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The Scottish Government

From the Chief Medical Officer
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21 October 2009

SGHD/CMO(2009)12

For action
Chief Executives, NHS Boards
General Practitioners
Practice Nurses
District Nurses
Health Visitors
Directors of Pharmacy
Immunisation Co-ordinators
CPHMs
Directors of Public Health
Medical Directors, NHS
Nurse Directors
Boards (for distribution to GP Practices)
Scottish Prison Service
Scottish Ambulance Service
Directors of Occupational Health
Community Pharmacists

For information
NHS Boards
Specialists in Pharmaceutical Public Health
Infectious Disease Consultants
Consultant Paediatricians
Consultant Physicians
Health Protection Scotland
Chief Executive, NHS Health Scotland
NHS 24
Directors of Human Resources
H1N1 Vaccination Programme Strategic and Operational Leads
COSLA
ADES
Scottish Care
Care Commission
SCG Coordinators
RCN
RCM
CPHVA

Dear Colleague

LAUNCH DATE FOR THE INFLUENZA A (H1N1) VACCINATION PROGRAMME 2009-2010 AND ADDITIONAL DETAILS ON VACCINE DOSAGE

INTRODUCTION

1. The purpose of this letter is to provide details of the Influenza A (H1N1) vaccination programme, including the launch dates and dosage schedule.

2. 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 and emergency health care services which are likely to come under heavy pressure during the months ahead.

3. The second wave of the A(H1N1) pandemic is under way. Current figures suggest that so far the virus is spreading more slowly than could have been the case. This is good news and gives added importance to our work to get the vaccine to as many people as we can as soon as we can.

Launch of vaccination programme in Health Boards

4. The first batch of the licensed vaccine has now been received in Scotland. In the initial stages of the programme vaccine supplies will be limited. NHS Boards should commence the programme from 21 October with priority being given initially to healthcare staff working in A&E, general medicine, intensive care, paediatrics and obstetrics, and following consultation with clinicians, patients in the clinical at risk groups in these specialities.

Launch of vaccination programme in GP Practices

5. Subject to reliable delivery of vaccine to Scotland the earliest possible date for the first supplies of vaccine to be issued to general practices is from week commencing Monday 26 October 2009. Supplies will be limited at the outset. All territorial NHS Boards should ensure that from the second delivery onwards, each general practice in their area receives a share of the available vaccine (on a pro rata basis to be determined by Boards) to allow individuals with the highest priority for vaccination to receive the vaccine as soon as possible.

6. GPs will be given as much notice as possible from Boards of the amount of vaccine they can expect to receive in the following week. As this is completely dependent on ongoing deliveries from the manufacturers it is unlikely that more than 1 weeks notice can be given. We recognise the challenges that this will present and would ask that GPs therefore check with local Board planners before they organise clinics.

Clinical priority groups

7. The clinical priority groups were identified by the Joint Committee for Vaccination and Immunisation (JCVI) and communicated in our letter of 6 October. They are prioritised as they are at greatest risk of complications if they become infected with H1N1, 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; and
d. People aged 65 and over in the current seasonal flu vaccine clinical at risk groups.

Further Enquiries:

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8. Please find attached a template letter at **Annex A** which GPs can adapt for use by their practice to invite patients for vaccination. A Q&A section is included in the letter which provides patients with initial information about the vaccination. However, GPs may wish to include a Public Information Leaflet with the letter once these are received by their practice. A pack of information materials will be issued to each practice containing 500 information leaflets, 8 information posters and 500 vaccination record cards. We expect deliveries of these materials to commence very soon. GPs will be able to order further supplies if needed and details of how to do this will be included in a letter accompanying the pack of materials.

Vaccines

9. The UK has purchased two different A(H1N1) vaccines, Pandemrix (from GSK) and Celvapan (from Baxter). Both have been licensed for use by the European Commission. Information on the vaccines and their licences can be found on the Medicines and Healthcare products Regulatory Agency website (see http://www.mhra.gov.uk).

