

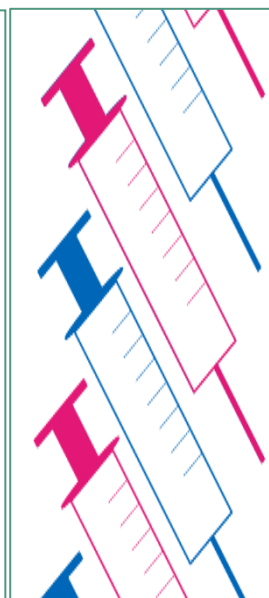
August 2022

PSNC Briefing 025/22: Guidance on the 2022/23 Seasonal Influenza Vaccination Advanced Service

This PSNC Briefing provides guidance for community pharmacy contractors and their teams on the 2022/23 NHS Seasonal Influenza Vaccination Advanced Service in England. Information and resources to support the service are also available at psnc.org.uk/flu.

Summary of key changes for 2022/23

- As part of patient consent, clarification on the information sharing that occurs;
- Wording on the requirements for a consultation room amended to reference the relevant Regulations (the requirements themselves have not changed).
- Changes to the training requirements for vaccinators;
- Addition of the UK Health Security Agency (UKHSA) [Flu vaccinator competency assessment tool](#) as a method of declaring vaccinator competence;
- Minor amendments to wording relating to vaccinations for staff;
- A change to the maximum claim period following provision of vaccinations;
- Patient cohorts updated to reflect the content of the 2022/23 Annual Flu Letter; and
- Vaccines updated to reflect the content of the 2022/23 Annual Flu Letter.



Key next steps for contractors

- Familiarise yourself with the service specification, Patient Group Direction (PGD), national protocol (if you will use it) and changes from the previous flu season;
- Ensure your standard operating procedure (SOP) is up to date;
- Ensure the training of all staff providing vaccinations on behalf of the pharmacy is up to date, and that support staff are aware of the service and eligible cohorts;
- Ensure that all staff providing vaccinations on behalf of the pharmacy sign the PGD or relevant national protocol;
- Use the checklist at the end of this PSNC Briefing to confirm all required pharmacy actions are complete ahead of service commencement; and
- Engage with local plans to drive up overall vaccination rates and consider any opportunities to provide off-site services.

a) Introduction

The Department of Health and Social Care (DHSC), the UKHSA and NHS England want to build on the momentum of higher uptake rates that occurred in the 2021/22 flu season partially driven by concerns about the COVID-19 pandemic. As social contact returns to pre-pandemic norms there is a higher risk of a resurgence in influenza activity in winter 2022 to 2023 to levels similar to or higher than before the pandemic. The potential for co-circulation of influenza, COVID-19 and other respiratory viruses could add significant pressures in the NHS. This co-circulation could add to or prolong the overall period for which respiratory viruses circulate in sequence. The plan, therefore, continues to centre around protecting as many lives as possible.

The [national flu immunisation programme letter](#) highlights the risk of there being a lower level of population immunity against influenza because of non-pharmaceutical intervention measures adopted during the COVID-19 pandemic, such as mask-wearing, physical and social distancing, and restricted international travel.

In line with Joint Committee on Vaccination and Immunisation (JCVI) advice, DHSC and NHS England published a [letter](#) to confirm the reimbursable vaccines and eligible cohorts for the 2022/23 NHS Seasonal Influenza (flu) Vaccination Programme. Following [amendments to the annual flu letter](#), the 2022 to 2023 flu season will include vaccination of those aged 50 to 64 years through the NHS **from 15th October 2022**. The delayed start is to ensure the clinical prioritisation of those most at risk from flu.

This document:

- provides detailed guidance for contractors and their teams on the regular in-pharmacy vaccination service;
- provides detailed guidance for contractors and their teams on the additional opportunities to provide the community pharmacy flu vaccination service in other environments;
- lists considerations that contractors may need to reflect on ahead of commencing service provision; and
- highlights other resources which may support contractors to provide the service.

b) Background and aims of the service

This year is the eighth year the service has been commissioned. It has the potential to be challenging following reports of more than double the number of diagnoses of flu in [Australia](#) in May 2022 compared to their previous record number in May 2019. Countries like Australia, are used to provide an indication of the likely impact of the disease ahead of the season in the northern hemisphere. When coupled with continued circulation of COVID-19 and its continued impact on our health and social care services, the NHS could be over-stretched this winter.

Provisional data from 1st September 2021 to 28th February 2022 in England, indicates that the NHS vaccination services had vaccinated a record 82.3% of those aged 65 years and over, compared to 80.9% in 2020/21. This again exceeded the World Health Organization uptake ambition of 75%. Building on last year's achievements and the successes of the COVID-19 vaccination programme, the Government wants the influenza programme for 2022 to 2023 to demonstrate a 100% offer and to achieve at least the uptake levels of 2021 to 2022 for each cohort.

Contractors do not have a fixed patient list from which to undertake call and recall activities however, contractors are being encouraged to proactively offer influenza vaccination to any patient they identify as being eligible to receive it should the patient present in the pharmacy for any reason.

Additionally, the aim is to reduce levels of inequality with no group or community having an uptake of more than 5% lower than the national average. As a consequence of this, providers of flu vaccination are being encouraged to put plans in place to try and increase provision amongst those living in the most deprived areas and from ethnic minority and underserved communities, as well as ensuring equality of access. This will require engagement with local communities, employers, faith and advocacy groups.

