Influenza A(H1N1)v virus vaccination programme

October 2009
Dr Syed Ahmed
Consultant in Public Health Medicine and Immunisation Coordinator
NHS Greater Glasgow and Clyde
Influenza A(H1N1)v Programme

• Background information about flu virus
• Emergence of A(H1N1)v virus
• Epidemiology of Flu A(H1N1)v virus
• Vaccines against Flu A(H1N1)v virus
• Indications, contraindications and safety of vaccines
• Implementation plan
Influenza A virus

- Genetic material (RNA) in the centre
- Two surface antigens:
  - Haemagglutinin (H)
  - Neuraminidase (N)
- Different types of each
Influenza viruses

Three types:

- **A**
  - Causes epidemics and pandemics
  - Animal reservoir – wildfowl; also carried by other mammals

- **B**
  - May cause epidemics
  - Predominantly found in humans

- **C**
  - Do not cause epidemics
  - Minor respiratory illness only
Genetic change

What this means:

**Antigenic drift**
small constant mutations of H and N
occurs in all types of flu virus

**Antigenic shift**
only occurs in type A
Antigenic shift

- A major change in one or both surface antigens, characteristic of type A influenza viruses.
- It is due to genetic recombination when virus particles of more than one strain infect a cell simultaneously.
- It can result in a worldwide pandemic.
- The previous major antigenic shift occurred in 1968 when H3N2 (Hong Kong) influenza appeared and replaced the type A strain (H2N2, or Asian influenza).
20th Century pandemics

Pandemics are caused by antigenic shift which usually appear in China and then spread westward through Asia, Europe and America.

There have been three major influenza pandemics in the past 100 years when epidemic activity reached global proportions.

<table>
<thead>
<tr>
<th>Year</th>
<th>Pandemic</th>
<th>Virus subtype</th>
<th>Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1918</td>
<td>Spanish</td>
<td>H1N1</td>
<td>Severe</td>
</tr>
<tr>
<td>1957</td>
<td>Asian</td>
<td>H2N2</td>
<td>Severe</td>
</tr>
<tr>
<td>1968</td>
<td>Hong Kong</td>
<td>H3N2</td>
<td>Moderate</td>
</tr>
</tbody>
</table>
Influenza A viruses

- 1918 pandemic by H1N1
- 1957 pandemic by H2N2
- 1968 pandemic by H3N2
- 1977 outbreaks by H1N1 (Red Flu)
- Until 2009, a combination of H3N2 and H1N1 (seasonal)
- 2009 pandemic by Flu A (H1N1)v, otherwise known as “swine flu”
- From 2010 which Flu A?
Flu A(H1N1)v virus

• Mid-February 2009 – outbreak of respiratory disease in La Gloria, Mexico
• Mid-April – new virus identified in two specimens in California – reported to WHO
• Contains segments of bird (avian), swine and human viruses – new unique combination and has similarities to current pig-type viruses
• First case in UK – 27th April 2009
• June 2009 – WHO went to pandemic phase 6
“Swine Flu”

- Not really a “swine flu” as “swine flu” mainly infects pigs
- Occasionally transmitted to humans in close contact with pigs
- Last outbreak of swine flu in 1976 in America
- First analysis of the Flu A(H1N1)v genetic materials showed genetic similarities with existing pig-type viruses
- WHO name: Influenza A (H1N1)v and also known as Influenza A(H1N1)2009
Disease

- Mild self-limiting illness in most cases (Fever, cough, sore throat, rhinorrhea, limb/joint pain, headache. Some cases have vomiting & diarrhoea)

- Severe outcomes
  - Viral pneumonia
  - Secondary bacterial pneumonia
  - Exacerbations of underlying chronic conditions
Age distribution lab confirmed new A/H1N1 cases & deaths:
Mexico – a disease of children and working age adults
Epidemiology/Surveillance

Pandemic H1N1 cases rate per 100,000 population by age group as of 16 July 2009 (n=33,112*) in the USA

*Excludes 7,505 cases with missing ages.

