

NHS Innovation Accelerator
Critical Care innovations

Oxford 
Academic Health
Science Network

PneuX System™

Implementation Support Pack
for Provider Organisations



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This is the second version of this Implementation Support Pack (September 2017)

Introduction

This Implementation Support Pack has been put together by the Oxford Academic Health Science Network (AHSN) with Dr Peter Young and Dr Maryanne Mariyaselvam (Consultant Intensivist and Clinical Fellow, Queen Elizabeth Hospital, King's Lynn), to assist provider organisations in implementing the PneuX System™.

The PneuX System™ is part of the NHS Innovation Accelerator (NIA), having been recognised as providing an evidence-based solution to a significant healthcare challenge. In addition, the PneuX System™ attracts NHS England's Innovation and Technology Tariff (ITT) until end of March 2019, providing an opportunity for Trusts to implement or trial these devices without the financial barriers to adoption.

The Oxford AHSN sees the PneuX System™ as an important innovation that reduces patient harm and improves patient safety. This Implementation Support Pack aims to offer Trusts all the necessary information needed to implement the PneuX System™, providing clinicians and project leads a step by step guide of how to implement the PneuX System™. The pack includes a number of resources to help simplify the process of implementation including a summary document, outline business case, guidance for procurement, tariff reimbursement procedures, PowerPoint presentations, and advice on how to handle challenges to adoption and overcome potential barriers to implementation.

The guidance in this document is based on the experiences of Trusts across England that have previously implemented the PneuX System™. Differences in practice, protocols and systems at different Trusts may mean that the processes described differ from what you experience locally. If this is the case, please do share these differences with the contacts at the Oxford AHSN, so that this can be captured for future learning and to help other partner organisations.

Four months since the launch of the ITT, the Oxford AHSN has been working with all the partners in the region to support implementation of the PneuX System™. Adoption in the region and nationally has gained significant momentum over recent months now with 8 large hospital Trusts across England already using the PneuX System™ and a significant number preparing to do so. Over this time new information about the devices, the suppliers and the processes for adoption has come to light. This document is the second version and includes these important updates.

Overview of Implementation Process

Below is an outline process for implementing the PneuX System™ that has been developed based on the experience of other Trusts. The process is made up of 3 core elements: engagement and building the case for adoption, securing reimbursement and implementing on the unit.

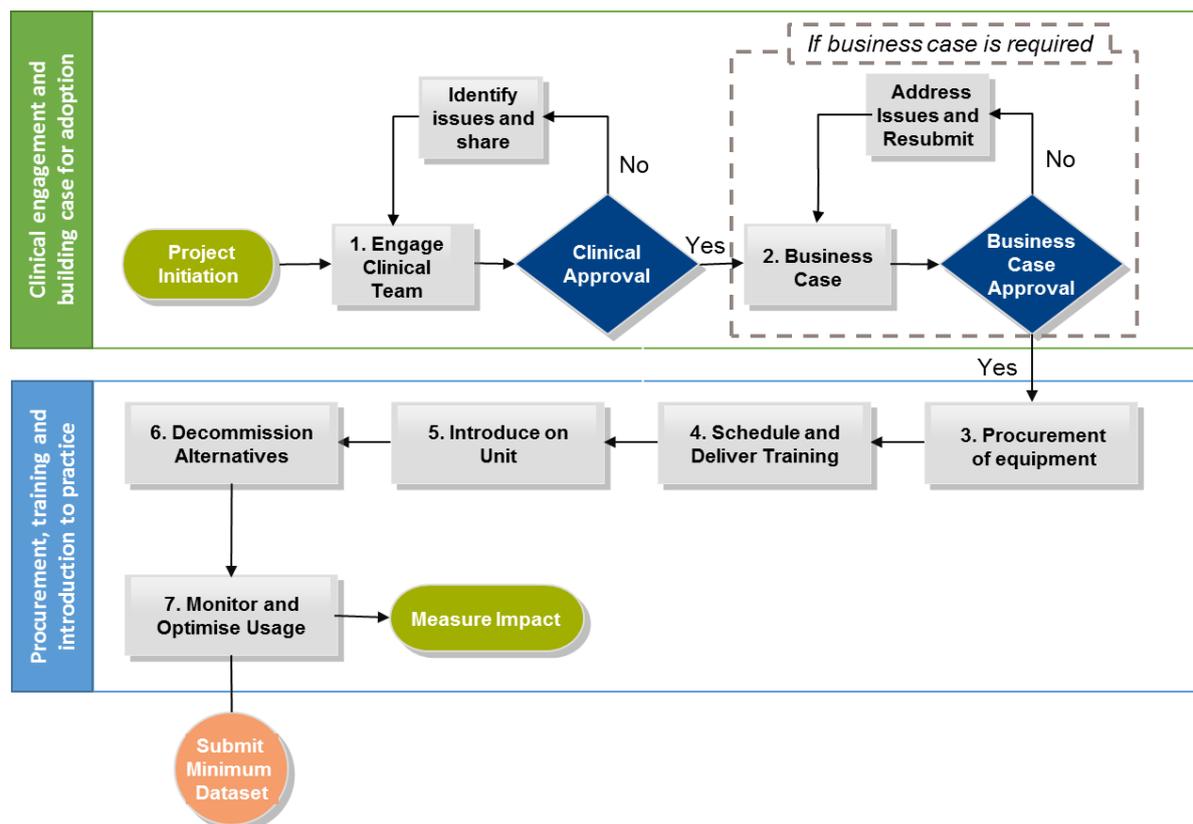


Figure 1 Outline Implementation Process for the PneuX System™.

