Department of Health

Public Health England

NHS England

28 April 2014

Dear Colleague,

The national flu immunisation programme 2014/15

1. We are writing to ensure that you have comprehensive information to prepare for the national flu immunisation programme in 2014/15, including the extension of the programme to children. This letter supports local planning to ensure good levels of flu immunisation which is one of the most effective interventions we can make to reduce harm from flu and pressures on health and social care services during the winter. We would like to thank you for all that you do to ensure that strong local plans are in place.
2. In 2014/15 the following people are eligible for flu vaccination:
    - those aged 65 years and over
    - those aged six months to under 65 in clinical risk groups
    - pregnant women
    - all two, three and four year olds
    - school-aged children in pilot areas
    - those in long-stay residential care homes
    - carers
3. Health and social care workers who are in direct contact with patients or service users we expect to be offered flu vaccination by their employer, including GP practice staff.
4. Those eligible should be given flu vaccination as early as possible between September and early November before flu starts circulating in the community. However, flu can circulate considerably later than this and clinicians should apply clinical judgement to assess the needs of individual patients for vaccination beyond this time period. This should take into account the level of flu-like illness in the community and the fact that the immune response following flu vaccination takes about two weeks to develop fully.
5. Winter 2013/14 has seen low levels of circulating flu, but we must not be complacent. There were estimated to be 11,000 deaths attributable to flu in the 2012/13 season, the highest since 2008/09[i].

PHE Gateway Ref: 2013521
NHS England Gateway Ref: 01287

6. Flu is also a key factor in NHS winter pressures. It impacts on both those who fall ill and the NHS services that provide direct care, and on the wider health and social care system that supports people in at-risk groups. The annual immunisation programme is a critical element of the system-wide approach for delivering robust and resilient health and care services throughout the year, helping to reduce unplanned hospital admissions and pressure on A&E.
7. The best way to improve the prevention and management of flu is to increase the uptake of vaccination, especially among those in clinical risk groups and health and social care workers with direct patient contact. Clinical risk groups include older people, pregnant women and those with underlying disease, particularly chronic respiratory or cardiac disease, children with severe neurological disease or learning disability, and those who are immunosuppressed.
8. Extending flu vaccination to children will reduce the impact of flu by directly averting many cases in children. The Joint Committee on Vaccination and Immunisation also concluded that, by reducing flu transmission in the community, it will avert many cases of severe flu and flu-related deaths in older adults and people with clinical risk factors.
9. For ease of use, the detailed planning information is set out in the attached Appendixes as follows:

Publicity and information materials

10. Ahead of the flu season updated NHS patient leaflets “The flu vaccination: Who should have it and why” and “Protecting your child against flu” will be available to print from www.gov.uk/government/collections/annual-flu-programme. The children’s leaflet will also be available to order through the Prolog Publications Orderline: www.orderline.dh.gov.uk/ecom_dh/public/home.jsf

Green Book

11. The influenza chapter in *Immunisation against infectious disease* (the 'Green Book'), which provides guidance for healthcare workers on administering the flu vaccine, will be updated and published ahead of the flu season on the GOV.UK website at: www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book This will include detailed information about the way that the available flu vaccines should be administered.

The Flu Plan

12. An updated plan for 2014/15 is being published today along with this annual flu letter. It can be found at www.gov.uk/government/organisations/public-health-england/series/immunisation

Conclusion

13. This Annual Flu Letter has the support of the Chief Medical Officer, Chief Pharmaceutical Officer and Director of Nursing.

14. We would like to thank everyone involved in delivering the flu immunisation programme for all your hard work. The continuing extension of the programme to include vaccination of more children this year will not only provide protection to those children but also an increasing opportunity to interrupt transmission of flu to the wider population, thereby saving more lives. We are grateful for the efforts from all parts of the system towards the continued implementation of this important enhancement of the national programme.

Yours sincerely,

Dame Barbara Hakin

NHS England,
Chief Operating Officer and Deputy Chief Executive

Dr Paul Cosford

Public Health England,
Medical Director and Director for Health Protection

Dr Felicity Harvey

Department of Health,
Director General,
Public Health

To:

General practices

Screening and immunisation leads

NHS regional directors

NHS England area team directors

NHS England regional and area team directors of commissioning

NHS England regional directors of public health and primary care

NHS England area team heads of public health commissioning

NHS England area team directors of nursing

Directors of nursing

Heads of nursing

Heads of midwifery

Clinical leaders of clinical commissioning groups

PHE centre directors

Directors of public health

Local authority chief executives

Directors of adult services

Directors of children's services

Local medical committees

Community pharmacies

For information via NHS News:

Chief pharmacists of NHS trusts

NHS foundation trusts

NHS trusts

Any enquiries regarding this publication should be sent to: immunisation@phe.gov.uk

To register for the immunisation monthly newsletter Vaccine Update please go to: https://public.govdelivery.com/accounts/UKHPA/subscribers/new?preferences=true

You can download this letter and the updated Flu plan from: www.gov.uk/government/organisations/public-health-england/series/immunisation

Appendix A: Groups included in the national flu immunisation programme

Flu vaccine should be offered to the eligible groups set out in the table below.

