



## Topic Brief: Supplemental Oxygen Prescribing Practices

**Date:** 10/8/2020

**Nomination Number:** 0922

**Purpose:** This document summarizes the information addressing a nomination submitted on July 16, 2020 through the Effective Health Care Website. This information was used to inform the Evidence-based Practice Center (EPC) Program decisions about whether to produce an evidence report on the topic, and if so, what type of evidence report would be most suitable.

**Issue:** Current prescribing practices for home oxygen are based on liters per-minute of oxygen output, which does not accommodate natural variations in oxygen needs based on variables such as physical activity. The nominator has indicated that a shift in home oxygen prescribing practices is needed to target oxygen saturation ranges and to include titration by patients based on physical activities. This change has the potential to improve health outcomes.

**Program Decision:** The EPC Program will not develop a new systematic review for this nomination because we did not find a sufficient number of primary studies to address the nomination.

### Key Findings

- We found no studies that addressed the first key question (KQ) regarding the comparative effectiveness and harms of oxygen prescribing practices in adults with chronic lung disease.
- We found only one study that addressed the second KQ regarding the comparative effectiveness and harms of oxygen devices in adults with chronic lung disease.

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### Background

Approximately 16 million Americans suffer from chronic obstructive pulmonary disease (COPD), and in 2010 the Centers for Disease Control and Prevention predicted that costs associated with the disease would increase from \$32.1 to \$49 billion over the course of the next decade.<sup>1,2</sup> Long-term oxygen therapy is a treatment for severe COPD that delivers oxygen as-needed to improve a patient's ability to breathe in their day-to-day life.<sup>2</sup> It is estimated that over one million Medicare recipients in the United States receive at-home oxygen therapy, with costs exceeding \$2 billion per-year.<sup>3</sup>

New technologies, including portable oxygen concentrating (POC) devices and inexpensive pulse oximeters, have become widely available in recent years, affording patients greater control over treatment delivery and enabling them to monitor their oxygen saturation levels as they engage in different activities.<sup>4</sup> However, although the evidence base for oxygen therapy in the COPD population is nearly 40 years old, it still serves as the primary underpinning for current prescription practices and treatment.<sup>5</sup> These prescribing practices, and corresponding

payment formulas established by the Centers for Medicare and Medicaid Services, require physicians to write flow prescriptions in liters per-minute (L/min). Despite this standard, most POCs are not designed with outputs calibrated in L/min, and are better suited for monitoring through oxygen saturation levels. This disconnect between technological innovation and prescribing practices is a source of confusion for both patients and practitioners, and has the potential to cause translational errors.<sup>3</sup>

## Scope

1. What is the comparative effectiveness and harms of oxygen prescribing practices in adults with chronic lung disease?
2. What is the comparative effectiveness and harms of oxygen devices in adults with chronic lung disease?

**Table 1.** Questions and PICOS (population, intervention, comparator, outcome, and setting)

Questions	1. Effectiveness and harms of oxygen prescribing practices	2. Effectiveness and harms of oxygen devices
Population	Adults with chronic lung disease (e.g., COPD, pulmonary fibrosis, pulmonary hypertension, cystic fibrosis) requiring supplemental oxygen.  Consider condition type and patient characteristics (e.g., age, sex, comorbidities, disease severity)	Adults with chronic lung disease (e.g., COPD, pulmonary fibrosis, pulmonary hypertension, cystic fibrosis) requiring supplemental oxygen.  Consider condition type and patient characteristics (e.g., age, sex, comorbidities, disease severity).
Interventions	<i>Prescribing practices:</i> e.g., liters per minute, target oxygen saturation range.	<i>Oxygen delivery device technologies:</i> e.g., continuous flow, inhalation-only oxygen delivery, LOX devices.  Consider device technology subtypes within pulse dose devices (e.g., continuous flow vs. active intermittent flow delivery devices).  Consider weight of the devices (e.g., POC vs. E-cylinders).
Comparators	Other prescribing practices.	Other oxygen delivery device technologies.
Outcomes	Benefits: Number of exacerbations, respiratory-related hospitalizations, physical activity level, quality of life, adherence with oxygen therapy, mobility with the device, maintenance of target oxygen saturation range, compliance with prescribed exercise.  Harms: hypoxemia, over-oxygenation, nasal/eye irritation, psychological effects of oxygen access.	Benefits: Number of exacerbations, respiratory related hospitalizations, physical activity level, quality of life, adherence with oxygen therapy, mobility with the device, maintenance of target oxygen saturation range, compliance with prescribed exercise.  Harms: hypoxemia, over-oxygenation, nasal/eye irritation, mobility with the device, psychological effects of oxygen access.
Setting	Outpatient	Outpatient

Abbreviations: COPD=chronic obstructive pulmonary disease; LOX=liquid oxygen saturation; POC= portable oxygen concentrator.

