Proceedings from a special symposium on

Respiratory Care Protocols: Benefits for Patients, Therapists and Hospitals

Presented at the 50th International Respiratory Congress of the

American Association for Respiratory Care

December 2004 • New Orleans, Louisiana

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American Association for Respiratory Care
9425 N. MacArthur Blvd, Suite100
Irving, TX 75063-4706
www.AARC.org

Ray Masferrer RRT FAARC
Editor

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Preface

Respiratory Therapy in the 21st Century

Sam P Giordano MBA RRT FAARC

For almost a decade and a half, the American Association for Respiratory Care (AARC) has been encouraging and promoting the use of protocols for all respiratory therapy clinical interventions. Protocols provide an excellent basis of scientific support for the use of persons with comprehensive expertise in respiratory therapy, such as respiratory therapists, to perform these clinical interventions. Yet we estimate that only about a third of the respiratory therapy ordered in this country is done so as part of a protocol process.

Protocols, as you will learn after reading this booklet, can be used in virtually all clinical circumstances. There is an ever-growing body of evidence which documents that when respiratory therapists are allowed to provide respiratory therapy via protocol, clinical outcomes improve, misallocation of respiratory therapy services decreases, and costs associated with respiratory therapy are reduced. AARC has an extensive bibliography of studies published in a wide range of peer-reviewed science journals describing such outcomes. Yet the protocol movement, while growing each year, is frankly not growing at a fast enough pace.

I hope you will find that the following manuscripts will be of assistance to you. I recognize that many respiratory therapists do provide respiratory therapy by protocol. You should find reassurance that you've made the right decision and are on the cutting edge of respiratory therapy service provision. There have been numerous attempts over the past several years to constrain health care costs. We have learned that protocols not only constrain costs, but since protocols require qualified experts in the provision of respiratory therapy, their use allows you to leverage the science available to document the value of respiratory therapists.

For those who still need convincing, I hope that the contents of this booklet will put you at the tipping point to begin the development and utilization of protocols. Ironically, some of the reasons given for not converting to protocol respiratory therapy are actually very good reasons to undertake the transition.

If we are to realize our potential in providing excellent clinical services, timely and efficacious care, protocols will help us to achieve these lofty goals. There are, of course, other advantages to protocols. For those of you short of staff, protocols can help narrow the gap between your supply of human resources and the demand for their services. With protocols you add the high value of being able to draw upon your critical thinking and assessment skills. Virtually all respiratory therapists know that there's much more that goes into aerosol therapy treatment than starting a nebulizer and coaching the patient to get optimum value from the medication. Protocols allow you to perform clinical decision-making in a much more timely fashion. Protocols provide the opportunity for you to influence the patient's care plan, and therefore, bring about a better match of respiratory therapy resource to respiratory therapy need.

Since protocols require their users to be expert in all respiratory therapy clinical interventions, the value of respiratory therapists is also supported. How many times have we seen a patient receiving respiratory therapy that simply was not a good fit for that patient?

Disclosure: S.P.G. does not have a financial relationship with Sepracor, Inc.

Sam P Giordano MBA RRT FAARC, Executive Director, American Association for Respiratory Care, 9425 N MacArthur Blvd, Irving, TX 75063. Email: giordano@AARC.org

By using the algorithms that are the backbone of every patient driven protocol, we'll be able to not just follow physician orders, but also assist the physician in matching the patient's clinical condition with the appropriate mode of intervention.

I foresee that the day will come when virtually all respiratory therapy will be ordered via protocol, not unlike the way it is done in physical therapy. Of course, there's a catch. You have to be up to the job. You must go beyond your comprehensive knowledge of respiratory therapy clinical interventions. You must at first engender the confidence and support of your respective medical communities in order to be allowed the clinical latitude that flows from the use of protocols. You must be able to assess the continued appropriateness of respiratory therapy orders, for many require change based on the changing clinical status of your patients. While we know our patients are dynamic without protocols, orders for their respiratory therapy cannot be driven based on that dynamic. And last, but not least, you must be able to communicate the results of your assessment to attending physicians and adhere strictly to the parameters incorporated into all protocols

There is a way to balance that expense and that is to assure that all patients receiving respiratory therapy medications are doing so using the correct modality for their condition and circumstances. If we are to assure that all patients receive the latest generation of respiratory medication, we must also assure that this valued resource is not squandered on patients who cannot benefit. We have an obligation to our patients to assure on behalf of the attending physician they receive the right respiratory therapy modality at the right time, using the right medication for the right cost. Those goals are the shared goals of all health care professions in the 21st century. The AARC hopes that the examples of successful protocol implementation contained in this booklet will provide that extra push to get respiratory therapy into the 21st century.

The Benefits of Respiratory Care Protocols

Patrick J Dunne MEd RRT FAARC

Introduction

The clinical, economic, and quality impact of providing protocol-based respiratory care has been well established in many sites of care nationwide. In most instances, the primary argument in support of adopting protocol-based care is that this relatively new and timely approach to providing care significantly improves the appropriateness of in-patient respiratory care services. This is especially compelling given the sustained public debate over the need for the nation's hospitals to address the inadequacies, inefficiencies, and wastefulness so characteristic of the existing delivery structure. In this regard, studies have repeatedly demonstrated that, when effectively implemented, respiratory care protocols do in fact reduce the misallocation of in-hospital respiratory care. Dr. James Stoller and his colleagues at The Cleveland Clinic Foundation, in Cleveland, Ohio, estimate that as much as 30–60% of the respiratory care currently provided in the in-patient setting may be inappropriate, suggesting that there is indeed a strong argument in favor of protocol-based therapy. Nonetheless, the widespread development and implementation of respiratory care protocols has yet to materialize, much to the consternation of the numerous advocates of this exciting, cost-effective, and timely care paradigm.

With respect to the misallocation of respiratory care services, of greatest concern economically, according to Stoller, is patient care that is over-ordered, which by some estimates, may be as high as 40% of all prescribed in-hospital therapy. Over-prescribed care is both unnecessary and unproductive, and, by its very nature, redirects valuable resources away from more appropriate recipients. Conversely, of greatest concern clinically is the estimated 10% of patients whose care is under-ordered, essentially depriving these patients of the most efficacious care available. In either regard, the misallocation of respiratory care in the acute care in-patient setting is cause for concern and should be a primary focus in developing more cost-effective and responsive processes for the delivery of health care services. This paper is an attempt to provide a conceptual framework for those interested in embarking on this new and exciting care paradigm, inclusive of a candid discussion of the formidable challenges that must be addressed if success is to be realized.

A Better Health Care System

In 2001, the Institute of Medicine released a landmark report entitled Crossing the Quality Chasm: A New Health System for the 21st Century, which was essentially a follow-up to the now infamous 1999 Institute of Medicine report that took the United States health care system to task on one urgent quality problem: patient safety. In its earlier report, To Err is Human: Building a Safer Health System, the Institute concluded that tens of thousands of Americans die each year from errors in their care, and that hundreds of thousands more suffer or barely escape from nonfatal medical mistakes that a truly high-quality care system would largely prevent. The patient safety report was a call for action to make health care safer, and one can see the impact today, as all of the major health care accrediting organizations now include specific standards designed to improve patient safety in all sites of care. Similarly, other patient safety advocacy

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Patirck J Dunne MEd RRT FAARC, HealthCare Productions Inc, 827 Rodeo Rd, fullerton, CA 92835. Email: pjdunne@sbcglobal.net

groups, most notably the Leapfrog Group, now routinely report how well hospitals have in fact implemented certain patient safety initiatives. The initial emphasis is on the implementation of computerized physician order-entry to reduce the potential for in-hospital medication errors. Clearly, patient safety remains a top concern in today's health care environment, but as the Institute's 2001 report asserts, patient safety issues are only the tip of the iceberg and raise serious doubts about the overall quality of health care in America.

Among the quality issues addressed in Crossing the Quality Chasm is the consensus that under the current system, the delivery of health care services in the United States is fragmented, disjointed, and suffers from what is now perceived to be an anachronistic delivery structure. Though there are many causes for this unsettling state of affairs, most agree that a major contributor to the problem is the way health care services have traditionally been reimbursed. Presently, reimbursement for health care services is based on a model that, by today's standards, is overly complex, skewed in terms of economic realities, and inherently wasteful. There are abundant examples of how the traditional fee-for-service system fails to offer providers realistic incentives to reduce the need for acute care services.

For example, while there has been much talk in recent years about the need for and value of preventive care, the current system still focuses on providing acute/episodic care. While the need for and value of appropriately provided acute care is not to be diminished, in actuality, over the past several decades the overall needs of the American public have changed. Care and treatment is increasingly being provided to individuals diagnosed with one or more chronic conditions, where the obvious objective is to empower and enable those affected to practice effective, self-directed disease management. Under the existing payment system, expending resources to promote such self-reliance during an acute admission is often all but impossible to achieve. However, eventually the dominant acute care reimbursement/payment system will, out of economic necessity, include realistic incentives to minimize the acute care needs of patients with chronic medical conditions.

The overall impact of chronic medical conditions on the United States health care system is staggering. Defined by the Institute as an illness lasting 3 months or longer and is not self-limiting, chronic medical conditions are the leading causes of illness, disability, and death. Such conditions are estimated to afflict more 100 million Americans (two thirds of whom are under the age of 65) and consume more than 60% of total health care spending each year. While all agree that care for chronic conditions differs substantially from acute/episodic care, under the existing delivery system this is all too often ignored. When a potentially life-threatening exacerbation of a chronic condition occurs, the focus of treatment is on the "here and now," as it rightly ought to be. But once the emergency crisis is under control, in a matter of minutes, hours, or even days, the current delivery system does not expend similar energies on major preventative care during the recuperation period - time and efforts that could easily go a long way toward reducing the likelihood of further exacerbations and subsequent readmissions.

In Crossing the Quality Chasm, the Institute identified 15 "priority chronic conditions," for which, the Institute argued, newer and more contemporary approaches to care could substantially improve both clinical and economic outcomes. Two of these 15 conditions, emphysema/COPD and asthma, are, for obvious reasons, of particular interest to respiratory therapists. For example, more than 30 million Americans have been diagnosed with emphysema/COPD or asthma, with many more millions yet to be diagnosed. Combined, both conditions cost the overall health care system billions of dollars each year. Sadly, the incidence and mortality of each continues to increase. Both conditions have extremely high rates of hospital readmission and place enormous demands on the daily workload of hospital-based respiratory therapists. Moreover, both conditions are notorious for having "one size fits all" physician orders for in-hospital respiratory care services. Wouldn't it be nice if respiratory therapists, despite the inadequacies of the current system, were able to provide more individualized, more thorough care when such patients present to the hospital for the all-too-frequent exacerbation!

The Impact of Misallocation

There is an economic as well as a clinical impact associated with the misallocation of respiratory care services in the acute care setting. In economic terms, there are the obvious direct costs associated with administering therapy that is prescribed but not clinically necessary or effective. There are likewise indirect costs, such as the impact of missing or delaying prescribed treatments because of excessive workloads, which, under the new patient safety standards, now constitutes a medication error. One must likewise question the value of having highly trained, credentialed respiratory therapists

administer prescribed treatments that elicit little or no therapeutic response. How long before highly motivated and skilled professionals begin to question the value of what they are doing when they wind up spending the majority of their time administering treatments to patients simply because they are prescribed by a physician?

The clinical impact of misallocation is similarly onerous. The most obvious concern is patients who need therapeutic interventions above and beyond what is prescribed by a physician, especially (as is more often the case than not) when the prescribing physician lacks expertise in pulmonary medicine. Another clinical concern relates to the wide differences between respiratory therapy orders from different physicians within the same institution, for patients admitted for essentially the same condition. There is also the issue of inevitable differences in practice and technique between therapists within the same facility.

For example, though the administration of rescue β agonists for an exacerbation of bronchospasm might appear to be rather straightforward, different therapists will do certain steps in a different sequence, or possibly skip steps altogether, either for the sake of expediency or as the result of slovenly performance. In either scenario, while a patient may indeed receive the prescribed treatment, he or she might not receive the same intensity of care with each interaction. Depending on the degree of practice difference, clinical outcomes could be (and often are) compromised. The late Avedis Donabedian - arguably the founding father of health care quality research - cautioned throughout his illustrious career that differences in practice is one of the primary factors contributing to lapses in quality outcomes. If quality care for all patients is the goal, then it can best be achieved when, using available resources, the most efficacious care is provided in the most cost-effective manner, and in an environment where the processes of care are designed to minimize practice differences.

Why Not Respiratory Care Protocols?

The use of respiratory care protocols greatly alters the way respiratory therapists administer patient care. Properly developed and implemented protocols, based on the most current scientific evidence, reduce misallocation of respiratory care services for non-intensive-care inpatients. It has also been demonstrated that respiratory care protocols, when used in an intensive-care setting for weaning from mechanical ventilation, are more effective that physician-directed weaning. Protocols promote an approach to patient care that is based solely on the individual needs and therapeutic responses of each patient. Protocols also help establish care/treatment parameters by which practice differences can be minimized, so as to maximize patient safety and desirable clinical outcomes. To say that the use of protocols represents a truly cost-effective alternative approach to providing respiratory care services is indeed an understatement.