Table 1: Groups included in the national flu immunisation programme

Eligible groups	Further detail
All children aged two to less than five years old	All those aged two, three and four years old (but not five years or older) on 1 September 2014 (ie date of birth on or after 2 September 2009 and on or before 1 September 2012). In the interests of maintaining the highest level of safety, and in order to set a clear and manageable limit, healthy children that turn two after the 1 September should not be offered the vaccine.
School-aged children who are part of the pilot childhood programme	Seven geographical pilots of primary school aged children started in 2013/14 will continue. Pilots of secondary school aged children in Years 7 and 8 will start in 2014/15. Immunisation for school-aged children will be directly commissioned by NHS England.
All patients aged 65 years and over	"Sixty-five and over" is defined as those aged 65 years and over on 31 March 2015 (ie born on or before 31 March 1950).
Chronic respiratory disease aged six months or older	Asthma that requires continuous or repeated use of inhaled or systemic steroids or with previous exacerbations requiring hospital admission. Chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema; bronchiectasis, cystic fibrosis, interstitial lung fibrosis, pneumoconiosis and bronchopulmonary dysplasia (BPD). Children who have previously been admitted to hospital for lower respiratory tract disease.
Chronic heart disease aged six months or older	Congenital heart disease, hypertension with cardiac complications, chronic heart failure, individuals requiring regular medication and/or follow-up for ischaemic heart disease.
Chronic kidney disease aged six months or older	Chronic kidney disease at stage 3, 4 or 5, chronic kidney failure, nephrotic syndrome, kidney transplantation.
Chronic liver disease aged six months or older	Cirrhosis, biliary atresia, chronic hepatitis
Chronic neurological disease aged six months or older	Stroke, transient ischaemic attack (TIA). Conditions in which respiratory function may be compromised due to neurological disease (e.g. polio syndrome sufferers). Clinicians should consider on an individual basis the clinical needs of patients including individuals with cerebral palsy, multiple sclerosis and related or similar conditions; or hereditary and degenerative disease of the nervous system or muscles; or severe neurological or severe learning disability.

Eligible groups	Further detail
Diabetes aged six months or older	Type 1 diabetes, type 2 diabetes requiring insulin or oral hypoglycaemic drugs, diet controlled diabetes.
Immunosuppression aged six months or older	Immunosuppression due to disease or treatment, including patients undergoing chemotherapy leading to immunosuppression, bone marrow transplant, HIV infection at all stages, multiple myeloma or genetic disorders affecting the immune system (e.g. IRAK-4, NEMO, compliment deficiency). Individuals treated with or likely to be treated with systemic steroids for more than a month at a dose equivalent to prednisolone at 20mg or more per day (any age), or for children under 20kg, a dose of 1mg or more per kg per day. It is difficult to define at what level of immunosuppression a patient could be considered to be at a greater risk of the serious consequences of influenza and should be offered influenza vaccination. This decision is best made on an individual basis and left to the patient's clinician. Some immunocompromised patients may have a suboptimal immunological response to the vaccine.
Asplenia or dysfunction of the spleen	This also includes conditions such as homozygous sickle cell disease and coeliac syndrome that may lead to splenic dysfunction.
Pregnant women	Pregnant women at any stage of pregnancy (first, second or third trimesters).
People in long-stay residential or homes	Vaccination is recommended for people living in long-stay residential care homes or other long-stay care facilities where rapid spread is likely to follow introduction of infection and cause high morbidity and mortality. This does not include, for instance, prisons, young offender institutions, or university halls of residence.
Carers	Those who are in receipt of a carer's allowance, or those who are the main carer of an elderly or disabled person whose welfare may be at risk if the carer falls ill.
Health and social care staff	Health and social care workers who are in direct contact with patients/service users should be vaccinated by their employer as part of an occupational health programme

The list above is not exhaustive, and the healthcare practitioner should apply clinical judgement to take into account the risk of flu exacerbating any underlying disease that a patient may have, as well as the risk of serious illness from flu itself. Flu vaccine should be offered in such cases even if the individual is not in the clinical risk groups specified above.

Appendix B: Extended flu programme for children

The Department of Health (DH), based on a recommendation received from the Joint Committee on Vaccination and Immunisation (JCVI) in July 2012, decided to extend the national flu programme to all children from the age of two to less than 17 years. In addition to providing direct protection to children who are vaccinated, the full programme, by interrupting transmission of influenza, will reduce the spread of flu to unvaccinated children and adults, including those in clinical risk groups and for whom flu can be extremely serious.

The JCVI statement published in July 2012 set out the basis and evidence for the extension of the flu immunisation programme to children. The JCVI recommendation to the Secretary of State for Health is based upon analysis that suggested that any vaccination campaign including school-aged children is highly likely to be cost effective when the direct and indirect benefits to the individual and the population are taken into account, particularly over the longer-term. The JCVI further recommended that a live attenuated influenza vaccine (LAIV) be used as the vaccine of choice for children (see Appendix C). Their statement can be found at: www.gov.uk/government/publications/jcvi-statement-on-the-routine-annual-influenza-vaccination-programme

This has led to the following delivery statement in the 2014/15 Section 7A service specification between DH and NHS England: “The best uptake of vaccination among five-16 year olds is likely to be achieved through a school-based programme. However, it is recognised that the capacity of school nursing services (where appropriate locally working with specialist immunisation services) is not currently adequate to enable the programme to be offered to all children in this way. Work is being undertaken jointly by DH and NHS England, and with PHE, Health Education England and professional bodies to:

- support the development of sustainable long-term solutions,
- ensure the availability of sufficient appropriately-trained staff, and
- work with local government to develop the associated commissioning arrangements for school nursing to deliver the programme”.

The implementation of the programme will be phased in a way that achieves the expected public health gains quickly, but maintains high levels of safety and quality and does not put undue pressure on other programmes.

The programme in 2013/14 covered the following cohorts:

- a routine offer of vaccination to all those aged two and three years old (but not four years or older) on 1 September 2013;
- all primary school aged children in seven geographical pilot areas.

The programme for 2014/15 expands 2013/14 delivery and is as follows:

- a routine offer of vaccination to all those aged two, three and four years old (but not five years or older) on 1 September 2014 (ie date of birth on or after 2 September 2009 and on or before 1 September 2012);

- seven geographical pilots of primary school aged children started in 2013/14 will continue;
- a minimum of 12 geographical pilots in secondary school aged children in Years 7 and 8 in 2014/15.

Pre-school aged children (aged two to four years old) are currently immunised under an NHS England Enhanced Services contract with the General Practitioners Committee (GPC) of the British Medical Association (BMA). This is likely to continue for the foreseeable future, but will be based on ongoing discussions between DH, PHE, NHS England and the GPC.

