OBJECTIVE:

Describe the effect of supplemental oxygen therapy on quality of life for patients with chronic lung disease.
OPTIMIZING OXYGEN THERAPY
(WITH SUSAN JACOBS AND PHILLIP PORTE)

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UNIVERSITY OF CALIFORNIA AT SAN FRANCISCO
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SAN FRANCISCO, CA

Chris Garvey FNP, MSN, MPA, MAACVPR is nurse practitioner at University of California San Francisco Pulmonary Rehabilitation (PR) and Sleep Disorders. Her international focus has been guideline development, research in exercise prescription and quality measures related to pulmonary rehabilitation. She has been an author in every recent US PR guideline. She helped lead development and implementation of the first large national registry of clinical outcomes and quality measures in PR as part of the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR). Chris is co-developer of the AACVPR outcome resource guide, a 50 page primer on use, validation and interpretation of PR outcome measures. Chris was a site coordinator of a US/Canadian registry evaluating long term PR outcomes in patients with interstitial lung disease and a satellite coordinator for the National Emphysema Treatment Trial. She has received the L Kent Smith national award for excellence and has two national research fellowship awards for clinical outcome evaluation in ER asthma outcomes. Chris is immediate past president of the California Thoracic Society and a member of the executive committee of the Pulmonary Education and Research Foundation. She is a former BOD member of AACVPR and former co-chair of the ATS pulmonary rehabilitation section.
Phillip Porte was born and raised in Chicago, Illinois and completed his undergraduate degree at the University of Wisconsin with a Bachelors Degree in English and a minor in Political Science (1970).

After a relatively short stint with City New Bureau, CBS News, and St. Mary of Nazareth Hospital Center, all in Chicago, he arrived in Washington, DC in 1976 to work at the National Health Policy Forum, a foundation funded program that runs educational seminars for Federal health policymakers. While going to graduate school at the George Washington University in the Masters Program for Public Administration, he immersed himself in the nuances of national health policy. In 1978 he opened his own health care consulting and lobbying firm, representing the American Association for Respiratory Care. In the 31 years since, GRQ has established a strong reputation in the field of pulmonary medicine, representing NAMDRC as well as other pulmonary medicine societies, device manufacturers, pharmaceutical companies, and providers of hospital, nursing home and home care.

He has published articles in numerous journals relating to pulmonary medicine coverage and payment issues and has served as Executive Director of NAMDRC, a client of GRQ since 1979, for approximately 40+ years, and as Executive Director of California Thoracic Society, a client of GRQ since 2016.
Optimizing Oxygen Therapy
Susan Jacobs RN, MS
Research Nurse Manager,
Pulmonary & Critical Care Medicine,
Nurse Coordinator, Interstitial Lung Disease Program
Stanford University

No Disclosures
Overview: Background and Evidence

I. From the Researchers: Evidence for Oxygen Rx
II. Patient-Reported Data
III. Multidisciplinary Consensus: Pt, HCP, DME, Policy

I. Evidence for Oxygen Therapy

• Survival
  • NOTT: 1980 improved survival for COPD patients with severe resting hypoxemia (PaO2 ≤55 torr or ≤59 torr with comorbidities)
  • MRC: 1981 improved survival for COPD patients with RHF and resting PaO2 40-60

NOTT Group Ann Intern Med 1980
I. Evidence for Oxygen Therapy

• **Survival**
  - **LOTT: 2016**
    - COPD patients with resting sat 89-93% OR resting sat ≥94% but with desat ≤90% for ≥ 10 seconds.
    - Randomized to receive oxygen or no oxygen
    - Result: No difference on all-cause mortality, hospitalizations, QOL or exercise performance in COPD patients with moderate resting (89-93%), or isolated exertional desaturation to 90%.


