



Enhanced Service Specification

COVID-19 vaccination programme 2020/21

Enhanced Service (ES) Specification

COVID-19 vaccination programme

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2.0	New 5.2 Amendments to 9.2

Equalities and health inequalities statement

"Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it;
- given regard to the need to reduce inequalities between patients in access to, and outcomes from, healthcare services and in securing that services are provided in an integrated way where this might reduce health inequalities."

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As of November 2020, several potential vaccines for COVID-19 are in the later stages of phase III trials. If one or more are authorised for use, the NHS needs to be ready to start immediate vaccination.

The NHS is a global leader in achieving high levels of vaccination coverage. The UK has one of the world's highest levels of public support for making a safe COVID-19 vaccine available. Through their place in local neighbourhoods, GP practices are well placed to reach out to our diverse communities and avoid inequalities in access. This means general practice will have an important role in a potential COVID-19 vaccination programme, alongside other providers.

Our plans for deployment of a COVID-19 vaccine build on the tried-and-tested rollout plans for influenza vaccine, which we deploy every autumn. Given the uncertainty over whether, and when, a vaccine may be approved, we are planning to be ready from any date from December, with mass vaccination more likely in the new year.

The BMA General Practitioners Committee in England has now agreed with NHS England that the general practice COVID-19 vaccination service will be commissioned in line with agreed national terms and conditions as an enhanced service directed by NHS England (ES). The ES will be offered to all GP practices and will not be capable of amendment by CCGs. This specification provides GP practices with sufficient information to commence planning whilst also noting that requirements and timescales will be subject to change.

This ES relates to COVID-19 vaccinations only.

Other formats of this ES specification are available on request. Please send your request to: england.cov-primary-care@nhs.net

1 Introduction

- 1.1 This ES¹ is subject to amendments from time to time as the COVID-19 vaccination programme develops.
- 1.2 This ES has been agreed between NHS England and the British Medical Association (BMA) General Practitioners Committee (GPC) in England. It is a national specification that cannot be varied locally. NHS England will agree any future amendments to the terms of this ES specification with the GPC unless it is necessary to amend it in line with recommendations or decisions of the JCVI, MHRA, vaccine manufacturers or Ministers, where NHS England will discuss the required changes with the GPC.
- 1.3 This ES is offered by the Commissioner (NHSE) to all General Medical Services, Personal Medical Services and Alternative Provider Medical Services contract holders.
- 1.4 An ES is designed to cover enhanced aspects of clinical care, all of which are beyond the scope of essential and additional services. No part of this ES specification by commission, omission or implication defines or redefines essential or additional services.
- 1.5 All GP practices are offered the opportunity to sign up to this ES provided they meet the requirements of this specification. By signing up to deliver this ES, a GP practice agrees to a variation of its primary medical services contract to incorporate the provisions of this ES. The provisions of this ES are therefore deemed a part of the GP practice's primary medical services contract.
- 1.6 On agreement to participate in this ES, a GP practice will work together with others in a collaborative manner and in accordance with the collaboration requirements at paragraphs 5 and 6 of this ES to deliver all aspects of this specification. The GP practice, in collaboration with other GP practices in the PCN Grouping, must have the ability to deliver this ES during the hours of 8am to 8pm, 7 days per week and including on bank holidays. The Commissioner (NHSE) will inform practices where this is required, based on the need to

¹ Section 7A functions are arrangements under which the Secretary of State delegates to NHS England responsibility for certain elements of the Secretary of State's public health functions, which add to the functions exercised by NHS England under the National Health Service Act 2006 ("the 2006 Act"). They are made under section 7A of the 2006 Act. They are described as 'reserved functions' which are not covered by the 'enhanced services delegated to CCG' category in the delegation agreement. NHS England remains responsible and accountable for the discharge of all the Section 7A functions. As this vaccination is defined as a Section 7A function, this agreement cannot be changed or varied locally.

maximise vaccinations when the supply of vaccine is available to reduce waste and in support of the mass vaccination of the population.

- 1.7 A GP practice need not be a member of an established Primary Care Network to participate in this ES. GP practices are expected to collaborate with neighbouring practices and established Primary Care Networks in a 'PCN Grouping' to deliver all aspects of this ES. All collaborating GP practices, whether they are members of an established Primary Care Network or not, will be expected to sign up to a COVID-19 ES Vaccination Collaboration Agreement as described in this ES. Practices should refer to the definition of PCN Grouping in paragraph 2.2.10 to see exactly how the term is used in this ES.
- 1.8 Where this ES sets out a requirement or obligation of a PCN Grouping, each GP practice of a Primary Care Network together with neighbouring GP practices as described above, is responsible for ensuring the requirement or obligation is carried out on behalf of that PCN Grouping.

2 Commonly Used Terms

- 2.1 This specification is referred to as this “**ES**”.
- 2.2 In this ES:
 - 2.2.1 the “**Commissioner (NHSE)**” refers to the organisation with responsibility for contract managing these ES arrangements and this is NHS England;
 - 2.2.2 “**COVID-19 ES Vaccination Collaboration Agreement**” refers to the agreement entered into by GP practices, including those that are members of an established Primary Care Network, and which incorporates the provisions that are required to be included in a COVID-19 ES Vaccination Collaboration Agreement in accordance with paragraph 6.4;
 - 2.2.3 a “**Designated Site**” refers to premises nominated by the PCN Grouping and approved by the Commissioner (NHSE) in accordance with the Designation Process as the premises from which the vaccination will be administered to Patients;
 - 2.2.4 the “**Designation Process**” refers to the General Practice Site Designation Process (which includes the site designation criteria) which is undertaken to ensure that any site delivering vaccinations

under this ES meets the specified site criteria and which may be updated and amended as required from time to time and is an integral part of this ES. A copy of Designation Process (as may be amended from time to time) is published on <https://www.england.nhs.uk/coronavirus/publication/preparedness-letters-for-general-practice/>;

