The MetaNeb® System in an Acute Care Hospital Setting: An Assessment of Impact on Hospital Length of Stay Using A Failure Mode and Effects Analysis

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ABSTRACT
A three-month evaluation was performed to determine the impact of use of The MetaNeb® System in hospitalized patients with pneumonia and multifocal or bilateral infiltrates on chest x-ray. The MetaNeb® System was used onsite from January to March 2012. To assess the impact of therapy, we performed a failure mode and effects analysis (FMEA) to evaluate the average length of stay (LOS) for the first sequentially treated patients with The MetaNeb® System, compared to the average LOS of a retrospective group of patients with an identical diagnosis treated at our facility one year prior. The mean LOS observed-to-expected (OE) ratio was calculated for each group. The mean LOS OE ratio is the observed average LOS over the expected mean LOS determined by The Centers for Medicare and Medicaid Services. Mean LOS OE ratio in The MetaNeb® System group was 0.807 ± 0.502 compared to 1.457 ± 0.752 in the retrospective group (difference 0.65; 95% CI: 0.075-1.225; P=0.029). The MetaNeb® System treatment had a statistically significant effect on reducing the mean length of stay OE ratio. Administering treatment using The MetaNeb® System for patients with pneumonia and multifocal or bilateral infiltrates on chest x-ray may lead to a reduction of the total mean length of stay and may yield cost savings.

Keywords: continuous high frequency oscillation, The MetaNeb® System, length of stay

CHALLENGE/OPPORTUNITY
Many conditions can affect normal mucociliary clearance resulting in retained secretions and the need for adjunctive therapy (AARC, 1991). We observed that hospitalized patients with pneumonia who presented with multi-focal or bilateral infiltrates on chest x-ray have an average length of stay (LOS) greater than the national geometric mean length of stay as determined and reported by The Centers for Medicare & Medicaid Services (CMS) (Federal Register, 2010). This observation pointed to the need to identify more effective therapy for this specific patient population.

In today's healthcare environment, clinicians have access to a wide variety of airway clearance technologies; however, for many therapies, clinical evidence of efficacy is lacking. Furthermore, the endpoints used to demonstrate the benefits of airway clearance therapy (i.e. mucus volume) are often of a short-term nature, difficult to quantify, or do not necessarily correlate with more significant health outcome measures (Hess, 2001; Hess, 2007). Recognizing the importance of therapy selection and the challenges associated with the collection and interpretation of traditional efficacy measures, we applied principles of failure mode and effects analysis (FMEA) to assess the impact of The MetaNeb® System (MetaNeb) on length of stay in hospitalized patients with pneumonia and multifocal or bilateral infiltrates on chest x-ray.

MATERIALS AND METHODS

The MetaNeb® System is a therapeutic device, available in the acute care setting, that employs a systematic approach to enhance mucus clearance and resolve or prevent patchy atelectasis ("MetaNeb, lung expansion," n.d.). The MetaNeb® System offers two modes of operation: Continuous High Frequency Oscillation (CHFO) and Continuous Positive Expiratory Pressure (CPEP). It is possible for the clinician to alternate between the two modes within a single treatment session. In addition, The MetaNeb® System allows for the delivery of aerosolized medication, such as bronchodilators, in both of these modes as well as separately ("The MetaNeb® System, lung expansion," n.d.).

To assess the effectiveness of The MetaNeb® System therapy within hospitalized pneumonia patients we used a FMEA methodological approach (Yang, 2003). This approach provides the opportunity to evaluate the impact of The MetaNeb® System therapy through review of potential failure effects (See Table 1). We rated potential failure effects according to severity and associated "longer length of stay" with a high severity rating. Subsequently, we considered potential causes of failure associated with therapy selection which included: non-pulmonary physician unaware of latest data, missed assessment due to work load, and ineffective therapy assignment.

