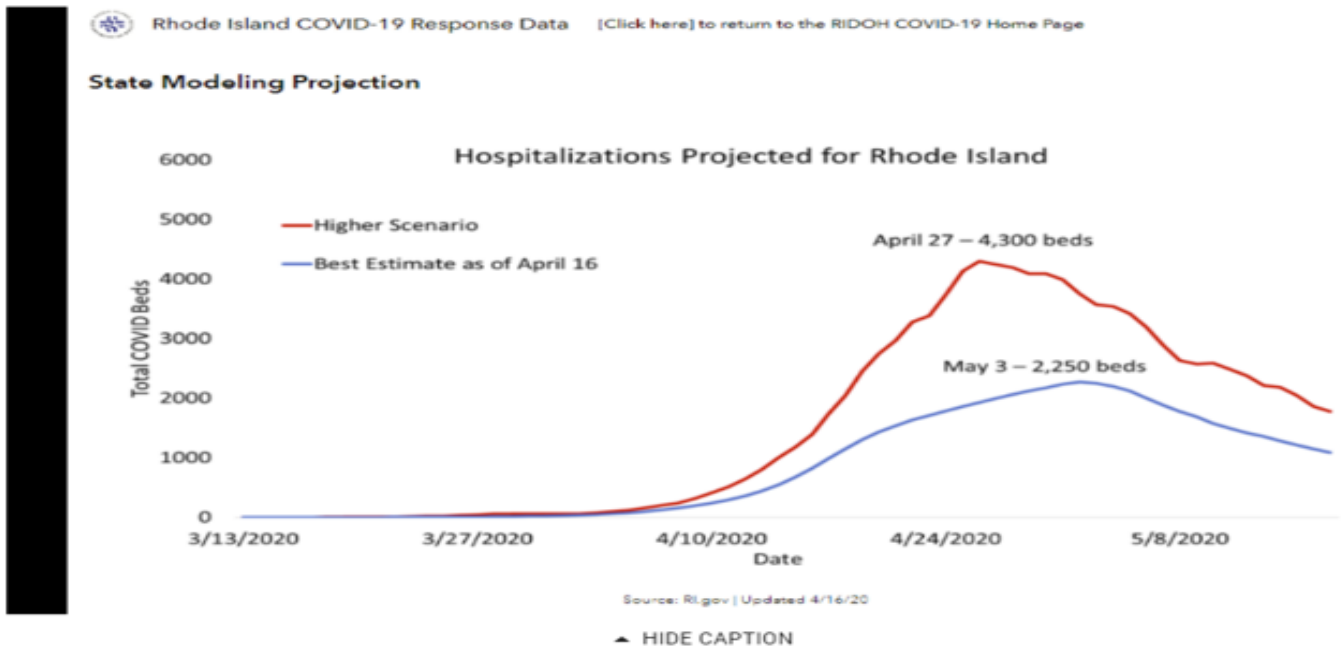


Data accessed 9/27/21 from the RIDOH website, "Rhode Island COVID-19 Response Data," 9/27/2021:
https://docs.google.com/spreadsheets/d/1c2QrNMz8pIbYEKzMJL7Uh2dtThOJa2j1sSMwiDo5Gz4/edit#gid=264100583

Providence Journal Opinion Editorial, April 30, 2020, reproduced RIDOH graphic, from model dated 4/16/21
https://www.providencejournal.com/opinion/20200430/editorial-modeling-was-grossly-inaccurate

Opinion

Editorial: Modeling was grossly inaccurate



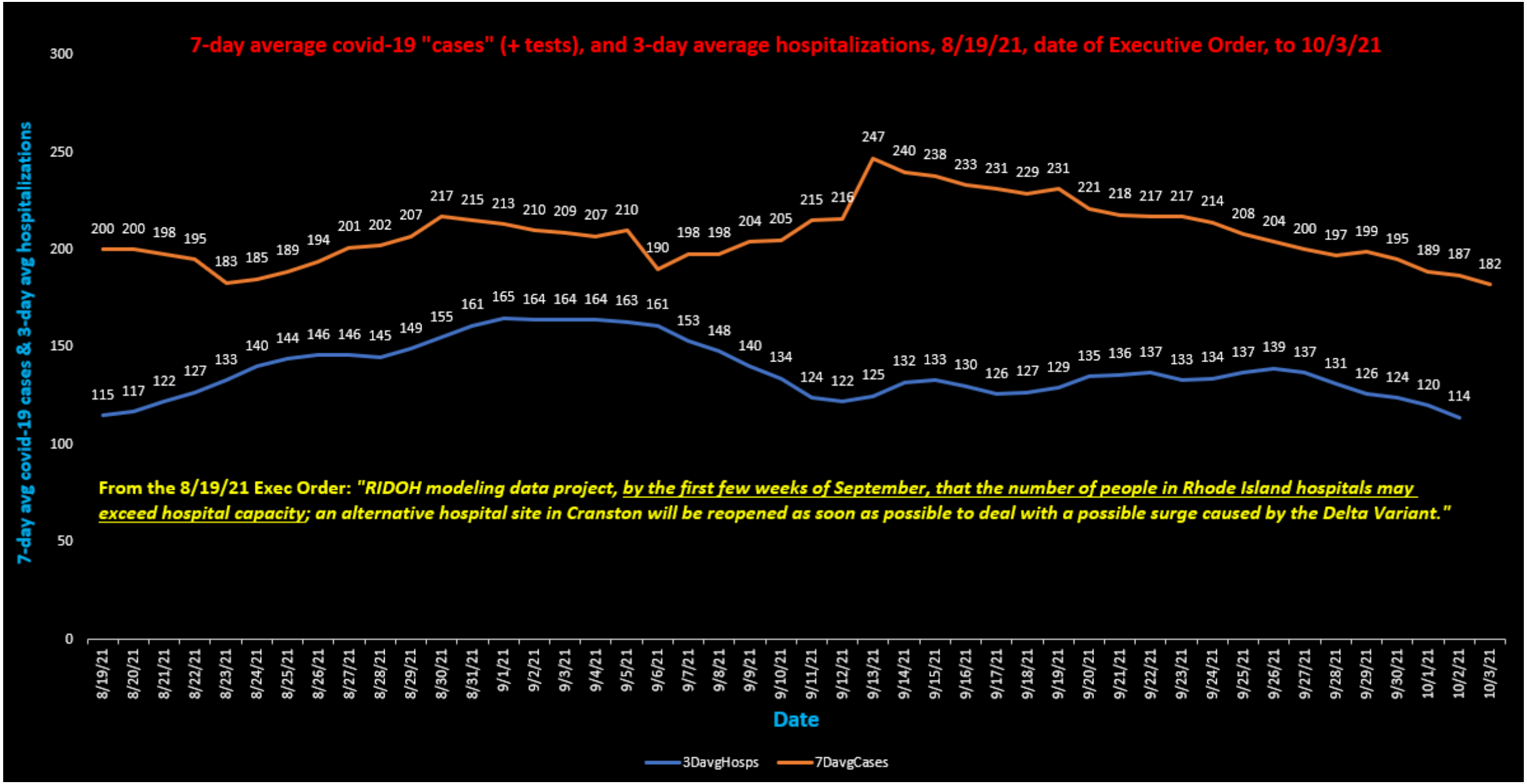
[RHODE ISLAND DEPARTMENT OF HEALTH, April 30]

