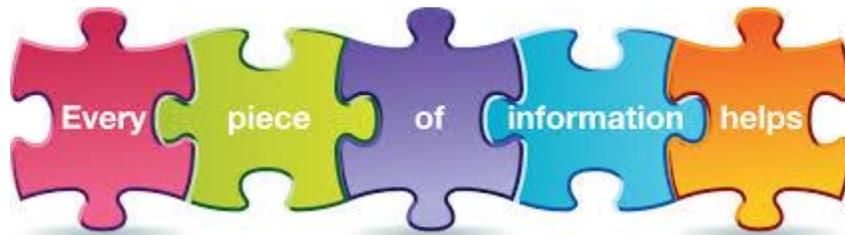


**Medication Delivery in a Continuum of Care (CoC)
Program for Chronic Obstructive Pulmonary
Disease (COPD) employing a Unique Aerosol
Delivery System, a Vibrating Mesh Nebulizer
Pocket Neb**



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Medication Delivery in a Continuum of Care (CoC) Program for Chronic Obstructive Pulmonary Disease (COPD) employing a Unique Aerosol Delivery System, a Vibrating Mesh Nebulizer, Pocket Neb

Abstract

High hospital readmission rates are seen by many as a key contributor to rising health care costs in the U.S. New government payment reforms are tackling the problem by penalizing hospitals for such readmissions, and innovative providers are responding with continuum of care programs utilizing in-patient planning, discharge planning and follow-up care after patients are discharged. COPD is one of the more common medical conditions that requires hospitalization and can lead to readmissions if at discharge; patients are not properly trained and advised for post hospitalization medication regiments.

The inclusion of a unique aerosol delivery system, the Pocket Neb vibrating mesh nebulizer in a continuum of care model used in-patient and post hospitalization may lead towards greater success in reducing hospital readmissions and highlight the valuable role that medication management, patient persistence and compliance have in improving patient outcomes and reducing related readmissions.

Chronic obstructive pulmonary disease (COPD) is a common respiratory condition characterized by progressive airflow limitation. The high prevalence and chronic nature of COPD result in increased health care utilization, with frequent doctor's office visits and hospitalizations due to acute exacerbations of COPD (AECOPD). Unfortunately, a good portion of patients are readmitted to the hospital within 30 days post-discharge due to non-persistence and non-compliance to medications. High readmission rates and the burden on the health care system have led to policy changes by the Centers for Medicaid and Medicare Services (CMS) whereby penalties are implemented on hospitals with high readmission rates for COPD patients. It is therefore imperative that providers actively design, promote, and evaluate transition models from hospital to home to decrease COPD readmissions.

Although there are many contributing factors to hospital readmissions non-persistence and non-compliance to medications is considered a major factor.

Non-Persistence: Refers to the act of discontinuing the treatment for the prescribed duration. It may be defined as "the duration of time from initiation to discontinuation of therapy. Patient-related reasons may include forgetfulness, the decision to omit doses, lack of information and emotional factors. Clinician-related reasons may include prescriptions of complex regimens, failing to explain the benefits and side-effects of treatment, not giving consideration to a patient's lifestyle or the cost of medicines, and having a poor therapeutic relationship with the patient. Alternatively, the term "adherence" is used.

Non-Compliance: Is the extent to which the patient's behavior does not match the prescriber's recommendations. Factors for non-compliance are a patient's perspectives in medication-taking, based on their own beliefs, their personal circumstances, the information and resources available for them.

As a result of CMS possible penalties, hospitals are improving their discharge planning processes and providing transitional patient care after hospital discharge. Medication management is at the core of advanced discharge planning and transitional care. This reflects three realities:

- Adverse events are a major cause of avoidable hospital readmissions
- More post-discharge adverse events are related to drugs than other causes
- Lack of adherence to medications prescribed at discharge [1]

With regard to aerosolized medications one way to improve persistence/compliance is having the right medications along with the right delivery system. As stated in the guidelines below, all devices work if used properly but consideration for a patient's or care givers ability is essential for persistence and compliance.