Why, then, the slowness in getting this new delivery paradigm to become the standard of care - to become the rule rather than the exception? Many explanations have been suggested for the slow pace of acceptance of respiratory care protocols, but 2 important obstacles seem to dominate. For some, the biggest hurdle is the way the current United States health delivery system is structured. In Crossing the Quality Chasm, the Institute of Medicine offers a compelling argument that the traditional system represents a "paternalistic approach" to medicine, wherein physicians and physicians alone make all decisions with respect to a particular patient's medical care. This is in sharp contract to the newer and still evolving patient-centered approach to providing health care services, espoused by the Institute, as one important step towards improving the quality of the nation's health care system. Under this new care model, decisions a physician makes about an individual patient's care reflect input received from other engaged clinicians, and often entails adjustments to prescribed therapy in the pursuit of the most effective clinical course of care.

As the name suggests, the patient-centered approach also seeks to actively engage patients and their caregivers (or legal guardians) in care decisions - yet another important difference from the aforementioned traditional mindset. Under the older system, patients and caregivers tend to be viewed as "medically naïve" and therefore not capable of making important decisions about their care or alternative approaches to managing their medical conditions. Under the patient-centered approach, patients and their caregivers are provided sufficient education and information so they too can become informed consumers. An important consideration in this regard is to ensure that such education and information is provided in language that is unambiguous and easily understood by lay people. Actively engaging patients and their caregivers in medical decision-making requires a major shift in both thought and action on the part of all providers. As millions of Americans obtaining medical care services through traditional employer-sponsored health plans continue to see out-of-pocket deductibles and co-pays increase each year, the notion of a patient

becoming an "informed consumer" is inevitable, by most accounts.

Without a doubt, our time-honored yet anachronistic approach to providing health care services offers a formidable challenge that must be addressed when attempting to shift from a somewhat inflexible structure-oriented care paradigm to a radically different approach to providing patient care that is more focused on processes and outcomes. It would be folly to underestimate the enormity and difficulty of such a challenge when attempting to move toward protocol-based care. Those attempting to implement protocol-based care will be well served by first conducting an informal situational analysis to determine how pervasive the traditional mindset is within a particular institution and how best to go about changing such attitudes.

Another major hurdle standing in the way of successful protocol use is reticence on the part of some respiratory therapists to re-invent themselves as clinical decision-makers. Indeed, protocol-based care is in sharp contrast to the more pervasive task-orientation toward practice so characteristic of the traditional structure. A task-orientated approach to patient care focuses on the number of procedures administered in a given period of time, typically a working shift. For many, the task-orientation to professional practice has created a situation where predictable patterns of activity have emerged, where the primary focus is to ensure that all prescribed treatments are administered on time and in the frequency so ordered. Regrettably, such a focus fails to allow for much, if any, discretion on the part of a therapist to alter prescribed treatment when a patient's response to therapy is not consistent with intended clinical outcomes.

There are also those respiratory therapists who fear that a transition to protocol-based care might result in staff layoffs because of reduced patient-treatment loads. Although adjustments to traditional staffing will accompany a move toward protocol-based care, such changes will be in the context of more effective utilization of limited human resources. There is a shortage of health care workers in general, and respiratory therapists in particular, and many respiratory therapy departments continue to report full-time position vacancies. However, a more innovative approach to meeting staffing levels to ensure adequate coverage is sorely needed. The current dependence on using excessive overtime or temporary per diem or traveling therapists to ensure adequate coverage has become prohibitively expensive and is becoming more difficult to sustain in the current cost-containment era.

Another disadvantage of the task-orientation approach to providing therapy is that there is seldom sufficient time during a shift to perform other important services, such as disease management for asthma and COPD patients. The rampant recidivism characteristic of both asthma and COPD not only drives up health care costs but extracts an enormous human toll as well. Patients who present to an emergency department with an exacerbation have usually failed to effectively self-manage their conditions at home. Protocol-based care offers an excellent opportunity to design innovative strategies that may reduce the frequency and intensity of subsequent exacerbations. Spending time and effort with patients during the recuperation phase of their hospitalization to enhance their ability to self-manage following discharge, if successful, would represent a substantial leap forward over current practice. Moreover, as in-patient smoking cessation counseling becomes a reimbursable service, respiratory therapists have yet another area in which to expand.

To summarize, it can be argued that instead of jeopardizing therapists' livelihoods, the move to protocol-based care actually results in professional enrichment and greater career satisfaction. Many therapists have remarked that protocol-based care allows them to practice how they were taught when they entered the profession and how they thought they would be practicing during their training. The respiratory therapist as a clinical decision maker is a far cry from the so-called treatment jockey - someone more concerned that all prescribed treatments are administered than how a patient does (or does not) respond to delivered therapy.

Changes in Workplace Behavior

Attempting to illustrate why American productivity lags behind that of other industrialized countries, Marcus Buckingham (senior consultant for the Gallop Organization and best-selling business author), in his recent book, offers a somewhat unflattering, albeit rather generalized, picture of the American workforce. Following extensive social research in different types of organizations (private, public, governmental, for-profit, not-for-profit, secular, religious), Buckingham argues that in the typical American workplace setting, employees can be segmented into 1 of 3 distinct groups. One group (about 26% of a company's workforce) consists of those who are "actively engaged": they are loyal, willing, and highly productive at their given tasks and responsibilities. Actively engaged employees are the "movers and shakers" of the organization - typically they are also early and eager adopters of new ideas and new technology. Actively

engaged workers support the organization's mission and do everything possible to ensure continued competitiveness.

The second group (about 55% of the workforce) are employees that Buckingham describes as being "passively disengaged": they come to the job each day and simply put in the required time. Passively disengaged employees prefer the comfort and peace of mind that accompanies a predictable pattern, specifically a daily routine in which there is very little day-to-day deviation from assigned tasks and responsibilities. The "passively disengaged" tend to be reluctant adopters of new ideas and technology. Moreover, these employees tend to require much more effort on the part of management when implementing workplace changes.

The third group (about 19%) are those Buckingham classifies as "actively disengaged": they are essentially disloyal, disruptive, and (knowingly or unknowingly) their behavior undermines the morale of the entire workplace. Further, by their actions and attitudes, actively disengaged employees tend to consume an inordinate amount of management time, resulting in valuable resources being redirected away from more worthy purposes. Actively disengaged employees seriously compromise the ability of an organization to remain competitive in its respective marketplace.

Buckingham goes on to argue that those in the 2 disengaged groups, which when taken together, represent an astounding 74% of an organization's entire workforce, are facing "a dismal future." There are "winds of change" in the air in all industries he argues, being driven primarily and intensely by the need to keep the American economy competitive in a quickly emerging and changing global marketplace. The strongest gust will be that of individual accountability: workers will increasingly be expected to consistently achieve defined results that are both realistic and measurable. When measurable job goals or outcomes are established, employee performance can be objectively assessed. Under the present system, assessing employee performance tends to be more subjective, focusing more on how well a particular employee adheres to myriad workplace rules and regulations instead of focusing more on the level and degree of employee productivity.

The next strongest gust of wind will be that of lifetime education - an indispensable requirement for remaining current and competitive in one's chosen career or occupation. Buckingham argues that once an organization's employees are held accountable for workplace performance and that they likewise embrace the need to periodically update their skills and abilities, productivity improves measurably. Since both the notion of being expected to achieve certain patient care outcomes and the need for continuing education are already part and parcel of a respiratory therapist's professional profile, it appears that as a profession we are already well on the way toward meeting Buckingham's conditions for improved productivity.

Whether or not one accepts some or all of Buckingham's views in general, or dismisses them outright as not being applicable to the health care industry, he does provide a useful framework for explaining why respiratory therapists might be reluctant to make the switch from task-performer to clinical decision maker. Given the growing angst in all circles about the overall dismal state of the nation's current health care delivery system, Buckingham's observations warrant more than a passing glance. In fact, one must wonder how long the nation's beleaguered health delivery system will be able to sustain the inefficient, ineffective, and duplicative work practices that are so much a part of the widespread misallocation of respiratory care services.

Benefits of Respiratory Care Protocols

Marin Kollef, an original adopter and continuing champion of therapist-driven protocols, offers a most complete summary of what he and others believe constitute the value, benefits and opportunities associated with protocol-based care. According to Kollef, properly developed and successfully implemented respiratory care protocols emanate first and foremost from the desire of a department's administrative and medical directors to:

- Reduce the costs of medical care
- Unburden physicians from tasks respiratory therapists can easily do, and
- Improve patient care outcomes

However, once up and running, Kollef suggests that respiratory care protocols can also:

- Improve the ability to quantify clinical improvement
- Assist in conducting more relevant and timely clinical studies or trials
- Provide the foundation for meaningful quality-improvement activities
- Minimize the risk of medical errors and mistakes
- Improve the effectiveness of available treatments and therapies

- Increase accountability of health care providers, and
- Assess the impact of variation from accepted clinical practice standards

For these reasons, there should be little doubt that the daunting task of moving a department, institution, or medical staff toward protocol-based care will eventually reap rewards well beyond the obvious start-up costs, both direct and indirect. Once in place, the positive impact of protocol-based care will likewise more than offset concerns about staff re-deployment. Moreover, the political capital expended to usher this novel concept through institutional bureaucracies, which typically are not enamored with such profound change, will be more than justified.

Requisite Elements for Protocol Development

It is essential that those eager to start the long journey toward implementing protocol-based care processes be able to differentiate truly bona fide protocols from those activities purporting to be protocol-based care. One common misconception is that the process of revising/updating existing policies/procedures, in and of itself, constitutes protocol-based care. Unless there is a fundamental change from traditional physician-directed care, protocol-based care will remain nothing more than an abstract concept.

Fortunately, there is now a rather robust body of knowledge coupled with proven experience in terms of the distinct characteristics and attributes unique to truly protocol-based care. First and foremost, the entire process must be assessment-driven. That is to say, a patient's response (or lack thereof in some cases) to administered therapy or care is the primary determinant in selecting the next intervention in the approved treatment/care pathway. This "assess, treat, and evaluate" model offers a safe and practical framework for providing individualized care within the clinical confines established when the protocol is finally approved for implementation.

A second essential requirement of a true clinical protocol is that all clinical decision pathways must be predicated on the most current, evidence-based information available. In certain settings, all too often clinical practice is more the result of years of doing it the same way. Protocol-based care represents a new care paradigm that must be built upon a foundation of the best available scientific evidence. In the absence of such evidence, efforts at protocol development will be less likely to realize maximum potential. Fortunately there already exists extensive and current scientific literature supporting the safety and effectiveness of properly designed and implemented respiratory care protocols.

A third essential ingredient for successful protocol development is an integral, ongoing evaluation process for both the outcomes of care and the overall utilization of available resources. Essentially, protocol-based care emphasizes the attainment of specific patient care outcomes. This is in sharp contrast to the more pervasive reliance on the presence of certain structural elements to make a determination of the quality of care. Clearly, the focus on outcomes introduces the opportunity to objectively quantify, in real time, the success or lack of success of designed interventions. Protocol-based care generates a treasure trove of valuable clinical data, which, when appropriately used, has unlimited potential in the quest for health care delivery processes that are more accessible, accountable, and cost-effective.

It has been suggested that an effective quality monitoring program for protocol-based care activities should address at least 5 key elements: staff competency, staff compliance, outcomes, feedback, and customer satisfaction. Obviously, the move toward protocol-based care requires that considerable effort be directed toward staff retraining. Moreover, major effort will be required to accelerate staff's willingness to actually change practice. For its part, outcomes assessment provides an objective tool to measure the impact of staff training and compliance, and providing feedback gleaned from formalized assessment activities effectively closes the loop. Efforts to measure customer satisfaction should include input solicited from patients, physicians, other providers as well as administrative personnel. Given the many different stakeholders who have a direct or indirect interest in any move toward protocol-based care, having a comprehensive, fully integrated quality monitoring component from the outset is not only essential but indispensable if/when the time comes to expand the concept beyond the initial stages.

Summary

As with most controversial issues and challenges to the status quo of traditional health care delivery processes, the shift to protocol-based care will not be easy. There are simply too many well-entrenched attitudes, perceptions, and practices that have been hardened by more than a quarter century of being considered the standard of care - this despite the fact that

newer thinking and experiences demonstrate otherwise. For their part, respiratory therapists eager to move into protocol-based care, whether they be clinicians, managers, or administrators, must recognize and address early-on these (as well as other) inherent obstacles. Of paramount importance will be the reluctance of many physicians to abrogate or share their traditional rolls and responsibilities. This will necessitate that physicians who favor protocol-based care advocate its benefits and advantages to their skeptical colleagues. Similarly, skeptical respiratory therapists need to be energized and convinced that protocol-based care will only heighten their professional stature. In the end, protocol-based care will ensure that patients who need more intensive therapy will receive it, while those who do not need the same level of care will continue to receive the most appropriate care for their conditions. At its essence, protocol-based care is all about providing individualized, assessment-driven care through the best use of available resources.

When successfully implemented, it has been shown that respiratory care protocols offer many advantages to several constituencies. Patients benefit since they receive care that is based upon their actual needs, not on a "one size fits all" approach. Therapists benefit because they are encouraged to practice in a manner more consistent with how they were trained: to conduct assessments and treat accordingly - not to simply follow physician orders. Physicians benefit because they are able to use therapists in the capacity of "physician-extender," thereby making their own daily schedule less hectic while ensuring that their patients receive the best possible care. Finally, hospitals benefit because it is now generally accepted that providing the most efficacious care in the safest and most cost-effective manner translates to a much enhanced cost/quality equation.

As hospitals continue to struggle with the myriad challenges they face as a result of the nation's continuing health care crises, protocol-based care offers a refreshing and practical strategy for improving the level and intensity of all respiratory care services.

