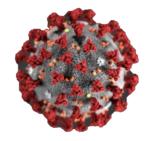
New Hampshire COVID-19 Healthcare Provider and Public Health Partner Call

May 12, 2022





NH DHHS COVID-19 Updates

- NH DHHS is transitioning from daily to weekly COVID-19 Press Release updates
- The new weekly update will be issued each Thursday (starting May 19th)
- Data dashboards will continue to be updated daily Mon-Fri
- Dashboard will also undergo updates to focus on more relevant metrics

NH Department of Health and Human Services 129 Pleasant Street - State Office Park South Concord, NH 03301



PRESS RELEASE FOR IMMEDIATE RELEASE May 5, 2022 CONTACT
Public Information Office
603-271-9389
pio@dhhs.nh.gov

NH DHHS COVID-19 Update May 5, 2022

Concord, NH – The New Hampshire Department of Health and Human Services (DHHS) has issued the following update on the new coronavirus, COVID-19.

On Thursday, May 5, 2022, DHHS announced 539 new positive test results for COVID-19 for Wednesday, May 4. Today's results include 372 people who tested positive by PCR test and 167 who tested positive by antigen test. DHHS also announced an additional 26 new cases from Tuesday, May 3 (16 by PCR and 10 by antigen test) for a new total of 585. Test results for previous days are still being processed and updated case counts for prior days will be reflected on the COVID-19 interactive dashboard. There are now 3,808 current COVID-19 cases diagnosed in New Hampshire.

Several cases are still under investigation. Additional information from ongoing investigations will be incorporated into future COVID-19 updates. Of those with complete information, there are sixty-three individuals under the age of 18 and the rest are adults with 56% being female and 44% being male. The new cases reside in Rockingham (105), Hillsborough County other than Manchester and Nashua (82), Strafford (78), Merrimack (51), Grafton (50), Cheshire (34), Belknap (25), Sullivan (16), Carroll (15), and Coos (9) counties, and in the cities of Nashua (41) and Manchester (39). The county of residence is being determined for twenty new cases.

There are currently 25 hospitalized patients being treated for COVID-19. In New Hampshire, since the start of the pandemic, there have been a total of 312,679 cases of COVID-19 diagnosed.

Current Situation in New Hampshire New Hampshire 2019 Novel Coronavirus (COVID-19) Summary Report (updated May 5, 2022, 9:00 AM)

312,679
306,384 (98%)
2,487 (1%)
3,808
25

The most up-to-date laboratory testing data, positivity rates and vaccination data are available on the COVID-19 dashboards at https://www.covid19.nh.gov/dashboard/overview. For additional hospitalization data, please visit the New Hampshire Hospital Association's COVID-19 information page at https://nhha.org/index.php/whats-new/1545-coronavirus-disease-2019-covid-19-outbreak.

For more information, please visit the DHHS COVID-19 webpage at https://www.covid19.nh.gov/.



COVID-19 Vaccine Updates



4 Questions

- 1. When will vaccination be available for children under 5 years of age?
- 2. Will children 5-11 years of age be eligible for a booster dose?
- 3. Will another COVID-19 vaccine booster be needed for everybody this fall or winter?
- 4. Will a fall/winter booster vaccine formulation need to be updated to cover emerging variants?



When Will COVID-19 Vaccine Be Available For Children Under 5 Years of Age?





NEWS RELEASE

Moderna Announces its COVID-19 Vaccine Phase 2/3 Study in Children 6 Months to Under 6 Years Has Successfully Met Its Primary Endpoint

3/23/2022

- Two 25 mcg doses in children provided "similar immunogenicity" compared to two 100 mcg doses in adults 18-25 years of age
- Vaccine efficacy (VE) at preventing infection was statistically significant (VE during Omicron: 38-44%)
- No severe COVID-19 cases were observed preventing estimates of VE against hospitalization or death
- No safety concerns





NEWS RELEASE

Moderna Files for Authorization of Its COVID-19 Vaccine in Young Children Six Months to Under Six Years of Age

4/28/2022



Coronavirus (COVID-19) Update: FDA Announces Tentative Advisory Committee Meeting Schedule Regarding COVID- 19 Vaccines



For Immediate Release: April 29, 2022

Today, the U.S. Food and Drug Administration is announcing its plans to hold virtual meetings of its Vaccines and Related Biological Products Advisory Committee (VRBPAC) in anticipation of complete submissions of emergency use authorization (EUA) requests in the coming months that have been publicly announced by COVID-19 vaccine manufacturers.

