

To:
All General Practitioners
Medical Directors
Nursing Directors
A&E Departments
Consultants in Obstetrics
All Pharmacists

Gateway Reference: 12781

15 October 2009

Dear Colleague

The H1N1 swine flu vaccination programme 2009-2010

This letter provides information for clinicians to assist you in delivering the swine flu (influenza A (H1N1v) 2009) vaccination programme.

Vaccination will ensure protection of the clinical risk groups, and frontline health and social care workers. Not only will vaccination help staff protect themselves, their patients, colleagues and families, it will reduce demand on critical care which is likely to come under heavy pressure during the months ahead.

The second wave of the flu pandemic is under way. There is an opportunity to get the vaccine programme in place to counteract later surges of cases. The number of people in intensive care is still relatively high. Every death is the loss of a person, not just a statistic. All this emphasises the public health importance of vaccine.

The first batches of licensed vaccine are now in the NHS distribution network. The vaccination programme will begin from the 21 October 2009. This is the date when the first deliveries of vaccine will be sent to NHS Acute Trusts. It will take 2-3 days to deliver to all Acute Trusts, with further supplies sent out in the following week. These supplies can be used for protecting frontline staff and patients in at-risk groups in hospital.

The earliest possible delivery date for the first supplies of vaccine to general practices is Monday 26 October 2009. It will take around 3-4 weeks to complete the distribution of first supplies to all practices. Initially practices will receive one box of Pandemrix vaccine containing 500 doses.

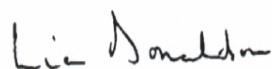
A supply of Pandemrix vaccine will be sent to every Primary Care Trust (PCT), Ambulance Trust and Mental Health Trust, in the week beginning 26 October. A stock of Celvapan vaccine will also be sent to PCTs in the week beginning 26 October. After this date PCTs and Acute Trusts will be able to order additional supplies of vaccine subject to supply from manufacturers.

We would like to take this opportunity to ask you to ensure your staff have a sound understanding of the rationale behind staff vaccination, so that they can make an informed decision about whether to take it, if they are offered it. Your local NHS communications team will currently be in the process of planning a campaign to encourage frontline staff vaccination. We hope you will be able to lend your support. If you would like to see a synopsis of the key arguments for staff vaccination, this is available to download at:

http://www.dh.gov.uk/en/Publichealth/Flu/Swineflu/DH_107125

More information on the vaccination programme including details on obtaining further supplies of vaccine is contained in Annex A to this letter.

We would like to take this opportunity to thank all NHS staff, and primary care contractors such as general practitioners and community pharmacists, for their dedicated and professional response to the swine flu pandemic so far, and for your continued efforts to protect our population.



SIR LIAM DONALDSON
CHIEF MEDICAL OFFICER



PROFESSOR CHRISTINE BEASLEY
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CHIEF PHARMACEUTICAL OFFICER

Swine Flu Vaccination Programme Details

Clinical priority groups

The clinical priority groups were identified by the Joint Committee for Vaccination and Immunisation (JCVI) and communicated in the CMO letter of 13 August 2009. They are prioritised as they are at greatest risk of complications if they become infected with swine flu, and hence the initial focus on protecting individuals in these groups.

The clinical risk groups, in order of priority are:

- a. Individuals aged six months and up to 65 years in the current seasonal flu vaccine clinical at risk groups
- b. Pregnant women
- c. Household contacts of immunocompromised individuals
- d. People aged 65 and over in the current seasonal flu vaccine clinical at risk groups

As more vaccine becomes available and in order to deliver the programme most efficiently, general practitioners may wish to invite those in the above groups at the same time.

Vaccines

The UK has purchased two different swine flu vaccines, Pandemrix (from GSK) and Celvapan (from Baxter). Both have been licensed for use by the European Commission. Information on the vaccines and their licenses are on the EMEA website (see www.emea.europa.eu)

Pandemrix, manufactured by GSK, is an adjuvanted inactivated vaccine. There are separate vials of adjuvant and antigen that need to be mixed in order to reconstitute the vaccine. The vaccine comes in multidose vials (10 0.5 ml doses per vial) and contains a preservative, thiomersal. Once reconstituted, the vial can be used for up to 24 hours. Each box of Pandemrix contains 500 doses.

