





26 March 2018

Dear colleague,

#### The national flu immunisation programme 2018/19

This letter (flu letter: no. 1) provides information about which patients and children are eligible for vaccination in the flu immunisation programme for 2018/19. A second letter will follow in late spring with information about frontline healthcare workers and social care workers.

#### Eligibility

- In 2018/19 the one change in eligibility is the extension to an additional cohort of children, those in school year 5. Therefore, in 2018/19 the following are eligible for flu vaccination:
- all children aged two to nine (but not ten years or older) on 31 August 2018
- all primary school-aged children in former primary school pilot areas
- those aged six months to under 65 years in clinical risk groups
- pregnant women
- those aged 65 years and over
- those in long-stay residential care homes
- carers
- 2. In addition, vaccination is recommended for frontline health and social care workers (see letter no.2 to follow)

### National flu immunisation priorities

3. The last season's higher level of flu activity is an important reminder that flu can have a significant impact and is highly unpredictable. This year saw record flu vaccination levels, with nearly one and a half million more people getting the vaccination than last year. We should strive to further improve vaccine uptake rates in all eligible cohorts next year.

- 4. NHS England has already written to GPs, community pharmacies and Clinical Commissioning Groups to confirm that the most effective flu vaccines for the population should be ordered, for the 2018/19 flu season. Based on the advice of the Joint Committee on Vaccination and Immunisation (JCVI), providers should offer:
  - the adjuvanted trivalent vaccine (aTIV) for all 65s and over. NHS England has recommended that the adjuvanted trivalent influenza vaccine (aTIV) be made available to all those aged 65 and over in 2018/19. This is the most effective vaccine currently available for this group. This reflects current JCVI advice and Green Book guidance published in December 2017 by Public Health England (PHE). Note: JCVI considers aTIV to be more effective and cost-effective than the non adjuvanted vaccines currently in use in the elderly (including quadrivalent vaccine (QIV)).
  - the quadrivalent vaccine (QIV) for 18 under 65s at risk. NHS England has
    recommended that adults aged 18 to under 65 in clinical at-risk groups are
    offered the quadrivalent influenza vaccine (QIV) which protects against four
    strains of flu. This reflects current JCVI advice and Green Book guidance that
    was updated in October 2017 on the basis of cost-effectiveness data produced
    by PHE.
- 5. The live attenuated influenza vaccine (LAIV) used for the children's programme is also quadrivalent. We ask that increased effort is given to the vaccination of preschool children as uptake is not as high as in schools. The effectiveness of LAIV offered to children is good; furthermore children under the age of five years old have the highest rate of hospital admissions for flu of all age groups. Improving uptake in these children and children with an underlying clinical risk factor will provide individual protection as well as helping to protect the wider community.

### Vaccine uptake ambitions

- 6. Vaccine uptake ambitions for 2018/19 are similar to previous years. The long-term ambition for eligible adults is a minimum 75% uptake rate is achieved, as recommended by the World Health Organization. In the case of at risk groups the ambition is an interim one because current uptake is some way from 75%.
- 7. As a key objective in the children's programme is to maximise reduction of flu transmission, in addition to individual protection, the ambition beyond 2018/19 will be based on levels of vaccine uptake needed to achieve this impact. The proposed ambitions are different for the preschool and school-aged children as achieving higher uptake in general practice is more challenging than in schools.

Table 1: Vaccine uptake ambitions in 2018/19

Eligible groups	Uptake ambition			
Routine programme				
Aged 65 years and over	<b>75%</b> , reflecting the World Health Organization (WHO) target for this group.			
Aged under 65 'at risk', including pregnant women	At least 55% in all clinical risk groups*, and maintaining higher rates where those have already been achieved. Ultimately the aim is to achieve at least a 75% uptake in these groups given their increased risk of morbidity and mortality from flu.			
Children's progran	nme			
Preschool children aged 2 and 3 years old	At least 48% with most practices aiming to achieve higher.			
School aged children (in reception class & years 1 to 5)	An average of at least 65% to be attained by every provider across all years.			

<sup>\*</sup> interim ambition

8. Providers should actively invite 100% of eligible individuals (e.g. by letter, email, phone call, text) and ensure uptake is as high as possible. Providers and commissioners will be required, if asked, to demonstrate that such an offer has been made. The benefits of the vaccine among all recommended groups should be communicated and vaccination made as easily accessible as possible.