Posted Apr 30, 2020 at 3:09 PM
Updated Apr 30, 2020 at 4:19 PM

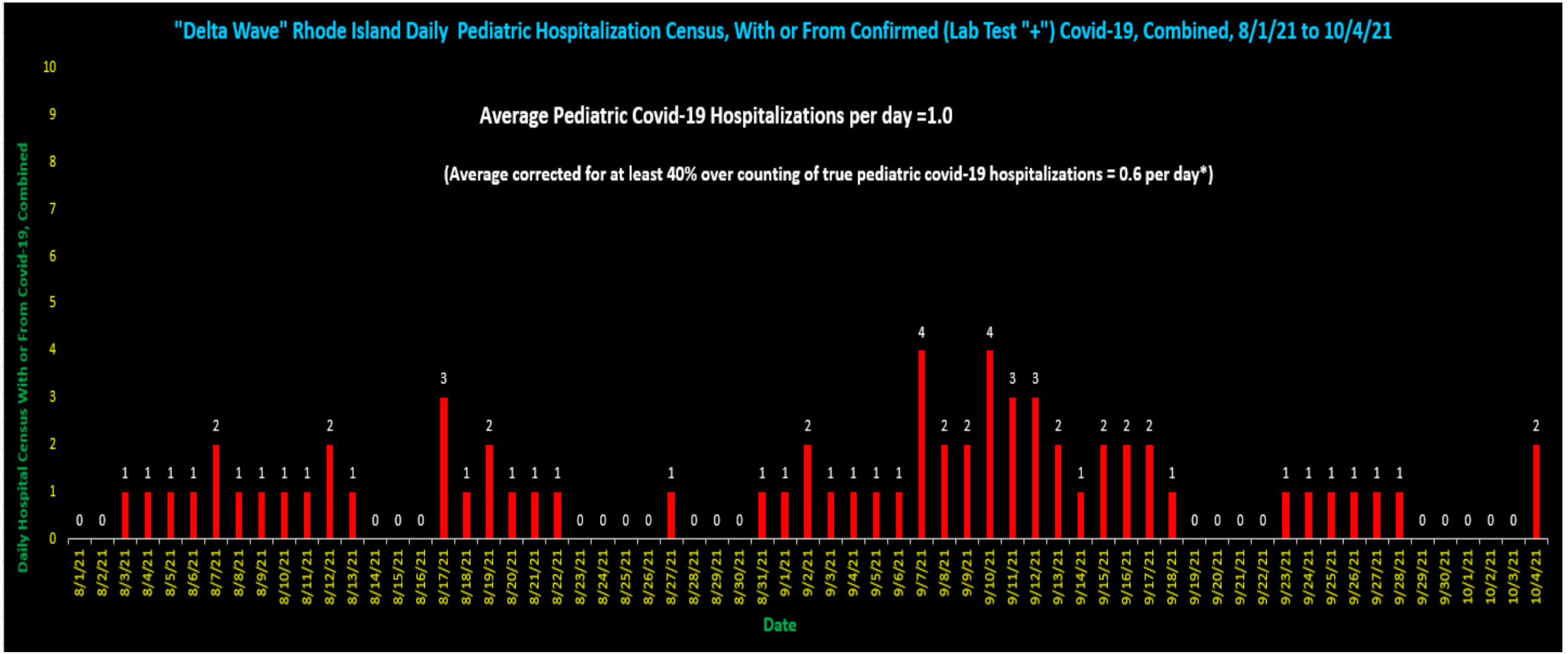
ACTUAL RIDOH DATA ON TOTAL HOSPITAL COVID-19 BED OCCUPANCIES:

- **April 27, 2020, N= 357**
- **May 3, 2020, N= 351**
- **April 28, 2020, N=374, which was the ACTUAL PEAK**

https://docs.google.com/spreadsheets/d/1c2QrNMz8pIbYEKzMJL7Uh2dtThOJa2j1sSMwiDo5Gz4/edit#gid=1592746937



Data accessed 10/4/21 from the RIDOH website, "Rhode Island COVID-19 Response Data"
https://docs.google.com/spreadsheets/d/1c2QrNMz8pIbYEKzMJL7Uh2dtThOJa2j1sSMwiDo5Gz4/edit#gid=264100583