Step 1: Engage Clinical Team

Key Points

- Clinical engagement is a crucial first step in ensuring there is a willingness to adopt the PneuX System™.
- The Summary Document in this section provides a good starting point for discussion with both clinical and managerial teams.
- A summary PowerPoint presentation is also provided in the Implementation Support Pack for leads to present back to clinical and managerial teams on the opportunity provided by the PneuX System™.
- Common clinical concerns or queries have been captured in the “Potential Barriers to Implementation and Mitigating Action” section of the pack. Any other queries can be directed to your regional AHSN who will support in addressing these issues.

Summary Overview – PneuX System™

PneuX System™ for Prevention of Ventilator Associated Pneumonia (VAP) Summary Document	
Summary of Device	<ul style="list-style-type: none"> The PneuX System™ is a unique system for the prevention of ventilator-associated pneumonia (VAP) during mechanical ventilation. Consists of endotracheal or tracheostomy tube and a tracheal seal monitor (TSM) which measures the cuff pressure and continuously adjusts this to seal the patient’s trachea. PneuX System™ produces an optimal tracheal seal and prevents aspiration of subglottic secretion, improving airway management and preventing VAP. Enables convenient drainage and irrigations of subglottic secretions. PneuX System™ is cost effective relative to standard endotracheal tubes. PneuX System™ is part of the NHS Innovation Accelerator and will attract the NHS England Innovation and Technology tariff from April 2017 for 2 years.
Patient Safety / Experience	<p>100,000 patients are admitted for ventilation in the UK critical care units each year and 10-20% will go on to develop VAP. Between 3,000 and 6,000 people die with this type of pneumonia every year and prevention would save many lives. Treating VAP costs the NHS between £10,000 – £20,000 per patient and conservative estimates for prevention are savings to the NHS of over £100 million. The significant burden of VAP justifies the implementation of specific preventative measures.</p> <p>The PneuX System™ is intended for airway management in critically ill patients who are receiving mechanical ventilation. The system is designed to prevent VAP by minimising the risk of pulmonary aspiration and micro-aspiration in patients requiring mechanical ventilation.</p>
Clinical Effectiveness	<p>Several studies of this device have shown that it prevents the aspiration of secretions both in the lab and in clinical studies. Data from New Cross Hospital [1] showed that in a trial of 240 elective cardiac surgical patients the incidence of VAP was reduced from 7% to 3% by using the PneuX System™.</p>

PneuX System™ for Prevention of Ventilator Associated Pneumonia (VAP) Summary Document	
Cost Effectiveness	<p>Based on the study above a cost effectiveness analysis was conducted by health economists from the University of Birmingham [2]. The key points from this study are outlined below:</p> <ul style="list-style-type: none"> • Cost of PneuX ET tube £150 • Cost of standard ET tube £ 3.35 • PneuX System™ reduces VAP rates by 50% relative to standard ET tube • Associated with less post-operative complications • Significantly shorter ICU and in-hospital length of stay • Associated with significant cost savings of £718/patient • PneuX ET tube – still cost beneficial if it reduced VAP incidence by only 8% • PneuX ET Tube – cost neutral if priced at £868 <p><u>NHS England Innovation and Technology Tariff</u></p> <p>The Innovation and Technology Tariff will enable Trusts to use the PneuX System™ for free, thereby providing a financial incentive for Trusts to adopt the innovation [3].</p> <p>The TSM will be loaned to the Trust by the supplier and a minimum of 24 ET tubes per TSM must be ordered per year. These can be ordered up front or can be staggered throughout the year.</p>
Benefits of Adoption	<p>The adoption of the PneuX System™ is expected to be associated with some significant benefits to the region based on implementation in the East Anglia region.</p> <p>Economic</p> <ul style="list-style-type: none"> • Through reduced VAP rates there is likely to be a significant reduction in VAP treatment costs • By preventing VAP, there will be a reduced length of stay in the ICU; this could enable an increase in surgical elective work <p>Clinical</p> <p>The system helps prevent VAP through a five-pronged approach:</p>

