Diagnostics Bulletin
May/June '01

American Association for Respiratory Care

Notes from the Chair

by Catherine M. Foss, BS, RRT, RPFT

Mark your calendars! It's not too early to plan to attend the AARC International Congress in San Antonio this December 1-4. From a record-breaking list of proposals, the Program Committee has put together a well-rounded and exciting lineup of diagnostic presentations, some of which will directly involve participants. Yes, the age of interactive presentations arrived last year at the 2000 Congress and was a big hit with attendees. During some presentations, each member of the audience was given a handheld device to respond to the presenters' questions. The attention level of the audience was high and the results interesting to review, with immediate feedback on a large screen. This year, some of the diagnostic presentations will take on this interactive format. Watch the AARC web site and your mailbox for the preliminary program!

We are still looking for volunteers for section committees. The AARC has issued a policy that each Specialty Section shall have a *Nominations Committee*, *Publications Committee*, *Program Committee*, *Recognition Committee*, and *Consultant Panel* to aid the section in the accomplishment of its goals and charges. Each committee shall have an appointed chair and members. Additionally, one or two people are needed to serve as Internet coordinators. Do you have a special interest in one of these areas? If so, contact me via email at foss0005@mc.duke.edu for details. All help is greatly appreciated. The AARC hopes to actively involve more practitioners in the Specialty Sections to help ensure that the sections are actively meeting the needs of individuals in each specialty.

In this *Bulletin*, Michael Snow, one of our *Bulletin* editors, shares his thoughts on the "Clinical Applications of Gas Exchange Testing." His article is a thorough review of the utility of gas exchange technology during exercise. He also provides an extensive reference list of classic papers and books on exercise, a valuable commodity for busy practitioners. Additionally, we are reprinting two recent official releases from the Food and Drug Administration on issues related to our practice. One is on the use of medical gases, and the other is on reuse of medical devices sold as single use. Both of these issues are pertinent in many diagnostic laboratories. I would appreciate your thoughts, via the section listserve, on the issues raised concerning these topics. ■

Clinical Applications of Gas Exchange Testing

by Michael Snow, RPFT, RCPT

Assessment of the cardiopulmonary response to exercise is becoming more frequent as the utility of the measurements become more accepted in a wide range of applications. These clinical applications include differential diagnosis, risk stratification, rehabilitation, evaluation of exertional dyspnea, and functional impairment for disability. The usefulness of the test requires an understanding of both cellular metabolism and exercise physiology. Unlike standard pulmonary function tests, response to exercise is not simply a matter of comparing a maximal measurement to a predicted value. The patterns of response are also important, since these patterns provide insight into both disease states as well as fitness levels.

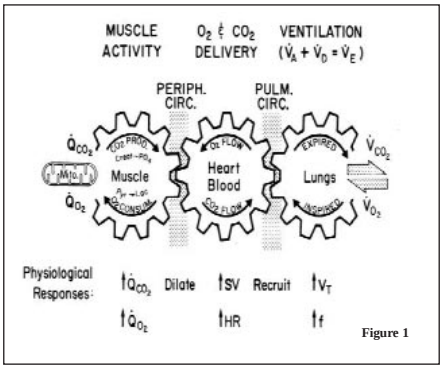

Figure 1

Exercise physiology

The cardiopulmonary response to increasing workloads may be divided into three general categories: cellular metabolic, cardiac, and ventilation. The metabolic response is primarily a result of the demand from working muscle groups for additional energy and clearance of CO_2. This consists of increasing oxygen uptake (VO_2) and carbon dioxide output (VCO_2) within the working muscle groups, as well as facilitating shifts in substrate utilization. Wasserman provides an elegant illustration of these interrelationships (Figure 1).[1] Due to the close coupling

"Clinical Applications" continued on page 2

"Clinical Applications" continued from page 1

and linkage between the mechanisms, impairment of any phase will cause compensatory changes in others and ultimately limit functional capacity.

