All LHD COVID Call
June 14th, 2022
# Opening Remarks & Leadership Update

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Diagnostic Tests

**Molecular**

1. Obtain Specimen: NP swab
2. Extract RNA from specimen and convert to DNA.
3. Amplify by PCR with SARS-CoV-2 specific primers.
4. Interpret results: presence of viral RNA indicates active SARS-CoV-2 infection.

**Laboratory**

- Sensitive
- Specific
- Several hours
- High throughput

**POC/Near-Patient**

- Less sensitive
- Specific
- Several hours
- Moderate throughput

**Antigen**

1. Obtain Specimen: SalivaDirect
2. RNA-extraction free process. Convert RNA from specimen to DNA and amplify by PCR with SARS-CoV-2 specific primers.
3. Interpret results: presence of viral RNA indicates active SARS-CoV-2 infection.

**POC/Near-Patient**

- Less Sensitive
- Specific
- <1 hour
- Low throughput

**Sample Collection**

**Rapid Diagnostic Test (RDT)**

**Result Check**
When to Get Tested

- If you have had COVID-19 in the past 90 days and recovered, you do not need to be tested unless you develop new symptoms.

- If you do have new symptoms, isolate immediately and get tested. Continue to stay home until you know the results.

- Wear a well-fitted mask around others.

Antigen Tests

**Asymptomatic**

- **Antigen Negative**
  - Close contact?
    - No
      - Up to date on vaccines?
        - Yes
          - No evidence of SARS-CoV-2 Infection: No need to quarantine
        - No
          - Quarantine for at least 5 days after close contact; continue to follow precautions through day 10
    - Yes
      - Up to date on vaccines?
        - Yes
          - No evidence of SARS-CoV-2 Infection: No need to quarantine
        - No
          - Quarantine for at least 5 days after close contact; continue to follow precautions through day 10

**Symptomatic (Test immediately)**

- **Antigen Positive**
  - Confirmatory NAAT or Serial Antigen Test
    - Positive
      - Evidence of SARS-CoV-2 Infection: Isolate for at least 5 days from date test specimen was collected or date of symptom onset
    - Negative
      - Close contact?
        - Yes
          - Up to date on vaccines?
            - Yes
              - Consider alternative diagnosis. Follow CDC guidelines for What to Do if You Are Sick.
            - No
              - Quarantine for at least 5 days after first day of symptoms; continue to follow precautions through day 10; consider alternative diagnosis
        - No
          - Quarantine for at least 5 days after first day of symptoms; continue to follow precautions through day 10; consider alternative diagnosis

- **Antigen Negative**
  - Close contact?
    - Yes
      - Up to date on vaccines?
        - Yes
          - Quarantine for at least 5 days after first day of symptoms; continue to follow precautions through day 10; consider alternative diagnosis
        - No
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1. Antigen tests have always been less sensitive than molecular tests, like PCR.

2. Antigen tests remain more specific than sensitive.
   • A positive result is truly a positive and no additional test is needed. The individual should isolate.
   • A negative result should be followed by a PCR if the individual is symptomatic and strongly considered if a close contact exposure.

3. Antigen tests remain an important testing tool when used correctly.
   • Always follow manufacturer’s directions to maximize accuracy.

4. Antigen tests should be used as intended and authorized by the FDA.
   • Some tests require certain frequency (i.e. 2 tests 24 to 48 hours apart).
   • Some should only be used within a specific time from symptom onset (i.e. 1 to 5 days).
   • Antigen tests currently authorized use nasal swabs or nasopharyngeal (NP) swabs, not throat (OP) swabs. Tests must be used with the authorized specimen type. Using other specimens increases the risk of false positive or false negative results.
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Monkeypox 2022: Vaccine Options and Request Procedure
## VACCINE OPTIONS

Both options thought to be ~85% effective at preventing monkeypox.

