



**Specialist
Pharmacy
Service**

NHS

Pfizer-BioNTech Vaccine pathway critical control points

Guidance for process supervisors

**The first stop
for professional
medicines advice**

www.sps.nhs.uk



Pfizer-BioNTech Vaccine pathway critical control points

The MHRA Conditions of Authorisation say that the preparation of the vaccine must...

“...be subject to NHS governance arrangements and standard operating procedures that ensure, the safety, quality or efficacy of the product is not compromised. Any guidance in respect of the final preparation of the product published by the licensing authority on Gov.uk must be appropriately adhered to”

<https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19>

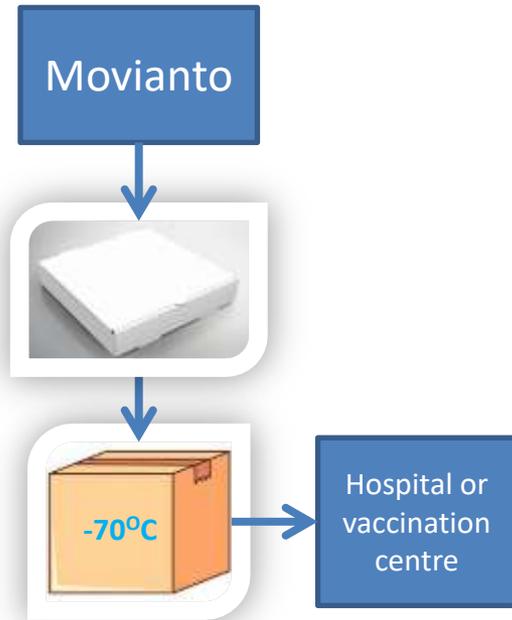
Introduction

This presentation provides an overview of the critical processes for vaccine handling to ensure that the safety, quality and efficacy of the vaccine is not compromised.

It includes

- Receipt and storage pathways, including expiry reduction at 2-8°C
- Expiry reduction for short term storage at room temperature
- Preparation process including critical control points
- Organising the preparation workstation to minimise risk of error