Cellular metabolism is dependent upon the availability of adequate high energy compounds such as adenosine triphosphate (ATP). ATP provides the energy necessary for maintaining the complex relationships between the neuromuscular, endocrine, and hemodynamic systems. Increases in metabolic activities rapidly consume local stores of ATP, creating an increased demand for its synthesis. The replenishment of ATP is accomplished through the breakdown of glucose, either aerobically or anaerobically. Both processes replenish ATP and produce a byproduct (CO_2). The aerobic process can be considered a " pay as you go" process and can continue indefinitely as long as adequate O_2 delivery and CO_2 removal are available. The anaerobic process " borrows" energy now against a future payback and is ultimately limited by the accumulation of lactic acid resulting from the insufficient O_2. Therefore, work that involves significant " borrowed" energy cannot be sustained. Cellular respiration is essentially the delivery of oxygen and the removal of CO_2. Large increases in oxygen delivery and CO_2 removal may be required to sustain working muscle groups during stress. These requirements are met by cardiovascular and ventilatory coupling to the cellular metabolism.

VO_2, VE, VCO_2, and cardiac output are directly tied to workload. During submaximal work, the metabolic demand (VO_2) is directly related to work (10.3ml/min/watt).[2] The VCO_2 represents the byproduct of the metabolism and essentially matches the VO_2. The cardiac response to this increased energy demand consists primarily of changes in heart rate (HR) and stroke volume (SV), and selective changes in cardiovascular resistance. Resultant increases in ventilation (VE) are accomplished through a combination of changes in respiratory rate and tidal volume as controlled by respiratory drive mechanisms such as hypercapnic drive and stretch receptors. All of these changes are interrelated in an integrative response to work.

Circulation provides increased cardiac output, initially facilitated by increases in stroke volume, then subsequently by increases in HR, matching metabolic demand. The increased cardiac output and the associated rise in systolic pressures are accompanied by expansion of the functioning pulmonary capillary bed to facilitate oxygen delivery and CO_2 removal. The relationship between VO_2 and HR provides an noninvasive assessment of SV changes based on the Fick equation (Figure 2). Selective changes in vascular resistance direct blood flow toward working muscles while maintaining essential areas such as the brain. Increased ventilation, achieved by varying the relationship between respiratory rate and tidal volume, coupled with expanded perfusion of the capillary bed, improves ventilation/perfusion matching. Ventilation is precisely regulated by changes in peripheral and central chemoreceptors in order to maintain arterial oxygen and carbon dioxide levels within narrow limits.

Fick Equation

Oxygen Uptake = Cardiac Output X Arteriovenous O2 Difference

Because blood flow distribution is extremely efficient during exercise The maximal systemic Arteriovenous O2 difference is relatively constant across a wide range of subjects and occurs early

VO_2 = (Heart Rate(HR) X Stroke Volume(SV)) X Constant

Therefore:

$VO_2 / HR = SV$

Provides a simple method of trending Stroke Volume

Figure 2

As workload increases, VO_2, HR, VCO_2, and VE all increase proportionally until the metabolic demands can no longer be sustained solely by aerobic metabolism. At this point, referred to as the anaerobic threshold (AT) or the onset of blood lactate (OBLA), energy production is supplemented by anaerobic metabolism. After the onset of AT, VO_2 and HR will continue to increase proportional to work, while the VCO_2 and VE will increase disproportionately. This accelerated increase is the result of the requirement to remove additional CO_2 resulting from the lactate byproduct of anaerobic metabolism. A common method of visualizing AT is illustrated in Figure 3.[3]

Since there is an upper limit on ventilatory capacity, as defined by respiratory rate and tidal volume, the lactate buildup cannot be completely compensated for by increased ventilation during the exercise. As a result, work above the AT cannot be sustained indefinitely. Energy released through anaerobic metabolism also creates an " oxygen debt" that will ultimately have to be repaid. Basically, this means that the elevated ventilation required to remove the excess CO_2 will require some degree of elevated VO_2 even after the cessation of external work. This can be seen during the recovery phase, where VE remains elevated for some time, resulting in very high transient respiratory exchange ratios (RER).

