

Schedule 1

Primary Care Contracted Services: Immunisations (Covid-19 Vaccines) Specification

1. Introduction

The long term response to the Covid-19 pandemic requires the deployment of a safe and effective vaccine with enough uptake in the 'at risk' and overall population to protect individual patients and reduce the burden on and risk to NHS services. Rapid progress has been made. UK governments announced the advanced purchase of four different Covid-19 vaccine technologies, totalling 350 million doses, including the Moderna Vaccine, the Oxford-Astra/Zeneca Vaccine and the Pfizer-BioNTech Vaccine (together referred to in the Directions and this Specification as "the Covid-19 vaccines").

Planning and the ongoing delivery of the programme, is challenging, due to the emerging nature of data on vaccine characteristics and the developing understanding of, and guidance in relation to, which individuals should receive a vaccine. The overall Wales Programme Covid-19 Vaccination strategic intent remains to immunise as many eligible individuals, as swiftly as possible, safely and with minimum waste.

Primary Care in Wales has an excellent track record of delivering immunisation programmes, and has the skilled and experienced workforce necessary to deliver a Covid-19 vaccination programme. Successful delivery will require significant resources to deliver a mass vaccination programme with additional workforce, venues, logistics and data management solutions to ensure safe and timely vaccine deployment.

This Primary Care Contracted Services: Immunisations ("PCCS:I") Specification specifically relates to the delivery of the Covid-19 vaccines by Primary Care providers, defined for the purpose of this specification as "engaged providers".

2. Background

SARS-CoV-2 virus is the official name of the strain of coronavirus that causes the disease known as Covid-19. When a human is exposed to the SARS-CoV-2 virus, spike glycoprotein (S) found on the surface of the virus binds to ACE2 receptors on human cells to gain entry to the cells and cause an infection. Early vaccines act by boosting the ability of the body to recognise and develop an immune response to the spike protein, and this will help stop the SARS-CoV-2 virus from entering human cells and therefore prevent infection.

Vaccinating people against the SARS-CoV-2 virus is key to reducing the severe morbidity and mortality it causes and providing a long term solution to

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controlling Covid-19. When safe and effective vaccines against Covid-19 are available it is essential that they are delivered quickly to those who need it.

The Moderna and Pfizer-BioNTech vaccines are nucleoside-modified messenger RNA (mRNA) vaccines. mRNA vaccines use the pathogen's genetic code as the vaccine; this then exploits the host cells to translate the code then make the target spike protein. The protein then acts as an intracellular antigen to stimulate the immune response. mRNA is then normally degraded within a few days. The Pfizer-BioNTech vaccine has been generated entirely in vitro and is formulated in lipid nanoparticles which are taken up by the host cells.

The Oxford/AstraZeneca vaccine is a non-replicating viral vector vaccine made from a weakened version of a common cold virus (adenovirus) that causes infections in chimpanzees. The virus has been genetically changed so that it is impossible for it to replicate in humans.

Covid-19 vaccine supply to Wales is being managed centrally by the Welsh Government in conjunction with Local Health Boards. Engaged providers who participate in the PCCS:I will not be required to purchase any stock of a Covid-19 vaccine. All vaccines will be free and mandatory vaccination is not planned. Private supplies of vaccine will not be available.

A Patient Group Direction for administering Covid-19 vaccines has been authorised by each Local Health Board.

The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020

(https://www.legislation.gov.uk/ukSI/2020/1125/pdfs/ukSI_20201125_en.pdf) also allow Covid-19 vaccines to be administered according to a two-step national protocol using registered, trained and competent health care professionals to carry out the clinical assessment, consent and preparation steps of delivery, whilst suitably trained, non-registered and competent members of staff will be able to administer a vaccine itself under clinical supervision by a registered health care professional. The Human Medicines Regulations do not specify who these non-registered vaccinators might be.

The relevant national protocol for each Covid-19 vaccine can be accessed via the following links;

- Moderna vaccine - <https://gov.wales/national-protocol-covid-19-moderna-vaccine>
- Oxford-Astra/Zeneca vaccine – <https://gov.wales/national-protocol-covid-19-astrazeneca-vaccine>
- Pfizer BioNTech vaccine - <https://gov.wales/national-protocol-pfizer-biontech-covid-19-vaccine>

Those persons engaged in delivery of Covid-19 vaccines under this PCCS:I

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will be covered by existing indemnity arrangements pursuant to regulation 8 of the NHS (Clinical Negligence Scheme) (Wales) Regulations 2019.