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<th>Indication</th>
<th>Dosing &amp; Administration</th>
<th>Availability</th>
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<td><strong>Jynneos</strong></td>
<td>FDA Approved for prevention of smallpox &amp; monkeypox in Adults 18+</td>
<td>2 doses (0.5 mL each) administered 4 weeks apart. Subcutaneous injection</td>
<td>SNS request; ~72,000 doses in SNS and growing</td>
<td><strong>Keep frozen</strong> at -25°C to -15°C (-13°F to +5°F). Once thawed, the vaccine may be kept at +2°C to +8°C (+36°F to +46°F) for 12 hours</td>
<td>Live attenuated virus vaccine; <strong>Non-replicating</strong> modified vaccinia Ankara-Bavarian Nordic (MVA-BN) May ship refrigerated for immediate use <strong>Single dose vials; SNS does not provide ancillary supplies</strong> <strong>Must use within 8 weeks</strong></td>
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<td><strong>ACAM2000</strong></td>
<td>FDA Approved for Smallpox prevention in Adults and Pediatrics &gt;1 y.o. Expanded access IND for monkeypox</td>
<td>1 drop of vaccine suspension via scarification using bifurcated needle. <a href="#">CDC Training Videos for ACAM2000 administration</a></td>
<td>SNS Request; &gt;100 Million doses in SNS</td>
<td><strong>Prior to reconstitution, store frozen</strong> at -15°C to -25°C (5°F to -13°F); may also be stored refrigerated at 2°C to 8°C (36°F to 46°F) for up to 18 months. Diluent stored at room temperature of 15°C to 30°C (59°F to 86°F).</td>
<td>Live vaccinia virus Myocarditis risk Contraindications for severe immunocompromise and ped &lt;1. Only administered by trained individuals Counseling on covering wound and handling bandages 100 doses per vial; comes with diluent and 100 bifurcated needles; transfer syringes not included.</td>
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Timing of PEP
• Vaccine should be administered within 4 days of exposure\(^1\)
• Vaccine administered between 4 to 14 days after exposure may reduce symptoms but not prevent disease

Determining who should receive PEP
• Transmission of monkeypox requires prolonged, close interaction with a symptomatic individual
• Brief interactions and those conducted using appropriate PPE in accordance with standard precautions are not high risk and generally do not warrant PEP.

Current PEP Recommendations Based on Degree of Exposure\(^2\)
• High
  – PEP recommended
• Intermediate
  – Individual risk/benefit analysis performed to inform clinical decision if PEP should be provided
• Low/Uncertain
  – PEP not recommended
• No Risk
  – PEP not recommended

\(^1\) [https://www.cdc.gov/poxvirus/monkeypox/clinicians/smallpox-vaccine.html](https://www.cdc.gov/poxvirus/monkeypox/clinicians/smallpox-vaccine.html)
\(^2\) [https://www.cdc.gov/poxvirus/monkeypox/clinicians/monitoring.html](https://www.cdc.gov/poxvirus/monkeypox/clinicians/monitoring.html)
PREEXPOSURE VACCINATION OF PERSONS AT RISK FOR OCCUPATIONAL EXPOSURE TO ORTHOPOXVIRUSES

At this time, most clinicians in the United States and laboratorians not performing the orthopoxvirus generic test to diagnose orthopoxviruses, including monkeypox, are not advised to receive orthopoxvirus PrEP.¹

The Advisory Committee on Immunization Practices (ACIP) recommends² that people whose jobs may expose them to orthopoxviruses, such as monkeypox, get vaccinated with either ACAM2000 or JYNNEOS

People who should get PrEP include:

- Clinical laboratory personnel who perform testing to diagnose orthopoxviruses, including those who use polymerase chain reaction (PCR) assays for diagnosis of orthopoxviruses, including Monkeypox virus
- Research laboratory workers who directly handle cultures or animals contaminated or infected with orthopoxviruses that infect humans, including Monkeypox virus, replication-competent Vaccinia virus, or recombinant Vaccinia viruses derived from replication-competent Vaccinia virus strains
- Certain healthcare and public health response team members designated by public health authorities to be vaccinated for preparedness purposes

¹ https://www.cdc.gov/poxvirus/monkeypox/clinicians/smallpox-vaccine.html
² https://www.cdc.gov/mmwr/volumes/71/wr/mm7122e1.htm
REQUESTING MONKEYPOX VACCINE

State health officials may request MCMs on behalf of those needing pre- or post-exposure prophylaxis or treatment for monkeypox.

For PEP Requests:
- CDC is only entertaining PEP requests following a confirmed orthopoxvirus (+) results from an Laboratory Response Network LRN reference lab
- An orthopoxvirus (+) result from SLPH would result in a conference call with partners at all levels to discuss overall situation, including PEP and treatment needs.
- MCM team will work with impacted jurisdiction to collect and submit all necessary information to CDC

For PrEP Requests:
- Being handled on a case-by-case basis
- LHDs or other partners who wish to request vaccine for PrEP use should email phpr.sns@dhhs.nc.gov
- The MCM team will work with IMT and state leadership to determine if PrEP is appropriate
- If deemed appropriate, MCM team will work with requesting jurisdiction/partner to collect necessary information and submit “Jynneos Request and Use Agreement Form” to CDC for adjudication

