

From the Chief Medical Officer
Dr Michael McBride



Department of
**Health, Social Services
and Public Safety**

www.dhsspsni.gov.uk

URGENT COMMUNICATION

HSS(MD)47/2009

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Care Board/ HSC Trusts/NIAS
Director of Public Health, Public Health Agency
Assistant Director Health Protection, Public Health Agency (*for
onward distribution to all health protection staff*)
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Board/Trusts
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Family Practitioner Service Leads, Health & Social Care
Board
GP Medical Advisers, Health & Social Care Board
All General Practitioners and GP Locums (*for onward distribution
to practice staff*)
All Community Pharmacists
Medical Directors, HSC Trusts (*for onward distribution to all
Consultants, Occupational Health Physicians &
School Medical Leads*)
Nursing Directors, HSC Trusts (*for onward distribution to all
Community Nurses, and midwives*)
Directors of Children's Services, HSC Trusts
RQIA (*for onward transmission to all independent providers
including independent hospitals*)
Prof P Johnston, Dean of Medical School at QUB
Heads of Occupational Health at QUB and UU
Prof L Johnston, Head of Nursing & Midwifery, QUB
Prof H McKenna, Head of Life and Health Sciences, UU
Dr O Barr, Head of School of Nursing, UU

AN ROINN

**Sláinte, Seirbhísí Sóisialta
agus Sábháilteachta Poiblí**

MÄNNYSTRIE O

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Your Ref:

Our Ref: HSS(MD)47/2009

Date: 15 October 2009

Dear Colleague

**LAUNCH DATE FOR H1N1 SWINE FLU VACCINATION PROGRAMME 2009-2010 AND
ADDITIONAL DETAILS ON VACCINE DOSAGE**

INTRODUCTION

1. The purpose of this letter is to provide final details of the swine flu vaccination programme, including the launch dates and dosage schedule. This letter follows the previous letter of 6 October (HSS (MD) 44/2009).

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 which is likely to come under heavy pressure during the months ahead.
3. The second wave of the swine flu 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 Trusts

4. The first batch of the licensed vaccine has now been received in Northern Ireland. Initial quantities of vaccine will be limited and these supplies will be delivered to Trusts. Trusts should therefore prepare to begin the vaccination programme **from 21 October**. These supplies can be used to protect frontline staff, patients in at-risk groups in hospitals and pregnant women.

Launch of vaccination programme in GP Practices

5. Subject to the delivery of vaccine to Northern Ireland, it is envisaged that all GP Practices will receive vaccine to allow them to begin the vaccination programme from week commencing **26 October**. GPs will be given as much notice as possible via the HSC Board primary care intranet site of the amount of vaccine they can expect to receive 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 the HSC Board intranet before they organise clinics.

Clinical priority groups

6. The clinical priority groups were identified by the Joint Committee for Vaccination and Immunisation (JCVI) and communicated in my letter of 6 October. 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

7. 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 licences 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 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.

Celvapan, manufactured by Baxter is an unadjuvanted inactivated vaccine. 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.

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).

Although the UK is now receiving supplies of vaccine, we are dependent on a biological process for manufacture so these dates remain subject to change.

Vaccine schedule

8. Following advice from the Joint Committee on Vaccination and Immunisation (JCVI) (8 October), the following vaccination schedule is recommended in Northern Ireland:

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 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).

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

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

9. 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 swine flu (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 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

10. 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 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 and co-administration

11. 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 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

12. 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

13. 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 online at www.dh.gov.uk/en/PublicHealth/Flu/Swineflu/InformationandGuidance/index.htm,

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.

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.

The GSK vaccine can be used for a period of up to 24 hours after reconstitution if stored below 25° 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.

Consent

14. 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

15. 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.

Vaccine Damage Payments Scheme

16. 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.

Patient Information Leaflet (PILs)

17. The Patient Information Leaflet (PILs) are currently being printed. In the interim PILs should be download via the following Web address www.mhra.gov.uk/swineflu. Trusts/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

18. Materials for health professionals including a new Immunisation Green Book chapter, fact sheet, Q&A and Patient Group Directive (PGD) template are in preparation. Training materials to support Trust staff are also being developed. These will be posted in draft on the DHSSPS website at www.dhsspsni.gov.uk

The materials will be available on the DHSSPS website in advance of hardcopies being produced.

Publicity campaign

19. 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 swine 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 people in the priority groups.

The national campaign materials and plans will be made available online on the Department's website and other relevant websites for local use. It will be important that we give the public consistent messages on the new vaccine to avoid confusion and all staff should use the nationally agreed set of materials.

Funding Arrangements

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

The HSC Board is familiar with arrangements for paying general practitioners for the delivery of services and appropriate arrangements for swine flu vaccination payments

will be made under a Directed Enhanced Service (DES). This is currently being drafted by the Department and subject to agreement with NIGPC will be issued to the Board. In the meantime the Board and GP Practices should ensure arrangements for the administration of the vaccine programme are in place. The Board will receive additional funding to support the delivery of the vaccination programme.

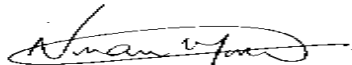
CONCLUSION

21. As mentioned in the letter of 6 October, vaccination provides true primary prevention of disease and is perhaps the most effective weapon at our disposal in the fight against swine flu. The success of this vaccination programme has the potential to reduce the impact of swine flu on mortality, morbidity and service pressures in Northern Ireland. It is our individual and collective responsibility to take every opportunity to protect ourselves and our patients from the impact of swine flu. Your full participation and support is vital and is greatly appreciated.

Yours sincerely



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Chief Medical Officer



Dr Norman Morrow
Chief Pharmaceutical Officer



Mr Martin Bradley
Chief Nursing Officer

Cc Dr A McCormick
Mrs Linda Brown, Deputy Secretary, DHSSPS
Donncha O'Carolan, Acting Chief Dental Officer, DHSSPS
Dr M McCarthy, DHSSPS
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This letter is available at www.dhsspsni.gov.uk and also on the DHSSPS Extranet which can be accessed directly at <http://extranet.dhsspsni.gov.uk> or by going through the HPSS Web at <http://www.n-i.nhs.uk> and clicking on DHSSPS.