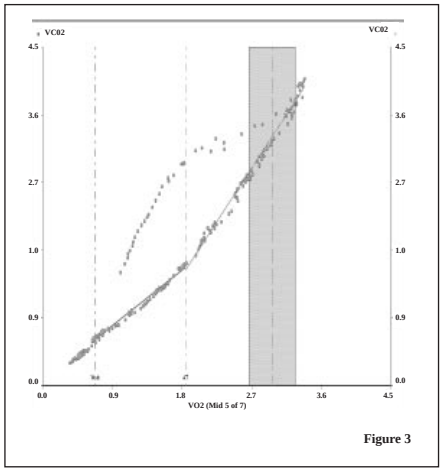

Figure 3

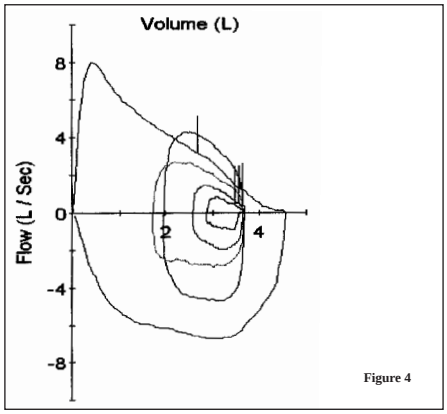

Figure 4

Flow limitation will develop as the patient is unable to increase flow sufficiently to match demand. Normally, ventilation increases are achieved through a combination of higher flows, permitting higher respiratory rates and deeper tidal breaths. With many disease states, the reduced maximal flow envelope may not permit

"Clinical Applications" continued on page 3

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American Association for Respiratory Care
11030 Ables Lane
Dallas, TX 75229-4593
(972) 243-2272
FAX (972) 484-2720
e-mail: info@aarc.org

Kelli Hagen
AARC communications coordinator

Debbie Bunch
Bulletin managing editor

Edwards Printing
Bulletin typesetting

Section Chair
Catherine M. Foss, BS, RRT, RPFT
Duke University Hospital
Durham, NC
(919) 844-8248
foss0005@mc.duke.edu

Bulletin *Editors*
Pauline Wulbrecht, RPFT
Scott and White Hospital
c/o Pulmonary Laboratory
2401 South 31st Street
Temple, TX 76508
(254) 724-2114
FAX: (254) 724-2497
pwulbrecht@swmail.sw.org

Mike Snow RPFT, RCPT
Vice President, Research & Development
Medical Graphics Corporation
(651) 766-3378
Fax (651) 766-3389
michael.snow@medgraphics.com

Internet Coordinators
Susan Blonshine
sblonshine@aol.com

Steve Nelson
sbnelson@kansascity.com

Medical Advisors
Robin Elwood, MD
(405) 271-4351

William Peruzzi, MD
(312) 926-2537

"Clinical Applications" continued from page 2

the higher flows necessary to sustain increases in ventilation. In the presence of significant overinflation, the available inspiratory capacity (IC) may not be adequate to permit larger tidal volumes. The three primary ways to quantify flow limitation are to evaluate tidal breathing flows during exercise compared to a baseline flow volume envelope or by evaluating tidal volumes versus IC or FEV1[4] Once flow limitation is reached, continued increases in ventilation are not possible. An illustration of flow limitation is shown in Figure 4.

Clinical applications

Ultimately, the limitation to exercise occurs when one of the interrelating mechanisms is unable to provide adequate oxygen delivery or carbon dioxide removal. Maximal VO_2 will occur when the combination of aerobic and anaerobic mechanisms can no longer increase and subsequent increases in workload cannot drive additional metabolism. The mechanisms behind the limitation to exercise provide a differential diagnosis.

