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Enhanced Service Specification

COVID-19 vaccination programme: phase 3
2021/22 and phase 4 2022/23

Enhanced Service (ES) Specification

COVID-19 vaccination programme: phase 3 and phase 4

Version 8.0

Version updates: (changes in version 7 are marked in yellow)

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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 ensuring that services are provided in an integrated way where this might reduce health inequalities."

Contents

1	Introduction	1
2	Commonly Used Terms	2
3	Background and Duration	4
4	Process	6
5	Collaboration Requirements: General	7
6	Collaboration Requirements: PCN groupings	8
7	Site Designation.....	11
8	Sub-contracting Arrangements	13
9	Service Delivery Specification	14
10	Monitoring and Reporting	25
11	Payment and Validation	26
12	Withdrawal from this ES	34
13	Variations To and Subsequent Withdrawal From this ES	34
	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	36
	Annex B : Vaccinations for Cohort xiii	38
	Annex C : JCVI advice on vaccination of children aged 12 to 15 years with underlying health conditions (31 August 2021)	39
	Annex D : Vaccinations for Cohort xiv	43

The NHS is a global leader in achieving high levels of vaccination coverage, and this has been reflected in a hugely successful COVID-19 vaccination programme. Between 8 December 2020 and 20 December 2021 over 100 million doses of COVID-19 vaccine have been given.

General practice has played a critical role in the success of phase 1 (the vaccination of patient cohorts 1-9) and phase 2 (the vaccination of patient cohorts 10-12) of the COVID-19 vaccination programme. Utilising their strong relationships in local places and neighbourhoods, GP practices have helped to tackle vaccine inequalities and improve vaccination take-up.

This next and third phase of the COVID-19 vaccination programme offers revaccination boosters (with additional vaccine) for those at the highest risk, to maintain protection against the risk of severe illness, and continue to offer vaccinations to those Patients which did not take up or were previously not eligible to receive vaccination in phases 1 and 2.

The COVID-19 vaccination programme: phase 3 will be delivered alongside the seasonal influenza vaccination programme, which runs each autumn. Together, the vaccinations will offer those at highest risk safe and effective protection against the risk of COVID-19 and seasonal influenza.

The general practice COVID-19 vaccination programme: phase 3 service will be commissioned in line with agreed national terms and conditions as an Enhanced Service (ES) directed by NHS England. The ES has been offered to all GP practices and is not be capable of amendment by CCGs.

This ES relates to phase 3 COVID-19 vaccinations and revaccinations only. Where GP practices delivered services under the Enhanced Service Specification: COVID-19 vaccination programme 2020/21 (phase 1 & 2) (“the ES 2020/21 (phase 1 & 2)”) and then subsequently services under this ES, they will need to ensure that they are clear under which Enhanced Service a Patient was vaccinated.

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: phase 3 develops.
- 1.2 This ES has been developed from the ES 2020/21 (phase 1 & 2) which was 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.
- 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 or during appropriate hours across the week, including weekends, to meet the needs of the local population as agreed by the Commissioner (NHSE). The Commissioner (NHSE) will inform practices where this is required, based on the need to maximise vaccinations when the supply of vaccine is available to reduce waste and in support of the mass vaccination of the population.

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.

- 1.7 A GP practice need not be a member of an established Primary Care Network or PCN grouping established to deliver the ES 2020/21 (phase 1 & 2), to participate in this ES. GP practices are expected to collaborate with neighbouring practices to deliver this ES and established Primary Care Networks in a 'PCN grouping' to deliver all aspects of this ES. GP practices may wish to utilise PCN groupings which were established to deliver the ES 2020/21 (phase 1 & 2) or may wish to form an alternative PCN grouping to deliver 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. Where a PCN grouping remains unchanged from the delivery of the services under the ES 2020/21 (phase 1 & 2), GP practices may update their COVID-19 ES Vaccination Collaboration Agreement to include the delivery of services under this ES. GP practices should refer to the definition of PCN grouping in paragraph 2.2.11 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. Only one PCN grouping shall be permitted to operate from each PCN Designated Site;