### **Timing**

- Although the enhanced service specification for flu includes payment for vaccines given up until 31 March 2019, vaccination, using the most effective vaccine, should be given as soon as possible to provide protection before flu starts to circulate. Ideally vaccination should be completed by the end of November.
- 10. In general it is appropriate to still offer vaccination to eligible patients at any subsequent point in the flu season, even if they present late for vaccination. This can be particularly important if it is a late flu season or when newly at risk

patients present, such as pregnant women who may have not been pregnant at the beginning of the vaccination period. The decision to vaccinate should take into account the level of flu-like illness in the community, bearing in mind that the immune response to vaccination takes about two weeks to develop fully.

11. It should be noted that for the children's programme, LAIV has a short shelf life and there will only be limited availability of vaccine late in the season.

#### Conclusion

- 12. We thank everyone for their hard work in supporting the programme and the significant contribution this makes to reducing illness and death from flu. Flu is a major cause of harm to individuals and a key factor in NHS winter pressures. Preventing flu infection through vaccination also contributes to preventing secondary bacterial infections such as pneumonia. This can help reduce the need for antibiotics and contribute towards preventing antibiotic resistance.
- 13. We encourage you to look at the National Institute for Health and Care Excellence (NICE) guidelines on increasing flu vaccination uptake which will be published shortly.
- 14. This Annual Flu Letter has the support of the Chief Pharmaceutical Officer, the Chief Nursing Officer and the Chief Nurse.

Yours sincerely,

Professor Dame Sally C Davies

Department of Health & Social Care, Chief Medical Officer

July CC

**Professor Paul Cosford** 

Public Health England, Medical Director and Director for Health

Protection

**Professor Stephen** 

**Powis** 

NHS England, National Medical Director

# Links to other key documents

Document	Web link		
Green Book Influenza Chapter	www.gov.uk/government/publications/influenza-		
	the-green-book-chapter-19		
National Institute for Health and	www.NICE.org.uk		
Care Excellence (NICE) guidelines			
on increasing flu vaccine uptake			
NHS England Public Health	www.england.nhs.uk/commissioning/pub-hlth-res/		
Functions Agreement 2018/19			
(known as Section 7A agreement)			
NHS England enhanced service	www.england.nhs.uk/commissioning/gp-contract/		
specification (For GP providers)			
Community Pharmacy Seasonal	www.PSNC.org.uk		
Influenza Vaccination Advanced			
Service			
Immform Survey User guide for	www.gov.uk/government/collections/vaccine-		
GP practices, local NHS England	uptake		
teams, and NHS Trusts			
Flu vaccine uptake figures			
Flu immunisation PGD templates	www.gov.uk/government/collections/immunisation-		
(Note: These templates require	patient-group-direction-pgd		
authorisation before use)	vanus improfessor de gravada		
ImmForm website for ordering child flu vaccines	www.immform.dh.gov.uk		
	www.gov.uk/government/collections/enguel flu		
National Q&As / training slide sets/ e-learning programme	www.gov.uk/government/collections/annual-flu- programme		
e-learning programme	www.e-lfh.org.uk/programmes/flu-immunisation/		
Seasonal flu/influenza GP practice	www.nhsemployers.org/vandi201819		
vaccination programmes			
supporting documents			
Vaccine Update	www.gov.uk/government/collections/vaccine-		
	update		
To <b>register</b> to receive the monthly	https://public.govdelivery.com/accounts/UKHPA/s		
newsletter by email please go to:	ubscribers/new?preferences=true		
PHE Flu Immunisation Programme	www.gov.uk/government/collections/annual-flu-		
home page	programme		

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

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### Appendix A: Groups included in the national flu immunisation programme

- Groups eligible for flu vaccination are based on the advice of the Joint Committee on Vaccination and Immunisation (JCVI). The programme aims to provide direct protection to those who are at higher risk of flu associated morbidity and mortality. This includes older people, pregnant women, and those with certain underlying medical conditions.
- 2. In 2012 JCVI recommended extending flu vaccination to children to provide both individual protection to the children themselves and reduce transmission across all age groups.
- 3. In 2018/19, flu vaccinations will be offered under the NHS flu vaccination programme to the following groups:
  - all those aged two and three (but not four years or older) on 31 August 2018 (date of birth on or after 1 September 2014 and on or before 31 August 2016)
  - all children in reception class and school years 1, 2, 3, 4 and 5 (date of birth on or after 1 September 2008 and on or before 31 August 2014)
  - all primary school-aged children in former primary school pilot areas
  - 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
    - o chronic heart disease, such as heart failure
    - o chronic kidney disease at stage three, four or five
    - o chronic liver disease
    - chronic neurological disease, such as Parkinson's disease or motor neurone disease, or learning disability
    - diabetes
    - o splenic dysfunction or asplenia
    - a weakened immune system due to disease (such as HIV/AIDS) or treatment (such as cancer treatment)
    - o morbidly obese (defined as BMI of 40 and above)
  - all pregnant women (including those women who become pregnant during the flu season)
  - people aged 65 years or over (including those becoming age 65 years by 31 March 2019)
  - 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

- those who are in receipt of a carer's allowance, or 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
- 4. The list above is not exhaustive, and the healthcare professional 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.

