

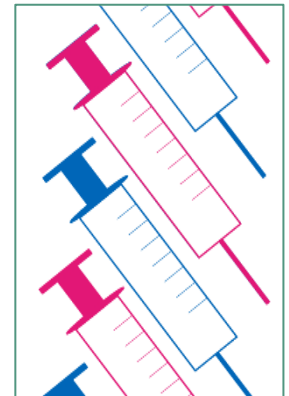
August 2021

PSNC Briefing 023/21: Guidance on the 2021/22 Seasonal Influenza Vaccination Advanced Service

This PSNC Briefing provides guidance for community pharmacy contractors and their teams on the 2021/22 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 2021/22

- Minor changes to the service spec to reflect the operational requirements of amendments to the Patient Group Direction (PGD) and development of a national protocol;
- Change from pharmacist only to the inclusion of other practitioners who are also able to use PGDs, e.g. nurses;
- Patient cohorts updated to reflect the content of the 2021/22 Annual Flu Plan; and
- Vaccines updated to reflect the content of the 2021/22 Annual Flu Plan.



Key next steps for contractors

- Familiarise yourself with the service specification, PGD, (national protocol, if it is made available and you choose to 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 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), Public Health England (PHE) and NHS England and NHS Improvement (NHSE&I) have set an even more ambitious plan for the flu vaccination programme in 2021/22. Preparations are underway to provide the biggest flu vaccination programme in English history with planning within

the NHS seeking to provide an expanded flu programme alongside a booster programme for COVID-19 vaccines as part of wider autumn and winter planning. The plan centres 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, such as mask-wearing, physical and social distancing, and restricted international travel, taken to protect the population in response to the COVID-19 pandemic.

As the population returns to pre-pandemic norms of social mixing and contact following the lifting of restrictions, the letter draws attention to how this could result in the 2021/22 winter having co-circulation of seasonal influenza virus (and other respiratory viruses) and COVID-19. With modelling suggesting the [influenza impact could be up to 50% larger](#) than that typically seen, it reinforces the message that the vaccination programme will be essential to reduce pressure on the health and social care system this winter. The programme has been expanded further this season, as was [announced by DHSC](#). As a result, more than 35 million people will be included in the eligibility criteria for the 2021-22 flu vaccination programme for England.

With PHE's [Infection Prevention and Control \(IPC\) guidance](#) remaining in place across all healthcare settings, contractors will need to continue the requirements of enhanced infection control when planning and providing the service. The negotiated changes that PSNC agreed as part of last season's provision of the service were enduring, so they will continue to support provision of the service in a COVID-safe way.

This document provides guidance for contractors and their teams on the service and highlights other resources which may support contractors to provide the service.

b) Background and aims of the service

This year is the seventh year the service has been commissioned and it has the potential to be challenging because of the continued impact of COVID-19 on our health and social care services. At the end of February 2021, NHS vaccination services had vaccinated a record 80.9% of those aged 65 years and over in England, exceeding the World Health Organization uptake ambition of 75%. The services also achieved the highest recorded vaccination levels for frontline healthcare workers, 2- and 3-year-olds, and at-risk groups. Building on last year's achievements and the successful roll-out of the COVID-19 vaccination programme, the Government wants to achieve an even greater ambition in the 2021/22 season. Their ambition is to achieve vaccination of:

- a minimum of 85% in those aged 65 years and older;
- a minimum of 75% uptake across the under 65 years clinical risk group, pregnant women and those aged 50 to 64 years; and
- at least 70% uptake in children.

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.

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 has been visible to all, and this coming winter we may be faced with co-circulation of COVID-19 and flu as well as the possibility of higher incidences of flu due to lower levels of population immunity. Those most at risk from flu are also most vulnerable to COVID-19, so, while the NHS has taken steps to prepare for the possibility of a [COVID-19 vaccine booster campaign](#) in the autumn or winter, flu vaccination is 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 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 2021 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 2022, 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.

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 2020. 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 NHS England 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 amendments to the Directions had not yet been published. DHSC will make these amendments to authorise the 2021/22 service prior to its commencement and PSNC will inform contractors when the amendment Directions have been signed and published.

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 PHE. NHSE&I 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 they mirror 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.

