

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)”

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On behalf of

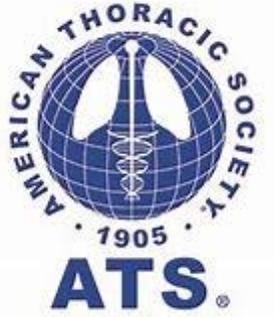
**The American Thoracic Society**





# Dr. Owens Personal COI Disclosures

- ResMed, a maker of positive airway pressure devices, gave a donation to the UCSD Sleep Center
- 2016: honorarium and travel reimbursement (<\$2,500) from ResMed
- 2017: Site PI (no salary) for ResMed sponsored multi-site research study.



# ATS Information

- American Thoracic Society (ATS) - More than 16,000 physicians, research scientists, and nurses and other allied healthcare professionals working to improve health worldwide by advancing research, clinical care, and public health in respiratory disease, critical illness, and sleep disorders.
- Dr. Owens Chair, forthcoming Clinical Practice Guideline “Long-term non-invasive ventilation in chronic stable hypercapnic chronic obstructive pulmonary disease: An Official American Thoracic Society Guideline.”

# Voting Questions

- **Patient selection criteria** that will improve outcomes with any NPPV device
- **NIPPV equipment parameters** necessary to improve patient reported outcomes
- Improvements can be attributed to the use of **NIPPV equipment alone**
- **Patient usage parameters** that will improve outcomes

