Multi-Society Discussion Group

American Academy of Sleep Medicine

American Academy of Neurology

American Thoracic Society

American College of Chest Physicians

Canadian Thoracic Society

Michael Howell MD
American Academy
of Neurology

Jeremy Orr, MD
American Thoracic
Society

Lisa Wolfe MD
American College
of Chest Physicians

Jennifer L. Martin , PhD
American Academy of
Sleep Medicine

Michelle Cao DO
American Academy
of Sleep Medicine

Rakesh Bhattacharjee MD
American Academy of
Sleep Medicine

Shannon Sullivan, MD
Moderator
AASM Public Safety Committee Chair

Sherri Katz MD
Canadian Thoracic
Society

Joshua O. Benditt, MD
Medical Director of Respiratory Care
Services, University of Washington MC

Background

- On June 14, 2021, Philips initiated a voluntary recall notification in the United States for specific models of continuous positive airway pressure (CPAP), bilevel positive airway pressure (BiPAP), and mechanical ventilator devices, stating that the recall is to “ensure patient safety in consultation with regulatory agencies.”

- The recall is to address identified potential health risks related to the polyester-based polyurethane (PE-PUR) sound-abatement foam used in these devices.

- Foam degradation may happen over time; process seems to be accelerated by high heat/high humidity environments and use of ozone-based cleaning systems.

CPAP and BiLevel PAP Devices

All Affected Devices Manufactured Before 26 April 2021, All Device Serial Numbers

Continuous Ventilator, Minimum Ventilatory Support, Facility Use

E30
(Emergency Use Authorization)

Continuous Ventilator, Non-life Supporting

DreamStation
ASV

DreamStation
ST, AVAPS

SystemOne
ASV4

C Series
ASV, S/T, AVAPS

OmniLab Advanced Plus
In-Lab Titration Device

Non-continuous Ventilator

SystemOne
(Q series)

DreamStation
CPAP, Auto CPAP, BiPAP

DreamStation GO
CPAP, APAP

Dorma 400, 500
CPAP

REMStar SE Auto
CPAP

Mechanical Ventilators

All Affected Devices Manufactured Before 26 April 2021, All Device Serial Numbers

Continuous Ventilator

Trilogy 100
Ventilator

Trilogy 200
Ventilator

Garbin Plus, Aeris, LifeVent
Ventilator

Continuous Ventilator, Minimum Ventilatory Support, Facility Use

A-Series BiPAP Hybrid A30
(not marketed in US)

A-Series BiPAP V30 Auto
Ventilator

What products are not affected and why?

Products that are not affected may have different sound abatement foam materials, as new materials and technologies are available over time. Also, sound abatement foam in unaffected devices may be placed in a different location due to device design.

Products not affected by this recall notification (U.S. only) / field safety notice (International Markets) include:

- Trilogy Evo
- Trilogy Evo OBM
- Trilogy EV300
- Trilogy 202
- BiPAP A40 EFL
- BiPAP A40 Pro
- M-Series
- DreamStation 2
- Omnilab (original based on Harmony 2)
- Dorma 100, Dorma 200, & REMStar SE
- All oxygen concentrators, respiratory drug delivery products, airway clearance products.

The recall notification (U.S. only) / field safety notice (International Markets) advises patients and customers to take the following actions:

For patients using life-sustaining mechanical ventilator devices:

- **Do not stop or alter your prescribed therapy until you have talked to your physician.** Philips recognizes that alternate ventilator options for therapy may not exist or may be severely limited for patients who require a ventilator for life-sustaining therapy, or in cases where therapy disruption is unacceptable. In these situations, and at the discretion of the treating clinical team, the benefit of continued usage of these ventilator devices may outweigh the risks.
- If your physician determines that you must continue using this device, use an inline bacterial filter. Consult your Instructions for Use for guidance on installation.

