TYPES OF HOME MECHANICAL VENTILATION:
WHEN IS IT REALLY A VENTILATOR?

PETER C. GAY, MD

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MAYO MEDICAL SCHOOL
ROCHESTER, MN

PETER C. GAY, MD, is Professor of Medicine, Mayo Medical School, Rochester, MN where he has been on staff since 1988. He also is Consultant, Division of Pulmonary and Critical Care Medicine. In 1976 he graduated with a B.A. from Middlebury College, Middlebury, VT. In 1981, he earned an MS in Physiology and his MD at the University of Hawaii, Honolulu, HI. He received all of his graduate training at Mayo Clinic Rochester and is Board Certified in Internal Medicine, Subspecialty Pulmonary Disease, Critical Care Medicine, and Sleep Medicine. He is a past chair of the ACCP Home Care Network and current President-elect of the Society of Anesthesia and Sleep Medicine. He has been a member of NAMDRC since 1996 and initially served as editor of NAMDRC’s “Clinical and Management Quarterly.” In 2000 he received NAMDRC’s President’s Award for his work in developing national coverage criteria for non-invasive positive pressure ventilation. Dr. Gay is a Past President of NAMDRC but has remained active with the executive office aiding with several NAMDRC causes and last year joined the board of NAMDRC directors.

OBJECTIVES:
Participants should be better able to:

- Discuss important issues about Home Ventilators;
- Summarize the possible role for a Ventilator when a Respiratory Assist Device just won’t do;
- Understand the new regulations and reimbursement criteria for Home Devices

THURSDAY, MARCH 12, 2015 8:45 AM
Walter died on July 22, 2002 of hemochromatosis and was struck down in the prime of his career at the age of 67. He was a Professor of Medicine at Creighton University School of Medicine in Omaha, Nebraska where he served as Chief of the Pulmonary/Critical Care Division and Director of the Internal Medicine Residency Program for 15 years, having also served for 11 years as the Department of Medicine Chairman.

We here were truly blessed as he was a charter member of NAMDRC serving on NAMDRC’s Board of Directors, and was President from 1995-97. Throughout his career in pulmonary medicine, Dr. O’ Donohue worked tirelessly to remove the bureaucratic obstacles that impeded quality patient care. His efforts shaped the goals and mission of NAMDRC, and his many contributions epitomized the professionalism, leadership, and ethics to which everyone in pulmonary medicine aspires.
DISCLOSURE

Dr. Gay has declared no conflicts of interest related to the content of his presentation.

Conflicts?

- Various Grants for Sleep Disordered Breathing Treatments with PAP
- Nothing Current
Objectives
You will:

• Understand the Title of the Talk
• Know How to Apply Outpatient NIPPV
• Describe Theory/Design of High Level PAP vs HMV Devices
  – Issue of a backup rate, Volume Targets
  – What makes an HMV a ventilator
• Support the NAMDRC White Paper
• Scream at the 2015 Coverage Criteria

Introduction

• How did we get here and why do we need different widgets?
• What are the differences in design, indications, and applications for:
  – Home Vents
  – High level RADS
Question 1

The most important consideration for the design of a portable ventilator is which of the following?

A. Ability to provide adequate oxygenation
B. Means to eliminate carbon dioxide
C. Capability of providing both A and B
D. Portability and Battery Backup
E. Revenue generation for physicians
EQUIPMENT

E0471- RADS

AVAPS

iVAPS

STELLAR
150
AVAPS
Average Volume Assured Pressure Support

• Automatically adjusts IPAP to maintain a consistent tidal volume

• Operates on S, S/T, T or PC modes

Average Volume Assured Pressure Support (AVAPS)

◆ RCT with crossover design of OHS who failed CPAP
  - CPAP failure defined as RDI>10 and TcCO₂ >45 mm Hg
  ◆ N=10
    - Mean age: 53.5; BMI: 41.6; PaCO₂ 47.4; RDI 74
◆ Randomized to Bilevel PAP-S/T (with a back up rate) or AVAPS and after 6 weeks patients were crossed over to the other arm

Storre JH et al. Chest 2006; 130:815
AVAPS’s impact on comfort and sleep quality

- Randomized cross-over design of 12 patients with treated OHS
  - Eight men, age 60, BMI 44, PaCO₂ 44±11 mm Hg, mean bilevel PAP/ST adherence of 6.5 h/night
  - On treatment with bilevel PAP/ST for 30 months
  - Two consecutive PSGs with bilevel PAP/ST and AVAPS