I. Evidence for Oxygen Therapy

- Oxygen improves survival for COPD patients with severe hypoxemia
- LOTT study results shouldn’t be extrapolated to other lung disease populations, especially ILD pts. with profound exertional hypoxemia
- We lack evidence for long term impact of intermittent hypoxemia (exertion only)

Swigris Ann Am Thorac 2017
DuPlessis et al. Respirology 2017
Exertional hypoxemia is more severe in fibrotic interstitial lung disease than in COPD

I. Evidence for Oxygen Therapy

• **Exercise Tolerance**
  • Mixed results for ILD and COPD patients for exercise or dyspnea improvements
  • Improved exercise endurance and dyspnea in ILD patient lab studies
  • Large gap in evidence for prescribing oxygen for exertion-only desaturation

Casaburi COPD CRN 2012
Adamali Cochrane Library 2016
Schaefer et al Eur Respir J 2017
Dowman et al Respirology 2017
Johannson Ann Am Thorac Soc 2017
I. Evidence for Oxygen Therapy

• Quality of Life
  • Breathlessness is strong determinant of QOL
  • Onset oxygen Rx = critical point in illness
  • Studies examining QOL with oxygen are challenged by small uncontrolled studies, and oxygen or saturations not masked
  • Impact of cumbersome therapy on mobility is difficult to measure
  • Critical to manage patient expectations

Swigris Ann Am Thorac Soc 2017
Swigris BMJ 2018
Bell et al Eur Respir Rev 2017

Effect of ambulatory oxygen on quality of life for patients with fibrotic lung disease (AmbOx): a prospective, open-label, mixed-method, crossover randomised controlled trial

Visca et al. Lancet 2018
• Significant improvement in K-BILD breathlessness and activity \( p < 0.0001 \)
• Significant improvement in chest symptom subdomains \( p = 0.009 \)
• No change in psychological domains

II. Patient–Reported Data

• May 2015:
  – ATS Nursing Assembly Program Planning Committee creates Oxygen Working Group (OWG)
• May 2016:
  – The OWG multidisc. group of 26 concludes objective data needed
• Sept 2016:
  – Survey developed by the OWG with multidisciplinary review and posted online on the ATS Public Advisory Roundtable (PAR) site and other sites for 6 weeks
  – Purpose: To describe the frequency and type of problems experienced by adult supplemental oxygen users in the United States
• Jan 2018: Oxygen Survey published in Annals of the ATS
• May 2017:
  – 8 hr. ATS workshop: Optimizing Supplemental Oxygen Therapy
• Dec. 2018: Official ATS Workshop Report published in Annals ATS
II. Patient–Reported Data

1. Patient Perceptions of the Adequacy of Supplemental Oxygen Therapy: Results of the ATS Nursing Assembly Oxygen Working Group Survey

2. Equipment, access and worry about running short of oxygen: Key concerns in the ATS patient supplemental oxygen survey.

3. Perspectives From COPD Subjects on Portable Long-Term Oxygen Therapy Devices

Lindell et al. Ann Heart Lung 2018
Almutairi et al. Resp Care 2018

ATS Survey Results (n=1926)

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Total Sample, %</th>
<th>Reported Problems, %</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Yes  No  P Value</td>
<td>Yes  No  P Value</td>
</tr>
<tr>
<td>Live in Competitive Bidding Area</td>
<td>44   55  45</td>
<td>44   55  45</td>
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<tr>
<td></td>
<td>11   49  51</td>
<td>11   49  51</td>
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<tr>
<td>Unsure</td>
<td>45   48  52</td>
<td>45   48  52</td>
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<tr>
<td>Duration of oxygen use</td>
<td>&lt; 1 year</td>
<td>17   41  59</td>
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<tr>
<td></td>
<td>1-5 years</td>
<td>51   51  49</td>
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<tr>
<td></td>
<td>&gt; 5 years</td>
<td>32   57  43</td>
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<tr>
<td>Oxygen requirement</td>
<td>Continuous (24 hrs/day)</td>
<td>60   54  46   0.008</td>
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<tr>
<td></td>
<td>25 LPM exertion (pulse or cont)</td>
<td>31   56  44   0.004</td>
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<tr>
<td>Health care utilization</td>
<td>Hospital admission past 12 mo.</td>
<td>29   57  43   0.005</td>
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<tr>
<td></td>
<td>Emergency Room visit past 12 mo.</td>
<td>34   56  44   0.008</td>
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<tr>
<td>Education</td>
<td>Attended pulmonary rehab</td>
<td>63   53  47   0.185</td>
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<td>Education re home oxygen</td>
<td>0.000</td>
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<tr>
<td></td>
<td>Oxygen delivery personnel</td>
<td>64   51  49   0.000</td>
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<tr>
<td></td>
<td>Healthcare personnel</td>
<td>8   43  57</td>
</tr>
<tr>
<td></td>
<td>None</td>
<td>10   64  36</td>
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### ATS Survey Results (n=1926)