3. Primary Care Contracted Services: Immunisations Scheme Aims

This PCCS:I provides a mechanism for Primary Care providers to enter into an arrangement with their Local Health Board (“the relevant Local Health Board”) to enable the provision of services to administer the Covid-19 vaccines as part of the health service in Wales and the wider Covid-19 vaccination programme led by Local Health Boards.

4. Cluster Working

Engaged providers are strongly encouraged to work collectively within cluster groupings, whether or not these have previously been in place and irrespective of which primary care services a provider usually provides, to maximise the level of vaccine delivery. For example, for a general medical practitioner this may mean administering vaccinations to people who are not registered with the provider administering the vaccine, whilst for other providers, it could also mean administering vaccines at venues away from their normal working location.

5. Eligible Cohorts for Vaccination under the Primary Care Contracted Services: Immunisations Scheme

The Joint Committee on Vaccination and Immunisation (JCVI) advises UK health departments on immunisation and determines eligibility for each Covid-19 vaccine. However, prioritisation amongst the eligible groups will depend on vaccine characteristics and advice from the JCVI. This means that the use of each Covid-19 vaccine needs to be considered as part of the wider Covid-19 vaccination programme, where multiple vaccines and multiple models of delivery are in use.

The current JCVI priority groups are listed in Appendix A, and the current advice on vaccinating children and young people aged 12 to 17 years with the Pfizer-BioNTech vaccine is set out in summary in Appendix B, along with a link to the full advice. Appendix B only applies in respect of the Pfizer-BioNTech vaccine as it is currently the only vaccine authorised for persons less than 18 years of age in the UK. Current JCVI guidance on the administration of a third dose Covid-19 booster vaccine is set out in summary at Appendix C, along with a link to the full advice.

Consequently, **this Specification only relates to those specific groups eligible for a Covid-19 vaccine as determined by the contracting Local Health Board based on the JCVI advice.** Engaged providers who participate in this PCCS:I should ensure all of their staff are aware of which groups are eligible for vaccination under this Specification and the prioritised sequence for delivery. Vaccination outside of these specific eligible groups will not receive payments under this PCCS:I.

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For full details of vaccination against Covid-19, health care practitioners should refer to the relevant chapters of the Green Book “Immunisation against infectious disease” at:

<https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>

and MHRA authorisation documents at:

[COVID-19 - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/collections/covid-19-vaccines).

6. Conditions for Service Delivery

In order for a primary care provider to be considered for participation in this PCCS:I specifically to provide services administering Covid-19 vaccines in accordance with this Specification, all of the following conditions must be met:

- a. There must be an up-to-date and appropriate level of equipment for **resuscitation and anaphylaxis**, specifically adrenaline, at any site where vaccination occurs.
- b. All persons who are involved in administration of vaccinations must be;
 - i. adequately **trained** in administration of multi-dose vaccinations, vaccine storage, handling, security and assessment and management of **resuscitation, anaphylaxis and aseptic no-touch techniques**, and
 - ii. **trained in the use of PPE, be supplied with and wear the appropriate PPE** for the setting in which they are working.
- c. All venues where vaccination occurs must have **been risk-assessed for transmission of coronavirus, based on local guidance**, and action taken to reduce risk where possible.
- d. Patients, who for the purposes of this Specification shall be defined to mean a person who will be or has been administered a vaccine under this PCCS:I, should be advised in advance not to attend if feeling unwell. Nonetheless, some patients may present to the vaccination location unwell, or may become unwell whilst attending the vaccination location. Facilities must be in place for the assessment and management of patients who are unwell and this must include resources to manage fainting and anaphylaxis/cardiac arrest to a primary care level of skill. Reliance on 999 Paramedics is not appropriate. All recipients of the Pfizer BioNTech and Moderna vaccines should be kept for observation and monitored for a minimum of 15 minutes immediately after a vaccine has been administered.
- e. The engaged provider and any person involved in the administration of a Covid-19 vaccine must have undertaken an appropriate training programme specific to the vaccine being used. Public Health Wales has provided an e-learning module:

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<https://www.e-lfh.org.uk/programmes/covid-19-vaccination/>

- f. Primary care providers are encouraged to collaborate with other primary care providers within existing clusters but also, where necessary, to form new clusters specifically to deliver this PCCS:I, which can be with providers outside of their own profession, if they have not already done so.
- g. A clinical record of immunisation with a Covid-19 vaccine must be entered onto the Welsh Immunisation System (“WIS”). Arrangements are being made at UK level with GP system providers for the WIS (and NHSE NIMS) to populate patient records automatically, to avoid double entry.