AVAPS improved nocturnal ventilation but decreased sleep efficiency

**Table**

<table>
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<th>With V&lt;sub&gt;t&lt;/sub&gt; targeting</th>
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<td>Sleep fragmentation index (n/h)</td>
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**iVAPS**

intelligent Volume Assured Pressure Support

iVAPS maintains the patient's opportunity to breathe spontaneously before bringing the patient back to target if backup breaths are required. IBR stays out of the way when not required. Automatically changing pressure support and IBR to maintain alveolar ventilation.
Objective:

- Compare high-intensity noninvasive positive pressure ventilation (HI-NPPV) compared with intelligent volume assured pressure support (iVAPS) and spontaneous breathing (SB) on daytime minute ventilation (MV) in hypercapnic COPD treated with NIPPV.

Results and Conclusions:

- 27 stable hypercapnic severe COPD pts treated with HI-NPPV for a median of 22 months with mean MV of 9.5 L/min during SB and 12.1 L/min during HI-NPPV (p < 0.001), or a 26% increase.

- MV during iVAPS was 11.7 ± 3.6 L/min, an increase of 1.8 L/min (p = 0.003), or a 19% increase compared with SB. There was no difference in MV between HI-NPPV and iVAPS (p = 0.25).
Randomized trial of 'intelligent' autotitrating ventilation versus standard pressure support non-invasive ventilation: impact on adherence and physiological outcomes.

OBJECTIVE:
• In a randomized crossover trial, iVAPS, with automated selection of ventilator settings, was compared to standard PS ventilation, with settings determined by bedside PSG techs in naïve NIV patients

METHODS:
• 18 pts with severe COPD or restrictive lung disease and newly diagnosed nocturnal hypoventilation (Mean wake PaCO2= 47.9 mmHg) were randomized to iVAPS and standard PS. PSG with tcPCO2 monitoring done at baseline and after 1 month treatment.

RESULTS AND CONCLUSIONS:
• iVAPS had lower median PS vs standard PS (8.3 vs 10 cmH2 O; p= 0.001) for the same overnight SpO2 of 96%; p= 0.13 and PtcCO2 = 48.7 mmHg; p= 0.54. There was no difference in outcome between ventilator modes for spirometry, respiratory muscle strength, sleep quality, or O2 desaturation index. Adherence at 1 month was greater with iVAPS (5-67 vs 4.33 hr/nt; p= 0.004).
Volume assured pressure support devices can improve ventilation primarily through which mechanism?

A. Guarantee of a minimum minute ventilation
B. Availability of a backup rate
C. Higher pressure support than a BPAP
D. Targeted MV or tidal volume
E. Can whisper sweet nothings to a patient

Correct Answer: D. Targeted MV or tidal volume
Equipment Issues

- Vendors tied to specific equipment
- Physicians/caregivers need to know the new and old ventilators
- Broader needs require an extensive array of equipment including those related to ventilation, secretion clearance, mobility
Efficacy Targets

• Reduced Arousals/Hypopneas
• Compliance
  – Increased comfort
  – Better patient-device synchrony
• Gas Exchange
  – Higher minute ventilation
  – Reduced daytime hypercapnia

Why Do Need So Many Widgets?

• We Need More Ventilation Scotty?
  – What do you need to ventilate?
  – When does a RAD fail?
  – Is this one or another better?
• The Needed Aspects for Success
  – More horsepower
  – Special features
    • Mouthpiece and other unique modes
    • Battery backup
    • Alarms and Better Monitoring
How Did We Get Here?

OVERVIEW

• Basic RAD RULES implemented on October 1, 1999 after NAMDRC addressed the issues related to ventilator assistance for patients with neuromuscular disease (NMD), COPD, and other hypoventilation syndromes (HS).
• Use of a BPAP backup rate was clinically and financially more similar to that of an HMV and therefore recognized as a ventilator by the FDA, resulting in need for a more ‘frequent and substantial servicing’ payment classification by Medicare.

Question 3

Which one of the following is correct about current RAD coverage law?

A. All categories require an elevated PaCO2
B. Only NM Disease Pts get an initial BR
C. Oximetry report is required for COPD pts
D. All have a 31-90 day compliance provision
E. None of the above are correct
Question 3
Which one of the following is correct about current RAD coverage law?

