



SERVIZIO SANITARIO REGIONALE
EMILIA-ROMAGNA
Azienda Unità Sanitaria Locale di Parma

La vaccinazione per l'influenza pandemica

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12 settembre 2009

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Documenti di riferimento



World Health
Organization
Organisation mondiale de la Santé

**Strategic Advisory Group of Experts on
Immunization
Report of the extraordinary meeting on
the influenza A (H1N1) 2009 pandemic
7 July 2009**

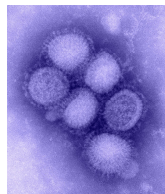


**ECDC INTERIM GUIDANCE
Use of specific pandemic influenza
vaccines during the H1N1 2009
pandemic
August 2009**

Il vaccino pandemico

Il virus contenuto nel vaccino pandemico deriva dal **nuovo virus A/H1N1** identificato dai laboratori di riferimento (WHO Collaborating Centers):

A/California/7/2009-like virus



Il vaccino pandemico

- La produzione avviene secondo le tecnologie utilizzate per i vaccini contro l'influenza stagionale (vaccini mock-up)
- La capacità produttiva complessiva è pari a 94 milioni di dosi per settimana



Il vaccino pandemico

La Commissione Europea ha autorizzato la produzione di quattro vaccini:

- Celvapan, Baxter AG;
- Daronrix, GlaxoSmithKline Biologicals S.A.;
- Focetria, Novartis Vaccines and Diagnostics S.r.l.;
- Pandemrix, GlaxoSmithKline Biologicals S.A..

Tre di questi vaccini, Daronrix, Focetria e Pandemrix, contengono adiuvanti, utilizzati per stimolare una migliore risposta immunitaria.

Il vaccino pandemico

- Gli studi clinici iniziati in luglio su adulti e bambini devono valutare la sicurezza e l'immunogenicità del prodotto
- La protezione dovrebbe essere simile a quella del vaccino stagionale anche se probabilmente è necessaria la somministrazione di due dosi a causa della totale assenza di immunità nella popolazione
- L'autorizzazione finale in Europa è a carico dell'EMA

http://www3.niaid.nih.gov/news/newsreleases/2009/H1N1pregnanttrials.htm

MediSys

National Institute of Allergy and Infectious Diseases
Leading research to understand, treat, and prevent infectious, immunologic, and allergic diseases.

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NIH News
U.S. Department of Health and Human Services
National Institutes of Health
FOR IMMEDIATE RELEASE
Wednesday, Sept. 9, 2009

NIAID Launches 2009 H1N1 Influenza Vaccine Trial in Pregnant Women

The first trial testing a candidate 2009 H1N1 influenza vaccine in pregnant women is launching this week, the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, announced today.

"Women are at higher risk of developing severe illness if they become infected with influenza virus while pregnant, which is why they are strongly encouraged to receive the seasonal influenza vaccine every year," says NIAID Director Anthony S. Fauci, M.D. "Data indicate that pregnant women are at higher risk for complications from the 2009 H1N1 influenza virus as well, so this trial will provide critical information for public health planning."