In both cases, approved requests are shipped directly to the clinic administering the vaccine/treatment.
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Vaccine Authorizations and Recommendations Timeline

Under 5 Vaccine Timeline

- **APRIL 28th**: Moderna 6m to 5y EUA Submission
- **JUNE 1st**: Pfizer 6m to 4y EUA Submission
- **JUNE 15th**: Pfizer and Moderna VRBPAC Review
- **TBD**: Pfizer and Moderna FDA Authorization
- **JUNE 17/18**: Pfizer and Moderna Emergency ACIP Meeting
- **TBD**: Pfizer and Moderna CDC Recommendations
- **Earliest JUNE 20th**: Vaccine in Arms

Other Upcoming VRBPAC Meetings

- **JUNE 7th**: Novavax VRBPAC Review
- **JUNE 14th**: Moderna 6-17 VRBPAC Review
- **JUNE 28th**: Fall Booster Composition VRBPAC Review

Updated: 6/6/2022
The Vaccines and Related Biological Products Advisory Committee (VRBPAC) is meeting on June 15th to review data for the Pfizer AND Moderna Under 5 products. The state anticipates that the Under 5 products may be available as early as June 20th.

Under 5 Vaccine Allocations will be initially distributed in 2 Waves. Wave 1 and 2 orders have closed. Last week, DHHS sent Wave 1 allocation confirmations and will send a confirmation email to locations receiving vaccines in Wave 2 this week.

If you are receiving vaccines during Wave 1, someone at your location must be available to receive vaccine shipment when delivered on Monday, June 20th.

Methodology: Fast, Fair, and Everywhere

- Every county will have vaccine allocated to it
- Every LHD will receive Under 5 vaccine in Wave 1 to ensure equitable access
- Providers with a history of equitable distribution (e.g., FQHCs) will be prioritized.
UNDER 5 ROLLOUT: WAVES 1 AND 2 RECAP

Where are the doses going?

- The federal allotment for the upcoming Under 5 products is being distributed to all 100 counties in the state.
- Geographic breakdown was determined by population, expected demand, and an emphasis on equitable distribution for counties with large HMPs.
- **118,600 doses allocated** across the state – comfortably exceeding our demand projections of 97,500 first doses
- This inventory will provide **~1 dose for every 6 kids** statewide
- Ordered **70,300 Pfizer** and **48,300 Moderna** combined in both waves, not to exceed our federal allotment
- **367 Providers** will be receiving vaccine for the Under 5 population, with over 400+ providers accounting for transfers
- Wave 1 orders are expected to arrive as early as June 20th and Wave 2 orders are expected to arrive as early as June 23rd

Projected Timeline

<table>
<thead>
<tr>
<th>JUN 7</th>
<th>JUN 13</th>
<th>JUN 15</th>
<th>JUN 17-18</th>
<th>JUN 20</th>
<th>JUN 23</th>
</tr>
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<tbody>
<tr>
<td>Wave 1 Orders Submitted</td>
<td>Wave 2 Orders Submitted</td>
<td>VRBPAC Meeting</td>
<td>ACP Meetings</td>
<td>Wave 1 Deliveries Begin</td>
<td>Wave 2 Deliveries Begin</td>
</tr>
</tbody>
</table>

*No Under 5 vaccines can be administered until the CDC has made its recommendation and is accepted by the CDC Director.

What’s Next?

- Under 5 Pfizer and Moderna vaccine will be available for weekly ordering in late June
On June 7th, the FDA Advisory Committee voted to recommend the Emergency Use Authorization of Novavax COVID-19 vaccine for those 18 years and older.

Overall efficacy was 90.4%, but there is limited data on the product's performance against current variants of the coronavirus (Delta, Omicron).

The rate of myocarditis was between 0.007% and 0.005%.

Common adverse reactions: headache, nausea/vomiting, myalgia, arthralgia, injection site tenderness/pain, fatigue, and malaise.

This product has NOT yet received FDA authorization or CDC recommendation.

Novavax has not yet been purchased by the US government, and there is no distribution plan at this time.
**COMIRNATY UPDATE**

**Comirnaty®**, the licensed Pfizer COVID-19 vaccine for adults will be available for ordering on or around **June 6th, 2022**. Patients who may have been waiting for a fully FDA authorized product can soon receive one.

- Please note that Comirnaty and the EUA-authorized Pfizer vaccine have different NDCs and labels; however, **the vaccines are identical and interchangeable**. See the [COVID-19 Vaccine Quick Reference Guide](#) for details.