“Devices used for the delivery of bronchodilators and steroids can be equally efficacious. When selecting an aerosol delivery device for patients with asthma and COPD, the following should be considered: device/drug availability; clinical setting; patient age and the ability to use the selected device correctly; device use with multiple medications; cost and reimbursement; drug administration time; convenience in both outpatient and inpatient settings; and physician and patient preference.” [2].

With COPD patients the persistence/compliance is often inadequate due to the patients' readiness and the correct handling of the inhalation device. A study evaluating the use of the inhalation devices, the time interval between dosage applications and critical technical errors in inhalation found that only 6% of participants had an adherence of over 80% [3], another study found that only 20% Of COPD patients used their inhalation devices correctly and at the right time [4]. A German retrospective cohort study, in which the correct inhalation technique was not considered separately, showed an adherence rate of 30% in over 45,000 COPD patients over 12 months, two thirds of the patients treated, did not continue after one year and about one third implement their treatment poorly during periods of general therapy [5].

Even with high patient motivation, technical errors in handling the inhalation system can lead to insufficient therapeutic success. In various studies, only about 30% of the patients showed error-free inhalation [6, 7]. Inhalation errors can be inherent to inhalation-device-general steps for end users, such as a complete slow exhalation before the inhalation of the drug, the deep inhalation, followed by a 5-10-second respiration and a slow exhalation [8].

In addition, specific mistakes can also be made for individual inhalation systems. For non-breath-controlled metered-dose aerosols, this is the inadequate coordination between inhalation and triggering of the metered-dose aerosol. In the case of powder inhalers, exhalation into the mouthpiece is problematic because of the moisture sensitivity of the powders. For some inhalers the instructions can be very confusing and example would be; shake before use but shaking after "charging" must be avoided to ensure correct dosage. However, the shaking of a powder inhaler, e.g. At the Easyhaler®, specifically states this step in the preparation of the inhalation. This is unclear for the patient without structured training and leads to little or no therapeutic value [9].

The importance of a continuum of care with regard to selection of device type, correct handling during the preparation of the device and the inhalation itself can affect persistence and compliance before and after discharge from the hospital.

In making the choice of aerosol drug/device combinations for an individual patient, we can ask the following questions:

1. Which devices are available that deliver the desired drug?
2. Is the device appropriate for the age and capability of the patient?
3. Is it covered by a third-party payer?
4. What are the costs to the patient? To society?
5. Is the drug/device combination approved by the Food and Drug Administration?
6. Can the same type of device be used for all inhaled drugs prescribed for an individual patient? (This would simplify the learning and teaching process.)
7. Which devices are the most convenient, inexpensive, portable, and time-saving in each clinical situation?
8. Which devices are the clinicians capable of teaching properly?
9. Which devices do the patient and/or parent prefer?

The principle of keep it simple definitely applies to the clinical use of aerosol devices. The devices should be simple and intuitive to use, and the clinicians should keep the treatment regimens as simple as possible while maintaining control over the airway disease.[10]

Pocket Neb Vibrating Mesh Nebulizer:

The Pocket Neb VMN, offers a small, handheld, battery-operated, portable, rapid delivery, quiet operation nebulizer for medication delivery. In mesh nebulization, medication is aerosolized in a single pass through of the mesh creating a fine respirable aerosol of less than 5 microns. The result is greater efficiencies in time, energy expenditure and volume of medication delivered. The Pocket Neb, VMN can operate with treatment times of around 4-7 minutes with an average dose of 3 ml and have residual volumes of about 0.1 mL.

The new generation of portable nebulizers could deliver either a lower dose (comparable to a pMDI) or a higher dose (comparable to jet nebulizer) of aerosol therapy in a variety of clinical settings [11].



