CLINICAL PRACTICE GUIDELINE

Use of a Passy-Muir Speaking Valve in a Non-Ventilated Patient

Preface:

This multi disciplinary clinical practice guideline provides an evidence based framework for the placement and care of Passy Muir Speaking Valves (PMV) at Princess Margaret Hospital. The document aims to guide consistent, safe PMV applications for infants and children with tracheostomies.

It is intended for use when:

A: Placing the valve for the first time:
• Speech Pathologists** (SP)
  **Speech Pathologists working in this specialty area should receive specialist training and support
• Clinical Nurse Consultant for Technology Dependent Children (CNC-TDC)
• Physicians and/or Paediatric Intensive Care Consultants

B: Placing valve according to an established documented management plan:
• A staff member/parent who has received training in supervising a PMV trial
1. Introduction

The use of a speaking valve is considered best practice for trachoeostomised infants and children. Drilling a relief port in the valve is a possible option to enable children with upper airway obstruction to achieve voice.

Guidelines for Speaking Valve Trials have been collaboratively developed to ensure consistency in assessment method and interpretation at PMH to promote best outcomes for tracheostomised children of Western Australia.

Click here for information relating to the development of this clinical practice guideline

2. Definitions

Air Trapping/ Breath stacking
Occurs when an individual is able to breathe in, but has difficulty breathing out due to small/narrow upper airway. Exhalation is incomplete resulting in the residual air in the lungs adding to the volume of the next inhalation.

Manometer
An instrument used to measure the pressure of exhaled air (cm H\textsubscript{2}O) through the upper airway when a child is fitted with a speaking valve.

Passive Exhalation
Quiet breathing with no attempt to cough or vocalise.

Phonation
Production of voice via vocal cord vibration.

Speaking Valve (SV)
A one-way valve attached to the tracheostomy tube. On breathing in the air goes in the tracheostomy tube. On breathing out, the air is exhaled out of the nose and mouth past the vocal chords to enable voice.

Trans-Tracheal Pressure (TTP) \textsuperscript{1}

The intra-luminal tracheal pressure in cmH\textsubscript{2}O on breathing out when the valve is closed. The range and the resting TTP is measured. The ‘resting’ TTP is the most common pressure reading noted in cmH\textsubscript{2}O.

Upper Airway Patency
The degree of opening/clearance through the upper airway.
3. Referral

☑ Referral must be received from either:
  • ICU Consultant
  • ENT Consultant
  • Respiratory Consultant

Exceptions: None. (Good Practice Point; Benchmarking: Rady’s Children’s Hospital, Los Angeles)

Where the referral does not come directly from ENT, they must be consulted to provide information related to the child’s upper airway patency and to confirm that the child is appropriate for trials.

NB: Children with a tracheostomy should be referred to Speech Pathology as an automatic referral for communication support even if the child is not eligible for a speaking valve.

3.1 Candidates for PMV Trial

Age of Candidate:
• 0-18 years: No restrictions on how young providing that infant is medically stable.

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<table>
<thead>
<tr>
<th>Historical Criteria for Candidacy²,³</th>
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<tbody>
<tr>
<td><strong>Indications for PMV placement</strong></td>
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<tr>
<td>☑ Medically stable</td>
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<tr>
<td>☑ Neuromuscular disease</td>
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<tr>
<td>☑ Head trauma</td>
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<tr>
<td>☑ Quadriplegia</td>
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<tr>
<td>☑ Chronic obstructive pulmonary disease</td>
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<tr>
<td>☑ Mild tracheal and/or laryngeal stenosis</td>
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<tr>
<td>☑ Ventilator dependency</td>
</tr>
<tr>
<td>☑ Bilateral vocal cord paralysis without significant airway obstruction</td>
</tr>
<tr>
<td>☑ Non-obstructive laryngeal tumours</td>
</tr>
<tr>
<td>☑ Tracheomalacia</td>
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<table>
<thead>
<tr>
<th>PMH Criteria for Candidacy</th>
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</thead>
<tbody>
<tr>
<td><strong>Indications for PMV Assessment and possible trial of a drilled speaking valve</strong></td>
</tr>
<tr>
<td>☑ As above</td>
</tr>
<tr>
<td>☑ Moderate tracheal and/or laryngeal stenosis (less than Grade 4 subglottic stenosis)</td>
</tr>
<tr>
<td>☑ Bilateral vocal cord paralysis</td>
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</tbody>
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³: Refer to PMV placement criteria and contraindications from the above table.
4. Assessment Equipment Kit:

- Gloves
- Protective eye-wear (optional)
- Suctioning equipment
- Hand held manometer
- Mild detergent (At PMH Suma Med Star detergent is used, with dilution ratio of 1mL-5mL per litre of water; domestic dishwashing detergent is suitable, but it is essential to adhere to manufacturer's dilution instructions).
- Oxygen tubing and connector piece to join the manometer to the valve.
- Pulse Oximeter
- Stop Watch
- 10 ml syringe (non-Luer lock) to deflate the cuff
- Appropriate PMV

<table>
<thead>
<tr>
<th>Suctioning equipment</th>
<th>Manometer</th>
<th>Oxygen tubing</th>
<th>Connector piece</th>
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<tbody>
<tr>
<td><img src="image1" alt="Suctioning equipment" /></td>
<td><img src="image2" alt="Manometer" /></td>
<td><img src="image3" alt="Oxygen tubing" /></td>
<td><img src="image4" alt="Connector piece" /></td>
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</table>

Passy Muir Valve Range used at PMH:
Specifications: 15mm inner diameter. 23mm outer diameter. Fit onto standard connector.

<table>
<thead>
<tr>
<th>PMV 2000 (Clear)</th>
<th>PMV 2001 (Purple)</th>
<th>PMV 007 (Aqua)</th>
<th>PMA 2000 Oxygen Adapter</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image5" alt="PMV 2000" /></td>
<td><img src="image6" alt="PMV 2001" /></td>
<td><img src="image7" alt="PMV 007" /></td>
<td><img src="image8" alt="PMA 2000" /></td>
</tr>
</tbody>
</table>

Identical to the PMV 2000
Fits inside ventilator tubing
Delivers low flow oxygen (<6L/min) and humidity.
5. Pre-Assessment Procedure
(Good Practice Point; Benchmarking: Children’s Hospital, Los Angeles)

**Required Personnel:**
- PMH Speech Pathologist (SP)

**Optional Personnel:**
- Clinical Nurse Consultant for Technology Dependent Children (CNC-TDC)
- Occupational Therapist (OT) as appropriate.
- Managing Community-based Speech Pathologist (mSP) invited to attend

**Roles:**
- SP and mSP to meet child and family and assess the child’s communication skills and +/- presence of leaked voice.
- SP to explain the procedure to the child and family. Teaching aids can provide visual support. See note below.
- Family given the PMH fact sheet on *How a Speaking Valve Works* (see Appendix 3)
- SP and mSP clarify/discuss parental expectations re: tolerance, transitioning and likelihood of vocalisations in line with developmental level.
- SP, mSP and OT (if possible) assists family to plan for the assessment session and determine optimal sensory-environment to calm/distract the child.
- Pre-Assessment manometry measure taken and recorded (see recording sheet-Appendix 1)
- Pre-Assessment Phonation score allocated and recorded (see recording sheet-Appendix 1)

NOTE: Education tools are available through Passy Muir Inc. including a downloadable colouring book and a Tracheostomy Tube Observation Model. Click [here](#) to view.

6. Assessment Procedure
(Refer to Assessment Procedure part a) and part b) and Algorithm 1.)

**Required Personnel:**
- Clinical Nurse Consultant-Technology Dependent Children (CNC-TDC)
- PMH Speech Pathologist (SP)

**Optional Personnel:**
- ENT Consultant or Registrar may be requested to attend for complex cases. The CNC-TDC will liaise to determine if this is necessary on a case-by-case basis.
- Managing, Community Speech Pathologist (invited to attend) (mSP)
- Occupational Therapist (OT) if appropriate.
Roles:
- CNC-TDC liaises with referring Consultant to determine required personnel for initial assessment.
- CNC-TDC selects suitable PMV. Valve costs are covered by PMH unless the child is compensable through ICWA.
- CNC-TDC to monitor vital signs, manometry reading and respiratory status of the child during assessment and trial.
- SP assists CNC-TDC to first assess leaked nasal/oral airflow on mirror and then monitor the child’s response during the trial.
- SP and mSP jointly determine voicing status before and during valve trials.
- SP and mSP monitor and interpret the child’s communication during the assessment and trial and to assist the child and family to determine a suitable communication system.

