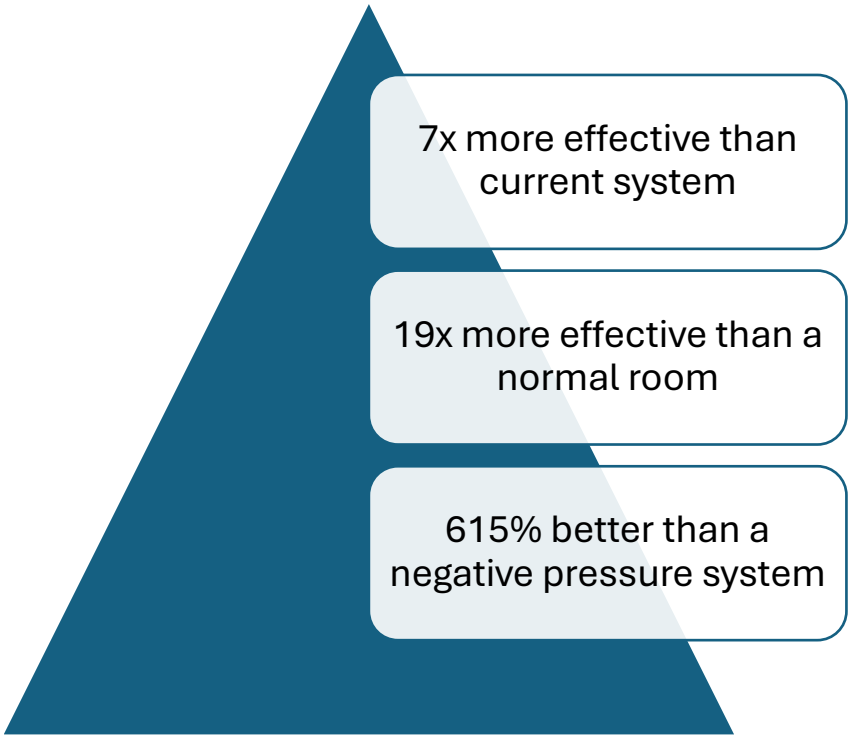
Presentation to:

Study: Mitigation of Fugitive Emissions of Nebulized Pentamidine Isethionate Using a Portable Negative Pressure System

Results:



In addition, the SafER Portable Respiratory Isolation Unit proved to be 1,840% better than a normal room with no system.

- Benefits of SafER Portable Respiratory Isolation Unit:
- Flexible – can be performed anywhere, ICU, ED, bedside in prone position
- Procedure can be performed without pt compliance – no need for pt to hold nebulizer
- 42% more medication
- Pt can utilize nebulizer system for entire hospital stay
- Space can be used for other procedures streamlining productivity
- No annual recertification needed on equipment

Mitigation of fugitive emissions of nebulized Pentamidine Isethionate using a portable negative pressure system.

Abstract

Background: Aerosolized Pentamidine is used in the treatment and prevention of Pneumocystis carinii pneumonia (PCP), in immune deficient persons such as those with acquired immune deficiency (AIDS) and post-transplant patients on extrinsic immunosuppressant therapy. Pentamidine is considered a hazardous drug, and in its aerosol form can create an occupational exposure risk to the healthcare worker due to its embryotoxic and respiratory irritant effects. Aerosolized Pentamidine is therefore administered using a Respigard® nebulizer in a negative pressure isolation room equipped with high air-exchange ventilation and HEPA filtered exhaust. Regulatory bodies have recognized that local exhaust ventilation is preferred over general ventilation for its efficiency in removing air contaminates at or near the source.

Goal: The study aimed at comparing the efficacy of a portable negative pressure system (PNPS) in reducing fugitive emissions generated during a simulated aerosol treatment of Pentamidine versus one performed in a airborne infection isolation room (AIIR).

Methods: The experimental study did not involve human or animal subjects and is therefore exempt from IRB oversite. The study took place in a 23 m^3 airborne infection isolation room (AIIR) equipped with HEPA filtered air inflow and outflow of 5.8 m^3/min, resulting in 15 air exchanges per hour. This air exchange rate results in 99% and 99.9% removal efficiency at 18 minutes and 28 minutes respectively. The baseline room temperature was 25^{o}C and 48% humidity.

