Department of Health | Public Health England

NHS England

27 March 2015

Dear Colleague,

The national flu immunisation programme 2015/16

Eligibility

1. We would like to thank everyone for their hard work on the national flu immunisation programme and we are now writing with information to begin preparations for 2015/16. The main change to the programme this year is the offer of flu vaccination to children of school years 1 and 2 age. Therefore, in 2015/16, the following 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 (but not five years or older) on 31 August 2015
    - all children of school years 1 and 2 age
    - those in long-stay residential care homes
    - carers
    - primary school-aged children in areas that previously participated in primary school pilots in 2014/15

2. We expect frontline health and social care workers to be offered flu vaccination by their employer. This includes general practice staff.

3. The influenza chapter in 'Immunisation against infectious disease' (the 'Green Book'), which is updated regularly, gives detailed descriptions of the groups outlined above and guidance for healthcare workers on administering the flu vaccine.

Vaccine effectiveness

4. Flu is a key factor in NHS winter pressures. It impacts on those who become ill, the NHS services that provide direct care as a result, and on the wider health and social care system that supports people in at risk groups. The annual immunisation programme helps to reduce unplanned hospital admissions and pressure on A&E and

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is therefore a critical element of the system-wide approach for delivering robust and resilient health and care services during winter.

5. The early vaccine effectiveness data that have been published for the 2014/15 mid-season estimates found that the overall flu vaccine programme, which is dominated by inactivated vaccine in adults, provided low protection against flu infection caused by one particular subtype, H3N2. This was because a drifted strain of flu A(H3N2) emerged in 2014/15 after the 2014/15 A(H3N2) vaccine strain had been selected in February 2014. Selection of strains for inclusion in the vaccine is made by the World Health Organization (WHO) each year in February (for the northern hemisphere); these strains are those predicted to circulate in the coming season. Throughout the last decade, there has generally been a good match between the strains of flu virus in the vaccine and those that subsequently circulated. Flu vaccination remains the best way to protect people from flu.

6. It is crucial that the above does not discourage people in any of the eligible groups from having flu vaccination this coming flu season. The communications strategy supporting the programme, and the associated materials and other patient information have been updated to reassure people, including those in at-risk groups and healthcare workers, that the flu vaccine remains their best protection against flu, and that a mismatch of this type is an unusual event.

7. The early vaccine effectiveness data published for the 2014/15 mid-season estimates relate to the overall flu vaccine programme, which mainly uses inactivated vaccine in adults. One of the reasons for the Committee on Vaccination and Immunisation (JCVI) recommending the use of the live attenuated influenza vaccine (LAIV) in children was the potential to provide coverage against circulating strains that have drifted from those contained in the vaccine. Vaccine effectiveness data specifically for LAIV in children is not yet available.

Extension of the programme to children

8. The children's programme began in 2013/14 with all two- and three-year-olds being offered vaccination through general practice and pilots in primary school-aged children. In 2014/15, this offer was extended to four-year-olds, with pilots in primary and secondary school-aged children. Vaccinating children each year means that not only are they protected but there should be reduced transmission across all age groups, lessening levels of flu overall and reducing the burden of flu across the population. Results from the first year of primary school-age pilot sites in 2013/14 were encouraging, with reduced numbers of GP attendances for influenza-like illness and reduced emergency department respiratory attendances in all age groups in pilot areas, compared to non-pilot areas. (See Appendix B).

9. In 2015/16, all two-, three- and four-year-olds continue to be eligible for flu vaccination, through general practice, as are primary school-aged children in areas that participated in primary school pilots last year. Local NHS England teams will commission the phase 2 extension of the programme to children of school years 1 and 2 age. Delivery models will vary by area, but are likely to be mainly through schools, for example, through school nursing teams or specialist immunisation teams, or in some instances through primary care services. A number of elements of the programme will be dependent upon local commissioning arrangements.

10. We anticipate that the children's programme, once fully implemented, will ultimately avert many cases of severe flu and flu-related deaths in older adults and people in clinical risk groups. We should continue, however, to work hard to ensure that we are communicating the benefits of the vaccine among all recommended groups, making vaccination as easily accessible for as many as possible.

