COVID-19 vaccines: Frequently asked questions

The following information concerns the storage, handling and use of COVID-19 vaccines from the following manufacturers:

- Moderna
- Pfizer/BioNTech
- University of Oxford/AstraZeneca

These vaccines have been included because they have received emergency use authorisations/ approvals and phase III clinical trial data are available about their safety and efficacy.

This document was published on 28 January 2021. As other COVID-19 vaccines become widely used, receive national approvals and possess phase III clinical trial data, they will be added to this document.

1. How do the different vaccines work, i.e., mRNA vaccines vs viral-vector?

Category	Developer	Mechanism
Nucleic acid vaccines (proteins that direct production of other proteins): mRNA or DNA	Moderna Pfizer/BioNTech	A person receives genetic material — mRNA — that encodes the viral protein. When these genetic instructions are injected the muscle cells translate them to make the viral protein directly in the body. This gives the immune system a preview of what the real virus looks like without causing disease. This preview gives the immune system time to design powerful antibodies that can neutralise the real virus if the individual is ever infected. For information about how mRNA vaccines work see: https://theconversation.com/how-mrna-vaccines-from-pfizer-and-moderna-work-why-theyre-a-breakthrough-and-why-they-need-to-be-kept-so-cold-150238 https://www.cdc.gov/vaccines/covid-19/hcp/mrna-vaccine-basics.html Further information on safety and efficacy: Polack FP, Thomas SJ, Kitchin N, et al, for the C4591001 Clinical Trial Group. Safety and efficacy of the BNT162b2 mRNA Covid-19 vaccine. New England Journal of Medicine 2020;383(27):2603–15. https://www.nejm.org/doi/full/10.1056/NEJMoa2034577 Baden LR, El Sahly HM, Essink B, et al, for the COVE Study Group. Efficacy and safety of the mRNA-1273 SARS-CoV-2 vaccine. New England Journal of Medicine 2020 (30 Dec) ePub ahead of print. https://www.nejm.org/doi/full/10.1056/NEJMoa2035389

Category	Developer	Mechanism
Viral-vector vaccines	Oxford/AstraZeneca	Viral vector-based vaccines use the body's own cells to produce antigens. They do this by using a modified virus (the vector) to deliver the genetic code for the antigen, which then triggers an immune response. The vaccine mimics what happens during natural infection with certain pathogens — especially viruses. This has the advantage of triggering a strong cellular immune response by T cells as well as the production of antibodies by B cells. Further information about how viral-vector vaccines work: https://www.gavi.org/vaccineswork/what-are-viral-vector-based-vaccines-and-how-could-they-be-used-against-covid-19 Further information on safety and efficacy: Voysey M, Clemens SAC, Madhi SA, et al, for the Oxford COVID Vaccine Trial Group. Safety and efficacy of the ChAdOx1 nCoV-19 vaccine (AZD1222) against SARS-CoV-2: an interim analysis of four randomised controlled trials in Brazil, South Africa, and the UK. Lancet 2021;397(10269):99–111. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32661-1/fulltext

2. How many doses can be taken from each vial of COVID-19 vaccine?

Follow guidance from the national regulator that approved the vaccine. Overfilling is common practice in vaccine production. However, this will depend on the specific COVID-19 vaccine and the associated guidance.

For guidance on vaccine storage, handling, safety and security (USA), see: https://www.ashp.org/-/media/assets/pharmacy-practice/resource-centers/Coronavirus/docs/Vaccine-storage-handling-safety-security-guidance

Moderna

Each multidose vial contains a suspension of the vaccine. Once the suspension is thawed and the first dose (0.5ml) withdrawn, the vial should be held between 2° and 25°C (36° and 77°F). Record the date and time of first use on the Moderna COVID-19 Vaccine vial label. Discard the vial after six hours. Do not refreeze.

A fact sheet for healthcare providers (USA) is available here:
https://www.fda.gov/media/144637/download

Pfizer/BioNTech

Once thawed, dilute vial contents with 1.8ml sterile 0.9% Sodium Chloride Injection. After dilution, one vial contains up to six doses of 0.3ml. Vial labels and cartons may state that after dilution, a vial contains five doses of 0.3ml. Follow the information provided by your national regulator regarding the number of doses per vial after dilution as it often supersedes the number of doses stated on vial labels and cartons (also refer to question 17).