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 [NHSE&I 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 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;
- in the case of pharmacists, has/have completed the Vaccination Services Declaration of Competence (DoC) self-assessment framework and has/have printed and signed the statement of declaration; 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 new 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 has already been used by many pharmacies participating in the COVID-19 vaccination programme. NHSE&I have confirmed such a protocol may be available to be used to support the flu vaccination programme for the 2021/22 season; the decision on authorising use of a national protocol is made by the Secretary of State for Health and Social Care. At the time of publishing this Briefing, a protocol has yet to be published. If a 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 administer a licensed influenza vaccine. Any national protocol for vaccines will be developed by PHE 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 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 the relevant section 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; and

- 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;
- 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 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/have completed their appropriate Declaration of Competence (DoC) / self-assessment framework and has/have printed and signed the authorisation sheet; 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 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 [NHSE&I, PHE and the DHSC annual flu letter](#).

Practitioners 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) Practitioners 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;
 - practitioners undertaking vaccinations should be advised to consider being vaccinated against hepatitis B;
 - 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 off the pharmacy premises, 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 comply with the following requirements:
 - the consultations room is clearly designated as a room for confidential consultations;
 - it is distinct from the general public areas of the pharmacy premises; and
 - it is a room where both the person receiving the service and the practitioner who is to administer the vaccine are able to sit down together and talk at normal speaking volumes without being overheard by any other person (including pharmacy staff).

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 pre-registration trainee 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, however, wherever possible to comply with the IPC guidance, this should be avoided this season to reduce the potential risk of transmission of COVID-19.

Provision of the service in the consultation room is the traditional model of delivery, but because of the COVID-19 pandemic and the IPC guidance, contractors will need to think through several considerations

Additional guidance on matters contractors may need to consider due to COVID-19

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.

Where vaccinations are undertaken off the pharmacy premises, the pharmacy 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 practitioners providing the service in their pharmacy have the skills needed to do so.

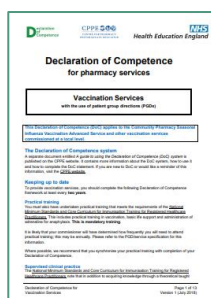
There are a number of organisations offering training and support for provision of flu vaccination services and contact details can be found on the [PSNC website](#).

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. NHSE&I has determined that pharmacists providing the service need to attend face-to-face training for both injection technique and basic life support training (including administration of adrenaline for anaphylaxis) at least **every three years**.

This requirement means a pharmacist who last undertook face-to-face training for both injection technique and basic life support in 2018 would need to undertake face-to-face training in 2021 to continue to provide the service.

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 2021/22 and any related matters, such as current guidance on infection control. 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 2021/22 for pharmacists](#)



The [Declaration of Competence](#) (DoC) approach has been agreed by NHSE&I and PSNC as being the way by which pharmacists providing the service must demonstrate their competence to the contractor who is contracted to provide the service and to NHSE&I.

The [Vaccination Services DoC](#), hosted on the Centre for Pharmacy Postgraduate Education (CPPE) website, must be completed by pharmacists who will be providing the Flu Vaccination Service. **Pharmacists providing the service should work through the DoC system every two years.**

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 2021/22 \(DHSC/NHSE&I/PHE\)](#) and authorised for use by the PGD (and national protocol, if published):

Product Name	Vaccine Type	Manufacturer
Quadrivalent Influenza vaccine	QIVe (standard egg-grown quadrivalent influenza vaccine), split virion, inactivated	Sanofi Pasteur vaccines
Quadrivalent Influvac sub-unit Tetra ▼	QIVe (standard egg-grown quadrivalent influenza vaccine), supplied as surface antigen, inactivated	Viartis (formerly Mylan)
Flucelvax® Tetra ▼	QIVc (cell-grown quadrivalent influenza vaccine), supplied as surface antigen, inactivated, prepared in cell cultures	Seqirus UK Ltd
Supemtek ▼	QIVr ((prepared in cell culture) quadrivalent Influenza vaccine) recombinant	Sanofi Pasteur vaccines
Fluad Tetra ▼	aQIV (egg-grown quadrivalent influenza vaccine), supplied as surface antigen, inactivated, adjuvanted with MF59C.1	Seqirus UK Ltd

The PGD (and national protocol, if published) does not cover the use of the Fluenz Tetra nasal spray listed in the national flu immunisation programme 2021/22.

