

Navigating Coronavirus Series

Ask the Experts September 29, 2020

This webinar series brought to you by



COMMUNITY CARE PHYSICIAN NETWORK









Today's Emcees



• Hugh Tilson, JD, director of the North Carolina Area Health Education Centers (NC AHEC) Program



• **Tom Wroth,** M.D. MPH, president and CEO of Community Care of North Carolina (CCNC)

Today's Presenters



 Infectious diseases: Ibukun C Akinboyo, M.D.
 Medical Director of Pediatric Infection Prevention, Duke University Hospital



 Mental health : Carrie Brown, M.D., MPH Chief Medical Officer, Behavioral Health, NCDHHS



• **Testing: "Chip" Watkins, M.D., MPH, FAAFP** Regional Medical Director, Community Care of North Carolina

COVID-19 in Children - Updates Ibukun Akinboyo, M.D.

Assistant Professor Pediatric Infection Prevention Medical Director Duke University Hospital

Objectives

- Review updated COVID-19 epidemiology
- Summarize concerns about COVID-19 and Influenza
- Discuss approach to disseminating evidence and supporting public education

Cumulative Number of Child COVID-19 Cases: 9/24/20

- 624,890 total child COVID-19 cases (cumulative)
- Twenty-one states reported 10,000+ child cases
- Four states reported fewer than 1,000 child cases



American Academy of Pediatrics



Possible Case of Vertical Transmission of SARS-CoV-2

- In Newborn with Positive Placental In Situ Hybridization of SARS-CoV-2 RNA.
- 32 yo G2Po at 35.6WGA had contractions and bleeding

 Also with fevers, chills, fatigue, anosmia & dysgeusia
 Partner worked as RT in ICU. Asymptomatic (-ve)
- Mother (+ve); Infant (+ve) at 24 and 48 HOL & 7D
- Mother masked during infant care.

o Infant roomed in (isolette). Formula and breastfeeding

Alamar I. et al., JPIDS, 2020

Possible Case of Vertical Transmission of SARS-CoV-2

Placenta path showed:

- No inflammation
- Central infarct– bleeding placenta previa, fetal placental vascular rupture, villous necrosis
- Increased CD68



Alamar I. et al., JPIDS, 2020

A Case of Early Re-infection with SARS-CoV-2



Secondary Exposure and Illness Exposure Incubation Cough Fever Myalgias Shortness of breath Fatigue **GI** symptoms RT-PCR 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 1 Date

Larson D. Brodniak SL. Clinical Infectious Diseases. 2020

COVID-19 and Influenza: Australia experience

Number of specimens tested and percentage testing positive for influenza, by year, using weeks 14 - 31



COVID-19 & Influenza: Experience in South Africa

Number of specimens tested and percentage testing positive for influenza, by year, using weeks 14 - 31



Are we heading into the "twin-demic" with COVID-19 and Influenza?

- COVID-19 and influenza have similar symptoms
- Efforts to curb COVID-19 may also curb influenza
- There are safe and available vaccines to prevent the flu
- There are approved flu antivirals
- Experience in the southern hemisphere suggests milder influenza season





Viewpoint

September 14, 2020

Should We Mandate a COVID-19 Vaccine for Children?



Douglas J. Opel, MD, MPH¹; Douglas S. Diekema, MD, MPH¹; Lainie Friedman Ross, MD, PhD^{2,3}

- We already mandate several vaccines
- Strategies to reopen schools or keep them open may be predicated on this
- The reproduction number [R_o] is approximately 1 for the influenza virus but for SARS-CoV-2, the R_o is 2 2.5
- Is there evidence that a COVID-19 vaccine is safe for children with an acceptable level of risk?

Viewpoint

September 14, 2020

Should We Mandate a COVID-19 Vaccine for Children?



Douglas J. Opel, MD, MPH¹; Douglas S. Diekema, MD, MPH¹; Lainie Friedman Ross, MD, PhD^{2,3}

Box. Criteria to Consider When Evaluating Antigens for Inclusion in Mandatory School Immunization Programs

- Vaccine related: Experience to date with the vaccine containing this antigen indicates that it is safe and has an acceptable level of adverse effects.
- Vaccine related: The antigen is effective as measured by immunogenicity and population-based prevention.
- 3. Vaccine related: The vaccine containing this antigen is as cost-effective from a societal perspective as other vaccines used to prevent disease.
- 4. Vaccine related: The vaccine containing this antigen should bear some relationship to increasing safety in the school environment.