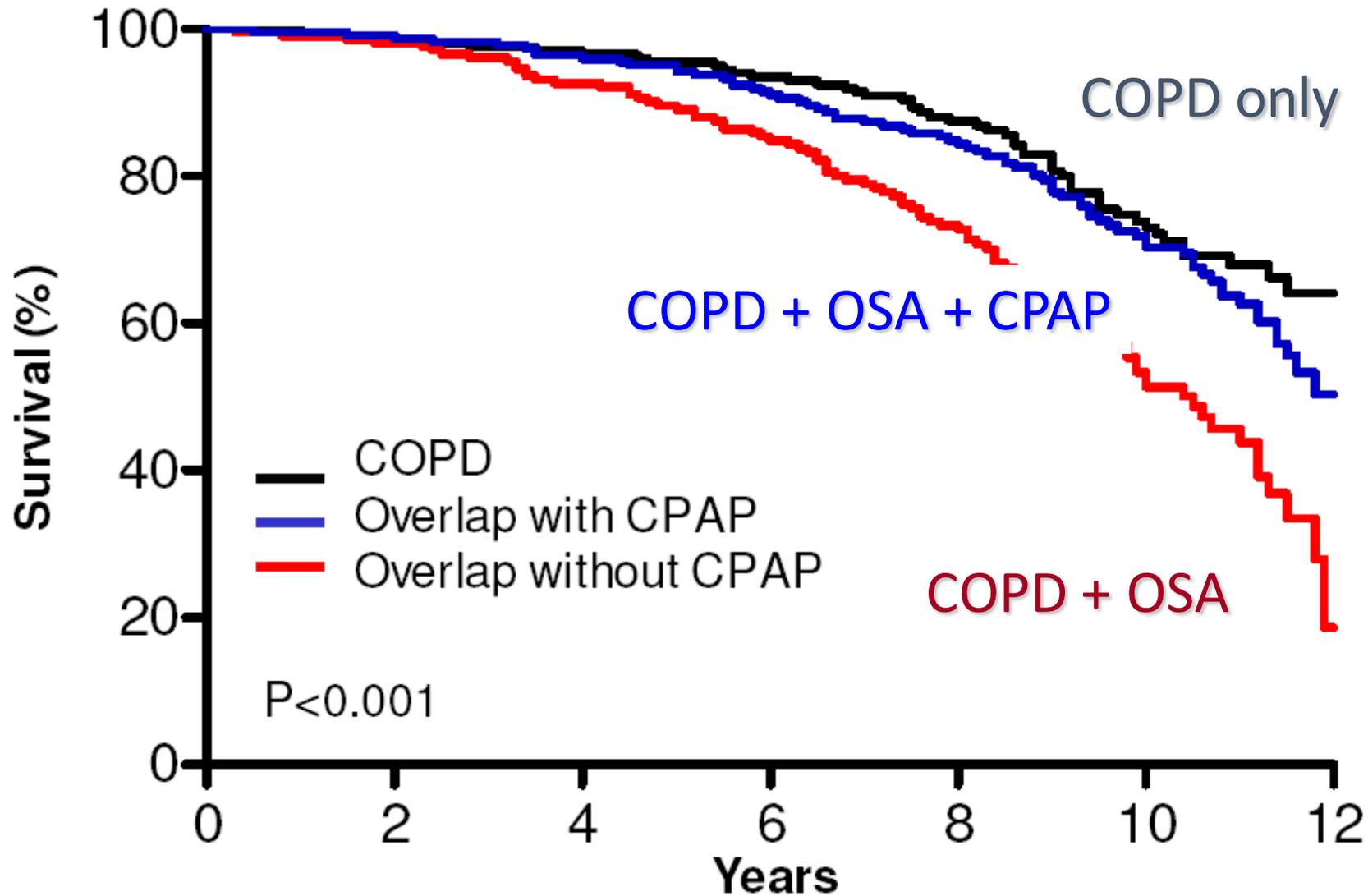
**COPD + OSA**

**Chronic Stable Hypercapnic COPD**

# COPD and Obstructive Sleep Apnea (OSA)

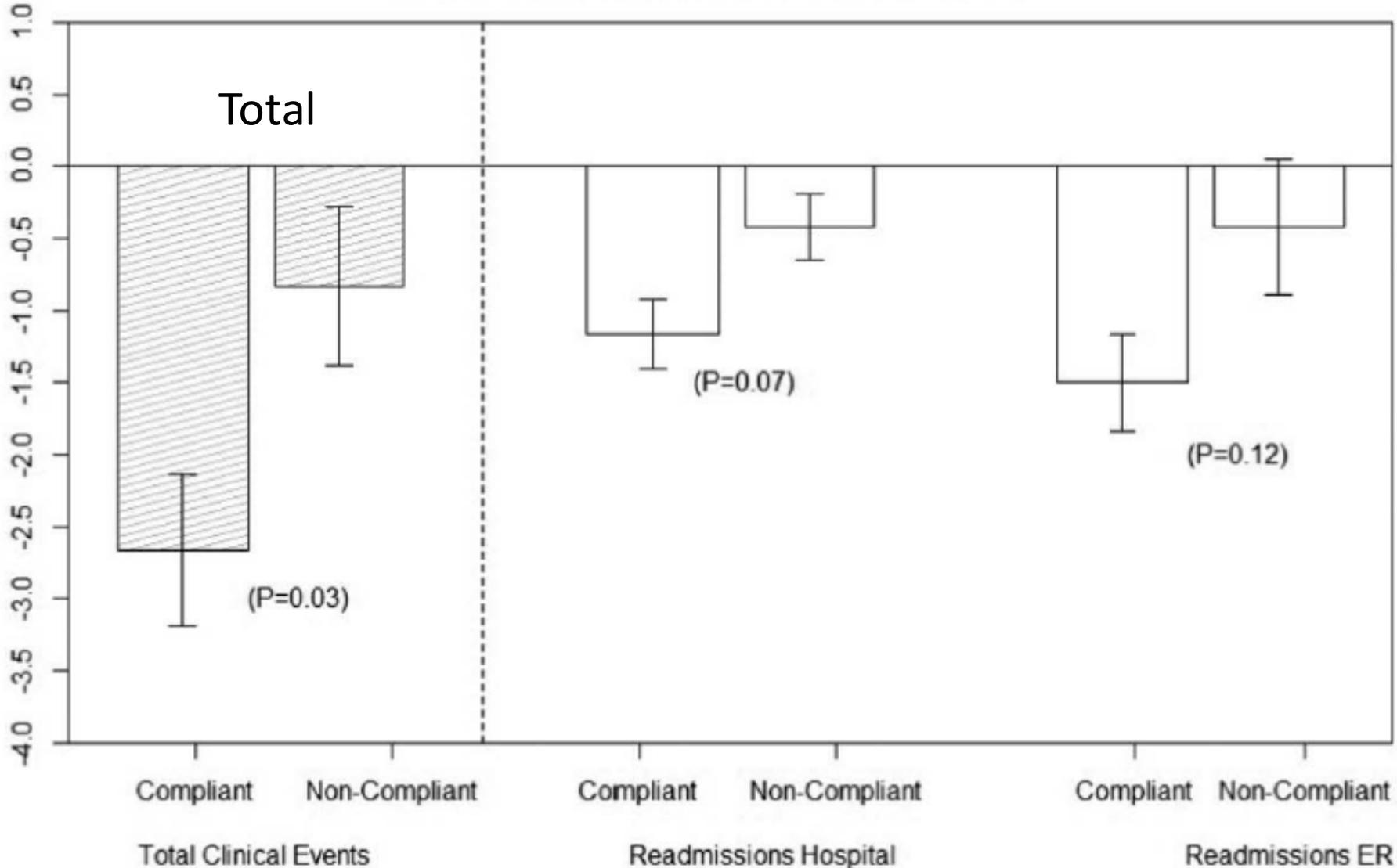
- This “Overlap Syndrome” is common
- **In absence of hypercapnia (high PaCO<sub>2</sub>)**, continuous positive airway pressure (CPAP) can be used
- Application of **CPAP** is associated with: improved mortality, reduced ER and hospital admission.
- More use is better, **but 4 hours per night is not a magic number**

