

A (H1N1) Vaccine Production Process

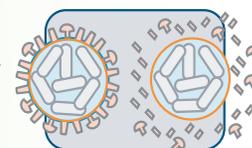
Surveillance

- Reference labs around the world collect wild virus carried by humans and characterize the genetic makeup. The virus is continually monitored and tracked by health authorities.



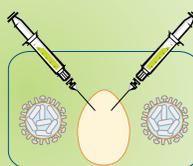
Strain Selection

- World health officials analyze and identify the dominant circulating strain.
- Health officials select virus strains and submit them to contracted laboratories to prepare seed virus.
- Laboratories distribute seed viruses to manufacturers to begin the production process.

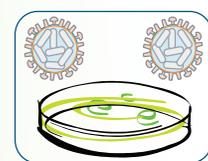


Preparation of Seed Virus

- Seed virus is prepared by contracted laboratories using conventional reassortment or reverse genetics methods:
- Conventional reassortment - Two flu strains with the preferred features for a new vaccine are injected into an egg and the genes reassort naturally.



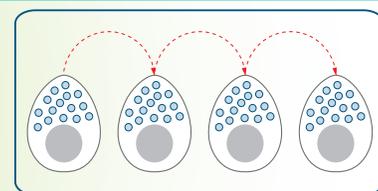
- Reverse genetics - Merges selected genetic information of the virus taken from the wild-type virus with the laboratory virus.



Seed Passaging and Selection

Once the seed virus is received, vaccine manufacturers begin passing the seed virus in eggs to determine the optimum growth conditions and to improve virus yield by acclimating the virus to growing in eggs.

The working seed developed by the manufacturer is certified by the FDA.



Bulk Manufacturing and Production^{a,b}

- Millions of specially-prepared chicken eggs are used to produce the vaccine. Throughout the year, fertilized eggs are delivered to the manufacturer. Each egg is injected with the working seed.
- The eggs are incubated for several days to allow the virus to multiply. After incubation, the virus-loaded fluid is harvested.



[Click here to see sanofi pasteur's Bulk Influenza Vaccine Manufacturing Process](#)

Clinical Trials

- Portion of manufactured vaccine is used for clinical trials.
- Clinical trials may occur simultaneously with manufacturing.



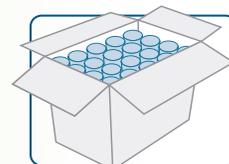
Purification and Testing^{a,b}

- Manufacturers test the vaccine concentrate with specially prepared reagents provided by the FDA to determine the potency of the vaccine for immunization.



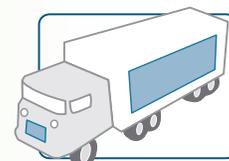
Formulation, Filling and Packaging

- Viral fragments from strains are collected from different batches, and combined upon completion of quality control tests.
- Upon FDA approval and licensing, the vaccine is released for distribution in time for immunization.
- Manufacturers begin filling the doses into vials and syringes, which are then sealed and carefully inspected before labels are applied to show the vaccine batch, lot numbers, and expiration date.
- Each lot must be specifically "released" by the FDA before manufacturers can ship supplies.



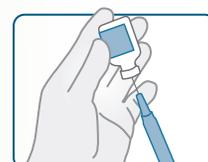
Shipping

- Vaccine shipments take place over time as vaccine is produced.
- Health authorities determine distribution process.



Vaccination

- Health authorities will establish recommendations and priorities for vaccination.



^aTo ensure safety and purity, vaccine is produced in a clean environment where quality control experts enforce strict standards, continuously monitoring the process; ^bThe majority of time for Bulk Manufacturing and Production and Purification and Testing is dedicated to testing and approval.