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Directors of Public Health
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Dear Colleague,

The flu immunisation programme 2013/14 – extension to children

This is the second of two letters about the flu immunisation programme for the 2013/14 winter. The [first letter](#) was published on 5 June and provides detailed guidance on the routine flu immunisation programme. This letter provides additional information about the extension of the 2013/14 flu immunisation programme to healthy children.

This supplementary letter has the support of the Department of Health's Chief Medical Officer, Chief Pharmaceutical Officer and Director of Nursing.

The extension of the flu immunisation programme to children

Flu immunisation is a key part of the Government's immunisation programme. It is based on the advice and recommendations of the Joint Committee on Vaccination and Immunisation (JCVI).

JCVI has recommended that the routine annual flu immunisation programme be extended to all children aged two to under 17 years. The extended programme is expected to appreciably lower the public health impact of flu by directly averting a large number of cases of disease in children, and, through lowering flu transmission in the community, indirectly preventing flu in unvaccinated younger children, people in clinical risk groups, and older adults. This is expected to substantially reduce flu-related illness, GP consultations, hospital admissions and deaths. JCVI found that extending the flu immunisation programme in this way is likely to be highly cost effective.

The JCVI statement is at: [Click to follow link](#)

Extending the flu immunisation programme to all children will also raise awareness of the benefits of flu immunisation amongst parents and children. We anticipate that as flu immunisation for children becomes accepted as routine, this will have a positive impact on uptake rates for others who are eligible for flu immunisation, particularly those in clinical groups for whom the risk of serious complications is highest, and for whom coverage is presently only around 50%.

The vaccine being used for most children is Fluenz®. JCVI has advised that, when extending the flu immunisation programme to children, most children should be offered a single dose of Fluenz®. However, children in clinical risk groups aged two to less than nine years who have not received flu vaccine before should be offered two doses, given at least four weeks apart.

JCVI advice on vaccine use for children can be found at Annex A.

The children's flu immunisation programme 2013/14

There are two elements to the children's flu immunisation programme this year:

- a routine offer of vaccination to all two and three year olds (but not four years or older) on the 1 September 2013; and
- geographical pilots for four to ten year olds (up to and including pupils in school year 6).

Extending the flu programme to all children will involve considerable planning and work in order to obtain a high level of uptake. For this reason, the programme will be rolled out over a number of seasons and will include pilots, allowing Public Health England and NHS England time to ascertain the most effective way of implementing it.

The Department of Health has secured Fluenz® vaccine for use in 2013/14 to allow the roll-out of the programme to all two and three year olds through general practice, as well as through a small number of local geographical pilots targeted at four to ten year olds.

Roll-out to two and three year olds

All GP practices in England should offer immunisation to all registered patients aged two and three years (but not four years or older) on the 1 September 2013 (i.e. date of birth on or after 2 September 2009 and on or before 1 September 2011). The vaccine should be offered on either:

- a proactive call basis, if not considered at-risk, or
- a proactive call and recall basis, if considered at-risk.

This programme has been agreed between NHS Employers (on behalf of NHS England) and the General Practitioners Committee (GPC) of the British Medical Association (BMA). The contract is available on the NHS Employers website: [Click to follow link](#)

As this is a new universal flu programme, practices are encouraged to ensure that uptake of flu vaccine in two and three year old children is as high as possible. This is important in order to maximise the health benefits that the extended programme is expected to bring.

It is also the responsibility of health visitors, school nurses and other relevant health professionals to encourage flu vaccination and to promote coverage of the vaccine, especially in the under-served groups.

Geographical pilots children aged four to ten years

PHE is in the final stages of agreeing pilots in a small number of locations across England. These pilots will test a range of delivery methods for vaccinating all pre and primary school age children within discrete geographical areas (though the two and three year olds in the pilot areas will be vaccinated via the GP contract as described above). These pilots will be in a cross-section of urban, rural and inner city settings, with the majority of immunisation undertaken in primary schools. These pilots will commence in September 2013 and should complete their work around the New Year.

The pilots will assess issues such as workload, uptake and logistics of delivery in a variety of settings that will reflect full-scale roll-out as closely as possible. They will also allow the testing of vaccine coverage monitoring systems by the pilot areas, which will be important in order to evaluate the programme in the longer term. Lessons learned from the pilots will serve to inform the national roll-out of the programme in the seasons to come.