Eight separate test solutions were made, containing 300mg of lyophilized Pentamidine Isethionate (CP Lab Chemicals, Novato, CA USA, CAS [140-64-7], batch P114-01), dissolved in 6ml of sterile water USP. To simulate a patient receiving an aerosol treatment, a teaching airway manikin is placed in center of the AIIR room, directly in front of the exhaust vent, with the head 90cm from the floor. A disposable unit dose nebulizer with an aerosol mask (Opti-Neb, Teleflex, Wayne, PA, USA) is strapped to the manikin face. The jet nebulizer reservoir was filled with 6ml of the test solution. A nebulizer pump (Mayluck portable compressor, China), producing 7 l/min of air is used to aerosolize the test solution. In order to simulate the breathing zone exposure of a healthcare worker (HCW), a personal sampling pump (PSP), (Airlight Sample Pump, Model 110-100; SKC, Eighty Four, PA, USA) calibrated at 2 l/min and fitted with a 37mm opaque PVC filter (Omega Specialty Instruments, Chelmsford, MA, USA) is affixed to a rolling IV pole, at a height of 150cm and positioned is 90cm in front of and to the right of the manikin.

To simulate a typical pentamidine treatment in a clinic or hospital, the control group simulated the nebulizer using the AIIR air filtration system only. This was performed

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directly in front of the exhaust vent to also simulate the effects expected from an exhaust cabinet.

For the experimental group, the air handling system in the AIIR was turned off. In place of relying on the AIIR air handling system to remove and filter aerosolized particulates produced during the nebulization, a portable negative pressure system (SafER Medical Products, Branson, MO, USA) is used. The system consists of a lunchbox-sized AC/DC vacuum source, utilizing HEPA filtration attached by 22mm smoothbore respiratory tubing to a clear polycarbonate barrier shield that in turn affixes to the outside of a conventional aerosol mask. The vacuum operates at 260 liters/min and provides an open negative pressure of vacuum of 5.2 kPa. This results in 4 air exchanges per second under the shield.

The experiment was divided into 8 separate runs. To simulate the typical duration of an inhaled pentamidine treatment, each run lasted for 30 minutes. During that time the PSP was run continuously, and a fresh PVC sampling filter was used in the PSP for each run. The AIIR room air handling and filtration system was allowed to operate for at least 30 minutes between runs to "clean out" the room. This would allow for a 99.9% removal efficiency of residual airborne particles.

Trial #1 was a "dry run" conducted without the nebulizer for background measurement.
Trials #2-4 represents the experimental arm, utilizing the nebulizer and portable negative pressure system while the AIIR air handling was turned off.
Trials #5-7 represented the control arm and only used the nebulizer and the AIIR.
Trial #8 was conducted with the nebulizer but without the AIIR nor the portable system turned on. This was done to simulate a treatment in a closed room in a "worse case" scenario.

The PSP sample filters were analyzed and reported utilizing NIOSH 5032 HPLC method (Wisconsin Occupational Health Laboratory, Madison, WI, USA). Statistical and data analysis was performed on Microsoft® Excel for Mac, version 16.86 (Microsoft®, Redmond, WA).

Results: A two sample, two-tailed, independent t-test of the control and experimental group was performed. The experimental group had a significantly lower mean concentration of fugitive Pentamidine (0.0876 mg/m3) vs the control group (0.622 mg/m3). The p-value is <0.05. The fugitive emission concentration of nebulized Pentamidine is reduced 7-fold by use of the PPNS when compared to a traditional airborne infection isolation room (negative pressure room) and 19-fold when compared to an enclosed treatment room.

Sample	Air Volume	Total *u*g	Air Concentration mg/m3
1	60.0 L	< 1.5	< 0.025
2	60.0 L	3.3	0.055
3	60.0 L	5.9	0.098
4	60.0 L	6.4	0.11
5	60.0 L	32	0.53
6	60.0 L	43	0.72
7	60.0 L	38	0.63
8	60.0 L	100	1.7

mg/m3	Mean	Standard Deviation
Experimental	0.0876	0.0289
Control	0.6266	0.0950

t-Test: Two-Sample Assuming Unequal Variances

	Variable 1	*Variable 2*
Mean	0.087666667	0.626666667
Variance	0.000836333	0.009033333
Observations	3	3
Hypothesized Mean Difference	0	
df	2	
t Stat	-9.397193074	
P(T<=t) one-tail	0.005567654	
t Critical one-tail	2.91998558	
P(T<=t) two-tail	0.011135307	
t Critical two-tail	4.30265273	

