
SUBORDINATE
LEGISLATION

WG No. 20-XX

**THE NATIONAL HEALTH
SERVICE (WALES) ACT 2006**

The Primary Care
(Oxford/AstraZeneca Vaccine
COVID-19 Immunisation Scheme)
Directions 2020

Made *** December 2020

Coming into force *** December 2020

The Welsh Ministers, in exercise of the powers conferred on them by sections 10, 12(3) and 203(9) and (10) of the National Health Service (Wales) Act 2006(1), make the following Directions.

Title, application and commencement

1.—(1) The title of these Directions is the Primary Care (Oxford/AstraZeneca Vaccine COVID-19 Immunisation Scheme) Directions 2020.

(2) These Directions are given to Local Health Boards.

(3) These Directions come into force immediately after they are signed.

Interpretation

2. In these Directions—

“the Act” (“*y Deddf*”) means the National Health Service (Wales) Act 2006;

“cluster” (“*clwstwr*”) means a group of local service providers involved in health and care who have agreed to collaboratively work together to deliver primary medical services across a specified geographical area;

“cluster lead practice” (“*practis arweiniol y clwstwr*”) means a **general medical practitioner** that

(1) 2006 c. 42.

has agreed to provide the Scheme to its registered patients, and to the registered patients of a **general medical practitioner** in its cluster that is not an engaged provider, and which the Local Health Board agrees will be a cluster lead practice;

“corporate optician” (“”) means a body corporate registered in the register of bodies corporate maintained under section 9 of the Opticians Act 1989⁽¹⁾, which is carrying on business as an optometrist;

“dentist” (“*deintydd*”) means a dental practitioner who is registered in the dentists register;

“dentists register” (“”) means the register referred to in section 14(1) of the Dentists Act 1984⁽²⁾;

“engaged provider” (“*XX â chytundeb*”) means a dentist, **general medical practitioner** (whether acting for itself, as a cluster lead practice or on behalf of another practice or group of practices), **optician** or pharmacist that agrees with a Local Health Board to provide services under the Scheme pursuant to an arrangement made in accordance with Direction 4;

“general medical practitioner” (“”) means a medical practitioner whose name is included in the General Practitioner Register kept by the General Medical Council under section 34C of the Medical Act 1983⁽³⁾;

“health care professional” (“*gweithiwr gofal iechyd proffesiynol*”) means a person who is a member of a profession regulated by a body mentioned in section 25(3) of the National Health Service Reform and Health Care Professions Act 2002⁽⁴⁾;

“Local Health Board” (“*Bwrdd Iechyd Lleol*”) means a Local Health Board established under section 11 of the Act (local health boards);

“optician” means a person registered in the register of optometrists maintained under section 7 (register of opticians) of the Opticians Act 1989 or in the register of visiting optometrists from relevant European States maintained under section 8B(1)(a) of that Act, or a corporate optician;

“pharmacist” (“*fferyllydd*”) means a person who is—

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- (1) 1989 c. 44.
 (2) 1984 c. 24, amended by S.I. 2005/2011 and S.I. 2007/3101.
 (3) 1983 c. 54. Section 34C was inserted by paragraph 10 of Schedule 1 to the General and Specialist Medical Practice (Education, Training and Qualifications) Order 2010 (S.I. 2010/234).
 (4) 2002 c. 17.

- (a) registered in Part 1 of the General Pharmaceutical Council Register⁽¹⁾ or in the register maintained under Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976⁽²⁾, or
- (b) lawfully carrying on a retail pharmacy business in accordance with section 69 of the Medicines Act 1968, and

whose name is included in a pharmaceutical list under regulation 10 (preparation and maintenance of pharmaceutical lists) of the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020, for the provision of pharmaceutical services in particular by the provision of drugs;

“registered patient” (“*claf cofrestredig*”) means—

- (a) a person who is recorded by the Local Health Board as being on a general medical practitioner’s list of patients, or
- (b) a person whom the general medical practitioner has accepted for inclusion on its list of patients, whether or not notification of that acceptance has been received by the Local Health Board and who has not been notified by the Local Health Board as having ceased to be on that list;

“Oxford/AstraZeneca Vaccine Primary Care COVID-19 Immunisation Scheme Specification” (“”) means the Oxford/AstraZeneca Vaccine Primary Care COVID-19 Immunisation Scheme Specification at the Schedule to these Directions;

“Scheme” (“*y Cynllun*”) means the Oxford/AstraZeneca Vaccine Primary Care COVID-19 Immunisation Scheme established by a Local Health Board in accordance with Direction 3;

“the vaccine” (“”) means the (ChAdOx1 nCoV-19) (Oxford) Vaccine.