- 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 the Designation Process (as may be amended from time to time) is published on <https://www.england.nhs.uk/coronavirus/covid-19-vaccination-programme/primary-care-guidance/>;
- 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 “**National Booking Service**” means the national system used by Patients to book coronavirus (COVID-19) vaccination appointments;
- 2.2.10 “**Patient**” means those patients eligible to receive the vaccination in general practice as set out at paragraph 9.2;
- 2.2.11 “**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; and
- 2.2.12 “**Point of Care System**” refers to a clinical system that has been assured by NHS Digital to record COVID-19 vaccination events;
- 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 with additional vaccination for those at the highest risk, to maintain protection against the risk of severe illness and to continue to offer initial vaccinations to those Patients who did not take up or were previously not eligible to receive vaccination. This ES begins on 6 September 2021 and shall continue for an initial period until 31 March 2022 unless it is terminated in accordance with paragraph 3.2. Where a GP Practice has sufficient workforce capacity and appropriately trained staff and does not terminate this ES by serving not less than 21 days notice to the Commissioner (NHSE), this ES shall continue for an extended period from 1 April 2022 to 30 September 2022 (“the Extended Period”).
- 3.1A During the Extended Period, the Commissioner (NHSE) may request and the GP practice together with the other GP Practices in the PCN Grouping may agree to only deliver services to Patients in specific cohorts.
- 3.1B During the Extended Period, where there is (in the reasonable view of the Commissioner (NHSE)) significantly reduced Patient demand, there is unacceptable wastage of the vaccine and/or the Designated Site does not represent acceptable value for money to the Commissioner (NHSE), the Commissioner (NHSE) may require the GP Practice together with the other GP Practices in the PCN Grouping to suspend the services (a “Pause”).
- 3.1C Where the GP practice together with the other GP practices in the PCN Grouping do not agree to the Pause, they may provide evidence to the Commissioner (NHSE) detailing that there is no significantly reduced Patient demand, there is not unacceptable wastage of the vaccine and/or the Designated Site represents acceptable value for money to the Commissioner (NHSE) and the Commissioner (NHSE) shall, acting reasonably, reconsider whether it remains appropriate to continue with the Pause.
- 3.1.D During a Pause, the GP practice shall not administer COVID-19 vaccinations and shall not be entitled to claim or receive any payment except in respect of the services which took place prior to the date on which the Pause occurred unless in the case of unavoidable and limited costs which have been exceptionally agreed with the Commissioner (NHSE) in advance of such costs being incurred.
- 3.1.E While the services are Paused the Commissioner (NHSE) and the GP practice shall use all reasonable efforts to ensure that no further Patients are referred

to the GP Practices within the PCN Grouping for vaccination and should direct Patients to available services, as appropriate.

- 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. The Commissioner (NHSE) will, where possible, arrange supply to meet local population need from providers that are best placed to meet that need. 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,

extension of the term and ongoing 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/>.
- 3.8 On termination of this ES, GP practices shall work with the Commissioner (NHSE) and any providers commissioned by the Commissioner (NHSE) for the delivery of any subsequent doses of vaccination to Patients.

4 Process

- 4.1 GP practices must indicate their willingness to participate in this ES before 17.00 on 28 July 2021 unless the Commissioner (NHSE) agrees otherwise in certain circumstances. Where the Commissioner (NHSE) is assured that the GP practices have the capacity to deliver this ES alongside their existing contractual requirements (and in compliance with any published guidance) the Commissioner (NHSE) will approve sign up to participate in this ES. GP practices and the Commissioner (NHSE) must record their agreement to participate in this ES in writing. Local CCGs may be asked to support the Commissioner (NHSE) in the administrative elements of this.
- 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 specific guidance is provided by the Commissioner (NHSE) setting out the circumstances in which a vaccination can occur at a different location and/or there is a specific reason not to.

Where 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, the GP practice must provide the vaccination to the Patient at another location.

GP practices must make arrangements to vaccinate Patients resident in care homes at their care home of residence.

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 at other locations or in care homes.

- 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 vaccination or course of vaccinations (where multiple doses are required) to Patients (unless exceptional circumstances apply).
- 4.4 A GP practice's participation in this ES shall only continue for so long as it is in compliance with its terms.
- 4.5 Where a PCN grouping remains unchanged from the delivery of the ES 2020/21 (phase 1 & 2) and the Designated Site for the delivery of this ES is the same as the Designated Site for the delivery of the ES 2020/21 (phase 1 & 2), GP practices should expect that the Designated Site will be approved, where that Designated Site demonstrates good access for Patients and value for money.

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 and/or the wider COVID-19 vaccination programme, or for the provision of any subsequent doses of the vaccine after the termination of 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 other relevant 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 contra-indications 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 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) and 3A(1) of the Human Medicines Regulations 2012 (as amended).

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: phase 3, 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 5 September 2021 or such other date as may be agreed by the Commissioner (NHSE) 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, including to enable GP practices to access information on the name and the manufacturer of any COVID-19 vaccinations previously received by the Patient;
- 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;
- 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 under Schedule 2L of an NHS standard contract), Primary Medical Services delivered by a sub-contractor, and the provision of 'Ancillary Health Services' by or for a Part 4 contractor or Primary Medical Services sub-contractor. Cover under CNSGP is not restricted to a GP

practice's registered patients so would apply to the provision of any NHS COVID-19 vaccinations by a GP practice to a person, including where they are not on the registered list of that GP practice;