# Overlap Syndrome has high mortality, CPAP use ameliorates

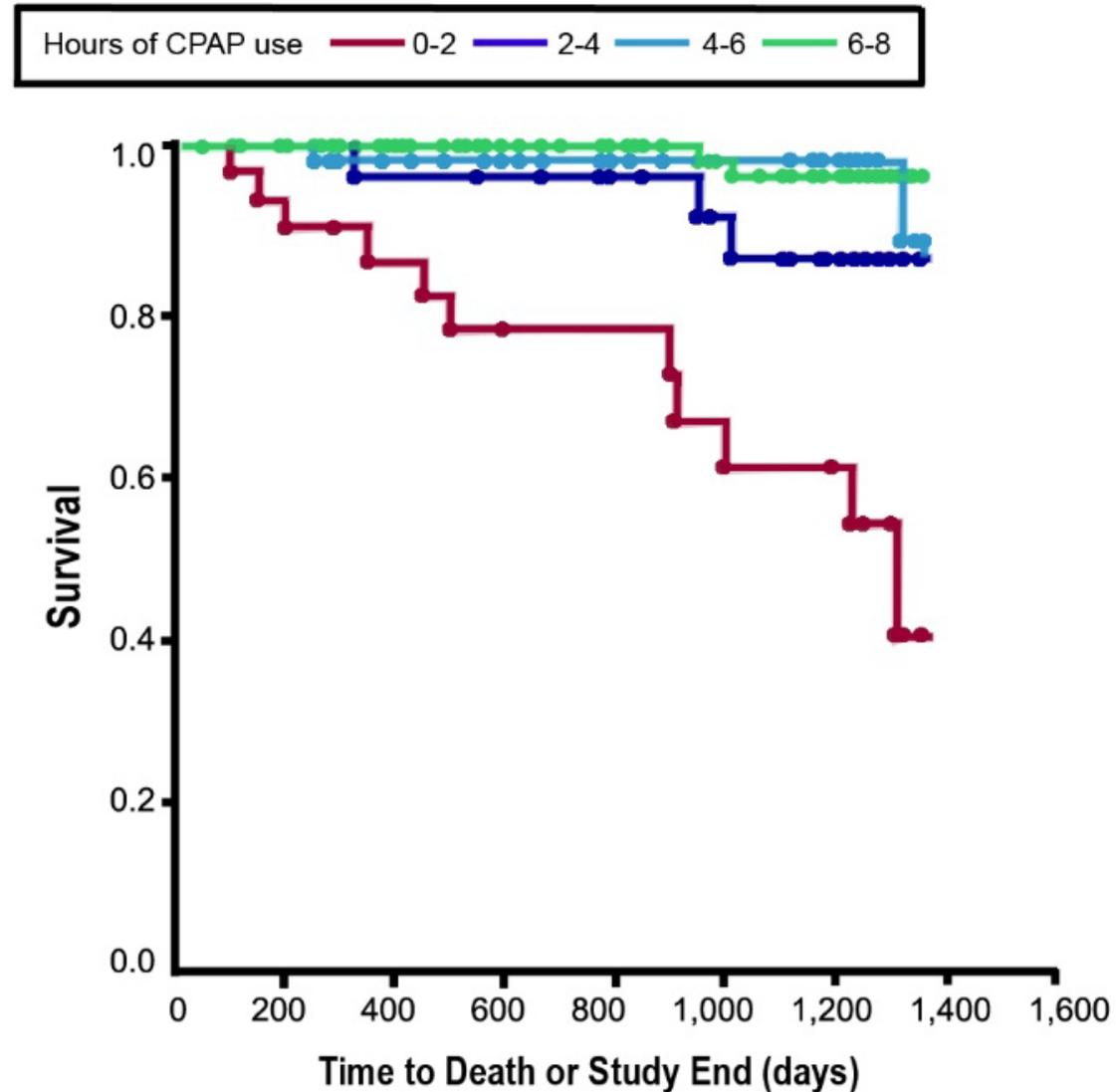


# Patients with COPD on CPAP, have reduced ER visits/admissions

Change