



2020/21 Service Specification

Community pharmacy seasonal influenza vaccination pilot service for:

- Patients over 65 years of age
- Patients aged 18-64 years in At Risk Groups
 - Unpaid Carers aged over 18 years
 - Pregnant women

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Key steps for contractors:

- Ensure you have read and understood the content of this service specification
- Ensure your standard operating procedure (SOP) is up to date and accurately describes your service model
- Ensure training of all pharmacists providing vaccinations on behalf of the pharmacy is up to date, and that support staff are aware of the service and eligible cohorts as per CMO letter for 20/21 flu season. (This will be added as Appendix F to the final SLA)
- Ensure that all pharmacists providing vaccinations on behalf of the pharmacy have signed and submitted copies of the NHS Lothian Patient Group Direction (PGD) to Primary Care Contracts Organisation (PCCO)
- Ensure you are aware of arrangements for supply and storage of vaccines including cold chain maintenance requirements
- Ensure you are familiar with the NEO recording system which will be used for recording patient consent, patient details and vaccination details
- Ensure stocks of consent forms and any other relevant paperwork that is not being completed electronically.

1. Service description and background

- 1.1 For most healthy people, influenza (flu) is an unpleasant but usually self-limiting disease. However, those with underlying diseases are at particular risk of severe illness if they catch it.
- 1.2 Flu is a key factor in NHS resilience. It impacts on those who become ill, the NHS services that provide direct care as a result, and on the wider health and social care system. The annual immunisation programme helps to reduce unplanned hospital admissions and pressure on A&E. It is therefore a critical element of the system-wide approach for delivering robust and resilient health and care services during winter.
- 1.3 This pilot service will operate in Community Pharmacies within NHS Lothian which have signed up to participate. Accredited pharmacists will administer influenza vaccine to eligible patients as a free NHS service under a PGD.
- 1.4 During the seasonal flu vaccination campaign period, pharmacy staff will identify people eligible for flu vaccination and encourage them to be vaccinated if they have not already been vaccinated in this flu season. This pilot service covers the following eligible patients:
 - all patients over 65 years of age
 - patients aged over 18 and under 65 who are specified as being at risk by the Scottish Government Chief Medical Officer's (CMO) letter
 - any additional cohorts identified in CMO letter
 - unpaid carers as outlined in the PGD
 - pregnant women(Healthcare workers and patients in residential care homes are not eligible)
- 1.5 The pilot community pharmacy seasonal flu immunisation service will run from 28th September 2020 to 31st March 2021. Focus should be given to vaccinating eligible patients between 28th September and 31st January 2021 in order to maximise the impact.
- 1.6 The vaccination is to be administered to eligible patients, who do not have any contraindications to vaccination, under the NHS Lothian patient group direction (PGD) which will be published on the NHS Lothian Intranet site and Lothian Community Pharmacy internet site (link will follow when website is live).
- 1.7 This service will operate as a pilot and will be available for all community pharmacies across NHS Lothian to sign up to.
- 1.8 This is a pilot being developed and evaluated as part of the Vaccine Transformation Programme (VTP) supporting delivery of the new GP contract by 2022.

2. Aims and intended service outcomes

2.1 The aims of this service are:

- a. to sustain and maximise uptake of flu vaccine in eligible groups by delivering the service from community pharmacies
- b. to provide more opportunities and improve convenience for eligible patients to access free NHS flu vaccinations
- c. to establish that community pharmacy should be considered as an option for future vaccination programmes

3. Service specification

- 3.1 The pharmacy contractor is required to offer eligible patients the opportunity of receiving a flu vaccination at the pharmacy. The contractor will receive a payment per eligible vaccination delivered from NHS Lothian. The vaccine is to be administered by an appropriately trained pharmacist under the authority of the NHS Lothian PGD.
- 3.2 **The service is effective from 28th September 2020 and runs to 31st March 2021.** Eligible patients should be vaccinated as early as possible after the vaccine becomes available. Widespread immunisation may continue until January in order to achieve maximum impact, but where possible, 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 2021. 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.
- 3.3 The patient groups eligible for seasonal flu vaccination under this service are:
- Those aged over 65 years
 - Those aged over 18 years but under 65 years in the At Risk categories as defined in the CMO letter (Appendix will be added once letter is published)
 - Additional cohorts identified in CMO letter
 - Pregnant women
 - Unpaid carers over the age of 18
- Healthcare workers and those in residential care homes are not eligible under this pilot. Contraindications to the vaccine are listed in the PGD and in the Summary of Product Characteristics (SPC) for each specific vaccine.
- 3.4 The seasonal flu vaccination to be administered under this service will be updated when determined by National Procurement (NP) as indicated by the Scottish Government seasonal influenza vaccination programme 2020-21.
- 3.5 Pharmacy 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.
- 3.6 The pharmacy contractor must have a standard operating procedure (SOP) in place for this service, which includes procedures to ensure cold chain integrity. All vaccines are to be stored in accordance with the manufacturer's instructions and all refrigerators in which vaccines are stored are required to have a maximum / minimum thermometer. Readings are to be taken and recorded from the thermometer on all working days. The NHS Lothian Guidance for Vaccine Storage and Handling must be followed ([Available Here](#)). The vaccines should not be used after the expiry date shown on the product.
- 3.7 Facilities must be available to ensure appropriate hygiene levels are maintained throughout service delivery including the use of recommended PPE. Details of recommended PPE will follow when national guidance is available.

