



Royal College
of Nursing

Leadership and Supervision for Delivery of Large Scale Vaccination

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Learning outcomes

The aim of this resource is to supplement the national training materials and provide additional support for those leading and supervising the large scale vaccine programmes.

The learning outcomes are:

- ◆ To outline the agreed training requirements for staff involved in large scale vaccine delivery
- ◆ To analyse roles and responsibilities of staff involved in mass vaccination
- ◆ To understand accountability and delegation requirements for all members of the team involved in vaccine delivery
- ◆ Understand the legislative framework for safe vaccine administration
- ◆ Understand medicines authorisation requirements for vaccine administration – Prescription or Patient Specific Direction (PSD) / Patient Group Direction (PGD) / National protocols
- ◆ Consider local planning, operating models and service planning

NB: all immunisers will also need to complete the specific COVID-19 vaccine training

RCN position re COVID-19 vaccination

- ◆ To support safe delivery of COVID-19 vaccines, maintain patient safety and public trust in vaccination ensure members have up to date and evidenced information
- ◆ Support, where possible, the delivery of vaccines approved by the MHRA and promote the guidance from the JCVI and national immunisation policy as published in [Immunisation against infectious disease the Green Book](#).
- ◆ Promote the nursing voice and celebrate the fundamental role of nursing teams to deliver vaccines safely and effectively
- ◆ The RCN supports expanding the workforce to help delivery of the vaccine, providing vaccinators are suitably trained and have the necessary support and supervision to deliver the programme safely.
- ◆ The RCN would expect organisations to make sure the vaccine is readily available and staff have all the information they need in order to get it

RCN position – should nurses have the influenza and COVID-19 vaccines?

- ◆ The RCN actively encourages all members to have the influenza and COVID-19 vaccines
- ◆ The RCN recommends that these vaccines should be taken up by staff to help protect themselves, their patients, their families and the wider community
- ◆ The RCN does not support mandating vaccination to staff as this would not be effective
- ◆ The RCN recommends that all organisations have a proactive approach and make sure their staff have easy access to the vaccine within the working day. Staff should not however, be coerced or forced to have the vaccines
- ◆ If RCN members decide they do not want the vaccine it may be appropriate for employers to consider redeploying them to lower risk areas

Overriding principles - maintaining patient safety and public trust in vaccination

- ◆ Trained, informed and supported workforce with access to appropriate supervision and rest periods [RCN COVID-19 vaccine resources](#)
- ◆ Vaccines kept, stored and transported in optimum conditions
- ◆ Vaccine preparation against agreed standard operating standards (SOP) and associated health care professional fact sheets or equivalent (similar to summary of product characteristics) see the Covid-19 vaccine SOPs on the Specialist Pharmacy Service web page <https://www.sps.nhs.uk/?s=&cat%5B%5D=3638>
- ◆ Staff access to appropriate personal protective equipment (PPE), see UK COVID-19 infection prevention and control (IPC) guidance <https://www.gov.uk/government/publications/wuhan-novel-coronavirus-infection-prevention-and-control>
- ◆ Members of the public and healthcare professionals are encouraged to report suspected side effects through the Yellow Card system <https://coronavirus-yellowcard.mhra.gov.uk/>

COVID-19 vaccines – January 2021

The following vaccines have been given authorisation for temporary supply by the UK Department for Health and Social Care (DHSC) and the Medicines and Healthcare Products regulatory Agency (MHRA), full details are available from the [MHRA](#):

- ◆ 2nd December 2020: **COVID-19 mRNA Vaccine BNT162b2 (Pfizer-BioNTech)**
 - messenger ribonucleic acid (mRNA) that contains the genetic sequence of the antigens found on the surface of the SARS-CoV-2 virus
- ◆ 30th December 2020: **COVID-19 Vaccine AstraZeneca (Oxford vaccine group)**
 - non-replicating viral vector vaccine. It uses a weakened adenovirus as a carrier to deliver the genetic sequence for part of the SARS-CoV-2 virus into the body
- ◆ 8th January 2021: **COVID-19 vaccine Moderna**
 - similar to the Pfizer vaccine and mRNA with the genetic sequence of the antigens found on the surface of the SARS-CoV-2. This vaccine will be available in the spring, when it will be added to the wider COVID-19 vaccine programme roll out.

COVID-19 vaccines – June 2021

The following vaccines have been given emergency authorisation for temporary supply by the UK Department for Health and Social Care (DHSC) and the Medicines and Healthcare Products regulatory Agency (MHRA), full details are available from the [MHRA](#):

◆ **2nd December 2020: COVID-19 mRNA Vaccine BNT162b2 (Pfizer-BioNTech)**

- messenger ribonucleic acid (mRNA) that contains the genetic sequence of the antigens found on the surface of the SARS-CoV-2 virus. For use in those 16 and over (MHRA approved for 12 – 16 year olds 4th June 2021 – awaiting further JCVI advice on use)

◆ **30th December 2020: COVID-19 Vaccine AstraZeneca (Oxford vaccine group)**

- non-replicating viral vector vaccine. It uses a weakened chimpanzee adenovirus as a carrier to deliver the genetic sequence for part of the SARS-CoV-2 virus into the body. For use in adults over 18 years.

◆ **8th January 2021: COVID-19 vaccine Moderna**

- mRNA with the genetic sequence of the antigens found on the surface of the SARS-CoV-2. 1st April 2021 Conditional Marketing Authorisation (CMA). For use in adults over 18 years.