Pilots are also being carried out in Wales, Scotland and Northern Ireland.

Vaccine ordering

Fluenz® has been procured centrally for the pilots and to cover anticipated demand and coverage of the two and three year old cohorts, including children in at risk groups, and will be available via ImmForm alongside the other childhood vaccines. Please see Annex B for information on ordering vaccine, including for those children who are not able to receive Fluenz®.

Data collections for 2013/14

The routine collection of data on flu vaccine uptake via the ImmForm website (see first annual flu letter issued on 5 June 2013) will be extended to include data on the immunisation of all children in England aged two to three years (but not four years or older) on the 1 September 2013. See Annex C for details of the data collection.

Programme assurance

NHS England Area Teams will be expected to feed back on the performance and outcomes of the programme as part of the responsibilities that NHS England has agreed under a Section 7A agreement with the Secretary of State for Health.

NHS England, through its Head of Public Health, Armed Forces Health and Offender Health and the Screening and Immunisation Teams, will work with local authority Directors of Public Health to improve the performance of local screening and immunisation programmes as described through Public Health Outcomes indicators, sharing Key Performance Indicators and use of outcome indicators where available.

Directors of Public Health in local authorities are expected to provide appropriate challenge to arrangements, and also to act as advocates within the local authority and with key stakeholders to improve access and uptake of flu immunisation.

Publicity and information materials

An updated patient leaflet will be available from the immunisation page of the [GOV.uk website](http://www.gov.uk) before the start of the flu immunisation programme. Leaflets and a poster have been prepared specifically for children's flu immunisation – both the pilots and the two and three year old cohorts – and have been tested with parent groups. Printed copies can be ordered by GP surgeries through the Publications Orderline at: http://www.orderline.dh.gov.uk/ecom_dh/public/home.jsf

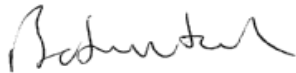
The Green Book

The Green Book, [Immunisation against Infectious Disease](#), provides guidance for healthcare workers on administering the flu vaccine. PHE will publish an updated influenza chapter of the Green Book on the Gov.uk in August 2013. This will include detailed information about the way that the available flu vaccines should be administered.

For ease of use, information is set out in the attached annexes as follows:

- Annex A Guidance on use of flu vaccine for children
- Annex B Vaccine ordering
- Annex C Vaccine uptake data collections for 2013/14

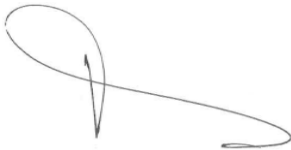
Yours sincerely,



Dame Barbara Hakin
NHS England, Chief Operating Officer and Deputy Chief Executive



Dr Paul Cosford
Public Health England, Medical Director and Director of Health Protection



Dr Felicity Harvey
Department of Health, Director General, Public health

For further information, please contact: immunisation@phe.gov.uk.

This letter will also be available at:

<https://www.gov.uk/government/organisations/public-health-england/series/immunisation#new-vaccine-introductions>

Annex A – Use of flu vaccine for children

JCVI has advised that a single vaccine – the live attenuated nasal spray flu vaccine (Fluenz® manufactured by AstraZeneca) that is authorised for children aged from two to under 18 years – should be the vaccine of choice for the extended programme. This is because it is more effective in children than other inactivated flu vaccines, it has a good safety profile in children aged two years and older and an established history of use in the United States. Furthermore, it may provide protection against flu strains that are not well matched to the vaccine strains.

A summary of the JCVI advice is available at: [Click to follow link](#)

The patient information leaflet provided with Fluenz® suggests children should be given two doses of this vaccine if they have not had flu vaccine before. However, JCVI considers that the public health benefit would be greater if the quantity of Fluenz® that is available is offered as a single dose to more children. This is because a second dose of the vaccine provides only modest additional protection. Therefore, it would be better if more children received the benefit of the protection provided by at least one dose of the vaccine.

On this basis, JCVI has advised that, when extending the flu immunisation programme to children, most children should be offered **a single dose** of the Fluenz®. However, children in clinical risk groups aged two to less than nine years who have not received flu vaccine before should be offered two doses of Fluenz® (given at least four weeks apart).