## Assessment Methods

See Appendix A.

## Summary of Literature Findings

We did not find any studies addressing the effectiveness and harms of oxygen prescribing practices. While we did find one systematic review<sup>6</sup> and primary literature addressing effectiveness and harms of oxygen devices, all but one of these studies did not evaluate our outcomes of interest. Specifically, these studies evaluated immediate outcomes from short, one-time tests, such as oxygen saturation during a walking test. In contrast, the outcomes of interest for the nominated topic were focused on clinical outcomes associated with longer periods of time using the oxygen devices.

**Table 2.** Literature Identified for Each KQ

Question	Systematic reviews (9/2015-9/2018)	Primary studies (9/2013-9/2018)
Question 1: Effectiveness and harms of oxygen prescribing practices	Total: 0	Total: 0
Question 2: Effectiveness and harms of oxygen devices	Total: 0	Total: 1 <ul style="list-style-type: none"><li>• RCT: 1<sup>7</sup></li><li>• Controlled pre-post: 0</li></ul>

Abbreviations: KQ=key question; RCT=randomized controlled trial.

## Summary of Selection Criteria Assessment

While oxygen prescribing practices may have changed, there is no literature on the effectiveness of different practices on health outcomes. Further, although there is literature on the effectiveness of oxygen devices during short spans of time, there is very little literature on evaluations of effectiveness of oxygen devices over longer periods that would provide data on broader clinical outcomes such as quality of life, number of hospitalizations, and adherence to oxygen use prescriptions.

Please see Appendix B for detailed assessments of individual EPC Program selection criteria.

## References

1. Chronic Obstructive Pulmonary Disease Costs. Centers for Disease Control and Prevention. doi: <https://www.cdc.gov/copd/infographics/copd-costs.html>.
2. COPD. National Institutes of Health. doi: <https://www.nlm.nih.gov/health-topics/copd>.
3. Branson RD, King A, Giordano SP. Home Oxygen Therapy Devices: Providing the Prescription. *Respir Care*. 2019 Feb;64(2):230-2. doi: 10.4187/respcare.06850. PMID: 30705145.
4. Giordano SP. A Guide to Portable Oxygen Concentrators. American Association for Respiratory Care. 2013. doi: <https://www.aarc.org/education/online-courses/a-guide-to-portable-oxygen-concentrators/>.
5. Branson RD. Oxygen Therapy in COPD. *Respir Care*. 2018 Jun;63(6):734-48. doi: 10.4187/respcare.06312. PMID: 29794207.

6. Gloeckl R, Osadnik C, Bies L, et al. Comparison of continuous flow versus demand oxygen delivery systems in patients with COPD: A systematic review and meta-analysis. *Respirology*. 2019 Apr;24(4):329-37. doi: 10.1111/resp.13457. PMID: 30556614.
7. Moy MI HKFSALKJAARKADHCRCGJDP. Characteristics at the time of oxygen initiation associated with its adherence: findings from the COPD Long-term Oxygen Treatment Trial. *Respiratory medicine*. 2019;149:52.

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**Author**

Emily Gean  
Charlotte Armstrong  
Robin Paynter

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Irina Jenkins  
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## Appendix A: Methods

We assessed nomination for priority for a systematic review or other AHRQ Effective Health Care report with a hierarchical process using established selection criteria. Assessment of each criteria determined the need to evaluate the next one. See Appendix B for detailed description of the criteria.

### Appropriateness and Importance

We assessed the nomination for appropriateness and importance.