PneuX System™ for Prevention of Ventilator Associated Pneumonia (VAP) Summary Document	
	<ul style="list-style-type: none"> Reduced cuff leakage Maintenance of cuff pressure Convenient drainage and irrigation of subglottic secretions Prevention of tube movement and accidental extubation Potential inhibition of biofilm formation in tube lumen <p>The reduction in the rate of VAP would result in improvements in mortality, morbidity and length of stay for patients.</p> <p>Patients</p> <p>VAP is a serious infection for patients already in a vulnerable condition and is a risk to patients’ health and recovery. The adoption of the PneuX System™ is likely to have a significant impact of reducing patient harm, and potentially improving the patient’s long term prognosis and quality of life.</p>
Workforce Implications	<ul style="list-style-type: none"> No changes to the way current services are organised or delivered are needed Trusts will need to understand existing VAP levels with standard endotracheal tubes Training to use the PneuX System™ will be important; training and educational material will be provided by the supplier
Devices Available From	<p>Devices can be ordered from Qualitech Healthcare: www.qualitechhealthcare.co.uk/products.html</p> <p>Contact: Nicki Dill: n.dill@qualitechhealthcare.co.uk or Megan Turner: m.turner@qualitechhealthcare.co.uk</p>
Relevant Links	<p>[1] Significant reduction in ventilator-associated pneumonia with the Venner-PneuX System™ in high-risk patients undergoing cardiac surgery: Low Ventilator-Associated-Pneumonia study. Eur J Cardiothorac Surg. 2015;47(3):e92-6 https://academic.oup.com/ejcts/article/47/3/e92/524144/Significant-reduction-in-ventilator-associated</p> <p>[2] Luckras 2016, VAP cost effectiveness study, 29th EACTS Annual Meeting.</p> <p>[3] NHS England, News, accessed Nov 2016 https://www.england.nhs.uk/2016/11/innov-tech-tariff/</p> <p>Full clinical information and training videos available at www.KLIPSuk.com</p>

PowerPoint Presentation

To support clinical leads in making the case to clinical and managerial teams a slide deck has been compiled to demonstrate the benefits of the device, how the device can be implemented and what stakeholders can expect during implementation. The slide deck is available by emailing james.rose@oxfordahsn.org or alison.gowdy@oxfordahsn.org

Step 2: Business Case

The business case for adoption of the PneuX System™ has been made extremely compelling through the inclusion of the device on the NHS England Innovation and Technology Tariff (ITT). **NHS England has confirmed the PneuX System™ will be free to provider organisations from April 2017 for 2 years.**

A summary of the ITT and how it will operate has been included below, and in addition the full ITT guidance is available as an electronic resource from the link below
<https://www.england.nhs.uk/resources/pay-syst/development/tech-tariff-17-19-technical-notes/>

Due to the Innovation and Technology Tariff, a formal business case submission may not be required. However, a semi-populated business case template has been included in this implementation pack should this be required either for initial implementation or after the tariff is no longer active. An electronic version is available as a word document which can be adapted to meet local requirements.

Innovation and Technology Tariff – PneuX System™

The Innovation and Technology Tariff (ITT) was introduced to incentivise the adoption and spread of transformational innovation in the NHS. It aims to remove the need for multiple local price negotiations and guarantees automatic reimbursement when an approved innovation is used.

NHS England has confirmed the PneuX System™ will be free to provider organisations from April 2017 for 2 years.

The ITT for the PneuX System™ operates under a zero-cost model, which has been established to minimise the number of financial transactions and create a more efficient system to administer across the NHS (Figure 2).