Immunisation is one of the most successful and cost-effective health protection interventions and is a cornerstone

of public health. High immunisation rates are key to preventing the spread of infectious disease, complications and possible early death among individuals and protecting the population's health through both individual and herd immunity. The impact of COVID-19 on the NHS and social care continues to be felt. Those most at risk from flu are also most vulnerable to COVID-19, so, while the NHS is taking steps to prepare for an [autumn COVID-19 vaccine booster campaign](#), flu vaccination continues to be one of the most effective interventions the NHS has to reduce pressure on the health and social care system this winter.

The aim of the seasonal influenza vaccination programme is to protect those who are most at risk of serious illness or death should they develop influenza, by offering protection against the most prevalent strains of influenza virus. Due to the combined risk from flu and COVID-19, as a sector, we must continue to do all we can to help protect those at risk of serious illness or death from the complications of influenza this winter.

c) Commencement and duration of the service

This service will commence on 1st September 2022 or the date on which the Secretary of State Directions (see section d) come into force, whichever is the later; contractors will be notified of this date via the PSNC website. The service ends on 31st March 2023, but in line with the guidance in the [service specification](#), focus should be given to vaccinating eligible patients between 1st September and 31st January each year.

The vaccination of those aged 50 to 64 years not in a clinical at-risk group can commence from 15th October 2022.

Widespread vaccination may continue until December to achieve maximum impact, but where possible, it should be completed before flu starts to circulate in the community. However, flu can circulate considerably later than this and pharmacists should apply clinical judgement to assess the needs of individual patients who are eligible for vaccination under this service to receive immunisation beyond 31st January 2023. This should take into account the level of [flu-like illness in the community](#) and the fact that immune response following immunisation takes about two weeks to fully develop.

d) The service specification and Directions

The [service specification](#) describes the requirements for provision of the service and it should be read and understood by all pharmacists and any appropriately trained person authorised under the national PGD, or relevant emergency national immunisation protocol, providing the service.

The [amendments to the Pharmaceutical Services \(Advanced and Enhanced Services\) \(England\) Directions 2013](#) (the Directions) provide the legal basis for provision of the service. At the time of publishing this Briefing, the Directions have yet to be published. When the Directions are published, an announcement on this will be provided to contractors via PSNC's usual communications channels.

e) The national Patient Group Direction

The administration of a flu vaccine - a Prescription Only Medicine – as part of the Flu Vaccination Service is legally authorised by a national PGD. The [national PGD for the Flu Vaccination Service](#) has been developed and clinically approved by the UKHSA. NHS England has authorised its use by an appropriately trained practitioner to provide the Advanced service. The practitioners who can legally supply and administer under the PGD are listed in the Qualifications and professional registration section of the PGD and mirrors the groups of practitioners authorised to supply or administer medication via a PGD under current legislation. Any listed practitioners must only provide the service under the supervision of a pharmacist, trained in vaccinations (including a clear understanding of this service). The PGD cannot be used to authorise administration of flu vaccines under any other NHS or private services. At the time of publishing this Briefing, the national PGD has yet to be published. When the PGD is published, an announcement on this will be provided to contractors via PSNC's usual communications channels.

Appropriately trained practitioners, who will administer flu vaccines under the authority of the national PGD must:

- download a copy of the latest version of the PGD from the NHS England website;
- read the PGD and ensure they fully understand its content, including the eligible patient groups, the inclusion and exclusion criteria and the record keeping requirements; and
- print off a copy of the PGD and complete the Practitioner declaration to confirm they have read and understood the content of the PGD and that they are willing and competent to work to it within their professional code of conduct – if there is more than one practitioner in the community pharmacy or working with the community pharmacy who will be providing the Flu Vaccination Service, one copy of the PGD can be printed and all practitioners can complete the practitioner declaration on this one copy.

The Authorising Manager declaration must then be completed. The Authorising Manager's role is to confirm the practitioner(s):

- is/are aware of the service specification and requirements for provision of the service;
- have demonstrated their competence to provide the service; and
- has/have the organisation's approval to provide the service.

In certain circumstances, for example, a community pharmacy where the pharmacist who will administer vaccines is also the superintendent pharmacist or contractor, it may be necessary for the authorising manager to be the same person as the practitioner, though this situation should be avoided wherever possible.

These steps **must** be completed before an individual practitioner is authorised to administer flu vaccines as part of the service.

f) The National Protocol

A [national protocol](#) is a legal mechanism for the supply or administration of prescription only medicines during a pandemic which was put in place following amendment of the Human Medicines Regulations. A national protocol is also used by many pharmacies participating in the COVID-19 vaccination programme. NHS England has confirmed a protocol will be available to be used to support the flu vaccination programme for the 2022/23 season. At the time of publishing this Briefing, the protocol has yet to be published. When the protocol is published, an announcement on this will be provided to contractors via PSNC's usual communications channels.

The protocol allows those who are registered healthcare professionals who cannot operate under a PGD, and those who are not registered healthcare professionals, in the context of the flu vaccination service, to safely administer a licensed influenza vaccine. The protocols for vaccines are developed by the UKHSA and will be written similarly to a PGD.

The protocol provides the flexibility to define the training and competence requirements of vaccinators. It also allows the process of administration to be split into its component parts, i.e. clinical assessment and consent, preparation of the vaccine (not required for flu vaccine) and administration of the vaccine. This therefore allows wider use of workforce skill mix to support the provision of the vaccination service. All these stages can be done by one competent person (the registered healthcare professional), but these tasks can also be split with each person trained and authorised to complete their specific task as defined in the protocol. The clinical assessment and consent process must be undertaken by a registered healthcare professional as defined within the protocol.

Where multiple person models are used, contractors must ensure that all elements of the protocol are complied with in the provision of vaccination to each patient.