10. Pandemrix, manufactured by GSK, is a split virion, inactivated, adjuvanted vaccine that is grown in hen's eggs. There are separate vials of adjuvant and antigen that need to be mixed together prior to administration of the vaccine. The vaccine comes in multidose vials (10 x 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.

11. Celvapan, manufactured by Baxter is whole virion, inactivated vaccine that does not contain an adjuvant. The vaccine comes in multidose vials (10 x 0.5ml doses per vial) and does not contain thiomersal. The vial must be used within 3 hours of removal from the fridge. Each box of Celvapan contains 200 doses.

12. Initial deliveries of vaccine will consist of Pandemrix only. As Celvapan becomes available, arrangements for distribution will be confirmed. Celvapan should be used to vaccinate those few people for whom Pandemrix is not suitable (see section on contraindications below).

Vaccine schedule

13. Following advice from the Joint Committee on Vaccination and Immunisation (JCVI) on 8 October, the following vaccination schedule is recommended in Scotland for the above clinical risk groups, and for frontline health and social care workers:

Pandemrix® (manufactured by GSK)

For all children aged from 6 months of age to less than 10 years of age (9 years, 364 days):

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

For immunocompromised individuals aged 10 years and over:

- Two doses (0.5ml) 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 (59 years, 364 days):

- 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).

Celvapan® (manufactured by Baxter)

For children from 6 months of age and adults:

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

Vaccines for children and young people

14. 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®.

15. People who have had laboratory confirmed influenza A(H1N1)v infection do not need to be vaccinated with A (H1N1) 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.

16. This dosage schedule is based on advice given by JCVI, following consideration of clinical data available on the vaccines. The need for a second dose of vaccine in individuals aged 60 years and above will be kept under review as more clinical data become available.

Pregnant Women

17. JCVI recommended that pregnant women should be given Pandemrix®. This vaccine is now available; it is licensed for use in pregnancy; and provides adequate levels of antibodies following administration of one dose, thereby conferring more rapid protection than a two-dose schedule. Expert scientific advice is clear that vaccines containing thiomersal do not present a risk to pregnant women or their offspring. More detailed advice is included in the new Immunisation Against Infectious Diseases (The Green Book) chapter on Pandemic Influenza A(H1N1)V**.** This is available via the website on www.healthscotland.com/H1N1vaccination.

Contraindications and co-administration

18. There are very few people who cannot receive A(H1N1) vaccines. The vaccine should not be given to people who have had an anaphylactic reaction to a 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.

Administration

19. 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 Pack Splitting, Wastage and Storage

20. Vaccine Holding Centres will require to split some packs of vaccine in order to provide GP practices and other sites where vaccination may take place with an appropriate quantity based on their practice list size. This must 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. In order to assist with this the UK NHS Quality Assurance Committee has developed a protocol for splitting of the vaccine packs. A copy of this is attached at **Annex B**.

21. In addition, the MHRA has issued a statement to support health care professionals who are administering the vaccines confirming that for the purposes of Patient Group Directions (PGDs), the supply and administration of vaccines in smaller packs produced by the splitting of the original authorised packs of H1N1v pandemic influenza vaccines Celvapan® and Pandemrix® will be deemed, for the duration of the WHO declared pandemic, to be equivalent to vaccines in the original packs as placed on the market by the holders of the marketing authorisations.

22. The vaccine is supplied in multi-dose vials and should be given using the fixed needle syringes provided for this programme. These are specially designed to reduce vaccine wastage. For training purposes, a DVD has been developed centrally on vaccine administration. This is available via the website on www.healthscotland.com/H1N1vaccination.

23. 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.

24. As with all vaccines, it is important that A(H1N1) vaccines are distributed and stored between +2^{O}C and 8^{O}C. Under no circumstances should they be frozen. Vaccines should not be stored in direct sunlight. It is important that GP practices maintain the cold chain requirements associated with these vaccines.

