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This thesis, COST-BENEFIT ANALYSIS OF A DOSIMETRIC NEBULIZER USING CIRCULAIRE AND A TRADITIONAL VIXONE NEBULIZER, by Nwakaego C. Okere, RRT, was prepared under the direction of the Master's Thesis Advisory Committee. It is accepted by the committee members in partial fulfillment of the requirements for the degree of Master of Science in the College of Health and Human Sciences, Georgia State University.

The Master's Thesis Advisory Committee, as representatives of the faculty, certifies that this thesis has met all standards of excellence and scholarship as determined by the faculty.

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COST-BENEFIT ANALYSIS OF A DOSIMETRIC NEBULIZER USING
CIRCULAIRE AND A TRADITIONAL VIXONE NEBULIZER

By

NWAKAEGO CHIOMA OKERE, RRT

A Thesis

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ABSTRACT

COST-BENEFIT ANALYSIS OF A DOSIMETRIC NEBULIZER USING CIRCULAIRE AND A TRADITIONAL VIXONE NEBULIZER

By

Nwakaego C. Okere, RRT

Aerosol administration via small-volume nebulizers are still being used by selected patient-population. In the economic market, several nebulizer designs have become available, with each incorporating unique features that will potentially establish it as the preferred choice in aerosol delivery. With the continuous rising cost of health care services, clinicians are faced with the task of identifying opportunities for cost reduction in respiratory care. **PURPOSE:** The purpose of this study was to conduct a cost-benefit analysis of dosimetric nebulization using the Circulaire system and the traditional VixOne nebulizer. The desired outcome was to elevate awareness of the potential impact of the Circulaire, and how its adoption might reduce costs and enhance productivity in respiratory care. **METHODS:** A retrospective study using existing data collected from an urban tertiary adult hospital with a Level II Trauma Center was completed. **DATA ANALYSIS:** Descriptive statistics were run for each variable. The total cost of a full-time Registered Respiratory Therapist (RRT) with benefits per hour was calculated. The average number of RRTs per 12-hour shift, average number of nebulizer treatments by an RRT per 12-hour shift, average costs of traditional VixOne nebulizer and the Circulaire system were also calculated. **RESULTS:** Descriptive statistics indicated the annual cost of delivering aerosol therapy using the traditional VixOne nebulizer at 9-minutes treatment time to be \$114,263.25 per year. The Circulaire was compared at two different treatment times of 5-minutes and 3-minutes, and the annual costs were \$137,422.50 per year and \$116,982.50 respectively. A sensitivity analysis was also conducted, and the treatment load was increased by 30%, with a reduction to 5 RRTs per shift. Data indicated an annual savings of 8% with the Circulaire at 5-minutes treatment time, and 21% with the Circulaire at 3-minutes treatment time. **CONCLUSION:** The use of the Circulaire system at 5-minutes or 3-minutes treatment time can reduce department expenditure by reducing labor costs.

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CHAPTER I

Introduction

The rising costs of health care in the United States have become a critical issue that can no longer be ignored anymore. It was among the forefront of issues raised during the debate for reforms in the health care system. What is not widely recognized, however, is that this rising costs at a disturbingly rapid rate is true throughout the world, most especially in all developed nations (Malach and Baumol, 2010).

With the new millennium, consumers of health care services have felt the need to cut down on their coverage as a result of the rising cost of health care. However, the reality remains that as the demand for health care services increases, additional funding in this area becomes highly unlikely, and all efforts should be geared towards finding possible avenues for cost reduction of health care services.

In this era of limited health care resources, the adoption of the least expensive treatment modalities and the development of cost-saving medical technology will go a long way in minimizing the burden of health care costs. Most health care administrators, chief executive officers, directors, and clinicians are now veering towards several cost saving alternatives as means of combating the economic aspect of health care. There is a new focus on the economic efficiency of a strategy versus its clinical impact by weighing the costs against the benefits that it might bring over a number of years in the future. If budget gatekeepers and other key decision-makers are to be won over, proponents of the new product need a strategic plan to gather and present empirical evidence that demonstrates both clinical improvement and overall cost-effectiveness (Dunne, 2002).

To facilitate the adoption of any new product, reliable and valid data are needed to support both the cost of the product and the benefits that are likely to arise from using the product. Cost-benefit analysis attempts to translate into dollar terms the improved clinical outcomes from a new care or treatment intervention (Dunne, 2002). The difference between cost-benefit analysis and cost-effectiveness analysis is that unlike cost-benefit analysis, cost-effectiveness analysis does not necessarily translate into a dollar amount. However, it compares the effectiveness of an intervention by measuring one or more outcomes and comparing it with the costs.

Just like any other sector in health care, there is also need to save costs in respiratory care. Most respiratory care establishments are adopting cost-effective modalities, aimed at saving resources for the department, improving productivity, and saving manpower/labor, most especially in facilities where the demand for respiratory therapists exceed their availability.

The administration of aerosol therapy via small-volume nebulizer accounts for a large proportion of the in-patient respiratory therapy workload in large health-care organizations (Hoisington, Chatburn, and Stoller, 2009). It is not uncommon to see that in most hospitals, the purchasing department rather than the respiratory care department oversee the selection of nebulizers, and the nebulizer brand selected is usually based on price. According to the study done by Hoisington et al. (2009), time spent delivering small volume nebulizer treatments accounted for approximately 40% of the clinical workload outside of the intensive care units.

Reducing the time spent on aerosol administration can be achieved by modification of the nebulizer equipment to deliver aerosol more rapidly, thus shortening the length of treatment time. For example, if a novel nebulizer is shown to result in 35% fewer treatments during hospitalization, the incremental increase in the cost of the device should be evaluated in the context of the overall savings realized (Dunne, 2002). The rationale being that fewer treatments given can indirectly save cost through fewer missed treatments, reduced length of hospital stay, greater satisfaction by patients, and decreased workload on respiratory therapists ensuring that more time is spent on other important respiratory patient-care activities.

