

To: Immunisation Leads in all Strategic Health Authorities in England
Pandemic Influenza Leads in all Strategic Health Authorities in England
Flu Directors in all Strategic Health Authorities in England

Flu Coordinators in all Primary Care Trusts in England
Immunisation Coordinators in all Primary Care Trusts in England
Pandemic Influenza Leads in all Primary Care Trusts in England

Regional Directors of Public Health in England

Gateway Reference: 12639

30 September 2009

Dear Colleague

The H1N1 swine flu vaccination programme 2009-2010

This letter provides information that will assist you in further planning for the swine flu (influenza A (H1N1v) 2009) vaccination programme.

We know that we must prepare for a possible surge in cases in the autumn or winter that could affect large numbers of people and put real pressure on the NHS. Vaccination has always been an important element of our resilience strategy. Delivering an effective vaccination programme will help us to save lives.

We are dealing with a number of uncertainties – for instance, regarding the number of doses needed for protection; and the delivery profile from the manufacturers –which means that we are unable to provide you with definitive guidance yet. However, there is much that can be taken forward in the meantime and this letter aims to give you as much information as presently possible regarding our vaccination strategy. This should help you with local planning.

Early details of the H1N1 swine flu vaccination strategy were circulated to Primary Care Trusts (PCTs) in a letter from me (26 June 2009).

http://www.immunisation.nhs.uk/Library/News/H1N1_Swine_Flu_Letter

Additional information, including confirmation of the priority groups for vaccination, was provided by the Chief Medical Officer (CMO) in his letter dated 13 August 2009. This information is summarised at Annex A.

http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearcolleagueletters/DH_104267

You will probably be aware that agreement has now been reached between the Department and the GPC to vaccinate the 9.5 million people identified as being in the clinical risk groups. This agreement puts us in the best possible position to deliver the swine flu vaccination programme. It builds on an established model of flu vaccination delivery, alongside special provision for the supply of consumables, and draws on the experience and expertise of our GPs, and the district nurse community, who will vaccinate the housebound (see:

http://www.dh.gov.uk/en/Publichealth/Flu/Swineflu/DH_105132).

The price agreed with the BMA is intended to cover the average costs involved in providing the vaccination to people in the at-risk groups recommended by the Joint Committee on Vaccinations and Immunisations (JCVI). A single price per dose of £5.25 provides a simple and transparent way of remunerating GP practices whilst encouraging high levels of take-up. PCTs are responsible for making community nurse time available for vaccinating housebound patients.

The GSK vaccine (Pandemrix H1N1) has now been licensed by the European authorities. Since the vast majority of the supplies we are expecting are due from GSK this is excellent news. We do not know when the Baxter product will be licensed. The supply details in this letter therefore relate to the GSK vaccine only at present.

Previously, we advised that vaccine would be delivered to a limited number of locations within each PCT (letter of 9th July - see www.immunisation.nhs.uk). Now that agreement has been reached with the GPC for a GP delivered programme, we will complement that arrangement by adding a delivery direct to each practice in the country.

Because supplies will initially be limited, we will send vaccine to all Acute and Mental Health Trusts first. This will ensure that frontline health care workers and vulnerable patients in these settings have access to vaccine first. Based on the current GSK delivery schedule, the earliest date that trusts could receive vaccine is the 14th October.

We will then send vaccine to every PCT nominated site within each PCT area. Based on the current GSK delivery schedule the earliest date that PCTs could receive the vaccine is the 14th October.

We will send a minimum of one box (500 doses) of vaccine to each trust and PCT – dependent on supplies we may be able to send more according to the size of the trust/PCT.

We will then send one box (500 hundred doses) of vaccine to every GP surgery in the country. This will take a minimum of two weeks to complete. Based on the current GSK delivery schedule the earliest date that GPs could receive the vaccine is the 19th October with deliveries to all GP practices in the country being completed within three weeks of this date.

Feedback from contacts in PCTs is that GPs tend to invite patients for vaccination only after they have received vaccine. This can mean that it can take a couple of weeks between a surgery receiving vaccine and its being administered. We will ensure that GPs are informed of when they can expect delivery of their vaccines so that their planning can begin before vaccine arrives.

These delivery plans will change if the delivery profile from GSK changes.

