Rapid consensus: Clinical risk stratification tool during Smiths Bivona® Tracheostomy paediatric range supply disruption

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Expert Working Group, representing the National Tracheostomy Safety Project, and the British Association for Paediatric Otolaryngology.

Context

Due to a raw material shortage, production of the entire range of Smiths Bivona® paediatric tracheostomy products has been temporarily paused. The current stock position is critical on several product lines, with low levels on many other sizes (Important Customer Notice). This supply disruption is likely to continue to affect systems for at least several weeks to months. It is important that affected families and their carers are engaged with and involved in any clinical decisions taken as a result of this issue.

This document is to provide support to clinicians who will be responsible for offering clinical advice to their patients, and their families/carers. It was formulated by an expert national clinical risk stratification group (initial meeting on 14/02/2022), comprising of consultant paediatric otolaryngologists representing the British Association of Paediatric Otolaryngology, and those with specialist expertise in this field, and senior clinical nurse specialists, working in regional and national networks including the National Tracheostomy Safety Project to make the following recommendations. There are similar products available (see appendix A), these will require clinical assessment, liaison with clinical specialists and review of the suitability of the device with the patient and their families and or carers before using.

The principle used in the development of this document is to support children and young people and their families, regardless of gender, ethnicity, or socioeconomic status.

Bivona® Tracheostomy

The Bivona® tracheostomy tube range are intended to provide direct airway access for a tracheotomised patient for up to 29 days. It may be reprocessed and sterilised for single patient use up to 5 times (see manufacturer's guidance in appendix B). Local protocols for methods of decontamination should be in place.

To reduce the risk of tubes blocking and necessitating earlier changes, vigilant secretion management is required with regular nebulisation and suctioning. Good documentation is required to ensure that the number of times a tube has been reprocessed/sterilised is recorded to prevent inappropriate disposal.

The Bivona® FlexTend™ products improve access to the airway in children when in a prone position, and it allows ventilation connections to sit away from the chin in neonates, infants or children who require this, reducing risk of pressure sores on the chin and improving comfort.

There are other devices that may assist in allowing ventilatory connections to sit further away i.e. the KAPITEX® mini extension piece, however these product lines are also constrained.

Clinical risk stratification

1. *Patients with established tracheostomy stomas using Bivona® tubes in the community.*

Available devices should initially be used for existing patients rather than directed towards acute use in new patients unless the clinical consensus is that using an alternative device will be harmful.

Patients currently established on a Bivona® device in the community are at higher risk of complications if a new device is used (e.g. disconnection for those children on long-term ventilation, and increased frequency of tube changes). Moreover, a change in device will necessitate training for all carers in the use and maintenance of the new device (and therefore more frequent reprocessing with a resulting decreased overall use period). Therefore, every effort should be made to ensure continuity in their care, and that a change of device is avoided. This should include vigilant secretion management and maximising the number of uses within manufacturer guidance to avoid degradation or damage to the device. If a patient's existing device has signs of wear and is not suitable for reprocessing, then a new device should be sought.

To mitigate the risks, it is proposed that mutual aid is utilised across clinical networks (e.g. Surgery in Children, Paediatric Critical Care, and Long Term Ventilation Operational Delivery Networks) to minimise the numbers of children in the community needing to change their usual device. If through a mutual aid request a device is not sourced, then a clinical request can be submitted through NHS Supply Chain, this will be reviewed by clinical experts and every effort will be made to get a device. There may be situations where despite these efforts this is not possible.

If the preferred Bivona® device(s) is not available through the above routes, then it may be necessary to review clinical alternatives. Clinical judgement should be applied when assessing whether it is appropriate and safe to use an alternative product. These products include:

- Shiley™ Devices (NCF, NEF, PEF, PELF, PCF, PLCF) (+/ - Kapitex® mini extension piece).
- TRACOE® Silcosoft, and TRACOE® Mini Kapitex® (+/ - Kapitex® mini extension piece).

