



MARA G. ASPINALL

Professor of Practice

Co-Founder **Biomedical Diagnostics Program** College of Health Solutions

Arizona State University

This webinar is sponsored by: **Abbott**



The speakers are presenting on behalf of Abbott. The information presented is consistent with applicable FDA guidelines. This program does not provide continuing medical education (CME) credits. © 2021 Abbott. All rights reserved. All trademarks referenced are trademarks of either the Abbott group of companies or their respective owners. Any photos displayed are for illustrative purposes only. COL-06331-01 07/21



Receiving speaker honorarium from Abbott.

Member of the Board of Directors:

- Abcam plc
- Allscripts
- Castle Biosciences
- OraSure
- Blue Cross Blue Shield Arizona



- The Good, the Bad and the Ugly
- School In-Person Index
 - Where did we end in the Spring
- School COVID Safety
 - 1. Vaccination
 - 2. Mitigation
 - 3. Confirmation
- School Funding Options for Testing



Polling Question #1 – TOPICS OF INTEREST

I am interested in learning the following: (check all that apply)

- A. Understanding different testing technologies
- B. Understanding testing protocols and processes
- C. Test funding and resources
- D. Finding alternate testing solutions
- E. Data tracking and reporting (including sending required data to agencies)
- F. Other



The Good, the Bad and the Ugly

The Good

- Cases are way down from a year ago (but recent surge is concerning)
- 50% of US adults are vaccinated (80% for teachers)
- 25-35% of 12–17-year-olds are vaccinated
- Vaccines are highly effective (50-90% depending on variant)

The Bad

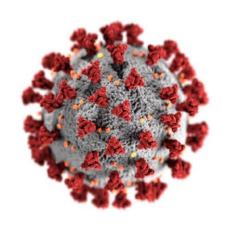
- Only 50% of adults and net 15% of all kids are vaccinated
- Few mitigation measures remain in place
- Delta Variant is more transmissible than any variant we have seen so far

The Ugly

- All viruses mutate more mutations will come
- At least 20% and maybe 50+% people are completely asymptomatic



The Making of a Variant



...UUU UUA AAC CGG...

mRNA strand is

29,903 bases long

A random "Mutation" occurs

...UUC UUA AAC CGG UUA...

No change because
UUU and UUC
code the same protein

More mutations occur

...UUC UUA CAC CGG UCA..

This mutation changes the protein and a new "Variant" is born

No effect on infectivity, virulence, severity or mortality

"VARIANT OF NOTE"

Growing its presence in the viral population

"VARIANT OF INTEREST"

Early confirmation of effect on patients

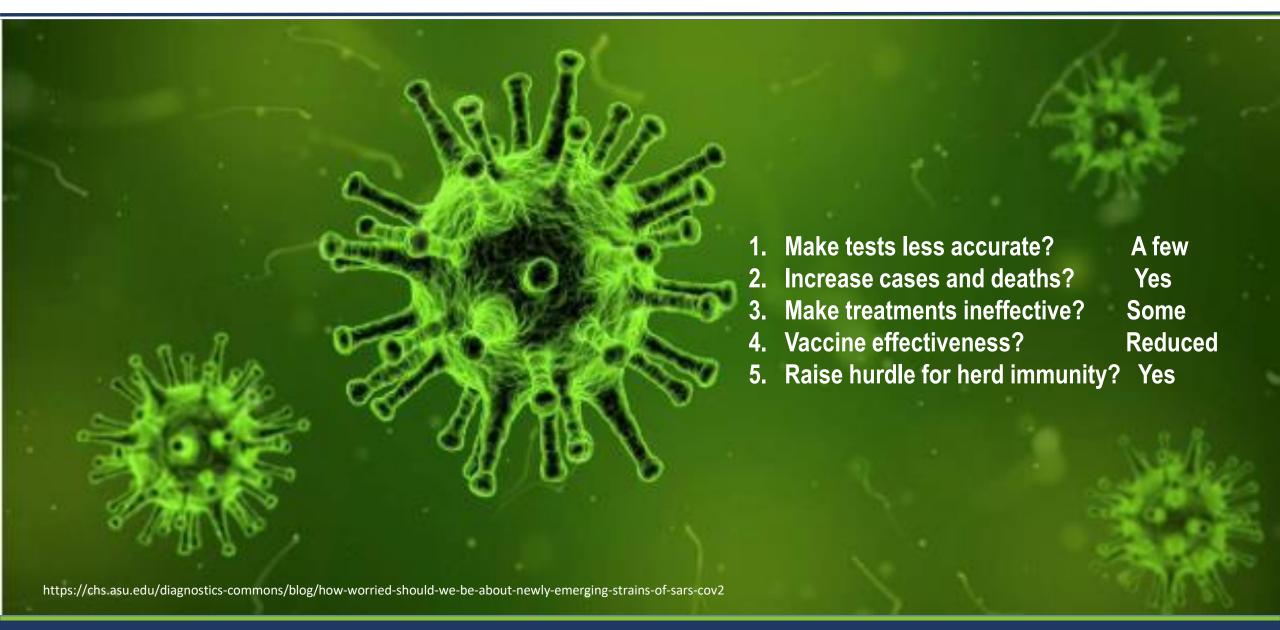
"VARIANT OF CONCERN"

that a variant is significant and well established

A new
"STRAIN"
is born



SARS-CoV-2 Variants: Five Questions





High Rate of Asymptomatic Cases Require Testing Vigilance

20-60% ASYMPTOMATIC ADULTS CASES (ALL COVID INFECTIONS)

- 19% of 213 isolated Korean contacts; Ct same in asymptomatics¹
- **20%** (17-25%) in 79 paper meta-study²
- 32% College students asymptomatic of whom 19% infected others, close to symptomatics with 25% onward infection³
- **40-45%** "narrative review"⁴