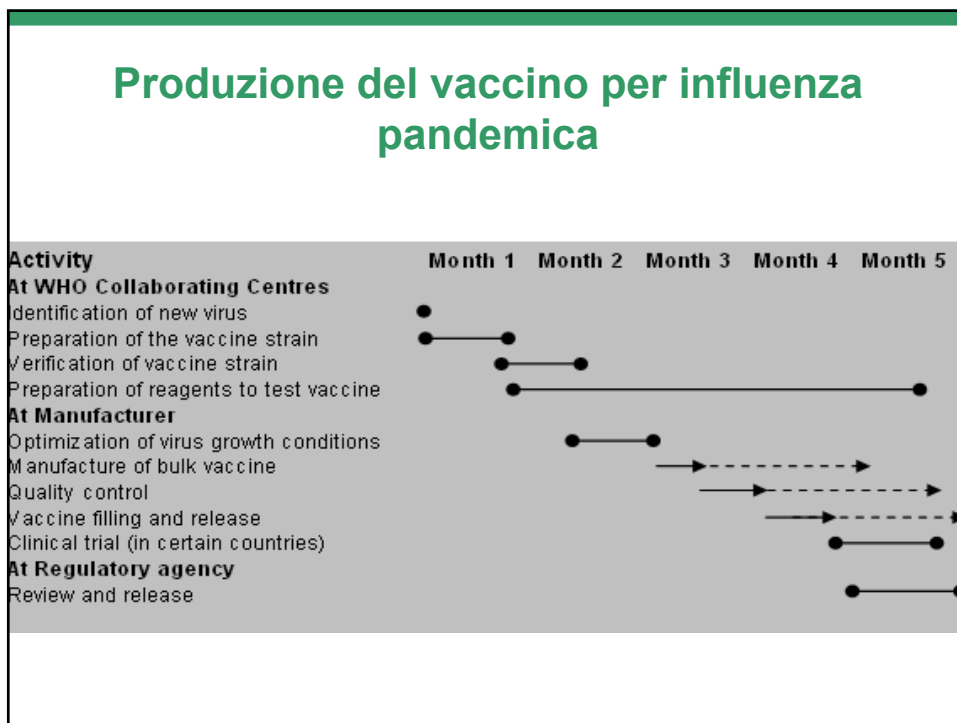
The trial is being conducted through the NIAID-funded national network of Vaccine and Treatment Evaluation Units (VTEUs).

"The American public has shown once again its remarkable willingness to step up and help during an emergency. The interest in this trial has been extraordinary, and participating medical centers expect to fill all the available slots for volunteers soon," Dr. Fauci adds.

Up to 120 women 18 to 39 years of age who are in their second or third

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Chi vaccinare con il vaccino pandemico

Key contents from the three organizations	World Health Organization Strategic Advisory Group of Experts. (7 th July 2009)	United States Centers for Disease Prevention and Control Advisory Committee on Immunization Practices. (August 28 th 2009)	United States Centers for Disease Prevention and Control Advisory Committee on Immunization Practices. (August 28 th 2009) – Plentiful Supply Option	European Union Health Security Committee. (August 25 th 2009)
General considerations and criteria for selecting the priority and target groups	"SAGE suggests the following groups for consideration, noting that countries need to determine their order of priority based on country-specific conditions."	"ACIP recommends that vaccination efforts should focus initially on persons in five target groups (below). In the event that vaccine availability is unable to meet initial demand, priority should be given to a subset of the five target groups (below)." – no priority order between the categories below	"ACIP recommends that vaccination efforts should focus initially on persons in five target groups (below). No priority order between the categories below	"It should be stressed that it is within the mandate and responsibility of Member States to develop a vaccination strategy for influenza A(H1N1) 2009. No priority order between the categories below
Priority and target groups	Health-care workers - all countries should immunize their health-care workers as a first priority to protect the essential health infrastructure.	Health-care workers and emergency medical services personnel who have direct contact with patients or infectious material.	Health-care and emergency medical services personnel, pregnant women,	Health-care workers.
	Pregnant women – since this group appears to be at increased risk for severe disease.	Pregnant women	Pregnant women	Pregnant women.
	Individuals aged >6 months with one of several chronic medical conditions – in order to reduce morbidity and mortality.	Children and adolescents aged 5–18 years who have medical conditions that put them at higher risk for influenza-related complications.	Persons aged 25–64 years who have medical conditions that put them at higher risk for influenza-related complications.	All persons from 6 months of age up with underlying chronic conditions – increasing the risk for severe disease, starting with the ones who have a severe underlying condition (e.g. severe asthma, unstable coronary heart disease, uncompensated heart failure, etc.).
	Healthy young adults (aged >15 years and <49 years) to reduce morbidity and mortality.	Persons who live with or provide care for infants aged <6 months	persons who live with or provide care for infants aged < 6 months (e.g. parents, siblings and daycare providers)	
	Healthy children.	Children aged 6 months to 4 years.	Persons aged 6 months to 24 years	
	Healthy adults aged >49 years and <65 years to reduce morbidity and mortality.			
	Healthy adults aged >65 years to reduce morbidity and mortality.			

EU Health Security Committee (HSC) / Early Warning and Response System (EWRS)

25 August 2009

Taking into account the above and the guidance developed by the European Centre for Disease Prevention and Control as well as the World Health Organisation recommendations (see links below), the following groups are proposed as priority groups for vaccination with influenza A(H1N1) 2009 vaccine, taking into account licensing considerations as appropriate.

