Covid-19
Autumn Booster Programme

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Supported by NW LPCs

NHS England

Agenda

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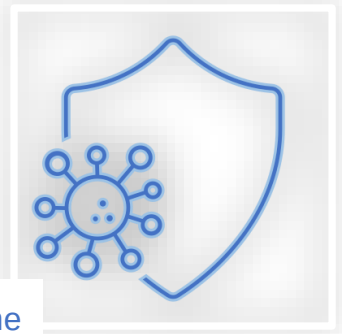
- Welcome and Introductions
  Housekeeping
  Programme Overview
  Making your Service a success

Programme Overview



Covid-19 Autumn 2022 Booster Programme

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"In the year ahead, winter will remain the season when the threat from COVID-19 is greatest both for individuals and for health communities."

2022 autumn booster programme is for:

- **Residents in a care home**
- **Frontline health and social care workers**
- **All adults aged 50 years and over**
- **Persons aged 5 to 49 years in a clinical risk group**, as set out in the Green Book (chapter 14a, tables 3 and 4)
- **Persons aged 5 to 49 years in household contacts of people with immunosuppression**
- **Persons aged 16 to 49 years who are carers**, as set out in the Green Book (chapter 14a, table 3)

Campaign Aims

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Have a Strong Start

- ✓ Robust regional site capacity and preparedness
- ✓ Agreement on invitation cadence
- ✓ Advice regarding which vaccines to use provided by JCVI here
- ✓ NBS open for booking from w/c 5th Sept for vaccinations post 12th Sept
- ✓ Provide sites with visibility of the first four weeks of vaccine delivery

Smart Sequencing

- ✓ Begin the programme w/c 5th September, with visits to care homes and housebound
- ✓ Commence vaccination of wider cohorts from w/c 12th September in a number of regionally agreed sites
- ✓ All sites to be actively vaccinating at full operational capacity w/c 19th Sept
- ✓ Over 65s, pregnant women and carers from 12th Sept

Co-admin of Flu and Covid vaccines

- ✓ Co-promote and co-administer vaccinations where possible to improve patient experience and uptake
- ✓ Deliver opportunistically in a permissive way whenever we can

Outcomes

- ✓ Regions/systems and sites to maximise uptake amongst eligible populations with focus on underserved communities
- ✓ Co-administration opportunities maximised
- ✓ Equality of vaccine availability
- ✓ Flexibility for ICSs to go at their own pace

Covid and flu co-administration

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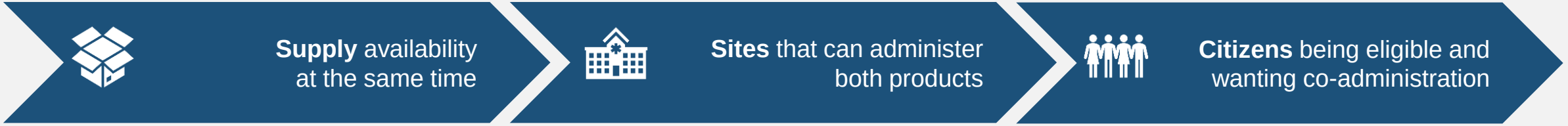
Increasing levels of co-administration provide a better patient experience whilst reducing the workload on the NHS during the peak winter season. Opening of Covid cohorts has been changed to align with Flu programme to allow greater operational flexibility to align programmes and allow maximising of co-administration opportunity.

To achieve co-administration, we need:



To support this we are:

- continuing contracting arrangements for GPs and CPs to enable providers participating in both services to co-administer – these are underpinned for general practice through the collaboration arrangements set out in the enhanced service specifications for flu and COVID-19
- continuation (until March 2024) of MHRA Regulation 19(4A) which allows for the movement of flu and COVID-19 vaccines without a wholesaler's dealer licence
- ensuring that the relevant PGDs and National Protocol are in place to enable flu to be delivered in VCs, and for unregistered vaccinators to deliver flu.