Viewpoint

September 14, 2020

Should We Mandate a COVID-19 Vaccine for Children?



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Box. Criteria to Consider When Evaluating Antigens for Inclusion in Mandatory School Immunization Programs

- 5. *Disease related:* The vaccine containing this antigen prevents disease(s) with significant morbidity and/or mortality in at least some subset of the population.^a
- 6. Disease related: Vaccinating the infant, child, or adolescent against this disease reduces the risk of person-to-person transmission.^b
- 7. Implementation related: The vaccine is acceptable to the medical community and the public.
- 8. *Implementation related:* The administrative burdens of delivery and tracking of vaccine containing this antigen(s) are reasonable.
- 9. *Implementation related:* The burden of adherence for the vaccine containing this antigen is reasonable for the parent/caregiver.

The ABC Science Collaborative

Uniting science and schools for a data-driven solution to decision making and implementation



Proposed solution: A data-driven approach to support decision making

- Initiate a direct-to-family and community-engaged approach
- Promote existing guidance from state and local health departments, provide data, and interpret emerging scientific evidence to keep children, teachers, and the community healthy and safe during the COVID-19 pandemic.
- Deploy a three-tier approach
 - Educational outreach
 - Data to support decisions
 - Targeted research opportunities





Aim 1: Educational outreach

- Provide school administrators, teachers, staff, and parents access to real-time, data-driven information about COVID-19.
- Collect, synthesize, and interpret available data in collaboration with educational leaders.
- Cultivate trust and facilitate the delivery of culturally appropriate information and support to educational leaders and the school communities.
- Communicate in layperson terms to help build trust.
- Lead with empathy and commitment to children's health.

DELIVERABLES

- Webinars for parents, administrators, teachers and staff
- Newsletter content for districts to share with teachers and staff
- Newsletter content for districts to share with families
- Information included on public-facing website, including an interactive map where communities can drill down to local data sets



Aim 2: Data to support school-specific decisions

- Provide weekly, customized, data-driven information to school administrators in preidentified districts.
 - Person-level data derived from members of the school district, as well as data about rates of disease in the local, state, and national communities
- Provide detailed information about potential consequences of actions.
 - Discuss and assess possible scenarios under consideration by school leaders.
- Support for implementation of local public health guidance

DELIVERABLES

- Initially identify and partner with local and national school districts
- Establishment of teams to deliver prepared customized scorecards
- Data "dashboards" at the individual school district level
- Collection and summary of up-to-date districtlevel data if available, including de-identified comparison to other districts and characteristics of those districts
- Customized risk assessments with scenario modeling using district-specific data
- Assessment of local impact from best practices related to public health practice



Potential structure



Program leadership team

COVID-related research experience, sponsored by NIH, and led by the team. For each project, a team member is the National Principal Investigator (PI)



Kanecia Zimmerman, MD Co-chair Associate Professor, Critical Care 2 children, Durham



Danny Benjamin, MD, PhD Co-chair Distinguished Professor, Epidemiology Therapeutics 4 children, CHCCS/college



Ibukun Akinboyo, MD Assistant Professor, Infectious Disease No school-aged children



Gabriela Maradiaga Panayotti, MD Assistant Professor, Primary Care, Latinx advocacy 2 children, Durham



Micky Cohen-Wolkoweiz, MD, PhD Distinguished Professor, Infectious Disease 2 children, Durham



David Weber, MD, MPH Assistant Chief Medical Officer UNC Health Care





COVID-19:

Managing Stress Today and Tomorrow

Carrie L. Brown, MD, MPH Chief Medical Officer for Behavioral Health & IDD North Carolina Department of Health and Human Services

Navigating COVID-19

September 29, 2020

"Daily news of large-scale COVID19 related disease and death in the community over months or years is almost certain to elevate psychiatric burden in the population. As such, the pattern of stress resembles that experienced by refugees or others exposed to chronic violence, rather than acute disasters like the September 11th terrorist attacks."

-Dost Ongur et al. JAMA Vol 324, #12

NC Behavioral Health Impacts of COVID-19

Anxiety & Depression

- Existing unmet need: 1.5 million North Carolinians 18+ have a mental illness in a given year - <u>1 in 5 don't receive</u> care or treatment

- Three-fold increase in reported symptoms of depression and/or anxiety disorders - 1 in 3, up from 1 in 9.

 Younger cohorts (18-29) report higher prevalence of anxiety and depression, while prevalence among racial groups is relatively consistent.