- 2.2.5 a “**GP practice**” refers to a provider of essential primary medical services to a registered list of Patients under a General Medical Services contract, Personal Medical Services agreement or Alternative Provider Medical Services contract who has agreed with the Commissioner (NHSE) to deliver this ES;
- 2.2.6 “**JCVI**” means the Joint Committee on Vaccination and Immunisation;
- 2.2.7 “**MHRA**” means the Medicines and Healthcare products Regulatory Agency;
- 2.2.8 “**Ministerial Decision**” means a decision issued by the Secretary of State for Health and Social Care;
- 2.2.9 “**Patient**” means those patients eligible to receive the vaccination in general practice and who fall under the cohorts listed at paragraph 9.2; and
- 2.2.10 “**PCN Grouping**” refers to the group of GP practices which collaborate to deliver the services under this ES, which may include established Primary Care Networks, and additional neighbouring GP practices and/or other groups of GP practices working together.

2.3 In this ES words importing the singular include the plural and vice versa.

3 Background and Duration

3.1 This ES is for the Commissioner (NHSE) to commission the provision of COVID-19 vaccinations to Patients. This ES begins on 8 December 2020 and shall continue until 31 August 2021 unless it is terminated in accordance with paragraph 3.2.

3.2 This ES may be terminated on any of the following events:

- 3.2.1 automatically when the COVID-19 vaccination programme comes to an end;

- 3.2.2 the Commissioner (NHSE) is entitled to require that the GP practice withdraws from this ES as set out in this ES;
 - 3.2.3 the Commissioner (NHSE) terminates this ES by giving not less than 42 days' notice to the GP practice;
 - 3.2.4 the Commissioner (NHSE) is entitled to terminate this ES by giving not less than 42 days' notice where the GP practice has failed to comply with any reasonable request for information from the Commissioner (NHSE) relating to the provision of the services pursuant to this ES; or
 - 3.2.5 the GP practice terminates this ES in accordance with paragraph 13.4.
- 3.3 GP practices should note that delivery of the vaccines and the administration of the vaccinations will not begin until the date notified under paragraph 9.1.
- 3.4 The Patients eligible for vaccination under this ES are set out in paragraph 9.2. Vaccinations must only be administered to Patients.
- 3.5 GP Practices will be provided with vaccines to deliver this ES. The GP practice, together with the other GP practices in the PCN grouping shall be **considered joint and several owners of the vaccine**. GP practices should understand that the vaccine availability and supply is challenging and may be constrained and is subject to change over time. The Commissioner (NHSE) is likely to need to make allocation decisions regarding the vaccine during the term of this ES. Allocation decisions could include prioritising GP practices' PCN Groupings or the use of a particular type of vaccine. GP practices support in relation to stock forecasting, use and ordering is important to this ES.
- 3.6 Please note that this ES will be updated from time to time as the vaccination programme develops and is subject to Ministerial Decision. This may include amendments to eligible cohorts and prioritisation of cohorts of Patients, and on-going adaptation of the requirements within this ES.
- 3.7 Details of this ES and the wider COVID-19 vaccination programme can be found at <https://www.england.nhs.uk/coronavirus/covid-19-vaccination-programme/>.

4 Process

- 4.1 GP practices must sign up to participate in this ES before 23:59 on 7 December 2020 unless the Commisisoner (NHSE) agrees otherwise in certain circumstances. GP practices must record their agreement to participate in this

ES in writing to the Commissioner (NHSE). Local CCGs will collate the written agreement of each GP practice to participate in this ES on behalf of the Commissioner (NHSE).

- 4.2 All GP practices participating in this ES must have nominated and have access to a Designated Site from which vaccinations must be administered unless there is a specific reason not to (for example, the medical condition of a Patient is such that, in the reasonable opinion of the GP practice attendance on the Patient is required and it would be inappropriate for the Patient to attend at the Designated Site, in which case the GP practice must provide the vaccination to the Patient at another location). The Commissioner (NHSE) may be able to support GP practices to work with community partners and other local providers as appropriate to identify pragmatic local solutions to vaccinating these Patients. GP practices must make arrangements to vaccinate Patients resident in care homes at their care home of residence.
- 4.3 Payment under this ES is conditional on GP practices:
- 4.3.1 entering into this ES, including any variations and updates;
 - 4.3.2 complying with the requirements of this ES; and
 - 4.3.3 completing the course of vaccinations to Patients (unless exceptional circumstances apply as set out at paragraph 11.3).
- 4.4 A GP practice's participation in this ES shall only continue for so long as it is in compliance with its terms.

5 Collaboration Requirements: General

- 5.1 Each GP practice participating in this ES will:
- 5.1.1 co-operate with others in so far as is reasonable, including any other person responsible for the provision of services pursuant to this ES, in a timely and effective way and give to each GP practice in its PCN Grouping and outside of its PCN Grouping (where appropriate) such assistance as may reasonably be required to deliver the services under this ES;
 - 5.1.2 openly, honestly and efficiently share information with relevant other parties including the GP practices in its PCN Grouping and outside of its PCN Grouping (where appropriate) that is relevant to the services, aims and objectives of this ES;

- 5.1.3 comply with any reasonable request for information from the Commissioner (NHSE) relating to the provision of the services pursuant to this ES;
 - 5.1.4 have regard to all relevant guidance published by the Commissioner (NHSE) or referenced within this ES;
 - 5.1.5 comply with all clinical protocols giving explicit consideration to contraindications and any guidance around concurrent administration of vaccinations (e.g influenza vaccinations);
 - 5.1.6 take reasonable steps to provide information (supplementary to national communications) to Patients about the services pursuant to this ES, including information on how to access the services and any changes to them; and
 - 5.1.7 ensure that it has in place suitable arrangements to enable the lawful sharing of data to support the delivery of the services, business administration and analysis activities.
- 5.2 GP practices will need to work together as a joint enterprise and the Patients who attend for COVID-19 vaccinations will attend what is deemed to be a temporary single medical practice for the purpose of regulation 3(8)(b) of the Human Medicines Regulations 2012.