Establishment of an Oxford/AstraZeneca Vaccine Primary Care COVID-19 Immunisation Scheme

3.—(1) Each Local Health Board must establish, operate and, as appropriate, revise an Oxford/AstraZeneca Vaccine Primary Care COVID-19 Immunisation Scheme.

(2) The underlying purpose of the Scheme is to enable the provision of services to administer the vaccine as part of the health service in Wales by dentists, **general medical practitioners, opticians** and pharmacists.

(1) Maintained under article 19 (establishment, maintenance of and access to the Register) of the Pharmacy Order 2010 (S.I. 2010/231).

(2) S.I. 1976/1213 (N.I.22).

Oxford/AstraZeneca Vaccine Primary Care COVID-19 Immunisation Scheme

4. As part of its Scheme, each Local Health Board may enter into arrangements for the provision of services in accordance with the Oxford/AstraZeneca Vaccine Primary Care COVID-19 Immunisation Scheme Specification with—

- (a) a dentist;
- (b) a **general medical practitioner**—
 - (i) in relation to the registered patients of that **general medical practitioner**,
 - (ii) one or more cluster lead practices, in relation to the registered patients of the cluster lead practice and the registered patients of those **general medical practitioners**, if any, in its cluster that have not agreed within such time period as the Local Health Board requires, to deliver the Scheme to their registered patients pursuant to sub-paragraph (i),
 - (iii) a **general medical practitioner** that has agreed to deliver the Scheme pursuant to sub-paragraph (i) in relation to the registered patients of another **general medical practitioner** or group of **general medical practitioners**, subject to the agreement of the other **general medical practitioner** or group of **general medical practitioners**;
- (c) an **optician**; or
- (d) a pharmacist.

5. Where the registered patients of a general medical practitioner will not receive the services under the Scheme, either from the general medical practitioner in relation to whom they are registered patients, or from a cluster lead practice, the Local Health Board must make arrangements to ensure the provision of the services to the registered patients of that general medical practitioner as close to the practice premises of that general medical practitioner as is reasonably practicable and the Local Health Board may deliver the services under the Scheme to those patients in any way it believes is appropriate (including, but not limited to, by providing the services itself or arranging for the delivery of those services by any engaged provider).

6. An arrangement made between a cluster lead practice and a Local Health Board in accordance with direction 4(b)(ii) must include a requirement that each engaged provider co-operates with the other engaged providers and the cluster lead practice in its cluster in order for the cluster lead practice to complete, by such date as the Local Health Board requires, a plan setting out the arrangement for the delivery of the services under the Scheme to all registered patients of the general medical practitioners across the cluster

(whether or not a general medical practitioner is a member of the cluster is an engaged provider or not).

7.—(1) Where arrangements are made between a Local Health Board and an engaged provider, those arrangements must include—

- (a) a requirement that the engaged provider—
 - (i) reads and takes account of these Directions alongside complying with the Oxford/AstraZeneca Vaccine Primary Care COVID-19 Immunisation Scheme Specification and its appendices which together provide the detailed requirements for the Scheme;
 - (ii) maintains and keeps up to date a record on the Welsh Immunisation System of all persons receiving treatment under the Scheme;
 - (iii) provides the services outlined in the Oxford/AstraZeneca Vaccine Primary Care COVID-19 Immunisation Scheme Specification and, where applicable, in line with the plan specified in direction 6;
- (b) a requirement that the engaged provider takes all reasonable steps to ensure that the lifelong medical records held by the general medical practitioner with whom the person receiving the vaccine is a registered patient are kept up-to-date with regard to that person's immunisation status, and in particular to include—
 - (i) any refusal of an offer of vaccination,
 - (ii) where an offer of vaccination was accepted—
 - (aa) details of the consent to the vaccination or immunisation (where a person has consented on another person's behalf, the relationship to the person receiving the vaccine must also be recorded),
 - (bb) the batch number, expiry date and title of the vaccine,
 - (cc) the dose of the vaccine administered,
 - (dd) the name of the person drawing up the vaccine,
 - (ee) the name of the person administering the vaccine (if different to the person in (dd)),
 - (ff) the date and time the vaccine was administered,
 - (gg) the route of administration and the injection site of each dose of the vaccine,