Table 1 Failure Modes Effect Analysis Worksheet

Process Step	Key Process Input	Potential Failure Mode	Potential Failure Effects	Potential Causes	Current Controls	Action Recommended	Responsibility
Most effective therapy ordered for pulmonary patient.	Pulmonary Assessment	Ineffective therapy ordered.	Longer length of stay.	Non-pulmonary physician unaware of latest data. Missed assessment due to work load. Ineffective therapy assigned.	Respiratory assessment protocols assigned for all patients ordered on therapy.	Implement new therapy specific for pneumonia-type patients.	Respiratory Therapy

In an effort to evaluate a new therapy specific for pneumonia patients, The MetaNeb® System was incorporated into our bronchopulmonary hygiene (BPH) protocol and was used over a three-month trial period from January to March 2012.

As part of our Respiratory Assessment Protocol, patients are assigned an acuity level based upon their severity level in eight individual assessments: level of consciousness, respiratory rate, bilateral breath sounds, cough, pulmonary history, surgical history this admission, chest x-ray, and pulmonary function. There are four severity levels for each individual assessment with one being the least severe and four being the greatest. If the patient scores either a two, three, or a four in either cough, surgical history or chest x-ray, then the assessing respiratory therapist is directed to place the patient within the BPH protocol.

Once the patient is placed within the BPH pathway, the respiratory therapist determines the patient's Total Acuity Score (TAS) by adding each of the eight acuity levels. The higher the TAS, the more aggressive the treatment plan. For example, a patient who is receiving therapy via the BPH protocol, and who has a TAS between 16 and 32, is to receive The Metaneb® System treatment QID with physician-prescribed bronchodilators if the chest x-ray acuity level is 4. A patient will be assigned an acuity level of 4 within the chest x-ray assessment if he or she has bilateral or multifocal infiltrates. Otherwise, he or she will receive postural drainage & percussion, positive expiratory pressure therapy, or The Vest® System QID & PRN.

To evaluate the impact of The MetaNeb® System in patients with pneumonia and multifocal or bilateral infiltrates, we compared the mean LOS observed-to-expected (OE) ratio for the first sequentially treated patients with The MetaNeb® System (The MetaNeb® System group) to the mean LOS OE ratio of a retrospective group of patients with an identical diagnosis treated at our facility one year prior (retrospective group). The OE ratio is the ratio of the observed average LOS over the expected mean LOS as reported by The Centers for Medicare and Medicaid Services. An OE ratio less than 1.0 indicates the observed length of stay was less than the

expected length of stay. The 11 retrospective, baseline test patients were the first 11 patients out of all pneumonia patients treated December 2010 to February 2011, approximately one year prior to the pilot test. Patients in both The MetaNeb® System group and retrospective group had an ICD-9 code of 486 for pneumonia, organism unspecified. The null hypothesis was that the mean LOS OE ratios of the retrospective group and The MetaNeb® System group were equal. We chose the time period of one-year prior to minimize the possibility of seasonal fluctuations on LOS. Medical records were used to collect data.

The Anderson-Darling Normality Test was used to confirm that the retrospective and The MetaNeb® System samples represented a normal distribution (where a small sample was deemed normally distributed when P>0.05). The Anderson-Darling test is a statistical test used to determine if a given sample of data came from a population with a specific distribution (Anderson & Darling, 1952; Stephens, 1974). The test fails to reject the null hypothesis of normality when the p-value is greater than 0.05. Where normality was present, a two-sample t-test and 95% confidence intervals (CI 95%) were calculated to compare groups. The length of stay between the retrospective and The MetaNeb® System groups was graphically examined using a boxplot, which depicts five-number summaries (minimum, lower quartile, median, upper quartile, and maximum).

RESULTS

Eleven patients with pneumonia and multifocal or bilateral infiltrates were included in the retrospective study group and eleven patients with pneumonia and multifocal or bilateral infiltrates were in The MetaNeb® System group. The MetaNeb® System patients received aerosol, CHFO and CPEP therapy alternating two minutes of CHFO and CPEP for a total treatment time of eight minutes. HIPAA Authorization was obtained for all patients. Using the Anderson-Darling test for normality, the result was P=0.871 for the retrospective group and P=0.200 for The MetaNeb® System group (Table 2). In addition, the variance of The MetaNeb® System group was reduced, although not statistically significant (P=0.219). Therefore, the data for both samples were normal, and a two sample t-test was an appropriate test of significance.