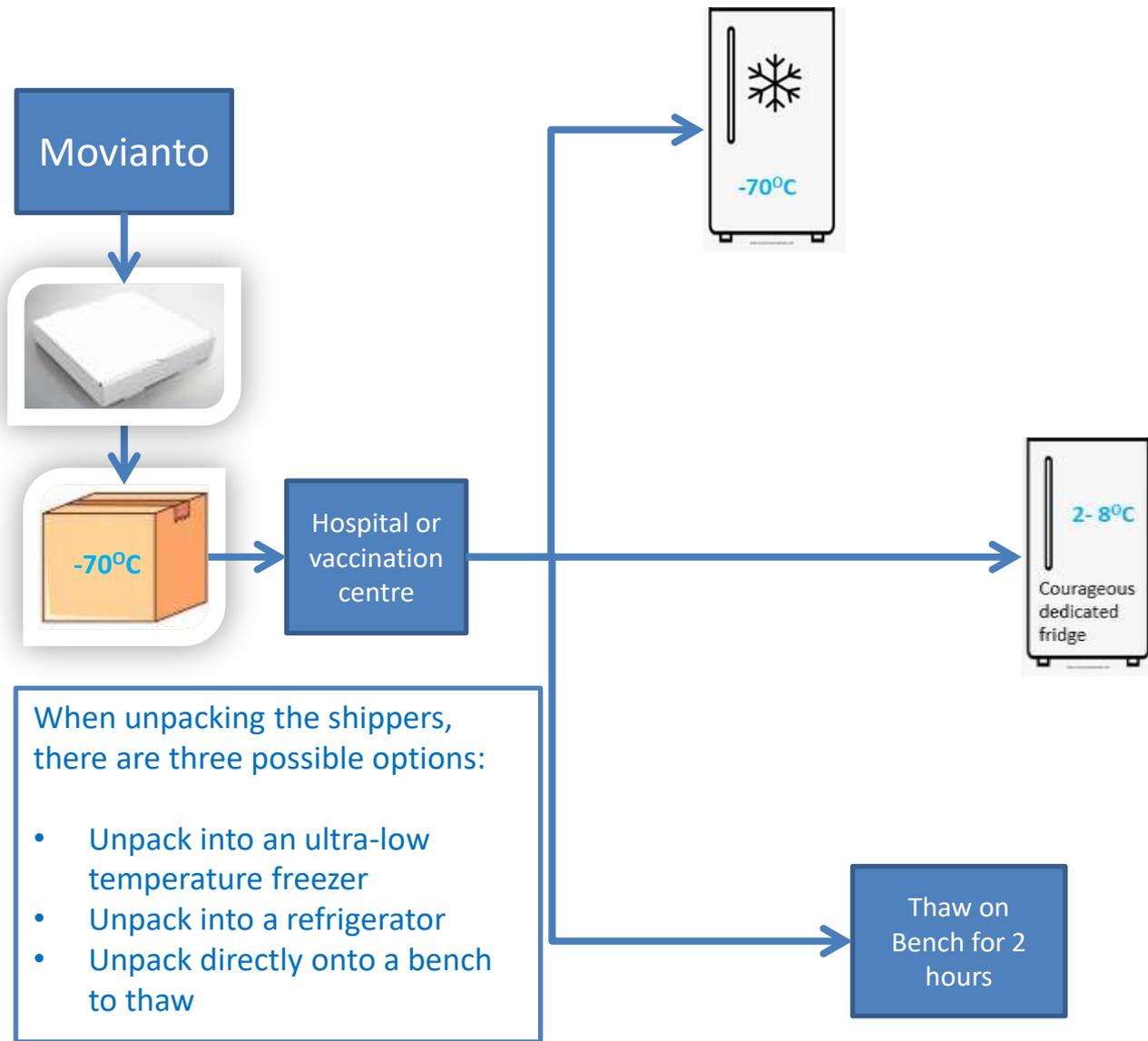
Receipt and storage in hospitals and Mass Vaccination Centres