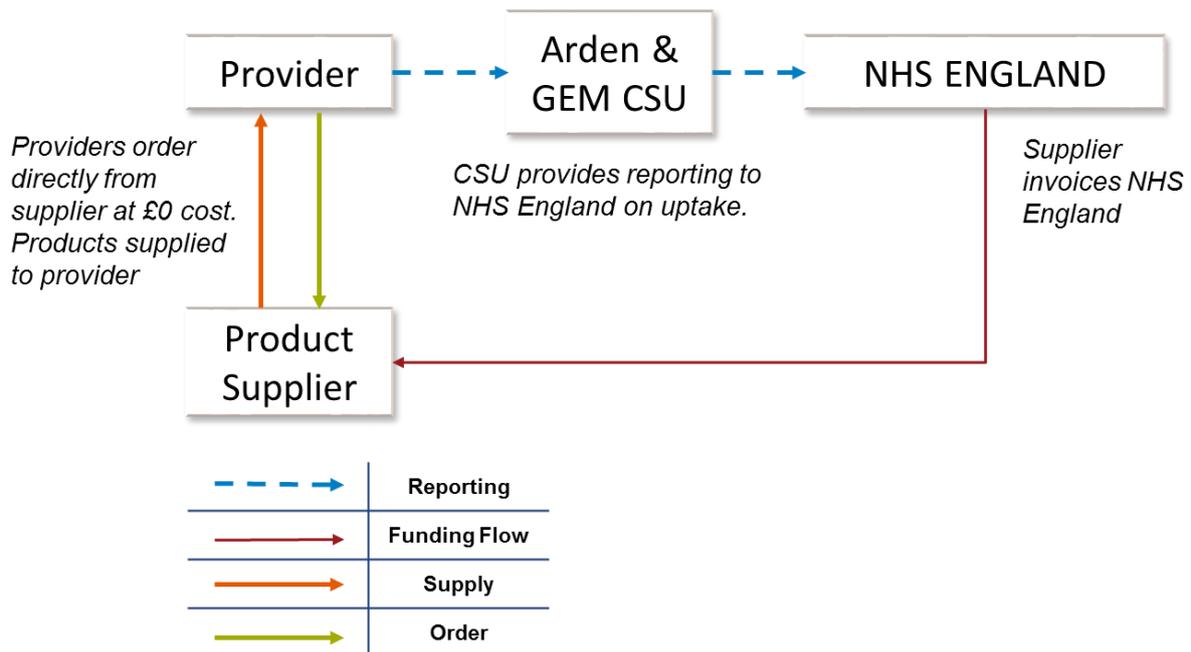


Figure 2 ITT Zero Cost Model

Key Points

1. Provider organisations will order the PneuX System™ direct from the Supplier (Qualitech Healthcare) – this includes both the TSM monitor (Tracheal Seal Monitor) and the ETT (EndoTracheal Tubes) or TT (Tracheostomy Tubes).
2. A minimum of 24 ETTs must be ordered for each TSM per year. The ETTs or TTs can be ordered upfront or staggered throughout the year.
3. Supplier will invoice NHS England for the devices, who will pay for the devices.
4. Provider organisations will need to contact Arden Gem CSU to confirm their intention to implement the PneuX System™ by emailing FinanceQueries@ardengemcsu.nhs.uk
5. Provider organisations will be required to provide a minimum data set to assess uptake of the innovation for each period of activity. Arden Gem CSU will send the necessary spreadsheet to the Trust for completion. This will need to be completed and returned to the CSU at FinanceQueries@ardengemcsu.nhs.uk, who in turn will collate and submit to NHS England. The minimum data set will include:
 - a. Prevalence of VAP for the previous financial year. This is only required for the first report.
 - b. Prevalence of VAP during this period of reporting.
 - c. Number of PneuX tubes or other approved VAP prevention devices used on patients ventilated for 24 hours or more.

Business Case Template

Improving Patient Safety - Implementation of the PneuX System™ for Prevention of Ventilator-Associated Pneumonia (VAP)	
Executive Sponsor	{insert}
Author	{insert}
Date	{insert}
Summary of service development	<p>To implement the PneuX System™ within the Intensive Care Unit, thereby improving the patient safety for approximately {insert approx. annual number of patients who will have the PneuX System™} patients per annum.</p> <p>The PneuX System™ is a unique system for the prevention of ventilator-associated pneumonia (VAP) during mechanical ventilation. It promotes patient safety through a five-pronged approach to VAP prevention:</p> <ul style="list-style-type: none"> ➤ Reduced cuff leakage ➤ Maintenance of cuff pressure ➤ Convenient drainage and irrigation of subglottic secretions ➤ Prevention of tube movement and accidental extubation ➤ Potential inhibition of biofilm formation in tube lumen <p>The system produces an optimal seal and significantly helps to reduce the risk of aspiration, improving airways management and is designed to prevent VAP by minimising the risk of pulmonary aspiration and micro-aspiration in patients having ventilation in the ICU or during prolonged major surgery.</p> <p>The PneuX System™ attracts the Innovation and Technology Tariff (ITT), and as such is free to provider Trusts to implement. The tariff operates under a zero-cost model. This means the Trust orders direct from the supplier, who in turn invoices NHS England.</p> <p>As well as improving patient safety for patients in critical care, the implementation of this innovation will provide a cost saving for the Trust over the life of the ITT.</p>
Link to Trust’s strategic aims	{insert}
Link to department’s annual plan	{insert}

Change in activity (IP / OP)	Not applicable
Change in staffing	Not applicable
Change in income	Not applicable
Change in costs	{insert cost saving per annum against reduced level of current tubes}

1. Strategic Overview

100,000 patients are admitted to critical care units for mechanical ventilation in the UK each year, and of these patients, 10-20% will develop ventilator associated pneumonia (VAP). Patients who develop VAP have an increased length of stay on ICU and increased mortality rate; of these 10,000 – 20,000 patients who develop VAP each year across the UK, between 3,000 and 6,000 will die with this type of pneumonia. VAP is the leading cause of nosocomial cause of mortality in ICU. The most common cause of VAP is aspiration of contaminated secretions from the oropharyngeal space. Aspiration occurs passed standard tubes or cuffs by three mechanisms:

- Channels or invaginations within the inflated cuff
- Movement of the cuff
- Loss of cuff pressure

The costs for treating VAP are significant, between £10,000 and £20,000 per patient. As such conservative estimates for prevention are savings to the NHS of over £100 million, and which does not account for savings from the associated reduced length of stay.

Within {insert Trust name} approximately {insert annual number of ICU patients} patients are admitted to the Intensive Care Unit each year, and the reported VAP rate is {insert}. This equates to {insert number} patients per annum.

Prevention and patient safety are key priority areas across the NHS, and this business case proposes a device that will address these for patients who are already critically ill. Subsequently through improving patient safety, significant cost savings will be released – the cost of treating {insert number} cases of VAP per year is in excess of £ {insert}.

2. Summary of Proposed Option

The PneuX System™ is intended for airway management in critically ill patients who are receiving mechanical ventilation. The system is designed to prevent ventilator-associated pneumonia by minimising the risk of pulmonary aspiration and micro-aspiration of bacteria contaminated subglottic secretions in patients having prolonged ventilation. The material of the tube and cuff has been specifically designed to overcome the problems which cause VAP with standard endotracheal tubes, such as folds and invaginations of the inflatable cuff, loss of seal due to patient or tube movement and maintenance of cuff pressure. The PneuX System™ allows for suctioning and irrigation of the subglottic space to remove infective material.

3. Option Appraisal

Option 1 – Do Nothing

This option maintains the status quo and would not see the PneuX System™ implemented within ICU. The current endotracheal tubes would remain in place and the potential for VAP would also remain. The Trust would not be able to attract the Innovation and Technology Tariff. Length of stay on ICU would not be reduced and savings from reduced treatment of pneumonia would not be realised.