First priority groups²

The first priority groups are the persons that should be vaccinated first when limited amounts of vaccine are available:

- all persons from 6 months with underlying chronic conditions increasing the risk for severe disease, starting with the ones who have a severe underlying condition (e.g. severe asthma, unstable coronary heart disease, uncompensated heart failure, etc.), the proposal optimally being made by the patient's direct healthcare provider
- pregnant women
- health care workers

Subsequent priority groups

After the first priority groups have been vaccinated, the vaccination could continue until the national targets have been reached.

*Ministero del Lavoro, della Salute e delle
Politiche Sociali*



Comunicato stampa n.381

11 settembre 2009

***Influenza A/H1N1: Viceministro Ferruccio
Fazio firma l'Ordinanza sulla profilassi
vaccinale***

*Ministero del Lavoro, della Salute e delle
Politiche Sociali*

In ordine di priorità l'offerta vaccinale sarà rivolta a:

- persone ritenute essenziali per il mantenimento della continuità assistenziale e lavorativa: personale sanitario e socio-sanitario; personale delle forze di pubblica sicurezza e della protezione civile; personale delle Amministrazioni, Enti e Società che assicurino i servizi pubblici essenziali; i donatori di sangue periodici;
- donne al secondo o al terzo trimestre di gravidanza;
- persone a rischio, di età compresa tra 6 mesi e 65 anni;
- persone di età compresa tra 6 mesi e 17 anni, non incluse nei precedenti punti, sulla base degli aggiornamenti della scheda tecnica autorizzata dall'EMA o delle indicazioni che verranno fornite dal Consiglio Superiore di Sanità;
- persone tra i 18 e 27 anni, non incluse nei precedenti punti.

Ministero del Lavoro, della Salute e delle Politiche Sociali

sono considerate persone a rischio quelle affette da:

- a) malattie croniche a carico dell'apparato respiratorio, inclusa asma, displasia broncopolmonare, fibrosi cistica e BPCO;
- b) malattie dell'apparato cardiocircolatorio, comprese le cardiopatie congenite ed acquisite;
- c) diabete mellito e altre malattie metaboliche;
- d) malattie renali con insufficienza renale;
- e) malattie degli organi emopoietici ed emoglobinopatie;
- f) neoplasie;
- g) gravi epatopatie e cirrosi epatica;
- h) malattie congenite ed acquisite che comportino carente produzione di anticorpi; immunosoppressione indotta da farmaci o da HIV;
- i) malattie infiammatorie croniche e sindromi da malassorbimento intestinale;
- j) patologie associate ad un aumentato rischio di aspirazione delle secrezioni respiratorie, ad esempio malattie neuromuscolari;
- k) obesità con Indice di massa corporea (BMI) > 30 e gravi patologie concomitanti;
- l) condizione di familiare o di contatto stretto di soggetti ad alto rischio che, per controindicazioni temporanee o permanenti, non possono essere vaccinati.

Programma di vaccinazione contro l'influenza da virus A/H1N1

L'individuazione dei gruppi target e della loro priorità di vaccinazione tiene conto della esigenza di proteggere prioritariamente :

- le persone che sono essenziali per rispondere alla pandemia ed assicurare l'assistenza alle persone ammalate;
- le persone che mantengono operativi i servizi essenziali
- le persone che presentano maggior rischio di sviluppare complicanze legate all'influenza (patologie croniche ma anche donne in gravidanza)
- i bambini e i ragazzi