Celvapan, manufactured by Baxter is an unadjuvanted inactivated vaccine. The vaccine comes in multidose vials (10 0.5ml doses per vial) and does not contain thiomersal. After first opening, the product should be used immediately. However, chemical and physical in use stability has been demonstrated for 3 hours at room temperature. Each box of Celvapan contains 200 doses.

To start with, Pandemrix vaccine only will be delivered to Trusts and GPs. In addition one box of Celvapan will be delivered to PCTs who will be responsible for making arrangements to vaccinate those few people for whom Pandemrix is not suitable (see section on contraindications below).

Trusts and general practitioners will be able to find out which day to expect delivery of their first supplies of vaccine by checking with their PCT immunisation co-ordinator or consulting <http://www.immform.dh.gov.uk>

Obtaining further supplies of Vaccine.

After the initial vaccine deliveries, PCTs can place online orders for delivery points within their PCT. The amount of vaccine PCTs can order will depend on stock availability.

The web site link is <http://www.immform.dh.gov.uk>

PCTs have provided details of users who will be responsible for ordering vaccine. These users have been provided with access to the web site. If further users are required, a request should be sent to vaccinesupplytechsupport@dh.gsi.gov.uk.

SHAs and PCTs have been reviewing the list of delivery points available to them on ImmForm to ensure it covers all the organisations PCTs will order vaccine for. PCTs will be responsible for ordering for organisations such as NHS Trusts as well as their practices.

How to login and place orders:

- PCT users should login to ImmForm using the address above and the login and password they have been given.
- The opening screen is the ImmForm homepage. Click on Vaccine Supply.
- This opens the Vaccine Supply Home Page. Click on Add New Bulk Order.
- Select the appropriate Swine Flu vaccine.
- Users can then select the appropriate PCT and enter order quantities.

Checking Order Status and Delivery Details:

- PCTs will receive email notification of orders they have placed.
- PCTs will have access to order delivery reports which provide full details of orders, including the scheduled delivery date.
- Delivery points that have been registered on ImmForm will receive an order confirmation email confirming the scheduled delivery date. Registered delivery points can also logon to ImmForm and view their full Order History.

Vaccine Schedule

Following advice from the Joint Committee on Vaccination and Immunisation, the following vaccination schedule is recommended in the UK:

Pandemrix (manufactured by GSK)

For all children aged from 6 months of age to less than 10 years of age,:

- Two half doses (0.25ml each) of Pandemrix should be given with a minimum of three weeks between doses.

For individuals aged from 10 years to less than 60 years of age:

- One dose (0.5ml) of Pandemrix.

For individuals aged 60 years and over

- One dose (0.5ml) of Pandemrix (this advice will be reviewed when more data become available).

For immunocompromised individuals aged 10 years and over

- Two doses (0.5ml each) of Pandemrix should be given with a minimum of three weeks between doses

Celvapan (manufactured by Baxter)

For children from 6 months of age and adults

- Two doses (0.5ml each) of Celvapan should be given with a minimum of three weeks between doses..

Vaccines for children and young people - JCVI confirmed its earlier advice that Pandemrix should be the vaccine of choice for children and young people up to 18 years of age. This is because currently there are no paediatric data available for Celvapan.

People who have had laboratory confirmed Influenza A(H1N1)v infection do not need to be vaccinated with swine flu vaccine. However, vaccine can be given to these individuals with no ill effects. In the absence of a laboratory confirmed diagnosis of Influenza A(H1N1)v infection, individuals should be vaccinated.

