Continuous Positive Airway Pressure (CPAP) and Bi-level PAP: Clinical risk stratification tool 19 July 2021

This document is to provide support to clinicians who will be responsible for offering clinical advice to their patients. It was formulated by an expert national clinical risk stratification group (first meeting on 30/06/2021), chaired by Professor Michael Polkey and comprising consultant respiratory physicians with an interest in this field, consultant paediatric respiratory and intensive care clinicians, senior clinical nurse specialists, healthcare scientists, senior allied health professionals and respiratory physiologists. This document may be subject to change as more information becomes available.

Context

Philips Respironics has identified potential health risks related to the polyester-based polyurethane (PE-PUR) sound abatement foam component in some models of their Continuous Positive Airway Pressure (CPAP), and non-invasive ventilatory (NIV) devices.

Following testing, it has been identified that there are possible risks to users related to this type of foam, specifically

a) that it may degrade into particles which may enter the device's air pathway and be ingested / inhaled by the user, and

b) that the foam may release volatile organic compounds (VOC) in gaseous form.

The magnitude of these risks may become clearer as Philips undertake more analysis but is currently considered based on expert advice to be substantially lower than the health risk associated with treatment interruption. The foam degradation may be exacerbated by use of unapproved cleaning methods, especially ozone. Thus we strongly advise not to use ozone to clean these products. It should be noted that environments with high heat and/or high humidity are thought to accelerate degradation.

Both the Field Safety Notices (FSNs) (for Ventilators and CPAP) and the MHRA information in relation to this issue advises that patients should continue to use these products unless otherwise advised by their clinician and seek clinical advice on where an alternative device would be appropriate.

Non-Invasive Ventilation

1. Acute use

It is suggested that clinicians consider replacing machines in acute use last, the rationale for this is that:

a) The cumulative exposure to chemical emissions for a single patient will be substantially less than longer term users of these devices.

b) In an acute setting, these devices are usually used with filters that are changed every 24 hours.

Whilst there could be consideration given to replacing some of the devices with ICU ventilators, this would impose a training need on acute care staff since those devices often use dual limbed circuits and non-vented masks, with attendant risk of accidental misuse.

2. Replacing existing machines versus new starters

Available devices should initially be used for new starters rather than as replacements for current patients except for patients with respiratory disease consequent to occupational exposure to isocyanates.

Patients without any treatment (not currently on a device) in the community in hypercapnic respiratory failure are at very high risk of clinical deterioration. It would therefore follow that patients that need a ventilator should be commenced on treatment as a priority. Those on existing treatment can remain on their device until an alternative can be sourced, but this is a lower priority than sourcing a device for those with no device at all. If a patient's device breaks down then this will need to be replaced as normal. Stratification of new starters is an approach to consider, but is likely to be far too complex, given the multiple patient and disease-specific factors that would need to be accounted for.

Suggested order of replacing devices for current patients

The decision tree (Figure 1) below should be applied alongside the decision-making clinician's expert clinical judgement. All groups except for the first group, of those with respiratory disease consequent to previous occupational exposure to isocyanates, should be advised to continue use of their existing device until the units are replaced.