7. Payment for administration of a Covid-19 vaccine under this PCCS:I

- a. The Local Health Board must pay to an engaged provider who qualifies for the payment in accordance with Directions 5 to 7, a payment of—
 - i. £12.58 in respect of each dose of a Covid-19 vaccine administered to a person under this PCCS:I, and
 - ii. £400 for every 1,000 vaccines administered under this PCCS:I.
- b. In addition to the payments specified in paragraph a., for the period beginning with 4 December 2021 and ending with 31 March 2022, the Local Health Board must pay to an engaged provider who qualifies for payment in accordance with Directions 5 to 7 a payment of—
 - i. £2.42 per Covid-19 vaccine administered on a working day or a Saturday under this PCCS:I,
 - ii. £7.42 per Covid-19 vaccine administered on a Sunday under this PCCS:I, and
 - iii. £17.42 per Covid-19 vaccine administered under this PCCS:I at the location where the patient normally resides, but which is not a care home.

8. PCCS:I Specification

Agreement of Eligible Cohorts

- a. The relevant Local Health Board will develop a proactive and preventative approach to offering the Covid-19 vaccines by adopting robust call and reminder systems to contact individuals within eligible cohorts, with the aims of;
 - i. maximising uptake in the interests of those persons, and
 - ii. meeting any public health targets in respect of the administration of each Covid-19 vaccine.
- b. The engaged provider must agree with the relevant Local Health Board

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to;

- i. participate in this PCCS:I to maximise the vaccination with the Covid-19 vaccines of specific cohorts of the population **listed in, or notified by the Welsh Ministers in accordance with, Appendix A, B or C**;
- ii. accept the order of the cohorts and timescale over which the vaccines will be administered; and
- iii. in the case of general medical practitioners, vaccinate appropriate people who are not registered with their practice.

Publicity & Promotion

- c. The engaged provider must **prominently display provided materials** advertising the availability of Covid-19 vaccinations for eligible groups. This should include displaying advertisements on the premises website, using social media as well as inside the premises.
- d. **Booking** of appointments for vaccination must be booked via the WIS Core. Patients will be able to change their pre-booked appointment, should they need to, via the online booking system.

Model for Delivery

- e. The **engaged provider and relevant Local Health Board must agree the timing and location of vaccination clinic sessions in the plan agreed in accordance with Direction 4(4)(a)(iv).**
- f. The engaged provider is actively encouraged to **work collaboratively with other engaged providers** in a cluster to share resources and maximise efficiencies to deliver this PCCS:I.
- g. The engaged provider **must notify the relevant Local Health Board of the number of vaccination slots they have available and of all vaccination clinic sessions** start and finish times, and their locations, at least 14 days in advance.
- h. **Vaccination appointments and number of people per session will be agreed between the relevant Local Health Board and engaged provider** and vaccines will be in multiples of 6 or 10 doses, to minimise waste as each Covid-19 vaccine is contained within a multi-dose vial.
- i. The engaged provider must **administer the appropriate Covid-19 vaccine to those persons allocated to them by the relevant Local Health Board in accordance with the Directions and this PCCS:I Specification**, after obtaining consent, and following guidance in the Green Book.
- j. The engaged provider must ensure that all persons who receive

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- vaccinations are eligible under the cohorts and suitable clinically in accordance with law and guidance;
- i. Informed consent is obtained by a registered health care 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 accordance with law and guidance;
- k. Consent obtained in accordance with sub-paragraph 8.j.i. must be recorded (as appropriate) for any necessary information sharing with the relevant Local Health Board, in accordance with data protection law and guidance;
 - l. Engaged providers must ensure a person receives the recommended vaccine as part of a course to comply with relevant JCVI guidance for each cohort of people
 - m. Engaged providers must ensure that:
 - i. the correct dosage of a Covid-19 vaccine is administered, as clinically appropriate;
 - ii. they comply with relevant guidance issued by the JCVI on, including but not limited to:
 - a) which Covid-19 vaccine is the most suitable for each cohort of people;
 - b) the relevant maximum and minimum intervals (as applicable) for administration of each vaccination;
 - c) the relevant vaccination time limitations and expiry date following reconstitution;
 - d) the number of doses of each vaccine required to achieve the desired immune response; and
 - e) any other relevant guidance relating to the administration of the different types of vaccine and the different cohorts from time to time.