#### Results by type of lung disease

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<thead>
<tr>
<th>Characteristic</th>
<th>COPD n (%)</th>
<th>ILD n (%)</th>
<th>PAH n (%)</th>
<th>AATD n (%)</th>
<th>LAM n (%)</th>
<th>Other n (%)</th>
<th>P Value</th>
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<tbody>
<tr>
<td><strong>Characteristic</strong></td>
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<tr>
<td>Live in Competitive Bidding Area</td>
<td>Yes 44</td>
<td>No 55</td>
<td>45</td>
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<tr>
<td>Duration of oxygen use</td>
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<td></td>
<td></td>
<td></td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>&lt; 1 yr.</td>
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<td>41</td>
<td>59</td>
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<td>1-5 yrs.</td>
<td>61</td>
<td>51</td>
<td>49</td>
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<td>&lt;0.001</td>
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<tr>
<td>&gt; 5 yrs.</td>
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<td>57</td>
<td>43</td>
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<td>Oxygen requirement</td>
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<td>46</td>
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<td>≥ 5 LPM exertion (pulse or cont)</td>
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<td>56</td>
<td>44</td>
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<td>0.004</td>
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<td>Health care utilization</td>
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<td>44</td>
<td></td>
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<tr>
<td>Attended pulmonary rehab</td>
<td>63</td>
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<td>0.185</td>
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<tr>
<td>Education at home oxygen</td>
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<td></td>
<td></td>
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<td>0.000</td>
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<tr>
<td>Oxygen delivery personnel</td>
<td>64</td>
<td>51</td>
<td>49</td>
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<td></td>
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<tr>
<td>Healthcare personnel</td>
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<td>43</td>
<td>57</td>
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<tr>
<td>None</td>
<td>10</td>
<td>64</td>
<td>36</td>
<td></td>
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<td></td>
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<tr>
<td>Age, mean (SD)</td>
<td>67 (9)</td>
<td>66 (11)</td>
<td>60 (13)</td>
<td>61(9)</td>
<td>55 (11)</td>
<td>62(12)</td>
<td>&lt;0.001</td>
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<td>Female sex</td>
<td>533 (72)</td>
<td>11 (61)*</td>
<td>300 (88)*</td>
<td>95 (61)*</td>
<td>69 (100)*</td>
<td>67 (72)</td>
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<tr>
<td>Residence</td>
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<td></td>
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<tr>
<td>Suburban</td>
<td>360 (49)</td>
<td>278 (55)</td>
<td>178 (52)</td>
<td>76 (49)</td>
<td>38 (56)</td>
<td>44 (48)</td>
<td></td>
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<tr>
<td>Rural</td>
<td>225 (30)</td>
<td>122 (24)</td>
<td>89 (26)</td>
<td>54 (35)*</td>
<td>15 (22)</td>
<td>15 (17)*</td>
<td></td>
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<tr>
<td>Urban</td>
<td>152 (21)</td>
<td>103 (21)</td>
<td>75 (22)</td>
<td>24 (16)*</td>
<td>15 (22)</td>
<td>32 (35)</td>
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<tr>
<td>Duration of oxygen use</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>&lt; 1 yr.</td>
<td>109 (15)</td>
<td>119 (24)</td>
<td>45 (14)</td>
<td>7 (5)</td>
<td>10 (15)</td>
<td>16 (19)</td>
<td></td>
</tr>
<tr>
<td>1-5 yrs.</td>
<td>352 (48)</td>
<td>287 (59)</td>
<td>177 (54)</td>
<td>58 (40)*</td>
<td>32 (48)</td>
<td>40 (47)</td>
<td></td>
</tr>
<tr>
<td>&gt; 5 yrs.</td>
<td>266 (37)</td>
<td>83 (17)*</td>
<td>106 (32)</td>
<td>80 (55)*</td>
<td>25 (37)</td>
<td>29 (34)</td>
<td></td>
</tr>
<tr>
<td>Oxygen requirement</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Continuous (O2 required)</td>
<td>487(66)*</td>
<td>298 (56)</td>
<td>191 (56)</td>
<td>94 (60)</td>
<td>22 (40)*</td>
<td>49 (53)</td>
<td></td>
</tr>
<tr>
<td>≥ 5 LPM</td>
<td>133 (18)*</td>
<td>229 (47)*</td>
<td>103 (32)</td>
<td>48 (33)</td>
<td>29 (44)*</td>
<td>27 (33)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
% Respondents Reporting Oxygen Problems by Diagnosis (n=887)

