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American Association
for Respiratory Care

Notes from the Guest Editor

by Heidi Weston, RRT

Once again it is my pleasure to serve as guest editor of the Bulletin. I hope all of you have found the past few issues informative and educational.

Our focus this issue is on noninvasive positive pressure ventilation (NPPV). Jacquelyn McClure, BS, RRT, manager of reimbursement services at Respironics, addresses some of the questions that were raised in a previous Bulletin article through a report on a Consensus Conference that was held recently to determine indications and coverage policies for this device. An update of the proposed government policy on NPPV therapy follows that article.

Our next issue will focus on updates and guidelines concerning the Joint Commission on Accreditation of Healthcare Organizations; Department

of Transportation; Occupational, Safety and Health Administration; and Food and Drug Administration.

With the new Bulletin format there has not been enough space to include all of the topics set forth during the Home Care Section meeting last year in New Orleans. As a result, the January-February issue will cover liability, CQI processes, and risk management, as well as the minutes from the section meeting that will be held in Atlanta.

Now is the time to be thinking about topics that you would like to see included in the 1999 issues of the Bulletin. As the NPPV update in this issue confirms, topics and concerns that are addressed in this publication are utilized, discussed, and follow-up on by leaders in our profession. ■

Consensus Conference Observer: NPPV Overview

by Jacquelyn McClure, BS, RRT, manager, reimbursement services, Respironics, Pittsburgh, PA

Editor's Note: The information contained in this document is solely Respironics' interpretation of the conference findings.

The National Association of Medical Direction of Respiratory Care (NAMDRC) recently hosted a consensus conference to look at the clinical indications for the use of noninvasive positive pressure mechanical ventilation (NPPV) in the home. The conference also sought to assist the Durable Medical Equipment Regional Carrier (DMERC) medical directors in assisting HCFA in the development of an appropriate coverage policy for noninvasive ventilation in the home for Medicare beneficiaries.

Recognized expert physicians in this field and selected representatives from professional organizations were invited. The invited organizations included: ACCP, ATS, ACP, ASDA, AAFP, AAHCP, and AARC. Manufacturers and suppliers were invited to send a limited number of observers to the meeting and were provided the opportunity to comment on discussions.

The agenda consisted of three presentations given by the leading experts in the field. Discussion and comment periods followed, and work groups were assigned tasks to accomplish—specifically, to consider the needs of the restrictive thoracic disorder population, the COPD population, and the sleep apnea/hypoventilation population.

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"Consensus Conference" continued from page 1

The draft Medicare coverage policy followed the consensus conference results. (See following article.) Draft policy guidelines will be submitted for public comment before a final Medicare coverage policy is adopted. The entire conference results will be published in CHEST, probably in the fall of 1998.

The following are the preliminary clinical indications for NPPV in the home:

Restrictive thoracic disorders: Most common disorders would include sequelae of polio, spinal cord

injury, neuropathies, myopathies and dystrophy's, amyotrophic lateral sclerosis, chest wall deformities, and kyphoscoliosis.

Indications for use: symptoms = fatigue, dyspnea, morning headache, and one of the following physiologic criteria—

- $\text{PaCO}_2 \geq 45\text{mmHg}$
- Nocturnal oximetry demonstrating oxygen saturation $\leq 88\%$ for five consecutive minutes
- $\text{MIP} \leq -50\text{cmH}_2\text{O}$ or $\text{FVC} \leq 50\%$

COPD: Most common obstructive lung diseases would include bronchitis, emphysema, bronchiectasis, and cystic fibrosis.

Indications for use: symptoms = fatigue, dyspnea, morning headache, and one of the following physiologic criteria—

- $\text{PaCO}_2 \geq (55\text{mmHg?})$ [General discussions revolved around an entry level for PaCO_2 of 50mmHg .]
- $\text{PaCO}_2 (50-55\text{mmHg?})$ and nocturnal desaturation ($\text{SpO}_2 \leq 88\%$ for five continuous minutes while on oxygen therapy at 2lpm) [General discussions revolved around an entry level for PaCO_2 of $45-50\text{mmHg}$.]
- $\text{PaCO}_2 (50-55\text{mmHg?})$ and hospitalization related to recurrent (>2 in a years time) episodes of hypercapnic respiratory failure. [General discussion revolved around an entry level for PaCO_2 of $45-50\text{mmHg}$.]

Mixed sleep apnea/hypoventilation: Before considering a mixed sleep apnea patient for NPPV, a physician must establish and document an appropriate diagnosis on the basis of history and physical examination. A polysomnogram (PSG) is required for diagnosis of sleep apnea. A CPAP trial is recommended as treatment unless a previous CPAP trial was unsuccessful or there is significant hypoventilation which is felt to require ventilation and

be unlikely to respond to CPAP alone, or Central Sleep Apnea (CSA) is present and requires ventilation, with a rate setting.

