From the Chief Medical Officer
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An Roinn Sláinte
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HSS(MD)11/2018

For Action:

Chief Executives, Public Health Agency/Health and Social Care Board/HSC Trusts/NIAS
GP Medical Advisers, Health and Social Care Board
All General Practitioners and GP Locums (*for onward distribution to practice staff)*

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Your Ref:
Our Ref: HSS(MD)11/2018
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Dear Colleague

SEASONAL INFLUENZA VACCINATION PROGRAMME 2018/19

ACTION REQUIRED

Chief Executives must ensure that this information is drawn to the attention of all staff involved in the seasonal flu vaccination programme, particularly school health teams, district nurses, treatment room nurses, Paediatric Consultants, Midwives, Health Visitors and Community Children Nurses and occupational health departments.

The HSCB must ensure that this information is cascaded to all General Practitioners and Practice Managers for onward distribution to all primary care staff involved in the seasonal flu vaccination programme.

Introduction

1. The purpose of this letter is to provide information about the annual seasonal influenza vaccination programme for winter 2018/19, including influenza vaccination for frontline health and social care staff.

2. The vaccination programme will officially begin on 1 October 2018 and run until the 29 March 2019. However GPs can begin offering the vaccine once they have received their first delivery of vaccine, prioritising groups as set out in Annex 1.

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

Annex 1 – Vaccination programme details 2018/19 (pages 6 to 17)
Annex 2 – Clinical risk groups 2018/19 (pages 18 to 20)
Annex 3 – Details of how to order vaccine (pages 21 to 22)
Annex 4 – Vaccination of health and social care workers (pages 23 to 25)

3. The following are important points to note:

- There are **different vaccines** recommended for those aged 65+ compared to those aged under 65.

- An **adjuvanted trivalent vaccine** (aTIV) will be available this year to be offered to all **those aged 65 years and over**. This reflects current JCVI advice and Green Book guidance published in December 2017. Note: JCVI considers aTIV to be more effective and cost effective than the non adjuvanted vaccines in use in the elderly (including quadrivalent vaccine (QIV). (See Annex 1 para 39)

- A **quadrivalent vaccine** (QIV) will be available this year to be offered to **those aged 6 months to under 65 years of age in an at risk group**. The quadrivalent influenza vaccine (QIV) will protect against four strains of flu. This reflects current JCVI advice and Green Book guidance that was updated in October 2017. (See Annex 1 para 41)

- Vaccine supply - While there will be a plentiful supply of flu vaccine, the delivery of the **adjuvanted vaccine** (aTIV) into the UK will be staggered over the months of September, October and November. Therefore practices will be restricted to ordering certain amounts over this period based on their patient lists.

- **Initial priority for the aTIV should be those aged 75 years and above.** Further vaccine delivery details will be provided by the PHA in due course. Practices should therefore plan accordingly.

- A live attenuated influenza vaccine (Fluenz Tetra®) will again be available and is strongly recommended as the vaccine of choice for eligible children **aged two years up to less than 18 years** (except those with contraindications such as immunodeficiency or with severe asthma, active wheezing). (See Annex 1 paras 42-48).

- The best way to improve the prevention and management of flu is to increase the uptake of vaccination, **especially among health and social care workers with direct patient contact.**

- Ordering - All GP practices must confirm or update their details on the current Movianto ordering system prior to being permitted to order vaccines for the 2018/2019 campaign. GP practices must complete this **before 13 August 2018.**

- All pre-school children aged two years or more on the 1 September 2018 (D.O.B range **02/07/14** – **01/09/16**) should be offered vaccination **by their GP.** GPs are requested to invite these children in for vaccination as early as possible, once they have received delivery of the Fluenz Tetra® vaccine. (See Annex 1 para 7). We would urge that an increased effort is given to the vaccination of preschool children as uptake is not as high as in schools.

- All children (**including those in a clinical risk group**) attending a primary school or special school (P1 to P7 inclusive) from the 1 September 2018 will be offered vaccination by a **school health team.** (See Annex 1 para 9).

- All pregnant women (at all stages of pregnancy) should be offered vaccination by their GP (See Annex 1 paras 17-20).

- GPs should ensure those with chronic neurological disease (especially children and young people) are prioritised (See Annex 1, paras 15-16).

4. We would like to re-emphasise the importance of vaccination for frontline Health and Social Care workers **to protect themselves, their families and vulnerable patients in their care**. The Public Health Agency has again commissioned NHS Employers to support Trust flu vaccination programmes through delivery of their Flu Fighter® campaign. Trusts are responsible for ensuring that their flu teams fully engage with the Flu Fighter support (see Annex 4).

Vaccine supply and ordering

5. The central procurement of the annual seasonal influenza vaccines has been completed. Orders for these can be placed from mid-August and should include orders for pre-school children aged two years or more. Deliveries are expected to be made to practices from mid to late September. **Restrictions will be in place for adjuvanted trivalent vaccine (aTIV), possibly until November**. The details of how to order are attached at Annex 3**.**

   Practices are also reminded of the importance of **not over ordering**. Ordering should be tailored to uptake. With the exception of the aTIV, orders can normally be fulfilled within 24 hours.

