

September 2018

PSNC Briefing 050/18: Flu Vaccination Service 2018/19: Adjuvanted trivalent inactivated influenza vaccine (aTIV)

For the 2018/19 flu season, NHS England has informed community pharmacy contractors that the following vaccines should be offered to patients:

- the adjuvanted trivalent inactivated vaccine (aTIV) for patients aged 65 years and over (including 64 year olds turning 65 years old by 31st March 2019) – there is currently only one aTIV licensed in the UK, this is called Fludax®; and
- a quadrivalent vaccine (QIV) for people in the 18 to under 65s at risk group.

This is the first year of the pharmacy Flu Vaccination Service, that different vaccines have been recommended for different eligible groups. There is also an added complexity this year, due to the fact that contractors will receive a phased delivery of Fludax® and that there is a recommended priority order for patients in the 65 years and above eligible group.

There have been several documents and news stories published containing information about aTIV and the recommendations for using it; a publication timeline is set out in Annex A as background information. This PSNC Briefing provides a summary of relevant information for contractors.

The guidance issued by NHS England has been developed by the aTIV working group, which has been meeting regularly since March 2018 and comprises representatives from Public Health England (PHE), NHS England, Department of Health and Social Care (DHSC), PSNC and the GP Committee (GPC) of the British Medical Association.

Why aTIV should be offered to patients aged 65 years and over

In June 2017, the Joint Committee on Vaccination and Immunisation (JCVI) reviewed the published data that aTIV has higher vaccine immunogenicity and higher effectiveness than non-adjuvanted vaccines in the elderly. Mathematical modelling by PHE indicated that, even under quite conservative estimates of improved effectiveness, aTIV would be highly cost-effective in both the 65-74 and 75 years and over age groups.

Given the low influenza vaccine effectiveness seen in the 65 years and over cohort in seasons dominated by A(H3N2), the Committee agreed that use of aTIV in those aged 65 years and over would be both more effective and cost-effective than the non-adjuvanted vaccines previously used. JCVI also agreed that the priority for aTIV should be for those aged 75 years and above, as this age group appear to derive little benefit from the non-adjuvanted vaccine.

In August 2017, an aTIV (Fludax®), licensed for use in those aged 65 years and older, gained marketing authorisation in the UK.

Ordering stock of Fludax®

The deadline for community pharmacy contractors to order stock of Fludax® was Thursday 12th April 2018 (this was an extended deadline put in place following a request from PSNC). If contractors did not order stock by the deadline, it is unlikely they will now be able to obtain stock of aTIV and therefore should not vaccinate patients aged 65 years

and over, except in exceptional circumstances (see Exceptional use of QIV for patients 65 years and over section below).

Contractors who did order stock of aTIV before the deadline should receive a phased delivery of stock: 40% of their order in September; 20% in October; and 40% in November. GP practices will also receive their orders in this way.

This approach was put in place, as there would not be enough stock of aTIV available in September for all pharmacies and GP practices to receive their orders that month. The phased delivery approach was agreed by Seqirus (the vaccine manufacturer), PHE and NHS England after discussions with PSNC, GPC and DHSC.

The initial proposal was for vaccines to be distributed on a first come, first served basis, i.e. practices and pharmacies that ordered aTIV early, would have received their full vaccine orders first. At PSNC's request, the phased approach was agreed, to ensure an equitable distribution of vaccines to practices and pharmacies, thus allowing a more equitable availability of aTIV to patients across the UK. The phased delivery arrangements are for the 2018/19 season only.

Contractors should have been contacted by Seqirus in August 2018, to inform them of their exact delivery dates and quantities. GP practice and community pharmacy orders for aTIV in England total ~7.8 m doses; in 2017/18 around 7.4m doses were given to this age group achieving 72.6% uptake against the target of 75%.

