Section Business
Meeting Minutes

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Notes from the Chair
by Carl Mottram, RRT, RPFT

The secret of success is constancy to purpose.
– Benjamin Disraeli (Earl Beaconsfield) 1840

I would like to express my appreciation to all the practitioners who attended our section business meeting at the AARC’s International Respiratory Congress in Atlanta. It was great to gather with other practitioners interested in the diagnostic arena. I only wish that each and every one of our members could have attended, but I do realize this is not possible, so I invite you to review Cathy Foss’s report of the minutes of that meeting in this Bulletin.

The most important topic of discussion at the meeting was the critical need to increase the membership in our section. As the AARC moves to a new and exciting method of governance, sections with memberships greater than 1,000 will have representation on the Board of Directors via a seat held by their section chairs. Currently, the Diagnostic Section does not qualify for this representation. Therefore, it is extremely important for all of us to encourage our colleagues in the diagnostic field to become section members. We have an excellent opportunity to shape the future of the organization, but our ability to do so will be limited if we are not represented on the Board.

As I look at the “benefits” of being a member of our section, I think it is clear that we have the value-added product that is worth the cost of membership. In recent years we have changed the format of the Bulletin to bring specific and timely information to our members. This information is almost impossible to find, collectively, from any other source. Our educational issues have been well represented at the national meeting as well because of the commitment and strength of our section and its leaders.

So please make your colleagues aware of the importance of membership. All practitioners specializing in diagnostics need to join the section in order to ensure our continued success. Personally, I am looking forward to another exciting year as chair, and I want all of you to feel free to contact me at anytime to share your thoughts and ideas on ways to improve our section.

Notes from the Medical Director: Point-of-Care Blood Gas Testing — Where Do We Go from Here?
by Peter Southorn, MD

The US military reported that point-of-care (POC) blood gas testing in the field saved lives when they were recently assisting the victims of natural disasters in South America. Nearer to home, our Mayo Clinic helicopter flight nurses found the same thing. These two examples illustrate current applications of POC blood gas testing. Depending on the situation in various hospitals, such tests have been employed to help manage medical emergencies (including cardiac arrests), provide blood gas services to geographically peripheral outlying patient areas, and provide a source of testing when the central lab capability is limited due to staffing or cost considerations.

“Point-of-Care” continued on page 2
Laboratory-based blood gas analysis started some 30 to 40 years ago and had a profound effect on acute care medicine. Prior to the introduction of POC testing, the two major innovations in the field were changes in equipment design that made the technology more user-friendly and reduced maintenance and the introduction of a mass of regulations for oversight by third parties.

Broader application of POC testing potentially offers a further, significant advance in the care of critically ill patients. Studies have shown that results obtained using POC testing equipment are as good as those which can be achieved using laboratory-based equipment. POC testing also requires less blood volume, an important consideration for some patients, such as neonates. The possibility of cost savings also exists because POC testing requires fewer people to execute the test.

We still don’t have enough data to assess whether such testing improves patient care and saves costs by reducing the turn around time between ordering the tests and initiating therapy. A recent study, however, did report on this issue in one specific situation where POC testing was utilized in the care of patients after coronary artery bypass surgery. (1) The investigators found that POC testing permitted more expeditious diagnosis of certain dangerous clinical scenarios. By preventing those scenarios from escalating, POC testing resulted in significant cost savings. Similar studies in other clinical settings are needed.

Reference

Section Business Meeting Minutes
by Catherine Foss, RRT

The Diagnostic Section held its annual business meeting during the 1998 AARC International Congress in Atlanta. The meeting, which was led by Section Chair Carl Mottram, RRT, RPFT, was well attended by practitioners and representatives from diagnostic-related vendors.

Communication issues were first on the agenda. Our Internet site coordinator, Susan Blonshine, explained that a new “listserv” electronic mailing system is now available to section members. To sign up:
2. Click on “Members Area,” then click on “AARC Specialty Sections,” then click on “Diagnostics Section.”
3. Type in your AARC member number beside both “name” and “password” when accessing “Members Area” and “Diagnostics Section.”
4. Follow the directions to subscribe to the listserv.