Coverage Outside of the Home

Actual vs Desired Hours That Portable Oxygen Lasts
Categories of Issues

What types of oxygen problems do you have? (n=899)

(Able to select more than one choice)

<table>
<thead>
<tr>
<th>Issue</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equipment Not Working</td>
<td>288</td>
</tr>
<tr>
<td>Travel oxygen problems</td>
<td>267</td>
</tr>
<tr>
<td>Delivery Problems</td>
<td>260</td>
</tr>
<tr>
<td>Lack of portables I can manage</td>
<td>220</td>
</tr>
<tr>
<td>Lack of high flow portable systems</td>
<td>219</td>
</tr>
<tr>
<td>Not enough tanks for activity outside home</td>
<td>201</td>
</tr>
<tr>
<td>Can’t change companies</td>
<td>177</td>
</tr>
<tr>
<td>Company does not respond to calls</td>
<td>169</td>
</tr>
<tr>
<td>Incorrect or delayed MD orders</td>
<td>166</td>
</tr>
<tr>
<td>Can’t mix systems</td>
<td>123</td>
</tr>
<tr>
<td>Need or used to use liquid and can’t get</td>
<td>86</td>
</tr>
<tr>
<td>Bills not explained</td>
<td>8</td>
</tr>
<tr>
<td>Not enough portables so I can work</td>
<td>40</td>
</tr>
</tbody>
</table>

Average # problems per respondent = 3.5

II. Patient –Reported Data

- Equipment, access and worry about running short of oxygen: Key concerns in the ATS patient supplemental oxygen survey.

  - “Not being able to change oxygen suppliers, not being able to get a POC with the company I have, having all sorts of problems with the supplier for the past 2 yrs. and being stuck with them. My life is just existence at home right now, with no hope of change for at least 3 yrs. and I hate it”

Lindell et al Heart Lung 2018
II. Patient –Reported Data

Perspectives From COPD Subjects on Portable Long-Term Oxygen Therapy Devices
Hejab J AlMutairi MSc RRT RRT-ACCS RRT-NPS, Constance C Musa PhD RRT RRT-NPS, Clement CM Lambert PhD, David L. Vines MHS RRT FAARC, and Shawna L. Strickland PhD RRT RRT-NPS RRT-ACCS AE-C FAARC

CONCLUSIONS:
“Oxygen-dependent individuals with COPD may be at risk of adverse outcomes associated with decreased mobility encouraged by unsatisfactory physical and technical characteristics of portable oxygen cylinders and concentrators.”

Almutairi et al Respiratory Care 2018

Case Study

• 68 year old woman with RA-related ILD is here for her first evaluation. Over that past 6 mo. she notes increasing DOE with stairs, ADLs, and some dry cough. FVC = 68%, DLCO 48%, 6MW resting RA sat = 95%, nadir exercise RA sat = 87%. In your discussion with the patient about the pros and cons of oxygen, you tell her:
  A. She needs oxygen because it will alleviate all of her breathlessness
  B. If she uses oxygen with exertion it will prolong her survival
  C. Oxygen with exertion may improve her quality of life by increasing her mobility and lessening her DOE
  D. She should purchase a small POC as advertised in the newspapers as it should meet her future oxygen needs
III. Multidisciplinary Consensus on Optimal Oxygen Therapy

**AMERICAN THORACIC SOCIETY DOCUMENTS**

**Optimizing Home Oxygen Therapy**
An Official American Thoracic Society Workshop Report


*This official workshop report was approved by the American Thoracic Society, October 2018*
III. Multidisciplinary Consensus on Optimal Oxygen Therapy

- May 2017
  - ATS full day workshop “Optimizing Home Oxygen Therapy”, 28 panelists to define optimal oxygen therapy, identify barriers to its achievement, and propose strategies
  - ATS, COPD, PH, PF, Alpha 1, LAM foundations, ALA, MDs, Nurses, Pts, NIH, FDA, DME, CMS