25. The GSK vaccine can be used for a period of up to 24 hours after reconstitution if stored below 25^{O}C, preferably stored 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.

26. Where practices are in receipt of split packs of the GSK vaccine, as opposed to complete packs, they must store the vials of antigen and adjuvant in the packaging they received it in. This will ensure that the correct batch of antigen and adjuvant are administered at the same time.

Consent

27. Informed 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 written consent for vaccinations given in general practice.

Health professionals involved in immunisation must ensure that:

- parents/carers should have access to information on the A(H1N1) 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

28. Monitoring vaccine safety is an important part of all vaccination programmes. Arrangements to report suspected adverse reaction to A(H1N1) 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.

Vaccine Damage Payments Scheme

29. Most vaccinations are given without any trouble at all, but very rarely there may be problems. Starting from 10 October, A(H1N1) 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 A(H1N1) vaccines. More information can be obtained from the website of the Department for Works and Pensions (www.dwp.gov.uk) that manages the scheme.

Patient Information Leaflet (PILs)

30. The Patient Information Leaflet (PILs) are currently being printed. In the interim PILs should be downloaded via the following Web address www.mhra.gov.uk/swineflu. Health Boards/GPs should ensure they have an adequate supply to cover the number of vaccines they administer. Hard copies of the PILs will be supplied immediately they become available.

Communications

31. Materials for health professionals including a new Immunisation Green Book chapter, fact sheet, Q&A, DVD, slideset and Patient Group Directive (PGD) template have been developed and these are available on the Health Scotland website at www.healthscotland.com/H1N1vaccination.

Publicity campaign

32. A UK advertising publicity campaign for H1N1 is in the final stages of development. The campaign will seek to raise awareness and encourage the public, particularly those in the initial priority groups, to ensure they are vaccinated against H1N1. This is likely to include publicity via media channels and PR commencing from 9 November. Further details will be provided to your Health Board shortly.

Funding Arrangements

33. Following negotiations between NHS Employers, on behalf of the 4 UK Health Departments, and the General Practitioners Committee (GPC) of the British Medical Association, the vaccination of the clinical risk groups will be managed by general practitioners.

34. The Board is familiar with arrangements for paying general practitioners for the delivery of services and appropriate arrangements for A(H1N1) vaccination payments will be made under a Directed Enhanced Service (DES). This will be issued formally to Boards within the next few days.

CONCLUSION

35. I would like to thank you for all your efforts in planning for this vaccination programme against considerable time pressures. As previously mentioned in this letter, vaccination provides true primary prevention of disease and is perhaps the most effective weapon at our disposal in the fight against H1N1. This vaccination programme for patients and staff in the identified categories will help to reduce the impact of H1N1 on mortality, morbidity and service pressures in Scotland. It is our individual and collective responsibility to take every opportunity to protect ourselves and our patients from the impact of this pandemic. Your full participation and support in delivering this vaccination programme is vital and is greatly appreciated.

Yours sincerely

Harry Burns	*Margaret McGuire*	*Bill Scott*
Dr Harry Burns **Chief Medical Officer**	**Dr Margaret McGuire** **Acting Chief Nursing Officer**	**Professor Bill Scott** **Chief Pharmaceutical Officer**

ANNEX A

Patient's name & surname
Patients Address

Date

Dear <Title & Surname>

Invitation for H1N1/Swine flu vaccination

I would like to invite you to have a vaccination against the H1N1/swine flu virus. Swine flu is a respiratory disease caused by a new strain of influenza. The symptoms are similar to those caused by seasonal flu viruses - sudden onset of fever, tiredness, cough and sore throat, but they can vary in their degree of severity. Swine flu is highly contagious and is easily spread by a cough or a sneeze. A vaccine against the virus is now available and vaccination is a very good way of protecting yourself and those close to you by preventing the further spread of the virus.

