“No one knows what he is able to do until he tries.”
—Publilius Syrus (ca. 50 BC)

This has been an incredibly exciting and productive year for member involvement in the Diagnostics Section. I would like to extend a big thank you to Catherine Foss and Bonnie Anderson for the coordination and production of our quarterly Bulletins. I would also like to thank everyone who submitted articles to this publication. Your contributions have certainly enhanced our knowledge in diagnostics this year. Thank you!

As you will note from the pullout section in our fall issue, we are continuing to expand our Resource Panel. Each of these individuals has graciously volunteered to help colleagues in his/her area(s) of expertise. Congratulations to each of you for your participation in this important communications network!

Beginning in this issue, the Diagnostic Section is expanding the Practitioner of the Year concept to include quarterly awards. Our goal is to recognize the contributions of more of our colleagues in the diagnostic area. The “Quarterly Practitioner of the Year” idea has proven very successful in other sections. Take the time to nominate a colleague! Our 1997 “Practitioner of the Year” will be selected from the quarterly winners.

Our focus in this issue on clinical laboratory medicine raises a number of questions and addresses several areas of controversy. In several of the articles, references are made to the College of American Pathologists (CAP) and the National Committee on Clinical Laboratory Standards (NCCLS), both of which are excellent resources in clinical laboratory medicine. NCCLS also serves as the Secretariat for International Standardization and frequently calls for nominations to standards committees as new projects are approved. If you are interested in serving on a NCCLS committee, please call or e-mail me at the number/address listed on the back page of this issue.

For those who attended the AARC Convention in San Diego, I hope you enjoyed the opportunity to network, spend time with friends, and expand your knowledge in diagnostics and respiratory care in general. Did the lectures meet your needs and expectations? We are currently in the process of submitting program proposals for the 1997 AARC Convention and I’d appreciate any feedback you could provide on this year’s program, as well as any ideas and/or suggestions for next year’s meeting.

Today’s rapidly changing health care environment requires the tenacity to persist and try again—regardless of the obstacles or challenges. If something doesn’t work the first time, we need to change the filters and look at things differently. It is amazing what each of us is capable of accomplishing if we only try.
Bonnie Anderson (co-editor) and I have been very pleased by the number of practitioners who contributed their viewpoints on diagnostic issues throughout this past year. In this issue, for example, we are featuring a variety of views on POC issues. The opportunity to serve as Bulletin editor has provided me with a year of professional development and it has been a pleasure to network with fellow practitioners across the country.

As the new year starts, I would like to encourage everyone to consider contributing to the Bulletin. Think of it as a sounding board for your ideas. Case studies, updates on procedures, helpful hints, FYI alerts, full articles or abstracts of your research are all appropriate for this publication.

I am pleased to announce that Vicky Ganey will join me as co-editor for 1997. If you were unable to attend our section business meeting at the AARC Convention in San Diego and would like more information about how you can contribute to the Bulletin, please contact either Vicky or me at the numbers/addresses listed on the back page of this issue. The general themes and deadlines for 1997 are as follows:

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(Note: we would like to see articles on both pediatric and adult issues)

I would like to thank everyone in the Diagnostic Section for their multiple contributions to their profession this past year. Your actions and deeds confirm that respiratory therapists not only continue to play an important role in the stat laboratory but often take a leadership position in making the work of these laboratories more relevant to the care of patients as well. This is even more apparent when one takes into account your involvement in point-of-care testing. As such, you are definitely meeting the goals of the profession to sustain, enhance, and expand the clinical status of the respiratory care practitioner.

As an aside, my own laboratories are currently evaluating new blood gas instruments for purchase and I thought it might be worthwhile to give you the list of criteria we are using to try to select the best instruments for our laboratories. Choosing such instruments is a complex task. One must assess the performance and usability of each manufacturer’s product by in-house evaluation. Unfortunately, I have heard of many laboratories that did not perform such evaluations. Instead, they chose an instrument based on an offer from a particular manufacturer that was too good to turn down, only to live to regret their choice over the long haul. The following is a list of criteria that we are using to try and select the right blood gas analyzers for our laboratories. I offer this list in the hope that it will be useful to others when they are confronted by this decision.