This dosage schedule is based on advice given by JCVI, following consideration of clinical data available on the vaccines. The dosage and recommendations will be kept under review as more clinical data become available

Vaccines in pregnancy

JCVI recommended that pregnant women should be given Pandemrix since a one-dose schedule with this vaccine appears to give adequate levels of antibodies and thereby confer more rapid protection than would be afforded by a two-dose schedule. Expert scientific advice is clear that thiomersal-containing vaccines do not present a risk to pregnant women or their offspring. More detailed advice will be in the new *Immunisation Against Infectious Diseases* (The Green Book) chapter on Swine Flu that will be issued shortly, to reinforce this point.

Contraindications

There are very few people who cannot receive swine flu vaccines. The vaccine should not be given to people who have had an anaphylactic reaction to the vaccine or a component of the vaccine.

Pandemrix should not be given to individuals, including children, with a history of severe anaphylactic reaction (shock or acute difficulty in breathing) after egg containing products; they should receive Celvapan.

Pandemrix should be given to individuals, including children, with less severe allergic reactions to egg.

Pandemrix and Celvapan can be co-administered with all other vaccines, including seasonal influenza and childhood vaccines.

Vaccine Storage

As with all vaccines, it is important that swine flu vaccines are distributed and stored between +2°C and +8°C. Under no circumstances should they be frozen. Vaccines should not be stored in direct sunlight.

Consumables

Sufficient needles and syringes to mix and administer the vaccine will be provided to Primary Care Trusts (PCTs) free of charge. Sufficient stocks will be delivered to PCTs, for onward distribution to general practitioners, in advance of the vaccine deliveries. No needles or syringes will be delivered direct to general practitioners.

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

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

Syringes

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. Each box of contains 200 fixed needle-syringes, and the size of the box is 130mm x 145mm x 414mm.

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 containing 100 syringes, and the size of the box is 68mm x 113mm x 375mm.

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 are: 88mm x 85mm x 112mm, and 93mm x 82mm x 113mm

Administration

Vaccines are routinely given intramuscularly into the upper arm of older children and adults. This is to reduce the risk of localised reactions, which are more common when the vaccine is given subcutaneously. For individuals with a bleeding disorder vaccines should be given by deep subcutaneous injection to reduce the risk of bleeding.

Multidose Vials 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, and other vaccine experts have developed a DVD on vaccine administration. This is available online at

www.dh.gov.uk/en/Publichealth/Flu/Swineflu/InformationandGuidance/index.htm,

and a DVD is currently in production for distribution to PCTs.

Vaccine wastage is likely to 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, if stored below 25°C, and preferably in a fridge. After first opening the Baxter product should be used immediately. However, chemical

and physical in use stability has been demonstrated for 3 hours at room temperature.

Repackaging packs of vaccine for onward distribution

In general, under the logistics arrangements for the distribution of vaccine, it should not be necessary to repack the bulk supply of vials into smaller quantities for onward distribution to vaccination points. Indeed PCTs should consider advising patients to attend a suitable vaccination point before deciding to repackage vials. However, if repackaging is deemed absolutely essential then it should be carried out by either licensed manufacturing sites (for example NHS hospital pharmacies with a "specials" Manufacturing Licence) under appropriate good manufacturing practice, or under professional pharmaceutical supervision. Further advice on this should be sought from hospital chief pharmacists. The NHS Pharmaceutical Quality Assurance Committee is preparing a protocol to support repackaging under pharmaceutical supervision. This will be made available to hospital and PCT chief pharmacists during the week commencing 19 October

Wholesale Dealers Licenses

Some NHS organisations, such as PCTs, may require Wholesale Dealers Licenses to support the procurement (ordering), storage or distribution of vaccine. This is being dealt with centrally by the Medicines and Healthcare Products Regulatory Agency and the Department of Health.

Consent

Consent must be obtained before administration of all vaccines. Further guidance is given in 'Immunisation Against Infectious Diseases 2006 (page 7 to 15) available at www.dh.gov.uk/greenbook. There are no legal requirements for consent to be in writing.

