Safety Notice 022/21

Preparation of Pfizer COVID-19 vaccines

17 September 2021

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- SHEOC

Action required by:

- Chief Executives
- Directors of Clinical Governance
- Vaccine hub clinical leads

We recommend you also inform:

- LHD staff involved in delivering vaccination
- Directors of Clinical Governance
- Directors of Pharmacy

Expert Reference Group

Content reviewed by:

- NSW Health Public Health Response Branch
- SHEOC
- Clinical Excellence Commission

Clinical Excellence Commission
Tel: 02 9269 5500
Fax: 02 9269 5599

Email: CEC-MedicationSafety@health.nsw.gov.au

Internet Website: http://health.nsw.gov.au/sabs

Intranet Website: http://internal.health.nsw.gov.au/quality/sabs

Review date

March 2022

Background

The Pfizer COVID-19 vaccine (Comirnaty®) is presented in a multi-dose vial which requires dilution with sodium chloride 0.9% injection prior to drawing up and administration. There have been incidents reported in another jurisdiction where a previously used COVID-19 Pfizer (Comirnaty®) vaccine vial was inadvertently diluted a second time. This resulted in six ultra-low doses of vaccine that were then administered to patients. A common contributing factor was that the used and unused vaccine vials were present together in the vaccine preparation area.

Contributing factors

Factors which may contribute to incidents include:

- Storing used vials in the same area as unused vials rather than disposing of used vials once the vaccine is drawn up and the checking process is completed
- Distractions and/or interruptions during the preparation or checking process
- More than one vial being present in each preparation area at any one time
- Inadequate staffing allocated to the preparation area
- Inadequate time to prepare vaccines before clinic opening time
- Non-adherence to work processes and procedures
- Multiple vials being removed from the fridge at once. In larger facilities ensuring allocation of one vial per preparation station is recommended
- Inadequate/non-standardised checking processes e.g. no independent second check
- Physical count of vaccine vials not being completed at the start, throughout and at the end of the day.

Recommendations

- Focused attention is required when drawing up vaccine doses to prevent errors.
- Staff preparing the refrigerated COVID-19 Pfizer (Comirnaty®) vaccine for administration **must** follow COVID-19 Vaccination Program Procedures – Management of COVID-19 Pfizer (Comirnaty) vaccine from refrigerator to administration.
- Diluted vials must be appropriately labelled
- Separate workspaces to be utilised for vaccine preparation, checking and administration.
- Preferably use separate workers for vaccine preparation and administration.
- Work with only one vial of vaccine and one sodium chloride 0.9% (normal saline) ampoule at a time in the preparation workspace.
- Once drawn up and checked by a second person, the used vaccine vial must be discarded immediately or removed from the workstation area with the drawn-up syringes.
- Follow the drawing up procedure described on the NSW Health COVID-19 vaccination webpage

Suggested actions by Local Health Districts/Networks

1. Distribute this Safety Notice to all stakeholders and clinical departments involved in the preparation and administration of the COVID-19 Pfizer (Comirnaty®) vaccine.
2. Develop a local plan to ensure that used vials are disposed of as soon as the checking process is complete.
3. Ensure a system is in place to document actions taken in response to this Safety Notice.
4. Confirm receipt of this notice to CEC-MedicationSafety@health.nsw.gov.au **within 24 hours**

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Adequate checking and labelling

Sites that use iPharmacy are to generate their own labels for vials and must clearly state that the vaccine has been diluted.

Health Protection NSW is currently progressing changes to the vaccine label to ensure clear reconstitution information (will be available soon).

CORRECT preparation station configuration

- ✓ Clean and orderly station.
- ✓ One Vial per station
- ✓ One Saline Ampoule