It is important to note that the dates below are tentative as none of the submissions are complete. The agency understands the urgency to authorize a vaccine for age groups who are not currently eligible for vaccination and will work diligently to complete our evaluation of the data. Should any of the submissions be completed in a timely manner and the data support a clear path forward following our evaluation, the FDA will act quickly and anticipates convening the following VRBPAC meetings:

- On June 7, FDA intends to convene VRBPAC to discuss an EUA request for a COVID-19 vaccine manufactured by Novavax to prevent COVID-19 in individuals 18 years of age and older.
- On June 8, 21 and 22, the FDA has held dates for the VRBPAC to meet to discuss
 updates to the Moderna and Pfizer-BioNTech EUAs for their COVID-19 vaccines to
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- On June 28, the FDA plans to convene the VRBPAC to discuss whether the SARS-CoV-2 strain composition of COVID-19 vaccines should be modified, and if so, which strain(s) should be selected for Fall 2022. This meeting is a follow-up to the April 6 VRBPAC meeting that discussed general considerations for future COVID-19 vaccine booster doses and the strain composition of COVID-19 vaccines to further meet public health needs.



COVID-19 Vaccination for Children Under 5 Years of Age

- Pfizer-BioNTech has not yet submitted data on immunogenicity and efficacy of their 3-dose series in younger children
- COVID-19 vaccines for children under the age of 5 years may not be available until summer
- Vaccination for this younger age group will occur primarily through a child's primary care provider or medical home:
 - See information on <u>How to Become a COVID-19 Vaccine Provider</u>



Will Children 5-11 Years of Age Be Eligible for Vaccine Booster Doses?





Pfizer and BioNTech Submit Application for U.S. Emergency Use Authorization for a COVID-19 Vaccine Booster Dose in Children 5 Through 11 Years of Age

Tuesday, April 26, 2022 - 04:30pm

- 10 mcg booster
- No new safety signals
- Study "demonstrated a strong immune response in this age group following a booster dose..."



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nature

Accelerated Article Preview

Increased Memory B Cell Potency and Breadth After a SARS-CoV-2 mRNA Boost

- Studied memory B cells (part of immune memory that produces antibodies in response to infection) in a cohort of 42 persons receiving 3 mRNA vaccine doses
- A 3rd dose of an mRNA vaccine resulted in:
 - Expansion of existing memory B cell clones
 - Emergence of new memory B cell clones
 - Increased memory B cells expressing more potent and broader antibodies
 - Ultimately resulted in a boosted antibody response to multiple variants

"Thus, individuals receiving 3 doses of an mRNA vaccine, have a diverse memory B cell repertoire that can respond rapidly and produce antibodies capable of clearing even diversified variants such as Omicron."



A Booster is Important for Maximum Expanded Protection

- An mRNA booster after a 2-dose primary mRNA vaccine series ("prime + boost") is necessary to have maximal and expanded protection against SARS-CoV-2, including variants not initially covered in the original vaccine formulation
- A booster dose should be considered as part of the initial and necessary vaccination series
- Booster doses are currently only recommended for persons 12 years of age and older
- By summer it's likely that booster doses will also be available/recommended for children 5-11 years of age



Will Another COVID-19 Vaccine Booster Be Needed for Everybody This Fall or Winter?



