### Opening Remarks & Leadership Update

| Opening Remarks & Leadership Update | Doug Urland, MPH, DrPH  
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| Policy                              | Elizabeth Cuervo Tilson, MD, MPH  
State Health Director  
Chief Medical Officer |
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COVID-19 Vaccine Program Director |
| Testing                             | Scott M. Shone, PhD, HCLD(ABB)  
Laboratory Director |
| Contact Tracing                     | Laura Farrell  
North Carolina Contact Tracing Manager |
| IP Guidance Updates                 | Emily Berns, MPH, RN  
Nurse Consultant  
Division of Public Health, Communicable Disease Branch |
| NCCOVID Update                      | Anita Valiani, MPH  
NC EDSS Epidemiologist and Manager |

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# Vaccine Update

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NC DHHS COVID-19 Vaccine Program
LHD Update

February 8, 2022
<table>
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<tr>
<th>Slide #</th>
<th>Topic</th>
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<tr>
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<td>Status of Vaccine Approval</td>
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<td>4</td>
<td>0-4 Approval Timeline</td>
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<tr>
<td>5</td>
<td>0-4 Demand Planning</td>
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<td>6</td>
<td>0-4 Product Handling &amp; Pfizer COVID-10 Vaccine Products</td>
</tr>
<tr>
<td>7</td>
<td>Distribution Wave 1</td>
</tr>
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<td>8</td>
<td>Distribution Wave 2 and Beyond</td>
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<td>9</td>
<td>Distribution and Ordering Visual</td>
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<td>Call to Action &amp; Opportunity to Connect</td>
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<td>Local Data Planning Resources</td>
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<tr>
<td>14</td>
<td>What You Can Do</td>
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<table>
<thead>
<tr>
<th>Adults 18+</th>
<th>Pediatrics</th>
<th>Additional Dose (Immunocompromised)</th>
<th>Booster*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pfizer</strong></td>
<td>Approved (August ‘21)</td>
<td>Approved (August ‘21)</td>
<td>EUA (May ‘21)</td>
</tr>
<tr>
<td><strong>Moderna</strong></td>
<td>Approved (Jan ‘22)</td>
<td>Under Review (June ‘21)</td>
<td>Under Review (June ‘21)</td>
</tr>
<tr>
<td><strong>Janssen</strong></td>
<td>EUA (Feb ‘21)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Novavax</strong></td>
<td>Under Review (Jan ‘22)</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

*Mix and Matching permitted as of October ‘21 for those 18+

EUA = Emergency Use Authorization
0-4 APPROVAL TIMELINE

Clinical trial and/or real-world data: Pfizer submits an EUA application for <5 year olds (Submitted 2/2)

Vaccines and Related Biological Products Advisory Committee (VRBPAC): VRBPAC (may) meet. If so, they assess the safety and effectiveness data. And vote to recommend (or not) the vaccine

FDA: FDA makes a decision

Advisory Committee on Immunization Practices (ACIP): ACIP meets to assess safety and effectiveness. But most importantly will decide policy of implementation. Then vote.

CDC: CDC makes a decision

Public: Vaccine in arms
The 6 month-4-year-old population is 609,770 children.

State market research expects 52% to get the vaccine.

Current projections show 16-19% of the under 5 population will be vaccinated within 3 months = 95,116 first doses.

Week 1 demand will be 20-30K.

Estimated Vaccination Rate by County

Estimated 1st doses (by day & running total)
**0-4 PRODUCT HANDLING**

Pfizer-BioNTech COVID-19 Vaccine Products
PRELIMINARY – SUBJECT TO CHANGE PENDING REGULATORY GUIDANCE AND AUTHORIZATION/APPROVAL; CDC DOCUMENT – SHARED FOR JURISDICTIONAL PLANNING PURPOSES ONLY