Persons involved in administering the vaccine

- n. The engaged provider must ensure that vaccinations are administered only by a person permitted to do so in accordance with the Human Medicines Regulations 2012, as amended by the Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020, including under a relevant Patient Group Direction or under a National Protocol approved by Welsh Ministers.
- o. All health care professionals administering a Covid-19 vaccine, must have:
 - i. read and understood the clinical guidance available at <http://nww.immunisation.wales.nhs.uk/covid-19-vaccination-programme>
 - ii. completed the additional online Covid-19 specific training modules available on the e-learning for health website when

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- available. Engaged providers will be expected to oversee and keep a record to confirm that all persons administering the vaccines have undertaken the training prior to participating in vaccinations;
- iii. the necessary experience, skills, training and competency 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;
 - iv. the necessary experience, skills, training and competency to administer vaccines in general, including training with regard to the recognition and initial treatment of anaphylaxis; and
 - v. ensured that registered health care 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.
- p. All other persons administering a Covid-19 vaccine must:
- i. be authorised, listed, referred to or otherwise identified by reference to the Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020, including under a relevant Patient Group Direction or National Protocol approved by Welsh Ministers;
 - ii. while preparing and/or administering vaccinations be supervised by a health care professional fulfilling the requirements of sub-paragraph o., above;
 - iii. have completed the additional online Covid-19 specific training modules available on the e-learning for health website when available. Engaged providers 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 Covid-19 vaccines that become available while this PCCS:I is in operation;
 - iv. 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; and
 - v. the necessary skills and training, including training with regard to the recognition and initial treatment of anaphylaxis.
- q. Engaged providers must ensure that all Covid-19 vaccines are received, stored, prepared and subsequently transported (where appropriate) in accordance with the relevant manufacturer's, Public Health Wales and Local Health Board instructions and all associated Standard Operating Procedures, including that all refrigerators in which vaccines are stored have a temperature data logger installed inside the refrigerator which continuously monitors the temperature inside the refrigerator and can be downloaded by trained personnel to give a continuous temperature record for that refrigerator. Refrigerator temperature readings must be taken and recorded from the refrigerator temperature thermometer display on

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all working days and engaged providers must ensure that appropriate action is taken when readings are outside the recommended temperature.

- r. 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 does not exceed 5% of the total number of vaccines supplied. Wastage levels will be reviewed by the relevant Local Health Board on an ongoing basis. Where wastage exceeds 5% of the vaccines supplied and that wastage is as a result of supply chain or relevant Local Health Board fault, those vaccines shall be removed from any wastage calculations when reviewed by the relevant LHB on an ongoing basis.
- s. Engaged providers must ensure that services are accessible, appropriate and sensitive to the needs of all persons. No person allocated by a relevant Local Health Board shall be excluded or experience particular difficulty in accessing and effectively using this PCCS:I 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.

Record-keeping

- t. The engaged provider must use the **Welsh Immunisation System**;
 - i. for recording consent for vaccination,
 - ii. for noting any contraindications,
 - iii. for recording when a vaccination has been given, including the batch number and manufacturer expiry date,
 - iv. for recording immediate adverse events,
 - v. for recording the refrigerator temperature(s) where Covid-19 vaccines are stored, twice daily (start and end of the day) on all working days, as per Local Health Board guidance,
 - vi. for recording receipt of delivery of the vaccine on the day of receipt
 - vii. for recording the daily vaccine stock check balance on all working days at the end of the last clinic session,
 - viii. for providing evidence for payments under this PCCS:I, including for Post Payment Verification.
- u. By using the Welsh Immunisation System, the record of vaccination of a person by the engaged provider will be sent electronically to the individual's GMS record.
- v. The engaged provider must;
 - i. supply Public Health Wales with information on persons who have received a Covid-19 vaccine, via the Welsh Immunisation

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System, for the purpose of monitoring local and national uptake;

- ii. supply NHS Wales Shared Services Partnership with information on persons who have received a Covid-19 vaccine, via the Welsh Immunisation System for the purposes of payment, and/or post payment verification;
- iii. provide data, to the cluster lead practice of a cluster (where applicable), Local Health Boards and Welsh Government when required; and
- iv. ensure consistent coding for capture of data and compliance with relevant information governance legislation.