Pocket Neb handset and mouthpiece

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**Medication cup, mouthpiece,
mask adapter, charger and
USB cable**

A key factor for selecting a Pocket Neb VMN is the simple operation of the device for the end user or care giver. The unit's one button operation can be used in continuous or on-demand mode providing full control of medication delivery.

Preparation for treatment is as follows:

- **Remove medication cup from handset**
- **Open cap on top of medication cup**
- **Place medication in medication cup as prescribed by physician**
- **Slide medication cup on to handset until the medication cup 'clicks' into place**
- **Attach mouthpiece or mask adapter to medication cup**
- **Press on/off button to start treatment**
- **After treatment remove medication cup and follow cleaning instructions [12]**
- **Remove medication cup from the handset**
- **Rinse the medication cup with distilled water**
- **Add a small amount of distilled water to the medication cup and replace the cup on the handset**

- **Run the unit for 15 seconds to clean mesh**
- **Allow medication cup to air dry.**

Inclusion of the Pocket Neb in a CoC can provide an opportunity to increase, not only the persistence to prescribed medication regimen and compliance with correct device use, but also improves control and management of patients medical condition for patients who by their very nature are vulnerable or in poor health and are most likely to benefit from the use of a VMN.

Program:

Criteria for inclusion of the Pocket Neb vibrating mesh nebulizer for in-hospital and outpatient use in a CoC program.

- Adopt the GOLD (Global Initiative for Chronic Obstructive Lung Disease). GOLD promotes clinical collaboration and coordination. In the process, creating a disease management model that could be replicated for other conditions. (asthma, emphysema)
- Utilize best practices for developing a transition model from hospital to home for aerosol medication delivery
- Identify patient factors contributing to high COPD readmission rates, non-persistence
- Implement the concept of concordance emphasizing an agreement between the clinician and the patient, which takes into account each other's perspective on medication-taking, to a broader process consisting of open discussions with the patient regarding medication-taking
- Incorporate the Pocket Neb, VMN for aerosol medication delivery in the Inpatient and Outpatient Management of COPD, in a continuum of care program using the 3-C's approach
- Convenience of taking medication anytime, anywhere with Pocket Neb
- Compliance to medication regiment due to convenience and understanding of medications purpose
- Control of medical condition due to persistence and compliance

Protocol: Hospital personnel will be trained on use and maintenance procedures of the Pocket Neb by MicroVapor Devices personnel or their authorized agents. Hospital personnel will subsequently train COPD patients on the use and maintenance of the Pocket Neb nebulizer.

Based on an initial diagnosis of COPD and the healthcare provider’s assessment, eligible patients will receive a Pocket Neb upon hospital admission. Patients will be trained on the use, operation and cleaning of the device while in the hospital and will take all solution medications with the device for the entire hospital stay. Upon discharge from the hospital the patient will continue to use the Pocket Neb with prescribed medications and will notify their primary care providers of their use of the Pocket Neb nebulizer.

Goal: Reduction of patient readmissions within 31 days of discharge from a hospital for a diagnosis of COPD due to non-persistence or non-compliance to aerosol medications. Hospital staff will determine rational for a readmission and if non-persistence or non-compliance was reason for readmission depending on design of their CoC.

To help implement this program the checklist below can be useful in development of a customized program.

Patient Name		Notes:
Patient Age		
Primary User	Yes ___ No ___	
Caregiver	Yes ___ No ___	
Read instructions	Yes ___ No ___	
Understands instructions	Yes ___ No ___	
Trained by Staff	Yes ___ No ___	

Unit operation	Yes _____ No _____	
Cleaning	Yes _____ No _____	
Maintenance	Yes _____ No _____	
Storage	Yes _____ No _____	
Medications	Yes _____ No _____	
Medication schedule	Yes _____ No _____	
Support information	Yes _____ No _____	
Patient treatment in hospital	Yes _____ No _____	
Treatment successful	Yes _____ No _____	
Patient requires additional instruction	Yes _____ No _____	
Patient/caregiver capable of using unit at home	Yes _____ No _____	
Sign Off	Patient:	Trainer:

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