It is likely that NHS England will commission the majority of immunisation for school-aged children in schools (including those in special schools). NHS England will, however, have options to commission services from a range of local healthcare providers, including in primary care or community pharmacies and those children of relevant ages outside the mainstream state and private school system. **Where children in clinical risk groups are in locations not covered by pilot areas, they should continue to be vaccinated in general practice.**

This letter does not contain detailed information on the pilots for school aged children as they are not yet part of the universal programme. More information will be available in a service specification referred to above: www.gov.uk/government/uploads/system/uploads/attachment_data/file/256502/nhs_public_health_functions_agreement_2014-15.pdf

More information about the learning from the seven geographical pilots in 2013/14 can be found in the *Flu plan* and a full evaluation report will be published at: www.gov.uk/government/organisations/public-health-england/series/immunisation

Appendix C: Use of the live attenuated influenza vaccine Fluenz Tetra®

The JCVI have recommended that a live attenuated influenza vaccine (LAIV) be used as the vaccine of choice for children. There is currently only one LAIV on the market, Fluenz Tetra®. This year, **Fluenz Tetra®** (a quadrivalent **live attenuated intranasal** influenza vaccine) will be supplied in place of Fluenz®.

JCVI recommended Fluenz Tetra® as it has:

- higher efficacy in children, particularly after only a single dose;
- the potential to provide coverage against circulating strains that have drifted from those contained in the vaccine;
- higher acceptability with children, their parents and carers due to intranasal administration; and
- it may offer important longer-term immunological advantages to children by replicating natural exposure/infection to induce potentially better immune memory to influenza that may not arise from the annual use of inactivated flu vaccines.

Fluenz Tetra® 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 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.

Fluenz® has been used for children for a number of years in the United States and during the 2013/14 flu season in England, Scotland, Northern Ireland and Wales. The experience has been very positive. Surveys of nurses administering the vaccine in Northern Ireland show that they preferred the nasal spray to injected vaccines.

The vaccine is licensed for those aged from 24 months to less than 18 years of age. **Given that this vaccine gives better protection for children, Fluenz Tetra® should be administered to all children eligible for vaccination (see Appendix A) except those with contraindications (see below).**

The patient information leaflet provided with Fluenz Tetra® states that children should be given two doses of this vaccine if they have not had flu vaccine before. However, JCVI considers that a second dose of the vaccine provides only modest additional protection. On this basis, JCVI has advised that, when extending the flu immunisation programme to children, most children should be offered **a single dose** of Fluenz Tetra®. 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 Tetra® (given at least four weeks apart).

For children for whom Fluenz Tetra® is contraindicated or not recommended, a suitable inactivated 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 inactivated vaccine should be offered (given at least four weeks apart).

Fluenz Tetra® has a shelf life of 18 weeks that starts at the point of release from the manufacturer. This is a shorter shelf life than other influenza vaccines and some of this time will have passed when the vaccine reaches you. It is important that the expiry date on the nasal spray applicator is checked before use. If the expiry date has passed, please make arrangements to have the vaccine disposed safely.

Vaccine has been ordered to cover the period over which historically the flu vaccine has been administered, extending from September to mid-December. **It is highly likely that all the Fluenz Tetra® supplied centrally will have expired before the end of January 2015. In the light of this it will be important to ensure that efforts are made to vaccinate children before the Christmas holidays.**

We will provide further information on vaccine expiry dates through Vaccine Update and the ImmForm website.

Contraindications and precautions

None of the influenza vaccines should 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 (other than ovalbumin – see the Green Book influenza chapter for egg allergy and inactivated influenza vaccines).

Fluenz Tetra® is contraindicated in children and adolescents who are:

- clinically severely immunodeficient due to conditions or immunosuppressive therapy;
- receiving salicylate therapy because of the association of Reye's syndrome with salicylates and wild-type influenza infection.

Fluenz Tetra® is not recommended in children and adolescents who have active wheezing at the time of vaccination or severe asthma.

Fluenz Tetra® may not be suitable for children and adolescents with egg allergy.

The advice in contraindications and precautions sections in the Green Book influenza chapter should be referred to: www.gov.uk/government/publications/influenza-the-green-book-chapter-19

Porcine gelatine

Vaccination is not compulsory in the UK, anyone who does not wish to be vaccinated with Fluenz Tetra® will be able to refuse vaccination. Current policy is that only those who are in clinical risk groups or have clinical contra-indications are able to receive an inactivated injectable vaccine as an alternative to Fluenz Tetra® (two doses will be required in many cases).

Fluenz Tetra® contains a wide range of ingredients, including porcine gelatine (as do many other pharmaceutical products). There is currently no alternative vaccine of equivalent efficacy that does not include porcine gelatine. Although broad acceptance has been gained from faith groups for the use of porcine gelatine in non-oral medicines (see PHE's website www.gov.uk/government/news/vaccines-and-gelatine-phe-response), it is recognised that there is still some uncertainty amongst some groups. The implications of this for the programme will continue to be monitored and considered carefully in light of evidence gathered through the pilots.

Appendix D: GP practice checklist

The GP practice checklist highlights good practice and is based upon the findings from a study examining the factors associated with higher vaccine uptake in general practice[ii]. GP practices are encouraged to review their systems in the light of the checklist.

General

1. The GP practice has a named individual within the practice who is responsible for the flu vaccination programme.

Registers and information

2. The GP practice has a register that can identify all pregnant women and patients in the under 65 years at risk groups, those aged 65 years and over, and those aged two to four years.
3. The GP practice will update the patient registers throughout the flu season paying particular attention to the inclusion of women who become pregnant during the flu season.
4. The GP practice will submit accurate data on the number of its patients eligible to receive flu vaccine and the flu vaccinations given to its patients on ImmForm (www.immform.dh.gov.uk), ideally using the automated function, and on uptake amongst healthcare workers in primary care using the ImmForm data collection tool.