The vaccine does not contain a preservative. Discard any unused vaccine six hours after dilution. Do not refreeze.

A fact sheet for healthcare providers (USA) is available here:
https://www.fda.gov/media/144413/download

University of Oxford/AstraZeneca

Each multidose vial contains 5ml of solution (10 doses) or 4ml of solution (eight doses) depending on the pack size marketed. Discard any unused vaccine six hours after dilution.

Information for healthcare professionals (UK) is available here: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/948334/Information_for_UK_healthcare_professionals_on_COVID-19_Vaccine_AstraZeneca.pdf

3. For how long can the vaccine be stored at the pharmacy?

Moderna

The Moderna COVID-19 vaccine multiple-dose vials are stored frozen between −25°C and −15°C (−13° and 5°F). Store in the original carton to protect from light.

Do not store on dry ice or below -40°C (-40°F).

Vials can be stored refrigerated between 2° and 8°C (36° and 46°F) for up to 30 days prior to first use.

Unpunctured vials can be stored between 8° and 25°C (46° and 77°F) for up to 12 hours.

After the first dose has been withdrawn, the vial should be held between 2° and 25°C (36° and 77°F). Discard vial after six hours. Do not refreeze.

A fact sheet for healthcare providers (USA) is available here: https://www.fda.gov/media/144637/download

You can track expiry dates here: https://www.modernatx.com/covid19vaccine-eua/providers/vial-lookup

Pfizer/BioNTech

Store in a freezer at −80° to −60°C (−112° to −76°F).

Store in the thermal container at −90 to −60°C (−130° to −76°F).

Store in the original package in order to protect from light.

Once removed from the freezer, the undiluted vaccine can be stored for up to five days at 2° to 8°C (35° to 46°F) and up to two hours at temperatures up to 25°C (77°F) prior to use. During storage, minimise exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Thawed vials can be handled in room light conditions.

After dilution, store the vaccine at 2° to 25°C (36° to 77°F) and use as soon as practically possible and within six hours. The vaccine does not contain a preservative. Discard any unused vaccine.

Once diluted, the vials should be marked with the dilution time and discarded within six hours of dilution. Do not refreeze.

A storage and handling summary is available here: https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/storage-summary.pdf

You can track expiry dates here: https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/expiration-tracker.pdf

Information on dry ice safety is available here: https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/dry-ice-safety-hcp.pdf

A temperature log for ultra-cold vaccine storage is available here: https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/temp-log-ultra-cold-storage-celsius.pdf

Storage and handling labels can be found here: https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/storage-handling-label.pdf

Beyond use date/time tracking labels can be found here: https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/bud-tracking-labels.pdf

Information for healthcare professionals (UK) is avaioable here: https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/information-for-healthcare-professionals-on-pfizerbiontech-covid-19-vaccine

A fact sheet for healthcare providers (USA) is available here: https://www.fda.gov/media/144413/download

University of Oxford/AstraZeneca

Unopened multidose vial should be stored in a refrigerator at 2 to 8°C (36° to 46°F). Do not freeze.

Keep vials in outer carton to protect from light.

Information for healthcare professionals (UK) is available here: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/948334/Information_for_UK_healthcare_professionals_on_COVID-19_Vaccine_AstraZeneca.pdf

Summary of vaccine storage temperatures

	Unopened vials			Opened vials
	Thermal container	Freezer	Room temperature	Room temperature
Moderna	N/A	−25° to −15°C (−13° to 5°F)	2° to 8°C (36° to 46°F) for 30 days or 8° to 25°C (46° to 77°F) for 12 hours	2° to 25°C (36° to 77°F) for 6 hours
Pfizer/BioNTech	−90° to −60°C (−130° to −76°F).	−80° to −60°C (−112° to −76°F)	2° to 8°C (36° to 46°F) for 5 days or up to 25°C (77°F) for 2 hours	2° to 25°C (36° to 77°F) for 6 hours
Astra Zeneca	N/A	N/A	2° to 8°C (36° to 46°F)	2° to 25°C (36° to 77°F) for 6 hours

4. What should be done with vaccines that are not used within specified periods?

The overriding principle should be to avoid wastage. If, following a vaccination programme, there is surplus vaccine, consideration should be given to vaccinating healthcare staff or redistributing the vaccine to other clinical areas (if the cold chain can be assured).