The choice of whether to operate under a protocol is the responsibility of the contractor. Contractors using the national protocol are responsible for ensuring:

- those persons involved in the service or elements of the service are trained and competent to safely provide the activity they are employed to provide under the protocol;

- as a minimum, competence requirements stipulated in the protocol under **Characteristics of staff** must be adhered to;
- they and registered healthcare professionals have adequate and appropriate indemnity cover;
- persons must be authorised by name to work under the protocol;
- the staff characteristics for the activity being undertaken are met;
- practitioners make a declaration of competence and are authorised in writing. This can be done by completing **Section 4** of the protocol or maintaining an equivalent electronic record;
- a clinical supervisor, **who must be a pharmacist**, must be present and take overall responsibility for provision of vaccination under the protocol at all times and be identifiable to service users;
- any time the protocol is used, the name of the clinical supervisor taking responsibility and all the people working under different stages of the protocol must be recorded for the session.

The clinical supervisor has ultimate responsibility for safe care being provided under the terms of the protocol. Staff working under the protocol may be supported by additional registered healthcare professionals, but the clinical supervisor retains overall responsibility. Staff working to the protocol must know who the clinical supervisor is at any time and only proceed with their authority. The clinical supervisor may withdraw this authority for all members of staff or individual members of staff at any time and has authority to stop and start service provision under the protocol as necessary. Every member of staff has a responsibility to, and should, report immediately to the clinical supervisor any concerns they have about working under the protocol in general or about a specific individual, process, issue or event.

Appropriately trained practitioners or staff, who will be authorised to work under the authority of the national protocol must:

- download a copy of the latest version of the national protocol from the NHS England website;
- read the protocol and ensure they fully understand its content and the appropriate stages that they are expected to be able to provide; and
- print off a copy of the protocol and complete the Practitioner/staff declaration to confirm they have read and understood the content of the protocol and that they are willing and competent to work to it under the supervision of a pharmacist. If there is more than one practitioner/staff member in the community pharmacy or working with the community pharmacy who will be providing the Flu Vaccination Service using the protocol, one copy of the protocol can be printed and all practitioners/staff can complete the practitioner/staff declaration on this one copy.

The Authorising registered healthcare professional declaration must then be completed. The individual taking on this role must be familiar with the competence required by all aspects of the protocol. The role is to confirm the practitioner(s) and staff:

- is/are aware of the service specification and requirements for provision of the service;
- has demonstrated their competence for the role and completed the necessary documentation; and
- has/have the organisation's approval to provide the service.

In certain circumstances, for example, a community pharmacy where the pharmacist who will administer vaccines is also the clinical supervisor and the authorising registered healthcare professional, it may be necessary for them to make a self-declaration of competency.

These steps **must** be completed before an individual practitioner or staff member is authorised to administer flu vaccines as part of the service. Contractors using this protocol should retain copies, along with the details of those authorised to work under it, for 10 years after the protocol expires.

g) Patient eligibility to receive the service

This service covers those patients most at risk from influenza **aged 18 years and older**, listed in Annex A of the service

specification (and listed in **Annex 2** of this guidance) unless contraindicated.

The selection of these eligible groups has been informed by the [DHSC, NHS England and the UKHSA annual flu letter](#).

Vaccinators are not authorised to administer flu vaccines to other patient groups as part of the Flu Vaccination Service. If a vaccine is administered to patients in other groups, the contractor will not be paid for that vaccination and the administration will have been undertaken outside the authority of the legal mechanisms (national PGD / national protocol).

h) Pharmacy eligibility to provide the service

There are several conditions that are specified in the Directions which contractors must comply with prior to provision of the service. These include:

- 1) Contractors must be satisfactorily providing all Essential Services and be compliant with the clinical governance requirements of the Community Pharmacy Contractual Framework (CPCF).
- 2) Staff who will provide the service must be competent to provide the service (see section i for further details).
- 3) Contractors must have an SOP in place for provision of the service, having regard to the requirements of the national PGD, the national protocol and service specification of which all pharmacy staff involved in provision of the service are aware, and which covers the following points as a minimum:
 - the provision of the service to patients and the roles of different staff members;
 - the ongoing conditions under which the service needs to be provided (specified in the service specification);
 - cold chain integrity;
 - needle stick injuries;
 - the identification and management of adverse reactions; and
 - the handling, removal and safe disposal of any clinical waste related to the provision of the service.

If the contractor is to provide the service out of the pharmacy, e.g. in a care home or patient's own home, the SOP must also detail provision of the service and the role of staff members in that location.

- 4) The pharmacy must have a consultation room. Vaccinations can be offered in any area of the pharmacy where suitable facilities are available and patient confidentiality is able to be respected. However, the vaccination must take place in the consultation room wherever the patient expresses this preference. The consultation room must meet the applicable requirements of the Pharmaceutical Services Regulations.

These requirements do not prevent the presence of other persons where the patient requests or consents to this. For example, where the practitioner uses a chaperone, or wishes to include a trainee pharmacist in the consultation as part of their training, this would be allowed if the patient consents. Similarly, the patient may prefer that they are accompanied by another person during the consultation.

Provision of the service in the consultation room is the traditional model of delivery but there are other models to support flexible provision of the service. To support these flexible provisions, contractors will need to think through several considerations. A list of these is provided in a [support guide](#) on the PSNC website.

Vaccinations under this Advanced service can also be undertaken in other suitable locations, such as in the patient's home, a care home, a long-stay residential facility or community venues (e.g. community centres). Vaccinations should be administered under the supervision of a pharmacist, trained in vaccinations (including a clear understanding of this service). A record should be maintained of who that person is at each premises at

any given time. Additionally, where vaccinations are undertaken in the patient's own home (including a care home), contractors must ensure that vaccinators have a valid Disclosure and Barring Service (DBS) certificate.

