



# Diagnos**t**ics

Nov./Dec.'98

Bulletin

## Notes from the Chair

by Carl Mottram, RRT, RPFT

By the time this issue is published I will have had the opportunity to serve as the chair of the Diagnostics Section for a complete year. I would like to thank the leadership of the section for their continued commitment. Cathy Foss, our chair-elect, and the co-editors of the *Bulletin*, Mary Kay Collins and Vickie Ganey, have been exceptional in their devotion to meeting the needs of our membership. I am routinely complimented on the quality of our *Bulletin*, and I cannot thank the co-editors enough. I also want to offer my congratulations to Vickie for being named our Specialty Practitioner of the Year. It is a well-deserved honor.

Although not all of my goals were achieved in the past year, I still believe we have one of the best specialty sections in the AARC, and it has been my pleasure to serve as chair. I am looking forward to another eventful year.

This issue of the *Bulletin* is dedi-

cated to sleep diagnostics. The evolution of the sleep diagnostic field has been nothing short of phenomenal. During my career I have seen our sleep lab at the Mayo Clinic grow from a small (one room) section of our pulmonary lab to a 13-bed sleep diagnostic center known throughout the world for its innovation and outcomes. The methodology of diagnosing sleep disorders continues to evolve with the advent of paperless, computer-assisted data acquisition processing software. Technology has recently even pushed the envelope of where and how some sleep testing can be performed. Many respiratory therapists find themselves choosing this profession as a natural career path, since many of the diagnostic and therapeutic modalities of this field parallel areas of their clinical background and expertise. ■

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## Specialty Practitioner of the Year:

Vickie Ganey, MBA, RRT, RPFT, RN

All of us in respiratory care are well aware of the need for greater multiskilling in our profession. As health care reforms continue to foster cost cutting measures in our nation's institutions, practitioners with a wide array of skills – some even outside of their traditional scope of practice – are the most sought-after personnel.

Our Specialty Practitioner of the Year for 1998 exemplifies this philosophy, not only through her efforts to spread the word about multiskilling in numerous articles in this publication, but also by setting an example that we all can follow. A quick look at the string of credentials following Vickie Ganey's name tell the story. Not only has she earned her RRT and RPFT

credentials, but recently went back to school to acquire an RN and an MBA as well.

The extra effort that Vickie has invested in formal education has paid off, both on the job as manager of the cardiopulmonary services department at Halifax Regional Hospital in South Boston, VA, where she is responsible for managing a wide array of services, and in her volunteer efforts on behalf of the section. Vickie regularly brings this wealth of knowledge to her position as co-editor of the *Bulletin*, and is also one of the primary members of our leadership team, helping to determine important future directions for respiratory diagnosticians. Congratulations Vickie! ■

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# The Visit

by Mary Gable, RPSGT, coordinator, Idaho Sleep Disorders Laboratory

There was a sense of excitement in the air – or was it a sense of foreboding? The paper clips sparkled under the fluorescent lights, the desk counters were clean and clear, and the file cabinets were neatly arranged. Everyone stood around waiting; some were

chewing their nails, some looking at the wall clock every few minutes, and some of us were pacing quietly up and down the hall.

The bedrooms had been given a special “grooming” that day. Housekeeping bustled here and there, shampooers hummed, and flies were coaxed out of light fixtures. Even the hook-up room looked great – no sticky gauze pads lying around, no electrode collars on the floor, and only a slight hint of the essence of Collodian hanging around the corners. So what was everyone doing in an otherwise empty sleep lab at 7 p.m., and why did everything look like a “Kodak moment”?

The answer, of course, was the anxiously awaited, mind-numbing, gut-wrenching, ego-humbling ACCREDITATION SITE VISIT!!

As we stood around waiting for the site visitors to arrive, I reflected on the hours of effort it took to get us to this point in time. We had already been accredited as a sleep-related breathing disorder laboratory three years ago and felt that we had the best sleep lab in the state. Then, last year, we were fortunate to have a physician boarded in sleep medicine become one of our medical directors. Now we had the last requirement necessary to apply for accreditation as a Sleep Disorders Center. This would enable our facility to diagnosis and treat all types of sleep disorders such as narcolepsy and insomnia.