A. All categories require an elevated PaCO2
B. Only NM Disease Pts get an initial BR
C. Oximetry report is required for COPD pts
D. All have a 31-90 day compliance provision

Local Coverage Determination (LCD) for Respiratory Assist Devices (L5023)

CMS Criteria
I. Restrictive Thoracic Disorders
II. Severe COPD
III. Central Sleep Apnea
IV. Hypoventilation Syndromes

http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=5023&ContrId=140&ver=60&ContrVer=2&CntrctrSelected=140*2&Cntrctr=140&name=CGS+Administrators%2c+LLC+(18003%2c+DME+MAC)&LCntrctr=140*2&bc=AgA+CAAIAAAAAA&
How Did We Get Here?

OVERVIEW

• Reimbursement ruling was changed to ensure that all BPAPs, even when used as a ventilator with a backup rate, were nevertheless paid as a capped rental item (CR). As later clarified in 2006 in the Federal Register, “Ventilators that are excluded from the FSS payment category are paid in accordance with section 1834(a)(7) of the Act under the CR category on a rental basis.”

• This ruling clarified reimbursement policy for BPAPs vs. HMVs, but did not help identify the clinical situations appropriate for FSS or CR equipment.

How Did We Get Here?

OVERVIEW

• FDA approved HMV (home mechanical ventilator) in 1977 focused upon ventilator dependent pediatric pts with a trach.

• BPAP (Bilevel positive airway pressure) were specifically addressed in the Federal Register and defined as “respiratory assist devices” or “RADs” in 1999. No distinction made in the Healthcare Common Procedure Coding System (HCPCS) whether or not a backup rate feature was employed.

• However, effective Jan 1, 1992, code E0453 with wording “therapeutic ventilator; suitable for use 12 hours or less per day” was added to the HCPCS.
RADs vs Vents

- **Frequent and Substantial Servicing vs Capped Rental**
  - CMS used term “therapeutic ventilator” without real definition, just as no true definition for a RAD with a backup rate.
  - CMS final regulation 1/27/06 shifted payment for any RADs in “frequent and substantial” payment category to “capped rental”
    - “Capped rental” payment continues 13 mos (mandated by Deficit Reduction Act).
    - “Frequent and substantial” payment, continues for the time the beneficiary requires the device

How Did We Get Here?

- Newer HMVs now capable of delivering therapy with “RAD-type” BPAP settings
- More difficult to tie device reimbursement to medically necessary treatment plans chosen for one patient or another when BPAP settings are deliverable with either a “RAD” or an HMV.
How Did We Get Here?

The problem:

- Current reimbursement policy creates a disconnect between a patient’s clinical status/needs and reimbursement because payment policies focus on devices rather than the clinical situation.

The Real Problem

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NAMDRC Working Group Report on the Use of Noninvasive Home Mechanical Ventilation in Adult Patients with Chronic Hypercapnic Respiratory Failure

THE AUTHORS-
• Charles Atwood, MD  UPMC, Pittsburgh, PA
• Joshua Benditt, MD  U Washington, Seattle, WA
• Kent Christopher, MD  Denver, Colorado
• Gerry Criner, MD  Temple U, Philadelphia, PA
• Peter Gay, MD  Mayo Clinic, Rochester, MN
• Nick Hill, MD  Tufts U, Boston, MA
• Sai Parthasarathy, MD  U Arizona, Tucson, AZ
• Lisa Wolfe, MD  Northwestern U, Chicago, IL

COVER LETTER TO R Hoover DME MAC Region C Dir
• The team determined that it wanted to focus primarily on the clinical aspects of home mechanical ventilation rather than attempt to tailor the standards of care to fit into current coverage and payment methodologies. Specifically, we recognize that current legislative and regulatory constraints, shaped over the past two+ decades, may require CMS to shape its coverage and payment rules to fit a particular environment that is not necessarily reflective of the standards of care and clinical practice guidelines for home mechanical ventilation.
NAMDRC Working Group Report on the Use of Noninvasive Home Mechanical Ventilation in Adult Patients with Chronic Hypercapnic Respiratory Failure

• Within that framework, we have created three specific categories for the consideration of HMV use:

  Neuromuscular, COPD and Hypoventilation syndromes

• While we certainly understand and appreciate the concept of mechanical ventilation being one solely and singularly aimed at a life support function, that premise does not match the science or the clinical literature that has evolved over the past 20+ years. The efficacy of non-invasive mechanical ventilation is well documented in the clinical literature, and to label that standard of care as something other than “mechanical ventilation” is inconsistent with the writing team’s principles.