◆ **28th May 2021: Janessen**

- non-replicating viral vector vaccine. Uses a weakened human adenovirus as a carrier to deliver the genetic sequence for part of the SARS-CoV-2 virus into the body – requires only one dose. For use in adults over 18 years. (supplies not yet available and awaiting JCVI advice on use)

UK COVID vaccine portfolio COVID vaccine delivery plan

Vaccine type	Vaccine	No of doses	Status
Adenovirus	Oxford/AstraZeneca	100 million	Approved / in deployment
mRNA	Pfizer/BioNTech	40 million	Approved / in deployment
mRNA	Moderna	17 million	Approved / in deployment
Protein Adjuvant	Novavax	60 million	Data and checks being undertaken prior to approval being sought
Adenovirus	Janssen	30 million	Approved by MHRA in use in US potential for UK in summer
mRNA	CureVac	50 million	Phase 3 trials being completed
Protein Adjuvant	GlaxoSmithKline/ Sanofi Pasteur	60 million	Phase 2/3 trials potential as booster
Inactivated whole virus	Valneva	60 million	Phase 2/3 trials potential for autumn booster?

Clinical overview – COVID-19 vaccines - 1

- ◆ For detailed information see the PHE resources;
 - ✓ *Green Book chapter* <https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a>
 - ✓ *Guidance for health care professionals;* <https://www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners>
 - ✓ *other resources including e-learning* <https://www.gov.uk/government/collections/covid-19-vaccination-programme>
- ◆ The initial aim of the COVID-19 vaccine programme in the UK, is to prevent severe disease in those most vulnerable. This is based on the current knowledge on the epidemiology of infection in the UK and the efficacy of the vaccines available.
- ◆ Long term efficacy data is not yet available for any COVID-19
- ◆ There is growing evidence on the impact of the vaccines currently in use and transmission
- ◆ People still need to be advised to follow guidance on social distancing etc

Clinical overview – COVID-19 vaccines - 2

- ◆ JCVI recommend a 7 day gap between having the COVID-19 vaccines and other vaccines
- ◆ Adverse events are likely, as with any vaccine, for example; local reactions, pain and tenderness at the injection site, mild systemic effects, headaches, fatigue, malaise, and general fever
- ◆ Patients need to be given post vaccine advice
- ◆ Advice on appointment for their 2nd dose.
- ◆ Patients need to be observed for immediate reactions. While anaphylaxis post vaccination is rare, the MHRA advise Vaccine recipients of the Pfizer BioNtech vaccine should be monitored for 15 mins after vaccination, with a longer observation period when indicated after clinical assessment
- ◆ As syncope (fainting) can occur following any vaccination patients should also be advised not to drive for 15 minutes post vaccination with either vaccine.

COVID-19 vaccines – Cautions and special consideration - 1

Allergy

- ◆ As with all vaccines the COVID-19 Vaccines - should not be given to those who have had a previous systemic allergic reaction (including immediate-onset anaphylaxis) to, a previous dose of the COVID-19 vaccines or any components of the vaccines

Pregnancy

- ◆ The JCVI now advise that pregnant women in the UK are offered the Pfizer-BioNTech or Moderna vaccines where available.
- ◆ There is no evidence that any of the COVID-19 vaccination causes any problem with pregnancy. There is data from the [United States](#) CDC data pregnant women vaccinated, with mRNA vaccines, Pfizer-BioNTech and Moderna, without any safety concerns.
- ◆ Pregnant women should discuss the risks and benefits of vaccination with their midwife or clinician.

See information in the green book and guidance from the RCOG on [COVID-19 vaccines, pregnancy and breastfeeding](#) and [Coronavirus infection and pregnancy](#).

COVID-19 vaccines – Cautions and special consideration - 2

Thrombosis and thrombocytopenia occurring after COVID-19 vaccination

- ◆ JCVI recommend offering the Pfizer-BioNTech or Moderna to people under 30 who have not previously had any doses of vaccine and where available
- ◆ Serious thromboembolic events accompanied by thrombocytopenia have been reported after AstraZeneca vaccination.
- ◆ The condition is rare ~ 5: 1000,000 higher in younger people
- ◆ Likely to be an idiosyncratic reaction related to an immune response to the AstraZeneca vaccine.
- ◆ There is no reason to believe that individuals with a past history of clots or of certain thrombophilic conditions would be at increased risk this includes pregnant, post-partum and women on the contraceptive pill
- ◆ There have been no confirmed cases reported in pregnant women to date.
- ◆ The advice is based on a risk benefit of vaccination

See .GOV [COVID-19 vaccination and blood clotting](#)



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Training requirement - dependent on registration and experience

See separate section for links to education and learning resources

Workforce – large scale vaccine delivery

Various models will support large scale vaccine delivery

- ◆ Hospital sites
- ◆ Community, primary care and primary care networks
- ◆ Large venues to facilitate large numbers
- ◆ Roving with teams to visit housebound and residential settings

Recognition with all models that staff will need to work in teams and not alone

The models will require staff to support in various roles

Vaccine delivery roles

- ◆ Non-clinical roles: administration and stewards
- ◆ Clinical managers
- ◆ Registered HCPs (RHCP) - experienced vaccinators
- ◆ Registered HCPs (RHCP) - untrained in immunisation (or have not vaccinated for 12 months)
- ◆ Unregistered support staff as immunisers, these will include nursing support workers and others trained to help administer vaccines

Training requirements

Depending on role, workforce will need training in the following:

- ◆ General principles of immunisation, Vaccine administration, legal issues for vaccine delivery and vaccine storage
- ◆ Medicines authorisation - National Protocol / Patient Group Direction (PGD) / Patient Specific Direction (PSD) / Written instruction (WI)
- ◆ Anaphylaxis / Basic Life Support
- ◆ COVID-19 vaccine programme overview
- ◆ COVID-19 - Vaccine specific training
- ◆ Statutory and mandatory training on board training
- ◆ On-site organisation training
- ◆ Competency assessment and sign off

NB – Nursing Associates (England only) cannot work from a PGD

Assessment of competence

There is no exact way to assess competence but there is some guidance in the National Minimum Standards (NMS) for immunisation which can support various approaches.

