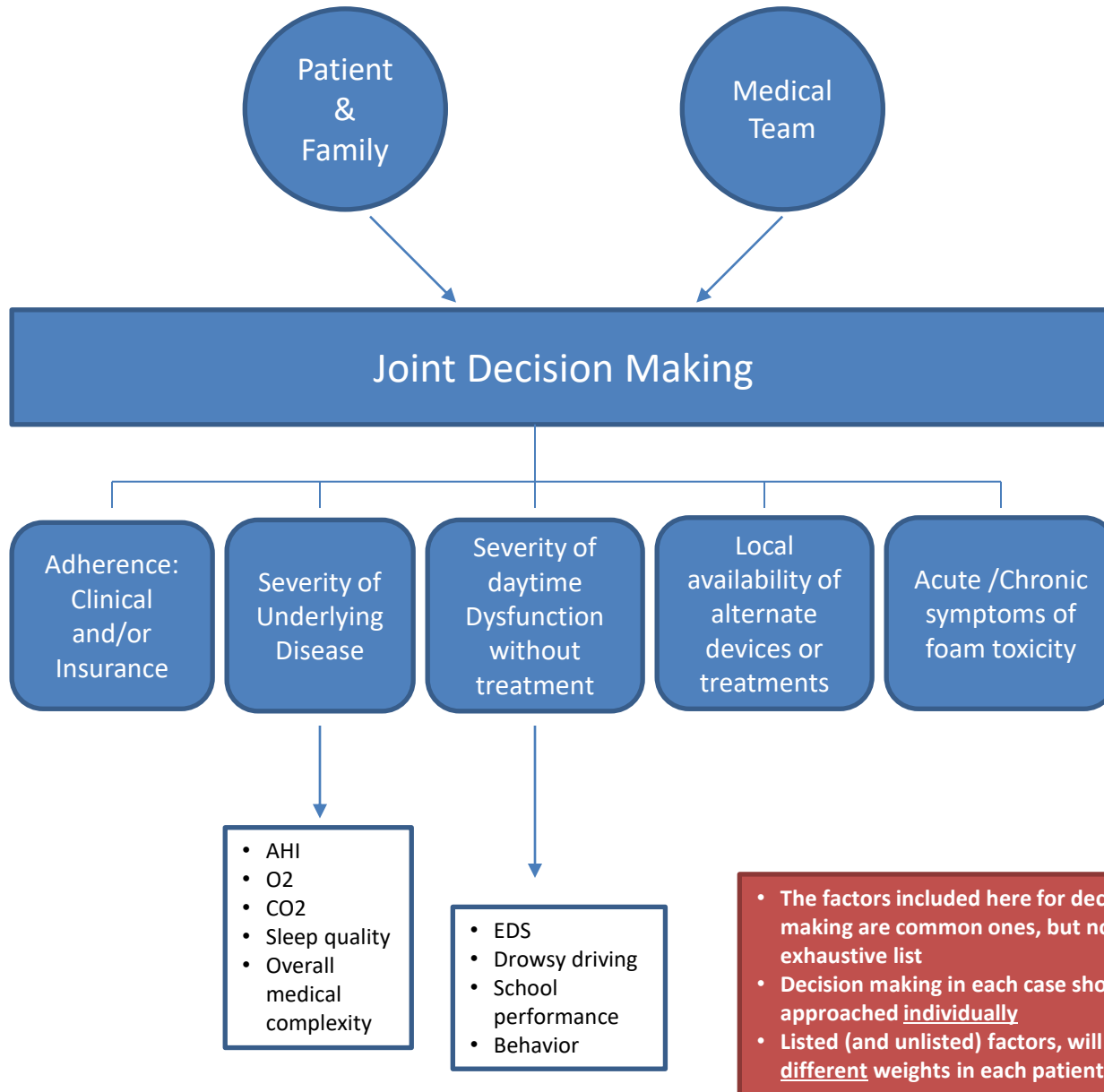


Philips PAP recall: Sample pediatric patient assessment for sleep medicine professionals (Updated 6/29/21)



Does the child using recalled device 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

No

Does the child have marked improvement in daytime and/or nighttime dysfunction related to using recalled device?

No

- Suggest to discontinue device
- Register for repair or replacement
- Get a replacement device if possible
- Discuss alternative treatments with child/family if they are uncomfortable with current options
- Offer a school note to family/child about PAP therapy suspension

Yes

Suggest to continue using PAP device until it is replaced or repaired, or make an appointment to discuss alternative treatment options with child and family

Yes

- Register for repair or replacement
- Get a replacement device if possible
- Assess routine cleaning regimen at home with recommendation to discontinue any ozone based cleaning or other nonapproved sanitizing methods
- For some ventilators (i.e. 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.

- Document patients decision or stated intention in medical chart or EHR

Recommendations: Shared Decision Making

This statement only serves as suggestions for guidance and clinicians should:

- Always consider the specific sleep breathing disorder and incorporate the opinions of patient and families when making recommendations.
 - E.g. - continuing PAP devices to prevent tracheostomy, and patients & families may opt to continue PAP to avoid tracheostomy
 - E.g. – a child with Prader-Willi syndrome using a PAP device to continue growth hormone therapy
- Acknowledge with patients and families that discontinuing PAP therapy, regardless of the severity of the underlying disorder, affects patients differently, as sleep disorders have variable presentations/phenotypes.
 - Possible risks of discontinuing PAP therapy in children include daytime dysfunction, severe daytime sleepiness, decreased mood or mood lability, inattention, hyperactivity, learning dysfunction, behavioral disturbance.
 - Long term risk of temporary discontinuation of PAP therapy in children is unclear.
- Acknowledge with patients and families that discontinuing PAP therapy may have an impact long term with maintaining adherence to PAP, and may result in children discontinuing PAP altogether.
- Provide guidance to alternative therapies at all times, as well as closely monitor patients for risks related to untreated sleep disordered breathing should children and/or families opt to discontinue PAP until a replacement device is available.