- (hh) any contraindications to the vaccination or immunisation, and
 - (ii) any adverse reactions to the vaccination or immunisation;
- (c) a requirement that the engaged provider ensures that it adheres to the current guidance on “Storage, distribution and disposal of vaccines in the latest edition of the “Green Book”(1) and has the minimum necessary security requirements specified in paragraph 8(cc) to (gg) of the Oxford/AstraZeneca Vaccine Primary Care COVID-19 Immunisation Scheme Specification;
- (d) a requirement that the engaged provider—
- (i) supplies Public Health Wales with information on persons they have administered the vaccine to, via automated data extraction, for the purpose of monitoring local and national uptake;
 - (ii) supplies NHS Wales Shared Services Partnership, via the Welsh Immunisation System, with information on persons who have received the vaccine, for payment and post payment verification purposes;
 - (iii) provides data, subject to paragraph (iv) below, to the cluster lead practice of a cluster (where applicable), Local Health Boards and Welsh Government when required;
 - (iv) ensures consistent coding for capture of data and compliance with relevant information governance legislation;
 - (v) ensures that each health care professional involved in the provision of services under the Scheme has the necessary skills, training, competence and experience in order to provide those services;
 - (vi) ensures that each health care professional involved in the provision of services under the Scheme completes any relevant training provided by Public Health Wales and that the engaged provider keeps a record to confirm that each health care professional has undertaken the relevant training prior to participating in the administration of vaccinations;
 - (vii) ensures each health care professional involved in the provision of services under the Scheme completes relevant CPD activity through, for example, regular educational updates, attendance at relevant courses

(1) “Green Book” means ‘Immunisation against infectious disease’ at <http://immunisation.dh.gov.uk/category/the-green-book/>

provided by the Local Health Boards, as well as self-directed learning, to be able to demonstrate they have adequate knowledge and skills through their annual appraisal and revalidation;

- (viii) ensures that each health care professional involved in the provision of services under the Scheme is adequately indemnified / insured for any liability arising from the work performed;
- (ix) ensures that any person involved in the administration of the vaccine who is not a health care professional—
 - (aa) is authorised, listed, referred to or otherwise identified by reference to the Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020,
 - (bb) is supervised by a health care professional who satisfies the criteria in sub-paragraphs (v) to (viii) while preparing and/or administering vaccinations,
 - (cc) has completed the online COVID-19 specific training modules available on the e-learning for health website when available,
 - (dd) has 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
 - (ee) has the necessary skills and training, including training with regard to the recognition and initial treatment of anaphylaxis;
- (x) in accordance with paragraph 9 of the Oxford/AstraZeneca Vaccine Primary Care COVID-19 Immunisation Scheme Specification gives at least 4 weeks' notice in writing prior to terminating their provision of the Scheme;
- (xi) supplies its Local Health Board with such information as the Local Health Board may reasonably request for the purposes of monitoring the performance of obligations under the Scheme and, where applicable, the cluster's performance in relation to the plan specified in direction 6; and
- (xii) completes an annual report of outcomes by 31 March each year;

- (e) payment arrangements for an engaged provider which must provide for it to be able to claim, in accordance with paragraph 7 of the Oxford/AstraZeneca Vaccine Primary Care COVID-19 Immunisation Scheme Specification, a payment of—
 - (i) £12.58 per vaccine administered, and
 - (ii) £400 per 1,000 vaccines administered.

(2) Any disputes arising as a result of provision of services under the Scheme will be dealt with in accordance with paragraph 10 of the Oxford/AstraZeneca Vaccine Primary Care COVID-19 Immunisation Scheme Specification.

(3) Where the Local Health Board delivers the Scheme pursuant to an arrangement in accordance with Direction 6, the Local Health Board must ensure that paragraphs (1) and (2) apply to such arrangements as they would to an engaged provider.



Signed by Alex Slade, Deputy Director, Primary Care Division under the authority of the Minister for Health and Social Services, one of the Welsh Ministers

Dated: 18 December 2020

Schedule Oxford / AstraZeneca Vaccine Primary Care COVID-19 Immunisation Scheme 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 have announced the advanced purchase of four different COVID-19 vaccine technologies, totalling 350 million doses, including the Oxford / AstraZeneca Vaccine, a collaboration between Oxford University and AstraZeneca.