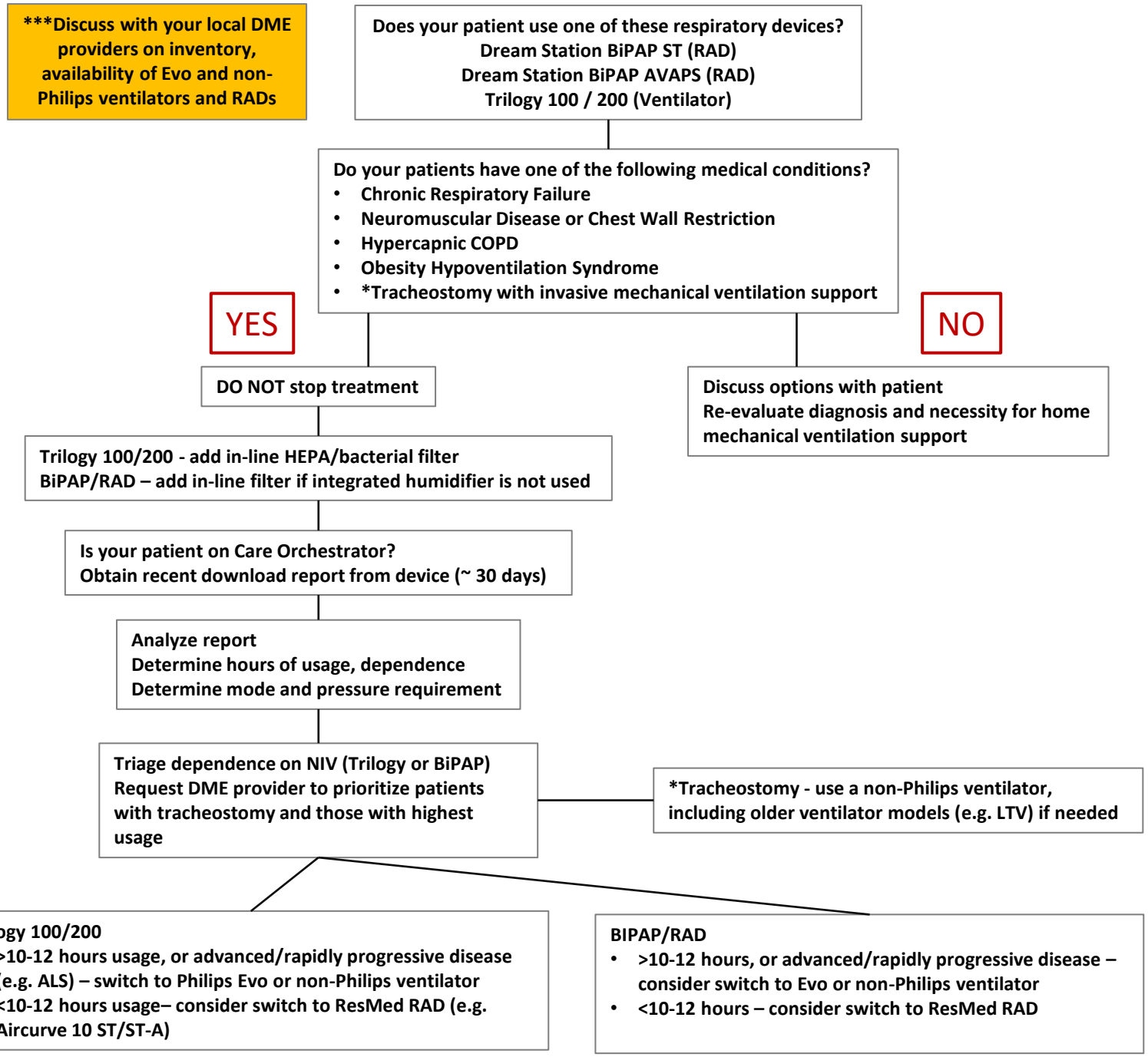
For patients using BiLevel PAP and CPAP devices:

- Discontinue use of your device and work with your physician or Durable Medical Equipment (DME) provider to determine the most appropriate options for continued treatment.

https://www.usa.philips.com/healthcare/e/sleep/communications/src-update

Thinking about allocation of resources, how can we approach vent-dependent patients such as those with NMD?

Triaging respiratory assist devices and home ventilators in patients with chronic respiratory failure



How is this similar/different than concerns facing practices early in the pandemic?

What about transitioning vent-dependent patients from hospital to home?