Fluenz® has been used for children for a number of years in the United States. It has also been offered to at risk children in Northern Ireland, where the experience has been very positive. Surveys of nurses administering the vaccine show that they preferred the nasal spray to injected vaccines. Some parents did need reassurance about its effectiveness if they noticed their child's nose dripping after the vaccine had been administered. However as the vaccine is absorbed very quickly, even if a child gets a runny nose or sneezes immediately after the spray, it is still likely to be effective.

Contraindications and precautions

Fluenz® should not be given to children less than two years of age.

Fluenz® should not be given to children or adolescents who are clinically severely immunodeficient due to conditions or immunosuppressive therapy such as: acute and chronic leukaemias; lymphoma; HIV infection not on highly active antiretroviral therapy (HAART); cellular immune deficiencies; and high dose corticosteroids. It is not contraindicated for use in children or adolescents with HIV infection receiving stable antiretroviral therapy; or who are receiving topical/inhaled corticosteroids or low-dose systemic corticosteroids or those receiving corticosteroids as replacement therapy, e.g. for adrenal insufficiency. It is contraindicated in children and adolescents younger than 18 years of age

receiving salicylate therapy because of the association of Reye's syndrome with salicylates and wild-type influenza infection.

Fluenz® should not be given to children with egg allergy. There are no data on the use of Fluenz® in children with egg allergy.

Fluenz® is not recommended for children with active wheezing at the time of vaccination or severe asthma (BTS SIGN step 4 or above) because of limited safety data in these groups.

There is a potential for transmission of live attenuated influenza virus in Fluenz® to very severely immunocompromised contacts (e.g. bone marrow transplant patients requiring isolation) for one to two weeks following vaccination. Where close contact with very severely immunocompromised patients (for example household members) is likely or unavoidable, appropriate alternative inactivated influenza vaccines should be considered.

The advice in contraindications and precautions sections in the Green Book influenza chapter should be referred to:

<https://www.gov.uk/government/publications/influenza-the-green-book-chapter-19>

For the small proportion of children for whom Fluenz® is contraindicated, a suitable inactivated injected flu vaccine should be offered. If these children are aged six months to less than nine years and have not received flu vaccine before, two doses of the injected inactivated vaccine should be offered (given at least four weeks apart).

For those who are contra-indicated to Fluenz®, the following vaccines are available:

Vaccines available for the 2013/14 flu immunisation programme

Supplier	Name of product	Vaccine Type	Age indications	Contact details
Abbott Healthcare	Influvac Desu®	Surface antigen, inactivated	From 6 months	0800 358 7468
	Imuvac®	Surface antigen, inactivated	From 6 months	
GlaxoSmithKline	Fluarix®	Split virion inactivated virus	From 6 months	0800 221 441
	Fluarix™ Tetra ▼	Split virion inactivated virus	From 3 years	
Janssen-Cilag Ltd (formerly Crucell UK)	Viroflu®	Surface antigen, inactivated	From 6 months	0844 800 3907
	Inflexal®/V	Surface antigen, inactivated	From 6 months	
MASTA	Imuvac®	Surface antigen, inactivated	From 6 months	0113 238 7552
	Inactivated Influenza Vaccine (Split Virion) BP	Split virion, inactivated virus	From 6 months	
	Fluarix®	Split virion inactivated virus	From 6 months	
Novartis Vaccines	Agrippal®	Surface antigen, inactivated	From 6 months	08457 451 500
	Fluvirin®*	Surface antigen, inactivated	From 4 years	
	Optaflu® ▼	Surface antigen, inactivated, prepared in cell cultures	From 18 years	

Pfizer Vaccines	CSL Inactivated Influenza Vaccine	Split virion Inactivated virus	From 5 years	T: 0800 089 4033
	Enzira®	Split virion Inactivated virus	From 5 years	
Sanofi Pasteur MSD	Inactivated Influenza Vaccine (Split Virion) BP	Split virion, inactivated virus	From 6 months	0800 085 5511

None of the influenza vaccines for the 2013/14 season contain thiomersal as an added preservative. *This vaccine states in its Summary of Product Characteristics (SPC) that it contains traces of thiomersal that are left over from the manufacturing process.