Planning for delivery is exceptionally challenging due to the emerging nature of data on vaccine characteristics and of developing understanding of which individuals are most at risk of severe COVID-19 infection. The overall Wales Programme Covid 19 Vaccination strategic intent is to immunise as many eligible individuals, as swiftly as possible, safely 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 COVID-19 Immunisation Scheme Specification specifically relates to the administration of the Oxford / AstraZeneca Vaccine 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 controlling the current COVID-19 pandemic. When safe and effective vaccines against COVID-19 are available it is essential that they are delivered quickly to those who need it.

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. Assuming successful trials demonstrate effectiveness and safety, and exemption or licensure, which are currently uncertain, it's expected the Oxford / AstraZeneca Vaccine will be available from January 2021.

Vaccine supply to Wales is being managed centrally by Welsh Government in conjunction with Local Health Boards. Engaged providers who participate in the Primary Care COVID-19 Immunisation Scheme (PCCIS) will not be required to purchase any stock of the vaccine. Supplies of the Oxford / AstraZeneca Vaccine will be delivered regularly but in limited quantities over several months and so care must be taken to ensure that the most vulnerable have adequate access before the general population. 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 vaccine has been authorised by each HB.

The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (https://www.legislation.gov.uk/ukxi/2020/1125/pdfs/ukxi_20201125_en.pdf) also allow the vaccine to be administered according to a two-step national protocol using registered trained and competent healthcare professionals to carry out the clinical assessment, consent and preparation and a suitably trained non registered trained and competent member of staff will be able to administer the vaccine itself under clinical supervision by a registered healthcare professional. The Regulations do not specify who these non-registered vaccinators might be. This will be covered in the protocol which will be published soon.

Those persons engaged in delivery of the PCCIS will be covered by existing indemnity arrangements pursuant to regulation 8 of the NHS (Clinical Negligence Scheme) (Wales) Regulations 2019.

3. Primary Care COVID-19 Immunisation Scheme Aims

The Primary Care COVID-19 Immunisation Scheme (PCCIS) will provide a mechanism for Primary Care providers to enter in to an arrangement with their Local Health Board ("the relevant LHB") to enable the provision of services to administer the Oxford / AstraZeneca Vaccine 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 increase the vaccine administration rates. 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 COVID-19 Immunisation Scheme

The Joint Committee on Vaccination and Immunisation (JCVI) advises UK health departments on immunisation and will determine eligibility for specific COVID-19 vaccines. However, prioritisation amongst the eligible groups will depend on vaccine characteristics and advice from the JCVI. This means that the use of the Oxford / AstraZeneca 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. JCVI priority groups are listed in Appendix A.

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

For full details of vaccination against COVID-19, healthcare 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 COVID-19 - GOV.UK (www.gov.uk)

6. Conditions for Service Delivery

In order for a primary care provider to be considered for participation in this PCIS, 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 the vaccine under the PCCIS, 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, 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

- e. The engaged provider and any person involved in the administration of the Oxford / AstraZeneca Vaccine must have undertaken an appropriate training program specific to the vaccine being used. Public Health Wales has provided an e-learning module: <https://www.e-lfh.org.uk/programmes/covid-19-vaccination/>
- f. Primary care providers are encouraged to collaborate with other primary care providers both within existing clusters but also, where necessary, to form new clusters specifically to deliver this PCCIS, which can be with providers outside of their own profession, if they have not already done so.
- g. A clinical record of immunisation with 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 Welsh Immunisation System (and NHSE NIMS) to populate patient records automatically, to avoid double entry.

7. Payment for administration of the (ChAdOx1 nCoV-19) (Oxford) COVID-19 Vaccine under the Scheme

- a. The Local Health Board must pay to an engaged provider who qualifies for the payment in accordance with paragraphs b to p, a payment of—
 - (i) £12.58 in respect of each dose of the vaccine administered to a person under the Scheme, and
 - (ii) £400 for every 1,000 vaccines administered under the Scheme.

Eligibility for payment

- b. A dentist, general medical practitioner, optician or pharmacist is only eligible for a payment for provision of services under the Scheme in circumstances where the following conditions are met—
 - i. they are an engaged provider,
 - ii. the person in respect of whom the payment is claimed was allocated to the engaged provider by the Local Health Board with whom the engaged provider has an agreement to provide services under the Scheme,
 - iii. all required details have been entered on to the Welsh Immunisation System to create a clinical record of immunisation with the vaccine for each person in respect of whom a payment is being claimed by the engaged provider,
 - iv. the engaged provider does not receive any payment from any other source in respect of the vaccine (if the engaged provider does receive payments from other sources in respect of any person, the Local Health Board must consider whether to recover any payment made under the Scheme in respect of that person

- pursuant to sub-paragraphs j and k (overpayments and withheld amounts), and
- v. the engaged provider creates the clinical record on the Welsh Immunisation System at point of administration of each dose.
- c. An engaged provider is not entitled to receive payment of more than £25.16 in respect of any one person under the Scheme.