The section would like to have a listing on the website of state chairs so that we may send group messages to diagnostic practitioners nationwide. Therefore, we need names, addresses, phone numbers, and e-mail addresses for the state contacts. If you hold one of these positions, please sign up for the listserv today.

There is an ongoing need to increase practitioner involvement in the section. The audience was queried about their suggestions and needs. Carl discussed the changes in the works for all of the AARC’s specialty sections. In the past, the chair, chair-elect, and Bulletin editors were appointed. The new guidelines, which passed a second reading by the AARC Board of Directors in November, call for the chair and chair-elect positions to be elected by the general membership. This change would go into effect gradually as the terms of current section officers expire.

Under the new rules, the chair for each section with an active membership of 1,000 or more will have voting privileges on the AARC Board. This has important implications for the sections because those with voting privileges on the Board will have a greatly increased presence and voice in the Association. In the past year, the Diagnostic Section has dropped below the 1,000 active member cutoff. (Associate members are not counted.)

Please, all active members — recruit your co-workers. Tell them about the benefits of joining and becoming involved in this section and how their participation will
help provide a voice for the diagnostic practitioner on the AARC Board. We need more members!

Every year the section provides an updated Resource Directory of fellow practitioners willing to field calls or receive e-mail questions about diagnostic issues. The list is divided into topics. If you would like to become a member of this panel, please follow the sign-up directions located on the AARC web site or call Carl Mottram at the number on page 2.

Our section publishes six excellent Bulletins a year covering topics such as cardiac testing, pulmonary function, exercise, bronchoscopy, sleep, and blood gases. Each issue features at least two major articles of around 1,000 words each, plus shorter FYI articles that may be of interest to the reader. Anyone interested in contributing an article is encouraged to contact our Bulletin editors (Vickie Ganey and Mary Kay Collins) at the addresses/numbers listed on page 2.

Our Practitioner of the Year Award was the next topic for discussion. The AARC has provided a structured process for us to use when nominating practitioners for this honor. Please think about fellow workers who are deserving of this honor and then look for the nomination requirements, which will be published in an upcoming issue of the Bulletin. We would also like to begin honoring, as other sections have in the past, a Practitioner of the Quarter. But we need your input to make this happen! Nominees must be members of the AARC and the section. Remember: we need to hear from YOU!

From there, Carl updated us on the AARC Clinical Practice Guidelines project. There are currently ten diagnostic guidelines available on the AARC web site. A new guideline on cardiopulmonary exercise is due out shortly and there will be an update soon for diffusing capacity. The six-minute walk test and muscle forces have been suggested as topics for future guidelines.

Educational Materials available to diagnostic practitioners were introduced to the audience. The AARC has five diagnostic-related Individual Independent Study Packages (IISPs), and the American Thoracic Society (ATS) has recently published a Pulmonary Function Procedure Manual. This manual is available on disk and/or in binder form. For copies call Ruth Kasloff at the American Lung Association, (212) 315-8735. The Alpha-1 ATD Educational Brochure, which describes diagnostic pulmonary testing to patients, is due out soon.

In an update on the Uniform Reporting Manual, Susan Blonshine reported that the survey process is under completion and the manual will be published soon. The manual will offer comprehensive coverage of pulmonary, cardiac, sleep, and laboratory diagnostics.

Susan, who is our AARC liaison to the National Committee for Clinical Laboratory Standards (NCCLS), also updated the group on recent developments at NCCLS. Specifically, NCCLS has published an update on arterial blood collection and will soon be compiling all of its blood gas-related documents in one book. Susan also gave an overview of the Quality Systems in Health Care and ISO 9000 standards for health care management, and invited anyone with suggestions regarding our NCCLS involvement to please provide comments.

A discussion on Ambulatory Care Guidelines was led by Jill Eicher, the AARC’s director of state government affairs in Washington, DC. The ambulatory payment classification (APC) system is a reimbursement system for outpatient diagnostic testing that is similar to the inpatient DRGs (although, unlike the DRGs, APCs are not disease-oriented). There are 346 APC categories. Originally, this process was to have been implemented by now, but the Health Care Financing Administration’s Y2K issues have delayed it until June 1, 2000. The proposed rule is in the September 9, 1998 Federal Register, and the comment period has been extended. For more information, contact Jill at eicher@aaarc.org or check the government website at www.hcfa.gov.