6.1 Manometry Assessment (See figure 2)
Based on the procedure described by Gereau, et al 1996\(^4\) and Utrarachkij, et al, 2005\(^5\).

<table>
<thead>
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<th>Patient Safety Alerts</th>
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<tbody>
<tr>
<td>▪ The cuff must be completely deflated when the PMV is on. Failure to deflate the cuff can result in immediate respiratory distress.</td>
</tr>
<tr>
<td>▪ Attach manufacturer stickers to the pilot line for cuffed patients to ensure cuff is fully deflated for future speaking valve trials</td>
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1. Attach Pulse Oximeter.
2. Record resting heart rate, oxygen saturation, colour, state and respiratory rate. Record resting SATS using the standard record sheet (Appendix 1).
3. Remove Humidivent
4. Perform tracheal +/- oral suctioning as indicated
   - For Cuffed Tracheostomy: deflate the cuff and suction again if needed
   - For Fenestrated Tracheostomy: remove unfenestrated inner cannula and replace with fenestrated inner cannula.

Figure 2: Manometry Assessment
5. Attach manometer and connection piece to PMV.

6. Place PMV with manometer onto the connector:
   • Monitor heart rate, oxygen saturation, colour, respiratory rate and state.
   • Measure passive exhalations* to obtain trans-tracheal pressure (TTP). Note the range of pressure measurement and note the resting (main) reading obtained.

   NB* Passive exhalations are breaths at rest. Results inaccurate if the child coughs, vocalises or cries.

7. Remove Manometer. Replace humidivent.
   • For Cuffed Tracheostomy: inflate the cuff.
   • For Fenestrated Tracheostomy: replace inner cannula (if unfenestrated)

8. Determine pass/fail and take appropriate action (see below)

<table>
<thead>
<tr>
<th><strong>Pass:</strong> Resting TTP &lt; 10 cm H20</th>
<th><strong>Fail:</strong> Resting TTP ≥ 10 cm H20</th>
</tr>
</thead>
<tbody>
<tr>
<td>Action: Proceed with PMV trial.</td>
<td>1. Review potential confounding effect if child vocalising, coughing or crying. If deemed inaccurate: Action: Retrial.</td>
</tr>
<tr>
<td>Children with mean TTP &lt; 5 cm H20 are more likely to proceed to full-tolerance status.</td>
<td>2. Contact Consultant. Next steps may include assessment of upper airway (e.g. LTB), downsizing the tracheostomy tube and/or drilling the valve.</td>
</tr>
<tr>
<td>Children with mean TTP 5-10 cm H20 – likely to cope with short trials.</td>
<td>Note: for children with known upper airway obstruction, permission to trial drilled valve usually obtained by Consultant prior to trial.</td>
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6.2 Speaking Valve Trial Assessment

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1. Repeat Steps 1-4 of Part 6.1.
2. Attach PMV onto the connector with a quarter clock-wise turn.
3. Observe and record heart rate, oxygen saturation, state, colour and respiratory rate.
   Record incidence of vocalisations, crying and coughs. Complete recording sheet in Appendix 2.
4. Leave valve on for as long as tolerated.
Remove Valve if:

- Child becomes very distressed and cannot be calmed.
- Respiratory distress; increased work of breathing e.g. breath stacking/air trapping, exhalation appears difficult with use of accessory muscles.
- Colour change or cyanosis.
- Tachycardia.
- Oxygen saturations <94% or less than normal for that child.

At cessation of trial:

5. Remove the PMV with a quarter anti-clockwise direction turn
   - For Cuffed Tracheostomy: re-inflate the cuff as required. Provide “Cuff must be deflated” warning sticker on the pilot cuff line for future trials with the cuffed tracheostomy.
   - For Fenestrated Tracheostomy:
     replace un-fenestrated inner cannula if required
6. Replace the Humidivent.
7. Clean the valve according to cleaning procedure (see 9.1).
8. Ensure the trial is recorded using the template provided in Appendix 1.
10. A management plan should be documented by the CNC and Speech Pathologist and recorded in patient notes with a copy left at the bed head (if inpatient). The plan must specify the recommended frequency and duration of trials and the required level of monitoring and supervision.
11. Demonstrate cleaning procedure to the family and provide written instructions.