6 Collaboration Requirements: PCN Groupings

- 6.1 GP practices are expected to work in their PCN Grouping to co-ordinate and deliver the vaccinations at scale and in line with the requirements set out in this ES.
- 6.2 GP practices are expected to participate in relevant PCN Grouping meetings relating to the COVID-19 vaccination programme, in so far as is reasonable.
- 6.3 All GP practices participating in this ES must ensure that they collaborate with other GP practices in the PCN Grouping in accordance with the Designation Process and agree (prior to participating in the ES) the site to be nominated as the Designated Site for delivering vaccinations under this ES.
- 6.4 All GP practices must have in place a COVID-19 ES Vaccination Collaboration Agreement signed by all collaborating GP practices in its PCN Grouping by no

later than the day before the date of the first administration of the vaccinations that sets out the clinical delivery model (i.e. how clinics are delivered and responsibility is shared between the GP practices within the PCN Grouping) deployed by the PCN Grouping and as a minimum contains additional provisions in relation to the following:

- 6.4.1 appropriate arrangements for Patient record sharing in line with data protection legislation;
- 6.4.2 appropriate arrangements for reporting of activity data, vaccine stock (to include stock use and stock forecasting which must include the brand of vaccine delivered and required by the PCN grouping), available capacity and submission of required data to the Commissioner (NHSE). Where appropriate access to mandatory national systems is required, these will be made available free of charge;
- 6.4.3 appropriate arrangements for communicating with Patients, including but not limited to call/re-call;
- 6.4.4 arrangements for any sharing and deployment of staff as agreed by the PCN Grouping in relation to the efficient delivery of the services pursuant to this ES;
- 6.4.5 financial arrangements between the collaborating GP practices and, if relevant, financial arrangements relating to other healthcare providers (such as community pharmacies) outside of its PCN Grouping involved in local delivery of this ES;
- 6.4.6 arrangements in relation to use of the Designated Site and any other relevant premises (as required);
- 6.4.7 sub-contracting arrangements (as required);
- 6.4.8 a lead contact email address for the PCN Grouping which shall be supplied to the Commissioner (NHSE) for use in disseminating information urgently; and
- 6.4.9 appropriate indemnity arrangements. The Clinical Negligence Scheme for General Practice (CNSGP) provides clinical negligence indemnity cover for all staff engaged by a GP practice under the CNSGP Regulations. It covers NHS activities delivered by a Part 4 contractor under a Primary Medical Services contract (including an NHS

standard contract with Schedule 2L), a Primary Medical Services sub-contractor, or the provision of 'Ancillary Health Services' for a Part 4 contractor or Primary Medical Services sub-contractor such as an Enhanced Service. Cover under CNSGP is not restricted to a GP practice's registered patients so would apply to the provision of an Enhanced Service (ES) by a GP practice to a person such as practice staff who are not on the registered list of that GP practice.

- 6.5 The Commissioner (NHSE) will publish a template COVID-19 ES Vaccination Collaboration Agreement on <https://www.england.nhs.uk/gp/investment/gp-contract/>, which the PCN Grouping may wish to use and adapt for the purpose of delivering this ES.
- 6.6 PCN Groupings will be expected to collaborate with any national and regional Sustainability and Transformation Partnership operations centre in relation to vaccine stock forecasting and ordering arrangements that are put in place, which will include complying with the processes and requirements set out in any relevant Standard Operating Procedures. This may include, for example, providing daily updates on actual stock use, vaccines delivered (including the brand of vaccine used) and forecasted requirements. PCN Groupings may need to submit information using the national Foundry system.
- 6.7 PCN Groupings will need to plan service delivery arrangements in line with stock forecasting and ordering arrangements including:
- 6.7.1 planning clinics according to expected vaccine supply;
 - 6.7.2 coordinating required trained staff;
 - 6.7.3 ordering required vaccine and consumables supply within required timeframes;
 - 6.7.4 receiving and safely storing supply; and
 - 6.7.5 amending clinic schedules if there is a disruption to supply and undertaking timely communication of any changes to Patients.

7 Site Designation

- 7.1 All GP practices must collaborate to identify at least one suitable premises from which their PCN Grouping is capable of delivering the requirements of this ES, and on approval of those premises as a Designated Site, from which vaccinations must be administered (unless exceptions apply in this ES).