Shingles vaccine supply

6. As with the previous years, the shingles vaccination programme for 2018/19 is also due to commence in October, details of this year's programme were announced in HSS (MD) 10/2018 dated 4 June 2018. See attached link – https://www.health-ni.gov.uk/sites/default/files/publications/health/hss-md-10-2018.pdf. As the eligible vaccination groups for the shingles programme overlap with the eligible seasonal flu vaccination groups it is considered appropriate to combine the order for the shingles vaccine, Zostavax® with the seasonal flu vaccines. **Please note** some shingles stock has an expiry date of **31 December 2018**. GPs should ensure they only order enough vaccine to meet their weekly needs.

Conclusion

7. The 2017/18 flu season saw the highest level of flu activity in Northern Ireland for several years which resulted in a substantial number of people being hospitalised. The 2017/18 season is an important reminder of the significant impact flu can have on the wider health service and that it is highly unpredictable.

8. Once again Northern Ireland delivered a very successful seasonal flu vaccination programme during 2017/18. We would like to thank everyone for their continued

hard work. Morbidity and mortality attributed to flu is a key factor in HSC winter pressures and a major cause of harm to individuals, especially vulnerable people. **The annual flu immunisation programme helps to reduce GP consultations, unplanned hospital admissions and pressure on A&E** and is therefore a critical element of the system-wide approach for delivering robust and resilient health and care services during winter.

9. Looking ahead we fully expect the HSC organisations and GPs to respond to whatever challenges will be presented during the winter of 2018/19, and to build on past experiences in order to continue to deliver a high quality service to protect the health of the people of Northern Ireland.

Yours sincerely



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Chief Medical Officer

Professor Charlotte McArdle
Chief Nursing Officer

Dr Mark Timoney
Chief Pharmaceutical Officer

This letter is available on the Department of Health website at

https://www.health-ni.gov.uk/topics/professional-medical-and-environmental-health-advice/hssmd-letters-and-urgent-communications

Annex 1

VACCINATION PROGRAMME DETAILS 2018/19

1. **The most important change about this season is that there are different vaccines recommended for those aged 65+ compared to those aged under 65.**

2. An **adjuvanted trivalent vaccine** (aTIV) called Fluad® should be offered to all those aged 65 years and over (see para 39 for more information). **Fluad® is only licensed for those aged 65 years and over**. Fluad® is **NOT** suitable for egg or latex allergic people and in these instances the Quadrivalent vaccine can be given if appropriate (see egg allergic section paras 52 to 55).

3. A **quadrivalent vaccine** (QIV) should be offered to those aged 6 months to under 65 years of age in an at risk group (see para 40 for more information).

4. The delivery of Fluad® (the adjuvanted vaccine) into the UK will be staggered over the months of September, October and November.

5. Due to delivery restrictions those **aged 75+ should be prioritised** for Fluad® and practices should organise their flu clinics accordingly.

6. Those aged 65-74 years of age should still receive Fluad® after those aged 75+ are vaccinated or when restrictions are lifted. Practices should **NOT** offer the quadrivalent vaccine to those aged 65-74 when supplies of Fluad® are restricted.

7. As with previous years, in addition to the eligible 'clinical risk' patients GPs will be responsible for offering a flu vaccine to all pre-school children aged two years or more on the 1 September 2018, i.e. those children within a D.O.B. range of **02/07/14** to **01/09/16**. Fluenz Tetra® vaccine is strongly recommended as the vaccine of choice for eligible children aged two and over, except those with contraindications.

   GPs are requested to invite these children in for vaccination as early as possible once they have received a delivery of the Fluenz Tetra® vaccine.

   The uptake rates achieved in this age category have declined in recent years therefore GPs are urged to encourage the parents/guardians of eligible children to take up this offer of vaccination.

   Only those pre-school children who are two years old or more on the 1 September 2018 should be invited for vaccination. However if a child turns two years of age during the vaccination period i.e. from September to December 2018 and their parents request that they receive the vaccine, GPs should vaccinate the child once

they are two years of age, in line with the vaccine license. GPs can claim the normal Item of Service (IOS) fee for these patients.

8. Only suitably trained GP employed staff should be used to vaccinate children as part of the children's flu programme.

9. All children (**including those in a clinical risk group**) attending primary school or a special school (P1 to P7 inclusive) from the 1 September 2018 will be offered vaccination by the school health teams. This means GP practices **do not** need to invite at risk children with date of birth range: 2 July 2007 to 1 July 2014.

10. GPs will still be responsible for inviting all other children in a clinical risk group for vaccination who are **NOT** in primary school.

11. There is no mop-up of children in primary school by the school health teams, if they miss vaccination. Therefore if a child is absent from school OR if they require a second dose of the flu vaccine, the parent/guardian will be advised by the school health team to contact their GP.