Before I go on, let me explain how the process begins. If you are planning to submit an application to the American Sleep Disorders Association (ASDA) for accreditation status as a sleep disorders laboratory or sleep disorders center, or if you have already submitted your application and are awaiting your first site visit, this information may help.

It all starts with the application. When I contacted the ASDA for information about applying for our first accreditation, I spoke in length to a very nice, very candid, and very knowledgeable individual who told me right off that the application itself takes about a year to complete. “Oh really?” I said, rolling my eyes and thinking, “You don’t know how fast I can type, buddy!” He then explained that we would receive a packet consisting of a blank application and a guideline on the ASDA’s requirements for accredited facilities. You just follow the guideline, and type the

answers to match. Sounds easy, doesn’t it? Well, it is easy, *sort of*, if you have a perfect facility and are doing absolutely everything right. I knew we did and were, so I wasn’t too concerned – and besides, I can type fast, right?

The application is relatively easy to complete and the guidelines are fairly straightforward. If you aren’t sure about anything, you can call the ASDA office and someone will explain the process step-by-step. Don’t be afraid to ask, and don’t be afraid to ask again if you don’t understand the first time. The staff there are knowledgeable and eager to help. After all, they want a good application too. Some of the questions are a little confusing the first time around, but after you read and re-read the guidelines, they usually clear up. One of the catch phrases that I began using on a fairly regular basis was, “They want WHAT?” And remember, our lab was the best!

Actually, we did have a good head start because we were a good lab and we were doing almost everything the right way. That probably saved at least two years of effort. If you are not doing things the way the guidelines suggest, then you had better start doing them the right way as soon as possible.

Policies and procedures need to be written (and used), files need to be organized, and physicians’ signatures need to be obtained. Patient follow-up forms need to be created (and used). Even if you are doing the follow-up, you need to document that you are. Meeting minutes need to be gathered so you can show that you do hold those patient care conferences and you do have educational inservices on a regular basis. Copies need to be made of any marketing or public information you have generated. Papers showing the staff’s continuing education efforts need to be compiled. Safety and Procedure Manuals have to be accumulated, and procedures need to be written.

Now you know why it takes one year to finish the application! Yes, it took nearly 12 months for our first application to be completed and when it was finished, it measured just a bit over the 1-inch maximum height limit mandated by the ASDA. But I pushed down hard and squeezed the papers

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tightly into the notebooks they had provided - all four of them - and sent it off, registered, and insured. Yes, you have to send four copies of the application. (I should own stock in Xerox!)

Well, back to the present. After we received notice that our application was accepted, the site visit was scheduled for a few months later. The ASDA lets you know where you are as each step in the process occurs. We received notice that our visit would be in August, and we began some preliminary planning.

We decided to study only one patient that night. We normally do two tests a night, but why ask for extra problems, right? We also scheduled our most senior night technologist to be there. Now, let me make a suggestion. When choosing the individuals to work on the night of your inspection, look not only at their technical skills and knowledge, but also at their personalities. Can they stand up to close observation under tension? Some people can and others cannot. Even the best, well-trained technologist can turn to quivering Jell-O when a site inspector is closely observing everything he or she does. It's also important to choose that night's patient well and inform him or her ahead of time that there will be an inspection and get his or her permission.

Our technical advisor, our two medical directors, and myself were also on hand to answer questions. And

let me tell you - they do ask questions!! They observed and inquired about our infrared lighting in the bedrooms; they asked how long our scheduling back-log was, how the test reports were transcribed and by whom; where the nearest crash cart was located; who responded to emergencies, etc. etc.

They also perused our policy/procedure manual, and asked to see charts on patients who had been tested and diagnosed with specific disorders - i.e., narcolepsy, periodic limb movements, insomnia, and apnea. While one inspector carefully read through the charts, the other observed the night tech setting up the computer. Then they both entered the hook-up room and watched our tech apply the electrodes.

Of course, nothing ever runs smoothly. It soon became apparent that there was a problem with the nasal thermistor channel. Our tech calmly attempted to fix the problem and, by the third or fourth try and after several nasty comments under her breath, it worked again. While everyone was sweating bullets in the monitoring room and the inspectors looked on, I asked if this kind of thing always happens during a site visit. They smiled and said it did. One of them also remarked how well our tech had done the trouble-shooting without panicking. (Little did they know!)