7. Drilling Speaking Valves

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>- Ensure that you can visualise the hole and it not obstructed.</td>
</tr>
<tr>
<td>- Ensure valve is thoroughly cleaned of any debris post-drilling.</td>
</tr>
</tbody>
</table>
The following procedure is based on drilling procedures at Cincinnati Children’s Hospital Medical Centre40 (benchmarking data) and the procedure outlined in the literature by Brigger & Hartnick, 2009.¹

**WARNING:** This practice voids the manufacture’s warranty. Ensure you obtain parental consent and provide clear explanation regarding additional precautions and cleaning requirements.

**Consider drilling the speaking valve under the following conditions:**

- The child has known laryngo-tracheal obstruction (e.g. ≥Grade 2 Subglottic Stenosis) yet ENT Consultant and Family keen to trial PMV
- Manometry pressures on passive exhalation of 10cm H20 or more
- The child does not tolerate the valve despite trying conventional trouble shooting methods

Speaking valves can be drilled in order to provide a relief port to decrease trans-tracheal pressure (TTP) on expiration (see Figure 3).

*Figure 3: Drilled speaking valves*

The presence of the hole is presumed to prevent possible pneumatic benefits obtained by the biased-closed position of the PMV diaphragm. However, the drilling modification may enable a child to comfortably tolerate the valve and still achieve voice (see Figure 4).

*Figure 4: Exhalation with a drilled speaking valve*
As described in an article by Brigger & Hartnick, 2009¹, a small hole is drilled into the valve without damaging the membrane. First a 1.6mm hole is drilled and manometry assessment is conducted. Brigger and Hartnick report that the presence of one hole may reduce pressures by 15-25cm H2O. If trans tracheal pressure remains excessive, a second 1.6mm hole may be drilled a minimum of 2mm from the first. It is not recommended that more than two holes are drilled. At PMH, we have introduced an additional step. Prior to drilling a 1.6mm hole, we may trial a 0.8mm sized drilled hole for children whose TTP resting reading only slightly exceeds 10cmH2O.

**Practice Notes**

- Drill valve and re trial in a single session to determine effect and minimise confounding effect on assessment findings.
- Ensure drill angle not toward the membrane of the valve.
- Ensure that the hole is not covered by chin (especially in the case of infants)
- Where 2 drilled holes are required consider drilling the holes 180° apart so that head movement does not obstruct the hole.

**8. PMV Restrictions**

Do not wear PMV during:

- Bathing or sleeping³
- Aerosol treatments⁶
- Chest Physiotherapy⁷
- Nebulizer treatments⁷

**Practice note:**

- Monitor children with high need for humidification as valve placement necessitates removal of the Swedish nose.
- Specific supervision needs will depend on the child’s independence (i.e. are they able to remove the valve themselves) and age (i.e. an infant may fall asleep if out of sight in pram or car).

**9. Infection control**

- PMV is single-patient use³
- PMV duration guaranteed for 2 months³
9.1 Cleaning Procedure

- Swish PMV daily in soapy*, warm water (not hot water). [3]
  *see section 6 for suitable detergents
- Rinse PMV very thoroughly in warm running water. [3]
- Allow PMV to air dry thoroughly out of the sun before placing in storage container. Do not apply heat to dry PMV. [3]
- DO NOT use hot water, peroxide, bleach, vinegar, alcohol, brushes or Q-tips to clean PMV. [3]
- DO NOT use ethylene oxide, autoclave or radiation sterilizer. [6]

10. Troubleshooting

1. Differentiating Behavioural vs. Physiological Intolerance
   - Consult ENT Surgeon. (Step 4 of Algorithm).
   - Consider trialling a pseudo-speaking valve: a PMV with its’ membrane removed (see Figure 5).
   - Consider a manometry assessment when the child is asleep. Please note that it is only conducted for a diagnostic purpose, routine PMV use during sleep is contra-indicated. [8]
     Permission must be gained from the ENT Surgeon and the assessment must be conducted with CNC-TDC present.