Healthcare practitioners should refer to the Green Book influenza chapter for further detail about clinical risk groups advised to receive flu immunisation.

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

#### Appendix B: GP practice checklist

Practices are encouraged to implement the guidelines below which are based on evidence about factors associated with higher flu vaccine uptake<sup>1</sup>.

#### Named lead

 Identify a named lead individual within the practice who is responsible for the flu vaccination programme and liaises regularly with all staff involved in the programme.

#### **Registers and information**

- Hold 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 three years.
- Update the patient register throughout the flu season paying particular attention to the inclusion of women who become pregnant and patients who enter at risk groups during the flu season.
- Submit accurate data on number of patients eligible to receive flu vaccine and flu vaccinations given to its patients on ImmForm (<a href="www.immform.dh.gov.uk">www.immform.dh.gov.uk</a>), ideally using the automated function. Submit data on uptake amongst healthcare workers in primary care using the ImmForm data collection tool.

#### Meeting any public health ambitions in respect of such immunisations

 Order sufficient flu vaccine taking into account past and planned improved performance, expected demographic increase, and to ensure that everyone at risk is offered the flu vaccine. For children guidance to be followed on ordering the vaccine from PHE central supplies through the ImmForm website.

#### Robust call and recall arrangements

- Invite patients recommended to receive the flu vaccine to a flu vaccination clinic or to make an appointment (eg by letter, email, phone call, text). This is a requirement of the enhanced service specification.
- Follow-up patients, especially those in at risk groups, who do not respond or fail to attend scheduled clinics or appointments and have not been offered the vaccine elsewhere.

#### Maximising uptake in the interests of at-risk patients

 Start flu vaccination as soon as practicable after receipt of the vaccine, with initial priority for aTIV being for those aged 75 years and over. Aim to complete immunisation of all eligible patients before flu starts to circulate and ideally by end of November.

- Collaborate with maternity services to offer and provide flu vaccination to pregnant women and to identify, offer and provide to newly pregnant women as the flu season progresses.
- Offer flu vaccination in bespoke clinics and opportunistically during routine primary care encounters.
- Where the patient has indicated they wish to receive the vaccination but is
  physically unable to attend the practice (for example is housebound) the
  practice must make all reasonable effort to ensure the patient is vaccinated.
  The GP practice and/or CCG will collaborate with other providers such as
  community pharmacies and community or health and social care trusts to
  identify and offer flu vaccination to residents in care homes, nursing homes
  and house-bound patients, and to ensure that mechanisms are in place to
  update the patient record when flu vaccinations are given by other providers.

For guidance on improving uptake among children in general practice see 'Increasing influenza immunisation uptake among children':

www.gov.uk/government/collections/annual-flu-programme

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<sup>1</sup> 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 C: National extension of flu programme to children

#### Rationale of programme

- 1. In 2012 the Joint Committee on Vaccination and Immunisation (JCVI), the independent expert group that advises Government on vaccination policy, recommended extending flu immunisation to children. The aim is to provide individual protection to the vaccinated children themselves and reduce transmission of flu across all ages. JCVI recommended that all eligible children are offered a live attenuated influenza vaccine (LAIV), administered as a nasal spray<sup>2</sup>. This is a quadrivalent vaccine.
- 2. Implementation of the programme began the following year with pre-school children offered vaccination through GP practices and a number of pilots for school aged children. In 2015/16 the programme began nationally in primary schools in a phased roll-out starting with the youngest school-aged children first. In 2018/9 the programme will include all children aged two and three years old and those in reception class and school years 1 to 5.
- 3. Vaccinating children each year means that not only does it help protect the children themselves but there will be reduced transmission across all age groups, lessening levels of flu overall and reducing the burden of flu across the population. Research into the first two years of the programme compared the differences between pilot areas, where the entire primary school age cohort was offered vaccination, to non-pilot areas. The results have shown a positive impact on flu transmission across a range of surveillance indicators from vaccinating children of primary school age. These include reductions in: GP consultations for influenza-like illness, swab positivity in primary care, laboratory confirmed hospitalisations and percentage of respiratory emergency department attendances<sup>3,4</sup>.<sup>5,6</sup>.