Interpretation of cardiopulmonary exercise testing can differentiate between cardiovascular, pulmonary, and conditioning limitations. Usually, this can be easily determined by identifying the limiting mechanism. For example, patients with mitral valve disease clearly show reduced SV response to increased work. Patients with obstructive pulmonary disease will show flow limitation. Restrictive lung disease patients will show ventilatory limitation, but the mechanism for increased VE will be predominantly rate increases rather than tidal volume changes. Deconditioned patients will show an abnormally low AT.

Patients with congestive heart failure and coronary artery disease demonstrate a reduced relationship between VO_2 and work rate, with the magnitude of the reduction correlated with disease severity (5-6ml/kg/min for severe Weber D or NYHA III classifications).[5] Rate adaptive pacing applications use cardiopulmonary exercise testing to confirm the adequacy of pacemaker functions, as well as assist in the development of new algorithms for pacing.[6,7] Some authors categorize preoperative risk as excessive when AT is reduced (<11ml/kg/min).[8,9] Functional impairment can be easily determined by cardiopulmonary exercise testing. Reduction in maximal VO_2 (< 16ml/kg/min) is required criteria for heart transplant. Heart Failure Classification is based on maximal VO_2, ranging from mild to moderate (16-20ml/kg/min) to critical (<6ml/kg/min) [10]. Maximal VO_2 is one of the highest performing clinical variables in predicting outcomes when compared to exercise time, right-heart catherization data, and other clinical variables.[11] Recent research indicates that ventilatory response to exercise is also a marker of poor prognosis in heart failure, and the slope of VE/VCO_2 can be an important submaximal assessment of exercise capacity in patients who cannot be exercised maximally.[12,13]

Disability evaluation is a growing area of application for cardiopulmonary exercise testing. Many sources provide tables of metabolic demands for various occupations and activities. If a patient cannot meet these requirements aerobically, this is an indication of disability. Training programs based on measured AT prescriptions can provide rehabilitation and effectively raise the AT level. Cardiac rehabilitation can use exercise prescriptions based on determination of AT to provide a safe and effective target heart range for exercise.

Summary

The expanded use of cardiopulmonary exercise testing is a result of a growing understanding of the value of the measurements. Cardiopulmonary exercise testing offers the potential to provide objective measurements in a wide variety of applications. Recent research continues to indicate new areas of correlation with differential diagnosis and clinical prognosis.

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FDA Releases Policy on Reuse of Single Use Devices

Editor's Note: *The following article, updated on April 6, is reprinted from the FDA web site.*

The Food and Drug Administration (FDA) has re-examined its policy on the issue of reuse of medical devices labeled for single-use. Our primary goal in doing so is to protect the health of the public by assuring that the practice of reprocessing and reusing single-use devices (SUDs) is safe and effective and based on good science.

The public expects and the law requires all medical devices to be safe, effective, and manufactured in accordance with good manufacturing practices (GMPs).

FDA has been actively engaged in reuse issues for some time. Our efforts have included research, outreach, inspections, and compliance investigations. In the recent past, we participated in a number of national meetings on this issue, presented an interactive

"Single Use Devices" continued on page 4

"Single Use Devices" continued from page 3

teleconference, held an open public meeting, and then published a proposed strategy. Our current guidance, published on August 14, 2000, was based on the information obtained in these public forums and comments received.

The guidance is an approach that equitably applies existing regulations to original equipment manufacturers (OEMs), third parties, and hospitals to minimize risks associated with reprocessed SUDs.

Despite a lack of clear data that directly link injuries to reuse, FDA has concluded that the practice of reprocessing SUDs merits increased regulatory oversight. We are concerned because we do not have enough information to be certain that SUDs are being reprocessed properly. FDA recognizes that our medical device problem reporting systems cannot adequately capture information about potential clinical problems related to reuse. Our plan is to phase in additional oversight based on assessment of current practice and potential risk. ■

FDA Issues Public Health Advisory on O_2 Mix-ups

Editor's Note: *The following article is reprinted from the FDA web site.*

This guidance is intended to alert hospitals, nursing homes, and other health care facilities to the hazards of medical gas mix-ups. The Food and Drug Administration (FDA) has received reports during the past four years from hospitals and nursing homes involving seven deaths and 15 injuries to patients who were thought to be receiving medical grade oxygen, but were receiving a different gas (e.g., nitrogen) that had been mistakenly connected to the oxygen supply system. This guidance makes recommendations that will help hospitals, nursing homes, and other health care facilities avoid the tragedies that result from medical gas mix-ups.

