NATIONAL COVID-19 VACCINATION PROGRAMME

Legal mechanisms for administration of the COVID-19 Vaccine(s)

Executive Summary:

1. It is known that the Patient Group Direction or the newly approved written direction - the National Protocol, for the first covid-19 vaccine, will not be in place for the start of the Covid 19 vaccination campaign which is currently for planning purposes "readiness" from 1st December. This is due to the need for regulatory authorisation before the documents can be written, this leaves a very short timescale for completion in time for commencement of the vaccination programme.

2. Normally a vaccine will already have UK marketing authorisation or license and specific detailed information about the product available is published in the form of a Summary of Product Characteristics (SmPC). This information covers the following information types: medicinal name and strength, vaccine effectiveness, patient groups the vaccine is licensed for use in, adverse reactions, contraindications and cautions storage, and reconstitution and administration routes. This is key information that informs the development of the prescribing documents and is usually available in advance of the commencement of a new immunisation programme.

3. This poses a key risk as the vaccine is a prescription only medicine (POM) which cannot be administered or supplied to patients unless one of four types of instruction are in place:
    a) a signed Prescription
    b) a signed Patient Specific Direction (PSD)
    c) a Patient Group Direction (PGD)
    d) a National protocol* (applies to influenza and COVID-19 vaccines only)

4. In order to manage the period between the commencement of the vaccination programme and the availability of the national PGD or national protocol which will be the overarching strategic prescribing approach for the mass vaccination programme it is necessary to implement a short-term interim step to support the delivery of vaccines until the relevant legal documents are available.

5. Primary focus is being placed on supporting the relevant organisations to complete the development of the PGD or National Protocol where possible for the quick conclusion of the governance and approval process.

6. **It is therefore proposed that the PSD mechanism, based on the framework agreed in this paper, is used to prescribe the vaccine until the national PGD/ national protocol is available. This will provide a legal mechanism for the administration of the vaccine as a short-term interim measure.**

7. The use of a PSD to support vaccine delivery is not a long-term viable solution due to the following reasons:

    a) Prescribers need to be medical practitioners, Independent nurse or pharmacist prescribers (who are suitably trained with experience in immunisation) limiting the number of staff who can prescribe.

    b) A Prescriber will need to give an authorised instruction to administer a medicine to a list of individually named patients where each patient on the list has been individually assessed by that prescriber. The prescriber must have adequate knowledge of the patient's health and be satisfied that the medicine to be administered serves the individual needs of each patient on that list.

    c) There is no restriction in law as to who can administer the medicine to the patient, under a PSD however the prescriber has a duty of care and is professionally and legally accountable for the care, he/she provides, including tasks delegated to others. Therefore, the prescriber must be satisfied that the person to whom practice is delegated has the qualifications, experience, knowledge and skills to provide the care or treatment involved.

8. All the above requirements mean that there will be a decrease in productivity. This is because each recipient of the process will take longer in modelling terms to be vaccinated therefore reducing the total numbers that can be vaccinated in a 12-hour period. Volumes are lower than expected due to the need for each prescriber to review each individual patient before they can be added to the PSD and are able to have the vaccine. This will affect all delivery models but will have the most impact on the large vaccination centres which will not be able to see as many people as would be expected under a PGD or National Protocol. **Minimum viable numbers have been modelled for this scenario and shared in Appendix A.**

9. All delivery models will need to include **additional prescriber roles** within the POD staffing models, ensuring that enough prescribers are included to review the numbers of patients that are likely to be seen each day. Currently the POD structure does not include any prescribers. In general practice and within trusts hubs more prescribers are available however they will have to be released from other commitments to support with the delivery of vaccinations.

10. The prescriber takes **full accountability and responsibility** for the patient and the members of staff administering the vaccine; unlike in a PGD or National Protocol where staff would be taking responsibility for their own tasks. In practice professions are only likely to take on responsibility for others when that person is known to them and they are aware of their skills and training. It is therefore essential that prescriber is content with taking on this responsibility and that there is no suggestion of expectation for them to take on this role. This should be confirmed with each prescriber at the start of a vaccination session.

11. Business continuity risks may need to be considered if large numbers of doctors are required to support in large numbers of vaccination centres as they would be removed from normal work.