- 3.8 Each patient being administered a vaccine should be given a copy of the manufacturer's patient information leaflet about the vaccine. Patients who are eligible for other vaccinations should be referred to their GP practice for these vaccinations, for example, pneumococcal vaccine.
- 3.9 Each patient will be required to confirm consent before being administered the vaccine. Pharmacy contractors must use the consent statements set out in the NEO module to obtain the patient's consent. The consent covers the administration of the vaccine and sharing the patient's details with the GP Practice and NHS Lothian. This notifies the patient of the information flows that may take place as necessary for the appropriate recording in the patient's GP practice record and for the purpose of post payment verification by NHS Lothian.
- 3.10 Consent forms should be retained for an appropriate period of time, but for the purposes of post-payment verification, the forms should be kept for a minimum of three years after the vaccination takes place. As pharmacy contractors are the data controller, it is for each contractor to determine what the appropriate length of time is, beyond three years. Decisions on this matter must be documented and should be in line with national and local policies. The NHS Lothian 'Records Policy incorporating Destruction and Retention of Records Procedure is [Available Here](#)
- 3.11 Where consent forms are scanned into a third-party data transfer software solution, care must be taken to ensure that the scanned copy is of a good quality and is a true copy of the original.
- 3.12 The information contained in the NEO consent statements may be shared on request with NHS Lothian PCCO for the purpose of post payment verification.
- 3.13 If the electronic transfer of information through the NEO system is not available, the pharmacy contractor will ensure that a notification of vaccination is sent to the patient's GP practice as soon as possible following the vaccination (Appendix C). This must reach the patient's GP within one week of vaccination. This information can be sent via post, delivered by hand or via a secure e-mail.
- 3.14 The pharmacy contractor must maintain appropriate records to ensure effective ongoing service delivery and post payment verification. Section 7 details the required records that must be kept as part of provision of the service.
- 3.15 Where a patient presents with an adverse drug reaction 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 either via the GP Notification Form (Appendix C) or by contacting the practice directly. Adverse events should be reported to the Commission on Human Medicines via the yellow card scheme.
- 3.16 Contractors are required to record and report any patient safety incidents. Any incidents should be reported to cpflu@nhslothian.scot.nhs.uk
- 3.17 Contractors are required to comply with arrangements that will be in place for the removal and safe disposal of any clinical waste generated in the provision of this service.
- 3.18 Any questions or comments regarding any aspect of the service from contractors

can be sent to cpflu@nhslothian.scot.nhs.uk .Any patient comments/ complaints should be directed to the Patient Experience Team email: feedback@nhslothian.scot.nhs.uk

4. Training and premises requirements

- 4.1 In order to provide the service, pharmacies must have a consultation room. The consultation room, which will be used to undertake vaccinations, must comply with the minimum requirements set out below:
- the consultation room must be clearly designated as an area for confidential consultations
 - it must be distinct from the general public areas of the pharmacy premises
 - it must be a room where both the person receiving services and the pharmacist providing those services are able to sit down together and talk at normal speaking volumes without being overheard by any other person (including pharmacy staff), other than a person whose presence the patient requests or consents to (such as a carer or chaperone).
- 4.2 The consultation room must also meet the General Pharmaceutical Council (GPhC) Standards for Registered Premises.
- 4.3 Vaccinations under this pilot service will be carried out on the pharmacy premises.
- 4.4 Contractors must ensure that Pharmacists providing the service are competent to do so. Pharmacists must be able to demonstrate to the contractor that they have the necessary knowledge, skills and competencies to provide the service. Undertaking this service whilst not meeting the necessary competencies may constitute or be treated as a Fitness to Practice issue. Contractors must be familiar with the competencies required by Pharmacists that they employ/engage to deliver the service on their premises.
- 4.5 All pharmacists delivering flu vaccination must undertake immunisation training including anaphylaxis management. The contractor must ensure that Pharmacists providing the service are aware of the National Minimum Standards ([available here](#)) in relation to vaccination training and are compliant with the training requirements within those Standards that apply to Pharmacists providing the service, as set out in the vaccination services Declaration of Competence. Pharmacists providing the service should undertake face-to-face training for injection technique and basic life support (including administration of adrenaline for anaphylaxis). Pharmacists due to undertake face to face training in 2020 can postpone this until 2021 under the current circumstances. The training must be delivered by a recognised private immunisation training organisation. Adrenaline injection for the management of anaphylaxis must be available.
- 4.6 Pharmacists providing this service should also be familiar with the Promoting Effective Immunisation Training available on TURAS Learn available [here](#)
- 4.7 The NHS Lothian Vaccine Storage and Handling Guidance must be followed. If a vaccine or cold chain incident occurs, the Health Protection Scotland Vaccine Incident Guidance should be followed [vaccine-incident-guidance-actions-to-take-in-response-to-vaccine-errors](#).