Vaccine uptake ambitions

11. In 2014/15, the latest available flu vaccine uptake data shows the following uptake rates were achieved (including range in vaccine uptake levels by area team):

Eligible group	**Overall uptake (%)**	**Range in uptake by area team (%)**
65 years or older	72.8	69.2 - 76.5
Clinical risk groups aged 6 months to under 65 years	50.3	46.3 - 54.6
Pregnant women	44.1	39.6 - 50.6
2 years old	38.5	30.3 - 45.6
3 years old	41.3	32.7 - 48.4
4 years old	32.9	23.6 - 52.9
Frontline healthcare workers	54.9	42.0 - 76.3

Provisional vaccine uptake data is cumulative from 1 September 2014 to 31 January 2015 and represents 99.7% of all GP practices in England, apart from healthcare worker data that is from 1 September 2014 to 28 February 2015.

12. For 2015/16, it is our ambition that all eligible individuals are offered flu vaccine and every effort is made to ensure as high an uptake rate as possible in those aged 65 years and over, with the aim of reaching a minimum 75% uptake rate. For healthcare workers, trusts must ensure that a 100% offer of flu vaccination is made for all frontline staff, reaching a minimum uptake of 75%. Vaccine uptake for those in clinical risk groups needs to improve, particularly for those who are at the highest risk of severe disease and mortality from flu but have low rates of vaccine uptake, including those with chronic liver and neurological disease, and people with learning disabilities.

13. For the children's flu immunisation programme there should be a 100% offer of immunisation to eligible children. Providers and commissioners will be required, if asked, to demonstrate that such an offer has been made. A minimum uptake of 40% has been shown to be achievable in pilots conducted to date. As a minimum, we would expect uptake levels between 40-60% to be attained. Uptake levels should be consistent across all localities and sectors of the population.

14. Those eligible should be given flu vaccination as soon as vaccine is available. Vaccination may continue until December but, where possible, should be completed before flu starts circulating in the community. Flu can circulate considerably later in the season and clinicians should apply clinical judgement to assess the needs of individual patients for vaccination later in the season. 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.

Appendices

15. Detailed planning information is set out in the following appendices:

The Flu Pan

16. An updated Flu Plan is being published today alongside this letter. It can be found at: www.gov.uk/government/organisations/public-health-england/series/immunisation

Conclusion

17. Flu is unpredictable. It is not possible for the WHO to predict fully the strains that will circulate in any given season, and there is always a risk of a drift and subsequent mismatch occurring as was seen last flu season. However, it is important to note that this occurs rarely. In nine out of the last ten seasons the vaccine has provided good to moderate protection against the circulating strains. Flu vaccine is still the best protection we have against an unpredictable virus that can cause severe illness and deaths each year.

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

Yours sincerely,

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

Professor Paul Cosford
Public Health England,
Medical Director and Director for Health Protection

Dr Felicity Harvey
Department of Health,
Director General,
Public and International Health Directorate

To:
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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

1. In 2015/16, flu vaccinations will be offered at NHS expense to the following groups:

    - people aged 65 years or over (including those becoming age 65 years by 31 March 2016)
    - people aged from six months to less than 65 years of age with a serious medical condition such as:
        - chronic (long-term) respiratory disease, such as severe asthma, chronic obstructive pulmonary disease (COPD) or bronchitis
        - chronic heart disease, such as heart failure
        - chronic kidney disease at stage three, four or five
        - chronic liver disease
        - chronic neurological disease, such as Parkinson's disease or motor neurone disease, or learning disability
        - diabetes
        - splenic dysfunction
        - a weakened immune system due to disease (such as HIV/AIDS) or treatment (such as cancer treatment)
    - all pregnant women (including those women who become pregnant during the flu season)
    - all those aged two, three, and four years (but not five years or older) on 31 August 2015 (i.e. date of birth on or after 1 September 2010 and on or before 31 August 2013) through general practice[1]
    - all children of school years 1 and 2 age through locally commissioned arrangements[2]
    - primary school-aged children in areas that participated in primary school pilots in 2014/15
    - 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
    - people who are in receipt of a carer's allowance, or those who are the main carer of an older or disabled person whose welfare may be at risk if the carer falls ill
    - consideration should also be given to the vaccination of household contacts of immunocompromised individuals, specifically individuals who expect to share living accommodation on most days over the winter and, therefore, for whom continuing close contact is unavoidable

2. 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.

3. Also recommended to be vaccinated as part of an employer's occupational health obligation:

    - health and social care workers with direct patient/service user contact

4. The JCVI has also advised that morbidly obese people (defined as BMI 40+) could also benefit from a flu vaccination. This has not been included as part of the GP contract in the 2015/16 DES. Many in this patient group will already be eligible due to complications of obesity that place them in another risk category. Practices will need to use clinical judgement to decide whether to vaccinate this group of patients, but vaccinations for morbidly obese patients with no other recognised risk factor will not attract a payment under the DES in 2015/16. The inclusion of this patient group into the flu programme from 2016/17 is currently under consideration.

