Dear Colleagues

2009-10 Pandemic influenza A H1N1v(2009) swine flu vaccination programme

1. This letter provides information that will assist you in further planning for the Pandemic influenza A H1N1v (2009) swine flu vaccination programme. It follows the information provided in CMO Letter (2009) 13 issued on 20 August 2009 – see: http://wales.gov.uk/topics/health/ocmo/publications/cmo/cm09/?lang=en

2. We are preparing for a possible surge in swine flu cases in the autumn or winter that could affect large numbers of people and put 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.

3. We are dealing with a number of uncertainties such as the number of doses needed for best protection and also when we will have vaccines from the manufacturers. This means that we are unable to provide you with full guidance yet. Seasonal flu vaccinations should therefore not be delayed until supplies of swine flu vaccines are available.

4. There is still much that can be taken forward and this letter aims to give you as much information as possible and to provide clarity about our vaccination strategy. This should help you with local planning.

5. The European Commission (EC) has granted a marketing authorisation to GlaxoSmithKline (GSK) for its Pandemrix vaccine and the European Medicines Agency (EMEA) has recommended Baxter’s Celvapan vaccine to the European Commission.

From the Chief Medical Officer
6. You will be aware that agreement has been reached between the four UK health departments and the General Practitioner Committee (GPC) for the vaccination of those people identified as being at increased risk of the disease. This agreement puts us in the best possible position to deliver the swine flu vaccination programme. It builds on the established model of flu vaccination delivery and draws on the experience and expertise of our GP practices, alongside the district nurse community who will vaccinate the housebound. The Minister’s statement on the agreement is available at:


7. The price agreed with the GPC 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 Vaccination & Immunisation (JCVI). A single price per dose of £5.25 provides a simple and transparent way of remunerating GP practices while encouraging high levels of uptake. Each Health Board will be responsible for encouraging the participation of their own staff, such as district nurses, in the vaccination programme.

8. Since the vast majority of supplies we are expecting are due from GSK, it is excellent news that the vaccine has been licensed. We expect the Baxter product to be licensed shortly. The supply details in this letter therefore relate at present only to the GSK vaccine.

9. Health Boards (HBs) 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 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 minimised. Social care providers will also be expected to make arrangements for frontline social care workers to receive the vaccine. The vaccine itself will be provided free of charge.

10. While vaccination is optional, frontline staff will be at increased risk of infection and of transmitting it to vulnerable patients. The vaccination will protect staff members from infection, minimise spread and reduce the risk to vulnerable patients.

11. Medical and Nursing Directors, GPs and Heads of Profession are encouraged to take a visible leadership role across their organisation to ensure that frontline staff are as protected as possible.

12. Arrangements to report suspected adverse reaction to swine flu vaccines will be the same as for oseltamivir (Tamiflu) and zanamivir (Relenza) antivirals. The Medicines & Healthcare Products Regulatory Agency (MHRA) has put in place a special web based reporting system based on the Yellow Card scheme – the Swine flu ADR Portal – see: www.mhra.gov.uk/swineflu

13. Most vaccinations are given without any trouble at all but very rarely there may be complications. Starting from 10 October, Influenza A H1N1(2009) 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 that manages the Scheme – see: www.dwp.gov.uk
14. Detailed information about the particulars of the vaccine programme is provided in the Annexes to this letter. As soon as more information is available, I will share this with you.

15. We must prepare as best we can for the likely rise in swine flu cases during the coming months. The vaccine is the best defence we will have against the H1N1v (2009) swine virus and the success of the vaccination programme depends on ensuring that our most vulnerable people, and the people who work on the frontline caring for them, are vaccinated as soon as it becomes available. I know that everyone at the local level is working hard on the necessary preparations and extend my thanks to each of you personally.

Dr Tony Jewell
Chief Medical Officer
Recommendations for use of the vaccine

A1. Confirmation of the priority groups for vaccination was given in CMO Letter (2009) 13 issued on 20 August 2009. This advised that the JCVI was continuing to review the situation and consider other issues such as advice for all people aged 65 years and over and healthy children.

