



Safety Notice 002/21

Variability in oxygen delivery with bag valve masks Absence of a valve to prevent air entrainment during spontaneous ventilation

15 February 2021

- Distributed to:**
- Chief Executives
 - Directors of Clinical Governance
 - Director Regulation & Compliance Unit

- Action required by:**
- Chief Executives
 - Directors of Clinical Governance

- Recommend to inform Directors and Managers of:**
- Medical Services
 - Anaesthetics
 - Nursing/ Midwifery Services
 - Paediatrics
 - Neonatology
 - Intensive Care Units
 - Cardiology Services
 - Emergency Departments
 - Mental Health
 - Community & Primary Health Services

- Also, the following staff:
- Clinical Product Managers
 - CERS/PACE Coordinators
 - Staff who participate in Advanced Life Support
 - Paramedics
 - Biomedical Engineers

- Expert Reference Group**
- Content reviewed by:
- HealthShare NSW
 - NSW Ambulance
 - Agency Clinical Innovation
 - Anaesthetic, Paediatric and Neonatology clinicians

Clinical Excellence Commission

Tel: 02 9269 5500

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

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

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

Review date

February 2024

Variability with oxygen delivery and concentration

A clinical working group has identified variability in fraction of inspired oxygen concentration (FiO₂) delivered by various bag valve masks (BVM). There are BVMs in use *without a valve to prevent air entrainment during spontaneous ventilation*. This anti air-entrainment valve is located in the expiratory pathway and can vary between models. It may be difficult to identify.



The absence of this valve (also called expiratory or flow diverter valve) for *spontaneously breathing* patients allows room air to mix with 100% oxygen from the reservoir. This can reduce the inspired oxygen concentration to less than 65%.

What is a Bag Valve Mask?

A BVM is a hand-held device used to provide positive pressure ventilation. It is also used for *preoxygenation of spontaneously breathing patients* before intubation to extend the safe apnoea time during intubation or in situations where 100% inspired oxygen is required for spontaneously breathing patients. BVMs are found in resuscitation and anaesthetic trolleys, ambulances, emergency rooms and critical care settings.

Assessment

Review of adult and paediatric BVM performance found that some devices without a valve to prevent *air entrainment* had FiO₂ as low as 60% in spontaneous ventilation.

- Optimal preoxygenation is achieved when end-tidal oxygen is at least 85%.
- Achieving this end tidal oxygen concentration is clinically important for reducing the risk of desaturation after preoxygenation.

Additional safety issues

- The review also found some BVMs have a positive end-expiratory pressure (PEEP) valve already attached and set to the 'on' position at up to 10cmH₂O. Although the PEEP valve also functions to prevent air entrainment, if a BVM with that level of PEEP were placed on a child/adult in respiratory distress it could cause significant harm.
- Some BVM do not have over-pressure release valves increasing the risk of high inspiratory pressures and barotrauma.

Recommendations

Use only BVMs with the following criteria:

- Equipped with a valve to prevent air entrainment during spontaneous ventilation
- Equipped with an overpressure valve (set close to 40cmH₂O).
- PEEP valves supplied unconnected to the BVM is preferred. If purchasing BVMs with inbuilt PEEP valves, preference should be given to those with the PEEP valve pre-set to as close to 0cmH₂O as possible.

Actions required by Local Health Districts/Networks

1. Distribute this Safety Notice to all relevant clinical staff
2. Each health entity undertake a local risk assessment of Bag valve mask, using [QARS audit tool](#) provided, via this link by 5pm on Thursday 25 February 2021
3. Ensure critical care areas have BVMs with a valve to prevent air entrainment for use on spontaneously breathing patients by 31 March 2021
4. LHD/SN Clinical Product Manager (CPMs) establish a phased transition plan for all BVMs in circulation to meet the minimum criteria where appropriate by 30 April 2021.
5. HealthShare liaise with CPMs to organise transition to recommended BVMs
6. Escalate concerns that are not able to be managed locally to HSNSW-HSCPM@health.nsw.gov.au
7. Report all issues in the Incident Information Management System (IIMS) or IMS+.