

Medicare Evidence Development Coverage  
Advisory Committee (MEDCAC) meeting:  
**“Home Use of Noninvasive Positive  
Pressure Ventilation in Patients with  
Chronic Respiratory Failure (CRF)  
Consequent to Chronic Obstructive  
Pulmonary Disease (COPD)”**

Comments from:

**CHEST** - The American College of Chest Physicians:  
Representing 15,000 US physicians, surgeons and  
healthcare providers focused on respiratory  
health.

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**COI:**

No Financial Conflicts to Disclose

## Patient Selection Criteria

### OSA COPD Overlap Syndrome

These patients have:

- OSA as determined by PSG
- COPD as determined clinically
- Daytime PCO<sub>2</sub> and Oxygen saturation are normal
- Nighttime O<sub>2</sub> saturation is very low even after appropriate therapy for OSA.

### Severe COPD

These patients have:

- COPD as determined clinically
- Stable daytime hypercapnia (↑PCO<sub>2</sub>).
- Hospitalizations

### Obesity Hypoventilation – COPD Overlap

These patients have:

- Obesity with a BMI >35
- COPD as determined clinically
- Daytime hypercapnia (↑PCO<sub>2</sub>).
- Hospitalizations

## NIPPV Equipment Parameters

### OSA COPD Overlap Syndrome

- These patients are treated when stable outpatients
- **CPAP** therapy is appropriate
- In lab PSG is often needed to add / titrate oxygen bleed into CPAP therapy

### Severe COPD

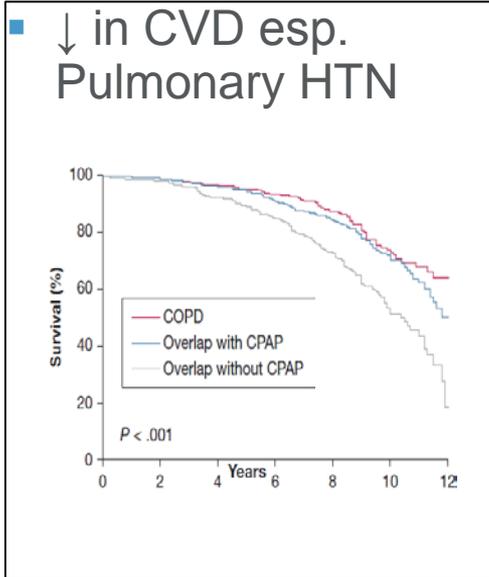
- These patients should be treated as stable outpatients
- High Intensity PS support therapy:
  - **BPAP with back up rate**
- Extras are often needed requiring **HMV**
  - High O<sub>2</sub> with blender
  - Back up battery
  - Daytime portability

### Obesity Hypoventilation – COPD Overlap

- These patients should be treated at the time of hospital discharge
- **HMV** is appropriate
  - Need for VAPS mode with Auto – EPAP
  - Need for higher pressures

# WHY treat? Is the evidence sufficient?

## OSA COPD Overlap Syndrome



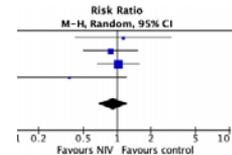
Walter T. McNicholas *Chest*  
Yr 2017 Vol 152, Is 6, P 1318-1326

## Severe COPD

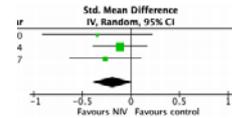
### The European Respiratory Society:

■ “This ERS Task Force suggests the application of long-term home non-invasive ventilation to improve health outcomes by targeting a reduction in carbon dioxide in COPD patients with persistent hypercapnic respiratory failure.”

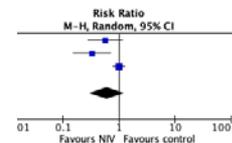
Ergan B et al ERS Guideline on Long-term Home NIV for Management of COPD. *Eur Respir J* 2019; in press



### Mortality

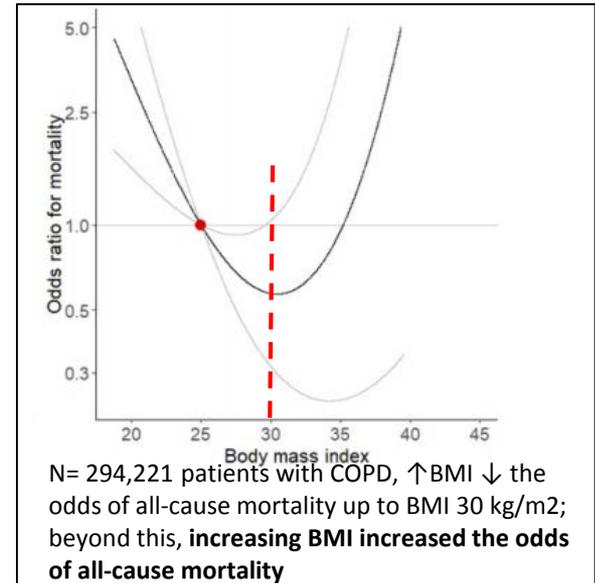


### Exacerbations



### Hospitalizations

## Obesity Hypoventilation – COPD Overlap



Mine, S etal *Am J Respir Crit Care Med*  
2020;201:A4580

# Equipment VS Other Support Services

## OSA COPD Overlap Syndrome

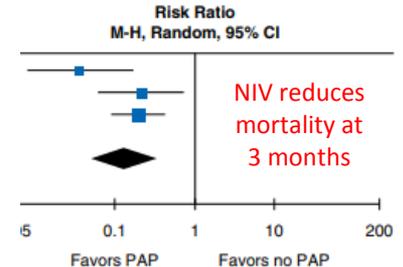
- These patients do not seem to need additional support services
- The patients are much less impaired