ADDITIONAL READING

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The Benefits of Asthma Care Protocols in Acute Care

Timothy R Myers BS RRT-NPS

Abstract

There are expert panel reports that identify medications that successfully manage asthma exacerbations. However, asthma management strategies differ markedly among institutions and among physicians at the same institution. Monitoring and assessing the exacerbation, medications, doses, timing of administration, duration of treatment, and assessment measures are often left to individual physician discretion; treatment plans often are not formulated on the basis of data that show efficacy, but rather on local availability and physician experience and preference. Well-designed asthma protocols are developed and implemented to improve quality of care and decrease misallocation of therapy, which contributes to higher costs, from longer hospital stays and greater resource utilization.

Introduction

Protocols (also called care paths or clinical or critical pathways) are structured sets of standing orders based on patient-specific diseases or objective assessments that allow bedside clinicians to initiate, alter, and discontinue therapy without additional orders. Protocol-directed care can be quite general and directed at the discretion of the managing physician, or more structured to provide specified or even mandated practices. Protocols should identify specific safeguards and instructions for obtaining physician input for patients who are unable to tolerate disease-management processes. Criteria for hospital discharge are generally specified, and recommendations for follow-up and home treatment may be included.

Protocols are developed to operationalize written practice guidelines that are aimed at the hospital management of common procedures, tasks, or disease states. Protocols developed and designed for disease management should be optimized to identify, initiate, and coordinate procedures, tasks, and care processes for which there is scientific evidence, or for established care practices that are typically administered by bedside caregivers. When there are gaps in the knowledge base, the standardization of protocols should include components to collect and analyze data to establish best practice, provide protocol quality-assurance, and conduct outcomes-based research. The ultimate objective is to develop and standardize protocols that convert asthma research or expert opinion into best medical practice, optimize disease-management education for patients and staff, and develop a systematic structure to monitor outcomes. Achieving those objectives establishes and documents evidence-based guidelines.

Diseases that lend themselves to protocols identify a population at risk for poor outcomes at high cost. Asthma disease-management protocols operate on the basic premise that there is an optimal strategy for better clinical, patient, and financial outcomes at a reduced cost. Asthma has a high frequency of emergency-department (ED) visits and hospitalizations and relatively limited pharmacologic management options for exacerbations, so it is an excellent disease to be treated by standardized protocols. In the past dozen years, an

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Timothy R Myers BS RRT-NPS, The Asthma Center at Rainbow Babies and Children's Hospital, Case Western Reserve University, 11100 Euclid Avenue, RB&C Building, Room 492, Cleveland, OH 44106. Email: timothy.myers@uhhs.com

increasing number of studies have reported outcomes of asthma protocol development and implementation in both the ED and in-patient settings. Asthma protocol content and reported results have differed considerably. I will review the literature and summarize the findings.

Emergency Department Asthma Protocols

Despite that there are over 1.9 million annual ED asthma visits in the United States,[1] there are relatively few published studies on ED care paths for acute asthma, and the existing studies have focused on adults. The National Heart, Lung, Blood Institute guidelines provide an expert-opinion-based algorithm for ED management of asthma. That guideline uses an "assess and treat" format.[2,3] The guidelines focus on acute asthma assessment (subjective and objective data) collected on presentation and then every 20 min for 1 hour. Suggested outcome measures include respiratory rate, air exchange, pulse oximetry, and peak expiratory flow. The expert panel's treatment recommendations, based on the literature, include inhaled β agonists, systemic corticosteroids, and supplemental oxygen based on response to previous therapy, using the assess-and-treat format. The addition of anticholinergics, primarily ipratropium bromide, has gained widespread use as an ED adjunct rescue medication for both adults and children, based on results from several studies.[4-9]

Despite the existence of the National Heart, Lung, Blood Institute's asthma guidelines since 1991, there are practice differences in the adaptation and implementation of these guidelines. McDermott et al studied ED care of asthma patients in a single large community.[10] They used a cross-sectional, self-administered survey to determine asthma care practices among medical directors of the 89 EDs serving the Chicago metropolitan area (6 counties). The survey was designed to include: asthma-specific demographics and selected utilization statistics; assessment practices; treatment practices; discharge and follow-up activities; and familiarity with, attitudes toward, and use of guidelines/protocols. They had a 71.9% survey-response rate. The mean ± standard error estimated ED stay was 3.0 ± 0.1 h, and the average disposition time (ie, the decision to admit) was 2.5 ± 0.2 h. During their visits, 73.2 ± 3.9% of the asthma patients at these Chicago EDs were administered systemic steroids (either intravenously or oral). The percentage who were prescribed systemic steroids at discharge was 55.9 + 3.5%. The returned surveys indicated that slightly more than half (57.0 + 5.4%) of the patients seen in these EDs received any type of written asthma-education materials. Approximately 25% of the patients reportedly were given, at the time of discharge, information that detailed a follow-up appointment. McDermott et al concluded that many of these Chicago-area EDs were providing asthma care consistent with key aspects of national guidelines. However, in certain critical aspects of care, these EDs had a high degree of practice difference, often with the community falling short of guideline recommendations. By identifying those practice differences in asthma care, it is now possible to target specific goals for community-wide quality improvement of asthma care among those EDs. As with most surveys, the data from the 29% of non-responding centers may have painted a vastly different picture.

The earliest published asthma protocol was in the ED literature. McFadden et al evaluated the effect of an ED asthma protocol and preprinted standing orders on hospital admissions, stay, and recidivism.[11] They employed a sequential study design, in which protocol outcomes were compared with data obtained in the 8 months prior to the protocol implementation (pre-protocol) and outcome data 12-months after strict protocol adherence had declined (admixture). In between the pre-protocol and admixture periods, they provided a preprinted protocol algorithm, which outlined standardized assessments and treatment decisions, and a document for charting the assessments and treatments. The protocol standardized medications and administration routes, assessments and observation timing sequence, and evaluator. A standardized set of discharge criteria were also used during the protocol period.

All 3 cohorts were statistically comparable groups for sample size, age, and gender. Each group had statistically comparable objective criteria (peak expiratory flow, blood oxygen saturation, and vital signs) on admission. Compared to the pre-protocol cohort, the protocol cohort had significantly shorter ED stay ($p < 0.001$), lower admission rates to acute care ($p < 0.005$) and intensive care ($p < 0.005$), lower charges per case ($p < 0.01$), and less 7-day recidivism ($p < 0.05$).

As a testament to the efficiency and efficacy of ED asthma protocols, there were also statistically significant differences between the protocol and admixture groups. Compared to the admixture group, the protocol group had significantly shorter stay ($p < 0.01$), lower admission rate to acute care ($p < 0.05$), and lower charges per case ($p < 0.01$). McFadden et al identified unnecessary or inappropriate physician practices that were counterproductive to efficient and

Table 1. Documented Improvements with Emergency Department Asthma Protocols

Publication	Study Design	ED LOS	Admission Rates	ICU Admission Rates	Cost	Relapse Rates	Documentation	Other
McFadden[11]	sequential study design (pre/post)	Decreased *	Decreased**	Decreased**	Decreased***	Decreased****		
McFadden[11]	sequential study design (protocol vs post protocol)	Decreased***	Decreased****		Decreased***			
Robinson[12]	retrospective						Increased*	Increased for: Adherence*** Compliance* Peak flows*
Akerman[13]	retrospective		Decreased****			Decreased*		
Goldberg[14]	retrospective							Increased for: Oral steroids**** MDIs* Decreased for: Oxygen use* Neb Tx* IV lines**** IV steroids****
Edmonds[15]	retrospective	Decreased****	Decreased****					Increased for: Peak flows* Decreased for: Time to beta-2* Time to steroids****
Sucov[16]	retrospective							Decreased for: Time to beta-2*** Steroid dose*** Diagnostic Test****

* $p < 0.001$ ** $p < 0.005$ ED: emergency department ICU: intensive care unit IV: intravenous
*** $p < 0.01$ **** $p < 0.05$ LOS: length of stay Tx: treatment MDI: metered dose inhaler

effective ED asthma management, and they demonstrated that their ED protocol for asthma exacerbations in adults provided rapid, efficient relief of symptoms, with positive clinical and financial outcomes.

Another ED study investigated the effect of a preprinted protocol on clinical data documentation and compliance with the British national management guidelines for adult asthma exacerbations.[12] This retrospective study compared protocol outcomes to a chart review audit of the ED asthma management practices in the 6 months prior to implementation of the preprinted asthma protocol. The protocol improved documentation of asthma history ($p < 0.001$), adherence to ($p < 0.01$) and compliance with ($p < 0.001$) the British treatment recommendations, use of predicted peak flow ($p < 0.001$) and percent of predicted peak flow ($p < 0.001$), and respiratory rate ($p = 0.007$). The protocol did not improve all the outcomes of interest to the study's authors; Robinson et al reported that the percentage of patients who received steroid prescriptions on discharge did not significantly improve ($p > 0.05$). The authors' overall conclusion was that the protocol resulted in superior documentation of data and better conformity with current guidelines for asthma management.

Frequently asthma protocols are implemented as a part of a continuous quality improvement process. A retrospective study by Akerman et al studied the effect of an asthma protocol on admission rates and relapse rates.[13] The authors compared over 19,000 consecutive adult asthma ED protocol visits (over 2.5 years) to almost 8,000 non-protocol visits in the prior 12 months. The protocol patients had a significantly lower monthly asthma admission rate ($p < 0.05$) and monthly asthma relapse rates rate ($p < 0.001$).

In another retrospective study, Goldberg et al studied the effect of an asthma protocol on ED resource utilization in a community hospital.[14] The protocol significantly decreased unnecessary oxygen use ($p = 0.001$), nebulizer treatments ($p = 0.001$), placement of intravenous lines ($p = 0.011$), and administration of intravenous steroids ($p = 0.034$). The protocol significantly increased treatments administered via metered-

dose inhaler with spacer ($p = 0.001$) and administration of oral corticosteroids ($p = 0.027$). Goldberg et al concluded that their protocol, designed according to national guidelines, provided effective asthma treatment and improved resource utilization.

In a retrospective study, Edmonds et al examined the effect of an ED practice guideline on acute asthma care.[15] They developed and implemented a local version of the National Asthma Education Program's practice guidelines, using a standard asthma order sheet, and provided new peak flow meters. The retrospective study group comprised all adults with acute asthma seen during January 1994 ($n = 51$), and the prospective group comprised all adults with acute asthma seen during October 1994, February 1995, and June 1995 ($n = 145$). There were no significant differences in acute asthma severity or patient demographics between the 2 groups. Prior to the guideline implementation, only 20% of asthma patients received initial peak flow measurements. During the guideline period, the percentage of patients who received initial peak flow measurements statistically improved to 82%, 84%, and 83%, respectively, during the 3 intervention months (p for trend < 0.001). The percentage of follow-up peak-flow measurements obtained also significantly improved, from 22% to 70%, 78%, and 62%, respectively, during the 3 intervention months ($p < 0.001$). There was a significant decrease in the delay of adminstering β agonist (16 min, $p < 0.001$) and corticosteroids (34 min, $p = 0.04$). Edmonds et al also reported significant decreases in median ED stay (58 min, $p = 0.01$), and in-patient admission ($p = 0.05$). However, there was no significant change in 4-week relapse rate. The authors concluded that a guideline-based ED asthma program changed clinical practice and caused sustained improvement in acute asthma care. The effect of the guideline on cost and other outcomes not measured is uncertain.

Sucov et al assessed the impact of an ED asthma care plan on quality of care, resource utilization, and outcomes at an urban university/trauma center.[16] They compared a retrospective cohort to the prospective cohort. The charts of all patients diagnosed with asthma during the 3-months prior to protocol implementation were retrospectively reviewed against predefined outcomes. For the prospective, protocol patients, triage nurses were instructed to begin use of the asthma care plan when patients presented with asthma as their primary complaint. The demographic profiles (age, race, gender, and insurance status) of the 2 cohorts were statistically the same, but differences in disease severity could not be determined. After introduction of the asthma care plan there was statistically significant improvement in the timeliness of β-agonist treatments (3 within 90 min, 86% vs 63%) and ED stay (3.39 ± 1.88 hours versus 3.87 ± 2.12 hours). In an unique twist, because of protocol adherence, only 55% of the patients diagnosed with asthma had care documented on the asthma care plan (asthma-care-plan+ group), compared to those treated during the asthma care plan phase but without the protocol (asthma-care-plan– group). In the 2 study-period subgroups, the asthma-care-plan+ group had more timely β-agonist treatments (93% vs 74%, $p < 0.01$), shorter ED stay (3.29 + 1.90 vs. 3.53 + 1.86 hours, $p < 0.05$), more appropriate corticosteroid dosages (67% vs 41%, $p < 0.01$), and fewer diagnostic tests (41% vs 59%, $p < 0.05$). There were no statistical differences in admission or relapse rates. Sucov et al concluded that their ED asthma care plan improved quality of care and decreased stay, but had limited impact on outcomes of admission/discharge or relapse rates.

In-Patient Asthma Protocols

Protocols for managing acute asthma with hospitalized patients should address a number of issues. The most frequently monitored protocol outcomes are cost of care, hospital stay, resource utilization and consumption, misallocation of therapy, and unnecessary laboratory and radiographic testing. Additional outcomes that should be monitored and addressed include improvement in patient care, delivery of patient education, identification of risk factors for future asthma exacerbations, determination of severity and control of chronic asthma symptoms, development of an asthma action plan, and post-discharge medical follow-up.