Recommendations from Patients’ Perspective (partial list):
1. Incorporate patient preference as to whether they want to use supplemental oxygen
2. Revise instruction to “titrate as they migrate” (home oximetry for self-titration)
3. Provide every patient with a:
   - “Bill of Rights” for supplemental oxygen users (CMS has one)
   - Clear, effective, and user-friendly written process for reporting unresolved oxygen problems to CMS
   - “FAQ” sheet, “Oxygen Start Sheet”
   - “YouTube”-type video instruction
   - “Oxygen Action Plan”—part of global assessment
4. Establish a national consumer mechanism to access clinician and patient feedback on all DMEs; have these data available to patients, clinicians, and CMS.
5. Emphasize potential role of DMEs/RCPs in keeping patients out of the hospital
6. Establish mandated, minimum required patient oxygen educational content and provide through novel approaches in clinics, pulmonary rehabilitation programs, and online programs
Getting the Message to Capitol Hill

• June 2017: LAMposium and Rare Lung Disease Consortium meeting
  • 40 meetings with senators and representatives by pts. and HCPs
  • I talked about oxygen issues with Anna Eshoo, Diane Feinstein’s MD rep, and met Nancy Pelosi for about 60 seconds

GOAL: Take the ‘Home’ out of Home Oxygen
IV. Summary

- The survival benefit of oxygen use for severe COPD patients is documented, but is unknown in other populations.
- Study results for exercise, dyspnea and QOL benefits from oxygen are varied and differ across populations.
- Patient-reported data reflects frustration and dissatisfaction with oxygen equipment, services, and its negative effect on mobility and travel.
- Multidisciplinary consensus confirms problems from all stakeholders.
- ATS Clinical Practice Guidelines “Supplemental Oxygen for Adults with Chronic Lung Disease” are underway (Co-Chairs Jacobs, Lederer, Krishna, Holland).

Thank you!
Optimizing MD / Patient / DME O₂ Interface

Chris Garvey FNP, MSN, MPA, MAACVPR
Nurse Practitioner, UCSF Pulmonary Rehabilitation, Sleep Disorders, Division of Pulmonary Medicine

Disclosures

Boehringer Ingelheim –
Speakers Bureau
Will not influence presentation

Thanks to Sally McLaughlin for sharing slides
MD / patient / DME / O₂ Interface

- **Tools**
  - CMS requirements for O₂ Rx
- **Communication**
  - Patient, caregiver, DME, clinical team
- **Equipment**
- **Resources**

Dante’s Home Oxygen Hell

- Qualify for O₂
- MD face to face visit
- DME
- Heavy equipment
- Can’t work
- Can’t leave home
- Can’t exercise
Barriers and Challenges

• DME / clinician / patient
  ▪ Limited access –
    ▪ RT, competent staff, customer service, communication
  ▪ Disconnect: CMS policies vs. medical necessity vs. reality
  ▪ Clinician burden: patient blames MD

• Equipment often doesn’t meet patient needs:
  ▪ Safe ambulation / portability / flow rate
  ▪ LOX, POCs, high flow, TTO, newer technology absent

• Patient knowledge gap, challenges
  – Clinical needs, proper use, problem solving, rights
  – Frail, ill
  – Work force, young, parents, VA caught in CMS rules

Complete O₂ Rx, Documentation

O₂ testing:
RA SpO₂ @ Rest: ___ if > 88%:
RA SpO₂ with exertion: ___ < 88%
SpO₂ ___ with exertion: ___ lpm O₂;
Demonstrates improvement

• If > 4 lpm: SpO₂ on ≥ 4 lpm – must be < 88%

• F2F & testing within 30 days prior to set up
• Rx: LPM
• Route: NC, mask
• System: M6, POC, E cylinder, OCD, etc.
• Frequency: rest, ambulation, sleep
• Pulmonary dx: hypoxia-related Dx or severe lung disease
Nocturnal O₂ Requirements

• Sleep study or nocturnal oximetry (ONO)
• ≥ 2 hours, SpO₂ <88% >5 minutes during sleep
• ONO: Pulmonary diagnosis: COPD, ILD, etc.