The term “nebulizer” derives from the Latin “nebula,” meaning “mist,” and reportedly was first used in 1872, followed by an 1874 definition as “an instrument for converting a liquid into fine spray, especially for medical purposes” (Rau, 2002). One of the oldest forms of delivering aerosol therapy is through the nebulizers. They are predominantly used to deliver bronchodilators to the lower respiratory tract. The liquid particles are converted into aerosol particles, and are deposited into the lower respiratory tract through inhalation.

Most aerosol devices do not generate a single particle size. Instead, they usually produce heterodisperse particle sizes. A measure used to determine a heterodisperse aerosol particle is the mass median diameter (MMD). The mass median diameter or mass median aerodynamic diameter (MMAD) indicates where the mass of drug is centered in a distribution of particle sizes (Gardenhire, 2008). When nebulizers are used to deliver medications like bronchodilators to the lungs, it is important to have the particle sizes within a specific range to ensure effective and better deposition into the lungs. Particle

sizes that are too small or too large end up being ineffective, and have no clinical benefits when administered. This is because particle sizes that are too small tend to be blown away during exhalation, thereby failing to deposit in the lung periphery, while the aerosol particles that are too large end up being deposited in the nose, mouth, and oropharynx. Aerosol particle sizes that are between 1 – 5 μm usually deposit in the lower respiratory tract, particle sizes between 5 – 10 μm mostly deposit in the upper airways, and particle sizes > 10 μm are usually found in the nose, mouth, and oropharynx.

Several literatures (Dolovich et al., 2005; Hess, 2002; Rau, 2002, 2004) have supported the use of small-volume nebulizers because some drugs are only available for inhalation in liquid solutions, and also some patients who are unable to either coordinate their breathing, or generate a high inspiratory flow unlike with the metered-dose inhalers and dry powder inhalers respectively are much more comfortable using the small-volume nebulizers.

There are two main types of nebulizers. These include pneumatic nebulizers, also called jet nebulizers, and ultrasonic nebulizers. These nebulizers differ based on their principles of operation, aerosol particle size generated, and time of nebulization. The operation of a pneumatic nebulizer requires a pressurized gas supply as the driving force for liquid atomization (Hess, 2000). The solution to be aerosolized is entrained into the gas stream as compressed gas is delivered through a jet. The solution is then sheared into a liquid film which separates into droplets as a result of surface tension. A more stable particle size is produced by placing a baffle in the aerosol stream. The baffle acts as a sieve by allowing the smaller particles to pass through, preventing larger particles from being aerosolized, as they will fall back in the liquid reservoir.

The ultrasonic nebulizer uses a piezoelectric transducer to produce ultrasonic waves that pass through the solution and aerosolize it at the surface of the solution (Hess, 2000). The piezoelectric effect is defined as the ability of some materials to convert electrical energy into mechanical energy which vibrates and causes the solution to be aerosolized. Ultrasonic nebulizers have been shown to produce particle sizes of smaller MMAD when compared with pneumatic nebulizers.

There are numerous advantages and disadvantages of using the small-volume jet nebulizers. Perhaps one of the greatest advantages similar with both small-volume jet nebulizers and ultrasonic nebulizers is the tidal breathing pattern. This is very simple and less complex, being the most convenient for patients who are unable to coordinate their breathing. Patients who are unable to generate high inspiratory flows and large volumes find this more effective. Another factor is also the ability to aerosolize more than one drug solution at a time. Jet nebulizers have the ability of modifying drug concentrations, allowing the delivery of higher doses.

In the United States, health care reimbursements are often determined by a number of issues. In most cases, patients tend not to use devices that they cannot afford. Medicare reimbursements do not cover the use of pressurized metered-dose inhalers (MDI) and dry powder inhalers (DPI) in non-hospitalized patients, but does for patients who use nebulizers in home therapy.

Some of the disadvantages of small-volume jet nebulizers include the length of time required to aerosolize, the need for an external power source, the size of the equipment, and its lack of portability. Another disadvantage to the use of small-volume

jet nebulizers is that it increases the risk of infections. There is an increased risk of patient contamination when the nebulizers are not properly cleaned after use, and are constantly stored in wet or moist conditions. This allows for the growth of bacteria and other unhealthy organisms.

There are various factors that affect the deposition of aerosol when using the small-volume jet nebulizers. Some of the factors are patient-related, while others can be due to technical issues. Some of the patient-related factors include the breathing pattern. Patients are encouraged to maintain normal tidal breathing with occasional deep breaths for better aerosol deposition in the lung periphery. Also, with the nose acting as a filter, some of the aerosolized drugs are lost on patients who breathe through the nose versus patients who breathe through the mouth. Other patient-related factors include the degree of airway obstruction, artificial airway, and mechanical ventilation.

Several studies (Hess, 2000, 2002; Rau, 2002, 2004) have attributed the differences in design and nebulizer models from various manufacturers as one of the major technical factors affecting the deposition of aerosol when using small-volume jet nebulizers. Other technical factors include the density of the gas used to deliver the aerosol; humidity and temperature; the solution of the liquid nebulized; and the device interface used to deliver the aerosol. Better aerosol deposition is obtained with patients who are encouraged to use the mouthpiece instead of the mask. Masks that do not properly fit cause aerosol particles to be deposited in the face or eyes instead of their intended location. The amount of gas flow and pressure also affect the size of aerosol particle generated. Lower gas flows and pressures tend to increase particle size, while higher flows create a smaller particle size. The fill volume and the dead volume also

affect the overall performance of the nebulizers. Several studies have also reported greater output from pneumatic nebulizers when the fill volume is increased (Hess, 2000, 2002; Rau, 2002, 2004). This can be explained by the fact that a greater fill volume increases the total output of aerosol generated, while the percentage of dead volume within the nebulizer increases with a small fill volume. The dead volume is the amount of the aerosol medication that is not delivered at the end of treatment. A fill volume of 4 – 5 mL has been recommended.