### Desirability of New Review/Absence of Duplication

We searched for high-quality, completed or in-process evidence reviews published in the last three years October 15, 2017 - October 15, 2020 on the questions of the nomination from these sources:

- AHRQ: Evidence reports and technology assessments
  - AHRQ Evidence Reports <https://www.ahrq.gov/research/findings/evidence-based-reports/index.html>
  - EHC Program <https://effectivehealthcare.ahrq.gov/>
  - US Preventive Services Task Force <https://www.uspreventiveservicestaskforce.org/>
  - AHRQ Technology Assessment Program <https://www.ahrq.gov/research/findings/ta/index.html>
- US Department of Veterans Affairs Products publications
  - Evidence Synthesis Program <https://www.hsrd.research.va.gov/publications/esp/>
  - VA/Department of Defense Evidence-Based Clinical Practice Guideline Program <https://www.healthquality.va.gov/>
- Cochrane Systematic Reviews <https://www.cochranelibrary.com/>
- PROSPERO Database (international prospective register of systematic reviews and protocols) <http://www.crd.york.ac.uk/prospetro/>
- PubMed <https://www.ncbi.nlm.nih.gov/pubmed/>

### Impact of a New Evidence Review

The impact of a new evidence review was qualitatively assessed by analyzing the current standard of care, the existence of potential knowledge gaps, and practice variation. We considered whether it was possible for this review to influence the current state of practice through various dissemination pathways (practice recommendation, clinical guidelines, etc.).

### Feasibility of New Evidence Review

We conducted a limited literature search in PubMed from the last five years October 15, 2015 - October 15, 2020. We reviewed all identified titles and abstracts for inclusion and classified identified studies by question and study design to estimate the size and scope of a potential evidence review.

### Search strategy

#### Ovid MEDLINE(R) ALL 1946 to October 15, 2020

Date searched: October 16, 2020

1 Cystic Fibrosis/ or exp Hypertension, Pulmonary/ or exp Idiopathic Pulmonary Fibrosis/ or exp Pulmonary Disease, Chronic Obstructive/ or exp Pulmonary Fibrosis/ (148429)

2 (COPD or "chronic obstructive pulmonary" or cystic fibrosis or (pulmonary adj2 (fibrosis or hypertens\*)))ti,ab,kf,kw. (171540)

3 or/1-2 (214322)

4 oxygen inhalation therapy/ or automatic oxygen concentrator/ or oxygen concentrator/ or oxygen delivery/ or oxygen therapy/ or portable oxygen concentrator/ (26136)

5 ("active intermittent" or auto-DODS or CONT or DODS or DOXT or ecylinder\* or e-cylinder\* or "inhalation only" or LOX or LTOT or POC or POCs or "pulse dose" or ((ambulat\* or auto\* or closed-loop or concentrat\* or continuous\* or control\* or demand or device\* or domicil\* or home or liquid or long-term or portable or therap\* or titrat\*) adj3 (O2 or oxygen\*))).ti,ab,kw,kf. (70987)

6 (FreeO2 or "FreeO(2)").ti,ab,kf,kw. (10)

7 or/4-6 (87858)

8 Oximetry/ or Blood Gas Monitoring, Transcutaneous/ (15259)

9 ((blood adj3 monitor\*) or desaturation or saturation or LPM or "L/min" or ((liter\* or litre\*) adj2 minute) or oximet\*).ti,ab,kf,kw. (151127)

10 or/8-9 (156217)

11 and/3,7,10 (740)

12 limit 11 to english language (626)

13 limit 12 to yr="2017 -Current" (148)

14 Cochrane database of systematic reviews.jn. (15025)

15 search.tw. (317464)

16 meta-analysis.pt. (120977)

17 Medline.tw. (121455)

18 systematic review.tw. (165386)

19 or/14-18 (502594)

20 and/13,19 (6)

21 limit 12 to yr="2015 -Current" (201)

22 randomized controlled trials as topic/ or random allocation/ or double-blind method/ or single-blind method/ or exp clinical trial as topic/ or placebos/ or research design/ or comparative study/ or exp evaluation studies/ or follow up studies/ or prospective studies/ (3480897)

23 ("randomized controlled trial" or "controlled clinical trial" or "clinical trial").pt. (847971)

24 ((clin\* adj25 trial\*) or ((single\* or doubl\* or trebl\* or tripl\*) adj25 (blind\* or mask\*)) or control\* or placebo\* or prospective\* or random\* or volunteer\*).ti,ab. (5355249)

25 or/22-24 (7649877)

26 animals/ not humans/ (4710899)

27 25 not 26 (6359650)

28 and/21,27 (123)

29 or/20,28 (124)

30 13 not 29 (56)

## **EBM Reviews - Cochrane Central Register of Controlled Trials September 2020**

Date searched: October 16, 2020

1 Cystic Fibrosis/ or exp Hypertension, Pulmonary/ or exp Idiopathic Pulmonary Fibrosis/ or exp Pulmonary Disease, Chronic Obstructive/ or exp Pulmonary Fibrosis/ (148429)