43% Icelandic adult screening – at time of testing

42% Vo' Italy - tracked and confirmed over time

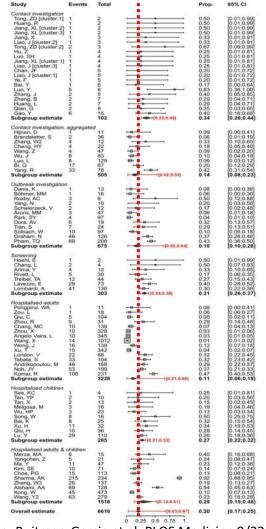
46.5% Diamond Princess

60% USS Roosevelt & Charles de Gaulle (younger, fitter population)

52.2% Seattle WA Nursing home

52% of 3105 PCR+ of 19.4 million international arrivals to China⁵

Many studies - Wide variation



Source: Buitrago-Garcia et al; PLOS Medicine 9/22/20

¹Ra et al, BMJ 8/17/20 ²Buitrago-Garcia et al; PLOS Medicine 9/22/20 ³Krieg et al; medRxiv 7/8/21 ⁴Oran/Topol; Annals of Int Med 9/1/20 ⁵Ren et al: JAMA 2/2/21



High Rate of Asymptomatic Cases Require Testing Vigilance

Seattle WA community screening¹

ASYMPTOMATIC

38% 7%

CHILDREN ADULTS

Similar viral loads

Child contacts of confirmed cases in Korea²

ASYMPTOMATIC PRE-SYMPTOMATIC*

22%

25%

Long post-infection viral shedding (19-20 days)

^{*}Pre-symptomatic at time of diagnosis, developed symptoms median 2.5 days post COVID-19 diagnosis.

¹Chung et al; JAMA Pediatrics 6/2021.

²Han et al; JAMA Pediatrics 1/2021.



- The Good, the Bad and the Ugly
- School In-Person Index
 - Where did we end in the Spring
- School COVID Safety
 - 1. Vaccination
 - 2. Mitigation
 - 3. Confirmation
- School Funding Options for Testing



Returning to Classroom Instruction (K-12 Schools)

7/5/21

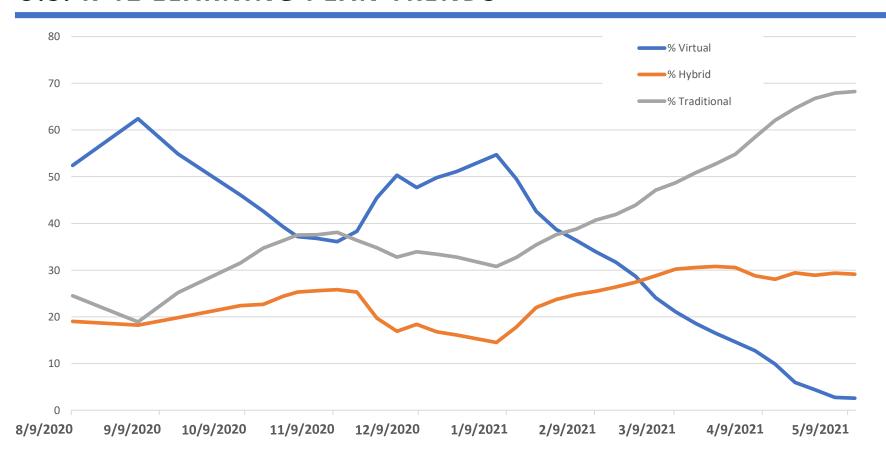
2.1% Virtual Instruction

28.2%

Hybrid Instruction

69.7%
Traditional Instruction

U.S. K-12 LEARNING PLAN TRENDS

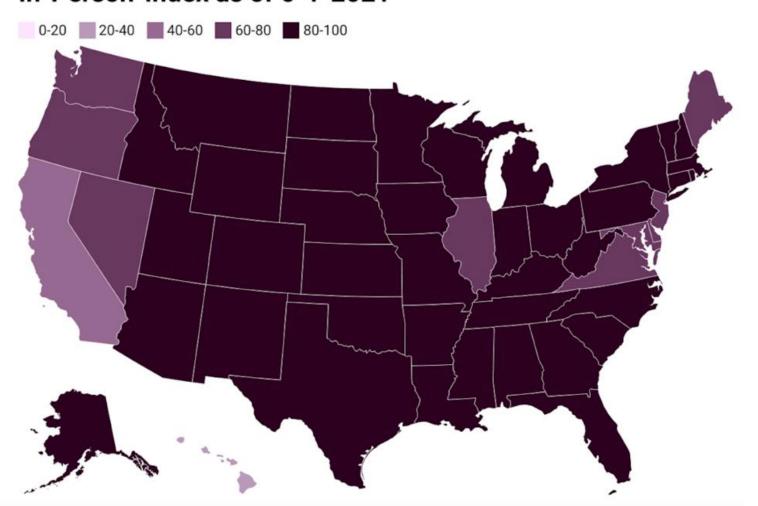


Source: Burbio



In-Person Index of Schools: Nationwide

In-Person-Index as of 6-1-2021



In-Person Index:

Weighed Average of Instruction **Type by School.**

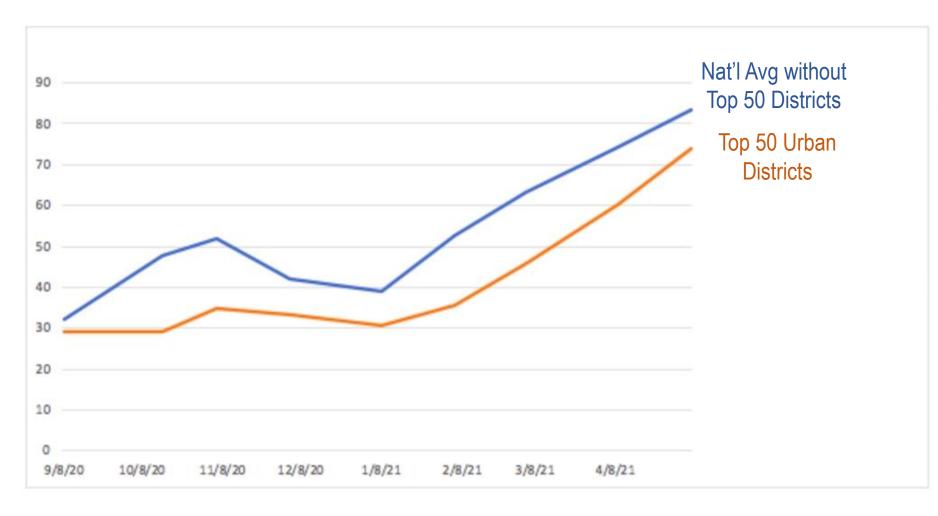
Index weights % virtual instruction schools at 0, % hybrid instruction schools (2-3 days a week in-person) at 50 and % traditional schools

(5-days in person) at 100

Source: Burbio - Accessed July 2021



In-Person Index of Schools: Urban vs. All Other



In-Person Index:

Weighed Average of Instruction

Type by School.