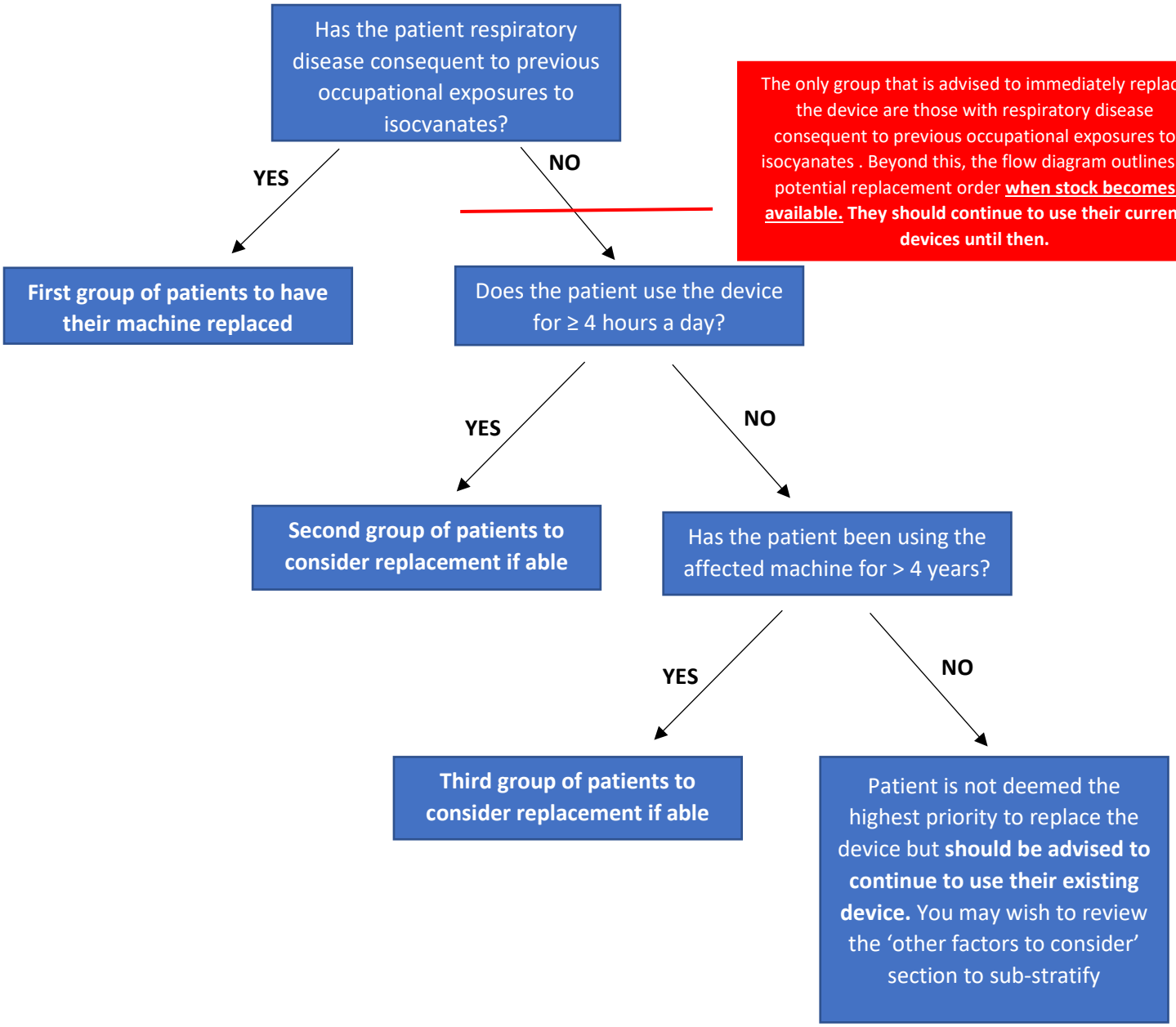

Figure 1: NIV Decision Tree

3. Deferring treatment versus starting on a Philips machine containing defective foam

The group agreed there was no difference between starting on a machine containing defective foam versus continuing patients on a machine containing defective foam. Therefore, if a circumstance arose where a 'new starter' had to choose between a machine covered by the FSN or no machine, the former may be an appropriate choice in some circumstances, always with the proviso that patients are informed and engaged in discussions about the risks and benefits of their choices.

Other factors to consider

The decision tree set out above can be used as an initial step, but it is important to apply expert clinical judgement. Factors that may also be considered include the patient's underlying diagnosis and risk of complications; specifically where a patient had good adherence, comfort and symptom control but a poor prognosis (e.g. rapidly progressive neuromuscular disease) then it might be inappropriate to exchange their machine. Other factors considered potentially relevant are:

a) If the patient is using tracheostomy intermittent positive pressure ventilation (T-IPPV), since the absence of filtering in the nose may increase their risk of particle inhalation.

b) Exposure to high humidity or heat environments, though these are unusual in the UK, because they increased risk of foam degradation.

c) Prior use of unapproved cleaning methods, especially if ozone-based.

Continuous Positive Airway Pressure

1. Replacing existing machines versus new starters

Available devices should initially be used for new starters rather than as replacements for current patients except for patients with respiratory disease consequent to occupational exposure to isocyanates.