Getting the Most out of DMEs

• Contact DME representative or +/or branch manager for O₂ Rx questions
• For suboptimal service, call local DMEs to discuss, meet, agree on expectations,
  – Provide direct contact for challenges
  – Resources for patient re: expressing concerns to CMS / Insurance
  – 1-800-MEDICARE
Clinical Effectiveness

- Assessment / management
  - Equipment – assess patient walking with own ambulatory O₂
  - Use / adherence
  - Safety
    - Titrate to migrate – Oximeter use; parameters
    - Assure valid and reliable signal from oximeter

When do I need oxygen? *Whenever you fall below 88%*

How much do I need? *Whatever flow keeps you 88% or more with any activity – at rest, with activity, at altitude*

Stationary Concentrators / Home-fill
### Duration – Compressed Gas Tanks (hrs)

<table>
<thead>
<tr>
<th>LPM flow rate</th>
<th>2</th>
<th>4</th>
<th>6</th>
<th>10</th>
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</thead>
<tbody>
<tr>
<td><strong>M6 continuous flow</strong></td>
<td></td>
<td>1.4</td>
<td></td>
<td></td>
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<tr>
<td><strong>M6 tank with OCD</strong></td>
<td>4</td>
<td>2</td>
<td>1.4</td>
<td></td>
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<tr>
<td><strong>E tank continuous</strong></td>
<td>5</td>
<td>3</td>
<td>1.75</td>
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High Flow

A Few Words About POCs

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<th>BAD</th>
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<td>Convenient</td>
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</tr>
<tr>
<td>Can take on airplanes</td>
<td>Not high flow</td>
</tr>
<tr>
<td>Decrease stigma</td>
<td>No standardization</td>
</tr>
<tr>
<td>Keep people active</td>
<td>Don’t adapt to &gt; O₂ needs</td>
</tr>
</tbody>
</table>
Carts and Backpacks

[Images of various carts and backpacks]

[Image of a person riding a motorcycle with medical equipment]
Evidence Gaps, Future Investigation

• Need DME mandated quality reports / surveys
  — Concerns, malfunction, incorrect equipment
  — Does system matches order?
  — Patient satisfaction
• Clinicians - CMS interface
• Improved evidence base, payment policy
• Reimbursement for RCPs in the home
• Standardized electronic CMN, O₂ Rx

Evidence Gaps, Future Investigation

• O₂ recertification –
  — Could save $$$, improve processes, outcomes
• CMS pays DME for non-use of O₂
  — CPAP follow up within 90 days vs. annual for O₂
  • Reassessment, monitor, address adherence for coverage
  • Improved adherence – patient engagement
Resources

DME / CMS
- 1-800-MEDICARE
- Insurance ombudsman, customer relations
- CB Implementation Contractor (CBIC) 1-877-577-5331
- DME Supplier Directory www.medicare.gov/supplier

Patients
- Pulmonary Fibrosis Foundation pulmonaryfibrosis.org
  - O₂ Info Line 844-825-5733
  - O₂ webinar, PFF Voices
- COPD Foundation copdfoundation.org
- O₂ and Travel
  - Aeromedic.com
  - Oxygentogo.com
  - travelo2.com

Thank you!
**Resource: Rx Requirements / Diagnosis**

<table>
<thead>
<tr>
<th>Rx requirements</th>
<th>Diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Patient’s name</td>
<td>• Severe lung disease or hypoxia-related symptoms expected to improve with O₂</td>
</tr>
<tr>
<td>• Item ordered</td>
<td>• Cause of hypoxemia; chronic/ not acute</td>
</tr>
<tr>
<td>• <strong>Prescriber’s: name, NPI, signature, date</strong></td>
<td>• O₂ not for short-term / acute conditions e.g., PNA</td>
</tr>
<tr>
<td>• Order date (if different)</td>
<td>• See Oxygen LCD</td>
</tr>
<tr>
<td>• Dosage or concentration</td>
<td></td>
</tr>
<tr>
<td>• Route (i.e., nasal cannula)</td>
<td></td>
</tr>
<tr>
<td>• Frequency of use</td>
<td></td>
</tr>
<tr>
<td>• Length of Need</td>
<td></td>
</tr>
<tr>
<td>• Hospital DC Rx, test ≤ 2 days before DC</td>
<td></td>
</tr>
<tr>
<td>• CMN</td>
<td></td>
</tr>
</tbody>
</table>