in number of ER visits and Admissions



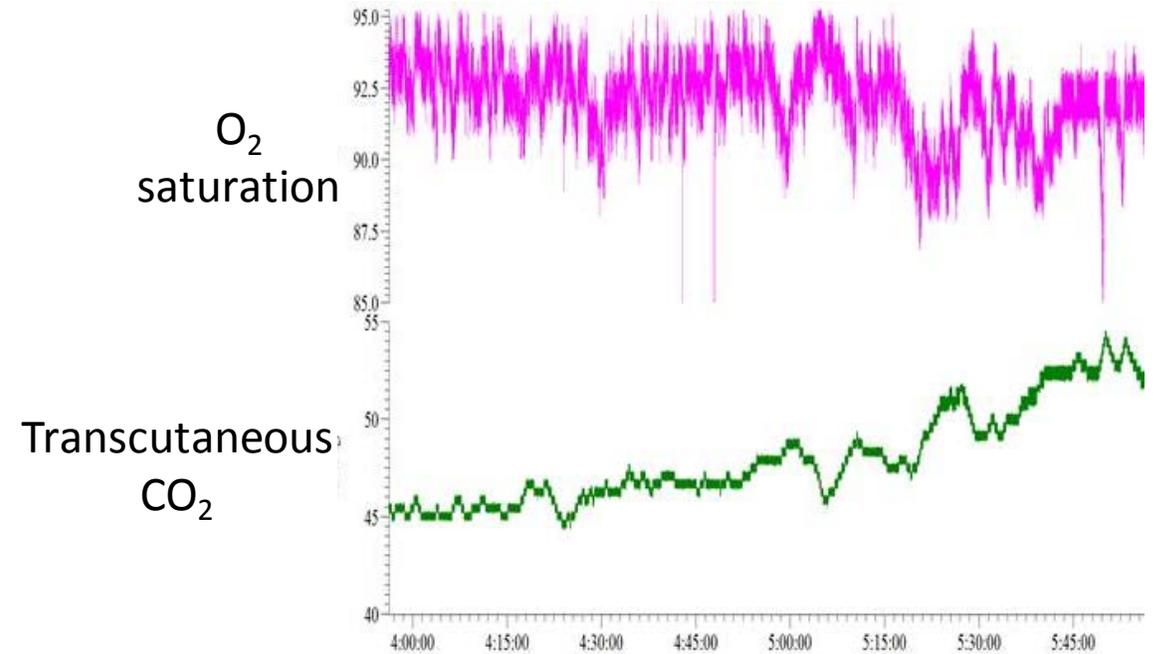
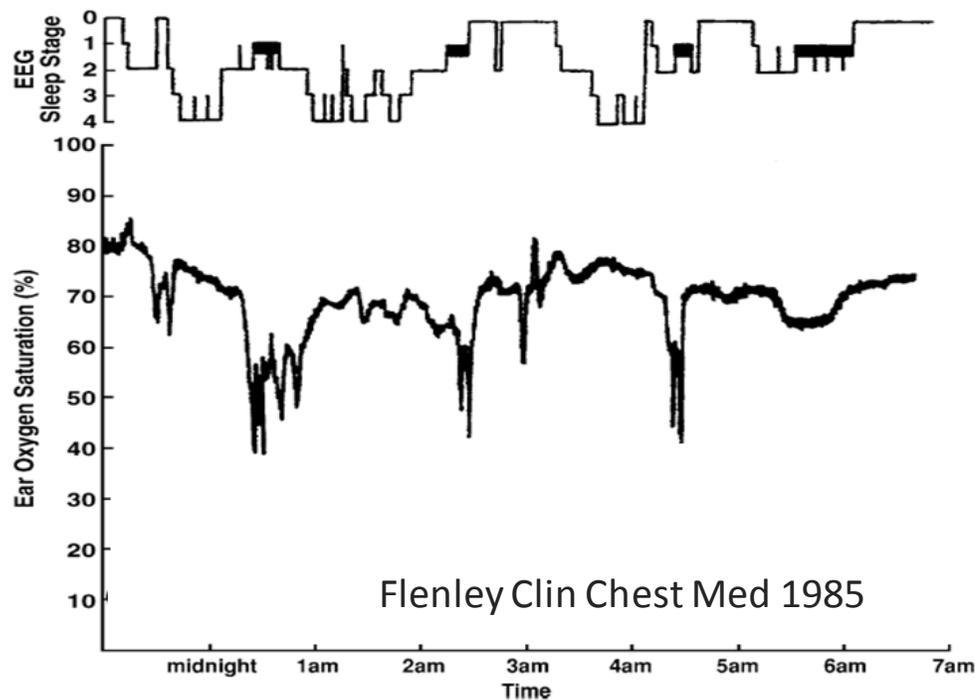
# More CPAP use associated with improved survival