With the advancements in bio-medical technology come newer and more efficient nebulizer designs. Jet nebulizers are predominantly classified under three major categories. They include constant-output nebulizers, breath-enhanced nebulizers, and dosimetric or breath-actuated nebulizers. Constant-output nebulizer is the type of nebulizer that delivers aerosol at a constant rate, without taking into account if a patient is inhaling or exhaling. Constant-output nebulizers are theoretically inefficient, as they (at least without accessory modification) result in making available for patient inhalation a maximum of only about one third of the total aerosol released, with the remaining two thirds of total aerosol output being released either during the patient exhalation or breath-hold phase (Dennis, 1998). The traditional nebulizer cup such as the Misty-Neb with a mouthpiece that is connected to a T-piece is an example of the constant-output nebulizer.

Breath-enhanced nebulizers have designed characteristics that allow them to release more aerosols during patient inhalation while dropping back to residual output capacity during non-inspiratory phases (breath-hold and exhalation phases) (Dennis, 1998). These devices are more superior to the constant-output nebulizers because fewer aerosols are lost during the non-inspiratory phases. However, a residual amount of

aerosol is still generated and lost to the atmosphere during the breath-hold and exhalation phases. Pari LC Plus and Ventstream are examples of breath-enhanced nebulizers.

Dosimetric nebulizers are designed to release aerosol only during the inspiratory phase. This can be achieved by generating aerosol only during inspiration, using a manual interrupter for the power-gas (as in the Pari LL) or a spring-loaded valve (as in the AeroEclipse) or by containing all aerosol in the device, with no release during expiration (as with the Circulaire) (Rau, 2002). This type of jet nebulizer design is the most efficient in the delivery of aerosol medications and has been shown to reduce treatment time and improve patient compliance (Dennis, 1998; Rau et al., 2004).

Specifically designed nebulizers have also been manufactured for aerosolizing specific medications. This is because the physical composition, efficiency, and efficacy of these drugs may be affected when used with regular nebulizers. Examples of such special nebulizer devices include the Respigard II for the delivery of aerosolized pentamidine (NebuPent), Small-Particle Aerosol Generator for aerosolization of ribavirin (Virazole), and Pari LC which is used to aerosolize tobramycin (TOBI). Some of these drugs require special scavenging systems as they have also been shown to contaminate the environment, thereby posing a health hazard to the health care professionals.

In the late 1980s and early 1990s, there were reports of increased aerosol delivery to the lower respiratory tract when a plastic chamber was used with the nebulizer to capture aerosol during the expiratory phase, and provide that to the patient during subsequent inspiration (Hess, 2000). This concept was incorporated into the design system of the Circulaire (Westmed, Tucson, Arizona). The Circulaire is designed with a

reservoir bag of 750mL that is used to store aerosol during exhalation. On subsequent inhalation, stored aerosol from the bag is delivered to the patient with a one-way valve preventing the patient from rebreathing exhaled carbon dioxide. The Circulaire uses a one-way flapper valve so that gas can travel only from the direction of the aerosol storage bag toward the patient, thus ensuring that exhaled gas goes directly from the patient to the ambient environment (Piper, 2000).

Mason, Miller, and Small (1994) compared aerosol delivery via Circulaire system versus conventional small volume nebulizer. They reported an MMAD of $0.51\mu\text{m}$, and concluded that the Circulaire system improved aerosol delivery to the lungs, less deposition in the non-targeted parts of the body, and less loss in the environment. In a similar study done on COPD patients, Mason and Miller (1996) also concluded that the Circulaire provided equal therapeutic effect with relative freedom from side effects and less exposure for caregivers. Hoffman and Smithline (1997) also compared Circulaire to conventional small volume nebulizers for the treatment of bronchospasm in the emergency department, and concluded that Circulaire showed greater improvement in bronchospasm as measured by peak flow meter. However, questions have been raised over the design performance of the conventional small-volume nebulizer used, as the Circulaire design has been shown to be of a much superior quality (Hess, 2000).

Purpose of the Study

The purpose of this study was to perform a cost-benefit analysis of dosimetric nebulization with Circulaire and the traditional VixOne nebulizer using data retrospectively collected from an urban tertiary adult hospital. As clinicians, we ought to

be well informed about the various nebulizer designs available and purchasing decisions should be based on a thorough selection process. Often, the assessment of needs becomes the driving force for the design of the selection and evaluation process. The goal in purchasing a new nebulizer design is to select the nebulizer with the best performance at the lowest relative cost. The desired outcome of this study is to elevate awareness of the potential impact of this nebulizer design, and how its adoption might reduce costs and enhance clinical efficiency most especially in respiratory care.

The following research questions were addressed to guide the acquisition of data required to justify the purpose of this study.

1. What was the total cost of a full-time RRT per hour?
2. What was the average number of respiratory therapists per 12-hour shift?
3. What was the average number of nebulizer treatments given by a respiratory therapist per 12- hour shift?
4. What was the average cost of traditional VixOne nebulizer?
5. What was the average cost of the Circulaire system?
6. What is the average yearly cost of utilizing the VixOne nebulizer?
7. What is the average yearly cost of utilizing the Circulaire system at a treatment time of 5 minutes?
8. What is the average yearly cost of utilizing the Circulaire system at a treatment time of 3 minutes?
9. Does the Circulaire system at 5 minutes reduce cost when compared to the VixOne nebulizer?

10. Does the Circulaire system at 3 minutes reduce cost when compared to the VixOne nebulizer?

Significance of Study

The study is significant in that it might present an alternative treatment modality that could be least expensive and easily adopted, thereby helping to reduce the rising cost of health care. This study may also identify certain areas where revenue can be generated for the health care establishment.

Definition of Words and Terms

Total cost: Average cost per hour of a full-time RRT plus benefits.