1. Systems to maximise opportunities to co-promote and co-administer Flu and Covid vaccinations although this is not mandated by JCVI, DHSC or NHSE.
2. Providers to actively co-promote and co-administer Flu and Covid vaccinations where clinically and operationally feasible, but this should not unduly delay administration of either jab.
3. GP Practices to work collaboratively within their Covid PCN Collaborative Groupings to maximise operational opportunity for co-administration of Covid and Flu.
4. Flu supply will continue to be procured directly by providers as per existing local arrangements.
5. Flu and Covid co-administration will remain opportunistic and tactical for the 22/23 season; providers will do their best where clinically and operationally feasible.
6. Providers to Make Every Contact Count and actively refer citizens to additional health interventions / vaccinations where these can not be clinically or operationally co-delivered with the Autumn Flu/Covid campaign.

Key Clinical Information

Staff must be made aware of and follow requirements related to legal mechanisms, consent, cohort eligibility, equipment, safety and infection control.

Date Action Due	Action	Where Sites Can Find Guidance on This
5th September	Staff to be made aware of and to follow (updated) requirements of the legal mechanisms for administration (NP/PGD/PSD).	New Published legal mechanism documents can be found here New National Protocol for Spikevax Bilvalent can be found here New National PGD for Spikevax Bivalent can be found here
5th September	Appropriate senior lead at site to understand what Emergency Equipment is required.	Resus kit checks have been reviewed and are in date Check list of recommended equipment Link
5th September	Staff to be made aware of their obligations in gaining consent.	Chapter 2 Green Book Link Children's A, B and C checklist Link Mental Capacity Act NHS England, Safeguarding Team, London Region have produced a flow chart which can be utilised and shared with colleagues (link) Additional information can be found in the following links Consent brief final can be found here Making decision for someone else (MCA) can be found here
5th September	Staff to understand cohort eligibility (including **dosing schedule**).	New Cohort eligibility document Link
5th September	Safety protocols to be used on site.	New Clinical Incident SOP Link Safety Huddle Checklist Link
5th September	Infection Prevention and Control guidance to inform practice at site.	Link to National IPC here and IPC assurance checklist here
5th September	Appropriate site lead to familiarise themselves with standard operating procedures.	Link to Specialised Pharmacy Services
5th September	Site leads to ensure they have ordered sufficient stock of UKHSA Autumn Booster products including patient information leaflet, a record card, Autumn Booster stickers and What to expect after your Covid-19 vaccination leaflet. Materials are available in a number of different languages and assessable formats.	New patient information leaflet New record card New Autumn Booster stickers New what to expect after your COVID-19 vaccination leaflet
5th September	For information: Confirmation that the 15min wait is suspended for those without identified risk of severe allergy or anaphylaxis to the vaccine	New MHRA link Chapter 14a, p42 Green Book Link

The clinical bulletin will provide updates to any key questions, colleagues are encouraged to review on a weekly basis link

Spikevax Bivalent – key characteristics

The initial supply of Spikevax Bivalent Original/Omicron, will have a different name on the carton - Spikevax Zero/Omicron (note the word 'Bivalent' is not included) and will also have slightly different carton and vial label artwork to the licensed product that will follow in later deliveries.

To ensure continuity in supply, the MHRA has agreed for these batches to be supplied to market via a Batch Specific Variation and therefore they are approved to be used as licensed product.

The leaflet supplied with the batches is approved, therefore please ensure that this Spikevax bivalent Patient Information Leaflet (PIL) is provided to vaccine recipients.

Please refer to published guidance covering regulatory approval of Spikevax Bivalent

Summary of Product Characteristics Spikevax bivalent Original/Omicron

Patient Information Leaflet Spikevax bivalent Original/Omicron

Copies of the Patient Information Leaflet (PIL) and Summary of Product Characteristics (SmPC) are also available by scanning the QR code on the carton.

Making your service a success

NHS England

Summary of Key Roles & Responsibilities

NHSE Team

- Stock ordering
- Mutual aid
- Stock-take & reporting
- SVOC
- Site support
- Service reviews
- Evergreen offer
- Phase 5 Autumn Booster: Moderna Bivalent & Pfizer Bivalent

Clinical Supervisor

- Before staff start their shift – Huddle
- Confirm sufficient trained staff to cover all required roles
- Review of Resus kit, vaccine and other equipment
- Ensure vaccination space is clear
- Ensure treatment areas for faints and resus are clear
- Ensure all staff are clear about their roles and who they report to,
- Observations during the shift and at the end of each shift