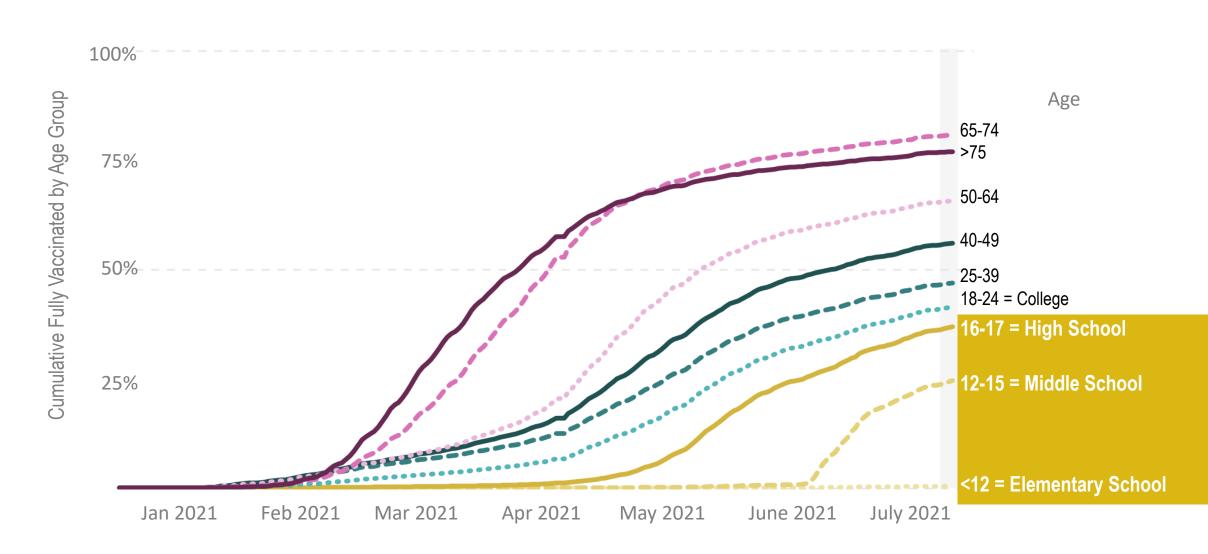
Index weights % virtual instruction schools at 0, % hybrid instruction schools (2-3 days a week in-person) at 50 and % traditional schools (5-days in person) at 100



- The Good, the Bad and the Ugly
- School In-Person Index
 - Where did we end in the Spring
- School COVID Safety
 - 1. Vaccination
 - 2. Mitigation
 - 3. Confirmation
- School Funding Options for Testing



Will Vaccination Plateau at Lower Levels for Younger Age Groups?



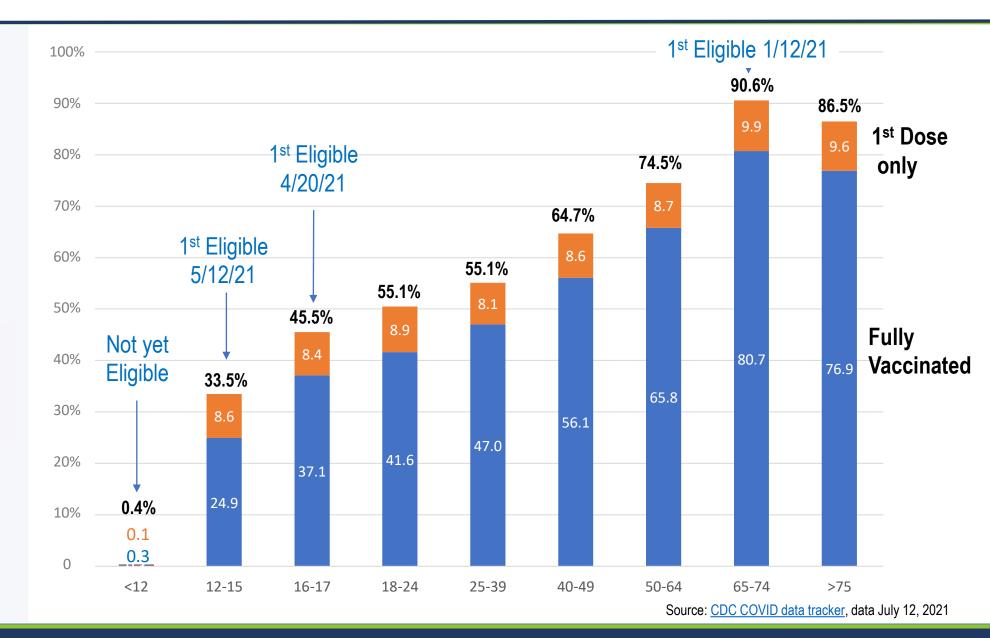
Source: CDC COVID data tracker



Younger Age Groups are Less Vaccinated, and May Stay That Way



THE WALL STREET JOURNAL.
Young Americans aren't getting vaccinated, jeopardizing COVID fight



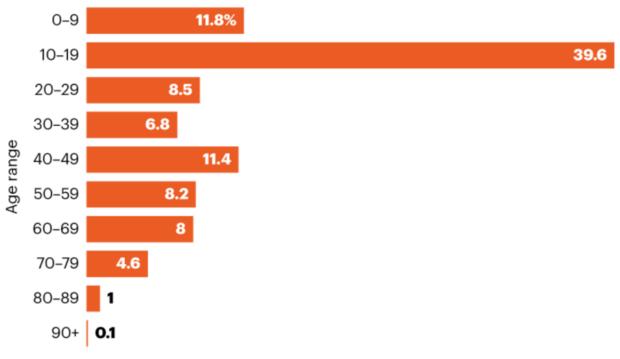


In a Highly Vaccinated Population – Israel COVID Spikes in Unvaccinated Middle and High School Children

TRENDING YOUNGER

With the majority of adults in Israel now vaccinated, just over half of the country's new COVID-19 cases in the month up to 5 July were in people aged 19 and under.

