

COVID-19 Vaccination 101

Overview Deck

October 16, 2020



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**



Table of Contents

3

NC's COVID-19 Response
Guiding Principles

5

COVID-19 Vaccine 101
What it is, how it works, how it is being developed

13

NC's Approach to COVID-19 Vaccine
Planning and Distribution

NC's COVID-19 Response

Since the start of the pandemic, North Carolina took early and aggressive action to slow the spread of the COVID-19. Our response has been driven by science and data, frequent and transparent communications, and, addressing the disproportionate impact of COVID-19 on historically marginalized populations.

	What the State is Doing	What You Can Do
Prevention Slow the Spread	<ul style="list-style-type: none"> • Phased reopening to minimize spread of COVID-19 • Require <u>face coverings</u> • Promote the 3Ws (<u>Wear, Wait, Wash</u>) • Preparing for a COVID-19 vaccine 	<ul style="list-style-type: none"> • <u>Practice the 3Ws</u> • Share <u>social media posts, videos, flyers</u> to encourage people to practice the 3Ws • Follow <u>NCDHHS guidance</u>
Testing and Tracing Know Who Has COVID-19 & Who Has Been Exposed	<ul style="list-style-type: none"> • Build a statewide <u>testing & contact tracing</u> infrastructure • Surge resources in hardest hit communities and populations 	<ul style="list-style-type: none"> • Get <u>tested if symptomatic</u> or if you think you are exposed to COVID-19 • Answer the call from the <u>COVID-19 Community Team</u>
Isolation and Quarantine Support People to Stay Home	<ul style="list-style-type: none"> • Ensure access to <u>non-congregate shelters</u> for people who need to isolate • Enact policies to enable people to miss work and stay at home 	<ul style="list-style-type: none"> • Stay home when you can, especially when sick • Support employees to stay home when sick to minimize the spread

Guiding Principles for NC COVID-19 Vaccine Planning and Distribution

GUIDING PRINCIPLES



All North Carolinians have equitable access to vaccines



Vaccine planning and distribution is inclusive; actively engages state and local government, public and private partners; and draws upon the experience and expertise of leaders from historically marginalized populations



Transparent, accurate, and frequent public communications is essential to building trust



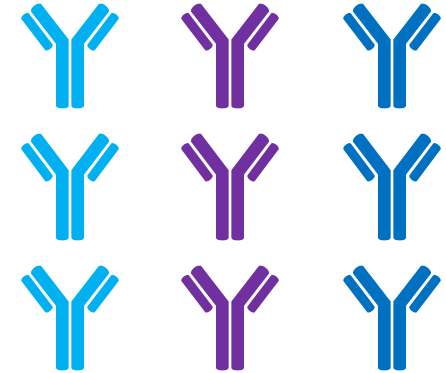
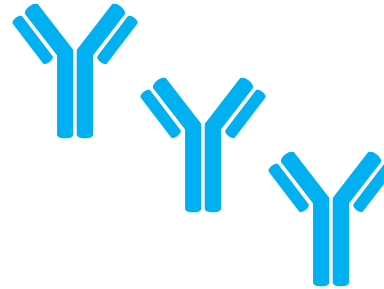
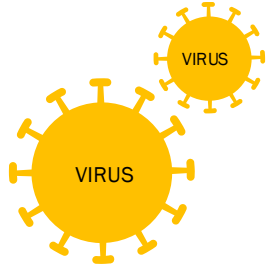
Data is used to promote equity, track progress and guide decision-making



Appropriate stewardship of resources and continuous evaluation and improvement drive successful implementation

How Do Vaccines Work?

To understand how vaccines work, you need to first understand how our body fights infections. Let's take the example of an infection with a virus:



When we are exposed to a virus, our body's immune system fights back

To fight the virus, our immune system creates proteins – called antibodies

Our immune systems create different antibodies for different viruses it meets

After the infection, our immune system remembers and has antibodies ready to go faster if the virus reappears, helping to prevent us from getting sick

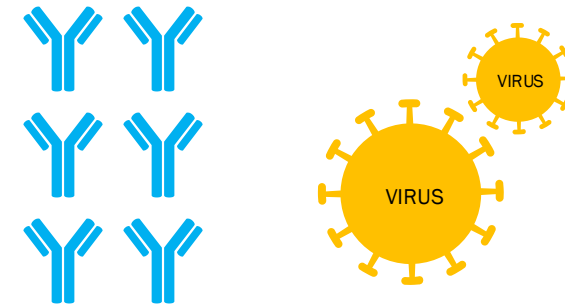
How Do Vaccines Work?

It takes time for the body to build enough antibodies. Some viruses can make people very sick, and even die, because their immune systems aren't able to fight it off.

That's where vaccines come in:



Vaccines imitate an infection, so that our bodies think a virus is attacking and our immune systems create the antibodies that we need if the real virus attacks



After getting vaccinated, you develop immunity to that disease so that your body remembers how to fight the virus in the future.

The Flu Vaccine

Let's take the flu vaccine for example...