Contract Holder

- Ensure SOPs, PGDs, Protocols and other documentation is in place
- Ensure sufficient trained staff to cover all required roles for a all shifts
- Site suitable for all areas
- Ensure all training is complete and up to date
- Comprehensive lists of staff and their roles
- Be able to provide assurance regarding site process to NHSE
- Ensure clinical consent is recorded
- Suitable storage of vaccines and equipment – pharmaceutical grade fridge
- PGD vs SOPs
- Process for managing patient traffic and safety at the site

Premises – Inside & outside your site

Outside your site:

- How will patients access your site
  - On foot
  - By car (is sufficient parking available locally)
  - Public transport
  - How will you manage queues outside the site – will you need marshals
  - Clear signage
  - Manage trip hazards and ensure safe access to the site

Inside your site:

- Have you got sufficient refrigerator capacity to store the vaccines, including sufficient space to store and separate up to three separate vaccine types
- Will you be able to ensure cold chain integrity and maintain the storage requirements for the vaccine, including the receipt of deliveries
- Where will you store equipment and waste
- Where will you prepare vaccines

Resource, planning & staffing

Planning and Rotas

- Plan ahead to ensure workforce, equipment, consumables booking systems and vaccine supply are in place to deliver
- Consider the pace at which vaccinations can be safely carried out
- Consider patient flow through your site
- Allow for the differences between a consenting vaccinator vs non-registrant vaccinator
- Regularly review available, staff vaccine, kit and equipment
- Managing unplanned closures
- Managing capacity and demand

Training and Staff

- Staffing levels, training and roles/responsibilities assigned (clinical supervisor, site supervisor, marshals (including car park, vaccinators, reception staff, observation stewards – do all staff understand roles/responsibilities and escalation points
- Maintaining adequate pharmaceutical provision (whether or not on Pharmacy premises)
- Marshalls to direct patients prior to entry
    - Managing queues and footfall
    - Social distancing
    - Patient flows (entry and exit)

Resource, planning & staffing

Role of the Clinical Supervisor

- Is the clinical supervisor visible and apparent? Do they have oversight or are they occupied elsewhere
- Ensure the area where vaccines are held while thawing or reconstituted is kept clean & clear of all obstructions “sterile space”
- Reconstitute vaccines
- Check and validate vaccinators presenting for their shift
- Must consent individual if vaccinator is non-registrant (Pharmacist/Nurse/Dr etc)
- To ensure each vaccinator has been set up with their own log in
- Must monitor and be on hand to provided clinical guidance e.g. queries such as timing between 1st & 2nd doses, allergies, pregnancies, vaccine type & clotting
- Must check that vaccinators have signed the relevant Protocol/PGD
- Must ensure that clinical waste is stored safely for disposal
- Must know how to request a waste collection

Resource, planning & staffing

SOPs

- Have all vaccinator staff signed the SOP / Protocol / Confidentiality agreements?
- Safe conditions for staff?
- Safe levels of staffing ?
- Staff training and record keeping

IT systems

- Training, log in details, rotas, booking calendars, grab a jab

Fridge

- type of fridge, use only to store vaccines

Infection prevention & control requirements

Vaccinators

Do vaccinators wear PPE. https://www.england.nhs.uk/wp-content/uploads/2022/04/C1691_National-infection-prevention-control-manual-for-england-V-2.3.pdf

Hand gel available for patients

Are gloves changed between patients, or handwashing / gelling between patients?

Hand / wrist jewellery / Bare Below Elbow

- Must sanitise after each patient (gloves must be changes between patients)
- Aprons must be worn
- Arms must be clear below the elbows i.e. no watch, embellished rings or false nails
- Non-registrants must ensure that individuals are lawfully consented
- Must ensure all relevant check are undertaken before administering the vaccine
- Non-registrant must seek clinical advice where required from the Clinical Supervisor or alert them to any clinical issue or concern
- Must ensure that excessive clinical waste is not held in the booth
- Must advise individuals of the during of their observation
- Give advice specifically around driving or cycling after being vaccinated