<sup>2</sup> JCVI (2012). 25 July 2012. Joint committee on Vaccination and Immunisation statement on the annual influenza vaccination programme – extension of the programme to children.

www.gov.uk/government/uploads/system/uploads/attachment\_data/file/224775/JCVI-statement-on-the-annual-influenza-vaccination-programme-25-July-2012.pdf

<sup>3</sup> 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

<sup>4</sup> Pebody, R et al. October 2015. Uptake and impact of vaccinating school age children against influenza during a season with circulation of drifted influenza A and B strains, England, 2014/15. Eurosurveillance, 20 (39).

www.eurosurveillance.org/images/dynamic/EE/V20N39/art21256.pdf

<sup>5</sup> 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

<sup>6</sup> Pebody, R et al. October 2015. Uptake and impact of vaccinating school age children against influenza during a season with circulation of drifted influenza A and B strains, England, 2014/15. Eurosurveillance, 20 (39). www.eurosurveillance.org/images/dynamic/EE/V20N39/art21256.pdf

4. Since the introduction of the LAIV programme for children in the UK the vaccine effectiveness for laboratory confirmed infection has been good. In 2016/17 the 65.8% vaccine effectiveness found in the UK was within the normal range for this vaccine<sup>7</sup>. JCVI have advised that greater priority should be given to improving vaccine uptake in children because of the indirect protection this offers to the rest of the population. Priority should be given to the preschool children where uptake has been lower and because children under the age of five have the highest hospital admission rate for flu of any age group<sup>8</sup>.

#### Children eligible for flu vaccination in 2018/19

- 5. All two- and three-year olds continue to be offered flu vaccination through GP practices. In 2018/19 the programme is being extended to school year 5 so that all children in reception year and school years 1 5 will be offered flu vaccination. It is anticipated that this will be in schools (apart from the Isles of Scilly where it is offered through general practice). See Appendix D for eligibility criteria for children.
- 6. In former school pilot areas all primary school aged children from reception class through to year 6 will be offered the vaccine.
- 7. At risk children who are eligible for flu vaccination via the school-based programme because of their age will be offered immunisation at school. However, these children are also eligible to receive vaccination in general practice if the school session is late in the season, parents prefer it, or they missed the session at school.
- 8. Arrangements should be made to ensure that children who missed out on vaccination during the routine school session are offered a second opportunity, if requested. Precise arrangements for achieving this are for local determination. Children who are home educated should also be offered vaccination. Children will be invited by the provider to a mutually acceptable appointment venue. Local NHS England teams should be consulted for details about local arrangements. Contact details can be found at: www.england.nhs.uk/about/regional-area-teams/
- 9. 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 and that the data is entered on the system.

<sup>7</sup> Pebody, R et al. 2 Nov 2017. End-of-season influenza vaccine effectiveness in adults and children, United Kingdom, 2016/17. Eurosurveillance, 22, issue 44. www.eurosurveillance.org/content/10.2807/1560-7917.ES.2017.22.44.17-00306 8 Cromer D, Jan Van Hoek A, Jit M, Edmunds W J, Fleming D, Miller E. (2014) "The burden of influenza in England by age and clinical risk group: a statistical analysis to inform vaccine policy". Journal Infect, 68 (4) (2014) pp 363-371.

#### Use of live attenuated influenza vaccine (LAIV)

- 10. JCVI recommended LAIV as the vaccine of choice for children. The vaccine is licensed for those aged from 24 months to less than 18 years of age. JCVI recommended LAIV as it has:
  - good efficacy in children, particularly after only a single dose
  - the potential to provide protection 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 better immune memory to influenza that may not arise from use of inactivated flu vaccines
- 11. LAIV is unsuitable for children with contraindications such as severe immunodeficiency, severe asthma or active wheeze. Those with clinical risk factors that contraindicated LAIV should be offered an inactivated influenza vaccine.
- 12. Following more evidence on the safety of LAIV in egg allergic children, JCVI amended its advice in 2015 that, except for those with severe anaphylaxis to egg which has previously required intensive care, children with an egg allergy can be safely vaccinated with LAIV in any setting (including primary care and schools); those with clinical risk factors that contraindicate LAIV should be offered an inactivated influenza vaccine with a very low ovalbumin content (less than 0.12 µg/ml).
- 13. Children with a history of severe anaphylaxis to egg which has previously required intensive care, should be referred to specialists for immunisation in hospital. LAIV is not otherwise contraindicated in children with egg allergy. Egg-allergic children with asthma can receive LAIV if their asthma is well-controlled.
- 14. LAIV should be offered to all eligible children when not medically contra-indicated. This includes children in clinical risk groups. Children who are in clinical risk groups should be offered a suitable inactivated alternative vaccine if medically contraindicated to LAIV.
- 15. LAIV contains a highly processed form of gelatine (derived from pigs). Some faith groups do not accept the use of porcine gelatine in medical products. **Only** those who are in clinical risk groups are able to receive an inactivated injectable vaccine as an alternative.

