NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance

SCOPE

The PneuX system for preventing ventilator-associated pneumonia in patients in intensive care

1 Technology

The PneuX system is designed to prevent ventilator-associated pneumonia (VAP) by minimising the risk of pulmonary aspiration and micro-aspiration during mechanical ventilation, which is expected to last more than 24 hours but no more than 30 days. The PneuX system consists of 3 component parts:

- PneuX endotracheal/tracheostomy tube – a flexible silicone tube with a low-volume, low-pressure (LVLP) cuff, fixation block, winged tube holder, integrated bite block, a flange, a drain tube, an inflation tube, a reservoir, sub-glottic line leading to 3 sub-glottic ports, inflation line, non-stick lining and boat-tip with murphy eye and a 15 mm standard connector. The tube is compatible with magnetic resonance imaging (MRI) and is available in 4 sizes: 6.0, 7.0, 8.0 or 9.0 mm inner diameter.

- The PneuX tracheal seal monitor – an electronic automated cuff pressure controller (formerly known as Venner PneuX TSM Cuff Pressure controller)

- Extension tube – a 2-metre extension tube for the PneuX tracheal seal monitor. It connects the air outlet on the PneuX tracheal seal monitor and the pilot valve of the PneuX endotracheal/tracheostomy tube.

The PneuX endotracheal/tracheostomy tube has a low-volume, low-pressure cuff made from a soft silicone material. The PneuX tracheal seal monitor is an electronic automatic pressure controller which controls and maintains the safe

inflation volume and pressure within the cuff during use. PneuX has 3 subglottic secretion drainage and irrigation ports above the proximal end of the cuff to ensure that the tube functions properly even if one of the ports is blocked. The small size of the subglottic ports is intended to prevent damage to the tracheal mucosa.

The manufacturer recommends that the PneuX endotracheal/tracheostomy tube and the PneuX tracheal seal monitor are used together, and so neither should be used with other devices. The PneuX system is not compatible with other endotracheal/tracheostomy tubes. Both the PneuX endotracheal /tracheostomy tube and the extension tube are supplied sterile and for single use. The PneuX system was formerly known as the Venner PneuX P.Y. - VAP Prevention System and the Lo-Trach system

1.1 Description of the technology

1.2 Regulatory status

The PneuX system received a CE mark in January 2006 for adult critical care patients who require intubation (primary or tube-exchange) and mechanical ventilation. The system has a class III device (the endotracheal/tracheal tube) and a class IIb device (the PneuX tracheal seal monitor, previously known as Venner tracheal seal monitor).

1.3 Claimed benefits

The benefits to patients claimed by the company are that the technology:

- Reduces the incidence of ventilator-associated pneumonia
- Facilitates the application of evidence-based VAP Preventative Measures
- Prevents/reduces aspiration
- Reduces complications
- Improves management
- Reduces mortality, since ventilator-associated pneumonia is consistently associated with an increased in mortality
- Increases life expectancy for all patients treated in the Intensive Care Unit

The benefits to the healthcare system claimed by the sponsor are that the technology:

- Reduces overall costs of care
- Reduces overall hospital length of stay for patients in critical care on mechanical ventilation
- Increases patient turnover/productivity due to change in practice

1.4 Relevant diseases and conditions

The PneuX system is intended for use in intensive or critical care patients requiring mechanical ventilation where the duration of intubation is expected to be more than 24 hours but not more than 30 days. The PneuX system is also compatible with tracheal intubation during routine anaesthesia. It is placed by anaesthetists and can be maintained by critical care nurses.

Ventilator-associated pneumonia (VAP) is a hospital-acquired infection. Although there is no consensus definition, it is often defined as a pneumonia that occurs in patients who have had continuous intubation with an endotracheal or tracheostomy tube for at least 48 hours before the onset of the infection (American Thoracic Society and Infectious Diseases Society of America, 2005). The presence of a tracheal tube interferes with the normal protective reflexes of the upper airway, such as coughing. This can result in impaired clearance of secretions and micro-organisms leading to the rapid colonisation of the oropharyngeal secretions with aerobic Gram-negative bacteria. These contaminated secretions gather above the cuff of the tracheal tube and slowly leak down into the airway, leading to the unintentional entry of very small amounts of contaminated material into the respiratory tract (micro-aspiration). This is thought to be the main cause of VAP (Gunasekera et al. 2016). There are no standard criteria to diagnose VAP; a diagnosis is usually based on a combination of clinical signs and symptoms and confirmed with chest X-rays and microbiological testing (American Thoracic Society and Infectious Diseases Society of America, 2005).

Around 100,000 patients are admitted for ventilation to UK critical care units each year and 10-20% of these will go on to develop VAP (NHS England). Between 3,000 and 6,000 people die from VAP every year (NHS England). It is acknowledged that the latest incidence of VAP is somewhat uncertain but that this will be considered in the assessment of the evidence.