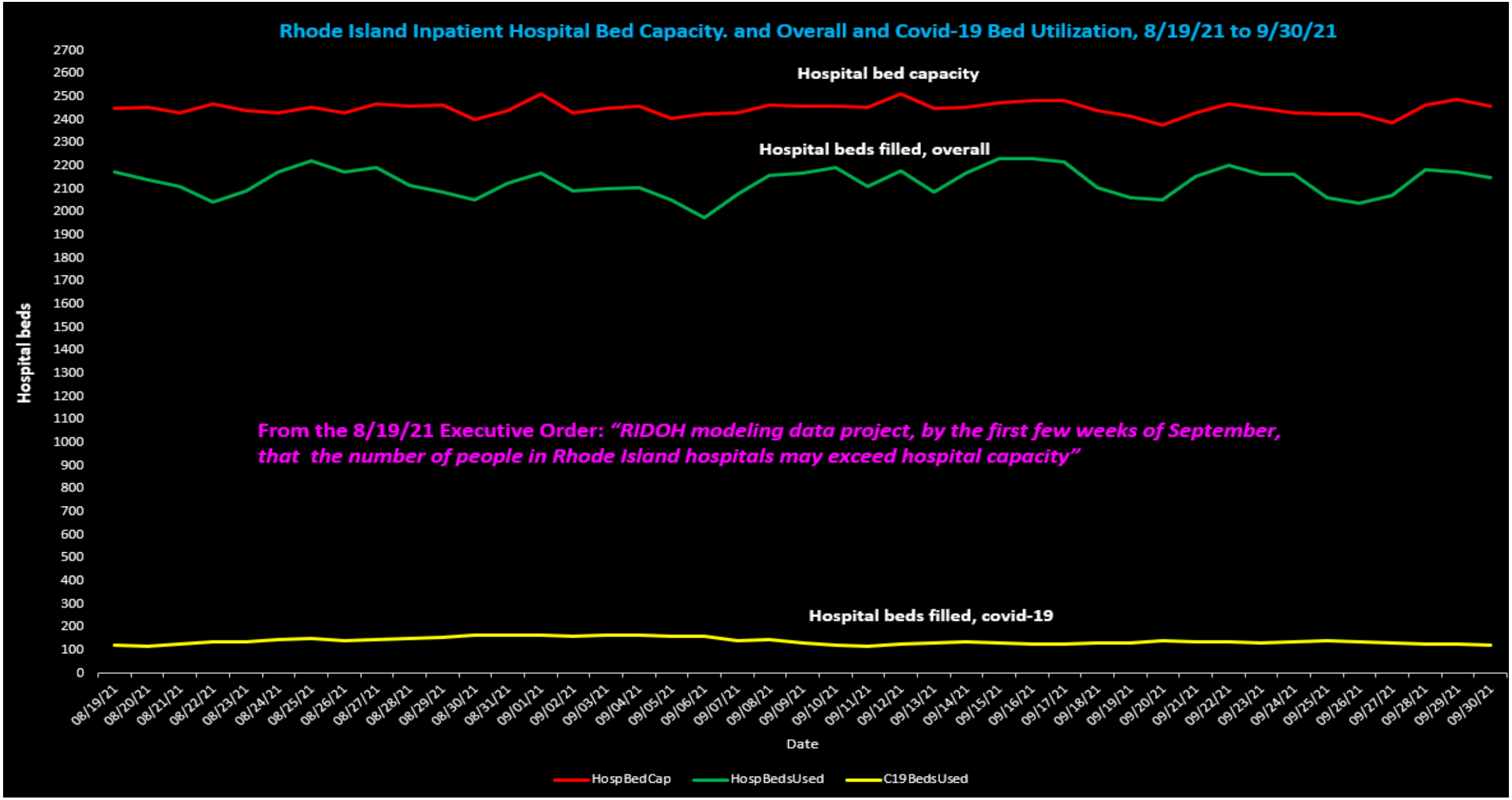


*Data imported from the Health and Human Services website, "COVID-19 Reported Patient Impact and Hospital Capacity by State", 8/1/21 through 10/4/21: https://beta.healthdata.gov/dataset/COVID-19-Reported-Patient-Impact-and-Hospital-Capa/6xf2-c3ie

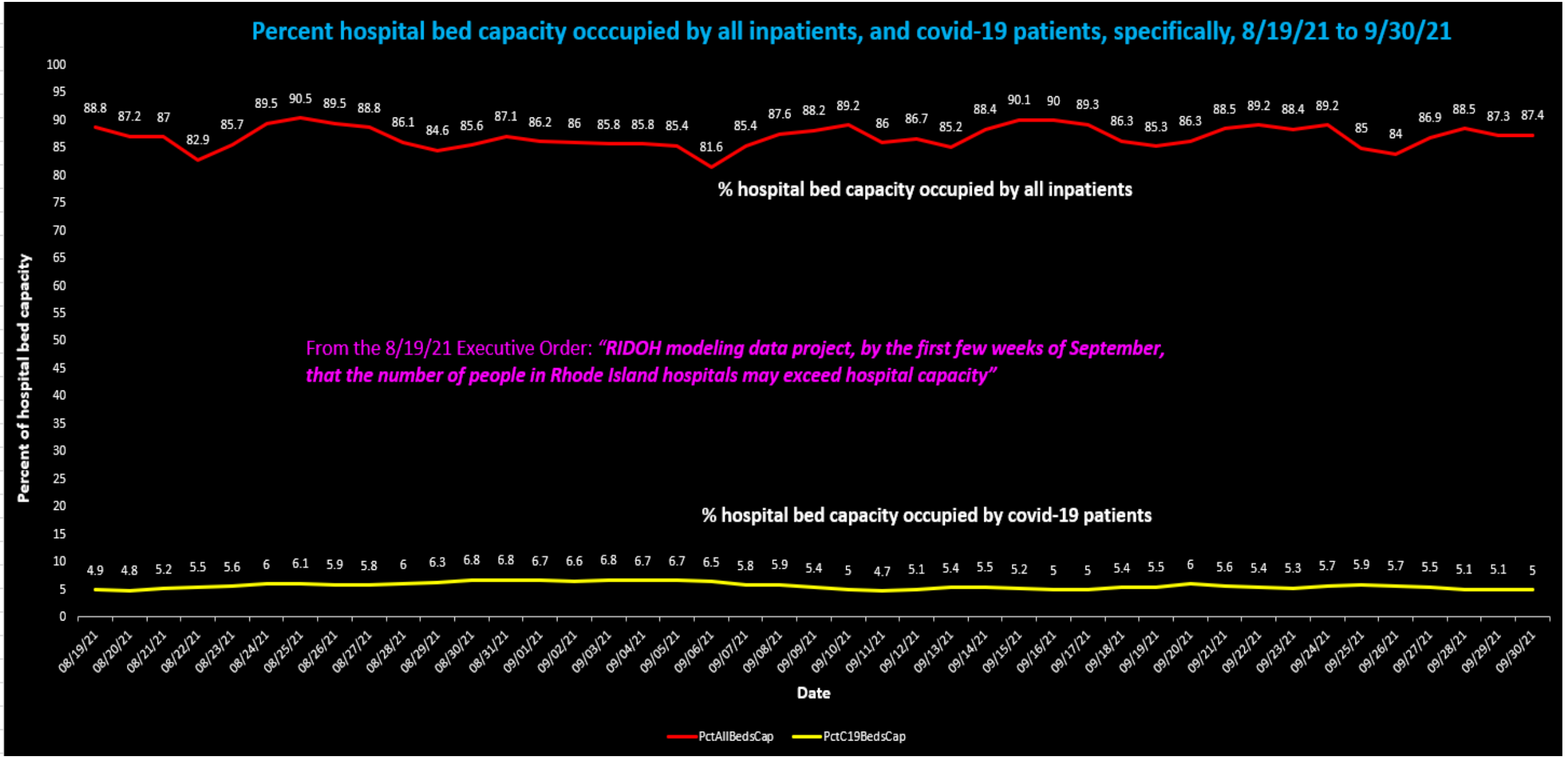
May 2021 *Hospital Pediatrics* included two reports demonstrating that true pediatric covid-19 hospitalizations were over counted by 40-45%:

a) Kushner LE, et al. “For COVID” or “With COVID”: Classification of SARS-CoV-2 Hospitalizations in Children. *Hosp Pediatr.* 2021; doi: 10.1542/hpeds.2021-006001.