Meeting any public health targets in respect of such immunisations

5. The GP practice will/has ordered sufficient flu vaccine taking into account past and planned performance, expected demographic increase, and to ensure that everyone at risk is offered the flu vaccine. It is recommended that vaccine is ordered from more than one supplier and from PHE central supplies through the ImmForm website in respect of children.

Robust call and recall arrangements

6. Patients recommended to receive the flu vaccine will be directly contacted (for example through letter, e-mail, phone call, text or otherwise although such strategies are for GP practices to determine) inviting them to a flu vaccination clinic or to make an appointment. PHE has produced a flu vaccination invitation template letter which can be found at: www.gov.uk/government/publications/flu-vaccination-invitation-template-letter
7. The GP practice will follow-up with patients who do not respond or fail to attend scheduled clinics or appointments.

Maximising uptake in the interests of at-risk patients

8. Flu vaccination will start as soon as practicable after receipt of the vaccine in the practice so that the maximum number of patients are vaccinated as early as possible prior to the flu season (ie by the end of October), to ensure they are protected before flu starts to circulate.

9. The GP practice will collaborate with midwives to offer and provide flu vaccination to pregnant women and to identify, offer and provide to newly pregnant women as the flu season progresses.
10. The GP practice will offer flu vaccination in clinics and opportunistically.
11. The GP practice and/ or CCG will collaborate with other providers such as Foundation Trusts to identify and offer flu vaccination to residents in care homes, nursing homes and house-bound patients.

Appendix E: Clinical risk groups and uptake expectations

Vaccine uptake rates

In 2014/15 it is our ambition that all eligible individuals are offered flu vaccine and that we reach a minimum 75% uptake for those:

- aged 65 years and over; and
- health and social care workers.

This year, for patients aged 6 months to under 65 in clinical risk groups, we are asking that GP practices and other providers prioritise improvements in vaccine uptake over and above last season in those with chronic liver and neurological disease, including people with learning disabilties, who are at the highest risk of mortality from flu but have the lowest rate of vaccine uptake, and in pregnant women.

Flu vaccine uptake rates for the last three years are given in the table below. In 2013/14 there was a marked improvement in vaccine uptake of frontline health care workers. We would like to thank trusts for all their hard work in achieving this. However, the overall uptake is still below the 75% aspiration and this remains a priority. More detailed information about the level of expectation in relation to frontline health care workers will be included in a separate letter about winter planning.

Table 2: Flu vaccine uptake rates 2011/12 – 2013/14

	2013/14 (%)	2012/13 (%)	2011/12 (%)
Patients aged 65 years or older	**73.2**	73.4	74.0
Patients aged six months to under 65 years in risk groups (excluding pregnant women without other risk factors)	**52.3**	51.3	51.6
Pregnant women	**39.8**	40.3	27.4
Health care workers	**54.8**	45.6	44.6
Carers	**44.8**	46.3	45.2
Children aged two years old (including those in risk groups)	**42.6**	N/A	N/A
Children aged three years old (including those in risk groups)	**39.6**	N/A	N/A

Source: Public Health England: ImmForm reporting website: Data submitted by NHS trusts and area teams.

GP practices can review their approach against the checklist set out in Appendix D. More information about reaching each of the groups eligible for flu vaccination are found in the following Appendixes: Appendix F – pregnant women; Appendix G – health and social care workers.

Clinical risk groups

Increasing flu vaccine uptake in clinical risk groups is important because of the increased risk of serious illness should people in these groups catch flu. The table below shows flu mortality by clinical risk group and demonstrates the increased risk of death.

Table 3[iii]: Influenza related mortality ratios and population rates among those aged six months to 64 years of age by risk group in England, September 2010-May 2011

	Number of fatal flu cases (%)	Mortality rate per 100,000 population	Age-adjusted relative risk*	Lower RR 95% CI	Upper RR 95% CI
In a risk group	213 (59.8)	4.0	11.3	9.1	14.0
Not in any risk group	143 (40.2)	0.4	Baseline	Baseline	Baseline
Chronic renal disease	19 (5.3)	4.8	18.5	11.5	29.7
Chronic heart disease	32 (9.0)	3.7	10.7	7.3	15.7
Chronic respiratory disease	59 (16.6)	2.4	7.4	5.5	10.0
Chronic liver disease	32 (9.0)	15.8	48.2	32.8	70.6
Diabetes	26 (7.3)	2.2	5.8	3.8	8.9
Immunosuppression	71 19.9)	20.0	47.3	35.5	63.1
Chronic neurological disease (exc. stroke/TIA)	42 (11.8)	14.7	40.4	28.7	56.8
Total*	378	0.8			

* Including 22 cases with no information on risk factors.

Mantel-Haenszel age-adjusted rate ratio (RR), with corresponding exact 95% CI calculated for each risk group using the two available age groups (from six months up to 15 years and from 16 to 64 years)

Despite those with liver disease and chronic neurological disease having some of the highest mortality rates, table 4 on the next page shows that they have the lowest flu vaccine uptake rate amongst those in clinical risk groups.

Table 4: Flu vaccine uptake by clincial risk group in 2012/13

Influenza vaccine uptake in patients aged six months to under 65 at risk, by clinical risk group 2012/13				
Age group	**six months to under two years**	**two years to under 16 years**	**16 years to under 65 years**	**Total by risk group**
Risk group	**Vaccine uptake (%)**	**Vaccine uptake (%)**	**Vaccine uptake (%)**	**Vaccine uptake (%)**
Chronic heart disease	23.7	27.2	55.2	**52.5**
Chronic respiratory disease	28.5	41.1	51.7	**50.0**
Chronic kidney (renal) disease	40.5	37.6	56.3	**56.1**
Chronic liver disease	34.5	36.0	43.0	**42.9**
Patients with diabetes	44.3	61.6	68.6	**68.5**
Patients with immunosuppression	36.1	44.7	55.0	**54.7**
Patients with chronic degenerative neurological disease (incl.stroke/TIA, cerebral palsy or MS)	18.6	28.2	50.8	**49.2**

For a number of years only around half of patients aged six months to under 65 in clinical risk groups have been vaccinated. For at-risk patients, including pregnant women, we know that increasing vaccine uptake is challenging and the true uptake rate is hard to establish because of difficulties in determining the denominator. This year, therefore, we are asking GPs and other providers to prioritise the improvement of vaccine uptake in those with chronic liver and neurological disease, including those with learning disabilities, who are at the highest risk of mortality from flu but have the lowest rate of vaccine uptake.