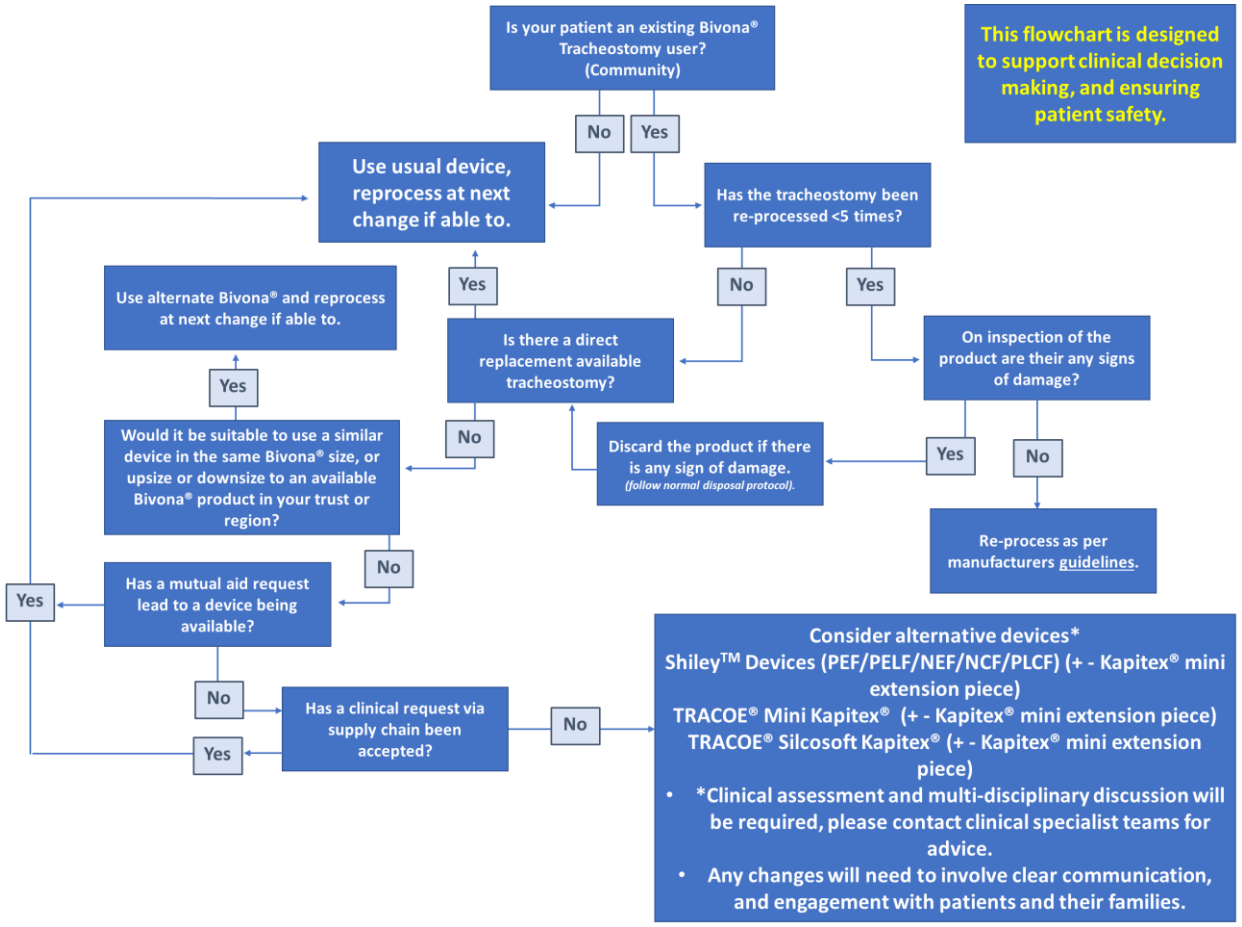
Any change of device will require clinical assessment, as these products have varying lengths, curvature, flanges and external diameters. If this difference has a potential clinical impact or patient specific risks, consider contacting the specialist clinical team at your tertiary trust for advice and or a face-to-face assessment of the infant, child, or young person.

Any changes will need to involve clear communication with patients and their families and or carers and their usual clinical teams. Extra support may be needed for patients, families and their carers during this transition including providing appropriate training on the new device.

Additional considerations

- If you are unable to find a different tube with the exact same measurements, or the preference is to keep same device then clinical discussion surrounding appropriate change of range, style, or size should be discussed between clinical teams.
- If a tube type is changed, associated documentation and emergency guidelines will need to be updated as per local policy.
- The decision tree below should be applied alongside independent and expert clinical judgement.

Figure 1. Flowchart for patients with established tracheostomy stomas using Bivona® tubes in the community.



2. Patients who require a new tracheostomy

Available devices should initially be used for existing patients rather than directed towards acute use in new patients. The suggested other products that are available for new patients that you may wish to consider are Shiley™NCF, NEF, PEF, PELF, PCF, PLCF, with or without a TRACOE® mini extension piece | KAPITEX® , or TRACOE® Silcosoft | KAPITEX® or TRACOE® Mini | Kapitex® (appendix A).

Neonates, infants of children requiring a tracheostomy will each have unique anatomical considerations and the clinical indication may mean that a Bivona®) device is the first preference. However, it is imperative that all due consideration is given to an alternate available device first. Clinical assessment of the need to use a Bivona® device should include assessing the criticality of its' use, and the benefits over alternative devices in the patient.