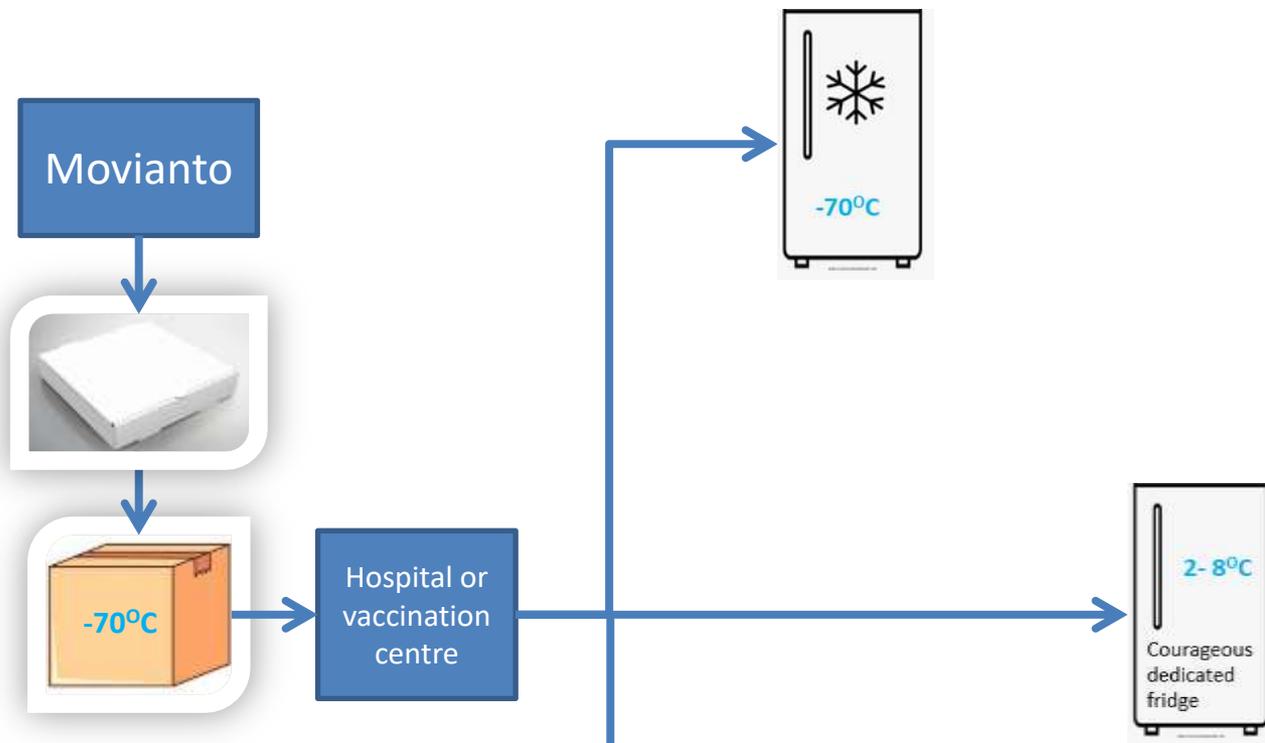


Movianto pack cartons of 195 vials into insulated shippers containing dry ice to maintain the vaccine at $-75^{\circ}\text{C} \pm 15^{\circ}\text{C}$.