Viewpoint

May 2, 2022

COVID-19 Vaccination—Becoming Part of the New Normal

Peter Marks, MD, PhD¹; Janet Woodcock, MD¹; Robert Califf, MD¹ *JAMA*. Published online May 2, 2022. doi:10.1001/jama.2022.7469

- Three factors that may increase COVID-19 risk this fall/winter:
 - 1. Waning immunity from prior vaccination or infection
 - 2. Continued evolution of SARS-CoV-2 (i.e., more variants emerging)
 - 3. Seasonality of respiratory virus infections (including likely SARS-CoV-2) with increased risk of transmission as people move indoors



Viewpoint

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- Potential Benefits of an additional booster dose (similar to reasons for influenza vaccination every year):
 - Boost protection against infection and transmission to be timed, if possible, with period of increased risk
 - Reduced lost days of productivity (school and work)
 - Reduced healthcare utilization
 - Increased protection against severe disease, hospitalization, and death (greatest benefit likely in older adults and immunocompromised)
 - Protection from long-COVID (i.e., post-COVID conditions)



Viewpoint

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Peter Marks, MD, PhD¹; Janet Woodcock, MD¹; Robert Califf, MD¹ *JAMA*. Published online May 2, 2022. doi:10.1001/jama.2022.7469

"A decision on composition will need to be made in the US by June 2022"

"Society is moving toward a new normal that may well include annual COVID-19 vaccination alongside seasonal influenza vaccination"



THE LANCET Infectious Diseases

Safety, immunogenicity, and reactogenicity of BNT162b2 and mRNA-1273 COVID-19 vaccines given as fourth-dose boosters following two doses of ChAdOx1 nCoV-19 or BNT162b2 and a third dose of BNT162b2 (COV-BOOST):

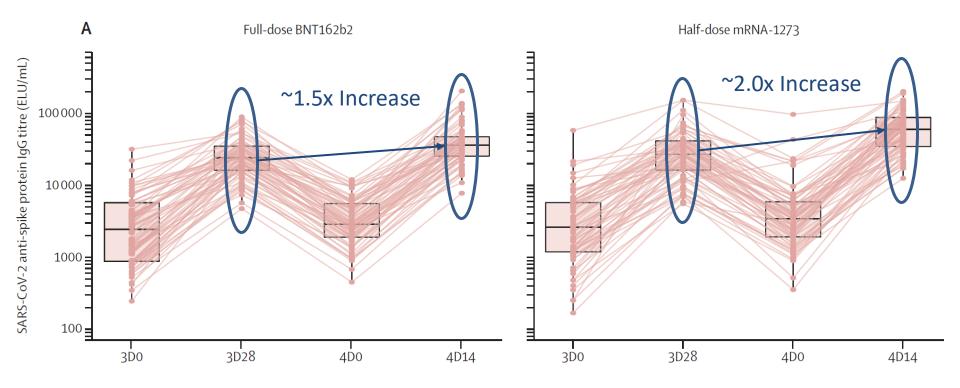
a multicentre, blinded, phase 2, randomised trial

- Multicenter, blinded, randomized controlled trial conducted at 18 sites in the UK
- Included persons 30 years of age or older (although median age of participants was 70 years)
- Investigated the safety and immunogenicity of a 4th dose (2nd booster) of an mRNA vaccine (either Pfizer or Moderna) administered ~7 months after a 3rd dose
 - Measured both antibody concentrations and cellular response



	Three doses of BNT162b2 (n=64)	
	Full-dose BNT162b2 (n=31)	Half-dose mRNA-1273 (n=33)
SARS-CoV-2 anti-spike protein IgG concentration, ELU/mL		
Fold change (day 14 after fourth dose vs day 28 after third dose)	1·54 (1·35–1·76); 30	1·99 (1·71–2·31); 33
Cellular response (wild-type), spot forming cells per 10° PBMCs*		
Fold change (day 14 after fourth dose vs day 28 after third dose)	1·12 (0·54–2·31); 8	2.83 (2.02–3.96); 8
Cellular response (beta), spot forming cells per 10° PBMCs*		
Fold change (day 14 after fourth dose vs day 28 after third dose)	1·03 (0·50–2·12); 8	3·45 (2·10–5·69); 8
Cellular response (delta), spot forming cells per 10 ⁶ PBMCs*		
Fold change (day 14 after fourth dose vs day 28 after third dose)	1·19 (0·59–2·40); 8	3·85 (2·39–6·21); 8







Will a Fall/Winter Booster Vaccine Formulation Need to be Updated to Cover Emerging Variants?