Prioritisation of patient groups in the 65 years and over group

Due to the phased deliveries of aTIV, NHS England has recommended that GP practices could use the profile of their population aged 65 years and over to inform the phasing of invitations to patients for a flu vaccination as set out in the table below:

Patient groups		Rationale
1.	Those aged 75 years and over Those in care homes	This group have been shown over recent years to be at highest risk of poor outcome from influenza and often have the poorest response to standard dose non-adjuvanted vaccines. Vaccination aims to reduce influenza outbreaks in care homes and the impact this has on health and care services as well as to protect vulnerable individuals.
2.	65 to 74 years olds in a clinical risk group	More vulnerable to severe disease following influenza because of underlying medical condition and to benefit from aTIV.
3.	65 to 74 years old NOT in a clinical risk group	Increased age elevates the risk of poor outcomes following infection with influenza; aTIV is the recommended vaccine.

As pharmacies do not have a registered list of patients, a formal call system for eligible patients is not a practical approach, however in a similar way to that described above for general practices, contractors could:

- communicate the specific 2018/19 arrangements to patients from August onwards through all the communications channels they usually use: website, posters, leaflets, messages on prescription bags etc.; and
- use the messages in the national communications and marketing strategy (vaccination will be offered to everybody before the end of November so make sure you get vaccinated by then) within their communications to patients.

Contractors could use the above profile of the population aged 65 years and over to inform the provision of the vaccination service from September to November, **but where the appropriate vaccine is available, and an eligible patient presents at the pharmacy seeking vaccination, contractors should vaccinate them rather than asking them to return later in the season.**

Off-label use of Flud[®]

Flud[®] is licensed for administration to individuals aged 65 years and over. It may be administered off-label under the national PGD to 64 year olds turning 65 years of age by 31st March 2019 in accordance with the recommendations for the national influenza immunisation programme for 2018/19.

Where a vaccine is recommended off-label, as part of the consent process, pharmacists should consider informing the patient/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence. If this advice is provided, it should be documented in the patient's record.

Route/method of administration of Flud[®]

Flud[®] is not licensed for subcutaneous administration so should only be administered intramuscularly under the national PGD. If Flud[®] needs to be administered at the same time as another vaccine, immunisation should be carried out on separate limbs.

Side effects of Flud[®]

There may be some mild reactions to any flu vaccine, but serious side effects are very rare. Flud[®] is slightly more likely to give a local reaction around the injection site; however, Flud[®] benefits people aged 65 years and over as it gives a better protection against flu. Further information on side effects can be found in the [PGD](#) and the [Summary of Product Characteristics](#) for Flud[®].

The presentation of Flud[®] in 2018/19

Due to the increased volume of Flud[®] required in the UK, Seqirus will, for the 2018/19 season only, deliver most of the supply in pre-filled syringes (Luer Lock) with a separate needle which will require attachment prior to administration of the vaccine. From the 2019/20 season onwards, Flud[®] will be supplied in the more usual presentation of a pre-filled syringe with an attached needle.

Patients with an egg allergy

Flud[®] contains more than the recommended ovalbumin content for patients with egg allergy (each 0.5ml dose contains less than or equal to 0.2µg ovalbumin). Patients aged 65 years and over with an egg allergy should therefore be given QIV with an ovalbumin content less than 0.12 micrograms/ml (0.06 micrograms in a 0.5 ml dose).

The ovalbumin content of influenza vaccines for the 2018/19 flu season can be found in PHE's [Influenza vaccines: 2018 to 2019 flu season](#).

Action to take where a pharmacy has temporarily run out of aTIV

If a pharmacy is awaiting further supplies of aTIV, from their expected deliveries in October and November, patients aged 65 and over should be encouraged to return when those supplies become available. If the patient wants to be vaccinated immediately, they should be referred to their GP practice (if they have aTIV in stock) or another local pharmacy that has stock available.

If a GP practice has temporarily run out of aTIV, they are likewise being advised by NHS England to ask patients to return for vaccination when stocks become available, or they may refer patients to local pharmacies that have stock available.

Action to take where a pharmacy will not receive any aTIV

Where a pharmacy has not been able to obtain aTIV, they should direct patients to a locally available source of aTIV at their GP practice or another local pharmacy that has stock available.

What happens where GP practices will not receive any aTIV?