- 6.4.10 appropriate arrangements to ensure that GP practices can identify, if appropriate, which Patients receive vaccinations under the ES 2020/21 (phase 1 & 2) and which under this ES; and
 - 6.4.11 where the collaborating GP practices consider that it is operationally expedient to do so, the COVID-19 ES Vaccination Collaboration Agreement shall set out the arrangements as between the collaborating GP practices for the co-administration of the COVID-19 vaccine and the seasonal influenza vaccine. Co-administration shall at all times be in line with the provisions set out in the [Green Book](#).
- 6.5 The Commissioner (NHSE) will publish a template COVID-19 ES Vaccination Collaboration Agreement on <https://www.england.nhs.uk/coronavirus/covid-19-vaccination-programme/primary-care-guidance/>, which the PCN grouping may wish to use and adapt for the purpose of delivering this ES. GP practices may update their COVID-19 ES Vaccination Collaboration Agreement to include the delivery of services under this ES to extended cohorts.
- 6.6 PCN groupings will be expected to collaborate with any national, regional and/or local Integrated Care System/Sustainability and Transformation Partnership operations centres 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 will include PCN groupings providing weekly updates on actual stock and may include, for example, providing daily or weekly updates on actual stock use, vaccines delivered (including the brand of vaccine used), vaccine wastage and forecasted requirements. PCN groupings will 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 supply within required timeframes from the National Programme and ordering required consumables supply,

where necessary from their chosen supply channel within required timeframes to ensure service continuity;

- 6.7.4 receiving and safely storing supply;
 - 6.7.5 amending clinic schedules if there is a disruption to supply and undertaking timely communication of any changes to Patients; and
 - 6.7.6 where it is operationally expedient, co-administration of the COVID-19 vaccine and the seasonal influenza vaccine may be provided if possible, in order to maximise efficiency for the GP practice and minimise the number of attendances required for Patients to receive these vaccinations.
- 6.8 Where a PCN grouping signs up to use the National Booking Service it must comply with the conditions of sign up. From the point that the PCN grouping is onboarded to the National Booking Service, this must be the only booking system that the PCN grouping uses for new initial dose appointments and any corresponding subsequent dose bookings for cohorts (i) to (xii). Any new call/re-call communications that the GP practices issue must direct Patients to the National Booking Service for cohorts (i) to (xii).
- 6.9 The JCVI have advised that “the COVID-19 booster vaccine programme should [not] disrupt or delay deployment of the annual influenza vaccination programme”. Therefore, it is important individuals are offered their COVID-19 and influenza vaccine as soon as they are eligible, rather than delaying for the purpose of co-administration. We recognise there will be some instances where a short delay will ensure that more individuals receive both vaccines, for example in care homes, and sites should use their discretion to maximise these opportunities.”

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). Where a PCN grouping remains unchanged from the delivery of the ES 2020/21 (phase 1 & 2) and the Designated Site for the delivery of this ES is the same as the Designated Site for the delivery of the ES 2020/21 (phase 1 & 2), GP practices should expect that the Designated Site will be approved by

the Commissioner (NHSE) where that Designated Site demonstrates good access for Patients and value for money.

- 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, the total number of Designated Sites that can be accommodated within vaccine supply arrangements and value for money. 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 phase 3 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 phase 3. Where a change occurs, the amended criteria will be published on <https://www.england.nhs.uk/coronavirus/covid-19-vaccination-programme/primary-care-guidance/> and GP practices will be notified in writing and through the Primary Care Bulletin (as referred to in paragraph 10.1). 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 together within the PCN grouping:
 - 7.8.1 must only enter new vaccinations into one Point of Care System in any calendar month except:

- (a) during the transition to a new Point of Care System where the use of two systems will be permitted for a period determined by the Commissioner (NHSE); or
- (b) where it is necessary to include amendments to vaccination events previously recorded.

7.8.2 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 or as agreed with the Commissioner (NHSE).

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 to eligible Patients:

- 9.1.1 which have received an initial course of vaccination and now need a subsequent vaccination; and
- 9.1.2 which have received part of an initial course of vaccination or who were not previously eligible to receive vaccination or who did not choose to take up the offer of vaccination and now wish to receive vaccination.

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).

9.1A Patients, including homeless patients, do not require an NHS number or GP registration to receive a vaccination and should not be denied vaccination on this basis.

9.2 Patients eligible to receive:

9.2.1 vaccination under paragraph 9.1.1 in general practice are those patients in JCVI cohorts (i) to (ix) and who also fulfil one of the following criteria:

- (a) whose name is included on the GP practice's registered patient list;
- (b) is an unregistered patient; or
- (c) is registered on another primary medical services practice's list of registered patients but has chosen to receive their vaccination from the PCN grouping; and

GP practices must deliver the vaccinations to Patients within the cohorts, in the order of the revaccination cohorts listed below.

9.2.1A subject to the authorisation, announcement and agreement of the Commissioner (NHSE), vaccination under paragraph 9.1.1 in general

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.

practice, where the GP practice has opted into the delivery of vaccinations to those patients in JCVI cohorts (x) to (xii.1) within 7 days of publication of this ES unless otherwise agreed with the Commissioner (NHSE) and have sufficient workforce capacity (including existing staff and those drawn down from their lead employer) to deliver the vaccinations to cohort (x) to (xii.1), who also fulfil one of the following criteria:

- (d) whose name is included on the GP practice's registered patient list;
- (e) is an unregistered patient; or
- (f) is registered on another primary medical services practice's list of registered patients but has chosen to receive their vaccination from the PCN grouping; and

GP practices must deliver the vaccinations to Patients within the authorised and announced cohorts, in the order of the revaccination cohorts listed below.