Proportion of recent COVID-19 cases in Israel by age group

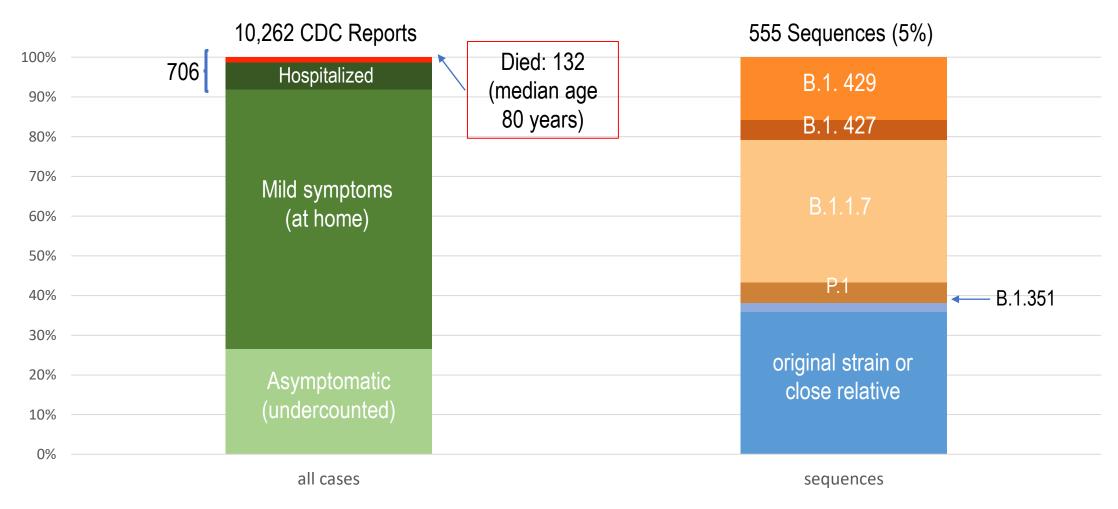


onature



CDC Data Breakthrough Infections Very Rare¹

(0.01%² of 101 million vaccinated individuals)



Note 1: Just 2 cases of breakthrough in 417 US Health workers = 0.5% incidence: 4/21/21 NEJM Brief Report: https://www.nejm.org/doi/full/10.1056/NEJMoa2105000

Note 2: Not a true prevalence since vaccinated population not constant over this time period

Source: May 28th CDC MMWR: January 1st-April 30th reported COVID infections (tracking limited to Hospitalized patients from May 1st)https://www.cdc.gov/mmwr/volumes/70/wr/mm7021e3.htm mara.aspinall@healthcatalysts.com

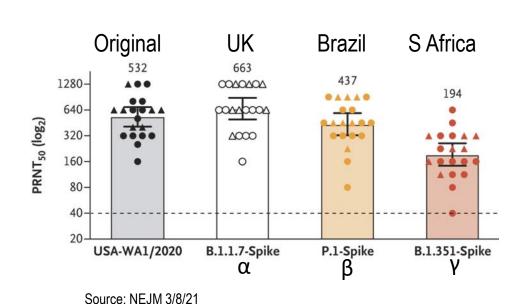


mRNA Vaccine Protection Persists as Variants Emerge

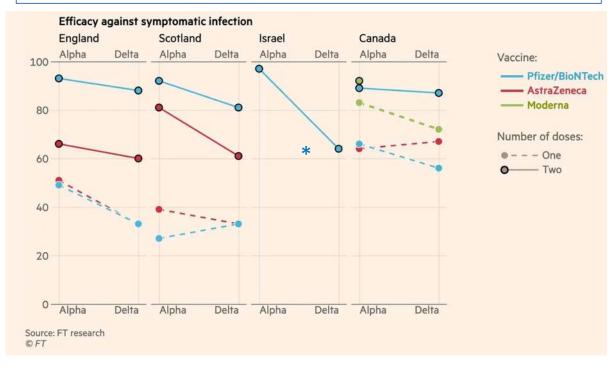
"90+% effective in a real-world setting"
- CDC MMWR 3/29/21

- 80% effective after first dose
- 3,950 healthcare personnel, tested weekly; asymptomatic and symptomatic identified
- One tenth the cases after vaccination (161 cases without 16 cases with vaccine)
- Consistent with Israel data, UCLA Health workers and others

Vaccine confirmed effective against α , $\beta \& \gamma$ variants



...and appear to remain effective against δ variant at lower level

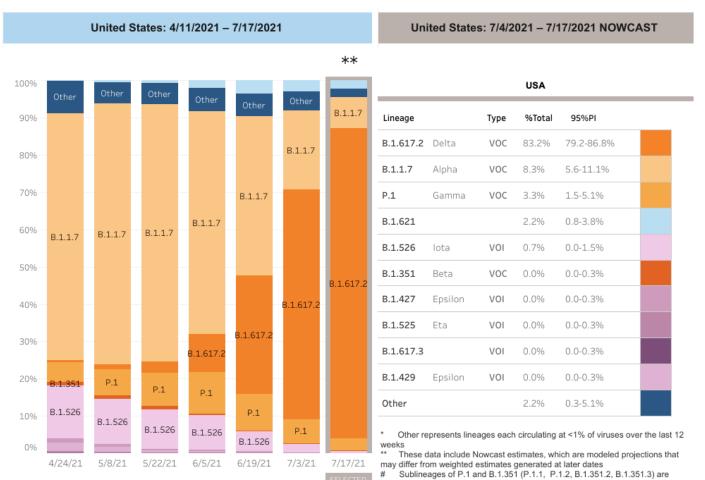


^{*} Single data point, sharply lower than prior month's 90+%, may be revised up



Rise of the Delta δ Variant

SARS-COV-2 LINEAGES: NATIONAL NOWCAST ESTIMATES



Collection date, two weeks ending

 α (B.1.1.7)

3 months

δ (B.1.617)

1 month

and is powering the surge among the unvaccinated

Source: https://covid.cdc.gov/covid-data-tracker/#variant-proportions

VARIANT TIMEFRAME TO REACH DOMINANT U.S. STRAIN

aggregated with the parent lineage and included in parent lineage's proportion. AY.1, AY.2, and AY.3 are aggregated with B.1.617.2.



