CALIFORNIA THORACIC SOCIETY
NORTHERN CALIFORNIA
ANNUAL EDUCATIONAL CONFERENCE

FRIDAY, JANUARY 17, 2020

OXYGEN THERAPY, COPD UPDATES,
AND ETHICS

REGISTRATION/EXHIBITS

Friday, January 17, 2020 – 7:00 a.m. – 8:00 a.m.
CTS Northern California Annual Educational Conference

PROGRAM SCHEDULE - FRIDAY, JANUARY 17, 2020

Oxygen Therapy, COPD Updates, and Ethics

7:00 am – 8:00 am
Registration, Exhibits and Breakfast

8:00 am – 8:15 am
Welcome and Introductions; Pre-Test
George Su, MD

8:15 am – 9:00 am
High Flow Oxygen for ARDS
KEYNOTE SPEAKER: Nicholas Hill, MD

9:00 am – 9:40 am
Navigating the DME World to Get Oxygen for your Patients
Michelle Cao, DO

9:40 am – 10:00 am
BREAK / EXHIBIT HALL OPEN

10:00 am – 10:40 am
What Are the Options: Unraveling the Myths and Mysteries of Oxygen Supply Systems (Including Oxygen Conserving Devices)
Trina M. Limberg, BS, RRT, MPA, MAACVPR

10:40 am – 11:20 am
Complications When Patient’s Oxygen Needs Are Not Met
Kimberly Langner, RRT-ACCS, RCP

11:20 am – 12:30 pm
Hands-On Session/Case Based Discussion: High-Flow Oxygen, Portable Oxygen Concentrators, Noninvasive Open Ventilation System
Gaurav Singh, MD; Anna Breiburg, NP; Kimberly Langner, RRT-ACCS, RCP; Susan Metcalfe, RCP, RRT; Justin Phillips, RCT, RRT-ACCS; Chris Garvey, FNP, MSN, MPA, MAACVPR; Trina M. Limberg, BS, RRT, FAARC, MAACVPR

12:30 pm – 1:30 pm
LUNCH / EXHIBIT HALL OPEN

1:30 pm – 2:10 pm
Updates on COPD: From Triple Therapy to Rehab
Brooks Kuhn, MD

2:10 pm – 2:50 pm
Advances in Interventional Pulmonology: Endobronchial Valve Therapy for Emphysema
Arthur Sung, MD

2:50 pm – 3:30 pm
Ambulatory Ventilatory Support in COPD
Gaurav Singh, MD

3:30 pm – 3:55 pm
BREAK / EXHIBIT HALL OPEN

3:55 pm – 4:35 pm
Ethics and Medically Inappropriate Therapies
David Chooljian, MD

4:35 pm – 5:15 pm
Updates to End of Life Care from California Law
Stephanie M. Harman, MD

5:15 pm - 5:20 pm
Adjourn and Post Test
George Su, MD

5:30 pm – 6:30 pm
Poster Competition

6:30 pm – 8:00 pm
Post Friday Program Special Event – Non-CME Special Fellows’ Reception: Career Prospecting and Opportunities – The Future
Welcome and Introductions

Pre-Test

George Su, MD
UC San Francisco
Associate Professor of Medicine

Friday, January 17, 2020 – 8:00 a.m. – 8:15 a.m.

George Su, MD is Associate Professor of Medicine in the University of California, San Francisco (UCSF) School of Medicine with a primary appointment in the Division of Pulmonary and Critical Care Medicine (PCCM) at Zuckerberg San Francisco General Hospital (ZSFG). I am a life-long Californian (since kindergarten) and include bulk collegiate and professional training through the University of California (UC) as part of my wonderful California journey. I serve ZSFG as PCCM faculty, Medical Director of Sleep and our Asthma/COPD Program, and serve the San Francisco Department of Public Health (SFDPH) and its clinical arm, the San Francisco Health Network (SFHN), as a specialty care informaticist in the Office of Health Informatics (OHI) and as Medical Director of Telehealth. My research interests have seen quantum evolution from basic mechanisms of endothelial cell-cell interactions and cytoskeletal dynamics to now, technology innovation for underserved populations. I am a champion for quality improvement at both local and national levels, including service to the American Thoracic Society (ATS) as a member of its Quality Improvement and Implementation Committee (QIIC). And, I consider medical education as elemental to my UCSF and overall professional identity, and as such, am proud of my service to the California Thoracic Society (CTS), as co-chair of our CTS Multidisciplinary Conference Committee over the past three years. I, Lisa, and our three children live humbly in the Richmond District “dunes” of San Francisco.
HIGH FLOW OXYGEN FOR ARDS

KEYNOTE SPEAKER

Nicholas S. Hill, MD
Tufts Medical Center in Boston
Chief of the Division of Pulmonary, Critical Care and Sleep Medicine

Friday, January 17, 2020 – 8:15 a.m. – 9:00 a.m.

NICHOLAS S. HILL, MD is Chief of the Division of Pulmonary, Critical Care and Sleep Medicine at Tufts Medical Center in Boston and Professor of Medicine at Tufts University School of Medicine. He received his M.D. from Dartmouth Medical School in 1975. He did his internship and residency in Medicine at Tufts-New England Medical Center. He did a fellowship in Cardiovascular Medicine at the University of Massachusetts Medical Center and in Pulmonary Medicine at Boston University School of Medicine. He is Board Certified in Internal Medicine, Pulmonary Diseases, and Critical Care Medicine. He has done extensive research and writing in the fields of noninvasive ventilation and pulmonary hypertension dating back over 35 years. He has edited several books related to these topics. He established the Pulmonary Hypertension Center at Tufts Medical Center. He is a Past President of the American Thoracic Society and has received a Distinguished Scholar Award in Critical Care from the Chest Foundation of the American College of Chest Physicians as well an Award for Excellence in Pulmonary Hypertension Care from the Pulmonary Hypertension Association.
Nasal High Flow for ARDS

Nicholas S Hill MD
Tufts Medical Center
Boston, MA

Disclosures

• Research Grants
  – Fisher Paykel
• Advisory Board
  – Alung technologies
  – Fisher Paykel
• Consultant
  – Respironincs
Outline

• Technical Considerations
• Physiologic effects
• Compare and contrast with NIV
• Evidence for Use in ARDS
• Use during NIV breaks c/w Standard oxygen
• Practical Considerations

Technical Aspects

<table>
<thead>
<tr>
<th></th>
<th>NIV</th>
<th>NHF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heat</td>
<td>Variable</td>
<td>31-34°C</td>
</tr>
<tr>
<td>Humidity</td>
<td>Variable</td>
<td>Saturated</td>
</tr>
<tr>
<td>Pressure</td>
<td>Pre-set insp and Exp</td>
<td>Variable</td>
</tr>
<tr>
<td>Flow</td>
<td>Variable</td>
<td>Continuous (20-60 L/min)</td>
</tr>
<tr>
<td>Circuit</td>
<td>Single or Double</td>
<td>Single-heated</td>
</tr>
<tr>
<td>Oxygen</td>
<td>Bled-in or blender</td>
<td>Blender (0.21-1.0)</td>
</tr>
</tbody>
</table>
Physiologic Rationale for NIV in COPD: Effect of Pressure Support plus PEEP

- CPAP:
  - Increased FRC
  - Re-expands flooded alveoli
  - Improved oxygenation
  - Increased compliance
  - Afterload reduction - ↑ cardiac function

- Pressure Support:
  - Further reduction in work

Appendini et al, AJRCCM 1994
Main Indications for Acute Noninvasive Ventilation (NIV)

Strong evidence (Level A)
Acute hypercapnic RF (COPD)
Cardiogenic pulmonary edema
ARF in immunocompromised

NIV for Hypoxemic Resp Failure

<table>
<thead>
<tr>
<th>PaO2/FIO2</th>
<th>131</th>
<th>184</th>
<th>206</th>
<th>153*</th>
<th>169</th>
</tr>
</thead>
</table>

Adjust Effect

↑ PEEP  ↑ O2
↑ PSV  ↓ WOB
↑ PSV  ↓ DYSPNEA

L’ Her et al AJRCCM 2005; 172:1112
NIV as “First Line” Therapy in ARDS

• 147 pts eligible of 479 (332 intubated), had dyspnea, RR > 30 and ≤ 2 new organ failures
• 54% avoided intubation –
  VAP rate 2 vs 20%, mortality 6 vs 53%
• Success more likely if SAPS II ≤ 34 and PaO2/FIO2 > 175 p 1st hr of NIV therapy

Lung Safe Study on ARDS

• International observational study of 2813 patients with ARDS 18% of whom used NIV
• NIV failure 22.2% in mild, 42.3% in moderate and 47.1% in severe ARDS
• Mortality 16.1% in NIV success, 45.4% in NIV failure
• In propensity matched analysis on P/F>150, mortality higher with NIV (36%) than IMV (25%)

Bellani G et al, AJRCCM 2017
De novo ARF-ERS/ATS Guideline
(Rochwerg B et al, ERJ 2017)

Recommendation
Given the uncertainty of evidence we are unable to offer a recommendation on the use of NIV for de novo ARF.

Allowance
A trial of NIV might be offered to a pt with hypox RF, CAP or early ARDS by .......an experienced team to a carefully selected pt (no contraindications), closely monitored in an ICU, reassessed [frequently] and intubated promptly if no improvement.
Why is NIV so challenging for ARDS/Severe Hypoxemic RF?

- Severe oxygenation defect – more PEEP, more leak, desaturation if mask “falls” off
- High minute volumes, tachypnea – harder to meet demands, synchronize
- Stiff lungs – Higher insp pressure, more leak, less comfort
- Sick patients – sepsis, secretions, MODS, deteriorating
- Prolonged respiratory failure

NHF: Heat and Humidification

- Enhances comfort and tolerance compared to traditional “high flow” oxygen or NIV
- Interface loose fitting and compact
- Permits unimpeded speaking and eating
NHF: Physiologic Effects

- Secretion hydration, preserves mucociliary fxn
- Effective oxygenator
  - Keeps up with insp flow rate
  - Flushes nasopharynx
- Improves ventilatory efficiency by ↓ dead space
- Decreases resp rate, ↓ work of breathing/min
- Positive end expiratory pressure
  - ↑ end expiratory lung volume

Flushing out nasopharyngeal dead space

Muller W, Tatkov S et al, JAP 2015
Reduced Work of Breathing:
WOB/min = RR \times (Pr \times Vol)/breath

Roca O et al, Respir Care 2010

Positive End Expiratory Pressure with NHF

Corley A et al, Brit J Anaesth 2011
The Case of Mr B

- 74 yo former professional hockey goalie visiting family from his horse farm in TN.
- History of radical neck surgery, XRT for squamous cell CA of tongue; chronic aspiration
- Now presents with fever, cough, SOB.
- In ED, RR 38, O2 sat 51%, using access muscles, diffuse crackles posterior, Rt > Lt
- On 100% NRB, RR lo 30s, O2 sat 84%
You Would:

- Add standard nasal prongs at 6 l/min to 100% NRB
- Place on CPAP
- Place on BPAP (NIV)
- Place on NHF
- Intubate
- Transfer to another institution in a hurry
What about HFNO for AHRF?

RCT of NHF v NIV v SO

- P/F ≤ 300, RR > 25, No PaCO2 > 45, no CRF
- 2506 pts with AHRF screened – 313 enrolled
- Baseline RR 33/min, P/F 155, 75-80% PNA
- NRB ≥ 10 l/min, NHF 50 l/min, FIO2 1.0 (actual 82 %), NIV VT 7-10 ml/kg (actual PS 8, PEEP 5, FIO2 67%), 8 hrs daily X 2d

Frat J-P et al, NEJM 2015

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RCT of NHF v NIV v SO in AHRF

<table>
<thead>
<tr>
<th></th>
<th>HFNO</th>
<th>SO</th>
<th>NIV</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>106</td>
<td>94</td>
<td>110</td>
</tr>
<tr>
<td>Intubation (%)</td>
<td>38</td>
<td>47</td>
<td>50</td>
</tr>
<tr>
<td>Intub P/F &lt; 200</td>
<td>35*</td>
<td>53</td>
<td>58</td>
</tr>
<tr>
<td>Vent free days</td>
<td>24*</td>
<td>21</td>
<td>18</td>
</tr>
<tr>
<td>Death ICU (%)</td>
<td>11*</td>
<td>19</td>
<td>25</td>
</tr>
<tr>
<td>Death 90d (%)</td>
<td>30*</td>
<td>45</td>
<td>49</td>
</tr>
</tbody>
</table>

* P<0.05

Frat J-P et al, NEJM 2015
RCT of NHF v NIV v SO in AHRF

- HFNO   SO   NIV
n 106   94   110
Intubation (%) 38   47   50
Intub P/F < 200 35*  53   58
Vent free days 24*  21   18
Death ICU (%) 11*  19   25
Death 90d (%) 30*  45   49
* P<0.05

Frat J-P et al, NEJM 2015

Outcomes for NIV even worse in a post-hoc subgroup analysis of immunocompromised patients with hypoxic ARF
Concerns re Frat Study

• Major outcome not statistically significant
• Actually 16hrs NHF, 8 hrs NIV for 1st 2 days
• Explanation for mortality difference?
  – Average VT 9.2 ml/kg during NIV (targeted)
  – More refractory shock in NIV group (6% v 17%)
• Impossible to blind
• Needs to be replicated

RCT Post Cardiac Surgery

(Pts with failed SBT or Failed extubation)

<table>
<thead>
<tr>
<th></th>
<th>NHF</th>
<th>BiPAP</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>414</td>
<td>416</td>
</tr>
<tr>
<td>Settings (l/min; cm H2O)</td>
<td>46.7</td>
<td>9.3/4.2(VT 7.2)</td>
</tr>
<tr>
<td>RR</td>
<td>26.7</td>
<td>29.7</td>
</tr>
<tr>
<td>Reintub (%)</td>
<td>14.0</td>
<td>13.7</td>
</tr>
<tr>
<td>Crossovers (%)</td>
<td>10.8</td>
<td>7.9</td>
</tr>
<tr>
<td>PaO2/FIO2</td>
<td>157</td>
<td>187*</td>
</tr>
<tr>
<td>Hrs /day</td>
<td>20</td>
<td>6.5*</td>
</tr>
</tbody>
</table>

Stephan F et al, JAMA 2015
What about Mr B?

- Placed on CPAP 10 in ED, O2 sats 92%, RR 30s
- Switched to HFNO, 50l/min 100% FIO2, O2 sat to 96%, RR hi 20s
- Weaned to 80%, 70% and 60% FIO2 next 4d
- Very comfortable and tolerated without difficulty
- Expectorated and cleared secretions well
- On day 5 FIO2 50%, 20l/min and converted to nasal prongs 6l/min
### Helmet for ARDS/Pneumonia

Consec pts placed on FFM for 8 hrs, then randomized, stopped early,

<table>
<thead>
<tr>
<th>Metric</th>
<th>Helmet (8/8)</th>
<th>FFM(5/11)</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>44</td>
<td>39</td>
</tr>
<tr>
<td>PaO2/FIO2</td>
<td>118</td>
<td>144</td>
</tr>
<tr>
<td>ETT (%)</td>
<td>18.2</td>
<td>61.5*</td>
</tr>
<tr>
<td>Resp Failure (%)</td>
<td>38</td>
<td>83*</td>
</tr>
<tr>
<td>Hosp LOS (days)</td>
<td>10.1</td>
<td>15.2</td>
</tr>
<tr>
<td>90d mortality (%)</td>
<td>34.1</td>
<td>56.4*</td>
</tr>
</tbody>
</table>

*P<0.05 Patel B et al, JAMA 2016

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### Helmet for ARDS

Patel B et al, JAMA 2016

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*Log-rank P=*
Helmet

Concerns re Helmet Study

• Very large reduction in intubations with helmet is hard to fathom
• 8 hr run-in period on FFM before randomization
• Different ventilators, different settings
• Single center, small numbers
• IMPOSSIBLE to blind
• Needs replication, c/w NHF
RCT of NHF during breaks from NIV

- Major outcome: Duration of NIV
- I/E Criteria: Patients treated with NIV for hypercapnic or hypoxemic resp failure, anticipated duration > 24 hrs, std NIV exclusions
- Unblinded, stopped early due to slow recruitment after 54 pts enrolled(of planned 70)
- NIV Vision or V60 6-8ml/kg, NHF F&P 850, 35 L/min Temp 37, FIO2 adjusted for O2sat > 92%

Spoletini G et al, JCC, 2019
Effect of NHF vs SO during breaks

**RR**

Dyspnea

Comfort

Spoletini G et al, JCC, 2019

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**RCT of NHF during breaks from NIV**

<table>
<thead>
<tr>
<th></th>
<th>NHF</th>
<th>SO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye Irritation</td>
<td>8%</td>
<td>22%*</td>
</tr>
<tr>
<td>Nasal Discomfort</td>
<td>2%</td>
<td>8%</td>
</tr>
<tr>
<td>Difficulty Breathing</td>
<td>13%</td>
<td>36%*</td>
</tr>
</tbody>
</table>

Spoletini G et al, JCC, 2019
HFNT: Practical Considerations

• What flow? Take advantage of high flow – dead space washout, greater effect on rate, higher PEEP
  • Start with 50l/min, adjust to comfort

• What heat? Some find 37° too hot, 34° may be preferable in those
  • Start with 37°, adjust to comfort

• What FIO2? Make sure flow is adequate first, then adjust FIO2.
  • Start at 100% if very hypoxic, lower if not

• Weaning – Lower FIO2 (50-60%), then lower flow (20-30L/min)

What role for Nasal High Flow?

Hypoxemic Respiratory Failure (ARDS/PNA)

SO₂ HFNO and/or NIV? Intubation ECMO
NAVIGATING THE DME WORLD TO GET OXYGEN FOR YOUR PATIENTS

Michelle Cao, DO
Stanford University School of Medicine
Clinical Associate Professor
Pulmonary, Critical Care, and Sleep Medicine
Division of Neuromuscular Medicine and Division of Sleep Medicine

Friday, January 17, 2020 – 8:15 a.m. – 9:00 a.m.