- Both products (Comirnaty and EUA-authorized Pfizer vaccine) will be co-circulating during this limited release with a **GRAY Cap** for both labels.

- The EUA and BLA are identical and interchangeable for both primary and booster vaccinations.
June is Pride Month!
Build COVID-19 confidence in our LGBTIQIA+ populations using this [toolkit](#).

Listen In!
Get prepared for the Under 5 launch by listening in to the AMA's [preliminary findings on COVID vaccine for kids under 5](#).

Share!
The UNC Collaborative for Maternal and Infant Health has assembled key resources for engaging pregnant populations. [Check it out here](#)!
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Reasons for Updated Guidance

• Guidance related to case investigation and contact tracing has changed

• COVID-19 transmission dynamics have changed

• Need increased flexibility for LHDs when reporting clusters
Outbreaks

• Outbreak settings remain the same: congregate living facilities
  • Nursing homes and residential care facilities
  • Correctional facilities
  • Housing facilities for migrant workers (e.g. farmworkers)
  • Shelters

• Changes to definitions:
  • Shortened time period from 28 days to 14 days between the cases in a setting to report an outbreak
  • Shortened time period from 28 days to 14 days since the last reported case in an outbreak to declare it over
New Outbreak Definitions

• Criteria to report an outbreak in a congregate living facility:
  • Two or more laboratory-confirmed cases of COVID-19 in residents or staff within 14 days in the same facility

• Criteria to declare an outbreak over:
  • 14 days since the date of specimen collection of the most recent outbreak-associated case in the facility
Clusters

• Cluster settings remain the same
  • Educational settings such as child care, schools, and colleges/universities
  • Occupational/workplace settings
  • Community settings (churches or other religious gatherings, camps, independent living facilities, other community locations and events)

• Changes:
  • Shortened time period from 28 days to 14 days since the last reported case in a cluster to declare it over
  • Different options for reporting clusters when cases have known epi-links vs. unknown
New Cluster Definitions

• Criteria to report a cluster in a non-congregate living settings:
  • A minimum of five laboratory-confirmed cases of COVID-19 within 14 days with evidence of epidemiologic linkage between cases OR
  • 15 or more laboratory-confirmed cases of COVID-19 within 14 days associated with the same setting or facility in the absence of specific information about epidemiologic linkage*

*LHDs may choose to investigate and report clusters that do not meet these criteria at their discretion (e.g. in small settings or settings with high-risk populations). NC DPH recommends a minimum of 5 cases associated with a setting before any cluster is reported

• Criteria to declare a cluster over:
  • 14 days since the date of specimen collection of the most recent cluster-associated case in the facility
Common question on cluster settings

• It can be difficult to know how to report clusters in some settings, particularly in schools and colleges/universities.

• What should be the “unit” that is reported? Classroom, grade level, school-wide, etc.?

• Starting with small units is acceptable. Once there are multiple clusters within a school, combining into one large school-wide cluster is preferred (per new cluster definition of 15 cases in a setting)

• Some settings are too large and smaller units are preferred (e.g. we don’t recommend reporting a university-wide cluster)

• Email outbreak-data@dhhs.nc.gov if consultation is needed
# Opening Remarks & Leadership Update

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**QUESTIONS?**

Please use the Zoom Q&A function or email your questions to: questionsCOVID19webinar@gmail.com
The orange line represents the percent of successful digital notifications (texts and/or emails) to case-patients reported to public health during the week specified.

The addition of the green and orange bars represent the percent of cases reached by interview, grouped by age and gender during the time frame specified in the above filters.
The donut charts can now be filtered by a specified time frame from the start of the pandemic.
Bars for contact tracing outcomes have been added to show outcomes among age and gender categories. These contact tracing outcomes can now be filtered by a specified time frame from the start of the pandemic.
Request access by submitting a request through [this survey](#). Note: The dashboard provides unsuppressed aggregate data and is not designed for public release. Access is designed for LHD and state staff and CCTC regional supervisors and team leads.

Use the [NC CI/CT SharePoint Dashboard job aid](#) to learn about the themes of the dashboard, how to use filters, reading the dashboard, and downloading it.
NEW CCTC REGIONAL STRUCTURE

• CCTC Structure split into three new regions: West, Central and East
• CI/CT Staff (including Team Leads) will be utilized across counties within their region (and consequently will need expanded access to NC COVID)
• For the moment, Regional Supervisors will remain in place, but that will change as numbers decrease

THANK YOU!
## Opening Remarks & Leadership Update

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UKRAINIAN NEWCOMERS

Ukrainian Humanitarian Parolees Eligible for Mainstream and Refugee Benefits and Services
As of May 21, 2022, the AUSAA gives specific Ukrainian populations and other non-Ukrainian individuals eligibility for mainstream and refugee benefits and services. Visit [this website](https://www.congress.gov/bill/117th-congress/house-bill/7691/text) for more details.