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 two letters from NHSE&I on 4th February 2021 and on 1st April 2021, the following recommended vaccines should be used for their respective adult patient groups:

Eligible group	Type of influenza vaccine
Aged 18 to 64 (including at risk, pregnant women, and the 50 to 64-year old cohort)	Offer: <ul style="list-style-type: none"> • QIVc (Flucelvax® Tetra ▼) or • QIVr, (Supemtek ▼) Or QIVe (if QIVc or QIVr are not available).
Aged 65 years and over*	Offer aQIV (Fluad Tetra ▼). Or offer QIVc or QIVr if aQIV is not available.** It is recommended that aQIV is offered 'off-label' to 64-year-olds turning 65 years of age before 31 March 2022.

* The Joint Committee on Vaccination and Immunisation (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, compared with standard dose egg-culture inactivated trivalent and quadrivalent vaccines. 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.

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 [Guidance on Consent](#) provides information on consent for pharmacists and their teams.

Prior to vaccination, consent must be sought from each patient. This consent should cover the administration of the vaccine as well as advising the patient of information sharing that will take place for the appropriate recording of the vaccination in their GP practice record. The patient should also be informed that information relating to their vaccination will be shared with NHSE&I and the NHS Business Services Authority (NHSBSA) as part of post-payment verification (PPV). 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 the current [COVID-19: infection prevention control guidance](#) to ensure their services are as COVID secure as possible. The guidance states that in some clinical settings, such as vaccination/injection clinics, where contact with individuals is minimal, the need for single use PPE items for each encounter, for example, gloves and aprons is not necessary. **Staff administering vaccinations/injections must apply hand hygiene between patients and wear a sessional Type IIR mask.**

In the latest guidance, gloves and aprons are only recommended when there is (anticipated) exposure to blood/body fluids or non-intact skin.

[The full PHE guidance can be accessed here](#) (on pages 14-17)

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.

Occupational health

Contractors must ensure that practitioners involved in the provision of vaccinations for this service are advised that they should consider being vaccinated against Hepatitis B and be advised of the risks should they decide not to be vaccinated.

Service records and IT support for the service

In many areas regional NHSE&I 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 E 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. 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 should 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:

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

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

- d. any adverse reaction to the vaccination and action taken/recommended to manage the adverse reaction; and
- e. 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 NHSE&I

Payment claims for the service will be made to the NHSBSA (see section I for further details) and they will subsequently share data on service provision with NHSE&I. 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 NHSE&I and NHSBSA for the purpose of PPV.

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 their NHS website profile to reflect that the service is not available from the pharmacy as soon as possible.

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 or their community pharmacy Primary Care Network (PCN) lead to understand whether conversations are happening within their PCN to support a more joined up approach to integrating the pharmacy service into local planning and messaging.

l) Payments and the process for claiming payments

In 2021/22, contractors will be paid £9.58 for each vaccine administered; this fee is funded from NHS vaccination budgets, not from the CPCF global sum. Contractors will also be reimbursed for the vaccine cost at the basic price (list price) of the individual vaccine administered and an allowance at the applicable VAT rate will also be paid.

Claims for payment for the service must be made electronically on a monthly basis, using the NHSBSA [Manage your Service \(MYS\) application](#). Claims will be accepted by NHSBSA within six months of administration of the vaccination or by 31st August 2022, whichever date is earlier, in accordance with the usual Drug Tariff claims process. Later claims will not be processed. Payments to contractors will be made monthly as part of their normal payment schedule.

In addition to the service fees and reimbursement for vaccine costs, contractors providing off-site flu vaccinations may be able to claim a contribution towards reasonable additional costs which may include the cost associated with the hire of a venue and cold storage.

At the time of publishing this Briefing, details of how to apply for such funding have yet to be published by NHSE&I, but they are expected to mirror arrangements that were in place for the 2020/21 flu season. An announcement on this and the process to make claims will be provided to contractors when they are confirmed via the usual channels.

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.

Additional guidance on matters contractors may need to consider if they intend to use this flexibility

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 NHSE&I 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, 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.

Additional guidance on matters contractors may need to consider if they intend to use this flexibility

NHSE&I requires that practitioners providing flu vaccinations in a patient's own home or a care home have a valid Disclosure and Barring Service (DBS) certificate in place.