Where vaccinations are undertaken off the pharmacy premises, the contractor must continue to adhere to professional standards; follow appropriate cold-chain storage measures; ensure that the setting used to administer the vaccinations is appropriate (including ensuring patient confidentiality as appropriate); and appropriately dispose of any clinical waste or personal protective equipment used during the vaccination process.

i) Training and competency requirements

All pharmacy staff involved in the provision of the service should receive appropriate training relevant to the role they will undertake. Contractors are required to demonstrate that all vaccinators and staff assisting with provision of the service in their pharmacy have the skills needed to do so.

There are a number of organisations offering vaccination training and support for provision of flu vaccination services and their contact details can be found on the [PSNC website](#).

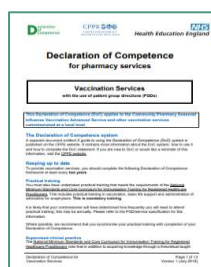
The [National Minimum Standards and Core Curriculum for Immunisation Training for Registered Healthcare Practitioners](#) set out the knowledge and skills that healthcare professionals undertaking vaccination services need to have. Practitioners who will provide the service must have completed practical training in vaccination that meets these requirements. NHS England advise that consideration is given to pharmacists and other authorised vaccinators providing the service undertaking periodic face-to-face refresher training to ensure consistency of practice, peer support and to discuss any clinical issues that are arising in practice.

They must also ensure that they are familiar with the various documents to support the season, including choice of vaccine and contents of the annual flu letter.

All practitioners that will provide the service are also required to undertake annual update training prior to commencing provision of the service, to ensure they have up-to-date knowledge in relation to the provision of flu vaccinations in 2022/23 and any related matters. This update training can be undertaken in a variety of ways, including self-directed learning and use of online training materials.

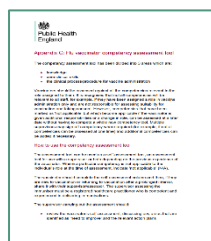
Further information on the training requirements in 2022/23 for pharmacists

Competence



The [Declaration of Competence](#) (DoC) approach has been agreed by NHS England and PSNC as being one of the ways by which pharmacists providing the service can demonstrate their competence to the contractor who is contracted to provide the service and to NHS England.

Where used, the [Vaccination Services DoC](#), hosted on the Centre for Pharmacy Postgraduate Education (CPPE) website, should initially be completed by pharmacists and they should then repeat the process every two years.



An alternative option to assure the competency of any vaccinators (including pharmacists) is the [Flu vaccinator competency assessment tool](#). This has been developed by the UKHSA. It is divided into three areas to assess knowledge, core clinical skills and the clinical process/procedure for vaccine administration. It can be used as a self-assessment tool, an assessment tool for use with a supervisor or both depending on the previous experience of the vaccinator.

The [recommendations](#) that accompany the assessment tool advise that all new flu vaccinators should complete the competency assessment for formal assessment and sign-off of their clinical competency. Any

flu vaccinators returning to vaccination after a prolonged interval should also complete flu-specific training and the flu-specific competency assessment. As the circumstances and training needs for individual practitioners returning to vaccination will vary, there is no defined time interval for 'prolonged', but vaccinators and their supervisors need to be assured of their competence before they deliver this year's programme.

Staff who are not vaccinators but are involved in administrative elements of vaccine provision, as defined within the national protocol, must be trained and competent to safely carry out the activity they are employed to provide. The competence requirements stipulated in the protocol under **Characteristics of staff** should be used to assist with assessing staff.

j) The vaccines to be used in the service

Contractors must ensure that vaccinations offered under this service are provided in line with Immunisation against infectious disease ([The Green Book](#)), which outlines all relevant details on the background, dosage, timings and administration of the vaccination, and disposal of clinical waste. The vaccines which can be used in the service are those listed in [The national flu immunisation programme 2022/23 letter \(DHSC/NHS England/UKHSA\)](#) and authorised for use by the PGD and national protocol:

Product Name	Vaccine Type	Manufacturer
Those aged 65 years and over		
Adjuvanted Quadrivalent Influenza Vaccine Seqirus ▼	aQIV (egg-cultured quadrivalent influenza vaccine), supplied as surface antigen, inactivated, adjuvanted with MF59C.1 OR	Seqirus UK Ltd
Supemtek ▼	QIVr (quadrivalent Influenza vaccine (recombinant prepared in cell culture))	Sanofi Pasteur vaccines
Flucelvax® Tetra ▼	QIVc (cell-cultured quadrivalent influenza vaccine), supplied as surface antigen, inactivated (only where aQIV or QIVr is not available)	Seqirus UK Ltd
At risk adults, including pregnant women, aged 18 to 64		
Flucelvax® Tetra ▼	QIVc (cell-cultured quadrivalent influenza vaccine), supplied as surface antigen, inactivated OR	Seqirus UK Ltd
Supemtek ▼	QIVr (quadrivalent Influenza vaccine (recombinant prepared in cell culture))	Sanofi Pasteur vaccines
Quadrivalent Influenza vaccine	QIVe (standard egg-cultured quadrivalent influenza vaccine), split virion, inactivated (only where QIVc or QIVr is not available)	Sanofi Pasteur vaccines
Quadrivalent Influvac® sub-unit Tetra ▼	QIVe (standard egg-cultured quadrivalent influenza vaccine), supplied as surface antigen, inactivated (only where QIVc or QIVr is not available)	Viatrix (formerly Mylan)
50 to 64-year olds NOT in a clinical at risk group		
Quadrivalent Influenza vaccine	QIVe (standard egg-cultured quadrivalent influenza vaccine), split virion, inactivated	Sanofi Pasteur vaccines
Quadrivalent Influvac® sub-unit Tetra ▼	QIVe (standard egg-cultured quadrivalent influenza vaccine), supplied as surface antigen, inactivated	Viatrix (formerly Mylan)
Flucelvax® Tetra ▼	QIVc (cell-cultured quadrivalent influenza vaccine), supplied as surface antigen, inactivated	Seqirus UK Ltd