- The Good, the Bad and the Ugly
- School In-Person Index
 - Where did we end in the Spring
- School COVID Safety
 - 1. Vaccination
 - 2. Mitigation
 - 3. Confirmation
- School Funding Options for Testing





HEALTH CHECKS / RESPIRATORY ETIQUETTE



HANDWASHING



CLASSROOM / SCHOOL BUILDING HYGIENE



SURVEILLANCE / MONITORING



PHYSICAL DISTANCING 6 / 3 FEET



MASKING



CDC Mask Guidance



Masks should be worn indoors by all individuals (age 2 and older) who are not fully vaccinated. Consistent and correct mask use by people who are not fully vaccinated is especially important indoors and in crowded settings, when physical distancing cannot be maintained.



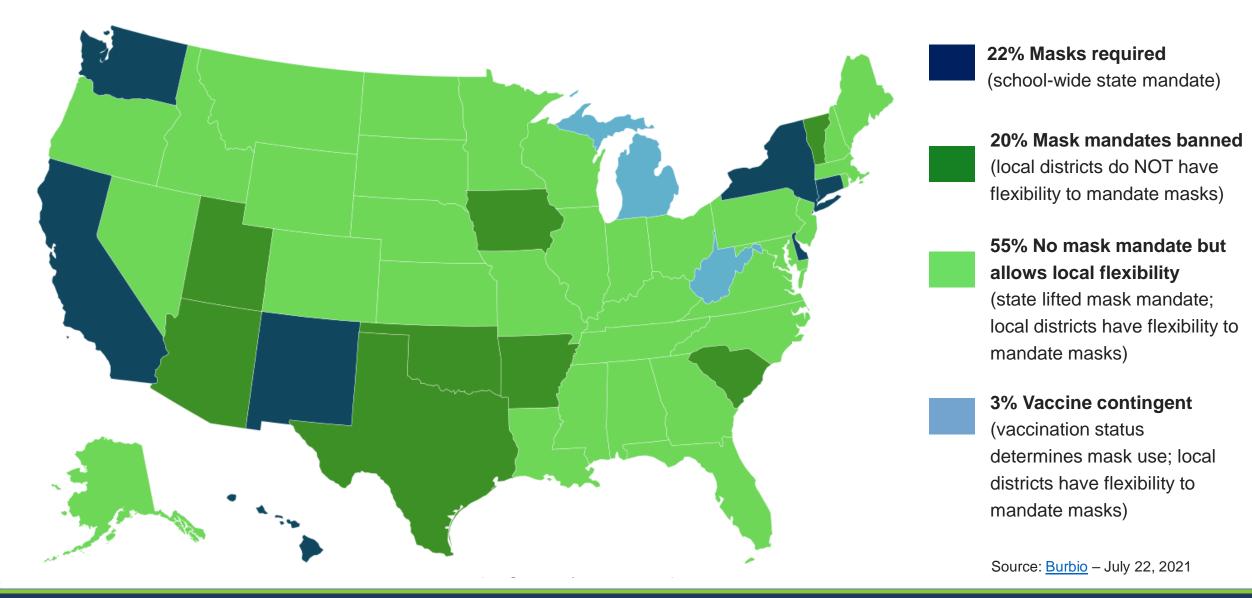
- CDC Updated Guidance July 2021

COVID-19

C



Current School Mask Policy Around the Country



2





HEALTH CHECKS / RESPIRATORY ETIQUETTE



HANDWASHING



CLASSROOM / SCHOOL BUILDING HYGIENE



SURVEILLANCE / MONITORING



PHYSICAL DISTANCING 6 / 3 FEET



MASKING

TESTING REMAINS CRITICAL TO SUPPLEMENTING ANY MITIGATION STRATEGY



Polling Question #2 – TESTING

For the 2021/2022 school year, we plan to:

- A. Require rapid, on-site testing Antigen
- B. Require send out testing PCR / Pooled PCR
- C. Provide optional rapid, on-site testing
- D. Provide rapid, at home testing
- E. Undecided on testing strategy
- F. Not doing any testing at all
- G. Other
- H. Doesn't apply to me

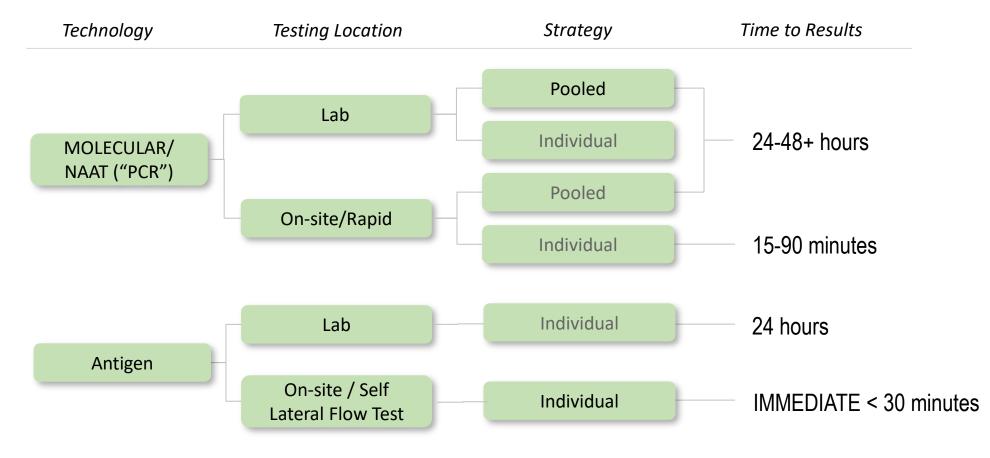


- The Good, the Bad and the Ugly
- School In-Person Index
 - Where did we end in the Spring
- School COVID Safety
 - 1. Vaccination
 - 2. Mitigation
 - 3. Confirmation
- School Funding Options for Testing