NHS England local teams, together with local public health commissioning teams, are working with CCGs to coordinate local plans for vaccination of patients where there are GP practices that will not receive any aTIV. In this

circumstance, NHS England is advising that the GP practice should work closely with local pharmacies to direct patients to contractors that have aTIV in stock and that are able to vaccinate patients. In this circumstance, the practice issuing prescriptions for aTIV would not be appropriate.

Exceptional use of QIV for patients 65 years and over

Only if there is **no** locally accessible supply of aTIV, **and no further supplies are expected**, would it be clinically appropriate to offer QIV to patients 65 years and over; this is only likely to occur in late November.

If offering QIV to individuals not recommended to have it, when gaining consent for immunisation, pharmacists should ensure they inform the individual the vaccine is not one nationally recommended for them. Pharmacists should ensure they explain to the individual the possible lower efficacy of the vaccine being offered to them, why it is being offered instead of the recommended vaccine and why it may still offer protection against seasonal flu or attenuate the progression of the infection should they get it. The discussion should be documented in the patient's record. Further information on consent to immunisation is available in [The Green Book](#).

Contractual ramifications of inappropriate administration of QIV to patients 65 years and over

The current [service specification](#) (published on 20th August 2018) is clear that pharmacy contractors participating in the service will not be reimbursed or remunerated for vaccines administered to patients outside of the eligibility criteria set out in Annex A of the service specification.

The vaccine is administered under the authority of the [NHS England Patient Group Direction](#), which sets out in section 5 the recommended vaccine choice for the two cohorts of patients. Where despite this advice, a contractor seeks reimbursement for vaccine other than the recommended vaccine choice, NHS England may make enquiries to understand how the evidence of clinical efficacy of aTIV and QIV was taken into account and how the clinical judgement to use the relevant vaccines was reached.

Where an appropriate clinical justification cannot be provided, NHS England may seek to take action against a contractor for breach of the terms of service for failing to provide the service and exercise their professional judgement consistent with standards generally accepted in the pharmaceutical profession.

Further information, resources and answers frequently asked questions are available at psnc.org.uk/flu.

If you have queries on this PSNC Briefing or you require more information please contact [Zainab Al-Kharsan, Service Development Pharmacist](#).

Annex A: Timeline of information relating to the ordering and use of aTIV (Fluad®)

The table below provides a timeline of the publication of documents relating to the ordering and use of aTIV.

Time period	Summary
December 2017	NHS England wrote to general practices and its local teams to provide guidance on the use of aTIV for the 2018/19 season.
January 2018	PSNC received correspondence from DHSC on the commissioning of the 2018/19 pharmacy Flu Vaccination Service.
February 2018	NHS England issued a letter to all community pharmacies and general practices giving final advice on ordering flu vaccine for the 2018/19 season.
March 2018	DHSC, PHE and NHS England published the national flu immunisation 2018/19 programme and letter, which included information on vaccine eligibility. Further information on the phased delivery of (Fluad®), an extension to the ordering deadline and the presentation of (Fluad®) in 2018/19 was released. PSNC Briefing 018/18: Flu Vaccination Service 2018/19 – important update for contractors was published which provided detail on this new information.
August 2018	Guidance for pharmacy contractors and general practices on providing the 2018/19 Flu Vaccination Service was issued by NHS England, with support from PSNC and the BMA. The guidance set out key information required to provide the 2018/19 Flu Vaccination Service, including prioritising patients for vaccination and how to address common patient queries regarding the service. An accompanying letter , jointly issued by NHS England, PSNC and the BMA, reminded general practices and community pharmacy teams of the clinical recommendations on the most effective flu vaccine for 2018/19 for different patient groups. The Patient Group Direction (PGD) for the Flu Vaccination Service was published (alongside the service specification) which included information on aTIV being the recommended vaccine for patients aged 65 years and over (including 64 year olds turning 65 years old by 31 March 2019). PSNC Briefing 042/18: Guidance on the Seasonal Influenza Vaccination Advanced Service 2018/19 was published which provided information on the use of aTIV. PHE published Inactivated influenza vaccine: information for healthcare practitioners which includes information on the different vaccines that should be used for different patient groups (page 7-9). The Green Book was updated to include new information on administration of the flu vaccine, including the use of aTIV.