Children in clinical risk groups

Vaccine uptake is particularly low in children with clinical conditions that put them at risk of complications or hospitalisation from flu. As the programme extension to provide flu vaccine to all children will take time to implement, it is important that at risk children continue to be offered flu vaccination. In pilot areas provision should be in place to vaccinate children in an at-risk group, preferably in the same setting as their peers. They should also still be able to receive it through their general practice if they or their parent wishes. Children for whom Fluenz Tetra® is contraindicated should be offered a suitable alternative influenza vaccine, preferably in the same setting as their peers with appropriate staff available to deliver the inactivated injectable vaccine. Pilots will have systems in place to let general practice know when at risk children have been vaccinated to reduce the risk of them being vaccinated twice and also to enable general practice to identify those in the at risk groups who remain unvaccinated.

Appendix F: Pregnant women

Rationale and target groups

There is good evidence that pregnant women are at increased risk from complications if they contract flu.[iv,v] In addition, there is evidence that having flu during pregnancy may be associated with premature birth and smaller birth size and weight[vi,vii] and that flu vaccination may reduce the likelihood of prematurity and smaller infant size at birth associated with an influenza infection during pregnancy.[viii] Furthermore, a number of studies show that flu vaccination during pregnancy provides passive immunity against flu to infants in the first few months of life.[ix,x,xi,xii]

A review of studies on the safety of flu vaccine in pregnancy concluded that inactivated flu vaccine can be safely and effectively administered during any trimester of pregnancy and that no study to date has demonstrated an increased risk of either maternal complications or adverse fetal outcomes associated with inactivated influenza vaccine.[xiii]

All pregnant women are recommended to receive the inactivated flu vaccine irrespective of their stage of pregnancy.

When to stop offering the vaccine to pregnant women

The ideal time for flu vaccination is between September and early November before flu starts circulating. However flu can circulate considerably later than this and it may therefore be necessary to continue offering the vaccine to groups such as newly pregnant women. Clincians should apply clinical judgement to assess the needs of an individual patient, taking into account the level of flu-like illness in their community and the fact that the immune response following flu vaccination takes about two weeks to develop fully.

Data review and data recording

Uptake of vaccine by pregnant women, along with other groups, will be monitored. GPs will need to check their patient database throughout the flu season in order to identify women who are not pregnant at the start of the immunisation programme but become pregnant during the winter. GPs should also review their records of pregnant women before the start of the immunisation programme to ensure that women who are no longer pregnant are not called for vaccination (unless they are in other clinical risk groups) and so that they can measure the uptake of flu vaccine by pregnant women accurately.

Midwifery services

Midwives need to be able to explain the benefits of flu vaccination to pregnant women and either refer them back to their GP practice for the vaccine or offer the vaccine in the midwifery service itself. A number of different models exist including running flu vaccination clinics alongside the midwifery service, where cold storage facilities exist. Area Teams will explore ways of commissioning midwifery services to provide flu vaccination or linking midwifery services with GP practices. If arrangements are put in place where midwives administer the flu vaccine, it is important that the patient's GP practice is informed in a timely manner so their records can be updated accordingly, and included in vaccine uptake data collections.

Appendix G: Health and social care workers

Frontline health and social care workers have a duty of care to protect their patients and service users from infection. This includes getting vaccinated against flu. In 2013/14 there was a very encouraging and marked improvement in flu vaccination of health care workers, with a final overall uptake rate of 54.8% compared to 45.6% the previous year. However, the overall level of uptake is still below the 75% aspiration and we know there is scope for improvement because 43 of 271 trusts were able to achieve the 75% coverage target. Those that did not meet the target this winter will need to demonstrate they have robust plans in place to meet it in 2014/15.

Flu outbreaks can arise in health and social care settings with both staff and their patients/service users being affected when flu is circulating in the community. Employers are responsible for ensuring that arrangements are in place for the vaccination of their health and social care workers in direct contact with patients and service users. It is important that health and social care workers protect themselves by having the flu vaccine, and, in doing so, they reduce the risk of spreading flu to their patients, service users, colleagues and family members.

Vaccination of healthcare workers against flu significantly lowers rates of flu-like illness, hospitalisation and mortality in older people in healthcare settings[xiv].[xv, xvi,xvii] Vaccination of staff in social care settings may provide similar benefits. Flu immunisation of healthcare workers with direct patient contact and social care staff is likely to reduce the transmission of infection to vulnerable patients, some of whom may have impaired immunity that may not respond well to immunisation.

Vaccination of health and social care workers can also help reduce the level of sickness absences and will contribute to keeping the NHS and care services running. This is particularly important in the face of winter pressures.

Responsibility for funding and administering the seasonal flu vaccine to staff (other than those in clinical risk groups) lies with employers. This includes GP practices who need to have arrangements in place.

It is the responsibility of the NHS and social care bodies to ensure, as far as is reasonably practicable, that health and social care workers are free of, and are protected from exposure to infections that can be caught at work. Trusts/ employers should ensure that health and social care staff directly involved in delivering care are encouraged to be immunised and that processes are in place to facilitate this and to provide data on uptake for primary care staff on ImmForm.