Rate / 100,000 by Single Year Age Groups; Denominator source: 2008 Census Estimates, U.S. Census Bureau at:
Epidemiology/Surveillance
Pandemic H1N1 case fatality ratio by age group
16 July 2009 (n=262) in the USA
Epidemiology/Surveillance
Distribution by age group of influenza hospitalised cases
Emerging Infections Programme
Pandemic H1N1 - 14 July 2009 in the USA

![Chart showing distribution by age group of influenza hospitalised cases during the Pandemic H1N1 in the USA from April 12 to June 30, 2009. The chart compares Seasonal 2007-08 and Pandemic 2009 data.](image-url)
UK age distribution: initial cases

Data source: HPA Centre for Infections
Confirmed Cases of H1N1 by Age Group
(Total number of cases 1092 in GGCNHSB since outbreak began)
Flu A(H1N1)v epidemiology: international situation

- Spread to every continent
- CFR ~ around 0.1%
- Most cases and deaths are in people aged <50 years
- H1N1 is the dominant Flu A virus in most parts of the world
- Most viruses still sensitive to oseltamivir
(H1N1)v epidemiology - Scotland

- Over 347 patients ever hospitalised by 16 October 2009
- About 50% have underlying medical conditions
- 15 deaths in Scotland, not all with underlying medical conditions
- Number of flu like illnesses has increased during September and October and now over the seasonal threshold
Trends in consultation rates from the PIPeR system (37 practices)
Oct 2007 to Sept 2009

![Graph showing consultation rates from the PIPeR system for 37 practices from Oct 2007 to Sept 2009. The graph includes data points and trend lines for 2007/08 and 2008/09, with 90% confidence limits.]
Influenza A(H1N1)v: risk factors for severe outcome

- Underlying chronic conditions
- Pregnancy (6 deaths in UK by 15th Oct)
- Immunocompromised individuals
- Metabolic abnormality, e.g. obesity
- But a significant proportion of severe cases have no underlying risk factors
New swine flu alarm after it kills a healthy woman of 24

By Chris Riches

THE family of a young swine flu victim last night urged other youngsters to be on the alert against the virus.

Former air hostess Louise Jones, 24, died soon after developed a headache, sore throat and flu-like symptoms while holidaying with friends in Crete.

Her grieving family, from Leigh, Greater Manchester, last night urged other young people to get medical help as soon as possible after seeing how quickly the virus can kill.

Doctors say Louise, a Virgin Trains customer services worker, may have been more vulnerable to the virus because she had childhood asthma.

Her mother, Theresa Legge, said: "We can't come to terms with it. Louise was healthy and fit. She had never had a day off work with asthma.

"She came back from holiday tanned and looking healthy and two weeks later she is gone."

Popular

"People, especially young people, need to be more worried about swine flu. If you think you have flu, get medical help quickly.

"She was my best friend as well as my daughter. She was so popular we had almost 300 people come to her funeral.

"She was so warm and fun loving and had a smile for everyone. We feel so empty now. We don't know what to do with ourselves."

Louise is thought to be one of only a handful of people from the north-west of England to have died from the disease, although health chiefs have refused to give regional numbers.

Kathy Earl, 25, who worked with her and holidayed with her on Crete, said the pair were enjoying a sunshine break on the Greek island at the beginning of September.

She said Louise "woke up with a headache on the day before we were due to come home. I thought it was sunstroke but she said it was a migraine."

Louise's condition worsened when she returned home and she died after two weeks in the intensive care unit at Hope Hospital, Salford.

Latest Government data shows children and young people aged five to 24 are more prone to swine flu than any other age group.

Seventy people with swine flu have died in England so far, but health bosses say it was not necessarily the cause of all the deaths as many of the victims had underlying medical conditions. Louise's family were told her childhood asthma condition may have caused her to be more susceptible to the virus.

But Theresa and her partner Ken say that although Louise was diagnosed with the condition as a youngster, she was a healthy, active young woman.

Furious

They are furious that an artificial lung machine was not available in the area and say that one of them may have saved her life.

The couple were told Louise was not sick enough to need the machine in the early stages of her treatment in Hope Hospital.

By the time her condition had worsened hospital staff said she was too sick to make the journey to Leicester were the nearest artificial lung was available.

Swine flu victim Louise Jones, 24, became ill on holiday
Swine Flu Mum, 17 and Baby Die

By Jack Matheson

A PREGNANT girl of 17 has died at a Scots hospital after catching swine flu.