Michelle Cao, DO is a Clinical Associate Professor in the Division of Sleep Medicine and the Division of Neuromuscular Medicine, at the Stanford University School of Medicine. She is board certified in Pulmonary, Critical Care, and Sleep Medicine. She completed internal medicine residency at Loma Linda University in California, then went on to complete Pulmonary and Critical Care fellowship training at Harbor-UCLA Medical Center in Los Angeles, California. She then completed Sleep Medicine fellowship training at Stanford University. Her clinical expertise is in complex sleep-related respiratory disorders and home mechanical ventilation for chronic respiratory failure syndromes. Dr. Cao is the Director of the Adult Noninvasive Ventilation Program for the Neuromuscular Medicine Program at Stanford Health Care. She is actively engaged in training of house staff for Sleep Medicine fellowship and the Neuromuscular Medicine fellowship at Stanford University.
Navigating the DME World to Get Oxygen for Your Patients

Michelle Cao, DO
Pulmonary, Critical Care, Sleep Medicine
Stanford University

Disclosures

• None to disclose
OUTLINE

- Analyze current barriers to oxygen prescription practices
- Become familiar with CMS guidelines and criteria for home oxygen approval
- Apply guideline or evidence-based recommendations for home oxygen in specific disease conditions
- Become familiar with available oxygen delivery systems and advances in technology
- Formulate a systematic approach to home oxygen prescription

Indications for Home Oxygen Use

- Quality of life: allow patients to maintain ambulatory status
  - Work
  - Travel
  - Leisure
- Treatment
  - Hypoxemia
  - Symptoms of breathlessness
  - Exercise tolerance
- Survival
A Conceptual Model of Optimal Oxygen Therapy


Need to Know Your Stakeholders:
Components For a Successful Process in Obtaining Home Oxygen

**Functionality**
- **Define need**: ambulatory vs stationary

**Technology**
- **Define type** of oxygen that best fits patient’s medical condition and lifestyle

**Financial**
- **Know** your local coverage determination, third party payor criteria for approval

**Education**
- **Utilize** your local DME provider resource, provide education to patient/caregivers

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**CMS Competitive Bidding Program**

How does the initiative affect home oxygen therapy?

- Reductions in reimbursement
- Limited access to respiratory therapist
- Lack of patient education
- Lack of in-home assessments
What we are faced with:

- Lack of resources
- Third party payor stipulations
- Durable medical equipment (DME) vendor stipulations
- Lack of staff expertise
- Less availability of oxygen systems (portable, LOX)
- Accessibility to respiratory therapist

Despite above limitations, technological advances in oxygen systems continue to develop

Patient Perceptions of Adequacy of Supplemental Oxygen Therapy

- N=1926
- 44% reported limitations to activities outside of home due to inadequate systems
- Patients living in CBA reported more problems compared to those outside of CBA

OUTLINE

- Analyze current barriers to oxygen prescription practices
- Become familiar with CMS guidelines and criteria for home oxygen approval
- Apply guideline or evidence-based recommendations for home oxygen in specific disease conditions
- Become familiar with available oxygen delivery systems and advances in technology
- Formulate a systematic approach to home oxygen prescription

CMS Long Term Oxygen Qualification Criteria

**Continuous Oxygen**
- Oxygen use for at least 15 hours per day
- Resting room air PaO₂ < 55 mmHg or SaO₂ < 88%
- Resting PaO₂ of 56 - 59 mmHg or P pulmonale (ECG), dependent edema suggesting chronic heart failure or polycythemia > 56%
- Documentation justifying the prescription & a summary of conservative therapy that has failed

**Intermittent Oxygen** (flow rate & # hours per day must be specified)
- During exercise: PaO₂ < 55 mmHg or SaO₂ < 88%
- During sleep: PaO₂ < 55 mm Hg or SaO₂ < 88% with **evidence that PAP therapy has been tried and failed**, and evidence of of chronic lung / heart disease that would explain hypoxemia.

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<table>
<thead>
<tr>
<th>Group I</th>
<th>Group II</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PaO₂&lt;55 mmHg or SpO₂ &lt; 88%</strong></td>
<td><strong>PaO₂&lt;56-59 mmHg or SpO₂ &lt; 89%</strong></td>
</tr>
<tr>
<td><strong>Resting RA</strong></td>
<td><strong>Resting RA</strong></td>
</tr>
<tr>
<td>SpO₂&lt;88</td>
<td>SpO₂&lt;89</td>
</tr>
<tr>
<td><strong>With Exercise</strong></td>
<td><strong>With Exercise</strong></td>
</tr>
<tr>
<td>SpO₂&lt;88</td>
<td>SpO₂&lt;88</td>
</tr>
<tr>
<td>Must document:</td>
<td>Must document:</td>
</tr>
<tr>
<td>--At rest</td>
<td>--At rest</td>
</tr>
<tr>
<td>--With exercise</td>
<td>--With exercise</td>
</tr>
<tr>
<td>--Improvement with O₂ with exercise</td>
<td>--Improvement with O₂ with exercise</td>
</tr>
<tr>
<td><strong>Sleep</strong></td>
<td><strong>Sleep</strong></td>
</tr>
<tr>
<td>SpO₂&lt;88 for 5 cumulative minutes</td>
<td>SpO₂&lt;88 for 5 cumulative minutes</td>
</tr>
</tbody>
</table>

- Documented severe lung or heart disease
- Alternative options tried or considered and deemed ineffective
- Documented severe lung or heart disease
- Dependent edema suggesting heart failure
- Pulmonary Hypertension, Erythrocythemia
## CMS Oxygen Prescription Components

Three options for testing (testing must be within 2 days prior to discharge or, 30 days of initial outpatient testing)

- Resting on room air
- With activity/exertion
- With current oxygen use

Documentation of clinical face-to-face evaluation is required by a qualified medical provider [for inpatient must complete a Written Order Prior to Discharge (WOPD)]

### INITIAL REQUIREMENT for Submitting Prescription and Certificate of Medical Necessity (CMN)

<table>
<thead>
<tr>
<th>Submit Form...</th>
<th>Blood Gas Study Testing Requirements</th>
<th>Physician Visit Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. With the initial claim for home oxygen therapy, even if the patient was on oxygen therapy prior to Medicare eligibility or oxygen was initially covered by an HMO.</td>
<td>Provide most recent test results completed within 30 days prior to the Initial Date. An exception applies to the 30-day test requirement: provide the most recent qualifying test obtained while the patient was covered under the HMO.</td>
<td>The patient must be seen and evaluated by the treating physician within 30 days prior to the date of initial certification.</td>
</tr>
<tr>
<td>2. During the first 36 months of the rental period, when a change in the patient's condition causes a break in medical necessity of at least 60 days plus whatever days remain in the rental month during which the oxygen need ended (do not include breaks in billing).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. When equipment is replaced because the reasonable useful lifetime (RUL) was reached.</td>
<td>A repeat test is not required. Provide most recent qualifying test results and date completed. It does not have to be completed within 30 days prior to the Initial Date. You may report testing results from most recent prior CMN for Oxygen.</td>
<td>A physician visit is not required.</td>
</tr>
<tr>
<td>4. When equipment is replaced because of a specific incident of damage beyond repair (equipment is dropped or broken, fire, flood) or item is lost or stolen.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Requirement for Submitting **RECERTIFICATION** of Certificate of Medical Necessity

<table>
<thead>
<tr>
<th>Submit Form...</th>
<th>Blood Gas Study Testing Requirements</th>
<th>Physician Visit Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Twelve months after initial certification (with the 13th month's claim) for patients whose blood gas study values meet Group I criteria following initial certification for situations 1 and 2 in the Initial CMN for Oxygen table. Include this information:</td>
<td>For patients initially meeting Group I criteria, report the most recent qualifying blood gas study prior to the 13th month of therapy.</td>
<td>The patient must be seen and re-evaluated by the treating physician within 90 days prior to date of any Recertification. For a home health patient, the attending physician must certify that retesting results establish continuing medical necessity for home oxygen therapy. Coverage will resume beginning on date of encounter if:</td>
</tr>
<tr>
<td>• Date of current oxygen order</td>
<td></td>
<td>• Encounter occurs after the 90-day window and</td>
</tr>
<tr>
<td>• Name of the provider who completed the most recent blood gas study prior to recertification date</td>
<td></td>
<td>• The patient continues to use oxygen</td>
</tr>
<tr>
<td>• The patient's most recent qualifying blood gas study values completed prior to recertification date</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Estimated length of need for oxygen and</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Details of current oxygen order</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

When is reassessment recommended?

- As clinically appropriate, at rest and with exertion
- Within **90 days post acute discharge**
- Certificate of medical necessity (CMN) is required **every 12 months** by CMS
- When changing delivery methods
- When increasing/decreasing workloads
- Following an exacerbation
OUTLINE

- Analyze current barriers to oxygen prescription practices
- Become familiar with CMS guidelines and criteria for home oxygen approval
- **Apply guideline or evidence-based recommendations for home oxygen in specific disease conditions**
- Become familiar with available oxygen delivery systems and advances in technology
- Formulate a systematic approach to home oxygen prescription

Need to know current CMS criteria for home oxygen with respect to disease:

- **Sleep, Daytime, Exertional, Ambulatory Status**
- **Chronic Lung or Heart Diseases causing hypoxemia**
  - COPD
  - Interstitial Lung Diseases (IPF)
  - Pulmonary Hypertension
  - Cystic Fibrosis
  - Heart Failure
Chronic sleep related respiratory disorders
• Requires demonstration that optimal PAP therapy (CPAP and Bilevel) has been tried but sleep hypoxemia persists
  • Sleep Apnea Syndromes
  • Obesity Hypoventilation Syndrome
  •Overlap Syndrome
  • COPD

Need to know current CMS criteria for home oxygen with respect to disease:

Sleep, Daytime, Exertional, Ambulatory Status

Chronic hypercapnic respiratory failure syndromes
• NIPPV is the recommended treatment of choice
  ▪ Oxygen should only be initiated along with NIPPV (not alone)
  ▪ Requires evidence that optimal NIPPV is ineffective in correcting hypoxemia
    • Obesity Hypoventilation Syndrome
    • Neuromuscular Diseases
    • Restrictive Thoracic or Chest Wall Diseases
    • Hypercapnic COPD
# Long Term Oxygen Therapy for COPD

<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>N</th>
<th>Intervention</th>
<th>Hypoxemia Level</th>
<th>Mortality Benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOTT 1980</td>
<td>RCT</td>
<td>203</td>
<td>Nocturnal O2 vs continuous O2</td>
<td>PaO$_2$ &lt; 55 or PaO$_2$ &lt; 60 w/polycythemia/PH Normocapnic</td>
<td>YES</td>
</tr>
<tr>
<td>UK-MRC 1981</td>
<td>RCT</td>
<td>87</td>
<td>No O$_2$ vs O2 for 15 hour/day</td>
<td>PaO$_2$ 40-60 Hypercapnic</td>
<td>YES</td>
</tr>
<tr>
<td>LTOT 2016</td>
<td>RCT</td>
<td>738</td>
<td>Oxygen vs No Oxygen</td>
<td>Mild to moderate resting hypoxemia 89-93% Exertional &lt;90%</td>
<td>NO benefit on hospitalization, death, QoL, or exercise performance</td>
</tr>
<tr>
<td>Oxygen group:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Moderate hypoxemia – continuous O$_2$</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Mild/exertional hypoxemia – O$_2$ with exercise and sleep</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**LTOT benefits severely hypoxemic COPD patients.**

---

## LTOT for COPD

**Grade A evidence**

Patients with stable COPD and a **resting PaO$_2$ ≤55 mmHg** should be assessed for LTOT, which offers survival benefit and improves pulmonary hemodynamics.

LTOT should be ordered for patients with stable COPD with a **resting PaO$_2$ ≤60 mmHg** with evidence of peripheral edema, polycythemia (hematocrit ≥55%) or pulmonary hypertension.

Resting hypercapnia is not a contraindication if above criteria is fulfilled.
Nocturnal Oxygen Therapy for COPD + Sleep Related Hypoxemia

<table>
<thead>
<tr>
<th>Study</th>
<th>Type</th>
<th>N</th>
<th>Intervention</th>
<th>Benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fletcher 1992</td>
<td>RCT</td>
<td>38</td>
<td>Oxygen vs No Oxygen</td>
<td>NO mortality benefit</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Slower rise in pulmonary pressure</td>
</tr>
<tr>
<td>Chaouat 1999</td>
<td>RCT</td>
<td>76</td>
<td>Oxygen vs No Oxygen</td>
<td>NO mortality benefit or change in pulmonary artery pressure</td>
</tr>
</tbody>
</table>

**Nocturnal Oxygen Therapy is NOT recommended for COPD with isolated nocturnal desaturations.**

LTOT for Chronic Lung Diseases (ILD, IPF, Pulmonary Hypertension)

**2011 JOINT ATS/ERS/JRS/ALAT CLINICAL PRACTICE GUIDELINE ON IPF**

- Offer oxygen to IPF patients with clinically significant resting hypoxemia (\(\text{PaO}_2\) 55-65 mmHg).
  (strong recommendation, very low quality evidence)

- No survival data, improvements in exercise capacity.

- Recommendation is extrapolated from COPD data.

**LTOT for Chronic Lung Diseases (ILD, Pulmonary Hypertension)**

**Grade D evidence**

**Benefit:** symptoms relief, complications of hypoxemia including pulmonary hypertension

LTOT should be ordered for patients with a resting $\text{PaO}_2 \leq 55$ mmHg.

LTOT should be ordered for patients with a resting $\text{PaO}_2 \leq 60$ mm Hg in the presence of peripheral edema, polycythemia (hematocrit $\geq 55\%$) or pulmonary hypertension.

---

**AmBox study: first randomized clinical trial assessing home oxygen in HRQoL in ILD**

Visca et al. Lancet Resp Med. 2018

- **N=84**
  - Age=67.9 years
  - Non-hypoxemic at rest: 31% female, 58% with IPF

**6MWT on oxygen and placebo air in randomised order**

- **2-week run-in**
- **Oxygen**
  - 2 weeks
  - No oxygen
- **Crossover (2 weeks)**
  - K.BILD, SGRQ, UCSQSOBQ, HADS
- **Last visit (4 weeks)**
  - K.BILD, SGRQ, UCSQSOBQ, HADS, SAB, patient diaries, global assessment of change

**Qualitative interviews in 23 patients at end of trial period**
**NOT for OSA, Obesity Hypoventilation Syndrome, Overlap Syndrome, Neuromuscular Diseases and Restrictive Thoracic Diseases**

### Grade A evidence
- **Noninvasive Ventilation (NIV) is treatment of choice**

### Grade D evidence
- LTOT can be used in addition to NIV, particularly where there is co-existing airways disease or obesity causing hypoxemia which NIV alone does not correct
OUTLINE

- Analyze current barriers to oxygen prescription practices
- Become familiar with CMS guidelines and criteria for home oxygen approval
- Apply guideline or evidence-based recommendations for home oxygen in specific disease conditions
- **Become familiar with available oxygen delivery systems and advances in technology**
- Formulate a systematic approach to home oxygen prescription

Home Oxygen Options

1. **Concentrators**—High flow up to 10 LPM
2. **Compressed Gas**—(needs 2 regulators, 2 cylinders & cart for high flow uses >6 LPM)
3. **Liquid**—few DME providers carry LOX, higher costs, diminishing reimbursement from CMS
4. **Trans-fill** Systems
5. **Portable Oxygen Concentrator (POC)**—continuous flow ≤ 3 LPM, Pulse up to 6 LPM
Oxygen Source: CONCENTRATOR

- Function: uses filtered room air, removes nitrogen
  - Fixed: home based
  - Portable: home based or external
- Performance varies with device and flow rate
  - 2 L: guaranteed saturation > 92%
  - 3 L: 85-94%
  - 4 L: 69-85%
- High (> 3 LPM) vs low flow (≤ 3 LPM)
  - Combine two high flow concentrators for > 8 L

Oxygen Source: CYLINDER (compressed gas)

- Function: compresses oxygen in fortified metal container
- Duration depends on cylinder size and flow rate
- Small cylinder is used for ambulatory purposes
- Functions as a back-up option for power outage
- “Home Fill” system uses small cylinder tanks to refill oxygen
**Oxygen Source: LIQUID**

- **Function:** cooled oxygen turns into liquid, stored in insulated containers
- **Advantages:**
  - Stores large amount for a given volume
  - Reservoir containing 30-40 LOX can last 8-10 days at 2 LPM
  - Small size, resembles a thermistor
- **Training is required to prevent complications (cold burns)**
- **Choice of device should take into account patient’s dexterity, visual acuity and strength**

**Oxygen Source: PORTABLE SYSTEMS**

- **Options:**
  - Liquid
  - “home fill” cylinder
  - Lightweight cylinder
  - Portable oxygen concentrator
- **Weight 3–5 kg**
- **Battery hour for portable concentrators: depends if using pulse vs flow rate**
  - Can be used / charged in car and during flight
- **Portable concentrators can deliver up to 3 LPM continuous, or 6 LPM pulse**
  - **Pulse flow cannot be used during sleep**
Comparison of Portable Oxygen Systems

<table>
<thead>
<tr>
<th></th>
<th>Portable Concentrator</th>
<th>Portable Cylinder</th>
<th>Liquid Oxygen</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Advantages</strong></td>
<td>Unlimited autonomy (*electricity/battery)</td>
<td>Limited mobility outside home Cylinder lifespan based on size</td>
<td>Autonomy limited by charge in backpack Rechargeable Best for &gt; 3 L/min</td>
</tr>
<tr>
<td><strong>Disadvantages</strong></td>
<td>Weight* Rechargeable Loss of efficacy with high flow Cannot be used with <strong>continuous</strong> flow &gt; 3 L/min</td>
<td>Weight* Requires distribution network Non-rechargeable</td>
<td>Weight* Requires distribution network</td>
</tr>
<tr>
<td><strong>Cost</strong></td>
<td>High</td>
<td>Low</td>
<td>Very High</td>
</tr>
</tbody>
</table>

