

# CDC Novel H1N1 Vaccination Planning Q&A

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## Vaccine Purchase

*Q. How will novel H1N1 vaccine be purchased?*

**A.** Planners should assume novel H1N1 vaccine will be procured and purchased by the federal government and made available for vaccinators at no cost. See section below titled “Vaccine administration fees” for information on cost of administration.

## Vaccine Distribution

*Q. When will the decision to administer vaccine be made?*

**A.** For planning purposes, it should be assumed that vaccine will be administered beginning in the fall.

*Q. When will vaccine shipping begin?*

**A.** Planners should assume shipping of vaccine will begin mid-October, although there is a possibility that some vaccine will be available for shipping starting late September.

*Q. How many manufacturers are producing vaccine?*

**A.** Five manufacturers are producing vaccine for the U.S.: Sanofi Pasteur, Novartis, GSK, Medimmune and CSL.

*Q. How much vaccine can be expected to be available for shipping when shipping begins?*

**A.** Planners should use the following scenarios: In the first scenario, approximately 120 million doses will be released beginning around mid-October over a 4 week period, followed by approximately 20 million doses per week (or 80 million doses per month) thereafter. In the second one, up to 20 million doses of vaccine will be released beginning late September, followed by approximately 20 million doses per week (or 80 million doses per month) thereafter.

*Q. How will vaccine be shipped to project areas (CDC Public Health Emergency Preparedness grantees)?*

**A.** Vaccine will be shipped to clinics, offices, health departments, and other project area-designated sites which may include a mix of public health and private sector sites via centralized distribution. This is the same process that is used to ship vaccines for the childhood immunization program to immunization providers. CDC's centralized distribution mechanism will be substantially enhanced to provide capacity for this activity in addition to shipping of other vaccines.

*Q. Will project areas (CDC Public Health Emergency Preparedness grantees) be able to limit the amount of vaccine they receive?*

**A.** Yes, project areas will be able to determine what proportion of their allocation they wish to receive.

*Q. How frequently will vaccine shipments arrive?*

**A.** As details of distribution are finalized, CDC will communicate with states about the anticipated time period between placing vaccine orders and receiving shipments.

*Q. How many sites can be designated as vaccine receiving sites?*

**A.** One of the key benefits of using a centralized, third party distributor to support H1N1 vaccine distribution is that it allows distribution of doses to a much larger number of providers sites than would be feasible with direct manufacturer distribution. Thus, we will be able to serve a significantly larger provider base than the original state ship to sites, and are planning to be able to accommodate more providers than are currently served by the VFC program. More information, including any limitations in the number of vaccine receiving sites, will be shared with state planners as soon as it becomes available.

*Q. Will vaccine be in multi-dose vials?*

**A.** The majority of vaccine will be in multi-dose vials, the remainder in single dose syringes or nasal sprayers. The aim is to have enough vaccine in single dose syringes (i.e. preservative free) for young children and pregnant women.

## **Vaccine Allocation**

*Q. How will vaccine be allocated among project areas (the CDC PHEP grantees)?*

**A.** Vaccine will be allocated to each project area in proportion to its population (pro rata).

*Q. Will there be a separate allocation for active duty DOD?*

**A.** Yes, there will be a separate allocation for active duty DoD. It is not included in the project area allocations.

*Q. Will there be a separate allocation for DoD dependants, retirees and civilian employees?*

**A.** There is no separate allocation for these groups. Military facilities may be willing to vaccinate these groups, but will need to be allocated vaccine for these populations by the project areas.

*Q. Will there be a separate vaccine allocation for IHS-served populations and other tribal communities?*

**A.** There will be no separate allocation. States and local areas need to work with their tribal populations to ensure access to vaccine.

## **Ancillary Supplies**

*Q. Which ancillary supplies will be provided with vaccine?*

**A.** HHS will provide needles, syringes, sharps containers and alcohol swabs.

*Q. How will ancillary supplies be distributed?*

**A.** Ancillary supplies will be distributed to the same project area-designated sites as vaccine. Plans for ensuring the distribution of these products are currently being developed.

## Vaccine Administration

*Q. Will two doses of vaccine be required?*

**A.** This will not be known until the late summer- early fall, once clinical trials are completed. For planning purposes, planners should assume that two doses will be needed.

*Q. What will be the recommended interval between the first and second dose?*

**A.** This will not be known until clinical trials are complete. For planning purposes, planners should assume 21-28 days between the first and second vaccination.

*Q. How much Thimerosal-free vaccine will be available?*

**A.** It is anticipated that enough thimerosal-free vaccine in pre-loaded syringes will be available for young children and pregnant women.

*Q. Will there be federal requirements to recall persons for their second dose, if a second dose is needed?*

**A.** There will be no federal requirement to send out recall notices. Providing information on second dose at the time of the first dose, as well as using the media to disseminate this message will be the primary means of educating persons about who needs a second dose administered.

*Q. Will it be necessary for the first and second dose to be the same product?*

**A.** Ideally, first and second doses would be from the same product. However, practical considerations make this difficult to implement. Planners should assume they will be interchangeable.