Examples of staff who may be directly involved in delivering care include:

- clinicians, midwives and nurses, paramedics and ambulance drivers
- occupational therapists, physiotherapists and radiographers
- primary care providers such as GPs, practice nurses, district nurses, school nurses and health visitors

- social care staff working in care settings
- pharmacists, both those working in the community and in clinical settings, and
- staff working in direct support of clinical staff, often with direct patient care

A complete list of staff is available at Appendix A of the following ImmForm guidance: www.gov.uk/government/uploads/system/uploads/attachment_data/file/259657/Seasonal_flu_HCWs_ImmForm_UserGuide_acc2_final.pdf

Students and trainees in these disciplines and volunteers who are working with patients should also be included. This is not an exhaustive list and decisions to provide immunisation should be made on the basis of a local risk assessment as described in *Immunisation against infectious disease* www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book. Employers need to make vaccines available free of charge to employees if a risk assessment indicates that they are needed. See: www.hse.gov.uk/coshh/basics/assessment.htm.

The NHS Employers flu fighter campaign provides advice and guidance on running local healthcare worker vaccination campaigns, as well as digital files of posters and other campaign resources. These can be found at www.nhsemployers.org/flu.

Appendix H: Vaccine supply and ordering

It remains the responsibility of general practices to order sufficient flu vaccine for eligible patients in 2014/15 directly from manufacturers, apart from children less than 18 years of age as this has been centrally procured.

Ordering from more than one supplier is recommended in case of supplier delays or difficulties in delivery of the vaccine. Practices should also order appropriate vaccines for those with egg allergy.

This year, **Fluenz Tetra®** (a quadrivalent **live attenuated intranasal** influenza vaccine) will be supplied in place of Fluenz®. As **Fluarix™ Tetra** (a quadrivalent **inactivated intramuscular** influenza vaccine) will also be supplied (see table in Appendix H), care must be taken not to confuse the two 'Tetra' brands, especially as Fluarix™ Tetra is not licensed for use in children less than three years.

Vaccine supply and ordering

In order to simplify the supply of Fluenz Tetra® and inactivated flu vaccine for GPs and other providers during the phased implementation of the children's programme, PHE has centrally procured flu vaccine for all children aged from six months to less than 18 years old. This is for both those children who are part of the extension of the programme, and those children in clinical risk groups who are not part of the extension (ie both LAIV (Fluenz Tetra®) and inactivated flu vaccine for those children for whom Fluenz Tetra® is contraindicated or not suitable).

All flu vaccines for children can be ordered through the ImmForm website, as for other centrally purchased vaccines (www.immform.dh.gov.uk).

Centrally purchased flu vaccines available for each eligible cohort in the children's programme in 2014/15 are as follows (order through ImmForm website):

Eligible cohort	Vaccine available
Six months to less than two years old in clinical risk group	Offer suitable inactivated flu vaccine.
Two year olds to less than 17 years old in roll-out cohort and pilots	Offer LAIV (Fluenz Tetra®). If Fluenz Tetra® is contraindicated, then offer suitable inactivated flu vaccine.
Two year olds to less than 18 years old clinical risk groups (not in roll-out cohort and pilots)	Offer LAIV (Fluenz Tetra®). If Fluenz Tetra® is contraindicated, then offer suitable inactivated flu vaccine.

For all other eligible populations within the national flu programme, GPs remain responsible for ordering vaccines directly from manufacturers. It is recommended that orders are placed with more than one manufacturer in case of supplier delays or difficulties in the manufacture or delivery of the vaccine.

Vaccine virus strains

Flu viruses change continuously and the World Health Organization (WHO) monitors the epidemiology of flu viruses throughout the world. Each year it makes recommendations about the strains to be included in vaccines for the forthcoming winter: www.who.int/influenza/vaccines/virus/recommendations/2014_15_north/en/

It is recommended that trivalent vaccines for use in the 2014-2015 influenza season (northern hemisphere winter) contain the following:

- an A/California/7/2009 (H1N1)pdm09-like virus
- an A/Texas/50/2012 (H3N2)-like viru;
- a B/Massachusetts/2/2012-like virus

It is recommended that quadrivalent vaccines containing two influenza B viruses contain the above three viruses and a B/Brisbane/60/2008-like virus.

Vaccines available for the 2014/15 flu immunisation programme

The table sets out the vaccines that will be available for the 2014/15 flu immunisation programme.

Supplier	Name of product	Vaccine Type	Age indications	Contact details
Abbott Healthcare	Influvac®	Surface antigen, inactivated virus	From six months	0800 358 7468
	Imuvac®	Surface antigen, inactivated virus	From six months	
AstraZeneca UK Ltd	Fluenz Tetra® ▼	Live attenuated, nasal	From 24 months to less than 18 years of age	0845 139 0000
GlaxoSmithKline	Fluarix™ Tetra ▼	Split virion inactivated virus	From three years	0800 221 441
MASTA	Imuvac®	Surface antigen, inactivated virus	From six months	0113 238 7552
	Inactivated Influenza Vaccine (Split Virion) BP	Split virion, inactivated virus	From six months	
	Enzira®	Split virion Inactivated virus	From five years	
Novartis Vaccines	Agrippal®	Surface antigen, inactivated virus	From six months	08457 451 500
	Optaflu®▼	Surface antigen, inactivated virus, prepared in cell cultures	From 18 years	

Supplier	Name of product	Vaccine Type	Age indications	Contact details
Pfizer Vaccines	CSL Inactivated Influenza Vaccine	Split virion, inactivated virus	From five years	0800 089 4033
	Enzira®	Split virion Inactivated virus	From five years	
Sanofi Pasteur MSD	Inactivated Influenza Vaccine (Split Virion) BP	Split virion, inactivated virus	From six months	0800 085 5511
	Intanza® 9 micrograms	Split virion, inactivated virus	From 18 years – 59 years	
	Intanza® 15 micrograms	Split virion, inactivated virus	60 years of age and over	

None of the influenza vaccines for the 2014/15 season contain thiomersal as an added preservative.

