

Official



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# COVID-19 vaccination programme

## Quality Assurance Framework: COVID-19 vaccination sites

Version 1, 4 March 2021

## Introduction

The purpose of this framework is to provide organisations delivering COVID-19 vaccine services with a quality assurance tool aligned to the operating frameworks and standard operating procedures underpinning the delivery models for these settings: Hospital Hubs, Local Vaccination Services (LVS) and Vaccination Centres (VC).

The tool can be used to ensure services have ongoing robust assurance in place, to demonstrate compliance with the legal frameworks for COVID-19 vaccine delivery and to ensure the standards expected for a healthcare setting are met. It will also help identify any areas of risk and show the corrective actions taken in response. The tool can be used as a self-assessment or by those responsible for reviewing the quality of healthcare in the locality. The tool can provide assurance to trust and PCN boards that organisational compliance has been systematically reviewed.

This framework is not mandated. If organisations don't use it, they should ensure they have equivalent mechanisms to evidence assurance. It is recommended that the assurance framework is used to establish the monitoring needed for day-to-day oversight as new services are developed, then completed within 8 weeks of opening (or as soon as possible if the service has been operational for longer than 8 weeks). The tool should also inform future service development including up-scaling of existing services.

The framework is aligned to the Care Quality Commission framework for ease of use alongside other quality assurance processes.

## Legislative mechanisms

The 2012 Human Medicines Regulations set out a comprehensive regime for the authorisation of medicinal products for human use; for the manufacture, import, distribution, sale and supply of those products; for their labelling and advertising; and for pharmacovigilance.

They also provide for enforcement powers for the authorisation and supervision or administration of medicinal products for human use.

All medicines are classified according to three legal categories which are: Prescription only Medicines, Pharmacy Medicines and General Sales List Medicines.

All vaccines are classed as prescription only medicines which means that they can only be supplied on the authority of a prescriber (doctor or other independent prescriber).

The regulations do not permit nurses, or other registered healthcare professionals (HCPs), who are not qualified prescribers to administer or supply prescription only medicines (POMs) unless one of four types of instruction is in place:

1. Signed prescription
2. Patient Specific Direction (PSD)
3. Patient Group Direction (PGD)
4. National Protocol (for influenza or COVID-19 vaccines only)

The vaccination service must operate under one of the above types of instruction.

# Service summary

Site name	Region	Vaccination service type (Model)	Type(s) of instruction in place for vaccine administration.
<p><b>Service summary</b></p> <p><i>Provide a narrative describing the service including location, the vaccines being administered, and for VCs, the number of PODs in operation:</i></p>			

Author:

Role

Date of completion:

## Assurance framework

Key Line of Enquiry	Suggested evidence	Gaps in assurance	Mitigating actions
<b>Safe</b>			
Clients using the vaccination service are protected from abuse and avoidable harm.			
<p>There is evidence of learning from incidents and a transparent reporting culture:</p> <ul style="list-style-type: none"> <li>• Serious Incidents and adverse events are escalated in accordance with the <a href="#">National SOP for the Management of COVID-19 vaccination clinical incidents and enquiries</a></li> <li>• Adverse vaccine events are reported via the MHRA (Medicines and Healthcare product Regulatory Agency) Yellow Card system; <a href="https://coronavirus-yellowcard.mhra.gov.uk/">https://coronavirus-yellowcard.mhra.gov.uk/</a></li> </ul>	<ul style="list-style-type: none"> <li>• Policy/SOP</li> <li>• Daily safety briefing</li> <li>• Thematic Incident data</li> <li>• Yellow card submission data</li> </ul> <p>Process for referring to the Clinical Advice and Response</p>		
The deployment, governance, handling, and preparation of	Approved SOPS pre vaccine in operation.		

vaccines is in accordance with the Specialist Pharmacy Service Technical Standard Operating Procedures (SOPs) for COVID-19 Vaccines	To include procedure for training vaccinators in PCNs (primary care networks).		
Cold chain monitoring is in place and breaches identified in a timely manner	<ul style="list-style-type: none"> <li>• Audit</li> <li>• SOP</li> <li>• Temperature audits</li> </ul>		
Delivery of the vaccine is checked, accepted, and recorded by a registered healthcare professional and cold chain maintained.	SOP		
There is a process in place to oversee and manage safe access and queuing – with scope to adapt in anticipation of each new cohort	<ul style="list-style-type: none"> <li>• SOP</li> <li>• Patient flow/patient</li> <li>• Pathway</li> </ul>		
National guidance and resources for COVID-19: infection prevention and control (IPC) is adhered to and overseen.	<ul style="list-style-type: none"> <li>• Policy</li> <li>• Nominated IPC lead</li> <li>• IPC audit/site assurance visit</li> <li>• Hand hygiene audit</li> </ul>		
There is an approved process to manage clinical waste from the point of usage to disposal/collection to ensure the	<ul style="list-style-type: none"> <li>• SOP</li> <li>• Audit</li> <li>• Clinical waste contract</li> </ul>		