*Q. Can seasonal vaccine and novel H1N1 vaccine be administered at the same time?*

**A.** Clinical trials are exploring this question. It is anticipated that seasonal vaccine and novel H1N1 vaccines may be administered together.

*Q. Will vaccine be adjuvanted?*

**A.** It is unlikely H1N1 vaccine will be adjuvanted. Definitive information will be available once clinical trial data are available.

*Q. If vaccine is adjuvanted, how will it be formulated?*

**A.** Formulation will vary by provider. For Novartis, vaccine may be preformulated with adjuvant. For CSL, GSK and Sanofi Pasteur, mixing of vaccine and adjuvant at the site of administration will be necessary. Specific information on storage requirements and procedures for mixing vaccine and adjuvant will be provided by CDC. Medimmune vaccine will not be adjuvanted.

*Q. Will the vaccine be administered under EUA (Emergency Use Authorization)?*

**A.** EUA will not be used for unadjuvanted vaccine if FDA licenses the vaccine under the current BLA (Biologics License Application) as a strain change.

*Q. For whom will novel H1N1 vaccine be recommended?*

**A.** The Centers for Disease Control and Prevention's Advisory Committee on Immunization

Practices (ACIP) met on July 29th to develop recommendations on who should receive the novel 2009-H1N1 vaccine when it becomes available, and to determine which groups of the population should be prioritized if the vaccine is initially available in extremely limited quantities. The committee recommended that vaccination efforts initially focus on 5 target groups: vaccination for pregnant women, people who live with or care for children younger than 6 months of age, healthcare and emergency medical services personnel, persons between the ages of 6 months through 24 years, and people ages 25 through 64 years who are at higher risk for novel H1N1 because of chronic health disorders or compromised immune systems. We do not expect that there will be a shortage of novel H1N1 vaccine, but flu vaccine availability and demand can be unpredictable and there is some possibility that initially, the vaccine will be available in limited quantities. So, the ACIP also made recommendations regarding which people within the groups listed above should be prioritized if the vaccine is initially available in extremely limited quantities. For more information see the CDC press release [CDC Advisors Make Recommendations for Use of Vaccine Against Novel H1N1](#). Once the demand for vaccine for the prioritized groups has been met at the local level, programs and providers should also begin vaccinating everyone from the ages of 25 through 64 years. Current studies indicate that the risk for infection among persons age 65 or older is less than the risk for younger age groups. However, once vaccine demand among younger age groups has been met, programs and providers should offer vaccination to people 65 or older. (see <http://www.cdc.gov/h1n1flu/vaccination/acip.htm>)

*Q. Will there be flexibility in how states implement the recommendations?*

A. The ACIP recommendations leave room for flexibility at the local level depending on the local vaccine supply situation.

*Q. Given the potential for large amounts of vaccine available during the first month of vaccine shipments, are priority groups needed?*

A. It is not expected that there will be a shortage of novel H1N1 vaccine, but availability and demand can be unpredictable, and there is some possibility that initially the vaccine will be available in limited quantities and priority groups may be needed.

*Q. Will there be requirements regarding documentation of priority group membership?*

A. There will be no federal requirements for vaccinators to require documentation of priority group status such as a doctor's note documenting pregnancy or risk status.

### **Doses administered Monitoring:**

*Q. What are the minimum data elements required by CDC?*

A. Minimum data requirements include age group, 1st or 2nd dose, date of vaccination, and state.

### **Pneumococcal vaccination:**

*Q. Are there any changes in recommendations for pneumococcal vaccines?*

A. The ACIP recommends that persons recommended for pneumococcal vaccine receive it in light of the potential for increased risk of pneumococcal disease associated with influenza. There

are at present no recommendations to give pneumococcal vaccine to groups for whom it is not currently recommended. ACIP will revisit this question over the summer as epidemiologic data from the Southern hemisphere influenza season and from the U.S. become available.

## **Cost of Vaccine Administration**

*Q. Will insurance plans reimburse private providers for administration?*

**A.** CDC asked America's Health Insurance Plans (AHIP) and on behalf of its members, AHIP provided this response:

"Every year health plans contribute to the seasonal flu vaccination campaign in several ways:

a) Health plans communicate directly with plan sponsors and members on the current ACIP recommendations and encourage immunization; they also provide information on where to get vaccinations, and who to contact with any questions.

b) Just as health plans have provided extensive coverage for the administration of seasonal flu vaccines in the past, public health planners can make the assumption that health plans will provide reimbursement for the administration of a novel (A) H1N1 vaccine to their members by private sector providers in both traditional settings e.g., doctor's office, ambulatory clinics, health care facilities, and in non-traditional settings, where contracts with insurers have been established"

*Q. Will private providers be able to charge patients for vaccine administration if they are uninsured?*

**A.** Yes, providers who have signed an H1N1 influenza vaccine Provider Agreement may charge uninsured patients up to the allowable Medicare charge for their region.

*Q. Can public health clinics charge or bill for vaccine administration?*

**A.** Public health departments will be able to bill (third part payers or cash) for an administration fee, but cannot turn anyone away due to inability to pay the administration fee. Public health will be receiving implementation funds to support vaccination clinics.