Cost-benefit analysis (CBA): Costs versus overall savings.

Cost-effectiveness Analysis: Cost per number of cures or lives saved.

Mass Median Aerodynamic Diameter (MMAD): The particle size above and below which 50% of the mass of the particles is found.

Heterodisperse: Aerosol particles comprised of different sizes.

Delimitations

This study involves retrospective data collected from an urban tertiary adult not-for-profit hospital with a Level II Trauma Center for the year 2010. The results of this study can only be generalized to this health care facility. The limitation factors noted in this study are beyond the control of the researcher, as information gathered was done retrospectively.

Assumptions

The intention of this study is to prove that aerosol administration using the Circulaire system will save costs in a tertiary care institution, when compared to aerosol administration using the traditional VixOne nebulizer. This assumption is based on the fact that with the additional aerosol bag attached to the Circulaire system, and the one-way expiratory valve, aerosol is effectively administered to the targeted area, and fewer drugs are lost to the environment at 3 and 5 minute treatment times. This will indirectly affect patient outcomes by reducing the length of hospital stay, thereby saving costs for the hospital facility.

CHAPTER II

Review of Literature

Methods of evaluating the costs and benefits of healthcare have become increasingly important due to the rising costs of healthcare, and the number of economic evaluations of healthcare has increased dramatically (Phillips, Veenstra, VanBebber, and Sakowski, 2003). With ongoing inflation in the healthcare system, there is need to ensure that proper economic evaluation is done on all costs and benefits resulting from an intervention.

Furthermore, with the limited funds available for healthcare, as well as competition from other areas like education and housing, it becomes imperative that total funds available are allocated appropriately. Economic evaluation is defined as ‘the comparative analysis of alternative courses of action in terms of their costs and consequences’ (Drummond et al., 1987; Kumar et al., 2006). However, this term is collectively used to describe a range of techniques that can be used to make comparison showing the costs, benefits, and consequences of each intervention.

There are several methods of economic evaluation in healthcare, and they include: cost-utility analysis, cost-minimization analysis, cost-effectiveness analysis, and cost-benefit analysis. Although these methods all share some similarities, they also vary in the way they compare different interventions. Cost-utility analysis tends to measure benefits in terms of quality adjusted life years (QALY), allowing different techniques to be compared by standardizing the denominator. In cost-minimization analysis, interventions expected to have similar outcomes are assessed, and the least expensive is identified.

Cost-effectiveness analysis is used for comparison when the expected outcomes may vary, but can be expressed as common units. While cost-benefit analysis estimates the total monetary value of costs and benefits of two interventions to determine which of them is worth the time or effort spent. Cost-effectiveness analysis and cost-benefit analysis in particular provide decision-makers with a framework whereby they can make decisions regarding healthcare provision, insurance reimbursement, and drug development given a fixed budget and competing choices (Phillips et al., 2003).

A thorough cost-benefit analysis should incorporate most of its founding principles. A common unit of measurement is one of the important principles of cost-benefit analysis. In order to arrive at a conclusion as to why an intervention is best suited, all aspects of the intervention should be evaluated and expressed in terms of their equivalent monetary value; in this case, the dollar amount. However, the most challenging aspect of cost-benefit analysis remains the fact that certain cost estimates are arbitrary by nature and as such, it becomes more difficult to obtain a true estimate of such costs.

In the course of this literature review, a systematic analysis on aerosol delivery and cost-saving modalities in respiratory care will be extensively discussed. It will also focus on cost-effectiveness and cost-benefit analysis of different nebulizer designs, comparing dosimetric nebulization using different nebulizer brands, and evaluating factors that can affect optimum aerosol delivery.

Resources for this review of literature were retrieved from databases such as Cumulative Index to Nursing and Allied Health Literature (CINAHL), the Web of

Science (WOS), PUBMED, Cochrane Library, and nursing and allied health (PROQUEST). The search terms used were “cost-benefit analysis”, “cost-benefit analysis in respiratory care”, and “cost-benefit analysis of dosimetric nebulization”. The articles reviewed spanned the last two decades, and were limited to research studies done in English language. These were all peer-reviewed articles, with references that are pertinent to the subject matter. The only setback in the course of this review was the use of peer-reviewed articles with greater than 10 years of publication. This can be attributed to the paucity of data to support this topic.

Cost-Benefit Analysis in Respiratory Care

Kollef et al. (2000) carried out a single center, quasi-randomized, clinical study to compare the effects of respiratory care practitioner (RCP)-directed treatment protocols versus physician-directed orders on patient outcomes and resource utilization. The need for this research arose from the fact that needless respiratory therapy treatments are often prescribed to patients who do not derive any benefit from its administration, thereby wasting resources for the department. The study involved 694 consecutive hospitalized non-ICU patients ordered to receive respiratory treatments. The main outcomes measured were respiratory care charges, discordant respiratory care orders, hospital length of stay, and patient-specific complications. The results of the study led to the conclusion that RCP-directed treatment protocols were significantly cost-effective when compared to physician-directed orders by improving patient outcomes, and reducing the cost of medical care.

The results of Kollef et al. (2000) were consistent with a previous study conducted by Stoller et al. (1998). In this randomized control trial, RCP-directed treatment protocols were compared to physician-directed orders, and the results associated RCP-directed treatment protocols with lower costs of medical care.

Hoisington et al. (2009) compared the respiratory care workload requirement in a hospital facility with a common small-volume nebulizer to that with a newer nebulizer design than can deliver a standard dose of bronchodilator in less time. The researchers hypothesized that the time saved on aerosol workload could be directed for use on other valued respiratory therapy patient-care activities. The respiratory care day-shift workload distribution in a post-thoracic-surgery ward during two consecutive 30-day periods was compared. For the baseline period, a standard nebulizer (VixOne, Westmed, Tucson, Arizona) was used, while a newer nebulizer with a higher aerosol output (NebuTech HDN, Salter Labs, Arvin, California) was used during the intervention period. The number of respiratory care procedures which have been assigned standard treatment times were compared during the baseline and intervention periods. The researchers concluded that aerosol administration time was significantly reduced with NebuTech HDN, and time saved was used for value-added patient-care activities. They also suggested that shorter treatment times may play a role in dealing with the nationwide shortage of respiratory therapists.

