Seasonal Flu 2018-2019

GUIDANCE FOR HEALTHCARE PROFESSIONALS - September 2018

HEALTH PROTECTION

Isle of Man Government

Health Protection

Public Health Directorate
INTRODUCTION

The purpose of this document is to provide you with some key information about the 2018/19 Isle of Man Seasonal Flu Immunisation Programme.

Public Health England (PHE) reports that morbidity and mortality attributed to flu is a major cause of harm to individuals, especially vulnerable people, and a key factor in NHS winter pressures. The Seasonal Flu 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. The last season’s higher level of flu activity is an important reminder that flu can have a significant impact and is highly unpredictable. As usual we should strive to further improve vaccine uptake rates in all eligible cohorts.

As you know there is no island-wide surveillance of influenza data and we all rely on good communication between practitioners to help alert us to circulating diseases. We must therefore guard against complacency and continue to improve vaccine uptake rates.

In 2018/19 there are NO changes to the eligible groups. The following are eligible for flu vaccination in the Isle of Man:

- 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
- in addition vaccination is recommended for frontline healthcare and social care staff.

Please note that the eligible groups differ from those in NHS England, Scotland, Wales, and Northern Ireland in that the Isle of Man does not include children without at risk factors.
We have already written to General Practitioners (GPs) and community pharmacies to confirm that the most effective flu vaccines for the population to be ordered for the 2018/19 flu season. The majority of flu vaccinations are given in primary care and general practice is key to the success of the flu vaccination programme. It remains the responsibility of GP practices to identify their eligible patients and to order sufficient flu vaccine for 2018/19. All those eligible should be given flu vaccination as soon as vaccine is available so that people are protected when flu begins to circulate.

Annex A and the influenza chapter in ‘Immunisation against infectious disease’ (the ‘Green Book’) gives detailed descriptions of eligible groups and guidance for healthcare workers on administering the flu vaccine.

**The most important change about this season is that there are different vaccines recommended for those aged 65+ compared to those aged under 65.** 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.** In line with NHS England the Isle of Man recommended that the adjuvanted trivalent influenza vaccine (aTIV) called **Fluad®**, 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)).

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

- 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.

- **The quadrivalent vaccine (QIV) for 18 – under 65s ‘at risk’.** In line with NHS England the Isle of Man 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.

• The live attenuated influenza vaccine (LAIV) used for the ‘at risk’ children’s
  programme is also quadrivalent. 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 (UK data). Improving uptake in
children with an underlying clinical risk factor will provide individual protection
as well as helping to protect the wider community.

Flu viruses change continuously and the WHO monitors the epidemiology of flu
viruses throughout the world. Twice a year it makes recommendations about the
strains to be included in vaccines for the forthcoming winter. It is recommended
that quadrivalent vaccines for use in the 2018-2019 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 2018-2019 northern hemisphere influenza season be:

• a B/Colorado/06/2017-like virus of the B/Victoria/2/87-lineage.

For further information see:

Vaccination Uptake Ambition

The long term ambition is, that most eligible groups for whom flu vaccination provides direct protection, a minimum 75% flu vaccine uptake rate is achieved (WHO). The uptake ambition for pregnant women is at least 55% with an ultimate ambition to 75% given their increased risk of morbidity and mortality from flu.

The Isle of Man has some limited data on flu vaccine uptake for 2017/18 - we did not do as well last season as the season before. We need to improve this downward rate.

| 65 years and over uptake was down to 57% from 55% the previous year |
| Pregnant women uptake was down to 47% from 51% the previous year - for pregnant women the target is 55% |

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 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 2018.

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.

It should be noted that the LAIV has a short shelf life and there will only be limited availability of vaccine late in the season.
CHOICE OF FLU VACCINE FOR ADULTS

For all eligible populations apart from children providers remain responsible for ordering vaccines directly from manufacturers.

On 13 February 2018 Isle of Man Public Health and Primary Care wrote to GPs and Community Pharmacies to confirm that the most effective flu vaccines for the population should be ordered.

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 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.

*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 and is ready for local authorisation.*

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.

In line with NHS England, Isle of Man advised that **65 year olds and over receive aTIV, and under 65s in at risk groups, including pregnant women, receive QIV** for the 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.

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

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

More detailed information on the characteristics of the available vaccines, including ovalbumin (egg) content will be published on the PHE Immunisation web pages.

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.

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.
Primary Care fridge capacity: 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.