- ◆ Immunisers will need opportunities to observe and discuss relevant issues with the experienced practitioner/supervisor
- ◆ They will need to be able to demonstrate an appropriate standard of practice
- ◆ Supervised practice should be structured and robust and follow the national competency checklist for the role they are undertaking
- ◆ A copy of this and evidence of the process should be retained in the practitioner's personnel file
- ◆ There is no evidence as to how many times this supervised practice should occur, or how many times a practitioner will need to give an injection. Both the supervisor and new immuniser will need to feel confident that the individual has the necessary skills and knowledge to advise on and/or administer the vaccines
- ◆ The supervisor does not require a formal teaching and assessing qualification but should be competent in immunisation and have the ability to make an assessment of a new immuniser's knowledge and skills

NB: while the NMS do not apply across the UK they provide a useful framework and tools to support practice



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Accountability and delegation

See separate section for links to useful resources and information

Summary of functions necessary for vaccination to be delegated under a national protocol

NB. The roles and functions are not necessarily the same across the UK

Registered Health Care Professional (RHCP)	Overall responsible person: Clinical supervisor / manager Oversee the process ensuring stocks and safety measures in place Responsible for staffing and skill mix Responsible for ensuring staff education and training and assessment of competence
Depending on the model these functions may be done by the same person or various people to support large scale delivery	
Registered Health Care Professional (RHCP)	Clinical assessment Assessment of the patient providing information about the vaccine. Gaining patients informed consent. Provide information on contraindications against the vaccine based on the published information green book and vaccine manufacturer guidance
RHCP / ? Unregistered practitioner	Drawing up and reconstituting the vaccine May work alongside a separate vaccinator to provide supervision Needs specific skills in vaccine preparation
? unregistered practitioner	Vaccine administration Responsible for supporting patient through injection process and verbally checking consent
? unregistered practitioner	Administration Provides administration support ensures all records and collated and transfer of record process

Who can give a vaccine? - Legal principles

- ◆ Consent
- ◆ Negligence
- ◆ Duty of care
- ◆ Accountability



Consent - principles

Consent is a process, not a one-off event

- ◆ Does the individual know what they are there for?
- ◆ Do they know the potential side effects of the vaccine?
- ◆ Have you advised where will you give the injection?
- ◆ Has it been explained how might they feel afterwards?
- ◆ Have they had information about what to do should they feel unwell and what they can do to help themselves, such as take paracetamol and when to seek further clinical advice?
- ◆ Have they had an information leaflet/ pre and post vaccine to read?
- ◆ Are they happy for you to give them the vaccine?

NB: There is no legal need to get consent in writing, but it helps to serve as a record that consent has been given in a large scale vaccination scenario.

Further guidance is available on the e-learning resources



Consent given legally by competent person

- ✓ Consent must always be obtained before vaccination
- ✓ Adults over 18 with capacity
- ✓ Young people 16- 17 are entitled to consent to their own treatment
- ✓ Younger children assessed as Gillick competent*
- ✓ In order to consent the person has to be informed
- ✓ Large vaccination centres may not be the appropriate place. The clinic supervisor needs to know of other opportunities for individuals to receive the vaccine

*** NB: Gillick competence / Fraser guidelines -**

- Fraser guidelines, apply to advice and treatment relating to contraception and sexual health.
- Gillick competency, is used in a wider context to help assess whether a child has the maturity to make their own decisions and to understand the implications of those decisions to consent.
- See <https://learning.nspcc.org.uk/child-protection-system/gillick-competence-fraser-guidelines>

Assessment of capacity to consent

Consent is a process and needs to be based on the specific situation, individual concerned and the context

Health care professionals must be guided by the tenets of the Mental Capacity Act 2005 MCA.

- ◆ Assume capacity to make a decision themselves, unless it's proved otherwise
- ◆ Support people to make a decision themselves wherever possible, optimise the persons ability to make the decision; this might include using communication tools, making sure it is someone the person knows and trusts and speaking to them at the best time of day
- ◆ While people's capacity to consent might fluctuate during the day, it is appropriate to take the persons decision to consent at the time
- ◆ Respect 'unwise decisions' don't assume this is due to a lack of capacity
- ◆ Where a decision is made for someone who doesn't have capacity, it must be in their best interests
- ◆ Any treatment and care provided to someone who lacks capacity should be the least restrictive of their basic rights and freedoms
- ◆ This might be best served in a familiar residential or GP practice setting

Best interest decision

- ◆ Peoples capacity to consent may fluctuate during the day
- ◆ In giving consent for a vaccine, the professional would accept consent given at the time
- ◆ If someone has always refused vaccination or says they don't like needles etc and refuses, then their decision needs to be respected

If they lack capacity:

- ◆ Ask their Health Lasting Power of Attorney (LPA) if they have one named
- ◆ Check if there is an advanced directive – unlikely for vaccination
- ◆ Consider best interest decision

A family member may be the health LPA and if making a best interest decision best practice would normally involve the family in the decision

The family CANNOT however, consent to a relative's treatment alone

Vaccine storage

The 'cold chain' is the system of transporting and storing vaccines within the safe temperature range. For vaccines in the routine vaccine programme this is 2°C to 8°C

There are likely to be variations to the storage requirements for some COVID-19 vaccines, refer to specific standard operating procedures

This needs to be in line with the published guidance

Further guidance is available on the e-learning resources

Who can give a vaccine? – Legalities?