Grant et al[17] conducted a survey on in-patient asthma care processes to determine the extent to which hospitals within a large community had implemented various types of asthma-specific health-care delivery processes. This cross-sectional, self-administered survey was mailed to a "key informant" in asthma care at each of the hospitals in the Chicago area. The survey response rate was 66.3%. Of the responding hospitals, only 42.4% indicated they had clinical practice guidelines for in-patient asthma management, and 37.3% reported using protocols. Fifty-four percent of the hospitals reported routinely administering some type of asthma education program prior to discharge. The hospitals that had implemented clinical practice guidelines were also more likely to have protocols ($p < 0.01$); to have asthma-specific intensive-care policies/guidelines/critical pathways ($p < 0.01$); to

Figure 1.

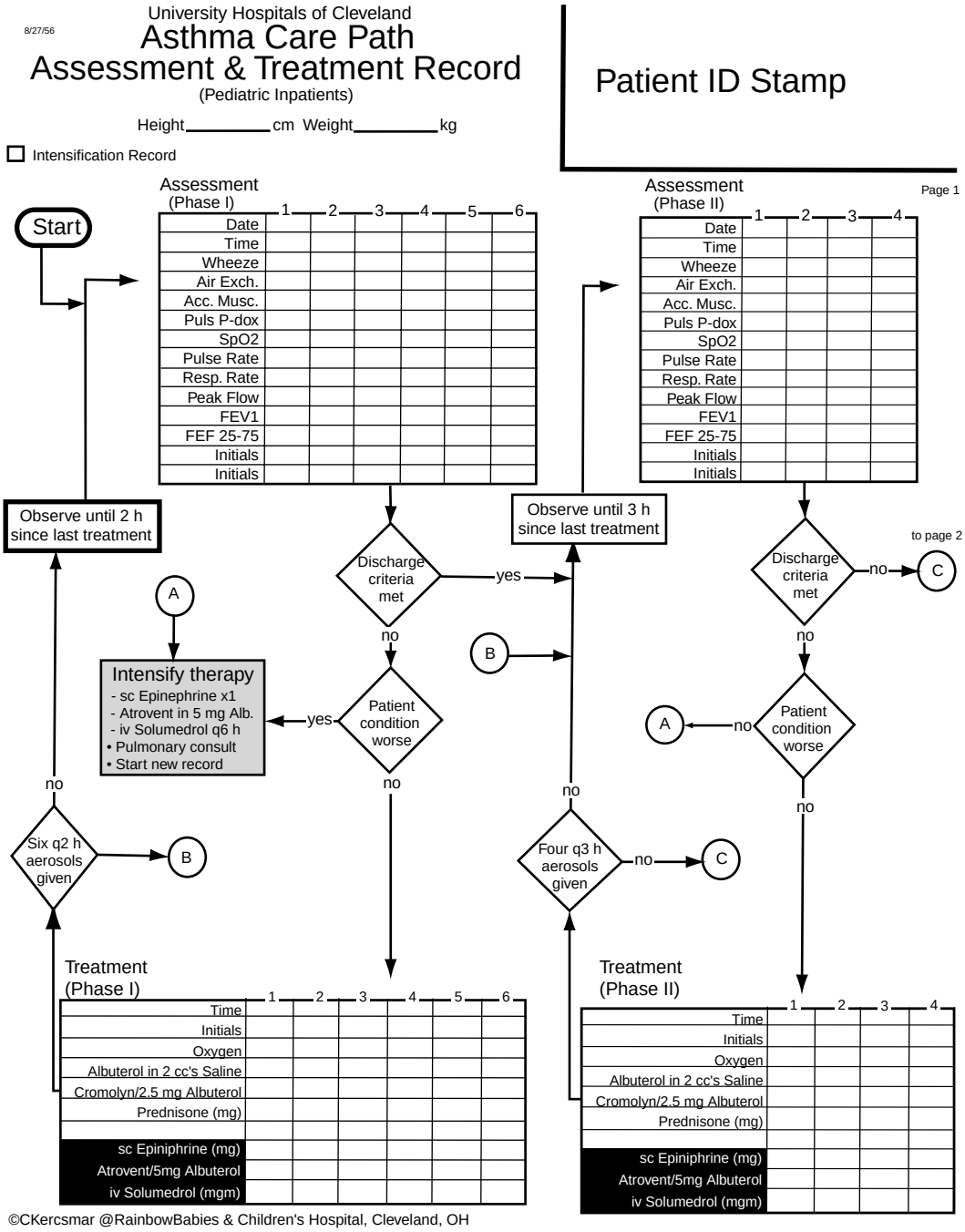

Figure 1. The Rainbow Babies and Children's Hospital's asthma clinical pathway "Algoform," which combines the pathway algorithm and data recording form to document patient assessments and treatments.

provide bedside instruction on the use of peak flow meters ($p < 0.01$); to provide asthma education prior to discharge ($p < 0.01$); and to conduct resource-utilization review. Grant et al concluded that the surveyed Chicago-area hospitals provide appropriate bedside asthma care, but that there are large differences in other types of asthma services and programs. The hospitals that had implemented asthma clinical practice guidelines were more likely to have other asthma-specific quality-improvement activities than were the hospitals that had not implemented guidelines. Grant et al thought that the relationship between guideline-use and quality of services needs further exploration, because it may be an important marker for hospitals with staff who are interested in improving asthma care.

Table 2. Documented Improvements with Inpatient Asthma Protocols

Publication	Study Design	LOS	Beta Agonist Treatments	Cost	Relapse Rates	Asthma Education	Other
Kwan-Gett [18]	retrospective			Decreased for Lab Cost**** Radiology*			
McDowell [19]	Prospective, randomized	Decreased*	Decreased*	Decreased*			
Johnson [22]	Prospective, randomized	Decreased***	Decreased****	Decreased for Routine* Respiratory Care*			
Lierl [24]	Prospective		Decreased**		Decreased+++		
Kelly [25]	Retrospective	Decreased*		Decreased*		Increased*	Increased for: Discharge Meds*** Peak Flow Meters**** Spacers*
Wazeka [26]	Retrospective	Decreased+		Decreased for Total Cost** Lab Cost**** Nursing Cost+++	Decreased+++		Decreased for: Lab Test++
Evans[27]	Retrospective	Decreased+++			Decreased****		Increased for: Patient satisfaction***
Mayo [28]	Retrospective	Decreased*				Increased for Patients* Residents*	Increased for: Inhaled Steroids* Peak Flow Meters* Spacers* Decrease for: IV Steroids* Methylxanthines*
Bailey [30]				Decreased for Aerosol Cost			Increased for MDI Use**

* $p < 0.001$ ** $p < 0.005$ + $p < 0.0001$ +++ Not Significant LOS: length of stay
*** $p < 0.01$ **** $p < 0.05$ ++ $p < 0.0006$ MD: metered dose inhaler

The number of studies on asthma protocols has been growing, but there are as yet few reports of randomized, controlled trials; most of the studies have compared an historical control group (1–2 years prior to protocol implementation) with the protocol group. Such historical-design studies can be confounded by independent variables such as seasonal differences, normal evolution in care practices, admission criteria, and availability of new treatments, which could impact outcomes apart from the protocol.

Though the majority of studies on ED asthma protocols have been with adult patients, most reports on inpatient asthma protocols have involved pediatric patients, perhaps in part because asthma is the most common cause of hospitalization in children's hospitals in the United States.[1]

In the first of several pediatric asthma protocol studies, Kwan-Gett et al related their 1-year experience with an in-patient asthma protocol in an academic children's hospital.[18] An asthma protocol was selected and developed because of the large number of asthma admissions, the involvement of multiple health care providers (nurses, physicians, and respiratory therapists), predictable hospital course, and variable length of hospital stay. The protocol's goals were to improve care of acute asthma by implementing best-care practices, documenting variations in care, improving coordination of care among service providers, and facilitating outcomes research. Data from the first year of the protocol group were compared to an historical control group of patients admitted in the year prior to the protocol's implementation. The outcomes included hospital stay, 14-day readmission rate, and resource utilization (peak expiratory flow meter and systemic steroid use, laboratory and radiology studies ordered, pharmacy and respiratory therapy charges). A standardized protocol flowchart was placed in the chart of all the patients, and the bedside nurses were responsible for identifying protocol variances. The analysis compared 342 protocol admissions to 353 similar admissions from the prior year. The protocol group differed from the historical control group in that it included more males and children of Asian descent. There were no significant differences in stay, steroid use, or total charges between the 2 groups, but the protocol group had significantly less laboratory and radiology services,

which amounted to a cost-savings of approximately $12,000 per year. The lack of impact on length of stay was in part attributed to the fact that length of stay had been relatively short (2 days) prior to the protocol's implementation. Most deviations from protocol were related to patient progress (50% were slower) and physician-order variances (27%). The authors conclude that better education for the nurses and physicians, with data feedback, computer and administrative support, and clinical severity scales, are needed to develop the potential utility of the clinical pathway as a research and quality assurance tool.

In one of the few prospective, controlled trials of a protocol for managing status asthmaticus in children, McDowell et al designed an assessment-based protocol that used a unique documentation approach.[19] The Rainbow Babies and Children's Hospital asthma "Algoform" combines the treatment algorithm within a documentation form on which to record patient assessments and treatments (Figure 1). The protocol directs care for patients who fail to achieve pre-established advancement or discharge criteria (based on predefined wheezing severity, respiratory rate, accessory muscle use, pulse oximetry, air exchange, and peak flow); they receive β-agonist aerosols and repeated assessment at a pre-set interval. The protocol algorithm directs medications, doses, and frequency. This assess-and-treat protocol is used by respiratory therapists and nurses. This trained team of asthma care providers administer treatments, perform assessments, and provide asthma education and written treatment plans prior to discharge. Patients were discharged when specific criteria were met while receiving treatments at a minimum of every 6 hours. In this prospective controlled trial, patients were randomly assigned (by admitting personnel, who were not involved with or aware of the study) to either the protocol group on one hospital division or to a non-protocol care group on a different in-patient division. An a priori analysis of historical in-patient stay data determined the number of patients needed to treat to detect a 0.5-day difference in stay. The protocol group had significantly shorter stay than the non-protocol group, by almost 1 day (31% shorter stay, $p < 0.001$), but there was no difference in readmission rate at 72 hours after hospital discharge. The protocol patients also received 38% fewer aerosol treatments ($p < 0.001$). The protocol also reduced hospital charges, saving over $700 per patient (a 23% reduction, $p < 0.001$). The protocol has been in use for 6 years, and it is associated with an average stay of 1.8 days, with a 0.5% readmission rate. In addition, all patients receive a brief asthma risk-assessment by the asthma counselor (medical social worker), asthma training in medication use and trigger avoidance, and medical follow-up. All patients also receive an appropriate home-going asthma action plan that stresses the importance of anti-inflammatory medication appropriate to the patient's disease severity. Despite excellent results in clinical, patient and financial outcomes, the researchers at Rainbow continue to utilize the asthma protocol as a vehicle for clinical research on new uses of existing drugs, such as ipratropium bromide,[20] and to investigate newly introduced drugs, such as levalbuterol.[21]

In a similar prospective, randomized, controlled design study of an in-patient pediatric asthma protocol, Johnson et al[22] conducted a study that had similar outcomes to that of McDowell et al. And similar results were obtained, although the reduction in stay was less (13 hours). The protocol caused an overall reduction in the use of β-agonists, at all stages of the protocol. Johnson et al speculated that trained nurses or respiratory therapists could function as the primary directors of the protocol, performing assessments and weaning treatments according to the protocol. That hypothesized scenario has in fact successfully been accomplished at Rainbow Babies and Children's Hospital, in their 10-bed asthma unit, which is staffed by respiratory therapists. There the protocol was associated with both financial and clinical improvement in outcomes of pediatric asthma patients.[23]

In another prospective study, Lierl et al compared a respiratory therapist-directed protocol for weaning b-agonist aerosols from pediatric patients with status asthmaticus[24] to the existing practice of physician-directed aerosol administration orders. The study compared outcomes between 71 controls and 70 protocol patients. In the protocol group, fewer aerosols were administered and the time required to achieve every-6-hour aerosol was shorter. However, the protocol group had a longer lag time between reaching the 6-hour aerosol frequency and being discharged, which resulted in no significant difference in length of stay. There also were no significant differences in aerosol frequency regression or recidivism to either the ED or hospital within 1 week of discharge. Lierl et al noted that the respiratory-therapist compliance to the protocol improved during the study period, but the protocol records indicated that approximately one third of the aerosol treatments administered during the protocol could have been withheld. This may have been one reason that the protocol did not decrease stay. Lierl et al thought that, with carefully designed assessment criteria and protocol training, a respiratory-therapist-directed protocol for weaning β-agonist aerosols can improve pediatric asthma care in a teaching hospital.

In a retrospective, pediatric asthma protocol study, Kelly et al also used an algorithm that permitted nurses and respiratory staff to adjust treatment dose and frequency based on individual patient assessment.[25] As in the studies by McDowell et al and Johnson et al, the study by Kelly et al also found a significant stay reduction (50%, 1 day, $p < 0.001$) and a 40 % reduction in cost of asthma care ($p < 0.001$). Protocol patients were significantly more likely to complete asthma education ($p < 0.001$), to be discharged with a controller medication prescription ($p < 0.01$), and to be issued a peak flow meter ($p < 0.05$) and a spacer device ($p < 0.001$) for home management. The study-design and protocol of Kelly et al differed slightly from that of McDowell et al and Johnson et al; the patients in the Kelly et al study were compared to a matched, historical control group, were few in number ($n = 34$), and achieved hospital discharge status when receiving β-agonist every 4 hours, rather than every 6 hours. Another potential limitation of the generalizability of the Kelly et al data is that they reported data only on a randomly selected group of 34 patients (149 children were protocol treated).