…and from home to hospital?

Hospital Questions
Acute Care to Homecare for Respiratory Failure

OHV	NMD
• Acute Care – – OK to use device bilevel with filter in house • Send them home – – Send home on NIV – ENCOURAGE – system wide plans to assure devices for new starts – ENCOURAGE - PSG titration at 3 months to see if you can back down therapy to CPAP	• Acute Care – – OK to use device bilevel with filter in house • Send them home – – Send home on NIV – ENCOURAGE – system wide plans to assure devices for new start • Include local ALS and MDA programs – AVOID the use of two devices – only in response to the crisis

Hospital Questions

Sleep apnea – medical admission

- Allow pt's to use their own devices
- Fight the use of oxygen in lieu of CPAP

Trach / Vent – Chronic on Home equipment

- Allow pts to use their own devices
- Get old devices out of moth balls – LTV's, transport vents and MRI vents

NIV Chronic on Home equipment

- Allow pt's to use their own devices
- OK to use device on recall with filter – The risk benefit is high in stopping therapy
  A) may need a triggering adjustment

What about other conditions requiring ventilatory support, such as COPD and OHS?

Respiratory therapy in hospitals – how are you navigating hospital needs due to the recall of the A/ V-Series facility–based devices?

Hospital Questions

Why V 30

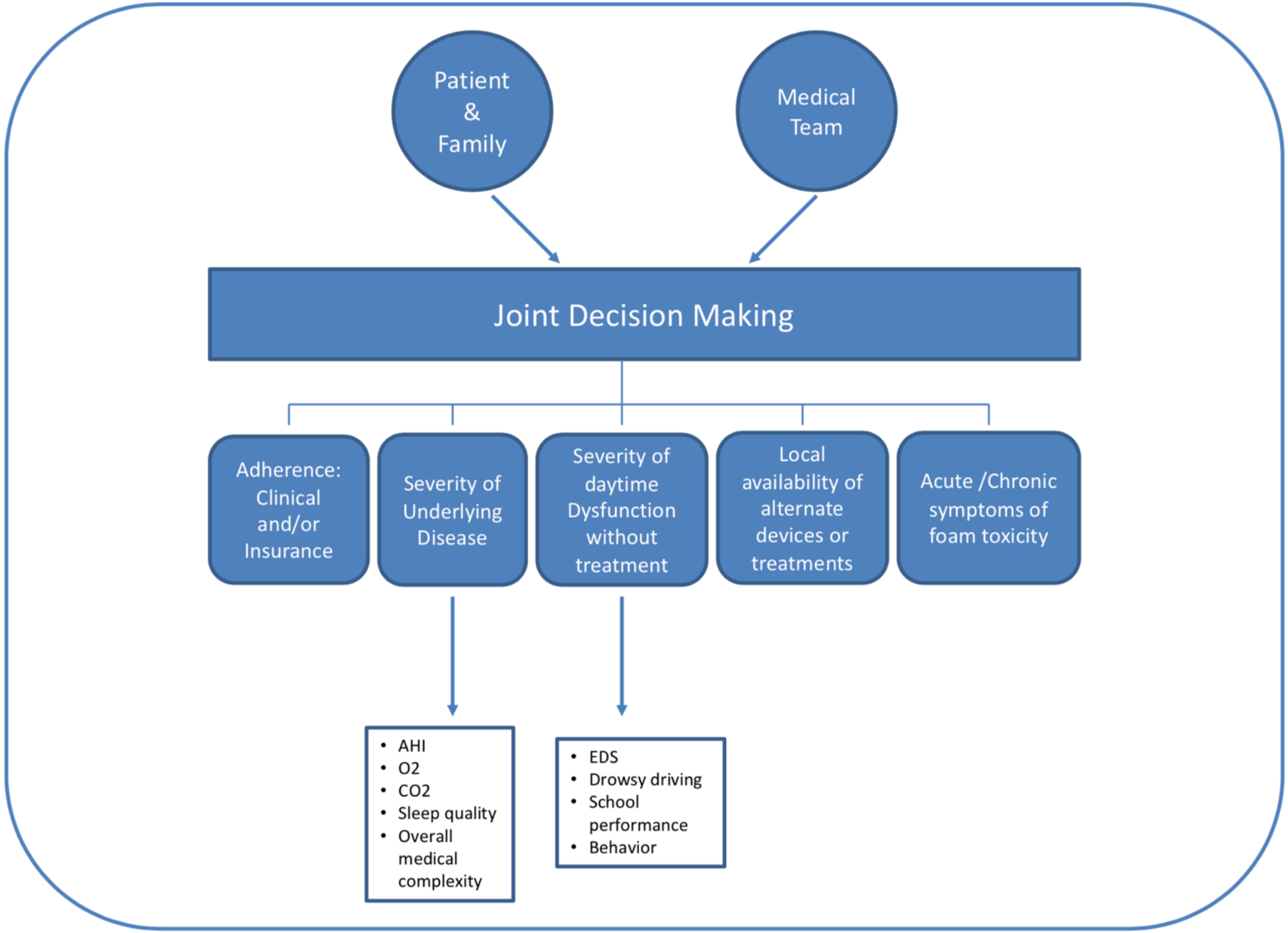
- This device may be the most challenging to replace. There are very limited choices if you need a device that has both ALL available modes and the ability to interface with monitoring systems.
- The devices can be extended with filters – but this is an imperfect solution.
- Alternatives:

