

# **AARC Clinical Practice Guideline**

## **Selection of a Device for Delivery of Aerosol to the Lung Parenchyma**

### **DALP 1.0 PROCEDURE:**

Selection of a device for delivery of aerosol to the lung parenchyma

### **DALP 2.0 DESCRIPTION:**

A device selected for administration of pharmacologically active aerosol to the lung parenchyma should produce particle sizes with a mass median aerodynamic diameter (MMAD) of 1-3 microns.(1-4)

Such devices include ultrasonic nebulizers (USNs, including the Porta-Sonic(5,6)), some large volume nebulizers (LVNs, such as the Small Particle Aerosol Generator(TM), or SPAG, which is intended only for ribavirin delivery(7)), some small volume nebulizers (such as the Circulaire,(8) RespirGard II,(5,6,9) and Pari IS 2,(6)) Other devices including metered dose inhalers (MDIs) may be developed for parenchymal deposition. Although some parenchymal deposition of particles < 1 micron probably does occur, selection of a specific device should be based on its ability to produce particles within MMAD of 1-3 microns.

### **DALP 3.0 SETTING:**

Aerosol therapy can be administered in a number of settings including but not limited to hospital, clinic, extended care facility, or home.

### **DALP 4.0 INDICATIONS:**

The indication for selecting a suitable device is the need to deliver a topical medication (in aerosol form) that has its site of action in the lung parenchyma or is intended for systemic absorption. Such medications may possibly include antibiotics, antivirals, antifungals, surfactants, and enzymes.

### **DALP 5.0 CONTRAINDICATIONS:**

**5.1** No contraindications exist to choosing an appropriate device for parenchymal deposition.

**5.2** Contraindications related to the substances being delivered may exist. Consult the package insert for product-specific contraindications to medication delivery.

### **DALP 6.0 HAZARDS/COMPLICATIONS:**

**6.1** Malfunction of device and/or improper technique may result in underdosing or overdosing.

**6.2** In mechanically ventilated patients, the nebulizer design and characteristics of the medication may affect ventilator function (eg, filter obstruction, altered tidal volume, decreased trigger sensitivity) and medication deposition.(10,11)

**6.3** Complications related to specific pharmacologic agents can occur.

**6.4** Aerosols may cause bronchospasm or irritation of the airway.

**6.5** Exposure to medications(12-23) and patient-generated droplet nuclei may be hazardous to clinicians.(24)

**6.5.1** Exposure to medication should be limited to the patient for whom it has been ordered. Nebulized medication that is released into the atmosphere from the nebulizer or exhaled by the patient becomes a form of "secondhand" exposure that may affect health-care providers and others in the vicinity of the treatment.

There has been increased awareness of possible health effects of aerosols, such as ribavirin and pentamidine. Anecdotal reports associate symptoms such as conjunctivitis, decreased tolerance to presence of contact lenses, headaches, bronchospasm, shortness of breath, and rashes in health-care workers exposed to secondhand aerosols. Similar concerns have been expressed concerning health-care workers who are pregnant or are planning to be pregnant within 8 weeks of administration. Less often discussed are the potential exposure effects of aerosolized antibiotics (which may contribute to the development of resistant organisms), steroids, and bronchodilators.(25)

Because the data regarding adverse health effects on the health-care worker and on those casually exposed are incomplete, the prudent course is to minimize exposure in all situations.(26)

**6.5.2** The Centers for Disease Control and Prevention recommend addressing exposure control issues by (1) administrative policy, (2) engineering controls, and (3) personal protective equipment, in that order.(27,28)

**6.5.2.1** Administrative controls:

Should include warning signs to apprise all who enter a treatment area of potential hazards of exposure. Accidental exposures should be documented and reported according to accepted standards.

Measures to reduce aerosol contamination of room air include:

**6.5.2.1.1** discontinuing nebulization of medication while patient is not breathing the aerosol;

**6.5.2.1.2** ensuring that staff who administer medications understand risks inherent with the medication and procedures for safely disposing of hazardous wastes;

**6.5.2.1.3** screening of staff for adverse effects of exposure to aerosol medication;

**6.5.2.1.4** providing alternative assignments for those staff who are at high risk of adverse effects from exposure (eg, pregnant women or those with demonstrated sensitivity to the specific agent).

**6.5.2.2** Engineering controls:

**6.5.2.2.1** Filters or filtered scavenger systems to remove aerosols that cannot be contained.

**6.5.2.2.2** Frequent air exchanges to dilute concentration of aerosol in room to eliminate 99% of aerosol before the next patient enters and receives treatment in the area.

**6.5.2.2.3** Booths or stalls for sputum induction and aerosolized medication administration in areas in which multiple patients are treated. Booths or stalls should be designed to provide adequate air flow to draw aerosol and droplet nuclei from the patient and into an appropriate filtration system, with exhaust directed to an appropriate outside vent.