**CHILDREN IN CLINICAL RISK GROUPS**

Please note that the eligible groups in the Isle of Man does not include children without at risk factors and as such differs from those in NHS England, Scotland, Wales, and Northern Ireland.

**Vaccine of choice - Live Attenuated Influenza Vaccine (LAIV)**

The Green Book states that LAIV, administered as a nasal spray, is the vaccine of choice for children. The vaccine is licensed for those aged 24 months to less than 18 years of age. The JCVI recommended LAIV as it:

- has good efficacy in children
- the potential to provide protection against circulating strains that have drifted from those contained in the vaccine
- has higher acceptability with children, their parents and carers due to intranasal administration
- 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

LAIV is unsuitable for children with contraindications such as severe immunodeficiency, severe asthma or active wheeze. Those under 18 years with clinical risk factors that contraindicate LAIV should be offered an inactivated quadrivalent influenza vaccine.

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).

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).

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.

PREGNANT WOMEN

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

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

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.

When to offer the vaccine to pregnant women

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. Clinicians 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.
Midwives need to be able to explain the benefits of flu vaccination to pregnant women and signpost back to the GP practice or local pharmacist for vaccination if they do not offer the vaccination service.

Where maternity providers or pharmacies provide the flu vaccine, it is important that the patient’s GP practice is informed in a timely manner (ideally 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.

References


Publicity and Information Materials

An updated patient leaflet will be produced and made available before the start of the Flu Immunisation Programme.

Further information and electronic copies of promotional material can be found by following the flu page links at:

www.gov.im/vaccinations

Please note that the Isle of Man eligible groups differ from those in NHS England, Scotland, Wales and Northern Ireland, in that the Isle of Man does not include children without at risk factors.

<table>
<thead>
<tr>
<th>Document</th>
<th>Web link</th>
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<tbody>
<tr>
<td>Green Book Influenza Chapter</td>
<td><a href="https://www.gov.uk/government/publications/influenza-the-">https://www.gov.uk/government/publications/influenza-the-</a></td>
</tr>
<tr>
<td></td>
<td>green-book-chapter-19</td>
</tr>
<tr>
<td>ImmForm website for ordering child flu vaccines</td>
<td><a href="https://portal.immform.dh.gov.uk/Logon.aspx?returnurl=%2f">https://portal.immform.dh.gov.uk/Logon.aspx?returnurl=%2f</a></td>
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<tr>
<td>Vaccine Update</td>
<td><a href="https://www.gov.uk/government/collections/vaccine-update">https://www.gov.uk/government/collections/vaccine-update</a></td>
</tr>
<tr>
<td>To register to receive the monthly newsletter by email please go to:</td>
<td><a href="https://public.govdelivery.com/accounts/UKHPA/subscribers/new?preferences=true">https://public.govdelivery.com/accounts/UKHPA/subscribers/new?preferences=true</a></td>
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</table>
Groups Eligible for the Isle of Man Seasonal Flu Vaccine 2018/19

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. In 2018/19, flu vaccinations will be offered under the NHS flu vaccination programme in the Isle of Man to the following groups:

- people aged from six months to less than 65 years of age with a serious medical condition such as:
  - chronic (long-term) respiratory disease, such as severe asthma, chronic obstructive pulmonary disease (COPD) or bronchitis
  - chronic heart disease, such as heart failure
  - chronic kidney disease at stage three, four or five
  - chronic liver disease
  - chronic neurological disease, such as Parkinson’s disease or motor neurone disease, or learning disability
  - diabetes
  - splenic dysfunction or asplenia
  - a weakened immune system due to disease (such as HIV/AIDS) or treatment (such as cancer treatment)
  - 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

- people who are in receipt of a carer’s allowance, or those who are the main carer of an older or disabled person whose welfare may be at risk if the carer falls ill
- consideration should also be given to the vaccination of household contacts of immunocompromised individuals, specifically individuals who expect to share living accommodation on most days over the winter and, therefore, for whom continuing close contact is unavoidable.

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

It is also recommended that health and social care workers with direct patient/service user contact should be vaccinated as part of an employer’s occupational health obligation.

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:


Please note the flu vaccination is not routinely offered to school children on the island – this differs from the UK Seasonal Flu Programme.
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.

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

• 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

• Use existing EMIS flu templates to record vaccinations.

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 ‘at risk’ 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 (e.g. by letter, email, phone call, text)

• 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.