12. To progress the operationalising of the solution in a rapid timeframe the following actions are deemed key to supporting implementation:

- A standardised template for the PSD has been developed by the clinical workstream and this is available in Appendix B.

- A rapid review of suggested staffing models has concluded and the preferred model for large vaccination sites has been developed. This includes at least 2 prescribers per POD within the POD model for the initial wave of large vaccination models where the vaccine will be administered under a patient specific direction. An additional model for Trust hubs has looked at different staffing models and opening times, allowing trusts the flexibility to operate the model most suited to their staffing mix and availability, whilst achieving the minimum number of 200 vaccinations per day to ensure low wastage. These options are detailed in Appendix A

  These should be reviewed as soon as possible by local teams with the aim of freeing up prescribers to support with vaccinations in the initial period until the PGD/National Protocol is available. To note additional staff will be required to cover the 12-hour shift, breaks, illnesses and any other absences.

- All staff working within the any of the above models will still be required to complete the relevant vaccine specific training. As this training module cannot be completed until the regulation 174 healthcare professional fact sheet is available it is not possible to train staff in advance of this being published following MHRA authorisation; therefore, the training burden, this places onto staff will need to be factored into any agreed start date for vaccinations locally.

- The clinical workstream nationally, will also ensure rapid engagement with professional groups and regulators so that staff will have confidence in the approach and the vaccine and feel they have sufficient information to enable them to write a patient specific direction.

- Work is taking place Nationally with the tech and data workstream with IT suppliers so that a line is included in the point of care system that allows the user to identify the legal basis for vaccine administration and indicates that the prescriber has approved the administration of the vaccine for that patient.

- Local organisations must ensure that they adhere to their usual clinical governance policies and procedures and associated arrangements. In addition, Chief Pharmacists for each organisation must be fully engaged in the development and sign off for each PSD that is developed.

Background on the Human Medicines Regulations

13. 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.

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

15. 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)

16. The regulations do not permit nurses, or other registered health care 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)

17. There are some specific exemptions from medicines legislation which may apply in limited circumstances e.g. administration of certain parenteral medicines such as adrenaline that can be administered in an emergency without the directions of a prescriber or in the case of occupational health services the legislation allows for the supply and/or administration of medicines by registered nurses as specified in a written instruction signed by a medical practitioner.

Instruction Types

18. **Patient Specific Direction (PSD)** is an instruction from a prescriber i.e. a doctor, dentist, or independent non-medical prescriber for medicines to be supplied and/or administered to a named patient after the prescriber has assessed the patient on an individual basis.

19. A prescriber will need to give an authorised instruction to administer a medicine to a list of individually named patients where each patient on the list has been individually assessed by that prescriber. The prescriber must have adequate knowledge of the patient's health and be satisfied that the medicine to be administered serves the individual needs of each patient on that list.

20. There is no restriction in law as to who can administer the medicine under a PSD however the prescriber has a duty of care and is professionally and legally accountable for the care, he/she provides, including tasks delegated to others. Therefore, the prescriber must be satisfied that the person to whom practice is delegated has the

qualifications, experience, knowledge and skills to provide the care or treatment involved.

21. A PSD is used for administration of medicines only. A PSD for the supply of medicines is classified as a prescription form. This form is a legal document and supply must comply with the legislation of the validity of prescriptions.

22. **Patient Group Directions (PGDs)** are written instructions for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment. They provide a legal framework that allows the supply and/or administration of a specified medicine(s), to a pre-defined group of patients needing prophylaxis or treatment for a condition described in the PGD, without the need for a prescription or an instruction from a prescriber.

23. PGDs need to include the name of the authorised, registered health professional using them and the registered healthcare professional must be trained in the use of the PGD.

24. PGDs can only be used by those registered health care professionals as listed in the legislation. These are: chiropodists and podiatrists, dental hygienists, dental therapists, dieticians, midwives, nurses, occupational therapists, optometrists, orthoptists, orthotists and prosthetists, paramedics, pharmacists, physiotherapists, radiographers and speech and language therapists.

25. Registered healthcare professionals using a PGD must have been assessed as fully trained and competent to use them and must comply with the standards set by their professional regulatory body.

26. PGDs must be authorised by an appropriate authorising body in line with the Human Medicines Regulations. For NHS Services this must be a CCG, Local authority, Public Health England or NHS England and Improvement.