- 16. Children who are not in clinical risk groups should only be offered LAIV. A child who is unable to have LAIV, for reasons other than being medically contraindicated, will continue to derive benefit from the programme by virtue of the reduction of transmission among their peers. They will not be eligible for an inactivated vaccine.
- 17. For the full list of contraindications please see the Green Book. GPs should ensure that they have ordered sufficient supplies of suitable alternative inactivated injectable vaccines through Immform for at-risk children who cannot receive LAIV for medical reasons.
- 18. The patient information leaflet provided with LAIV 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 LAIV. 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 LAIV (given at least four weeks apart).

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 D: Child eligibility for flu vaccine and type to offer

Age on 31 August 2018	Is child eligible for LAIV?		
Under 2 years of age	Universal programme: No. Only at risk children offered vaccination.		
or age	At risk children: LAIV is not licenced for children under 2 years of age. At risk children over six months of age to be offered suitable quadrivalent inactivated flu vaccine (QIV).	practice	
Aged 2 to 3 years old  [Born between 1 September	Universal programme: All 2 and 3 year olds offered LAIV.  Children who turn two after 31 August 2018 are not eligible.  Children who were three on 31 August 2018 and turn four		
2014 and 31 August 2016].	afterwards, are still eligible.  At risk children: Offer LAIV. If child is contraindicated (or it is otherwise unsuitable), then offer suitable quadrivalent inactivated flu vaccine (QIV).		
Aged 4 to 9 years old:	Universal programme: All primary school years from reception class to year 5* offered LAIV.		
[Born between 1 September 2008 and 31 August 2014]	At risk children: Offer LAIV. If child is contraindicated (or it is otherwise unsuitable), then offer suitable inactivated flu vaccine.		
Adgust 2014]	At risk children may be offered vaccination in general practice if the school session is late in the season, parents prefer it, or they missed the school session. Also, some schools may not offer inactivated vaccines to at risk children in whom LAIV is contraindicated.		
Aged 10 years old to	<b>Universal programme:</b> No. Only at risk children offered vaccination.	General practice	
less than 18 years	At risk children: Offered LAIV. If contraindicated (or it is otherwise unsuitable), then offer suitable quadrivalent inactivated flu vaccine (QIV).		

<sup>\*</sup> Reception class (4 to 5 year olds); Year 1 (5 to 6 year olds); Year 2 (6 to 7 year olds); Year 3 (7 to 8 year olds); Year 4 (8 to 9 year olds); Year 5 (9 to 10 year olds).

All childhood vaccines can be ordered from central supplies through the Immform website: www.immform.dh.gov.uk

#### Appendix E: 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. 9, 10 In addition, there is evidence that having flu during pregnancy may be associated with premature birth and smaller birth size and weight 11, 12 and that flu vaccination may reduce the likelihood of prematurity and smaller infant size at birth associated with an influenza infection during pregnancy. 13 Furthermore, a number of studies show that flu vaccination during pregnancy provides protection against flu in infants in the first few months of life. 14, 15, 16, 17, 18
- 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.<sup>19</sup>

<sup>9</sup> 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

<sup>10</sup> 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.

<sup>11</sup> Pierce M, Kurinczuk JJ, Spark P et al. (2011) Perinatal outcomes after maternal 2009/H1N1 infection: national cohort study. BMJ. 342:d3214.

<sup>12</sup> 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.

<sup>13</sup> 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.

<sup>14</sup> 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.

<sup>15</sup> 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.

<sup>16</sup> 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.

<sup>17</sup> 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.

<sup>18</sup> 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? Article Id=20959

<sup>19</sup> Tamma PD, Ault KA, del Rio C et al. (2009) Safety of influenza vaccination during pregnancy. Am. J. Obstet. Gynecol. 201(6): 547-52.

### 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 vaccination should continue to be offered to those at risk and 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 duration of the flu vaccination programme in order to identify women who become pregnant during the season. 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.

#### Maternity services

- 6. All pregnant women are able to access flu immunisation from their GP practice or a community pharmacy. In addition local NHS England teams have commissioned maternity providers to provide flu immunisation covering around 70% of maternity services in 2017/18.
- 7. Midwives need to be able to explain the benefits of flu vaccination to pregnant women and offer them the vaccine, or signpost women back to their GP or community pharmacy if they are unable to offer the vaccine.
- 8. Where maternity providers or pharmacies provide the flu vaccine, it is important that the patient's GP practice is informed in a timely manner (within 48 hours) so their records can be updated accordingly, and included in vaccine uptake data collections. Maternity providers should ensure they inform GPs when a woman is pregnant or no longer pregnant.

