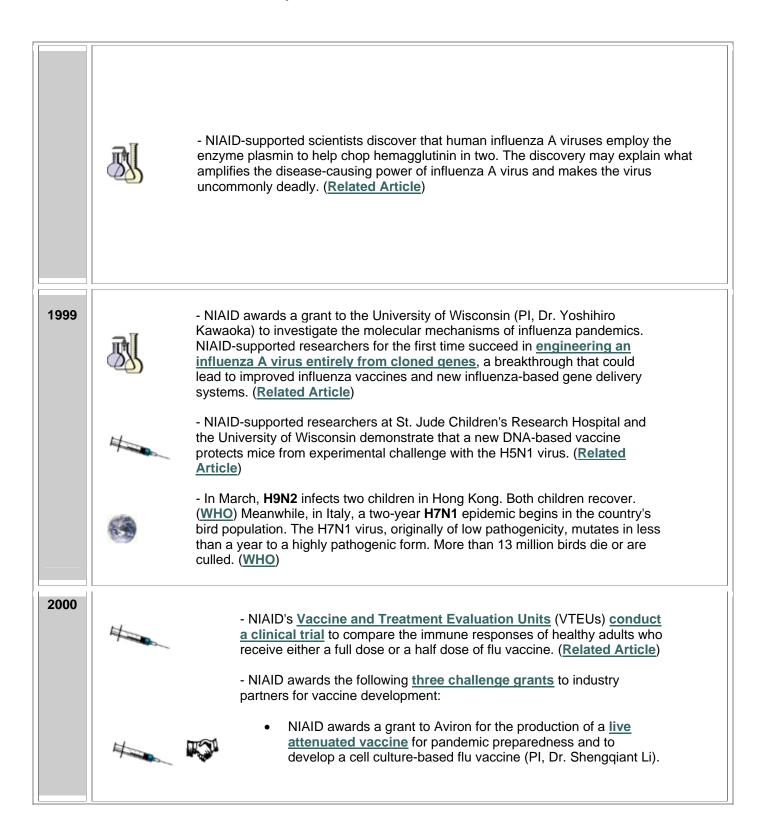
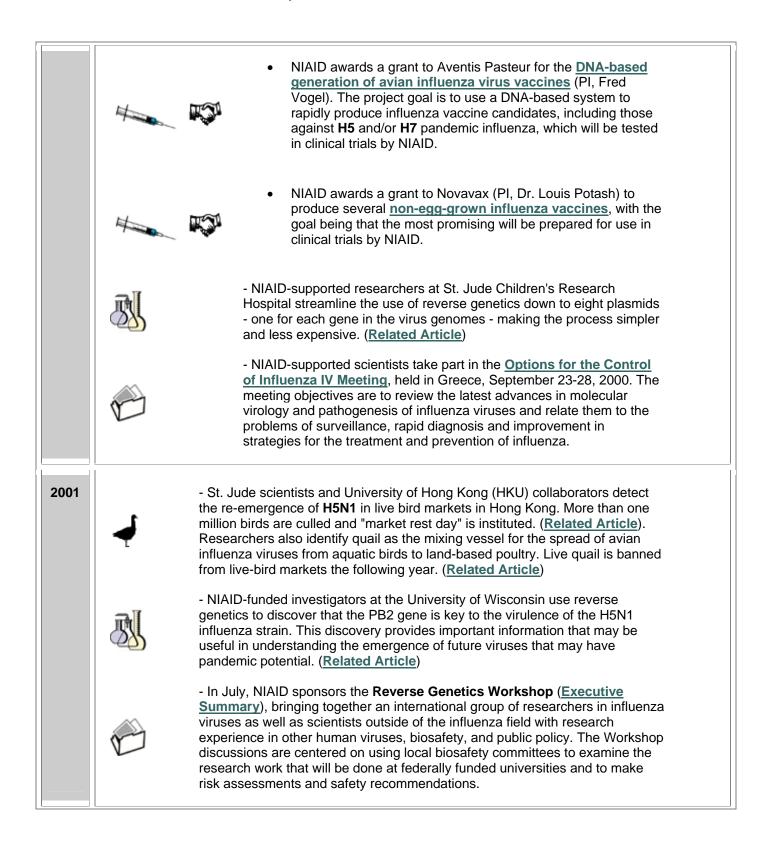
The NIAID Pandemic Influenza Preparedness Program supports research in basic biology, surveillance and epidemiology, vaccine development and evaluation, and the development of antivirals against influenza.