Healthcare practitioners should refer to the Green Book influenza chapter for further detail about clinical risk groups included in the national flu immunisation programme.
This is regularly updated, sometimes during the flu season, and can be found at: www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book
Further information on the service specification for delivery of the seasonal influenza immunisation programme and the seasonal influenza programme for children can be found at:www.gov.uk/government/publications/public-health-commissioning-in-the-nhs-2015-to-2016

[1] Some four-year-olds who have started school may be offered flu vaccination through a school-based provider depending on local commissioning arrangements
[2] Year 1 is defined as five- rising to six-year-olds (ie date of birth between 1 September 2009 and on or before 31 August 2010)
Year 2 is defined as six- rising to seven-years-olds (ie date of birth between 1 September 2008 and on or before 31 August 2009)
Some children in years 1 and 2 might be outside of these date ranges (eg if a child has been accelerated or held back a year). It is acceptable to offer and deliver immunisations to these children with their class peers.

Appendix B: National extension of flu programme to children

Background

1. Following advice from JCVI the routine annual flu vaccination programme is being extended to include children in England (with similar schemes being taken forward in Wales, Scotland and Northern Ireland). This extension is being phased in over a number of years

2. Vaccinating children each year will provide a number of benefits:
   - providing direct protection thus preventing a large number of cases of flu in children
   - providing indirect protection by lowering flu transmission from children:
     - to other children
     - to adults
     - to those in the clinical risk groups of any age

     thus averting many cases of severe flu and flu-related deaths in older adults and people with clinical risk factors
   - reducing absence from work or school which would otherwise result because people are ill or need to remain home to care for someone else who is ill

3. In 2014/15, a drifted strain of A(H3N2) emerged and circulated after the A(H3N2) vaccine strain had been selected resulting in a mismatch between the A(H3N2) strain selected for the vaccine and the main A(H3N2) strain that was circulating. The early vaccine effectiveness estimates that have been published for the 2014/15 mid-season relate to the overall flu vaccine programme, which is dominated by inactivated vaccine in adults. Vaccine effectiveness data specifically for LAIV in children are not yet available. One of the reasons for JCVI recommending the use of LAIV was the potential to provide coverage against circulating strains that have drifted from those contained in the vaccine. Once the impact of the drifted strain on LAIV effectiveness in 2014/15 is known we will provide further information for health professionals and the public as appropriate.

Implementation of the childhood flu immunisation programme

4. Implementation of the programme began in 2013/14, with all two- and three-year-olds being offered vaccination through GP surgeries and four- to 11-year-old children in seven areas being offered vaccination through pilot programmes. The pilots have been testing a variety of delivery methods and have mostly been in primary schools, with some working through general practice and community pharmacies.

5. In 2014/15, the vaccination was offered to all two- to four-year-olds, and the pilot programme extended to include children in years 7 and 8 (aged 11 to 13 years) in selected pilot areas.

6. Despite the low flu activity in 2013/14, early results, although statistically non-significant, suggest a positive impact on flu transmission of the pilot vaccination programmes in primary schools. Results were obtained from a range of surveillance indicators including GP consultations for influenza-like illness, swab positivity in primary care, laboratory confirmed hospitalisations and percentage of respiratory emergency department attendances[1]:

    - the cumulative GP consultation rate for 'influenza-like illness' in all age groups over the 2013/14 season was higher in non-pilot (64.5/100,000) compared to pilot areas (17.7/100,000)
    - the cumulative influenza positivity rate in all ages in primary care in pilot areas was 8.5% compared to 16.2% in non-pilot areas
    - the cumulative proportion of emergency department respiratory attendances was 5.5% in pilot compared to 8.7% in non-pilot areas

Cohorts eligible from 2015/16

7. In 2015/16, all two-, three- and four-years-olds (but not five years or older) on 31 August 2015 will continue to be offered flu vaccination through GP surgeries. Four-year-olds who have started school could receive their vaccination from either primary care or a school-based provider depending on local commissioning arrangements.

8. In 2015/16, extension of the programme will be to children of school years 1 and 2 age. It is likely that the children will be vaccinated predominantly in primary school settings, with local NHS England teams commissioning these services directly with local providers. Vaccination will continue to be offered to primary school-aged children in the areas that participated in the primary school pilots in 2014/15.