**6.5.2.2.4** Handling of filters, nebulizers, and other contaminated components of the aerosol delivery system used with suspect agents (such as pentamidine and ribavirin) as hazardous waste.

**6.5.2.3** Personal protection devices:

**6.5.2.3.1** Personal protection devices should be used to reduce exposure when engineering alternatives are not in place or are not adequate. Use properly fitted respirators with adequate filtration when exhaust flow cannot adequately remove aerosol particles.(28)

**6.5.2.3.2** Goggles, gloves, and gowns should be used as splatter shields and to reduce exposure to medication residues and body substances.

## **DALP 7.0 LIMITATIONS OF PROCEDURE OR DEVICE:**

**7.1** A relatively small fraction of nebulizer output deposits in the lung parenchyma.(2)

**7.2** Efficacy of the device is technique dependent (eg, coordination, ability to follow instructions, and breathing pattern including inspiratory flow and inspiratory hold).(2,29-32)

**7.3** Efficacy of the device is design dependent (ie, output and particle size).(33-36)

**7.4** The following clinical situations are associated with reduced deposition of aerosol to the lung parenchyma and may require consideration of increased dose:

**7.4.1** Mechanical ventilation(37-42)

**7.4.2** Artificial airways(43-45)

**7.4.3** Reduced airway caliber (eg, infants and pediatrics)(46)

**7.4.4** Severity of obstruction(4)

**7.4.5** Hydrophilic formulations(2)

**7.4.6** Failure of patient to comply with procedure.

**7.5** Limitation of specific devices:

**7.5.1** MDI:

**7.5.1.1** Particle size varies with drug formulation, propellants, evaporation rate, and humidity.

**7.5.1.2** Accessory device is recommended with MDI use(26,47)

**7.5.1.2.1** assure optimal deposition

**7.5.1.2.2** reduce oropharyngeal deposition

**7.5.1.2.3** decrease caregiver exposure.

**7.5.1.3** Relatively few formulations are targeted to the lung parenchyma.

**7.5.2** SPAG(TM)40 (intended only for ribavirin delivery)

**7.5.2.1** Limited to acute and critical care setting

**7.5.2.2** Requires close monitoring

**7.5.2.3** Requires compressed gas source

**7.5.2.4** Vulnerable to contamination

**7.5.2.5** Reconcentration of solution may occur over a long period of time due to evaporation by dry gas source.(49-52)

**7.5.3** SVN:

**7.5.3.1** Few devices produce particles with MMAD of 1-3 microns.

**7.5.3.2** MMAD may vary with nebulizer model, medication, gas flow, and gas pressure.

**7.5.3.3** Requires compressed gas source.

**7.5.3.4** Vulnerable to contamination.

**7.5.3.5** Reconcentration may occur.(49-52)

**7.5.4** LVN:

**7.5.4.1** Generally limited to acute and critical care setting although anecdote suggest some home use.

**7.5.4.2** Requires close monitoring.

**7.5.4.3** Few devices produce particles with MMAD of 1-3 microns.

**7.5.4.4** Vulnerable to contamination.

**7.5.5** USN:

**7.5.5.1** Cost may be a factor.

**7.5.5.2** May be mechanically unreliable.

**7.5.5.3** Requires electrical power source.

**7.5.5.4** Some units do not reliably produce MMAD of 1-3 microns.(44-

54)

**7.5.5.5** Reconcentration of solution may occur over long period of time due to evaporation by heat generated by piezoelectric cell.(53,55) The ultrasonic device may denature the medication.(56,57)

#### **DALP 8.0 ASSESSMENT OF NEED (Selection Criteria for Device):**

**8.1** Availability of prescribed drug in solution or MDI formulation.

**8.2** Availability of appropriate scavenging or filtration equipment.

**8.3** Patient preference for a given device that meets therapeutic objectives.

**8.4** Although specific devices may give known ranges of particle size and output, clear superiority of any one method or device for achieving specific clinical outcomes has not been established. Cost, convenience, effectiveness, and patient tolerance of procedure should be considered.(26,53)

**8.5** When spontaneous ventilation is inadequate (eg, kyphoscoliosis, neuromuscular disorders, or respiratory failure) consider augmentation with mechanical ventilation.

#### **DALP 9.0 ASSESSMENT OF OUTCOME**

Appropriate device selection is reflected by evidence of

**9.1** use of proper technique in applying device;

**9.2** patient compliance with procedure;

**9.3** a positive clinical outcome. (However, appropriate device selection and application does not guarantee a positive outcome.)

#### **DALP 10.0 RESOURCES**

**10.1** Equipment:

**10.1.1** MDI and accessory device (holding chamber or spacer).

**10.1.2** SPAG (nebulizer with drying chamber supplied by manufacturer); gas source; tent, hood or ventilator; scavenger or filter system to prevent aerosol from being released outside immediate treatment area.