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Safety, Immunogenicity and Antibody Persistence of a Bivalent Beta-Containing Booster Vaccine

- Studied a bivalent Moderna vaccine (mRNA-1273.211) containing equal amounts of spike protein mRNA sequences from both the ancestral SARS-CoV-2 strain and the Beta variant
- Included adults who previously received the primary 2-dose Moderna vaccine series (the original and currently authorized Moderna vaccine)
- Study group 1: 50 mcg bivalent Moderna booster (300 participants)
- Study group 2: 100 mcg bivalent Moderna booster (596 participants)
- Comparator group: 50 mcg original/authorized Moderna booster (171 participants)



Table 2: Neutralizing antibody estimated geometric mean titers after the 50-µg mRNA-1273.211 an d the 50-µg mRNA-1273 booster doses.

	Day after booster	mRNA-1273.211	mRNA-1273	Geometric Mean Ratio
	dose	50 μg booster dose	50 μg booster dose	
		GMT* (95% CI)	GMT*(95% CI)	
Ancestral SARS- CoV-2 with		2278.0	1782.7	1.28
D614G	Day 29	(2074.0, 2502.1)	(1561.3, 2035.6)	(1.08, 1.51)
	Doy 101	1040.0	617.2	1.68
	Day 181	(926.4, 1167.3)	(525.1, 725.5)	(1.38, 2.06)
Beta	Day 29	1095.3	825.6	1.33
	Day 29	(981.1, 1222.7)	(706.6, 964.7)	(1.09, 1.61)
	Day 181	343.5	125.2	2.74
	Day 101	(303.7, 388.5)	(105.4, 148.8)	(2.22, 3.40)
Omicron	Day 29	1389.8	630.5	2.20
	Day 29	(1212.1, 1593.4)	(520.0, 764.9)	(1.74, 2.79)
	Day 181	312.9	145.6	2.15
	Day 101	(269.5, 363.4)	(118.1, 179.5)	(1.66, 2.78)
Delta	Day 29	1481.2	844.1	1.75
	Day 23	(1335.8, 1642.3)	(730.2, 975.8)	(1.47, 2.10)
	Day 181	491.3	408.0	1.20
	Day 101	(437.8, 551.5)	(347.5, 479.1)	(0.99, 1.47)

Table 2: Neutralizing antibody estimated geometric mean titers after the 50-µg mRNA-1273.211 and the 50-µg mRNA-1273 booster doses.

	Day after booster dose	mRNA-1273.211 50 μg booster dose	mRNA-1273 50 μg booster dose	Geometric Mean Ratio
	dosc	GMT* (95% CI)	GMT*(95% CI)	
Ancestral SARS- CoV-2 with D614G	Day 29	2278.0 (2074.0, 2502.1)	1782.7 (1561.3, 2035.6)	1.28 (1.08, 1.51)
	Day 181	1040.0 (926.4, 1167.3)	617.2 (525.1, 725.5)	1.68 (1.38, 2.06)
Beta	Day 29	1095.3 (981.1, 1222.7)	825.6 (706.6, 964.7)	1.33 (1.09, 1.61)
	Day 181	343.5 (303.7, 388.5)	125.2 (105.4, 148.8)	2.74 (2.22, 3.40)
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Delta	Day 29	1481.2 (1335.8, 1642.3)	844.1 (730.2, 975.8)	1.75 (1.47, 2.10)
	Day 181	491.3 (437.8, 551.5)	408.0 (347.5, 479.1)	1.20 (0.99, 1.47)

Study Findings

- Neutralizing antibody titers against the ancestral strain and all three variants (Beta, Delta, and Omicron) significantly increased 1 month and 6 months post-boost
- The bivalent Moderna vaccine showed <u>superior</u> immunogenicity when compared to the original/authorized Moderna vaccine
- The 100 mcg bivalent vaccine elicited higher neutralizing antibody titers than the 50 mcg bivalent vaccine, but with higher reactogenicity



Summary

- COVID-19 vaccination is the most important way for a person to protect themselves from COVID-19
- A booster dose is important and necessary to have the maximum expanded protection against emerging variants
- Vaccination for children under the age of 5 years may come as early as June (summer)
- Children 5-11 years of age may become eligible for a booster dose around the same time frame
- There is a good chance another booster dose will be recommended for a potential fall/winter surge
- Limited data so far suggest a multi-valent COVID-19 vaccine may offer increased protection



COVID-19 Mortality





COVID-19 Direct Mortality in U.S.