HOW TO CHOOSE A TEST: ASYMPTOMATIC SCREENING OPTIONS

Multiple technologies and systems needed to meet school demand and diversify the supply chain

TYPES OF SCREENING TESTING:





Choosing The Right Testing Strategy

Model-estimated >90% infection transmission reduction



Testing daily





Daily testing with 80%+ sensitive tests and results in one day





OR Daily testing with 70%+ sensitive tests and immediate results

Model-estimated 80-90% infection transmission reduction



Testing every 1-3 days





Daily testing with 70%+ sensitive tests and results in one day





OR Testing every three days with 80%+ sensitive tests and immediate results Model-estimated
70-80% infection
transmission reduction



Testing every 1-3 days





Daily testing with 85%+ sensitive test and results in two days





OR Testing every three days with 97%+ sensitive tests and results in one day





OR Testing every three days with 70%+ sensitive tests and immediate results Model-estimated 60-70% infection transmission reduction



Testing every 3-7 days





Testing every three days with 70%+ sensitive tests and results in one day





OR Weekly testing with 97% sensitive test and immediate results

MORE THAN ONE WAY TO GET THE SAME RESULT

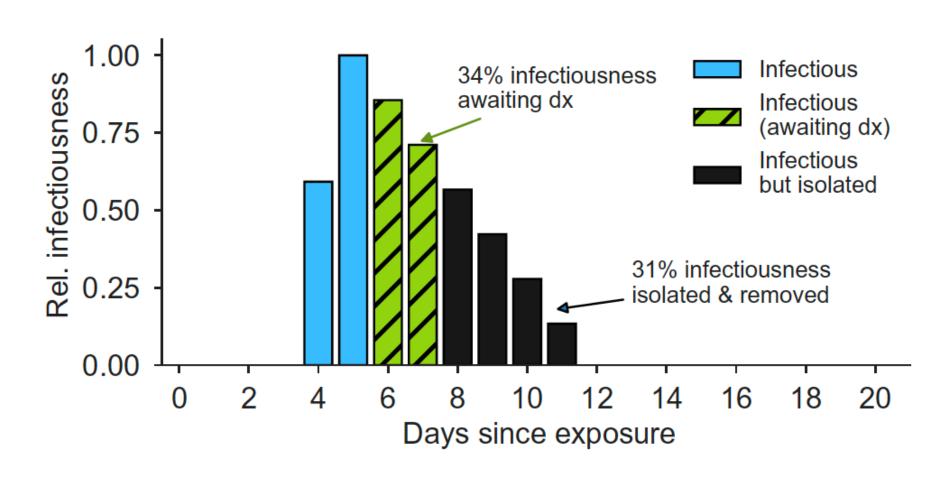
Combination of:

- Test sensitivity
- Test frequency
- Time to results
- Costs
- Logistics



Fast & Frequent Wins Over Slow & Sensitive

TEST AROUND SYMPTOM ONSET



Source: Larremore DB, et al. Science Advances. 01 Jan 2021: Eabd5393.

mara.aspinall@healthcatalysts.com

WHAT DO SCHOOLS DO: RUBBER HITS THE ROAD — OPERATION OVERVIEW

There are 4 key steps to executing K-12 NTAP, but each component within the key steps must be designed and executed based on individual needs of the school

Key steps 2) Testing modality selection 3) Facility set-up 4) Results reporting 1) Coordination & administration Establish key positions & roles Choose testing partner(s) Set-up on-site, centralized, Decide reporting strategy Hire, train and build partnerships with • Finalize protocols for Step 1 decentralized or other Establish procedures for local public health officials Asymptomatic Screening and physical models reporting positive results and Create a communication plan for Step 2 Follow-up Testing for confirmatory testing updates and changes to the process positive pools Receive authorization and registration • **Decide on Initiation Testing** for testing Considerations for tailoring design and execution







Student population needs (age, special needs, etc.)



Access to approved contracts and vendors



Proximity to labs



Human and financial resources



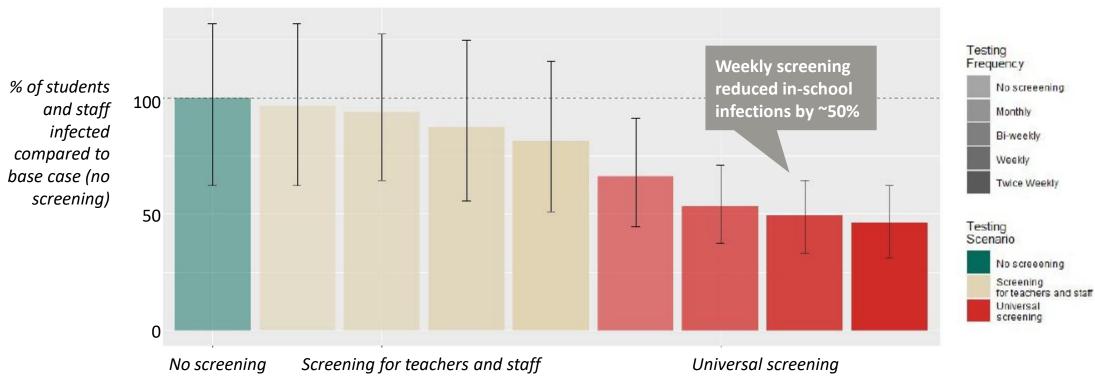
Number of students, teachers and staff



REGULAR TESTING IN SCHOOLS CAN REDUCE INFECTION

Evidence from Mathematica, supported by The Rockefeller Foundation, found that weekly testing of all students, teachers and staff can reduce in-school infections by an estimated 50%

Cumulative COVID-19 infections among students and staff in high schools



TESTING BRINGS STUDENT, PARENT AND TEACHER CONFIDENCE

"I feel more safe now knowing solid facts about who has it and that the people who have it are not at school. So, it's keeping everything safer." - Parent

