Oxygen Delivery Devices and Inhaler Technique

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Literature review current through June 2024
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Educational Objectives:
1. Review indications for chronic supplemental oxygen
2. Discuss differences between standard continuous oxygen and oxygen conserving devices
3. Practice completing a certificate of medical necessity for supplemental oxygen
4. Review inhaler delivery devices and varied mechanisms of drug delivery

Scenario 1:
Mr. Shah is a 58-year-old male with advanced COPD (FEV1 25% predicted). He notes a progressive decrement in his exercise tolerance over the last 6-8 months and chronic daily cough. He is currently on tiotropium and fluticasone/salmeterol. He has not had any exacerbations in the last year. His exam is remarkable for decreased breath sounds bilaterally. His vitals are normal except for his oxygen saturation which is 94% at rest on room air. You review his testing and note that he had a six-minute walk test today that showed a saturation of 85% on room air with exertion. He walked 824 feet.

Question 1: What is the approximate conversion from liters per minute to \( \text{FiO}_2 \)? If someone is on 40% \( \text{FiO}_2 \) in the hospital, approximately what flow rate via nasal cannula should you expect they will need?

Each additional liter per minute (LPM) in oxygen flow increases the \( \text{FiO}_2 \) by approximately 4%. A patient using 2 LPM is inspiring approximately 28% \( \text{FiO}_2 \) (room air is 21% \( \text{FiO}_2 \)). This estimate assumes a normal total minute ventilation and may be less accurate in acutely ill patients.

Figure 1. Borrowed from “Portable oxygen delivery and oxygen conserving devices.” UpToDate 2024. Each additional stacked colored block represents approximately 4% increase in \( \text{FiO}_2 \).
Question 2: What is the benefit of supplemental oxygen in chronic lung disease?

Approximately one million patients per year receive long term oxygen therapy through Medicare alone, costing over $2 billion annually. Long-term oxygen use has been most well studied in patients with COPD. Patients with chronic resting hypoxemia (PaO$_2$ < 55 mm Hg or SpO$_2$ < 88%) treated with continuous oxygen supplementation experience a mortality reduction, as seen in the Nocturnal Oxygen Therapy Trial (NOTT) and the Medical Research Council (MRC) trial. In those with severe resting hypoxemia, supplemental oxygen may also improve quality of life, cardiovascular morbidity, depression, cognitive function, exercise capacity, and frequency of hospitalization.

Figure 2. Overall mortality observed in the Nocturnal Oxygen Therapy Trial as a function of time from randomization. The top line (open circles) represents those in the continuous O2 therapy group. The bottom line (open squares) represents nocturnal O2 therapy group. From the NOTT trial, Annals of Internal Medicine 1980.

Conversely, the Long-Term Oxygen Treatment Trial (LOTT) found that adding long-term supplemental oxygen therapy to those with stable COPD and either moderate resting desaturation or moderate exercise desaturation (SpO$_2$ 89-93% or SpO$_2$ < 90% for ≥ 10 seconds and ≥ 80% for ≥ 5 minutes while walking) did not result in improvement in mortality, all cause first hospitalization, quality of life, lung function, or walk distance. A randomized control trial in 2020, studying potential benefits of nocturnal oxygen supplementation in patients with COPD who had nocturnal desaturations but otherwise did not qualify for long-term oxygen therapy, was inconclusive due to being underpowered.

Note that these results should not be generalized to other chronic lung disease populations with hypoxemia, such as interstitial lung disease and pulmonary hypertension.
**Question 3:** What are the different ways in which home oxygen therapy is delivered? What is the difference between continuous and pulse dose oxygen therapy?

Continuous flow oxygen is oxygen delivered at a constant rate, regardless of respiratory rate.

Pulse dose (PD) oxygen is delivered during inspiration only, thus respiratory rate will determine amount of oxygen delivered per minute. With PD, there is no oxygen flow while the patient exhales, thus conserving oxygen supply and improving efficiency. These are generally reserved for patients requiring lower amounts of supplemental oxygen (<4 LPM).

**Question 4:** Would Mr. Shah qualify for long-term oxygen therapy? What are the indications for chronic supplemental oxygen therapy? What testing do you need to qualify for oxygen?