CMS Criteria and Type of Device Covered

<table>
<thead>
<tr>
<th>CMS Criteria</th>
<th>Type of Device Covered</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CMS Criteria</strong></td>
<td><strong>Daytime/Ambulatory</strong></td>
</tr>
<tr>
<td>PaO₂ mmHg</td>
<td>Stationary + Portable</td>
</tr>
<tr>
<td>&lt; 55</td>
<td>Covered</td>
</tr>
<tr>
<td>56-59</td>
<td>89</td>
</tr>
<tr>
<td>&gt; 60</td>
<td>&gt; 90</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
OUTLINE

- Analyze current barriers to oxygen prescription practices
- Become familiar with CMS guidelines and criteria for home oxygen approval
- Apply guideline or evidence-based recommendations for home oxygen in specific disease conditions
- Become familiar with available oxygen delivery systems and advances in technology
- **Formulate a systematic approach to home oxygen prescription**

1. Determine the clinical scenario in which oxygen is recommended:

<table>
<thead>
<tr>
<th>Nocturnal</th>
<th>Daytime</th>
<th>Exertional</th>
<th>High Altitude</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulse oximetry</td>
<td>ABG</td>
<td>6MWT</td>
<td>At altitude</td>
</tr>
<tr>
<td>Sleep study</td>
<td>Oxygen saturation</td>
<td></td>
<td>Simulation</td>
</tr>
<tr>
<td></td>
<td>6MWT</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
2. Determine how much flow patient requires:

<table>
<thead>
<tr>
<th>Low Flow: &lt; 3 liters</th>
<th>High Flow: &gt; 3 liters</th>
</tr>
</thead>
<tbody>
<tr>
<td>All are options:</td>
<td>Limitations with portable systems</td>
</tr>
<tr>
<td>▪ Stationary</td>
<td>▪ Liquid oxygen is difficult to obtain</td>
</tr>
<tr>
<td>▪ Portable</td>
<td>▪ Only continuous flow (no pulse)</td>
</tr>
<tr>
<td>▪ Pulse systems</td>
<td></td>
</tr>
</tbody>
</table>

3. Based on clinical scenario and flow requirement - determine type of oxygen device:

<table>
<thead>
<tr>
<th>Stationary</th>
<th>Portable</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Home based, not portable</td>
<td></td>
</tr>
<tr>
<td>▪ Ambulatory status is limited to the home</td>
<td></td>
</tr>
<tr>
<td>❖ For nocturnal oxygen – can only get stationary</td>
<td></td>
</tr>
<tr>
<td>▪ Ambulatory, outside of the home, travel</td>
<td></td>
</tr>
<tr>
<td>▪ Efficacy should be confirmed with exercise test</td>
<td></td>
</tr>
</tbody>
</table>
Is Home Oxygen Saturation (SpO₂) Monitoring Recommended?

- Recommend patients purchase a pulse oximeter for home use
- Most guidelines support oxygen saturation goal > 90%
- Due to oximeter standard deviation of ±2%, recommend goal of ≥ 94%
- How long do you wait between setting changes and assessment? Approximately 5 minutes
- Train your patients in self-monitoring, periodic spot check and when symptomatic

Defining Optimal Home Oxygen Therapy

- Effective and transparent interface between patient, caregiver, clinician, DME vendor, third party payor
- Expert clinician providing “evidence or guideline-based” prescription for rest, exertional, sleep and ongoing assessment of need
- Collaboration between clinician and DME vendor to deliver oxygen systems that meet the specific needs of the patient; physical, mobility, and financial constraints
Summary

- Know chronic lung (and heart) diseases that would benefit from long term oxygen supplementation
- Determine specific needs such as sleep, daytime, exercise, ambulatory, travel
- Stay up to date with evidence based guidelines
- Know your local coverage determination (LCD)/payor policies
- Stay up to date with technological advances in oxygen delivery systems
- Get to know your DME vendors; which systems they offer, support staff, availability of respiratory therapists – set expectations
- Provide education for patient and caregivers
Multifunction Ventilator (VOCSN)

**INCLUDES**

1) **Ventilator** - portable with internal battery, standard modes to include invasive and noninvasive ventilation, 6 modes of ventilation (volume/pressure targeted), active/passive circuit compatible, mouth piece ventilation (MPV) option

**Intended Application:** Home, Hospital, Long-Term, and Transport Ventilation for pediatric patients ≥ 5 kg* in addition to adult patients

*Comparable to the Philips Trilogy 100/200/202 ventilators

**Available Configurations**

<table>
<thead>
<tr>
<th>Configuration (Located on Device Rear Label)</th>
<th>Ventilation (V)</th>
<th>O2 Concentration (+O)</th>
<th>Cough (+C)</th>
<th>Suction (+S)</th>
<th>Nebulizer (+N)</th>
<th>High-Pressure External Oxygen and FIO2 Monitor (+Pro)</th>
<th>Low-Pressure External Oxygen</th>
</tr>
</thead>
<tbody>
<tr>
<td>V+O+C+S+N+Pro (or “VOCSN”)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>V+O+C+S+N</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>V+C+Pro (or “VOCSN-VC”)</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>V+C</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

2) **Oxygen** - Pulse Dose 0.5 - 6 L/min (FIO2 0.4)

   a. Internal concentrator, but can be connected to external concentrator source
   b. Has low pressure ports (external concentrators) and high pressure ports (walls and tanks) for external oxygen

3) **Cough Assist** - 10-70 cm H2O, three programmable modes

4) **Suction** – compatible with open and in line suction catheters, internal suction pump with proprietary removable suction canister

5) **Nebulizer** – integrated pneumatic nebulizer (6L/min flow to power, external flow compensation available), can use simultaneously with ventilator on
<table>
<thead>
<tr>
<th><strong>HCPCS code (Medicare part B)</strong></th>
<th>E0467</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Competitive Bidding</strong></td>
<td>No</td>
</tr>
<tr>
<td><strong>Frequent and Substantial Service Policy</strong></td>
<td>Yes (monthly rental fee covering vent and all accompanying accessories as long as medically necessary)</td>
</tr>
<tr>
<td><strong>Single Owner Policy</strong></td>
<td>DME provider owns all 5 therapies (vs patient owns cough assist, nebulizer, suction after 13 months)</td>
</tr>
<tr>
<td><strong>Indications</strong></td>
<td><strong>Conditions with chronic respiratory failure</strong> (neuromuscular disease, restrictive thoracic cage disease, COPD, multiple sclerosis, quadriplegia C1-C7 incomplete/complete)</td>
</tr>
<tr>
<td><strong>patients who meets medical necessity a portable ventilator and ONE additional therapy</strong></td>
<td><strong>Eligibility</strong></td>
</tr>
<tr>
<td>- Must document need for ventilator and need for each additional therapy, respectively</td>
<td>New vent users</td>
</tr>
<tr>
<td></td>
<td>Current vent users</td>
</tr>
<tr>
<td></td>
<td>- Vent users that have used cough, suction, and/or nebulizers for &lt; 13 months or &gt; 60 months</td>
</tr>
<tr>
<td></td>
<td>- Vent users that have oxygen for &lt; 36 months or &gt; 60 months</td>
</tr>
<tr>
<td><strong>Battery life</strong></td>
<td>9 hours (vent use only)</td>
</tr>
<tr>
<td><strong>Remote monitoring</strong></td>
<td>yes</td>
</tr>
<tr>
<td><strong>Weight</strong></td>
<td>20 lbs</td>
</tr>
</tbody>
</table>

**Medical documentation: all required**
- Multi-function ventilator ordered in the chart notes
- Documentation supporting condition and need for ventilator and additional function
- Test results or documentation of severity of disease
- Proof of use of multi-function ventilator to support dependency (printout from machine or physician documentation of actual use) – follow up visits
BREAK
EXHIBIT HALL OPEN

Friday, January 17, 2020 – 9:40 a.m. – 10:00 a.m.
WHAT ARE THE OPTIONS:
UNRAVELING THE MYTHS AND
MYSTERIES OF OXYGEN SUPPLY
SYSTEMS (INCLUDING OXYGEN
CONSERVING DEVICES)

Trina M. Limberg, BS, RRT, FAARC, MAACVPR
Owner, Pulmonary Care Consulting and Training
San Diego, CA

Friday, January 17, 2020 – 10:00 a.m. – 10:40 a.m.

Trina M. Limberg, BS, RRT, FAARC, MAACVPR, served as the Director for the Pulmonary Rehabilitation Department for UC San Diego Health System for over 25 years and as a respiratory pulmonary rehab specialist for over 36 years. She has been recognized for distinguished service and awarded credentials from the American Association of Cardiovascular and Pulmonary Rehabilitation and from the American Association of Respiratory Care. She is a contributing author to the 5th Edition of the AACVPR Pulmonary Rehab Guidelines. She has served as a BOD member for state and national professional organizations for over 30 years and continues to serve her community sharing her experience and expertise.
WHAT ARE THE OPTIONS: UNRAVELING MYTHS & MYSTERIES OF O2 SYSTEMS

Trina M. Limberg, BS, RRT, FAARC, MAACVPR
Pulmonary Care Consulting and Training

DISCLOSURE STATEMENT

• No financial conflicts
• Blue Marble Inc.
• The France Foundation
• Mylan Theravance
OBJECTIVES

• Supporting Evidence
• CMS Criteria
• Misconceptions and Myths
• Delivery Systems

THE IMPORTANCE OF OXYGEN THERAPY

• Oxygen is one of the only treatments for COPD proven to increase survival.
• In addition to improving survival, oxygen therapy improves activity levels and mobility of people with chronic lung disease.
• Oxygen use in the hypoxemic patient can help to prevent damage to other vital organs.

THE LANCET

Continuous or Nocturnal Oxygen Therapy in Hypoxemic Chronic Obstructive Lung Disease: A Clinical Trial

NOCTURNAL OXYGEN THERAPY TRIAL GROUP*

VOLUME 357, ISSUE 9222, P985-986, MARCH 18, 1991

LONG TERM DOMICILIARY OXYGEN THERAPY IN CHRONIC HYPOXIC COR PULMONALE COMPLICATING CHRONIC BRONCHITIS AND EMPHYSEMA

Report of the Medical Research Council Working Party
2019 GOLD COPD GUIDELINES

OXYGEN THERAPY AND VENTILATORY SUPPORT IN STABLE COPD

OXYGEN THERAPY

• The long-term administration of oxygen increases survival in patients with severe chronic resting arterial hypoxemia (Evidence A).

• In patients with stable COPD and moderate resting or exercise-induced arterial desaturation, prescription of long-term oxygen does not lengthen time to death or first hospitalization or provide sustained benefit in health status, lung function and 6-minute walk distance (Evidence A).

• Resting oxygenation at sea level does not exclude the development of severe hypoxemia when traveling by air (Evidence C).

VENTILATORY SUPPORT

• NPPV may improve hospitalization-free survival in selected patients after recent hospitalization, particularly in those with pronounced daytime persistent hypcapnia (PaCO2 ≥ 52 mmHg) (Evidence B).


NON-COPD POPULATIONS

ATS/ERS/JRS/ALAT Statement On IPF

Recommendation: To treat IPF patients with clinically significant resting hypoxemia with long-term oxygen therapy. (strong recommendation, very low-quality evidence)

AmbOx Study evaluating the effects of ambulatory oxygen on HRQOL in patients w. fibrotic lung disease (UK)

76 patients R to O2 vs no O2 x 2 weeks F/B crossover

Primary outcome: Kings Brief Interstitial Lung Disease Questionnaire (KB-ILD)

O2 users had improved scores: breathlessness, activity and chest symptoms

LONG TERM OXYGEN THERAPY TRIAL (LOTT)

- RCT w. 738 COPD Patients w resting SpO2 89-93% and/or desaturated w activity (SpO2 <90% for > 10 sec. w 6 MWT but >80% for > 5 min.)

- **Primary Outcomes** – Time to death or first hospitalization
- **Other Outcomes** – No diff. in QOL, 6 MWD, HADs or hosp. rates

- **Treatment Group**
  - O2 at rest & during sleep w. mod. hypoxemia
  - O2 w. activity & sleep w. resting RA SpO2 above 93% w. desat. criteria
  - Mean f/u 18. 4 months


---

CMS OXYGEN THERAPY REQUIREMENTS

- **Continuous Oxygen:**
  - Resting Room Air PaO2 < 55 mm Hg or SaO2 < 88 %
  - Resting PaO2 of 56 to 59 mm Hg w. PH or P pulmonale (ECG)
    - Dependent edema sugg. recurring CHF or Polycythemia > 56 %
    - Only w. documentation justifying the prescription & a summary of conservative therapy that has failed.

- **Non-continuous Oxygen:** (flow rate & # hours per day must be specified)
  - During exercise: PaO2 ≤ 55 mm Hg or SaO2 ≤ 88 %
  - During sleep PaO2 < 55 mm Hg or SaO2 < 88 % w. associated complications, such as PH, daytime somnolence, and cardiac arrhythmias.

CMS PRESCRIPTION REQUIREMENTS

- 3 Step Testing (w/i 2 days of D/C or 30 days of initial certification)
  - Resting
  - With Activity/Exertion
  - Test w. O₂

- MD/PA/NP must examine pt., note face to face and complete a Written Order Prior to Discharge (WOPD)

MISCONCEPTION #1

Oxygenation assessments occur upon hospital D/C in COPD patients

Less is known about Non—COPD populations upon discharge
• Retrospective EMR review
• 335 COPD patients
• 1 in 5 had adequate documentation of supp. O₂ assessment beyond resting


MISCONCEPTION #2

Oxygen therapy prescriptions are routinely reconciled in the EMR

Oxygen is not seen as a medication therefore not listed. May be listed in the subjective narrative or in the summary but not in the Meds section, making it difficult to find and track over time across settings ED, Ot. Pt. visits & acute settings.
WHAT WE CAN DO BETTER

• Meet w. our teams (include RT) to improve assessments, create a standard if it’s lacking
• Ask EMR IT (EPIC) specialists to create options that improve clinical assessment & documentation
• List O₂ prescriptions w/i medication section & reconcile at subsequent visits
• For patients: Education resources for access by all providers and include w. d/c instructions:
  • http://www.thoracic.org/patients/patient-resources/resources/oxygen-therapy.pdf

Out –patient EMR documentation:
• Specify O₂ flow rates w. vitals
• At min., subjective narrative to include delivery device and reported patient use
• Studies show regular discussions w. patients can improve adherence

MISCONCEPTION #3

• Patients are reassessed (following the CPG) within 60-90 days post discharge

2 scenarios:
1) O₂ naïve – req. O₂ upon D/C (new), order a reassessment at D/C or at the 1ˢᵗ follow up office visit. Without a standard or an order, reassessments can get missed when different providers are involved.
2) Pt. w pre-admission O₂ prescription and the flow setting is changed @ D/C – may necessitate a change not only in O₂ flow setting but also equipment.
WHAT WE CAN DO BETTER

• Order reassessments for patients w. new O2 prescriptions & w. changed prescriptions
• Verbally reinforce the importance of the reassessment appointment w. the patient and /or family
• List reassessments in the treatment plan and D/C summary notes

MISCONCEPTION #4 AND #5

Prescribed LPM flow is = to pulse dose settings

&

All Oxygen Conservation Devices (OCDs) produce the same size bolus
OXYGEN CONSERVING DEVICE (OCD) PERFORMANCE

OCDs have varying performance characteristics, which include bolus volume, trigger sensitivity & trigger response time.

Bliss PL, McCoy RW, Adams AB. Respir Care 2004;49(2) 160-165

OXYGEN DELIVERY AND RESPIRATORY RATE

- Exercise compounds device shortfalls, some devices deliver less O2 as RR increases
- Delivery method is as critical as volume of dose, monitoring during exercise/activity is key to accurate titration

Courtesy of Robert McCoy RRT, Inspired Technologies
Do Patients Get Assessed on Their Ambulatory Delivery Systems?

Why are patients still walking around hypoxemic after assessment?

UCSD Pulmonary Rehab reviewed 65 patients post discharge:

- 60% did not meet target
- 20% needed setting adjusted upward
- 40% could not be titrated at any setting (replaced device)

Source: Limberg et al. Changes in Supplemental Oxygen Prescription in Pulmonary Rehabilitation, Resp Care Nov 06; Vol 51 (11), pg 1302.
LTOT STORAGE OPTIONS

• **Compressed Gas** – gas (need 2 regulators, 2 cylinders & cart for high flow uses ≥6 LPM)
• **Liquid** – VERY few DMEs providing service, higher costs, diminishing reimbursement from CMS
• **Concentrators** – High flow 10 lpm
• **Transfill** Systems
• **POCs and Transportable Concentrators** – continuous flow 3 lpm, Pulse up to #6

CONSIDERATIONS FOR POC USE

• Assessments are generally done on 99%+ FiO2 (wall source or cylinder)
• POCs currently do not deliver above 3 LPM continuous
• POCs may deliver up to pulse doses of #5-6
• The smaller the POC generally the lower the oxygen production capability
• Transportable POCs - >10 # have higher production capabilities
• Patients who have a home concentrator, an OCD and a POC may require different flow setting w. each delivery device.
• Pulse ox. use may be very helpful for patients.
MISCONCEPTION #6

Oxygen equipment requires little to no maintenance.