- ◆ The law imposes a ***duty of care*** on anyone who delivers health care, at all levels and in any setting
- ◆ This applies whether you are bathing patients or undertaking complex surgery

Once a duty of care applies the key question is: ***what standard of care is expected of practitioners performing particular tasks or roles?***

- ◆ When delegating any work to staff, consider:
 - Medicines legislation
 - Accountability and delegation

Accountability and delegation

All health care practitioners have a legal responsibility and accountability:

- ◆ **To their employer** – contract, JD, name badges
- ◆ **To the patient** – respect, consent, information
- ◆ **To themselves** – be appropriately trained and experienced and follow best practice
- ◆ **To society** – trustworthy, honesty

Registered health care practitioners i.e registered nurses, medical practitioners, pharmacists and registered nursing associates, (in England) are also accountable in law and to their regulator (such as the NMC) for their practice

Accepting responsibility and delegation consider?

- ◆ **Ability** – can you perform the task?
- ◆ **Accountability** - you have accepted responsibility and agreed to undertake this role and task as part of your job description?
- ◆ **Authority** - You can perform the task and work within the policies and protocols of the organisation, including having the authority to administer a medicine

National Minimum Standards (NMS)

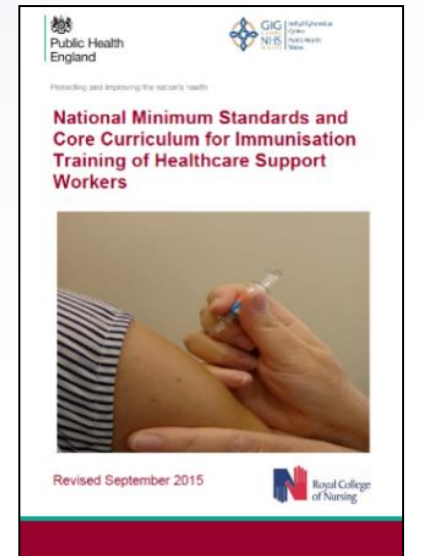
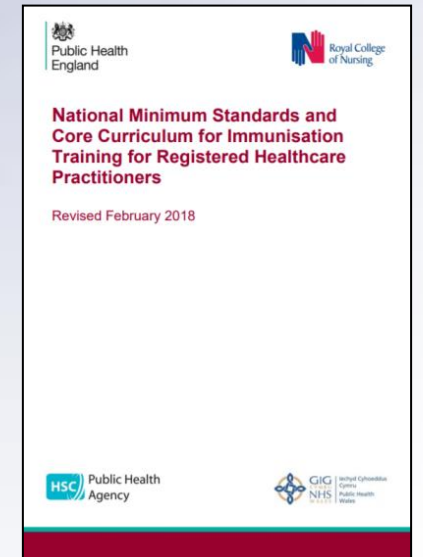
- ◆ Registered health care practitioners (updated 2018)
- ◆ Non-registered practitioners (2015)

How do you know if someone has the ability and the necessary skills and competence?

The NMS provide an agreed standard framework for the content of training

‘A high level of knowledge and a positive attitude to immunisation in healthcare workers are important determinants in achieving and maintaining high vaccine uptake. Good basic training and regular updates should be provided to achieve this.’

NB. while the NMS do not apply across the UK they provides a useful framework and tools to support practice



Knowledge and skills

All immunisers need to have the knowledge and skills

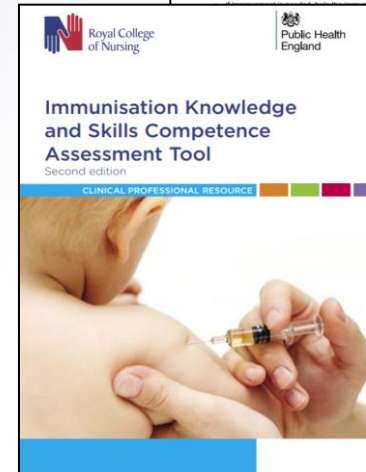
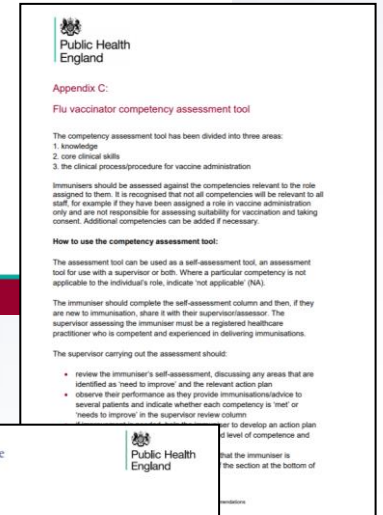
It depends on the individual's role, which vaccines and the scope of practice

What would constitute core immunisation training?