    This is especially important for clinical risk children. Parents will be advised of the need for this and the onus will be on them to contact the GP surgery. GPs are asked to facilitate vaccination when contact is made, however GPs do not need to identify and send for these children. GPs can claim the normal IoS fee for these children. This will only apply to those primary school children born between 2 July 2007 to 1 July 2014.

12. **Annex 2** sets out the eligible 'clinical risk' groups in full. In offering influenza vaccine to people in the clinical risk groups, GPs should take into account the risk of influenza infection exacerbating any other underlying disease that a patient may have as well as the risk of serious illness from influenza itself.

JCVI advice regarding the number of flu vaccine doses for children

13. JCVI has advised that only children aged six months to under nine years who are in clinical risk groups and have not received influenza vaccine previously or are being offered inactivated influenza vaccine for the first time should be offered a second dose of vaccine. All other children should receive a single dose of influenza vaccine, including those receiving live attenuated influenza vaccine, irrespective of whether they have received influenza vaccine previously.

    This advice differs from that in Summary of Product Characteristics (SPCs) of influenza vaccines. Children who only received one dose of influenza vaccine or who only received the pandemic monovalent influenza A(H1N1)v vaccine before should be considered as previously vaccinated.

    This means that any children under the age of 9 years who are being vaccinated for the first time will NOT require a second dose unless they are in a risk group or they require the injected vaccine.

    Given that some influenza vaccines are restricted for use in particular age groups, the SPCs for individual products should always be referred to when

ordering vaccines to ensure that they can be given appropriately to particular patient age groups.

Vulnerable Groups

14. The lessons learnt from recent years should be taken into account when deciding who should be included within the target groups. For chronic neurological disease, in particular, it is now clear that this group should also include children and young people with any chronic neurological disease and includes Multiple Sclerosis and related conditions and hereditary and degenerative diseases of the central nervous system.

15. The Pandemic flu in 2009 also showed that vulnerable children and adults with complex medical healthcare needs such as (but not confined to), those attending special schools for severe learning disability and day care centres are particularly vulnerable to influenza infection. **These people should be offered seasonal flu vaccine**. These children **will not** be vaccinated in school **unless they are in years P1 to P7 (inclusive)** so it is important that those at risk are identified and vaccinated in primary care. When any doubt exists as to whether the vaccine should be given it is best to err on the side of caution and offer the vaccine.

Pregnant Women

16. All pregnant women should be offered the seasonal flu vaccine by their GP, including those who become pregnant during the flu season. This applies to pregnant women at any stage of pregnancy (first, second or third trimesters). Inactivated vaccine should be used, including for anyone under 18 years old as Fluenz Tetra® is contraindicated in pregnancy.

    Flu is the most frequent single cause of death in pregnancy.

17. 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 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 influenza infection during pregnancy[5]. Furthermore, a number of studies show that flu vaccination during pregnancy provides passive immunity against flu to infants in the first few months of life.[6,7,8,9]

18. 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[10].

19. Whilst the vaccination of pregnant women against pertussis continues it is important to note that these two vaccines can be given at the same time when it is convenient to do so. However as set out in HSS (MD) 9/2016, the pertussis vaccine can now be given from 16 weeks gestation, see attached link: https://www.health-ni.gov.uk/sites/default/files/publications/dhssps/hss-md-9-2016.pdf, whereas flu vaccine can

be given at all stages of pregnancy. It is important not to delay flu vaccine in order to give it at the same time as pertussis vaccine.

When to stop offering the vaccine to pregnant women

20. The ideal time for flu vaccination is between October and early December before flu normally reaches its peak of circulation. However flu can circulate considerably later than this and it may therefore be necessary to continue offering the vaccine to groups such as newly pregnant women. Clinicians should apply clinical judgement to assess the needs of an individual patient, taking 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. The PHA will provide advice on extending the flu vaccination period if necessary.

Monitoring Vaccine Uptake

21. The PHA will take the lead in monitoring vaccine uptake on behalf of DoH. The PHA is asked to put in place arrangements to supply a minimum data set on the uptake of influenza immunisation for regional monitoring purposes. It is essential to supply this information in the required format by the agreed deadlines. Specific arrangements for surveillance will be issued by PHA at a later date.

22. GPs should note that in order to ensure accurate records of all vaccinations are recorded GPs should inform the Child Health System (CHS) of **all seasonal flu vaccinations of children.** In order to help achieve this, the CHS will provide all GP Practices with a list of their pre-school patients aged two years old or more. Practices should return lists of children vaccinated to Child Health on a regular basis, in surname order, also stating forename, H and C number, DOB, address, date and vaccine batch number. These lists can be returned by internal mail or secure email to the Pre-school flu personnel in each Trust. Children of primary school age who for whatever reason are not vaccinated in school but are vaccinated in primary care should have a CHS7 form completed and returned to Child Health

Primary Care fridge capacity

23. GPs should ensure that they will have the fridge capacity to store the vaccines required. There is no need to stockpile large quantities of flu vaccine and this is actively discouraged.