Indications for use: PSG criteria for one of the following—

- For mixed sleep apnea not responsive to CPAP
- For hypoventilation not responsive to CPAP
- For CSA (Central Sleep Apnea)

Initiation of NPPA:

- May be in the outpatient or inpatient setting
- Should be performed by personnel experienced and skilled in the treatment of NPPV under the direction of a physician experienced and skilled in the treatment of NPPV

Documentation for medical necessity should:

- Document diagnosis
- Document indications
- Provide required device settings—
 - Initial setting guidelines for the pressure support ventilation titration required, such as tidal volume, pressure, inspiratory time, to be adjusted by personnel experienced and skilled in the treatment of NPPV and under the direction of a physician experienced and skilled in the treatment of NPPV.
 - Final IPAP and EPAP settings must be documented at the 60 day reassessment. (rate) [supplemental oxygen (flow rate or FiO_2)] [alarms (as clinically indicated)]

Monitoring of effectiveness

- Physician reassessment of patient adherence with the use of NPPV at 60 days (machine usage of ≥ 20 hours/week for 1-2 months)
- Ongoing monitoring and yearly recertification by physician ■

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Visit us on the Internet—
<http://www.aarc.org>

New Website for Oxygen Dependent Patients

The AARC is proud to introduce the Breathin' Easy website, <http://www.oxygen4travel.com>, designed to make traveling easier for oxygen dependent patients.

The website lists information on oxygen refill sites throughout the United States and also provides consumer information like the AARC "Traveling with Oxygen" guide and other related travel tips. Visitors to the site will also find helpful links to other websites that might be useful to the oxygen user on the go.

This innovative new site is based on the Breathin' Easy Travel Guide which has for the past two years served as an excellent resource for traveling oxygen users and also for the home care providers and therapists who work with them. Now the indispensable information provided annually in the travel guide is online for easy reference to the most current information and some also provide e-mail and website links.

Visitors have unrestricted access to the information on the site, and it

is provided free of charge. Visit the new Breathin' Easy website and discover all it has to offer and then encourage your oxygen dependent patients to take advantage of the information available right at their fingertips.

If you would like information about promotional opportunities with the Breathin' Easy website, contact Tim Goldsbury by e-mail, goldsbury@aarc.org, or by telephone at 561/745-6793. ■

DMERC Policy May Restrict NPPV Therapy

At the request of the Health Care Financing Administration, the National Association for Medical Direction of Respiratory Care (NAM-DRC) held a consensus conference on noninvasive positive pressure ventilation therapy (NPPV) in Washington late last winter. (See previous article.)

The AARC and other groups gath-

ered to develop guidelines and appropriate clinical indicators for NPPV therapy. The durable medical equipment regional carriers (DMERCs) have now issued the draft of their policy for coverage of NPPV therapy. Unfortunately, the draft differs significantly from the recommendations produced by the February meeting. If

left unchanged, the policy would significantly affect a Medicare beneficiary's ability to receive NPPV therapy.

The AARC is in the process of developing extensive comments to the draft policy. Those comments will be posted on AARC Online (www.aarc.org) in their entirety as soon as they are finalized. ■

HME Update

by Cheryl West, MHA, AARC director of government affairs

The Health Care Financing Administration (HCFA) has been hard at work on a number of issues concerning home respiratory care:

Surety bonds: HCFA recently issued a proposed rule setting the requirements for HME suppliers to obtain the surety bonds that will now be necessary to participate in the Medicare program. At or about the same time, HCFA also issued a set of surety bond regulations for home health agencies. These were much more restrictive and demanding than those required for HME dealers. The home health care industry protested its surety bond requirements so strenuously that HCFA rescinded, at least until February of 1999, the requirement that HHAs obtain a surety bond. The HME industry is also requesting a postponement in the implementation of its surety bond requirement. HCFA has indicated

that HMEs will not be required to obtain the surety bonds until a final rule is published, perhaps sometime this fall.

Competitive bid project: Polk County, FL, was selected this summer as the first site for the HCFA demonstration project on competitive bidding. HCFA has already begun to hold HME "bidders" conferences and has also initiated an information campaign aimed at the county's Medicare beneficiaries. HME suppliers will probably have to begin submitting bids in one or more of the five categories of like items and services late this winter. (Oxygen therapy is one of the five categories.) The project is slated to begin in April of 1999.

Inherently reasonable (IR): HCFA now has expanded authority to raise or lower, by 15% per year, items it deems over- or under-priced.

HCFA has put the industry on notice that it is studying seven items. Most people believe these will be the first items to come under the new expanded IR authority and thus subject to lowered reimbursement fee schedules. The seven items are: lancets, gel mattress pads, glucose test strips, catheters, enteral products, eyeglass frames, and albuterol sulfate.