The purpose of this document is to review available evidence and provide expert consensus opinion regarding the use of home non-invasive mechanical ventilation in adults, attempting to describe different clinical scenarios that dictate the need for different levels of ventilator assistance and support.
1) Need for daytime use beyond nocturnal period
2) Persisting hypercapnia despite BiPAP use
3) Hypoxemia attributed to inadequate ventilation
4) Daytime dyspnea/Mouthpiece support
5) Speech and swallowing
6) Very severely reduced lung volume
7) Nocturnal BPAP failure
1) An arterial blood gas $\text{PaCO}_2$, done while awake and breathing the patient’s usual $\text{FiO}_2$, is $> 52$ mmHg, and

• **Recommendation:** In addition to the above requirement, pts should have severe COPD.

2) Sleep oximetry demonstrates oxygen saturation $\leq 88\%$ for at least 5 minutes, done while breathing oxygen at 2 LPM or the pt’s usual $\text{FiO}_2$ (whichever higher), and

• **Recommendation:** Requirement of hypercapnia alone should be sufficient to justify medical necessity of BPAP. The requirement regarding nocturnal $\text{O}_2 \text{SpO}_2$ is not medically justified, and should be eliminated from the policy.
3) Prior to initiating therapy, OSA and treatment with CPAP has been considered and ruled out but does not require formal sleep testing.

4) If all of the above criteria for COPD patients are met, a RAD without backup will be covered… For COPD patients who qualified for a RAD without backup, if at a time no sooner than 61 days after compliant use of a RAD without backup, the treating physician believes the patient requires a RAD with backup, the RAD with backup will be covered if PaCO2 and oximetry criteria……

Recommendation: Removing the current requirement regarding backup rate will greatly simplify the process for both providers and payers and will permit upfront initiation of what will likely be more effective therapy for patients.

To summarize:
- Severe and very severe COPD and
- An arterial blood gas PaCO2, while awake and breathing the patient’s usual FiO2, is > 52 mmHg
- Drop all backup rate and oximetry stipulations
- 61-90 day mandatory compliance evaluation
NAMDRC COPD Working Group Report

• New evidence indicates that BPAP improves outcomes including survival and may decrease hospitalization readmissions. These data also provide important information regarding:
  1) The level of resting hypercapnia in pts likely to benefit
  2) The use of higher inspiratory pressure settings during BPAP than have been used in previous studies
  3) The importance of a backup respiratory rate


NAMDRC COPD Working Group Report

4) Lack of need to perform a sleep study or nocturnal oxygen desaturation challenge to select COPD pts who demonstrate improvements in survival
5) Reduced need for hospital readmission with the use of long-term nocturnal BPAP.
6) Data demonstrate that following an admission for acute exacerbation complicated by acute hypercapnic respiratory failure, patients who used BPAP post discharge at home on a daily basis had lower readmission rates, reduced readmissions requiring a stay in the ICU, and improved event-free survival.

**Recommended Revised Algorithm for NIV via HMV in COPD**

1. **SEVERE COPD**
   - ABG while awake breathing usual FiO₂ demonstrates PaCO₂ > 52 mmHg

2. **Prescribe BPAP**
   - Successfully achieve ventilation goals
   - Continue BPAP
   - • Failure on a BPAP Device
   - • Progressively increased hours of nocturnal and diurnal use/need for baggy backup/volume targeted modes
   - • Enhanced alarm requirement

3. **Initiate HMV**

**NAMDRC Hypoventilation Syndromes Working Group Report**

**INDICATONS for HMV after NPPV Use:**

1) Need for daytime use beyond the nocturnal period

2) Persisting hypercapnia despite BPAP use
   - Awake PaCO₂ ≥ 45mmHg or persistence of sleep-disordered breathing (AHI > 10/hr or hypoventilation with SpO₂ <88% for > 5 min in the absence of respiratory events of sleep apnea) detected during PSG or HST) despite the use of nocturnal BPAP and reasonable levels of supplemental oxygen (up to 5 LPM) suggests failure of the BPAP and need for HMV.
   - Patients with severe chronic respiratory failure may require volume targeted modes best provided by an HMV.
3) Inability to qualify for a BPAP despite respiratory failure:
   - Some patients with overlap syndrome (COPD and OSA with hypercapnia) may fail PaCO$_2$ or oximetry criteria to obtain a BPAP from other categories.
   - Patients with OSA/OHS whose AHI cannot be lowered below 10 events per hour with PAP who also need oxygen will not be able to get oxygen and PAP given the latest LCD ruling of January 2014.