	(only to be offered where it does not divert stock from clinical at-risk groups and those age 65 years and over) OR	
Supemtek ▼	QIVr (quadrivalent Influenza vaccine (recombinant prepared in cell culture)) (only to be offered where it does not divert stock from clinical at-risk groups and those age 65 years and over)	Sanofi Pasteur vaccines

The PGD and national protocol does not cover the use of the Fluenz Tetra nasal spray listed in the national flu immunisation programme 2022/23.

k) Providing the service

This section of the guidance covers some of the practical requirements related to provision of the Flu Vaccination Service. A checklist to help contractors and their teams to prepare for and to provide the service can be found at the end of this Briefing (**Annex 1**).

Clinical recommendations for vaccine type

As set out in the letter from DHSC/NHS England and UKHSA (amended on 21st July 2022), the following recommended vaccines should be used for their respective adult patient groups:

Eligible group	Type of influenza vaccine
Aged 65 years and over*	Offer: <ul style="list-style-type: none"> • aQIV (Adjuvanted Quadrivalent Influenza Vaccine Seqirus ▼) • QIVr, (Supemtek ▼) <p>Or offer QIVc (only where aQIV or QIVr is not available).**</p> <p>It is recommended that aQIV is offered 'off-label' to 64-year-olds turning 65 years of age before 31 March 2023.</p>
At-risk adults, including pregnant women, aged 18 to 64	Offer: <ul style="list-style-type: none"> • QIVc (Flucelvax® Tetra ▼) or • QIVr, (Supemtek ▼) <p>Or QIVe (only where QIVc or QIVr is not available).</p>
50- to 64-year olds NOT in a clinical at-risk group	Offer: <ul style="list-style-type: none"> • QIVe • QIVc / QIVr (these should only be offered where it does not divert stock from clinical at-risk groups and those age 65 years and over)

* The JCVI recommended the high dose quadrivalent influenza vaccine (QIV-HD) is offered alongside aQIV because of the additional benefit from the use of aQIV and QIV-HD in those aged 65 years and over. However, QIV-HD is not currently available in the UK market.

**QIVe is not recommended in this age group as aQIV, QIVc and QIVr are preferable on the grounds of clinical effectiveness.

Co-administration of the vaccine

The JCVI confirmed that the ComFluCOV trial indicates that co-administration of the influenza and COVID-19 vaccines is generally well tolerated with no reduction in immune response to either vaccine. Therefore, the two vaccines may be co-administered where operationally practical.

Based on advice from the [COVID-19 vaccination programme - Information for healthcare practitioners](#), where co-administration does occur, patients should be informed about the likely timing of potential adverse events relating to each vaccine. Where more than one vaccine is given at the same time, they should preferably be given in different

limbs. Where this is not possible, they should be given at least 2.5cm apart and the site at which each vaccine was given should be clearly documented in the patient's records.

Storage of vaccines

Vaccines should be stored in line with the requirements set out by their manufacturer in the [Summary of Product Characteristics](#). PHE in 2014 issued guidance on the [protocol for ordering, storing and handling vaccines](#) for all healthcare providers involved in vaccinations, including community pharmacies.

All refrigerators in which vaccines are stored must have a maximum / minimum thermometer. Readings must be taken and recorded from the thermometer on all working days.

Consent

As with the provision of any pharmacy service, the patient must consent to being vaccinated. The General Pharmaceutical Council's (GPhC) [Guidance on Consent](#) provides information on consent for pharmacists and their teams.

Consent should cover the administration of the vaccine as well as advising the patient of information sharing. The patient should be informed that information relating to their vaccination will be shared with their GP practice for the appropriate recording of the vaccination in their GP practice record and may be shared with NHS England for the purposes of service evaluation and research.

Patient consent can be **obtained verbally** and should be recorded in the pharmacy's clinical record for the service.

Personal Protective Equipment

Pharmacy professionals providing the service will need to ensure they follow any current Infection Prevention and Control (IPC) measures that are in place or put in place during the life of the service.

At the time of publishing this Briefing, the UKHSA had updated its UK IPC guidance with [new COVID-19 pathogen-specific advice](#) for health and care professionals. This advice should be read alongside the [National Infection Prevention and Control Manual \(NIPCM\)](#) for England and applies to all NHS settings or settings where NHS services are provided.

Read the current guidance

Contractors are reminded that they can access free PPE and related items using the [Department of Health and Social Care PPE portal platform](#).

Information for patients

Each patient being administered a vaccine should be given a copy of the manufacturer's patient information leaflet about the vaccine or be directed to a web-based version of the leaflet.

Clinical waste

Contractors are required to make arrangements for the removal and safe disposal of any clinical waste and PPE related to the provision of this service. This includes vaccinations carried out in long-stay residential care homes, other long-stay care facilities, off-site or in a patient's home.

Contractors must also ensure that staff are appropriately trained and made aware of the risks associated with the handling and disposal of clinical waste and that correct procedures are used to minimise those risks. A needle stick injury procedure must be in place.

Service records and IT support for the service

In many areas regional NHS England teams have previously been able to arrange IT support for the service. Contact [your LPC](#) to find out whether that is the case in your area.