Programma di vaccinazione contro l'influenza da virus A/H1N1

I FASE

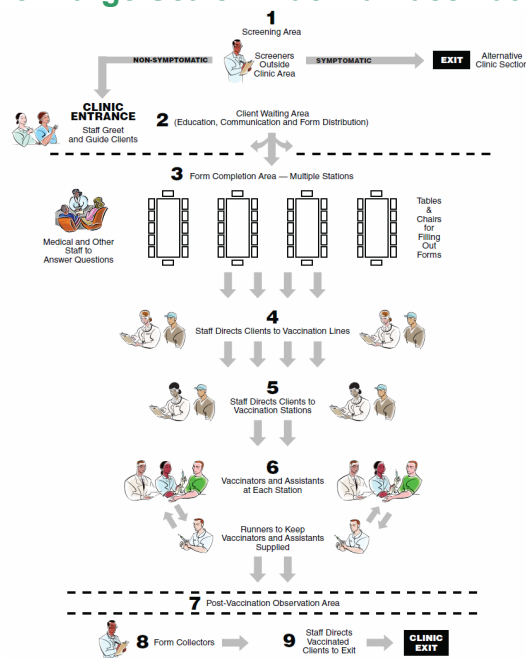
- Personale sanitario, circa **6.000 operatori**
- Personale dei servizi essenziali, circa **6.000 persone**.
- Persone a rischio sanitario tra i 2 e i 65 anni, circa **40.000 persone**.

II FASE (gennaio / febbraio 2010)

- Tutte le persone di età compresa fra 2 e 27 anni, **circa 100.000 persone**

La vaccinazione coinvolgerà circa il 40% della popolazione

Example of Large Scale Influenza Vaccination Clinic



Equipe type de vaccination pour une période de 4 heures

Fonctions	Personnels administratifs ou techniques	Personnels soignants travaillant sous la responsabilité d'un professionnel de santé de plein exercice	Paramédicaux de plein exercice	Médecin ou interne en médecine*
Accueil et orientation	2			
Questionnaire médical	1	1		
Traitement des questionnaires	X		1	
Consultation médicale et prise en charge des effets secondaires	X	X	X	1
Préparation des injections	X	2	1	
Sortie administrative	2			
Supervision	X			1
Total	5	6	2	2

* Au plus un interne sur les deux profils médicaux

PANDEMIC INFLUENZA CLINIC SUPPLIES AND EQUIPMENT

General Supplies and Equipment	Vaccine Administration Supplies	Emergency Supplies
Tables Chairs Water and cups Paper Pen, pencils Envelopes Rubber bands Tape Stapler/staples Scissors Post-it Notes Clipboards File boxes Telephone/Cell phones Paper towel Kleenex tissue Table pads/clean paper Trash containers/bags ID badges for staff List of emergency phone numbers	Cooler/refrigerator for vaccine Needles Syringes "Sharps" containers Latex gloves Latex-free gloves Antibacterial hand-washing solutions Alcohol wipes Rectangle band-aids Gauze Adhesive tape Spray bottle of bleach solution	Standing orders for emergencies Epinephrine 1:1000 SQ Diphenhydramine 50 mg IM 3cc syringes with 1", 25-gauge needles 1.5" needles Tuberculin syringes with 5/8" needles (for epinephrine) Alcohol wipes/Sterile dry pads Bandages Tongue depressors Adult and pediatric pocket masks with one way valve Adult and pediatric airways tubes Tourniquet Gurney Stethoscope Flashlight/batteries Blood Pressure Monitor Instant Cold Packs Cots Blankets Pillows
	Crowd Management Supplies Signs for clinic stations and between stations Queue partitions (to keep people in lines), roping	
		Computer Equipment and Supplies Computers Printers/Ink Cartridges Paper Internet access

Programma di vaccinazione contro l'influenza da virus A/H1N1

Essenziali per la fattibilità di una campagna vaccinale di questo tipo:

- Campagna informativa
- Collaborazione dei medici di medicina generale
- Collaborazione di personale sanitario esterno al Dipartimento di Sanità Pubblica
- Organizzazione e coordinamento

Programma di vaccinazione 2009/2010 al 12/09/09

Tipo di vaccino	Fasce di età	Categoria	Chi vaccina	Quando
Vaccino stagionale	=> 65 anni	=> 65 anni	MMG	1° ottobre
Vaccino pandemico + stagionale		Personale sanitario e socio-assistenziale	DSP	15 ottobre?
Vaccino pandemico + stagionale		Servizi essenziali	DSP + medici esterni	15 ottobre?
Vaccino pandemico + stagionale		Donne al 2° e 3° trimestre di gravidanza	DSP	15 ottobre?
Vaccino pandemico + stagionale	6 mesi–64 anni	A rischio	MMG PDC <18 anni	15 ottobre?
Vaccino pandemico?	6 mesi–17 anni	No rischio	PDC	Gennaio?
Vaccino pandemico	18-27 anni	No rischio	DSP	Gennaio?

New Jersey, 1976