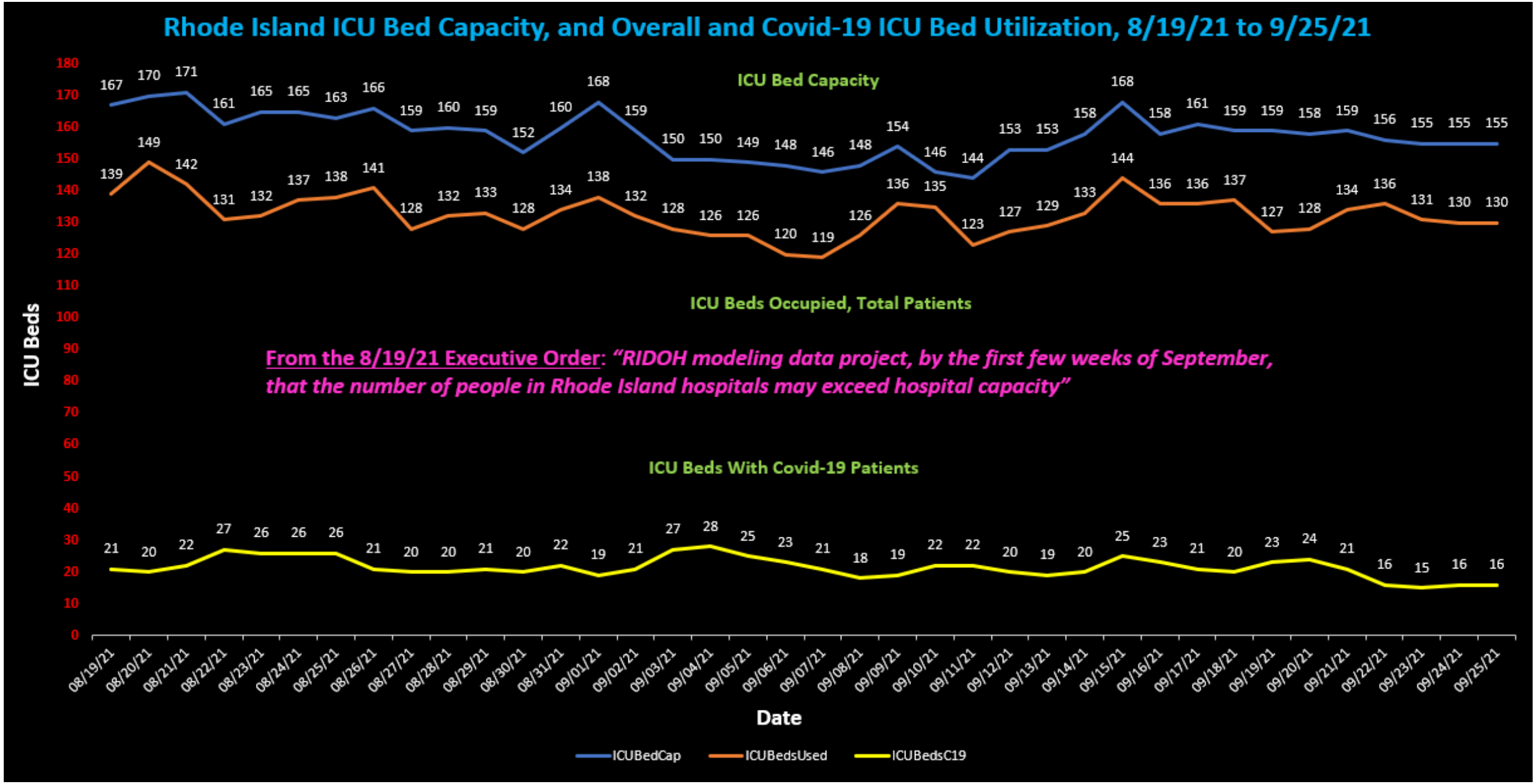
b) Webb NE and Osburn TS. Characteristics of Hospitalized Children Positive for SARS-CoV-2: Experience of a Large Center. *Hosp Pediatr.* 2021; doi: 10.1542/hpeds.2021-005919.



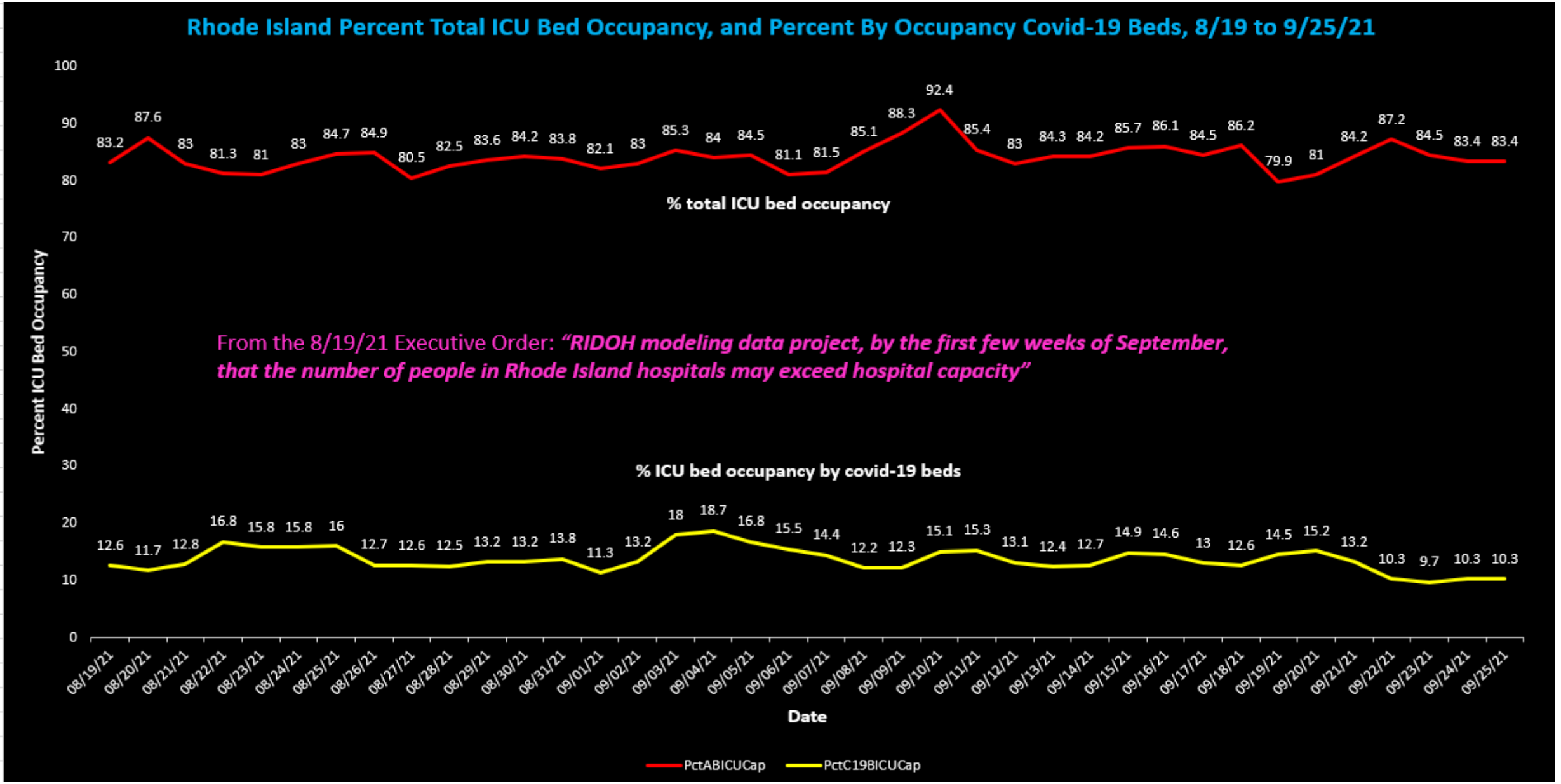
Data imported 10/3/21, from the Health and Human Services website, "Hospital Utilization" https://protect-public.hhs.gov/pages/hospital-utilization, and RIDOH https://ri-department-of-health-covid-19-data-rihealth.hub.arcgis.com/