For more information about the vaccination see the information overleaf or call the NHS 24 vaccination information line on 08000 282 816.

As our current medical records show that you may be at an increased risk of against the virus, I strongly recommend that you have the vaccine. Depending on your personal circumstances, and which of the two swine flu vaccines you are given, you may require one or two doses. Your GP will tell you whether you need to make a follow-up appointment for a second dose.

Please contact us now on <telephone number> to make an appointment. If you have already made an appointment with the doctor, or you have received your swine flu vaccination already, please ignore this letter.

Yours sincerely

Swine flu and the swine flu vaccination

What is swine flu?

It is a respiratory disease caused by a new strain of influenza virus. The symptoms of swine flu are very similar to those caused by seasonal flu. Swine flu is generally a mild infection that comes on quickly and lasts for about a week. It causes fever, tiredness, cough and sore throat. Other symptoms may include headache, aching muscles, chills, sneezing, runny nose, loss of appetite, vomiting or diarrhoea.

However, for a very small number of healthy people, and for those with underlying health conditions; who are pregnant; or who are having medical treatment such as chemotherapy, these symptoms can lead to very serious complications and even death.

Who is being offered the swine flu vaccination?

The vaccine is being offered firstly to people who are most likely to become seriously ill if they catch swine flu. These people are in the following groups:

- Adults and children over six months of age who have a long-term health condition and normally receive the seasonal flu vaccine;
- Pregnant women at any stage of pregnancy; and
- People who live in the same house as someone whose immune system is compromised by disease or treatment.

In order to gain adequate protection, you may require two doses depending on your personal circumstances. Your GP will advise you whether you will need a follow up appointment.

If you have a severely compromised immune system, ask the people you live with to also think about getting the vaccination to help protect you from swine flu.

Will my regular seasonal flu vaccination protect me against swine flu?

No. Seasonal flu and swine flu are caused by different flu viruses. The seasonal flu vaccine does not protect against swine flu. If you usually have the seasonal flu vaccine, you should have the swine flu vaccine also.

Will there be any side effects?

All vaccinations can produce side effects such as redness, soreness and swelling at the site of the injection. Flu vaccines can cause symptoms like fever, headache and muscle aches, but they are much milder than the flu itself and only last a day or so. This vaccine is not live so cannot cause flu.

How can we be sure these new vaccines are safe and effective?

Pandemrix and Celvapan are both licensed vaccines. Similar vaccines containing another flu virus strain (H5N1) have been clinically tested in trials involving over 5,000 people including older people. When they licensed the vaccines, the European Commission carefully considered all the evidence and recommended that they could be used.

Is the vaccine safe for pregnant women?

The European Medicines Agency has said that both new vaccines can be given to pregnant women. Pregnant women are recommended to have the swine flu vaccine because they are at greater risk of being seriously ill with swine flu. They also have a higher risk of needing to go to hospital if they catch swine flu. These risks increase during later stages of the pregnancy.

If you are about to give birth, having the swine flu vaccine could help avoid catching swine flu and then passing it to your baby.

Please speak to your GP or midwife if you have any further questions.

Further Questions

If you have any further questions relating to having this vaccination please talk to your GP.

For general information on the swine flu vaccination, please contact the Scottish Swine Flu Vaccination Helpline on 08000 282 816.

ANNEX B

NHS Pharmaceutical Quality Assurance Service

Safe Handling Standard Operating Procedure for the Repackaging of Bulk Packs of H1N1 Influenza Vaccines under the Supervision of a Pharmacist.

1. Introduction

1.1. This procedure gives general direction on the safe repackaging of bulk packs of H1N1 Influenza Vaccines into smaller units for onward distribution to GP practices, Health Centres and other similar sites.

1.2. Supplies in the UK are composed of 2 vaccines:

Pandemrix is produced by GSK and will be supplied in bulk packs containing one inner box of 50 x 5ml multi-dose vials, each containing 2.5ml of antigen suspension, and 2 inner boxes each containing 25 x 2.5ml vials of adjuvant emulsion. The adjuvant emulsion is mixed with the vaccine antigen prior to administration to produce 10 x 0.5ml doses of adjuvanated vaccine.