Adverse Events

- w. All adverse events relating to a Covid-19 vaccine **must** be reported to;
 - i. the MHRA using the Yellow Card scheme www.yellowcard.gov.uk, and
 - ii. the Health Board Primary Care Team (by using DATIX or the all Wales Concerns Management System, or existing local arrangements).
- x. Studies are on-going to support co-administration of Covid-19 vaccines with influenza in the 2021/22 season. Where co-administration does occur, patients should be informed about the likely timing of potential adverse events relating to each vaccine. Engaged providers should refer to the available guidance which can currently be found [here](#).
- y. The engaged provider must ensure the person receiving a Covid-19 vaccine has understood that failure to receive all recommended doses of a 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.

Vaccine stock and consumables

- z. The relevant Local Health Board will;
 - i. coordinate vaccine supplies; and
 - ii. provide consumables such as PPE, syringes and needles.

Publicity and Information Materials

- aa. Publicity materials and information leaflets will be provided by the relevant Local Health Board.

Security

- bb. The security assessment related to delivery of a Covid-19 vaccine

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is continually evolving. In order to ensure the safety of patients, staff and the vaccines themselves, engaged providers must have robust security measures in place.

- cc. At this moment, as a minimum this must include:
 - i. lockable temperature controlled storage (vaccine fridge). This can include adaptation of an existing fridge;
 - ii. lockable internal doors preventing access to vaccine storage by unauthorised persons;
 - iii. lockable external windows and doors;
 - iv. an operational intruder alarm, preferably linked to an Alarm Receiving Centre; and
 - v. a robust and operational security process which all staff are aware of and are compliant with.

- dd. All packaging relating to Covid-19 vaccines must be destroyed or defaced in such a manner that prevents them being reused for any purpose. This includes the safe and secure disposal of empty vials via the clinical waste stream to ensure they cannot be reused.

- ee. Additional security measures that should also be considered but are desirable, include:
 - i. operational external CCTV covering all entry points;
 - ii. external lighting; and
 - iii. operational internal CCTV covering the location of the vaccine storage.

- ff. Due to the continually changing nature of the response to Covid-19 and the resources and vaccines that the NHS is able to deploy, these security arrangements must be responsive and may be frequently updated as necessary, dictated by any changes in the threat assessment. Engaged providers are expected to be alive to this issue and committed to providing the best possible delivery of this PCCS:I.

9. Notice Period

- a. Notice period for ending the agreement for service provision under this Specification will be four weeks for the relevant Local Health Board and the engaged provider, unless varied by mutual agreement between the Local Health Board and engaged provider. Notice must be given in writing setting out detailed reasons.

- b. The arrangements between an engaged provider and a relevant Local Health Board for the provision of Covid-19 vaccines pursuant to this PCCS:I and Specification may be terminated on any of the following events:
 - i. automatically, when the Covid-19 vaccination programme

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comes to an end;

- ii. the relevant Local Health Board is entitled to require that the engaged provider withdraws from the arrangement;
 - iii. the relevant Local Health Board terminates the arrangement with the engaged provider by giving not less than 4 weeks' notice to the engaged provider;
 - iv. the relevant Local Health Board is entitled to terminate the arrangement by giving not less than 4 weeks' notice where the engaged provider has failed to comply with any reasonable request for information from that Local Health Board relating to the provision of the services under this PCCS:I; or
 - v. Where the engaged provider cannot meet any of the requirements of this PCCS:I it must withdraw from this PCCS:I by serving written notice on the relevant Local Health Board to that effect with supporting reasons as to why it cannot meet the requirements, such notice must be received by the relevant Local Health Board no less than 4 weeks' prior to the date on which the engaged provider wishes to withdraw its provision of services under this PCCS:I.
- c. The arrangement cannot be terminated until the completing dose of a patient's required course of a Covid-19 vaccine has been administered to those persons who have received a first dose on the date the engaged provider or relevant Local Health Board gives notice of termination.