Data imported 10/3/21, from the Health and Human Services website, "Hospital Utilization" https://protect-public.hhs.gov/pages/hospital-utilization, and RIDOH https://ri-department-of-health-covid-19-data-rihealth.hub.arcgis.com/



Data imported 10/3/21, from the Health and Human Services website, "Hospital Utilization" https://protect-public.hhs.gov/pages/hospital-utilization, and RIDOH https://ri-department-of-health-covid-19-data-rihealth.hub.arcgis.com/



Data imported 10/3/21, from the Health and Human Services website, "Hospital Utilization" https://protect-public.hhs.gov/pages/hospital-utilization, and RIDOH https://ri-department-of-health-covid-19-data-rihealth.hub.arcgis.com/

Pediatric Multisystem Inflammatory Syndrome (MIS) Associated with SARS-CoV-2 (Covid-19)

- Rare in association with SARS-CoV-2, and a very murky diagnosis also associated with a host of other respiratory viruses, including common cold causing rhinovirus and human coronaviruses (as well as unknown/ non-infectious etiologies) www.pediatrics.org/cgi/doi/10.1542/peds.2015-0950

- Refreshingly sober perspective on covid19-associated MIS based upon review from May, 2020 of 100 purported "cases": ***"rare and children are probably still spared from most morbidities and mortality linked to COVID-19 infection"*** https://www.preprints.org/manuscript/202005.0160/v1

- Largest U.S. national series found only 31% (168/539) were both SARS-CoV-2 rtPCR, and antibody positive, and the exceedingly few fatalities that occurred were difficult to link directly to a covid-19 syndrome, vs. other non-SARS-CoV-2 primary causes of death https://jamanetwork.com/journals/jama/fullarticle/2777026

Pediatric “Long Covid,” or “Long Pandemic” Syndrome?

- **Conclusions from *Pediatr Infect Dis J* review of 14 studies of pediatric “Long Covid-19 Syndrome”:**

“In summary, the evidence for long COVID in children and adolescents is limited, and all studies to date have substantial limitations or do not show a difference between children who had been infected by SARS-CoV-2 and those who were not. ***The absence of a control group in the majority of studies makes it difficult to separate symptoms attributable to long COVID from pandemic-associated symptoms****”*

https://journals.lww.com/pidj/pages/articleviewer.aspx?year=9000&issue=00000&article=95677&type=Abstract

Pediatric Covid-19 Mortality in Rhode Island, and the U.S.

- **As confirmed by RIDOH, there have been ZERO primary cause covid-19 deaths in Rhode Island, since the pandemic began**
  - Indeed, according to the American Academy of Pediatrics (AAP), 7 other states in the U.S. share that distinction of having ZERO pediatric covid-19 deaths during the entire course of the pandemic
  - Moreover, through 9/23/21, AAP reported just "0.00%-0.03% of all child COVID-19 cases resulted in death," a survival rate of AT LEAST 99.97%, after covid-19 infection
  - Using May 2021 CDC (under-) estimate of 26,838,244 pediatric covid-19 infections, and corrected 311 covid-19 deaths, pediatric infection fatality ratio =0.0012%, or a 99.9998% survival rate

https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/children-and-covid-19-state-level-data-report/ ; https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/burden.html

- **Rhode Island, in contrast, sustained 3 confirmed H1N1 pediatric covid-19 deaths during a 12-month period in 2009-2010, mirroring the ≥ 6-fold increased U.S. national pediatric mortality risk that pandemic H1N1 influenza conferred, relative to covid-19**

https://health.ri.gov/publications/surveillance/2011/Influenza.pdf; p. 14

Recent annual U.S. pediatric influenza (seasonal/ 1 year pandemic), and covid-19 deaths

Disease/Period (9-12 months for C19; 9-12mos for flu)	Age range (years)	Deaths
Covid-19, 2020[a]	**0-17**	***198/129 [i]***
Covid-19, 2021[a]	**0-17**	***280/182 [i]***
Pandemic H1N1 Flu, 2009-10[b]	**0-17**	**1282**
Seasonal Flu, 2012-13[c]	**0-17**	**1161**
Seasonal Flu, 2014-15[d]	**0-17**	**803**
Seasonal Flu, 2017-18[e]	***0-17***	***643***
Seasonal Flu, 2018-19[f]	***0-17***	***477***
Seasonal Flu, 2019-20[g]	***0-17***	***434***
Seasonal Flu, 2010-11[h]	**0-17**	**352**

Covid-19 data updated through 9/29/21

a) "Weekly Updates by Select Demographic and Geographic Characteristics: Provisional Death Counts for Coronavirus Disease 2019 (COVID-19)" https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm
b) "Estimating the Burden of 2009 Pandemic Influenza A (H1N1) in the United States (April 2009–April 2010)" https://academic.oup.com/cid/article/52/suppl_1/S75/499147
c) "Burden Estimates for the 2012-2013 Influenza Season" https://www.cdc.gov/flu/about/burden/2012-2013.html
d) "Burden Estimates for the 2014-2015 Influenza Season" https://www.cdc.gov/flu/about/burden/2014-2015.html
e) "Burden Estimates for the 2017-2018 Influenza Season" https://www.cdc.gov/flu/about/burden/2017-2018.htm
f) "Burden Estimates for the 2018-2019 Influenza Season" https://www.cdc.gov/flu/about/burden/2018-2019.html
g) "Burden Estimates for the 2019-2020 Influenza Season" https://www.cdc.gov/flu/about/burden/2019-2020.html
h) "Burden Estimates for the 2010-2011 Influenza Season" https://www.cdc.gov/flu/about/burden/2010-2011.html
i) Adjusted for CDC 35% over counting of covid-19 pediatric deaths by death certificate review, per "Death Certificate–Based ICD-10 Diagnosis Codes for COVID-19 Mortality Surveillance — United States, January–December 2020" https://www.cdc.gov/mmwr/volumes/70/wr/mm7014e2.htm?s_cid=mm7014e2_x

TABLE 1. Distribution of death certificates with COVID-19 diagnosis* across five mutually exclusive categories defined by presence and classification of co-occurring diagnoses, by demographic characteristics, setting of death, and manner of death characteristics — National Center for Health Statistics, United States, January–December 2020