Celvapan is produced by Baxter and will be supplied in bulk packs of 20 x 5ml multi-dose vials each containing 10 x 0.5ml doses. No adjuvant vials are required.

1.3. Both products must be stored between 2°C and 8°C.

1.4. During the repackaging process, maintenance of the cold chain is critical. Caution is advised when considering the number of items that can be safely repackaged in one run. It is important to design the process so that vaccine vials do not remain exposed to ambient temperatures any longer than necessary.

1.5. Comprehensive written records must be kept for each repackaging session, and must be at hand throughout the process in order that entries may be made in real time. Critical information to be included within the records is detailed in the following sections.

1.6. The process must be performed under the supervision of a pharmacist. A pharmacist must perform the final check and release of the repackaged product for use.

2. Assembly Of Materials

2.1. All assembly and repackaging activities must take place in a designated area clear from other activities and materials at the time of repackaging. This should be checked and recorded in the repackaging records.

2.2. All staff involved in the repackaging process should maintain good standards of personal hygiene at all times. Strict hand hygiene procedures must be followed.

2.3. Assign each repackaging run a unique reference and document this in the repackaging records.

2.4. All entries in records should be clear, legible and in indelible ink. Initials of staff performing critical checks should be recorded. Alterations must be endorsed and must not obscure the original entry.

2.5. Generate sufficient labels for the repackaged items and two extra labels for the records. The labels must reproduce all information on the manufacturer's original outer, as required by current labelling regulations, with the following exceptions:

2.5.1. Replace the manufacturer's name and address with the name and address of the repackaging pharmacy.

2.5.2. Omit the product licence/marketing authorisation information, and any pictograms.

2.5.3. Include the unique repackaging reference.

2.6. Record the number of labels generated. Affix examples of the first and last labels generated to the repackaging records.

2.7. Check all labels generated for errors and print quality. Destroy any damaged or incorrect labels. Document these checks in the repackaging records.

2.8. Assemble and prepare the correct number of cartons/outers of the appropriate size.

2.9. Assemble appropriate numbers (1 per dose) of the correct Patient Information Leaflets for each vaccine (and other technical leaflets). Record the number issued for later reconciliation. Only the current version of leaflets must be available to repackaging staff. Attach examples of leaflets used to the repackaging records.

2.10. At the last possible moment, remove the appropriate number of bulk packs from the refrigerator and extract all vials as quickly as possible. Record the time the bulk packs are removed from the refrigerator in the repackaging records. Avoid excessive handling of the vials.

2.11. Document the number of vials, batch number(s) and expiry date(s) in the repackaging records.

2.12. Check that the correct vials and labels have been assembled and check them for physical defects and errors. Document these checks in the repackaging records.

3. Repackaging and Labelling

3.1. Immediately proceed to pack the number of vials required into the new outers, along with the correct number of each type of information leaflet.

3.2. Physically segregate the newly filled outers from the empty outers.

3.3. Neatly apply the previously printed labels to the filled outers. Physically segregate the labelled outers from the unlabelled outers.

3.4. Once repackaging and labelling is completed, perform a reconciliation check of all vials, labels and information leaflets. Document this check in the repackaging records.

3.5. Tidy and clean the repackaging area. Once satisfied that the area has been cleared and all materials are accounted for, document this in the repackaging records.

4. Release

4.1. A pharmacist must perform the final check and release of the repackaged product and associated documentation. The release must be undertaken prior to the repackaged material being returned to the refrigerator and must therefore be performed in a timely manner.

4.2. Document in the repackaging records the time that the repackaged material is to be returned to the refrigerator. A check that the cold chain has been maintained must be included by the pharmacist as part of the release process.

4.3. The pharmacist must document the release in the repackaging records.