Payment

- d. The engaged provider will receive an automatic payment based on information recorded on the Welsh Immunisation System in respect of each person who has received a vaccine and, where applicable, for every 1,000 vaccines administered, and the activity of the engaged provider will be captured by NHS Wales Shared Services Partnership as at the tenth day of each calendar month.
- e. Any amount payable in accordance with sub-paragraph d falls due following the expiry of 14 days after the activity is captured under sub-paragraph d—
- i. in the case of a GDS contractor, on the next date when the GDS contractor's payable monthly Annual Contract Value Payment falls due in accordance with the relevant GDS Statement of Financial Entitlements;
 - ii. in the case of a GMS contractor, on the next date when the GMS contractor's Global Sum monthly payment falls due in accordance with the relevant Statement of Financial Entitlements;
 - iii. in the case of a GOS contractor, on the date in the next month when the GOS contractor's General Ophthalmic Services monthly reimbursement falls due in accordance with the Statement of Remuneration;
 - iv. in the case of a pharmacist, on the next date when the pharmacist receives any other payments due under the Drug Tariff, and
 - v. in the case of any other engaged provider, no later than 8 weeks beginning with the date on which the engaged provider creates or updates the clinical record on the Welsh Immunisation System or as otherwise may be agreed between the Local Health Board and the engaged provider.
- f. The Local Health Board must ensure that the receipt and payment in respect of any automatic payments made pursuant to sub-paragraph d are properly recorded and that each such payment has a clear audit trail.

Conditions attached to payment

- g. A payment under the provisions of these Directions is only payable if an engaged provider satisfies the following conditions;

- i. in respect of each person for which a payment under the Scheme is claimed, the engaged provider has supplied the Local Health Board, via the Welsh Immunisation System, with—
 - a. the name of the person,
 - b. the date of birth of the person,
 - c. the NHS number, where known, of the person,
 - d. the date each dose of the vaccine is administered
- h. to the Local Health Board may request from an engaged provider any information which the Local Health Board does not have but needs, and the engaged provider either has or could be reasonably expected to obtain, in order for the Local Health Board to form an opinion on whether the engaged provider is eligible for payment under the provisions of the Scheme,
- i. the Local Health Board may, in appropriate circumstances, withhold payment of any, or any part of, payments due under the Scheme if an engaged provider breaches any of these conditions.

Overpayments and withheld amounts

- j. If the Local Health Board makes a payment to an engaged provider pursuant to the Scheme and;
 - i. the engaged provider 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);
 - ii. the Local Health Board 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
 - iii. the Local Health Board is entitled to repayment of all or part of the money paid,
 - iv. the Local Health Board may recover the money paid by deducting an equivalent amount from any payment payable pursuant to these Directions, and where no such deduction can be made, it is a condition of the payments made pursuant to these Directions that the engaged provider must pay to the Local Health Board that equivalent amount.
- k. Where the Local Health Board is entitled pursuant to sub-paragraph j to withhold all or part of a payment because of a breach of a payment condition, and the Local Health Board does so or recovers the money by deducting an equivalent amount from another payment made in accordance with sub-paragraph b, it may, where it sees fit to do so, reimburse the engaged provider the amount withheld or recovered, if the breach is cured.

Underpayments and late payments

- l. If the full amount of a payment that is payable pursuant to the Scheme has not been paid before the date on which the payment falls due, then unless;
 - i. this is with the consent of the engaged provider; or
 - ii. the amount of, or entitlement to, the payment, or any part thereof, is in dispute,
 once it falls due, it must be paid promptly.

- m. If the engaged provider's entitlement to the payment is not in dispute but the amount of the payment is in dispute, then once the payment falls due, pending the resolution of the dispute, the Local Health Board must;
 - i. pay to the engaged provider, promptly, an amount representing the amount that the Local Health Board accepts that the engaged provider is at least entitled to, and
 - ii. thereafter pay any shortfall promptly, once the dispute is finally resolved.

- n. However, if an engaged provider has;
 - i. not claimed a payment to which it would be entitled pursuant to the Scheme if it claimed the payment; or
 - ii. claimed a payment to which it is entitled pursuant to the Scheme but a Local Health Board is unable to calculate the payment until after the payment is due to fall due because it does not have the information it needs in order to calculate that payment (all reasonable efforts to obtain the information having been undertaken),
 that payment is (instead) to fall due on the first working day of the month after the month during which the Local Health Board obtains the information it needs in order to calculate the payment.