2 (COPD or "chronic obstructive pulmonary" or cystic fibrosis or (pulmonary adj2 (fibrosis or hypertens\*))).ti,ab. (167365)

3 or/1-2 (212217)

4 oxygen inhalation therapy/ or automatic oxygen concentrator/ or oxygen concentrator/ or oxygen delivery/ or oxygen therapy/ or portable oxygen concentrator/ (26136)

5 ("active intermittent" or auto-DODS or CONT or DODS or DOXT or ecylinder\* or e-cylinder\* or "inhalation only" or LOX or LTOT or POC or POCs or "pulse dose" or ((ambulat\* or auto\* or closed-loop or concentrat\* or continuous\* or control\* or demand or device\* or domicil\* or home or liquid or long-term or portable or therap\* or titrat\*) adj3 (O2 or oxygen\*))).ti,ab. (69459)

6 (FreeO2 or "FreeO(2)").ti,ab. (9)

7 or/4-6 (86919)

8 Oximetry/ or Blood Gas Monitoring, Transcutaneous/ (15259)

9 ((blood adj3 monitor\*) or desaturation or saturation or LPM or "L/min" or ((liter\* or litre\*) adj2 minute) or oximet\*).ti,ab. (149237)

10 or/8-9 (154914)

11 and/3,7,10 (720)  
12 limit 11 to english language (606)  
13 limit 12 to yr="2015 -Current" (182)

## **EBM Reviews - Cochrane Database of Systematic Reviews 2005 to October 14, 2020**

Date searched: October 16, 2020

1 (COPD or "chronic obstructive pulmonary" or cystic fibrosis or (pulmonary adj2 (fibrosis or hypertens\*))).ti,ab. (398)  
2 ("active intermittent" or auto-DODS or CONT or DODS or DOXT or ecylinder\* or e-cylinder\* or "inhalation only" or LOX or LTOT or POC or POCs or "pulse dose" or ((ambulat\* or auto\* or closed-loop or concentrat\* or continuous\* or control\* or demand or device\* or domicil\* or home or liquid or long-term or portable or therap\* or titrat\*) adj3 (O2 or oxygen\*))).ti,ab. (96)  
3 (FreeO2 or "FreeO(2)").ti,ab. (0)  
4 or/2-3 (96)  
5 ((blood adj3 monitor\*) or desaturation or saturation or LPM or "L/min" or ((liter\* or litre\*) adj2 minute) or oximet\*).ti,ab. (109)  
6 and/1,4-5 (3)  
7 limit 6 to last 3 years (0)

## **Prospero**

Date searched: October 16, 2020

(COPD OR "chronic obstructive pulmonary" OR cystic fibrosis OR pulmonary fibrosis OR pulmonary hypertension) AND ("active intermittent" OR auto-DODS OR CONT OR DODS OR DOXT OR ecylinder\* OR e-cylinder\* OR "inhalation only" OR LOX OR LTOT OR POC OR POCs OR "pulse dose" OR ambulatory OR auto\* OR closed-loop OR concentrat\* OR continuous OR control\* OR demand OR device\* OR domicil\* OR home OR liquid OR long-term OR portable OR titration) AND ("oxygen monitoring" or desaturation or saturation or LPM or "L/min" or "liters per minute" OR "litres per minute" or oximet\*) AND (Respiratory disorders):HA WHERE CD FROM 01/01/2017 TO 10/16/2020 (37)

## **ClinicalTrials.gov**

Date searched: October 15, 2020

( EXPAND[Concept] "active intermittent" OR auto-DODS OR CONT OR DODS OR DOXT OR ecylinder OR e-cylinder OR EXPAND[Concept] "inhalation only" OR LOX OR LTOT OR POC OR POCs OR EXPAND[Concept] "pulse dose" OR ambulatory OR auto OR closed-loop OR concentrator OR continuous OR control OR demand OR device OR domiciliary OR home OR liquid OR long-term OR portable OR titration ) AND ( EXPAND[Concept] "oxygen monitoring" OR desaturation OR saturation OR LPM OR EXPAND[Concept] "L/min" OR EXPAND[Concept] "liters per minute" OR EXPAND[Concept] "litres per minute" OR oximeter OR oximetry ) | Active, not recruiting, Completed Studies | COPD OR EXPAND[Concept] "chronic obstructive pulmonary" OR EXPAND[Concept] "cystic fibrosis" OR EXPAND[Concept] "pulmonary fibrosis" OR EXPAND[Concept] "pulmonary hypertension" | First posted from 01/01/2015 to 10/16/2020 | Applied Filters: Active not recruiting Completed (154)