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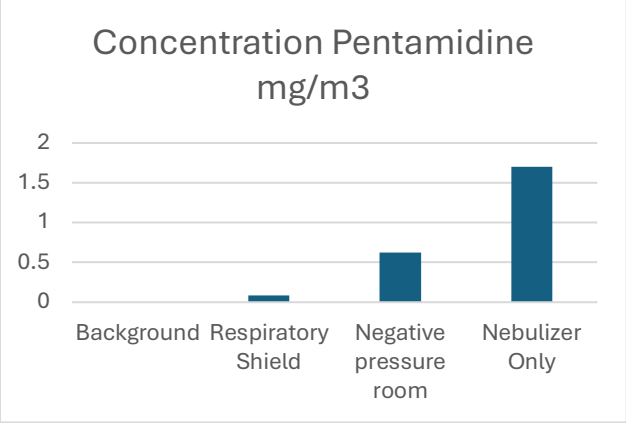
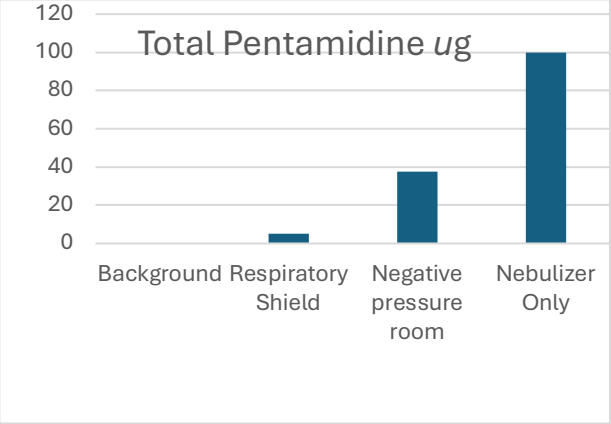
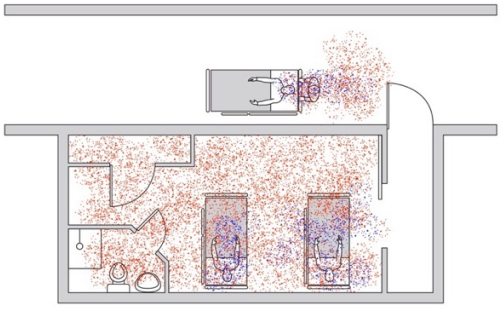
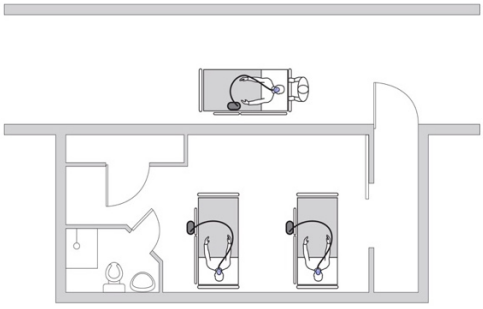




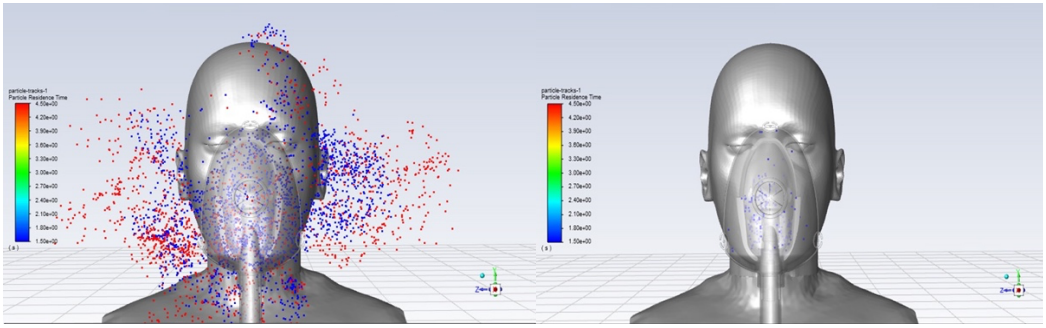
Conclusion: The tested portable negative pressure system, utilizing local filtration-at-source, is superior, by 7-fold in reducing fugitive emissions of nebulized Pentamidine when compared to a negative pressure airborne infection isolation room and a 19-fold reduction in observed when compared to an enclosed treatment room.



Without SafER Respiratory System



With SafER Respiratory System



Without Negative Pressure Vacuum

With Negative Pressure Vacuum

SafER Portable Negative Pressure System with Respiratory Shield