9. It is important that children in clinical risk groups are immunised for their own benefit to reduce their risk of morbidity and mortality associated with influenza infection. Every effort should be made to ensure all at-risk children are immunised where appropriate.

10. Once the first round of vaccination has occurred in all children in eligible school year groups, providers should target children in at-risk groups who have not yet been vaccinated – to offer them individual benefit. Then, if considered necessary, a limited number of sessions for children who missed out on vaccination during the first round could be considered towards the end of the season. Such arrangements would be subject to local commissioning agreement.

11. Children who are not in clinical risk groups should be offered Fluenz Tetra® only. A child who is unable to have Fluenz Tetra for reasons other than being medically contraindicated will continue to derive benefit from the programme by virtue of the interruption of transmission among their peers. The impact of this policy continues to be monitored and kept under review in line with the requirements of the Equality Act.

12. Children who are in clinical risk groups should be offered a suitable alternative vaccine if medically contraindicated to Fluenz Tetra.

13. Where a child is vaccinated but not by their GP, it is important that the vaccination information is provided to the practice for the timely update of clinical records.

National extension schedule beyond 2015/16

14. The principle for the future extension of the programme beyond 2015/16 will be to extend upwards through the age cohorts. Plans are subject to the outcome of the Spending Review, and the annual agreement between the Department of Health and NHS England regarding public health functions (Section 7A agreement).

[1] Pebody, R *et al*. 5 June 2014. Uptake and impact of a new live attenuated influenza vaccine programme in England: early results of a pilot in primary school age children, 2013/14 influenza season. *Eurosurveillance*, **19**, Issue 22. www.eurosurveillance.org/ViewArticle.aspx?ArticleId=20823

Appendix C: Health and social care workers

Background

1. Frontline health and social care workers have a duty of care to protect their patients and service users from infection. Therefore, as in previous years, flu immunisation should be offered by NHS organisations to all employees directly involved in delivering care. This is not an NHS service, but an occupational health responsibility being provided to NHS staff by employers. Social care providers and independent primary care providers such as GP, dental and optometry practices, and community pharmacists, should offer vaccination to staff.

2. Doctors are reminded of the General Medical Council's (GMC) guidance on Good Medical Practice (2013), which advises immunisation 'against common serious communicable diseases (unless otherwise contraindicated)' in order to protect both patients and colleagues (see paragraph 29 at: www.gmc-uk.org/guidance/good_medical_practice/your_health.asp)

3. Chapter 12 of the Green Book provides information on which groups of staff can be considered as directly involved in delivering care, but examples might include:

    - clinicians, midwives, nurses, and ambulance crew
    - 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
    - students and trainees in these disciplines and volunteers who are working with patients should also be included

4. This is not an exhaustive list and decisions to provide immunisation should be based on local assessment of likely risk and exposure.

Rationale for vaccination

5. While vaccination of NHS staff remains voluntary, we would encourage all employers to offer the vaccine in an accessible way, and all staff to consider seriously the benefits to themselves and their family contacts, their patients, and the NHS and as a result accept the offer of the vaccine.

6. Flu outbreaks can occur in health and social care settings with both staff and their patients/clients being affected. It is important that health professionals protect

themselves by having the flu vaccine, and, in doing so, they reduce the risk of spreading flu to their family members.

7. Vaccination of healthcare workers with direct patient contact against flu has been shown to significantly lower rates of flu-like illness, hospitalisation and mortality in the elderly in long-term healthcare settings.[1, 2, 3, 4] Vaccination of staff in acute care settings may provide similar benefits. Flu immunisation of frontline health and social care staff may reduce the transmission of infection to vulnerable patients, some of whom may have impaired immunity increasing their risks of flu and who may not respond well to immunisation.

8. Vaccination of frontline workers also helps reduce the level of sickness absences and can help ensure that the NHS and care services are able to continue operating over the winter period. This is particularly important when responding to winter pressures, and winter planning should seek to take account of the importance of staff vaccination across the NHS and care services.

9. The mid-season vaccine effectiveness estimates for the overall flu vaccine programme in 2014/15 found that the vaccine provided low protection against flu infection due to one particular subtype, H3N2. This was because a drifted strain of flu A(H3N2) emerged after the A(H3N2) vaccine strain had been selected resulting in a mismatch between the vaccine strain and the main A(H3N2) that circulated. The PHE study, based on the results from 1,314 patients presenting in primary care across the UK, found that vaccine effectiveness in preventing laboratory-confirmed influenza was estimated to be 3% overall (with an upper 95% confidence interval of 35%).[5] This compares with approximately 50% vaccine effectiveness that has typically been seen in the UK over recent years. It is crucial that this experience does not discourage healthcare workers or people in at-risk groups from having flu vaccination this coming flu season. Throughout the last decade, there has generally been a good match between the strains of flu in the vaccine and those that subsequently circulated and flu vaccination remains the best way to protect people from flu.