Below is an overview of NIAID-supported research and global events dating back to 1997, when the word's first known cases of human infection with avian influenza viruses were documented.

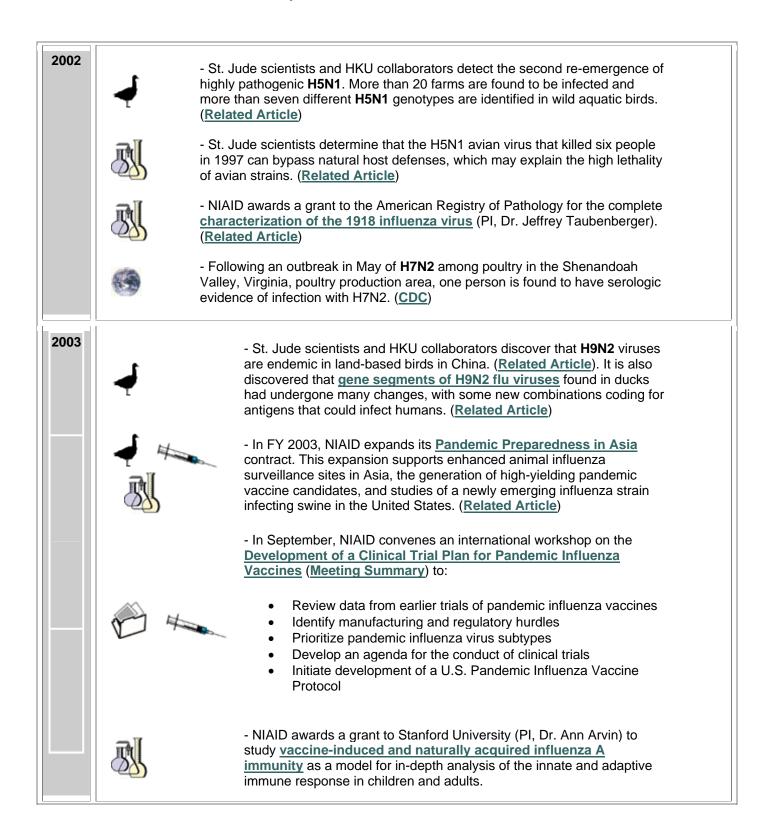


YEAR	RESEARCH DEVELOPMENTS & GLOBAL EVENTS		
1997		- In August, avian influenza (H5N1) infections occur in both poultry and humans in Hong Kong. This is the first time an avian influenza virus has ever been found to transmit directly from birds to humans. The virus kills six out of 18 people infected. All poultry in Hong Kong is culled. (<u>WHO</u>)	
	Harrison .	- NIAID awards a grant to Baylor College of Medicine (PI, Pedro Piedra) to examine whether <u>vaccinating a large percentage of children</u> can protect a community from a possible influenza pandemic.	
1998	H-	- NIAID awards a contract to Protein Sciences Corporation (PI, John Treanor) for the production of a recombinant H5 hemagglutinin vaccine. Within three weeks, the company produces an investigational vaccine which is tested in NIAID-supported clinical trials. (<u>Related Article</u>)	
		 NIAID awards the <u>"Influenza Pandemic Preparedness in Asia"</u> contract to St. Jude Children's Research Hospital (<u>PI, Dr. Robert Webster</u>) to: 	
	Ą	 Establish an animal influenza surveillance center in Hong Kong Determine the molecular basis of transmission of avian flu viruses Provide characterized viruses suitable for vaccine development Support training of new laboratory personnel Produce reagents 	