Prioritisation

A2. Following advice from independent expert committees, including the JCVI, the following groups should be prioritised for vaccination in the following order once the vaccine has been licensed:

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

The Ministerial Letter on the 2009-10 seasonal flu programme is available at:


A3. The full statement from JCVI is available at:

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

Pregnant women

A4. The JCVI have recommended the vaccination of all pregnant women because of the increased risk of severe disease in this group. Further guidance will be provided when the licensing indications are known. Evidence suggests that pregnant women are four times more likely than the general population to develop serious complications following infection with the H1N1 virus.

A5. The licensing recommendations for the GSK vaccine allow use in pregnancy. There is no evidence of risk to the mother or the baby from vaccinating women with inactivated virus vaccines when they are pregnant or breast-feeding.

Children aged from 6 months to 3 years of age

A6. 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. These recommendations should be reflected in local protocols and Patient Group Directions (PGDs).
Vaccination of frontline health and social care workers (HCWs & SCWs)

A7. My earlier letter explained that frontline HCWs & SCWs would be offered the swine flu vaccine because they 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 letter that is available at:

http://wales.gov.uk/topics/health/ocmo/publications/cmo/cmo09/?lang=en

A8. This is a risk-based approach. Following the above guidance, those frontline staff who have regular clinical contact with patients and who are directly involved in patient care will be eligible for the vaccine. The local risk assessment should consider the appropriateness of including community pharmacists, dentists, optometrists and their staff.

A9. Employers are responsible for organising the vaccination of frontline HCWs & SCWs through existing occupational health arrangements or by establishing new local arrangements. The agreement reached with GPC was in respect of payments to GP practices for the vaccination of those people in the priority groups recommended by the JCVI (see A2. above). GPs will therefore need to make arrangements for vaccination of themselves and their staff. Health Boards should not charge local authorities and the independent sectors for the support provided by NHS vaccinators where normal occupational health arrangements or opportunities to enhance capacity are unlikely to meet demand.

A10. Uptake of seasonal flu vaccine by HCWs has tended to be very low in the past. Arrangements should be developed locally to increase uptake of swine flu vaccine in frontline HCWs & SCWs. These plans will need to make access to the vaccine as easy as possible. Any perceived barriers to vaccination must be considered and minimised.
The vaccines

B1. The GSK vaccine (Pandemrix) is a split virion, inactivated, adjuvanted vaccine. It is a monovalent vaccine containing 3.75 micrograms 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.

B2. The Baxter vaccine (provisional brand name Celvapan) is a whole virion, inactivated, vero cell derived vaccine containing 7.5 micrograms of antigen. The antigen used 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 and is not propagated in fertilised hens’ eggs. The EMEA is currently considering further information from the company and has not yet issued a positive opinion on the vaccine.

Product Dimensions

GSK Vaccine (Pandemrix)

B3. Pandemrix vaccine will be presented in a pack containing one box of 50 multi-dose vials of 2.5ml suspension and two smaller boxes of 25 x 2.5ml vials of adjuvant. Each 5.0ml of reconstituted vaccine should provide 10 doses. Each box should provide 500 doses.

B4. The pack size is 260mm x 113mm x 97mm. This is about the size of a small shoe box.

Baxter Vaccine (provisional brand name Celvapan)

B5. Celvapan vaccine will be presented in a pack of 20 multi-dose vials of 5ml suspension per pack. Each 5ml vial should provide 10 doses, with each pack providing 200 doses.

B6. The pack size is 206mm x 166mm x 55mm.

Contraindications

B7. JCVI has advised that individuals with a confirmed history of an anaphylactic reaction to egg, which is a very rare condition, should not be offered the GSK vaccine (Pandemrix). Individuals with a confirmed anaphylactic reaction to egg should be offered the Baxter vaccine when it is available.

B8. A new Green Book chapter on pandemic influenza is being drafted and will reflect JCVI advice. It will be available at:


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.