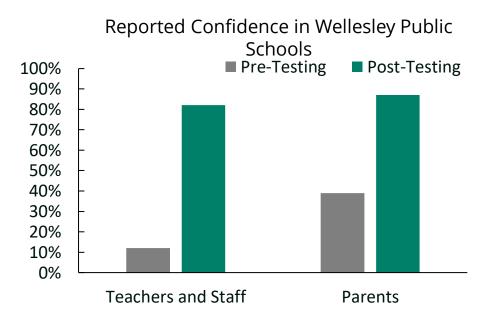
Participants strongly supported the use of testing to confidently return to in-person learning



UNITEDHEALTH GROUP

SURVEY RESULTS (% agree/strongly agree)	Parents	Students	Staff
Testing students, staff and teachers on a regular basis is important to ensure that school can remain open and the WIS community can be as safe as possible	91.8	95.1	92.6
Post-launch: I am open to being part of a pooled testing protocol once or twice a week, with an individual confirmatory test required if the pool is positive	90.3	93.4	98.8
I feel that students or teachers who refuse to be tested individually or as part of a pool on a frequent basis should not be allowed to attend in person classes		83.13	74.1

Baseline testing increased confidence of safety of in-person learning



SCHOOL PREVALENCE RATES ARE 10X LOWER THAN COMMUNITY RATES

Aggregate data across multiple schools and their contiguous communities shows average school positivity is 0.25% to 0.5% while surrounding community positivity is ~ 7.23%*



0.53%
positivity
rate in K-12
schools

5.60% positivity rate in community



0.5% 4%positivityrate among rate acrossteachers the state

CDC and others support a return to in-person schooling, citing low prevalence rate in schools as a key part of the justification

Disclaimer: It is important to note that community testing is an opt-in process, and the actual community positivity may be different *Calculated by aggregating data collected by Ginkgo, CiC Health and JCM Analytics

SUCCESSFUL K-12 TESTING: MASSACHUSETTS SCHOOLS

Program overview:

- Weekly testing for every classroom across the state (900K+ students)
- Students and staff **self-swab** with a lower nasal swab
- 10+ swabs pooled together and run using an accurate molecular test
- Samples processes at local and regional labs
- Follow-up testing for individuals in positive pools using Abbot BinaxNOW

Initial data:

154

school districts have rolled out testing



940 or 50% of public schools participating



~13,000 tests in first week of testing

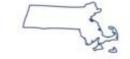


THE Massachusetts Program

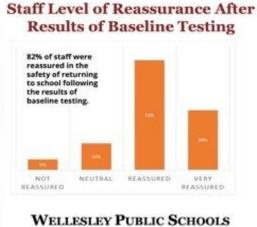


The Boston Blobe

Baker announces coronavirus pool testing to be made available to all Massachusetts public schools







Learning • Caring • Innovating

Boston Herald

Massachusetts teachers unions laud Charlie Baker's new coronavirus pool testing program for schools





SUCCESSFUL K-12 TESTING: BALTIMORE CITY SCHOOLS

Baltimore City Schools have been utilizing weekly testing with different systems for elementary, middle and high schools





Baltimore City Schools To Offer Weekly COVID-19 Testing For Students, Staff

By Kelsey Kushner February 24, 2021 at 11:15 pm
Filed Under: Baltimore: Baltimore City Public Schools: Baltimore News. Coronavirus Outbreak in Maryland: WJZ Complete Coverage. COVID-19. Local TV. Tali



Baltimore City Schools re-open with voluntary inperson learning

by Rachel Aragon | Monday, March 1st 2021

Current status:

- ~10K students and staff tested
- **750**+ pools
- 78 schools (soon to be 110)

Elementary and middle schools:

- Students and staff self-collect with lower nasal swabs
- 5-25 individuals pooled together
- Samples processed at local or regional lab
- Results ~24 hours from when samples arrive at the lab
- If a positive result, classrooms will quarantine for 2 weeks and follow up with individual PCR tests

Common characteristics:

- Weekly testing
- Parent consent is required for inperson learning, which includes Covid-19 screening/testing

High schools:

- Students and staff self-collect individual saliva samples
- Samples processed at a mobile lab in DC
- Results ~8 hrs from when samples arrive at the lab
- Individuals and close contacts will quarantine for 2 weeks if a positive result



SUCCESSFUL K-12 TESTING: DELAWARE PUBLIC SCHOOLS

School testing in Delaware, a collaborative effort between the Delaware Health and Social Services and Department of Education, has successfully demonstrated a scalable, in-person, low-resource program utilizing BD antigen tests. This program started in a handful of public charter schools and has quickly expanded across the state with buy-in from parents, staff and administrators



Current status:

75+ public schools participating

33% of schools in Delaware

5,000+ students and staff tested

Easy to implement:

- Flexible program implemented by school staff. Estimated need for 2-3 FTE / 1,000 people
- Automated results reporting expected to simplify workflow further

Return to school:

- Positive cases have been identified without impacting school opening
- Schools see parents switching back from virtual to in-person education







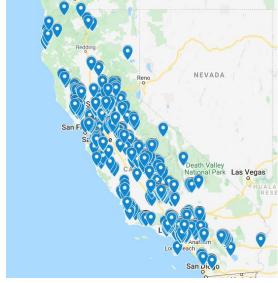
Key learnings

- Prioritizing **communication** to all stakeholders throughout the process is key
- Students can be introduced to swabbing in a drivethrough environment with parents nearby
- Focusing on logistics is crucial. Walk-up service may work well for older students, while classroom service may fit for cohorted and youngest students
- **Self-swabbing** under observation with oldest students improves throughput and logistics
- Clear guidance on obtaining consent and addressing legal requirements early is critical
- Continuous feedback from all stakeholders can make the program sustainable
- Objective assessment of test results minimizes staff confusion and improve logistics
- Reporting and documentation is a significant resource challenge. Automating reporting may save 2 FTE time