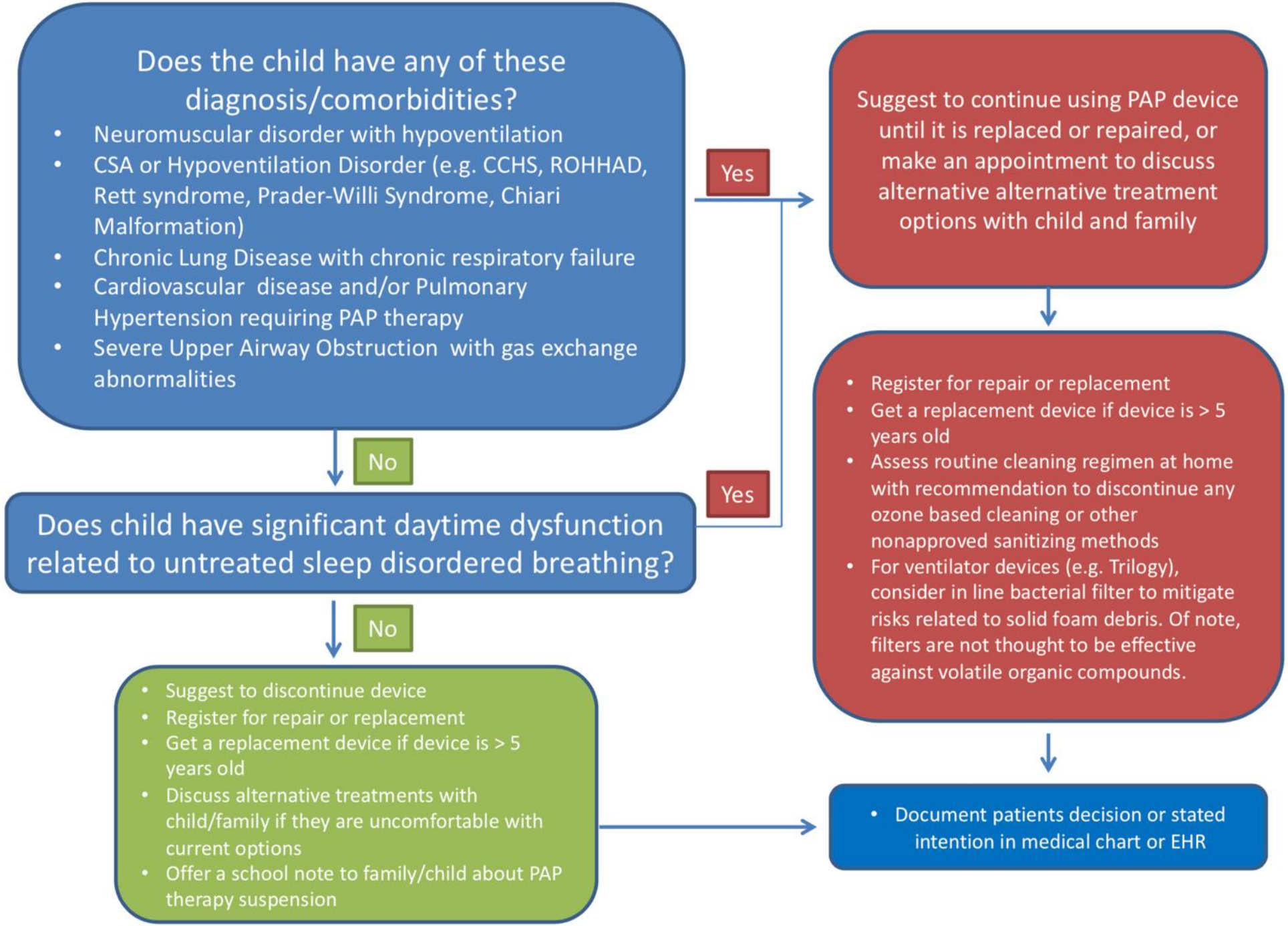
  A) Respironics/ The V60 and Trilogy 202 are not on the recall- limited modes
  B) Breas / The Vivo's have nurse call systems – with cable or blue tooth- limited modes
  C) ResMed / The Lumis TX has all modes but no call system.
  D) Consider using pulse ox as an alternative to monitoring the PAP device