EQUIPMENT MAINTENANCE CONSIDERATIONS

• POC sieve bed chambers changed at 1 year or before w. frequent use
• Concentrators – wipe outside damp cloth, no chemical use 1-2 x weekly
  inlet filters – rinse w. hot H₂O 2 x weekly, some say Qmo. or when visibly soiled or damaged) no soap use
• Humidifiers – used w. >4LPM require cleaning weekly & distilled H₂O ▲ 2 x wk
• O ring washers between the cylinder neck and regulator will degrade over time causing gas leaks
• Replace extension tubing Q 6-12 mo.
• N.C. change weekly, when soiled & w. illness

https://lunginstitute.com/blog/keep-oxygen-equipment-clean/
https://irscanada.ca/oxygen-therapy/oxygen-cleaning-instructions/
MYTH

• Patients don’t adhere because they don’t want to.
  • Reported Adherence 45=70%
  • Poor adherence is multifactorial
  • Some studies show lower adherence w. males
  • Low health literacy & those lacking social support
  • When no perceivable benefit exists
  • Equip. that impedes activity & poor functioning equip.
  • Poor instructions for use and inadequate supplies for activity/travel

What can we as providers do better?
  • Involve the pt. & family, provide written and verbal instructions, review/reinforce at each visit (i.e. as with inhaled med delivery devices)

OPTIMIZING HOME OXYGEN THERAPY

• An ATS Workshop Report approved Oct. 2018
• Comprehensive detailed review of the problems surrounding oxygen therapy
• Impetus for workshop was the findings from the May 2016 ATS Nursing Assembly ad hoc Oxygen Work Group
• Incorporates patient experiences
• Identifies problems w. DME and CMS regulations
• ATS Special Interest Group - Collaborative effort inclusive of all major pulmonary patient advocacy groups, providers and researchers
PATIENT PERCEPTIONS OF O2 THERAPY USE

- More than 50% of users experienced numerous & varied problems mainly having restricted mobility(38%) and isolation.
- Equipment malfunctions
- Lack of testing and education
- Economic restraints were common
TITRATE TO MIGRATE: OXIMETRY MONITORING

• Cell phone apps
• Device variability – scarce info. (opt to trend)
• Clarify pt. readings when obtaining a history – w. activity
• ATS patient series on Pulse Oximetry:
  • http://www.thoracic.org/patients/patient-resources/resources/pulse-oximetry.pdf

Track Your All-Day Wellness | Wrist-Based Pulse Ox Sensor

Oximeter - Apps on Google Play
https://play.google.com/store/apps/details

This application is only for use with the Pulse Oximeter. Bluetooth Pulse Oximeter combined with this application will allow you to noninvasively track and trend.
WHAT HELPS IMPROVE LTOT USE?

• Regular follow-up and sincere clinician-patient communication

• Written prescription and precise instructions given by the treating physician regarding LTOT use are indispensable factors affecting adherence.

• More education is essentially needed in LTOT assessment and management.

• The “right” portable system/adds freedom time

IN SUMMARY

• F/U on oxygen reassessments post-acute D/C 60-90 days
• Strive to improve EMR documentation of O2 prescriptions & patient use (including w. vital sign intake)
• LPM does not = OCD flow settings
• POCs and OCDs lack standardized bolus supply at any given setting
• Oximetry monitoring can help patients (ask for readings w reg. activities)
• Pt. use may be improved w. written prescriptions, written resources & regular provider engagement on use
• The best delivery device achieves desired SpO2 >90% with all activities…it’s often the one the patient will use

PATIENT RESOURCES

• COPD Foundation: www.copdfoundation.org
  • Living with Oxygen
  • Oxygen Guide
• Pulmonary Fibrosis Foundation: https://www.pulmonaryfibrosis.org/
  • Living with Oxygen
    • https://www.pulmonaryfibrosis.org/life-with-pf/oxygen-therapy
  • Oxygen Booklet
    • https://www.pulmonaryfibrosis.org/pft_oxygenbooklet.digital.pdf
• IPF https://www.lungsandyou.com/management/oxygen-therapy
MORE RESOURCES

• The Pulmonary Paper; every other month publication for patients living with lung disease:
  • https://www.pulmonarypaper.org/

• American Lung Association videos and information guide:

Thank You!!

tlimberg@ucsd.edu or tlليمberg61@gmail.com
COMPLICATIONS WHEN PATIENT’S OXYGEN NEEDS ARE NOT MET

Kimberly Langner, RRT-ACCS, RCP
Clinical Specialist
Respiratory Care Services
Stanford Healthcare

Friday, January 17, 2020 – 10:40 a.m. – 11:20 a.m.
Complications When a Neuromuscular Patient’s Oxygen Needs Are Not Met

Kimberly Langner RRT-ACCS
Stanford Healthcare

Disclosures

• No Conflicts/Disclosures
Objectives

• Know the disease processes that affect respiratory function
• The importance of Bronchopulmonary hygiene in NM population
• Reasons why high concentrations oxygen should be used only in emergency situations
• Reasons why spontaneous ventilation is key

Neuromuscular Diseases That Affect Respiratory Function

• Amyotrophic lateral sclerosis
• Multiple sclerosis
• Spinal muscle atrophy
• Myasthenia gravis
• Guillian-Barre Syndrome
• Spinal cord injuries
Case Study

A Brief History of Mr. J

- 63 year old with ALS
- Diagnosed 3 years ago
- Wears AVAPS by mask at night due to nocturnal hypoventilation
- Ordered for Cough Assist 4 times a day
- 3% hypertonic Saline 2 times a day.
Mr. J was brought into the ED for the following

- Fever 103 degrees F
- SOB
- SpO2 80% on room air
- Poor chest rise with BiPAP

Upon Admission in the ED

- Mr. J has decreased level of consciousness
- BiPAP settings increased
- DuoNeb given
- Suctioned for thick yellow secretions
- CXR shows a bilateral lower lobe pneumonia
- ABG obtained
- MIF & VC done
- Increased oral secretions
- Started on broad-spectrum antibiotics for pneumonia
Respiratory Failure in Neuromuscular Disease

- Inspiratory Muscle Weakness
- Upper Airway Muscle Weakness
- Expiratory Muscle Weakness
Upon Admission in the ICU

• BiPAP settings 22/5.
• FiO2 was decreased to 60%
• Cough assist was ordered every 4 hours
• ABG done 1 hour after ICU admission
• Mr. J is not following commands

The ICU Stay

• Patient was intubated and sedated
• Placed on VC/AC
• Bronchoscopy was done after intubation
• IPV was started after intubation
• MIF and VC ordered
• Mr. J failed spontaneous breathing trials
• Anxiety
The ICU Stay

- Tracheostomy placed 10 days after admission
- Mr. J is able to tolerate PSV trials 4 times per day
- Able to participate in PT, SLP, and OT.

Multidisciplinary Care

- Improved survival
- Optimizes treatment
- Improved communication
What was done well with Mr. J’s Care?

- Comprehensive H&P done
- Patient started on antibiotics
- Suctioned
- Intubation for decreased LOC
- Early Tracheostomy
What could be done better in Mr. J’s care?

• Placing the patient on AVAPS in the ED
• Starting the cough assist and IPV in the ED to help prevent intubation every 2 hours
• Keeping the patient on spontaneous ventilation
• Decrease the amount of FiO2

References

Hands-On Session/Case Based Discussion: High-Flow Oxygen, Portable Oxygen Concentrators, Noninvasive Open Ventilation System

Friday, January 17, 2020 – 11:20 a.m. – 12:30 p.m.

Gaurav Singh, MD
Staff Physician - VA Palo Alto Healthcare System
Clinical Assistant Professor - Stanford University

Gaurav Singh, MD completed all of his medical education and training locally. He attended UC Berkeley for undergraduate studies and UCSF for medical school. He also obtained a Masters of Public Health at UC Berkeley. He completed residency training in Internal Medicine at Stanford University, followed by Pulmonary and Critical Care fellowship as well as Sleep Medicine fellowship at Stanford University. Dr. Singh is currently a Staff Physician at the VA Palo Alto Healthcare System in the Section of Pulmonary, Critical Care, and Sleep Medicine. He is an Affiliated Clinical Assistant Professor at Stanford University.

Anna Breiburg, NP
Sanford/Palo Alto
VA Health Care System

Kimberly Langner, RRT-ACCS, RCP
Clinical Specialist, Respiratory Care Services
Stanford Healthcare

Susan Metcalfe, RCP, RRT
Stanford University

Susan Metcalfe, RRT-ACCS, RCP is an Adult Critical Care Respiratory Therapist at Stanford Health Care. There she serves as a bedside therapist and RT Coordinator for Stanford's Neuromuscular clinic. Susan is interested in enhancing the quality of life for patients with Neuromuscular diseases and wishes to expand Stanford's Home Ventilation Program under the guidance of Dr. Michelle Cao.
Justin Phillips, RRT-ACCS
Adult Critical Care Respiratory Therapist
UC San Francisco
Zuckerberg San Francisco General Hospital and Trauma Center

Justin Phillips, RRT-ACCS, is a Adult Critical Care Respiratory Therapist for the University of California San Francisco, Department of Anesthesia at Zuckerberg San Francisco General Hospital and Trauma Center (ZSFG). There, he currently serves as a bedside therapist and educator. Justin is a lecturer for the Critical Care Residency Program at ZSFG on the topics of Mechanical Ventilation Mechanics and ARDS management. Additionally, he is Adjunct Faculty for the Respiratory Care Program at Ohlone College for Health Sciences and Technology. Justin is a published researcher and has spoken nationally on the subjects of strategic ventilation practices and the use of non-invasive end-tidal monitoring.

Chris Garvey, FNP, MSN, MPA, MAACVPR
Nurse Practitioner
UCSF Pulmonary Rehabilitation (PR) and Sleep Disorders

Chris Garvey FNP, MSN, MPA, MAACVPR is nurse practitioner at UCSF Pulmonary Rehabilitation (PR) and Sleep Disorders. Her focus is guideline development, research and publication in exercise prescription, hypoxia, oxygen prescription, technology supported home exercise and coverage for pulmonary rehabilitation. She helped lead development and implementation of the first large national registry of clinical outcomes and quality measures in PR. Chris is co-developer of the AACVPR outcome resource guide, a national resource for PR outcomes. She is a recipient of the L Kent Smith award for excellence, and is immediate past president of CTS.

Trina M. Limberg, BS, RRT, FAARC, MAACVPR
Owner, Pulmonary Care Consulting and Training, San Diego, CA

Trina M. Limberg, BS, RRT, FAARC, MAACVPR, served as the Director for the Pulmonary Rehabilitation Department for UC San Diego Health System for over 25 years and as a respiratory pulmonary rehab specialist for over 36 years. She has been recognized for distinguished service and awarded credentials from the American Association of Cardiovascular and Pulmonary Rehabilitation and from the American Association of Respiratory Care. She is a contributing author to the 5th Edition of the AACVPR Pulmonary Rehab Guidelines. She has served as a BOD member for state and national professional organizations for over 30 years and continues to serve her community sharing her experience and expertise.
Cheat Sheet: Noninvasive Open Ventilation System (NIOV)

Patient populations that may benefit from NIOV:
• Chronic obstructive pulmonary disease (COPD)
• Interstitial lung diseases (i.e., idiopathic pulmonary fibrosis)
• Neuromuscular diseases (i.e., amyotrophic lateral sclerosis)
• Other restrictive lung diseases (i.e., kyphoscoliosis)
• For pulmonary rehab, pre and post lung transplant

Reimbursement codes:
• HCPCS E0465 - home ventilator, any type, used with invasive interface (e.g., tracheostomy tube)
• HCPCS E0466 - home ventilator, any type, used with non-invasive interface (e.g., mask)
• CPT code 94660

General features and requirements:
• Weighs 1 lb (i.e., portable)
• Rechargeable battery lasts up to 6 hours
• Requires oxygen tank with regulator or alternatively can be used with compressor
• Uses pillows interface for oxygen delivery along with entrainment of air to augment tidal volume

Settings:
• 3 activity levels – low (e.g., sitting), medium (e.g., ADLs at home), and high (e.g., walking, outdoor activities)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Range</th>
<th>Parameter</th>
<th>Range</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume</td>
<td>50-750 ml</td>
<td>High BR</td>
<td>5-120</td>
<td>Breach timeout</td>
</tr>
<tr>
<td>I-time(^1)</td>
<td>0.15 - 3.00 sec</td>
<td>Low BR</td>
<td>0-119</td>
<td>Period</td>
</tr>
<tr>
<td>PEEP(^2)</td>
<td>0 - 10 cmH20</td>
<td>High PIP</td>
<td>5-40</td>
<td>Action</td>
</tr>
<tr>
<td>Sensitivity</td>
<td>0-9</td>
<td>Low PIP</td>
<td>1-15</td>
<td>3 LPM or 12 BPM</td>
</tr>
<tr>
<td>Breath rate (BR)(^2)</td>
<td>0-40</td>
<td>Source Gas</td>
<td>Air or O(_2)</td>
<td></td>
</tr>
</tbody>
</table>

\(^1\)Only available on newest model. Referred to as inspiratory time% on prior model (range from 10-40%)
\(^2\)Only available on newest model.

Example of initial settings:
• Low activity: 100 ml
• Medium activity: 180 ml
• High activity: 200 ml
• I-time: 1 sec
• PEEP: 0-5 cmH20
• Trigger sensitivity: 4
• BR: 10-12 BPM

Titration of settings:
• Volume titration: based on patient comfort and oxygenation
• I-time titration: minimum augmentation time = set volume (in L) x 2
  - e.g., Set augmentation volume of 200 ml (or 0.2 L) requires minimum I-time of 0.4 sec
• Trigger sensitivity: determines how easily patient can trigger device to deliver a breath; 0 is most sensitive and 9 is least sensitive
**HFNC O2 Therapy**

**Description**
- Comprises an air/O2 blender
- A wide-bore nasal cannula
- An active humidifier
- A single limb heated circuit
- Delivers heated, humidified medical gas at up to 60 L/m

**Contraindications:**
- Hypercarbic respiratory failure
- Maxillary facial trauma
- Pneumothorax

**Physiological Effects of HFNC:**
- Reduction of anatomical dead space
- Peep effect and a constant FiO2
- Good humidification
- Innovative respiratory support for critically ill patients

**Clinical Applications:**
- Hypoxemic respiratory failure
- Acute exacerbation of COPD
- Post-extubation, pre-intubation oxygenation
- Patients with sleep apnea
- Acute heart failure
- Do not intubate order
Benefits of HFNC vs. Low-flow nasal cannula

- Improved oxygenation
- Decreased anatomic dead space
- Decreased metabolic cost of breathing
- Generation of positive nasopharyngeal and tracheal airway pressure
- Improved work of breathing
- Better secretion clearance
- Superior comfort
- Reduced room air entrainment
Portable Oxygen Concentrators (POCs)

See device brochures for details, operations, limitations, etc. All POCs below are FAA approved for flight. Information below should be considered estimates.

<table>
<thead>
<tr>
<th></th>
<th>Inogen One G 5</th>
<th>Inogen One G 4</th>
<th>Inogen One G 3</th>
<th>Invacare Platinum</th>
<th>Precision EasyPulse 3/5</th>
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<tbody>
<tr>
<td><strong>Maximum oxygen production</strong></td>
<td>1.26 LPM</td>
<td>0.63 LPM</td>
<td>1.05 LPM</td>
<td>0.88 LPM</td>
<td>0.52 LPM (EP3) 0.78 (EP5)</td>
</tr>
<tr>
<td>(liters per minute)</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td><strong>Pulse delivery</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Max. delivered pulse volume</td>
<td>15 BPM 84 ml</td>
<td>15 BPM 42 ml</td>
<td>15 BPM 70 ml</td>
<td>15 BPM 59 ml</td>
<td>15 BPM 35/ 52 ml</td>
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<tr>
<td></td>
<td>30 BPM 42 ml</td>
<td>30 BPM 21 ml</td>
<td>30 BPM 35 ml</td>
<td>30 BPM 29 ml</td>
<td>30 BPM 17/26 ml</td>
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<tr>
<td><strong>Weight + 1 battery</strong></td>
<td>5 lb.</td>
<td>3 lb.</td>
<td>5 lb.</td>
<td>6 lb.</td>
<td>5/7 lb.</td>
</tr>
<tr>
<td><strong>Battery time</strong></td>
<td>4 hours</td>
<td>2.3 hours</td>
<td>3 hours</td>
<td>2.5 hours</td>
<td>4 / 3.4 hours</td>
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<tr>
<td><strong>Max altitude</strong></td>
<td>10,000 ft.</td>
<td>10,000 ft.</td>
<td>10,000 ft.</td>
<td>10,000 ft.</td>
<td>9,000 ft.</td>
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<td><strong>Estimated price</strong></td>
<td>$1895</td>
<td>$1795</td>
<td>$1965</td>
<td>$195</td>
<td>$1665</td>
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<td><a href="store.mainclinic.com">store.mainclinic.com</a></td>
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<td><a href="oxygendirect.com">oxygendirect.com</a></td>
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<td>Respiration SimplyGoMini</td>
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<td>Respiration SimplyGo</td>
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<tr>
<td>SeQual Eclipse 5</td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>Maximum oxygen production</strong></td>
<td>0.5 (FS3)1.05 (FS5)</td>
<td>1.05 LPM</td>
<td>1.0 LPM</td>
<td>2.0 LPM</td>
<td>3.0 LPM</td>
</tr>
<tr>
<td>(liters per minute)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Pulse delivery</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Max. delivered pulse volume</td>
<td>15 BPM 33/ 67 ml</td>
<td>15 BPM 70 ml</td>
<td>15 BPM 55 ml</td>
<td>15 BPM 72 ml</td>
<td>96 ml</td>
</tr>
<tr>
<td></td>
<td>30 BPM 17/33 ml</td>
<td>30 BPM 35 ml</td>
<td>30 BPM 33 ml</td>
<td>30 BPM 66 ml</td>
<td></td>
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<tr>
<td><strong>Weight + 1 battery</strong></td>
<td>5/7 lb.</td>
<td>5 lb.</td>
<td>5 lb.</td>
<td>10 lb.</td>
<td>18.4 lb.</td>
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<tr>
<td><strong>Battery time</strong></td>
<td>3.5 / 2.5 hours</td>
<td>4 hours</td>
<td>4.5 hours</td>
<td>3 hours</td>
<td>3 hours</td>
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<td><strong>Max altitude</strong></td>
<td>12,000 ft.</td>
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<td><a href="directhomemedical.com">directhomemedical.com</a></td>
</tr>
</tbody>
</table>

*Add ≥ 5 lb. for accessories  **Pulse & night mode; pulse volumes shown; night mode: minute volume. *** See device manual.