4) Alarms and Backup Ventilator:
   - Those with unstable medical conditions may require more robust alarm systems and this may require the use of an HMV.
   - Rarely, if ever, would a backup ventilator be clinically appropriate, and claims for a backup ventilator are frequently denied even for patients with a tracheostomy.

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**Hypoventilation Syndrome**

- $\text{PaCO}_2 \geq 45$ mmHg (while awake at baseline $FIO_2$) after PSG, hypoxemia with AHI<10
- Body mass index > 30 Kg/m$^2$

**Existing Pathway**

- BPAP Device

**Direct Pathway**

- Severe Respiratory Failure

**Special Feature of HMV Needed**

- Progressive hourly use/day
- Mouthpiece ventilation
- Volume target
- Super obesity
- Transition Tracheostomy
- Unresolved gas exchange issues related to cardiopulmonary conditions

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* Note that a sleep study is required to initiate device therapy except with acutely worsening hypercapnia

$^1$ Severe Chronic respiratory failure (ICD9 code 518.83)

$^2$ BPAP Device failure- persistent hypoxemia $<$88% for 5 minutes; AHI > 10 per hour despite BPAP therapy; or unresolved daytime hypercapnia $>$45mmHg)

$^3$ Use of the BPAP for progressively greater use in a 24-hour time period necessitated by symptoms and signs of respiratory insufficiency as judged by patient, caregiver, or provider.

$^4$ Body mass index > 50 Kg/m$^2$

$^5$ Transitioning from tracheostomy-based to non-invasive mask-based ventilation

$^6$ Right Heart failure and/or pulmonary hypertension with high $FIO_2$ ($>$ 5 LPM) requirement
VENTILATOR WITH NOINVASIVE INTERFACES

The Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations Manual (Internet-Only Manual, Publ. 100-3) in Chapter 1, Part 4, Section 280.1 stipulates that ventilators (E0450, E0460-E0464) are covered for the following conditions:

“Neuromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to chronic obstructive pulmonary disease.”

Each of these disease categories are comprised of conditions that can vary from severe and life-threatening to less serious forms. These disease groups may appear to overlap conditions described in the Respiratory Assist Devices LCD but they are not overlapping. Choice of an appropriate device i.e., a ventilator versus a bi-level PAP device is made based upon the severity of the condition.

CMS distinguished the use of respiratory product types in a National Coverage Analysis Decision Memo (CAG-00052N) in June 2001 saying that RAD is “distinguished from ventilation in a patient for whom interruption or failure of respiratory support leads to death.”
The conditions described in the Respiratory Assistance Devices (RAD) local coverage determination are not life-threatening conditions where interruption of respiratory support would quickly lead to serious harm or death. These policies describe clinical conditions that require intermittent and relatively short durations of respiratory support. Thus, any type ventilator would not be eligible for reimbursement for any of the conditions described in the RAD LCD even though the ventilator equipment may have the capability of operating in a bi-level PAP (E0470, E0471) mode. Bi-level PAP devices (E0470, E0471) are considered as reasonable and necessary in those clinical scenarios.

Claims for ventilators (E0450, E0460-E0464) used for the treatment of conditions described in the RAD LCD will be denied as not reasonable and necessary.

• Some manufacturers and providers seem interestingly optimistic and others seem to just "not know". I interpret the verbiage "interruption or failure of respiratory support leads to death" to mean the patients can't live without it for minutes or maybe a few hours max. If the DME standard is 2 hour response time then that means interruptions or failure would mean to me if the patient would die before you could get there to replace or before EMS could arrive at their home.
Question 4
Which one of the following best describes your reaction to this law?

A. I’m accepting and will not likely order HMVs
B. I can only ask pts to write to Congress
C. I expect a NAMDRC ‘Call to Arms’
D. The industry got what they deserved
E. It is not relevant to my practice

A. B. C. D. E. 76% 2% 2% 13% 7%
Conclusions

• The landscape will certainly drastically change for NIPPV patients and possibly even for those with a tracheostomy when HMV treatment plans are sought
• NAMDRC BOD is presently crafting a response plan possibly including a legislative approach to appropriately address this immense barrier to proper patient care