- 4.8 The pharmacy contractor should ensure that they have reviewed the Service Specification and other associated documents
- 4.9 The pharmacy contractor must 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.
- 4.10 The pharmacy contractor must ensure that staff involved in the provision of 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.
- 4.11 Vaccine waste **from the pilot** should be placed in NHS Lothian provided sharps boxes for uplift by NHS Lothian.
- 4.12 A service checklist is available at Appendix B

5. Stock Ordering Process

- 5.1 Stock will be provided from National Procurement and distributed by Movianto.
- 5.2 Order processes are being finalised and will be communicated as Appendix E as soon as available.

6. Service availability

- 6.1 The pharmacy contractor should seek to ensure that the service is available throughout the pharmacy's contracted opening hours as far as possible.
- 6.2 The pharmacy contractor should ensure that locums or relief pharmacists are adequately trained, to ensure continuity of service provision across the opening hours of the pharmacy as far as possible.
- 6.3 If the pharmacy cannot offer the service at any given time the pharmacy staff should signpost patients appropriately to either a different time/ date to re-present or to an alternative participating nearby contractor.
- 6.4 The pharmacy contractor must ensure the service is accessible, appropriate and sensitive to the needs of all service users. No eligible patient shall 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.
- 6.5 Off-site provision of this vaccination service is out with the scope of this pilot.

7. Data collection and reporting requirements

- 7.1 The pharmacy contractor must maintain appropriate records to ensure effective ongoing service delivery.
- 7.2 Where record forms are scanned either into a patient's notes or into a third-party data transfer software solution, care must be taken to ensure that the scanned copy is of a good quality and is a true copy of the original.

8. Payment arrangements

- 8.1 Prior to provision of the service, the pharmacy contractor must ensure that both their premises and all pharmacists administering NHS flu vaccinations meet the requirements outlined in this service specification.
- 8.2 Claims for payments for this service will be submitted electronically via the NEO system. This will generate payment automatically and no paper claims are required. There is a claim form in Appendix D should NEO become unavailable for any reason.
- 8.3 Payment will be a minimum of £7.67 per administered dose of vaccine or at the same level as any nationally agreed uplift. The vaccine used is expected to be that recommended by NHS Scotland. Additional costs related to use of alternative vaccines will not be paid. Supplies of vaccine are accessed as per national procurement arrangements.
- 8.4 Payments will be made on a quarterly basis. Claims made for vaccinations given in October, November or December will be paid in January 2021. Claims made for vaccinations given in January February or March will be paid in April 2021.
- 8.5 Claims for pharmacy contractor to be reimbursed or remunerated, under this pilot service, for vaccines administered to patients outside of the eligibility criteria set out will not be paid.

Appendix A: Service Agreement Form

Service Agreement Community Pharmacy Seasonal Influenza Vaccination Pilot

| | | |
|----------------------------|-----------|-----------------------|
| NHS Lothian Representative | Signature | Name (Block Capitals) |
|----------------------------|-----------|-----------------------|

I have read and understood the Flu Pilot 2020/21 Service Specification and agree to provide the service in accordance with the terms set out

| | | |
|---------------------------|-----------|-----------------------|
| Contractor Representative | Signature | Name (block capitals) |
| Trading name of pharmacy | | |
| Contractor Code | | |
| Date | | |

Return by e-mail (using contractor generic mailbox) to:

CommunityPharmacy.Contract@nhslothian.scot.nhs.uk

or

Return by post to:

Community Pharmacy Contracts Support Officer,
Primary Care Contracts Organisation
NHS Lothian,
2nd Floor
Waverley Gate
2-4 Waterloo Place
EDINBURGH
EH1 3EG