- 7.2 PCN Groupings must complete the Designation Process so that they can include the name of the Designated Site in their sign-up confirmation in accordance with paragraph 4.1.
- 7.3 The Commissioner (NHSE) shall determine whether any proposed premises meets (and is likely to continue to meet) the requirements of the Designation Process while having regard to issues of Patient access, the geographical distribution of sites and the total number of Designated Sites that can be accommodated within vaccine supply arrangements. The Commissioner (NHSE) shall have regard to the PCN Groupings' preferences. The Commissioner (NHSE) shall have the right to choose between multiple premises put forward by a PCN Grouping.
- 7.4 The Commissioner may invite PCN Groupings to nominate additional sites for designation as Designated Sites. Such sites will also need to comply with the Designation Process and become a Designated Site prior to vaccinations being administered from them.
- 7.5 If it is necessary to amend a Designated Site, the application in accordance with the Designated Process must be undertaken as soon as possible to minimise the impact on the delivery of this ES to Patients.
- 7.6 As the COVID-19 vaccination programme develops, there may be the requirement for additional Designated Sites.
- 7.7 It may be necessary to periodically update the Designated Site designation criteria to reflect changes to the COVID-19 vaccination programme. Where a change occurs, the amended criteria will be published on <https://www.england.nhs.uk/gp/investment/gp-contract/> and GP practices will be notified in writing and through the Primary Care Bulletin (as referred to in paragraph 10). Designated Sites must continue to (at least) meet the Designated Site designation criteria in place at the time of their application and approval by the Commissioner.
- 7.8 GP practices are responsible for ensuring that the quality and connectivity of internet broadband at the Designated Site is sufficient to support access to the point of care system 7 days a week between the hours of 8am and 8pm.
- 7.9 Where the Commissioner (NHSE) requires the GP practices to put into place any reasonable security requirements regarding the vaccine and the Designated Site, the GP practice shall make all reasonable efforts to ensure that these requirements are put into place as soon as possible.

8 Sub-contracting Arrangements

- 8.1 The Commissioner (NHSE) acknowledges that to deliver the services pursuant to this ES, a GP practice may require the ability to sub-contract the delivery of the required clinical services to another GP practice in the PCN Grouping or another party. Where a GP practice is considering sub-contracting arrangements related to the provision of services under the ES, the GP practice must comply with the requirements set out in the statutory regulations or directions that underpin its primary medical services contracts in relation to sub-contracting, which will also apply to any arrangements to sub-contract services under the ES.
- 8.2 GP practices and their PCN Grouping must make available, on request from the Commissioner (NHSE), any reasonable information relating to the sub-contracting arrangements and reporting information relating to the delivery of ES.
- 8.3 Insofar as the sub-contracting of the clinical services pursuant to this ES is necessary to deliver these services and is compliant with the primary medical services legal and contractual requirements, the Commissioner (NHSE) will not object to the sub-contracting.

9 Service Delivery Specification²

- 9.1 The requirement to provide vaccinations under this ES will begin on the date to be notified to GP practices in writing by the Commissioner (NHSE). The commencement date for vaccine delivery will not be less than 10 calendar days following notification from the Commissioner (NHSE).
- 9.2 Patients eligible to receive the vaccination in general practice are those Patients who are on the GP practice's registered patient list; are unregistered patients; are registered on another primary medical services practice's list of registered patients, but that primary medical service has not signed up to deliver this ES; or are care home workers or primary medical services workers which are registered on another primary medical services practice's list of patients, but who have been advised by the Commissioner (NHSE) that they may elect to receive the vaccination from the GP practice for convenience; **and** fall under the cohorts listed below. GP practices must deliver the vaccinations to Patients within the cohorts, in the order of the cohorts listed below. The

² GP practices must ensure they have read and understood all sections of this document as part of the implementation of this programme and to ensure understanding of the payment regime.

Commissioner (NHSE) will announce the authorisation of cohorts for vaccination. Vaccination will be permitted to Patients outside of the announced cohort where the GP practice can demonstrate exceptional circumstances, that it is clinically appropriate and where resources would otherwise have been wasted. Patients eligible to receive the vaccination in general practice and the cohorts set out below are as currently defined in published interim guidance and are subject to change (which may include consolidation, expansion and reprioritisation). This paragraph 9.2 is therefore a snapshot in time and accurate as at the date of publication of this ES. Patients eligible to receive the vaccination in general practice and the cohorts will change in line with the JCVI authorised announced eligible Patients and cohorts, which will be available at <https://www.gov.uk/government/groups/joint-committee-on-vaccination-and-immunisation>. GP practices are required to keep up to date with these criteria which will change from time to time and will be notified by NHS England of amendments through the Primary Care Bulletin (as referred to in paragraph 10). The cohorts of Patients referred to above following JCVI advice published on 2 December 2020³ are as follows:

- i. Residents in a care home for older adults and their carers;
- ii. All those 80 years of age and over and frontline health and social care workers ⁴;
- iii. All those 75 years of age and over;
- iv. All those 70 years of age and over and clinically extremely vulnerable individuals;
- v. All those 65 years of age and over;
- vi. All individuals aged 16 years to 64 years with underlying health conditions which put them at higher risk of serious disease and mortality;
- vii. All those 60 years of age and over;
- viii. All those 55 years of age and over; and
- ix. All those 50 years of age and over.

³ <https://www.gov.uk/government/publications/priority-groups-for-coronavirus-covid-19-vaccination-advice-from-the-jcvi-2-december-2020/priority-groups-for-coronavirus-covid-19-vaccination-advice-from-the-jcvi-2-december-2020>

⁴ JCVI will publish guidance describing frontline health and social care workers for this cohort

Implementation should also involve flexibility in vaccine deployment at a local level with due attention to:

- mitigating health inequalities, such as might occur in relation to access to healthcare and ethnicity
- vaccine product storage, transport and administration constraints
- exceptional individualised circumstances
- availability of suitable approved vaccines, for example for specific age cohorts

Operational considerations, such as minimising wastage, may require a flexible approach, where decisions are taken in consultation with national or local public health experts. To be assured that outcome is maximised however, JCVI would like to see early and regular comprehensive vaccine coverage data so that the Committee can respond if high priority risk groups are unable to access vaccination in a reasonable time frame.