Unopened vials should be used before their expiry date. Any vaccine remaining in opened vials must be discarded after 6 hours. If the amount of vaccine remaining in the vial cannot provide a full dose, discard the vial and any excess volume.

5. How different is the administration of these vaccines?

Vaccine	Dosing and method of administration
Moderna	The vaccination course consists of two separate doses of 0.5ml each. The second dose should be administered between four and 12 weeks after the first dose. Intramuscular (IM) injection only, preferably in the deltoid muscle.
Pfizer/BioNTech	Administered intramuscularly after dilution as a series of two doses (0.3ml each) at least 21 days apart
University of Oxford/AstraZeneca	Administered intramuscularly as a series of two doses (0.5ml each) 1 month apart.

6. Does the new vaccine require specific equipment or other requirements at pharmacies?

Pfizer/BioNTech

For storage an ultra-low temperature freezer with a temperature between –80° and –60°C (–112° and –76°F) is necessary (the thermal container in which the Pfizer-BioNTech COVID-19 vaccine arrives may be used as temporary storage). Pfizer/BioNTech COVID-19 vaccine can be stored frozen in the thermal shipping container for up to 30 days if maintained properly or in the refrigerator for five days (120 hours). For equipment specifications and needs, you should consult and coordinate with your national immunisation programme.

Vials must be kept frozen between –80° and –60°C (–112° and –76°F) and protected from light until ready to use.

Information for healthcare professionals (UK) is available here:
https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/information-for-healthcare-professionals-on-pfizerbiontech-covid-19-vaccine

Pfizer/BioNTech vaccine information (USA) is available here: https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/pfizer-bioNTech-faqs.html

A fact sheet for healthcare providers (USA) is available here:
https://www.fda.gov/media/144413/download

See Question 3 for information about other COVID-19 vaccines.

7. What PPE and other safety measures/procedures are required?

For vaccine administration, COVID-19 personal protective equipment (PPE) includes:

Face mask: Recommended for all healthcare providers (N95 masks not recommended). Follow national protocols.

Eye protection: Recommended in areas of moderate/substantial community transmission. Optional in areas of minimal/no community transmission unless otherwise indicated as a part of standard precautions

Gloves: National protocols should be followed.

Information on PPE is available here: https://www.cdc.gov/vaccines/hcp/admin/downloads/COVID-19-vaccine-administration-PPE-508.pdf

An aide-memoire on infection prevention and control principles and procedures for COVID-19 vaccination activities is available here: https://apps.who.int/iris/handle/10665/338715

8. Can pharmacists participate in national vaccination programmes?

This varies globally – please refer to national policy.

All COVID-19 vaccination providers (including pharmacists) participating in vaccination programmes will need to store and handle COVID-19 vaccines under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with authorised emergency use or vaccine package insert, manufacturer guidance, and any relevant national guidance. The following should be noted:

- Monitor storage unit temperatures at all times, using equipment and practices that comply with national guidance;
- Comply with immunisation programme guidance for handling temperature excursions;
- Monitor and comply with COVID-19 vaccine expiration dates;
- Preserve all records related to COVID-19 vaccine management for a minimum requirement specified nationally; and
- Comply with national instructions and timelines for disposing of COVID-19 vaccine and diluent, including unused doses.

All staff members who receive vaccine deliveries as well as those who handle or administer vaccines should be trained in vaccine-related practices and procedures.

9. What are the contraindications to receiving the COVID-19 vaccines? Is a positive IgG test (i.e., previous exposure to coronavirus disease) an exclusion criterion for vaccination?