The next day was more of the same. The visitors arrived promptly at 8 a.m. and began meeting individually, behind closed doors, with our consultants (who represent pulmonary,

ENT, neurology, and psychology) and with our hospital administrator. I should mention that support from your hospital administration is very important and is closely examined. Then the inspectors put our medical director in the spotlight and asked him to go through the previous night's test on the computer, staging sleep and respiratory events.

At approximately 11 a.m. the inspectors went into seclusion for an hour to discuss our case. Then at noon, we pretended to eat lunch while they explained how very good we were in some areas and what could be improved in others. They don't tell you whether you passed or not. They do tell you it will be 4-6 weeks before you are notified.

I have to be honest and say that going through the accreditation process really is a good experience. It is important both professionally and financially to achieve status as an accredited lab or sleep center. In more and more states, insurance companies are denying payment to facilities that are not accredited. Also, many physicians will refer patients to a facility that is accredited over one that is not, knowing that their patients will receive qualified diagnostic testing and care.

It's also very rewarding to know that your facility has been rated by an organization that takes this responsibility very seriously. An accreditation is not a “Cracker-Jack” prize; it's something that has to be earned by lots of planning, effort, and teamwork. ■

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## **On the Impeachment of Clinical Outcomes: A Different Kind of “Star Report”**

*by Daniel V. Draper, MS, clinical applications manager, SensorMedics Corporation*

Stop me when this begins to sound familiar. On second thought, don't stop me. The familiarity of the following polysomnography chronology tends to lull us into a false sense of clinical success - a fragile sense of “mission accomplished.”

It seems that we have been a bit premature in determining the clinical endpoints of successful treatment strategies for obstructive sleep apnea (OSA).

Consider the following scenario (set early in the Year 2000):

Ross is a 54-year-old male complaining of excessive daytime sleepiness. He is overweight, with a Body Mass Index (BMI) of 30. He finds it difficult to find a dress-shirt that fits

the 18.5 inch circumference of his rotund neck. His snoring has forced his lovely wife Barbara to relocate her sleeping quarters to the carpeted floor of the bathroom, where the ventilation fan drowns out his persistent grunts, groans, and snorts - a veritable Chinese water-torture of sound.

Ross is referred to the sleep lab for evaluation, where it is quickly determined that he will undergo a complex polysomnographic evaluation. Within the first 90 minutes of the all-night evaluation, his aberrant sleep and staccato breathing behavior expose the severity of his OSA, and the night technologist enacts lab protocol to begin immediate CPAP habituation and titration. The CPAP is successful,

and the apneas, hypopneas, and respiratory effort-related arousals are abated. Arterial oxygen saturation values return to a stable, waking, baseline value, and appear to be constant. Cardiac sinus rhythm is normal and regular, with the expected variability during REM sleep, which has dominated the last third of the sleep study.

### ***The happy ending***

The decision is made to send Ross home with a CPAP machine. He is overwhelmed by an improved sense of holistic wellness. Barbara is nothing short of euphoric, and she no

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longer finds somnolent sanctuary beyond the bedposts. The bedroom is still characterized by periodic intervals of loud grunts and groans and moans, but of an altogether different origin.

### **The sad ending**

Four weeks later, Ross falls asleep at the wheel of his Yugo while returning from a campaign fund raiser in Hartford. The vehicle careens into a loaded school bus, and bursts into flames. Ross is killed, seven preschoolers are injured, and Barbara’s life is decimated.

Back at the sleep lab, the medical director, unaware of the demise of his patient, argues that the clinical outcomes of his laboratory prove the efficacy of the laboratory diagnostics and treatment regimens. In fact, Ross’ case is used as direct evidence of a typical positive patient outcome - the patient was very sick, was tested and treated, and made to “feel better.” Unfortunately, those who provide payment for procedures (the insurance companies and corporate entities that reimburse for the evaluations) see the case in a very different light.

The lab is unable to document good clinical outcomes. The reimbursed dollar amount per procedure is reduced to a level that is incommensurate with the economic viability of the lab. In June of 2000, the lab closes. The need for sleep testing within the community is well-established, but the polysomnography providers have failed to make a case for sustained good clinical patient outcomes for the procedures performed, and the brutal economics associated with running the lab have forced it to close.

Ross was a treatment success! Or was he? The CPAP worked! Or did it?