To qualify for home oxygen therapy, most insurance providers follow the criteria outlined by the Centers for Medicare and Medicaid Services (CMS) which require either:

- \( \text{PaO}_2 \leq 55 \text{ mmHg} \) or \( \text{SpO}_2 \leq 88\% \) on room air at rest or with exertion, or
- \( \text{PaO}_2 \leq 59 \text{ mmHg} \) or \( \text{SpO}_2 \leq 89\% \) if there is evidence of cor pulmonale, right heart failure or erythrocytosis (Hct > 55%)

The measurement of cutaneous oxygen saturation by pulse oximetry is commonly used but is less accurate than measurement of PaO2 via blood gas, particularly in individuals with darker skin complexion.\(^6,7\) The patient should have a chronic lung disease (ex: COPD, ILD, CF, etc) and/or hypoxia-related symptoms or findings (ex: pulmonary hypertension, heart failure due to cor pulmonale, erythrocytosis, etc). For safety reasons, many guidelines have recommended that smoking (cigarettes or e-cigarettes) is a contraindication to home oxygen therapy, though recent guidelines have been less stringent and emphasize the need for education on oxygen safety, including smoking cessation and fire prevention.\(^8\)

Oxygen can be prescribed for continuous use, with exertion, or with sleep (though mortality benefit has been only shown with continuous use, as noted in Question 2). Oxygen flow is typically titrated to achieve a target \( \text{SpO}_2 >90\% \) or \( \text{PaO}_2 > 60-80 \text{ mmHg} \). From initiation of long-term oxygen therapy, median survival in patients with COPD is typically around 24-36 months.

Nocturnal Oxygen Supplementation qualification requires either:

- \( \text{SpO}_2 \leq 88\% \) during sleep for \( \geq 5 \) cumulative minutes OR decrease in \( \text{SpO}_2 > 5% \) during sleep for \( \geq 5 \) cumulative minutes, minimum 2-hour test time

Of note, a complete “face to face” encounter is required by CMS within 30 days of signing the certificate of medical necessity (CMN) form and recertification is required annually. Documentation must include a statement that the addition of supplemental oxygen effectively treats the hypoxemia (i.e. use of 2 LPM of supplemental oxygen maintains saturations above 89%).

Qualifying testing should include:

- Resting saturations + exertional saturations on room air
- If saturations \( \leq 88\% \), repeat testing on 2 LPM oxygen with titration as needed at rest or with exertion, as appropriate
- If the patient needs \( > 4 \text{ LPM} \), CMS requires testing results on 4 LPM plus at the higher, final flow rate
**Scenario 1 (cont.):**
On room air, Mr. Shah desaturates to SpO2 86% during exertion. He requires 2 LPM to maintain SpO2 90% while walking.

**Question 5: Mr. Shah mentioned that he had a difficult time handling the oxygen tank used during his titration due to its weight. What types of oxygen delivery devices are available for use at home?**

Standard oxygen supplementation is typically provided with continuous flow nasal canula. Stationary oxygen delivery systems limit patients within the confines of 50 feet of tubing from the concentrator. However, there are alternative modes of oxygen delivery, particularly for those patients who are more severely hypoxemic and or want to be more active outside of their own home. Portable oxygen delivery devices are compact enough to be carried or wheeled outside the home. Oxygen conserving devices attempt to deliver oxygen more efficiently and can be added to most delivery systems. Examples of portable oxygen delivery devices and oxygen conserving systems are outlined in the following tables.

*An important note: pulse dose settings do not automatically equate to continuous flows (i.e.: PD setting 4 may not equal 4 LPM via continuous oxygen). These should be titrated in the appropriate setting to achieve target saturations.*