Characteristic	No. of death certificates	No. (row %) COVID-19 only	COVID-19 and ≥1 chain-of-event condition only	COVID-19 and ≥1 significant contributing condition only	COVID-19 and ≥1 chain-of-event and ≥1 significant contributing condition	COVID-19 with no plausible chain-of-event or significant contributing condition
Age group, yrs						
<18	182	8 (4.4)	70 (38.5)	18 (9.9)	22 (12.1)	64 (35.2)

A > ~5-Fold Increased Risk of Annualized Pediatric Respiratory Syncytial Virus (RSV) Deaths, vs. Covid-19 Deaths, in U.S. Children Up to 4 Years Old

RSV & covid-19 mortality comparison for U.S. <1 to 4-year olds

Respiratory Syncytial Virus (RSV)	SARS-CoV-2 (Covid-19)
N=346[a]	N=77[b]/**50**[c] (2020)[b,c] N=87[b]/**63**[c] (2021)[b,c]

a) "Mortality Associated With Influenza and Respiratory Syncytial Virus in the United States", Table 4, p. 184, "Estimated Annual Age-Specific Influenza and Respiratory Syncytial Virus-Associated Deaths for the 1990-1991 Through 1998-1999 Seasons," "All-Cause Deaths" https://jamanetwork.com/journals/jama/fullarticle/195750

b) "Provisional COVID-19 Deaths by Sex and Age" (Data as of 9/29/21) https://data.cdc.gov/widgets/9bhg-hcku?mobile_redirect=true

c) Adjusted for CDC 35% over counting of covid-19 pediatric deaths by death certificate review, per "Death Certificate–Based ICD-10 Diagnosis Codes for COVID-19 Mortality Surveillance — United States, January–December 2020" https://www.cdc.gov/mmwr/volumes/70/wr/mm7014e2.htm?s_cid=mm7014e2_x

Whither covid-19 mortality in Rhode Island?

- **80% of covid-19 deaths are among those ≥ 70 years old**
- **57% of covid-19 deaths are among those ≥ 80 years old**
  - **i.e., 57% of covid-19 deaths occurring in Rhode Island are among those above the state life expectancy of 79.9 years old**

https://docs.google.com/spreadsheets/d/1c2QrNMz8pIbYEKzMJL7Uh2dtThOJa2j1sSMwiDo5Gz4/edit#gid=31350783;

https://www.worldlifeexpectancy.com/usa/rhode-island-life-expectancy

- **48% of covid-19 deaths are among those residing in nursing homes or elder assisted living facilities**

https://docs.google.com/spreadsheets/d/1c2QrNMz8pIbYEKzMJL7Uh2dtThOJa2j1sSMwiDo5Gz4/edit#gid=500394186

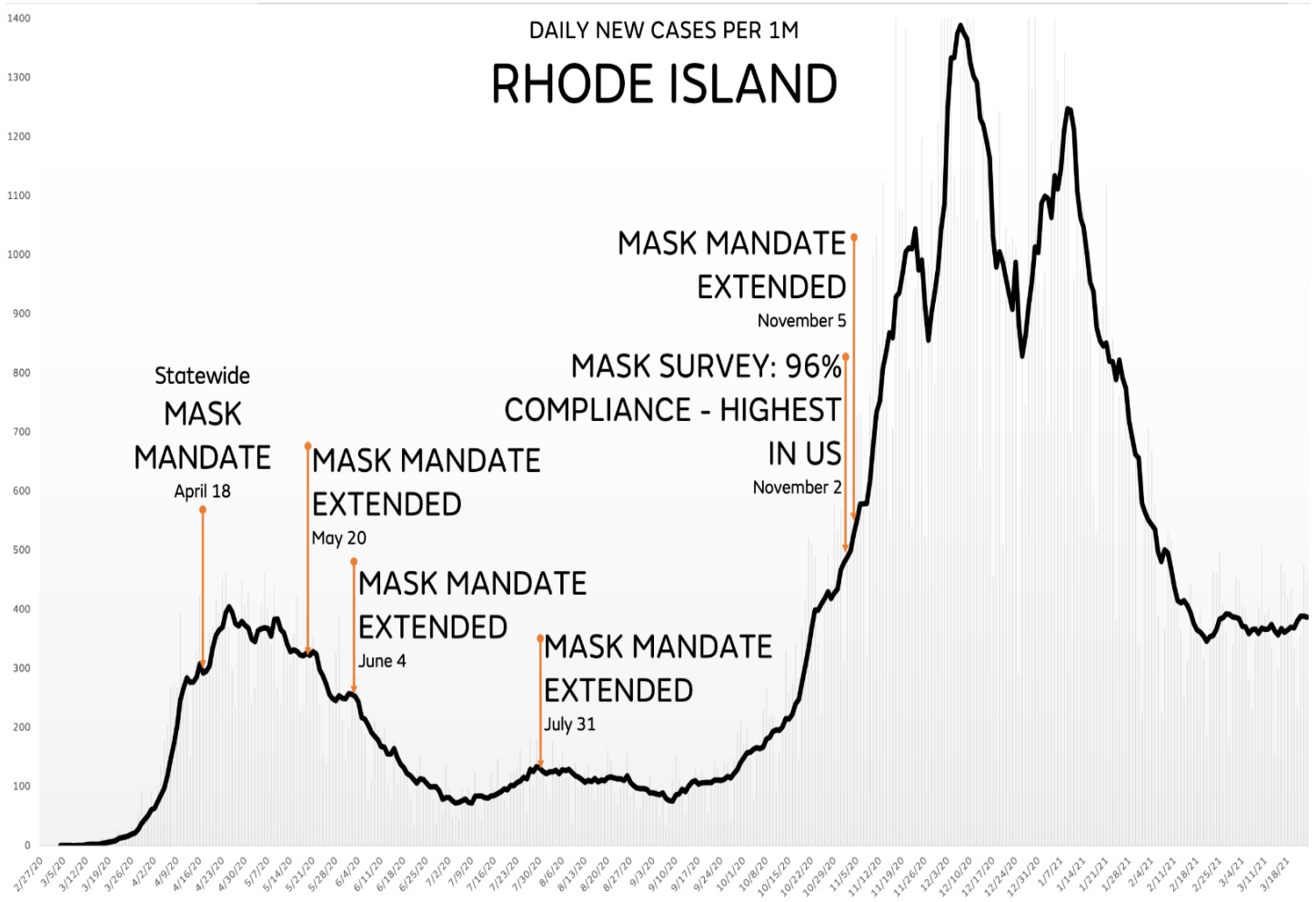
Masking During the 1918 Influenza Pandemic:
Plus ça change, plus c'est la même chose?