Chris Garvey thanks the following for review and input: Richard Casaburi Phd, MD, Susan Jacobs RN, MS, Trina Limberg RRT, BS, Bob McCoy RRT, Ryan Diesem BS, RRT.and Celeste Belyea.
The Good and Bad about POCs: *The following information is not a substitute for your provider's care and recommendations.*

**Good:** Improved independence for travel with less dependence on durable medical equipment companies (DMEs).
- All POCs in the table on page one are approved by FAA for air travel.
- Light weight devices may encourage activities outside of the home

**Bad:** Oxygen experts caution POC technology has multiple unknowns about that make device purchase and use complex.
- Smaller, lighter units produce a limited amount of oxygen (often in the range of 1 L/min), and produce less than larger units. POCs generally rely on "pulsed dose" oxygen delivery, providing oxygen only during the parts of the breath (generally the beginning of inspiration).
- POCs are expensive and may not be covered by insurance or provided by your DME.
- POCs using pulse dose (vs. continuous flow) are not a suitable substitute for continuous flow oxygen during sleep.

**Caution:** Increase in respiratory rate such as with exercise results in lower oxygen pulse volume per breath especially if pulse setting is not increased to compensate for increased respiratory rate. Check oximeter values to make sure your oxygen level is at least 88% during activity and exercise.

**Worse:** POC’s oxygen pulse-dose settings do not correspond to the continuous 'liters/minute' flow rates prescribed by your provider when you were tested (unless you were tested at rest and exercise using the same POC you will be buying).
- You need to monitor your oxygen saturation (SpO2) with an oximeter under various circumstances while using your POC to assure your oxygen level is safe. For most 88% or above based on your provider’s recommendations.
- POCs cannot be used with sleep, CPAP or bi-level, or with an Oxymizer cannula (unless continuous flow setting, e.g., SimplyGo or Sequal Eclipse.

**What You Need to Know before You Buy:** Ask your pulmonary MD or pulmonary rehabilitation staff for guidance regarding your oxygen needs. See ‘maximum oxygen production’ in the chart above to determine if a POC will meet those needs. Consider that a flairup (exacerbation), pneumonia, worsening of lung disease, exercise and travel (high altitude +/or aircraft) normally increase your oxygen needs. Ask your provider if you should always keep your oxygen setting at the same number setting or change it based on your oxygen saturation (SpO2) reading. This is called ‘titrate to migrate’ or ‘titrate to saturate’. Anyone using oxygen should invest in an oximeter and understand how to use it. If you aren’t sure, ask your provider or pulmonary rehab staff. Be aware that any machine that retails for less than $1000 is probably not an oxygen concentrator. Read credible sources (below) to understand how POCs work. Find out:
- The amount of oxygen the POC produces, settings, battery life (duration), size, weight, sound level and how you will carry it or roll it.
- Investigate and understand a POC’s benefits and limitations before buying. Explore POC manufacturer’s and seller’s ratings and owner’s manual.
- Purchase a POC with a warranty.
- Understand that your oxygen needs may increase over time and you may ‘outgrow’ your POC’s oxygen supply capability.

**After You Buy a POC:** Read the owner’s manual carefully. Look for youtube videos for your POC. Review POC settings and discuss with your physician & pulmonary rehab staff. They may recommend the following:
- Plug the POC into the wall and turn it on. Put on your oximeter. Find out the POC setting that keeps your oxygen saturation 88% or higher at rest, with daily activities and exercise. Check the oxygen saturation (SpO2) regularly under various circumstances especially activity and exercise to be sure you are getting enough oxygen. Remember that oxygen is not addicting. Use it as prescribed: It only improves oxygen levels during the time it is used.

**Resources**
- [https://www.copdfoundation.org/COPD360social/Community/COPD-Digest/Article/309/How-a-Pulse-Oximeter-Works.aspx](https://www.copdfoundation.org/COPD360social/Community/COPD-Digest/Article/309/How-a-Pulse-Oximeter-Works.aspx)
LUNCH
EXHIBIT HALL OPEN

Friday, January 17, 2020 – 12:30 p.m. – 1:30 p.m.
Brooks Thomas Kuhn, MD, MAS
UC Davis School of Medicine
Assistant Professor, Division of Pulmonary and Critical Care Medicine
Dean's Fellow in Informatics

Friday, January 17, 2020 – 1:30 p.m. – 2:10 p.m.

Brooks Thomas Kuhn, MD, MAS is an assistant professor of clinical medicine in the UC Davis Division of Pulmonary and Critical Care Medicine. He is the Co-Director of the Comprehensive COPD Clinic and Director of the UC Davis Alpha-1 Anti-Trypsin Deficiency Clinic. The focus of Dr. Kuhn's research is in the application of natural language processing and machine learning to the prediction of severe COPD exacerbations.
Clinical Update of COPD: From Triple Therapy to Rehab

Brooks Kuhn, MD, MAS
Assistant Professor
UC Davis
Disclosures

- Speakers’ Bureau: Grifols
- Consulting Fees from: Theravance
- The opinions and slides in this presentation are my own

Topics of focus....

- Epidemiology: How does California compare to the rest of the country?
- Pharmacotherapy: Who should be on triple therapy and why?
- COPD Exacerbation Treatment: Who should get antibiotics and is there a role for CRP?
- COPD Exacerbation Prevention: Is there a role for metoprolol?
- COPD Self-Management Programs: If it works for CHF, then why not for COPD?
- Pulmonary Rehab: Can we get similar benefits from home-based programs in COPD?
California Epidemiology

Age-Adjusted Percentage of U.S. Adults with COPD by State or Territory, 2011*

- Prevalence is 4.3% of population (1,321,100 Californians)
- Mortality is 31.3 Californians per 100,000 per year
- Cost: 2.43 billion dollars
- Vaccinations:
  - 48.8% of Medicare patients had annual flu vaccine
  - 67% of Medicare patients had pneumococcal vaccine


### California Epidemiology

#### Percentage of California Adults with COPD, 2011 BRFSS*, n=16,914

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>%</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age Group (Years)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18–44</td>
<td>2.3</td>
<td>(1.8–2.9)</td>
</tr>
<tr>
<td>45–54</td>
<td>4.4</td>
<td>(3.6–5.3)</td>
</tr>
<tr>
<td>55–64</td>
<td>6.5</td>
<td>(5.5–7.5)</td>
</tr>
<tr>
<td>65–74</td>
<td>10.1</td>
<td>(8.7–11.7)</td>
</tr>
<tr>
<td>≥75</td>
<td>9.5</td>
<td>(8.1–11.0)</td>
</tr>
<tr>
<td><strong>Race/Ethnicity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>6.0</td>
<td>(5.5–6.6)</td>
</tr>
<tr>
<td>Black</td>
<td>6.1</td>
<td>(4.0–9.2)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>2.9</td>
<td>(2.3–3.6)</td>
</tr>
<tr>
<td>Other</td>
<td>3.5</td>
<td>(2.6–4.7)</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>3.9</td>
<td>(3.4–4.5)</td>
</tr>
<tr>
<td>Women</td>
<td>5.3</td>
<td>(4.7–5.9)</td>
</tr>
<tr>
<td><strong>Employment Status</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employed</td>
<td>2.7</td>
<td>(2.3–3.2)</td>
</tr>
<tr>
<td>Unemployed</td>
<td>4.6</td>
<td>(3.4–6.3)</td>
</tr>
<tr>
<td>Homemaker/Student</td>
<td>4.6</td>
<td>(2.4–8.4)</td>
</tr>
<tr>
<td>Retired</td>
<td>9.0</td>
<td>(8.0–10.1)</td>
</tr>
<tr>
<td>Unable to work</td>
<td>15.4</td>
<td>(12.7–18.6)</td>
</tr>
</tbody>
</table>

**Education Level**
- Less than High School Diploma: 4.6% (3.7–5.7)
- High School Diploma or GED: 5.2% (4.3–6.1)
- At least Some College: 4.5% (4.0–5.0)

**Income**
- <$25,000: 6.2% (5.4–7.2)
- $25,000–$49,999: 5.4% (4.5–6.3)
- $50,000–$74,999: 4.8% (3.8–6.2)
- >$75,000+: 2.7% (2.2–3.3)

**Marital Status**
- Married: 3.3% (2.9–3.7)
- Divorced/Widowed/Separated: 9.6% (8.6–10.7)
- Never Married: 4.0% (3.1–5.1)
- Member of Unmarried Couple: 3.5% (2.2–5.7)

**Smoking Status**
- Current: 10.5% (8.9–12.4)
- Former: 7.0% (6.2–7.9)
- Never: 2.5% (2.1–2.9)
- Ever Had Asthma: Yes: 14.6% (12.9–16.6) No: 2.8% (2.3–3.1)

---

**Diagnosis**

**Spirometry** is the current standard of COPD diagnosis. Spirometry is a simple breathing test administered by a healthcare professional that measures how much air you breathe out and how fast you can blow air out. Spirometry can also determine how severe COPD is and help guide doctors to decide on the appropriate treatment.

**Management**

Although there is no cure for COPD, treatment exists that can prevent worsening of the disease. Daily COPD medications can be used to manage symptoms.

**Doctor Visits and Hospitalization**

COPD poses a significant economic burden. In 2006, the cost to the nation for COPD and asthma was estimated to be approximately $68.0 billion in healthcare expenditures and lost productivity.1

**Quality of Life**

COPD causes shortness of breath, which makes it difficult to do things you used to be able to do at work and at home. These symptoms can cause decreased quality of life and loss of productivity.

---

California Epidemiology

- Cost more likely an obstacle to care
- Poorer self-reported health status
- COPD more likely to limit activity
- More likely to have >14 days/month characterized as “poor mental health days”
- More likely to not exercise in past month
Pharmacotherapy: Who should be treated with an ICS?

**FACTORs TO CONSIDER WHEN INITIATING ICS TREATMENT**

Factors to consider when initiating ICS treatment in combination with one or two long-acting bronchodilators (note the scenario is different when considering ICS withdrawal):

<table>
<thead>
<tr>
<th><strong>- STRONG SUPPORT -</strong></th>
<th><strong>- CONSIDER USE -</strong></th>
<th><strong>- AGAINST USE -</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>history of hospitalization(s) for exacerbations of COPD</td>
<td>1 moderate exacerbation of COPD per year</td>
<td>repeated pneumonia events</td>
</tr>
<tr>
<td>≥ 2 moderate exacerbations of COPD per year</td>
<td>blood eosinophils 100-300 cells/μL</td>
<td>blood eosinophils &lt;100 cells/μL</td>
</tr>
<tr>
<td>blood eosinophils &gt;300 cells/μL</td>
<td>history of or concomitant asthma</td>
<td>history of mycobacterial infection</td>
</tr>
</tbody>
</table>

Lancet Post-Hoc

*Note: Despite appropriate long-acting bronchodilator maintenance therapy (see Table 3.4 and Figure 4.3 for recommendations); not to be used as a first-line treatment. Quoted values represent approximate cut-points; eosinophil counts are likely to fluctuate.*

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**IMPACT: Exacerbation Prevention**

- **Cohort:**
  - Symptomatic COPD (CAT > 10)
  - FEV1 < 50% + 1 mod/sep exac or between 50 and 80% with > 1 mod/sep exac in past year
- **Intervention:**
  - Prospective ICS/LAMA/LABA vs. LAMA/LABA

---

**ORIGINAL ARTICLE**

Once-Daily Single-Inhaler Triple vs Dual Therapy in Patients with COPD

David A. Lippe, M.D., Frank Banzhoffer, O.M., Nicholas Buhl, M.D., Jean-Bruno, M.D., Ganou, C., Conin, M.D., Nafis, C., Ray, Ph.D., Mark T. Gerrard, M.D., David M. Han, M.D., Michael A. Hitosugi, M.D., Edouard E. H. Hu, M.D., C., Claire Jones, Ph.D., Safa Men bore, M.D., Peter Lange, M.D., Ph.D., for the IMPACT Investigators
IMPACT: Exacerbation Prevention

Moderate or Severe COPD Exacerbations (Intention-to-Treat Population)

- The annual rate of severe exacerbations resulting in hospitalization in the triple-therapy group was 0.13, as compared with 0.19 in the umecclidinium–vilanterol group
  - rate ratio, 0.66; 95% CI, 0.56 to 0.78; 34% difference; P<0.001
- There was a higher incidence of pneumonia in the inhaled-glucocorticoid groups

• Conclusion:
  - In this population of exacerbators, triple therapy compared to LAMA/LABA lowered the rate of moderate and severe exacerbations
  - These benefits were observed regardless of the patients’ blood eosinophil levels at randomization
**SUNSET: ICS De-Escalation**

- **Cohort:**
  - Stable COPD patients on triple therapy in past year
  - Post-bronchodilator FEV1 of 40% to 80% predicted
  - Not frequent exacerbators (i.e., they had a history of no more than one moderate or severe exacerbation in the previous year).

- **Intervention:**
  - Compare ICS/LAMA/LABA to LAMA/LABA (ICS withdrawal)
**Conclusion:**

- ICS withdrawal is associated with significant but appreciable difference in FEV1 for all patients on triple therapy. The effect is most pronounced in those with blood eosinophils >300 cells/mL.
- No change in exacerbation rate during trial.
Lancet Post-Hoc:

- Analyzed data from three AstraZeneca randomized controlled trials of budesonide-formoterol in patients with COPD with a history of exacerbations and available blood eosinophil counts.
- Patients with any history of asthma were excluded.
- Negative binomial regression analysis was done using splines for modelling of continuous variables to study the primary outcome of annual exacerbation rate adjusted for exposure time and study design.
Lancet Post-Hoc:

- At eosinophil counts of $0.10 \times 10^9$ cells per L or more, a significant treatment effect was recorded for exacerbation reduction with budesonide-formoterol compared with formoterol alone (rate ratio 0.75, 95% CI 0.57-0.99; $p_{interaction}=0.015$).

The Role of CRP

- 86 general medical practices in the United Kingdom
- Afiniton desktop devices for CRP point-of-care testing (Alere, now Abbott)

Providers were given CRP guidance:
- CRP level lower than 20 mg per liter, antibiotics are unlikely to be beneficial and usually should not be prescribed;
- for those with a CRP level from 20 to 40 mg per liter, antibiotics may be beneficial, mainly if purulent sputum is present;
- and for those with a CRP level higher than 40 mg per liter, antibiotics are likely to be beneficial.
The Role of CRP

- Conclusion:
  - "CRP-guided prescribing of antibiotics for exacerbations of COPD in primary care clinics resulted in a lower percentage of patients who reported antibiotic use and who received antibiotic prescriptions from clinicians, with no evidence of harm."

- Limitations:
  - Need point-of-care CRP measurement

COPD Exacerbations

A Freedom from Exacerbation of COPD

B Freedom from Severe or Very Severe Exacerbation of COPD

Severity of Exacerbations

<table>
<thead>
<tr>
<th>Table 2. Rate of Exacerbation of COPD, According to Severity.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Severity of Exacerbation</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>-------------------------------</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Any severity</td>
</tr>
<tr>
<td>Mild</td>
</tr>
<tr>
<td>Moderate</td>
</tr>
<tr>
<td>Severe</td>
</tr>
<tr>
<td>Very severe</td>
</tr>
<tr>
<td>Moderate or greater</td>
</tr>
<tr>
<td>Severe or very severe</td>
</tr>
</tbody>
</table>

Conclusions

- Among patients with moderate or severe COPD who did not have an established indication for beta-blocker use, the time until the first COPD exacerbation was similar in the metoprolol group and the placebo group.
- Hospitalization for exacerbation was more common among the patients treated with metoprolol.

Self-Management COPD Programs

JAMA | Original Investigation

Effect of a Hospital-Initiated Program Combining Transitional Care and Long-term Self-management Support on Outcomes of Patients Hospitalized With Chronic Obstructive Pulmonary Disease

A Randomized Clinical Trial

Hanan Abdoumatar, MD, MPH; Mohammad Naqibuddin, MBBS, MPH; Suna Chung, MPH; Hina Chaudhry, MPH; Samuel W. Kim, BA; Jamia Saunders, MD, MS; Lee Bone, MPH; Ayse P. Gurses, MS, MPH, PhD; Amy Knowlton, ScD, MPH; Peter Pronovost, MD, PhD; Nirupama Putcha, MD, MHS; Cynthia Rand, PhD; Debra Roter, DrPH; Carol Sylvester, RN, MS; Carol Thompson, MS, MBA; Jennifer L. Wolff, PhD; Judith Hibbard, PhD, MPH, FCCM; Robert A. Wise, MD
Reverse course...