The shippers will be assigned an expiry time, before which the cartons must be unpacked and stored on site.

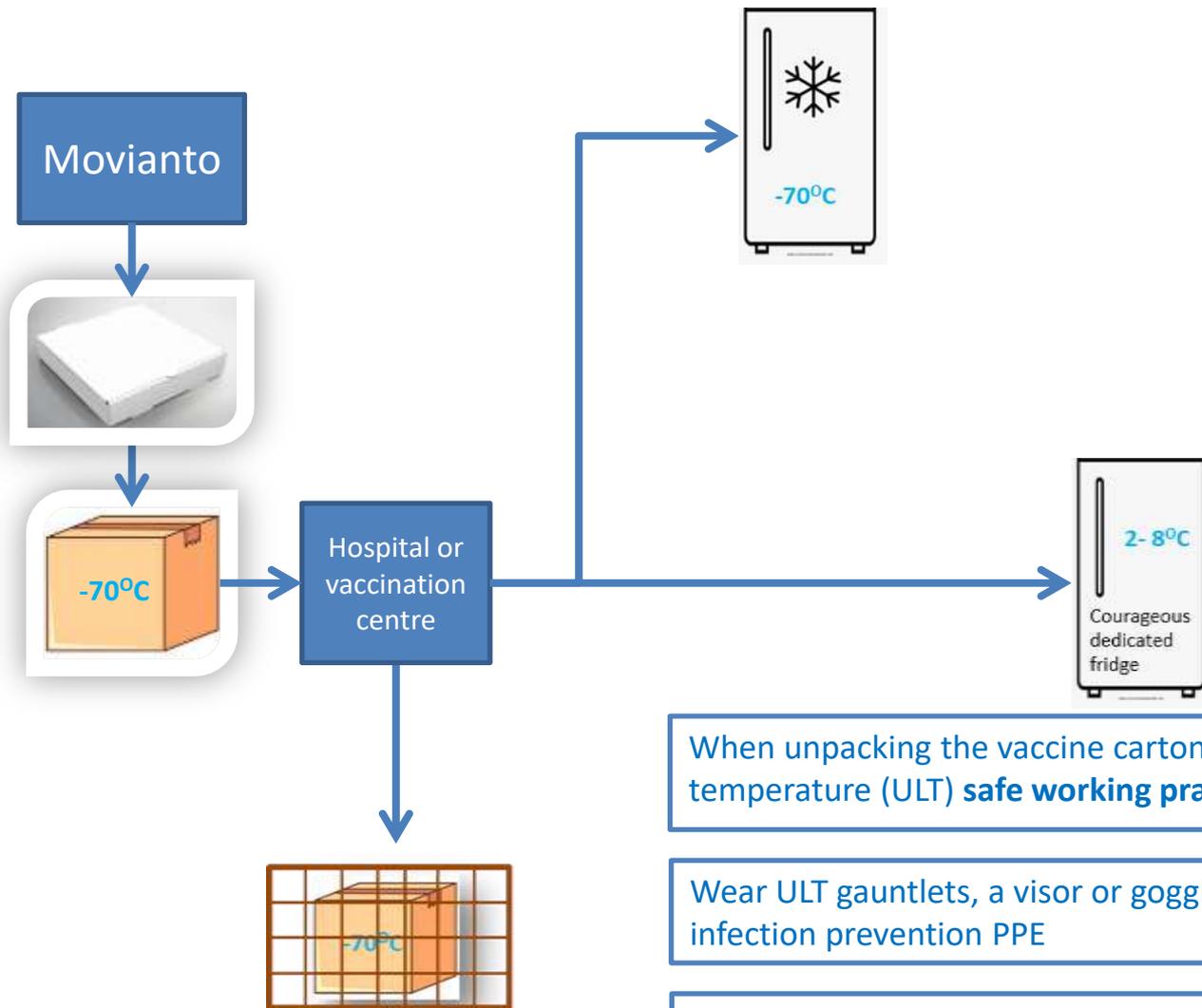
There will be no datalogger in the shipper.