Contraindications to COVID-19 vaccines are as follows:

Moderna

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components
- Immediate allergic reaction of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components (including polyethylene glycol [PEG])
- Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG)

For more information, see COVID-19 Vaccine Moderna, European Medicines Agency: https://europa.eu/!mY63cn

Pfizer/BioNTech

- Hypersensitivity to the active substance or to any of the excipients

For more information (USA), see Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Contraindications

For more information (EU), see European Medicines Agency: https://europa.eu/!Jq76yd

University of Oxford/AstraZeneca

- Hypersensitivity to the active substance or to any of the excipients.

A positive IgG test (i.e., having been exposed to the disease) is not an exclusion criterion for vaccination; available data suggest that previously infected individuals can be at risk of COVID-19 reinfection and could benefit from vaccination.

The administration of COVID-19 vaccines should be postponed in individuals suffering from acute severe febrile illness.

Individuals with bleeding disorders may receive a COVID-19 vaccine if considered safe to do so by a physician familiar with the individual's bleeding risk.

For more information, see COVID-19 The Green Book (UK):
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/948757/Greenbook_chapter_14a_v4.pdf

Pfizer/BioNTech FAQs are available here: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/pfizer-biontech-covid-19-vaccine-frequently-asked-questions

10. Can COVID-19 vaccines be co-administered with other vaccines?

The COVID-19 vaccine series should routinely be administered alone, with a minimum interval of 14 days before or after administration of any other vaccine. However, circumstances in which COVID-19 and other vaccines may be administered within a shorter period include tetanus toxoid-containing vaccination as part of wound management, measles or hepatitis A vaccination during an outbreak or to avoid barriers or delays to mRNA COVID-19 vaccination.

For more information (USA), see Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Contraindications

For more information (UK), see COVID-19 The Green Book:
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/948757/Greenbook_chapter_14a_v4.pdf

Guiding principles for maintaining immunisation services during COVID-19 pandemic can be found here: https://www.health.gov.au/sites/default/files/documents/2020/05/atagi-guiding-principles-for-maintaining-immunisation-services-during-covid-19-pandemic.pdf

11. How do the supply chains work for COVID-19 vaccines?

Each of the COVID-19 vaccines manufacturers have developed logistical plans and tools to support transportation, storage and temperature monitoring.

The World Health Organization provides information on vaccine management and logistics support here: https://www.who.int/immunization/programmes_systems/supply_chain/en/

Information from Pfizer on manufacturing and distributing the COVID-19 vaccine is available here:
https://www.pfizer.com/products/coronavirus/manufacturing-and-distribution

You can find a vaccine storage and handling toolkit here:
https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf
https://assets.kpmg/content/dam/kpmg/xx/pdf/2020/12/five-ways-to-optimize-the-covid-19-vaccine-supply-chain.pdf

12. How will equitable access to the vaccine be maintained across nations of all income levels?

COVAX is a global collaboration aimed not only at accelerating the development and manufacture of COVID-19 vaccines (as well as diagnostics and treatments), but also at guaranteeing rapid, fair and equitable access to them for people in all countries.

COVAX is coordinated by Gavi, the Vaccine Alliance, the Coalition for Epidemic Preparedness Innovations (CEPI) and the WHO. It will act as a platform that will not only support the research, development and manufacturing of a wide range of COVID-19 vaccine candidates, but also negotiate their pricing. The aim is for all participating countries, irrespective of income levels, to have equal access to COVID-19 vaccines once they are developed.

More information about COVAX is available here: https://www.gavi.org/vaccineswork/covax-explained

13. What are the possible adverse events of COVID-19 vaccines? And if they occur, how should they be managed at the pharmacy?

Vaccine	Adverse reactions from clinical studies
Moderna	Pain at the injection site (92.0%), fatigue (70.0%), headache (64.7%), myalgia (61.5%), arthralgia (46.4%), chills (45.4%), nausea/vomiting (23.0%), axillary swelling/tenderness (19.8%), fever (15.5%), swelling at the injection site (14.7%), and erythema at the injection site (10.0%). Information for healthcare providers (USA): https://www.fda.gov/media/144637/download Summary of product characteristics (EU): https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-moderna-product-information_en.pdf
Pfizer/BioNTech	Pain at the injection site (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%), injection site swelling (10.5%), injection site redness (9.5%), nausea (1.1%), malaise (0.5%), and lymphadenopathy (0.3%). Severe allergic reactions have been reported following the Pfizer-BioNTech COVID-19 vaccine during mass vaccination outside of clinical trials. Information for healthcare providers (USA): https://www.fda.gov/media/144413/download
University of Oxford/AstraZeneca	Injection site tenderness (>60%); injection site pain, headache, fatigue (>50%); myalgia, malaise (>40%); pyrexia, chills (>30%); and arthralgia, nausea (>20%).