With a slightly different methodology from the therapist-driven or nurse-driven protocol, Wazeka et al implemented an asthma protocol directed by asthma specialists (pulmonologist or allergist).[26] This was a retrospective study that analyzed data from a large subset of pediatric asthma patients. As in many of the previously described protocols, Wazeka et al provided guidelines for type and frequency of patient assessment, medication use, laboratory and radiologic testing, discharge criteria and planning, and patient education. However, the exact dose of medications was left to the discretion of the specialist in charge. Patients enrolled in the protocol group had significantly shorter stay (4.2 vs 2.7 days, $p < 0.0001$), fewer laboratory tests, lower laboratory and nursing care costs. The protocol was also associated with significantly lower annual total charges for admissions ($2 million vs $1.4 million, $p < 0.005$). Moreover, there was an extremely low readmission rate (0.02%) within 2 weeks of hospital discharge. The major limitation of the study was an uncertainty whether decisions about admission, discharge, and accounting practices changed over the 4-year study period between the historical control data and the protocol data.

In a similar variation to a pediatric asthma protocol, Evans et al examined the effects of restructuring asthma care in an inner-city pediatric hospital, in a retrospective comparison.[27] The key elements of the restructuring included: (1) establishing a pulmonary unit with expanded bed capacity (from 8 beds to 22 beds) for asthma patients; (2) a standardized treatment protocol; (3) availability of direct admission by primary care physicians, who maintained management of their patients, with the option of consultation with a specialist; and (4) use of case managers who helped patients and their families overcome obstacles to optimum care. The interventions in this program included a standardized, protocol care for asthma and the use of case managers to facilitate adherence to treatment. The restructured asthma care program reduced average stay and use of the ED (compared to an observation unit), reduced readmissions to both the in-patient unit and the ED, and improved parent satisfaction with treatment. Evans et al concluded that an inner-city hospital can provide optimum care for asthma patients by standardizing treatment, aggregating asthma patients in one location, and having case managers provide education and follow-up. They suggested that the protocol shifts some costs from expensive services such as the pediatric intensive care unit and the ED to less costly case management and outreach personnel. It was also hypothesized that reallocation of resources should help to lower costs as well as improve quality.

The literature on asthma protocols for hospitalized patients also yields 3 studies on adult asthmatic patients. Mayo et al implemented an asthma protocol to assess its effectiveness in improving care of adult patients hospitalized for asthma.[28] In this retrospective analysis, Mayo et al investigated the protocol's impact on patient education and house staff education, patterns of medication use, spacer and peak flow meter utilization, and length of stay. The study compared all hospitalized patients admitted with a primary diagnosis of asthma exacerbation from 2 separate, similar calendar periods, 1 year apart. Patients hospitalized for less than 24 hours or greater than 10 days were excluded from data analysis. There were 61 patients in the control group and 65 patients in the protocol group, and the groups were well matched in demographic characteristics and severity of disease. The protocol significantly increased the use of spacers, peak flow meters, and inhaled corticosteroids, and it decreased the administration of systemic corticosteroid and methylxanthines. The protocol also decreased the length of stay, without increasing the hospital readmission rates. Mayo et al concluded that the protocol improved the treatment process for adults hospitalized for asthma.

In a slightly different perspective on the effectiveness of an asthma protocol, Nakano et al examined the efficacy of an adult asthma protocol and analyzed the

factors associated with unresponsiveness to the protocol therapy.[29] They examined 93 consecutive adult patients who presented for acute asthma and who had peak expiratory flow less than 50% of the predicted value (moderate to severe airflow obstruction). International asthma guidelines were adhered to, and all subjects received 400 µg of salbutamol every 20 min for 3 doses, and 400 µg of oxitropium bromide with each of the 3 salbutamol doses via metered-dose inhaler with spacer. The patients also received 8 mg betamethasone intravenously. Peak flow was measured at baseline and again at 20, 40, 60, and 120 min. Sixty-nine percent of the subjects improved sufficiently to be discharged. The protocol therapy failed with 31% of the subjects. Between the patients who were admitted and those who were discharged, there were no significant differences in age, gender, smoking status, or β-agonist use within 6 hours. Logistic regression analysis established that, among these adult asthmatics, there was a significant association between unresponsiveness to the protocol and peak expiratory flow less than 35% of predicted at presentation (odds ratio 16.3, 95% confidence interval 4.5–59.9), viral respiratory-tract infection symptoms for > 2 days (odds ratio 4.8, 95% confidence interval 1.3–17.1), and asthma hospitalization in the past year (odds ratio 4.6, 95% confidence interval 1.1–19.9). Nakano et al concluded that unresponsiveness to protocol therapy occurs in nearly one third of individuals presenting with acute, severe asthma. That finding indicates a need to explore for more effective strategies to improve lung function and reduce hospital admissions.

At a large community-based teaching hospital, Bailey et al studied the efficacy of a protocol to treat adults hospitalized for acute asthma.[30] The protocol was similar to many of the pediatric protocols in that it used a pre-printed order sheet and algorithm. Key components this assess-and-treat protocol included criteria for admission to the intensive care unit or regular in-patient unit, assessment intervals and conversion from nebulizer treatments to metered-dose inhaler treatments. The study compared 3 groups: those admitted in a 7-month interval 1 year prior to protocol implementation; those admitted during the 7-month protocol period but not entered into the protocol care path; and those treated with the protocol. Group assignment to the latter 2 cohorts was based on physician preference, and was not randomized. Outcome measures of interest to Bailey et al included length of stay, conversion from nebulizer treatment to metered-dose inhaler treatment, 30-day readmission, and ED visit rates. The lone outcome measure that showed a statistically significant difference was conversion from nebulizer to metered-dose inhaler (35% in the non-protocol group vs 68% in the protocol group). Bailey et al estimated that the nebulizer-to-metered-dose-inhaler conversion rate provided an annual cost savings of $288,000. The conclusions from the study are somewhat limited, however, and at an increased risk of type II error, because of the relatively small number of patients (historical control n = 38, non-protocol = 23, protocol group n = 19).

Conclusions

Protocols offer numerous potential benefits, including shorter length of stay, faster patient-improvement, and decreased medication use. Protocols can and should be designed to evaluate the causes of outpatient treatment failure, such as adherence problems, poor quality of care, and inadequate patient knowledge and management skills. Based on information gathered during the admission, each patient should be provided with an appropriate asthma action plan that includes instructions for managing chronic stable asthma, worsening asthma, and acute severe episodes. Differences and variations in care that increase cost but do not improve the quality of care can and should be eliminated with protocols or guidelines. Asthma protocols that are prospectively designed to provide quality assurance or improvement feedback and that are implemented in conjunction with clinical research can effectively produce valuable evidence (institutional, at the very least) as future medications and treatment and care process are developed. Asthma protocols, when properly designed, carefully implemented, and closely adherent to national guidelines or evidence-based medicine, can improve patient care and education, improve clinical processes of care, and may provide cost savings.

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Nebulizer Selection: Options Available to Maximize Aerosol Delivery

Dean R Hess PhD RRT FAARC

Introduction

Nebulizers convert liquids into aerosols to be inhaled into the lower respiratory tract. Nebulizers remain useful, despite the common use of pressurized metered-dose inhalers and dry powder inhalers. Some drugs for inhalation are available only in solution form, some patients cannot master the correct use of metered-dose inhalers or dry powder inhalers, and some patients prefer the nebulizer over other aerosol devices. The physiologic effects of inhalers and nebulizers are virtually equivalent and the choice of device is often based on clinician or patient preference rather than clear superiority of one device over the other. Table 1 lists characteristics of an ideal nebulizer.

Pneumatic Jet Nebulizers

Technical Factors That Affect Jet Nebulizer Performance

Nebulizer performance is affected by both technical and patient-related factors (Table 2). Gas flow is delivered through a jet, the drug solution is entrained into the gas stream and is sheared into a liquid film, surface tension forces break the film into droplets, and a baffle produces smaller particles (Fig. 1). The aerosol is delivered into the inspired gas stream and it may be further conditioned by environmental factors such as the relative humidity of the carrier gas before being inhaled by the patient.

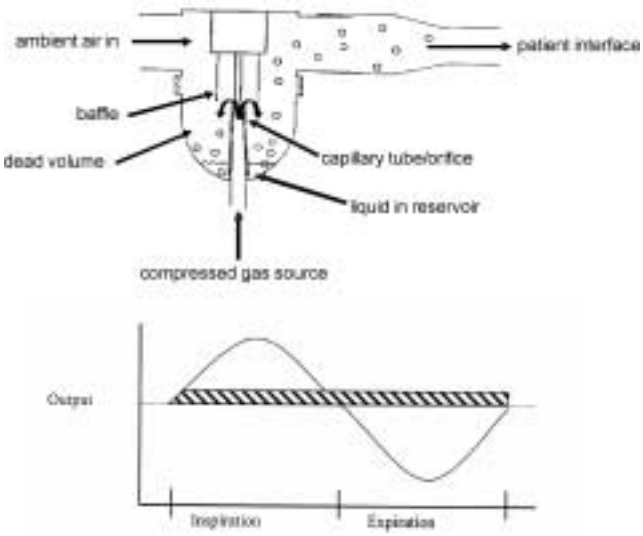

Fig. 1. A: Components of a jet nebulizer. (From Hess DR. Nebulizers: principles and performance. Respir Care 2000;45:609-622.) B: The output of the traditional jet nebulizer (represented by the shaded area of the graph) is constant throughout the respiratory cycle. (From Rau JL. Design principles of liquid nebulization devices currently in use. Respir Care 2002;47:1257-1275, with permission.)

Droplet size is an important characteristic of an aerosol. Droplet size is determined by characteristics of the solution (density, viscosity, surface tension), characteristics of the gas powering the nebulizer (density), and the gas flow rate used to power the nebulizer. Droplet size is usually reported as mass median aerodynamic diameter (MMAD), which is the diameter around which the mass of the aerosol is equally divided. Because the volume, and hence the mass, of the droplet is determined by the cube of the radius, most of the droplets have a size less than the MMAD.

Disclosure: D.R.H. does not have a financial relationship with Sepracor, Inc.

Dean R Hess PhD RRT FAARC, Respiratory Care, Ellison 401, Massachusetts General Hospital, 55 Fruit Street, Boston, MA 02114. Email: dhess@partners.org

Table 1. Performance Characteristics of an Ideal Nebulizer

Reliable performance; independent of fill volume, flow, power, and ventilation pattern
Appropriate aerosol droplet size
Simple to use for caregiver and patient
Performance is independent of drug formulation and carrier gas
Operation is independent of position or orientation of device or patient
Efficient dose delivery to the lungs
Portable
Multiple dose delivery
Easy to clean
Difficult to contaminate
Minimal environmental contamination (limits release of aerosol to ambient air)
Durable
Quiet
Cost-effective

Another important characteristic of nebulizers is dead volume, which is the amount of the solution trapped in the nebulizer that will not be nebulized and is thus not available for inhalation. The dead volume is typically in the range of 1–3 mL. Because of evaporative water loss, the solution in the nebulizer becomes increasingly concentrated and the nebulizer solution cools during nebulization. Nebulizer output and droplet size vary directly with temperature.

The most important characteristic of nebulizer performance is respirable dose, which is determined by the mass output of the nebulizer and the size of the droplets. The respirable dose is sometimes reported as respirable mass, which is the output of aerosol droplets in the respirable range (diameter < 5 μm). Other important characteristics of nebulizer performance include nebulization time, cost, ease of use, and requirements for cleaning and sterilization. Nebulization time is important for patient compliance in the out-patient setting and for clinician supervision of aerosol administration for hospitalized patients. A short nebulization time that delivers an effective dose is desirable.

There are performance differences between nebulizers made by different manufacturers and between nebulizers from the same manufacturer. The output from a pneumatic nebulizer increases when the fill volume is increased (a fill volume of 4–5 mL is recommended), but increasing the fill volume also increases nebulization time. However, nebulization time can be reduced by increasing the flow used to power the nebulizer. Increasing the flow used to power the nebulizer also has the benefit of decreasing the droplet size. A flow of 8 L/min is recommended, unless the nebulizer is designed specifically for low-flow operation.

Patient Factors That Affect Aerosol Delivery with Jet Nebulizers

Breathing pattern affects the amount of aerosol deposited in the lower respiratory tract. To improve aerosol penetration and deposition in the lungs, encourage the patient to use a slow and deep breathing pattern. Aerosol can be administered with a mouthpiece or a face mask; bronchodilator response occurs with either technique, and some have argued that the selection of interface should be based on patient preference. However, the nasal passages effectively filter aerosol droplets. With nasal inhalation a 50% reduction in aerosol delivery to the lungs has been reported. Thus, whether a mouthpiece or a face mask is used, it is important to instruct the patient to inhale through the mouth. Use of a mouthpiece may encourage oral breathing.

Airway caliber also affects lung delivery of nebulized bronchodilators; it is ironic that airflow obstruction, which produces the need for inhaled bronchodilator therapy, also decreases the effectiveness of that therapy.