Appendix B: Community Pharmacy Checklist

Pharmacy Checklist

- Pharmacist
 - competent to deliver immunisation
 - has read and signed the PGD(s)
 - has completed immunisation training
 - has had required training in CPR and anaphylaxis
 - has appropriate occupational immunisations
 - is competent with standard hand hygiene procedures
 - has read the SPC for the product

- Product
 - Product is fit for use
 - Recommended flu vaccines available

- Resources
 - Copies of the PGD(s) are available
 - Copies of standard reference texts are available
 - A telephone is available
 - PPE is available
 - Vaccine supplies and sharps bins are available
 - Standard operating procedures for cold chain/ fridge monitoring and vaccine incident management
 - Adrenaline / Epinephrine is available

- Premises
 - A private clinical area is available
 - A pharmaceutical grade refrigerator is used to store vaccine
 - Hand cleaning facilities are available
 - The cleanliness of the clinical area is maintained
 - Appropriate PPE is available

Appendix C: NHS Community Pharmacy Seasonal influenza Vaccination Service - Notification of administration of flu vaccination to Patient's GP practice and consent (only required if NEO not available)

Details can be completed by patient requesting influenza vaccine or by pharmacy staff

| | |
|---------------------------|--|
| GP Practice | |
| Patient Name | |
| Patient DOB | |
| Patient CHI Number | |

Consent to participate in the NHS Lothian Community Pharmacy Seasonal Influenza Vaccination Pilot.

I agree to being given a flu vaccination by a trained pharmacist. I confirm I have not already had a flu vaccination for this flu season and am eligible to receive an NHS flu vaccination.

| | |
|---------------------|--|
| Patient's signature | |
| Date | |

We will send your name, address and information about your flu vaccination to your GP practice so they can update your health record.

To GP Practice: Please update your records for this patient using the read code below.

| | | |
|------------------|--------------|---|
| Read code | 65ED0 | Seasonal influenza vaccination given by pharmacist |
|------------------|--------------|---|

We may send this completed form to NHS Lothian if they need to check our payments for providing this service. If they need to, this will allow them to contact you to check that we gave you the flu vaccination.

If you have any queries about how we process your personal data or would like to exercise your rights under data protections legislation please speak to a member of staff.

FOR PHARMACY USE ONLY

| | |
|-------------------------------|--|
| Name of vaccine | |
| Date of administration | |
| Batch number | |
| Expiry Date | |
| Pharmacist Name | |
| Pharmacist Signature | |

Appendix D: Flu Vaccination Service Pilot Claim Form (only to be used if NEO not available)



NHS Lothian COMMUNITY PHARMACY CLAIM FORM PILOT INFLUENZA IMMUNISATION SERVICE

| | |
|-------------------------|---|
| Contractor Code: | <input style="width: 30px; height: 30px; border: 1px solid black;" type="text"/> <input style="width: 30px; height: 30px; border: 1px solid black;" type="text"/> <input style="width: 30px; height: 30px; border: 1px solid black;" type="text"/> <input style="width: 30px; height: 30px; border: 1px solid black;" type="text"/> |
|-------------------------|---|

| | |
|--|---|
| Section A – Immunisations administered for the month of | <input style="width: 150px; height: 25px; border: 1px solid black;" type="text"/> |
| Number of claims submitted for Influenza vaccination | |
| | TOTAL <input style="width: 50px; height: 25px; border: 2px solid black;" type="text"/> |
| Completed client consent forms may be requested for the purpose of payment verification. | |

| |
|--|
| Payment Fee applicable £7.67 per immunisation (or as per any national uplift) |
| Claims should be submitted by the 1st^h of the month to: <i>PCCO, Waverley Gate, 2-4 Waterloo Place Edinburgh EH13EG</i> |
| <i>Report details of any patient safety incidents here:</i> |

| | |
|---|-----------------------|
| I declare that the information I have given on this form is correct and complete and I understand that if it is not, action may be taken against me. I acknowledge that my claim will be authenticated from appropriate records, and that payment will be made to my Pharmacy, which will be subject to Payment Verification. Where Primary Care Contracting Organisation is unable to obtain authentication, I acknowledge that the onus is on me to provide documentary evidence to support this claim. | |
| Signed by | Pharmacy Stamp |
| Date | |

| | |
|---|---|
| FOR OFFICE USE ONLY | |
| Received by Vaccine Transformation Programme Team | |
| Passed for payment: | <input style="width: 150px; height: 50px; border: 1px solid black;" type="text"/> |
| Signed | Date |