Lastly, the group brought up ideas for the 1999 AARC Congress and pointed out that there were not many diagnostic-related presentations in the 1998 Open Forum. We want to encourage everyone to play a more active role in the presentations this year. Start thinking of diagnostics-related ideas for abstracts and poster presentations today so that we will be better represented in Las Vegas.

What Does This Really Mean to the Respiratory Therapist?
by Vickie Ganey, MBA, RRT, RPFT, RN

Every time I talk to people about writing for the Diagnostic Bulletin, I hear, “but I don’t know what to write about — I don’t do diagnostics.”

If you really think about what we do for our patients to help them get well — or at least better for a time — you will see that everything we do is based on some form of diagnostic procedure. You could even say that the manager of a department uses diagnostic tools to run the department in an efficient manner. The manager looks at the needs of the patient floors and at his/her department personnel, then decides if he/she has the staff to provide the necessary coverage for those patient care areas.

Diagnostic procedures are really the main tools of our trade. The word “diagnosis” is defined as the “identification of a disease by analysis and examination.” Certainly, diagnostic procedures are used in the identification of a disease by analysis and examination. A diagnostician is the person who uses the diagnostic tools to gather the information, and a physician is the person who makes the diagnosis of a disease from all of the information gathered.

When we think about diagnostics, however, most of us tend to think in terms of the traditional: the pulmonary function test, indirect calorimetry, arterial blood gas, and studies related to lung transplants. But diagnostics can also be related to other things that all of us do as respiratory therapists. For example: When you perform a patient assessment you are using your skill as an evaluator to determine the...
Point-of-Care Testing: A Review of the Post Graduate Course

by Susan Blonshine, BS, RRT, RPFT and Catherine Foss, BS, RRT, RPFT

Point-of-care testing (POCT) was the subject of one of the post graduate courses held prior to the AARC Congress in Atlanta. Practitioners from around the country were introduced to thought-provoking issues as POCT was compared to current central laboratory practices and standards. Faculty involved in various aspects affecting POCT spoke in their respective specialties. Laboratorians, respiratory therapists, researchers, scientific industry experts, and information systems experts were involved as faculty.

Patient-attached blood gas sensors

Patient-attached blood gas sensors were the focus of the first lecture, which was presented by Bruce McKinley, PhD, from the University of Texas Medical School in Houston. The utilization of patient-attached arterial blood gas (ABG) “monitors” as compared to benchtop analyzers was discussed in terms of performance, accuracy, precision, and regulatory implications.

In a comparison study of the SensiCath and clinical laboratory data, the performance of the SensiCath in an adult intensive care unit was comparable to laboratory ABG analysis. The ABG was available on demand within one minute at the ICU bedside from a closed arterial monitor system without recalibration for up to three days. Subsequently, the data was analyzed without recalibration for up to six days. The ABG monitor was found to provide accurate results under this scenario as well. Frequency of use by the medical staff and cost effectiveness were considered. ABGs were obtained more frequently with the SensiCath than with the standard clinical laboratory system. A further randomized comparative study is required to assess the implications on outcome and cost.

Coagulation studies

Susan Blonshine BS, RRT, RPFT, from TechEd in Mason, MI, spoke on the expansion of the respiratory therapist’s scope of POCT practice into coagulation studies. Prothrombin time (PT), activated partial thromboplastin time (APTT), activated coagulation time (ACT), and the International Normalized Ratio (INR) were discussed in detail. Indications for use include diagnosis of hemostatic disorders and monitoring of anticoagulation therapies. Multiple settings were suggested, including the emergency department, critical care units, ECMO, subacute care, bronchoscopy, catheterization laboratories, hemodialysis, surgery department, and home care.