9.3 GP practices must liaise with Primary Care Networks which are responsible for delivery of the Enhanced Health in Care Homes provisions in the Network Contract Directed Enhanced Service to ensure that a joined up service is delivered to all PCN-linked Care Homes to be served by the relevant PCN.

9.4 GP practices will not be eligible for payment for the administration of vaccinations outside the announced authorised cohorts unless they are able to evidence exceptional circumstances at the request of the Commissioner (NHSE).

9.5 GP practices must ensure they offer vaccinations to Patients in accordance with paragraph 9.2 and:

9.5.1 GP practices are required to ensure:

- (a) that, in addition to any national call/re-call service, they write, text or call Patients (as appropriate) using standard nationally determined text;
- (b) that they actively co-operate with any national call/re-call service requirements; and
- (c) that they maintain clear records of how they have contacted (including 'called' and recalled) Patients; and
- (d) to support high uptake of vaccinations and minimise vaccine wastage, that they proactively contact Patients for vaccinations. This may include additional contacts over and

above the call/re-call requirements set out in paragraph 9.5.1(a) where appropriate to do so. GP practices are not required under this ES to offer call/re-call to care home residents, and Health and Social Care workers. Where these Patients are easily identifiable, GP practices may wish to offer call/re-call;

- 9.5.2 that vaccinations are not administered where contra-indicated as per JCVI published guidance;
- 9.5.3 that vaccinations must be administered during the period of this ES;
- 9.5.4 that all Patients who receive vaccinations are eligible under the cohorts and suitable clinically in accordance with law and guidance;
 - (a) Informed Patient consent is obtained by a registered healthcare professional and the Patient's consent to the vaccination (or the name of the person who gave consent to the vaccination and that person's relationship to the Patient) must be recorded in the point of care system and in accordance with law and guidance;
- 9.5.5 Patient consent obtained in accordance with paragraph 9.5.4(a) is recorded (as appropriate) for any necessary information sharing with the Commissioner (NHSE) in accordance with data protection law and guidance;
- 9.5.6 that they comply with the Standard Operating Procedures relating to delivery of local vaccination services and continue to meet the designation criteria as set out in the Designation Process;
- 9.5.7 that Patients receive a complete course of the same vaccine, unless in exceptional circumstances in which, for a patient attending for a second vaccination, that first vaccine type is not available, or the vaccine type received is not known. In such circumstances GP practices should offer a single dose of the locally available product in line with available guidance.⁵

⁵ <https://www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners>

- 9.5.8 that the correct dosage of the vaccine is administered, as clinically appropriate;
- 9.5.9 that they comply with relevant guidance issued by JCVI on:
- (a) which vaccine is the most suitable for each cohort of Patients;
 - (b) the relevant maximum and minimum timescales (as applicable) for administration of each vaccination;
 - (c) the number of doses of each vaccine required to achieved the desired immune response; and
 - (d) any other relevant guidance relating to the administration of the different types of vaccine and the different cohorts from time to time; and
- 9.5.10 that they provide to each Patient being administered a vaccine the vaccination information as directed by the Commissioner (NHSE), which may include a printed copy of the manufacturer's patient information leaflet about the vaccine (which would be provided to GP practices) and any other relevant information.
- 9.5.11 Although no data for co-administration of COVID-19 vaccine with other vaccines exists, in the absence of such data, first principles would suggest that interference between inactivated vaccines with different antigenic content is likely to be limited. Based on experience with other vaccines, any potential interference is most likely to result in a slightly attenuated (weaker) immune response to one of the vaccines. There is no evidence of any safety concerns, although it may make the attribution of any adverse events more difficult. Because of the absence of data on co-administration with COVID-19 vaccines, COVID19 vaccine should not be routinely offered at the same time as other vaccines. Based on current information about the first COVID-19 vaccines which may be used, scheduling of COVID-19 vaccine and other vaccines should ideally be separated by an interval of at least 7 days to avoid incorrect attribution of potential adverse events. As both of the COVID-19 vaccines which may be authorised for use first are considered inactivated, where individuals in an eligible cohort present having received another inactivated or live vaccine, COVID-19 vaccination should still be considered. The same applies for other live and inactivated vaccines where COVID-19 vaccination has been

received first. In many cases, vaccination should proceed to avoid any further delay in protection and to avoid the risk of the patient not returning for a later appointment. In such circumstances, patients should be informed about the likely timing of potential adverse events relating to each vaccine. In the circumstances described in this paragraph, GP practices should refer to the available guidance⁶.

9.6 GP practices must adhere to defined standards of record keeping ensuring that the vaccination event is recorded the same day that it is administered within the specified point of care system in line with guidance published on <https://www.england.nhs.uk/coronavirus/covid-19-vaccination-programme>. GP practices must ensure that all staff recording the vaccination have received the relevant training.

9.7 The GP practice must ensure the Patient has understood that failure to receive all recommended doses of the vaccine may render the vaccination ineffective and should ensure that a follow up appointment to receive the subsequent dose has been booked, acknowledging that in exceptional circumstances appointments may need to be moved, before administering the first dose of the vaccine. The Patient should receive all doses in the regimen from the same provider unless, in the exceptional circumstances as per paragraph 11.3, the GP practice is unable to complete the regimen.