W.H. Kellogg, MD, infectious diseases expert, and then executive officer of the California State Board of Health, made this remorseful, brutally honest 1920 observation on the failure of masking to contain rampant influenza spread during the devastating 1918 pandemic (***Am J Public Health*** *[N Y]*. 1920;10(1):34-42. p. 35):

"The failure of the mask was a source of disappointment, for the first experiment in San Francisco was watched with interest with the expectation that if it proved feasible to enforce the regulation the desired result would be achieved. The reverse proved true. ***The masks, contrary to expectation, were worn cheerfully and universally, and also, contrary to expectation of what should follow under such circumstances, no effect on the epidemic curve was to be seen. Something was plainly wrong with our hypotheses*****."**

Masking in Rhode Island During the Initial Two Waves of the 2020-21 Covid-19 Pandemic: *Plus ça change, plus c'est la même chose*?

- Per a survey of 5,000 Americans, reported 11/2/20, Rhode Island had the highest percentage—96%– of those who wear a mask "every time they go out" https://slickdeals.net/article/news/united-states-face-mask-wearing-habits-survey/
- Yet we still had an enormous late fall, early winter spike in covid-19 positive "cases" despite this 96% mask compliance, and the mandate extension, 11/5/20.



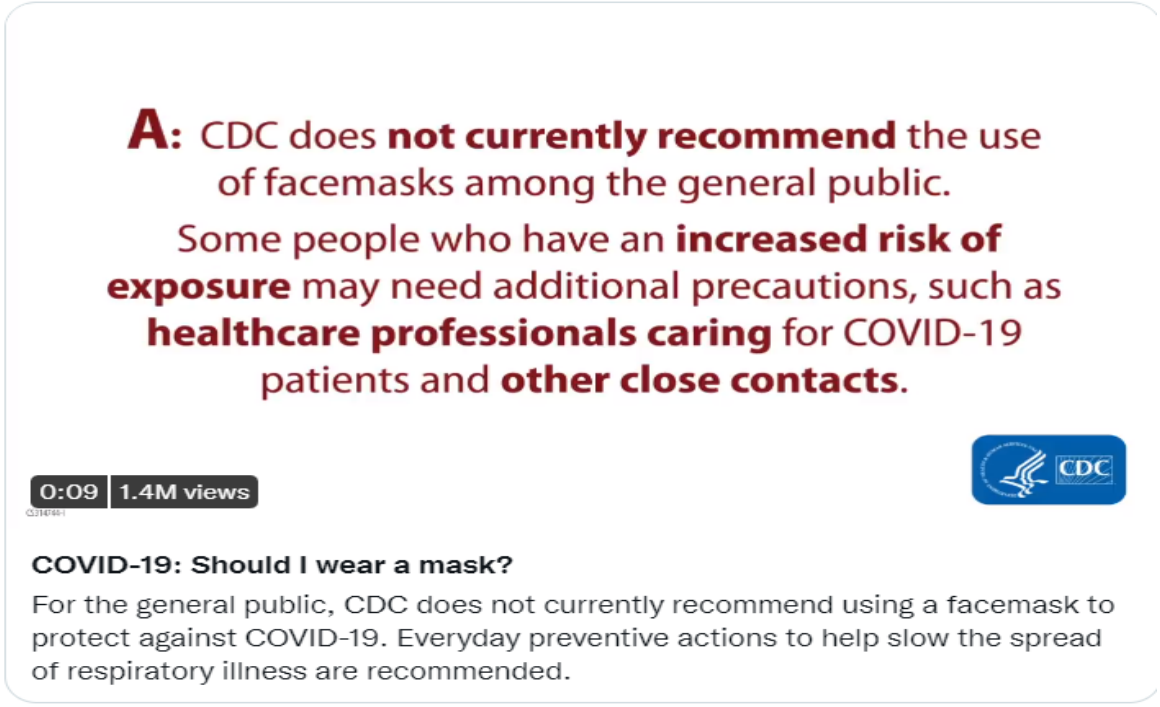
[Raw data for plot from RIDOH google doc]: https://docs.google.com/spreadsheets/d/1c2QrNMz8pIbYEKzMJL7Uh2dtThOJa2j1sSMwiDo5Gz4/edit#gid=264100583

Centers For Disease Control and Prevention (CDC) on Masking to Prevent Covid-19, February 27, 2020

← Tweet

CDC
@CDCgov

CDC does not currently recommend the use of facemasks to help prevent novel #coronavirus. Take everyday preventive actions, like staying home when you are sick and washing hands with soap and water, to help slow the spread of respiratory illness. #COVID19 bit.ly/37Ay6Cm



4:00 PM · Feb 27, 2020 · Twitter Media Studio

Randomized, Controlled Trials as the Requisite Gold-Standard Evidence for *Recommendations* (*Let Alone "Mandates"*)

- In 1963 Campbell and Stanley published their seminal monograph on research methodology entitled "Experimental and Quasi-Experimental Designs for Research."
  - This work, which shaped research designs ever since highlighted the major threats to validity that ***are avoided, uniquely, by the randomized controlled trial***—a true experimental design—**but NOT by purely observational studies and all other non-randomized designs lacking parallel control groups**, **which they referred to "*quasi-experimental*", and fraught with intractable biases we attempt to control for, with limited success, after the fact**.
- Guyatt et al in their 2008 BMJ paper "GRADE: an emerging consensus on rating quality of evidence and strength of recommendations" https://www.bmj.com/content/336/7650/924.long, updated and reinforced these ideas, appropriately assigning highest priority to randomized, controlled trial evidence

Factors that affect the strength of a recommendation

Factor	Examples of strong recommendations
Quality of evidence	Many high quality randomised trials

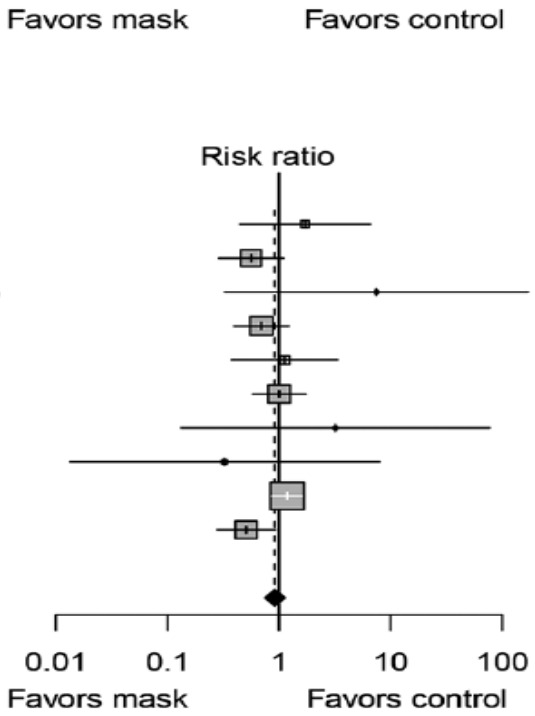
Thirteen Randomized, Controlled Trials of Community Masking for the Prevention of Respiratory Viral Infections, Including SARS-CoV-2, Published 2008, to August 2021, Were Uniformly NEGATIVE (I)