SHAs in conjunction with PCTs should ensure that local plans are in place to cover the vaccination of all frontline staff. SHAs have a responsibility to report any variation in the national delivery plan necessary to address local gaps in frontline staff and 'at risk' vaccination delivery plans.

Ian Dalton, National Director of NHS Flu Resilience, has written to NHS Chief Executives, setting out clearly the next steps for all NHS Chief Executives and organisations, in terms of preparation for the swine flu vaccination programme.

SHAs and PCTs have been asked to develop plans to identify, communicate with and vaccinate patients in the at-risk groups, including those not registered with a GP practice. Additionally, every NHS organisation has been asked to develop a plan to vaccinate those frontline staff eligible for vaccination and Ian has emphasised that NHS boards will need to take responsibility for maximising participation in local staff vaccination programmes. These plans will need to ensure that access to the vaccine is as easy as possible. Any perceived barriers to vaccination must be considered and removed.

While vaccination is optional, at the time of a second wave of this pandemic, frontline staff will be at increased risk of infection and of transmitting that infection to vulnerable patients. The vaccination will both protect staff members from infection, and minimise the risk of patients also becoming infected.

To support Chief Executives as they plan to deliver this programme, the NHS Leadership team has also written out to their respective staff groups encouraging every Medical and Nursing Director, GP and Head of Profession to take a visible leadership role across their organisation to ensure their staff are as well protected as possible. You have an important role to play in helping to develop these plans; please take the earliest opportunity to get involved in these discussions.

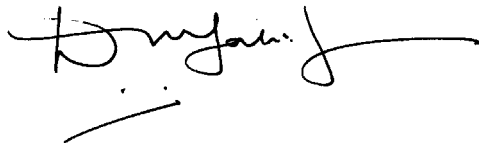
In terms of other progress, arrangements to report suspected adverse reaction to swine flu vaccines will be the same as for Tamiflu and Relenza. MHRA has put in place a special web based reporting system – the swine flu ADR Portal (www.mhra.gov.uk/swineflu) based on the Yellow Card scheme.

Most vaccinations are given without any trouble at all, but very rarely there may be problems. Starting from 10th October, H1N1 swine flu vaccine will be included in the Vaccine Damage Payments Scheme. This is designed to help with the present and future financial burdens on the person affected and their family. It covers the routine childhood vaccines and is being extended to include swine flu vaccines. More information can be obtained from the website of the Department for Works and Pensions (www.dwp.gov.uk) that manages the Scheme.

Detailed information about the particulars of the vaccination programme is included within the Annexes to this letter. As soon as more information is available about deliveries and dosage, I will share this with you.

The success of the swine flu vaccination programme will depend on the commitment of all those health professionals who play important roles in ensuring the effectiveness of our immunisation programme and I would like to take this opportunity to thank all of you for what you have done so far, and what I am sure you will continue to do.

Yours sincerely

A handwritten signature in black ink, appearing to read 'D M Salisbury', with a long horizontal flourish extending to the right.

Professor D M SALISBURY CB
FRCP FRCPCH FFPH
Director of Immunisation

Annex A

Recommendations for use of the vaccine

Confirmation of the priority groups for vaccination was given in the CMO's letter dated 13 August 2009.

http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearcolleagueletters/DH_104267

Prioritisation

Following advice from independent expert committees, including the Joint Committee for Vaccination and Immunisation (JCVI), the following groups should be prioritised for vaccination in the following order, once the vaccine has been licensed:

- I. individuals aged six months and up to 65 years in the current seasonal flu vaccine clinical at-risk groups
- II. all pregnant women, subject to licensing conditions on trimesters
- III. household contacts of immunocompromised individuals
- IV. people aged 65 and over in the current seasonal flu vaccine clinical at-risk groups

The full statement from JCVI is available at:

http://www.dh.gov.uk/ab/JCVI/DH_094744

Children aged from 6 months to 3 years of age

JCVI gave very careful consideration to its recommendations for vaccination of children. It recommended that children in clinical risk groups from six months of age upwards should be offered the swine flu vaccine because of the severity of the disease seen in these groups.

Pregnant women

There is good evidence that pregnant women are at higher risk of the serious consequences of H1N1 infection. Evidence suggests that pregnant women are four times more likely to develop serious complications from swine flu and pregnant women are four to five times more likely to be hospitalised with swine flu than non-pregnant women.