9.8 **Persons involved in administering the vaccine:**

9.8.1 all healthcare professionals administering the vaccine, must have:

- (a) read and understood the clinical guidance available and to be published on <https://www.england.nhs.uk/coronavirus/covid-19-vaccination-programme/>;
- (b) completed the additional online COVID-19 specific training modules available on the e-learning for health website when available. GP practices will be expected to oversee and keep a record to confirm that all staff have undertaken the training prior to participating in vaccinations;

⁶ <https://www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners>

- (c) the necessary experience, skills and training to administer vaccines in general, including completion of the general immunisation training available on e-learning for health and face-to-face administration training, where relevant;
- (d) the necessary experience, skills and training, including training with regard to the recognition and initial treatment of anaphylaxis; and
- (e) understood and be familiar with the Patient Group Direction for the COVID-19 vaccines, made available by Public Health England and authorised by the Commissioner (NHSE) including guidance on who can use them <https://www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them>; and
- (f) ensured that registered healthcare professionals were involved in the preparation (in accordance with the manufacturer's instructions) of the vaccine(s) unless unregistered staff have been trained to do this.

9.8.2 all other persons administering the vaccine, must:

- (a) be authorised, listed, referred to or otherwise identified by reference to The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020;
- (b) while preparing and/or administering vaccinations be supervised by a healthcare professional fulfilling the requirements of paragraph 9.8.1 above;
- (c) have completed the additional online COVID-19 specific training modules available on the e-learning for health website when available. GP practices must oversee and keep a record to confirm that all staff have undertaken the training prior to participating in administration of the vaccination. This includes any additional training associated with new vaccines that become available during the period of this ES;
- (d) have the necessary skills and training to administer vaccines in general, including completion of the general immunisation

training available on e-learning for health and face-to-face administration training, where relevant;

- (e) the necessary skills and training, including training with regard to the recognition and initial treatment of anaphylaxis; and
- (f) be familiar with, understand and act within the scope of the national protocol for the COVID-19 vaccines, made available by Public Health England and approved by the Secretary of State for Health and Social Care.

9.9 GP practices should ensure that all vaccines are received, stored, prepared and subsequently transported (where appropriate) in accordance with the relevant manufacturer's⁷, Public Health England's⁸ and NHS England's instructions and all associated Standard Operating Procedures, including that all refrigerators in which vaccines are stored have a maximum/minimum thermometer and that the readings are taken and recorded from that thermometer on all working days and that appropriate action is taken when readings are outside the recommended temperature. Where vaccinations are administered away from a Designated Site (for example, at a care home), the GP practice must ensure that appropriate measures are taken to ensure the integrity of the cold chain, following any guidance issued by JCVI or Public Health England. Appropriate procedures must be in place to ensure stock rotation, monitoring of expiry dates and appropriate use of multi-dose vials to ensure that wastage is minimised and certainly does not exceed 5% of the total number of vaccines supplied. Wastage levels will be reviewed by the Commissioner (NHSE) on an ongoing basis. Where wastage exceeds 5% of the vaccines supplied and that wastage is as a result of supply chain or Commissioner (NHSE) fault, those vaccines shall be removed from any wastage calculations when reviewed by the Commissioner (NHSE) on an ongoing basis.

9.10 GP practices should ensure that services are accessible, appropriate and sensitive to the needs of all Patients. No eligible Patient shall be excluded or experience particular difficulty in accessing and effectively using this ES due to a protected characteristic, as outlined in the Equality Act (2010) – this includes Age, Disability, Gender Reassignment, Marriage and Civil

⁷ Information from the manufacturer suggests that there will be very specific handling requirements to preserve stability. Vaccines will require 2-8c storage on-site

⁸ PHE's ordering, storing and handling protocol

<https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines>

Partnership, Pregnancy and Maternity, Race, Religion or Belief, Sex or Sexual Orientation.

- 9.11 GP practices and the PCN Groupings they each work within must ensure that Designated Sites and the vaccination clinics are operated in accordance with the Designation Process and any other criteria published alongside this ES specification. GP practices should inform the Commissioner (NHSE) immediately if for any reason a Designated Site ceases to meet the criteria set out in this ES and the Commissioner (NHSE) reserves the right to require a GP practice to withdraw from this ES in these circumstances, in accordance with the withdrawal criteria at paragraph 13.4.
- 9.12 The Commissioner (NHSE) may be able to provide support to PCN Groupings by way of equipment loan. Where such support is made available, all equipment will be maintained by the GP practices and shall be returned to the Commissioner (NHSE) at the end of the delivery of service under this ES.

Monitoring and Reporting

- 10 GP practices delivering this ES must (if they have not already done so) sign up to receive the Primary Care Bulletin published by the Commissioner (NHSE) so key information in relation to the delivery of this ES can be communicated in a timely manner. GP practices can sign up to the Primary Care Bulletin at: <https://www.england.nhs.uk/email-bulletins/primary-care-bulletin/>.
- 10.1 GP practices and PCN Groupings must monitor and report all activity information in accordance with the monitoring and reporting standards as published by the Commissioner (NHSE).
- 10.2 GP practices will be responsible for recording adverse events and providing the Patient with information on the process to follow if they experience an adverse event in the future after leaving the vaccination site, including signposting the Yellow Card service. GP practices will be expected to follow MHRA incident management processes in the case of a severe reaction.

11 Payment and Validation

- 11.1 A payment of £25.16 shall be payable to the GP practice on completion of the second administration of the vaccination to each Patient. This £25.16 is made up of two items of service payments of £12.58 each and is intended to reflect the two vaccinations per Patient which make up the course of treatment. The Commissioner (NHSE) does not intend to make payment for the administration

of a single vaccination, to encourage GP practices to ensure that Patients are called/re-called to second vaccination appointments and to reduce bureaucracy for practices. Payment will however be available for single administration of the vaccination in exceptional circumstances as set out at paragraph 11.3.