Option 2 – Implement the PneuX System™ on ICU (preferred option)

This option would see the PneuX System™ implemented within ICU, and in doing so the potential for VAP would be removed. Staff and patients would have assurance that the incidence of VAP would be substantially mitigated, and the Trust would have assurance that increased expenditure and increase length of stay would not be required due to VAP.

Furthermore, as the PneuX System™ attracts the Innovation and Technology Tariff there is no cost-implication of introducing this device. In fact, it will generate a cost saving (from April 2017 for 2 years) as there will be a reduction in the number of current endotracheal tubes required.

4. Activity Implications for Preferred Option

- Using the PneuX System™ will likely improve the flow of patients coming to ICU (preventing VAP leads to reduced length of stay) and could enable an increase in elective surgical work
- There will be an impact on the staff due to initial training requirements to use the PneuX System™
- Training will be provided by the supplier and a training video is also available to ensure staff can conveniently access training
- Data collection for the Innovation and Technology Tariff will be required for NHS England to assess uptake of the innovation. This includes:
 - Prevalence of VAP for the previous financial year (This is only required for the first report)
 - Prevalence of VAP during this period of reporting
 - Number of PneuX tubes or other approved VAP prevention devices used on patients ventilated for 24 hours or more

5. Financial Analysis for Preferred Option

Currently {insert number} endotracheal tubes are ordered per annum in the ICU, at a cost of {insert cost}.

The PneuX System™ will significantly reduce the number of endotracheal tubes currently used. While the current tubes may still be required, there will be a reduced level of stock required which will generate a cost saving. **{Trusts may wish to add proposed reduction in current ETT usage}**

The cost of the PneuX System™ is £150 per ETT or TT. The Tracheal Seal Monitors (TSMs) are free to Trusts and are provided on loan, with a minimum of 24 ETT to be ordered per year for each TSM. The cost of the ETT currently used is {insert cost}. After a 2 year period the Innovation and Technology Tariff will be evaluated by NHS England to determine whether it should be continued. The clinical team recommend the use of the PneuX System™ for the lifespan of the tariff, with further discussions regarding the continuation at a later date.

6. Project Implementation

Action / Milestone	Responsible Person	Timescale
Agreement of business case		
Training plan for staff to ensure staff are aware of PneuX System™ and how to use it. This will include training by the supplier and include 'train the trainer' sessions for senior nursing staff	Practice Development Nurse / Qualitech Healthcare	
Transition from old ETT to new ones: sufficient number of staff need to be trained on the system before it is introduced. The system will then be introduced for appropriate patients, with this transition being used as further learning opportunities		
Completion and submission of NHS England minimum data set requirement		Quarterly reporting

7. Risk Management / Service Development Sensitivities

Risks	Mitigation
Wastage of current endotracheal tubes	Transition plan for moving from old ETT to the PneuX System™ has been agreed to minimise wastage. This will include a reduction in volume ordered, but some standard ETT will still be required for

	<p>patients requiring intubation for less than 24 hours.</p> <p>The current tubes can also be used in operating theatres and the Emergency Department</p>
<p>Significant number of staff to receive training before device can be implemented</p>	<p>Training plan has been confirmed which will ensure all clinical staff receive timely training on the using the PneuX System™. Training will be provided by the supplier and training materials are also available to assist staff in the provision of training to other staff on the unit</p>

Step 3: Procurement of Devices

Once there is agreement from clinical and managerial teams to proceed, leads will need to work with procurement and finance. An overview of the procurement process has been provided to help leads at each Trust understand the steps needed to make the PneuX System™ available for ordering (Figure 3 Overview of Process for Procuring PneuX System™).

In addition, the key information for procurement has been collated into a simple one page document for leads at each Trust to share with procurement at the appropriate time (See Information for Procurement).