Patients with symptomatic untreated Obstructive Sleep Apnoea (OSA) have reduced quality of life and may suffer economic harm if prohibition on driving precludes either working or travelling to work, and may interfere with other important activities, including caregiving to other family members/children. If a patient's device breaks down then this will need to be replaced as normal.

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The group agreed there was no difference between starting on a machine containing defective foam versus continuing patients on a machine containing defective foam. Therefore, if a circumstance arose where a 'new starter' had to choose between a machine covered by the FSN or no machine, the former may be an appropriate choice in some circumstances, always with the proviso that patients are informed and engaged in discussions about the risks and benefits of their choices. It was recognised that when patients are fully informed, uptake for CPAP may be lower.

3. Stratification of new starters if insufficient CPAP devices are available

Clinicians should review patients on an individual basis but may wish to consider the following when coming to a decision:

a) Patients who have a vigilance-critical occupation. The most obvious examples would be HGV/PSV license holders but could also include (though not be limited to) pilots, operators of heavy machinery and air traffic controllers. Within this group sub-stratification would be those with marked sleepiness as evidenced by an Epworth Sleepiness Score of 18 or more (1), those with ESS 10-17 and then those with ESS<10.

b) Patients with an AHI>5 who need to drive to travel to and from work or to fulfil caregiver responsibilities. Within this group sub-stratification would be those with marked sleepiness as evidenced by an Epworth Sleepiness Score of 18 or more (1) then those with ESS 10-17. For patients (typically ESS <10) who have not been advised to cease driving but in whom treatment is being considered for other reasons (e.g. relief of snoring or management of co-morbidities), consideration should be given to deferring treatment until a device is available.

c) Patients with an AHI>5 who either don't drive or do not need to drive to travel to and from work or to fulfil caregiver responsibilities. Within this group sub-stratification would be those with marked sleepiness as evidenced by an Epworth Sleepiness Score of 18 or more (1) then those with ESS 10-17 would be key groups. For patients (typically ESS <10) in whom treatment is being considered for other reasons (e.g. relief of snoring or management of co-morbidities), consideration should be given to deferring treatment until a device is available.

d) If there is a shortage of CPAP machines, CPAP should not be considered as a treatment modality for simple snoring or Catathrenia.

The group noted that other factors may be of relevance for individual patients; these included but were not limited to the following:

a) Co-morbidities where CPAP is known to be effective (e.g. systemic hypertension) and cannot be controlled by medications in the absence of CPAP.

b) Individual perception of anxiety related to the FSN; while the overall assessment is that the risk of continuing with an affected device is low, if the patient does not share this assessment, anxiety may cause mental health issues.

c) Individual perception of anxiety related to co-morbidities; even if the clinician feels the risks are low and manageable (e.g. with medications), if the patient does not share this assessment, anxiety may cause mental health issues.

d) Where simple snoring cannot be managed by other strategies (e.g. Mandibular Advancement Splints, sleeping in a separate room) and significant domestic events are thought likely to ensue.

4. Substitution of variable level devices for fixed level

Especially in the post COVID era many units have switched from fixed level CPAP to variable level device since, by removing any necessity for a titration study it reduces footfall in the hospital. Where a patient has a variable level device it is of course preferred to replace it with another variable level device. However if a variable level device is not available it is reasonable to replace with a fixed level device. The fixed level device should be programmed to deliver pressure at the 90th or 95th centile airway pressure downloaded from the variable level machine covered by the FSN that is being substituted.

Suggested order of replacing devices for current patients

The decision tree (Figure 2) below should be applied alongside independent and expert clinical judgement.