health and safety of staff, volunteers and clients.			
Staff and volunteers are tested using Lateral Flow point of care testing. The plan is overseen and meets the Lateral Flow national protocol of twice-weekly testing	T&T compliance data.		
There is evidence that the environment is assessed as safe; in line with COVID secure guidance by the HSE (Health and Safety Executive) There is good ventilation throughout the service	Environmental checklist and assurance certificate by H&S/Estates Lead.		
Provision for the management of adverse reactions is in line with guidance with the Green Book Ch14a, recommendations for medicines and equipment by the Resuscitation Council UK, are risk assessed and monitored.	<ul style="list-style-type: none"> <li>• Policy</li> <li>• Resus medicines and equipment audit</li> <li>• Risk assessment</li> </ul>		
Attendees are safeguarded against abuse and neglect. Staff comply with provider safeguarding policies (adults and children). Safeguarding concerns attributed to the vaccination service are reported and monitored	<ul style="list-style-type: none"> <li>• Policies (adults and children).</li> <li>• Safeguarding audits.</li> </ul>		

There is a process to review staff rosters to ensure staffing and the supervision of delegated practice is in accordance with the legal framework in place	Staffing data: <ul style="list-style-type: none"> <li>• Turnover</li> <li>• Vacancies</li> <li>• Sickness</li> <li>• Bank fill rates</li> </ul>		
Clinical records are maintained according to policy. Personal identifiable data (PID) is managed in accordance with provider approved information governance process	<ul style="list-style-type: none"> <li>• Policy in place</li> <li>• Documentation audit (for example an information governance audit)</li> </ul>		
Risks are managed, reviewed and kept up to date	Risk register		
All staff including volunteers have undergone appropriate recruitment checks prior to appointment.	Employment checks		
Procedures are in place to handle multiple vaccines safely including staff awareness and training, IT, storage, and separation in 'time and space'	<ul style="list-style-type: none"> <li>• SOP</li> <li>• Medicines management audit</li> <li>• Daily Safety Huddles</li> </ul>		
There is a process in place to ensure equipment is used and tested as per manufactures guidance and fit for purpose	Equipment audit		
<b>Effective:</b> The vaccination service successfully achieves intended outcomes. Service provision is evidence based.			



<p>Available capacity is in line with the site target max throughput per day. Alternatively, operational ramp up plans are in place to resolve the use of capacity.</p>	<ul style="list-style-type: none"> <li>• Vaccine utilisation data</li> <li>• Capacity data</li> <li>• DNA (Did Not Attend) data</li> </ul>		
<p>The consenting processes is in line with the legal framework as detailed in the Green Book, overseen in practice by a suitably skilled practitioner. The support provided is in line with the Mental Capacity Act and Equality Acts to including the provision of reasonable adjustments and documentation of best interest decisions.</p>	<ul style="list-style-type: none"> <li>• SOP</li> <li>• Workforce allocation</li> <li>• MCA (Mental Capacity Act) audit</li> </ul>		
<p>There is sufficient oversight and monitoring to prevent vaccine wastage.</p>	<ul style="list-style-type: none"> <li>• Vaccine utilisation data</li> <li>• Reserve lists in place to prevent</li> </ul>		
<p>Public health messaging following vaccination is available, up to date and regularly reviewed in line with national PHE (Public Health England) policy and guidance (PHE 'What to Expect' Leaflet).</p>	<p>Information inventory</p>		

Workforce models are agile and flexible to enable increase in throughput as supplies increase	Plan for scale up including consideration of non-registered and registered workforce.		
Staff overseeing and delivering vaccines are appropriately trained and competent and up to date with current vaccines.	Policy. Education audit including training and competency sign off compliance. <a href="#">Competency Audit.</a>		
<b>Caring:</b> Clients are treated equitably with care, compassion dignity and respect.			
Service user experience is captured and informs service and quality improvement	Service user feedback. Service user engagement.		
Complaints and compliments are responded to in accordance with policy. Themes inform ongoing quality improvement.	Policy. Complaints records. Complaints audit.		
Patient advocate or support roles (for example from St John Ambulance in Vaccination Centres) are in place to support attendees and to support with navigation and throughput.	Workforce model. Role specification.		
<b>Responsive:</b> The vaccination service is organised to meet the needs of the designated population.			
Information for attendees is regularly reviewed and updated	Policy. Information inventory.		