↓  
Less CPAP use

# COPD with stable hypercapnic respiratory failure

- A group with high morbidity and mortality, **with few treatments shown to improve outcomes** (smoking cessation, O<sub>2</sub> therapy)
- Both oxygenation and ventilation (**rarely measured**) are problems



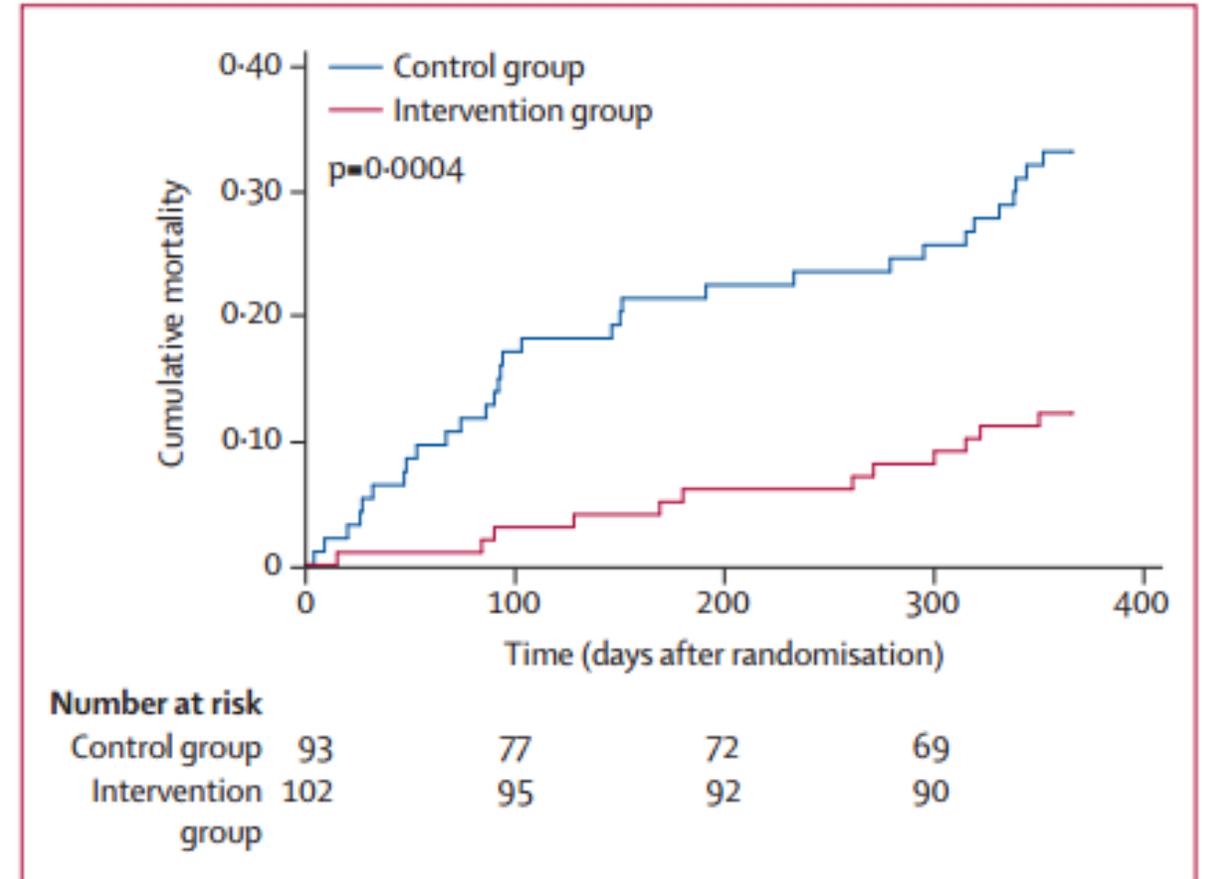
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# Non-invasive positive pressure ventilation for the treatment of severe stable chronic obstructive pulmonary disease: a prospective, multicentre, randomised, controlled clinical trial

*Thomas Köhnlein, Wolfram Windisch, Dieter Köhler, Anna Drabik, Jens Geiseler, Sylvia Hartl, Ortrud Karg, Gerhard Laier-Groeneveld, Stefano Nava, Bernd Schönhofer, Bernd Schucher, Karl Wegscheider, Carl P Criée, Tobias Welte*

- Inclusion: GOLD IV, PCO<sub>2</sub> >51 with pH >7.35, no recent exacerbation
- Exclusion: BMI >35, other lung or heart disease
- Control: Medical COPD treatment, NPPV OK during exacerbation
- Intervention: Addition of NPPV 6+ hrs/day, **PS mode with high back up** targeting 20% reduction in PCO<sub>2</sub>

- 33% of controls and 12% of NIV patients dead at 1 year (HR 0.24)
- **QOL improved** with NIV
- Intervention included scheduled hospitalizations and extensive follow-up



**Figure 2: Kaplan-Meier estimate of cumulative all-cause mortality during the first year after randomisation (primary outcome)**  
 The p value results from a log-rank test of the between-group difference.