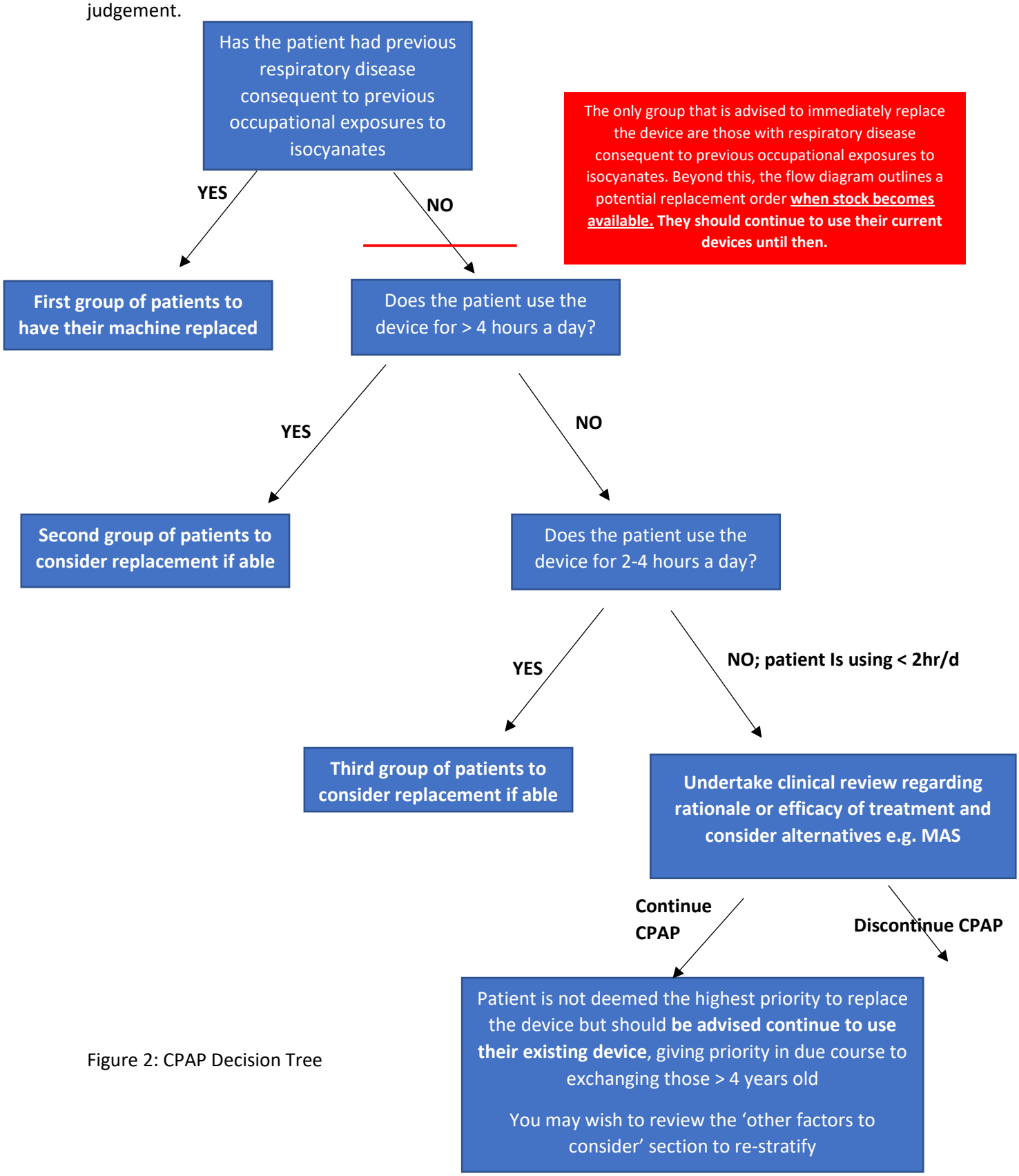

Figure 2: CPAP Decision Tree

Other factors to consider

The decision tree set out above (Figure 2) can be used as an initial step, but it is important to apply expert clinical judgement. Factors that may also be considered include whether the patient is in an occupation where vigilance is critical (e.g. professional drivers, air traffic controllers) and the impact CPAP withdrawal would have on their quality of life or activities of daily living.

Considerations in paediatric NIV and CPAP

The clinical risk stratification group determined that there were no specific issues for children, such that the same flow diagrams and principles for NIV and CPAP could be applied in this patient group.

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Queries: england.covid-clinical@nhs.net

References

1. BTS position statement on driving and OSA: https://www.brit-thoracic.org.uk/quality-improvement/clinical-resources/sleep/

Links

Phillips Respironics Field Safety Notice Ventilators

Phillips Respironics Field Safety Notice CPAP

MHRA National Patient Safety Alert

FAQs – to follow