	The majority of adverse reactions were mild to moderate in severity and usually resolved within a few days of vaccination. By day 7 the incidence of subjects with at least one local or systemic reaction was 4% and 13%, respectively. When compared with the first dose, adverse reactions reported after the second dose were milder and reported less frequently. Information for healthcare professionals (UK): https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca/information-for-healthcare-professionals-on-covid-19-vaccine-astrazeneca

In the event of an acute anaphylactic reaction occurring following vaccine administration, appropriate treatment must be immediately available on site.

14. What are the next steps in terms of safety and testing?

Manufacturers have submitted pharmacovigilance plans to regulators to monitor the safety of COVID-19 vaccines. This includes a plan to complete longer-term safety follow-up for participants enrolled in ongoing clinical trials as well as other activities aimed at monitoring the safety profile of the COVID-19 vaccines and ensuring that any safety concerns are identified and evaluated in a timely manner.

In the USA, the Food and Drug Administration expects manufacturers whose COVID-19 vaccines are authorised under an emergency use authorisation to continue their clinical trials to obtain additional safety and effectiveness information and pursue approval (licensure).

For more information, see FDA Briefing Documents for the Moderna COVID-19 vaccine here: https://www.fda.gov/media/144434/download and for the Pfizer/BioNTech COVID-19 vaccine here: https://www.fda.gov/media/144245/download

15. What advice should be given to patients?

Follow national guidance based on the approval for use information. Generally, provide a patient information leaflet for recipients of the vaccine or their care givers. Explain if the vaccine has been approved for emergency use and give the recipient or care giver the option to accept or refuse the vaccine. Explain the significant known and potential risks and benefits of the COVID-19 vaccine, and the extent to which such risks and benefits are unknown. Also provide information about available alternative vaccines and the risks and benefits of those alternatives

The most common side effects are:

- Tenderness, swelling and/or redness at the injection site;
- Fatigue;
- Headache;
- Muscle ache; and
- Fever/high temperature (37.8°C [100°F] or greater).

If these cause some discomfort for the patient, paracetamol may be taken (if not contraindicated) or a community pharmacist can be contacted for advice.

Moderna

A fact sheet for healthcare providers (USA) is available here:
https://www.fda.gov/media/144637/download

Pfizer/BioNTech

Information for healthcare professionals (UK) is available here:
https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/information-for-healthcare-professionals-on-pfizerbiontech-covid-19-vaccine

A fact sheet for healthcare providers (USA) is available here:
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University of Oxford/AstraZeneca

Information for healthcare professionals (UK) is available here:
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/948334/Information_for_UK_healthcare_professionals_on_COVID-19_Vaccine_AstraZeneca.pdf