Doctors could not save the teenager's unborn child.

The mum-to-be was from Galashiels in the Borders and was named locally as Denise Murray.

She is the 15th Scots swine flu victim to die. It emerged yesterday that the UK death toll has passed 100.

The Scottish government has announced a vaccination programme for up to 1.3 million people will begin next week.

The girl and her baby died on Wednesday morning at Borders General Hospital near Melrose.

Health secretary Nicola Sturgeon said: "The death of this young mother-to-be and her baby is deeply sadening and my thoughts are with her family and friends."

Sturgeon said doctors had found no evidence that the teenager was suffering from...
Flu A (H1N1)v: best guess

- Number will continue to increase over the next few weeks/months
- Peak uncertain but experience in Southern Hemisphere encouraging
- Prepare for the worst case scenario but hope for the best
- Vaccination will change the epidemiology
Flu A (H1N1)v vaccination

• UK Government’s aspiration to vaccinate 100% of the population from October 2009
  Agreed to purchase 130 million doses with a 2 dose schedule
• Vaccine supply will come in stages over a number of months
• Various groups to be prioritised in phase 1
• Phase 2 still to be decided based on experiences over next few months
Flu A(H1N1)v vaccine: priority order

- People aged over 6 months and in the current seasonal flu clinical at-risk groups due to various chronic conditions
- Health care staff with direct patient contact
- Social care staff who are employed to provide personal care to children and adults, both in care homes and in the community
- Pregnant women
- Household contacts of immunosuppressed individuals
Immunosuppressed individuals

- As detailed in the “Green Book”
  - Due to disease or treatment
  - Patients undergoing chemotherapy
  - Asplenia or splenic dysfunction
  - HIV patients
  - Individuals on systemic steroids for more than a month at a dose equivalent to Prednisolone at 20mg or more per day, or children under 20kgs at a dose of 1mg or more/kg/day
Flu A(H1N1)v vaccine

- Which products
- Schedule
- Licensing process and time scale
- Adjuvants
- Other composition
- Safety data and side effects
Two (H1N1)v specific vaccines in the UK

- GSK- Pandemrix®
- Baxter- Celvapan®
- Approximately 50:50 split but initially more of GSK than Baxter product
- Both vaccines licensed by EU countries
Flu A(H1N1)v vaccination

- Both vaccines initially developed and tested as a pandemic vaccine by using antigen from H5N1 influenza (bird flu)
- Used exactly the same methods and ingredients as above but using Flu A (H1N1)v antigen
- Very similar process as seasonal flu vaccines
GSK vaccine - Pandemrix®

- Inactivated split virion vaccine, so no live viruses
- Virus grown in hens’ eggs
- Contains an adjuvant (ASO3) to boost immune response
- Contains thiomersal as preservative and has longer shelf life once opened
Baxter vaccine - Celvapan®

- Inactivated whole virion vaccine, so no live viruses
- Virus grown in cell culture, so no egg allergy issue
- No adjuvant
- No thiomersal as preservative, so shorter shelf life once opened
Adjuvants

- Added to vaccine to increase immune response
- Most adjuvants used in vaccines in the UK are aluminium salts. They have been in use over 70 years and are safe
- GSK vaccine has ASO3 as adjuvant
- Adjuvant drive immune response
Other Composition: Thiomersal

- Mercury based substance that has been used widely in vaccines for over 60 years
- Most new vaccines do not use thiomersal as a precaution
- Added to some multi-dose vaccines to prevent them from being contaminated by bacteria and fungi
- Added to the GSK products
Mercury

- Heavy metal naturally found in the environment
- Main source of exposure is the diet mainly organic form methylmercury, found in fish such as tuna
- Methylmercury can accumulate in the body if individuals eat large quantities of predatory fish or seafood
- Mercury in thiomersal is ethylmercury in a very small amount and is rapidly broken down in the body.
## Dosage and Schedule: Pandemrix®

<table>
<thead>
<tr>
<th>Age</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults and children of 10 years and above</td>
<td>Single injection of 0.5ml</td>
</tr>
<tr>
<td>Immuno compromised individuals aged 10 years and above</td>
<td>Two injections of 0.5ml at least 3 weeks apart</td>
</tr>
<tr>
<td>All children aged 6 months to 10 years</td>
<td>Two injections of 0.25ml at least 3 weeks apart</td>
</tr>
</tbody>
</table>
Dosage and schedule: Celvapan®

- Two doses of 0.5ml at least 3 weeks apart for all individuals aged 6 months and above
Which vaccine?