<table>
<thead>
<tr>
<th>Age Indications*</th>
<th>Current Products</th>
<th>Future Product</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 years and older</td>
<td>5 through 11 years</td>
<td>6 months through 4 years*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Vial Cap Color and Label with Color Border</th>
<th>Current Products</th>
<th>Future Product</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gray</td>
<td>Orange</td>
<td>Maroon</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Preparation</th>
<th>Current Products</th>
<th>Future Product</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do Not Dilute</td>
<td>Dilute Before Use</td>
<td>Dilute Before Use</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Amount of Diluent Needed per Vial*</th>
<th>Current Products</th>
<th>Future Product</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do Not Dilute</td>
<td>1.3 mL</td>
<td>2.2 mL</td>
</tr>
<tr>
<td>0.3 mL/30 mcg</td>
<td>0.2 mL/10 mcg</td>
<td>0.2 mL/3 mcg</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Dose Volume/Dose</th>
<th>Current Products</th>
<th>Future Product</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 doses per vial</td>
<td>10 doses per vial (after dilution)</td>
<td>10 doses per vial (after dilution)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Storage Conditions</th>
<th>Current Products</th>
<th>Future Product</th>
</tr>
</thead>
<tbody>
<tr>
<td>ULT Freezer (-90°C to -60°C)</td>
<td>9 months</td>
<td>9 months</td>
</tr>
<tr>
<td>Freezer (-25°C to -15°C)</td>
<td>DO NOT STORE</td>
<td>DO NOT STORE</td>
</tr>
<tr>
<td>Refrigerator (2°C to 8°C)</td>
<td>10 weeks</td>
<td>10 weeks</td>
</tr>
<tr>
<td>Room Temperature (8°C to 25°C)</td>
<td>12 hours prior to first puncture (including any thaw time)</td>
<td>12 hours prior to first puncture (including any thaw time)</td>
</tr>
<tr>
<td>After First Puncture (2°C to 25°C)</td>
<td>Discard after 12 hours</td>
<td>Discard after 12 hours</td>
</tr>
</tbody>
</table>

* Use the appropriate product based on the age of the recipient.
* Diluent: Sterile 0.9% Sodium Chloride Injection, USP. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.
* Regardless of storage condition, vaccines should not be used after 9 months from the date of manufacture printed on the vial and cartons.
* The vaccine is currently under emergency use authorization review by the Food and Drug Administration (FDA) for children 6 months through 4 years old.

- The product will have a Maroon top
- Minimum Order Quantity: 100 dose orders; 10 dose vials.
- The 0-4 product requires 2.2mL diluent – this is different than the 5-11 product.
- Ultra-Cold Freezers are **not necessary** for a provider to offer Pfizer pediatric vaccine - The new pediatric formulation will be able to be stored in the fridge for up to 10 weeks.

[Download the updated Pfizer product guide](#)
The product will ship initially in 2 waves. Shipments will start to ship as soon as an FDA EUA issued for the product.

Wave 1: Product Launch/Pre-Orders
- NCDHHS will use a “push” model to distribute the Pfizer 0-4 vaccine to Local Health Departments and Vaccine for Children Sites. Selected sites will receive allocation notifications starting February 8, 2022.
  - There are 57,800 doses available for NC in the Wave 1 product launch. Not all providers will be allocated product for this wave.
  - Allocation Methodology:
    - Each of the 100 counties will be allocated doses based on the eligible population size.
    - County vaccine allotments will be modified with expected demand input generated with data from the 5-11 program.
    - Significant differences in vaccination rates between counties will also inform the allocation strategy.
    - Vaccine will be allocated to Local Health Departments and Vaccine for Children Locations based on the percentage of the 5-11 administrations for their given county.

- The first wave is projected to deliver vaccines starting February 21, 2022 - Vaccine Locations must be able to receive the vaccine on the President’s Day Holiday

- Allocation Responses are due by Thursday, February 10th at 10 am

- NCDHHS is committed to offering this vaccine in a way that is fast, fair and everywhere. Therefore, we will lead with equity by ensuring that our Local Health Departments and Vaccine For Children Providers have immediate access to vaccine.
  - It is expected that the Local Health Department will accept this push allocation, as they are the only provider type in NC that serves all 100 counties.

- Local Health Departments may transfer vaccines locally as they see fit to support local effort to ensure a "fast, fair, and everywhere" vaccine program.
Wave 2: Post Program Launch

• NCDHHS will use a “pull” model to distribute requested 0-4 Pfizer vaccine to all Enrolled Vaccine Providers.
  • Providers will be able to request vaccine beginning Thursday, February 10th for Wave 2.
  • Submission is due by Wednesday, February 16th @ 10am.
  • It is estimated that 57,800 doses will be available for the Wave 2 post-product launch. This will be confirmed with our federal partners at a later date.

• Order Threshold Methodology:
  • All orders requests will be reviewed and modified to ensure that vaccine is shipped to appropriate locations based on the eligible county population and expected vaccine demand.
  • DHHS will distribute product according to demand, capacity, and equity data.
  • All enrolled COVID-19 Vaccine Providers are eligible for requesting vaccine

• The second wave is projected to start delivering vaccines starting February 22, 2022 but they may arrive throughout the week.