The pre-analytical issues for coagulation studies are different than those for ABGs and must be considered in training. Various members of the audience shared their experiences in adding coagulation studies to the respiratory therapist’s responsibilities. In general, the experiences were positive and increased the potential of adding other analytes. Susan mentioned a relevant study from the University of Washington in St. Louis, MO, that was published in 1998. Researchers there demonstrated that point of care (POC) coagulation studies dramatically improved patient outcomes and length of stay in certain situations.

Expanding beyond ABGs

John Ancy, MA, RRCP, RRT, from St. Elizabeth Hospital in Belleville, IL, presented a series of intriguing case studies on an expanded menu of analytes beyond ABGs. He encouraged and challenged the audience to think beyond the traditional blood gas panel and to look for discrepancies in the results. By using their critical thinking skills and suggesting expanded menu options for blood analysis, the respiratory staff will “know more, do more, and be worth more,” thus impacting patient outcomes.

Regulatory issues

Sharon Ehrmeyer, PhD, MT

“Point-of-Care Testing” continued on page 5
"Point-of-Care Testing" continued from page 4

(ASCP), from the University of Wisconsin in Madison spoke on the many regulatory issues affecting POCT and how they compare to central laboratory regulations. Since the requirements vary with the inspecting agency, method verification and quality control requirements, including electronic quality control, were discussed.

Each site employing POCT must be familiar with the regulatory requirements from both CLIA and other inspecting agencies that are specific to their setting. Dr. Ehymeyer gave several excerpts from her book, “The New Poor Man’s (Person’s) Guide to the Regulations (CLIA 88, JCAHO, CAP, COLA).” This 240-page resource would be invaluable to any manager involved in POCT. It is available from R&S Consultants. Another resource mentioned was Dr. Westgard’s web site, which features regular updates from various authors on quality assurance and quality control issues. The site is located at www.westgard.com.

Partnership opportunities

John Ancy and Sharon Ehymeyer teamed up for the first afternoon lecture to demonstrate and discuss opportunities for partnerships between respiratory therapy and the clinical laboratory — a win-win situation. Indeed, the process of planning and implementing POCT requires collaboration and teamwork on the part of multiple departments. They suggested that we capitalize on the strength of respiratory therapy’s capability of working with both the stat laboratory and the patient at the bedside, combining that strength with the laboratory’s analytical expertise. The laboratory inspecting agency will help define the relationship between respiratory care and the laboratory. Currently, several groups accredit laboratories and meet “deemed status” for CLIA. It is important to determine which of these accrediting organizations will be used for the point of care system. This generally determines whether the partnership will be accredited under the respiratory therapy department or under the clinical laboratory.

What are some of the areas where the laboratory can help? Clinical laboratories can help with the test menu and instrument selection, instrument evaluation, operating protocols, personnel training, maintenance of ongoing quality assurance and quality control, and an ongoing performance improvement plan. The respiratory care department can help the clinical laboratory with POCT, depending on the test menu and the analytes selected. When the instrument is selected, it is important to evaluate reliability, maintenance requirements, manufacturer’s support, and the type of quality control that will be required.

In most cases, respiratory care will be the expert on blood gasses. But you may want to look to the laboratory for systems with other analytes, Clinical laboratories have a long history in instrument evaluation and the importance of the evaluation phase to assess the accuracy or bias of the instrument and the precision. It’s also important to review the reportable range and the reference range the equipment will allow. Some of the ways to validate the performance specifications for a piece of equipment are similar to accreditation requirements from the College of American Pathologists (CAP). Both reference materials and split samples may be used for evaluation. It is important to remember that with split samples one must use the appropriate anticoagulant, based on the piece of equipment used for analysis.

Clinical validation may also be done by chart review. The clinical laboratory may already have operating protocols, so it’s only a matter of modifying these protocols for POCT. In addition to the protocols for analysis, there must be collection procedures available in every area where a health care professional will be collecting specimens for analysis. It is extremely important to have an operating protocol that addresses all the pre-analytical considerations. This should include the type of anticoagulant, how to transport the specimen, and the storage requirements based on the analytes. Analytical procedures, as well as post analytical considerations, should be defined.