However... product that has been thawed at room temperature must be **diluted for use within 2 hours**, and then **administered within 6 hours**.

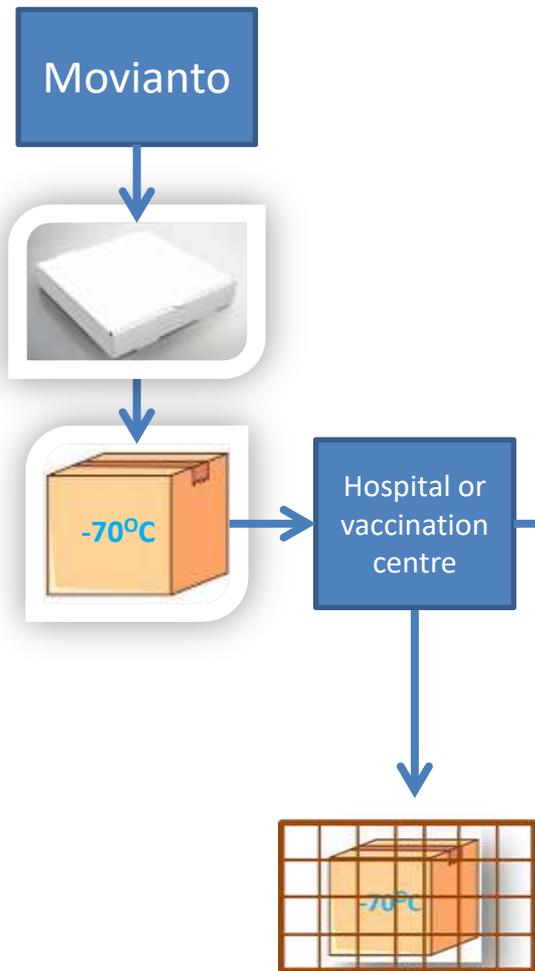
This is unlikely to be practicable, so the cold chain options are only considered here.



When unpacking the vaccine cartons (or “pizza boxes”), ultra-low temperature (ULT) **safe working practices** will need to be followed.