Because of the low density of heliox (a helium-oxygen gas mixture), flow becomes less turbulent with this gas mixture, which theoretically improves the transport of aerosols through constricted airways to more peripheral lung regions. Several studies have reported that heliox improves pulmonary penetration of aerosols in patients with stable asthma and with acute airway constriction. The density of the gas used to power the nebulizer affects nebulizer performance. The inhaled mass of albuterol is reduced when the nebulizer is powered with heliox, and there is a greater than 2-fold increase in nebulization time with heliox. Increasing the heliox flow can increase the respirable mass to a level similar to that produced when the nebulizer is powered with air. Studies of the use of heliox for aerosol bronchodilator delivery to patients with asthma have reported mixed results, which may, in part, be related to failure to consider the effect of heliox on nebulizer performance. Moreover, heliox-driven nebulizer systems must be configured to minimize heliox dilution from ambient air.

Table 2. Factors That Affect Lung Penetration and Deposition of Aerosols From a Jet Nebulizer

Technical Factors
Manufacturer of nebulizer
Gas flow used to power nebulizer
Physical characteristics of driving gas
Physical characteristics of formulation
Fill volume of nebulizer
Mask versus mouthpiece
Designs to enhance nebulizer output
Continuous versus breath-actuated aerosol output
Patient Factors
Breathing pattern
Nose versus mouth breathing
Physical characteristics of inspired gas
Airway obstruction
Bias flow (eg, tracheostomy collar)
Positive-pressure delivery
Artificial airway and mechanical ventilation

Designs to Improve Jet Nebulizer Performance

Several nebulizer designs are available that decrease aerosol loss during the expiratory phase. These include reservoir bags to collect aerosol during the expiratory phase, an open vent design to increase the nebulizer output during the inspiratory phase (breath-enhanced nebulizers), and nebulizers that only generate aerosol during the inspiratory phase (breath-actuated nebulizers). Because these designs improve drug delivery to the patient, they have the potential to reduce treatment time, which should improve patient compliance with nebulizer therapy.

Reservoir Bag to Collect Aerosol During the Expiratory Phase

The Circulaire and AeroTee nebulizers use a reservoir bag design (Fig. 2). Both use a 750-mL bag to store aerosol during exhalation, but the designs differ in how they prevent rebreathing. The Circulaire uses a 1-way valve to prevent exhaled gas from entering the reservoir bag, whereas the AeroTee allows some exhaled gas to enter the bag. The Circulaire incorporates a variable inspiratory/expiratory resistor that is set to maximize inspiration from the reservoir bag and to provide a positive-expiratory-pressure effect.

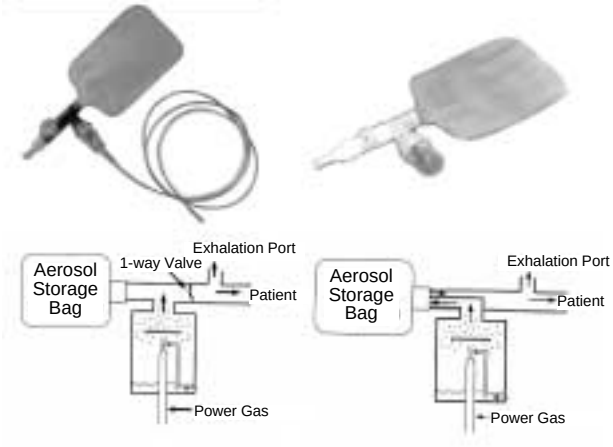

Fig. 2. Two nebulizers that use a reservoir bag design: Circulaire (left) and AeroTee (right). (From Hess DR. Nebulizers: principles and performance. Respir Care 2000;45:609-622, and Rau JL. Design principles of liquid nebulization devices currently in use. Respir Care 2002;47:1257-1275, with permission.)

Breath-Enhanced Nebulizers

The traditional nebulizer design incorporates the nebulizer sidestream to the airflow moving toward the patient. Some newer nebulizers use a mainstream design with valves. In this valved, open-vent design, the patient breaths through the nebulizer during inspiration, which enhances the nebulizer output. During the expiratory phase, a 1-way valve directs the patient's expiratory flow away from the nebulizer chamber (Fig. 3). Because the output is increased (enhanced) during the inspiratory phase, the overall effect is to decrease the amount of aerosol wasted during the expiratory phase.

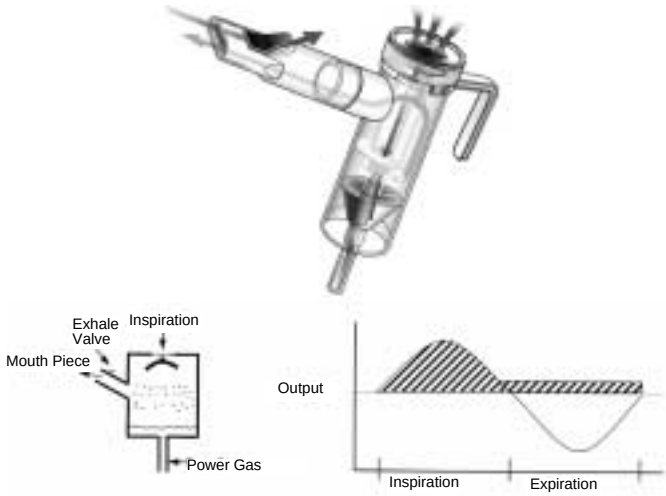

Fig. 3. The Pari is a "breath-enhanced" nebulizer, meaning that the aerosol output (represented by the shaded area of the graph) is greater during the inspiratory phase. (From Hess DR. Nebulizers: principles and performance. Respir Care 2000;45:609-622, and Rau JL. Design principles of liquid nebulization devices currently in use. Respir Care 2002;47:1257-1275, with permission.)

Breath-Actuated Nebulizers

Aerosol waste from the nebulizer during the expiratory phase can be eliminated if the nebulizer is only active during the inspiratory phase. Methods to manually actuate the nebulizer during the inspiratory phase have been available for many years, and this aerosol-generation strategy is commonly used in mechanical-ventilator-actuated designs. Pneumatically controlled, breath-actuated nebulizers are available (Fig. 4) and allow the nebulizer to be used in a dosimetric manner.

Continuous Nebulization

Continuously aerosolized bronchodilators are occasionally used in the treatment of acute asthma. The available evidence suggests that this therapy is safe, at least as effective as intermittent nebulization, and may be superior to intermittent nebulization with patients who have the most severe pulmonary function. Several configurations have been described for continuous nebulization, including frequent refilling of the nebulizer, use of a nebulizer and infusion pump, and use of a large-volume nebulizer.

Nebulizers for Specific Applications

Specially constructed small-volume nebulizers are used for specific drug delivery. An example is the small-particle aerosol generator, which is used to aerosolize ribavirin. When it is necessary to avoid contaminating the ambient environment with the aerosolized drug (eg, with pentamidine), the nebulizer is fitted with 1-way valves and filters.

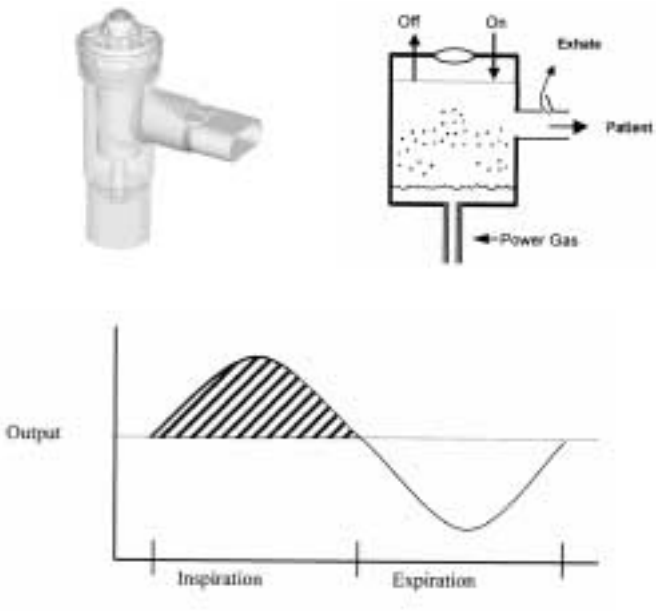

Fig. 4. The AeroEclipse is a "breath-actuated" nebulizer, meaning that it produces aerosol only during the inspiratory phase (represented by the shaded area of the graph). (From Hess DR. Nebulizers: principles and performance. Respir Care 2000;45:609-622, and Rau JL. Design principles of liquid nebulization devices currently in use. Respir Care 2002;47:1257-1275, with permission.)

Electronic Nebulizers

Ultrasonic Nebulizers

An ultrasonic nebulizer uses a piezoelectric transducer to produce ultrasonic waves in the medication solution. At the surface of the solution the ultrasonic waves create an aerosol. The frequency of the ultrasonic waves determines the size of the particles, with an inverse relationship between frequency and particle size. Increasing the wave amplitude increases the aerosol output. Ultrasonic nebulizers have fallen from favor in recent years and they have nearly disappeared from the armamentarium of the respiratory therapist.

Vibrating-Mesh Nebulizers

Several manufacturers have developed aerosol-generators that produce aerosol with a vibrating mesh (or plate) that has multiple apertures (Fig. 5). These devices generate aerosols with a high fine-particle fraction (ie, particles < 5 μm diameter), which results in more efficient lower-respiratory-tract delivery than a conventional nebulizer. The aerosol is generated as a fine mist, and no internal baffling system is required. These nebulizers are portable, battery-operated, and

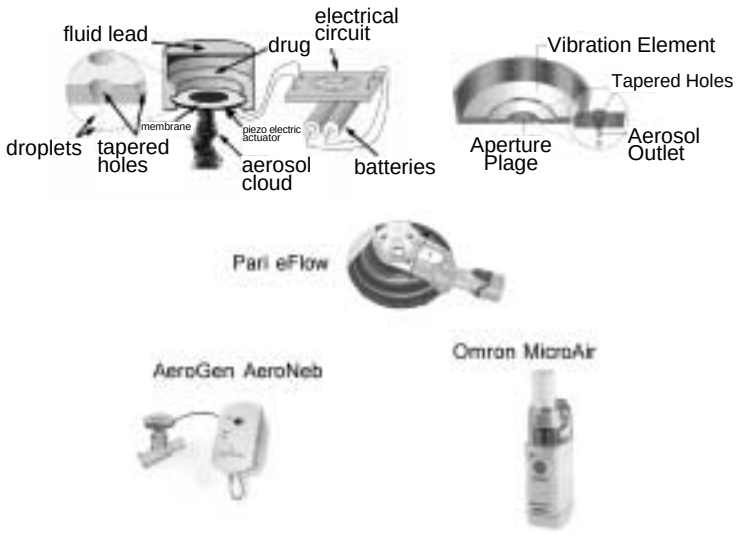

Fig. 5. A: The vibrating-mesh device that creates the aerosol in certain newer-generation nebulizers. B: Three vibrating-mesh nebulizers: Pari eFlow, AeroGen AeroNeb, and Omron MicroAir. (Diagrams and photographs courtesy of Pari, Aerogen, and Omron.)

Table 3. Factors That Affect Aerosol Delivery From a Nebulizer During Mechanical Ventilation

Endotracheal tube size
Position of nebulizer in the circuit
Type of nebulizer
Fill volume
Humidification of the inspired gas
Treatment time
Duty cycle (ratio of inspiratory time to total respiratory-cycle time)
Ventilator brand
Bias flow
Volume-controlled versus pressure-controlled ventilation

they have minimal residual medication volume. Some are breath-actuated. Vibrating mesh nebulizers are likely to be used increasingly in the future, particularly for expensive drugs.

Nebulizer Use With Mechanically Ventilated Patients

Nebulizers are commonly used with mechanically ventilated patients. A number of factors are known to affect nebulizer-aerosol delivery during mechanical ventilation (Table 3). Delivery of aerosol only during the inspiratory phase and use of a dry (ie, nonhumidified) gas during nebulizer therapy significantly increases the amount of aerosol delivered into the lower respiratory tract. There are important disadvantages of nebulizer use during mechanical ventilation, including circuit contamination, decreased ability of the patient to trigger the ventilator (if the nebulizer is not powered by the ventilator), and increases in the delivered tidal volume and airway pressure (if the nebulizer is not powered by the ventilator).

Nebulizers can be used in combination with noninvasive ventilation. Both in vitro and in vivo studies indicate that a physiologic bronchodilator dose can be delivered if the nebulizer is inserted between the mask and the circuit.

Summary

Despite the increasing use of metered-dose inhalers and dry powder inhalers, it is likely that nebulizers will continue to be used with selected patients. Clinicians should understand the various factors that affect nebulizer performance and aerosol delivery into the lungs. Several new designs have recently become available that improve nebulizer performance, but the cost-effectiveness of these new designs remains to be determined. Because bronchodilators are relatively inexpensive, there is little market pressure to improve nebulizer performance. In fact, the market generally prefers an inexpensive nebulizer rather than a high-performance nebulizer for bronchodilator administration. However, there are certain newer inhalable drugs that are expensive and with which precise dosing may be important. Moreover, a better nebulizer may prove to be cost-effective and may provide better patient satisfaction.

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Breath Actuator Nebulizer and Levalbuterol Help to Manage a Shortage of Respiratory Therapists and to Contain Costs: Development of a Respiratory Care Protocol at Crouse Hospital

Russell A Acevedo MD FAARC

Introduction

Crouse Hospital, in Syracuse, New York, like many other hospitals across the country, was faced with the problem of a decreasing respiratory-therapy work force. In the early 2000s there were about 5,500 graduates per year from respiratory care schools. By 2002 that number had dropped to 4,000 per year, and it continues to drop. Even though there are 2 respiratory schools in Syracuse and 2 other nearby schools (approximately 1 hour east and west of Syracuse), respiratory care positions remained unfilled. Crouse Hospital was in Chapter 11 bankruptcy protection, which made recruitment much more difficult. As well, 6 members of the respiratory department were leaving shortly: 3 because of permanent relocation, and 3 because of maternity leave. Those 6 members accounted for approximately 15% of the work force. The respiratory therapy department delivers about 45,000 aerosol treatments per year, and it became clear we could not meet that demand with the depleted staff.