In 1994, LeBouef's study of one respiratory care department's contribution to the 'bottom line' analyzed the financial statements of a 240-bed, not-for-profit hospital to determine the respiratory care department's actual contribution to the hospital's revenue above expenditures. In his study, he reviewed the hospital's profit and loss statement, the

respiratory care department's financial statement, and the financial statements for all 54 hospital departments. His analysis revealed that the respiratory care department was the hospital's largest revenue contributor, with it generating 42.8% of the hospital's revenue above expenditures. He further suggested the need for pursuing therapist-driven protocols and critical pathways to become even more efficient and cost-effective in providing services.

Aerosol Delivery

Due to costs consideration, the expense and risk associated with utilizing reusable devices that needs to be sterilized between patients, disposable single-patient use-nebulizers have become the mainstay in today's economy. There are mass productions of low-cost single-patient use-nebulizers, and various factors affect the characteristics of these nebulizer performances. The time required for nebulization, the drug output, the ease of use, the costs of purchasing these nebulizers are all contributing factors that may affect the performances of these nebulizers.

Dolovich et al. (2005) conducted a systematic review of randomized controlled clinical trials taken from MEDLINE, EmBase, and the Cochrane Library databases to determine the efficacy and adverse effects of treatment using nebulizer versus pressurized metered-dose inhalers (MDIs) with or without a spacer/holding chamber versus dry powder inhalers (DPIs), as delivery systems for beta-agonists, anticholinergic agents, and corticosteroids. This was done to provide recommendations for clinicians when choosing an aerosol delivery device. A total of 394 trials assessing inhaled corticosteroid, beta₂-agonist, and anticholinergic agents delivered by an MDI, an MDI with a spacer/holding

chamber, a nebulizer, or a DPI were identified for the years 1982 to 2001. A total of 254 outcomes were tabulated. Of the 131 studies that met the eligibility criteria, only 59 (primarily those that tested beta₂-agonists) proved to have useable data. The result of the studies did not show any significant difference between devices in any efficacy outcome and in any patient group. In conclusion, the authors surmised that the basis for selecting an aerosol delivery device for respiratory care patients should be based on the patient's age and the ability to use the selected device correctly among other things.

Hess, Fisher, Williams, Pooler, and Kacmarek (1996) conducted a study to evaluate the effects of diluent volume, nebulizer flow, and nebulizer brand on medication nebulizer performance. A total of 17 nebulizers were evaluated using three different fill volumes, and three different oxygen flow rates. With each trial, the amount of aerosol left in the nebulizer and the amount deposited in the airway was measured using spectrophotometry. The researchers concluded that medication nebulizer function is affected by diluent volume, flow, and nebulizer brand and recommended that nebulizers should be evaluated in a setting similar to its clinical use.

Camargo and Kenney (2000) compiled a literature review assessing costs of aerosol therapy. The article introduced basic economic concepts, compared outcomes of beta-agonist delivery via nebulizer and MDI/spacer, and finally evaluated selected economic analyses of nebulizer and MDI/spacer treatment. They suggested that a useful way to evaluate two different interventions was to assess their cost-effectiveness, stating that an intervention was only cost-effective in relation to another course of action. Their article provided an interesting introduction to cost-benefit analysis, showed the

importance of critically evaluating cost analysis, and identified potential areas of improvement in aerosol delivery.

Dosimetric Nebulization

Rau, Ari, and Restrepo (2004) performed an in vitro study to evaluate the total drug deposition of constant-output, breath-enhanced, and dosimetric nebulizers, using simulated normal adult breathing. The five nebulizer brands tested include Misty-Neb and SideStream (constant-output nebulizers); Pari LCD (breath-enhanced nebulizers); Circulaire and AeroEclipse (dosimetric nebulizers). Three of each of the five nebulizer brands were tested, and each device nebulized 2.5-mg unit-dose of albuterol sulfate solution, with a 3 mL total fill volume, powered by oxygen at 8 L/min. The outcomes measured were the total inhaled drug mass, exhaled/ambient drug loss, drug lost in the device, and drug remaining in the unit-dose bottle. Their results showed a significant difference in the percentage of total inhaled drug mass among all nebulizer brands tested. The Circulaire was approximately half that of the constant-output and breath-enhanced nebulizers, while the total inhaled drug mass of AeroEclipse was about 2.5 times greater. However, the AeroEclipse average time to sputter was over 20 minutes. The dosimetric nebulizers also had the least exhaled/ambient drug loss. A significant limitation to this study was the use of the United States Pharmacopoeia (USP) throat as a simple model of the upper respiratory tract, instead of obtaining a measurement of particle size distribution and fine particle fraction.

A study conducted by Mason et al. (1994), suggested that the Circulaire system improved aerosol delivery to the lungs, reduced aerosol deposition in the body outside of the lungs, and showed the least ambient drug loss when compared to a conventional small

volume nebulizer. Based on the outcomes of their study, they suggested the replacement of conventional nebulizers with the Circulaire system so as to reduce the risk of environmental drug exposure to respiratory therapists and caregivers.

A follow-up study carried out by Mason et al. (1996) also supported their previous study. They compared aerosol delivery via Circulaire system versus a disposable nebulizer in chronic obstructive pulmonary disease (COPD) patients. The inclusion of patients having this disease process introduced abnormal physiology and the opportunity to evaluate therapeutic response and side effects. The study was a prospective randomized, crossover-controlled study comprised of 10 COPD out-patients. Their results showed that the Circulaire and conventional nebulizer appeared to deliver about the same amount of aerosol in the lungs. However, extrapulmonary deposition in the body and environmental contamination were significantly higher with the conventional nebulizers.