Substance Use – Alcohol & Opioids

- Existing unmet need: 8 out of 9 North Carolinians with SUD don't received treatment in a specialized SUD treatment facility

 Liquor sales in North Carolina increased 12% in State Fiscal Year 2019-20

Recent nationwide survey found 1 in 4 respondents reported binge drinking at least once (up from 1 in 6)
In 2020, while NC experienced a 12% decrease in overall Emergency Department visits, we have seen a 19% increase in Medical/Drug Overdose ED visits – largely driven by a 21% increase in opioid overdose ED visits.

Suicide

- For every five-percentage point increase in the rate of unemployment, an additional 304 North Carolinians would be expected to die each year from suicide (126) and drug overdose (178).



Targeted Interventions

\$<u>116 M in funding from the CARES Act</u> and \$<u>3.5 M from other federal sources</u> have been allocated to address emerging issues – crisis, prevalence of specific disease, etc. -- targeted toward specific populations. These efforts are designed to <u>leverage other programs for a coordinated response that drives systemic change</u>.



Evidence Based Behavioral Health Messaging Aimed at Prevention

The SCOOP on Managing Stress

S	Stay connected to family and friends.	Social connections build resiliency.
С	Compassion for yourself and others.	Self-compassion decreases trauma symptoms and stress.
0	Observe your use of substances.	Early intervention can prevent problems.
0	Ok to ask for help.	Struggling is normal. Asking for help is empowering.
Ρ	Physical activity to improve your mood.	Exercise boosts mood and lowers anxiety.

HOPE 14 NC HELPLINE 1-855-587-3463

Awareness, Managing Crisis, Building Resiliency

- Hope4NC (1-855-587-3463)
 - The Hope4NC Helpline connects North Carolinians to mental health and resilience supports
 - Available statewide, 24 hours a day, seven days a week during the COVID-19 crisis
 - Hope4NC includes a Crisis Counseling Program tailored for COVID-19, which will provide immediate crisis counseling services to individuals affected by the ongoing COVID-19 public health crisis.
- Hope4Healers Helpline (919-226-2002)
 - Partnership with the North Carolina Psychological Foundation
 - Provides mental health and resilience supports for health care professionals, emergency medical specialists, first responders, other staff who work in health care settings who are experiencing stress from being on the front lines of the state's COVID-19 response
 - Available 24 hours per day, seven days a week, staffed by licensed mental health professional for follow-up

Do you or your family members need FREE emotional support from being on the COVID-19 frontlines?



In partnership with the NC Department of Health and Human Services and the North Carolina Psychological Foundation



Carrie L. Brown, MD, MPH

Chief Medical Officer for Behavioral Health & IDD

North Carolina Department of Health and Human Services

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Carrie.Brown@dhhs.nc.gov

COVID-19 Testing Update R.W. "Chip" Watkins, M.D., MPH, FAAFP Regional Medical Director, Community Care of North Carolina

Bio Page

- 3 years Medical Director Genova Diagnostics, Asheville, NC
- I2 years CMO NeuroLab, Inc., Asheville, NC
- 5 years AAFP appointee COLA Board of Directors
- Physician Member CDC's CLIAC (Clinical Laboratory Improvement Advisory Committee)
- COVID-19 Testing: Fundamentals & Application to Practice Webinar for AAFP (can get AAFP CME credit if member) – on CCPN website under Webinars for Providers

"You cannot fight a fire blindfolded. And we cannot stop this pandemic if we don't know who is infected."

World Health Organization Director-General

○ F N 016 March 2020 ○ L I N A

Let's Look at the Virus Time Course



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Testing Resources from CCNC/CCPN

- NCDHHS Provider Guidance on SARS-CoV-2 Testing
- https://www.communitycarenc.org/provider-guide-to-sarscov-2-testing
- Point of Care COVID-19 Testing: Guidance for Practicing Physicians
- <u>https://www.communitycarenc.org/point-of-care-covid-19-</u> <u>testing</u>

Let's Take a More In-depth Look at the Tests

Community Care

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Diagnostic Testing

Testing Modalities

- Molecular (RT-PCR) tests that detect the virus's genetic material (RNA)
- Antigen tests that detect specific proteins on the surface of the virus
- Diagnostic tests should be used when active viral infection is suspected, either because the patient is symptomatic and/or they have been in close contact (within 6 feet for 15 minutes or more) with someone with confirmed COVID-19 diagnosis, regardless of symptoms.