The laboratory may also be able to help with personnel training. A cooperative effort between respiratory care and the laboratory can utilize the same documents for orientation, competency review of blood borne pathogens meeting Occupational Safety and Health Administration regulations, and record keeping. The clinical laboratory also has a long history of understanding quality control and the maintenance of ongoing quality. In this area, they may be very helpful in assessing and selecting the appropriate control rules, particularly for those analytes outside of blood gasses. They may be able to help with the quality control review, both for the operators and the laboratory. The clinical laboratory has extensive experience with analytes such as electrolytes and coagulation studies.

Proficiency testing (PT) is mandated regardless of the type of analytes tested. There must be a mandatory external assessment of testing quality. The department performing PT, laboratory, or respiratory care may depend on who has the CLIA certificate, if there is one institutional certificate, or if there are multiple certificates. If the same analytes are tested on two different pieces of equipment, it’s also important to look at how laboratory and respiratory care can work together in the performance improvement area. It will be important to do correlation studies. In addition, you may want to evaluate the response to critical values and the pre-analytical considerations.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) clearly states that there may only be one level of care within an organization. This again confirms the need to correlate test results between different types of equipment and care sites. The quality assurance (QA) plan must have mechanisms in place to resolve identified problems. It is important to review the QA on a continuum, as well as document the response to requests for corrective action.

Managing quality

Kevin Fallon, PhD, from Instrumentation Laboratories, continued with the next lecture, “Managing Quality in POCT.” Establishing quality management and the purpose of quality management is the first step in managing quality. Each individual and department must have a good understanding of the definition of quality for the specific POCT system and quality control. At the onset, it’s important to identify the acceptable stan-
Dr. Fallon gave an excellent example by relating the case of a POCT director who shut down the analytical system on a device that had a coefficient of variation of less than one percent every time a quality control (QC) value exceeded two standard deviations. The reason the POCT director shut down the analytical system was because the QC program called for running another QC whenever a value of more than 2 SD was observed. In this case, the cost in terms of money, time, and effort may have outweighed the benefit of shutting down the analytical device, because the device had a coefficient of variation that was actually less than one percent.

Quality control is a part of quality assurance. There are three phases of testing that one must consider in any quality assurance system. The phases include:

1. the pre-analytical phase or all the activities associated with the actual analysis of the sample, and
2. the analytical phase or all the activities associated with transportation, use, and storage of the information.

The pre-analytical operating procedures are no different in a POCT system than those seen when samples are sent to the central laboratory. The quality control system should be tested for continuing accuracy and for continuing precision in the analytical phase. In the analytical phase one must consider proper handling of cartridges and issues related to single use cartridges, such as calibration and quality control acceptability.

What are some of the quality control issues that must be considered for single test devices? One of the dilemmas the clinician faces is the fact that if the device is used up the test cannot be subjected to normal quality control procedures. One suggested solution to this dilemma is to demand that the manufacturer claims for the failure rate of the cartridge against a quality control standard be provided to the end user. We must remember that an electronic test is good, but it is not quality control. In order to define the quality control system, we must determine the level of acceptability and the instrument performance. The three areas that need to be considered in terms of acceptability include the clinical need, the application of the data, and operator training. Instrument verification was discussed earlier in the day, and Dr. Fallon elaborated further on those discussions.

Personnel

Susan Blonshine continued the course with a discussion of the personnel issue, with a primary focus on training. The first step is to develop policies, processes, and procedures to define a quality system. POCT requires clearly defined job qualifications and job descriptions. This is particularly important since different members of the health care team may be responsible for various aspects of the testing. A well-designed process for orientation and training must be in place. A process must be in place to assess competence and overall job performance. In addition, the training program should provide for the training of the trainers and continuing education.

She suggested three keys to success: tailor the program to the educational level and background of the trainer, select trainers based on well-defined criteria, and select training methods applicable to the skills and knowledge that must be achieved. The training should include all aspects of POCT across the path of workflow. Competence assessment should occur twice the first year and annually thereafter. When testing is performed infrequently, competence assessment may need to be done more frequently. Assess competency in all three domains of the job. Ultimately, the laboratory director or designer must approve and sign off on training and competence assessment records. A successful training program incorporates a thorough and comprehensive initial training program and emphasizes on ongoing training.