The GSK vaccine has been licensed for use in pregnancy. It is therefore recommended that all pregnant women are offered the swine flu vaccination.

Vaccination of frontline health and social care workers

The letter from the CMO explained that frontline health and social care workers would be offered the swine flu vaccine. The rationale for this, as detailed in the letter, is that these frontline staff are at increased risk of exposure to the virus and increased risk of transmitting the virus to vulnerable

patients. These frontline staff are those who have regular clinical contact with patients and who are directly involved in patient care. The definitions of these frontline staff are set out in the annexes to the CMO's letter.

This is a risk-based approach. Following the above guidance, those health and social care workers who have regular clinical contact with patients and who are directly involved in patient care will be eligible for the vaccine. Similarly other health professionals falling outside that definition will not be eligible for vaccination as a priority group.

Uptake of seasonal flu vaccine by healthcare workers has tended to be very low. Arrangements need to be made locally to increase uptake of swine flu vaccine in frontline health and social care workers. These plans will need to make access to the vaccine as easy as possible. Any perceived barriers to vaccination must be considered and removed.

Annex B

The vaccines

The GSK vaccine (brand name Pandemrix) is a split virion, inactivated, adjuvanted vaccine. It is a monovalent vaccine containing 3.75µg of antigen. The antigen used is A/California/07/2009 (H1N1)v-like strain (X-179A), propagated in fertilised hens' eggs. The vaccine contains an adjuvant – AS03 – to help boost the immune response, and it contains thiomersal as a preservative.

The Baxter vaccine (**provisional** brand name Celvapan) is a whole virion, inactivated, vero cell derived vaccine containing 7.5 µg of antigen. The antigen used in the Baxter vaccine is the wild-type A/California/07/2009 H1N1 strain. The whole virion is inactivated both by formaldehyde and UV-irradiation. It does not contain an adjuvant or thiomersal.

The EMEA is currently considering further information from Baxter and has not yet issued a positive opinion on this vaccine.

Product Dimensions

GSK Vaccine - Pandemrix

Pandemrix vaccine will be presented in a box of 50 multi-dose vials of 2.5ml suspension and two boxes containing 25 2.5ml vials of adjuvant. Each 5.0 ml of reconstituted vaccine should provide 10 0.5ml doses. Each pack should provide 500 doses.

The pack size for the 500 dose pack of GSK vaccine is 260mm x 113mm x 97mm. This is about the size of a small shoe box.

Baxter Vaccine - Celvapan

Celvapan vaccine will be presented in a pack of 20 multi-dose vials of 5ml suspension per pack. Each 5ml vial should provide 10 0.5ml doses, with each pack providing 200 doses.

The pack size for the 200 dose pack of Baxter vaccine is 206mm x 166mm x 55mm. This is about the size of a box of chocolates.

Contraindications

JCVI has advised that individuals with a confirmed history of anaphylactic reaction to egg, which is a very rare condition, should not be offered the GSK swine flu vaccine (Pandemrix). Individuals with a confirmed anaphylactic reaction to egg should be offered the Baxter vaccine, when available.

A Green Book chapter on pandemic influenza, which is currently being drafted, will reflect JCVI advice and is likely to read as follows:

There are very few individuals who cannot receive the swine flu vaccine.

The vaccines should not be given to those who have had:

- A confirmed anaphylactic reaction to a previous dose of the vaccine, or
- A confirmed anaphylactic reaction to any component of the vaccine.

The GSK product should not be given to those who have had:

- A confirmed anaphylactic reaction to egg products as the vaccines are prepared in hens' eggs.

GSK vaccine Pandemrix

The following information on the GSK vaccine Pandemrix has been recommended by the Committee for Medicinal Products for Human Use (CHMP) :The SPC lists the following contraindications and precautions for use:

History of an anaphylactic (i.e. life-threatening) reaction to any of the constituents or trace residues (egg and chicken protein, ovalbumin, formaldehyde, gentamicin sulphate and sodium deoxycholate) of this vaccine.

Caution is needed when administering this vaccine to persons with a known hypersensitivity (other than anaphylactic reaction) to the active substances(s) to any of the excipients, to thiomersal and to residues (egg and chicken protein, ovalbumin, formaldehyde, gentamicin sulphate and sodium deoxycholate).