9.2.2 vaccination under paragraph 9.1.2 in general practice are those Patients in JCVI cohorts (i) to (xii) and who also fulfil one of the following criteria:

- (a) whose name is included on the GP practice's registered patient list;
- (b) is an unregistered patient; or
- (c) is registered on another primary medical services practice's list of registered patients but has chosen to receive their vaccination from the PCN grouping; and

9.2.3 vaccination under 9.1.1 and 9.1.2 in general practice where the GP practice complies with the provisions of Annex B, are those Patients in JCVI cohort (xiii) and who also fulfil one of the following criteria:

- (a) whose name is included on the GP practice's registered patient list;
- (b) is an unregistered patient; or

- (c) registered on another primary medical services practice's list of registered patients but have chosen to receive their vaccination from the PCN grouping.

GP practices must deliver the vaccinations to eligible Patients in the priority order announced and authorised by the JCVI relevant to the vaccination they are due to receive.

9.2.4 vaccination under 9.1.2 in general practice where the GP practice complies with the provisions of Annex D, are those Patients in JCVI cohort (xiv) and who also fulfil one of the following criteria:

- (a) whose name is included on the GP practice's registered patient list;
- (b) is an unregistered patient; or
- (c) registered on another primary medical services practice's list of registered patients but have chosen to receive their vaccination from the PCN grouping.

The 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 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 but subject to JCVI announcement(s) regarding eligible cohorts. Patients eligible to receive 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 10.1):

i. All those:

- i.1 residents in a care home for older adults; and

- i.2 their carers;
- ii. All those:
 - ii.1 80 years of age and over; and
 - ii.2 frontline health and social care workers;
- iii. All those 75 years of age and over;
- iv. All those 70 years of age and over and clinically extremely vulnerable individuals³;
- v. All those;
 - v.1 65 years of age and over; and
 - v.2 65 years of age and over with underlying health conditions which put them at higher risk of serious disease and mortality;
- vi. All individuals aged 16 years to 64 years either:
 - vi.1 who are immunosuppressed, as defined in the Green Book; or
 - vi.2 with underlying health conditions which put them at higher risk of serious disease and mortality⁴;
- vii. All those 60 years of age and over;
- viii. All those 55 years of age and over;
- ix. All those 50 years of age and over;
- x. All those 40 years of age and over;
- xi. All those 30 years of age and over;
- xii. All those:

³ Clinically extremely vulnerable individuals are described here: <https://www.gov.uk/government/publications/guidance-on-shielding-and-protecting-extremely-vulnerable-persons-from-covid-19/guidance-on-shielding-and-protecting-extremely-vulnerable-persons-from-covid-19>.

⁴ This also includes those who are in receipt of a carer's allowance, or those who are the main carer of an elderly or disabled person whose welfare may be at risk if the carer falls ill.

- xii.1 18 years of age and over; and
- xii.2 16 years of age and over but not yet 18 years of age;
- xiii. All those who are:
 - xiii.1 aged 12 to 15 years of age and:
 - xiii.1.1 at increased risk of serious COVID-19 disease that includes those with the conditions listed at Annex C; or
 - xiii.1.2 who are the household contacts of individuals (either adults or children) who are immunosuppressed; or
 - xiii.1.3 the Commissioner (NHSE) has requested and the GP Practice has agreed to administer vaccinations to this 12 -15 years of age cohort; or
 - xiii.1.4 who are immunosuppressed, as defined in the Green Book;

but only where the patient has been assessed as competent to consent and does consent, or is not assessed as competent but does not object and consent is provided by somebody with parental responsibility.
- xiv. All those who are:
 - xiv.1 aged 5 to 11 years of age and:
 - xiv.1.1 at increased risk of serious COVID-19 disease that includes those with the conditions listed at Annex C; or
 - xiv.1.2 who are the household contacts of individuals (either adults or children) who are immunosuppressed; or
 - xiv.1.3 the Commissioner (NHSE) has requested and the GP Practice has agreed to administer vaccinations to this 5 -11 years of age cohort;

but only where the patient has been assessed as competent to consent and does consent, or is not assessed as competent but does not object and consent is provided by somebody with parental responsibility.