At risk groups aged 10 years and above
   Either but GSK (Pandemrix®) needs only one dose

Children under 10 years
   If possible GSK as clinical trial data for children is available

Pregnant women
   Preferably GSK as earlier protection
Flu A (H1N1)v vaccine: contraindications

- Pandemrix® – if severe life threatening allergic reaction to egg and egg products
- Previous life threatening allergic reaction to flu vaccines
- Life threatening reaction to any components of the vaccines
- Confirmed case of (H1N1)v infection
- Skin rash following flu vaccines not a contraindication
Flu A (H1N1)v vaccine

• Side effects similar to seasonal flu vaccines
  – Headache, fatigue, fever, arthralgia, myalgia and pain and redness at injection site
• Other rare side effects detailed in the SPC
• If second dose delayed, do not need to restart course but protection delayed.
Guillain-Barré Syndrome (GBS)

- Reversible neurological condition
- Usually following infections
- Thought to be due to auto-immune process
- Recent study showed risk of GBS about 17 times higher following infection with a flu like illness compared to background risk
Flu vaccines and GBS

• A cluster of GBS cases reported following swine flu vaccines used in America in 1976. Estimated one case for every 100,000 vaccine used but reason not known.

• Surveillance since 1976 found no link between seasonal flu vaccine and GBS

• Flu vaccine found to be protective against GBS
Flu A (H1N1)v vaccine

- Vaccines are not interchangeable
- Co-administration with other vaccines
- Side effects monitored by
  - Yellow card scheme
  - “swine flu” ADR Portal at
    www.mhra.gov.uk/swine_flu
Implementation in NHSGGC
Those to be Immunised

Clinical Priority Groups
(c. 240,000 in GG&C)

- Individuals aged between six months and up to 65 years in the current seasonal flu vaccine clinical at-risk groups.
- All pregnant women.
- Household contacts of immunocompromised individuals.
- People aged 65 and over in the current seasonal flu vaccine clinical at-risk groups.

Health & Social Care Workers
(c. 56,000 in GG&C)

- Healthcare workers with direct patient contact.
- Social care staff who are employed to provide personal care to children and adults, both in care homes and in the community.
Those to be Immunised

Health & Social Care Workers Example Roles

Healthcare workers with Direct Patient Contact.

- Community Pharmacists
- Doctors (including GPs + Practice staff)
- Dentists (hospital & GDPs)
- Midwives
- Nurses
- Occupational Therapists
- Physiotherapists
- other AHPs
- Radiographers
- Students and trainees in these disciplines
- Local risk assessment of non-clinical staff with Direct Patient Contact e.g. ward clerks

Social Care Staff who provide Personal Care

- Care home staff in residential/nursing homes who provide personal care to residents
- Domiciliary care workers employed by agencies who provide personal care to service users in their own homes
- Personal assistants – staff employed to provide personal care to a single service user
- Students and trainees
Immunisation Responsibility Areas

- **GPs/Primary Care**
  - Clinical Priority Groups (c. 240,000) + Practice Staff

- **Occupational Health**
  - Acute Health-based Health Care Staff (c. 21,000)

- **CH(C)Ps**
  - Community-based Health & Social Care Staff (c. 35,000)

**Co-operate**
Immunisation Responsibility Areas

- Acute Health
  - Long stay Clinical Priority Groups
e.g. Mental Health, or patients more than 3-4 weeks in hospital
Identify & Call

**GPs**
- New software to interrogate GP systems for clinical risk groups
- Template letters for GPs To use for patients

**Occupational Health**
- Work Force Planning
- Staffnet/Posters/Email

**CH(C)Ps**
- Staff lists
- Letters/other Publicity materials
Identify and call

• Pregnant women
  – GP practices to identify them and invite
  – Raised awareness among pregnant women by media and midwives advising to contact GP