Here are the 5 PCR (Molecular) Tests that can be run in Labs that have a Certificate of Waiver

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1. Xpert Xpress swabs. The test coronavirus SAF with less than a Sensitivity 100% 30/30 "spiked" s



ent pandemic positive results* e sample. amples and

Genexpert system with Xpert Xpress SARS-CoV-2 test. Credit: Cepheid Inc.

The ** denotes a test system that is portable and can be used outside the clinical laboratory like mobile, nursing homes, or temporary sites like a drive thru or health fair.

2. Accula SARS-Covand nasal swabs, resund negative samples and the Accula SARS-Co' Easy Work Flow Like

Combining molecular PCR acci

- PCR
- Cost Effective
- Easy to Use
- Room Temperature Storage
- Small Footprint
- CE Mark
- CLIA Waived



The ** denotes a test system that is portable and can be used outside the clinical laboratory like mobile, nursing homes, or temporary sites like a drive thru or health fair.



Navigating COVID-19 Webinar Series



Cue Health Monitoring System & COVID-19 Test Cartridge

Diagnostic Testing - Multianalyte

- 5. Cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test (Roche Molecular Systems, Inc.). (waived, moderate and high complexity laboratories) To be used with the cobas® Liat® Analyzer (P/N 07341920190) Including cobas® Liat® System Software (Core) Version 3.2 or higher and cobas® SARS CoV-2 & Influenza A/B Assay Script v1.0 or higher.
- Just got EUA approval on September 14, 2020

Diagr Table 22 Comparison o cobas® Liat®		We put a lab in a tube because they put their trust in you. The cobas ® Liat® PCR System	a A/B & RSV	a A/B & RSV for use on the	
			ement Stat	istics	
Virus	Num San		Percent Agreement (%)	95% CI (LCL, UCL)*	
SARS-CoV-2*	2	Left.	96.4%	(87.7%, 99.0%)	
3/113-001-2	J		98.0%	(95.6%, 99.1%)	
Influenza A	2		100.0%	(94.0%, 100.0%)	
innuchza / Y	3		99.6%	(98.0%, 99.9%)	
Influenza B	2		100.0%	(90.6%, 100.0%)	
	3		99.7%	(98.2%, 99.9%)	
	10				

Here are the 4 Antigen Tests that can be run in Labs that have a Certificate of Waiver

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1. Sofia 2 SARS Antigen FIA (Quidel Corporation) (waived, moderate and high complexity laboratories) using the Sofia 2 instrument. The assay demonstrated acceptable clinical sensitivity (80%) when compared to an EUA molecular device. The assay demonstrated excellent clinical specificity (100%). There was no demonstrable crossreactivity with seventy-nine (79) specimens containing seasonal CoVs detected by the BioFire® FilmArray® Respiratory Panel.

July 17, 2020 Quidel updated the performance data for its Sofia® SARS Antigen FIA test on its package insert to 96.7% PPA using direct nasal swab specimens versus PCR as a result of further studies included in its amended Emergency Use Authorization (EUA) that were submitted to the U.S. Food and Drug Administration (FDA).







Happy Thanksgiving!!



Antibody Testing

• Antibody tests should not be used to diagnose SARS-CoV-2 and cannot determine a person's immunity to reinfection with SARS-CoV-2 and should not be used as an "immunity voucher" for work or daycare in an attempt to assure the safety of individuals.

Antibody Testing



Antibody Testing – Assure COVID-19 IgG/IgM Rapid Test Device

Total of 42 positive and 113 negative fingerstick whole blood samples were collected and tested at 3 different POC sites. These samples were tested with both RT-PCR method for SARS-CoV-2 infection and Assure COVID-19 IgG/IgM Rapid Test device for antibodies. The PPA/sensitivity and NPA/specificity results are summarized in following tables.