A similar study was performed by Hoffman and Smithline (1997) for the treatment of bronchospasm in the emergency department. The results obtained from their study supported previous studies on the superiority of the Circulaire system over conventional small-volume nebulizers. The researchers reported a greater improvement of bronchospasm in the Circulaire group as measured by peak flow meter.

Piper (2000) compared AeroTee and Circulaire, two nebulizer designs that incorporate the use of reservoir bags during patient exhalation with the conventional nebulizer T-piece with corrugated tubing. Three of each of the three nebulizer designs was tested with similar three VixOne nebulizers. Medication delivery rates were

calculated using the ratio of the inspiratory flow to the sampling flow and the total amount of mass collected. The result of this in vitro study was contradictory to the previously performed studies. The researcher found out that the AeroTee delivered superior performance when compared to a nebulizer T-piece with corrugated tubing. While the Circulaire system delivered less medication when compared to the nebulizer T-piece with corrugated tubing.

Conclusion

Regardless of the fact that MDIs and DPIs have attained much popularity as the preferred choice of aerosol delivery due its portability and convenience, nebulizers are still being used on selected patient-population. The assessment of need becomes the driving force for the design of the selection and evaluation process. When considering the purchasing of new nebulizers, focus should be on the selection of the nebulizer with the best performance at the lowest relative cost.

Research has established the need for the adoption of RCP-directed treatment protocols as an avenue for reducing the rising cost of medical care. It has shown that this treatment option is cost-effective, and improves patient outcomes. With the advancements in technology, techniques for aerosol delivery have not been left out. The introduction of dosimetric nebulization has been shown to work on selected patient-population unable to coordinate the use of MDIs and DPIs. Direct comparisons of selected nebulizer brands by researchers have also established the efficiency and cost-effectiveness of these newer nebulizer designs. Research has shown the superiority of the Circulaire system over the small-volume jet nebulizers and recommendations have been

made for its adoption in hospital facilities as it reduces the risk of environmental drug exposure to caregivers during aerosol delivery.

CHAPTER III

Methodology

The study performed is a retrospective study using existing data collected from an urban tertiary adult hospital with a Level II Trauma Center. The objective of this study was to perform a cost-benefit analysis of dosimetric nebulization with the Circulaire system and the traditional VixOne nebulizer using data retrospectively collected. The data collected will be used to answer the preset research questions.

The analytical process involves identifying if there are monetary benefits associated with the use of the Circulaire system as a device for aerosol delivery, and if its adoption has been able to generate revenue for the respiratory care department. The desired outcome of this study is to elevate awareness of the potential impact of this nebulizer design, and how its adoption might reduce costs and enhance clinical efficiency most especially in respiratory care.

Population

The data used for this cost-benefit analysis was retrospectively collected from the respiratory care department of an urban tertiary adult medical center serving Northwest Georgia and Northeast Alabama. The hospital is a 304-bed, not-for-profit teaching hospital with a full range of ancillary services and a state-designated Level II Trauma Center.

In an effort to save costs and possibly enhance the delivery of more efficient and effective respiratory care services, the hospital's respiratory care department adopted the

use of a new aerosol device for dosimetric nebulization. This new device is the Circulaire system. A cost-benefit analysis of changing aerosol devices was conducted to determine if the Circulaire would save resources for the respiratory care department and the hospital in general. Data collected for the research study was for the year 2010.

Data Analysis

The data collection for this project was performed by the researcher. The researcher requested information from the respiratory care director of the hospital facility. The director supplied the data from the existing records of the respiratory care department for the year 2010. The researcher met with the major professor and discussed the key steps in conducting a cost-benefit analysis. The models that will be used to assess costs, benefits/effects, and outcomes were determined. All possible variables were discussed and estimates for costs were developed.

Descriptive statistics were calculated to answer the preset research questions. For the purpose of this study, the Circulaire system was compared with the traditional VixOne nebulizer at two treatment times of 5-minutes and 3-minutes. Hoisington et al. (2009) in their bench observation established the standard small-volume nebulizer treatment time with the VixOne to be 9 minutes. Research studies on comparison of dosimetric nebulizers have also shown the Circulaire system to deliver the same, if not a greater percentage of aerosol to the airways using a lesser treatment time when compared to the traditional VixOne nebulizer (Gardenhire, 2011).

Sensitivity analysis was also performed, and certain variables were altered, with calculations redone so as to determine which key variables would affect the results.

Sensitivity analysis can be conducted by varying the assumptions about one variable and assessing the effect on the evaluation of the decision (one-way analysis) or by simultaneously allowing assumptions about multiple variables to vary and reanalyzing the decision (multi-way analysis) (Phillips et al., 2003).

CHAPTER IV

Results

The purpose of this study was to perform a cost-benefit analysis of dosimetric nebulization with the Circulaire and the traditional VixOne nebulizer using existing data retrospectively collected from an urban tertiary adult hospital with a Level II Trauma Center for the year 2010. This research study explored the overall costs associated with the use of each nebulizer design, benefits/effects, and outcomes.

Descriptive Data

The total cost of a full-time Registered Respiratory Therapist (RRT) with benefits per hour, average number of RRTs per 12-hour shift, average number of nebulizer treatments by an RRT per 12-hour shift, average costs of traditional VixOne nebulizer and the Circulaire system was presented in Table I.

Table I. Average cost of variables

Average cost per hour of a full-time RRT with benefits	\$30.00
Average number of RRTs per 12-hour shift	6.5
Average number of nebulizer treatments by RRT per 12-hour shift	28
Average cost of traditional VixOne nebulizer	\$1.11
Average cost of the Circulaire system	\$4.30

The average cost per hour of a full-time RRT was calculated to be \$24.00/hr plus 28% for benefits making a total cost of \$30.00/hr. In a 12-hour shift, an average number of 6.5 RRTs were required per shift, with each giving an average of 28 nebulizer

treatments per 12-hour shift. The average cost of a traditional VixOne nebulizer was \$1.11, while the Circulaire was priced at \$4.30.