Payments on account

- o. Where the Local Health Board and the engaged provider agree (but the Local Health Board's agreement may be withdrawn where it is reasonable to do so and if it has given the engaged provider reasonable notice thereof), the Local Health Board must pay to an engaged provider on account any amount that is;
 - i. the amount of, or a reasonable approximation of the amount of, a payment that is due to fall due pursuant to the Scheme; or
 - ii. an agreed percentage of the amount of, or a reasonable approximation of the amount of, a payment that is due to fall due pursuant to the Scheme, and if that payment results in an overpayment in respect of the payment, sub-paragraphs j and k apply.

Post payment verification

- p. Post payment verification⁽⁹⁾ applies to the provision of services under the Scheme.

8. Scheme Specification

Agreement of Eligible Cohorts

- a. The relevant LHB will develop a proactive and preventative approach to offering the Oxford / AstraZeneca Vaccine 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 the Oxford / AstraZeneca Vaccine .

The engaged provider must agree with the relevant LHB to;

- b. participate in a scheme to maximise the vaccination of specific cohorts of the population with the Oxford / AstraZeneca Vaccine **listed in Appendix A;**
- c. accept the order of the cohorts and timescale over which the vaccines will be administered; and
- d. in the case of general medical practitioners, vaccinate appropriate people who are not registered with their practice.

Publicity & Promotion

- e. The engaged provider must **prominently display provided materials** advertising the availability of the Oxford / AstraZeneca vaccinations for eligible groups. This should include displaying advertisements on the premises website, using social media as well as inside the premises.
- f. **Booking** of the first appointments for vaccination and any appointments for second vaccinations, will be according to local policy set by the Health Board and the Welsh Immunisation System will be used.

Model for Delivery

- g. The **engaged provider and LHB must agree the timing and location of the vaccination clinic sessions**
- h. The engaged provider is actively encouraged to **work collaboratively with other engaged providers** in a cluster to share resources and maximise efficiencies to deliver the PCCIS.
- i. The engaged provider **must notify the relevant LHB 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.
- j. **Vaccination appointments and number of people per session will be agreed between the LHB and engaged provider** and will be in multiples of 8 or 10 doses, depending on vial supplier to minimise waste

(9) For more information on post payment verification, please see; <https://nwssp.nhs.wales/ourservices/primary-care-services/general-information/post-payment-verification-ppv/>

- as the Oxford / AstraZeneca Vaccine is contained within a multi-dose vial.
- k. The engaged provider must **administer the Oxford / AstraZeneca Vaccine to those persons allocated to them by the relevant LHB in accordance with the Directions and this PCCIS**, after obtaining consent, and following guidance in the Green Book.
 - l. The engaged provider must ensure that all persons who receive vaccinations are eligible under the cohorts and suitable clinically in accordance with law and guidance;
 - i. Informed 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 accordance with law and guidance;
 - m. Consent obtained in accordance with paragraph k(i) must be recorded (as appropriate) for any necessary information sharing with the relevant LHB in accordance with data protection law and guidance;
 - n. Engaged providers must ensure a person receives a complete course of the same vaccine, unless in exceptional circumstances in which, for a person attending for a second vaccination, that first vaccine type is not available, or the vaccine type received is not known.
 - o. Engaged providers must:
 - i. ensure the correct dosage of the vaccine is administered, as clinically appropriate;
 - ii. that they comply with relevant guidance issued by JCVI on, but not limited to:
 1. which vaccine is the most suitable for each cohort of people;
 2. the relevant maximum and minimum intervals (as applicable) for administration of each vaccination;
 3. the relevant vaccination time limitations and expiry date following reconstitution;
 4. the number of doses of each vaccine required to achieve the desired immune response; and
 5. 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

- p. 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.
- q. All healthcare professionals administering the 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 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 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.
- r. All other persons administering the 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 healthcare professional fulfilling the requirements of paragraph p, 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 vaccines that become available while this PCCIS 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.
- s. Engaged providers must ensure that all 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 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. 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 relevant LHB on an ongoing basis. Where wastage exceeds 5% of the vaccines supplied and that wastage is as a result of supply chain or relevant LHB fault, those vaccines shall be removed from any wastage calculations when reviewed by the relevant LHB on an ongoing basis.