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 their own and where appropriate other 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 including where GP practices are not being requested to administer vaccinations to Patients during a Pause; 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, Patients in a residential setting for whom it has been agreed with the Commissioner (NHSE) that they should receive their vaccinations in a residential setting rather than a vaccination site, and frontline 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 recommended vaccine in line with JCVI guidance;⁵
- 9.5.8 that the correct dosage of the vaccine is administered, as clinically appropriate;
- 9.5.9 that they comply with all relevant guidance issued by JCVI, the Commissioner (NHSE), MHRA and/or UKHSA on:
- (a) which vaccine is the most suitable for each cohort of Patients;
 - (b) any relevant maximum and minimum timescales (as applicable) for administration of each vaccination where multiple doses of the vaccine are required;
 - (c) the number of doses of each vaccine required to achieved the desired immune response;
 - (d) any other relevant guidance relating to the administration of the different types of vaccine and the different cohorts from time to time.

In the event of a conflict between guidance issued by these organisations, NHS England shall confirm which guidance shall be adopted;

- 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. Practices should advise Patients where required of any current policy as recommended by the JCVI and as set out at paragraph 9.5.9(b) in relation to the timing of the administration of any necessary subsequent dose where this is not reflected in the manufacturer's patient information leaflet.

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

9.5.11 The circulation of influenza was limited in the UK in the 2020 to 2021 season and as a result, a lower level of population immunity against influenza is expected.

Therefore the 2021 to 2022 influenza season in the UK could be larger and begin earlier than usual. To mitigate the potential impact from influenza, JCVI has advised extension of the influenza vaccination programme to adults aged 50 years and over in winter 2021 to 2022.

It is paramount that as many eligible adults as possible take up the offer of influenza vaccination, with those at highest risk vaccinated as early as possible. An approach that therefore supports the co-administration of COVID-19 vaccinations and influenza vaccination, where this is operationally expedient, may maximise uptake of both vaccines in the population.

9.6 Persons vaccinated with the COVID-19 vaccine early during phase 1 of the COVID-19 vaccination programme will have completed their primary course of vaccination approximately 6 months prior to the date of this ES. This booster vaccine programme is to begin in line with JCVI guidance as soon as is operationally practicable. 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 Point of Care System and all mandatory fields are completed accurately. GP practices must ensure that all staff recording the vaccination have accessed the relevant training provided by the supplier of the Point of Care System.

9.6A The defined standards of record keeping referred to in paragraph 9.6 must include use of robust user and access management processes to ensure high levels of security, including frequent updates to system access levels to add users who join the site team or remove accounts where staff leave employment or do not have shifts scheduled at the site.

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 any subsequent dose has been booked, acknowledging that in exceptional circumstances appointments may need to be moved.

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;
- (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 Directions for the COVID-19 vaccines^{6,7} 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;

⁶ <https://www.england.nhs.uk/coronavirus/publication/patient-group-direction-for-covid-19-mrna-vaccine-bnt162b2-pfizer-biontech/>

⁷ <https://www.england.nhs.uk/coronavirus/publication/patient-group-direction-for-covid-19-vaccine-astrazeneca-chadox1-s-recombinant/>

- (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 vaccines⁸, made available by Public Health England and approved by the Secretary of State for Health and Social Care.

9.9 GP practices must ensure that all vaccines are received, stored, prepared and subsequently transported (where appropriate) in accordance with the relevant manufacturer's⁹, Public Health England's¹⁰ 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

⁸ <https://www.gov.uk/government/publications/national-protocol-for-covid-19-mrna-vaccine-bnt162b2-pfizerbiontech>

⁹ Information from the manufacturer suggests that there will be very specific handling requirements to preserve stability. Vaccines will require 2-8c storage on-site

¹⁰ UKHSA (previously PHE's) ordering, storing and handling protocol
<https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines>

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 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 services under this ES.

10 Monitoring and Reporting

- 10.1 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/>.

- 10.2 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). This includes guidance published by the Commissioner (NHSE) on the recording of COVID-19 vaccination appointments to ensure consistent national data captures.
- 10.3 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 Validation¹¹

11.1 Subject to compliance with this ES, a payment of:

11.1.1 £12.58 shall be payable to the GP practice for administration of each vaccination to each Patient except where paragraph 11.1A applies;
and

11.1.2 £10.00 shall be payable to the GP practice:

- (a) for administration of each vaccination to each Patient where that Patient is:
 - (i) resident in and receives the vaccination at a care home or residential setting (including care homes for people with learning disabilities or mental health problems, or hostel/hotel accommodation for the homeless, where it would not be possible for these patients to attend vaccination sites); or
 - (ii) employed or engaged by a care home and receives the vaccination at that care home or residential setting; or
- (b) for administration of each vaccination to each Patient where:
 - (i) the medical condition of a Patient is such that, in the reasonable opinion of the GP practice the Patient is classed as housebound due to being unable to leave

¹¹ For further information on payments please see the PCN Finance and Payments Guidance available here: https://future.nhs.uk/P_C_N/view?And_objectId=88259013

their home at all or requires significant assistance to leave the house due to illness, frailty, surgery, mental ill health or nearing end of life and is recorded as such in their clinical notes;

- (ii) where that Patient requires administration of a vaccination; and
- (iii) where the GP practice has recorded the status of the Patient in the Point of Care System prior to making the claim for payment; **or**