- After initial publication in 2018, *JAMA* was notified of a statistical analysis error that lead to *REVERSAL* of the conclusions: the intervention is associated with harm rather than benefit.
  - “While results of the retracted publication suggested that patients in the intervention group had fewer COPD-related acute care events (hospitalizations and emergency department visits), the reanalysis demonstrated that the intervention substantially increased the risk of COPD-related acute care events”
- Aforementioned study is revised analysis of the data

![Graph showing the probability of no event over time](image)
Mean Change in Health-Related Quality of Life, as Measured by St George’s Respiratory Questionnaire, at 6 Months After Discharge by Study Group

<table>
<thead>
<tr>
<th>Measure</th>
<th>Intervention</th>
<th>Usual Care</th>
<th>Adjusted Difference, Mean Change (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Co-primary Outcomeb</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total score</td>
<td>63.3 (18.8)</td>
<td>65.1 (23.0)</td>
<td>3.81 (−3.73 to 9.34)</td>
<td>.11</td>
</tr>
<tr>
<td></td>
<td>63.6 (17.4)</td>
<td>60.9 (21.0)</td>
<td>3.60 (−9.34 to 3.90)</td>
<td></td>
</tr>
<tr>
<td>Post Hoc Outcomesb</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Symptom score</td>
<td>65.7 (21.3)</td>
<td>64.9 (23.0)</td>
<td>−0.79 (−6.36 to 4.78)</td>
<td>.53</td>
</tr>
<tr>
<td></td>
<td>67.3 (20.2)</td>
<td>60.2 (23.0)</td>
<td>7.12 (−15.90 to 1.66)</td>
<td></td>
</tr>
<tr>
<td>Activity score</td>
<td>79.8 (21.2)</td>
<td>80.3 (21.4)</td>
<td>−0.49 (−9.71 to 10.68)</td>
<td>.62</td>
</tr>
<tr>
<td></td>
<td>82.6 (17.4)</td>
<td>78.4 (21.8)</td>
<td>4.23 (−12.86 to 4.39)</td>
<td></td>
</tr>
<tr>
<td>Impact score</td>
<td>51.3 (21.9)</td>
<td>56.6 (26.0)</td>
<td>5.27 (−1.90 to 12.45)</td>
<td>.10</td>
</tr>
<tr>
<td></td>
<td>51.5 (20.8)</td>
<td>50.6 (24.7)</td>
<td>0.88 (−7.08 to 8.26)</td>
<td></td>
</tr>
</tbody>
</table>

*St George’s Respiratory Questionnaire measures health-related quality of life for patients with respiratory disease, provides a total score and 3 domain scores for symptom, activity, and impact (measuring respiratory symptoms, ability to do physical activity, and impact of illness on life, respectively), and the scores range for total and domain scores is 0 (best) to 100 (worst), with a 4-point difference being clinically meaningful.17,18

b Adjusted for hospital enrolment unit and St George’s Respiratory Questionnaire score at baseline. Negative numbers suggest the intervention group did better.

"Analysis completed with linear regression. Normality of residuals was good. There was no evidence of heteroskedasticity of residuals with respect to group (P = .25, .87, .70, and .12 for total symptom, activity, and impact scores, respectively).

Data were available for patients as follows: total score: n = 91 in usual care, n = 88 in intervention; symptom score: n = 94 usual care, n = 88 in intervention; activity score: n = 91 in usual care, n = 88 in intervention; and impact score: n = 93 in usual care, n = 88 in intervention."
Role of Self-management?

- Other studies have had similar results (Fan et al.)
- Mechanism of harm?
- Current guideline-based recommendations:
  - Smoking cessation
  - Influenza vaccination
  - Oxygen for patients with resting hypoxia
  - Pulmonary rehab
  - Comorbidities and Socioeconomic factors
- Role of future technology


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Pulmonary Rehabilitation in California

Figure 4. Distribution of the States Based on the Number of COPD Patients per Pulmonary Rehabilitation Program - United States, 2014-2015a

aData derived from the American Association for Cardiovascular and Pulmonary Rehabilitation.13

No data available for Puerto Rico

36
Benefits of PR in COPD

- In Stable COPD Patients:
  - Improve dyspnea
  - Improve health status
  - Reduction in anxiety/depression
  - Improve exercise tolerance

- Post Exacerbation
  - Reduce readmission
  - Reduced mortality

Mortality Reduction with PR post Admission

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Early rehabilitation</th>
<th>Usual care</th>
<th>Risk Ratio</th>
<th>Risk Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Events</td>
<td>Total</td>
<td>M-H, Random</td>
<td>M-H, Random</td>
</tr>
<tr>
<td>1.5.1 During admission</td>
<td>1</td>
<td>14</td>
<td>0.86 [0.06, 12.28]</td>
<td>0.86 [0.06, 12.28]</td>
</tr>
<tr>
<td>Behnke 2000</td>
<td>14</td>
<td>12</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total events</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heterogeneity: Tau² = 0.00; Chi² = 0.05; df = 1 (P = 0.91); I² = 0%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect: Z = 0.11 (P = 0.91)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1.5.2 After discharge

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Early rehabilitation</th>
<th>Usual care</th>
<th>Risk Ratio</th>
<th>Risk Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Events</td>
<td>Total</td>
<td>M-H, Random</td>
<td>M-H, Random</td>
</tr>
<tr>
<td>Ko 2011</td>
<td>0</td>
<td>30</td>
<td>0.33 [0.01, 7.87]</td>
<td>0.33 [0.01, 7.87]</td>
</tr>
<tr>
<td>Man 2004</td>
<td>20</td>
<td>21</td>
<td>0.53 [0.05, 3.35]</td>
<td>0.53 [0.05, 3.35]</td>
</tr>
<tr>
<td>Subtotal (95% CI)</td>
<td>50</td>
<td>51</td>
<td>0.45 [0.07, 2.91]</td>
<td>0.45 [0.07, 2.91]</td>
</tr>
<tr>
<td>Total events</td>
<td>3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heterogeneity: Tau² = 0.00; Chi² = 0.03; df = 1 (P = 0.92); I² = 0%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect: Z = 0.84 (P = 0.40)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Early rehabilitation</th>
<th>Usual care</th>
<th>Risk Ratio</th>
<th>Risk Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Events</td>
<td>Total</td>
<td>M-H, Random</td>
<td>M-H, Random</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>64</td>
<td>63</td>
<td>0.55 [0.12, 2.57]</td>
<td>0.55 [0.12, 2.57]</td>
</tr>
<tr>
<td>Total events</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heterogeneity: Tau² = 0.00; Chi² = 0.21; df = 2 (P = 0.90); I² = 0%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect: Z = 0.75 (P = 0.45)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for subgroup differences: Chi² = 0.15; df = 1 (P = 0.70); I² = 0%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


Home-based PR?

- Nolan et al. compared the real-world responses of 154 patients with COPD undergoing home-based exercise with a matched group attending supervised PR.
- Observed smaller improvements in exercise capacity with home-based exercise compared with PR, but similar improvements in quality of life.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Response to the intervention</th>
<th>Between-group difference</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PR (n=40)</td>
<td>Home (n=40)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6MWT</td>
<td>56 (45-78)</td>
<td>28 (10-40)</td>
<td>-28 (-49 to -11)</td>
</tr>
<tr>
<td>CRQ-dyspnea</td>
<td>5.0 (4.0-6.0)</td>
<td>3.0 (2.5-5.0)</td>
<td>1.0 (2.5 to 0.0)</td>
</tr>
<tr>
<td>CRQ-fatigue</td>
<td>2.9 (2.1-3.8)</td>
<td>2.1 (0.8-3.8)</td>
<td>0.8 (1.5 to 0.1)</td>
</tr>
<tr>
<td>CRQ-young</td>
<td>4.4 (0.0-6.0)</td>
<td>4.1 (4.0-5.0)</td>
<td>0.3 (2.6 to 2.8)</td>
</tr>
<tr>
<td>CRQ-mood</td>
<td>3.4 (2.3-4.6)</td>
<td>2.6 (3.3-3.6)</td>
<td>0.8 (2.5 to 0.4)</td>
</tr>
<tr>
<td>CRQ-total</td>
<td>15.7 (13.9-16.5)</td>
<td>13.0 (12.2-14.6)</td>
<td>2.7 (0.8 to 2.7)</td>
</tr>
</tbody>
</table>

Data reported as mean (95% CI) or p value for group difference.

CRQ, Chronic Respiratory Questionnaire; 6MWT, incremental shuttle walk; PR, pulmonary rehabilitation.

- Supervised PR remains the standard of care, with home-based exercise a less effective alternative for those unable to attend PR.
Summary

- **Epidemiology**: How does California compare to the rest of the country?
- **Pharmacotherapy**: Who should be on triple therapy and why?
- **COPD Exacerbation Treatment**: Who should get antibiotics and is there a role for CRP?
- **COPD Exacerbation Prevention**: Is there a role for metoprolol?
- **COPD Self-Management Programs**: If it works for CHF, then why not for COPD?
- **Pulmonary Rehab**: Can we get similar benefits from home-based programs in COPD?
Advances in Interventional Pulmonology: Endobronchial Valve Therapy for Emphysema

Arthur Sung, MD, FCCP
Stanford University School of Medicine
Director, Interventional Pulmonology and Bronchoscopy
Associate Chief, Innovation and Strategy
Division of Pulmonary and Critical Care Medicine Clinical
Associate Professor of Medicine

Friday, January 17, 2020 – 2:10 p.m. – 2:50 p.m.

Arthur Sung, MD, FCCP is the Director of Interventional Pulmonology and Bronchoscopy at Stanford HealthCare and also the Associate Chief of the Pulmonary and Critical Care Division at Stanford. His clinical interests include lung cancers and molecular testing of small samples acquired by means of minimally invasive approaches, the functional imaging of the central and peripheral airways, and epigenetics of lung cancer pathogenesis. He is integrally involved in leading strategic efforts for programmatic expansion of the division regionally, as well as overseeing quality projects in pulmonary medicine.”
• No financial conflicts
• No Conflicts/Disclosures
OR
• List any other disclosures such as Novartis – Consulting Fees, Boehringer Ingelheim Speakers’ Bureau, etc.
COPD- Emphysema phenotype
  ▪ NETT and LVRS
  ▪ Pathophysiology – Collateral Ventilation
  ▪ Techniques - BLVR
    ▪ Lobar Exclusion – Endobronchial Valve
    ▪ Airway Bypass
    ▪ Biogel
    ▪ Vapor Steam
    ▪ Coils
  ▪ LIBERATE Trial

The core issue in advanced emphysema is reduced elasticity, leading to gas trapping and lung hyperinflation.
Creates a downward spiral of deconditioning and lung function decline that results in death.

6 Million people in Europe and the US suffer from emphysema; 1.5M of these are severe or very severe.

4th leading cause of death worldwide

Costs the US healthcare system >$30B in direct expense annually

Medical Management
- Stop smoking
- Medication/inhalers to help breathing
- Supplemental oxygen
- Pulmonary rehabilitation

Lung Volume Reduction Surgery
- Remove diseased part of lung

Lung Transplant
- Replace diseased lung
Medical Management
• %FEV1 improvement: 3.9%
  (vs. MCID of 15%)

New Solutions Needed

Lung Volume Reduction Surgery
• 30 day mortality rate: 5%
• Extended hospitalization: 59%

NETT began enrolling in 1997 and completed enrollment in 2002

Compare LVRS and best medical therapy vs best medical therapy alone

In 2001, the Data and Safety Monitoring Board found high risk of death in subgroup of patients
  ▪ FEV1 ≤ 20% and one of the following
    o DLCO ≤ 20%
    o or Homogeneous Emphysema
Median sternotomy

VATS
  ▪ Stapling
  ▪ YAG Laser
  ▪ Reinforcement patches
  ▪ Biologic fibrin glue or blood

Removal of 25-30% of diseased lung

Upper lobe approach

• Pts with mostly upper lobe emphysema and low exercise capacity has increase in life expectancy and QOL
• Pts with mostly upper lobe and high capacity had no difference
  □ 15% of LVRS group had more than 10 watt improvement in exercise vs 3 % in medical group
• Non-upper lobe emphysema and low exercise capacity similar survival and exercise capacity but less dyspnea
• **Non-upper lobe and high capacity** had poorer survival after LVRS

Chest 2003;123:1026–37
Bronchoscopic Lung Volume reduction

- Endobronchial Valves
- Biological Sealant
- Vapor ablation
- Hydrogel
- Nitinol Coils

• Achieve volume reduction by lobar exclusion
• Avoidance of Dynamic Hyperinflation
• Re-direction of gases to better ventilatory units
Uni-directional valve implanted in airway

- Lobar exclusion via valve implantation in all airways supplying target lobe
- Silicone coated, self-expanding scaffold ensures tight seal in airway
- Valve allows trapped air and fluids to escape

Benefits
FEV1 4.3% improvement (35ml)
5.8% 6MWD
25% FEV1, 30% 6MWD,
11–point SGRQ in complete fissure

Risks
4.2% Complication @3 month and 6.1% at 6 month
Complication: Exacerbation/PTx, Hemoptysis/PNA/migration

Collateral ventilation is like a backdoor for airflow between lobes in the lungs.

If there is low collateral ventilation, the EBVs will keep air from entering the diseased area, reducing lung volume.

If there is collateral ventilation, air can enter the diseased area from behind the EBVs and lung volume will not reduce.
Low Vent

Normal Vent

Volume Reduction

No Dynamic Hyperinflation on exercise

High Collateral Resistance

Collateral Channels
Incomplete Fissures

Low Collateral Resistance Channels
The EBV System consists of:

- Endobronchial Valve (EBV)
- Valve Loading system
- Delivery Catheter (EDC)
A bronchoscope is inserted through the nose or mouth and into the lungs.

The EBV is delivered through the bronchoscope.

- If needed, the EBV may also be removed through the bronchoscope.
The Zephyr® EBV allows air and secretions to pass out through the valve but not back in, resulting in lung volume reduction.

In turn, the healthy part of the lung expands again and takes part in the exchange of oxygen and carbon dioxide.

The Chartis® System consists of:

- Console for measuring flow and pressure
- Balloon catheter

Similar to the EBV, the low pressure balloon catheter is delivered through a bronchoscope.
(A) Chartis output demonstrating a reduction in expiratory airflow but maintenance of inspiratory pressure following balloon occlusion of the treatment lobe indicating the absence of collateral ventilation.

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SdwhqweHdofwirq#girup hge | #ulru# dqIfdd#
H {shuhqfh

VENT RCT
All Valve Patients

VENT RCT
Patients with Low Collateral Ventilation
(subgroup)

BeLieVeR-HIFI RCT
Patients with Low Collateral Ventilation
Purpose of Study

• To determine the safety and effectiveness of bronchoscopic lung volume reduction using the Zephyr® EBV for treatment of emphysema

Key Endpoints

• Primary: Proportion of treated patients achieving a clinically significant improvement in FEV1 % compared to control patients
• Secondary: Improvements in lung function measures, shortness of breath, and quality of life
• Safety: Frequency of adverse events or complications in study participants who receive the EBV

US IDE approval trial, designed in collaboration with FDA
• 4th RCT using Zephyr valves in CV- patients
• First with 12 month follow-up in both treatment and control arms

Multicenter, international randomized controlled study
• 909 patients consented
• 255 had Chartis procedure
• 190 severe heterogeneous emphysema subjects with little to no collateral ventilation, randomized 2:1
  Zephyr valve to Standard-of-Care
• 24 sites in 4 countries

Key Methods

• Subjects meeting key inclusion/exclusion criteria and pulmonary rehabilitation underwent Chartis” assessment to determine CV status; only subjects with little to no CV were randomized
• Zephyr EBVs were delivered bronchoscopically to occlude all bronchi of the targeted lobe
• Subjects were kept in hospital for 5 days following the procedure for observation
• Valve adjustment allowed after 45-day CT review if no lobar occlusion and target lobe volume reduction less than 50%

Criner G et al, AJRCCM, 2018
INCLUSION

• Age 40 to 75 years.
• BMI < 35 kg/m².
• Stable with < 20mg prednisone daily
• Nonsmoking for 4 months
• Post-bronchodilator FEV₁ ≥15% or ≤ 45% of predicted
• RV ≥ 175% predicted (body pleth)
• TLC ≥ 100% predicted
• DLCO ≥ 20% predicted
• PaCO₂ ≤ 50mm Hg room air

EXCLUSION

• >2 pneumonia episodes in last year
• MI or CHF < 6 months
• Unable to discontinue anti-coagulants or platelet activity inhibitors for 7 days.
• Pulmonary hypertension (SPAP >45 mm Hg)
• Pulmonary nodule requiring surgery
• WBC >10,000 cells/µL
• 6 MWD < 100 or > 500 meters after PR
• Presence of AATD
• Plasma cotinine level >13.7 ng/ml or carboxyhb >2.5% if using nicotine products

Criner, AJRCCM, 2018
Percent of Subjects with FEV\textsubscript{1} Change from Baseline to 12 months of ≥15%
FeVI - Change from Baseline

6MWD - Change from Baseline

SGRQ - Change from Baseline

Values are Least Square Means ± SEM for n=128 (EBV) and n=62 (Control)

Pneumothorax Occurrence from Most Recent Bronchoscopy

Cotner, AJRCCM, 2018
### Serious Adverse Events

#### Serious Adverse Events Occurring in at Least 3.0% of Subjects in Either Group

<table>
<thead>
<tr>
<th>Event</th>
<th>Treatment Period Day of Procedure/Randomization or to 45 Days</th>
<th>Longer-Term Period 45 Days from the Study Procedure/Randomization or until 12-month Visit Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>EBV (N=128)              4 (3.1)%*</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Pneumothorax</td>
<td>34 (26.6)%*</td>
<td>0</td>
</tr>
<tr>
<td>COPD exacerbation</td>
<td>10 (7.8%)</td>
<td>3 (4.8%)</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>1 (0.8%)</td>
<td>0</td>
</tr>
<tr>
<td>Respiratory failure</td>
<td>2 (1.6%)</td>
<td>0</td>
</tr>
<tr>
<td>Arrhythmia</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Diverticulitis</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

* P<0.05  
* Inclusion Criteria:
  - Upper lobe dominant
  - RV > 175% pred.
  - DLCO > 20% pred.