Beyond:

• The Provider Ordering Guidance will be updated at a later date to explain how future supply can be obtained.
• Providers are responsible for ordering vaccine for 2nd doses, and potentially 3rd doses if authorized.
**WAVE 1**

**WHO**
Local Health Departments & VFC Providers

**HOW**
Distributed for you according to geographic, equity, and demand data

**ACTION NEEDED**
Accept you Allocation by 10am on Thursday, February 10th

**WHEN**
Delivery Expected Monday 2/21/2022 (Presidents’ Day)

---

**WAVE 2**

**WHO**
ALL COVID-19 Vaccine Providers, including Wave 1

**HOW**
Providers can REQUEST doses based on expected demand, DHHS will reconcile & allocate

**ACTION NEEDED**
Request by 10am Wednesday, February 16th. Instructions to come.

**WHEN**
Orders Open 2/10. Expected Delivery the week of 2/22.

---

Providers are responsible for ordering 2nd, and 3rd doses if applicable. The Ordering Guidance will be updated at a later date.
LHDs are the only providers present in all 100 counties

You will be a lynchpin in broad access to vaccine for this age group!

NCDHHS wants to understand your existing outreach program work and community collaborations that can be leveraged to better inform State planning. We are asking for LHD subject matter experts to participate in a stakeholder planning discussion - especially from program areas that have active connections with target recipients and current/potential vaccine providers such as:

• CMARC
• Childcare Health Consultant
• Pregnancy Care Managers
• NFP

• WIC
• Immunization Managers
• Health Educators
• COVID vaccine operations.

Please send recommended staff names and contact information through your NCALHD Regional Representative to Kimberly.McDonald@dhhs.nc.gov
Figure 9

Pediatricians Are Top Trusted Source Of Child Vaccine Information For Parents Across Community Types

Percent of parents who say they trust each of the following a great deal or a fair amount to provide reliable information about the COVID-19 vaccines for children:

<table>
<thead>
<tr>
<th>Source</th>
<th>Rural</th>
<th>Suburban</th>
<th>Urban</th>
</tr>
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<tbody>
<tr>
<td>Their child’s pediatrician or health care provider</td>
<td>76%</td>
<td>76%</td>
<td>78%</td>
</tr>
<tr>
<td>Their local public health department</td>
<td>50%</td>
<td>58%</td>
<td>67%</td>
</tr>
<tr>
<td>The CDC</td>
<td>45%</td>
<td>56%</td>
<td>65%</td>
</tr>
<tr>
<td>Their child’s school or daycare</td>
<td>36%</td>
<td>43%</td>
<td>53%</td>
</tr>
<tr>
<td>Other parents they know</td>
<td>24%</td>
<td>32%</td>
<td>37%</td>
</tr>
</tbody>
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NOTE: Among parents or guardians of children under 18. See topline for full question wording.

LOCAL DATA RESOURCES

CLICK HERE to access statewide market research

CLICK HERE to access Demand Estimations by County

CLICK HERE to view enrolled COVID-19 Provider coverage by county
0-4: WHAT YOU CAN EXPECT FROM US

- Forecasting Potential Provider Capacity
- Anticipated County-specific <5 demand rates
- Providing increased opportunities to connect and ask questions with DHHS
- Resources to counsel vaccine-hesitant families
- Guidance for future vaccine distribution/ordering
- Visual aid resources to prepare
- Vaccine distribution information by county
- Offering provider support for NCIR/CVMS to ensure ease of documentation

(send recommended staff names and contact info to Kimberly.McDonald@dhhs.nc.gov)
What You Can Do:

1) Accept your Wave 1 Allocation
   As soon as possible, and no later than Thursday, February 10 @ 10am

2) Check in with the providers in your area.
   • Are they enrolled in the COVID-19 vaccine program? Share our Become an Under 5 Vaccine Provider broadly (especially with pediatric providers!)
   • Should they consider extended or weekend hours during the initial wave of under 5 vaccines?

3) Send recommended focus group staff names and contact info to Kimberly.McDonald@dhhs.nc.gov
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# Contact Tracing

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In this pandemic moment, vaccine, testing, and masking are best practices to prevent viral spread. CI/CT are important tools but less effective in reducing transmission outside of congregate settings.

CI/CT prioritization

- Outreach to all case patients continues through texts and email
- Do case investigation and contact tracing for priority groups 1 and 2: these are outbreaks/clusters reported to you, in congregate living, or working in or potentially exposed in certain high density settings.

Prioritizing case phone outreach ensures that priority cases are investigated in a timely way, and that diagnosis notification and support for under resourced populations is not interrupted.