Publicity and Information Materials

24. Publicity and information materials will be launched in September to encourage those eligible as well as health and social care workers and unpaid carers to take up the offer of the vaccine. Information leaflets will be distributed in August by the PHA to GPs and Trusts in line with normal arrangements. As was done last year, funding will be provided to allow GPs to actively contact their patients and encourage a high uptake rate.

Training for Health Professionals

25. Due to the fact that two new vaccines suitable for different age groups are being used for the first time in the annual flu vaccination programme, it is more important than ever that everyone involved in the programme is appropriately trained. This will allow them to discuss the new vaccines with patients and will minimise the likelihood of patients being given vaccines outside of their product license.

    It is important that all practice receptionists and administrative staff are also aware of the new vaccines and the need to prioritise those over 75 for the initial stocks of Fluad®.

26. Leaflets, professional information and training videos will be made available on the PHA website to support the delivery of the programme: http://www.publichealth.hscni.net/directorate-public-health/health-protection/immunisationvaccine-preventable-diseases

The 'Green Book'

27. The Green Book chapter on influenza is available online, see attached link: https://www.gov.uk/government/publications/influenza-the-green-book-chapter-19 It should be noted that the chapter is updated on an ongoing basis and therefore all medical and clinical staff should ensure they refer to the latest version of the chapter as required

Consent and Capacity

28. Health professionals must ensure that for each person who attends an immunisation session, appropriate information and advice about the influenza vaccine is given and that the person's consent is obtained. Individuals coming forward for vaccination should be given a reasonable opportunity to discuss any concerns before being vaccinated.

    For further information on consent, please see Chapter 2 of the 2006 edition of *Immunisation against infectious disease* (the 'Green Book'). https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/144250/Green-Book-Chapter-2-Consent-PDF-77K.pdf

29. Healthcare professionals should refer to relevant guidelines and legislation when assessing a person's capacity to consent to vaccination: https://www.health-ni.gov.uk/articles/consent-examination-treatment-or-care

Vaccine Uptake Targets

30. The following uptake targets have been set for 2018/19:

    - Over 65s and the under 65 'at risk' groups - **75%**;
    - Pregnant women - **60%**;
    - Pre-school children aged two years or over - **60%**; and
    - Primary school aged children - **75%**.
    - Front line HSC staff – **40%**

Vaccination Records

31. On occasions the PHA may need to contact GPs to get vaccination details of particular patients to better understand vaccine efficacy. GPs are urged to action any request received from the PHA immediately.

Funding and Contractual Arrangements

32. The arrangements and funding for the seasonal flu vaccination programme remain the same as in previous years. Under the arrangement associated with the GMS contract financial envelope, the HSCB has already been allocated funding for the immunisation with flu vaccine of those over 65s and for those under 65s at risk. Additional money will be allocated in 2018-19 to the HSCB, from the PHA, to cover:

    - payments to GPs for all pre-school children aged 2 years old or more.
    - payments to GPs for any primary school aged children i.e. those born between **02/07/2007** to **01/07/2014**, who present for vaccination if they were unable to be vaccinated by the school health team
    - payments to GPs for immunisation of carers;
    - payments to GPs for immunisation of pregnant women;
    - payment of a data collection fee to general practices;
    - Trust support for the delivery of the Influenza programme;
    - targeted support for pharmacies in specific areas helping to boost uptake rates, if required;
    - funding for call/recall of patients.

Vaccination of patients outside the clinical risk groups

33. Where a person **not in a clinical risk group** requests/requires an influenza vaccination, the decision to immunise is based on the GP's clinical judgement (see also Annex 2). **If the GP** considers the patient to be at risk of flu exacerbating an underlying disease or of serious illness from flu itself, then seasonal flu vaccine may be offered from centrally procured stock even if the individual is not in one of the clinical risk groups specified in this circular. For monitoring purposes these patients should be recorded as 'others'.

    For any other patients who wish to avail of the flu vaccine they should be advised that these are available (privately) at many community pharmacies.

Vaccine virus strains and available vaccines

34. Flu viruses change continuously and the World Health Organization (WHO) monitors the epidemiology of flu viruses throughout the world. Each year WHO makes recommendations about the strains to be included in vaccines for the forthcoming winter. 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.

35. The WHO has announced that quadrivalent vaccines for use in the 2018-2019 northern hemisphere influenza season should 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).

WHO also recommended that the influenza B virus component of trivalent vaccines for use in the 2018-2019 northern hemisphere influenza season be a B/Colorado/06/2017-like virus of the B/Victoria/2/87-lineage. Therefore the aTIV will include:

- an A/Michigan/45/2015 (H1N1)pdm09-like virus;
- an A/Singapore/INFIMH-16-0019/2016 (H3N2)-like virus; and
- a B/Colorado/06/2017-like virus (B/Victoria/2/87 lineage).

36. As with previous years all vaccines required for this programme has been centrally procured. The following vaccines have been purchased following a tender process:

- Quadrivalent Influenza Vaccine - Sanofi Pasteur t/a Aventis Pharma Limited;
- Adjuvanted trivalent Influenza Vaccine (aTIV), Fluad® - Seqirus UK Limited;
- Fluenz Tetra® - AstraZeneca UK Limited.