Risk factors for the development of VAP include the duration of mechanical ventilation, the need for reintubation, the use of intracuff pressure of less than 20 cmH_2O, older age, lying flat and the presence of comorbidities (Timsit et al. 2017). The risk for patients is highest during the early part of an ICU stay when it is estimated to be 3% per day during days 1–5 of ventilation, 2% per day during days 5–10 of ventilation and 1% per day thereafter (Masterton, 2008).

Various strategies have been developed to reduce the risk of ICU patients developing VAP, including advances in endotracheal tube technology. These developments include features for continuous subglottic drainage and ensuring adequate pressure of the endotracheal-tube cuff is maintained to prevent leakage of colonised subglottic secretions into the lower airway (Fernandez et al. 2012).

1.5 Current management

VAP prevention strategies vary considerably in current practice. In 2008, the Working Party on Hospital‑Acquired Pneumonia of the British Society for Antimicrobial Chemotherapy produced evidence‑based guidance (Masterton et al. 2008). The scope of the guidance excluded oral antiseptic treatments, management of severely immunocompromised patients, children under 16 years old and people with cystic fibrosis. The guidance states that measures should be taken to prevent VAP by reducing the risk of pulmonary aspiration using subglottic secretion drainage; by correctly positioning the endotracheal tube (ETT); and by ensuring a correct cuff pressure to avoid aspiration but prevent tracheal damage.

Bundles of care to prevent ventilator-associated pneumonia (VAP) have also been recommended in more recent guidelines published by the Scottish

Intensive Care society/Health Protection Scotland and the Intensive care Society. The Intensive Care Society identifies 4 key elements to be addressed together to minimise the risk of VAP: elevation of head of bed (30°-45°), daily sedation interruption and assessment of readiness to extubate, use of subglottic secretion drainage and avoidance of scheduled ventilator circuit changes.

NICE has produced medtech innovation briefings on the PneuX endotracheal tube system and the TaperGuard Evac oral tracheal tube (now the Shiley Evac oral tracheal tube with TaperGuard cuff).

2 Statement of the decision problem

	Scope issued by NICE
Population	Adult patients requiring ventilation in a critical care setting for at least 24 hours and up to 30 days.
Intervention	PneuX system
Comparator(s)	• conventional endotracheal tube • conventional tracheostomy tube • any other equivalent or similar endotracheal tube aimed at VAP prevention including subglottic secretion drainage (both intermittent versus continuous suction)
Outcomes	The outcome measures to consider include: • incidence of VAP • length of ICU/ITU stay • length of hospital stay • incidence of aspiration • duration of mechanical ventilation • incidence of unplanned extubation and/or re-intubation • antibiotic usage • mortality • sedation usage • difficulty of placement and maintenance of tube position • device-related adverse events e.g. tracheal injury
Cost analysis	Comparator(s): • any other equivalent or similar endotracheal tube aimed at VAP prevention • conventional endotracheal tube • conventional tracheostomy tube • Early versus late onset of VAP Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared.

	Sensitivity analysis will be undertaken to address uncertainties in the model parameters.	
Subgroups to be considered	Endotracheal tubes Tracheostomy tubes Specific patient groups: for example, severely immunocompromised patients burns and polytrauma patients, Prone ventilated patients, major heart surgery patients, neurological patients and transplant patients	
Special considerations, including those related to equality	Risk factors for VAP include age (incidence increases with advancing age) and chronic illnesses (including underlying chronic lung disease, cancer and diabetes), which may significantly affect activities of daily living to the point where a person can be considered to be disabled. Age and disability are protected characteristics under the Equality Act (2010).	
Special considerations, specifically related to equality issues	None	
	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristics?	No
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure MTAC will have relevant information to consider equality issues when developing guidance?	No

3 Related NICE guidance

Published

- Pneumonia in adults: diagnosis and management. NICE clinical guideline 191 (2014). Available from www.nice.org.uk/guidance/CG191
- Healthcare-associated infections: prevention and control. NICE public health guidance 36 (2011). Available from www.nice.org.uk/guidance/PH36

4 External organisations

4.1 Professional organisations

The following societies have been alerted to the availability of the scope for comment:

- British Association of Critical Care Nurses
- Royal College of Anaesthetists
- Royal College of Nursing

- Society for Cardiothoracic Surgery of Great Britain and Ireland
- The British Thoracic Society
- The Faculty of Intensive Care Medicine

4.2 Patient organisations

At the selection stage, NICE's Public Involvement Programme contacted the following organisations for patient commentary and alerted them to the availability of the scope for comment:

- British Lung Foundation
- Critical Care Patient Liaison Committee (CritPaL)
- ICU Steps