The excipients in Pandemrix are:

Suspension vial

Polysorbate 80

Octoxynol 10

Thiomersal

Sodium chloride

Disodium hydrogen phosphate

Potassium dihydrogen phosphate

Potassium chloride

Magnesium chloride

Water for injections

Adjuvant vial:

Sodium chloride

Disodium hydrogen phosphate

Potassium dihydrogen phosphate

Potassium chloride

Water for injections

Adjuvant

Squalene

DL- α -tocopherol

Polysorbate 80

The draft Summary of Product Characteristics (SPC) can be found at <http://www.emea.europa.eu/humandocs/PDFs/EPAR/pandemrix/Pandemrix-PU-17-en.pdf>

Baxter vaccine Celvapan

More information on the Baxter vaccine Celvapan is available from the SPC for the 'mock-up' H5N1 vaccine (upon which the pandemic vaccine is based). The SPCs lists the following contraindications and precautions for use:

History of an anaphylactic reaction to any of the constituents or trace residues (e.g. formaldehyde, benzonase, sucrose) of this vaccine.

Caution is needed when administering this vaccine to persons with a known hypersensitivity (other than anaphylactic reaction) to the active substances(s) to any of the excipients and to trace residues e.g. formaldehyde, benzonase, sucrose.

The excipients in Celvapan are trometamol, sodium chloride, water for injections, polysorbate 80.

The full Summary of Product Characteristics can be viewed at www.emea.europa.eu/humandocs/Humans/EPAR/celvapan/celvapan.htm (Click on the 'en' option for the English version of the documents).

Other common questions

How many doses of vaccine will be needed to give protection?

The EMEA's CHMP has recommended a two-dose vaccination schedule, with a 3-week interval in all age groups, including pregnant women, from the age of 6 months. For those aged from 6 months to 9 years, half the adult dose (i.e. 0.25ml rather than 0.5ml) is recommended. Based on preliminary data, the proposed recommendations also allow for 1 dose to be given to those aged between 10 to 60 yrs. The Agency is expecting further data from ongoing clinical studies over the coming months and these recommendations may be updated. These dosage recommendations, and licence, have yet to be agreed by the EC.

Further advice will be sought from JCVI on the dosing schedule and this will be shared with colleagues as soon as it is available.

Swine flu vaccines and Guillain-Barré syndrome (GBS)

Guillain-Barré syndrome is a rare but serious disease of the peripheral nervous system. Influenza-like illness has been shown to be associated with an increased risk of GBS. A recent study showed that the risk of GBS was about seventeen times higher in the period following infection with a flu-like illness compared to the usual risk of GBS (Stowe et al., 2009).

In 1976, the swine influenza vaccines used in the United States were associated with an increased risk of GBS. It is thought that one extra case of GBS occurred with every 100,000 doses of the vaccine (Schonberger et al., 1979). The exact reason why the 1976 vaccine increased the risk of GBS remains unknown. Many studies have since looked at whether other influenza vaccines used since 1976 carry a risk of GBS and no robust evidence of a causal link has been found (Stratton et al., 2004). An epidemiological study of seasonal flu vaccines recently used in the UK found no risk of GBS (Stowe et al., 2009).

There is no evidence to suggest that either the GSK or Baxter swine flu vaccine, or seasonal flu vaccine, will carry an excess risk of GBS. As with any new vaccine, we will have robust systems in place to identify any serious side effects.

Schonberger LB et al., Guillain-Barre syndrome following vaccination in the national influenza immunization program, United States, 1976-1977. *Am J Epidemiol* 110(2):105-123.

Stratton K et al., (eds). (2004) *Immunization Safety Review. Influenza Vaccines and Neurological Complications*. Washington: The National Academies Press

Stowe J et al., Investigation of the temporal association of Guillain-Barre syndrome with influenza vaccine and influenza like illness using the United Kingdom General Practice Research Database. *Am J Epidemiol* 169(3):382-8.

Thiomersal

The GSK vaccine contains very low levels of thiomersal, a preservative that contains mercury. The presence of thiomersal permits use of the opened vials for up to twenty four hours.