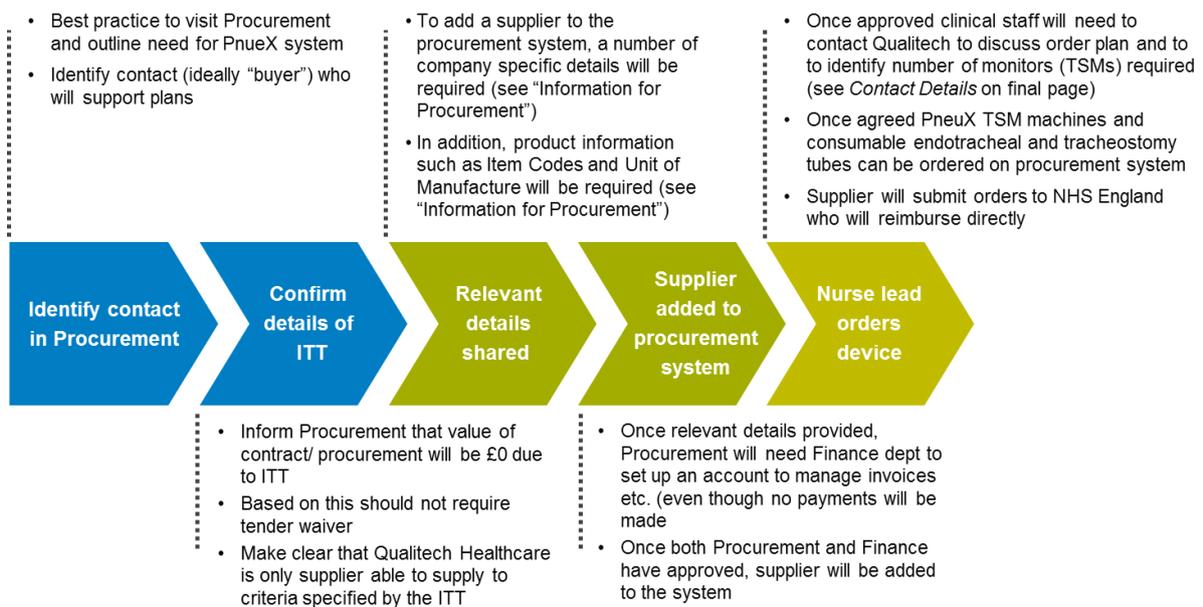


Figure 3 Overview of Process for Procuring PneuX System™

Information for Procurement

Leads at each Trust can use the text and details below to share relevant information with Procurement department.

After approval from clinical leads and management to proceed, ICU would like to procure and implement a novel product: PneuX System™ from Qualitech Healthcare. The system is used in ventilated patients and consists of a mains powered monitor which connects with consumable endotracheal or tracheostomy tubes. As part of the new NHS England Innovation and Technology Tariff (ITT) the device is available at zero cost to Trusts (see Theme 2 <https://www.england.nhs.uk/resources/pay-syst/development/tech-tariff-17-19-technical-notes/>). Qualitech Healthcare is a supplier that will need to be added to our procurement system. We have gathered the relevant information below which we hope is enough for you to proceed. Please let us know if further information is required.

Total value of contract per annum: £0 (due to ITT reimbursement) - assume no waiver needed

Suppliers able to provide goods to specification: Currently Single Source - only Qualitech Healthcare is able to provide the product according to the specifications outlined in the ITT

Supplier Details:

Qualitech Healthcare Limited
 16 Cordwallis Park
 Clivemont Rd
 Maidenhead
 Berkshire
 SL6 7BU
 Tel: +44 (0)1628 854042
 Email: info@qualitechhealthcare.co.uk
 VAT Number: 180535219
 GHX Number: GS1 – GLN5060456660000 – SID4GOV 464885

Supplier Classification: Small to Medium Enterprise (SM/E) SME

Products to be added to procurement System:

Product Description	Product Code	Unit Size
PneuX™ Tracheal Seal Monitor	7000TSM/T	1
PneuX™ Extension Tubes (Box of 10)	7000EXT/T	10
PneuX™ Endotracheal Tube Size 7.0 MRI Compatible	7170PETM/T	1
PneuX™ Endotracheal Tube Size 8.0 MRI Compatible	7180PETM/T	1
PneuX™ Endotracheal Tube Size 9.0 MRI Compatible	7190PETM/T	1
PneuX™ Tracheostomy Tube Size 7.0 MRI Compatible	7170PTTM/T	1
PneuX™ Tracheostomy Tube Size 8.0 MRI Compatible	7180PTTM/T	1
PneuX™ Tracheostomy Tube Size 9.0 Compatible	7190PTTM/T	1

Step 4: Schedule and Deliver Training

Qualitech Healthcare will use a phased training approach to facilitate implementation in line with current industry practice. Qualitech Healthcare has a team of five clinical specialists who will deliver ‘train the trainer’ sessions, with each session lasting approximately 1 hour. A commitment by clinical and managerial leads to allocate sufficient time for training is essential to ensure successful adoption. A member of the clinical team should also be designated as the Training Co-ordinator, such as a practice development nurse.

Training will be carried out a maximum of two weeks prior to the user start date, to ensure retention of information. Training dates can be arranged following receipt of order and in conjunction with the advised delivery date to Trust. The training programme consists of:

- Introduction to the PneuX System™ (Endotracheal Tube and Tracheal Seal Monitor)
- Practical demonstration (Subglottic Irrigation and Drainage)
- Hands-on session
- Questions and answers
- Verification of Understanding certificate
- Training evaluation forms and training records

An excellent training resource has also been developed by staff at Queen Elizabeth Hospital, King’s Lynn which can be accessed using the following links:

PneuX System™ Tube Exchange: https://www.youtube.com/watch?v=U_nF9UJQjH0

Irrigation with the PneuX System™: <https://www.youtube.com/watch?v=E5QeyKXwFfo>

Intubating with the PneuX System™: <https://www.youtube.com/watch?v=SPA6FOCYDIU>

Step 5: Introduce the PneuX System™ to the ICU

Once training has been delivered and stock has been received, leads should look to introduce the PneuX System™ into practice. Specifying a date at which the other ET tubes will no longer be available would provide a defined timeframe for staff to become accustomed to the new device whilst allowing old stock to be run down to minimise wastage. Practice development nurses may wish to audit usage over this time and continue to drive usage through reinforcing the benefits of usage of the PneuX System™. During the implementation phase, support is available from Qualitech Healthcare.

Step 6: Decommission Alternatives

There will be a requirement for some of the current endotracheal tubes to remain in stock, and these standard ETT will be needed for patients requiring intubation for less than 24 hours. The current tubes can also be used in operating theatres and the Emergency Department. As such there should be no wastage of current stock.