**10.1.3** SVN, gas source, tubing, one-way valves, mouthpiece or mask, scavenger or filter system to prevent aerosol from being released outside immediate treatment area.

**10.1.4** LVN, gas source, flowmeter, connecting tubing, mouthpiece or mask scavenger or filter system to prevent aerosol from being released outside immediate treatment area.

**10.1.5** Mechanical ventilator with SPAG unit, adapter in inspiratory line of circuit, filter system in expiratory line to prevent obstruction of expiratory valves, scavenger or filter system to prevent aerosol from being released outside immediate treatment area.

**10.1.6** IPPB machine (ie, pressure-cycled ventilator), nebulizer gas source, connecting tubing, mouthpiece or mask, scavenger or filter system to prevent aerosol from being released outside immediate treatment area.

## **10.2** Personnel

**10.2.1** Level-II personnel should establish the need for a specific device by patient assessment and complete the first administration of the medication. Level-II personnel should continue to care for the unstable patient. We recommend that the Level-II caregiver be credentialed (eg, RRT, CRTT, RN). Level-II personnel must have documented knowledge of and demonstrated ability to perform regarding:

**10.2.1.1** Indications and limitations for SPAG, MDI with accessory devices, SVN, LVN, and USN.

**10.2.1.2** Proper use, maintenance and cleaning of equipment, including filter and scavenging systems.

**10.2.1.3** Risks inherent to the medications and specific devices.

**10.2.1.4** Safe disposal of hazardous wastes and medical waste.

**10.2.1.5** Optimal breathing patterns and coughing techniques.

**10.2.1.6** Technique modification in response to adverse reactions.

**10.2.1.7** Dosages and/or frequency modification as prescribed, in response to severity of symptoms.

**10.2.1.8** Assessment of patient condition and response to therapy.

**10.2.1.9** Performance of auscultation, inspection, and monitoring of vital signs.

**10.2.1.10** Performance of peak expiratory flowrate, spirometry, and ventilatory mechanics.

**10.2.1.11** Recognition and response to therapeutic or adverse response and complications of medication administration and/or the procedure.

**10.2.1.12** Understanding and compliance with Universal Precautions(58) and guidelines for prevention of the spread of tuberculosis(28,59) and other infection control measures.

**10.2.2** Level-I caregiver may be the provider of service to the stable patient after Level-II personnel have established need for a specific device by patient assessment and the first administration has been completed. We recommend that Level-I personnel be credentialed (eg, RRT, CRTT, RN). They must have documented knowledge and demonstrated ability to perform related to:

**10.2.2.1** preparing, measuring, and mixing medication;

**10.2.2.2** demonstrating proper technique for administration of medication;

**10.2.2.3** using equipment properly;

**10.2.2.4** cleaning equipment;

- 10.2.2.5** properly disposing of wastes;
- 10.2.2.6** encouraging effective breathing patterns and coughing techniques;
- 10.2.2.7** modifying technique in response to adverse reactions as instructed, with appropriate communication with physician, in response to severity of symptoms;
- 10.2.2.8** implementing and observing Universal Precautions and guidelines to avoid transmission of tuberculosis and proper infection control.

**DALP 11.0 MONITORING:**

- 11.1** Performance of the device and scavenging system
- 11.2** Technique of device application
- 11.3** Assessment of patient response

**DALP 12.0 FREQUENCY:**

A device for delivery of aerosolized medication to the lung parenchyma is selected

- 12.1** on initiation of therapy, after careful assessment of need (as outlined);
- 12.2** when the decision is made to change the device because of a change in patient condition or because the patient is unable to use the specific device.

**DALP 13.0 INFECTION CONTROL:**

- 13.1** Caregiver should exercise Universal Precautions for body substance isolation and follow CDC recommendations for control of exposure to tuberculosis and droplet nuclei.(28,58)
- 13.2** Nebulizers should not be used between patients without disinfection.
- 13.3** Nebulizers should be changed or sterilized:
  - 13.3.1** at conclusion of dose administration or at least every 24 hours;
  - 13.3.2** at 24-hour intervals with continuous administration;
  - 13.3.3** when visibly soiled.
- 13.4** Nebulizers should not be rinsed with tap water between treatments but may be rinsed with sterile water. CDC Guidelines recommend sterile water rinsing and air drying.(60)
- 13.5** All medications should be handled aseptically.
- 13.6** CDC guidelines suggest that if multidose medications containers are dated upon opening and handled aseptically, medication may be used until exhausted or until the manufacturer's expiration date unless visible or suspected contamination occurs.(61,62) However, it is not clear whether this applies only to solutions containing a bacteriostatic agent. Caution is advised particularly for reconstituted solutions.

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