Data management

Jack Low, PhD, from Instrumentation Laboratory in Lexington, MA, presented a comprehensive and thought-provoking overview of the data management issues in POCT. He stated that data management must be able to maximize the benefits and minimize the costs. These systems should provide:

- hard data to support the needs of the staff;
- the ability to monitor and prove good practices and good performance of staff and equipment;
- information to the staff, management, and inspectors on patient results, analyzer maintenance, analyzer status, and performance;
- up to the second communication, with messages to staff, status of the analyzers, and reminders when to perform key functions such as maintenance and quality control; and
- accurate retention of all the data relevant to your activities.

Data management should actually help track the therapists and equipment, making everyone more responsible for their actions. Use of the system should be intuitive, solving problems rather than creating them. Jack emphasized that data management does change the way we work. Careful planning and understanding are required to ensure that it provides usefulness, not uselessness. Time invested up front will reap rewards in the long run. The emphasis should be on striving to reduce the overall workload.

Care paths

Judy Tietsort, RRT, RN, from Denver, CO, summarized the essence of the discussions and the application of the knowledge through a presentation on the use of care paths and outcomes assessment. Judy demonstrated the process for care path development through a COPD pathway. The need to understand your hospital’s current process-of-care issues was emphasized. She recommended collecting data on current processes and available resources to begin the discussions. It is advisable to review the diagnostic tests, indications, applications, frequency of use, and costs in relation to the disease-specific care paths. Once the
The current process-of-care and clinical outcomes are well understood, goals and solutions can be proposed to improve the process of care. Judy reviewed a care map, explaining each of the components as well as an implementation strategy. The data management lecture was applicable to the care paths as, ultimately, one must evaluate, evaluate, evaluate.

A golden opportunity

Point of care testing is a golden opportunity for respiratory therapists. The AARC's post-graduate course left each attendee with a greater level of knowledge in this area and, hopefully, the enthusiasm to seek out opportunities to implement such programs in their own institutions.

**Hot List topics: AARC Times Wants Your Input**

*AARC Times* is looking for clinical topics to feature during 1999 and is asking the members of our section to help come up with a “hot list.” What are the key issues that we would like to see featured in the magazine over the coming year? Please take a minute to jot down the topics you would most like to read about in ‘99 and e-mail them to *AARC Times* Editor Marsha Cathcart at cathcart@aarc.org. If you would like to write on one of those topics, please let Marsha know and she’ll get back to you with the details regarding article submission.

**FYI**

**Age matters**

The level of lung function that asthmatics can attain after treatment with inhaled steroids or bronchodilators appears to be limited by aging, say Italian researchers who studied 50 asthmatics with a mean age of 59.7 years and 51 others with comparable disease duration and baseline functional impairment who had a mean age of 35.7 years.

All of the participants underwent spirometry and a bronchodilator test with 200 mcg. of inhaled salbutamol. Those whose FEV1 values were not at least 85 percent of predicted were given a four-week course of inhaled steroids.

Upon reevaluation, researchers found that while the difference in maximum response following steroid or bronchodilator treatment was not statistically significant between the older and younger patients, mean lung function attainable after treatment was significantly lower in the older age group. (Chest, 11/98)

**Immunotherapy found effective**

Allergy vaccinations are 98% effective in treating sinusitis in individuals who are predisposed to allergies, says investigators from Colorado and elsewhere who studied 114 sinusitis patients who were being treated with antibiotics and who had received allergy vaccines for at least a year.

Patients filled out two questionnaires during the same visit. One asked about their symptoms prior to starting allergy treatment and the second asked about current symptoms, including missed days of work or school and use of antibiotics. Ninety-eight percent of patients believed that immunotherapy had improved their symptoms, and most also noted fewer missed days of school or work and reduced use of antibiotics after beginning immunotherapy.

The vaccines used in the study included any combination of pollen, mold, house dust mite, or animal dander extracts. The study was presented at a recent meeting of the American College of Allergy, Asthma and Immunology. (ACAAI news release, 11/6/98)

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