The UK Commission on Human Medicines (CHM) keeps the safety of vaccines, including other thiomersal containing vaccines, under continual review. The view of the CHM remains that there is no evidence of neurodevelopmental adverse effects caused by levels of thiomersal in vaccines. The only evidence of harm due to thiomersal is a small risk of hypersensitivity reactions (that typically include skin rashes or local swelling at the site of injection). The CHM advises that the balance of risks and benefits of thiomersal-containing vaccines is overwhelmingly positive. Further information is available at www.mhra.gov.uk (search for 'thiomersal').

Porcine product

Some porcine products are used in the manufacturing process of the Baxter vaccine; however there are no detectable traces of these products in the vaccine itself.

The GSK vaccine does not contain porcine products.

Previous advice regarding faith communities and vaccines containing porcine products can be accessed at

<http://www.immunisation.nhs.uk/Library/Search?stags=&terms=porcine>

Annex C

Programme implementation and logistics

Vaccine Supply

Once the arrangements outlined in the letter are complete then PCTs will be able to order swine flu vaccine for their use and for individual general practices via the ImmForm website: www.immform.dh.gov.uk. This is the website used for routine childhood and HPV vaccine ordering. We expect to be able to send out vaccine, on a rolling basis within two weeks of receiving an order.

Needles and Syringes

Sufficient needles and syringes to mix and administer the vaccine will be provided to PCTs free of charge. Sufficient stocks will be delivered to PCTs, for onward distribution to GPs, in advance of the vaccine deliveries. No needles or syringes will be delivered direct to GPs.

For more information on the use of needles and syringes see -

http://www.dh.gov.uk/en/Publichealth/Healthprotection/Immunisation/Greenbook/DH_4097254

Size of syringe boxes

For the administration of both the Baxter and the GSK vaccine a dose sparing, orange, 25g, 25mm (1.0") fixed needle 1ml syringe is needed. These will be supplied in boxes (height x width x length in mm): 130 x 145 x 414. There are 200 fixed needle-syringes per pack.

For further information on needles for administration, see

https://register.livgroup.co.uk/Uploads/Event_184/Downloads/9249%20Practical%20Aspects%20of%20Vaccination%20for%20Website.ppt

For the GSK vaccine, a mixing syringe is needed for the mixing of the antigen suspension and the adjuvant. The mixing syringe is 3ml capacity, scale, calibrated to 0.5ml increments. These will be supplied in boxes (height x width x length in mm): 68 x 113 x 375. There are 100 syringes per pack.

Size of needle boxes

A green, 21g, 38mm (1.5") needle is needed for mixing the GSK vaccine. There are two manufacturers of these needles, both of which supply 100 needles per box. The dimensions of the boxes (height x width x length in mm) are:

88 x 85 x 112

93 x 82 x 113

Administration and Wastage

Many staff will not be used to using multi-dose vials or the above fixed needle syringes. In order to assist training, we, together with the Health Protection Agency, the Royal College of Nursing and vaccine experts have developed a DVD on vaccine administration. An early draft will be available online next week, and the completed DVD will be available soon after.

Vaccine wastage may be greater when using multi-dose vials rather than single doses. The fixed needles and syringes supplied will help to reduce vaccine wastage. Local planning should take into account the need to reduce wastage.

The GSK vaccine can be used for a period of up to 24 hours after reconstitution. The Baxter vaccine can be used for a period of 3 hours after removal from the fridge.

Data Recording

New READ codes will be published by Connecting for Health no later than 1st October 2009. These will be published via the TRUD website for download (<https://www.uktcregistration.nss.cfh.nhs.uk/trud/>). There will be two new product/drug codes for the two respective vaccines and they are due to be published in the October release. There will also be new procedure codes that will differentiate between doses (i.e. dose 1 or 2) and brand of vaccine; these are being finalised and will be published shortly. Accurate data recording is essential for the clinical record and to allow vaccine uptake collection. Guidance on which codes to use is to be prepared and will be issued in due course.

Data Collection

The data collections set out below are subject to ROCR approval.

GP-Based Collection

Vaccine uptake data will be collected from GP practices in a similar way to the seasonal flu vaccine data collections, via the ImmForm website. The datasets will be confirmed and issued shortly .