### Appendix F: Vaccine supply and ordering

#### Vaccine composition for 2018/19

- 1. Flu viruses change continuously and the WHO monitors the epidemiology of flu viruses throughout the world making recommendations about the strains to be included in vaccines for the forthcoming winter. It is recommended that quadrivalent vaccines for use in the 2018/19 northern hemisphere influenza season contain the following:
  - an A/Michigan/45/2015 (H1N1)pdm09-like virus;
  - an A/Singapore/INFIMH-16-0019/2016 (H3N2)-like virus;
  - a B/Colorado/06/2017-like virus (B/Victoria/2/87 lineage); and
  - a B/Phuket/3073/2013-like virus (B/Yamagata/16/88 lineage).

It is recommended that the influenza B virus component of trivalent vaccines for use in the 2018/19 northern hemisphere influenza season be a B/Colorado/06/2017-like virus of the B/Victoria/2/87-lineage<sup>20</sup>.

### Vaccine supply for children's programme

- 2. Flu vaccines for the national offer to all children aged two to three years, children in reception class and school years 1 to 5, and for children in risk groups aged six months to less than 18 years, are supplied centrally by PHE. This includes both LAIV and quadrivalent inactivated flu vaccine.
- 3. For children in clinical risk groups under 18 years of age where LAIV is contraindicated, a suitable quadrivalent inactivated influenza vaccine will be supplied by PHE and should be offered. Fluenz Tetra and the quadrivalent inactivated influenza vaccine (injectable) can be ordered through the ImmForm website: www.immform.dh.gov.uk
- 4. Ordering controls using allocations based on previous years' uptake were first introduced two years ago on centrally supplied flu vaccines. These were put in place to reduce the amount of excess vaccine, in particular LAIV, ordered by NHS providers but not administered to children. The latest information on ordering controls and other ordering advice for LAIV will be available in Vaccine Update and on the ImmForm news item both prior to, and during, the flu vaccination period. It is strongly advised that all parties involved in the provision of flu vaccines to children ensure they remain up to date with this information.

<sup>20</sup> www.who.int/influenza/vaccines/virus/recommendations/2018\_19\_north/en/

#### Choice of flu vaccine for adults

- 5. For all other eligible populations apart from children providers remain responsible for ordering vaccines directly from manufacturers.
- 6. On 5 February NHS England wrote to GPs and community pharmacies, and Clinical Commissioning Groups to confirm that the most effective flu vaccines for the population should be ordered<sup>21</sup>.
- 7. The adjuvanted trivalent inactivated flu vaccine (aTIV), (Fluad®: Seqirus) was licensed late in 2017 and is available for use in the 2018/19 season. JCVI concluded at its October 2017 meeting that adjuvanted trivalent flu vaccine is more effective and highly cost effective in those aged over 65 years and above compared with the non-adjuvanted or 'normal' influenza vaccines currently used in the UK for this age-group. JCVI agreed that aTIV would be considered the optimal clinical choice for all patients aged 65 years and over. The JCVI specifically considered that the use of the adjuvanted trivalent flu vaccine should be a priority for those aged 75 years and over, given that the non-adjuvanted inactivated vaccine has showed no significant effectiveness in this group over recent seasons<sup>22</sup>.
- 8. JCVI have also reconsidered the use of quadrivalent influenza vaccines (QIV), which offer protection against two strains of influenza B rather than one. As influenza B is relatively more common in children than older age groups, the main clinical advantage of these vaccines is in childhood. Because of this, those vaccines centrally supplied for the childhood programme in recent years have been quadrivalent preparations. Further modelling work by PHE suggests that, the health benefits to be gained by the use of quadrivalent vaccines compared to trivalent vaccines, is more substantial in at risk adults under 65 years of age, including pregnant women. On average use of quadrivalent over trivalent is likely to lead to reduced activity in terms of GP consultations and hospitalisations, and PHE's work suggests that the overall public health benefit would justify the additional cost of the vaccines compared to trivalent vaccines.
- NHS England therefore advised that 65 year olds and over receive aTIV, and under 65s in at risk groups, including pregnant women, receive QIV for the

<sup>21</sup> www.england.nhs.uk/publication/vaccine-ordering-for-2018-19-influenza-season-letters/

<sup>22</sup> Although aTIV is not licensed in those less than 65 years of age "off label" use is an option. Public Health England in consultation with NHS England are of the opinion that it is clinically appropriate to offer this vaccine "off label" to those becoming 65 before 31st March 2019. The Public Health England (PHE) Patient Group Direction (PGD) for inactivated influenza vaccine for 2018/19 is likely to incorporate this off label indication. This will be confirmed later when the PGD has completed the authorisation process.