Background

On December 7, 2000, a nursing home in Bellbrook, OH, reported two patient deaths and eight patients injured following a mix-up in their oxygen supply system. The nursing home had supposedly received a shipment of four cryogenic vessels containing medical grade oxygen. Included in the delivery, however, was a cryogenic vessel of industrial grade nitrogen. The nursing home was running low on oxygen and sent a maintenance employee to connect a new oxygen vessel to the oxygen supply system. The employee selected the nitrogen vessel and discovered, correctly, that he was unable to connect the vessel to the oxygen system — as a safeguard, the connectors for oxygen vessels are specially fitted so they are compatible only with oxygen delivery systems. The employee removed a fitting from an empty oxygen vessel and installed it on the nitrogen vessel. He then connected the deadly product to the oxygen system. Several days later, two of the injured patients died from exposure to industrial nitrogen, bringing the death total from this one incident to four.

On April 22, 1998, a hospital in Idaho discovered that a large cryogenic vessel of industrial nitrogen had been connected to the oxygen system supplying the operating rooms, labor and delivery rooms, and emergency room. The hospital discovered that the medical gas delivery person initially had been unable to connect the incompatible nitrogen vessel outlet fitting to the oxygen system, but had used a wrench to disconnect the nitrogen fitting and replace it with an oxygen fitting. Two patients died as a result of this medical gas mix-up.

In October 1997, a hospital in Nebraska received a shipment of medical grade oxygen in large cryogenic vessels. The shipment included one cryogenic vessel of industrial grade argon that was properly labeled. The hospital was running low on oxygen and sent a maintenance employee to connect an oxygen vessel to the oxygen supply system. Without examining the label, the employee selected the argon vessel, and, discovering he was unable to connect the vessel to the oxygen supply system, he removed a fitting from an empty oxygen vessel, installed it on the argon vessel, and connected the deadly product to the oxygen system. Argon was administered to a patient undergoing minor surgery. The patient died.

On December 2, 1996, a children's home located in New York reported adverse reactions experienced by nine patients due to the inhalation of carbon dioxide. An employee of the home, asked to attach a large cryogenic vessel of medical grade oxygen, unknowingly selected a carbon dioxide vessel from the home's inventory. He noted that the fitting on the carbon dioxide vessel was not compatible with the connector on the oxygen system. Nonetheless, he removed an oxygen fitting from an empty vessel, installed it on the carbon dioxide vessel, and attached it to the oxygen supply system. Two patients were injured critically, and four patients experienced varying stages of respiratory distress.

All four cases reveal striking similarities:

- The person connecting the vessel to the oxygen system (e.g., the delivery person or the facility employee) was not properly trained and did not understand that connection incompatibility is a built-in safeguard.
- Prior to installing the cryogenic vessel to the oxygen supply system, the person making the connection did not examine the drug label applied to the cryogenic vessel to ensure that the product was medical oxygen.

The Agency has identified additional practices that may contribute to continuing medical gas mix-ups resulting in injury and death:

- Although recommended by the Compressed Gas Association, many of the large cryogenic vessels used to contain medical gases do not have permanently brazed, or welded, connections or fittings that cannot be removed.
- Unfortunately, not all medical gas vessels are labeled using 360-degree wrap-around labels.
- Separate storage areas often are not provided either in the delivering vehicle or at the receiving facility to sufficiently separate medical grade products from industrial grade products.

As a result, many medical gases are improperly or poorly labeled; the wrong gases are delivered accidentally to hospitals, nursing homes, and other health care facilities; and poorly trained personnel are connecting the wrong vessels to oxygen supply systems, despite connection incompatibilities. Patients continue to suffer injury or death.