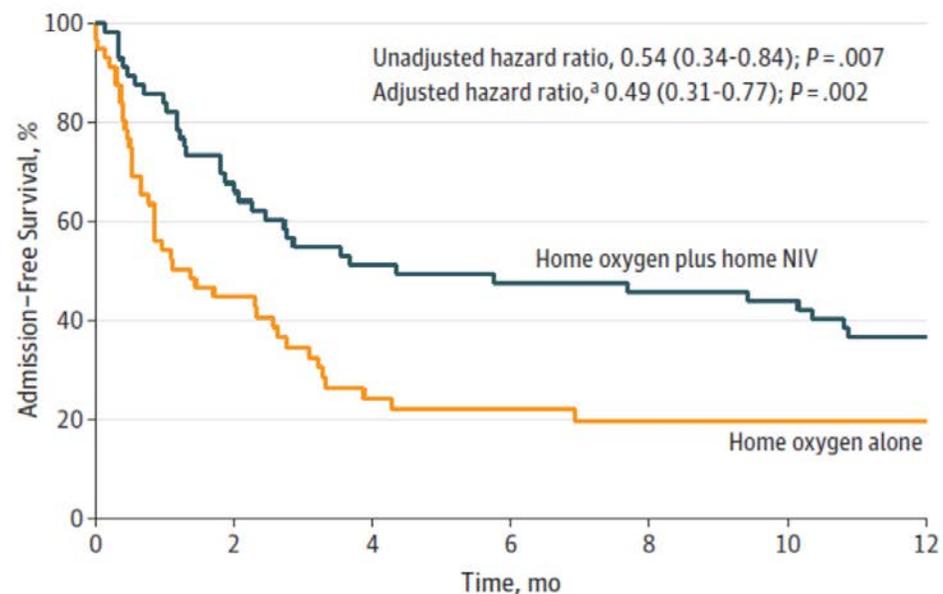
# Effect of Home Noninvasive Ventilation With Oxygen Therapy vs Oxygen Therapy Alone on Hospital Readmission or Death After an Acute COPD Exacerbation

## A Randomized Clinical Trial

Patrick B. Murphy, PhD; Sunita Rehal, MSc; Gill Arbane, BSc (Hons); Stephen Bourke, PhD; Peter M. A. Calverley, PhD; Angela M. Crook, PhD; Lee Dowson, MD; Nicholas Duffy, MD; G. John Gibson, MD; Philip D. Hughes, MD; John R. Hurst, PhD; Keir E. Lewis, MD; Rahul Mukherjee, MD; Annabel Nickol, PhD; Nicholas Oscroft, MD; Maxime Patout, MD; Justin Pepperell, MD; Ian Smith, MD; John R. Stradling, PhD; Jadwiga A. Wedzicha, PhD; Michael I. Polkey, PhD; Mark W. Elliott, MD; Nicholas Hart, PhD

2017

Figure 2. Kaplan-Meier Survival Plot of Time to Readmission or Death From Randomization to the End of Trial Follow-up at 1 Year



No. at risk	0	2	4	6	8	10	12
Home oxygen plus home NIV	57	37	28	26	25	24	16
Home oxygen alone	59	23	11	10	8	8	6

# Home initiation of chronic non-invasive ventilation in COPD patients with chronic hypercapnic respiratory failure: a randomised controlled trial

Marieke L Duiverman <sup>1,2</sup>, Judith M Vonk,<sup>2,3</sup> Gerrie Bladder,<sup>1,2</sup> Joost P van Melle,<sup>4</sup> Jellie Nieuwenhuis,<sup>1,2</sup> Anda Hazenberg,<sup>1,2</sup> Huib A M Kerstjens,<sup>1,2</sup> Job F M van Boven,<sup>2,5</sup> Peter J Wijkstra<sup>1,2</sup>

## What is the key question?

- ▶ Is home initiation of non-invasive ventilation (NIV) in stable hypercapnic COPD non-inferior to in-hospital NIV initiation?

## What is the bottom line?

- ▶ Home initiation of chronic NIV in stable hypercapnic COPD patients is non-inferior to in-hospital initiation, safe and saves over 50% of the costs.

# Voting Questions

- **Patient selection criteria** that will improve outcomes with any NPPV device
  - COPD + OSA**
  - COPD + chronic hypercapnia**
- **NIPPV equipment parameters** necessary to improve patient reported outcomes
  - CPAP**
  - BPAP with back up rate**
- Improvements can be attributed to the use of **NIPPV equipment alone**
  - Yes, but ancillary services clearly help, too**
- **Patient usage parameters** that will improve outcomes
  - 4 hours/night is not a magic number**
  - More is better**

# Additional Comments

- **BPAP with back up rate** has shown improvement for those with hypercapnic COPD, but it can be easier to satisfy requirements to get a home mechanical ventilator (HMV)
- Modifying requirements to obtain BPAP with back up rate will impact HMV utilization