None of the influenza vaccines for the 2018/19 season contain thiomersal as an added preservative.

37. It is anticipated that initial seasonal flu vaccine supplies will arrive in Northern Ireland during September 2018 although deliveries of the adjuvanted vaccine (Fluad®) will be staggered over 3 months. This should permit GPs and Trusts to schedule clinics once they have received their first delivery of vaccine during late September. PHA will inform GPs when deliveries of flu vaccines will commence once stocks have arrived in Northern Ireland.

Adjuvanted influenza vaccine (Fluad®)

38. 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 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.

39. 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. Those aged 65-74 years of age should still receive Fluad® after those aged 75+ are vaccinated or when restrictions are lifted. Practices should **NOT** offer the quadrivalent vaccine to those aged 65-74 when supplies of Fluad® are restricted.

Quadrivalent influenza vaccine

40. 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 Public Health England 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.

Live attenuated influenza vaccine (Fluenz Tetra®)

41. JCVI have recommended that a live attenuated influenza vaccine (LAIV) be used as the vaccine of choice for children. There is currently only one LAIV on the market, Fluenz Tetra® (a quadrivalent live attenuated intranasal influenza vaccine). JCVI recommended that by extending the flu vaccination to all children this should reduce the impact of flu by directly averting many cases in children and, by reducing flu transmission in the community, it will avert many cases of severe flu and flu related deaths in older adults and people with clinical risk factors. While the long term effectiveness of the programme is still being assessed it should be noted that since the programme was introduced the levels of GP consultation rates for influenza-like illness during each flu season has been lower in Northern Ireland compared to other parts of the UK and the Republic of Ireland where either a more limited or no flu vaccination programme for healthy children exists.

    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;

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

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

44. 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).

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

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

47. Vaccine has been ordered to cover the period over which historically the flu vaccine has been administered, extending from late September to mid-December. **It is highly likely that most of the Fluenz Tetra® supplied centrally will have expired before the end of January 2019.**

    In light of this it will be important to ensure that efforts are made to vaccinate all children as soon as possible.

Contraindications and precautions

48. None of the influenza vaccines should be given to those who have had:

    - a confirmed anaphylactic reaction to a previous dose of the vaccine, or
    - a confirmed anaphylactic reaction to any component of the vaccine (other than ovalbumin – see the Green Book influenza chapter for egg allergy and inactivated influenza vaccines).

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

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

50. Fluenz Tetra® is not recommended in children with:

    - a history of active wheezing at the time of vaccination (until at least 72 hours after wheezing has stopped); or those who have increased their use of bronchodilators in the previous 72 hours. If their condition has not improved after a further 72 hours then, to avoid delaying protection in this high risk group, these children should be offered an inactivated influenza vaccine;

- or who are currently taking or have been prescribed oral steroids in the last 14 days;
- or who are currently taking a high dose inhaled steroid – Budesonide ≥ 800micrograms/day or equivalent (e.g. Fluticasone ≥ 500 micrograms/day) because of limited safety data in these groups.

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

Egg allergy

52. In recent years, inactivated flu vaccines that have a very low ovalbumin content (<0.12 micrograms/ml) have become available and studies show that they may be used safely in individuals with an egg allergy (*Gagnon et al*, 2010). The only exception to this is when the egg allergy resulted in anaphylaxis that required an intensive care admission. This year one of the vaccines centrally procured, (Inactivated Quadrivalent Influenza Vaccine from Sanofi Pasteur t/a Aventis Pharma), for use in Northern Ireland has an ovalbumin content of < 0.12 micrograms/ml, and can be used in egg allergic patients.

    NOTE – The advice in the Green Book differs from the SPC for the quadrivalent vaccine which lists as a contraindication:

    "Hypersensitivity to the active substances, to any of the excipients listed in Section 6.1or to any component that may be present as traces such as eggs (ovalbumin, chicken, proteins), neomycin, formaldehyde and octxinol-9"

53. The adjuvanted influenza vaccine (aTIV), Fluad®, however, has a higher ovalbumin content and is **NOT** suitable for egg allergic patients. Any egg allergic patient aged 65 years and above should be offered the Inactivated Quadrivalent Influenza vaccine (if their allergy did not result in anaphylaxis that required intensive care).

54. For anyone who has had **confirmed anaphylaxis to egg (requiring intensive care) there is no licensed egg-free vaccine available in the UK.** These individuals should be discussed with a relevant specialist to consider what is most appropriate for the individual patient given their history, for example vaccination in hospital using vaccine with an ovalbumin content less than 0.12 micrograms/ml.

55. Fluenz Tetra®, which has an upper ovalbumin limit of 1.2 micrograms/ml, has also been recently shown (JCVI, 2015) to be safe for use in most egg allergic children, unless they have had anaphylaxis that required an intensive care admission / the vaccine is contra-indicated for other reasons. <u>All other egg allergic individuals without other contraindications</u>, can be given inactivated influenza vaccine with an ovalbumin content less than 0.12 micrograms/ml as a single dose (two doses in the case of children aged under 9 years that have not been previously vaccinated) in primary care.