Wear ULT gauntlets, a visor or goggles and an apron, as well as normal infection prevention PPE

After the cartons have been unloaded, the shipper, still containing the dry ice, will need to be put into a **secure well ventilated location** so the dry ice can sublime. This can take up to 24 hours.
Movianto will not collect the empty boxes.



Loading into a freezer will need to be done **quickly** to ensure the product does not begin to thaw.

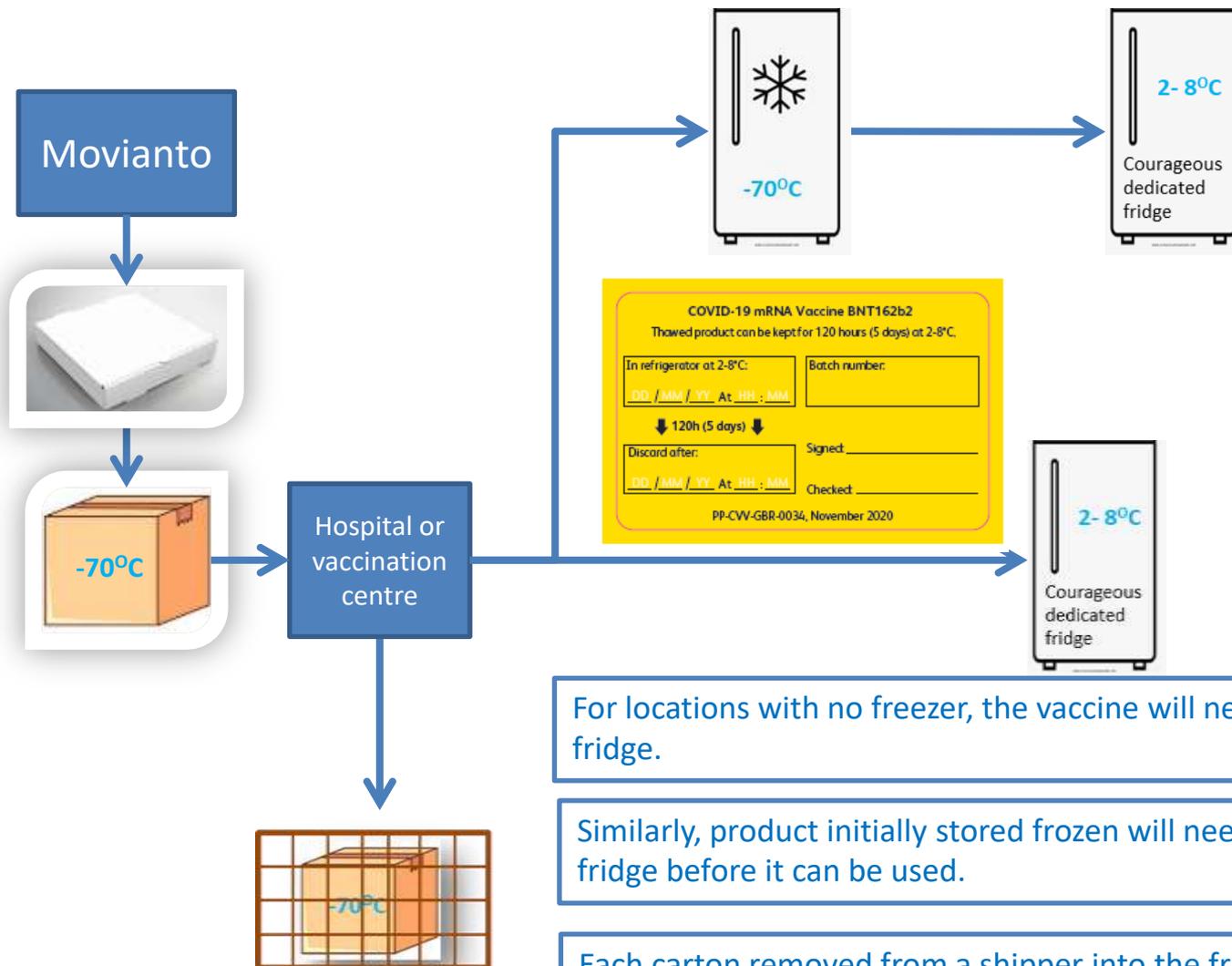
Ultra-low freezers will be supplied by NHSEI, and will be installed by the manufacturer. They have two inner chambers, each with its own door.