SUCCESSFUL K-12 TESTING: CALIFORNIA SCHOOLS

A collaboration between Color and Perkin Elmer to provide access to high-quality, fast PCR testing for public and private schools throughout California started with a focus on testing staff and has expanded to include students and student athletes. The program led by the California Department of Public Health has supported statewide onboarding for all school districts and standardized a scalable model across diverse populations





Map of CA K-12 schools testing

10,000+

Schools eligible for program

1,600+

School staff trained

50,000+

K12 tests in less than 6 weeks

Key learnings

- Standardized, state-level onboarding of over 1,000 districts helps provide clean, school-level data to the state for public health planning and interventions
- Creating plug-and-play processes such as pre-assembled testing kits significantly reduces errors during sample collection and increases scalability
- One-time consent and HIPAA authorization early is critical to streamline testing processes
- In-house staff can be trained at scale to support sample collection and program administration when coupled with easy-to-use software and centralized support infrastructure
- Clear funding models help improve access for underserved populations
- In addition to capacity requirements, key pieces of successful implementation also include coordinated onboarding, shipping and information management between testing partners
- Simplified logistics and consistent, easy-to-understand processes has supported effective use of time and resources and increased time spent in the classroom in K-12 California schools



SUCCESSFUL K-12 TESTING: CROSS-CITY LEARNING GROUP PILOT SITES

The Cross-City Learning Group was formed through The Rockefeller Foundation's partnerships with HHS, Duke-Margolis Center for Health Policy, Johns Hopkins University, Mathematica and six cities/states willing to pilot testing programs



Washington D.C.

8 learning hubs



Tulsa

70 schools



Rhode Island

78 schools and learning education agencies



Louisville

12 regional testing sites



New Orleans

45 schools



Los Angeles

60
Parks and Recreation centers

Key learnings

- Engaging early with district administrators and local partners can help gain their buy-in and support for identifying resources
- Clear communications, delivered by trusted leaders in the community, are needed to build community members' understanding of the program and encourage participation
- The testing approach should be designed using both evidencebased guidance and on-theground knowledge of what will be acceptable to students, parents, teachers and staff





Polling Question #3 – Impediments

For the 2021/2022 school year, impediments to testing:

- A. Costs too high
- B. Resources needed to administer to implement and report
- C. Complexity too much hassle
- D. Teachers don't want testing
- E. Parents don't want testing
- F. Don't need it infection rate low
- G. Don't need it vaccination rate high
- H. Other
- Doesn't Apply



- The Good, the Bad and the Ugly
- School In-Person Index
 - Where did we end in the Spring
- School COVID Safety
 - 1. Vaccination
 - 2. Mitigation
 - 3. Confirmation
- School Funding Options for Testing



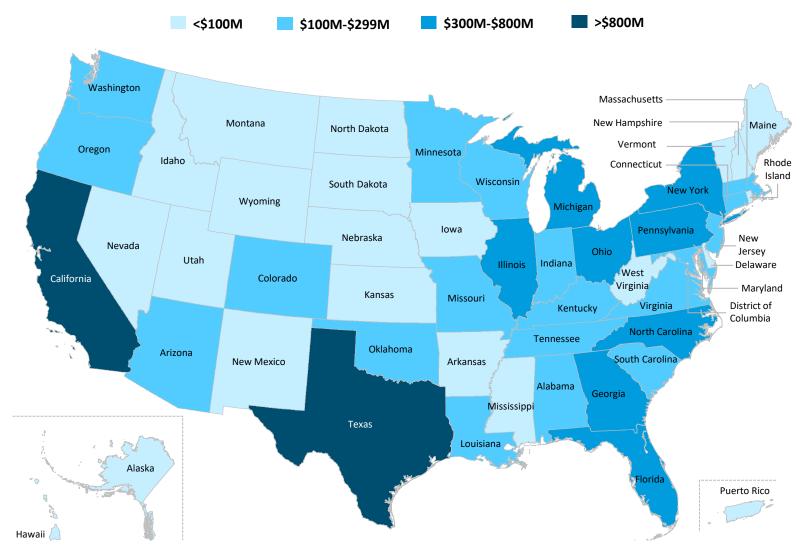
School Federal Funding Options

	ELC National Testing Action Program (NTAP)	Coordination Hubs Operation: Expanded Testing (ET)	Increasing Community Access to Testing (I-CATT)	ESSER
K-12 Schools Covered	Public, Private & Charter	Public, Private & Charter	Public	Public & Charter
Focus: Settings Covered?	All K-12 Schools and Summer Programs	Underserved Populations including Schools and Congregant Settings	Underserved Schools	Broad education related issues
Funding	\$10 billion (CDC to State, large local & territories' Depts of Health)	\$650 million (HHS / DOD to 4 regional Coordination Hubs)	\$255 million (Direct service / not a reimbursement program)	Majority of funds directly to school districts
Timing	April 2021 – July 2022	May - November 2021	April – September 2021	Funds allocated
Test Technology Choice	Technology agnostic: Up to schools / districts / States	Input from HHS / DoD and schools / districts – may differ between hubs	Primarily individual PCR today	School / district decision



Source: CDC COVID-19 Funding

Distribution of \$10B Government Funding for School Testing



American Rescue Plan Act of 2021 for Epidemiology and Lab Capacity for School Testing

85%

To fund or provide materials (e.g., test kits, PPE, staffing, etc.) and services (e.g., sample collection, laboratory testing, etc.) to increase screening testing in all K-12 schools (public or private) within the recipient's jurisdiction

15%

For coordination, management, technical assistance, monitoring, and data collection and reporting activities to support K-12 screening testing programs



The Good, the Bad and the Ugly

The Good

- Cases are way down from a year ago (but recent surge is concerning)
- 50% of US adults are vaccinated (80% for teachers)
- 25-35% of 12–17-year-olds are vaccinated
- Vaccines are highly effective (50-90% depending on variant)

The Bad

- Only 50% of adults and net 15% of all kids are vaccinated
- Few mitigation measures remain in place
- Delta Variant is more transmissible than any variant we have seen so far

The Ugly

- All viruses mutate more mutations will come
- At least 20% and maybe 50+% people are completely asymptomatic



THANK YOU!