10. Application for Participation

Signature of engaged provider

Date

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Appendix A

List of eligible cohorts that may be chosen by the Local Health Board for inclusion in this PCCS:I:

1. residents in a care home for older adults and their carers
2. all those 80 years of age and over and frontline health and social care workers
3. all those 75 years of age and over
4. all those 70 years of age and over and clinically extremely vulnerable individuals
5. all those 65 years of age and over
6. all individuals aged 16 years to 64 years with underlying health conditions which put them at higher risk of serious disease and mortality
7. all those 60 years of age and over
8. all those 55 years of age and over
9. all those 50 years of age and over
10. all those aged 40 to 49 years
11. all those aged 30 to 39 years
12. all those aged 18 to 29 years
13. all those aged 16 to 17 years (see Appendix B for further information)
14. children and young people aged 12 to 15 years (see Appendix B for further information)

These priority groups are set by the JCVI and are correct at the date the Directions establishing this PCCS:I come into force. The priority groups are subject to change and the Welsh Ministers will notify Local Health Boards in writing of any additional eligible cohorts which may be included in this PCCS:I.

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Appendix B

This appendix provides a summary of the information on vaccinating children and young people aged 12-17 years with the Pfizer BioNTech (Comirnaty) Covid-19 vaccine.

The information contained in this Appendix is correct at the time the Directions that establish or amend this PCCS:l come into force. Engaged providers must read the current and any future advice from the JCVI and Welsh Government's Chief Medical Officer in this regard.

Summary of JCVI advice – JCVI advice on the UK vaccine response to the Omicron variant - GOV.UK (www.gov.uk) , 29 November 2021

1. All children and young people aged 12 to 15 years should be offered a second dose (30-micrograms) of the Pfizer-BioNTech COVID-19 vaccine at a minimum of 12 weeks from the first dose.

Summary of JCVI advice - Joint Committee on Vaccination and Immunisation (JCVI) advice on COVID-19 vaccination in people aged 16 to 17 years: 15 November 2021 - GOV.UK (www.gov.uk)

1. JCVI advises that young people aged 16 to 17 years who are not in an at-risk group should be offered a second dose of Pfizer-BioNTech (Comirnaty) COVID-19 vaccine. See the Summary of JCVI advice of 4 August 2021 below for further information on the at-risk groups for young people aged 16 to 17 years.

2. The second vaccine dose should be given 12 weeks or more following the first vaccine dose.

3. For persons who have had proven SARS-CoV-2 infection and a first dose of vaccine, the second vaccine dose should be given 12 weeks or more following the first vaccine dose, or 12 weeks following SARS-CoV-2 infection, whichever is later.

Summary of UK Chief Medical Officers' advice – (Written Statement: COVID-19 Vaccination – JCVI & Chief Medical Officers' advice on vaccinating 12-15 year olds (14 September 2021) | GOV.WALES)

1. The UK CMOs recommend that all children and young people aged 12-15 years not already covered by existing JCVI advice should be offered a first dose of Pfizer-BioNTech (Comirnaty) COVID-19 vaccine.

Summary of JCVI advice – 31 August 2021 (JCVI statement on COVID-19 vaccination of children aged 12 to 15 years: 3 September 2021 - GOV.UK (www.gov.uk))

1. A small number of children and young people with underlying chronic conditions are at increased risk of serious COVID-19 disease and therefore,

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children and young people aged 12 years and over with specific underlying health conditions should be offered a course of the Pfizer-BioNTech (Comirnaty) Covid-19 vaccination. This includes:

(a) Children and young people aged 12 to 15 years with the following specific underlying health conditions that put them at risk of serious COVID-19; severe neuro-disabilities, Down's Syndrome, underlying conditions resulting in immunosuppression, those with profound and multiple learning disabilities, severe learning disabilities or who are on the learning disability register, haematological malignancy, sickle cell disease, type 1 diabetes, congenital heart disease and other health conditions as described with the JCVI advice under 'COVID-19 clinical risk groups for children aged 12 to 15 years'.

(b) Children and young people with poorly controlled asthma are at higher risk from COVID-19. Those children and young people with poorly controlled asthma should be offered a course of COVID-19 vaccination.

(c) 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).

(d) Children and young people aged 12 years and over who are household contacts of persons (adults or children) who are immunosuppressed should be offered vaccination on the understanding that the main benefits from vaccination are related to the potential for indirect protection of their household contact who is immunosuppressed.