Some flu vaccines are restricted for use in particular age groups. The Summary of Product Characteristics (SPC) for individual products should be referred to when ordering vaccines for particular patients. Please note the JCVI advice on the dosage of Fluenz® set out on page 6 above.

More detailed information on the characteristics of the available vaccines, including age indications and ovalbumin (egg) content can be found in the Seasonal Flu chapter of the Green Book. A revised chapter will be issued ahead of the flu season.

Fluenz® is administered by the intranasal route and is supplied in an applicator that allows a divided dose to be administered in both nostrils. The device allows intranasal vaccination to be performed without the need for additional training. Neither divided dose needs to be repeated if the patient sneezes, or blows their nose following administration. The live attenuated vaccine can be given at the same time as other vaccines including live vaccines.

Please be aware that, before use, the vaccine may be taken out of the refrigerator, without being replaced, for a maximum period of 12 hours at a temperature not above 25°C. If the vaccine has not been used after this 12-hour period, it should be disposed of.

Fluenz® has a shorter shelf life (18 weeks) than other influenza vaccines and some of this will have passed by the time the vaccine has been supplied to you. The expiry date on the nasal spray applicator should always be checked before use. Vaccine has been ordered to cover the period over which historically the flu vaccine has been used, extending from September to mid-December. All the Fluenz® will have expired by 16th January 2014. In the light of this it will be important to ensure that efforts are made to vaccinate children before the Christmas holidays.

Annex B - Vaccine ordering

Fluenz®

Fluenz® has been procured centrally to cover the pilots and anticipated demand and coverage of the two and three year old cohorts, including children in at risk groups.

Vaccine ordering for two and three year olds:

The vaccine will be available to GPs to order through ImmForm in the normal manner. The vaccine will appear on the ImmForm vaccine ordering pages alongside the other vaccines available under the childhood programme.

Vaccine ordering for the four to ten year old pilots:

The vaccine will be available to be ordered through ImmForm. Only the organisations participating in the pilot will be able to place orders.

ImmForm is available via the following link:

<https://www.immform.dh.gov.uk/>

If you require any further information or assistance in relation to the ordering process please call the ImmForm Helpdesk on 0844 376 0040.

Inactivated Influenza Vaccine (TIV) for children contraindicated to Fluenz®

For those two and three year olds who are contraindicated to Fluenz®, inactivated influenza vaccines which have already been ordered by GPs for two and three year olds in clinical risk groups can now be utilised for the contraindicated two and three year olds. You will be reimbursed for this as per children in clinical risk groups. If you experience difficulties in sourcing inactivated influenza vaccine for the contraindicated 2 and 3 year olds please contact the ImmForm helpdesk on 0844 376 0040 which will be able to assist in ordering inactivated influenza vaccine. Guidance on which vaccine to use for those children who cannot receive Fluenz® can be found at Annex A.

For the four to ten year old pilots, inactivated influenza vaccine for children contraindicated for Fluenz® is available and can be ordered via ImmForm. To order inactivated influenza vaccine for children in the pilots please call the ImmForm Helpdesk, who will give you access to order this stock and explain how you need to proceed.

You will not receive a personal administration fee for inactivated influenza vaccine ordered through ImmForm for the pilots.

Annex C – Vaccine uptake data collections for 2013/14

The routine collection of data on flu vaccine uptake via the ImmForm website ([see first annual flu letter issued on 5 June 2013](#)) will be extended to include data on the immunisation of all children in England aged two to three years (but not four years or older) on the 1 September 2013.

As described in the first annual flu letter, PHE will co-ordinate the routine monitoring of uptake of the seasonal flu programme including the roll-out to all two and three year olds. PHE will issue details of the collection requirements by the end of July 2013 and guidance on the data collection process by early September 2013.

Pilot areas will be responsible for standardised collection and reporting of vaccine uptake data in four to ten year olds as part of the evaluation of the programme, with guidance from PHE.

Queries about data collection content or process should be directed to influenza@phe.gov.uk.

Queries about ImmForm login details and passwords should be directed to helpdesk@immform.org.uk

More details about the data collection are available in Annex E of the [first annual flu letter issued on 5 June 2013](#).

PHE will undertake the epidemiological assessment of the impact of the programme as it is rolled out.