**Write a complete Rx & document**

- *Specific* equipment – M6, oxygen conserving device, POC, stationary concentrator
- Liter flow – continuous or with activity
- Delivery - nasal cannula, oxymizer, mask, etc.
- Continuous or with activity, sleep, altitude
- “Please have RT titrate flow to keep sat ≥ 90%”
- Any special equipment: cart, high flow concentrator
- Diagnosis and ICD-10
- Signature, date, NPI
- Clinic notes showing face-to-face visit and stating need for oxygen
Sample O₂ Rx:

✓ Please supply M6 tanks with oxygen conserving device (POC, etc) to be worn at 4 lpm with activity via nasal cannula (see 3 part walk test)
✓ Titrate flow to keep saturation >88% with activity.
✓ Stationary concentrator for home use
✓ Please also supply backpack (or cart, etc)
✓ DX: Interstitial lung disease J84.890
✓ Signature, date, NPI

✓ Please supply e-tanks to be worn at 8 lpm continuous via oxymizer pendant cannula.
✓ Titrate flow to keep saturation > 88% at all times
✓ High flow stationary concentrator for home use, with humidifier
✓ Please also supply 4-tank cart
✓ DX: Interstitial lung disease J84.890
✓ Signature, date, NPI

Documentation

F2F by MD, NP, PA within 30 days prior to prescribing O₂ must include:
✓ Evaluation of pt
✓ Needs assessment
✓ Treatment
✓ Relevant diagnosis
✓ Medical record must support need for oxygen

Sample documentation to include in visit note:
Three-part walk test was performed today in clinic during visit. Saturation as follows:
Resting room air – 93%
Walking room air – 84%
Walking on O₂ at 2 LPM – 87%
Walking on O₂ at 4 LPM – 90%
Pt requires supplemental oxygen at 4 lpm with activity
Competitive Bidding and its Toll on Oxygen

Phil Porte
Executive Director
NAMDRC

Disclosures

• Consulting Agreement with Philips/Respironics

• No Effect on this Presentation
Competitive Bidding

• Numerous Ways to Look at Competitive Bidding
  – Historical Perspective
  – Financial Perspective
  – Medicare Beneficiary Perspective
    • Quality of Care
    • Access to Care
    • Cost of Care

Historical Perspective

• “Throw Away” one sentence comment in Inspector General report nearly 20 years ago.
• Durable Medical Equipment (DME) benefit fraught with abuses in 1990s/early 2000s.
• Provision in authorizing statute requires that any competitively bid item lead to substantial savings.
• Pilot studies led to Congressional action
• NAMDRC and sister societies strongly urged DME community to okay a push for pulmonary (oxygen, CPAP, ventilator) exemptions but were rebuffed.
Financial Perspectives

- Difficult to overstate Congressional animosity toward broad DME community in late 1990s, early 2000s. Politically ripe for picking.
- Archaic statutory language for oxygen payment was not reflective of 21st century technologies
  - Lightweight liquid oxygen – Helios and others
  - Portable oxygen concentrators
  - Transfil systems
- The business model was shifting to a non delivery model of service
- CMS has no statutory authority to pay for RT services

Beneficiary Cost/Access

- CMS’ #1 argument for competitive bidding: With lower prices, beneficiary co-pays go down, so cost savings passed on to patients.
- CMS refused to take “snapshot” of access PRIOR to competitive bidding; therefore, a bit disingenuous to indicate no access problems after competitive bidding is implemented.
Actual Structure of Competitive Bidding

• DMEs bid on a particular category i.e. oxygen, walkers, etc. and identify their capacity to serve in competitively bid region
• Bids ranked on pricing, with corollary of capacity. Once capacity, as estimated by CMS data, is met, median price determined.
• Half are under, half are over final price.
• Unlike E-Bay, winning bidders are NOT obligated to participate, so pricing can be skewed.
• Some DMEs would, in effect, sell their winning contracts.