Communications

10. Misconceptions about flu vaccine are common, including amongst health and social care workers. The following messages should be promoted to frontline staff in acute, primary, community and social care services:

    - as professionals, it is part of our duty of care to patients or residents to do everything in our power to protect them against infection, including being immunised against flu
    - getting vaccinated against flu can help protect us, our patients and family

- we are all susceptible to flu, even if we are in good health and eat well. Frontline health and social care staff are, however, in frequent contact with people who are particularly vulnerable to the effects of flu
- you can be infected with the virus and have no symptoms of flu but can still pass the virus to others including patients or residents
- good infection control measures are also essential. They reduce the spread of flu and other acute respiratory infections in healthcare settings, but are not sufficient alone to prevent them
- the impact of flu on frail and vulnerable patients can be fatal and outbreaks of the virus can cause severe disruption in communities, care homes and hospitals
- the flu vaccine has a good safety record and will help protect you. It cannot give you flu. Having the vaccination can encourage your colleagues to do likewise
- throughout the last ten years there has generally been a good to moderate match between the strains of flu virus in the vaccine and those that subsequently circulated
- it means that staff act as positive role models for patients aged 65 and over, those with long-term health conditions and pregnant women, to take up the offer too

11. NHS Employers runs the ‘Flu Fighters’ campaign and provide useful resources to support flu vaccination among healthcare workers. Information on its campaign, and the clinical evidence behind the key messages outlined above, can be found at: www.nhsemployers.org/campaigns/flu-fighter
12. Clinics should, as far as possible, be arranged at the place of work and should include clinics during early, late and night shifts, at convenient locations throughout the workplace. Clinics should be run efficiently with administrative support to deal with paperwork, to manage staff and data collection. This will result in staff having quick, easy access to the vaccine.

13. Drop-in clinics should also be considered for staff unable to make their designated appointment or who may have changed their mind.

Vaccination in non-NHS organisations

14. For non-NHS organisations, responsibility for provision of occupational flu immunisation also rests with employers. Immunisation should be provided through occupational health services or other arrangements with private healthcare providers. It is vital that health and social care staff not only protect themselves against flu, but recognise the importance of protecting patients in their care and their professional responsibility in this regard.

15. It is recommended that NHS independent contractors (GPs, dentists, community pharmacists and optometrists) consider vaccination of their employed staff, and responsibility for this lies with employers as above. Staff should not be asked to go to their GP for their immunisation unless they fall within one of the recommended at-risk groups, or GPs have been contracted specifically to provide this service.

16. Teams involved in the vaccination of staff are reminded that occupational health services are recommended to keep records of staff who have been immunised. The information on vaccination should also be sent to GP practices, with the patient's permission, to update their patient records. It is important that accurate and up-to-date information on vaccine uptake in staff is available.

[1] 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.
[2] 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.
[3] 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
[4] 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.
[5] Pebody, R *et al.* (2015) Low effectiveness of seasonal influenza vaccine in preventing laboratory-confirmed influenza in primary care in the United Kingdom: 2014/15 mid-season results. *Eurosurveillance.* **20.** Issue 5. www.eurosurveillance.org/ViewArticle.aspx?ArticleId=21025

Appendix D: Pregnant women

Rationale and target groups

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

2. There is good evidence that pregnant women are at increased risk from complications if they contract flu.[1, 2] In addition, there is evidence that having flu during pregnancy may be associated with premature birth and smaller birth size and weight[3, 4] and that flu vaccination may reduce the likelihood of prematurity and smaller infant size at birth associated with an influenza infection during pregnancy.[5] Furthermore, a number of studies show that flu vaccination during pregnancy provides protection against flu to infants in the first few months of life.[6, 7, 8, 9, 10]

3. 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.[11]

When to offer the vaccine to pregnant women

4. The ideal time for flu vaccination is before flu starts circulating. However, even after flu is in circulation vaccine should continue to be offered 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

5. 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

6. 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. Local NHS England teams will explore ways of commissioning midwifery services to provide flu vaccination or linking midwifery services with GP practices or community pharmacies where relevant. If arrangements are put in place where midwives or pharmacists 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.