2. Child appears unable to exhale through upper airway and consistently responds to trials with excessive coughing and attempts to forcibly expel the valve.
   - Remove valve
   - Assess for air-trapping
   - Position child to optimise ventilation (where possible, consult Physiotherapy)
   - If pressures are still high despite drilling the valve, this behaviour is related to physiological intolerance and therefore valve shouldn’t be used.
   - Consult ENT. (Step 4 of Algorithm).
3. **Addressing Behavioural Intolerance**

*NB: These should be considered in the pre-assessment phase where possible, rather than following a failed attempt.*

- Trial distraction techniques\(^8,^9\) e.g. favourite toy, songs, increased family involvement, change of environment, consider a clown doctor consult.

- Consider sensory impact of PMV placement. Sensory dysregulation has been noted in previous studies of children with tracheostomy.\(^10\) Ensure OT referral whenever possible to prevent or reduce distress. Jointly build rapport with the child and ascertain sensory preferences in order to guide a more pleasurable environment for trials.

- Maximise the child’s understanding of the procedure and encourage participation:
  - Embed consistent touch cues and/or Key Word Signs into the child’s daily routines to build awareness of the start/finish of activity and develop a cue to warn the infant before placing on the valve.
  - Work on establishing augmentative and alternative receptive/expressive communication in order to promote the child’s participation in trials.
  - Create a social story or photo/picture sequence to promote child’s participation, comprehension and reduce anxiety.
  - Depending on the child’s age, trial doll play with tracheostomy and valves. Use play-dough to demonstrate the pathway of air flow when wearing the valve (as demonstrated by the Speech Pathologist).
  - For older children, access the free Toby Tracheosaurus resources online ([http://www.passy-muir.com](http://www.passy-muir.com)). Openly discuss what the procedure involves and rationale for trialling the valve.
  - Consider group therapy with a child who is tolerating the valve well to provide positive modelling.

- Implement a reward system for valve use. If possible, visually endorse progress in duration of trials through graph charts or stickers.

- Consider the impact of anxiety on all family members.\(^8,^9\) Research indicates that parents of a child with a tracheostomy may be exhausted, overwhelmed, overprotective and anxious.\(^11,^12\) Consider a partnership approach with Clinical Psychology pending on age of child, parental acceptance and perceived level of child anxiety and parent anxiety.
Consider trialling a pseudo-valve (see figure 5) for the child to get used to the sensation of wearing a valve. Once tolerance is established, consider trialling a drilled valve, even if pressures are <10cmH20 as an additional step in a graded progression towards placement of an unmodified Passy-Muir valve.

4. Child tolerates the valve very well but is unable to vocalise

It is not uncommon for children to take time to learn to vocalise with a valve on, particularly if the child has not had the experience of using his/her voice. Voice may not be achieved on the first trial.\(^8,9\) Voice may need to be elicited through cry, laughter or effortful closure assisted by a Physiotherapist.

If voice is not achieved within one month of trials:

- Consult ENT surgeon. ENT surgeon may recommend flexible nasendoscopy or video stroboscopy assessment to determine functional vocal cord movement.
- Ensure child has access to an Augmentative and Alternative Communication device.
- Consider therapy focused on cause-effect play with oral airstream (e.g. harmonica, whistle, blowing cotton ball, blowing bubbles).
- Support parents in interacting with their child and to recognise and encourage non-verbal cues, gesture and joint attention noises.
- Consider possible concomitant motor speech disorder (e.g. dyspraxia).

5. PMV is noisy or vibrates

- Ensure valve has been cleaned
- Replace the valve

11. Division of Responsibilities - PMH & Community Partnership

A. PMH Management of a child with a Speaking Valve

- SP and CNC-TDC are responsible for initial speaking valve trial assessments. If the child is under a community service, all efforts should be made for the managing therapists to attend.
- SP and CNC-TDC are responsible for provision of a documented management plan completed for ongoing trials in medical records.
- SP to provide AAC (alternative/ augmentative communication system) for a child who is exclusively under PMH service and cannot tolerate a speaking valve.
• SP to refer to Community SP when the child has a stable speaking valve plan or for a child who is unable to use a speaking valve. At this point, child may be discharged from PMH SP caseload. PMH SP to provide second opinion assessment and consultancy on request.