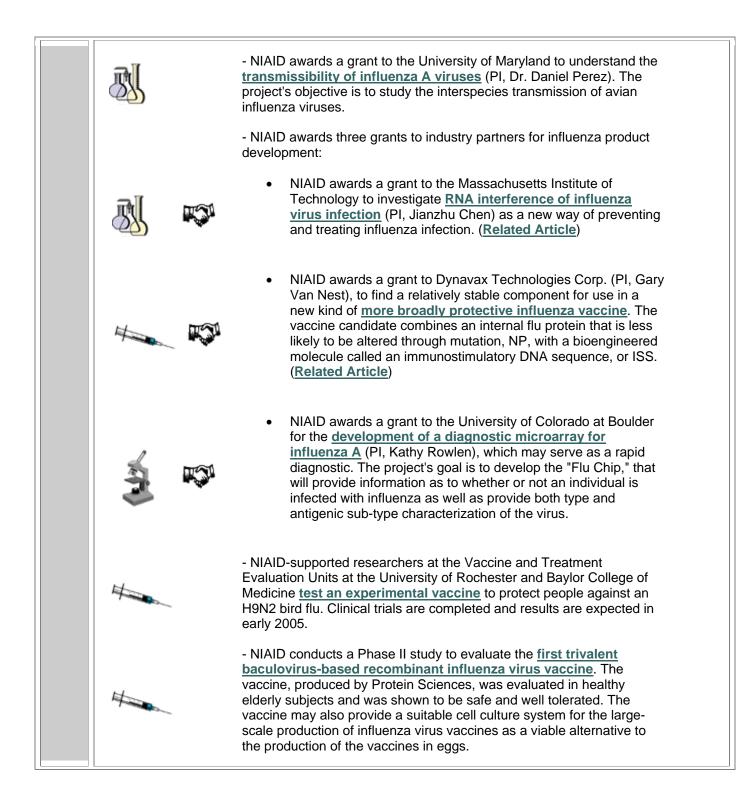




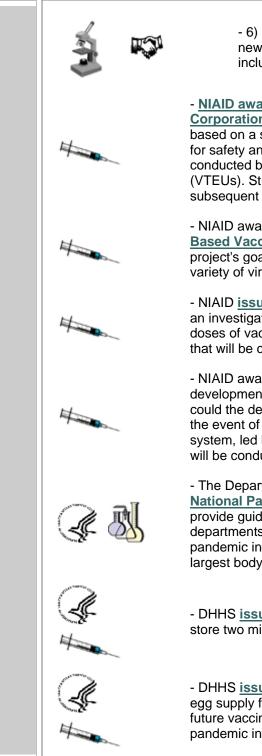
Recent Developments in NIAID Pandemic Influenza Research



Recent Developments in NIAID Pandemic Influenza Research



		- In February, two cases of avian influenza (H5N1) infection occur in a Hong Kong family that had traveled to southern China, resulting in one death. Less than two months later, a widespread outbreak of H7N7 occurs on poultry farms in the Netherlands, killing a veterinarian. Cases of mild disease or conjunctivitis associated with H7N7 are reported in more than 80 other individuals during this outbreak. (WHO) Later the same year in New York, a patient is admitted to a hospital in November with respiratory symptoms, recovers, and goes home after a few week. Subsequent confirmatory tests conducted in March 2004 show that the patient had been infected with an H7N2 avian influenza virus. (CDC). In December, Korea reports an outbreak of avian influenza in chickens, verified to be H5N1, and more than one million chickens are infected. (WHO). That same month, a child in Hong Kong is infected with H9N2 and recovers. (WHO)
2004		
	₽	 NIAID supports animal influenza training courses in Hong Kong and Japan.
		 In 2004, NIAID awards <u>challenge grants</u> to six industry partners to develop new diagnostics, therapeutics, and vaccines against influenza virus:
	₩ 10 ⁰	 - 1) Shire Biologics, Inc., for the <u>development of a tissue</u> <u>culture-derived influenza vaccine</u> (PI, Jonathan Seals).
	₩	 - 2) Delsite Biotechnologies, Inc., for the <u>development of an</u> inactivated intranasal influenza vaccine (PI, Yawei Ni).
	i	 - 3) Biota Scientific Management, for the <u>development of a</u> <u>novel long-acting influenza antiviral drug (neuraminidase</u> <u>inhibitor)</u> (PI, Jane Ryan).
	N	 - 4) Columbia University/Griffin Analytical Technologies for the development of new diagnostics (PI, Walter Lipkin) to discriminate between several pathogens including influenza and SARS.
	S	 - 5) University of Texas at Austin/Radix BioSolutions for the development of new diagnostics discriminate between several pathogens including influenza and SARS.



- 6) BD Diagnostics (PI, Tobin Hellyer), for the development of new diagnostics to discriminate between several pathogens including influenza and SARS.

- NIAID awards contracts to Aventis Pasteur and Chiron

Corporation to support the production of an investigational vaccine based on a strain of **H5N1** avian influenza. The vaccines will be tested for safety and immunogenicity in Phase I and Phase II clinical trials conducted by NIAID's Vaccine and Treatment Evaluation Units (VTEUs). Studies will test the vaccine in healthy adults first with subsequent studies planned in children and the elderly.