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[1] 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

[2] 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.

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

[4] 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.

[5] 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.

[6] 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.

[7] 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.

[8] 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.

[9] 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.

[10] Dabrera G, Zhao H, Andrews N *et al.* (2014) Effectiveness of seasonal influenza vaccination during pregnancy in preventing influenza infection in infants, England, 2013/14. *Eurosurveillance*. Nov 13;**19**. www.eurosurveillance.org/ViewArticle.aspx?ArticleId=20959

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

Appendix E: Vaccine supply and ordering

Vaccine composition for 2015/16

1. Flu viruses change continuously and the 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. For the 2015/16 flu season (northern hemisphere winter) it is recommended that trivalent vaccines contain the following:

    - an A/California/7/2009 (H1N1)pdm09-like virus
    - an A/Switzerland/9715293/2013 (H3N2)-like virus
    - a B/Phuket/3073/2013-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.

2. For further information see: www.who.int/influenza/vaccines/virus/recommendations/consultation201502/en/

3. The WHO recommendation includes changing the H3N2 component to include a vaccine strain to better match the drifted H3N2 strain seen in the northern hemisphere 2014/15 flu season.

Vaccine suppliers

4. **All** flu vaccines for children are purchased centrally by PHE. This includes vaccine for the national offer to all children aged two to four years and children of school years 1 and 2 age, and for children in risk groups aged six months to less than 18 years.

5. For children in risk groups under 18 years of age where Fluenz Tetra is contraindicated, suitable inactivated influenza vaccines will be provided centrally and should be offered. The quadrivalent inactivated influenza vaccine (Fluarix™ Tetra®) is authorised for children aged from three years and is preferred because of the additional protection offered. Children aged from six months to less than three years should be given inactivated influenza vaccine (Split Virion) BP®. Fluenz Tetra and inactivated injectable vaccines can be ordered through the ImmForm website: www.immform.dh.gov.uk.

6. Care must be taken not to confuse the two 'Tetra' brands available for children:

    - **Fluenz Tetra** is a quadrivalent **live attenuated intranasal** influenza vaccine.
    - **Fluarix Tetra** is a quadrivalent **inactivated intramuscular** influenza vaccine and is not licensed for use in children aged less than three years.

7. For all other eligible populations apart from children providers 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.

8. The vaccines that will be available for the 2015/16 flu immunisation programme are set out in the table below.

Supplier	Name of product	Vaccine type	Age indications	Contact details
AstraZeneca UK Ltd	Fluenz Tetra ▼	Live attenuated, nasal	From 24 months to less than 18 years of age	0845 139 0000
BGP Products Ltd, formerly Abbott Healthcare*	Influvac®	Surface antigen, inactivated virus	From six months	0800 358 7468
	Imuvac®	Surface antigen, inactivated virus	From six months	
GSK	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	
	Agrippal®	Surface antigen, inactivated virus	From six months	
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	
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® 15µg	Split virion, inactivated virus	60 years of age and over	

None of the influenza vaccines for the 2015/16 season contain thiomersal as an added preservative.

* The name of this company might be subject to change.

9. 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.

10. More detailed information on the characteristics of the available vaccines, including ovalbumin (egg) content will be available in due course. Usually published as part of the influenza chapter of the Green Book, this year it will be published separately so that we can issue the updated Green Book chapter earlier than usual.

Central strategic flu reserve

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

12. Orders can be placed through the ImmForm website and a guidance document outlining the circumstances under which the reserve will be made available to the NHS can be found at: www.gov.uk/government/publications/accessing-the-flu-vaccine-strategic-reserve-in-england

Use of live attenuated influenza vaccine Fluenz Tetra®

13. The Green Book states that the live attenuated influenza vaccine (LAIV), administered as a nasal spray, is the vaccine of choice for children because of higher efficacy in children compared with other flu vaccines. The vaccine is licensed for those aged from 24 months to less than 18 years of age. 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
- 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

14. Fluenz Tetra is unsuitable for children with contraindications such as severe immunodeficiency, severe asthma or active wheeze. Following more evidence on the safety of Fluenz Tetra in egg allergic children, JCVI has amended its advice on offering it to children with egg allergy. For the full list of contraindications please see the Green Book, where the amended advice on egg allergy will be published shortly. GPs should ensure that they have ordered sufficient supplies of suitable alternative inactivated injectable vaccines for children who cannot have Fluenz Tetra for medical reasons.