### **The impeachment of current clinical outcomes**

Ask anyone if CPAP or bilevel CPAP works to improve the well-being of a patient with documented OSA and they will likely wonder from which planet you have just arrived. “Of course it works,” they will say, and recount the many incidents where they believe the device has been life-saving. Anecdotally speaking, they are correct. We know, without a question of a doubt, that CPAP can make a person with OSA feel better, sleep better, and snore less. We determine these outcomes by simple methods,

such as a post-test interview, an Epworth Sleepiness Scale score, and a follow-up screening exam. But is the patient really experiencing improved health? Do CPAP patients actually live longer? Do they have fewer motor vehicle accidents after treatment? Is their hypertension normalized? Do they experience an overall better quality of life?

In most cases, we simply do not know.

In the classic sleep testing scenario, we document sleepiness before and after the test. Change in sleepiness is a measurable outcome. For example, the Epworth Sleepiness Scale is a limited psychometric instrument that can reliably show changes in the patient’s perceived state of sleepiness. For years, the documented changes in the Epworth pre- and post-treatment have been used as an outcome parameter, a tool to show that the intervention either is or is not successful. Prior to psychometric instruments like the Epworth, sleep professionals relied most heavily on the subjective data gathered by personal interview. Additionally, they used physiological indices of post-test improvement, like sustained and normal levels of arterial oxygen saturation (SaO<sub>2</sub>), as evidence that the patient had, indeed, improved, was “healthier,” or was even cured of the affliction that so severely affected his or her breathing throughout the night.

But the times are changing. It seems there has been a bit of a “rush to judgment” regarding the actual benefits of our therapeutic interventions for breathing problems during sleep.

### **The clinical outcomes of the new millennium.**

CPAP makes patients with severe disease feel better. It also makes patients with mild and moderate disease feel better. But in spite of these irrefutable facts, there is limited data on whether CPAP really makes its users healthier. In the famous (or infamous, depending on your point of view) report published last year in the *British Medical Journal* [BMJ Clinical Research Edition 1997;314 (7084):851-860] the authors sought to examine the actual research evidence for the health consequences of OSA, and the actual effectiveness and benefit of CPAP in the treatment of the disorder. They came to a stunning conclusion: after their massive literature review and analysis, they determined that “the effectiveness of continuous

positive airway pressure in improving health outcomes has been poorly evaluated.” In other words, they directly impugned the anecdotal evidence that CPAP works that has been accepted for years.

The report, which was conducted in the United Kingdom, listed a primary author by the name of Wright and was jokingly referred to as the “Wrong Report” by many. But its message did not fall on deaf ears. Many in the sleep testing community realized that they had done a poor job of actually documenting and publishing sustained good outcomes associated with CPAP use. The studies in the literature are largely either longitudinal, anecdotal, or case reports. The lack of powerful, high rigor, randomized controlled trials that truly show the efficacy of CPAP on relevant sleep outcomes is evident.

What the Wright, et.al. paper does demonstrate is that sleep laboratories of the future must do a better job of demonstrating sustained good outcomes for their patients. In fact, most believe that third-party payment and reimbursement for sleep testing procedures will be predicated upon the documentation of relevant outcomes. Justification for CPAP will require more and more evidence that it is genuinely effective in helping the patient establish an overall better quality of life – not that it simply makes them feel “less sleepy.” Think of sleepiness as a symptom. It is important to track sleepiness, and it is a component of the patient’s quality of life. However, the research that links the patient’s rating of sleepiness to long-term health consequences is lacking.

Some of the key outcomes that may be required documentation in the sleep lab of the future will be changes in:

- Motor vehicle accident history – are CPAP users safer drivers?
- Morbidity – are CPAP users actually healthier?
- Mortality – do CPAP users live longer?
- Quality of life – does CPAP truly improve the holistic living experience?
- Worker absenteeism – a major drain on corporate profits.
- Worker productivity – a major determinant of corporate profitability.

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Sleep labs that are able to document and demonstrate that their treatment interventions do, indeed, result in sustained good outcomes will, most likely, be the most viable and economically successful labs.