The PneuX System™ will however mean a reduced number of current endotracheal tubes are required. The individual member of staff with designated responsibility for ordering stock should be informed of this reduced level of stock.

Step 7: Monitor and Optimise Usage

Once implemented on the ICU, continual monitoring and reinforcement to ensure use of the PneuX System™ is important. As part of the ITT, provider organisations will be required to provide a minimum data set to assess uptake of the innovation for each period of activity. This dataset will be sent to Arden Gem CSU at FinanceQueries@ardengemcsu.nhs.uk, who will collate and submit to NHS England. The minimum data set will include:

- a. Prevalence of VAP for the previous financial year. This is only required for the first report
- b. Prevalence of VAP during this period of reporting
- c. Number of PneuX tubes or other approved VAP prevention devices used on patients ventilated for 24 hours or more

Baseline Data Requirements

The table below outlines the data that may be of value if a business case is required. The data would also provide the baseline against which the impact of the device can be measured. The system by which the data can be collated is given, although it is recognised that this may vary by Trust.

Table 1 Baseline Data Requirements – PneuX System™

Data requirement	System/department to provide data	Proposed time period for which data is required
1. Reported VAP rate	ICU	Previous 12 months
2. Annual volume of ETT ordered	Procurement	Previous 3 years

Potential Barriers to Implementation and Mitigating Action

Implementation of innovation is rarely straightforward and in many cases barriers and challenges faced at one Trust will be similar to those experienced at other Trusts. In the table below, some of the most common issues arising from implementation have been captured along with how best to circumvent or overcome this hurdle (

Table 2).

Table 2 Barriers to implementation captured from previous site implementations of the PneuX System™ and how they have been overcome

Issue Raised	Counter Argument
Additional cost required to implement the innovation	<p>The Innovation and Technology Tariff covers the cost of the device. The Tracheal Seal Monitors are issued to each hospital based on consignment meaning the use of the PneuX system is free for Trusts for 2 years from April 2017.</p> <p>Trusts need to order a minimum number of ET tubes (24) per monitor per annum. The cost of the tubes is covered by the tariff.</p>
Training is required before the device can be implemented.	<p>Training is required to ensure staff are accustomed to the device, and understand the safety features. Representatives from Qualitech Healthcare will be available to deliver hands-on ‘train the trainer’ sessions at your hospital. These sessions take approximately 1 hour. It is suggested that a member of the clinical team is designated as the training coordinator, for example the PDN.</p> <p>In addition, a number of training videos have been produced and published online covering insertion; irrigation; subglottic suction etc. (see www.KLIPSuk.com)</p>

Issue Raised	Counter Argument
<p>The PneuX System™ will require changes in clinical practice.</p>	<p>The PneuX System™ will require some small changes in clinical practice which will benefit the patient significantly.</p> <p>The most significant benefits are their ability to aspirate subglottic secretions and regularly undertaken high volume saline irrigation of the patient’s subglottic space. Irrigation allows washout and cleaning of the bacteria laden secretions sitting deep in the oropharynx above the cuff. This change will have a positive impact in terms of preventing tracheal colonisation and VAP.</p> <p>The use of a Tracheal Seal Monitor is a new addition to the use of cuffed endotracheal tubes on ventilated patients. However, the monitors are exceptionally easy to use, comparative to other cuff pressure monitors available. Once set, they maintain the cuff pressure without the need for the current practice of 4 hourly nurse monitoring.</p> <p>If the position of the ETT has moved or there is an air leak the monitor will alarm and will alert staff to the problem, helping to quickly resolve any clinical airway issues.</p> <p>The PneuX ETT cuffs can be manually inflated without a TSM if required for example immediately following intubation or when transferring the patient, and will maintain in inflation for approximately 3-4 hours.</p>
<p>Our ICU unit has a large number of the standard endotracheal tubes in stock.</p>	<p>There is a case for keeping stock of standard ETT for patients requiring intubation for less than 24 hours. For high risk patients it is beneficial to choose the PneuX even if intubation is subsequently shorter than expected (<24hr). The study in high risk major surgical patients in New Cross Hospital showed that a substantial health benefit alongside cost savings occurred when the PneuX was used in patient groups who were ventilated for an average of 14hr.</p> <p>Regarding other subglottic drainage tubes, due to the need for training of staff, there will be a short period in which to run down the current stock levels.</p>

Issue Raised	Counter Argument
<p>The Innovation and Technology Tariff is only in place for 2 years. There could be a potential cost pressure after that time.</p>	<p>The tariff is in place to provide Trusts with the opportunity to try proven evidence-based and cost saving innovations that are known to improve patient safety.</p> <p>The ITT provides Trusts with the opportunity to use the PneuX System™ for free for 2 years, meaning the Trust will have a cost-saving as the PneuX System™ will reduce the number of current endotracheal tubes required.</p> <p>The PneuX System™ prevents VAP. VAP is associated increased mortality but also increased antibiotic use. This is an important pressure for antibiotic resistance driven by ICU. It has been reported that 50% of antibiotics used in the ICU are used for treating VAP [Kalanuria et al., Critical Care, 2014, 18:208]. Preventing VAP not only improves patient safety but reduces the need for increased expenditure on drugs.</p>