B9. The following information on the GSK Pandemrix vaccine has been recommended by EMEA’s Committee for Medicinal Products for Human Use (CHMP):

The Summary of Product Characteristics (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

B10. The full Summary of Product Characteristics can be viewed at:


B11. More information on the Baxter vaccine is available from the SPC for the ‘mock-up’ H5N1 vaccine (upon which the pandemic vaccine is based). The SPC lists the following contraindications and precautions for use:
**Baxter vaccine (Celvapan)**

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 administrating 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

B12. The full Summary of Product Characteristics can be viewed at:


(Click on the ‘en’ option for the English version of the documents)

**Vaccine doses needed to give protection**

B13. EMEA’s CHMP has recommended a two dose vaccination schedule with a 3 week interval in all age groups from the age of 6 months. For those aged from 6 months to 9 years of age, 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 from 10 to 60 years old. The Agency is expecting further data from ongoing clinical studies over the coming months and these recommendations may be updated. These dosage recommendations, and license, have yet to be agreed by the EC. Further advice is being sought on the dosing schedule from the JCVI and will be shared as soon as it is available.

B14. Early data from the clinical trials from GSK indicate that the immune response to one dose of vaccine in healthy adults may be sufficient. The European regulator, the EMEA, will consider whether the evidence is sufficient to make any recommendations in relation to whether just one dose might be sufficient in some individuals e.g. healthy adults. The amount of available data is limited at present and there is no information from these new studies in relation to older people or children.

**Swine flu vaccines and Guillain-Barré syndrome (GBS)**

B15. 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).

B16. In 1976, 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 increased risk of GBS (Stowe et al., 2009).

B17. 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.


Thiomersal

B18. The GSK vaccine (Pandemrix) contains very low levels of thiomersal, a preservative that contains mercury. The presence of thiomersal permits use of the reconstituted vials for up to 24 hours.

B19. 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 neuro-developmental 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

B20. 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.

B21. The GSK vaccine does not contain porcine products.

B22. Previous advice regarding Faith communities and vaccines containing porcine products can be accessed at:

http://www.immunisation.nhs.uk/Library/Search?stags=&terms=porcine
Programme implementation and logistics

Vaccine Supply

C1. Previously, HBs have designated 16 delivery points for vaccines. These will be the only points that will receive vaccines for distribution within the area.

C2. We are waiting for vaccine supply information from GSK and will then be able to provide information about the forecast delivery timetable and initial supplies. The amounts will be based on the amount of the vaccines available and be proportional to the population size of the HB. Distribution will not begin to individual delivery points until they have confirmed they are ready to receive them. These initial supplies will enable HBs to commence their vaccinations.

Needles and Syringes

C3. Sufficient needles and syringes to mix and administer the vaccine will be provided to HBs free of charge and WAG’s Health Emergency Preparedness Unit are leading on supply issues with HB stock managers. Sufficient stocks will be delivered to HBs for onward distribution to GP practices in advance of the vaccine deliveries. No needles or syringes will be delivered direct to GP practices.

Size of syringe boxes

C4. For the administration of both the Baxter and the GSK vaccines a dose-sparing, orange, 25g, 25mm (1.0”) fixed needle 1ml syringe is needed. These will be supplied in boxes (130mm x 145mm x 414mm in mm). There are 200 fixed needle-syringes per pack. For further information on needles for administration see: https://register.livegroup.co.uk/Uploads/Event_184/Downloads/9249%20Practical%20Aspects%20of%20Vaccination%20for%20Website.ppt

C5. For the GSK vaccine, a 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. This is for single use only i.e. to draw up the content of one adjuvant vial and inject it into one antigen suspension vial only. The empty syringe and needle are then to be disposed of in a sharps bin. More information about the process will be provided to vaccinators in the training DVD. These will be supplied in boxes (68mm x 113mm x 375mm in mm). There are 100 syringes per pack.

Size of needles boxes

C6. A green, 21g, 38mm (1.5”) needle is needed for mixing the GSK vaccine. There are two manufacturers of this needle, both of which supply 100 needles per box. The dimensions of the boxes are 88 x 85 x 112 and 93 x 82 x 113

Administration and wastage

C7. Many staff will not be used to using multi-dose vials or the above fixed needle syringes. In order to assist training, DH, the Health Protection Agency, the Royal College of Nursing and vaccine experts have led the development of a DVD on vaccine administration that will be a useful training resource for competent vaccinators. Copies will be supplied to the service but there are several issues yet to
be resolved. As an interim measure, a draft version will be available on the DH website. We will advise about access arrangements separately.