Recommendations

All of the incidents described above could have been avoided if a few simple safety procedures had been followed. It is important that *all* employees handling a medical gas be alerted to and reminded of the possible hazards associated with using medical gas.

The Agency recommends implementing the following:

1. If your facility receives medical gas deliveries, you should store medical grade products separately from industrial grade products. The storage area for medical grade products should be well defined with one area for receiving full cryogenic vessels and another area for storing empty vessels.
2. All personnel who will be handling medical gases should be trained to recognize the various medical gas labels. Personnel should be trained to examine all labels carefully.
3. If your supplier uses 360-degree wrap-around labels to designate *medical oxygen*, personnel should be specifically trained to make sure each vessel they connect to the oxygen system bears such a label.
4. Make sure that all personnel in your facility who are responsible for changing or installing cryogenic vessels are trained to connect medical gas vessels properly. Personnel should understand how vessels are connected to the oxygen supply system and be alerted to the serious consequences of changing connections.
5. You should emphasize repeatedly that the fittings on these vessels should *not be changed* under any circumstances. If a cryogenic vessel fitting does not seem to connect to the oxygen supply system fitting, the supplier should be contacted immediately. The vessel should be returned to the supplier to determine the fitting or connection problem.
6. Once a cryogenic vessel is connected to the oxygen supply system, but *prior* to introducing the product into the system, a knowledgeable person should ensure that the correct vessel has been connected properly.

"O_2 Mix-ups" continued on page 5

"O_2 Mix-ups" continued from page 4

We urge you to take every opportunity to promote the importance of properly handling medical gases. Alert all personnel in your facility, but especially those who are directly responsible for handling medical gas, to the potential hazards involved.

Reporting adverse events or errors to the FDA

Medical gases are prescription drugs. Therefore, all medical gas manufacturers who receive reports of death or serious injury associated with the use of medical gases are required under 21 CFR 310.305 and/or 314.80 to report those incidents to the FDA.

Hospitals, nursing homes, and other health care facilities should submit reports to CDER (301-594-0095) or directly to FDA's voluntary reporting program, MedWatch, by phone (800) FDA-1088, by facsimile (800) FDA-0178, or by mail to MedWatch, Food and Drug Administration (HFA-2), 5600 Fishers Lane, Rockville, MD, 20857-9787.

To read the guidance in full, go to: http://www.fda.gov/cder/guidance/4341fnl.htm ■

Section Membership: *Each Voice Is Important*

by George Gaebler, MS.Ed., RRT, director, respiratory care and cardiovascular service line; administrator, University Hospital, Syracuse, NY

As a past member of the AARC Taskforce for Organizational Restructuring, past-speaker of the AARC House of Delegates, and current AARC Transition Committee member, I thought I might offer some thought-provoking insights about the role of the AARC Specialty Sections with respect to the Bylaws changes enacted by the Board of Directors (BOD). The ratification of these very significant Bylaws changes in late 1998 brings us to a point where membership in the Specialty Sections should be desired by all members of the AARC.

One of our major objectives in restructuring the BOD membership was to streamline the connection of the profession to its members. The Bylaws now stipulate that the BOD shall include " a Section Director from each Specialty Section of at least 1000 active members of the Association." While the Bylaws are a living document, responsive to change by the membership, this new provision indicates a new commitment on the part of Association leaders to include greater diversity of opinion in the decision-making process at the highest level of the organization.

The new role of the section chairs places them at the apex of communications, where they can serve as a defined, direct voice for the specialty practitioners of any section meeting the 1000 member requirement. Never before have specialty practitioners from the grassroots within respiratory care practice had such a clearly defined voice at the AARC Board level. This allows any specialty practitioner a clear path for communications directly to the BOD, unencumbered by the affiliate communications pathways that may unintentionally filter a message so that it loses significance or relevance to the original perspective of the section member. Likewise, it provides the Board with a clear message, direct from specialty practice grassroots members, about issues confronting them in their everyday practice.