11.2 GP practices will only be eligible for the payment of £25.16 in accordance with this ES where all of the following requirements have been met:

11.2.1 the Patient which received the vaccinations was a Patient at the time the vaccine was administered, and all of the following apply (except where the claim for reimbursement is for a qualifying exception):

- (a) the GP practice has used the specified vaccines recommended in the JCVI guidance⁹;
- (b) the Patient in respect of whom payment is being claimed was within an announced and authorised cohort at the time the vaccine was administered, unless the exceptional circumstances set out in this ES apply;
- (c) the vaccination has been recorded on the point of care system; and
- (d) the GP practice has not received and does not expect to receive any payment from any other source (other than any discretionary funding made available by the Commissioner (NHSE) relating to the delivery of the COVID-19 vaccination programme and/or under their COVID-19 ES Vaccination Collaboration Agreement) in respect of the vaccine or vaccination.

11.2.2 the Patient's vaccinations have been administered by the GP practice's PCN Grouping. GP practices must make arrangements within their PCN Grouping for payments in respect of unregistered patients; and care home workers and primary medical services workers which are registered on another primary medical services practice's list of patients, but who have elected to receive the vaccination from the GP practice for convenience; **and** who fall within the definition of Patient and who are vaccinated at the PCN Grouping's Designated Site. GP practices must nominate a single GP practice

⁹ <https://www.gov.uk/government/groups/joint-committee-on-vaccination-and-immunisation>

within the PCN Grouping to claim and receive (on their own behalf) payment for these unregistered patients, care home workers and primary medical services workers which shall be set out in the COVID-19 ES Vaccination Collaboration Agreement.

- 11.2.3 GP practices must make arrangements within their PCN Grouping for the nomination of a host GP practice for the PCN Grouping which will receive payments due under this ES for and on behalf of the GP practice. This is necessary as existing systems are unable to support payment in a timely manner and to facilitate the payment system for this novel and complex situation where vaccination of the population across multiple locations and settings is required. The PCN Grouping should ensure that arrangements are in place so that the correct ODS code is entered to enable payment to the host GP practice. The host GP practice will then receive data which enables it to identify how many Patients on the GP practice's list of registered patients have been vaccinated, for verification and the transfer of funds to the GP practice. Payment arrangements may be reviewed in line with subsequent developments to I.T. systems.

Exceptional circumstances criteria and process:

- 11.3 There may be exceptional circumstances where a GP practice should be paid for the administration of a single dose of the vaccine which are:

11.3.1 unsuitability of the Patient:

- (a) because of medicine intolerance or allergy discovered during administration of the first dose of the vaccine;
- (b) if the Patient has commenced end of life care before a second dose of the vaccine could be provided; or
- (c) if the Patient has died before a second dose of the vaccine could be provided;

11.3.2 changed circumstances in relation to the Patient:

- (a) Patient choice: the Patient has definitively chosen not to receive the second dose of the vaccine following a discussion with a clinician;

- (b) no response: the Patient did not attend a booked appointment to receive the second dose of the vaccine and the GP practice has made at least two separate attempts to contact the Patient and a period of 60 days has elapsed following the administration of the first dose of the vaccine;
- (c) the Patient's name has been removed from the GP practice's list of registered patients between the first and second doses of the vaccine and their name is on the list of registered patients of another primary medical services practice outside of the PCN Grouping;
- (d) the GP practice is unable to access the Patient to administer a vaccination within the recommended time period: the Patient is in hospital or has moved to a new form of residence such as the detained estate, a residential care home or other long-stay care facility since receiving the first dose of the vaccine and the GP practice is unable to access or it is not appropriate for the GP practice to access the location to administer the second dose of the vaccine; or
- (e) the GP practice has not been provided with the vaccine in order for the GP practice to administer the vaccination within the recommended time frame.

11.4 GP practices must keep a record of the relevant exceptional circumstances to support a payment claim in accordance with the reporting requirements and payment processes which will be published. Where the exceptional circumstances criteria have been satisfied, the relevant Patient will be a **"qualifying exception"** for payment purposes.

11.5 Payment under this ES, or any part thereof, will be made only if the GP practice satisfies the following conditions:

11.5.1 they have in place a COVID-19 ES Vaccination Collaboration Agreement that complies with the requirements of paragraph 6.4;

11.5.2 they comply (and maintain compliance) with the requirements of this ES;

11.5.3 they make available to the Commissioner (NHSE) any information under this ES which the Commissioner (NHSE) needs and the GP practice either has or could be reasonably expected to obtain;

- 11.5.4 they make any returns or provide any information reasonably required by the Commissioner (NHSE) (or on the Commissioner's behalf) (whether computerised or otherwise) to support payment and do so promptly and fully; and
- 11.5.5 all information supplied pursuant to or in accordance with this paragraph 11.5 must be accurate.
- 11.6 If the GP practice does not satisfy any of the above conditions, the Commissioner (NHSE) may withhold payment of any, or any part of, an amount due under this ES that is otherwise payable.
- 11.7 Practices may not claim payment for Patients vaccinated outside of the PCN grouping (for example, at a vaccination centre).
- 11.8 If the Commissioner (NHSE) makes a payment to a GP practice under this ES and:
- 11.8.1 the GP practice was not entitled to receive all or part thereof, whether because it did not meet the entitlement conditions for the payment or because the payment was calculated incorrectly (including where a payment on account overestimates the amount that is to fall due);
- 11.8.2 the Commissioner (NHSE) was entitled to withhold all or part of the payment because of a breach of a condition attached to the payment, but is unable to do so because the money has already been paid; or
- 11.8.3 the Commissioner (NHSE) is entitled to repayment of all or part of the money paid,
- the Commissioner (NHSE) may recover the money paid by deducting an equivalent amount from any payment payable to the GP practice, and where no such deduction can be made, it is a condition of the payments made under this ES that the contractor under its General Medical Services contract, Personal Medical Services agreement or Alternative Provider Medical Services contract (as relevant) must pay to the Commissioner (NHSE) that equivalent amount.
- 11.9 Where the Commissioner (NHSE) is entitled under this ES to withhold all or part of a payment because of a breach of a payment condition, and the Commissioner (NHSE) does so or recovers the money by deducting an equivalent amount from another payment in accordance with this ES, it may,

where it sees fit to do so, reimburse the GP practice the amount withheld or recovered, if the breach is cured.