Some flu vaccines are restricted for use in particular age groups. The Summary of Product Characteristics (SPC) for individual products **should always** be referred to when ordering vaccines for particular patients.

More detailed information on the characteristics of the available vaccines, including age indications and ovalbumin (egg) content can be found in the Influenza chapter of the Green Book.

Central strategic flu reserve

PHE will hold a central strategic reserve of inactivated flu vaccine. This will be used to mitigate the impact of any shortages in delivery of flu vaccines direct to GPs, should they occur. The reserve is intended as an insurance policy and will only be issued when PHE and DH determine that it is required to address national shortages that cannot be managed locally.

A guidance document outlining the circumstances under which the reserve will be made available to the NHS can be accessed here: www.gov.uk/government/publications/accessing-the-flu-vaccine-strategic-reserve-in-england, and orders will be placed through the ImmForm website.

Appendix I: Assurance, contractual arrangements, service reviews and funding

Contractual arrangements, service reviews and funding

NHS England is responsible for commissioning the seasonal flu immunisation programme under the NHS public health functions (Section 7A agreements) with the Secretary of State for Health, with two service specifications for the 'routine' seasonal flu programme (No.13) and for the extension of the programme to children (No. 13A).

Published in November 2013 the service specification for children stated that the programme will commence within secondary school children, the extent of the roll-out to be determined by April 2014. Copies of the agreements, including a variation to the original 2014/15 agreement on the programme for children which will specify the detail of the roll-out, can be found at: www.gov.uk/government/publications/public-health-commissioning-in-the-nhs-2014-to-2015

Delivery in General Practice

NHS England has developed a new national specification for delivering an influenza and pneumococcal immunisation scheme by GMS & PMS providers. The enhanced service covers securing flu immunisation services for the majority of the at risk groups including pregnant women, and in the case of pneumococcal immunisation, at risk patients. It also includes a new national price agreed with the General Practitioners Committee of the BMA (£7.64 per dose). NHS England may enter into arrangements with any other local provider, for example Alternative Providers of Medical Services and community pharmacies, to provide a flu immunisation service for all risk groups.

Screening and Immunisation Teams in NHS England Area Teams should note the requirements in the enhanced service and use these to assess the services provided. They will also check to ensure that the contracts for the flu immunisation programme are drafted in such a way as to ensure that general practice and other providers are obliged to provide the relevant data returns.

Delivery outside of General Practice

In addition to those patients who can attend a surgery or clinic to receive a vaccination, Area Teams need to plan to offer vaccination to those who require home visits; those who are in long-term care; those who are not registered with a general practice; and those adults and children that do not readily engage with the health system.

Robust plans must be in place to ensure that delivery of flu vaccinations outside general practices are collected and passed back to patients' GPs for timely entry on the electronic patient record and submission to ImmForm for the national data survey. Area Teams should work with GPs to ensure all data is recorded in a timely fashion. This is important for clinical reasons (such as any adverse events) and also to ensure that these vaccinations will be included in the vaccine uptake data collections.

Assurance

NHS England Area Teams will recognise the need to assess the quality of their local flu immunisation services, drive towards continuous improvement including progress to reaching and exceeding aspiration uptake levels, be responsive to patient needs, provide value for money and extend the reach of their immunisation programme to those who need it most. Patients who fail to attend for vaccination should be followed up and their needs reviewed. Area Teams should plan for the agreed targets and/ or performance measures set by the Public Health Section 7A service specifications. Area Teams ensure that:

- robust flu vaccination plans are in place to meet or exceed the vaccine uptake aspirations for 2014/15
- sufficient amounts of vaccine have been ordered from manufacturers for those aged 18 and over or from central supplies for children less than 18
- sufficient supplies of certain flu vaccines have been ordered for patients who require particular flu vaccines due to their age or because of contraindications; and
- arrangements are in place to ensure the collection and provision of data on immunisations to support the local and national monitoring of the delivery of the programme and flu vaccine uptake
- arrangements are in place to actively reduce any health inequalities; plans include provision of vaccinations for adults and children that do not readily engage with the health system in high risk settings such as care homes and special schools

For details about assurance arrangements for the children's pilots see the Section 7A service specification.

Supply and administration of vaccines

A range of mechanisms can be used for the supply and administration of vaccines, including Patient Group Directions (PGDs), Patient Specific Directions (PSDs) or prescribing. Where PGDs are developed, they must comply with the legal requirements specified in the Human Medicines Regulations 2012, and should reflect NICE good practice guidance on PGDs: http://publications.nice.org.uk/patient-group-directions-mpg2

For nationally commissioned immunisation and vaccination services, the PGDs need to be authorised by the commissioner of those services i.e. NHS England. This needs to be done by local director level staff with responsibility for clinical governance e.g. Area Team Medical or Nursing Directors.

Appendix J: Data collection

As in previous years, flu vaccine uptake data collections will be managed using the ImmForm website (www.immform.dh.gov.uk). PHE coordinates the data collection and will issue details of the collection requirements by the end of July and guidance on the data collection process by early September 2014. This guidance will be available at: www.gov.uk/government/collections/vaccine-uptake

The email contact for flu queries concerning data collection content or process should be directed to influenza@phe.gov.uk. Queries concerning ImmForm login details and passwords should be directed to helpdesk@immform.org.uk

Reducing the burden from data collections

Considerable efforts have been made to reduce the burden on GPs of data collections by increasing the number of automated returns that are extracted directly from GP IT systems. Over 90% of GP practices benefited from using automated IT data returns for flu vaccine uptake for the final 2013/14 survey. GP practices that are not able to submit automated returns should discuss their arrangements with their GP IT supplier. Health care worker uptake data can only be submitted manually.