Health professionals involved in immunisation must ensure that:

- Parents/carers should have access to information on the swine flu vaccine
- That there is sufficient opportunity for them to discuss any issues arising
- And that they are properly informed of the benefits of the vaccines, the possible side effects and how to treat them.

Adverse Reactions

Monitoring vaccine safety is an important part of all vaccination programmes. Arrangements to report suspected adverse reaction to swine flu vaccines will be through the MHRA 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.

Data Collection

We are collecting weekly and monthly swine flu vaccine uptake data from general practices for the clinical priority groups via the ImmForm website, similar to the collection for seasonal flu. Both collections will run in parallel. The swine flu data collection will commence 2 November 2009. The clinical risk group READ codes specification and dataset are at www.dh.gov.uk/swinefluvaccinetools. PRIMIS+ are providing a swine flu library for their CHART tool for general practices (see www.primis.nhs.uk).

We are also collecting weekly uptake data for both seasonal and swine flu from all Trusts for frontline health care workers involved with direct patient care. This data collection will also start on 2 November 2009.

The health care worker (HCW) collection will be made from each NHS Trust (eg Acute, Mental Health and Ambulance), PCT and Care Trust. Each Trust will be responsible for providing their own data.

Each Trust will need to provide details of a data provider contact, as set out in the letter of 8 October 2009 on ordering and collecting uptake data for swine flu vaccine (Gateway 12638). The contacts will be registered on the ImmForm website and, once registered, will be able to access the on-line survey form. User guidance will be provided.

The collection will be weekly and run for up to 23 weeks, with the first collection commencing on the 2 November 2009 (for data up to the end of Sunday 1 November). Cumulative data will be collected each week up until the week ending Sunday 4 April 2010. The data will be for seasonal flu and Swine Flu vaccinations given from 1 September 2009.

The data are for the week ending each Sunday during the collection period. The surveys will be open for data collection the following Monday. Data must be submitted by midnight each Tuesday. Strategic Health Authorities (SHAs) and the Health Protection Agency (HPA) will have one day to check and quality assure the data and amend as appropriate. Data will be considered as available for 'publication' each Thursday.

Information Resources

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>

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 close to completion. 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.nhscommslink.nhs.uk/public/default.aspx> for local use. It will be important that we give the public consistent messages on the new vaccine to avoid confusion. We would therefore advise PCTs not to develop their own materials until the final nationally agreed set of materials 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.

Vaccination programme start date

The earliest possible delivery date of the first supplies of vaccine to the NHS Acute Trusts is from **Wednesday 21st October**. These supplies can be used for protecting frontline staff and patients in the at-risk groups in hospital. The number of boxes of Pandemrix vaccine sent to each Acute Trust will vary according to its size and number of staff.

The earliest possible delivery date of the first supplies of vaccine to general practices is from Monday 26th October. It will take around 3-4 weeks to complete the distribution of first supplies to all general practices. Each practice will receive one box of Pandemrix vaccine initially.

A supply of Pandemrix vaccine will be sent to every Primary Care Trust (PCT), Ambulance Trust and Mental Health Trust, in the week beginning 26 October. A stock of Celvapan vaccine will also be sent to PCTs in the week beginning 26 October. After this date PCTs and Acute Trusts will be able to order additional supplies of vaccine subject to supply from manufacturers.

Funding and Service Arrangements

The vaccines will be made available and distributed to the NHS users free of charge.

Following successful negotiations between the Department of Health, General Practitioners Committee (GPC) of the British Medical Association (BMA and NHS Employers, the vaccination of the clinical risk groups will be administered by general practitioners. The new deal will mean that general surgeries will receive £5.25 per dose of vaccine given. It will help surgeries to contact patients, administer the vaccine and, if necessary, take on extra staff.

The Department of Health will transfer appropriate funding to SHA / PCT budgets for the general practitioners administration costs of the swine flu vaccination programme to priority groups.

SHAs and PCTs are familiar with arrangements for paying general practitioners for the delivery of services and appropriate arrangements for swine flu vaccination payments will be made locally under a national Directed Enhanced Service (DES).