Criteria for Choosing an ABG Instrument

1. Accuracy and precision equivalent or greater than current practice.
2. User-friendly (programs and functions easily, accessible, and easy to understand).
3. Hospital computer patient data system interfaceable, preferably bi-directional.
4. Test selectivity. The ability to create own
desired panels of tests (minimum of five).

5. No priming required to get consistent results once maintenance and controls are run.

6. Minimal time to bring system back up after maintenance.

7. Bar code reader for both patients and quality control.

8. One sample aspiration or injection for all analytes.

9. Minimal re-membraning, if applicable.

10. Replacement parts easy to obtain. Allowed to perform in-house repairs.

11. Long-lived electrodes.


13. Ability to store both QC and patient data on disk and retrieve data at any time (archive).

14. Sample number entry of up to 9 digits, preferably alpha-numeric.

15. Linear ranges with controls and verification packages to meet CLIA and CAP requirements.


17. Quality Control management package onboard, Levy-Jennings and Westgaard.

18. Economical log, scheduling, and records onboard instrument.

19. Data printed to a stand-alone printer.

20. Field service availability in person within 24 hours of request. Rapid response by telephone when called.

21. Low cost per test (reagents).

22. Compact.

D I A G N O S T I C S  S E C T I O N  B U L L E T I N

DIAGNOSTICS SECTION SPECIALTY PRACTITIONER OF THE YEAR:
Catherine M. Foss, BS, RRT, RPFT

As senior clinical technologist in the adult blood gas and outpatient pulmonary diagnostic laboratories at the University of Michigan, Catherine Foss, BS, RRT, RPFT, is responsible for a wide range of technical and managerial duties. In addition to supervising staff, overseeing equipment repair and maintenance, and handling inventory control and purchase ordering, she is in charge of QA and QC for all instruments and participates in the writing and updating of policies and procedures. Catherine coordinates the patient information system program for the department as well, and teaches clinical rotations for students from Monroe Community College.

The biggest challenge she has faced since joining the University of Michigan three and a half years ago, however, has been the need to expand her skills to match the more complex case mix seen there. “As a member of a cross disciplinary team of professionals who care for and educate patients with pulmonary problems, I have been given the opportunity to advance my respiratory cross disciplinary skills,” says Catherine. “Some of the region’s most difficult to diagnose cases are referred to our institution for evaluation. To assist in solving these puzzling cases, I have learned several new skills . . . I have become proficient in EMG phrenic nerve stimulation studies, esophageal balloon placement with compliance studies, and arterial line placement.”

Catherine has a Bachelor of Science degree in education from the University of Michigan and an Associate degree in respiratory therapy from Washtenaw Community College. Prior to joining the University of Michigan, she worked as a pulmonary function lab co-coordinator at Catherine McAuley Health Systems in Ann Arbor, MI, and has also taught pulmonary function testing to students at both Washtenaw and Monroe Community Colleges. She is an active member of both the AARC and the Diagnostics Section, and is currently serving as our Bulletin co-editor.

Section membership is important, says Catherine, because it provides RCPs working in specific areas of the profession with the chance to “join together to have issues discussed, problems solved, and standards agreed upon.” She values
her membership in the AARC for the educational opportunities it provides, as well as the common voice it raises on behalf of RCPs everywhere. “In these times of downsizing, reengineering, and cross-training, I feel the AARC has positioned its members to prepare for the ongoing changes in the health care field.”

In addition to her accomplishments on the job and as Bulletin co-editor, Catherine has presented lectures and papers at Michigan Society for Respiratory Care (MSRC) meetings and other local and area respiratory care-related events. She was the Diagnostic Section Chair for the MSRC in 1995. In 1994, she presented a research poster at the 1994 AARC Convention that was subsequently published in RESPIRATORY CARE. Congratulations, Catherine!