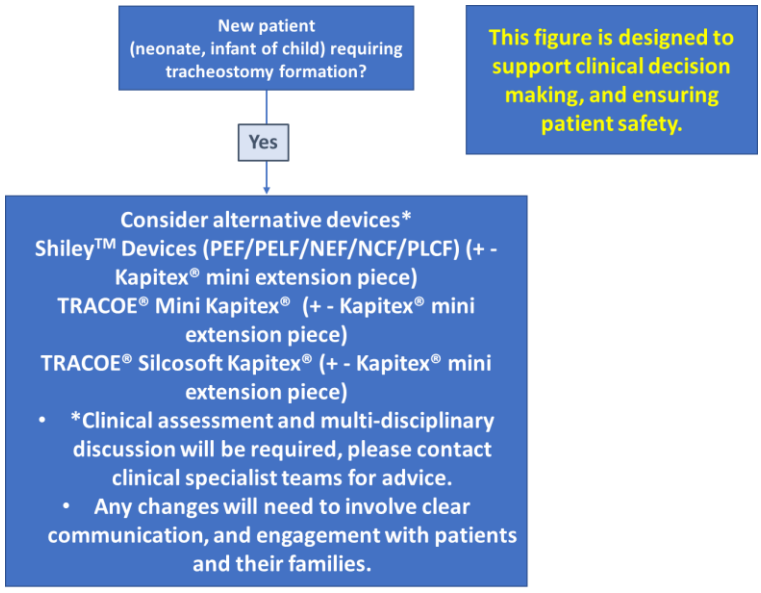
Discharge preparation

You may wish to review your parent/carer training programme

Given the low stock levels and increased need for alternative devices across the system, parent training may need to be reviewed. Please consider using simulation for early parent/carer training. If discharge is not imminent then consider delaying tube changes (unless due or clinically required).

The decision tree below should be applied alongside independent and expert clinical judgement.

Figure 2. Patients who require a new tracheostomy



Appendices:

Appendix A

Shiley™ Neonatal and Paediatric Tracheostomy Tubes: A product guide brochure can be found here. Note, there has recently been a significant change to the Shiley Tracheostomy Product lines

KAPITEX® Tracoe® Mini, and Tracoe® Silcosoft: Product links can be found at: TRACOE® Silcosoft | KAPITEX® , TRACOE® Mini | Kapitex® and TRACOE® mini extension piece | KAPITEX®

Appendix B

Bivona® Reprocessing guidance

Product information for the Portex® Bivona® tracheostomy tubes can be found at here.

- Organisations have a responsibility to systematically identify, assess and monitor all decontamination processes relating to reusable medical devices, ensuring that they are compliant with required standards and processes. Please ensure the appropriate Health Technical Memoranda have been referred to and followed in terms of use of washer disinfector and gravity displacement sterilizers.
- Locally agreed protocols for methods of decontamination for in hospital re-use should be in place in organisations.
- Managers of departments and units will need to add any significant infection prevention and control risks to organisational risk registers. Any significant on-going unresolved risks will need to be identified and discussed at Infection Control Committee or equivalent.

Appendix C

Background Information

A child may require a tracheostomy for the following reasons:

- Upper air way obstruction (e.g. a neonate, infant, or child with subglottic stenosis, vocal cord palsy, micrognathia, or haemangioma of the upper airway)
- For ventilation (e.g. a neonate, infant, or child requiring long-term ventilation)
- Aspiration of bronchial secretions (e.g. a child has an ineffective swallow/cough and carries a risk of aspiration and recurrent chest infections.
- Reduction of airway resistance (e.g. to improve ventilation in a neonate, infant, or child and reduce the upper airway resistance experience in inspiration and expiration through upper airways).
- Surgery to upper airway (e.g. a neonate, infant, or child requiring major head and neck surgery)

There a numerous types of tracheostomy tubes which may be chosen to suit a neonate, infant, or child's individual clinical needs and anatomy.

These include (most commonly):

- Uncuffed tubes- made from plastic or silicone consisting of a single tube or an inner and outer tube
- Uncuffed FlexTend tubes made of silicone for children that require extra external length
- Low pressure/low volume air filled cuffed tube made of plastic or silicone used to aid ventilation
- A high pressure/low volume tight to shaft (TTS) FlexTend cuffed tube made of silicone used for ventilation of children who require extra external length.

A patient is determined to have an established tracheostomy stoma after their first tube change.

As part of a patients' care plan, parents and carers will be trained in managing the tracheostomy. This is key to the child's care in the community and is a milestone for discharging a patient. Parents and carers with babies and children with established tracheostomy stomas in the community are trained to use the fitted device. Further information on the care for children with tracheostomies can be found at the National Tracheostomy Safety Project here.

Neonates, infants, or children with tracheostomies will have emergency equipment available to them including a spare tracheostomy tube of the same size and one size smaller for emergencies.

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