1. Attend training or e-learning and preferably some element of virtual interactive / face to face participatory learning which meets the curriculum
2. Work through the relevant competence assessment tool (under supervision)

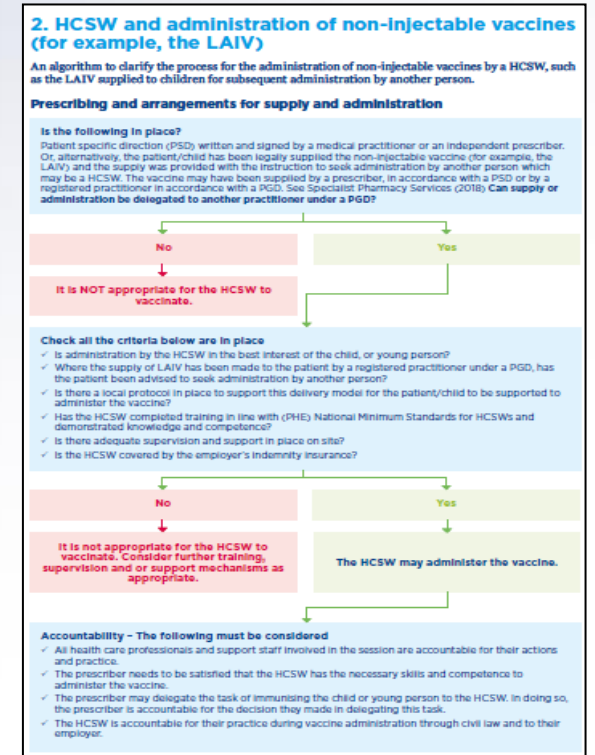
Follow the RCN and PHE link below for explanation on how to use this

<https://www.rcn.org.uk/professional-development/publications/pub-005336>



Delegating and accepting responsibility - Decision making process #1

- ◆ The administration of the COVID vaccine will require a range of different people working together
- ◆ The exact background education and professional experience of staff working to support this programme varies across the UK
- ◆ The RCN has guidance to support unregistered practitioners support vaccination in some countries of the UK
- ◆ The principles in these would apply for supporting workforce skill mix to deliver the COVID-19 vaccination programme



[Health Care Support Workers Administering Inactivated Influenza, Shingles and Pneumococcal Vaccines for Adults and Live Attenuated Influenza Vaccine \(LAIV\) for Children](#)
[The Role of Nursing Associates in Vaccination and Immunisation](#)

Delegating and accepting responsibility – Decision making process #2

Is the following in place?

- ◆ Legal authorisation to administer a medicine prescription, PSD, PGD, written instruction, national protocol?
- ◆ Has the worker completed the required education modules and been assessed as competent?

Delegating and accepting responsibility – Decision making process #3

Are the following criteria in place?

- ◆ Is the delivery of the vaccine and setting in the best interest of the individual?
- ◆ Is the clinic supervisor / manager satisfied that the worker administering the vaccine has the qualifications, experience, knowledge and skills needed?
- ◆ Has the worker completed training in line with agreed training standards
- ◆ Is there adequate supervision and support in place on site?

NB: the national protocol for COVID-19 vaccine administration provides indemnity insurance see RCN [COVID-19 and indemnity](#)

Delegating and accepting responsibility – decision making process #4

Accountability – the following must be considered:

- ◆ All health care professionals and support staff involved are accountable for their actions and practice
- ◆ The clinic supervisor / manager needs to be satisfied that the support worker has the necessary skills and competence to administer the vaccine
- ◆ The clinic supervisor / manager is accountable for the decision for the support worker to be able to work to the national protocol. A record of their training assessment and ongoing supervision should be kept
- ◆ All workers are accountable for their practice during vaccine administration through civil law and to their employer

Legal authorisation – Medicines administration

- ◆ Vaccines are Prescription Only Medicines – POM
- ◆ Require authorisation to supply and or administer from an appropriately registered practitioner
- ◆ This would ideally be in the form of a; Prescription or Patient Specific Direction (PSD), which are essentially the same

Alternative medicines authorisation mechanisms:

The legislation identifies the following relevant to vaccination:

- **Patient Group Direction (PGD):** these are an exemption under the regulations for enabling the supply and/or administration of a POM. They are limited to be used by certain listed health care professionals (HCP) and all processes under the direction must be carried out by the same HCP
- **Written Instruction:** limited to Occupational Health Schemes and HCP listed in legislation and link to operating under and instruction from a physician, see: <https://www.sps.nhs.uk/articles/written-instruction-for-the-administration-of-seasonal-flu-vaccination/>
- **National protocol:** applicable under emergency changes to the Human Medicines Regulations to authorise administration of specific vaccines in an emergency situation
- **Emergency medicines:** i.e. adrenaline given in response to anaphylaxis does not need a prescription, see: <https://www.legislation.gov.uk/ukxi/2012/1916/schedule/19/made>

Patient Specific Direction (PSD)?

A PSD is an instruction to supply and/or administer a medicine written and signed by the prescriber.

It could be an electronic record made in the patient notes where it is identifiable to the prescriber.

It could also be an instruction from a prescriber to administer a medicine to a list of patients.

Each patient on the list must be individually assessed by that prescriber

The PSD must include the:

- ◆ name(s) of patient(s) and/or other individual patient identifiers (including age if a child)
- ◆ name, form and strength of medicine
- ◆ route of administration
- ◆ dose
- ◆ frequency
- ◆ date of treatment/number of doses/frequency/date treatment ends as applicable
- ◆ signature of prescriber

CQC Nigel's surgery 19: Patient Group Directions (PGDs)/Patient Specific Directions (PSDs) <https://www.cqc.org.uk/guidance-providers/gps/nigels-surgery-19-patient-group-directions-pgdspatient-specific-directions>

Patient Group Directions (PGD)?