11.1.3 Only in circumstances where the GP practice is not eligible for payment in accordance with paragraph 11.1.2, £10.00 shall be payable to the GP practice for administration of each vaccination to each Patient in cohort xiii.1.1, cohort xiii.1.2, cohort xiv.1.1, cohort xiv.1.2 **or cohort xiv 1.3; or**

11.1.4 a total supplement of £30.00, to support an increase in the number of vaccinations administered to Patients, shall be payable to the GP Practice for the administration of each vaccination in accordance with paragraph / or 9.1.2 **and** the Patient falls within the definition of paragraph 11.1.2(b) from 16 September 2021 to 31 December 2021. Previous versions of this ES have provided for smaller supplements in respect of this group of Patients. Where a smaller payment has been in made in respect of this group, this shall be increased to the total supplement of £30.00. The total supplement in this regard shall not exceed £30.00 for the administration of each vaccination to Patients in this group; **or**

11.1.5 £10.00, to support sites to increase the number of vaccinations administered to Patients during this period, shall be payable to the GP practice during the period 1 December 2021 to 31 March 2022 where the Patient was severely immunosuppressed in proximity to previous vaccination due to underlying health conditions or medical treatment as defined by the JCVI on 1 September 2021 (<https://www.gov.uk/government/publications/third-primary-covid-19-vaccine-dose-for-people-who-are-immunosuppressed-jcvi-advice/joint-committee-on-vaccination-and-immunisation-jcvi-advice-on-third-primary-dose-vaccination>) or the Green Book;

For the avoidance of doubt, where a Patient qualifies for more than one supplementary payment in respect of the administration of the vaccination to a Patient, the highest cost supplement shall be paid to the GP practice only. Supplementary payments set out in paragraph 11.1.5 are in recognition of the need to re-run searches to identify those eligible and ensure the GP practices within the PCN Grouping maintain an accurate list of those eligible Patients in this cohort.

11.1A Subject to compliance with this ES and only in respect of vaccinations administered during the period set out below, a payment of:

11.1A.1 £15.00, to support an increase in the number of vaccinations administered to Patients during December 2021 and January 2022, shall be payable to the GP practice for administration of each vaccination to each Patient during the period 1 December 2021 to 31 January 2022 and where the administration of the vaccination occurs on a Monday to Saturday (but exclusive of days designated as a Bank Holiday, or 25 December 2021 to 3 January 2022 (inclusive)); **or**

11.1A.2 £20.00, to support an increase in the number of vaccinations administered to Patients on Sundays and Bank Holidays, shall be payable to the GP practice for administration of each vaccination to each Patient during the period 1 December 2021 to 31 January 2022 and where the administration of the vaccination occurs on a Sunday or a day which is designated as a Bank Holiday or is between 25 December 2021 to 3 January 2022 (inclusive).

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

11.2.1 the Patient who received the vaccination(s) 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 guidance¹²;
- (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;

¹² <https://www.gov.uk/government/groups/joint-committee-on-vaccination-and-immunisation>

- (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: phase 3 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;
- patients without an NHS number;
- patients registered on another primary medical services practice's list of registered patients, or the primary medical services provider is a Defence Medical Services practice commissioned by the Ministry of Defence;
- frontline health and social care workers; and/or patients in a residential setting who 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 within the PCN grouping to claim and receive (on their own behalf) payment for these unregistered patients, frontline health and social care workers and patients in a residential setting 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 IT systems. Any changes to the host practice must be notified to the Commissioner (NHSE) providing no less than 10 days' notice of the change and cannot be made retrospectively.

- 11.2.4 GP practices must submit a claim to the Commissioner for payment before the end of the period of 3 months beginning on the final day of the month in which completion of administration of the vaccination to which the payment relates occurred. This requirement is necessary due to the high volume of vaccinations being delivered under this ES and to ensure timely post payment verification which is necessary to ensure correct payments to PCN groupings and dissemination to GP practices.
- 11.2.5 GP practices must not reschedule vaccinations or vaccination clinics for the purposes of receiving the Sunday and Bank Holiday, 25 December 2021 to 3 January 2022 (inclusive) payment as set out at paragraph 11.1A.2. GP practices are required to maintain a broadly comparable vaccination clinic schedule, as was delivered prior to the 1 December 2021 and may provide additional Sunday and Bank Holiday and 25 December 2021 to 3 January 2022 (inclusive) clinics where this is necessary due to operational issues, staffing and to meet Patient demand. For the avoidance of doubt, rescheduled clinics for the purposes of receiving Sunday and Bank Holiday and 25 December 2021 to 3 January 2022 (inclusive) payments, would not satisfy all relevant provisions of this ES and the Commissioner (NHSE) may determine to withhold payment.