PRIMIS+ are producing the Swine Flu Clinical Risk Group READ Codes specification. It is based on the seasonal flu specification, with the addition of pregnant women. We will publish this specification once finalised. PRIMIS+ will also be releasing a swine flu library for their CHART tool, which provides facilities to identify patients in clinical risk groups and extracts the uptake data for submission to ImmForm.

The collection will be monthly and may run for up to 12 months, depending on how the later stages of the vaccination programme turn out. As with seasonal flu, we will also do a weekly collection from a sentinel group of around 50% of GP practices. The sentinel group will be those practices that use IT systems where their IT suppliers are able to extract their data on their behalf and

submit it to the ImmForm website; this will place no burden on the practices to provide these data.

Health care workers data collection

We wish to collect swine flu vaccine uptake data for health care workers involved in direct patient care via the ImmForm website. We plan to collect vaccine uptake data from all trusts (including foundation trusts), namely:-

- NHS Trusts (including Acute Trusts, Mental Health Trusts and Ambulance Trusts)
- Care Trusts
- Primary Care Trusts

The dataset will be confirmed and issued shortly.

The collections will be weekly and are expected to run from early November to the end of March 2010. We recognise that a weekly collection will take resources to collect, record, collate and provide data. However, vaccination is seen as a vital part of safeguarding the operational resilience of the NHS and it is vital that those responsible for command and control of the NHS at local, regional and national level have access to timely data on the progress of the immunisation programme.

Social care workers' data collection

Details for a vaccine uptake data collection will be confirmed once implementation details have been agreed.

Annex D

Communication Materials

Materials for health professionals including a new Immunisation Green Book chapter, fact sheet, Q&A, consent template, Patient Group Directive (PGD) template and patient vaccine invitation letters are in preparation. Training materials to support NHS staff are also being developed. These will be posted in draft on the Department of Health website at:

<http://www.dh.gov.uk/en/Publichealth/Flu/Swineflu/InformationandGuidance/index.htm>

These materials will be finalised once we have further information about the licensing of the vaccines. The materials will be available on the Department of Health website before any hardcopies are supplied.

Publicity campaign

Publicity campaign plans for the swine flu vaccine are in development. This is a complex task, as they need to be considered against the wider picture of other communications that might be required about flu, for example on where to get treatment and on prevention via good hygiene practice.

We anticipate that the first phase of the publicity campaign will commence around the start of the delivery stage of the vaccination programme and will focus on “inviting” people in the prioritised groups to present themselves for their vaccination.

The national campaign materials and plans will be made available via the Comms Link website <http://www.nhscommlink.nhs.uk/public/default.aspx> for local use. It will be important that we give the public a consistent message on the new vaccine to avoid confusion. We would therefore advise PCTs not to develop their own materials until the final nationally agreed set has been published.

In the meantime, information about the communications approach for the seasonal flu immunisation will be posted on the DH and Comms Link websites shortly along with material for use in your local programmes.

Further updates on progress will be provided via Directors of Communications at SHA level and on Comms Link.

If you have further queries, please email pandemicflucommunications@dh.gsi.gov.uk

NHS staff engagement campaign

We are working with the NHS and the Social Partnership Forum to develop an effective communications strategy to encourage maximum uptake of the

vaccine amongst frontline staff. This will need to be supported by a proactive, visible and easily accessible staff vaccination process.

The strategy will set out the rationale behind prioritising staff for the vaccine, providing clear benefits in terms of patient care, while providing authoritative content about the vaccine and ensuring staff know when and where to receive it.

We will be utilising a range of media to communicate messages, including the trade press, stakeholder bulletins and websites and our Departmental channels. We will be working with our professional leads in the Department and encouraging them to engage with their respective clinical leadership communities across the NHS – and also encouraging clinical champions and ownership at a local level.

We will produce a toolkit for local communications leads to use, comprising a range of materials, that they can adapt and use locally.

Our messages will be developed in partnership with stakeholders and NHS communication colleagues and we will look to incorporate them in as many Departmental communications and initiatives this Autumn/Winter as possible and appropriate.

PCT Immunisation leads conferences

To assist with planning, two swine flu conferences have been held for PCT immunisation leads.

Slides from the conference on 08/07/2009 and 10/09/2009 can be found via the following link:

http://www.immunisation.nhs.uk/Professional_information/Events/Event/flu_July2009