**The challenge: A different kind of “Star Report”**

So how does one track relevant outcomes? The process requires forethought and diligence. First, define the outcomes that your lab will track to document sustained good clinical outcomes. (Some labs may choose to document financial outcome parameters like cost per test in the lab versus cost in the alternate site.) Next, good outcomes analyses require that the laboratory or sleep-testing service develop and/or secure a database – a large data reservoir that can collect anthropometric, demographic, history

and physical, polysomnographic, and treatment-related data on individual patients and “pool it” in a common place. The database will allow lab personnel to search for relevant and sustained good outcomes across a population of individuals. This is where the concept of the “Star Report” comes in.

STAR is an acronym that stands for Sleep Trending, Analysis, and Reporting. It is not a product or commercial service. It is a mnemonic device used to demonstrate that the path to establishing a good outcomes reputation for your lab requires that you collect high quality data, that you look for trends and patterns in the data, and that you analyze those trends with data that reflect improved quality of life. As many individuals are amassed into a large database, the idiosyncratic characteristics that make us all different from one another begin to cancel each other out. Thus, we are able to scan population data for emerging outcomes that, hopefully,

demonstrate the efficacy of the treatment. If the polysomnographic and treatment data correlate with the desired outcome data, then reporting the sustained good outcomes becomes vital to the success of the lab. Indeed, it is the *report* of the evidence proving sustained good outcomes that is used as the interface to the third party payors, the corporate wellness program executive, and/or the hospital administration. This report is what will make or break the sleep lab of the new millennium.

*Start tracking clinical outcomes today and spare your lab the embarrassment of censure by the payors of tomorrow. We know what evidence is being sought, and it will be up to us to expose it, to trend and analyze it, and to report on it. But this will not, and cannot, happen overnight. (Although I suppose that depends on the meaning of the word “overnight” . . . )* ■

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## Radiofrequency Energy Proves Effective Against a Major Cause of OSA

Last year the FDA approved radiofrequency energy as an effective treatment to reduce snoring. Now a new study demonstrates that the same technology is effective in achieving tongue base reduction, a procedure previously done only with surgery to alleviate obstructive sleep apnea.

Eighteen subjects, (17 men) 27 to 61 years of age were recruited for the study. All had, at a minimum, failed palatopharyngoplasty. All underwent a history and physical examination, with a detailed airway evaluation with cephalometric radiographs and fiberoptic nasopharyngoscopy. This was to confirm that tongue base obstruction existed and that the palate region was clear or had been treated. Additionally:

- Each patient underwent nocturnal polysomnography to document sleep parameters and SDB severity.
- A cephalometric head film was taken prior to radiofrequency treatment to assess traditional airway measurements.
- Airway scanning was done on a GE Sigma 1.5 Telsa MRI scanner. Scans of the upper airway from the dorsum of the tongue to the pedicle of the epiglottis were taken on three separate occasions.
- Quantitative evaluations were taken to measure speech and swallowing before and after treatments.
- Questionnaires were administered to preclude research bias. Subject areas included quality of life, pain assessment, difficulty of speech, swallowing, and taste.

Radiofrequency energy was delivered at 465kHz using an RF generator with a custom fabricated needle electrode and delivery device. The 18 patients underwent 99 treatment sessions comprising 180 individual treatments, with a mean of 1.82 treatments per session. Pre- and post-treatment MRI data showed a reduction in tongue volume and increase in posterior airway space. The average reduction was 17.1% and was comparable to that achieved by surgical reduction techniques. Researchers believe this, along with a reduction in apnea by the test subjects, establishes the efficacy of the procedure. (Source: American Academy Of Otolaryngology-Head And Neck Surgery, 9/19/98) ■

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## New Product Suggestions

As you know, new product development is an important component of the services that any association provides its members. But where do these new products originate?

Quite often they originate with you. You and your staff encounter problems and needs everyday. Perhaps you require an educational product on a procedure or disease. Or maybe you need a manual to help you manage

certain components of your department.

Tell us what products or services the AARC can develop that will help you perform your job. We will research your suggestion, and if it is viable, produce it and make it available to the profession.

Please provide the following information when submitting your product or service suggestion:

- Brief description of the product
- Describe who will use this product
- Tell why you believe potential users will buy this product
- List your name, member number, and specialty section/committee

Send this information to: New Products, AARC, 11030 Ables Lane, Dallas, TX 75229; email: info@aarc.org; FAX: (972) 484-2720. ■

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