Mapping will be performed by one hospital, and this data will be shared. Units can then perform their own mapping at a later date. This approach falls within the MHRA's guidance on regulatory flexibilities during Covid.

Initial results from the mapping recommend:

- The background ambient temperature should remain under 25°C
- The freezer set point is -74°C
- After loading, allow the chamber to recover for 1 hour before opening again
- After unloading allow the chamber to recover for 30 minutes before opening again

On-going temperature monitoring will need to be undertaken locally, preferably as part of local continuous monitoring systems. **Probes will need to be suitable for and calibrated at low temperatures.**

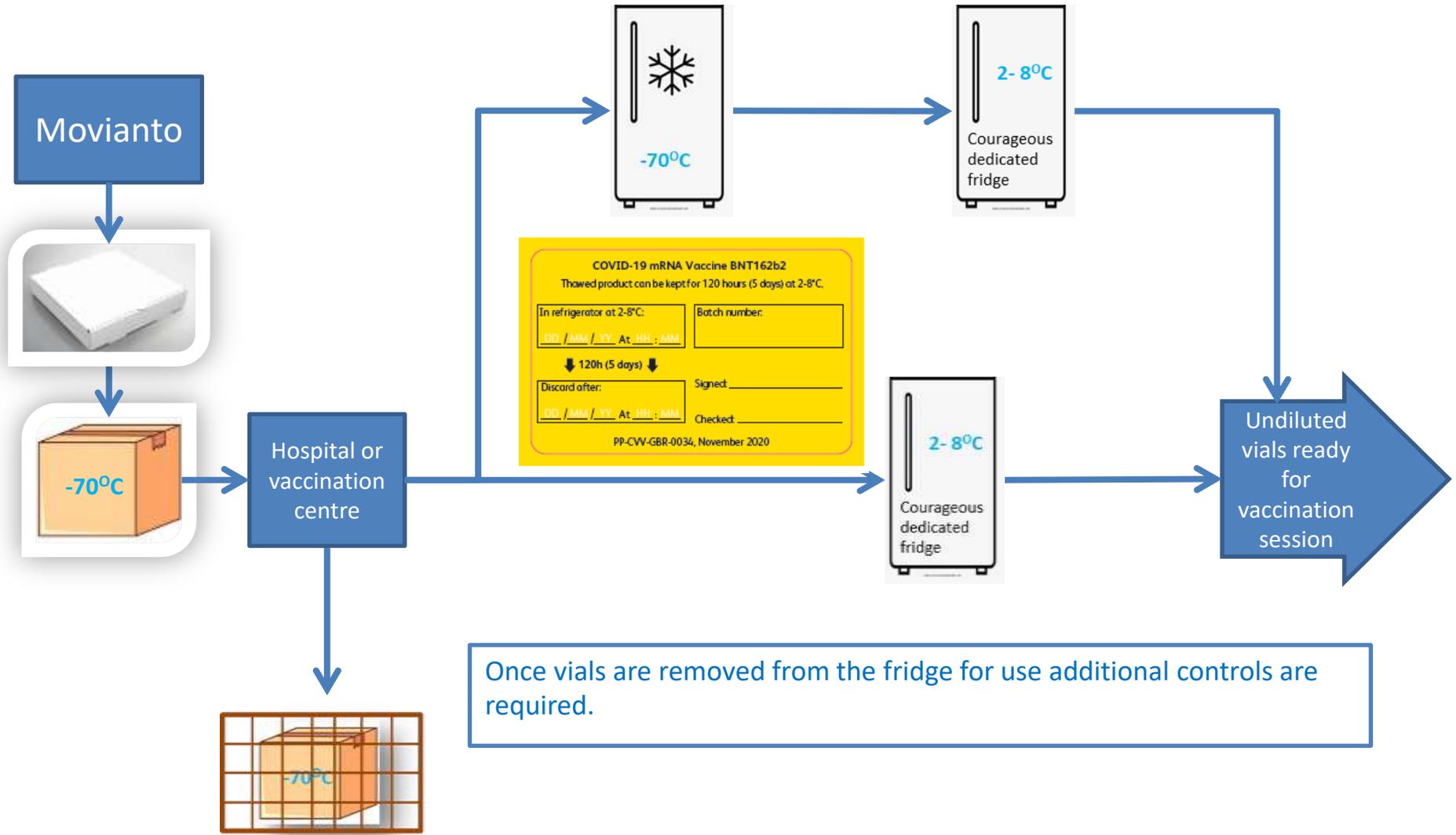


For locations with no freezer, the vaccine will need to be thawed in a fridge.

Similarly, product initially stored frozen will need to be thawed in a fridge before it can be used.

Each carton removed from a shipper into the fridge, or from the freezer into the fridge needs to have its **expiry reduced to 120 hours**.

Pfizer will supply pre-printed thaw labels that can adhere to low temperature surfaces. **Calculation of expiry date and application of the labels needs to be carefully controlled.**



Once vials are removed from the fridge for use additional controls are required.

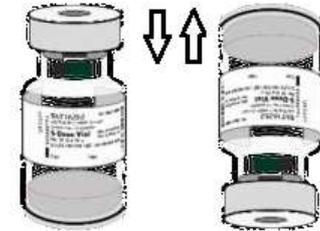
Key Areas Requiring Controls



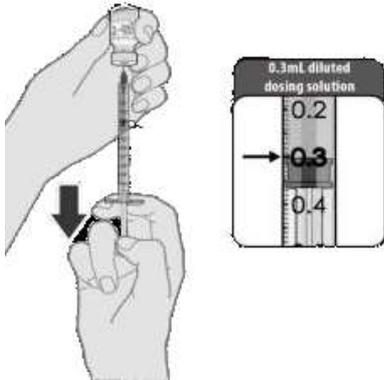
Changes of vial expiry between storage conditions and post dilution



Segregation of concentrated and diluted vials



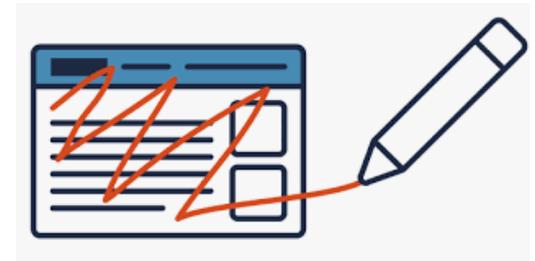
Mixing prior to dilution and post dilution following method of 10 gentle inversions



Identity and volume of diluent, and volume of diluted vaccine syringes



Risk of needle stick injury from fixed needle syringes used for administration

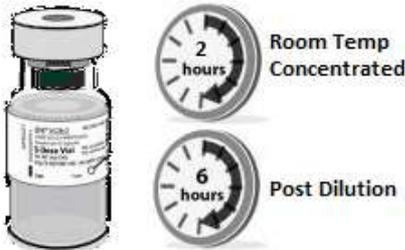


Risk of theft of empty packaging – ensure vials are discarded into clinical waste and labelled packaging is defaced or destroyed

Example of one potential process design.

**Designed to enable efficient delivery at scale with
effective control of risks**

Application of Room Temperature expiry



Remove the required number of thawed vaccine vials from the outer carton and seal them in a grip lock bag. Remove the approximate number of vials required for the next hour of the vaccination session.