The [National Flu Vaccination Record Form](#) (Annex C of the service specification) should be used to maintain a clinical record for the service. If a contractor has access to an IT system which allows capture of the data elements within the Flu Vaccination Record Form, this can be used to maintain the clinical record for the service, without the need for a paper record to be retained.

Communicating with GP practices

Contractors must ensure that a notification of the vaccination is sent to the patient's GP practice on the same day the vaccine is administered or on the following working day. This can be undertaken by post, hand delivery, secure email (such as the pharmacy's NHSmail account) or secure electronic data interchange. Please note, notifications cannot be sent by fax.

If an electronic method is used to transfer data to the relevant GP and a problem occurs with this notification platform, the contractor must ensure a hard copy of the paperwork is sent to the GP practice.

Where the notification to the GP practice is undertaken via hardcopy the [National GP Practice Notification Form](#) (Annex B of the service specification) must be used.

The information sent to the GP practice should include the following details as a minimum:

- the patient's name, address, date of birth and NHS number (where known);
- the date of the administration of the vaccine;
- the applicable SNOMED CT code;

Code Type	Code	Description
SNOMED CT	955691000000108	Seasonal influenza vaccination given by pharmacist

- any adverse reaction to the vaccination and action taken/recommended to manage the adverse reaction; and
- reason for patient being identified as eligible for vaccination (for example, aged 65 or over, has diabetes, etc).

Where a patient presents with an adverse drug reaction (ADR) following the initial vaccination and the pharmacist believes this is of clinical significance, such that the patient's GP practice should be informed, this information should be shared with the GP practice as soon as possible.

Adverse Drug Reactions

In addition to the requirement to report clinically significant ADRs experienced by a patient to their GP practice, pharmacists are reminded to report all serious suspected ADRs, even if the effect is well recognised, and all suspected ADRs linked to new medicines and vaccines to the Medicines and Healthcare products Regulatory Agency (MHRA) via the Yellow Card scheme. New medicines and vaccines that are under additional monitoring are indicated by an inverted black triangle symbol (▼) displayed on their package, in their leaflet and summary of product characteristics.

Pharmacy professionals can report suspected side effects directed to the MHRA electronically via:

- [the Yellow Card website](#); or
- the free Yellow Card app, downloadable from the [Apple App Store](#) or [Google Play Store](#).

Provision of data to NHS England

Claims for payment for the service will be made to the NHS Business Services Authority (NHSBSA) (see section I for further details) and they will subsequently share data on service provision with NHS England. Where a clinical records system is used, which submits data on service provisions into the NHSBSA's Manage Your Service (MYS) portal via an application programming interface (API), information from the clinical record detailed in the service specification will be shared with NHS England and NHSBSA for the purpose of post payment verification.

Availability of the service

Contractors will naturally want to ensure that their service is as accessible as possible for patients in order that they can maximise service provision. To facilitate this, contractors will therefore want to ensure that staff are appropriately trained to ensure continuity of service provision across the opening hours of the pharmacy.

If the pharmacy temporarily or permanently ceases to provide the service, they should update the [NHS Profile Manager](#) to reflect that the service is not available from the pharmacy as soon as possible.

The contractor must ensure the service is accessible, appropriate and sensitive to the needs of all service users. No eligible patient should be excluded or experience particular difficulty in accessing and effectively using this service due to their race, gender, disability, sexual orientation, religion or belief, gender reassignment, marriage or civil partnership status, pregnancy or maternity, or age.

Local support and coordination

With this year's demand for vaccination likely to be high, and the risk that capacity could possibly be lower than normal, local partnership working across primary care could support pharmacies and general practices to ensure they collectively maximise the value of the flu vaccination programme.

Contractors should check with their LPC to understand whether conversations are happening within their systems to support a more joined up approach to integrating the pharmacy service into local planning and messaging.

I) Payments and the process for claiming payments

The fees associated with provision of the flu vaccination service for 2022/23 can be found in the [Drug Tariff](#). Contractors can also refer to the [Funding](#) pages on the PSNC website for further details.

Funding for the service comes from the NHS vaccination budget and is in addition to and outside of global sum funding for 2022/23. The total funding delivered will be dependent on uptake of the service, but no cap has been set for this.

Claims for payment for the service must be made electronically on a monthly basis, using the NHSBSA [MYS application](#).

Claims will be accepted by the NHSBSA **within three months** of administration of the vaccination in accordance with the usual Drug Tariff claims process. Payments to contractors will be made monthly as part of their normal payment schedule.

m) Flexibilities within the service and considerations related to their use

The flexibilities and approaches that were introduced into the 2020/21 Seasonal Influenza Vaccination Advanced Service are enduring changes. These include:

Vaccination in the pharmacy, outside the consultation room, but elsewhere within the premises

This aims to allow contractors to provide the service in an alternative location in the pharmacy where this supports better social distancing, provided it can be undertaken in a way which maintains patient safety and confidentiality.

Off-site provision

Flu vaccinations can be provided to patients in their own homes (including care homes) or at other off-site locations. Contractors are not required to submit a notification of intent to provide off-site NHS flu vaccinations to their regional NHS England team.

Provision of the service in locations outside of the pharmacy premises may provide greater space for patients, greater ability to manage patient flow to maintain social distancing (if reintroduced), and better waiting facilities in the event of poor weather.

The sites could include:

- Marquees outside the pharmacy premises;
- Local village, town or community halls;
- Church halls, temples or mosques;
- Adapted mobile units such as buses or vans;
- Car parks; and
- Sports halls / Stadiums.

NHS England requires that practitioners providing flu vaccinations in a patient's own home or a care home have a valid DBS certificate in place. Contractors needing to arrange this should refer to the [DBS checking website](#) for details.