• Household contacts of immunosuppressed
  – Awareness raising through media
  – Practices to identify through patient
  – Letter to clinicians in secondary care
Roll out Approach

GPs
- Letters to at risk groups
- And pregnant women
- Practice/Health Centre Sessions after checking vaccine delivery

Occupational Health
- Staffnet/Posters/Email
- Acute Venue Sessions

CH(C)Ps
- Letter/other publicity
- Health Centres, Other Community Venues, On Site Delivery

Seasonal Flu Offered at Same Time to Health Care Staff
Consent

• Written consent not required for vaccination in primary care/community clinics
• Need evidence of informed consent
• Consent required at school setting
• Consent required from Health and Social Care staff to transfer data
If you have a chronic medical condition making you eligible for the seasonal flu vaccine, then your GP should be writing to you to offer you the H1N1 vaccine. You can choose where to have the vaccine. If you have the vaccine through this clinic as a Health/Social Care Worker then please do not attend your GP for it, and vice versa.

* If you are pregnant, please do not present for H1N1 vaccination at the clinic for Health/Social Care Worker. You will be offered the vaccine by your GP, who can advise on vaccination during pregnancy and other pregnancy-related matters. ** NHS Staff: you can also choose to receive the Seasonal Flu vaccination with the H1N1 vaccine. Co-administration of both vaccines is entirely safe. Non-NHS Staff may approach their employers or GP for Seasonal Flu vaccination as appropriate.

To avoid you receiving repeat vaccination appointments in the future, the information within this form will be recorded centrally and shared with other relevant health care professionals e.g. your GP. Please let one of the clinic staff know if you have any objection to this.

** For office use only **

Name of CH(C)P: __________________________

Health and Social Care Workers H1N1 Immunisation Record Form

Please bring this form with you when you attend for vaccination

PERSONAL DETAILS

<table>
<thead>
<tr>
<th>Surname</th>
<th>Forename</th>
<th>Date of Birth</th>
<th>Male or Female</th>
<th>Home address</th>
<th>Postcode</th>
<th>Tel. number</th>
<th>Email address</th>
<th>Mobile number</th>
<th>GP</th>
<th>GP address</th>
<th>Health board of residence</th>
</tr>
</thead>
</table>

Please answer the following questions:

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Do you have a history of a severe, life threatening allergic reaction to eggs and/or egg products?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Have you ever had a severe, life threatening allergic reaction to influenza vaccine in the past?</td>
<td></td>
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<tr>
<td>3. For female staff: Are you, or do you think you might be, pregnant? (*see below for advice on this matter)</td>
<td></td>
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<tr>
<td>4. Do you have a condition, or are you having any medical treatment, that has weakened your immune system?</td>
<td></td>
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</tr>
<tr>
<td>5. NHS Staff Only: If you have not yet had a seasonal flu jab this year, would you like to be offered this with the H1N1 vaccine? (** see below table for advice on this matter)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If you have a chronic medical condition making you eligible for the seasonal flu vaccine then your GP should be writing to you to offer you the H1N1 vaccine. You can choose where to have the vaccine. If you have the vaccine through this clinic as a Health/Social Care Worker then please do not attend your GP for it, and vice versa.

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Signature __________________________ Date __________________________

For office use only

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Date Given</th>
<th>Brand</th>
<th>Batch Number</th>
<th>Expiry Date</th>
<th>Site of Injection</th>
<th>Name</th>
<th>Designation</th>
<th>Signature</th>
</tr>
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<tbody>
<tr>
<td>H1N1</td>
<td></td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Seasonal flu</td>
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</tbody>
</table>
Information Flow

GPs

HPS/Government

Occupational Health/CHP/SIRS Report (after December 2009)
Start Dates

Health & Social Care Staff

Wednesday 21st October, 2009

Clinical Priority Groups

(from)

Monday 26th October 2009 depending on vaccine availability
Flu A (H1N1)v vaccine: communications

- Public
  - TV/radio
  - Leaflets/posters
  - Vaccination record card

- Professional
  - Fact sheets/Q&As/DVD
  - Template letter for GPs to invite patients
  - “Green Book” chapter
  - Websites