Once removed from a refrigerator and stored at room temperature the vials must be used within **2 hours as a concentrate followed by 6 hours if diluted**



Attach a label to the bag which states the new time (24hr clock format) and date of expiry which is 2 hours from the point of removal from the refrigerator. 2nd person checks the expiry label.



Place vials inside a lidded box labelled as 'CONCENTRATE VIALS' at the preparation workspace and close the lid. This segregates concentrated vials.

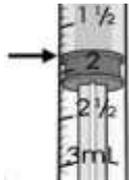
Dilution of the Vial (1)



1. Checking the bag expiry time, remove one vaccine vial from the box. **ONLY ONE** vaccine vial must be in use in the preparation workspace at any one time.



If recently removed from the fridge, allow the thawed vial to come to room temperature. Gently Invert the concentrated vaccine vial 10 times to mix the contents thoroughly. **DO NOT SHAKE**



Draw up 1.8 ml of unpreserved sodium chloride 0.9% using a 2ml syringe and 21 g needle. Dispose of remainder of the ampoule. Check the volume drawn up is 1.8ml



Using aseptic technique, cleanse the thawed vaccine vial stopper with a single use antiseptic swab, and dilute the concentrate vaccine vial by adding 1.8ml of unpreserved sodium chloride 0.9%



Ensure vial pressure is equalized by withdrawing 1.8 ml air into the empty diluent syringe before removing the needle from the vial. Dispose of syringe and needle.

Dilution of the Vial (2)



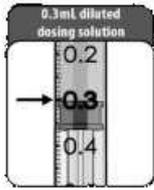
Gently Invert the diluted vaccine vial 10 times to mix the contents thoroughly. DO NOT SHAKE

The diluted vaccine should present as an off-white solution with no particulates visible. Discard the diluted vaccine if particulates or discolouration are present.

Write the time and date dilution took place on the vial to indicate the vial is now diluted. Use immediately, and within 6 hours after dilution.



Preparing the Syringes



Using aseptic technique, cleanse the vial stopper with a single use antiseptic swab, and draw up 0.3 mL of the diluted vaccine solution using a 1ml administration syringe

Adjustments to remove air bubbles should be done with the needle still in the vial to avoid loss of dosing solution. Check the volume drawn up is 0.3ml

The newly filled syringe must be used for immediate administration. Local consideration required of process to reduce risk of needle stick injury.

For each additional dose, use a new sterile syringe and needle and ensure the vial stopper is cleansed with antiseptic before each withdrawal. A total of 5 doses may be prepared from each diluted vial

Once empty, or if there are no further patients immediately awaiting vaccination, discard the diluted vial into a sharps bin. Diluted vials must not be stored

To prevent diluted and undiluted vials becoming mixed up, the workstation needs to be organised, and a controlled workflow must be followed.

The next slides show layouts and workflows for

- Dilution of the vial and drawing up syringes to give to the vaccinator
- Dilution of vials only, for the vaccinator to withdraw from

Injection work station layout and workflow (Pod model)

1. Store the undiluted vaccines at the back of the workstation, with the consumables, sharps bin etc.

Concentrate vials



2. Bring one vial into the work zone

3. Dilute according to instructions. DO NOT SHAKE



8. Repeat

7. Remove all wrappers and clean workstation before bringing forward the next vial

6. Discard the vial

4. Draw up the first syringe and pass to the vaccinator



5. Repeat for the next four syringes

Injection work station layout and workflow (vial reconstitution only)

1. Store the undiluted vaccines at the back of the workstation, with the consumables, sharps bin etc.

**Concentrate
vials**



6. Repeat

5. Remove all wrappers and clean workstation before bringing forward the next vial

2. Bring one vial into the work zone



3. Dilute according to instructions. **DO NOT SHAKE**

4. Pass to the vaccinator



Thank you for viewing this presentation.

If you have any questions, please send your query to your Regional QA Specialist in the first instance.