Other Questions Raised	Response
<p>Why is the bite block on the PneuX ETT far longer than standard ETTs?</p>	<p>The PneuX ETT has been designed to be able to cope with variations in patients’ tracheal and mandibular dimensions. Having a longer tube ensures the tube can fit all patients.</p> <p>Whilst this may mean that there is more “overhang” of the tube from the patient mouth than standard tubes, this has not caused any clinical or patient safety issues. A degree of flexibility of this portion outside of the mouth reduces drag on the lower tube with circuit movements and tugs.</p> <p>The bite block is stiffer, thereby reducing unintentional extubation compared to a completely flexible tube, however the distal portion of the tube remains flexible to remain gentle on the arytenoids, larynx and trachea.</p> <p>Because of the longer tube, standard tracheal suction catheters emerge from the tip of the PneuX at a more appropriate level and over insertion and bronchial placement of the catheter tip is reduced.</p>
<p>Is the PneuX system compatible with our Intellicuff system?</p>	<p>The cuff on PneuX tube is only compatible with the PneuX Tracheal Seal Monitor (TSM) and this is the only way to maintain a safe and effective tracheal wall pressure. Likewise, the TSM must NEVER be used with standard HVLP cuffed tubes. The TSMs are small, light and can be affixed in a multitude of ways to ensure minimal disruption to the near-patient equipment.</p>

Is there good evidence for the PneuX reducing VAP rates?

The PneuX System was trialled in New Cross Hospital, Birmingham and the economic evaluation showed a saving of £718 per patient for those who had the PneuX system in place. This study compared the cost effectiveness of converting to the PneuX™ endotracheal tube from standard endotracheal tube. The study results were independently analysed by statisticians at the Royal College of Surgeons and health economists at the University of Birmingham, who found the using the PneuX™ endotracheal tube saved their hospital >£700 per patient. They found that using the PneuX™ reduced VAP by 50%, however for it to be cost neutral it only had to reduce VAP rates by 8% (Presented at the 29th European Association for Cardio-Thoracic Surgery. 2015, Amsterdam).

In a UK, randomised controlled trial (RCT) with 240 high-risk patients having cardiac surgery, PneuX was associated with a significant reduction in VAP incidence compared with a standard endotracheal tube (10.8% compared with 21%, p=0.03) (NICE, November 2015).

A UK-based retrospective cohort study in 53 critically ill patients found no incidence of VAP or even tracheal colonisation while the PneuX System was in place (NICE, November 2015). No antibiotics were instituted for new chest colonisation or infection in the PneuX group.

The quantity and quality of evidence supporting the benefits of using the PneuX system are orders of magnitude above what would normally be expected from the use of a consumable low cost medical device.

Is intubation more difficult with the PneuX, given it is a flexible tube?

The PneuX has been specifically designed to be flexible to minimise trauma to the patient's airway and to ensure fit with the widest range of patients.

Intubation must be done with the use of either a stylet or a Bougie. Intubation with a PneuX ETT is no different to any other flexible ETT. Whilst this may mean some staff require time to get used to the new tubes, the long-term benefits of using the PneuX clearly outweigh the negatives of the small disruption in practice.

<p>Potential risk of endobronchial and / or failed intubation.</p>	<p>Very stiff tubes are injurious to the delicate laryngeal structures and the anterior upper trachea with case reports of tracheal perforation with stiffer subglottic drainage tubes. Very flexible tubes, although being much kinder to the upper airway, carry the risk of unintentional extubation as there is more risk of them pulling back with tube movement.</p> <p>The PneuX has a longitudinally stiffer bite block portion at the oro-pharyngeal portion and a more flexible pharyngo-laryngo-tracheal section thereby balancing the risks of unintentional extubation with care of the deep upper airway structures.</p>
<p>The number of tube changes required is a potential issue.</p>	<p>The number of tube exchanges could be reduced if the patient was intubated with the ET tube in theatres initially. For high risk patients, it is beneficial to choose the PneuX even if intubation is subsequently shorter than expected (<24hr). The study in high risk major surgical patients in New Cross Hospital showed that a substantial health benefit alongside cost savings occurred when the PneuX was used in patient groups who were ventilated for an average of 14hr.</p>
<p>PneuX tracheostomy tubes do not have an internal tube, which is recommended by NCEPOD.</p>	<p>The design has been optimised to minimise occlusion of the tube. The inner coating is a medical non-stick polymer called Parylene which when used with active humidification seems to have minimal secretion accretion on the tubes and as a result minimal risk of blockage. For example, one PneuX tracheostomy was used for >6 months without occluding at a leading London hospital.</p> <p>Patients who are self-ventilating on an HDU or ward environment frequently will either have the PneuX cuff deflated or have an elective step down change to a conventional tube once the protection from aspiration afforded by the PneuX cuff becomes less important with the return of the patients’ intrinsic airway protective reflexes. In a ward environment, a conventional inner-tubed TT should be used in all but exceptional circumstances weighing up risks.</p>

The Oxford AHSN would be keen to understand other barriers to adoption that you may encounter, in order that we can share these nationally with other providers and AHSNs. Please use the contacts overleaf to inform us of any challenges you face that have not been captured in the table above.

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