Based on MCID for: FEV$_1$+15%; RV-350ml; 6MW+25m; SGRQ-4pts

---

#### Adjudicated Events

![Graph with adjudicated events]

- p=0.053
- p=0.033
OYU

Planned 2500 patients, enrolled 1218

<table>
<thead>
<tr>
<th><strong>Risks</strong></th>
<th><strong>Benefits</strong></th>
<th><strong>Complications</strong></th>
<th><strong>Indications:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall mortality over 29 months same Overall Risk of death: LVRS (7.9%) vs Medical (5.3%) Risk of death first 3 months (non-high risk) LVRS (5.2%) vs medical (3.5%)</td>
<td>&gt;10 watt increase at 2 yrs: 15% in LVRS vs 3% @ 2 yrs: increase lung function, exercise capacity, 6MWD, QOL (SGRQ)</td>
<td>9% intra-op &gt;50% post-op: 18% PNA, 18% arrhythmia, 21% reintubation, 11% ICU admission, 8% trach 7 day air leak (median) in 90% of cases 30 day post-op hospitalization: 28%</td>
<td>Age &lt;75 MRC score &gt;3 Severe Emphysema, TLC &gt;125%, RV/TLC 65%, FEV1 &lt;35% ULPD with low capacity Contraindication DLCO &lt;20%, FEV1 &lt;60%, PAH, PCHF &gt;35, CAD, Homogeneous Dz</td>
</tr>
<tr>
<td>Condition</td>
<td>LIBERATE (N=128)</td>
<td>NETT Total# (N=236)</td>
<td></td>
</tr>
<tr>
<td>----------------------------</td>
<td>------------------</td>
<td>---------------------</td>
<td></td>
</tr>
<tr>
<td>PTX and chest tube</td>
<td>&lt; 30%</td>
<td>&gt; 90%</td>
<td></td>
</tr>
<tr>
<td>Respiratory Failure</td>
<td>&lt; 30%</td>
<td>&gt; 90%</td>
<td></td>
</tr>
<tr>
<td>Pneumonia</td>
<td>4 %</td>
<td>8 %</td>
<td></td>
</tr>
<tr>
<td>90 day Mortality</td>
<td>3.1 %</td>
<td>5.0 %</td>
<td></td>
</tr>
</tbody>
</table>
AMBULATORY VENTILATORY SUPPORT IN COPD

Gaurav Singh, MD
Staff Physician
VA Palo Alto Healthcare System
Clinical Assistant Professor
Stanford University

Friday, January 17, 2020 – 2:50 p.m. – 3:30 p.m.

Gaurav Singh, MD completed all of his medical education and training locally. He attended UC Berkeley for undergraduate studies and UCSF for medical school. He also obtained a Masters of Public Health at UC Berkeley. He completed residency training in Internal Medicine at Stanford University, followed by Pulmonary and Critical Care fellowship as well as Sleep Medicine fellowship at Stanford University. Dr. Singh is currently a Staff Physician at the VA Palo Alto Healthcare System in the Section of Pulmonary, Critical Care, and Sleep Medicine. He is an Affiliated Clinical Assistant Professor at Stanford University.
BREAK
EXHIBIT HALL OPEN

Friday, January 17, 2020 – 3:30 p.m. – 3:55 p.m.
ETHICS AND MEDICALLY INAPPROPRIATE THERAPIES

David Chooljian, MD
Loma Linda University
Assistant Professor of Pulmonary and Critical Care Medicine
Instructor in Medical Ethics

Friday, January 17, 2020 – 3:55 p.m. – 4:35 p.m.

David Chooljian, MD is an Assistant Professor of Pulmonary and Critical Care Medicine and an Instructor in Medical Ethics at Loma Linda University. He obtained his undergraduate degree in Anthropology from UCLA, after which he became the first student to complete the joint degree program in medicine and law at Vanderbilt University. He then received internal medicine training at the Cleveland Clinic and became a member of the State Bar of California during his internship year. He came to Loma Linda after completing his pulmonary and critical care medicine training at Stanford University. In addition to practicing pulmonary and critical care medicine at the VA, he became one of the ethics consultation fellows of the VA’s National Center for Ethics in Health Care and completed a fellowship in clinical medical ethics at the MacLean Center for Clinical Medical Ethics at the University of Chicago. He is the Chief of the Ethics Consultation Service and Chair of the Consultative Ethics Committee for the VA Loma Linda Healthcare System. Along with his ethics consultation activities, he teaches courses at Loma Linda University including Advanced Medical Ethics for the School of Medicine and Law and Bioethics for the School of Religion. He is also the current Chair of the Ethics and Conflict of Interest Committee of the American Thoracic Society.
When They Want “Everything Done”: Requests for Medically Inappropriate Therapies in the Critical Care Setting

David M. Chooljian, M.D., J.D.
California Thoracic Society Northern California Annual Educational Conference
January 17, 2020
Objectives

- Recognizing the importance of patient/surrogate decision maker-derived goals in shared decision making regarding critical care.
- Promoting awareness of pertinent legal/regulatory elements in responding to therapeutic requests in critical care.
- Promoting awareness of ethics best practices in responding to requests for excessive therapies in the critical care setting.
Disclosures

- I have no financial conflicts of interest regarding the content of this presentation.
- Past Fellow, VA National Center for Ethics in Health Care.
- Current Chair, Ethics & Conflict of Interest Committee, American Thoracic Society.
Legal information in this presentation is meant as general education and should not be construed as advice for a specific legal case, actual or potential.

- In other words: I’M NOT YOUR ATTORNEY!!!
Overview

- The F-Word: Definition & Evolution of Concept of Futility
- Legal Standards
- Professional Standard
- Best Practices for Responding
“It’s Futile” vs “Everything Done” : A Recurrent Struggle

Jahi McMath
5/26/2000-12/12/2013(?)

“[Hospital says] it’s futile to treat a ‘dead’ patient.” - 12/21/13
“the mother...wants to do everything possible...” – 1/7/14


- T&A/UPPP/turbinate resections 12/9/13 c/b cardiac arrest, ROSC after 2+hr.
- Declared dead by neuro criteria (ultimately 6 physicians), death certificate issued 1/3/14 listing 12/12/13 as date of death (no cause).
- C&D letter 12/17/13, TRO issued by Alameda County Superior Court 12/23/13 for eval, then extended to 1/7/14.
- Body released 1/5/14 (CHO→Coroner→Family) & transferred...to NJ.
- Cardiac arrest d/t hemorrhage, “died” (?!?) 6/22/18.
Futility: Implications

- Common: up to 32% any given ICU day.
- Distressing: associated with intent to leave the field.
- Concept a result of backlash against increasing Pt autonomy?
  - 1986: Futility - The Profession Strikes Back
    - Danger of “unbalanced approach to autonomy”
    - If no “modicum of potential benefit” from medical perspective, no obligation to provide therapy to informed competent patients, no matter how strongly they disagree.

- Brett AS, McCullough LB. When patients request specific interventions. NEJM 1986;315:1347-1351.
Defining “Futility”

- “Extremely difficult” – VA NCEHC
- **Medical futility** - physician’s determination that a therapy will be of no benefit to a patient, and therefore should not be prescribed.
  - **Physiologic** - *impossible* for desired response to be achieved by intervention
  - **Probabilistic** – “vanishingly low” likelihood of providing desired benefit

Jonsen AR, Siegler M, Winslade WJ. Clinical Ethics: A Practical Approach To Ethical Decisions In Clinical Medicine, 7th Ed. 2010: §1.2.2.
Defining Probabilistic Futility: Methods

- **Quantitative**
  - “<1%” chance of benefit
  - Pro: takes into account patient preference
  - Cons:
    - Unrealistic precision assumptions.
    - Variability in acceptable thresholds.

- **Qualitative**
  - No reasonable expectation of benefit (furthering worthwhile goal)

The Reasonable Person

- “A hypothetical person used as a legal standard, esp. to determine whether someone acted with negligence. The reasonable person acts sensibly, does things without serious delay, and takes proper but not excessive precautions.” – Black’s Law Dictionary, Abr 7th Ed.
- “A mythical creature on par with the Yeti.” – DMC.
- Reality: A person found within a community of similarly situated individuals. That community’s potential actions set the boundaries of an acceptable standard of behavior.
Defining Probabilistic Futility: Methods (cont’d)

- **Quantitative**
  - “<1%” chance of benefit
  - Pro: takes into account patient preference
  - Con: Unrealistic precision. High bar, rarely reached.

- **Qualitative**
  - No reasonable expectation of benefit (furthering worthwhile goal)
  - Pro: Community standard (physicians)
  - Con: May override patients’ autonomy

“Life” often more **qualitative** than **quantitative**. (e.g. meaningful *activities* often more central to decisions)

Who defines acceptable quality of life (and therefore “benefit” of therapies)?

- The **Patient**, or if no decision making capacity...
- ...the ethically appropriate **Surrogate Decision Maker**.
Defining Futility: A Shared Task

- **Goal** (& therefore **Benefit**): Patient-Defined
- **Probability of Achieving Goal**: Physician-Defined
- Respect for Autonomy dictates deference to patients’ wishes in borderline-benefit cases, with rare exceptions:
  - Physiologic futility
  - (Pre-defined) Quantitative futility
- Result: Futility invoked on increasingly rare basis, in favor of more nuanced concepts.
- see: Helft PR, Siegler M, Lantos J. The rise and fall of the futility movement. NEJM 2000. [& Letters]
Legal Standards

- State Legislation
- Federal (Administrative) Law
- State Common Law
Model State Legislation


- **§7: Obligations of Health Care Providers**
  - (f): A health-care provider or institution may decline to comply with an individual instruction or health-care decision that requires *medically ineffective health care* or health care contrary to generally accepted health-care standards applicable to the health-care provider or institution.
California HCDA: “Medically Ineffective Health Care”

- Not directly defined, but...
- California Probate Code §4650:

  The Legislature finds the following:
  
  - (a) In recognition of the dignity and privacy a person has a right to expect, the law recognizes that an adult has the fundamental right to control the decisions relating to his or her own health care, including the decision to have life-sustaining treatment withheld or withdrawn.
  
  - (b) Modern medical technology has made possible the artificial prolongation of human life beyond natural limits. In the interest of protecting individual autonomy, this prolongation of the process of dying for a person for whom continued health care does not improve the prognosis for recovery may violate patient dignity and cause unnecessary pain and suffering, while providing nothing medically necessary or beneficial to the person.
California: Ability to Decline Patient’s Health Care Instruction/Decision

- **Basis:**
  - *Conscience* (California Probate Code §4734), OR
  - Would require *medically ineffective* health care (§4735), OR
  - Would require health care *contrary to generally accepted health care standards* (§4735)

- **Process (§4736):**
  - Promptly **inform** Pt/SDM, AND
  - Make “all reasonable efforts” to assist in **transfer** to another provider/institution (unless Pt/SDM refuses), AND
  - Provide **continuing care** until transfer accomplished/appears it cannot be accomplished. Emphasis on appropriate pain relief/palliation.
California: Immunity in Healthcare Decisions

California Probate Code §4740
- Provider/institution not liable for actions [under Health Care Decisions Act] if:
  - Acting “in good faith” AND
  - “in accordance with generally accepted health care standards”
- In cases of declining instructions/decisions, must comply with applicable sections. (§§4734-4736)
Federal: VHA Ethics Policies & Publications

www.ethics.va.gov
Futility situations should be handled on case-by-case basis, with consistent review process.

Recommended review process elements:

- Second physician concurring with futility determination
- An individual or group designated by the facility (such as an Ethics Advisory Committee) must:
  - (1) Discuss situation with the involved parties & attempt to reach a resolution, AND
  - (2) make a formal recommendation on the case.
- Pt/Surrogate informed of plan & offered assistance in process of transfer.
- Pt/Surrogate given reasonable time to seek transfer/court intervention.

Cites VALLHCS DNR policy!
Federal: VALLHCS Policy

11-52 Withdrawal of Life-Sustaining Therapy:

- No definition of futility.
- LST: “necessary for the continuation of life”
- Pt/Surrogate, Physician, Nursing, & RT (where applicable) consensus required to withdraw LST (except if dead by neurologic criteria).
- No consensus → refer to Ethics Committee.
Facts:

- Elizabeth Alexander, 70, diagnosed in 2012 @ LLUMC w/Stage IV pancreatic CA, elected to “continue fighting” via palliative [non-curative-intent] chemotherapy & XRT. Also seen @ UCLA & UCI.

- Despite therapies, admitted to SNF January 2013 d/t inability to perform self-care. Advance Directive instructs receipt of “all measures...to prolong her life.” Son participates in completing POLST including orders for full medical therapies pre-arrest and for CPR.

- Deteriorates despite initiation of tube feedings. Son advised that death was imminent and that resuscitation efforts would be ineffective and would cause suffering. Refuses change to DNR. Pt transferred to Scripps 2/18/13. Admission notes include Pt status of minimally responsive & Son wanting “everything done” to save/prolong Pt’s life.

Oncology informs Son no further therapies could be provided safely. Palliative Care notes Son “was very difficult” despite assessment that survival unlikely beyond a few days. Discussed with CoS, informed Son of plan to not provide “non-beneficial or ineffective medical care”. CoS convenes Appropriate Care Committee, 2/20/13.

Committee recommends against advanced life support measures. Discussed with Son, who did not agree. Ethics consultation requested & transfer recommended, provided would not cause harm.

Opiates continued & Lorazepam initiated; IVF held d/t edema & TF held d/t abd pain. DNR order entered by Palliative Care. Transfer back to SNF arranged 2/21/13 but Pt died shortly before transfer time.
**Causes of Action** *(inter alia)*:

- Elder Abuse Act violation via neglect, consisting of “failure to provide medical care” (California Welfare & Institutions Code §15610.57(b)(2))

**Holdings:**

- Elder Abuse: “Disagreements between physicians and the patient or surrogate about the type of care being provided does not give rise to an elder abuse cause of action.” [emphasis added]
- Healthcare Decisions Act: “…physicians are not required to render medically ineffective health care, defined as treatment that would not offer any significant benefit.” [citing §4735, emphasis added]

Professional Standard: Key Concepts & Recommendations

1) **Prevention** strategies (System- & Clinician-level)
2) Clear & Consistent **Terminology**
   - “Futile”
   - “Legally Proscribed”
   - “Legally Discretionary”
   - “Potentially Inappropriate”
3) **Process for Conflict** Resolution
4) Management of **Time-Pressured** Requests
Professional Standard: Prevention Strategies (selected)

System:
- **Regular** structured inter-professional *family meetings*
- Integrate palliative care and/or ethics into ICU difficult cases
- Maintain **dedicated meeting space** for ICU family meetings

Clinician:
- Coordinate effective ICU family meetings (achieve **pre-meeting clinician consensus**, introduce everyone, use private space)
- Provide family-centered communication (elicit surrogates’ understanding early, avoid jargon, deliver information in small chunks)
- Foster shared decision-making (evaluate **SDM preference for degree of decision-making responsibility**, elicit goals, advocate for good medical practices)
**Futile**: therapy “simply cannot accomplish the intended physiologic goal” (Ex: CPR to achieve ROSC, despite rigor mortis)
Legally **Proscribed**: therapy may work, but legally **prohibited** (Ex: circumventing organ donation process)

Legally **Discretionary**: therapy may work, but law **allows limited use** based on medical judgment (Ex: “medically ineffective treatment” law)

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**Flowchart:**

- Legally Proscribed or Legally Discretionary Treatment
  - Clinicians need not provide requested treatment(s)
  - Clinicians should explain the situation and provide emotional support for the family/surrogate

- Does the urgency of the clinical situation preclude carrying out the procedural resolution process and do the clinicians involved have a high degree of certainty that the requested treatment lies outside the boundaries of accepted practice?
**Potentially Inappropriate**: therapy has “at least some chance” of accomplishing effect, but *not justified* based on competing ethical considerations (e.g. non-maleficence). Note: term reflects need for **review**, possible conflict.
1) Enlist expert consultation for mediation (separate from eventual review committees) & continue throughout process.

2) **Give notice** of process to SDMs (written & verbal).

3) Obtain a **second medical opinion**.

4) Review by interdisciplinary hospital committee (providing conclusions to all parties, with discussion).
   a) If agree with clinician, inform of **right to seek extramural appeal/transfer** (& facilitate same).
   b) If agree with Pt/SDM, provide requested therapy (or transfer to alternate provider).
Ex: ECMO request for frail Pt on max pressors.

Key Elements:

- Explain situation & decision basis to SDM.
- To extent possible, engage other clinicians (incl check for “moral blind spots”)
- If high degree of certainty re: inappropriate nature, don’t include requested Rx in even a temporary plan.
Best Practices in Responding to Requests for Inappropriate Therapies

- **Acknowledge Emotions** Behind Request (“I Wish” Language)
- Therapy (receiving/avoiding) ≠ Goal
- **Activity-Focused** Goal Discussions
Empathy, tempered with Reality

“I wish” instead of:

- “I’m sorry…”
- “I feel…”
- “I hope…”

Goals of Care Conversations, Part 1: Reframing. VHA National Center for Ethics in Health Care.
Best Practices in Responding: Avoiding Therapy as Goal

- Can be overt ("He wants every available treatment.") or implied ("She’s always been such a fighter.")
- Applies to therapy avoidance as well ("He didn’t like the idea of chest compressions", "She doesn’t want a tube in her throat.")
- Common issue: equating intensity/variety of therapy with valuation of person. (Emphasize non-abandonment.)
- Core strategy: assigning meaning to seemingly dispositive statement (Ex: “I understand she’s a fighter. What does she want to be fighting for?”)
Best Practices in Responding: Expressing Goals in Terms of Activities

- Adds **objectivity**
- Encourages **inter-observer consistency** (Pt, Family, Providers)
- May offer greater insight into core values, acceptable QoL
  - “He wouldn’t want any of this if it can’t get him back to fishing.”
  - “As long as she can watch her stories with her dog in her lap, she’ll be happy.”
  - “I just want to be able to go shopping with my wife.”
Summary

- Concept: “Futile” → “Potentially Ineffective”
- Professional/Ethical Standards:
  - No obligation to provide potentially inappropriate therapies, but...
  - Have a process for disputes, and inform Pt/SDM of process.
- Legal Standards:
  - No obligation to provide ineffective/nonstandard care, but...
  - Inform Pt/SDM of decision & offer assistance w/transfer.
- Techniques for Responses:
  - Acknowledge Emotions Behind Request (“I Wish” Language)
  - Therapy (receiving/avoiding) ≠ Goal (“Everything done” starts conversation.)
  - Activity-Focused Goal Discussions
Key References/Further Resources

- VHA National Center for Ethics in Health Care: www.ethics.va.gov
- LLU Center for Christian Bioethics: https://religion.llu.edu/bioethics
- University of Chicago MacLean Center for Clinical Medical Ethics: https://macleanethics.uchicago.edu
The End

- Questions?
- Comments?
- Concerns?
- Hopes?
- Dreams?
- Wishes?
- Desires?