C8. Vaccine wastage may be greater when using multi-dose vials rather than single doses. Local planning should take into account the need to reduce wastage.

C9. 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.

DES arrangements

C10. NHS Employers and the GPC have reached an agreement on payments to support the vaccination of people in the clinical risk groups. A DES that is being drafted will provide GP practices with a payment of £5.25 per dose.

Data Recording

C11. New READ codes will be published by Connecting for Health via the TRUD website for download:

http://www.uktcregistration.nss.cfh.nhs.uk/trud/

and there will two new product/drug codes for the respective vaccines. There will also be new procedure codes that will differentiate between doses 1 or 2 and brand of vaccine given. 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 about the codes to use is being prepared and will be issued in due course.

Data Collection

GP practice based collection

C12. A dedicated swine flu vaccination module within Audit+ will shortly be made available to practices as part of the Assembly’s Data Quality Service (DQS). As with seasonal flu vaccine audit, this module will support practices in identifying patients at risk and managing the vaccination programme. Health Boards will need to ensure that those practices not participating in Audit+ make arrangements to submit the necessary data electronically by other means.

C13. In addition, this module will provide an automated weekly data submission of vaccination uptake rates to the DQS central reporting system, AuditWeb. Dedicated reports within AuditWeb will subsequently provide the Assembly and the NPHS with uptake rates for each risk group as defined by PRIMIS+ in England. This alignment to the PRIMIS+ definitions of risk groups will enable cross border comparison of risk groups and uptake rates.

C14. GP practices are reminded that vaccinations of those under the age of 18 years must be reported to the local Child Health Department using unscheduled forms or printed lists from the GP computer listing name, DoB, address, gender, NHS number, vaccine type, first or second dose, date given et as appropriate.

Health and social care workers data collection
C15. The National Public Health Service (NPHS) are liaising with hospital Occupational Health Departments (OHDs) to collect information on vaccines given to healthcare workers. The NPHS will provide OHDs with tally sheets on which to record vaccinations given. These are to be returned electronically on a monthly basis. Further information is available from Simon Cottrell:

    simon.cottrell@nphs.wales.nhs.uk

C16. The NPHS will provide with a template form to report vaccines given to health and social care workers outside of OHDs.

C17. Health Boards will need to ensure that those OHDs not participating in the NPHS system make other arrangements to submit the necessary data electronically by other means.

C18. We recognise that resources will be needed 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 vaccination programme.
Communication materials

D1. Materials for health professionals include the Green book chapter, Factsheet, 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.

D2. These materials will be finalised once we have full information about the use of the vaccines. As an interim measure, they will be available in draft at:

www.wales.gov.uk/swineflu

Publicity campaign

D3. UK 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.

D4. We will confirm when the first phase of the campaign will commence but it is expected that it will commence at the start of the delivery stage of the vaccination programme. It will explain that those being offered vaccination will receive an appointment from their GP practice.

D5. The national campaign materials and plans will be made available 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 all HBs to utilise the UK agreed materials when they have been published.

D6. 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.

NHS staff engagement campaign

D7. We are working with the other UK health departments 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.

D8. The strategy will set out the rationale behind prioritising staff for the vaccine, providing clear benefits in terms of patient care, while providing content about the vaccine and ensuring staff know when and where to receive it.

D9. At the UK level, a range of media to communicate messages, including the trade press, stakeholder bulletins and websites will be used. 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.

D10. Materials are in production for local communications leads to adapt and use locally.
D11. 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.

DH Immunisation leads conferences

D12. To assist with planning, DH held two swine flu conferences that NPHS and service immunisation leads attended:

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

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

Slides from the conference 10/09/2009 are available via this link:

http://www.immunisation.nhs.uk/Professional_information/Events/Event/PandemicFlu_conference_Sept09