Care homes

Contractors can continue to offer to vaccinate patients 18 years of age or over who are living in long-stay residential care homes, or other long-stay care facilities as well as the care home staff at their place of work.

There is no requirement for contractors to have notified the patient's general practice in advance of vaccination when providing flu vaccinations at a care home. However, contractors should bear in mind that Primary Care Networks, as part of their COVID-19 vaccinations plans, have been encouraged to co-administer vaccines where possible. As is the case for provision of flu vaccinations in the pharmacy, contractors who undertake vaccinations in care homes, must ensure that a notification of the vaccination is sent to the patient's practice on the same day the vaccine is administered or on the following working day. See section k for further details.

Contractor can refer to the flu hub page on the PSNC website for [additional considerations](#) associated with these flexibilities.

n) Discontinuation of service provision

If the pharmacy temporarily or permanently ceases to provide the service, they should update the [NHS Profile Manager](#) to reflect that the service is not available from the pharmacy, as soon as possible.

o) Promoting the service to patients

Materials to help promote the Flu Vaccination Service to patients are available from and via the [PSNC website](#). The National Pharmacy Association (NPA) and some LPCs have also developed materials to help contractors promote the service.

If contractors develop their own marketing materials to promote the service, they must ensure they comply with the requirements of the [Terms of Service](#) relating to promotion of services funded by the NHS.

If the NHS logo is used in materials related to the service, this must comply with [the guidelines for use of the NHS identity by community pharmacies](#).

If contractors are considering using social media to advertise the Flu Vaccination Service, [PSNC Briefing 001/17: Social media guide for community pharmacy teams and LPCs](#) provides community pharmacy teams and LPCs with a guide to help them to consider the benefits of using Twitter and other social media. The on-demand recording of [PSNC's Making the most of social media webinar](#) also offers guidance on what social media is and how to get the most from it.

The [NPA](#), the [Royal Pharmaceutical Society](#) and the [GPhC](#) have also all issued guidance on social media, which should be considered when advertising the service in this way.

p) Frequently Asked Questions

The PSNC website contains a wide range of [Frequently Asked Questions \(FAQs\)](#) and answers and these will be updated on an ongoing basis.

q) Further information and resources

The following links provide further information on the service and vaccinations and many are essential reading for pharmacists and staff who will be providing the service.

NHS England documents

[Flu Vaccination Advanced service specification](#)

[The national Patient Group Direction](#) *(to be published shortly)*

[The national protocol for influenza vaccination](#) *(to be published shortly)*

UKHSA guidance / briefing documents

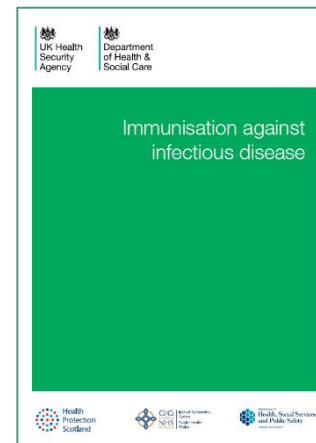
[National flu immunisation programme plan 2022/2023](#)

[UKHSA flu programme website hub page](#)

[Ovalbumin content of flu vaccines for the 2022/23 season](#)

[Inactivated influenza vaccine: information for health care practitioners](#)

[Patient leaflet – Flu vaccination: who should have it this winter and why](#)
(to be published shortly)



Other resources

[Immunisation against infectious disease: the green book](#)

Practical resources

Practical resources to support provision of the Flu Vaccination Service are available on the [PSNC website](#).

If having read this PSNC Briefing and the information and resources on the PSNC website you have further queries about the Flu Vaccination Service, or you require more information please contact the [PSNC Services Team](#).

Annex 1 - Checklist for the Flu Vaccination Service

Preparing to provide the service		Completed
1.	Visit the PSNC website and read through the PSNC Briefings and other service information / documentation and familiarise yourself with the resources available.	<input type="checkbox"/>
2.	Where required, complete face-to-face training covering injection technique and basic life support (including the administration of adrenaline for anaphylaxis) – a list of training providers can be found at psnc.org.uk/fluttraining . This is now listed as a periodic requirement, so it is for the contractor to determine when retraining is needed.	<input type="checkbox"/>
3.	Read the service specification .	<input type="checkbox"/>
4.	Read the national Patient Group Direction (PGD) and the national protocol (if you intend to use this) to ensure you fully understand the content including the eligible patient groups, the inclusion and exclusion criteria and the record keeping requirements.	<input type="checkbox"/>
5.	Complete the Practitioner declaration on the PGD and (if the national protocol is also to be used) the Practitioner/staff declaration to confirm you have read and understood the content of the PGD and/or national protocol and that you are willing and competent to work to it within your professional code of conduct. You must sign a copy of the PGD and /or national protocol in each pharmacy that you work in.	<input type="checkbox"/>
6.	Request that the relevant person for the pharmacy completes the Authorising Manager section of the PGD. An Authorising Manager must sign a copy of the PGD in each pharmacy that you work in. Where the national protocol is being used, an Authorising registered healthcare professional is needed to sign a copy of the protocol. This must also occur in each pharmacy that you work in where the protocol is to be used.	<input type="checkbox"/>
7.	Ensure the competency of staff involved in the service. Pharmacists can complete or check their Declaration of Competence (DoC) . Where the DoC process is used, it must be completed every two years . Another option for assuring staff competency is to use the Flu vaccinator competency assessment tool .	<input type="checkbox"/>
8.	Vaccinators should consider getting vaccinated against hepatitis B if they haven't previously had the vaccination. UKHSA's advice in the Green Book is that hepatitis B vaccination is recommended for healthcare workers who may have direct contact with patients' blood, blood-stained body fluids or tissues. This includes any staff who are at risk of injury from blood contaminated sharp instruments. The Health and Safety Executive guidance on blood borne viruses in the workplace provides further advice on this issue.	<input type="checkbox"/>
9.	Read and sign the standard operating procedure (SOP) for the service in each pharmacy you intend to work at. <ul style="list-style-type: none"> • Ensure you know what role support staff will have in providing the service; • Review your working practices to ensure that the Flu Vaccination Service can be built into your routine work as well as continuing be able to offer other services; • Ensure you know whether an appointment system for the service will be used or whether the pharmacy allows 'walk ins'; and • Ensure relevant staff have read, understand and have signed up to the SOP. 	<input type="checkbox"/>
10.	Familiarise yourself with relevant service documents, for example: <ul style="list-style-type: none"> • anaphylaxis telephone card (display near the phone); • chaperone policy • needle stick injury procedure; and 	<input type="checkbox"/>