- Between 2008-2020, twelve negative randomized controlled trials on masking were published. These studies conducted among ~18,000 persons, worldwide, all indicated that masking does not reduce community respiratory virus transmission. (1-3)
- Ten negative studies, focusing primarily on influenza, 2008 to 2016, were “meta-analyzed” [their data “pooled”], confirming the individual negative results (1)

C

Author (reference)	Mask Events	Mask Total	Control Events	Control Total	Weight	Risk ratio (95% CI)
Aiello et al. 2010 (*9*)	7	663	3	487	2.1%	1.71 (0.45–6.59)
Aiello et al. 2012 (*10*)	18	741	16	370	13.0%	0.56 (0.29–1.09)
Barasheed et al. 2014 (*33*)	1	11	0	28	0.2%	7.43 (0.33–169.47)
Cowling et al. 2009 (*11*)	18	258	28	279	16.3%	0.70 (0.39–1.23)
Cowling et al. 2008 (*12*)	4	61	12	205	3.3%	1.12 (0.37–3.35)
Larson et al. 2010 (*13*)	25	938	24	904	14.9%	1.00 (0.58–1.74)
MacIntyre et al. 2009 (*34*)	1	94	0	100	0.3%	3.19 (0.13–77.36)
MacIntyre et al. 2016 (*35*)	0	302	1	295	0.9%	0.33 (0.01–7.96)
Simmerman et al. 2011 (*15*)	66	291	58	302	34.6%	1.18 (0.86–1.62)
Suess et al. 2012 (*17*)	16	136	19	82	14.4%	0.51 (0.28–0.93)
Fixed effect model		3,495		3,052	100.0%	0.92 (0.75–1.12)

Heterogeneity: I^2 = 30%, τ^2 = 0.0593, p = 0.17
Test for overall effect: z = −0.84 (p = 0.40)



Thirteen Randomized, Controlled Trials of Community Masking for the Prevention of Respiratory Viral Infections, Including SARS-CoV-2, Published 2008, to August 2021, Were Uniformly NEGATIVE (II)

- Independently validating these pooled findings are the results from a single large randomized controlled trial of masking among another cohort of Hajj pilgrims whose enrollment [n=6338] (2) equaled the sum enrollment of all the 10 studies in the May, 2020 “meta-analysis.” Published online in mid-October, 2020, this “cluster randomized” (i.e., by tent) controlled trial confirmed mask usage did ***not*** reduce the incidence of clinically defined, or laboratory-confirmed respiratory viral infections, primarily influenza and/or rhinovirus. Indeed, there was a suggestion masking increased laboratory-confirmed infections by 40%, although this trend was not “statistically significant.” (2).
- Subsequently, Danish investigators published the results during mid-November, 2020 of a randomized, controlled study conducted in 4862 persons which found that masking did not reduce SARS-CoV-2 (covid-19) infection rates to a statistically significant, or clinically relevant extent. (3) Covid-19 infections (detected by laboratory testing or hospital diagnosis) occurred among 1.8% of those assigned masks, versus 2.1% in control participants. Moreover, a secondary analysis including only participants who reported wearing face masks “exactly as instructed,” revealed a further narrowing of this non-significant, clinically meaningless infection rate “difference” to 0.1%, i.e., 2.0% in mask wearers versus 2.1% in controls.

Thirteen Randomized, Controlled Trials of Community Masking for the Prevention of Respiratory Viral Infections, Including SARS-CoV-2, Published 2008, to August 2021, Were Uniformly NEGATIVE (III)

- Finally, a vast (n=342,000) Bangladesh randomized trial of community masking, just reported 8/31/21 as a preprint, found cloth masks did not prevent SARS-CoV-2 infections. (4) Odd, contradictory findings were reported regarding surgical masks: they conferred a minimal, clinically irrelevant overall absolute risk reduction of 0.09%, which was somehow selectively limited only to those over 50 years old. (4)

- ***In aggregate from 2008 through August 2021, these thirteen consecutive negative randomized controlled trials of community masking for the prevention of respiratory viral infections, including SARS-CoV-2, underscore the punitive, anti-scientific fecklessness of public mask mandates.***

References

1) “Nonpharmaceutical Measures for Pandemic Influenza in Nonhealthcare Settings—Personal Protective and Environmental Measures” https://wwwnc.cdc.gov/eid/article/26/5/19-0994_article

2) “Facemask against viral respiratory infections among Hajj pilgrims: A challenging cluster randomized trial” https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7553311/pdf/pone.0240287.pdf

3) “Effectiveness of Adding a Mask Recommendation to Other Public Health Measures to Prevent SARS-CoV-2 Infection in Danish Mask Wearers: A Randomized Controlled Trial” https://www.acpjournals.org/doi/full/10.7326/M20-6817

4) “The Impact of Community Masking on COVID-19: A Cluster-Randomized Trial in Bangladesh” https://www.poverty-action.org/sites/default/files/publications/Mask_RCT____Symptomatic_Seropositivity_083121.pdf

Medical and Psychological Problems Created By Masking (I)

- Those who have myopia/ near sightedness can have difficulty seeing because the mask fogs their glasses. (This has long been a problem for medical students in the operating room.)

- Masks can cause severe acne and other skin problems. (My wife is a Dermatologist here in RI who has seen many such patients in the past 18 months)

[The points above, per John Hopkins University MD-Epidemiologist Marty Makary's summary in: https://www.wsj.com/articles/masks-children-parenting-schools-mandates-covid-19-coronavirus-pandemic-biden-administration-cdc-11628432716]

- The discomfort of a mask distracts some children from learning, and can cause social isolation as described during the 2003 SARS-CoV-1 epidemic in a Hong Kong study of preschool children.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7097388/pdf/13158_2009_Article_BF03168205.pdf

Medical and Psychological Problems Created By Masking (II)

- By **increasing** airway resistance during exhalation, masks can lead to increased levels of carbon dioxide in the blood:
  - A 2013 published report from ICU nurses found the increased blood CO2 levels after several hours of mask usage were associated with complaints of headaches, perceived shortness of breath, increased perceived exertion, and difficulty communicating http://dx.doi.org/10.1016/j.ajic.2013.02.017
  - A 2021 cross-sectional survey of 1001 Singapore residents assessed before & during mask use found self-reported dyspnea (SOB) was associated with moderate physical activity, ***use for ≥ 3 hours***, & use of an N95 vs. surgical mask https://pubmed.ncbi.nlm.nih.gov/34600453/
  - A 2019 controlled randomized, crossover study of N95 masking in children reported that within 5-minutes, masking significantly raised blood CO2 concentrations vs. a controlled 5-minute period when unmasked https://pubmed.ncbi.nlm.nih.gov/31831801/

- And masks can be vectors for pathogens if they become moist or are used for too long
  - A 2018 study of surgeons which cultured their masks after surgery found multiple pathogens and concluded surgeons should change their masks after 2-hours in the operating room to avoid causing wound infections https://www.sciencedirect.com/science/article/pii/S2214031X18300809?via%3Dihub