    Facilities should be available and staff trained to recognise and treat anaphylaxis (as is the case when any vaccines are given).

A summary of the vaccines available and their suitability for use in patients with an egg or latext allergy is shown in the table below.

Marketing Authorisation Holder	Name of Product	Vaccine Type	Admin route	Age	Suitable for Egg Allergy Patients	Suitable for latex Allergy Patients
Seqirus UK Limited;	**Fluad®** **Adjuvanted Trivalent Influenza Vaccine (aTIV)**	Surface antigen, inactivated Adjuvanted with MF59C.1	Intramuscular injection	65 years and over	No	No
Sanofi Pasteur t/a Aventis Pharma Limited	**Quadrivalent Influenza Vaccine**	Split virion, inactivated virus	Intramuscular injection	From 6 months	Yes	Yes
AstraZeneca UK Ltd	**Fluenz Tetra®**	Live Attenuated	Nasal spray	From 24 months to less than 18 years old	Yes	Yes

Audit

56. At the end of this season's influenza programme, to inform the arrangements for next year, the PHA **will carry out an audit of the number of vaccines delivered to practices and the number recorded as used**. Given the procedures in place and the frequency of deliveries available, the Department would expect all practices to have robust arrangements in place to ensure that wastage is low. Excessive waste of vaccines is totally unacceptable and practices will be required to account for such situations which are under the close scrutiny of the Department.

    An analysis of vaccine use last year showed that in a number of instances vaccine was lost because of cold chain failures. To prevent a recurrence it is important that practices ensure they have in place comprehensive up to date cold chain policies that will minimise the risk. If a cold chain failure occurs unavoidably, e.g. due to a power cut at a weekend, then advice should be sought from the PHA duty room, prior to vaccine disposal, as it is sometimes still possible to use these vaccines.

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Annex 2

Clinical risk groups 2018/19

Flu vaccine should be offered to the eligible groups set out in the table below, which continues overleaf.

Eligible groups	Further detail
All children aged two years of age and over, not yet at primary school.	All those aged two years and over, not yet at primary school on 1 September 2018. (**i.e. date of birth 2 July 2014** to **1 September 2016**) should be invited for vaccination by their general practice.
All children attending primary school.	All children attending P1 to P7 in primary school (**D.O.B. 2 July 2007 to 1 July 2014**.) will be offered the vaccine in school. Any who miss it in school should be given it *on request* by their practice.
All patients aged 65 years and over	"Sixty-five and over" is defined as those 65 and over on 31 March 2019 (i.e born on or before 31 March 1954).
Chronic respiratory disease aged six months or older	Asthma that requires continuous or repeated use of inhaled or systemic steroids or with previous exacerbations requiring hospital admission. Chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema; bronchiectasis, cystic fibrosis, interstitial lung fibrosis, pneumoconiosis and bronchopulmonary dysplasia (BPD). Children who have previously been admitted to hospital for lower respiratory tract disease. **See precautions section on live attenuated influenza vaccine**
Chronic heart disease aged six months or older	Congenital heart disease, hypertension with cardiac complications, chronic heart failure, individuals requiring regular medication and/or follow-up for ischaemic heart disease.
Chronic kidney disease aged six months or older	Chronic kidney disease at stage 3, 4 or 5, chronic kidney failure, nephrotic syndrome, kidney transplantation.
Chronic liver disease aged six months or older	Cirrhosis, biliary atresia, chronic hepatitis
Chronic neurological disease	Stroke, transient ischaemic attack (TIA). Conditions in which respiratory function may be compromised due to neurological disease (e.g. polio syndrome sufferers). Clinicians should offer immunisation, based on individual assessment, to clinically vulnerable individuals including those with cerebral palsy, learning difficulties, multiple sclerosis and related or similar conditions; or hereditary and degenerative disease of the nervous system or muscles; or severe neurological disability
Diabetes aged six months or older	Type 1 diabetes, type 2 diabetes requiring insulin or oral hypoglycaemic drugs, diet controlled diabetes.

Immunosuppression **(see contraindications and precautions section on live attenuated influenza vaccine)**	Immunosuppression due to disease or treatment. Patients undergoing chemotherapy leading to immunosuppression, bone marrow transplant, HIV infection at all stage, multiple myeloma or genetic disorders affecting the immune system (e.g. IRAK-4, NEMO, complement disorders). Individuals treated with or likely to be treated with systemic steroids for more than a month at a dose equivalent to prednisolone at 20mg or more per day (any age) or for children under 20kg a dose of 1mg or more per kg per day. It is difficult to define at what level of immunosuppression a patient could be considered to be at a greater risk of the serious consequences of flu and should be offered flu vaccination. This decision is best made on an individual basis and left to the patient's clinician. Some immunocompromised patients may have a suboptimal immunological response to the vaccine.
Asplenia or dysfunction of the spleen	This also includes conditions such as homozygous sickle cell disease and coeliac syndrome that may lead to splenic dysfunction.
Pregnant women	Pregnant women at any stage of pregnancy (first, second or third trimesters). **(see contraindications and precautions section on live attenuated influenza vaccine)**
Morbid obesity (class III obesity)*	Adults with a Body mass Index ≥ 40kg/m²

* Many of this patient group will already be eligible due to complications of obesity that place them in another risk category.