Compliance programs: HCFA has issued a proposed rule that would require HME suppliers to develop a formal and written compliance program in order to participate in the Medicare program. The majority of the requirements set forth in the regulation are straightforward "good business" practices and meet current Medicare supplier standards. It is unclear when this rule will become final. ■

FYI . . .

New reports profile changing dynamics of the home care marketplace

According to a new set of reports released by Medical Data International late last summer, the impact of managed care on the home care products market is visibly slowing. In its place, new factors are emerging as the key determinants of future market gains. The cumulative dollar volume of these markets is expected to approach \$4.4 billion by the year 2002.

The two reports, *The Impact of Managed Care on Home Care Product Markets* and *U.S. Markets for Home Care and Alternate Site Products*, conclude that traditional social and medical indicators, such as demographic trends and changes in the prevalence and incidence of major chronic diseases, will emerge as the key determinants of future market gains. Opportunities for manufacturers now and in the future will lie in the continued evolution of home care toward disease management, reconfiguration of technologies to home-based applications, and increasing sophistication of the diagnostic and therapeutic approaches to home-based patient care.

In order to stay competitive, manufacturers will need to be able to recognize the growth opportunities associated with the treatment of chronic diseases in alternate sites, especially those which utilize a disease management approach emphasizing prevention and integrated management. In the years ahead, say the reports, home/alternate care providers will be willing to pay for the medical devices which support such proactive patient care.

Medical Data International is a business knowledge company serving the medical technology and managed care segments of the worldwide health care industry. (PRNewswire)

Studies disagree on home care savings

Treat patients in their homes and you'll save money, right? Two new studies offer conflicting answers to that question.

Not so, say investigators from England who conducted a randomized, controlled trial comparing the costs and quality of at-home care and inpatient care for surgical conditions, including hip replacement, knee replacement, and hysterectomy; and illnesses such as chronic obstructive air-

ways disease and diseases related to old age.

The study, which involved 538 patients, found no cost savings for patients being treated for hip or knee replacement or for elderly patients. Home care was actually more expensive for those recovering from hysterectomy and patients with chronic obstructive airways disease. While there was no significant difference in health outcomes for most of the conditions treated at home, knee replacement patients and some of the elderly patients did experience complications that required follow-up care.

Another British study that compared 241 elderly patients discharge early to home with those who remained hospitalized, however, found a significant cost savings for the home care group with no differences in mortality rates or quality of care. An economic analysis showed that four patients could receive home care for about the same cost that three patients could receive inpatient care. Most of the patients were suffering from orthopedic conditions.

Both studies were published in the *British Medical Journal*.

Antireflux therapy improves asthma symptoms but not lung function

The treatment of gastroesophageal reflux (GER) disease in asthmatics may reduce asthma symptoms and reduce the need for asthma medication but has minimal or no effect on lung function, say researchers from the University of Calgary in Alberta, Canada, who reviewed 171 peer-reviewed studies involving 326 patients. The study was published in the July issue of CHEST, the journal of the American College of Chest Physicians.

Researchers note that the association between GER and asthma has been reported in the literature for the past 35 years, and symptomatic GER is known to be about four to five times more prevalent in patients with asthma than in other patient groups. Hiatal hernia and esophagitis are also more prevalent in asthmatics.

The authors report that of the 171 studies, only 12 were published on antireflux medication in asthmatics with GER. Within these 12, comparison of findings was difficult because of differences in study design and the fact that different

medications and doses were used over a 15-year period. However, the inclusion of studies using different regimens was justified by the fact that the outcomes were so similar.

The analysis of the combined data showed that among asthma patients with GER who were treated with anti-reflux therapy:

- asthma symptoms improved in 69%
- asthma medication dose was reduced in 62%
- evening peak expiratory flow improved in 25%
- spirometry (in any of the placebo-controlled studies) did not improve.

The authors were surprised by the findings. "The challenge for future investigators will be to explain the paradox of the strong association between GER and asthma and between improvement in asthma symptoms with anti-reflux therapy and the absence of demonstrable changes in lung function," they say, adding that it remains to be determined which asthmatics will benefit from anti-reflux therapy. (Source: ACCP Press Release)

Impaired breathing may raise stroke risk

High blood pressure, prior stroke, and having an irregular heartbeat are all well-established risk factors for stroke. Now Australian researchers have added another risk factor to that list: impaired breathing. Their study of the hospital and death records of 2,805 men and women over the age of 60 found that those whose peak expiratory flow was most impaired by chronic bronchitis had a 77% higher risk for having a stroke when compared to those whose breathing was the least impaired.

"The relationship between impaired peak expiratory flow and ischemic stroke has not, to our knowledge, been previously reported," say the authors. "A suggested link between inflammation and atherosclerosis is very topical, especially with recent research on the link between respiratory infection and heart disease. Our data allows the possibility of speculation and extrapolation, but more specific research needs to be done on this link."

The study was published in the June issue of *Stroke: Journal of the American Heart Association*. (Source: AHA Press Release) ■