Seeking Solutions to a Shortage of Respiratory Therapists

We considered limiting respiratory therapy to the critical care areas, but decided that was unacceptable because we did not want to limit our services. The hospital records the number of treatments missed due to respiratory therapists (RTs) being unavailable, and it was clear that if the workload stayed the same and the number of RTs dropped, the number of missed aerosol treatments would increase, which was unacceptable. We considered the possibility of performing treatments concurrently, which was not our practice, and we thought it undesirable to have the department depend on such concurrent therapy, so other solutions were explored.

The Syracuse area is "The Land That Managed Care Forgot"; it is only about 18% managed-care-penetrated. This is the reason why a vast majority of our aerosol therapy is delivered via small-volume nebulizer (SVN). For outpatients, SVNs are paid 100%, but if the patient is discharged home with a metered-dose inhaler (MDI), he or she faces substantial co-payments. The time required to deliver an MDI treatment is far less than that to deliver an SVN treatment, but it was clear that our medical staff were not interested in converting from SVN to MDI.

For the small percentage of patients who receive their aerosol via MDI, we have a self-administration protocol in which the RT delivers the first day of MDI treatments and teaches the patient how to use the MDI. In the outpatient setting, a patient's ability to correctly self-administer MDI treatment tends to deteriorate over time. An RT teaches every MDI patient how to use the MDI. After the RT signs off that the patient is competent to self-administer MDI treatments, then the nursing service documents that the patient has self-administered. But, because the number of MDI patients is small, patient self-administration with MDI would not have solved our staffing problem.

We re-examined our basic processes in delivering aerosol therapy, to see if any efficiency could be gained. We explored decreasing the time required to deliver aerosol therapy and decreasing the number of treatments delivered. Our standard SVN was the Airlife Misty-Neb (Allegiance Healthcare Corporation, McGaw Park, Illinois), which has an approximate treatment-delivery time of

Disclosure: R.A.A. does have a financial relationship with Sepracor, Inc.

Russell A Acevedo MD FAARC, Crouse Hospital, 736 Irving Avenue, Syracuse, NY 13210. Email: russacevedomd@crouse.org

8–10 min. If that time could to be reduced, RTs' time could be better used. Since we deliver over 40,000 nebulizer treatments a year, even a few minutes of time saved per treatment could make an important difference. In fact, we are trying to get the time advantages of an MDI with an SVN. The most common aerosol therapy order was racemic albuterol 2.5 mg every 4 hours, plus every 2 hours as needed. If that frequency could be reduced to every 6 or 8 hours it would substantially decrease the respiratory department's workload, which would free up RTs to perform other higher-level functions.

Evaluating the Aero-Eclipse Nebulizer

We evaluated the Aero-Eclipse nebulizer (Fig. 1), which is marketed by Monaghan Medical Corporation (Plattsburgh, New York). The Aero-Eclipse is a "breath-actuated" nebulizer, meaning that it nebulizes the medication only during inspiration. When the patient makes an inspiratory effort, a valve opens, which initiates nebulization. The aerosol's only available path is into the patient, which greatly decreases the amount of drug lost to the ambient air, compared to a traditional T-shaped nebulizer, which creates and emits aerosol continuously. With the Aero-Eclipse, when the patient's inspiratory flow decreases, near the end of inspiration, the valve closes and nebulization stops.

The Aero-Eclipse's aerosol droplet-size distribution is in the respirable range (ie, most droplets are < 5 µm diameter). Lung-deposition studies suggested that the Aero-Eclipse could deliver more than twice as much

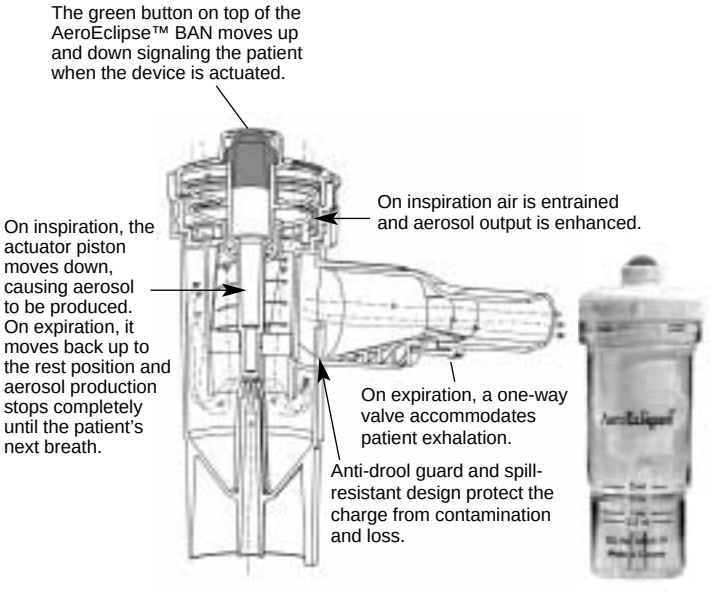

Fig. 1. The AeroEclipse nebulizer. (Courtesy of Monaghan Medical.)

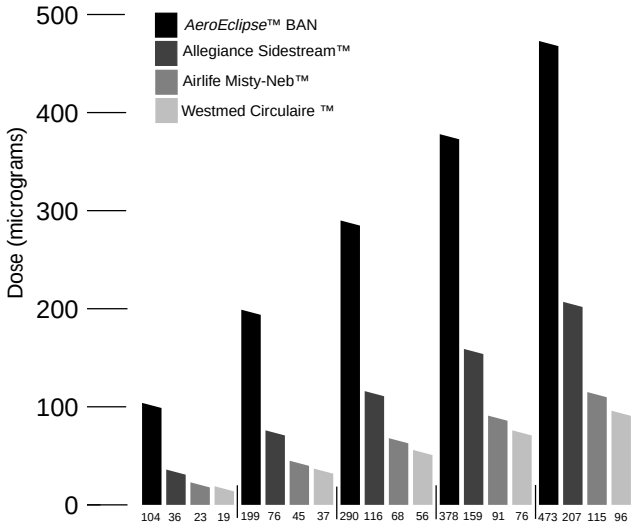

Fig. 2. Respirable dose in 5 minutes from 4 nebulizer brands. (Courtesy of Monaghan Medical.)

drug as a conventional SVN. In a bench study, the Aero-Eclipse delivered in 1 min approximately the same amount of drug as the Misty-Neb delivered in 5 min (Fig. 2).[1] With undiluted racemic albuterol, the Aero-Eclipse delivered in 2–3 min the same amount of drug the Misty-Neb delivered in 8–10 min. We compared the performance of the Aero-Eclipse to the Misty-Neb in delivering undiluted racemic albuterol (2.5 mg of drug in 1.0 mL of solution) to 64 patients with chronic obstructive pulmonary disease (COPD). We measured the patients' forced expiratory volume in the first second (FEV_1) and found that FEV_1 improved similarly with the Aero-Eclipse (in approximately 3 min) and the Misty-Neb (in approximately 8 min), but, unfortunately, 17 of 64 patients had adverse effects (tremors) from the treatment. Conversely, 0.5 mL of pure racemic albuterol diluted with 0.5 mL of normal saline had the same desirable clinical effect in 2.7 min, but with this diluted dose none of the patients reported tremors. The mean treatment time with the Aero-Eclipse was 2.8 min, which was slightly less than that of the MDI (2.9 min), and far less than that of the Misty-Neb (8.3 min).[2]

Not all COPD in-patients can use the Aero-Eclipse with a mouthpiece. We estimated that 60% of the patients could be converted to the Aero-Eclipse. Thus, the Aero-Eclipse would only solve part of the problem, so we explored ways of decreasing the total numbers of aerosol treatments.

Evaluating Levalbuterol

We reviewed the literature on levalbuterol, which is the R-isomer of racemic albuterol (Fig. 3). Bronchodilation is

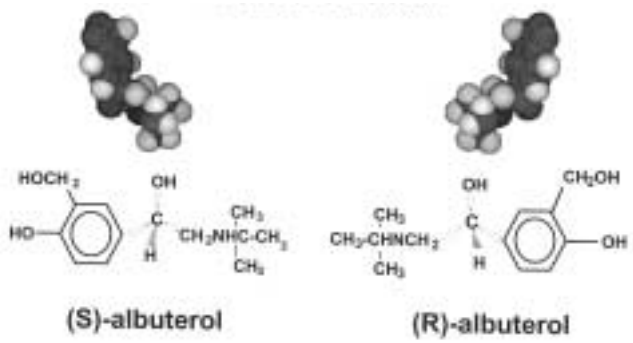

Fig. 3. Chemical structure of the albuterol isomers. (Courtesy of Sepracor.)

mediated by the R-isomer, which decreases airway reactivity and promotes mucus clearance. The R-isomer is metabolized faster than the S-isomer. R-albuterol is responsible for bronchodilation. The S-isomer was initially wrongly believed to be inert. The S-isomer causes minimal bronchodilation and may cause inflammation and bronchospasm, and those adverse effects persist for a longer period than the desirable effects of the R-isomer. Because the S-isomer has a longer half-life than the R-isomer, it also may interfere with the action of the R-isomer.[3,4]

In a study by Nelson et al, comparing racemic albuterol (2.5 mg) with levalbuterol (1.25 mg), levalbuterol improved FEV_1 more and had a longer duration of action than racemic albuterol. Both doses have the same amount of the R-isomer, but the racemic albuterol also contains 1.25 mg of the S-isomer. If the S-isomer were inert, the levalbuterol and racemic albuterol would have the same effect. However, in the group with the most severe bronchoconstriction, FEV_1 improvement at 4 hours with racemic albuterol was roughly the same as at 8 hours with levalbuterol (Fig. 4).[5] If those same results could be accomplished in our clinical setting, our treatment load would decrease, which would help us deal with our staff shortage.

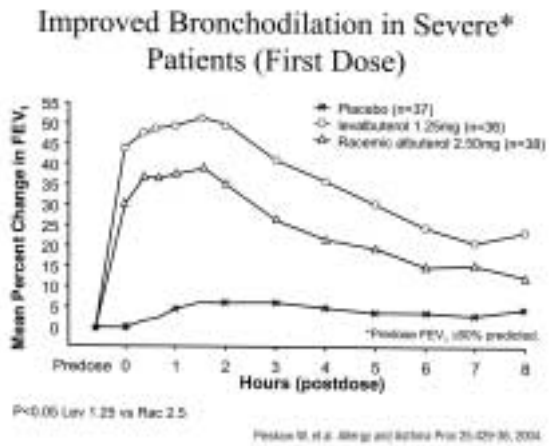

Fig. 4. Percent mean change in forced expiratory volume in the first second (FEV_1) in patients with severe bronchoconstriction (ie, whose FEV_1 was ≤ 60% of the predicted value). (Courtesy of Sepracor.)

Unfortunately, there was no clinical data on the Aero-Eclipse's performance with levalbuterol. Since undiluted levalbuterol was not available, we evaluated 5-min Aero-Eclipse treatments with diluted levalbuterol. We compared levalbuterol (0.63 mg or 1.25 mg) to racemic albuterol (2.5mg). In our primarily COPD population, the 3 treatment groups had equal improvements in FEV_1 and peak flow. The 1.25-mg levalbuterol dose caused significantly greater tachycardia than the 0.63-mg dose,[6] but this was expected because the β-mediated effects are solely related to the R-isomer.

We asked our Pharmacy and Therapeutics Committee for an automatic substitution of racemic albuterol (2.5 mg every 4 hours) to levalbuterol (0.63 mg every 6 hours for cardiac patients, and 1.25 mg every 6 hours for all other patients). All groups would receive levalbuterol every 2 hours as-needed "breakthrough" treatments. This automatic substitution was set up as an RT-driven protocol, partly because of time constraints to ask the attending physician about every permission to substitute.

At the time we implemented this protocol, Crouse Hospital was under Chapter 11 bankruptcy protection. The pharmacy was under a different service line and budget from the respiratory care department. If all treatments were automatically converted to levalbuterol, the increase in drug cost would be approximately equal to the salary and benefits cost of 0.6 of a respiratory therapy full-time-equivalent (FTE). RTs to fill the vacant RT positions were unavailable. One FTE was traded from our respiratory care department to pharmacy, to get unlimited use of levalbuterol. This ended up being a financial benefit to the pharmacy department, and they fully supported our automatic substitution. This also sent a message to our respiratory care department that we needed to make this conversion work, since we were investing resources into the project. The pharmacy and therapeutics committee approved our automatic substitution, but in 4 months the committee wanted us to report back on the results. They wanted to know whether (1) the number of treatments decreased, and they were very concerned that, (2) if we changed the treatment interval from every 4 hours to every 8 hours, the RTs would be called to deliver breakthrough treatments at 4-hour intervals, in which case the number of treatments would not decrease. In addition the chief financial officer wanted to see the economic breakdown of the change to levalbuterol.