The flu vaccine is the **single best way to prevent the flu and its complications**

The flu vaccine **lowers your likelihood of getting sick**. And if you do catch the flu, it's likely to be milder

The vaccine works by triggering your body to produce **protective antibodies** that help fight off an infection with the real flu virus



How is it developed?

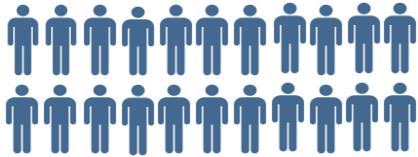
Each year, scientists develop flu vaccines to protect against the 3-4 flu strains that research suggests will be most common in the upcoming season

How are Vaccines Tested and Approved in the US?

Vaccines go through the following phases to be approved:

PHASE ONE

Safety & Dosing



20-100 healthy volunteers

Questions Addressed:

- Is the vaccine safe?
- Are there any serious side effects?
- How is the size of the dose related to side effects?

PHASE TWO

Safety & Immune Response



Several hundred volunteers

Questions Addressed:

- What are the most common short-term side effects? Are they tolerable?
- How are the volunteers' immune systems responding to the vaccine?

PHASE THREE

Safety & Efficacy



Thousands of volunteers

Questions Addressed:

- Is the vaccine effective in preventing illness?
- What are the most common side effects?
- Is the vaccine safe?

How are COVID-19 Vaccines Being Developed?

Vaccine Timeline

- **Multiple** COVID-19 vaccines are being developed
- Promising vaccines are being manufactured at the same time they are being tested, so there will be an **initial supply ready to go right away** when the science shows which vaccines are found to be safe and effective
- Once we have a vaccine or vaccines, it will still be **some time before it is widely available** to everyone. States will receive limited supplies at the start

Volunteer Process

- **Thousands of people** have volunteered as part of research trials to see if a vaccine prevents COVID illness and to learn more about its safety in overlapping steps
- There have been **intentional efforts to recruit historically marginalized populations** to participate in these vaccine trials. Significant barriers to overcome include racism that has been embedded into societal and health care systems, resulting in unequal access to care, maltreatment and neglect for historically marginalized communities

Developing, Manufacturing and Distributing a COVID-19 Vaccine

PHASE 1 & 2:

Safety & Dosing

10s-100s of healthy volunteers

- Are there any side effects? How many volunteers experience side effects?
- What is the best vaccine dose to create an immune response with the fewest tolerable side effects?

PHASE 2 & 3:

Safety & Efficacy

>30,000 of volunteers

- Does the vaccine prevent COVID-19 infection?
- What are the most common side effects?
- Do the benefits of the vaccine outweigh the risks?

Approval & Distribution

- FDA reviews the safety and efficacy data to determine if benefits are greater than risks
- An independent, non-FDA scientific committee reviews findings
- Vaccine is authorized and recommended for use (may only be for certain populations)
- Vaccine is labeled for use, benefits, side effects

Manufacturing

Preparation: Manufacturing development, scaling up, quality-control testing

Large-Scale Manufacturing: Making millions of vaccine doses for nationwide distribution, continued quality-control testing of vaccine batches and manufacturing facilities, FDA and CDC continually monitor vaccinated patients for safety

Availability: Limited availability in the beginning. More widely available over time.

When Will a COVID-19 Vaccine be Approved?

When scientific evidence demonstrates that a COVID-19 vaccine is safe and effective



Multiple COVID-19 vaccines in Phase 3 trials, the last major stage of data collection before Food and Drug Administration (FDA) approval



In the United States, once a vaccine has demonstrated that it is safe and can prevent COVID-19, it will most likely be authorized under an FDA Emergency Use Authorization



The Emergency Use Authorization authority allows FDA to help strengthen the public health protections by facilitating the availability and use of medicines needed during public health emergencies



Even after vaccines are authorized, they continue to be closely monitored for safety by the FDA and CDC

<https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html> (Oct 3)

When Will a COVID-19 Vaccine be Available?

Once we have an approved COVID-19 vaccine or vaccines, it will still be some time before it is widely available to everyone



Once a vaccine is approved, it will take time for manufacturers to ramp up production, even if they started early



Limited COVID-19 vaccine doses may be available by this year, but vaccine supply will increase substantially in 2021



States will receive limited vaccine supplies at the start

The infographic is divided into three vertical panels. The first panel shows a cloth mask icon with the text 'WEAR a cloth mask over your nose and mouth.' The second panel shows two human figures with a double-headed arrow between them labeled '6 FEET' and the text 'WAIT 6 feet apart. Avoid close contact.' The third panel shows hands being washed with soap bubbles and the text 'WASH your hands or use hand sanitizer.'

Until and after a vaccine is available for everyone, we will need to keep practicing the 3Ws

Leading with Equity

Racism embedded into societal and health care systems has resulted in unequal access to care, maltreatment and neglect for historically marginalized communities

These longstanding racial and ethnic injustices in our health care system contribute to lack of trust in vaccines

- North Carolina is drawing upon the experience and expertise of leaders from historically marginalized communities to develop and implement its vaccine plan.
- The prioritization for distribution is based on framework developed by an independent Vaccine Advisory Committee convened by the NC Institute of Medicine.
- Principles guiding prioritization were equity, maximization of benefits, transparency, operational feasibility, reliance on a strong evidence base, and “do no harm.”