- t. Engaged providers must ensure that services are accessible, appropriate and sensitive to the needs of all persons. No person allocated by a relevant LHB shall be excluded or experience particular difficulty in accessing and effectively using this PCCIS 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

- u. The engaged provider must use the **Welsh Immunisation System (WIS)**;
 - 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 expiry date,
 - iv. for recording immediate adverse events,
 - v. for providing evidence for payments under the PCCIS, including for Post Payment Verification.
- v. By using the Welsh Immunisation System (WIS), the record of vaccination of a person by the engaged provider will be sent electronically to the individuals GMS record
- w. The engaged provider must;
 - i. supply Public Health Wales with information on persons who have received the vaccine, via the Welsh Immunisation System (WIS), for the purpose of monitoring local and national uptake;
 - ii. supply NHS Wales Shared Services Partnership with information on persons who have received the vaccine, via the Welsh Immunisations System (WIS) 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

- x. All adverse events relating to the vaccine **must** be
 1. reported to the MHRA using the Yellow Card scheme www.yellowcard.gov.uk
 2. And reported to the Health Board Primary Care Team (by using DATIX or the all Wales Concerns Management System, or existing local arrangements).
- y. Although no data for co-administration of COVID-19 vaccine with other vaccines exists, in the absence of such data, first principles would suggest that interference between inactivated vaccines with different antigenic content is likely to be limited. Whilst there is no evidence of any safety concerns, the Oxford / AstraZeneca Vaccine should not be routinely offered at the same time as other vaccines. Engaged providers should refer to the available guidance which can currently be found here.
- z. The engaged provider must ensure the person receiving the Oxford / AstraZeneca Vaccine has understood that failure to receive all recommended doses of the vaccine may render the vaccination ineffective and should ensure that a follow up appointment to receive the subsequent dose has been booked, acknowledging that in exceptional circumstances appointments may need to be moved, before administering the first dose of the vaccine.

Vaccine stock and consumables

- aa.
 - i. Vaccine supplies will be coordinated by the Health Board.
 - ii. Consumables such as PPE, syringes and needles will be provided by the Health Board.

Publicity and Information Materials

- bb. Publicity materials and information leaflets will be provided by the Health Board.

Security

- cc. The security assessment related to delivery of the vaccine is continually evolving. In order to ensure the safety of patients, staff and the vaccine itself, engaged providers must have robust security measures in place.

dd. At this moment, at a minimum this must include:

1. Lockable temperature controlled storage (vaccine fridge). This can include adaptation to an existing fridge;
2. Lockable internal doors preventing access to vaccine storage by unauthorised persons;
3. Lockable external windows and doors;

4. An operational intruder alarm, preferably linked to an Alarm Receiving Centre; and
 5. A robust and operational security process which all staff are aware of and are compliant with.
- ee. All packaging must be destroyed or defaced in such a manner that prevents it being reused for any purpose. This includes the safe and secure disposal of empty vials to ensure they cannot be reused.
- ff. Additional measures that should also be considered but are desirable, include:
1. Operational external CCTV covering all entry points;
 2. External Lighting; and
 3. Operational internal CCTV covering the location of the vaccine storage.
- gg. Due to the continually changing nature of the COVID-19 pandemic 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 COVID-19 PCCIS.

9. Notice Period

Notice period for ending the agreement for service provision will be four weeks for the relevant LHB and the engaged provider, unless varied by mutual agreement between the LHB and engaged provider. Notice must be given in writing setting out detailed reasons.

The arrangements between an engaged provider and a relevant LHB may be terminated on any of the following events:

- i. automatically when the COVID-19 vaccination programme comes to an end;
- ii. the relevant LHB is entitled to require that the engaged provider withdraws from the arrangement
- iii. the relevant LHB terminates the arrangement with the engaged provider by giving not less than 4 weeks' notice to the engaged provider;
- iv. the relevant LHB 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 the relevant LHB relating to the provision of the services pursuant to this PCCIS; or

- v. Where the engaged provider cannot meet the requirements of this PCCIS it must withdraw from this PCCIS by serving written notice on the relevant LHB to that effect with supporting reasons as to why it cannot meet the requirements, such notice must be received by the relevant LHB no less than 4 weeks' prior to date on which the engaged provider wishes to withdraw its provision of services under the PCCIS.

The agreement cannot be terminated until any second completing dose has been administered to those persons who have received a first dose on the date the engaged provider or relevant LHB gives notice of termination.