Racemic albuterol (2.5 mg every 4 hours) was automatically changed to levalbuterol (0.63 mg every 6 hours for patients in the coronary care area or on telemetry monitoring, or 1.25 mg levalbuterol every 8 hours for other patients). All patients received levalbuterol every 2 hours as needed. If ipratropium was ordered, it was adminis-

tered at the same frequency as levalbuterol. All bronchodilator treatments (scheduled or breakthrough) were recorded in a database. We collected data for 4 months and presented it to the pharmacy and therapeutics committee. They approved the results. We collected data for an additional 4 months and reported our results at the CHEST conference in 2002.[7] Both levalbuterol groups (ie, every-6-hours, and every-8-hours) had less than half the number of breakthrough treatments than the every-4-hours racemic albuterol group. The group receiving racemic albuterol without ipratropium had the greatest number of breakthrough treatments. The total treatment load was decreased by 24%. The higher cost of levalbuterol was offset by the decrease in personnel costs. With the reduction in treatment load, our staffing problem was mitigated. There was a substantial decrease in the number of missed treatments caused by RT-unavailability. In a similar analysis, with the Aero-Eclipse the reduction in personnel cost associated with Aero-Eclipse's shorter treatment times exceeded the Aero-Eclipse's higher cost.[7,8]

We further evaluated using 0.63 mg levalbuterol every-8-hours dose for all patients. We set up a similar protocol and collected data for 4 months. The 0.63 mg every-8-hours group did not perform as well as the 0.63 mg every-6-hours group or the 1.25 mg every-8-hours group. In the 0.63 mg every-8-hours group the total daily dose was 1.88 mg, whereas the total daily dose in the 0.63 mg every-6-hours group was 2.5 mg, and the group that did the best was the 1.25 mg every-8-hours group, with a total dose of 3.75 mg. The difference in total daily levalbuterol dose probably explains that finding.

For patients who cannot use the Aero-Eclipse with mouthpiece, a mask can be used, and the Aero-Eclipse can be set for continuous nebulization. We did not collect data on how many patients used the Aero-Eclipse with the mouthpiece verses with the mask, so our data represents a mix of mouthpiece use and mask use.

It was unclear what the levalbuterol dose should be with the Aero-Eclipse. With racemic albuterol the standard MDI dose is 0.18 mg and the standard SVN dose is 2.5 mg. With levalbuterol the standard SVN dose is 1.25 mg. Our pulmonary function testing data indicated that 1.25 mg levalbuterol via Aero-Eclipse with mouthpiece was too much, because of unacceptable adverse effects. The Aero-Eclipse can deliver 2–4 times as much drug as an SVN, but in Aero-Eclipse's continuous-nebulization mode the amount of drug lost to the atmosphere is not known. To better understand dosing, device data also need to be collected.

Dealing With an Increased Work Load: Evaluating Tiotropium and Developing a Respiratory Care Protocol

In 2004, Crouse Hospital is in sound financial shape. There has been a marked increase in the number of patients, and the respiratory care department's monthly number of aerosol treatments has almost doubled. The every-4-hour treatments were almost completely eliminated, and the vast majority of treatments are delivered every 6 hours. Because of the marked increase in the number of aerosol treatments, the number of treatments missed because of RT unavailability again increased, so we needed substantial changes to the protocol. Again we needed to find a way to decrease the number of treatments or otherwise deal with the increased workload. We studied the bronchodilator tiotropium, which is administered once a day, as a possible partial solution to our workload problem. We tried (1) once-a-day administration of tiotropium, (2) better utilization of the Aero-Eclipse to maximize the time efficiencies with the mouthpiece mode, and (3) utilizing concentrated levalbuterol.

The data that supports the use of tiotropium is compelling. Tiotropium is a selective anticholinergic, and its duration of action is markedly longer than other bronchodilators. Compared to ipratropium, tiotropium's total dyspnea score is better and the number of breakthrough treatments and exacerbations per year is less.[9] Tiotropium can be delivered once a day, which eliminates a large number of aerosol treatments. However, tiotropium is only available as an inhalable powder, in the HandiHaler (Fig. 5) (made by Boehringer Ingelheim), which restricts its use to patients who are able to use the mouthpiece. The RT must assess the patient's ability to use the dry powder inhaler device. Despite the limitation that it can't be used with a mask, administering tiotropium during the day shift

Fig. 5. The HandiHaler powder inhaler. (Courtesy of Boehringer Ingelheim.)

mostly eliminates anticholinergic aerosol treatments in the evening and night shifts, which reduces RT workload. The time savings from personnel cost approximately equals the higher cost of the tiotropium. Any reduction in breakthrough treatments or in length of stay would increase the advantages of tiotropium over ipratropium.

The availability of levalbuterol concentrate helps to maximize the benefit of the Aero-Eclipse. The smaller the volume in the Aero-Eclipse, the less time it takes to nebulize. The smallest volume that can be effectively nebulized with the Aero-Eclipse is 1.0 mL. We found in our pulmonary function testing laboratory that we could deliver undiluted racemic albuterol in less than 3 min. It was our assumption that we could do the same with undiluted levalbuterol. The Aero-Eclipse is most cost-effective with small volumes of medication and short administration time. Patient satisfaction is also better with shorter treatment-time, when the patient is breath-activating the device.

The new protocol has the RT assess the patient's ability to use the Aero-Eclipse with the mouthpiece. Those patients who can use the mouthpiece receive one half of a 1.25-mg unit dose of levalbuterol 3 times a day, and every 2 hours as needed. Using the Aero-Eclipse with mouthpiece, the effective delivered dose should be approximately 0.63 mg. The volume of the half unit dose is 1.5 mL. If an anticholinergic is ordered, the patient receives tiotropium, via HandiHaler, once a day, during the day shift. The total daily administration time should be approximately 3 min for each of the levalbuterol or tiotropium treatments, making a total delivery time of approximately 9–12 min a day. Approximately 60% of our in-patients are in that group. Patients who cannot use the mouthpiece receive, via Aero-Eclipse with mask, 1.25 mg of levalbuterol concentrate (which comes in a 0.5-mL vial) mixed with 0.5 mL of saline, for a total administered volume of 1.0 mL, delivered 3 times a day, and every 2 hours as needed. If an anticholinergic is ordered, the patient receives, via Aero-Eclipse with mask, half a unit dose of ipratropium, mixed with 1.25 mg levalbuterol concentrate, for a total administered volume of 2.0 mL, delivered 3 times a day. The assumption is that, with the mask, half the drug is lost to the atmosphere, so the levalbuterol dose is doubled. The administration time is in the range of 3–4 min, so with 3-times-a-day delivery, the total daily delivery time is in the range of 9–12 min.

The Pharmacy and Therapeutics Committee reviewed and accepted our protocol. We will collect data on use of the Aero-Eclipse with the mouthpiece and with the mask, and data on levalbuterol with and without tiotropium or ipratropium. A review of the first 1,000 levalbuterol treatments indicates far fewer breakthrough treatments than with the every-4-hours racemic albuterol. The majority of our aerosol treatments are now on an every-8-hours schedule, with minimal breakthrough treatments. In the first month, the number of missed treatments due to RT unavailability decreased 60%.

Adopting Patient-Focused Respiratory Care: Benefits to Patients, Respiratory Therapists, and the Hospital

Our respiratory care department is transitioning from being a task-oriented department to being a patient-focused department. The goals are to enhance the professional practice of our RTs, to most effectively use our respiratory therapy consult service, and to promote our RTs as the primary agents in COPD disease management. The RT's value is maximized when he or she is involved in higher-level functions, including conscious sedation, respiratory consultation, and disease management. It is difficult to advance professional practice unless we take better control over the tasks, and our respiratory care protocols have improved control over RTs' time, increased efficiency, and changed the way respiratory care is practiced at Crouse Hospital. The 3 new technologies we adopted (Aero-Eclipse, levalbuterol, and tiotropium) are more expensive than their predecessor technologies, but the benefits—to patients, to cost-containment, and to optimizing the use of highly-trained professionals—associated with the new technologies far outweigh the higher cost of the new drugs and device, because time is money.

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The questions for each session in the proceedings are found in pages 34-37.

The Benefits of Respiratory Care Protocols

Patrick J Dunne MEd RRT FAARC

Objectives:

1. State at least 2 advantages of providing protocol-based care.
2. Provide examples of misallocated respiratory care services.
3. Describe at least 2 impediments to the implementation of protocol-based care.
4. Describe the essential components of assessment-driven protocols.
5. List factors that could hasten the development and implementation of protocol-based care.

Questions:

1. Which of the following is a desirable outcome of providing protocol-based care?
   a. Access to patient care can be controlled.
   b. Patient care is individualized and appropriate for clinical condition.
   c. Treatments and procedures can be more evenly assigned.
   d. Individual providers have less job responsibilities and can therefore be more productive.

2. Which of the following is an example of the misallocation of respiratory care?
   a. Routinely providing prescribed treatments at a lower frequency.
   b. Continuing to administer prescribed treatments when there is no discernible clinical response.
   c. Prescribing care and treatment based on patient condition and acuity.
   d. Assessing the continuing need for care.

3. Which of the following pose potential obstacles to the development and implementation of protocol-based care?
   a. Physician concern about abrogating responsibility for care.
   b. Institutional hesitancy toward radically new care paradigms.
   c. Practitioner concern over job security.
   d. All of the above.

4. In an assess-treat-evaluate approach to providing respiratory care, which of the following is/are true?
   a. Initial assessment data establishes a baseline for further comparisons.
   b. Treatment regimens are periodically re-evaluated to ensure continued medical necessity.
   c. Practitioners cease focusing on administering a pre-determined volume of assigned treatments.
   d. All of the above.

The Benefits of Asthma Care Protocols in Acute Care

Timothy R Myers BS RRT-NPS

Objectives:

1. Describe the benefits of implementing asthma protocols.
2. Discuss the improved clinical, financial or patient benefits of emergency department protocols for asthma.
3. Discuss the improved clinical, financial or patient benefits of inpatient asthma protocols.
4. Identify key outcomes that should be monitored for guideline-based asthma care in the emergency department.

Questions:

1. Based on the National Heart, Lung, Blood Institute guidelines for emergency room asthma management, which of the following is not considered a standard of treatment?
   a. Inhaled β agonists and anticholinergics
   b. Systemic corticosteroids.
   c. Broad spectrum antibiotics
   d. Supplemental oxygen based on response to previous therapy

2. Which of the following outcomes was most frequently cited (4 studies total) to have a decrease in the emergency department studies?
   a. Costs
   b. Recidivism
   c. Admission rates
   d. ICU admissions

3. Which of the following study designs were most common in this article?
   a. Sequential study design
   b. Prospective
   c. Double-blind, randomized control
   d. Retrospective

4. Which of the following are potential benefits to asthma protocols?
   a. Improved patient care and education
   b. Improved clinical processes of care
   c. Reduction in asthma care costs
   d. All the above

Nebulizer Selection: Options Available to Maximize Aerosol Delivery

Dean R Hess PhD RRT FAARC

Objectives:

1. Describe the principle of operation of a jet nebulizer.
2. Discuss factors that affect the performance of a jet nebulizer.
3. Describe methods that are used to increase the performance of a jet nebulizer.
4. Describe the principle of operation of a vibrating mesh nebulizer.
5. List factors that affect nebulizer performance during mechanical ventilation.

Questions:

1. Which of the following best defines dead volume?
   a. The volume of solution remaining in the nebulizer at the end of therapy
   b. The volume of solution placed into the nebulizer cup.
   c. The inhaled mass delivered from the nebulizer.
   d. The amount of aerosol wasted during the expiratory phase

2. Which of the following is the optimal flow to power a jet nebulizer?
   a. 4 L/min
   b. 6 L/min
   c. 8 L/min
   d. 10 L/min

3. Which of the following affect aerosol delivery from a jet nebulizer?
   a. Fill volume of the nebulizer
   b. Gas flow to power the nebulizer
   c. Density of gas to power the nebulizer
   d. All of the above

4. Which of the following are methods used to decrease aerosol waste during the expiratory phase when using a nebulizer?
   a. Aerosol collection bags
   b. Breath-enhanced techniques
   c. Breath-actuated techniques
   d. All of the above

Breath Actuator Nebulizer and Levalbuterol Help to Manage a Shortage of Respiratory Therapists and to Contain Costs: Development of a Respiratory Care Protocol at Crouse Hospital

Russell A Acevedo MD FAARC

Objectives:

1. Describe the clinical advantages and treatment issues of using a breath-actuated nebulizer.
2. Discuss the differences in the isomers of racemic albuterol and the clinical advantages of levalbuterol.
3. Describe the differences between ipratropium and tiotropium.
4. Present a model for utilizing protocols to evaluate and implement new technologies.
5. Discuss economic models where time and efficiency savings offset increased device or drug costs.

Questions:

1. The breath-actuated nebulizer is most cost-effective when:
   a. Used in mask mode
   b. Used in continuous mode
   c. The medication volume is close to 1.0 mL
   d. The medication volume is close to 3.0 mL

2. Lavalbuterol, the R-isomer of racemic albuterol, has been shown in practical and clinical studies to have the following properties:
   a. Anti-inflammatory
   b. Primarily responsible for the bronchodilatory actions of racemic albuterol
   c. Greater improvement in FEV_1 at lower doses compared to racemic albuterol
   d. Long acting
   e. All of the above

3. Tiotropium, when compared with ipratropium:
   a. Has a longer duration of action
   b. Has greater need for breakthrough treatments
   c. Costs less
   d. Is a non-selective anticholinergic

4. The most expensive cost in aerosol delivery is:
   a. The nebulizer
   b. The bronchodilator
   c. The anticholinergic
   d. The therapist

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