- 11.10 The Commissioner (NHSE) is responsible for post payment verification. This may include auditing claims of practices to ensure that they meet the requirements of this ES.

12 Withdrawal from this ES

- 12.1 Where a practice wishes to withdraw from this ES it must provide the Commissioner (NHSE) with no less than 42 days' notice of its intention to withdraw to enable the recommissioning of services for Patients unless otherwise agreed with the Commissioner (NHSE).

13 Variations To and Subsequent Withdrawal From this ES

- 13.1 Due to the continually changing nature of the COVID-19 pandemic and the resources and vaccines that the NHS is able to deploy, this ES will need to be responsive and may be frequently updated. GP practices are expected to be alive to this issue and committed to providing the best possible COVID-19 vaccination service to Patients.
- 13.2 Variations to this ES will be published on <https://www.england.nhs.uk/gp/investment/gp-contract/> and will take effect immediately on publication. GP practices will also be notified of any changes via the Primary Care Bulletin (as referred to in paragraph 10).
- 13.3 In order to simplify the participation process, where there are any in-year variations to this ES specification after 8 December 2020, the GP practice participating in this ES will automatically be enrolled.
- 13.4 If a GP practice cannot meet the requirements of this ES it must withdraw from this ES by serving written notice on the Commissioner (NHSE) to that effect with supporting reasons as to why it cannot meet the revised requirements, such notice must be received by the Commissioner (NHSE) no later than 42 days after publication of the relevant variation and providing no less than 42 days' notice of the GP practice's withdrawal. The GP practice will also need to make the necessary amendments to the COVID-19 ES Vaccination Collaboration Agreement.

13.5 Following notice of their intention to withdraw from the ES, but prior to the actual withdrawal date, GP practices must comply with their COVID-19 ES Vaccination Collaboration Agreement and co-operate with their PCN Grouping during and following their withdrawal from this ES.

13.6 The provisions of Annex A will apply to practices that withdraw from this ES.

Annex A: Provisions relating to GP practices that terminate or withdraw from this ES (subject to the provisions below for termination attributable to a GP practice formation or merger) and New GP practices

- 1 Where a GP practice has entered into this ES but its primary medical services contract subsequently terminates or the GP practice withdraws from this ES prior to the end of this ES, the GP practice is entitled to a payment in respect of its participation if such a payment has not already been made, in accordance with the provisions set out below. Any payment will fall due on the last day of the month following the month during which the GP practice provides the information required.
- 2 In order to qualify for payment in respect of participation under this ES, the GP practice must comply with and provide the Commissioner (NHSE) with the information in this ES specification or as agreed with the Commissioner (NHSE) before payment will be made. This information should be provided in writing within 28 days following the termination of the contract or the GP practice's withdrawal from this ES.
- 3 The payment due to a GP practice whose primary medical services contract subsequently terminates or that withdraws from this ES prior to the end of this ES will be based on the number of completed vaccination courses provided to Patients or single doses where a qualifying exception applies (as set out at paragraph 11.3), prior to the termination of the primary medical services contract or withdrawal from this ES.

Provisions relating to GP practices who merge or are formed

- 4 Where two or more GP practices merge or a new primary medical services contract is awarded and as a result two or more lists of registered patients are combined, transferred (for example from a terminated practice) or a new list of registered patients is developed, the new GP practice(s) may enter into a new or varied arrangement with the Commissioner (NHSE) to provide this ES.
- 5 In the event of a practice merger, the ES arrangements of the merged GP practices will be treated as having terminated (unless otherwise agreed with the Commissioner (NHSE)) and the entitlement of those GP practice(s) to any payment will be assessed on the basis of the provisions of paragraph 11 of this ES.

6 The entitlement to any payment(s) of the GP practice(s), formed following a practice merger, entering into the new or varied arrangement for this ES will be assessed and any new or varied arrangements that may be agreed in writing with the Commissioner (NHSE) will begin at the time the GP practice(s) starts to provide this ES under such arrangements.

7 Where that new or varied arrangement is entered into and begins within 28 days of the new GP practice(s) being formed, the new or varied arrangements are deemed to have begun on the date of the new GP practice(s) being formed and payment will be assessed in line with this ES specification as of that date.

8 Where the GP practice participating in the ES is subject to a practice merger and:

8.1 the application of the provisions set out above in respect of practice mergers would, in the reasonable opinion of the Commissioner (NHSE), lead to an inequitable result; or,

8.2 the circumstances of the split or merger are such that the provisions set out above in respect of practice mergers cannot be applied,

the Commissioner (NHSE) may, in consultation with the GP practice or GP practices concerned, agree to such payments as in the Commissioner's (NHSE) opinion are reasonable in all of the circumstances.

New contract awards

9 Where a new primary medical services contract is awarded by the Commissioner (NHSE) after the commencement of this ES, the GP practice will be offered the ability to opt-in to the delivery of this ES where it is able to join a PCN Grouping.