- As staff are available, make phone calls to case patients to provide information and resources (no case investigation/contact tracing) for groups 3 and 4:
  - General public whose text is not delivered
  - People in under resourced communities

- Contact tracing call center is available to case patients and contacts; phone number for call center is in emails and texts
- Flex CI/CT staff to support vaccine and testing duties as needed
- Use efficient NC COVID strategies to move cases through workflows- Data Entry support available through CCTC (email nmatyas@carolinactc.org for Data Entry support)
Current CI/CT data

Most LHDs are interviewing a subset of case patients; contact tracing is limited

Although some outreach was delayed at the peak of this wave, most outreach is timely
84% of case patients are electronically notified
# IP Guidance Updates

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Testing

Create a Plan for Testing Residents and HCP for SARS-CoV-2

- **FDA** evaluates test characteristics and facilities should be aware of how tests perform for circulating variants.
- Anyone with even mild symptoms of COVID-19, regardless of vaccination status, should receive a viral test as soon as possible.
- Newly-admitted residents and residents who have left the facility for >24 hours, regardless of vaccination status, should have a series of two viral tests for SARS-CoV-2 infection; immediately and, if negative, again 5-7 days after their admission.
- Asymptomatic residents with close contact with someone with SARS-CoV-2 infection, regardless of vaccination status, should have a series of two viral tests for SARS-CoV-2 infection. In these situations, testing is recommended immediately (but generally not earlier than 24 hours after the exposure) and, if negative, again 5-7 days after the exposure.
- In general, testing is not necessary for asymptomatic people who have recovered from SARS-CoV-2 infection in the prior 90 days; however, if testing is performed on these people, an antigen test instead of a nucleic acid amplification test (NAAT) is recommended. This is because some people may remain NAAT positive but not be infectious during this period.
Manage Residents with Close Contact

Manage Residents who had Close Contact with Someone with SARS-CoV-2 Infection

- Residents who are not up to date with all recommended COVID-19 vaccine doses and who have had close contact with someone with SARS-CoV-2 infection should be placed in quarantine after their exposure, even if viral testing is negative. HCP caring for them should use full PPE (gowns, gloves, eye protection, and N95 or higher-level respirator).
  - Residents can be removed from Transmission-Based Precautions after day 10 following the exposure (day 0) if they do not develop symptoms. Although the residual risk of infection is low, healthcare providers could consider testing for SARS-CoV-2 within 48 hours before the time of planned discontinuation of Transmission-Based Precautions.
- Residents can be removed from Transmission-Based Precautions after day 7 following the exposure (day 0) if a viral test is negative for SARS-CoV-2 and they do not develop symptoms. The specimen should be collected and tested within 48 hours before the time of planned discontinuation of Transmission-Based Precautions.

Guidance Reminders for Long-term Care Facilities

Visitors

- Even if they have met community criteria to discontinue isolation or quarantine, visitors should not visit if they have any of the following and have not met the same criteria used to discontinue isolation and quarantine for residents (typically until 10 days after last exposure or onset of symptoms):
  - a positive viral test for SARS-CoV-2,
  - symptoms of COVID-19, or
  - close contact with someone with SARS-CoV-2 infection

COVID Units

- Some facilities may face circumstances where a dedicated COVID-19 unit is not feasible. When large numbers of residents are actively infected and there are staffing shortages that prevent dedicating staff to a COVID unit, it may be safer to care for residents in their current location in order to minimize movement and room changes.
- LHDs and facilities are encouraged to assess relevant factors and individual facility capabilities to determine the safest options for facility residents and staff.

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| Contact Tracing                     | Laura Farrell  
North Carolina Contact Tracing Manager |
| IP Guidance Updates                 | Emily Berns, MPH, RN  
Nurse Consultant  
Division of Public Health, Communicable Disease Branch |
| NCCOVID Update                      | Anita Valiani, MPH  
NC EDSS Epidemiologist and Manager |

**QUESTIONS?**

Please use the Zoom Q&A function or email your questions to: questionsCOVID19webinar@gmail.com
NC COVID Reminders

• We understand there are a lot of events in your workflows and you are trying to clear it out. Please refer to the documents on the CD manual under NC COVID on how to report events to the state (with case interview and without case interview).

• Please remember that for NC COVID when you submit an event to the State, the classification status should match the lab result. For example, if the person has only an Antigen result, please submit to the State with the classification status as probable.

• We are seeing users have some difficulty entering At Home tests, we have a job aid to help with this located on our training materials page

• The link to the NC COVID page is on the NC COVID log in page as well, in the notes section on the left.

• We have split the workflows and refreshed all of them at this point.

• Reminder for reports, please run reports in small batches. We have had many LHDs running large reports that make the system run sluggish and IT has had to re-start the servers. Please be mindful of all the users and try to run reports in 1-2 week timeframes depending on the size of your county.

• Trainings are still ongoing for NCEDSS basic and NC COVID, when requesting trainings supervisors please include the name and email address for the participants. Please email NCEDSStrainings@dhhs.nc.gov
  o There will be focused webinar on Thursday Feb 10 on Interstate Notifications where the helpdesk/training staff will be available to answer questions.