## Severe COPD

- There appears to be a need for a full respiratory care team
- Struik Vs Galli
  - Struik
    - ✓European - both sides had homecare
    - ✓ICU enrollment for domiciliary NIV
    - ✓FAILED
  - Galli
    - ✓US – Only NIV pt had home care
    - ✓ICU enrollment for domiciliary NIV
    - ✓SUCCESS

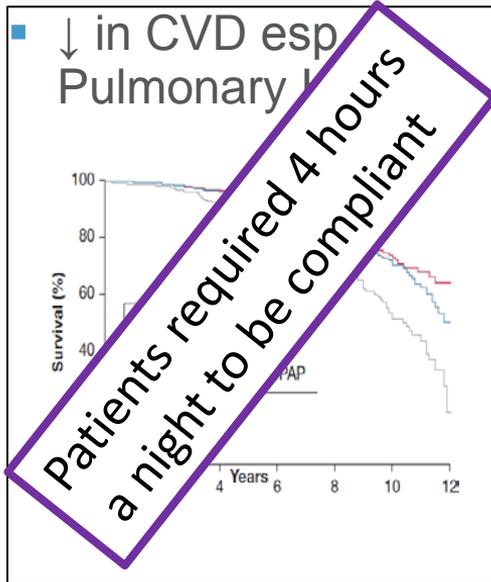
## Obesity Hypoventilation – COPD Overlap

- The data on this group is limited but the obesity group getting NIV + homecare



# When is the PAP use sufficient?

## OSA COPD Overlap Syndrome



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## Severe COPD

**Kholein** - Usage time was less than 3 hr in 18.8% of patients (23.8% of periods). Mean NPPV usage was 5.9 hr per day.

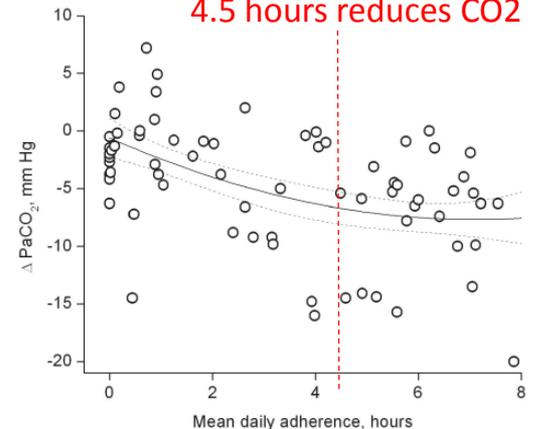
**Murphy**— the longer in the study the higher the use

Visit	Number of patients attended	Number of patients with adherence data	Median usage <sup>a</sup> (25 <sup>th</sup> to 75 <sup>th</sup> percentile) hours/night
6 weeks	45	38	4.73 (2.50 to 5.6)
3 months	40	34	6.02 (4.0 to 7.4)
6 months	40	30	5.37 (3.48 to 7.1)
12 months	36	26	7.61 (3.55 to 8.37)

## Obesity Hypoventilation – COPD Overlap

### 2 examples

Mokhlesi, *B J Clin Sleep Med* 2006;2(1):57-62.  
4.5 hours reduces CO<sub>2</sub>



Priou, *P. CHEST* 2010; 138(1):84–90  
Increased survival with >5 hours/day

## Summary

1. Do we feel that we know best **“patient selection criteria”**
  - The COPD patients need to be divided into groups and daytime PCO<sub>2</sub> is the most important marker
2. Do we feel that we know best **“NIPPV equipment parameters”**
  - The COPD phenotypes allow us to best assign appropriate PAP therapy
3. Do we feel that we know if the benefit is due to NIV or **“the use of the equipment alone as opposed to the concomitant provision of other support services”**
  - The presence of Daytime Hypercapnia is a hallmark for the need of more aggressive homecare
4. Do we feel that **“the evidence is sufficient to provide the patient usage parameters”**
  - The time cut offs are not specific but the greater the use the greater the effect

## Final Thoughts

- There is no doubt that the system for assigning and managing domiciliary PAP needs to be modernized and better integrated across the board including ALL disease states and pathologies
- Attempts to correct the NCD and policies around HMV use for COPD will be most effective if the BPAP (RAD) criteria are fixed at the same time
- More research is needed to best assess the role of these devices in the US population