15. The type of vaccine to offer children under 18 is as follows:

Eligible cohort	**Vaccine available: Children in clinical risk groups***	**Vaccine available: Children <u>not</u> in clinical risk groups**
Six months to less than two years old	Offer suitable inactivated flu vaccine.	Not applicable.
Two, three and four years olds (but not five years or older) on 31 August 2015	Offer LAIV (Fluenz Tetra). If Fluenz Tetra is medically contraindicated, then offer suitable inactivated flu vaccine.	Offer LAIV (Fluenz Tetra) (unless medically contraindicated).
Children of school years 1 and 2 age	Offer LAIV (Fluenz Tetra). If Fluenz Tetra is medically contraindicated, then offer suitable inactivated flu vaccine.	Offer LAIV (Fluenz Tetra) (unless medically contraindicated).
Children older than school year 2 age but less than 18 years old	Offer LAIV (Fluenz Tetra). If Fluenz Tetra is medically contraindicated, then offer suitable inactivated flu vaccine.	Not applicable.

* 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).

16. 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 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).

17. Fluenz Tetra contains a highly processed form of gelatine (derived from pigs). Some faith groups do not accept the use of porcine gelatine in medical products. Current policy is that **only** those who are in clinical risk groups and have clinical contra-indications to Fluenz Tetra are able to receive an inactivated injectable vaccine as an alternative. The implications of this for the programme will continue to be monitored.

Healthcare practitioners should refer to the Green Book influenza chapter for full details on contraindications and precautions for flu vaccines. This chapter can be found at: www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book.

Appendix F: Data collection

Introduction

1. 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 2015. This guidance will be available at: www.gov.uk/government/collections/vaccine-uptake which is where flu vaccine uptake data is also published.

2. 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

3. 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 2014/15 survey. GP practices that are not able to submit automated returns should discuss their arrangements with their GP IT supplier. Healthcare worker uptake data can only be submitted manually.

Data collections for 2015/16

4. Monthly data collections will take place over four months during the 2015/16 flu immunisation programme. Subject to the Burden Advice and Assessment (BAAS) approval, the first data collection will be for vaccines administered by the end of October 2015 (data collected in November 2015), with the subsequent collections monthly thereafter, and with the final data collection for all vaccines administered by the end of January 2016 (data collected in February 2016). These collections will enable performance to be reviewed at local NHS England team level during the programme, with time to take action if needed, and for the uptake from the completed programme to be measured.

5. Data will be collected and reported monthly at national level and by local NHS England team level. Additionally, data at local authority level will be collected once at the end of the campaign.

6. 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)
    - access previous years' data to compare with the current performance

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

Monitoring on a weekly basis

8. 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 90% 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 at: www.gov.uk/government/publications/weekly-national-flu-reports.

Vaccine uptake data collection of healthcare workers

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

10. PHE will be responsible for monthly collections of flu vaccine uptake data over four months during the 2015/16 flu season. Guidance will be provided to trusts and through local NHS England teams to all those involved in the collection and reporting of these data. Data will be published on the PHE website.

11. Local NHS England 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 local NHS England teams – it is the responsibility of the local NHS England teams 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 local NHS

England teams to collect staff flu vaccination data from GP practices and other organisations that carry out work on behalf of the NHS.

Vaccine uptake data collection of children of school years 1 and 2 age

12. PHE will be responsible for monthly collections of flu vaccine uptake for children of school years 1 and 2 age over four months during the 2015/16 flu season. Collection will be undertaken through the Immform data entry tool.

Appendix G: Contractual arrangements and GP practice checklist

Delivery in general practice

1. The enhanced service specification for seasonal influenza and pneumococcal immunisation outlines the additional services that GP practices must provide for these vaccines for those contracted to provide this service. The programme has been agreed between NHS Employers (on behalf of NHS England) and the General Practitioners Committee (GPC) of the British Medical Association (BMA).

2. The patients eligible for flu vaccination under the enhanced service are those patients aged 65 and over on 31 March 2016, pregnant women, those patients aged six months to 64 years (excluding patients aged two, three and four as of 31 August 2015) defined as at-risk in the Green Book.

3. There is a separate enhanced service specification for the childhood seasonal influenza vaccination programme, covering the vaccination of children aged two, three and four as of 31 August 2015.

4. General practices are reminded that the enhanced service requires that a proactive call and recall system is developed to contact all at-risk patients through such mechanisms as letter, e-mail, phone call, text or otherwise although such strategies are for GP practices to determine. Revised template letters for practices to use will be available at www.gov.uk/government/collections/annual-flu-programme nearer the time.