- Officially, 998,699 US deaths
 - Will surpass 1M
 - Already estimated 1.3M
 - 16% of global deaths
- 3rd leading cause of death in 2020 and 2021 (1 in 8 deaths)
 - 2nd in those 85+
- For hospitalized patients, at least <u>3x CFR as flu</u>
 - 675k 1918 pandemic influenza deaths in U.S.



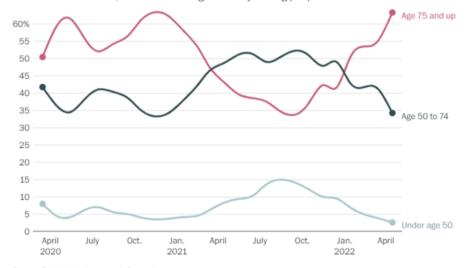
CFR Estimates

The estimated case fatality rate of COVID-19 in different subgroups.

Group	Pooled estimation (%)	95% CI	Q	I ² (%)
General population	1.00	1.0-3.0	P < 0.001	94.3
Hospitalized patients	13.0	9.0-17.0	P < 0.001	95.6
ICU admitted	37.0	24.0-51.0	P < 0.001	97.8
Unknown	4.0	3.0-5.0	P < 0.001	97.8
≤ 50	3.0	0.0-6.0	P < 0.001	93.7
> 50	19.0	13.0-24.0	P < 0.001	98.1
Unknown	2.0	1.0-3.0	P < 0.001	99.8
Overall	10.0	8.0-11.0	P < 0.001	99.7

39 of 516 studies included in systematic review and metaanalysis

During the delta variant's surge, most of the deaths were people under age 75. After the arrival of the omicron variant, the deaths are again mostly among people 75 or older.



Share of deaths in that month for each age group

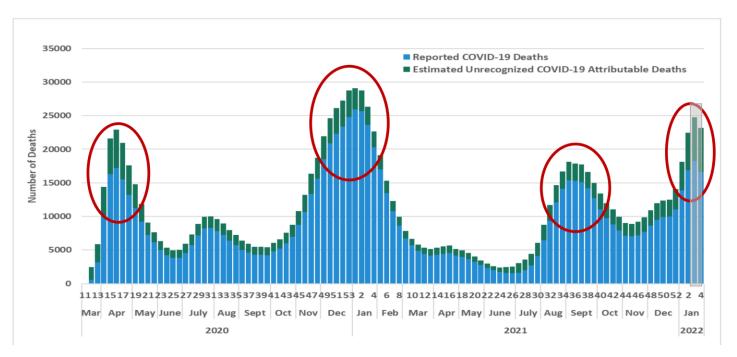
Source: Centers for Disease Control and Prevention

DAN KEATING / THE WASHINGTON POST

Oldest Seniors Again Majority of Deaths

Direct COVID Mortality in US is Underestimated

- CDC analysis demonstrates esp true during surges
- Underestimates are greater in other countries
 - Systems, staffing, definitions, politics



https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/burden.html#how-est-symptomatic

A. Danielle Iuliano, Howard H. Chang, Neha N. Patel, et al., Estimating under-recognized COVID-19 deaths, United States, march 2020-may 2021 using an excess mortality modelling approach, The Lancet Regional Health - Americas, Volume 1, 2021, 100019, https://doi.org/10.1016/j.lana.2021.100019