<https://clinicaltrials.gov/ct2/results?cond=COPD+OR+EXPAND%5BConcept%5D+%22chronic+obstructive+pulmonary%22+OR+EXPAND%5BConcept%5D+%22cystic+fibrosis%22+OR+EXPAND%5BConcept%5D+%22pulmonary+fibrosis%22+OR+EXPAND%5BConcept%5D+%22pulmonary+hypertension%22&term=%28+EXPAND%5BConcept%5D+%22active+intermittent%22+OR+auto-DODS+OR+CONT+OR+DODS+OR+DOXT+OR+ecylinder+OR+e-cylinder+OR+EXPAND%5BConcept%5D+%22inhalation+only%22+OR+LOX+OR+LTOT+OR+POC+OR+POCs+OR+EXPAND%5BConcept%5D+%22pulse+dose%22+OR+ambulatory+OR+auto+OR+closed-loop+OR+concentrator+OR+continuous+OR+control+OR+demand+OR+device+OR+domiciliary+OR+home+OR+liquid+OR+long-term+OR+portable+OR+titration%22+AND+%28+EXPAND%5BConcept%5D+%22oxygen+monitoring%22+OR+desaturation+OR+saturation+OR+LPM+OR+EXPAND%5BConcept%5D+%22L+min%22+OR+EXPAND%5BConcept%5D+%22liters+per+minute%22+OR+EXPAND%5BConcept%5D+%22litres+per+minute%22+OR+oximeter+OR+oximetry%22+AND+%28+Respiratory+disorders%29+HA+WHERE+CD+FROM+01+01+2017+TO+10+16+2020>

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## Appendix B. Selection Criteria Assessment

Selection Criteria	Assessment
<b>1. Appropriateness</b>	
1a. Does the nomination represent a health care drug, intervention, device, technology, or health care system/setting available (or soon to be available) in the US?	Yes.
1b. Is the nomination a request for an evidence report?	Yes.
1c. Is the focus on effectiveness or comparative effectiveness?	Yes.
1d. Is the nomination focus supported by a logic model or biologic plausibility? Is it consistent or coherent with what is known about the topic?	Yes.
<b>2. Importance</b>	
2a. Represents a significant disease burden; large proportion of the population	Approximately 16 million Americans suffer from COPD. <sup>2</sup>
2b. Is of high public interest; affects health care decision making, outcomes, or costs for a large proportion of the US population or for a vulnerable population	Approximately 16 million Americans suffer from COPD, and in 2010 the CDC predicted that costs associated with the disease would increase from \$32.1 to \$49 billion over the course of the next decade. <sup>1, 2</sup>
2c. Incorporates issues around both clinical benefits and potential clinical harms	Yes.
2d. Represents high costs due to common use, high unit costs, or high associated costs to consumers, to patients, to health care systems, or to payers	In 2010 the CDC predicted that costs associated with the disease would increase from \$32.1 to \$49 billion over the course of the next decade. <sup>1, 2</sup>
<b>3. Desirability of a New Evidence Review/Absence of Duplication</b>	
3. A recent high-quality systematic review or other evidence review is not available on this topic	Yes. There were no systematic reviews found addressing the KQs.
<b>4. Impact of a New Evidence Review</b>	
4a. Is the standard of care unclear (guidelines not available or guidelines inconsistent, indicating an information gap that may be addressed by a new evidence review)?	Current oxygen prescribing practices have changed.
4b. Is there practice variation (guideline inconsistent with current practice, indicating a potential implementation gap and not best addressed by a new evidence review)?	There is a discrepancy between prescribing guidelines and how most oxygen devices operate.
<b>5. Primary Research</b>	
5. Effectively utilizes existing research and knowledge by considering: - Adequacy (type and volume) of research for conducting a systematic review - Newly available evidence (particularly for updates or new technologies)	We did not find any literature for the effectiveness of oxygen prescribing practices and found only one study on the effectiveness of oxygen devices.

Abbreviations: AHRQ=Agency for Healthcare Research and Quality; CDC=Centers for Disease Control and Prevention; COPD=chronic obstructive pulmonary disease; KQ=key question; US=United States