QUESTIONS AND ANSWERS ABOUT BLOOD LACTATE MEASUREMENT
by James A. Kruse, MD, FCCM

Dr. Kruse is associate professor of medicine at Wayne State University School of Medicine, and director of the medical intensive care unit and medical director of respiratory care and diagnostics at Detroit Receiving Hospital in Detroit, MI.

What is lactate?

All of the cells comprising the human body need energy in order to carry out the various chemical reactions involved in growth, healing, digestion, muscle contraction, and other bodily processes. Much of this energy is derived from glucose, a simple sugar present in most dietary carbohydrates. If there is sufficient oxygen available, each molecule of glucose is metabolized to carbon dioxide by a process called aerobic metabolism. Under hypoxic conditions glucose can only be partially metabolized, and the by-product is a chemical substance called lactate. Because this latter process can occur in the absence of oxygen, it is referred to as anaerobic metabolism.

One drawback to anaerobic metabolism is that it does not result in as much energy production as occurs during the more complete breakdown of glucose to carbon dioxide. Therefore, although anaerobic metabolism can provide the energy needed to keep our cells alive and functioning in the absence of oxygen, it can only do this for a short time. Accumulation of lactate in the blood is an indication that there is critically decreased oxygen available at the tissue level. Prolonged and severe hypoxia will eventually lead to death.

What is the normal blood concentration of lactate?

A small amount of lactate is normally present in the blood, amounting to a concentration of about 1 mmol/L. Some laboratories report lactate using the older weight/volume units, which translate to about 10 mg/dL. Higher levels are not of clinical concern unless they exceed about 2.5 mmol/L.

Does blood lactate ever increase in healthy people?

A healthy heart and lungs can provide our muscles with sufficient oxygen to readily carry out moderately strenuous exercise. As long as enough oxygen is delivered to our muscles to allow them to completely metabolize glucose (i.e., by aerobic metabolism), the muscles will not invoke the anaerobic metabolic pathway. However, a healthy person’s muscles are capable of performing more work than can be fueled by the oxygen supplied to them by the heart and lungs. If this occurs the muscles must resort to producing lactate if they are to work still harder. This happens only during severely strenuous exercise, generally the type of exercise that can be performed for only short intervals. Jogging, for example, is an aerobic exercise for healthy individuals in good physical condition, whereas
sprinting requires anaerobic metabolism. Thus, it is normal for blood lactate concentration to increase transiently during and immediately after extreme exertion such as sprinting.

**What is the main cause of elevated lactate in patients?**

Blood lactate concentrations above 2.5 mmol/L are abnormal in resting patients. The most common cause is lack of oxygen at the tissue level. This can occur during severe hypoxemia, i.e., when the amount of oxygen in the blood is critically low. However, tissue hypoxia is most often due to circulatory shock. Shock can develop when heart function is severely impaired, resulting in inadequate blood flow. Another common cause is severe sepsis. Shock can also occur when the blood volume becomes critically low, such as from excessive bleeding or severe dehydration. In most of these situations the hypoxia is due to insufficient blood flow to vital organs, potentially resulting in damage to those organs.

A critical decrease in blood flow means that inadequate oxygen is delivered to the tissues. Thus, it is important to recognize that tissue hypoxia can occur even when there is plenty of oxygen in the arterial blood (such as when the PaO₂ is normal). This is because oxygen delivery depends not only on the amount of oxygen in the blood but also on the rate of blood flow to the tissues.

Shock is a life-threatening condition accompanied by a high mortality rate. Patients in shock often have low blood pressures. Occasionally, however, they are able to maintain a normal or near normal blood pressure, at least for a while. In these cases, finding an elevated blood lactate level can be helpful in uncovering this serious clinical disorder.

**What is lactic acidosis?**

Excessive lactate production is accompanied by the production of acid. If the blood lactate concentration rises to about 5 mmol/L or more, there is often enough accumulated acid in the blood to measurably lower the pH. When this occurs in the resting state it is called lactic acidosis. Lactic acidosis is a form of metabolic acidosis. Other common etiologies of metabolic acidosis include kidney failure, severely uncontrolled diabetes, and severe diarrhea.