<table>
<thead>
<tr>
<th>Max pulse dose (PD)</th>
<th>Max continuous flow</th>
<th>Hours of usage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>E tank</strong> (standard tank on cart)</td>
<td>5</td>
<td>10-15</td>
</tr>
<tr>
<td><strong>M6 tank</strong> (smaller tank with carrier bag)</td>
<td>5</td>
<td>5-normal regulator 10-High flow regulator</td>
</tr>
<tr>
<td><strong>Portable oxygen concentrator</strong></td>
<td>1-4 PD most commonly 5-6 PD less common 7-9 PD rare</td>
<td>3</td>
</tr>
<tr>
<td><strong>Liquid oxygen (Helios Marathon)</strong></td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td><strong>Liquid oxygen (Companion 1000T)</strong></td>
<td>6</td>
<td>15</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Photos</th>
<th>Stores O2 during exhalation; during inhalation patient receives stored O2 plus the supply O2</th>
<th>Delivery of brief pulse of nearly 100% FiO2 during early inspiration; can be stand alone, portable O2 concentrator, compressed gas</th>
<th>Wearable augmentation ventilator attached to portable O2 cylinder, delivers 50-250 mL boluses of pressurized O2</th>
<th>Deliver O2 directly through opening in neck; bypass dead space; increase CO2 elimination efficiency</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>How it works</strong></td>
<td>16 LPM</td>
<td>n/a</td>
<td>Larger pulses</td>
<td>16 LPM</td>
</tr>
<tr>
<td><strong>Highest flow</strong></td>
<td>2:1 to 4:1</td>
<td>3:1 to 7:1</td>
<td>Not available</td>
<td>2:1 to 3:1</td>
</tr>
<tr>
<td><strong>Efficiency</strong></td>
<td>Inexpensive, simplest to use</td>
<td>Maximal O2 delivery; studies show good performance compared to NC</td>
<td>Studies show reduced dyspnea, higher exercise work rate, increased oxygenation</td>
<td>Reduced work of breathing, no tubing</td>
</tr>
<tr>
<td><strong>Pros</strong></td>
<td>Can be physically obtrusive</td>
<td>Audible pulses, mechanical failure (may require battery), variability in oxygenation</td>
<td>Cost</td>
<td>Requires surgical procedure Can lead to tracheal desiccation and trouble with secretions</td>
</tr>
<tr>
<td><strong>Cons</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


When prescribing portable oxygen systems, the tanks should ideally weigh less than 10 lbs, be able to provide at least a 4 hr supply and be easily carried by the patient.
<table>
<thead>
<tr>
<th>Type of System</th>
<th>Ambulatory Component</th>
<th>Stationary Component</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lightweight compressed gas system</strong></td>
<td>Small, pre-filled tanks delivered on a weekly basis, depending on how much oxygen is required, or tanks that fill overnight at home (aka a <em>home-fill system</em>) from a concentrator. Carried in a bag rather than a cart. Good for patients who are highly mobile and active.</td>
<td>Stationary concentrator:</td>
</tr>
<tr>
<td></td>
<td><img src="image" alt="Lightweight compressed gas system" /></td>
<td>Home-fill compressed gas system: concentrator on the bottom, filling station on the top:</td>
</tr>
<tr>
<td><strong>Liquid oxygen system</strong></td>
<td>Small, refillable thermos-like tank filled from the reservoir as needed. Smallest and most portable. (~3.5 lbs). Often combined with pulse device or reservoir canula to maximize efficiency. Some oxygen may bleed off into the atmosphere, decreasing how long it lasts; may freeze in cold weather</td>
<td>Oxygen reservoir, typically used with 50 feet of tubing</td>
</tr>
<tr>
<td></td>
<td><img src="image" alt="Liquid oxygen system" /></td>
<td><img src="image" alt="Liquid oxygen system" /></td>
</tr>
<tr>
<td><strong>Portable oxygen concentrator (POC)</strong></td>
<td>A small electrical device that runs on regular electricity or on a battery, is easily recharged even in a car, and requires no tanks or filling. The maximum tubing length for proper delivery of oxygen is 7 feet.</td>
<td><img src="image" alt="Portable oxygen concentrator" /></td>
</tr>
<tr>
<td></td>
<td>These units can be taken onto airplanes.</td>
<td><img src="image" alt="Portable oxygen concentrator" /></td>
</tr>
</tbody>
</table>

Table 2. Summary of varied oxygen delivery systems.
Question 6: You are preparing to write a prescription for Mr. Shah’s home oxygen. What elements must be included?
The prescription must include the following:
- Length of need, date of order, signature, NPI, LPM
- Specific equipment requested
  - Stationary equipment - liquid or concentrator (normal is up to 5 LPM, specific high flow if patient needs >5 LPM)
  - Portable equipment
    - specify if pulse or intermittent flow
    - specify if conserving device
    - accessories backpack, cart humidifier
- If a patient has Medicare, a certificate of medical necessity (CMS form 484) is also needed. An example form is included as an appendix.