27. PGDs can usually only be used for licensed medicines. The recent amendment to the regulations (October 2020) allows the registered healthcare workforce that already operates under PGDs to deliver vaccinations to continue to do so in the case of an unlicensed or temporarily authorised COVID-19 vaccine.

28. The COVID-19 Vaccine PGD is currently being developed by Public Health England and will follow an expedited process for development and publication once the required vaccine characteristic details are published.

29. A **National Protocol** is a new type of instruction that was introduced to support the expanded influenza and COVID-19 Vaccination Campaign. This is a new legal mechanism which has been put in place following amendment of the Medicines Regulations.
30. The protocol needs to be authorised in law by the Secretary of State for Health, it will allow those who are registered healthcare professionals who cannot operate under a PGD, and those who are not registered healthcare professionals, to safely administer a licensed or temporarily authorised COVID-19 or influenza vaccine.

31. This protocol is being developed by PHE and will be written similarly to a PGD and would provide the flexibility to define the training and competence requirements of vaccinators. It also allows the process of administration to be split into its component parts i.e. clinical assessment and consent, preparation of the vaccine and administration of the vaccine.

32. All these stages can be done by one competent person (the registered healthcare professional) but in the case of large vaccination centres these tasks can be split with each person trained and authorised to complete their specific task as defined in the protocol. The clinical assessment and consent process must be undertaken by a registered healthcare professional and the preparation of the vaccine must only be undertaken and overseen by those health care professionals trained in aseptic technique and have the skills for dilution and drawing up as required by the vaccine.

Staff Vaccinations

33. Administration of influenza or COVID-19 vaccine by an organisation to employees, including peer-to-peer vaccination, is provision of an occupational health service (OHS). Medicines can be supplied or administered in the course of an OHS by a registered nurse acting in accordance with the written and signed instruction of a doctor – this instruction is commonly called a **written instruction**.

34. OHS are not a regulated activity and so are not registered with the CQC. Therefore, in accordance with the current legislation PGDs cannot be used by independent providers of OHS but can be used by NHS organisations to vaccinate their own staff.

35. The use of a **written instruction** allows medicines to be provided under an exemption to the regulations which is applicable to OHS. Under the exemption registered nurses can be instructed to administer a medicine. This exemption cannot be used by any other registered healthcare professional however in October 2020, the Regulations were amended to allow occupational health vaccinators (that is registered nurses, midwives, nursing associates; operating department practitioners, paramedics or physiotherapists and pharmacists) who are employed or engaged by a person operating an occupational health scheme to administer influenza or coronavirus vaccines as part of an NHS Body or Local Authority (LA) occupational health scheme in accordance with the written directions of a doctor. This amendment is time-limited to April 2021.

36. This amendment only applies to an NHS Body or local authority operating an occupational health scheme and occupational health vaccinators (as listed in the legislation) other providers such as independent occupational health providers cannot use this amendment.

Delivery Models for COVID-19 Vaccines

37. Table 1 on the following page shows the various types of instructions and whether these can be used for the proposed COVID-19 delivery models, including the use of roving vaccinators in the community.

Legal Mechanism	Who?	Large Vaccination Centre	Community Vaccination Centres	Roving Model	NHS Trust Model for vaccinating Staff
Patient Specific Directions	**Prescribers only** doctors, independent nurse or pharmacist prescribers Non-registered and registered staff can work under a patient specific direction if prescriber agrees and takes full accountability.	No prescribers are available in the current POD model – will need adaption to include prescribers.	No Prescribers in the current POD model – will need adaption to include prescribers. Can be used in General practice where prescribers could be available, and teams are known to them.	Could be used for general practice led models but not preferred	Not preferred as requires a prescriber to review each member of staff.
Patient Group Directions	**Registered Health Care Professionals** as defined by the law: **non-registered staff are not able to administer under a PGD as the task cannot be delegated.**	Cannot be used in current POD model which uses an expanded workforce. Can be only be used where healthcare professionals are carrying out all tasks in the POD.	Cannot be used in current POD model which uses an expanded workforce. Can be used where registered healthcare professionals are carrying out all tasks in the POD e.g. primary care delivery by practice nurses. Or community pharmacy	Used by registered healthcare professionals in the roving model.	Can be used by an NHS body but **not independent** Occupational Health Providers.
National Protocol	2-step process that enables tasks to be split between: • **non-registered healthcare workers** (e.g. new recruits to NHS and HCW) • **Registered health care professionals.**	Should be used under current POD structure which uses an expanded workforce.	Should be used under current POD structure which uses an expanded workforce. Could be used in primary care if non- registered staff needed to administer the vaccine alongside registered healthcare professionals.	Nonregistered staff are not currently in the roving model due the extra skills required for treating vulnerable patients in care homes.	Could be used but not specifically defined in law.
Written Instruction*	**Registered Healthcare Professionals** only within an occupational health setting. i.e. Registered nurses, midwives, nursing associates, operating department practitioners, paramedics or physiotherapists and pharmacists.	Cannot be used	Cannot be used	Cannot be used	Must be used by private Occupational Health teams and NHS organisations providing OHS to other Trusts if operating an occupational health service