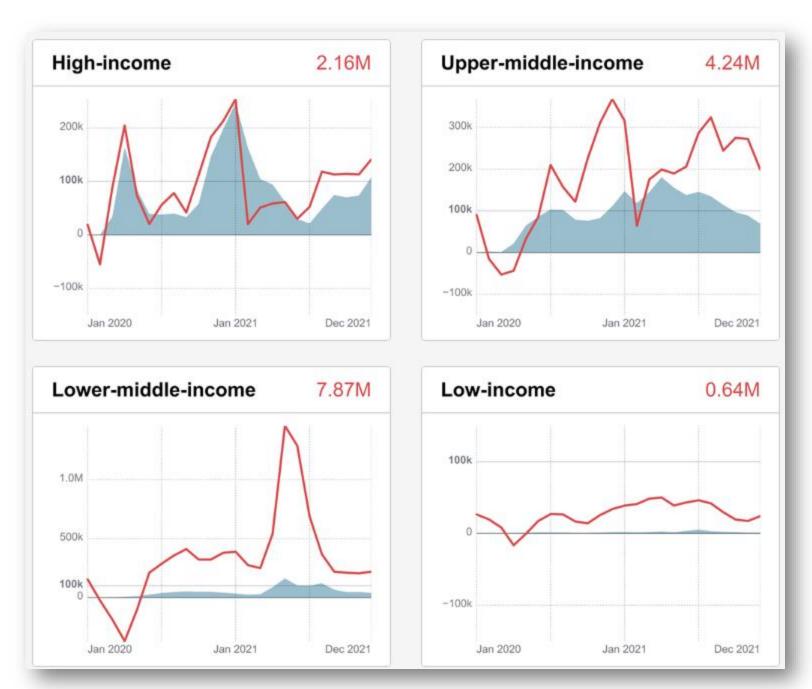
Global: 15M Excess Deaths

- WHO model estimates 15M people have died globally 2020-2021, due to causes directly or indirectly related to pandemic
 - Range 13.3 16.6M
 - 3 times official number
 - Defined as would not have died from a different cause over the same course of time, in addition to those who passed away due to a lack of healthcare accessibility caused by pandemic-associated lockdowns or overburdened healthcare systems
- UW Institute for Health Metrics and Evaluation estimates 17M
 - 1 out of every 500 people globally
- Compared to death from other infectious diseases in 2019:
 - 1.5 diarrheal diseases
 - 1.4M TB
 - 0.5M malaria

WHO Estimates of 2-y Excess Mortality, May 2022



'Excess mortality' is defined as the difference between the total number of deaths that have occurred and the number of deaths that would have been expected in the absence of the pandemic i.e. a no-COVID-19 scenario



WHO Estimates of 2-y Excess Mortality, May 2022

THE LANCET Regional Health Europe

ARTICLES | ONLINE FIRST, 100394

Long-term mortality following SARS-CoV-2 infection: A national cohort study from Estonia

Open Access • Published: April 28, 2022 • DOI: https://doi.org/10.1016/j.lanepe.2022.100394

Cohort study used electronic health care data

- 66,287 PCR+ Feb 2020 Feb 2021
 - Within 5w, 92.1% non-severe, 5.4% hospitalized, 2.2% critical disease
- 254,969 index date time-matched randomly selected from ref pop without evidence of infection
 - Within 5w, 0.8% hospitalized, 0.3% critical disease

Long-term Mortality Following SARS-CoV-2 Infection

Acute (5w) mortality 13.8 fold higher

- PCR+: 1,623 per 10,000 person-years (95% CI 1,526.4-1,725.7)
- Ref pop: 117.8 per 10,000 person-years (95% CI 105.0-132.3)

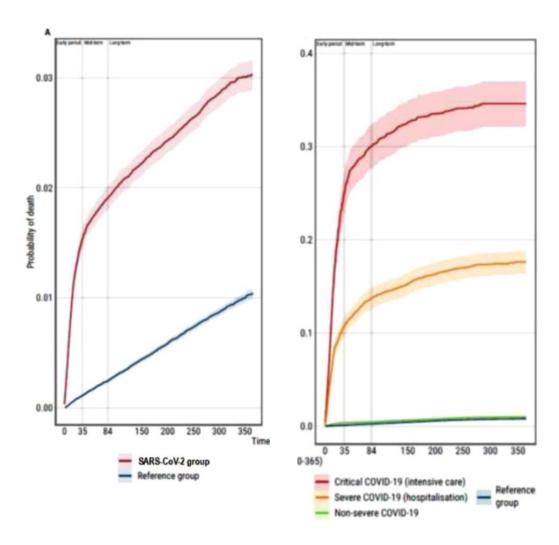
Mid-term (5w-12w) mortality 2.8 fold higher