	Days from symptom	# PCR Positive	IgG (Assure Device)		IgM (Assure Device)			
Site			Antibody Positive	PPA	95%CI	Antibody Positive	РРА	95%CI
(Site 1+2+3)	0-7 days	2	0	0%	0%-57.5%	2	100%	42.5%-100%
	8-14 days	12	10	83.3%	55.2%-95.3%	10	83.3%	55.2%-95.3%
	≥15 days	28	28	100%	91.2%-100%	25	89.3%	72.8%-96.3%

Table 5. IgG/IgM PPA for the Assure COVID-19 IgG/IgM Rapid Test Device

Recent Guidance from CMS/AMA and NCDHHS on Antigen Testing

- <u>https://medicaid.ncdhhs.gov/blog/2020/09/21/special-</u> bulletin-covid-19-132-laboratory-codes-coronavirus-covid-19testing
- NC Medicaid is adding the following code into NCTracks for medically necessary laboratory testing effective Sept. 1, 2020, as follows:

Recent Guidance from CMS/AMA and NCDHHS on Antigen Testing

 CPT 87426-Infectious agent antigen detection by immunoassay technique (e.g., enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step method; severe acute respiratory syndrome coronavirus (e.g., SARS-CoV, SARS-CoV-2 [COVID-19]).

Recent Guidance from CMS/AMA and NCDHHS on Antigen Testing

- *Positive* antigen tests should be considered an indication of likely SARS-CoV-2 infection, especially when pretest probability is high.
- *Negative* antigen test results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with an FDAauthorized molecular assay, if necessary, for patient management.

Recent Guidance from CMS/AMA and NCDHHS on Antigen Testing

- All positive and negative antigen results must l required reporting of COVID-19 diagnostic test methods of reporting for antigen tests are the s PCR tests.
- Guidance on Reporting can be found here:
- <u>https://files.nc.gov/covid/documents/guidanc</u> <u>Order-Guidance-SL-2020-4-Sec.4.10.a.pdf</u>



SPECIAL BULLETIN COVID-19 #132: Laboratory Codes for Coronavirus (COVID-19) Testing

Monday, September 21, 2020

The Centers for Medicare & Medicard Services (CMS) and the American Medical Association have released a CPT code for an antigen test designed to detect proteins from the virus that causes COVID-19 in respiratory specimens.

NC Medicald is adding the following code into NCTracks for medically necessary laboratory testing effective Sept. 1, 2020, as follows-

CPT 8749-Intectious agent antigen detection by immunoassay technique (e.g., enzyme immunoassay (EMA), enzyme-linked immunoassay (EMA) [ELISA] immunochem Laminometric assay (INCA) qualitative or semiquantitative, multiple-step method, severe acute respiratory syndrome correnzivas (e.g., SASE-SOL, SASE-SOL (FASE-SOL))

NC Medicald noise that antigen tests are generally less sensitive than PCR-based methods and their clinical performance depends on the circumstances in which they are used. Due to the lower sensitivity, antigen testing is best when there is a high procedure of probability of SARS-COV-2 infection (e.g. high providence of intection in the community, clinical centest and symptoms of the negligent of the test).

Example populations or circumstances in which antigen testing could be considered.

- Symptomatic individuals in whom COVID-19 is suspected, particularly within 5-7 days of symptom onset. Note that two of the four antigen tests with FDA EUA are approved for use within 5 days, one within 7 days, and one within 12 days of symptom onset.
- Symptomatic and asymptomatic individuals in congregate settings, like numing homes or similar settings, where less frequent, highly sensitive tests are not available or subject to prolonged turnaround times and in accordance with federal guidance.

Evaluating Antigen Testing Results

Positive antigen tests should be considered an indication of likely SARS-CoV-2 intection, especially when pretest probability is high.

Negative antigen text results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms considered with COVID-19, and continued with an PDA-subhoted molecular assay. If necessary, for patient management. Specific considerations is integrating antigen enable in neural phenesit. These been posted by the COC.

Reporting Antigen Test Results

All positive and negative antigen results must be reported as part of required reporting of COVID-19 diagnostic tests. The requirements and methods of reporting for antigen tests are the same as for molecular PCR tests.

Laboratories are required to report electronically, either via Electronic Lab Reporting (ELR) or in accordance with the laboratory data automation process outlined in the guidance for reporting results 0 .

Physicians and other health care provides are required to report all positive and regaritie test results that will not be reported by a laboratory the accordance with the galabace within 24 hours of recording the test result is the local health divertor in the careful test index of the partiest rections. The State is developing an online survey where providers can report the aggregate number of positive and regarity an enders and the aggregate includes and the aggregate and the aggregate includes and the aggregate includes and the aggregate and

Physicians are required to report accompanying data for all positive tests by telephone or secure fas to the local health director in the <u>county or</u> <u>district where the patient resides</u>, even if the result is reported by a laboratory in accordance with this guidance.

Additional guidance can be found here, Our guidance II .

Contact

NCTracks Contact Center 800-888-8896

Questions?

