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North Carolina H1N1 Vaccine Frequently Asked Questions

32. How will ancillary supplies be shipped?

Needles, syringes, alcohol swabs, shot cards and sharps containers will be provided. They will be shipped to the same locations as vaccine, but not necessarily in the same shipment. They will be packaged in 100 dose kits. Sharps containers will be provided but the exact number and mechanism has not been finalized.

Previous vaccine FAQs

Updated information is in RED and underlined

1. Who is manufacturing the H1N1 vaccine?

There are currently five pharmaceutical companies working on H1N1 vaccines. They are Novartis, Sanofi-pasteur, CSL, Medimmune and Glaxo Smithkline.

2. When will the H1N1 vaccine be available?

CDC currently anticipates that the H1N1 vaccine will be available in October 2009. There is some discussion that vaccine may be released as early as late September. If this occurs it will be a small amount (20 million doses) of vaccine, and, the decision to release it has not officially been made. We will continue to update you as information is available.

3. How much H1N1 vaccine will be available?

The current vaccine manufacturing plan calls for enough vaccine to vaccinate everyone. The initial release is expected to be between 40 and 160 million doses, followed by weekly shipments between 10 and 30 million doses.

CDC provided the following estimates to NC for planning purposes ONLY. These estimates reflect the amounts based on the 3 scenarios that NC may receive during vaccine distribution. These numbers WILL change based on actual amounts of vaccine produced and distributed.

40M-dose initial bolus	80M-dose initial bolus	160M-dose initial bolus	10M doses per week	20M doses per week	30M doses per week
1,148,907	2,297,814	4,595,627	287,227	574,453	861,680

4. Will this be an injectable or nasal spray vaccine?

The bulk of the supply will be injectable vaccine. However, Medimmune is also working on a nasal spray version of the vaccine.

5. How will the doses be packaged?

H1N1 vaccine will be filled/finished in a 5mL vial/10 doses per vial. Approximately 15% of the vaccine may come in pre-filled syringes or nasal sprayers (LAIV) for the pediatric population. Information on vaccine packaging for shipping is not currently available.



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6. How many doses of the H1N1 vaccine will people need to receive?

This vaccine is expected to be a two dose series, with the doses given 21 days apart.

7. Will this vaccine also cover seasonal influenza?

No, people will also need to have a regular seasonal flu vaccination.

8. Who will distribute this vaccine?

H1N1 vaccine will be distributed through McKesson to public and private providers, similar to how UCVD (childhood) vaccines are currently distributed. Each shipment will have a minimum of 100 doses (10 vials). Counties should keep this in mind as they make the list of sites to provide vaccine within their county. The list must be kept on the spreadsheet provided by the state.

9. Who will be given priority to receive this vaccine?

The ACIP recommended the following priority groups:

- pregnant women;
- household contacts of infants under 6 months;
- healthcare and emergency-services workers;
- young people between 6 months and 24 years of age;
- and nonelderly adults with underlying risk conditions, such as diabetes and chronic lung disease.

10. Where will people go to get this vaccine?

Vaccine will be shipped to locations in every county based on the list of authorized sites provided to the state by the county. Counties should include the health department, hospitals, private providers, local clinics, pharmacies, etc on their list. The state will not allow vaccine to be shipped to any location that is not listed by the county.

11. Will providers be able to order this vaccine themselves from the manufacturer or pharmaceutical distributors?

No, this vaccine is being manufactured for the federal government, and its distribution will be determined by the CDC. It will not be available for private purchase.

12. If providers are given a supply of vaccine to administer, will they be able to charge for the vaccine?

CDC has not resolved this issue. It is likely that providers will not be able to charge for the vaccine itself because it is being paid for by the federal government. However, providers may be able to charge an administration fee. (This would be similar to how we currently handle state supplied vaccines.)

In addition, The Association of Health Plans collected information from their members about how to cover the reimbursement of the H1N1 vaccine. Overall, the information was positive with a sense that plans want to cover this, even if the vaccine is issued under an EUA.

We will update you as we learn more about this issue.

13. How will doses administered be tracked?

The tentative plan is that providers who use NCIR will enter doses into the system. Providers who do not use NCIR or those who are not able to utilize the system at their clinic sites will complete paper documentation which will be entered into NCIR by data entry staff at local health departments (hired specifically for this purpose.) PLEASE NOTE: CDC requires that each dose of the vaccine be accounted for and tracked. Because this is a two dose series, there must be adequate documentation of when the doses are given. The Immunization Branch is required to report information on doses administered in NC to CDC on a weekly basis.

14. How will providers report adverse vaccination events?

The current plan is for adverse reactions related to the H1N1 vaccine to be reported through the Vaccine Adverse Event Reporting System (VAERS), as is done for other vaccines. VAERS reports can be filed on-line at <https://secure.vaers.org/VaersDataEntryintro.htm>, by fax to 1-877-721-0366 or by mail. The VAERS form is online at http://vaers.hhs.gov/pdf/vaers_form.pdf.

15. Where can providers/public get up to date information about the vaccine?

www.cdc.gov/h1n1flu is the most up to date resource for general information about H1N1 influenza, disease rates and management and vaccine development.