FUTILITY

No matter how hard you try, you will fail.

David.Chooljian@VA.gov
DChooljian@LLU.edu
UPDATES TO END OF LIFE CARE
FROM CALIFORNIA LAW

Stephanie M. Harman, MD
Stanford University School of Medicine
Clinical Associate Professor of Medicine

Friday, January 17, 2020 – 4:35 p.m. – 5:15 p.m.

Stephanie Harman, MD received her medical degree from Case Western Reserve University. She completed her internal medicine residency at Stanford University and her palliative care fellowship at the Palo Alto VA. Currently, she is the Clinical Section Chief of Palliative Care at Stanford and co-chairs the Stanford Health Care Bioethics Committee. Dr. Harman is a Clinical Associate Professor of Medicine in the Stanford University School of Medicine.
Update in Bioethics from California State Law

Stephanie Harman, MD
Clinical Associate Professor, Stanford Dept of Medicine
Co-chair, Bioethics Committee of Stanford Health Care

Disclosures

- VitalTalk.org: course facilitator for regional and national courses
- UptoDate, Inc: receive royalties as an author
Acknowledgments

Holly Tabor, PhD
David Magnus, PhD
Jose Maldonado, MD
Eric Fromme, MD

Goals for the next 45 minutes

1. Review the landscape of physician-assisted death in the US and in California.
2. Discuss lessons learned from the implementation of the End of Life Option Act.
3. Learn approaches for decision-making for patients who lack capacity and lack surrogates.
Before June 9, 2016: Consults for Physician Assisted Death

Before the law...a typical case

Elderly man w/Parkinson's

Aspiration pneumonia, +decision-making capacity, keofeed in place, self-dc'd x1

Consult to palliative care: Patient requesting to die, would like to take a lethal prescription
Foreshadowing

Patients and families often do not distinguish between PAD, refusing unwanted treatments, hospice, etc.

In practice, many who raise the issue of PAD are using it as a surrogate for end of life conversations.

*It is problematic if we frame these conversations under the auspices of PAD.*

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Some Definitions

Physician-Assisted Death: a physician providing, at the patient’s request, a prescription for a lethal dose of medication that the patient can self-administer by ingestion, with the explicit intention of ending life.

Euthanasia: physician administers a medication to intentionally end a patient’s life with the mentally competent patient’s explicit request.

Oregon Experience since 1997

1. A tiny % of MD’s ever write prescriptions (92 MDs out of >10,000 MDs)
2. A small # patients ever get lethal prescriptions or utilize PAD
3. Even more rare are in-patient cases: to date 1 in 17 years at OHSU; 1 at UW.

Positions of Clinical Societies: AMA and ANA

“It is understandable, though tragic, that some patients in extreme duress—such as those suffering from a terminal, painful, debilitating illness—may come to decide that death is preferable to life. However, permitting physicians to engage in assisted suicide would ultimately cause more harm than good. Physician-assisted suicide is fundamentally incompatible with the physician's role as healer, would be difficult or impossible to control, and would pose serious societal risks.”

“The American Nurses Association (ANA) prohibits nurses' participation in assisted suicide and euthanasia because these acts are in direct violation of Code of Ethics for Nurses….Nurses have an obligation to provide humane, comprehensive, and compassionate care that respects the rights of patients but upholds the standards of the profession in the presence of chronic, debilitating illness and at end-of-life.”
Our Tribe: AAHPM, NHPCO, and HPNA

“It is the position of the Hospice and Palliative Nurses Association (HPNA) that physician-assisted death/physician-assisted suicide is not part of palliative care.”

“...the National Hospice and Palliative Care Organization does not support the legalization of physician assisted suicide."

“AAHPM takes a position of studied neutrality on the subject of whether PAD should be legally permitted or prohibited. However, as a matter of social policy, the Academy has concerns about a shift to include physician-assisted dying in routine medical practice, including palliative care.”

PAD in the US

- Oregon Death With Dignity Act passes
- Montana Supreme Court rules to protect MD providing PAD
- New Mexico court case rules in favor of right to die
- Colorado passes End of Life Options Act
- D.C. Death With Dignity Act goes into effect
- NJ Aid in Dying for the Terminally Ill Act passed

1997

- Supreme Court rules PAD is not a constitutional right, leaves it to states
- Oregon Death With Dignity Act passes
- Washington Death With Dignity Act passes
- Vermont Patient Control and Choice at End of Life Act passes
- California End of Life Option Act passes
- Hawaii Our Care Our Choice Act passes

The public discourse

PAD Internationally

PAD and Euthanasia
Belgium
Netherlands
Luxembourg
Colombia
Canada

PAD only
Switzerland
US (Select states)

California Law

California’s End of Life Option Act

The End of Life Option Act (ABX2-15) was signed into law on October 5, 2015.

Effective June 9, 2016.

Language based on the Death With Dignity Act in Oregon.

Limits direct contact by insurance companies.

Sunsets in 10 years
Key Elements: the Patient

- Adult: 18 years or older
- CA resident
- Terminal illness: 6 month prognosis or less
- 3 verbal requests:
  1. To the prescribing attending MD—initial request
  2. To the consulting attending MD—consultant visit
  3. To the prescribing attending MD—repeat request nor earlier than 15 days after initial request
- 1 written request submitted to the prescribing MD

Key elements: Attending Physicians

Prescribing attending MD: at least 2 visits which include documentation of terminal illness (<6 month, decision-making capacity evaluation, and discussion of options

1st visit is the initial request: patient must be alone
2nd visit no earlier than 15 days after the initial request

Consulting MD: 1 visit, documenting decision-making capacity; prognosis; review of options;

Referral to psychiatry/psychology IF “indications of a mental disorder” to determine if capacity is impaired
How does an institution decide to participate or opt out?

Example: UW-Seattle Cancer Care Process for Determining Institutional Stance

Step 1: Series of Town Hall meetings.

Step 2: Survey
200 physicians surveyed; 81 responded (40.5):
  - 36% willing to do both = 29 MDs
  - 26% willing to consult only
  - 38% unwilling to participate or undecided

Conclusion: Opt-in

How did we decide?

1. Governance: Initial discussion with the Medical Staff Executive Committee
2. Town Halls: 19 of them
4. Vote by the executive committee

Town Hall Summary and Comments

Providers express general concerns about the operations & compliance burdens of participating in EOLA.

Who will usher the patients to an alternate provider if their primary one conscientiously objects? A social worker?

With the exception of primary care providers, most clinicians welcome and agree with consultations to ethics and/or palliative care.

Psychiatry had suggested a mandated psychiatry evaluation (UCSF is doing this).
Differing Perspectives on Palliative care and PAD

Palliative Care should be the prescribers.

Palliative Care should act as a safeguard.

Palliative Care should not be a requirement.

All agreed that patients requesting PAD have palliative care needs.

Case Example

89 y/o woman BIBA after a fall
Maxillary fracture, also had a urinary tract infection

During the discharge process, the patient communicates that she "had a good life and was ready to die" and asks "is there a pill she could take"

Is this a PAD request?
Stanford’s policy for the End of Life Option Act: Our "Add-ons"

Required Ethics consultation: Attending MD calls ethics upon initial patient request.

When an attending MD refuses to participate, Social Work coordinates/navigates patient to an attending MD willing to prescribe.

Advance Directive and POLST completion are required.

Hospice is strongly recommended

The Stanford Landscape: Shifting for Some, not All

“When I hear Palliative Care is seeing a patient, I assume that you have been called to withdraw Treatment…”

-a cardiothoracic surgeon in 2018

We continue to disarticulate palliative care from death, and from hastened death.

We did not want to be in the position of prescriber.

We strive to facilitate dialogue, not death.
Palliative Care in the Stanford Process

D. Willing Consulting Physician: This physician will be an SHC palliative medicine physician to both serve as the consulting physician and to explore available options which may not have been discussed, including physical, social, emotional and spiritual assessment. This will also provide access for the patient and their family to the range of services from the palliative care program.

Palliative Care at Stanford: unique services to offer

- Multi-disciplinary team (MD, nursing, social work, chaplaincy)
- Inpatient and in 3 different clinic sites
- Pediatric Guidance program for patients who are parents of children age 18 and under

Basic Process for Physician Aid in Dying (PAD) Request

The California End of Life Options Act

In effect June 9, 2016
Our Experience

We’ve needed to expand who can be the consulting palliative medicine physician.

No physician wants to be known as the “go-to” for PAD.

How do we triage PAD patients in palliative care clinic?

Patients pursuing aggressive, innovative treatments (clinical trials) seek PAD sometimes as a back up option.

Forms, forms, forms
PAD Operations Work Group

EPIC

Medication changes

Case review

Peer support

California ELOA 2018

[Diagram showing the number of individuals with prescriptions written in 2018, those who ingested and died from the drugs during 2018, those who died from underlying illness or other causes, and those with unknown ingestion status.]
California ELOA 2018

Median age: 74
51% Female, 49% Male

Demographics of CA ELOA in 2018

<table>
<thead>
<tr>
<th>Education</th>
<th>N</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No High School Diploma</td>
<td>8</td>
<td>(2.4)</td>
</tr>
<tr>
<td>High School Diploma or GED</td>
<td>56</td>
<td>(16.6)</td>
</tr>
<tr>
<td>Some College</td>
<td>60</td>
<td>(17.8)</td>
</tr>
<tr>
<td>Associate’s Degree</td>
<td>29</td>
<td>(8.6)</td>
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<tr>
<td>Bachelor’s Degree</td>
<td>90</td>
<td>(26.7)</td>
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<tr>
<td>Master’s Degree</td>
<td>53</td>
<td>(15.7)</td>
</tr>
<tr>
<td>Doctorate or Professional Degree</td>
<td>38</td>
<td>(11.3)</td>
</tr>
<tr>
<td>Unknown</td>
<td>3</td>
<td>(0.9)</td>
</tr>
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Demographics, cont’d

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<thead>
<tr>
<th>Race/Ethnicity</th>
<th>N</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>White</td>
<td>298</td>
<td>(88.4)</td>
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<tr>
<td>Black</td>
<td>3</td>
<td>(0.9)</td>
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<tr>
<td>American Indian/Alaskan Native</td>
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<td>(0.0)</td>
</tr>
<tr>
<td>Asian</td>
<td>20</td>
<td>(5.9)</td>
</tr>
<tr>
<td>Hawaiian/Pacific Islander</td>
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<td>(0.0)</td>
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<tr>
<td>Other</td>
<td>1</td>
<td>(0.3)</td>
</tr>
<tr>
<td>Multi-Race</td>
<td>2</td>
<td>(0.6)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>13</td>
<td>(3.9)</td>
</tr>
<tr>
<td>Unknown</td>
<td>0</td>
<td>(0.0)</td>
</tr>
</tbody>
</table>

The Role of Hospice

88% enrolled in Hospice
Not required
California 2018 ELOA Insurance status

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>2018</th>
<th>(N=337)</th>
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</thead>
<tbody>
<tr>
<td>Insurance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicare or Medicare with another type of insurance</td>
<td>237</td>
<td>(70.3)</td>
</tr>
<tr>
<td>Private insurance</td>
<td>35</td>
<td>(10.4)</td>
</tr>
<tr>
<td>Medi-Cal</td>
<td>9</td>
<td>(2.7)</td>
</tr>
<tr>
<td>Other (including VA and Covered California)</td>
<td>1</td>
<td>(0.3)</td>
</tr>
<tr>
<td>Has Insurance, but unknown type</td>
<td>36</td>
<td>(10.7)</td>
</tr>
<tr>
<td>No Insurance</td>
<td>2</td>
<td>(0.6)</td>
</tr>
<tr>
<td>Unknown</td>
<td>17</td>
<td>(5.0)</td>
</tr>
</tbody>
</table>

Medications

Premedicate, premedicate, premedicate 1 hour before:
- ondansetron 8mg PO
- metoclopramide 10mg PO

Prescriptions:
- Secobarbital 9gm
- DDMP2
  - Digoxin 50mg 30 min prior, then
  - Diazepam 1gm, Morphine 15gm, Propanolol 2gm
<table>
<thead>
<tr>
<th>OPTION</th>
<th>Barbitalrate</th>
<th>Medication Combo (DDMP2)</th>
<th>Compounded Medication</th>
<th>Medication Combo</th>
</tr>
</thead>
<tbody>
<tr>
<td>INGREDIENTS</td>
<td>Seccobarbital (Seconal) 9 grams, 900 capsules (100mg each) (28 liquid if available)</td>
<td>Pre-medication (30-60 mins prior to combination): Digosin 50mg (crushed tablets or powder) diluted to 4oz with apple juice or similar liquid Combination Medication: Diazepam 1 gram + Propomanol (Infernal) 2 grams + Morphine 15 grams</td>
<td>Phenobarbital 20 grams + Morphine 3 grams (can double if opioid tolerant) + Chloral hydrate 20 grams + Water 120 mL</td>
<td>Pre-medication (30 mins prior to combination): Digosin 100mg (crushed tablets or powder) diluted to 4oz with apple juice or similar liquid Combination Medication: Diazepam 1 gram + Amitriptyline 8 grams + Morphine 15 grams</td>
</tr>
<tr>
<td>DIRECTIONS</td>
<td>Mix contents 4-5 ounces of water or applesauce (may need to extract powder just prior to taking in capsule form). Medications can be crushed or compounded and: Buffer suspension, shia 1.5 g; + H2O or clear juice, 2-3 oz. for mixing the above substances in; use a small dark glass, and agitate until smoothy mixed</td>
<td>Pharmacy will mix into solution.</td>
<td>Dispense combination medications as Powder in 120cc brown glass bottle. Add liquid of choice to fill bottle and shake well. Patient takes all liquid PO in 2 minutes (10 minutes after taking digoxin).</td>
<td></td>
</tr>
<tr>
<td>Estimated Cost*</td>
<td>$3,000 - $4,500</td>
<td>$600</td>
<td>$500</td>
<td></td>
</tr>
<tr>
<td>Access</td>
<td>- Patient may have to prepare some portion - Costs may be prohibitive if not covered by insurance</td>
<td>- Limited availability of Chloral hydrate. Dependent on location and insurance coverage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient Considerations</td>
<td>- Patient may have to prepare if compounding pharmacy not utilized - &quot;Chloral hydrate causes burning sensation&quot; - Requires access to compounding pharmacy</td>
<td>- Patient may have to prepare if compounding pharmacy not utilized</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

What we hear

Aid-In-Dying Requires More Than Just A Law, Californians Find

The Mercury News

Bay Area doctors learn to navigate California’s right-to-die law

HEALTHCARE POLICY AND LAW
Early Experience With the California End of Life Option Act Balancing Institutional Participation and Physician Conscientious Objection
Balancing conscientious objections with institutional participation

Any physician can decline to participate.

As an institution, we have committed to participating and providing this as an option for our patients.

What if they are willing to participate under additional safeguards:
- longer wait time
- mandatory psychiatric evaluation

Unanticipated questions

Virtual Medicine/Telehealth

Patient’s reasons for request
  Avoiding a prison death;
  If the clinical trial doesn’t work...

Patients without surrogates

Who can be the consulting physician?

How to triage patients requesting PAD?

Our Experience

We’ve needed to expand who can be the consulting palliative medicine physician.

No physician wants to be known as the “go-to” for PAD.

How do we triage PAD patients in palliative care clinic?

Patients pursuing aggressive, innovative treatments (clinical trials) seek PAD sometimes as a back up option.
Our Learnings

Elicit all voices, and listen.

Some patients view this option as a backup plan, not as the plan.

All patients requesting PAD have palliative care needs.

By codifying palliative care into the PAD process, we are recognized resources and support for clinicians and patients

HOW DOES DECISION MAKING HAPPEN FOR PATIENTS WHO LACK CAPACITY AND LACK SURROGATES?
California State Law and Unbefriended Patients who lack capacity

CANHR v Chapman
A Process-Based Approach

CANHR v Smith

Ongoing
Thank you!

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smharman@Stanford.edu

Stanford Medicine
Palliative Care

Stanford Department of Medicine
George Su, MD
UC San Francisco
Associate Professor of Medicine

Friday, January 17, 2020 – 5:15 p.m. – 5:20 p.m.

George Su, MD is Associate Professor of Medicine in the University of California, San Francisco (UCSF) School of Medicine with a primary appointment in the Division of Pulmonary and Critical Care Medicine (PCCM) at Zuckerberg San Francisco General Hospital (ZSFG). I am a life-long Californian (since kindergarten) and include bulk collegiate and professional training through the University of California (UC) as part of my wonderful California journey. I serve ZSFG as PCCM faculty, Medical Director of Sleep and our Asthma/COPD Program, and serve the San Francisco Department of Public Health (SFDPH) and its clinical arm, the San Francisco Health Network (SFHN), as a specialty care informaticist in the Office of Health Informatics (OHI) and as Medical Director of Telehealth. My research interests have seen quantum evolution from basic mechanisms of endothelial cell-cell interactions and cytoskeletal dynamics to now, technology innovation for underserved populations. I am a champion for quality improvement at both local and national levels, including service to the American Thoracic Society (ATS) as a member of its Quality Improvement and Implementation Committee (QIIC). And, I consider medical education as elemental to my UCSF and overall professional identity, and as such, am proud of my service to the California Thoracic Society (CTS), as co-chair of our CTS Multidisciplinary Conference Committee over the past three years. I, Lisa, and our three children live humbly in the Richmond District “dunes” of San Francisco.
6th Annual CTS Fellow/Multidisciplinary Poster Competition

Friday, January 17, 2020 – 5:30 p.m. – 6:30 p.m.