Must log out at the end of their shift and surfaces have been sanitised

Infection prevention & control requirements

Vaccine Site
Is the Vaccination site and vaccine preparation area clean and clutter free
Is the vaccination site safe and free of obstruction – health and safety requirements met
Are the floors wipeable and porous free
Is there enough materials (sanitiser, cleaning material, leaflets etc)

Vaccine preparation area
Vaccination booths / rooms
Clean and Clutter free
Wipeable, non-porous floors
Check there is enough materials available (sanitiser, cleaning material, leaflets etc)
Waste location in close proximity to the patient

Vaccination Management

- Safe storage and preparation of vaccine
- Good clinical governance
- Vaccine handling including management of different vaccine
- Delivery of volume
- Safe storage and preparation of vaccine
- Vials swabbed before removing vaccine EACH TIME
- Waste location in proximity to patient
- Record keeping
- Management of post vaccination observation and management of ADRs

Patient Journey

Patient flow

- How will patients flow between entrance, reception, vaccination area, observation area and exit will marshals be required

Booking in (Reception)

- Booked appointments or walk-in
- How will patients be checked in
- What information will be provided to patients (written / verbal)
- How will queries and concerns be escalated to clinicians

Vaccination area

- Room, booth or screens – how to maintain confidentiality for patient
- Clinician or vaccinator –how will a vaccinator know that consent has been obtained
- Equipment to hand – gels, biowaste bin, sharps bin, IT, cotton balls etc
- Data entry into IT or onto paper?

Patient Journey

Observation area

- Are patients advised when they must wait
- Are patients clearly advised how long to wait in observation? How do patients know when to leave?
- Waiting area observed correctly – marshals with a clear view of all patients. Marshals know what to do with fainters, reactions, anaphylaxis i.e. when to seek assistance
- Sufficient and socially distanced seating? 2m or clear barriers
- Marshalls observing – are they able to and are they distracted
- Chairs decontaminated between patients?
- Exit route clearly marked

Storage and disposal of waste

- Biowaste / Sharps waste: Safe storage & removal
- Waste location in proximity to patient
- Biowaste and Sharps waste to be stored safely away from patients at all times. Ideally a secure room or an area not routinely accessible to patients.
- Biowaste and sharps waste must not be in immediate reach of patients within the vaccination area
- Biowaste and sharps waste must not be allowed to build up to maximum. If there is no space for safe storage of waste, then the vaccination service must cease to prevent generating further waste
- Biowaste and sharps waste only to be transported from the site by approved and licensed waste carriers

Regulations

The GPhC element:

- What is the different between the Responsible Pharmacist and Clinical Supervisor
- Safeguarding systems in place with staff aware of how to handle relevant situations

The Responsible Pharmacist

- The RP for the pharmacy is aware of their responsibility for oversight of the vaccination activities
- When the clinical supervisor can or cannot also be a vaccinator. Typically with multiple vaccination areas, the clinical supervisor cannot also vaccinate as they will be unable to safely maintain their oversight.

Mutual Aid (supply of additional vaccines from another site) can be provided in specific situations.

- This follows a strict MHRA / SVOC process.
- Sites must provide a weekly stock take position AND report when they suspect that vaccines are likely to time expire before use

All sites MUST have adequate indemnity at all times.

Antivaxxers – what to expect

- CPPE training now available - Health inequalities: focus on vaccine hesitancy

Key Questions

- Ask why a patient is hesitant
- Counter any misinformation
- Know you are the most trusted information source
- Tell patients they need to get the vaccine
- Tailor your message
- Address patients' fears about side effects
- Prepare your staff to answer questions

Quality Assurance

- What is reviewed during any visit: Clinical Supervisor Observations, IPC, Signatures to documents, Staff are able to describe their safe operation and roles etc. without prompting.
- Site support and reviews conducted by the local teams or NHSE/I

Consider reviewing your vaccination site with regard to the following areas as a minimum:

- Contractual
- Infection, Prevention Control (IPC)
- Governance
- Training
- Workforce
- Premises
- Overall patient safety and confidentiality
- Patient Journey, safety, clinical governance, access and staffing

Common queries and where to find the answers

- What queries can you expect? How to handle these ?
- Immunocompromised patients: What enquiries can you expect? How to handle these?

Support

- Where to make enquiries / obtain support.
- Peer support (WhatsApp Group)
- NHSE/I and ICB Support
- LPC support