10. Disputes

Local resolution of contract disputes

- a. In the case of any dispute arising out of or in connection with the Scheme, the engaged provider and the Local Health Board must make every reasonable effort to communicate and cooperate with each other with a view to resolving the dispute, before referring the dispute for consideration and determination to the Welsh Ministers in accordance with the NHS dispute resolution procedure (or, where applicable, before commencing court proceedings) specified in paragraphs b to n of this section.

NHS dispute resolution procedure

- b. The procedure specified in the following sub-paragraphs applies in the case of any dispute arising out of or in connection with the Scheme which is referred to the Welsh Ministers.
- c. Any party wishing to refer a dispute as mentioned in sub-paragraph b must send to the Welsh Ministers a written request for dispute resolution which must include or be accompanied by—
 - i. the names and addresses of the parties to the dispute;
 - ii. a copy of any arrangement made under the Scheme; and
 - iii. a brief statement describing the nature and circumstances of the dispute.
- d. Any party wishing to refer a dispute as mentioned in sub-paragraph b must send the request under sub-paragraph c within a period of 3 years beginning with the date on which the matter giving rise to the dispute happened or should reasonably have come to the attention of the party wishing to refer the dispute.
- e. The Welsh Ministers may determine the matter themselves or, if the Welsh Ministers consider it appropriate, appoint a person or persons to consider and determine it.

- f. Before reaching a decision as to who should determine the dispute, under sub-paragraph e, the Welsh Ministers must, within 7 days beginning with the date on which a matter under dispute was referred to them, send a written request to the parties to make in writing, within a specified period, any representations which they may wish to make about the matter under dispute.
- g. The Welsh Ministers must give, with the notice given under sub-paragraph f, to the party other than the one which referred the matter to dispute resolution a copy of any document by which the matter was referred to dispute resolution.
- h. The Welsh Ministers must give a copy of any representation received from a party to the other party and must in each case request (in writing) a party to whom a copy of the representations is given to make within a specified period any written observations which it wishes to make on those representations.
- i. Following receipt of any representations from the parties or, if earlier at the end of the period for making such representations specified in the request sent under sub-paragraph f or h, the Welsh Ministers must, if they decide to appoint a person or person to hear the dispute;
 - i. inform the parties in writing of the name of the person or persons whom it has appointed; and
 - ii. pass to the person or persons so appointed any documents received from the parties under or pursuant to paragraph c, f or h.
- j. For the purpose of assisting the adjudicator in the consideration of the matter, the adjudicator may—
 - i. invite representatives of the parties to appear before the adjudicator to make oral representations either together or, with the agreement of the parties, separately, and may in advance provide the parties with a list of matters or questions to which the adjudicator wishes them to give special consideration; or
 - ii. consult other persons whose expertise the adjudicator considers will assist in the consideration of the matter.
- k. Where the adjudicator consults another person under sub-paragraph j.ii., the adjudicator must notify the parties accordingly in writing and, where the adjudicator considers that the interests of any party might be substantially affected by the result of the consultation, the adjudicator must give to the parties such opportunity as the adjudicator considers reasonable in the circumstances to make observations on those results.
- l. In considering the matter, the adjudicator must consider—

- i. any written representations made in response to a request under sub-paragraph j, but only if they are made within the specified period;
 - ii. any written observations made in response to a request under sub-paragraph h, but only if they are made within the specified period;
 - iii. any oral representations made in response to an invitation under sub-paragraph j.i.;
 - iv. the results of any consultation under sub-paragraph j.ii.; and
 - v. any observations made in accordance with an opportunity given under sub-paragraph m.
- m. In section 10 of this Specification, “specified period” means such period as the Welsh Ministers specify in the request, being not less than 2, nor more than 4, weeks beginning with the date on which the notice referred to is given, but the Welsh Ministers may, if they consider that there is good reason for doing so, extend any such period (even after it has expired) and, where they do so, a reference in this paragraph to the specified period is to the period as so extended.
- n. Subject to the other provisions within section 10 of this Specification and to any agreement by the parties, the adjudicator has wide discretion in determining the procedure of the dispute resolution to ensure the just, expeditious, economical and final determination of the dispute.

Determination of dispute

- o. The determination of the adjudicator and the reasons for it, must be recorded in writing and the adjudicator must give notice of the determination (including the record of the reasons) to the parties.

11. Application for Participation

Signature of engaged provider

Date

Appendix A

List of eligible cohorts that may be chosen by the LHB for inclusion in this PCIS:

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