according to information standards.			
The services are responsive to meet the needs of diverse and seldom heard populations. <ul style="list-style-type: none"> <li>• Privacy and dignity</li> <li>• Translation</li> <li>• Accessibility</li> <li>• Navigation and access</li> </ul>	Policy in place. Demographic data. Service user feedback. Equality Impact assessments Disability access provisions		
<b>Well Led</b>			
There is evidence of effective leadership and robust governance processes in place to oversee activity within the vaccination service.			
There is a clinical lead responsible for the delivery of all aspects of vaccination service	Service specification		
Clinical governance and supervision processes are in place and signed off by the Vaccination Site Clinical Lead	Approved SOP		
There is Pharmacist oversight into the vaccination process.	Named person available for day-to-day vaccine queries		
Statutory and Mandatory Training records demonstrate compliance with local policy	Training data		
There are policies and procedures in place to oversee the experience and wellbeing of	Policy. Staff survey results.		

staff including the safe provision of adequate staff rest areas	Roster review (break allocation). COVID-19: Secure assessment of Staff break areas.		
There is an agreed process to facilitate ongoing quality improvement.	QI plan. Lessons learned. Quality boards Daily huddles		
Staff Indemnity has been considered through honorary contracts or service level agreements where not directly employed (including volunteers where vaccinating)	Lead employer agreement for staff.		
There are business continuity plans applicable to the site in the event of a major incident. <ul style="list-style-type: none"> <li>• IT down time</li> <li>• Fire</li> <li>• Cold/hot weather</li> <li>• Security</li> <li>• Traffic management arrangements</li> <li>• Power failure</li> </ul> (These are examples only not exhaustive)	BCPs. Local Health Resilience Forums Cold chain management policy Including out of hours.		

# Summary

<b>Final comments:</b>	
<b>Overall summary of assurance</b> Select as applicable:	<p>The evidence provides:</p> <p><b>Substantial assurance:</b> The service demonstrates robust processes for ongoing assurance across all domains and evidence is consistent with good practice.</p> <p><b>Full assurance:</b> The service demonstrates robust processes for ongoing assurance across all domains. Further evidence is required to demonstrate good practice</p> <p><b>Limited assurance:</b> The service is developing robust processes for ongoing assurance across all domains.</p> <p><b>Concerns highlighted:</b> Improvements required and a repeat assurance review in [insert due date]</p>

## Action plan template

Issue	Mitigating Action	Lead	By when	Status	Comments

## References and links to further information

Anaphylaxis guidance for vaccination settings: <https://www.resus.org.uk/about-us/news-and-events/rcuk-publishes-anaphylaxis-guidance-vaccination-settings>

Asymptomatic staff testing for COVID-19:  
[Coronavirus » Asymptomatic staff testing for COVID-19 \(england.nhs.uk\)](#)

Care Quality Commission: [Monitoring questions for hospital-led COVID-19 vaccination services: https://www.cqc.org.uk/guidance-providers/how-we-inspect-regulate/monitoring-questions-hospital-led-covid-19-vaccination#accordion-4](#)

COVID-19 vaccinator competency assessment:  
[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/943646/Core\\_competency\\_assessment\\_tool\\_v3.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/943646/Core_competency_assessment_tool_v3.pdf)

Green Book, Chapter 14a - COVID-19 - SARS-CoV-2. 12 February 2021:  
[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/955548/Greenbook\\_chapter\\_14a\\_v6.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/955548/Greenbook_chapter_14a_v6.pdf)

Health and Safety Executive: [Making your workplace COVID-secure during the coronavirus pandemic \(hse.gov.uk\)](#)

2012 Human Medicines Regulations:  
<https://www.legislation.gov.uk/ukxi/2012/1916/contents/made>

Legal mechanisms for administration of the COVID-19 Vaccine(s): [C0923-legal-mechanisms-for-administration-of-the-covid-19-vaccines-v2-10-december-2020.pdf \(england.nhs.uk\)](#)

National guidance and resources for COVID-19: infection prevention and control (IPC): <https://www.gov.uk/government/publications/wuhan-novel-coronavirus-infection-prevention-and-control>

Public Health England information leaflet 'What to expect after vaccination':  
<https://www.gov.uk/government/publications/covid-19-vaccination-what-to-expect-after-vaccination>

Public Health England Coronavirus (COVID-19) Resource Centre: <https://coronavirusresources.phe.gov.uk/>

Specialist Pharmacy Service Technical Standard Operating Procedures (SOPs):  
<https://www.sps.nhs.uk/home/publications/standard-operating-procedures/>

Standard operating procedure Management of COVID-19 vaccination  
clinical incidents and enquiries:  
<https://www.england.nhs.uk/coronavirus/publication/standard-operating-procedure-management-of-covid-19-vaccination-clinical-incidents-and-enquiries/>