Other Groups

The list above is not exhaustive, and the medical 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. Vaccination should also be offered to of household contacts of immunocompromised individuals i.e. individuals who expect to share living accommodation on most days over the winter and therefore whom continuing close contact is unavoidable. This may include carers (see below). Influenza vaccine should be offered from centrally procured stock in such cases even if the individual is not in the 'clinical risk' groups specified above. For monitoring purposes these patients should be recorded as 'others'

In addition to the above, immunisation should be provided to Health and social care workers who are in direct contact with patients/clients to protect them and reduce the transmission of influenza within health and social care premises, to contribute to the protection of individuals who may have a suboptimal response to their own immunisations, and to avoid disruption to services that provide their care. This would include:

- Health and Social Care staff directly involved in care of their patients or clients;

- Those 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 prisons, young offender institutions, university halls of residence etc);

- Those who are in receipt of a carer's allowance, or those who are the main carer, or the carer of an elderly or disabled person whose welfare may be at risk if the carer falls ill. Vaccination should be given on an individual basis at the GP's discretion in the context of other clinical risk groups in their practice;

- Others involved directly in delivering health and social care such that they and vulnerable patients/clients are at an increased risk of exposure to influenza.

Annex 3

Details of how to order vaccine

1. As with last year the Public Health Agency has authorised the implementation and use of the Movianto N.I. web-based Vaccine Ordering System for all GP Practices in Northern Ireland.

   The web-based system is available to all GP Practices and will facilitate simple and accurate ordering of all centrally procured seasonal influenza vaccines for the forthcoming 2018/19 immunisation campaign. As well as being the most efficient way to order vaccines, the system will increasingly be used to provide information and reports on vaccine ordering.

   ONLY GP Practice orders received via the web-based Movianto N.I. Vaccine Ordering System will be processed and delivered.

   Please do not attempt to place orders for seasonal influenza vaccines and/or shingles vaccine (Zostavax®) in any other way.

   Trust hospital pharmacies should continue to place orders via their pharmacy computer systems

2. GPs and hospital pharmacies must only order sufficient vaccines to meet their weekly needs and only the quantity that they have sufficient refrigerated capacity to store (Note- Storage Conditions: 2 to 8°C refrigerated storage / Protect from light / Do not freeze).

   Practices are reminded that it is important that orders are made in line with anticipated need and that wastage is kept to an absolute minimum.

3. The vaccine manufacturer has advised that delivery of the **adjuvanted vaccine** (aTIV) into the UK will be staggered over the months of September, October and November. At present the proposed delivery split is 40% September, 20% October, 40% November. As a result, and in order to ensure all Practices have access to an equitable proportion of the vaccine, orders will be have to be restricted. **Initial priority for aTIV should be those aged 75 years and above.** Further details will be provided by the PHA in due course and Practices should therefore plan accordingly.

How to Order

Orders for seasonal influenza vaccines and the Shingles vaccine (Zostavax®) must be placed **only** with Movianto N. Ireland
Movianto N. Ireland
Sandyknowes Business Park
605 Antrim Road

Belfast, BT36 4RY
Tel: 028 9079 5799

Opening hours: 8.30am to 5.00pm (Monday to Friday)

4. **How can I access the web-based Movianto N.I. Vaccine Ordering System?**

   The Movianto N.I. vaccine ordering system is a secure website. This protects the data held on it from unauthorised access.

   All GP practices must confirm or update their details on the current system prior to being permitted to order vaccines for the 2018/2019 campaign. GP practices must complete this before 10 August 2018. To do this they should login in the usual manner, on the link below, and follow the online instructions.

   GP practices will be able to place their initial orders from w/c 13 August 2018, once they have re-registered.

   For details about how to register please go to:
   http://orders.ni.movianto.com/csp/age/WebLogin.csp

5. **What help will be available to GP practices in using the Movianto N.I. web-based vaccine ordering system?**

   The Movianto N.I. web-based system has been designed to be user-friendly and user manuals via the website will be made available to all GP Practices. Help is also available through a dedicated email address info.ni@movianto.com or by calling 028 9079 5799.

   Initial Orders

   Initial orders for your first delivery of influenza vaccine 2018/19 and/or shingles vaccine can be placed with **Movianto N. Ireland from w/c 13 August 2018.**

   Please note initial delivery dates will be confirmed at a later date (once stocks of seasonal flu vaccine 2018/19 have been received).