Exceptional circumstances when any recommended subsequent dose cannot be administered:

11.3 We recognise that there may be exceptional circumstances where a GP practice may not be able to administer any recommended subsequent dose of the vaccine including:

11.3.1 unsuitability of the Patient:

- (a) because of medicine intolerance or allergy discovered during or following administration of any prior dose of the vaccine;
- (b) if the Patient has commenced end of life care before any subsequent dose of the vaccine could be provided; or
- (c) if the Patient has died before any subsequent 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 any subsequent dose of the vaccine following a discussion with a clinician;
- (b) no response: the Patient did not attend a booked appointment to receive any subsequent dose of the vaccine and the GP practice has made at least two separate attempts to contact the Patient and an appropriate period has elapsed following the administration of a prior dose of the vaccine;
- (c) the Patient's name has been removed from the GP practice's list of registered patients between any prior and subsequent 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 any prior 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 any subsequent 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.

Where the exceptional circumstances in paragraph 11.3 apply and the GP practice is not able to administer any subsequent dose of the vaccine required to complete the course of treatment, the GP practice will not be eligible for any subsequent payment.

- 11.4 GP practices must keep a record of the relevant circumstances to support reporting requirements and payment processes which will be published.
- 11.5 Payment under this ES, or any part thereof, is conditional on the GP practice satisfying 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 (including payment claims as required by paragraph 11.2.4) 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.

11.11 The Commissioner (NHSE) acknowledges that some GP practices may be continuing to provide vaccinations to Patients under the ES 2020/21 (phase 1 & 2) as at the commencement of this ES and that payment in consideration of those vaccinations will be made under the ES 2020/21 (phase 1 & 2). GP practices must ensure that a clear record of which Patients have been vaccinated under which enhanced services arrangement are retained and made available to the Commissioner (NHSE) on request. The Commissioner (NHSE) may make additional discretionary payments available to GP practices to support the delivery of or incentivise vaccinations, in particular seldom heard groups in exceptional circumstances. Details of those additional payments, will be made available on

<https://www.england.nhs.uk/coronavirus/covid-19-vaccination-programme/primary-care-guidance/>.

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/coronavirus/covid-19-vaccination-programme/primary-care-guidance/> 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 10.1).
- 13.3 In order to simplify the participation process, where there are any variations to this ES after 28 July 2021, the GP practice which has indicated its willingness to participate in this ES and the Commissioner (NHSE) is assured that the GP practice has the capacity to deliver this ES alongside their existing contractual requirements (and in compliance with any published guidance), 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 withdraws from this ES prior to the end of this ES will be based on the number of completed vaccinations provided to Patients, 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.

Annex B: Vaccinations for Cohort xiii

Where a GP Practice has:

- 1.1.1 sufficient workforce capacity (including existing staff and those drawn down from the national workforce pool) to deliver the vaccinations to Cohort xiii; and
- 1.1.2 has appropriately trained staff, with the necessary experience and skills to administer the vaccinations to Patients in cohort (xiii);
- 1.1.3 referred to the clinical guidance available including but not limited to the National Minimum Standards and Core Curriculum for Immunisation Training for Registered Practitioners (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/679824/Training_standards_and_core_curriculum_immunisation.pdf);

that GP practice shall be eligible to vaccinate Patients in accordance with paragraph 9.2.3:

- 1.2 Eligibility to vaccinate Patients in accordance with paragraph 9.2.3 shall only commence, following the announcement and authorisation of cohort (xiii).
- 1.3 GP practices must follow all published Commissioner (NHSE) guidance on the call/recall of Patients.
- 1.4 Where the GP practice ceases to meet the requirements at paragraph 1.1 of this Annex B, the GP practice shall not provide any additional initial doses of the vaccine to Patients in accordance with paragraph 9.2.3 without the approval of the Commissioner (NHSE).

Annex C: JCVI advice on vaccination of children aged 12 to 15 years with underlying health conditions (31 August 2021)

“JCVI has reviewed further UK data on hospital admissions, paediatric intensive care unit (PICU) admissions and deaths in children aged 12 to 15 years. For the vast majority of children aged 12 to 15 years, SARS-CoV2 infection is asymptomatic or mildly symptomatic, and is self-limiting. Of the very few children aged 12 to 15 years who develop more severe illness requiring hospital attendance, the majority have underlying health conditions.

In the latest analysis of UK data from the Royal College of Paediatrics and Child Health (RCPCH) together with the NHS England (NHSE) National Clinical Director for children and young people (see the ‘References’ section below), estimates of the incidence of PICU admission for children aged 12 to 15 years without underlying health conditions were 2 per million, compared to over 100 per million for those with underlying health conditions. These estimates are imprecise due to the small number of children requiring PICU admission over the course of the pandemic.

Previously, JCVI advised that children with severe neuro-disabilities, Down’s Syndrome, underlying conditions resulting in immunosuppression, profound and multiple learning disabilities (PMLD), severe learning disabilities or who are on the learning disability register, should be offered COVID-19 vaccination.