Table 3 presents descriptive statistics for the LOS OE ratio, and Figure 1 depicts the boxplot for length of stay OE ratio for The MetaNeb® System group and retrospective group. The median LOS OE ratio and interquartile range for The MetaNeb® System group was 0.67 (0.50-1.0) and 1.52 (0.70-2.09) for the retrospective group. The mean LOS OE ratio was 0.807 ± 0.502 in The MetaNeb® System group compared to 1.457 ± 0.752 in the retrospective group (difference 0.65; 95% CI: 0.075-1.225; P=0.029). Therefore, the null hypothesis was rejected as The MetaNeb® System had a statistically significant effect on reducing the mean LOS OE ratio.

Table 2 Anderson-Darling Test for Normality Test for Length of Stay Observed-to-Expected Ratio

Anderson-Darling	Retrospective Group	MetaNeb Group
A2	0.19	0.47
P-value	0.871	0.200

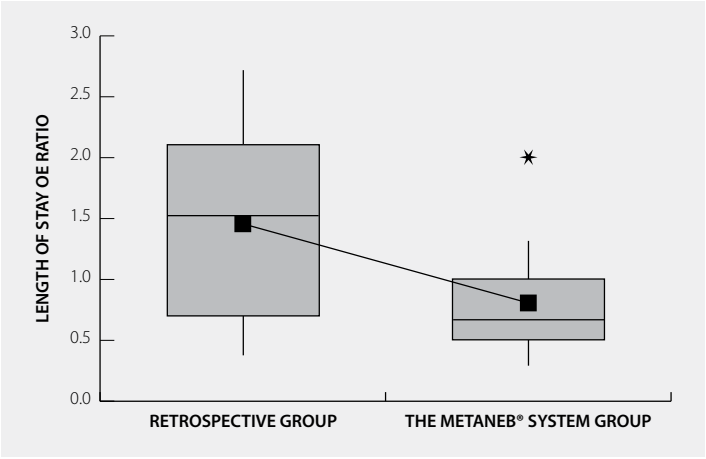
Table 3 Descriptive Statistics of Length of Stay Observed-to-Expected Ratio

Length of Stay OE Ratio	Retrospective Group N=11	The MetaNeb® System Group N=11	*P*-value
Mean	1.457	0.807	
Median (IQR)	1.52 (0.70-2.09)	0.67 (0.50-1.0)	
Standard Deviation	0.752	0.502	
Variance	0.565	0.252	0.219†
Min., Max.	0.38, 2.73	0.25, 2.00	
Mean difference	0.65		
95% CI	0.075, 1.225		
P-value	0.029*		

** Two sample t-test of difference*

† F - Test of Equality of Variances

Figure 1 Boxplot of Length of Stay Observed-to-Expected Ratio



DISCUSSION

It is critical that clinicians identify and select the most effective therapies for hospitalized patients. However, for many pulmonary conditions (e.g, pneumonia) there are a number of potential treatment options. We incorporated The MetaNeb® System, a novel treatment designed to enhance mucus clearance and resolve or prevent patchy atelectasis, into our bronchopulmonary hygiene protocol. This protocol is a necessary part of our Respiratory Assessment Protocol which requires that we perform an assessment on all patients ordered to receive adjunctive respiratory therapy. The goal of the bronchopulmonary hygiene protocol is to ensure that appropriate therapy is selected for those patients whose symptoms and diagnosis are significant for this type of therapy.

To assess the appropriateness of The MetaNeb® System on indicated patients, we utilized FMEA principles and evaluated differences in LOS between a retrospective group and The MetaNeb® System treatment group. In our evaluation, we observed a statistically significant decrease in mean LOS OE ratio in the group treated with The MetaNeb® System. Furthermore, we observed a smaller interquartile range within The MetaNeb® System group. This is a favorable observation in that it suggests there is less variability in length of stay for patients treated with this therapy device. These observations carry important implications as a primary goal of healthcare is to provide efficacious and efficient patient care. Finally, of note, The MetaNeb® System was well received by both patients and respiratory care staff. Patients reported that The MetaNeb® System helped them feel better during and immediately following treatment.

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