   All GP practices must ensure that **all stocks** of last year's supplies of Influenza Vaccine 2017/18 are removed and destroyed (according to disposal policy) **prior** to placing your initial order as they are now all date expired and it is essential they are not mixed with this year's vaccine supply. **GPs should check expiry date for Shingles vaccine before removing for disposal.**

   GPs and hospital pharmacies must only order sufficient to meet their weekly needs and only the quantity that they have sufficient refrigerated capacity to store. (Note – Storage Conditions: 2 to 8 °C refrigerated storage/ Protect from light/ Do not freeze).

Annex 4

Vaccination of health and social care workers

SEASONAL INFLUENZA VACCINATION PROGRAMME FOR FRONTLINE HEALTH AND SOCIAL CARE WORKERS

Rationale and Target Groups

1. It is important that health and social care workers (HSCW) **protect themselves and their patients** by having the influenza vaccine.

2 The seasonal flu uptake rate amongst frontline HSCWs in 2017/18 was **33.4%** across all Trusts, although there was substantial variation between some Trusts (range 26.3% to 40.1%). The number of vaccines administered across Trusts also significantly improved (16,167) compared to previous seasons.

3. While this is an improvement on the previous year's figures (29.3% and 11,879 respectively), the uptake of the seasonal flu vaccine **is still much too low**. The uptake rate achieved for HCWs in England during 2017/18 was **over 60%.** It is important that lessons from previous vaccination programmes are learnt, and are used to drive seasonal flu vaccination uptake levels much higher in frontline HSCWs.

   This year a minimum uptake target of 40% has been set across all Trusts.

4. Influenza outbreaks can arise in health and social care settings with both staff and their patients affected when influenza virus is circulating in the community. Vaccination of health and social care workers against influenza has been shown to significantly lower rates of influenza-like illness, hospitalisation and mortality in the elderly in health and social care settings[14,15,16,17]. It can be assumed that social care settings may also benefit from vaccination of staff in the same way.

5. The influenza immunisation given to health and social workers directly involved in patient care (known as frontline) acts as an adjunct to good infection control procedures. As well as reducing the risk to the patient of infection, reduction of influenza infection among staff and reduced staff absenteeism has also been documented.

6. This year, the Public Health Agency has again commissioned NHS Employers for a second year to deliver the Flu Fighter® campaign in Northern Ireland. Throughout the season, the flu fighter's team will provide advice, guidance and campaign materials to support Trust staff flu vaccination campaigns.

7. Trusts have a responsibility to ensure that their flu teams fully engage with the support provided by Flu Fighters as the Trusts that more actively engaged with them in 2017/18 achieved the best improvements in their uptake.

8. Whilst Trusts/employers may wish to offer flu vaccine to all their employees, they should ensure that health and social care staff directly involved in patient care (known as frontline) are **actively encouraged** to be immunised.

The Responsibility for HSC Trusts

9. The responsibility for achieving high uptake in frontline health and social care workers lies with HSC Trusts. Please ensure that your flu teams have adequate time and resources to fully engage with the support offered from the Flu Fighters campaign

Collection of Vaccine Uptake in Health and Social Care Workers

10. Trusts have a responsibility to collect and submit data on vaccine uptake for **frontline HSCWs only** to the PHA by agreed time scales.

11. Trusts should refer to the "*2018/19 Trust guidance on data collection of vaccine uptake in frontline HSCWs"* from the PHA for information on staff grouping definitions, data collection requirements and reporting dates. It is the responsibility of Trusts to ensure that data is collected in accordance with this guidance and submitted to the PHA within the agreed time scales. . See attached link: http://www.publichealth.hscni.net/publications/frontline-health-and-social-care-worker-201819-seasonal-influenza-vaccine-campaign-trus

12. The PHA will collect vaccine figures monthly and submit to the DoH. These are the official figures – sent to flu fighters and used for comparisons across UK. Trusts therefore must report their figures throughout the season by the agreed timeframes. This year the PHA are changing the reporting requirement to align with when they send all the vaccine uptake figures to DoH

Community Pharmacists and Staff Involved In Supplying Medication

13. Community Pharmacists and those staff involved in supplying medicines will also be able to receive the vaccine via the Occupational Health Service in their local Trust. PHA will provide details of the available clinics nearer the time.

Private Nursing and Residential Home Staff

14. Frontline private nursing and residential home staff can also receive the vaccine **via the Occupational Health Service** in their local Trust. PHA will provide details of the available clinics nearer the time.

Contractual Arrangements

15. **Employers are responsible for vaccination of their staff**, and should put appropriate arrangements in place to ensure high uptake.

Health and social care staff should not routinely be referred to their GP for their vaccination unless they fall within one of the recommended clinical risk groups, or a local agreement is in place for this service.

Information Materials

16. Information materials will be available via the PHA in due course, including detail on definitions of staff directly involved in patient care.

Consent

17. Trusts must ensure that for each person offered the vaccine, appropriate information and advice about the influenza vaccine is given and that the person's consent is obtained. Individuals coming forward for vaccination should be given a reasonable opportunity to discuss any concerns before being vaccinated.

For further information on consent, please see Chapter 2 of the 2006 edition of *Immunisation against infectious disease* (the 'Green Book')[1]

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