16. What are the practice implications, including how to handle the vaccine vials and injection technique?

Vaccine	Practice including handling and injection technique
Moderna	*Storage and handling* • Moderna COVID-19 vaccine multiple-dose vials are stored frozen between −25° and −15°C (−13° and 5°F.). Store in the original carton to protect from light. • Do not store on dry ice or below −40°C. • Vials can be stored refrigerated between 2° and 8°C (36° and 46°F) for up to 30 days prior to first use. • Unpunctured vials can be stored between 8° and 25°C (46° and 77°F) for up to 12 hours. Do not refreeze. • After the first dose has been withdrawn, the vial should be held between 2° and 25°C (36° and 77°F). Discard vial after 6 hours. Do not refreeze. *Dose preparation* • The Moderna COVID-19 vaccine multiple-dose vial contains a frozen suspension that does not contain a preservative and must be thawed prior to administration. • Remove the required number of vial(s) from storage and thaw each vial before use. • Thaw in refrigerated conditions between 2° and 8°C (36° and 46°F) for 2 hours and 30 minutes. After thawing, let vial stand at room temperature for 15 minutes before administering. • Alternatively, thaw at room temperature between 15° and 25°C (59° and 77°F) for 1 hour. • After thawing, do not refreeze. • Swirl vial gently after thawing and between each withdrawal. Do not shake the vial. Do not dilute the vaccine. • The Moderna COVID-19 vaccine is a white to off-white suspension. It may contain white or translucent product-related particulates. Visually inspect the vials for other particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered. • Each dose is 0.5ml. • After the first dose has been withdrawn, the vial should be held between 2° and 25°C (36° and 77°F). Record the date and time of first use on the vial label. Discard vial after 6 hours. Do not refreeze. *Administration* • Visually inspect each dose of the vaccine in the dosing syringe prior to administration. The white to off-white suspension may contain white or translucent product- related particulates. During the visual inspection: ○ Verify the final dosing volume of 0.5 mL

	○ Confirm there are no other particulates and that no discoloration is observed ○ Do not administer if vaccine is discoloured or contains other particulate matter • Administer the vaccine intramuscularly. A fact sheet for healthcare providers (USA) is available here: https://www.fda.gov/media/144637/download

Vaccine	**Practice including handling and injection technique**
Pfizer/ BioNTech	*Storage and handling* • During storage, minimise exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. • Do not refreeze thawed vials. • Cartons of Pfizer-BioNTech COVID-19 vaccine multiple dose vials arrive in thermal containers with dry ice. Once received, remove the cartons immediately from the thermal container and store in an ultra-low temperature freezer between −80° and −60°C (−112° and −76°F). Vials must be kept frozen between −80° and −60°C (−112° and −76°F) and protected from light until ready to use. • If an ultra-low temperature freezer is not available, the thermal container in which the vaccine arrives may be used as temporary storage when consistently refilled to the top of the container with dry ice. Refer to the re-icing guidelines packed in the original thermal container for instructions regarding the use of the thermal container for temporary storage. The thermal container maintains a temperature range of −90° and −60°C (−130 and −76°F). Storage within this temperature range is not considered an excursion from the recommended storage conditions. *Vial preparation* • Thaw vials before dilution • For vials thawed under refrigeration — thaw and then store undiluted vials in the refrigerator (2° to 8°C [35° to 46°F]) for up to 5 days (120 hours). A carton of 25 vials or 195 vials may take up to 2 and 3 hours, respectively, to thaw in the refrigerator. A smaller number of vials will thaw in less time. • For vials thawed at room temperature — for immediate use, thaw undiluted vials at room temperature (up to 25°C [77°F]) for 30 minutes. Thawed vials can be handled in room light conditions. Vials must reach room temperature before dilution. • Undiluted vials can be stored at room temperature for no more than 2 hours. • Before dilution invert the vial gently 10 times. • Do not shake the vial. • Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles. • Do not use if liquid is discoloured or if other particles are observed. *Dilution* • Only use sterile 0.9% Sodium Chloride Injection as the diluent. • Using aseptic technique, withdraw 1.8 ml of diluent into a transfer syringe (21-gauge or narrower needle). • Cleanse the vaccine vial stopper with a single-use antiseptic swab. • Add 1.8 ml of diluent into the vaccine vial. • Equalize vial pressure before removing the needle from the vial by withdrawing 1.8ml of air into the empty diluent syringe. • Gently invert the vial containing the vaccine 10 times to mix. • Do not shake the vial. • Inspect the vaccine in the vial. The vaccine will be an off-white suspension. Do not use if vaccine is discoloured or contains particulate matter. • Record the date and time of dilution on the vaccine vial label. • Store between 2° and 25°C (35° and 77°F).