- Eligible for mainstream benefits (e.g., Temporary Assistance for Needy Families, Medicaid, Supplemental Nutrition Assistance Program, Supplemental Security Income).
- Eligible for resettlement assistance, and most other benefits available to refugees including Refugee Medical Assistance and [Refugee Health Screening](https://www.acf.hhs.gov/orr/fact-sheet/benefits-ukrainian-humanitarian-parolees).
APPLICANTS TIED TO NORTH CAROLINA AS OF JUNE 6, 2022

- 820 Uniting for Ukraine (U4U) applications from NC supporters for Ukrainian newcomers = 147 NC zip codes, 95 NC cities, 45 NC counties. [https://www.uscis.gov/ukraine](https://www.uscis.gov/ukraine)

- Ukrainians can come through other programs as well.

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<table>
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<th>Top 10 Cities</th>
<th>Top 10 Counties</th>
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</thead>
<tbody>
<tr>
<td>Charlotte</td>
<td>Mecklenburg</td>
</tr>
<tr>
<td>Raleigh</td>
<td>Wake</td>
</tr>
<tr>
<td>Cary</td>
<td>Union</td>
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<tr>
<td>Apex</td>
<td>Buncombe</td>
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<td>Indian Trail</td>
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</tr>
<tr>
<td>Asheville</td>
<td>New Hanover</td>
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<td>Greensboro</td>
<td>Orange</td>
</tr>
<tr>
<td>Washington</td>
<td>Wakey</td>
</tr>
<tr>
<td>Hudson</td>
<td>Tazwell</td>
</tr>
<tr>
<td>Matthews</td>
<td>Ashe</td>
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</table>
• **Vaccination coverage** in Ukraine is among the lowest in the WHO European Region.
• **Vaccine hesitancy** is a major concern.
• Increased risk of **diarrheal disease** in children as the rotavirus vaccine not included in Ukraine’s national **routine vaccination schedule**.
• **Measles** is endemic in Ukraine.
• In October 2021, an outbreak of vaccine-derived **polio** was confirmed in Ukraine. The national polio immunization campaign was suspended following the Russian invasion.
• Ukraine is considered a high priority country and has a high burden of **multidrug-resistant (MDR) tuberculosis (TB)**. The estimated TB incidence is 73 per 100,000 and 29.55% of all new and relapse TB cases diagnosed in Ukraine in 2020 were started on treatment for either rifampin-resistant or MDR TB.
IMMUNIZATIONS AND TB

• Few Ukrainian arrivals will have had an overseas immigration examination – so no overseas Tuberculosis screening and many may not have any immunization records.

• Some of the Ukrainian arrivals will have to attest to the Department of Homeland Security within 2 weeks after arrival that they have had at least one dose of the following vaccines: polio, measles and COVID-19.

• Some also may have to attest within 2 weeks to have undergone tuberculosis screening starting with an IGRA (interferon-gamma release assay) blood test. The attestation includes agreeing to take appropriate measures, including additional screening and treatment measures should the screen be positive.

• Failure to comply can lead to termination of their parole, detention and removal from U.S.

• [https://www.uscis.gov/humanitarian/uniting-for-ukraine/uniting-for-ukraine-vaccine-attestation](https://www.uscis.gov/humanitarian/uniting-for-ukraine/uniting-for-ukraine-vaccine-attestation)
• May be eligible for mainstream and refugee benefits, so they should apply for Medicaid and Refugee Medical Assistance. Eligible and recommended for Refugee Health Screening.

• Tool for clinicians to conduct routine post-arrival medical screening: https://careref.web.health.state.mn.us/.

• Can be referred to a refugee resettlement agency or service provider for various services: health promotion, specialized case management, employment services, English language training, driver’s education, cultural orientation, legal services, etc. https://www.ncdhhs.gov/media/7883/download.

• CDC Resources in Languages Other than English

• COVID-19 Resources for Ukrainian New Arrivals | National Resource Center for Refugees, Immigrants, and Migrants (NRC-RIM) (nrcrim.org)

• NC DHHS DPH Refugee Health Program, jennifer.morillo@dhhs.nc.gov, (919) 755-3181
# Opening Remarks & Leadership Update

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