Based on the information in Table I, the following calculations were made in Table II to estimate the annual costs of nebulizer treatment using each of the nebulizer designs at different treatment times. With a standard treatment time of 9 minutes for the traditional VixOne nebulizer, and an average cost per hour of a full-time RRT with benefits of \$30.00, it would cost \$4.50 to give a treatment. When the cost of a nebulizer is added to that, it amounts to \$5.61 per treatment. To calculate the labor and cost of nebulizer treatments per RRT for a 12-hour shift, multiply \$5.61 by 28 treatments to get \$157.08. For a day (24-hour period), \$157.08 is multiplied by 2 to get \$314.16. Data collected suggests that the nebulizers were only changed as needed, thus calculations will be made using one nebulizer per day. The cost of the VixOne nebulizer is subtracted from \$314.16, resulting in a total cost and labor of \$313.05 per day. Therefore, the annual cost of delivering aerosol treatment using the traditional VixOne nebulizer would be \$114,263.25 a year.

When the Circulaire is used with a treatment time of 5 minutes and an average cost per hour of a full-time RRT with benefits of \$30.00, it would cost \$2.50 to give a treatment. When the cost of a nebulizer is added to that, it amounts to \$6.80 per treatment. To calculate the labor and cost of nebulizer treatments per RRT for a 12-hour shift, multiply \$6.80 by 28 treatments to get \$190.40. For a day (24-hour period), \$190.40 is multiplied by 2, and the cost of the nebulizer is subtracted to get \$376.50. Therefore, the annual cost of delivering aerosol treatment with the Circulaire system using a treatment time of 5 minutes would amount to \$137,422.50 a year.

However, when the Circulaire is used with a treatment time of 3 minutes and an average cost per hour of a full-time RRT with benefits of \$30.00, it would cost \$1.50 to deliver a treatment. When the cost of a nebulizer is added to that, it amounts to \$5.80 per treatment. To calculate the labor and cost of nebulizer treatments per RRT for a 12-hour shift, multiply \$5.80 by 28 treatments to get \$162.40. For a day (24-hour period), \$162.40 is multiplied by 2 and the cost of the nebulizer is subtracted to get \$320.50. Therefore, the annual cost of delivering aerosol treatment with the Circulaire system using a treatment time of 3 minutes would amount to \$116,982.50 a year.

Table II. Annual cost of nebulizer treatment with each nebulizer design

Nebulizer design and Treatment time	VixOne (9 minutes)	Circulaire (5 minutes)	Circulaire (3 minutes)
Cost per treatment	\$4.50	\$2.50	\$1.50
Cost of nebulizer plus cost per treatment	\$5.61	\$6.80	\$5.80
Cost of nebulizer treatment per 12-hour shift	\$157.08	\$190.40	\$162.40
Cost of nebulizer treatment per day	\$313.05	\$376.50	\$320.50
Cost of nebulizer treatment per year	\$114,263.25	\$137,422.50	\$116,982.50

Sensitivity Analysis

I assumed an increase in treatment load by 30%, allowing a reduction to an average of 5 full-time RRTs per 12-hour shift. The VixOne nebulizer with 6.5 RRTs per 12-hour shift will result in \$742,711.13 annually. However, calculations cannot be made for 5 RRTs per 12-hour shift. Using the Circulaire at 5 minutes treatment time, an annual cost of \$893,246.25 will be accrued with 6.5 RRTs per 12-hour shift. Whereas with 5

RRTs per 12-hour shift an annual cost of \$687,112.50 is estimated, thus resulting in 8% savings. When the Circulaire is used with a treatment time of 3 minutes, and 6.5 RRTs per 12-hour shift, the annual cost will be \$760,386.25 a year. When the number of RRTs per 12-hour shift is reduced to 5, an annual cost of \$584,912.50 is estimated, consequently resulting in 21% savings. This multi-way sensitivity analysis is represented below in Table III.

Table III. Multi-way sensitivity analysis

Nebulizer design and Treatment time	VixOne (9 minutes)	Circulaire (5 minutes)	Circulaire (3 minutes)
6.5 RRTs per 12-hour shift	\$742,711.13	\$893,246.25	\$760,386.25
5 RRTS per 12-hour shift	**	\$687,112.50	\$584,912.50
Dollar savings from VixOne	**	\$55598.63	\$157,798.63
Percent savings from VixOne	**	8%	21%
Note: ** not able to calculate.			

CHAPTER V

Discussion

Aerosol administration through liquid nebulization accounts for a greater percentage of the respiratory care workload. The administration of aerosol therapy using small-volume nebulizers has evolved over the years. In the economic market, different nebulizer designs are being manufactured, with each incorporating unique features that will potentially establish it as the preferred choice in aerosol delivery. There is a need to identify further opportunities for cost reduction in respiratory care. Most health care administrators, chief executive officers, directors, and clinicians are now faced with the tasks of deciding which of these several nebulizer designs can be used as an alternative to combat the rising cost of health care now at a disturbingly rapid rate.

The focus of this study was to perform a cost-benefit analysis of dosimetric nebulization with Circulaire and traditional VixOne nebulizers using data retrospectively collected from an urban tertiary adult hospital with a Level II Trauma Center. A cost-benefit analysis appraises and adds up the equivalent money value of the benefits and costs of an intervention to determine whether it is worthwhile. However, one major challenge in cost-benefit analysis is that certain cost estimates, most especially indirect costs are, by nature, arbitrary making them more difficult to quantify.

As clinicians in respiratory care, we ought to be well informed about the various nebulizer designs available and purchasing decisions should be based on a thorough selection process. The desired outcome of this study was to elevate awareness of the

potential impact of the Circulaire system, and how its adoption might reduce costs and enhance clinical efficiency most especially in respiratory care.