Peri- Op Sleep Apnea

- Use of CPAP for naïve pt's is over rated
- Alternatives:
  A) Allow pt's to use their own devices
  B) Consider using high flow on RA
  C) Consider monitoring pulse ox only
  - Position changes may help these pt's – elevated HOB as well as side sleeping

What are some of the unique issues facing pediatrics, and how should approaches be adjusted to take these into account?


Patient & Family
Medical Team
Joint Decision Making
Adherence: Clinical and/or Insurance
Severity of Underlying Disease
Severity of daytime Dysfunction without treatment
Local availability of alternate devices or treatments
Acute /Chronic symptoms of foam toxicity
AHI
O2
CO2
Sleep quality
Overall medical complexity
EDS
Drowsy driving
School performance
Behavior


Does the child have any of these diagnosis/comorbidities?
• Neuromuscular disorder with hypoventilation
• CSA or Hypoventilation Disorder (e.g. CCHS, ROHHAD, Rett syndrome, Prader-Willi Syndrome, Chiari Malformation)
• Chronic Lung Disease with chronic respiratory failure
• Cardiovascular disease and/or Pulmonary Hypertension requiring PAP therapy
• Severe Upper Airway Obstruction with gas exchange abnormalities
Yes
Suggest to continue using PAP device until it is replaced or repaired, or make an appointment to discuss alternative alternative treatment options with child and family
No
Does child have significant daytime dysfunction related to untreated sleep disordered breathing?
Yes
• Register for repair or replacement
• Get a replacement device if device is > 5 years old
• Assess routine cleaning regimen at home with recommendation to discontinue any ozone based cleaning or other nonapproved sanitizing methods
• For ventilator devices (e.g. Trilogy), consider in line bacterial filter to mitigate risks related to solid foam debris. Of note, filters are not thought to be effective against volatile organic compounds.
No
• Suggest to discontinue device
• Register for repair or replacement
• Get a replacement device if device is > 5 years old
• Discuss alternative treatments with child/family if they are uncomfortable with current options
• Offer a school note to family/child about PAP therapy suspension
• Document patients decision or stated intention in medical chart or EHR

Research trials – how have you approached ethically navigating the recall for those enrolled in clinical trials?

- Are these AEs/ UPs if no participants have reported symptoms?
- Notifying participants, IRB, and DSMB
- What are the risks of stopping therapy in at-risk participants?
- Pausing randomization of new participants
- Trials that are PAP adherence interventions: is following the instructions to stop using actually demonstrating good adherence?

Allocation of limited supplies – how can we approach prioritizing the most urgent need the limited supply of devices for patients needing them?

Questions?

- Email: recall@aasm.org

- AASM Engage: engage.aasm.org
  - Members Forum
    - AASM members can join the discussion!