2018-19 flu season. QIV should also be offered to healthcare workers aged under 65 years. Those healthcare workers aged 65 years and over should be offered aTIV.

#### Vaccines available in 2018/19

10. The vaccines that will be available for the 2018/19 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 (quadrivalent)	From 24 months to less than 18 years of age	0845 139 0000	
GSK	Fluarix Tetra ▼	Split virion inactivated virus (quadrivalent)	From six months	0800 221 441	
MASTA	Quadrivalent Influenza Vaccine (split virion, inactivated) ▼	Split virion, inactivated virus	From six months	0113 238 7552	
Mylan (BGP Products)	Quadrivalent Influenza vaccine Tetra MYL	Influenza virus surface antigen (inactivated)	From 18 years	0800 358 7468	
	Quadrivalent Influvac sub- unit Tetra	Influenza virus surface antigen (inactivated)	From 18 years		
Sanofi Pasteur vaccines	Quadrivalent Influenza Vaccine (split virion, inactivated) ▼	Split virion, inactivated virus	From six months	0800 854 430	
Segirus UK	Agrippal®	Surface antigen, inactivated virus (trivalent)*	From six months		
Ltd	Fluad®	Surface antigen, inactivated, Adjuvanted with MF59C.1	65 years of age and over	08457 451 500	

<sup>\*</sup> This is a non adjuvanted trivalent vaccine and not one of the recommended vaccines for 2018/19.

- 11. None of the influenza vaccines for the 2018/19 season contain thiomersal as an added preservative.
- 12. 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.
- 13. More detailed information on the characteristics of the available vaccines, including ovalbumin (egg) content will be published on the PHE Immunisation web pages.
- 14. Flu vaccines generally start to be distributed from late September each year. However, vaccine manufacture involves complex biological processes, and there is always the possibility that initial batches of vaccine may be subject to delay, or that fewer doses than planned may be available initially. Immunisers should therefore be flexible when scheduling early season vaccination sessions, and be prepared to reschedule if necessary.
- 15. aTIV may be delivered in stages throughout the coming flu season. If this is the case, then initial priority for aTIV should be those aged 75 years and above as this age group are likely to derive little clinical benefit from the standard non-adjuvanted influenza vaccine and are at highest risk of serious outcome. Once this group has been covered, 65-74 year olds should then be targeted as further deliveries of vaccine are made. Delivery timings will be confirmed by the supplier in the early summer. Providers will need to plan their clinics based on this advice on prioritisation.
- 16. As in previous years, PHE advise that school sessions are not planned before the second week in October, to reduce the risk of having to reschedule, due to vaccine availability.

#### Appendix G: 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 2018 and guidance on the data collection process by early September 2018. This guidance will be available at: www.gov.uk/government/collections/vaccine-uptake which is where flu vaccine uptake data is also published.
- 2. Queries concerning data collection content or process should be emailed to influenza@phe.gov.uk. Queries concerning ImmForm login details and passwords should be emailed to helpdesk@immform.org.uk.

#### Reducing the burden from data collections

3. Considerable efforts have been made to reduce the burden of data collections on GPs 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 2017/18 survey. GP practices that are not able to submit automated returns should discuss their arrangements with their GP IT supplier. If automated returns fail for the monthly data GPs will be required to submit data manually on to ImmForm to meet contractual obligations.

#### Data collections for 2018/19

- 4. Monthly data collections will take place over four months during the 2018/19 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 2018 (data collected in November 2018), with the subsequent collections monthly thereafter, and with the final data collection for all vaccines administered by the end of January 2019 (final data collected in February 2019). Uptake data for healthcare workers will collect information on immunisations given up to the end of February 2019 (final data collected in March 2019).
- 5. Data will be collected and published 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 rights 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

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

#### Monitoring on a weekly basis

- 7. 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. These data will be published in the PHE weekly flu report available throughout the flu season at: www.gov.uk/government/statistics/weekly-national-flu-reports.
- 8. During the data collection period, those working in the NHS with relevant access rights are able, through the ImmForm website to view this data as per the monthly collections.

### Vaccine uptake data collection of school aged children

9. PHE will be responsible for monthly collections of flu vaccine uptake for children in reception class and in school years 1 - 5 over four months during the 2018/19 flu season. Collection will be undertaken through the ImmForm data entry tool. NHS England teams will agree responsibility for completion of this monthly data entry to ImmForm with their providers.