- NIAID awards a grant to Washington University for the <u>M2 Peptide</u> <u>Based Vaccines Against Influenza</u> project (PI, Andrew Pekosz). The project's goal is to generate an influenza vaccine with activity against a variety of virus strains using the M2 protein.

- NIAID **issues a task order** to Chiron Corporation for the production of an investigational **H9N2** vaccine. Chiron will produce up to 40,000 doses of vaccine with and without the MF59 adjuvant for clinical trials that will be conducted by NIAID, slated for 2005.

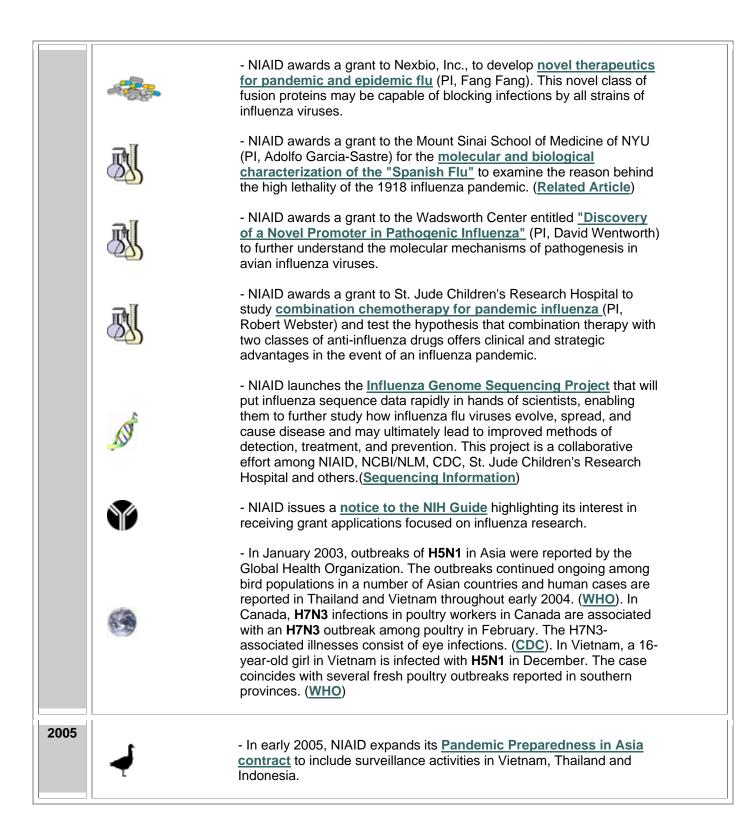
- NIAID awards a grant to Innoject, Inc. (PI, Richard Gillespie) for the development of an <u>auto-injector vaccine delivery system</u>. Not only could the device be easy to use, but it could be broadly distributed in the event of an influenza pandemic. The clinical trial of the new delivery system, led by Dr. William Barr of Virginia Commonwealth University, will be conducted during the 2005-2006 flu season.

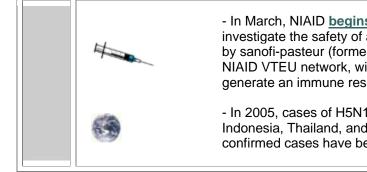
- The Department of Health and Human Services (DHHS) issues the <u>National Pandemic Influenza Preparedness Plan</u>, designed to provide guidance to national, state, and local policy makers and health departments for public health preparation and response in the event of pandemic influenza outbreak. As outlined in <u>Annex 10</u> of the Plan, the largest body of pandemic influenza research is supported by NIAID.

- DHHS issues a contract to Aventis Pasteur to manufacture and store two million doses of avian influenza H5N1 vaccine.

- DHHS **issues a contract to Sanofi Aventis Inc.**, to secure future egg supply for flu vaccines in the event of a pandemic flu outbreak or future vaccine shortages and to obtain initial investigational lots of pandemic influenza vaccines for clinical trials.

Recent Developments in NIAID Pandemic Influenza Research





- In March, NIAID **begins recruitment for a clinical trial** to investigate the safety of an H5N1 avian influenza vaccine produced by sanofi-pasteur (formely Aventis Pasteur). Clinical sites, part of the NIAID VTEU network, will test the vaccine's safety and ability to generate an immune response in 450 healthy adults.

- In 2005, cases of H5N1 avian influenza are confirmed in Cambodia, Indonesia, Thailand, and Vietnam. By November 14th, 64 of 126 confirmed cases have been fatal. (WHO)