Two trials are underway to test the safety and efficacy of a candidate pediatric vaccine for novel H1N1 influenza.

An independent safety monitoring committee recommended in mid-August that trials of a candidate vaccine begin in children. The National Institute of Allergy and Infectious Diseases (NIAID) concurred with the recommendation. The two trials are being conducted through the agency’s Vaccine and Treatment Evaluation Unit (VTEU) network.

The safety monitoring committee reviewed data from more than 500 healthy adult and elderly volunteers enrolled in three VTEU trials of candidate novel H1N1 vaccines that began Aug. 7 and found no safety concerns in those trials that would preclude the start of pediatric trials, the NIAID said in a statement.

One trial is investigating the immune response to two different strengths of a candidate vaccine manufactured by Sanofi Pasteur. Led by the VTEU at the University of Maryland, Baltimore, the trial is enrolling up to 650 children aged 6 months to 17 years at five locations. Immune responses will be measured following doses of either 15 mcg or 30 mcg of vaccine at the first visit and a second dose 3 weeks later.

The second trial, led by the VTEU at St. Louis University and occurring at five other institutions, is testing administration of seasonal influenza vaccine along with a candidate novel H1N1 vaccine. The study will assess the candidate vaccine’s safety and how immune responses vary when the novel H1N1 vaccine is given before, after, or at the same time as the seasonal vaccine.

Six Steps for Influenza Control

**Novel H1N1 from page 1**

from 6 months to 24 years, and people aged 25-64 years with underlying medical conditions such as asthma and diabetes.

Concurrent with the news conference, the agencies released a set of written recommendations and resource materials for schools on the government’s flu Web site, flu.gov. The documents are on a school-planning page in the “Plan and Prepare” section of the site.

The CDC guidance lists six recommended steps for K-12 schools to take for influenza control as the new term starts:

- Have sick students and staff stay home when sick until at least 24 hours after they no longer have a fever or signs of a fever without using fever-reducing medications, advice that applies whether antiviral drugs are used or not.
- When students and staff develop flu-like illness at school, have them immediately stay in a separate room until they go home. While waiting to go home, sick people should wear a surgical mask, and individuals who care for those who are sick should also wear protective gear such as a mask.
- Have students and staff wash hands frequently with soap and water and cover coughs and sneezes with a tissue, a shirt sleeve, or an elbow.
- Have school staff routinely clean surfaces that students and staff touch often.
- Encourage people at high risk for flu complications who develop flu-like illness to be seen as soon as possible by their health care provider; early treatment with antiviral medication is important.
- Provide communities with the option to close a school in which most or all students are at high risk from flu, although not many schools are in this category.

The CDC also said it might make additional recommendations if novel H1N1 infections this fall turn out to be more severe than they were last spring.

The H1N1 vaccine is expected to be ready for distribution by mid-October, and will likely require two separate doses administered about 3 weeks apart.