I am sure many AARC members and non-members alike have asked themselves how their voices can be heard, especially concerning their area of practice. Joining one or more of the AARC Specialty Sections is the solution, thanks to this new allowance in the AARC Bylaws.

The future growth and direction of the profession depends on consistent input and feedback from AARC members. The Specialty Sections provide the best opportunity for that feedback. You could think of the sections as " mini-associations" representing specially focused practitioners across the breadth of the Association. Your membership in the section provides the opportunity to directly impact the activities and direction of the profession in a way never possible before this change occurred. Indeed, a simplified and multi-directional membership voice in the Association was a baseline assumption by the Taskforce for Organizational Restructuring.

I invite all of you to seek out section membership in your chosen area of practice, pull others in to augment your collective voice, and help the profession move in the direction needed for the future. The emphasis on clinical activities in the Specialty Sections prompts the BOD to pause and listen to members who live the profession, teach the profession, and care for the profession. After all, our profession belongs to the folks in the trenches, and the future depends on your involvement and insight.

All of the sections probably include members who were part of the HOD and BOD process that brought the Specialty Sections to prominence. I challenge them to step up and lead the transition process. ■

Experience the Best of the Science, Tradition, and Future of Respiratory Care

28th Annual Donald F. Egan Scientific Lecture

COPD — On the Exponential Curve of Progress

John Heffner, MD, of the Medical University of South Carolina will the address COPD and its growing significance for respiratory therapists.

16th Annual Phil Kittredge Memorial Lecture

Mechanical Ventilation: How Did We Get Here and Where Are We Going?

Among therapists, Rich Branson, RRT, FAARC, of the University of Cincinnati Medical Center, is well recognized as an authority and visionary when it comes to mechanical ventilation.

27th Annual OPEN FORUM

Hundreds of original research papers will be showcased over the four days of the Congress, reviewing the latest in pediatric, adult, critical care, home care, and education. (You can still submit your research project - deadline July 31). Learn about cutting edge research in the OPEN FORUM and see the latest technology in the Exhibit Hall.

17th Annual New Horizons Symposium

This year the topic is airway clearance techniques. This featured symposium attracts an audience of hundreds who come to immerse themselves in the most thorough review of a clinical topic.

Secure your early bird low-cost registration fee now! Register online at www.aarc.org. Also, continue checking the AARC website for the latest information on the Congress.

The AARC's International Respiratory Congress is the gold standard of respiratory care meetings. The Congress boasts:

- The lowest cost of continuing education per credit of any show, any where.
- The largest and most impressive exhibit hall with the most vendors, where you can make you best deals on major purchases AT THE SHOW!
- The largest gathering of respiratory care experts and opinion-makers in the world.
- The most diverse and most dynamic series of lectures.
- The most opportunities for YOU to participate in your profession through research and networking. ■

Specialty Practitioner of the Year

Don't forget to nominate a fellow section member for Specialty Practitioner of the Year!
Submit your nomination online at: www.aarc.org/sections/diagnostics_section/diagnostics.html.

JCAHO Accreditation Report

The AARC is currently seeking information on JCAHO accreditation site visits. Please use the following form to share information from your latest site visit with your colleagues in the Association. The information will be posted immediately on the AARC web site at http://www.aarc.org/members_area/resources/jcaho.html and will also be featured in the *Bulletin*.

Accreditation visit you are reporting (choose one):

❏ Home Care
❏ Hospital
❏ Long Term Care
❏ Pathology & Clinical Laboratory Services

Inspection Date: _____

Facility Name: _____

Contact: _____
(Please provide name and e-mail address.)

1. What was the surveyors' focus during your site visit? _____

_____

_____

_____

2. What areas were cited as being exemplary?

_____

_____

_____

3. What suggestions were made by the surveyors?

_____

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_____

4. What changes have you made to improve compliance with the guidelines?

_____

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Additional comments:

_____

_____

_____

_____

Mail or fax your form to:
William Dubbs, RRT
AARC Associate Executive Director
11030 Ables Lane
Dallas, TX 75229
FAX (972) 484-2720