NCIOM COVID-19 Vaccine Advisory Committee

North Carolina is drawing upon the experience and expertise of leaders from historically marginalized communities and other key stakeholders to develop and implement its vaccine plan.

The prioritization for distribution is based on framework developed by an independent Vaccine Advisory Committee convened by the NC Institute of Medicine. More than 65 people served on the committee.

Co-Chairs

Art Apolinario, *Clinton Medical Clinic/NC Med Society*
Goldie Byrd, *Wake Forest Univ.*
Leah Devlin, *UNC-CH*

Steering Committee

Crystal Wiley Cené, *UNC Health*
Viviana Martinez-Bianchi, *Duke Health*
David Tayloe, *NC Pediatric Society*
Doug Urland, *NC IPH*
Weyling White, *Roanoke Chowan Community Health Center & Mayor of Ahoskie, NC*
Cameron Wolfe, *Duke Health*

Advisory Committee

Jenie Abbotts, *NC CHCA*
Rebecca Bean, *Novant*
Michele Boyd, *Charlotte AHEC*
Vickie Bradley, *Eastern Band of Cherokee*
Sharon Brown-Singleton, *NCCHCA*
Jay Campbell, *NC Board of Pharmacy*
Juan Carabana, *Episcopal Farmworker Ministry*

Julie Casani, *NC State*
Joy Cook, *NC NAACP*
Andy Ellen, *NCRMA*
Chris Evans, *BCBS NC*
Ellen Essick, *NC DPI*
Chris Evans, *BCBS NC*
Brent Fisher, *Nash County Emergency Management*
Aimee Forehand, *BCBS NC*
Kelly Fuller, *NC Chamber Foundation*
Cindy Gay, *UNC School of Medicine*
Ophelia Garmon-Brown, *Novant Health*
Tina Gordon, *NC Nurses Assoc.*
Charlene Green, *Old North State Medical Society*
Kevin High, *Wake Forest Baptist*
Jeff Horton, *NC Senior Living Assoc.*
Nicole Johnson, *NC Council of Churches*
Randy Jordan, *NCAFCC*
Gary Junker, *NC DPS*
Debra Kosko, *NC Immunization Coalition*
John Lumpkin, *BCBS NC Foundation*
Tammy Maynor, *Lumbee Tribe*
Bruce McClenathan, *Defense Health Agency*

Tyler Means, *Mecklenburg County Public Health Sarajane Melton, Area Agency on Aging, Southwestern Commission Council of Governments*
Jill Moore, *UNC School of Gov.*
Adam Pridemore, *NCCCA*
Michael Olender, *AARP NC*
Cheryl Parquet, *BCBS NC*
Lu-Ann Perryman, *AHIP*
Adam Pridemore, *NCCCA*
David Priest, *Novant Health*
Andrea Reed, *Novant Health*
David Rinehart, *NCAFP*
Pilar Rocha-Goldberg, *El Centro Hispano*
Caitlin Ryland, *LegalAid*
Susanne Schmal, *NC DPI*
Catherine Sevier, *AARP NC*
Chris Shank, *NCAHCH*
Adam Sholar, *NC HCF*
Paula Swepson Avery, *West Marion Community Forum*
James Stackhouse, *Wayne Co. Health Dep.*
Larkin Taylor-Parker, *Disability Rights NC*

Jim Thomas, *UNC*
Robin Tutor-Marcom, *NC Agromedicine Institute*
Mark Tuttle, *Eastern Band of Cherokee Indians*
Michael Waldrum, *Vidant and NCHA*
Rebecca Walker, *UNC-CH*
Chip Walter, *Duke Human Vaccine Institute*
Brenda Weis, *Wayne County Health Dep.*
Cass Wolfe, *Child Care Services Association*

NCIOM

James Coleman
Emily Hooks
Brienne Lyda-McDonald
Alison Miller
Michelle Ries

NC's COVID-19 Vaccine Prioritization Plan



North Carolina submitted an interim state level plan to the CDC that included the state's approach to prioritizing populations for vaccination because vaccine supply will be limited initially

Four phases of risk-based prioritization based on National Academy of Medicine and refined by NC COVID-19 Vaccine Advisory Committee. May be revised based on additional federal guidance, data from clinical trials, EUA criteria, and Advisory Committee for Immunization Practice recommendations.

Phase 1 Prioritized groups:

Healthcare Workers
at High Risk for
exposure

Long-Term Care
Staff and
Residents

Adults with
2+ chronic
conditions



Prioritizing people in high exposure
settings – e.g., congregate living,
front line workers

North Carolina's Commitment

Provide early, transparent, consistent, and frequent communications so that North Carolinians:



Trust the information that they receive from NCDHHS and local health departments about COVID-19 vaccinations



Understand the benefits and risks of COVID-19 vaccinations



Make informed decisions about COVID-19 vaccinations



Know how and where to get a COVID-19 vaccination