5. GP practices are encouraged to review their systems in the light of the GP practice checklist in the box at the end of the appendix. The checklist highlights good practice and is based upon the findings from a study examining the factors associated with higher vaccine uptake in general practice[1].

6. NHS England, through local NHS England teams, will monitor the enhanced services that GP practices provide for flu vaccination to ensure that services comply with the specifications. Local NHS England teams will need assurance that providers have robust implementation plans in place to meet or exceed the vaccine uptake aspirations for 2015/16 and that they have the ability to identify eligible ‘at-risk’ patients and two-, three- and four-year-olds.

Other providers

7. GP practices will continue to be the main provider of flu vaccinations but local NHS England teams 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, particularly to promote uptake amongst groups

who traditionally find services hard to access or where vaccine uptake needs improving such as in at-risk groups and pregnant women.

8. Data on flu vaccinations administered outside general practice, including those undertaken in schools, must be passed back to the patients' GP surgery for timely entry on the electronic patient record and submission to ImmForm for the national data survey. This is important for clinical reasons (such as any adverse events) and also to ensure that these vaccinations are included in the vaccine uptake figures.

Vaccination of children of school years 1 and 2 age

9. NHS England will commission the services for all children of school years 1 and 2 age who will now be offered flu vaccination from 2015/16 onwards. The majority of the vaccinations will be delivered in schools although NHS England will have options to commission services from a range of local healthcare providers, including in primary medical care or community pharmacies.

10. Children of school years 1 and 2 age in clinical risk groups may be offered Fluenz Tetra alongside their peers as part of local provision. If a child in an at-risk group does not receive flu vaccination through this route, then they should be offered it in general practice. For instance, a child may miss out because of being absent from school on the day the vaccination was offered or because the child is contraindicated to Fluenz Tetra and the local service provider does not offer inactivated flu vaccines.

Supply and administration of vaccines

11. 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.

12. For nationally commissioned immunisation and vaccination services, the PGDs need to be authorised by the commissioner of those services ie NHS England. This needs to be done by local director level staff with responsibility for clinical governance eg local NHS England team medical or nursing directors.

The enhanced service specifications for seasonal flu and the childhood flu vaccination programmes can be found at: www.england.nhs.uk/commissioning/gp-contract/

GP practice 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.
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 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 community or health and social care trusts to identify and offer flu vaccination to residents in care homes, nursing homes and house-bound patients.

[1] 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

Appendix H: Communications

1. An integrated communications strategy will be produced for the national flu immunisation programme 2015/16. The strategy will be led by PHE and will provide communications colleagues in partner organisations with information and resources to assist the delivery of the programme. Partners include DH, NHS England, NHS Employers, the Department for Education and the Local Government Association – for the health and social care audience.

Publicity and information materials

2. Ahead of the flu season, NHS-branded patient information leaflets for different eligible groups will be reviewed. This will include revisions to reassure people that the flu vaccine remains their best protection against flu, despite the mismatch last year between the vaccine strain and the main strain of flu that circulated.

3. The following template letters will also be available to GP practices:

    - to invite at-risk patients and those aged 65 and over for flu vaccination
    - to invite two-, three- and four-year-olds

4. The following materials for the delivery of flu vaccination through schools will be available:

    - a briefing pack for schools
    - a national consent form
    - template letters to invite children in years 1 and 2 for flu vaccination
    - the ‘Protecting your child against flu’ leaflet

5. NHS Employers have run a ‘Flu Fighters’ campaign to support flu vaccination of healthcare workers in previous years, and their resources have been available to order from their website at: www.nhsemployers.org/campaigns/flu-fighter.

6. National training slide sets for healthcare professionals will be updated, including:
    - the National flu programme training slide set for healthcare professionals
    - the Childhood flu programme training slide set for healthcare professionals
    - Influenza vaccine and porcine gelatine: Q&A for health professionals

National marketing campaign

7. The 2014/15 marketing campaign (‘It’s free because you need it’) is being evaluated and the lessons learned will inform any campaign plans for 2015/16. Further information will be issued in due course.

All materials will be made available on the GOV.UK website at: www.gov.uk/government/collections/annual-flu-programme. Materials used in previous years can also be found here. Free copies of the leaflets will be available to order through the Prolog Publications Orderline: www.orderline.dh.gov.uk/ecom_dh/public/home.jsf