In this study, data was retrospectively collected from the respiratory care department of an urban tertiary adult hospital with a Level II Trauma Center. The hospital's respiratory care department had recently adopted the use of the Circulaire system as its modality for liquid aerosol delivery, and sought to perform a cost-benefit analysis to determine if the Circulaire would save resources for the respiratory care department and the hospital in general. The costs attached to the adoption of the Circulaire system was compared to the traditional VixOne nebulizer being the device previously used by the department. The respiratory care director of the hospital facility supplied the data from the existing records of the respiratory care department for the year 2010.

The results of the study further addressed some of the research questions that were previously raised. The total cost of a full-time RRT with benefits per hour, average number of RRTs per 12-hour shift, average number of nebulizer treatments by an RRT per 12-hour shift, average costs of traditional VixOne nebulizer and the Circulaire system were calculated and used to determine the costs, benefits, and outcomes associated with the use of the Circulaire and traditional VixOne nebulizer. The Circulaire was compared at two different treatment times of 5-minutes and 3-minutes. Research from several studies have shown that aerosol treatment time using dosimetric nebulizers are often shorter when compared to traditional constant-output nebulizers, and the dosimetric nebulizers have also been known to generate a higher percentage of drug deposition in the targeted areas (Gardenhire, 2007, 2011; Hess, 2000, 2002; Rau, 2002, 2004). With the

growing concerns of the Joint Commission on Accreditation of Health Care Organizations (JCAHO) on concurrent therapy in respiratory care, the adoption of a nebulizer design that allows for a shorter treatment time will potentially eliminate the problem of “treatment stacking” and indirectly improve the quality of patient care. In areas where the demand is high for RRTs, dosimetric nebulization using the Circulaire at 3-minutes treatment time will be cost-effective and decrease the workload of the respiratory therapists.

Overall, the annual cost of delivering aerosol treatment using the Circulaire with a 5-minute treatment time was considerably higher than the traditional VixOne nebulizer at a treatment time of 9-minutes. Nevertheless, it is important to note that given the length of treatment time, the inhaled drug mass is greater with the Circulaire at 5-minutes versus the VixOne at 9-minutes. Dosimetric nebulization using the Circulaire at 5-minutes and 3-minutes treatment time can reduce department expenditure by reducing labor costs. This was clearly stated in the calculations made for the cost of nebulizer treatments per year using the different nebulizer designs at different treatment times. The time saved reduces labor costs, ensures fewer missed therapy, and enhances effective and skilled patient care.

When the treatment load was increased by 30%, with a reduction to an average of five respiratory therapists, calculations could not be made for the VixOne nebulizer. This is primarily because with a treatment time of 9-minutes, a reduction in the number of respiratory therapists per 12-hour shift will rather give room for concurrent therapy, increase the number of missed treatment, and potentially reduce the quality of patient

care. With the Circulaire at 5-minutes and 3-minutes treatment time, annual savings of 8% and 21% were recorded.

Previous studies conducted on cost-benefit analysis in respiratory care were centered on respiratory care protocols (RCP) versus physician directed treatments as a means of saving costs for the respiratory care department. Kollef et al. (2000) surmised that RCP-directed treatment protocols were significantly cost-effective when compared to physician-directed orders. This conclusion was in line with a similar study carried out by Stoller et al. (1998) associating RCP-directed treatment protocols with lower costs of medical care. When Hoisington et al. (2009) compared the respiratory care workload requirement in a hospital facility with different nebulizer designs at different treatment times; they also arrived at the conclusion that shorter treatment times may play a role in dealing with the nationwide shortage of respiratory therapists with time saved being used for value-added patient-care activities.

The efficiency of the Circulaire system as a device for aerosol administration was the purpose of the study conducted by Mason et al. (1994, 1996) and it acknowledged better lung deposition of aerosols, with lesser amount lost in the ambient environment. In addition, Hoffman et al. (1997) supported the superiority of the Circulaire system over conventional small-volume nebulizers in the treatment of bronchospasm.

Significant limitations were considered in this study. Data collected suggests that the nebulizers were only changed as needed. This can be when the nebulizers are visibly soiled, or can no longer function properly. Although calculations were made with the assumption that a new nebulizer is used per daily treatment, we cannot clearly quantify

how often these nebulizers were changed. This may have an effect on the overall savings realized. The fewer times we use a new nebulizer for each daily treatment, the greater the percent savings. In reality, there will be additional savings and revenues generated for the respiratory care department. There was no mention if additional costs were incurred with training the respiratory therapists on the use of the Circulaire system. Lastly, another limitation to this study was that the researcher only factored in the costs of treatment and labor costs to arrive at an annual cost for each nebulizer design. The researcher was unable to calculate productivity.

Recommendations for future research

Future research in the area of cost-benefit analysis using dosimetric nebulization should be conducted. A similar study should be conducted using existing data from more hospital facilities. Additional variables that will possibly address productivity and quality of care should be included in future research studies. Furthermore, the economic aspect of introducing new nebulizer designs should be thoroughly explored in a clinical setting. Cost-effectiveness analysis, cost-minimization analysis, and cost-utility analysis comparing dosimetric nebulization of aerosols are useful areas that can be delved into with future research studies.

Conclusion

Current studies on cost-benefit analysis of dosimetric nebulization are limited and this study along with others should aim at saving resources for the respiratory care department, improving productivity, and saving manpower/labor in areas where there are insufficient respiratory therapists. The study should elevate awareness of the potential

impact of the Circulaire, and how its adoption might reduce costs and enhance productivity in respiratory care. According to this study, the use of the Circulaire system at 5-minutes or 3-minutes treatment time can reduce department expenditure by reducing labor costs. It is hoped that future research will be carried out to strengthen the need to adopt cost-reductive modalities in respiratory care.

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