Preparing to provide the service		Completed
	<ul style="list-style-type: none"> guidance on infection control procedures, including use of appropriate PPE and hand hygiene guidance. 	
11.	Determine whether your regional NHS England team has made an IT system available to support record keeping and notification of GP practices of vaccinations undertaken. Ensure you have the required logon credentials for the system and are familiar with how to use it.	<input type="checkbox"/>
12.	Ensure you have any necessary equipment/supplies needed for provision of the service, for example: <ul style="list-style-type: none"> flu vaccines; a spill kit; an anaphylaxis pack (check the expiry of the adrenaline ampoules, syringes and needles); Any recommended PPE; and a clinical waste bin. 	<input type="checkbox"/>
13.	Reviewed the additional guidance in the vaccinating outside the consultation room & off-site support guides to ensure any additional considerations that contractors may need to take into account when using these flexibilities have been actioned.	<input type="checkbox"/>
14.	Sign up to PSNC's email newsletters to ensure you don't miss out on further information on the service as it becomes available.	<input type="checkbox"/>

Daily checks when providing the service		Completed
1	Ensure your consultation room or other area being used for vaccination is clean and tidy and clear of clutter and there are no trip hazards.	<input type="checkbox"/>
2	Check you have enough equipment/supplies needed for provision of the service.	<input type="checkbox"/>
3	Check the fridge temperature.	<input type="checkbox"/>
4	Ensure you have supplies of the relevant service paperwork.	<input type="checkbox"/>
5	Check your stock of vaccine is enough for likely demand.	<input type="checkbox"/>

Annex 2 - Patient eligibility to receive the flu vaccination service

Eligible groups	Further details
All people aged 50 years to 64 years not in a clinical at-risk group	Including those becoming age 50 years by 31 March 2023. This cohort will be eligible for vaccination from 15th October 2022 .
All people aged 65 years or over	Including those becoming age 65 years by 31st March 2023.
People aged from 18 years to less than 65 years of age with one or more serious medical condition(s) outlined below:	
Chronic (long term) respiratory disease, such as severe asthma, chronic obstructive pulmonary disease (COPD) or bronchitis	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).
Chronic heart disease, such as heart failure	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 at stage three, four or five	Chronic kidney disease at stage 3, 4 or 5, chronic kidney failure, nephrotic syndrome, kidney transplantation.
Chronic liver disease	Cirrhosis, biliary atresia, chronic hepatitis.
Chronic neurological disease, such as Parkinson's disease or motor neurone disease, or Learning disability	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 disabilities, multiple sclerosis and related or similar conditions; or hereditary and degenerative disease of the nervous system or muscles; or severe neurological disability.
Diabetes	Type 1 diabetes, type 2 diabetes requiring insulin or oral hypoglycaemic drugs, diet-controlled diabetes.
Immunosuppression, a weakened immune system due to disease (such as HIV/AIDS) or treatment (such as cancer treatment)	Immunosuppression due to disease or treatment, including patients undergoing chemotherapy leading to immunosuppression, bone marrow transplant, HIV infection at all stages, multiple myeloma or genetic disorders affecting the immune system (e.g. IRAK-4, NEMO, complement disorder). 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. 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 influenza and should be offered seasonal influenza vaccination. This decision is best made on an individual basis and left to the patient's clinician. Some immune-compromised patients may have a suboptimal immunological response to the vaccine.

Eligible groups	Further details
Splenic dysfunction or Asplenia	This also includes conditions such as homozygous sickle cell disease and coeliac syndrome that may lead to splenic dysfunction.
Morbid obesity (class III obesity)	Adults with a Body Mass Index $\geq 40 \text{ kg/m}^2$.
Pregnant women (including those women who become pregnant during the flu season)	Pregnant women aged 18 or over at any stage of pregnancy (first, second or third trimesters).
People living in long-stay residential care homes or other long-stay care facilities	People aged 18 or over 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.
Carers	People aged 18 or over 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.
Close contacts of immunocompromised individuals	People who are close contacts, aged 18 and over, 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.
Frontline health and social care workers	Health & social care staff, employed by a registered residential care/nursing home or registered domiciliary care provider, who are directly involved in the care of vulnerable patients/clients who are at increased risk from exposure to influenza. Vulnerable means those patients/clients in a clinical risk group for flu or who are aged 50 years and over.
Hospice workers	Health & social care staff, employed by a voluntary managed hospice provider, who are directly involved in the care of vulnerable patients/clients who are at increased risk from exposure to influenza.
Workers employed through Direct Payments and/or Personal Health Budgets to deliver domiciliary care	Health and social care workers employed through Direct Payments (personal budgets) and/or Personal Health Budgets, such as Personal Assistants, to deliver domiciliary care to patients and service users.