Following consideration of the updated data, JCVI advises that the offer of a course of COVID-19 vaccination should be expanded to include children aged 12 to 15 years with the following:

haematological malignancy

sickle cell disease

type 1 diabetes

congenital heart disease

other health conditions as described below under ‘COVID-19 clinical risk groups for children aged 12 to 15 years’ (these health conditions reflect the basket of diagnoses used in the RCPCH and NHSE analyses mentioned above).

Asthma is one of the commonest underlying health conditions prevalent among children and young people. The RCPCH and NHSE analysis found that those with asthma, as a broad group, were not at particular risk from COVID-19. The British Thoracic Society, in collaboration with academic partners, have agreed a consensus view regarding which children and young people with poorly controlled asthma are at higher risk from COVID-19. These people with poorly controlled asthma should be offered a course of COVID-19 vaccination.

It is recognised that there are a number of less common conditions in children, often due to congenital or metabolic defects, where respiratory infections of any sort can result in severe illness. Clinical judgement would need to be applied in identifying these children, and they should be offered a course of COVID-19 vaccination as well.

A course of COVID-19 vaccination refers to a 2-dose primary schedule unless the individual is severely immunosuppressed when a 3-dose primary schedule is advised in accordance with the latest JCVI advice on third primary vaccine doses (see the green book, Chapter 14a).

COVID-19 clinical risk groups for children aged 12 to 15 years

Chronic respiratory disease:

Includes those with poorly controlled asthma that requires continuous or repeated use of systemic steroids or with previous exacerbations requiring hospital admission, cystic fibrosis, ciliary dyskinesias and bronchopulmonary dysplasia.

Chronic heart conditions:

Haemodynamically significant congenital and acquired heart disease, or milder heart disease with other co-morbidity.

Chronic conditions of the kidney, liver or digestive system:

Includes those associated with congenital malformations of the organs, metabolic disorders and neoplasms, and conditions such as severe gastro-oesophageal reflux that may predispose to respiratory infection.

Chronic neurological disease:

Includes those with:

neuro-disability and/or neuromuscular disease including cerebral palsy, autism, epilepsy and muscular dystrophy

hereditary and degenerative disease of the nervous system or muscles, or other conditions associated with hypoventilation

severe or profound and multiple learning disabilities (PMLD), Down's syndrome, or those on the learning disability register

neoplasm of the brain

Endocrine disorders:

Includes diabetes mellitus, Addison's and hypopituitary syndrome.

Immunosuppression:

Immunosuppression due to disease or treatment, including:

those undergoing chemotherapy or radiotherapy, solid organ transplant recipients, bone marrow or stem cell transplant recipients

genetic disorders affecting the immune system (for example, deficiencies of IRAK-4 or NEMO, complement disorder, SCID)

those with haematological malignancy, including leukaemia and lymphoma

those receiving immunosuppressive or immunomodulating biological therapy

those treated with or likely to be treated with high or moderate dose corticosteroids

those receiving any dose of non-biological oral immune modulating drugs – for example, methotrexate, azathioprine, 6-mercaptopurine or mycophenolate

those with auto-immune diseases who may require long term immunosuppressive treatments

Asplenia or dysfunction of the spleen:

Includes hereditary spherocytosis, homozygous sickle cell disease and thalassaemia major.

Serious genetic abnormalities that affect a number of systems:

Includes mitochondrial disease and chromosomal abnormalities.

References

Deaths in Children and Young People in England following SARS-CoV-2 infection during the first pandemic year: a national study using linked mandatory child death reporting data. C Smith, D Odd, R Harwood, J Ward, M Linney, M Clark, D Hargreaves, SN Ladhani, E Draper, PJ Davis, SE Kenny, E Whittaker, K Luyt, RM Viner, LK Fraser. medRxiv 2021.07.07.21259779. doi: <https://doi.org/10.1101/2021.07.07.21259779>

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Some of the data considered by JCVI were unpublished analyses from the studies cited above.”

Annex D: Vaccinations for Cohort xiv

- 1.1 Where a GP Practice has not opted out of the delivery of vaccinations to those patients in JCVI cohort (xiv) within 14 days of publication of this ES unless otherwise agreed with the Commissioner (NHSE) and who also fulfil the following criteria:
 - 1.1.1 has appropriately trained staff, with the necessary experience and skills to administer the vaccinations to Patients in cohort (xiv) (including an introduction to the key consideration for Level 3 Child Safeguarding);
 - 1.1.2 has referred to the clinical guidance available including but not limited to the COVID-19 Vaccinator Training Recommendations (<https://www.gov.uk/government/publications/covid-19-vaccinator-training-recommendations>);
- 1.2 Eligibility to vaccinate Patients in accordance with paragraph 9.2.4 shall only commence, following the announcement and authorisation of cohort (xiv).
- 1.3 GP practices must follow all published Commissioner (NHSE) guidance including guidance on the call/recall of Patients.
- 1.4 Where the GP practice ceases to meet the requirements at paragraph 1.1 of this Annex D, the GP practice shall not provide any additional initial doses of the vaccine to Patients in accordance with paragraph 9.2.4 without the approval of the Commissioner (NHSE).