Data collections for 2014/15

Monthly data collections will take place over four months during the 2014/15 flu immunisation programme. Subject to the Review of Central Returns (ROCR) approval, the first data collection will be for vaccines administered by the end of October 2014/15 (data collected in November), with the subsequent collections monthly thereafter, with the final data collection for all vaccines administered by the end of January 2015 (data collected in February). These collections will enable performance to be reviewed at Area Team level during the programme, with time to take action if needed, and for the uptake from the completed programme to be measured.

Data will be collected and reported monthly at national level and by Area Team. Additionally, data at local authority level will be collected once at the end of the campaign.

During the data collection period, those working in the NHS with relevant access are able, through the ImmForm website, to:

- see their uptake by eligible groups
- compare themselves with other anonymous general practices or areas
- validate the data on point of entry and correct any errors before data submission
- view data and export data into Excel, for further analysis
- make use of automated data upload methods (depending on the IT systems used at practices); and
- access previous years' data to compare with the current performance.

These tools can be used to facilitate the local and regional management of the flu vaccination programme.

Monitoring on a weekly basis

Weekly uptake data will be collected from a group of GP practices that have fully automated extract and upload facilities provided by their IT suppliers. This scheme has been implemented successfully for several vaccination seasons and provides high quality data from approximately 70% of GP practices allowing national level monitoring of the vaccination programme. These data will be published in the PHE weekly flu report that is published on its website throughout the flu season.

Vaccine uptake data collection of healthcare workers

Approval for a mandatory collection will be sought from the ROCR. Further details about this will be published at: www.gov.uk/government/collections/vaccine-uptake

PHE will be responsible for monthly collections of flu vaccine uptake data over four months during the 2014/15 flu season. Guidance will be provided to trusts and through Area Teams to all those involved in the collection and reporting of these data. Data will be published on the PHE website.

Area Teams can use their own methods of collecting information from GP practices so as to best meet the needs of their area. The recommended method of collecting healthcare worker data from GPs is through the ImmForm data entry tool. It is important to note that this data entry tool is not a route for GP practices to submit data directly to PHE and thus bypass Area Teams – it is the responsibility of the Area Team to submit the data collected via the data entry tool; this application is not monitored by PHE and no data are extracted from it by PHE. This data entry tool is one of many different options for Area Teams to collect staff flu vaccination data from GP practices and other organisations that carry out work on behalf of the NHS.

Appendix K: Footnotes

[i] *Excess winter mortality 2012-13, Figure 6:* https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/229819/Excess_winter_mortality_2012.pdf

[ii] Dexter L *et al* (2012) Strategies to increase influenza vaccination rates: outcomes of a nationwide cross-sectional survey of UK general practice. bmjopen.bmj.com/content/2/3/e000851.full

[iii] Table reproduced from Health Protection Agency's report *Surveillance of influenza and other respiratory viruses in the UK 2010-2011 report*. See: hpa.org.uk/webc/HPAwebFile/HPAweb_C/1296687414154

[iv] Neuzil KM, Reed GW, Mitchel EF *et al.* (1998) Impact of influenza on acute cardiopulmonary hospitalizations in pregnant women. *Am J Epidemiol.* **148**: 1094-102

[v] Pebody R *et al.* (2010) Pandemic influenza A (H1N1) 2009 and mortality in the United Kingdom: risk factors for death, April 2009 to March 2010. *Eurosurveillance* **15**(20): 19571.

[vi] Pierce M, Kurinczuk JJ, Spark P *et al.* (2011) Perinatal outcomes after maternal 2009/H1N1 infection: national cohort study. *BMJ.* **342**: d3214.

[vii] McNeil SA, Dodds LA, Fell DB *et al.* (2011) Effect of respiratory hospitalization during pregnancy on infant outcomes. *Am J Obstet Gynecol.* **204**: (6 Suppl 1) S54-7.

[viii] Omer SB, Goodman D, Steinhoff MC *et al.* (2011) Maternal influenza immunization and reduced likelihood of prematurity and small for gestational age births: a retrospective cohort study. *PLoS Med.* **8**: (5) e1000441.

[ix] Benowitz I, Esposito DB, Gracey KD *et al*. (2010) Influenza vaccine given to pregnant women reduces hospitalization due to influenza in their infants. *Clin Infect Dis.* **51**: 1355-61.

[x] Eick AA, Uyeki TM, Klimov A *et al*. (2010) Maternal influenza vaccination and effect on influenza virus infection in young infants. *Arch Pediatr Adolesc Med*. **165**: 104-11.

[xi] Zaman K, Roy E, Arifeen SE *et al*. (2008) Effectiveness of maternal influenza immunisation in mothers and infants. *N Engl J Med.* **359**: 1555-64.

[xii] Poehling KA, Szilagyi PG, Staat MA *et al.*(2011) Impact of maternal immunization on influenza hospitalizations in infants. *Am J Obstet Gynecol.* **204**: (6 Suppl 1) S141-8.

[xiii] Tamma PD, Ault KA, del Rio C, Steinhoff MC *et al*. (2009) Safety of influenza vaccination during pregnancy. *Am. J. Obstet. Gynecol*. **201**(6): 547-52.

[xiv] Potter J, Stott DJ, Roberts MA, et al. (1997) The influenza vaccination of health care workers in long-term-care hospitals reduces the mortality of elderly patients. *Journal of Infectious Diseases* **175**: 1-6.

[xv] Carman WF, Elder AG, Wallace LA, et al. (2000) Effects of influenza vaccination of healthcare workers on mortality of elderly people in long term care: a randomised control trial. *The Lancet*; **355**: 93-7.

[xvi] Hayward AC, Harling R, Wetten S, et al. (2006) Effectiveness of an influenza vaccine programme for care home staff to prevent death, morbidity, and health service use among residents: cluster randomised controlled trial. *British Medical Journal* doi:10.1136/bmj.39010.581354.55

[xvii] Lemaitre M, Meret T, Rothan-Tondeur M, et al. (2009) Effect of influenza vaccination of nursing home staff on mortality of residents: a cluster randomised trial. *Journal of American Geriatric Society* **57**:1580-6.