	• Discard any unused vaccine 6 hours after dilution. • Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.3ml of the vaccine preferable using a low dead-volume syringe and/or needle. • Administer immediately. *Administration* • Visually inspect each dose in the dosing syringe prior to administration. The vaccine will be an off-white suspension. During the visual inspection, verify the final dosing volume of 0.3m and confirm there are no particulates or discoloration. • Do not administer if vaccine is discoloured or contains particulate matter. • Administer the Pfizer-BioNTech COVID-19 Vaccine intramuscularly. • After dilution, vials of Pfizer-BioNTech COVID-19 Vaccine contain up to six doses of 0.3mL. Low dead-volume syringes and/or needles can be used to extract up to six doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. Irrespective of the type of syringe and needle each dose must contain 0.3ml of vaccine. If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3ml, discard the vial and contents. Do not pool excess vaccine from multiple vials. A fact sheet for healthcare providers (USA) is avaipoable here: https://www.fda.gov/media/144413/download
University of Oxford/AstraZeneca	*Storage and handling* • Unopened multidose vials should be stored in a refrigerator (2 to 8°C [35° to 46°F]). • Do not freeze. • Keep vials in outer carton to protect from light. • After first use, use vials as soon as practically possible and within 6 hours. • The vaccine can be stored between 2° and 25°C (35° and 77°F) during the in-use period. *Administration* • The vaccine is a colourless to slightly brown, clear to slightly opaque solution. The vaccine should be inspected visually prior to administration and discarded if particulate matter or differences in the described appearance are observed. • Do not shake the vial. • Each vaccine dose of 0.5ml is withdrawn into a syringe for injection to be administered intramuscularly. Use a separate sterile needle and syringe for each individual. It is normal for liquid to remain in the vial after withdrawing the final dose. • The vaccine does not contain any preservative. Aseptic technique should be used for withdrawing the dose for administration. • After first dose withdrawal, use the vial as soon as practically possible and within 6 hours (stored at 2°C to 25°C [35° to 77°F]). Discard any unused vaccine. • To facilitate the traceability of the vaccine, the name and the batch number of the administered product should be clearly recorded for each recipient. *Disposal* • COVID-19 Vaccine AstraZeneca contains genetically modified organisms. Any unused vaccine or waste material should be disposed of in accordance with local requirements. Spills should be disinfected with an appropriate antiviral disinfectant. Information for healthcare professionals (UK) is available here: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/948334/Information_for_UK_healthcare_professionals_on_COVID-19_Vaccine_AstraZeneca.pdf

For further information about storage and handling, including inadvertent temperature excursions, contact the manufacturer directly.

17. What are the timelines and issues of access/equity for the COVID-19 vaccines?

Each nation has developed a plan that prioritises vaccinations of its more vulnerable people first. These people usually include:

- Care home residents and staff;
- Those at high risk (concurrent long-term conditions);
- All over the age of 50; and
- All health and care workers.

A vaccination programme playbook (USA) is available here: https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf

18. How can rural health facilities and poorly resourced health care settings set up and maintain such supply chain systems as the required storage facilities will not be universally affordable?

The World Health Organisation has produced guidance on developing a national deployment plan for COVID-19 vaccines. It advises that countries need to conduct careful assessments of existing supply chains in order to identify and tackle gaps, such as storage, distribution, temperature monitoring etc.. Countries that are unable to support all the required storage facilities may consider contracting private sector resources to address any gaps. This could also be applied to transportation and other parts of the supply chain as it may be more efficient and cost- effective.

The WHO guidance is available here: https://www.who.int/publications/i/item/WHO-2019-nCoV-Vaccine_deployment-2020.1

See also Question 11.

19. How should substandard or falsified COVID-19 vaccines be prevented from infiltrating the supply chain?

Increased vigilance is advised on the possible manufacture and distribution of substandard or falsified COVID-19 vaccines. Vaccines should not be sourced from unofficial manufacturers or distributors. For more information, see Fight the Fakes Alliance: http://fightthefakes.org

INTERPOL has warned of organised crime threat to COVID-19 vaccines. See: https://www.interpol.int/News-and-Events/News/2020/INTERPOL-warns-of-organized-crime-threat-to-COVID-19-vaccines

Additional resources

- Learning from Errors with the New COVID-19 Vaccines. See https://ismp.org/resources/learning-errors-new-covid-19-vaccines
- Vaccine handling toolkit. See https://www.usp.org/covid-19/vaccine-handling-toolkit