• PMH CNC-TDC to provide consultancy as required

• CNC-TDC and SP to provide appropriate PD to teach staff regarding speaking valve trials at school.

• CNC-TDC and SP to ensure regular PD to nursing staff (including Ambulatory Care staff) managing a child with a speaking valve.

• CNC-TDC and SP to provide the patient’s Ambulatory Care team and General Practitioner with a written report concerning speaking valve management plan.

• PMH to supply ongoing speaking valve to the family of a child with a speaking valve unless the child is compensable. Valves are ordered through Consumables Coordinator if an outpatient or via the ward if a long term inpatient.

B. Community Management of a child with a Speaking Valve

• Community SP to act as the Managing therapist in the support of the child and family once there is a documented management plan completed for ongoing SV trials.

• Community SP to monitor valve use according to PMH-provided management plan and contact the SP or CNC at PMH when a new valve needs to be ordered.

12. Health Facts (information for parents)

• Speaking Valves

• Drilled Speaking Valves

13. Companion Documents:

• Guideline development information

• Table of Evidence.

• Appendix 1. Speaking Valve Pre-Assessment Record for Non-Ventilated Child

• Appendix 2. Speaking Valve Trials Recording Form

• Appendix 3. Vital Signs Reference Table

• Appendix 4. Speaking Valve Assessment Consent Form

• Appendix 5. Speaking Valve Trial Consent Form
14. More information

- Speech Pathology Australia position Paper: Tracheostomy Management

- American Speech and Hearing Association position paper: Managing Adults With Tracheostomies and Ventilator-Dependence

This document should be read in conjunction with disclaimer in the introduction to these guidelines
Algorithm: Multidisciplinary clinical pathway for valve introduction. Princess Margaret Hospital,

**Step 1. Speaking Valve Referral received**
- Referral must be received from either:
  - Intensive Care Consultant
  - ENT Consultant
  - Respiratory Consultant
- If not from ENT, seek information concerning condition of the patient’s upper airway.

**Diagnosis of Significant Upper Airway Obstruction**

**ENTRY POINT for recruitment for Drilling trials:**
- Child identified by ENT with known upper airway obstruction likely to need modification of the valve in order to have sufficiently low pressures to safely wear it.

**Step 2. Pre-Assessment by SP**
- Communication Assessment
- Family education
- SP liaises with CNC re: Selection and ordering of valve

**Step 3. Manometry Assessment**
- Refer to Assessment Procedure 8.1
- Conducted with SP and CNC-TDC
- Doctor present only if requested by the managing Consultant

**“PASS”**
- TRANS-TRACHEAL PRESSURE <10cm H2O.
- No significant change in SATS or increased work of breathing.
  - Skip Step 4.

**Step 5. Speaking Valve Trial Assessment**
- Refer to Procedure 8.2
- Conducted with SP + CNC-TDC

**“FAIL”**
- TRANS-TRACHEAL PRESSURE ≥10 cm H2O
  - +/- Significant change in SATS
  - +/- Increased work of breathing.

**Step 4. FAILED CASE**
- Consult ENT
- ENT MUST AUTHORISE NEXT STEP
- ENT may want to conduct further investigation of upper airway patency

**Known Diagnosis of Upper Airway Obstruction**
- Drill 0.8 mm size hole
- Repeat Step 3.
  - If FAIL. Consider 1.6mm hole
  - Drill 1.6mm size hole
  - Repeat Step 3.
  - If FAIL. Drill a 2nd 1.6mm hole
  - Drill 2 x 1.6mm holes
  - Repeat Step 3.
  - If FAIL. Discontinue Assessment

**Tolerance <1 minute - overt distress noted**
- Fail
  - Go to Step 4

**Tolerance <5 minutes SATS NAD**
- Cautionary Pass
  - Clinic Trials only

**Tolerance ≥ 5 minutes in Clinic SATS NAD**
- Conditional Pass
  - Home Trials as directed by CNC and SP
  - Supervised by Parent or Carer

**Full Pass**
- Can wear for full waking hours
References – Clinical Practice Guideline for the use of a Passy-Muir Speaking Valve in a Non-Ventilated Patient