Table 1 summarising types of instruction and which delivery model they can be used within and who is able to work under them.

**Whilst a Written Instruction could be used, NHS and Social Care Staff will be included as a patient cohort so can be vaccinated under a PGD or National Protocol so a written instruction wouldn't be required for receiving the covid vaccine.*

Use of a Patient Specific Direction – Key issues for Consideration

38. As discussed, it is unlikely that either the Patient Group Direction or the National Protocol will be in place in time for the first vaccinations; these are the primary types of instructions that can be used to allow non-prescribers to administer the COVID-19 vaccine within the delivery models developed. The only other solution would be to use a PSD; however, this solution is not without its drawbacks and we will need to ensure that processes are put in place to ensure use is time limited and does not impact on staff and patient safety.

39. It must be noted that in order to be able to issue a patient specific direction the prescriber must have sufficient information on the vaccine to enable them to confidently write the instruction and 'prescribe' the vaccine for each individual patient. This requires sufficient time for them to familiarise themselves with the contents of healthcare professional fact sheet once published (SPC equivalent under the 174 regulation for temporary authorisation of the vaccine) and the updated chapter in the Green Book and / the e-learning module if available.

40. The vaccine whilst authorised is still not fully licensed. Therefore, the types of prescribers that can issue a patient specific direction for the vaccine are medical doctors and independent nurse or pharmacist prescribers only. All prescribers are required to work within their own area of competence only and those unfamiliar with immunisations may not feel they are competent to prescribe the vaccine and this decision must be supported.

41. Other non-medical prescribers with prescribing rights are not able to prescribe unlicensed medicines so are not able to issue a PSD covering the COVID-19 Vaccine. Dentists can only prescribe certain medicines to NHS patients that are listed in the BNF Dental formulary and are not able to prescribe or issue a PSD for an unlicensed medicine.

42. Key issues that use of a PSD will impact on are:

    a) **Throughput and volumes of delivery:** Volumes will be lower than expected due to the need for each prescriber to review each individual patient before they can be added to the PSD and are able to have the vaccine. This will affect all delivery models but will have the most impact on the large vaccination centres which will not be able to see as many people as would be expected under a PGD or National Protocol. Minimum viable numbers have been modelled and shared in the appendix. It should be noted that cover will be required for 12hrs/day and break cover.
    b) **Types of workforce required to support with administration of the vaccine**: All delivery models will need to include prescribers within staffing models and will need to make sure that enough prescribers are included to review the numbers of patients that are likely to be seen each day. Currently the POD structure does not include any prescribers; however, in general practice and within trusts there are more prescribers available however they will have to be freed up to support with the delivery of vaccinations.

c) **Professional responsibility and accountability**: A key issue to consider is that in the case of a PSD the prescriber takes full accountability and responsibility for the patient and the members of staff administering the vaccine; unlike in a PGD or National Protocol where staff would be taking responsibility for their own tasks. In practice professions are only likely to take on responsibility for others when that person is known to them and they are aware of their skills and training. It is therefore essential that the prescriber is content with taking on this responsibility and that there is no suggestion of expectation for them to take on this role.

d) **Business as usual work:** there are business continuity risks if large numbers of doctors are required to support in large numbers of vaccination centres as they would be removed from normal work, whether this is on the wards or in primary care and the impact of this will need to be considered.