PGDs provide a legal framework that allows some registered health professionals to supply and/or administer a specified medicine(s) to a pre-defined group of patients, without them having to be assessed by a prescriber

- ◆ Supplying and/or administering medicines under PGDs should be reserved for situations in which this offers an advantage for patient care, without compromising patient safety
- ◆ The complete direction - patient assessment through to supply and or administration of the vaccine is by the healthcare professional named in the PGD
- ◆ Health care professionals cannot deviate from the PGD and they cannot delegate any function within the PGD

Legal mechanisms for COVID-19 vaccine delivery: <https://www.england.nhs.uk/coronavirus/covid-19-vaccination-programme/legal-mechanisms/>

NICE Guidance on PGDs: <http://www.nice.org.uk/guidance/MPG2/chapter/Summary>

Patient Group Directions and Patient Specific Directions in general practice: <http://bma.org.uk/practical-support-at-work/doctors-as-managers/prescribing>

Written instruction – legal framework peer to peer vaccination

- ◆ Written instructions are exemptions under the regulations for occupational health schemes and support peer to peer vaccination
- ◆ They are locally agreed mechanisms
- ◆ The HMR amendments allow for other registered professionals to use written instructions within NHS or local authority provided OHS. (This includes registered nursing associates in England)
- ◆ Specialist Pharmacy Services (SPS) National template for Influenza vaccine for 2020 – 20 21 there will be a similar national template for COVID-19 vaccines



<https://www.sps.nhs.uk/articles/written-instruction-for-the-administration-of-seasonal-flu-vaccination/>

Temporary changes to legislation

- ◆ Legislative changes to the Human Medicines Regulations (HMR) The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020
<https://www.legislation.gov.uk/uksi/2020/1125/contents/made>
- ◆ The legislative changes for vaccine delivery include the temporary authorisation of vaccines and indemnity cover for people working to deliver the vaccines as per the agreed guidance.
- ◆ The changes allow for vaccine administration under a national protocol for large scale Influenza vaccination and COVID-19 vaccination
- ◆ The delegation of functions is not permissible under a PGD but is possible under a national protocol
- ◆ The changes also allow other professionals than nurses to use written instructions in NHS and local authority provided Occupational Health Schemes
- ◆ NMC – support the use of national protocols, they will be producing support materials and liaising with other regulators

NB: While the legislative changes are applicable across the UK the protocol and identified roles and functions are determined nationally, they are not necessarily the same across the UK

National Protocol

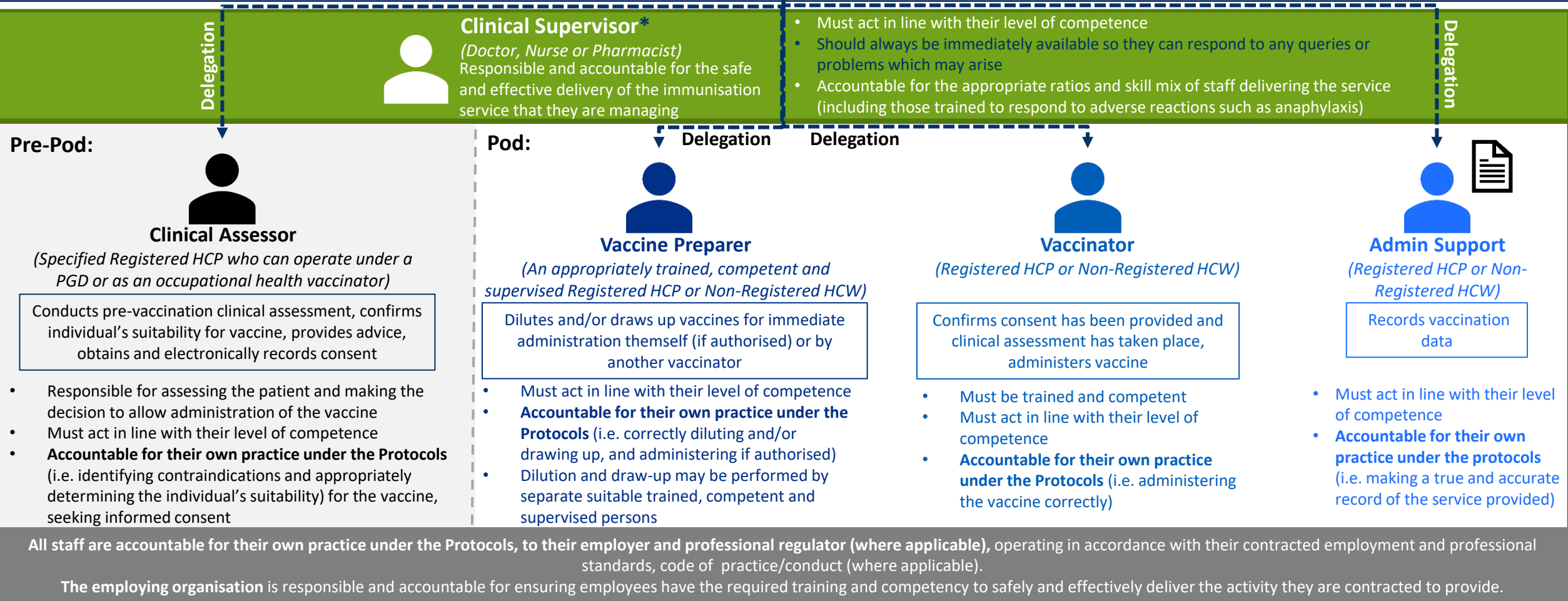
Legal mechanisms guidance <https://www.england.nhs.uk/coronavirus/covid-19-vaccination-programme/legal-mechanisms/>

- ◆ The aim of the protocol is for the safe administration of a vaccine to those eligible in the population
- ◆ It will support the challenge of delivery for such a large percentage of the population and the need to do this quickly
- ◆ For some parts of the vaccine delivery process it may be possible to use trained unregistered practitioners to expand the workforce.
- ◆ The protocol allows for delegation and administration of vaccines under a separate mechanism to a PSD or PGD
- ◆ The protocol allows for different people to carry out various functions of the process such as: clinical assessment and gaining patient consent, vaccine administration and administrative support
- ◆ The national protocol is similar to a PGD format, it includes;
 - ◆ the characteristics and training required of persons permitted to administer the COVID-19 vaccine under the protocol,
 - ◆ the requirement for individuals to be designated and authorised to administer medicines under the protocol by an appropriate manager (in the employing organisation),
 - ◆ record keeping requirements (including the requirement to record the name of the person who administers the vaccine)
 - ◆ requirements for the supervision, where appropriate, of the persons administering the vaccine.