Impact on Oxygen

• Classic case of “circular firing squad.”
• With non delivery model taking hold, pricing drops as companies save $$ on high cost of actual delivery of O2.
• Beginning almost immediately, delivery of liquid declines even though competitive bidding contracts require contractors to provide it when requested.
• Remember, basic payment structure for oxygen based on 1980s technology i.e. quantity and flow rate.
Impact on Liquid O2 a Great Illustration

<table>
<thead>
<tr>
<th>YEAR</th>
<th>CHARGES</th>
<th>CLAIMS</th>
<th>PATIENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004</td>
<td>$153,508,470</td>
<td>737,321</td>
<td>61,443</td>
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<tr>
<td>2005</td>
<td>$143,814,414</td>
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<td>2006</td>
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<td>56,911</td>
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<td>2007</td>
<td>$130,285,460</td>
<td>653,005</td>
<td>54,286</td>
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<tr>
<td>2008</td>
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<tr>
<td>2009</td>
<td></td>
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<tr>
<td>2010</td>
<td>$67,355,848</td>
<td>386,645</td>
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<tr>
<td>2011</td>
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<tr>
<td>2013</td>
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<tr>
<td>2014</td>
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<td>136,656</td>
<td>11,388</td>
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<tr>
<td>2015</td>
<td>$10,829,115</td>
<td>99,252</td>
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<tr>
<td>2016</td>
<td>$7,482,476</td>
<td>71,377</td>
<td>5,948</td>
</tr>
</tbody>
</table>

Portable Liquid More Problematic

<table>
<thead>
<tr>
<th>YEAR</th>
<th>CHARGES</th>
<th>CLAIMS</th>
<th>PATIENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004</td>
<td>$33,337,087</td>
<td>966,846</td>
<td>80,571</td>
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<tr>
<td>2005</td>
<td>$32,000,258</td>
<td>990,322</td>
<td>82,527</td>
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<tr>
<td>2006</td>
<td>$30,993,007</td>
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<td>81,438</td>
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<tr>
<td>2007</td>
<td>$29,158,453</td>
<td>917,702</td>
<td>75,933</td>
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<td>2008</td>
<td>$28,199,074</td>
<td>887,309</td>
<td>73,942</td>
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<tr>
<td>2009</td>
<td>$15,756,604</td>
<td>547,900</td>
<td>45,658</td>
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<tr>
<td>2010</td>
<td>$14,127,684</td>
<td>491,253</td>
<td>40,938</td>
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<td>2011</td>
<td>$12,439,576</td>
<td>442,027</td>
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<tr>
<td>2012</td>
<td>$9,728,130</td>
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<td>2013</td>
<td>$6,814,689</td>
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<td>2014</td>
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<td>173,161</td>
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<td>2015</td>
<td>$2,455,215</td>
<td>128,727</td>
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</tr>
<tr>
<td>2016</td>
<td>$2,020,306</td>
<td>97,690</td>
<td>8,141</td>
</tr>
</tbody>
</table>
Easy Rhetorical Questions

• Has patient population needing liquid actually changed?
• Are suppliers adhering to their contractual obligations?
• Have physicians pushed hard for their patients?
• Have patients been sold a bill of goods regarding liquid?

Audience Response Question 1

• Yes or No – I have tried to secure a liquid system for my patients but have been rebuffed in that effort within the past two years.
Question 1 (Porte) - Yes or No – I have tried to secure a liquid system for my patients but have been rebuffed in that effort within the past two years.

A. Yes
B. No

Audience Response Question 2

• Yes or No – I feel comfortable choosing between different oxygen modalities when selecting a device for my patients (compressed gas via e-cylinder, stationary & portable concentrators, liquid, etc).
Competitive Bidding – Home Mechanical Ventilators

• Is there any reason to believe that the liquid 02 experience will be any different from HMV if/when CMS includes these devices?

• Remember the words of astronaut John Glenn:
  
  *Do you have any idea what it is like to sit on the very top of a rocket built by the lowest bidder?*
2019-2020

- CMS recognizes structural problems, suspends bidding process until 2021.
- That actually translates to spring/early summer of 2020 to accommodate rulemaking
- Any willing provider can participate, at 2018 competitive bidding rates
- No contractual requirements, so previous suppliers of liquid can drop the service.

The Prognosis

- There is every indication that CMS will not do the “right thing” on oxygen or home mechanical ventilation
  - $$$ involved; CMS personalities involved
- Therefore, only genuine solution is legislative:
  - Revamp entire oxygen benefit
  - Preclude inclusion of HMV in competitive bidding
- BIGGEST CHALLENGE – GRASS ROOTS
  - “Why haven’t I heard from my constituents about this?”