Recommendations:

43. In order to overcome the issues above it is suggested that the following safeguards are put in place:

- A review of all staffing models developed locally to include at least 2 - 3 prescribers per POD within the POD model for large vaccination models where the vaccine will be administered under a patient specific direction. If anyone other than the prescriber is carrying out the clinical assessment and consent process the prescriber must be able to assure themselves of the process being undertaken, and the ability of the assessing individual to carry out and record the same reliably. The prescriber must be able to review the person being assessed prior to vaccination and intervene should this be necessary. Usually, the clinical assessment would be carried out by the prescriber.

- To re-model local numbers to ensure adequate time to carry out the additional task of prescribing. An extra 3 minutes has been included in the modelling for this additional step.

- Ensure adequate engagement with the local professional groups and their regulators so that they have confidence in the approach and vaccine and feel they have sufficient information to enable them to write a patient specific direction.

- A phased approach to numbers of vaccinations given through the large vaccination centres could be considered in the early weeks so prescribers can be freed up in sufficient numbers whilst reducing the impact on business-as-usual work.

- A PSD must be a written authorisation, this is not written in law but is recommended by the Medicines and Healthcare products Regulatory Agency (MHRA) and is good practice for groups of patients. It should include the following information as a minimum:

    - Name of patient and/or other individual patient identifiers

- Name, form and strength of medicine (generic or brand name where appropriate)
- Route of administration
- 1st or 2nd Dose
- Date of treatment
- Signature of prescriber/GMC number

An example form is available here or in the appendix for adaptation or adoption locally.

- PSDs will need to be supported by a local procedures or guidelines to support safe supply and/or administration of the medicine by an appropriately trained and competent healthcare professional. Prescribers and anyone administering or supplying medicines must ensure that they adhere to their employer clinical governance policies and procedures and associated arrangements.

- It is advised that local organisations discuss the use of a PSD with their Chief Pharmacist or Head of Medicines Management if they are unclear about the legal basis for their use and the arrangements that should be in place.

Appendix A – updated POD model to include prescribers in large vaccination centres and hospital hubs

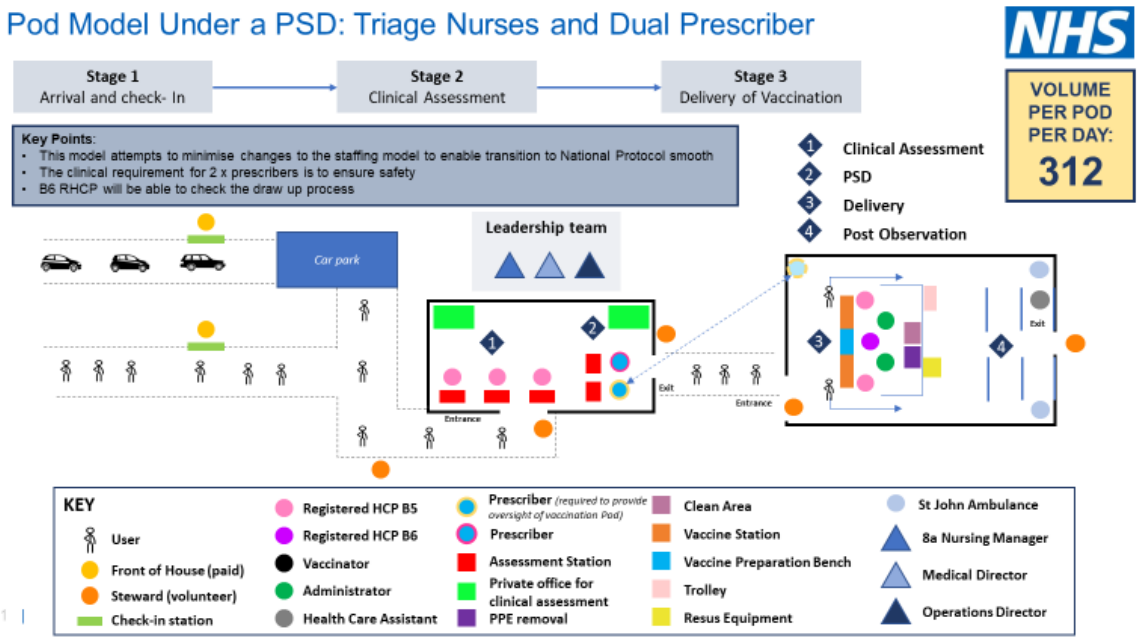
Vaccination centre model

Four scenarios were modelled and two were removed as they were either not delivering the minimum volume requirements, or they were not operationally deliverable. The remaining model uses mainly prescribers so would have the most impact on business-as-usual work.