Care homes

Contractors can continue to offer to vaccinate patients over 18 years of age 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 as confirmed in the recent [flu letter](#).

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 as is the case for provision in the pharmacy, 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. See section k for further details.

Additional guidance on matters contractors may need to consider if they intend to use this flexibility

Additional points for all off-site provision

Support

Pharmacists should consider being accompanied by a trained pharmacy support staff member when providing flu vaccinations off-site. The primary role of the support staff member is to assist in the event of an emergency, but they could also undertake administrative tasks and, where necessary, act as a chaperone.

Clinical Waste

Contractors must ensure they meet the requirements of the Waste (England and Wales) (Amendment) Regulations 2012 in terms of transferring pharmaceutical waste from the site of vaccination back to the pharmacy premises for subsequent safe disposal.

Maintaining the cold chain

Practitioners must ensure that the cold chain storage of the vaccines is maintained. Vaccines should be taken from the pharmacy fridge and placed into an appropriate validated cool box (which will maintain the vaccines at a temperature between 2°C and 8°C) just before travel to the off-site location.

The vaccines should be kept in their packaging and should be insulated from the cooling system within the cool box, e.g. using bubble wrap, to avoid the risk of freezing. Any unused vaccines should be returned to the pharmacy fridge within eight hours of first removal.

Professional Standards

When considering any provision of flu vaccination services outside the pharmacy, contractors and their pharmacists are reminded that all the usual [professional standards](#) apply in whatever setting the service is provided. Any planning or risk assessments need to keep these standards central to considerations of how to provide the service, as they will offer a useful framework to help decision making.

n) Discontinuation of service provision

If the pharmacy temporarily or permanently ceases to provide the service, they should update their NHS website profile 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 [General Pharmaceutical Council](#) 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 who will be providing the service.

NHSE&I documents

[Flu Vaccination Advanced service specification](#)

[The national Patient Group Direction](#)

PHE guidance / briefing documents

[National flu immunisation programme plan 2021/2022](#)

[Public Health England flu programme website hub page](#)

[Ovalbumin content of flu vaccines for the 2021/22 season](#)

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

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

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.	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/flutraining . This must be done at least every three years .	<input type="checkbox"/>
3.	Read the service specification .	<input type="checkbox"/>
4.	Read the national Patient Group Direction (PGD) (and the national protocol, if issued and you decide 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.	Pharmacists should complete or check their Declaration of Competence (DoC) . The DoC process must be completed every two years . If this is the first year you are providing the service, or it is two years since you completed your DoC, you must complete the DoC before providing the service. If you are unfamiliar with the DoC process, download and read <i>A guide to using the Declaration of Competence (DoC) system</i> , which is available at cppe.ac.uk/doc . PSNC also has a guide that can further assist in the process - Completing your CPPE Vaccination DoC .	<input type="checkbox"/>
8.	Vaccinators should consider getting vaccinated against hepatitis B if they haven't previously had the vaccination. PHE'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 to 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 <p>Ensure relevant staff have read, understand and have signed up to the SOP.</p>	<input type="checkbox"/>

Preparing to provide the service		Completed
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 • guidance on infection control procedures, including use of appropriate PPE and hand hygiene guidance. 	<input type="checkbox"/>
11.	Determine whether your regional NHSE&I 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); • Required PPE; • Cleaning products to support cleaning of the consultation room or consultation area between patients; and • a clinical waste bin. 	<input type="checkbox"/>
13.	Review the appropriate considerations in the Additional guidance to ensure any additional actions in response to provision during the COVID-19 pandemic have been reviewed and actioned as appropriate.	<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 or over	Including those becoming age 50 years by 31 March 2022.
People aged from 18 years to less than 50 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	<p>Asthma that requires continuous or repeated use of inhaled or systemic steroids or with previous exacerbations requiring hospital admission.</p> <p>Chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema; bronchiectasis, cystic fibrosis, interstitial lung fibrosis, pneumoconiosis and bronchopulmonary dysplasia (BPD).</p>
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	<p>Stroke, transient ischaemic attack (TIA). Conditions in which respiratory function may be compromised due to neurological disease (e.g. polio syndrome sufferers).</p> <p>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.</p>
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)	<p>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).</p> <p>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.</p> <p>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.</p> <p>Some immune-compromised patients may have a suboptimal immunological response to the vaccine.</p>
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.