North Carolina specific H1N1 information can be found at www.epi.state.nc.us/epi/gcdc/H1N1flu.html

16. A vaccine information sheet is needed.

The CDC provides a Vaccine Information Statement (VIS) for each vaccine they supply. The VIS provides information about risks, benefits, contraindications and adverse events and is an excellent patient education tool. The CDC tells us that they are currently developing a VIS for H1N1 vaccine. However, it cannot be finalized until clinical trials are completed because important details will not be available until the vaccine is actually tested. The CDC also tells us that the VIS should be circulated quickly once it is finalized and certainly by the time vaccine is distributed. The VIS will be online but copies will not be sent with the vaccine. We will provide more information about the H1N1 vaccine VIS once it is available.

17. Our county population has increased and we have a large number of commuters. Will we get enough vaccine?

We expect that all counties have seen population increases since the last population data estimates and we are aware of the issues with commuters. Population estimates are considered estimates and only used as a starting point. We will continue to ship vaccine as long it is needed and available.

18. What is the State's current distribution plan? Will local allotments all be coming to the County Health Depts.?

With the decision to use centralized distribution through McKesson, the state is revising our allocation scheme and distribution plans. Counties should continue to make a list of authorized H1N1 vaccine providers and include ALL locations in the county including hospitals, the health department, local providers, clinics, pharmacies, etc that the health department intends to receive and administer H1N1 vaccine. The list should include the following:

1. Name of entity
2. Contact person
3. Shipping address (MUST be a physical address)
4. At least two 24/7 contact phone numbers
5. What priority groups the practice serves
6. Number of vaccines they expect to administer (number of doses of seasonal flu vaccine administered is a place to start)
7. Days and times when the entity is available to receive vaccine

This information must be collected on the spreadsheet provided by the state.

19. Will standing orders for epinephrine be sent with SNS standing orders for flu?

Counties should not expect any standing orders related to H1N1 vaccine to be circulated from the state.

20. Can EMT's administer flu vaccine?

Based on communications with Dr. Greg Mears, EMS Intermediates and Paramedics can administer immunizations as part of a public health initiative. The EMS System must work with the local health department to assure things are collaborative and integrated so that follow-up and any other post immunization needs are met.

Local health departments should contact their local EMS system and work with them to develop a protocol for vaccine administration. Once the protocol is developed, the Health Director will need to provide a letter to the EMS system to send in with the vaccination protocol for approval.

21. Do vaccinators need both doses of H1N1 before participating in a vaccination campaign?

No.

22. Will nasal spray vaccine be recommended for children? Can parents administer this?

Yes, the nasal spray will be available for use in children. It is not intended for parental administration.

23. Will a parent be able to take away a vaccine to their child not at a dispensing site?

No, all persons must present at the vaccination site to be vaccinated.

24. Is there any expected mandate from the Department of Public Instruction at the State level to provide support for vaccination clinics in schools, or will this be the role of each local health department to organize?

The state is working with DPI to engage them in the planning process and support the vaccination campaigns.

25. Will the military bases receive vaccine through the state or through Federal lines?

Military bases will receive vaccine for active duty soldiers only. All family members and civilian workers will be the responsibility of the county. A county may work with the base to provide the base with additional vaccine if the base has the capability and is willing to vaccinate family members and civilian workers.

26. Is the 21-day interval for H1N1 vaccine administration recommended or absolute? Is there a problem if the interval is greater than 21 days?

Clinical trial data is needed to know if the 21 day interval is recommended or absolute. We will share information as soon as it is available.

27. Will a list of all sites (by county) that are already on the registry be supplied to each county health department, so they will know who they may need to approach and let them know to get on the registry?

A list of providers registered with the immunization program in the Universal Childhood Vaccine Distribution Program (UCVDP) **will be distributed on 8/10/09**. However, counties **MUST** contact each site on that list to ensure they are willing to administer H1N1 vaccine and collect the required information (see question 18). **ALL** sites, including those already on the UCVDP list **MUST** be placed on the county list of those who will administer vaccine. Because a provider participates in the UCVDP does not mean that they will choose to give H1N1 vaccine. Non-traditional providers (pharmacies for example) will not be signed up to use the registry, but can be signed up with the immunization program to receive H1N1 vaccine. They will be provided with an alternative method for recording vaccinations and collecting the necessary data for CDC. Currently there are about 600 UCVDP providers who routinely provide childhood vaccinations still on a waiting list to be rolled out on NCIR, and those practices are priority for training and rollout.

28. What kind of education on vaccine storage and handling will these non-traditional sites receive?

CDC will be issuing storage and handling guidance for the H1N1 vaccine prior to its being distributed. Providers who elect to receive H1N1 vaccine will be required to sign a provider agreement stating they will adhere to the CDC's storage and handling requirements for the vaccine. We have not yet determined the specific procedure providers will need to go through to demonstrate they have adequate storage and handling knowledge and capabilities. Further information is forth coming on this topic.

29. What is effectiveness of the first dose of vaccine?

This information will be determined by the current clinical trials. We will share this information as it becomes available.

30. How do we know which pharmacists are certified to give vaccinations? Is a list available from the board of pharmacists?

PHP&R has received a list from the Board of Pharmacy of pharmacists who declared in the license renewal process they are certified to vaccinate. **We are in the process of sorting and sending the list for each county to the PC. The PHRST Regional Pharmacists will be sending out the lists in the week of 8/10/09.** The list is based on business address, so each list will provide you with the information for pharmacists working in your county who are certified to vaccinate.

31. Does NCIR have the capability to import data electronically? Excel? Access?

NCIR does not accept data downloads. NCIR staff is currently working on determining the best methods for collecting the required data for CDC and accounting for each dose of H1N1 vaccine, as well as determining the most efficient way to be able to recall patients for their second vaccination. When a final determination is made on what those methods will be, we will share this information