Therefore, the preferred model delivers **312 vaccines per day** through a revised pod model (60% of optimum capacity)

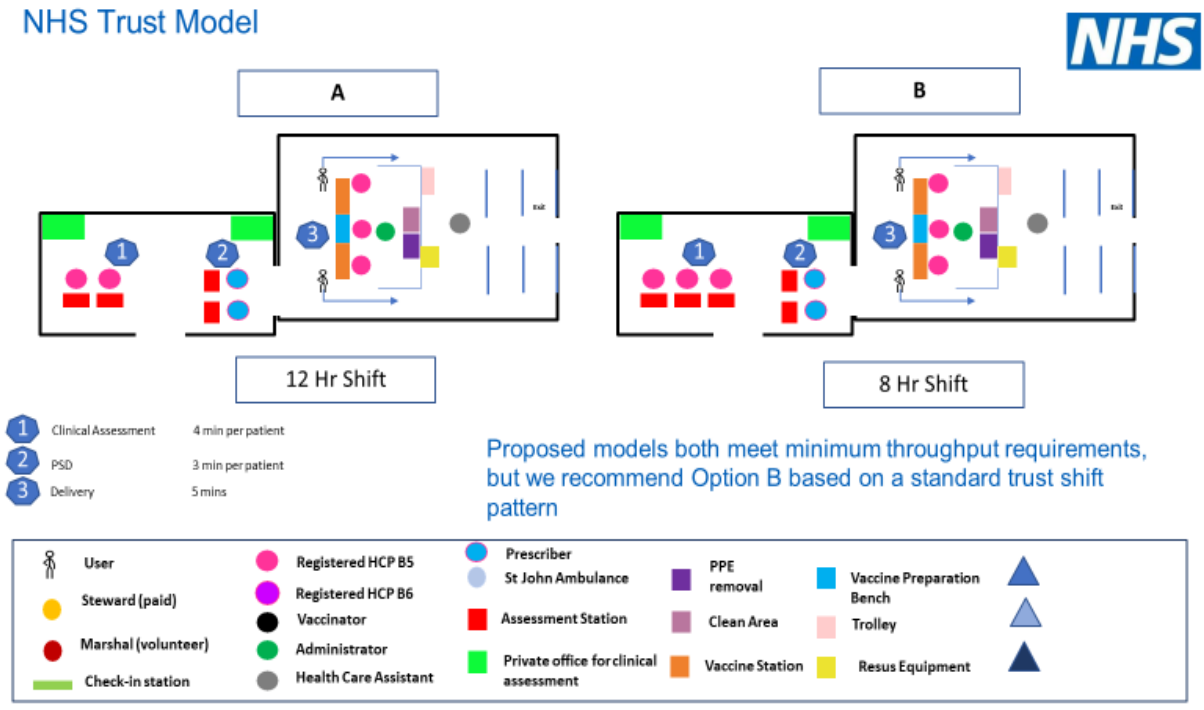
This is based on a minimum of:

3 x RCHPs for clinical triage (clinical assessment)
2 x Prescribers (PSD) – one of whom maybe required to oversee administration (at the start of the session) and support with the PSD review.
2 x RHCP to vaccinate



NHS Trust Model

Two scenarios were modelled both are shown below for local adaption. To note that as the prescriber will need to oversee both the clinical assessment and the administration of the vaccine therefore it is recommended that prescribers are situated where they can access both teams.