* 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
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 will collaborate with other providers such as community pharmacies and community health and social care 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.
## APPENDIX C:

### Vaccines Available for the 2018/19 Flu Immunisation Programme

<table>
<thead>
<tr>
<th>Supplier</th>
<th>Product details</th>
<th>Vaccine type</th>
<th>Age indications</th>
<th>Ovalbumin content micrograms/ml (micrograms/dose)</th>
<th>Contact details</th>
</tr>
</thead>
<tbody>
<tr>
<td>AstraZeneca UK Ltd</td>
<td>Fluenz Tetra ▼</td>
<td>Live attenuated, nasal (quadrivalent)</td>
<td>From 24 months to less than 18 years of age</td>
<td>≤0.12 (&lt;0.024/0.2ml dose)</td>
<td>0845 139 0000</td>
</tr>
<tr>
<td>GSK</td>
<td>Fluarix™ Tetra ▼</td>
<td>Split virion inactivated virus (quadrivalent)</td>
<td>From 6 months</td>
<td>≤0.1 (&lt;0.05/0.5ml dose)</td>
<td>0800 221 441</td>
</tr>
<tr>
<td>MASTA</td>
<td>Quadrivalent Influenza Vaccine (split virion, inactivated) ▼</td>
<td>Split virion, inactivated virus</td>
<td>From 6 months</td>
<td>≤0.1 (&lt;0.05/0.5ml dose)</td>
<td>0113 238 7552</td>
</tr>
<tr>
<td>Mylan (BGP Products)</td>
<td>Influvac® sub-unit Imuvac®</td>
<td>Surface antigen, inactivated virus (trivalent)*</td>
<td>From 6 months</td>
<td>0.2 (0.1/0.5ml dose)</td>
<td>0800 358 7468</td>
</tr>
<tr>
<td></td>
<td>Quadrivalent Influenza vaccine Tetra MYL</td>
<td>Influenza virus surface antigen (inactivated)</td>
<td>From 18 years</td>
<td>0.2 (0.1/0.5ml dose)</td>
<td></td>
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<tr>
<td></td>
<td>Quadrivalent Influvac sub-unit Tetra ▼</td>
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<tr>
<td>Pfizer Vaccines</td>
<td>Influenza vaccine (split virion, inactivated), pre-filled syringe</td>
<td>Split virion, inactivated virus (trivalent)*</td>
<td>From 5 years</td>
<td>≤2 (&lt;1/0.5ml dose)</td>
<td>0800 089 4033</td>
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<tr>
<td>Sanofi Pasteur Vaccines</td>
<td>Quadrivalent Influenza Vaccine (split virion, inactivated) ▼</td>
<td>Split virion, inactivated virus</td>
<td>From 6 months</td>
<td>≤0.1 (&lt;0.05/0.5ml dose)</td>
<td>0800 854 430</td>
</tr>
<tr>
<td>Seqirus UK Ltd</td>
<td>Fluad®</td>
<td>Surface antigen, inactivated, Adjuvanted with MF59C.1 (trivalent)</td>
<td>65 years of age and over</td>
<td>≤0.4 (&lt;0.2/0.5ml dose)</td>
<td>08457 451 500</td>
</tr>
</tbody>
</table>

Note the ovalbumin content is provided in units of micrograms/ml and micrograms/dose. None of the influenza vaccines for the 2018/19 season contain thiomersal as an added preservative.

* Note: Trivalent vaccine only.
APPENDIX D:

Influenza Vaccination Summary Chart for Winter 2018/19

Chart summarising the advice on influenza vaccination for the 2018/19 Influenza Vaccination Programme.

This chart should be read in conjunction with the Green Book and the individual product’s SPC. Please note that the Isle of Man differs from the UK guidance re: some eligible vaccination groups.

ADULTS

65 years and over on 31 March 2019

- adjuvanted trivalent vaccine

Under 65 years on 1 March 2019 in ‘at risk’ groups

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

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

More detailed information on the characteristics of the available vaccines, including ovalbumin (egg) content will be published on the PHE Immunisation web pages.
USEFUL LINKS

BTS/SIGN British Management of Asthma

EMC Electronic Medicines Compendium – for Summary Product Characteristics (SPC)
https://www.medicines.org.uk/emc

Isle of Man Government Vaccinations and Immunisations
https://www.gov.im/vaccinations

Public Health England (PHE) - The Green Book

UK Government immunisation
www.gov.uk/government/collections/immunisation

World Health Organisation (WHO)
Recommended composition of influenza virus vaccines for use in the 2018-2019 northern hemisphere influenza season

Date issued: August 2018
Review date: July 2019
The information in this leaflet can be provided in large format or in audio format on request.