Under the National Protocols all responsibilities in the vaccination process are delegated directly to the individuals performing the tasks.

National protocols authorise the safe supply and administration of a vaccine. Each element of activity under a protocol may be carried out by a different person or the same person, depending on the delivery model, so long as the minimum training requirements are met for fulfilling each stage of activity. The name of the immuniser and, where different from the immuniser, the professional assessing the individual, person preparing the vaccine, and person completing the vaccine record must be identified in the vaccination record.

- Legislation requires protocols to be authorised by ministers (SoS).
- Legal authority to supply and administer a Prescription Only Medicine is provided to those working in accordance with the national protocols.
- The clinical particulars in the protocols will be required to instruct and inform the safe and appropriate administration of vaccine in accordance with national recommendations. Standard Operating Procedures (SOPs) for the handling of vaccines and preparation of doses are available [here](#).
- All staff must play their part in ensuring that the efficacy of all vaccines is protected, by following the correct procedures for the ordering, receipt, storage, supply and administration of vaccines. Responsibilities are described [here](#) (specific responsibilities for PCN designated sites are [here](#)).



*Please note: the Clinical Supervisor in the National Protocols is different from the "Band 6 RHCP Clinical Supervisor (Vaccinations)" in the workforce models. Please see the supportive statement [<link when published>](#) for more detail.

Priority groups including health and social care staff

The JCVI have issued guidance on priority groups.

The details are in the COVID-19 green book chapter

<https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a>

as it stands the priority groups are:

- Older adults resident in a care home and care home workers
- All those 80 years of age and over and health care and social care workers
- All those 75 years of age and over
- All those 70 years of age and over and clinically extremely vulnerable individuals (excluding pregnant women and those under 18 years of age)
- All those 65 years of age and over
- Adults aged 18 – 65 in at risk groups
- All those 60 years of age and over
- All those 55 years of age and over
- All those 50 years of age and over
- ? Rest of the population (priority to be determined)

Indemnity

- ◆ The amended Human Medicines Regulations say that, provided that the vaccine is administered as recommended (i.e. in accordance with the recommendations of the MHRA and any product information) the staff administering the vaccine and their employers will be immune from civil liability
- ◆ All staff, even those temporarily employed would be covered by their employers indemnity scheme. As a nationally commissioned service this would be through the:

Clinical Negligence Scheme for General Practice Clinical Negligence Scheme for Trusts or equivalent arrangements in the devolved administrations

- ◆ A contract of employment or honorary contract needs to be in place
- ◆ The decision to roll out mass vaccination programmes for temporarily licenced COVID-19 vaccines, or indeed any pandemic disease treatments, will be taken nationally, not by the individual companies manufacturing or marketing the product
- ◆ The roll out of the COVID-19 vaccine programme will be through NHS contracts either via primary care or NHS trusts only. Private providers (at least initially) will not be able to procure COVID-19 vaccines

Keeping up to date

- ◆ Subscribe to Vaccine update and keep up to date with all the latest news
[Sign up to receive the Vaccine update newsletter](#)
- ◆ Don't miss important emails from Public Health England
To make sure you receive the Vaccine update newsletters:
add onlineservices@subscriptions.phe.gov.uk to your Contacts (Address book) or Safe Senders list
- ◆ If you find emails from '@subscriptions.phe.gov.uk' in your 'Spam' or 'Junk email' folder, open the email and click the 'Not spam' or 'Not junk' button to allow emails from this address in the future
- ◆ The Green Book has the latest information on vaccines and vaccination procedures, for vaccine preventable infectious diseases in the UK. See: <https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>

Finding and trusting the evidence

You can look up almost anything on the internet. Most of what's offered is really trying to sell a product, service, or point of view. Use the 'SMELL' test:

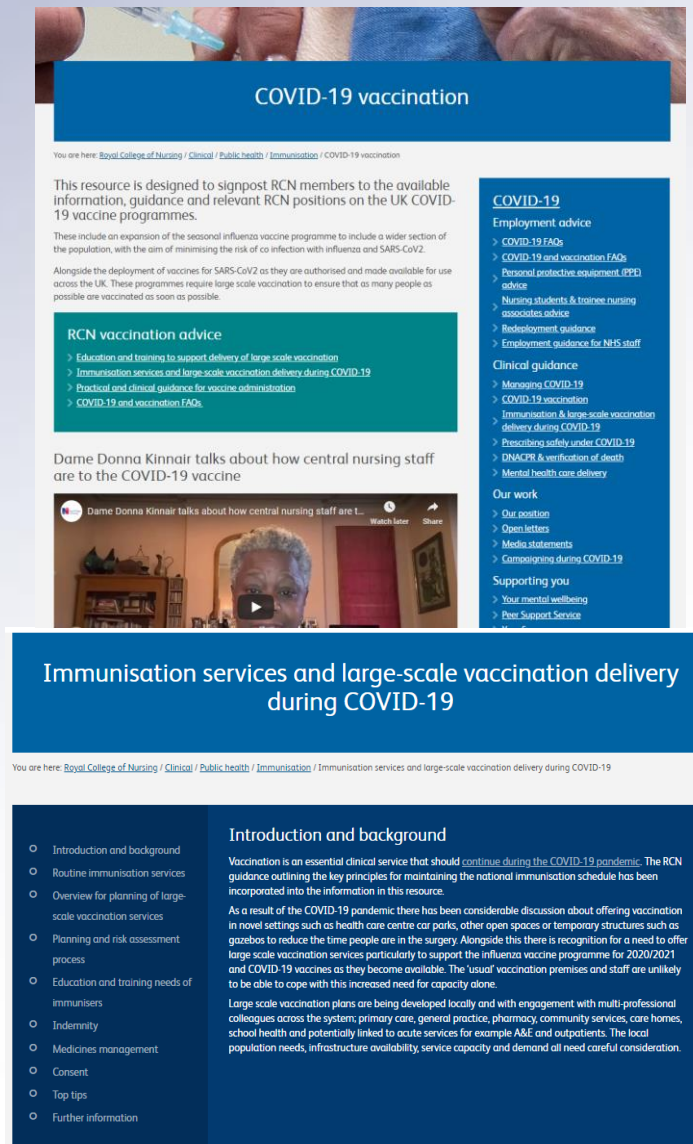
S	Source - Who is providing the information?
M	Motivation - Why are they telling me this?
E	Evidence - What evidence is provided, and when was it posted?
L	Logic - Do the facts logically compel the conclusions?
L	Left out - What's missing that might change our interpretation of the information

Don't Be Fooled: Use the SMELL Test To Separate Fact from Fiction Online John McManus February 2013

<http://mediashift.org/2013/02/dont-be-fooled-use-the-smell-test-to-separate-fact-from-fiction-online038/>

Further information

- ◆ RCN COVID-19 vaccination hub <https://www.rcn.org.uk/clinical-topics/public-health/immunisation/covid-19-vaccination>
- ◆ Immunisation services and large-scale vaccination delivery during COVID-19
<https://www.rcn.org.uk/clinical-topics/public-health/immunisation/immunisation-services-and-large-scale-vaccination-delivery-during-covid-19>
- ◆ NMC code
<https://www.nmc.org.uk/standards/code/>
- ◆ NMC. Caring with confidence – the Code in action
<https://www.nmc.org.uk/news/news-and-updates/code-in-action/>



The screenshot shows the RCN COVID-19 vaccination hub page. At the top, there is a blue header with the text "COVID-19 vaccination". Below this, a breadcrumb trail reads "You are here: Royal College of Nursing / Clinical / Public health / Immunisation / COVID-19 vaccination". The main content area is divided into several sections:

- RCN vaccination advice:** A green box containing links to "Education and training to support delivery of large scale vaccination", "Immunisation services and large-scale vaccination delivery during COVID-19", "Practical and clinical guidance for vaccine administration", and "COVID-19 and vaccination FAQs".
- Video:** A video player showing Dame Donna Kinnair talking about how central nursing staff are to the COVID-19 vaccine.
- COVID-19:** A blue sidebar menu with categories: "Employment advice" (including COVID-19 FAQs, COVID-19 and vaccination FAQs, Personal protective equipment (PPE) advice, Nursing students & trainee nursing associates advice, Redeployment guidance, and Employment guidance for NHS staff), "Clinical guidance" (including Managing COVID-19, COVID-19 vaccination, Immunisation & large-scale vaccination delivery during COVID-19, Prescribing safely under COVID-19, DNACPR & verification of death, and Mental health care delivery), and "Our work" (including Our position, Open letters, Media statements, Campaigning during COVID-19, Supporting you, Your mental wellbeing, and Peer Support Service).

Below the video, there is a blue header for "Immunisation services and large-scale vaccination delivery during COVID-19". The breadcrumb trail reads "You are here: Royal College of Nursing / Clinical / Public health / Immunisation / Immunisation services and large-scale vaccination delivery during COVID-19". The main content area includes:

- Introduction and background:** A section stating that vaccination is an essential clinical service that should continue during the COVID-19 pandemic. It mentions that the RCN guidance outlining the key principles for maintaining the national immunisation schedule has been incorporated into the information in this resource. It also notes that as a result of the COVID-19 pandemic, there has been considerable discussion about offering vaccination in novel settings such as health care centre car parks, other open spaces or temporary structures such as gazebos to reduce the time people are in the surgery. It acknowledges a need to offer large scale vaccination services particularly to support the influenza vaccine programme for 2020/2021 and COVID-19 vaccines as they become available. It states that the usual vaccination premises and staff are unlikely to be able to cope with this increased need for capacity alone. Finally, it mentions that large scale vaccination plans are being developed locally and with engagement with multi-professional colleagues across the system, primary care, general practice, pharmacy, community services, care homes, school health and potentially linked to acute services for example A&E and outpatients. It concludes that the local population needs, infrastructure availability, service capacity and demand all need careful consideration.
- Table of Contents:** A list of links for "Introduction and background", "Routine immunisation services", "Overview for planning of large-scale vaccination services", "Planning and risk assessment process", "Education and training needs of immunisers", "Indemnity", "Medicines management", "Consent", "Top tips", and "Further information".

Carry on vaccinating 😊

RCNDirect <https://www.rcn.org.uk/contact>

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