- PCR+: 276.5 (95% CI 243.7-313.6)
- Ref pop: 97.9 (95% CI 87.9-109.0)

Long-term (>12w) mortality 1.5 fold higher

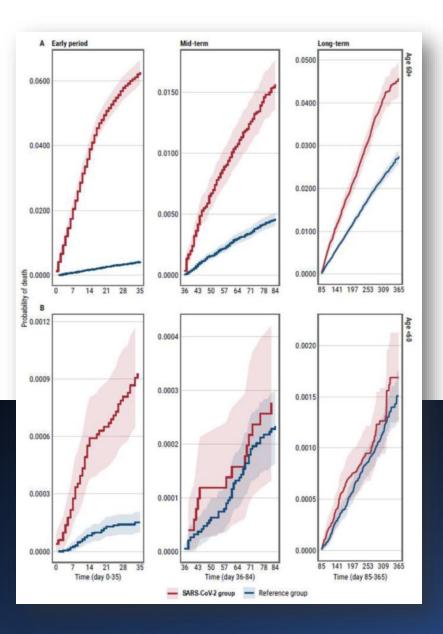
- PCR+: 118.7 (95% CI 110.1-128.1)
- Ref pop: 77.5 (95% CI 73.8-81.3)

Higher 1y Mortality with More Severe Disease



Among cases, 60.6% of deaths occurred among those with severe or critical COVID-19

Differences in Mortality More Pronounced 60+



One Year Mortality 3.1 Times Higher Among SARS-CoV-2 Cases

- For cases ≥60y, increased mortality related to increased risk for
 - Cardiovascular (aHR 2.1, 95% CI 1.8-2.3)
 - Cancer (aHR 1.5, 95% CI 1.2-1.9)
 - Respiratory diseases (aHR 1.9, 95% CI 1.2-3), and
 - Other causes of death (aHR 1.8, 95% CI 1.4-2.2)
- Multiple proposed mechanisms by which acute COVID can lead to clinical sequelae or exacerbate pre-existing conditions
- SARS-CoV-2 infected individuals may be at higher risk of mortality through biological effects in combo with other determinants, such as belonging to racial/ethnic minority groups, low SES, limited health care access

The Final Pandemic Betrayal

- · Millions of people are mourning
 - For every death, ~9 with complicated grief
- Complicated because
 - Deaths from COVID have been unexpected, untimely, prolonged, preventable, sometimes from mourner
 - Social isolation abounds: no rituals, less support
 - Frequent triggers
 - Private grief to public scrutiny
 - Judgment
- When COVID grievers tell others about their loss, often questioned:
 - Do you know how they were exposed?
 - How old were they?
 - Did they have a pre-existing condition?
 - Were they vaccinated, boosted?
- The decedent's "life becomes devalued, and their death becomes less tragic"

Underappreciated Direct COVID-19 Impacts

- Morbidity and mortality
 - Acute disease, MIS-C and MIS-A
- Post acute COVID syndrome (PACS, PASC, long COVID) in 43% of global cases
 - April 16 <u>meta-analysis/SR</u> of 4,438 pubs, representing 1.7M
- Vulnerability to dementia
- Increased type 1 and 2 diabetes



Indirect COVID-19 Impacts

- Opportunity to reset
- Emergence of AMR
- Delayed diagnosis/care of other diseases
- Reduced transmission of some IDs
- Global economy resulting in increased disparities: 26T spent on response yet COVID has pushed 100M into extreme poverty
- Diminished health and public health workforce and credibility
- Political tumult and societal divisions
- Disrupted education
- Children's welfare and health such as abuse; reduced immunization, socialization, mental health
 - 167k US children lost parent or caregiver

Q&A



Healthcare Provider & Public Health Partner Calls

- Monthly on the 2nd Thursday of each month from 12:00-1:00 pm (Next call will be June 9th)
- Webinar/call information:
 - Zoom link: https://nh-dhhs.zoom.us/s/94059287404
 - Webinar ID: 940 5928 7404
 - Passcode: 353809
 - Telephone: 646-558-8656