Appendix B - Individual Patient assessment to assist the creation of Patient Specific Direction for the administration of Pfizer BioNTech COVID-19 mRNA Vaccine BNT 162b2 [to be adapted]

Name		**Date of birth**	
Surname			
Home Address			
		Postcode	

Assessors Name or ID Number	**ID No**			
Please ask the person presenting for vaccination these questions and record that they have received appropriate counselling as to the purpose of the vaccine and side effects				
Have you had any vaccination in the last 7 days?	**No**	☐	**Yes**	☐
Are you currently unwell with fever?	**No**	☐	**Yes**	☐
*** Have you ever had any serious allergic reaction?**	**No**	☐	**Yes**	☐
***Have you ever been prescribed an adrenaline autoinjector such as an epipen?**	**No**	☐	**Yes**	☐
Are you, or could you be pregnant, breastfeeding or planning to become pregnant in the next three months?	**No**	☐	**Yes**	☐
# Are you or have you been in a trial of a potential coronavirus vaccine?	**No**	☐	**Yes**	☐
Are you taking anticoagulant medication, or do you have a bleeding disorder	**No**	☐	**Yes**	☐

If any of the boxes in red are ticked, then a further review by the prescriber must take place. If you or the person presenting are uncertain as to the response or counselling, they receive they must be brought to the attention of the prescriber. See later for specific advice.

Patient Specific Direction (PSD) for the administration of Pfizer BioNTech Coronavirus Vaccine XXX to Adults by Non prescribers suitably trained in Vaccination.[to be adapted]

Date of PSD:

The patient named below is eligible to receive

Covid-19 mRNA Vaccine BNT 162b2 0.3mls Intra-Muscular (IM) Injection

in accordance with Public Health England Immunisation against infectious disease (Green Guide) and JVCVI recommendations for the purpose of protection against COVID-19.

Patient Details

Name		**Date of birth**	
Surname			
Home Address			
		Postcode	

ONE DOSE OF Covid-19 mRNA Vaccine BNT 162b2 – 30µg in 0.3mls of the diluted vaccine by Intra-Muscular injection.

Vaccination Centre/ PCN /Hospital Hub Name and Address

Name of Prescriber	Signature of Prescriber	Date and Registration Number

This PSD will expire within 7 days of signature

Name of Vaccine Administrator (I.e. person giving the vaccine)	Signature of Administrator	Date

Notes for Prescriber/Clinician

The prescriber should be aware of the MHRA Conditions of authorisation and the vaccine's contraindications, together with the advice from JCVI regarding the avoidance of pregnancy within 2 months of the second dose of vaccine: https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19

** Any person with a history of immediate-onset anaphylaxis to a vaccine, medicine or food should not receive the Pfizer BioNTech vaccine. A second dose of the Pfizer BioNTech vaccine should not be given to those who have experienced anaphylaxis to the first dose of Pfizer BioNTech vaccination.*

 # Any person who has been involved in a coronavirus trial should be advised to contact the trial organisers to seek guidance on whether or when vaccination should take place.

Taking anticoagulants or a bleeding disorder is not a contraindication to intramuscular injections, but the recipient needs to be aware that they may have increased bruising and be advised to apply pressure. Those with bleeding disorders may wish to time vaccination to occur shortly after appropriate therapies. Please also refer to the relevant chapter in the Green Book – Chapter 14a. https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a

References

1) Specialist Pharmacy Services: https://www.sps.nhs.uk/articles/patient-specific-directions-qa/
2) National Institute for Health and Care Excellence (NICE) 2017: https://www.nice.org.uk/guidance/mpg2
3) Royal College of Nursing: https://www.rcn.org.uk/clinical-topics/medicines-management/patient-specific-directions-and-patient-group-directions#:~:text=A%20Patient%20Specific%20Direction%20(PSD,patient%20on%20an%20individual%20basis.
4) GMC: https://www.bma.org.uk/advice-and-support/gp-practices/prescribing/patient-group-and-patient-specific-directions
5) Royal Pharmaceutical Society of Great Britain: https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Professional%20standards/SSHM%20and%20Admin/Admin%20of%20Meds%20prof%20guidance.pdf?ver=2019-01-23-145026-567
6) South Staffordshire Joint Formulary example flu patient specific direction for group of patients: http://www.southstaffordshirejointformulary.nhs.uk/docs/ccg_pgds/Patient%20specific%20directions/Patient%20specific%20direction%20template-Flu%20PSD%20Aug%2015%20V3%2027%20Sept%2017.pdf
7) Public Health England: Immunisation against infectious diseases: https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book
8) MHRA: Regulatory approval of Pfizer / BioNTech vaccine for COVID-19 - GOV.UK (www.gov.uk)