Scenario 1 (cont.):
Ultimately you decide to prescribe Mr. Shah 2 LPM oxygen using a lightweight compressed gas system.

Question 7: How do you instruct Mr. Shah on the use of his inhalers? What is the difference between each of the delivery devices?

<table>
<thead>
<tr>
<th>Class</th>
<th>Examples</th>
<th>Mechanism</th>
<th>Comments/Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>MDI (MDI)</td>
<td></td>
<td>Pressurized canister contains the drug suspended in a mixture of propellants, surfactants, preservatives, etc.</td>
<td>Most popular, oldest</td>
</tr>
<tr>
<td></td>
<td></td>
<td>HFA replaced CFC (chlorofluorocarbon) as the propellant in inhalers.</td>
<td>Convenient, good lung-to-oropharynx distribution with spacer</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Compatible with spacer</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Requires coordination</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Some environmental impact</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(hydrofluoroalkane (HFA) propellant)</td>
</tr>
<tr>
<td>Class</td>
<td>Examples</td>
<td>Mechanism</td>
<td>Comments/Use</td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>----------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| DPI (dry powder inhaler)          | ![Image](image1) | Breath actuated device; drug is delivered to the airways by the inhalation of air over a punctured capsule, blister, or reservoir; need sufficient inspiratory flow rates to deliver drug | Easier to use than HFA, less coordination needed, drug stable for longer, no environmental impact  
Not compatible with spacer  
Less dose uniformity and dependent on patient inspiratory force  
Can cause laryngeal irritation, particularly in patients with concomitant vocal cord dysfunction |
| Soft mist inhaler (SMI)           | ![Image](image2) | Drug in solution in cartridge, patient twists device storing energy in a spring; when patient presses a button the spring releases and pushes liquid into uniblock with 2 channels that produce aerosol particles | Combines advantages of MDI and nebulizers  
Propellant-free, portable and better lung-to-oropharynx delivery than MDI but not as good as MDI+valved holding chamber/spacer  
Variable spacer compatibility |
<table>
<thead>
<tr>
<th>Class</th>
<th>Examples</th>
<th>Mechanism</th>
<th>Comments/Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nebulizer</td>
<td>![Nebulizer Image]</td>
<td>Pour liquid medicine into delivery chamber, connect tubing, position mouthpiece or mask on face, turn on compressor, breathe via mouth until medicine is fully delivered.</td>
<td>3 different mechanisms: jet nebulizers, ultrasonic nebulizers, and vibrating mesh (membrane) nebulizers. Portable versions allow for use when away from home. Certain medications (hypertonic saline, DNase/dornase alfa, etc) can only be nebulized.</td>
</tr>
</tbody>
</table>

Table 3. Summary of varied inhaler types, mechanisms of delivery, and instructions for use.

All inhaler delivery devices are equivalent in terms of overall patient outcomes based on multiple meta-analyses and systematic reviews. Selection of inhaler should be based upon convenience, patient preference, and insurance coverage. Common problems with inhaler use include improper technique/difficulty with coordination of actuation and inhalation, deposition of drug in the oropharynx, and insufficient breath hold. Use of a spacer or valved holding chamber with an MDI can improve delivery of drug to the airways and minimize deposition in the oropharynx. Spacers are not used with DPI devices, and only some SMIs (Spiriva Respimat).

When prescribing inhaled therapies, education and training on the use of these devices is paramount. Studies indicate that errors of inhaler use are common and that increased inhaler error is significantly associated with poor disease outcomes. Having a patient teach back to you the steps of their technique is superior to simply asking them if they are using their inhalers. Having them demonstrate their technique for you in real-time is preferred.