### Appendix H: Contractual arrangements

# General practice

- The Directed Enhanced Service (DES) specification for seasonal influenza and pneumococcal immunisation outlines the responsibilities of GP practices and details the service they will provide in respect of the flu vaccination programme. The DES specification 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 people eligible for flu vaccination under the enhanced service are those patients aged 65 and over on 31 March 2019, pregnant women, those aged six months to 64 years (excluding patients aged two and three as of 31 August 2018) 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 and three years as of 31 August 2018.
- 4. Children in clinical risk groups in reception year and school years 1 to 5 may be offered LAIV alongside their peers as part of school based delivery. If a child in an atrisk 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 LAIV and the local service provider does not offer inactivated flu vaccines. Some parents may choose to continue to have children in clinical risk groups immunised by their GP, rather than at school.
- 5. It should be noted that no payment will be made for children not in clinical risk groups who are vaccinated in general practice, unless they are in the eligible two to three year old age cohort.
- 6. 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 mechanisms such as by letter, e-mail, phone call, or text. Template letters for practices to use will be available at <a href="https://www.gov.uk/government/collections/annual-flu-programme">www.gov.uk/government/collections/annual-flu-programme</a> nearer the time.
- 7. Every effort should be made to ensure all at-risk children who are not in one of the age groups eligible for flu vaccination at school are immunised in general practice.
- 8. NHS England will monitor the DES and enhanced service that GP practices provide for flu vaccination to ensure that services comply with the specifications. NHS

England teams will need assurance that providers have robust implementation plans in place to meet or exceed the vaccine uptake aspirations for 2018/19 and that they have the ability to identify eligible 'at-risk' patients as well as two- and three-year-olds.

#### Community Pharmacy Seasonal Influenza Vaccination Advanced Service

- 9. Since 2015 all community pharmacies can register to provide flu vaccination to eligible adult patients (that is those aged 18 years and over). The service can be provided by any community pharmacy on the NHS England Pharmaceutical List that has a consultation room, can procure the vaccine, meet the data recording requirements, and has appropriately trained staff.
- 10. Vaccination for children will not be offered through the Community Pharmacy Seasonal Influenza Vaccination Advanced Service.
- 11. Contractors will be required to offer the service in accordance with the service specification for 2018/19 which will be published on www.PSNC.org.uk. This service specification will include details such as:
  - payment and reimbursement details
  - details of eligible patients
  - accreditation requirements
  - data recording requirements
  - claiming for payments
  - post payment verification arrangements
- 12. Pharmacists are encouraged to use every opportunity to offer flu vaccination to eligible groups, such as identifying patients from their prescription history and during medical reviews.
- 13. Data on flu vaccinations administered outside general practice must be passed back to the patients' GP practice (i.e. by close of business on the working day following the immunisation) 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 weekly and monthly vaccine uptake figures.

#### School-based provision

14. NHS England will make local provision for delivery of flu vaccination to school aged children. It is anticipated that this will be in primary school settings apart from the Isles of Scilly (where provision will be through general practice).

#### Supply and administration of vaccines

- 15. 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 for individual patients. 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: www.nice.org.uk/guidance/mpg2.
- 16. PHE PGD templates, and a PGD to support the pharmacy advanced service, will be available to support the national flu immunisation programme 2018/19. Please note, these PGD templates must not be altered or amended in any way and must be suitably authorised locally before use. These will be available prior to commencement of the programme from: www.gov.uk/government/collections/immunisation-patient-group-direction-pgd

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

#### Appendix I: Communications

 An integrated communications strategy will be produced for the national flu immunisation programme 2018/19. 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 DHSC, NHS England, the Department for Education and the Local Government Association.

### Publicity and information materials

- 2. Ahead of the flu season, NHS-branded patient information leaflets for different eligible groups will be reviewed including:
  - The flu vaccination: who should have it and why
  - Protecting your child against flu
  - All about flu and how to stop getting it: Easy read version for people with learning disabilities
  - All about flu and how to stop getting it: Easy read version for children with learning disabilities
  - Pregnancy: How to help protect you and your baby
- 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-, and three-year-olds
  - an easy-read invitation letter template for people with learning difficulties
- 4. The following materials for the delivery of flu vaccination through schools will be available:
  - briefing for head teachers and other staff
  - a national consent form
  - template letters to invite eligible school age children for flu vaccination
  - the 'Protecting your child against flu' leaflet
- 5. Updated training and information materials for healthcare practitioners will also be available. These will include:

- National flu programme training slide set
- Childhood flu programme training slide set
- Inactivated influenza vaccine: information for healthcare practitioners
- Childhood flu immunisation programme: information for healthcare practitioners
- Flu immunisation e-learning programme

### National marketing campaign

 The 2017/18 marketing campaign ('Stay well this winter') is being evaluated and the lessons learned will inform any campaign plans for 2018/19. Further information will be issued in due course and resources can be downloaded from https://campaignresources.phe.gov.uk/resources/

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 DH health and social care order line: www.orderline.dh.gov.uk/ecom\_dh/public/home.jsf