Summary of JCVI advice for young people aged 16 to 17 years – August 2021 (JCVI statement on COVID-19 vaccination of children and young people aged 12 to 17 years: 4 August 2021 - GOV.UK (www.gov.uk))

1. JCVI advises that all young people aged 16 to 17 years, should be offered a first dose of Pfizer-BioNTech (Comirnaty) Covid-19 vaccine. This is in addition to the existing offer of 2 doses of vaccine to 16 to 17-year-olds who are in 'at-risk' groups included in the Green Book.

2. Pending further evidence of effectiveness and safety in this age group, a second vaccine is anticipated to be offered later to increase the level of protection and to contribute towards longer term protection. Further data and the potential availability of alternative vaccine options will inform exact details which will be provided in a subsequent update of JCVI advice before second doses are due at approximately 12 weeks after the first dose.

3. It is considered operationally reasonable to allow a lead-in time to offer vaccination to those young people who are within three months of their 18th birthday to ensure good uptake of vaccine in newly-turned 18 year olds (2 doses).

This Schedule is a consolidated version prepared by the Welsh Government, it incorporates the amendments made by The Primary Care (Contracted Services: Immunisations) (Amendment) Directions 2021 to assist readers, but is not an official version of the Subordinate Legislation.

Appendix C

This appendix provides a summary of the information on the administration of booster doses.

The information contained in this Appendix is correct at the time the Directions that establish or amend this PCCS:I come into force. Engaged providers must read the current and any future JCVI advice in this regard.

JCVI advice on the UK vaccine response to the Omicron variant - GOV.UK (www.gov.uk) , 29 November 2021

1. Booster vaccination eligibility should be expanded to include all adults aged 18 years to 39 years.

2. Booster vaccination should now be offered in order of descending age groups, with priority given to the vaccination of older adults and those in a COVID-19 at-risk group. Booster vaccination should not be given within 3 months of completion of the primary course.

3. Severely immunosuppressed individuals who have completed their primary course (3 doses) should be offered a booster dose with a minimum of 3 months between the third primary and booster dose. Those who have not yet received their third dose may be given the third dose now to avoid further delay. A further booster dose can be given in 3 months, in line with the clinical advice on optimal timing.

4. Both the Moderna (50 microgram) and Pfizer-BioNTech (30 microgram) vaccines should be used with equal preference in the COVID-19 booster programme. Both vaccines have been shown to substantially increase antibody levels when offered as a booster dose.

Update to JCVI advice on booster vaccination in adults, 15 November 2021 - GOV.UK (www.gov.uk)

1. JCVI advises that all adults aged 40 to 49 years should be offered a booster vaccination with an mRNA COVID-19 vaccine, 6 months after their second dose, irrespective of the vaccines given for the first and second doses.

2. Booster vaccination should preferably be undertaken with either the Pfizer-BioNTech vaccine (BNT162b2/Comirnaty®), or a half dose of Moderna (mRNA-1273/Spikevax®) vaccine, as previously advised.

3. Future considerations include the need for booster vaccination (third dose) for 18 to 39 year olds who are not in an at-risk group, and whether additional booster vaccination (fourth dose) for more vulnerable adult groups may be required. At present, it is not known whether recurrent boosters will be required in the long term, and more data is required to inform these decisions as we move into 2022.

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JCVI statement regarding a COVID-19 booster vaccine programme for winter 2021 to 2022 - GOV.UK (www.gov.uk) 14 September 2021

1. JCVI advises that for the 2021 COVID-19 booster vaccine programme individuals who received vaccination in Phase 1 of the COVID-19 vaccination programme (priority groups 1 to 9) should be offered a third dose COVID-19 booster vaccine. This includes:

- those living in residential care homes for older adults
- all adults aged 50 years or over
- frontline health and social care workers
- all those aged 16 to 49 years with underlying health conditions that put them at higher risk of severe COVID-19 (as set out in the green book), and adult carers
- adult household contacts (aged 16 or over) of immunosuppressed individuals

2. As most younger adults will only have received their second COVID-19 vaccine dose in late summer or early autumn, the benefits of booster vaccination in this group will be considered at a later time when more information is available. In general, younger, healthy individuals may be expected to generate stronger vaccine-induced immune responses from primary course vaccination compared to older individuals. Pending further evidence otherwise, booster doses in this population may not be required in the near term.

3. JCVI will review data as they emerge and consider further advice at the appropriate time on booster vaccinations in younger adult age groups, children aged 12 to 16 years with underlying health conditions, and women who are pregnant.