There are also multiple resources available online to help with inhaler education, including videos available in multiple languages. A few examples include:
- [https://www.cdc.gov/asthma/inhaler_video/default.htm](https://www.cdc.gov/asthma/inhaler_video/default.htm)
- [http://use-inhalers.com](http://use-inhalers.com)

**Text references:**


**Image references:**
3. Inogen One G4
4. Invacare M9 HomeFill Oxygen System with Concentrator and SensO2 Sensor
6. Rockoshop Mouthpiece Metered Dose Asthma Inhaler
7. Advair, GSK
8. Wixela, Inhub
10. Stiolto Respimat, Boehringer Ingelheim
11. UpToDate, Graphic 120583
12. Phillips InnoSpire Go portable nebulizer
13. Patin nebulizer machine
Appendix

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICARE SERVICES  

CERTIFICATE OF MEDICAL NECESSITY  
CMS-484 — OXYGEN  

SECTION A  Certification Type/Date: INITIAL / / REVISED / / RECERTIFICATION / /  

PATIENT NAME, ADDRESS, TELEPHONE and HIC NUMBER  

(Supply Name, Address, Telephone and NSC or applicable NPI NUMBER/legacy number)  

PLACE OF SERVICE  

HCPCS CODE  

PT DOB / / Sex (MF)  

NAME and ADDRESS of FACILITY  

if applicable (see reverse)  

PHYSICIAN NAME, ADDRESS, TELEPHONE and applicable NPI NUMBER or UPIN  

UPIN or NPI #  

SECTION B  Information in This Section May Not Be Completed by the Supplier of the Items/Supplies.  

EST. LENGTH OF NEED (# OF MONTHS): 1-99 (99=MORRISON)  

DIAGNOSIS CODES (ICD-9):  

ANSWERS  

ANSWERS QUESTIONS 1-9. (Circle Y for Yes, N for No, or D for Does Not Apply, unless otherwise noted.)  

a) mm Hg  
b) %  
c) / /  

1 2 3  

2. Was the test in Question 1 performed (1) with the patient in a chronic stable state as an outpatient, (2) within two days prior to discharge from an inpatient facility to home, or (3) under other circumstances?  

1 2 3  

3. Circle the one number for the condition of the test in Question 1: (1) At Rest; (2) During Exercise; (3) During Sleep  

Y N D  

4. If you are ordering portable oxygen, is the patient mobile within the home? If you are not ordering portable oxygen, circle D.  

_____ LPM  

5. Enter the highest oxygen flow rate ordered for this patient in liters per minute. If less than 1 LPM, enter a “X”.  

a) mm Hg  
b) %  
c) / /  

6. If greater than 4 LPM is prescribed, enter results of most recent test taken on 4 LPM. This may be an (a) arterial blood gas PO2 and/or (b) oxygen saturation test with patient in a chronic stable state. Enter date of test (c).  

ANSWER QUESTIONS 7-9 ONLY IF PO2 = 56-59 OR OXYGEN SATURATION = 89 IN QUESTION 1  

Y N  

7. Does the patient have dependent edema due to congestive heart failure?  

Y N  

8. Does the patient have cor pulmonale or pulmonary hypertension documented by P pulmonary on an EKG or by an echocardiogram, gated blood pool scan or direct pulmonary artery pressure measurement?  

Y N  

9. Does the patient have a hematocrit greater than 56%?  

NAME OF PERSON ANSWERING SECTION B QUESTIONS, IF OTHER THAN PHYSICIAN (Please Print):  

NAME:  

TITLE:  

EMPLOYER:  

SECTION C  Narrative Description of Equipment and Cost  

(1) Narrative description of all items, accessories and options ordered: (2) Supplier’s charge and (3) Medicare Fee Schedule Allowance for each item, accessory and option. (See instructions on back.)  

SECTION D  Physician Attestation and Signature/Date  

I certify that I am the treating physician identified in Section A of this form. I have received Sections A, B and C of the Certificate of Medical Necessity (including charges for items ordered). Any statement on my letterhead attached hereto, has been reviewed and signed by me. I certify that the medical necessity information in Section B is true, accurate and complete, to the best of my knowledge, and I understand that any falsification, omission, or concealment of material fact in that section may subject me to civil or criminal liability.  

PHYSICIAN’S SIGNATURE  

DATE / /  

Signature and Date Stamps Are Not Acceptable.