In the past, lactic acidosis was commonly identified by determining the presence of a low blood pH and excluding other possible explanations for the acidosis. Because there are numerous other causes of acidosis besides increased lactate, measuring blood pH is not the ideal method for determining that lactate is elevated. In addition, significant increases in blood lactate are not always associated with a low pH or clear evidence of acidosis. This can occur, for example, if there is concomitant respiratory or metabolic alkalosis. However, if an arterial blood gas profile indicates the presence of metabolic acidosis, lactic acidosis should be a consideration. This diagnostic possibility can be readily confirmed or excluded by measuring blood lactate.

**What causes tissue hypoxia besides shock?**

The amount of oxygen carried by the arterial blood is decreased if PaO₂ is very low (hypoxemia) or if the blood hemoglobin level is low (anemia). Thus, either of these disorders could cause tissue hypoxia, resulting in increased blood lactate. However, this rarely occurs because the normal heart is able to compensate for these derangements by augmenting blood flow and thereby maintaining adequate oxygen delivery to the tissues. Therefore, if cardiac function is normal, lactate will not increase unless the PaO₂ or hemoglobin level is profoundly decreased. On the other hand, for patients with poor cardiac reserve, low levels of PaO₂ and/or hemoglobin can contribute to increased lactate production.

Other conditions that interfere with the balance between systemic oxygen supply and demand can lead to increases in blood lactate. It rises during cardiac arrest because there is no
blood flow, and therefore no oxygen delivery, to the tissues. In status asthmaticus the blood lactate level may increase, in part due to the strenuous work of breathing imposed by the severe bronchospasm, as well as the decreased PaO₂ that is often present. It is also related to impaired cardiovascular function secondary to the deep negative fluctuations in intrathoracic pressure that occur as the patient struggles to inspire against constricted airways. Seizure is another common cause of increased blood lactate. The involuntary muscle contractions that occur in this condition can be severe enough that the muscles need more energy than can be supplied by aerobic metabolism. In that case, anaerobic metabolism is utilized and lactate production increases.

Are there any other causes of high lactate besides tissue hypoxia?

Tissue hypoxia is the most common explanation for the finding of an elevated resting lactate level. There are other causes, but for the most part they are either uncommon or inconsistently associated with high lactate levels. Examples include certain types of cancer, deficiency of vitamin B₁, certain types of poisoning (e.g., ingestion of methanol, ethylene glycol, cyanide, or strychnine) or drug overdoses (e.g., isoniazid, acetaminophen), and a small number of rare, congenital metabolic disorders.

High lactate levels are commonly associated with severe sepsis. There is controversy as to whether this is always due to tissue hypoxia or whether it may in some cases be due to a poorly understood metabolic effect of the sepsis.

What is the clinical significance of an elevated lactate level?

For hospitalized patients whose blood lactate concentration exceeds about 2.5 mmol/L, their risk of dying parallels the degree of lactate elevation. Studies have found that patients with blood lactate levels exceeding 5 to 10 mmol/L will usually succumb to their acute illness. There is some evidence that by identifying these patients early, therapeutic interventions can be instituted that, in some cases, may improve tissue oxygenation and thereby improve their chances for survival.

How should blood be sampled for lactate measurement?

Blood obtained from a peripheral vein can, in some cases, be higher in lactate than blood found elsewhere in the body. For that reason, many institutions measure lactate only on arterial blood specimens. Blood drawn from a pulmonary artery catheter (mixed venous blood) is equally acceptable.

The concentration of lactate in a blood specimen rises over time because the blood cells produce lactate even in vitro. A common way to minimize this effect is to place the blood sample on ice, transport it to the laboratory quickly, and perform the analysis promptly. Because lactate levels are frequently measured on arterial blood specimens, and because blood samples for both of these tests are ideally transported on ice and assayed as soon as possible, lactate analysis is best performed in the same laboratory where blood gas measurements are made. Certain models of the newest generation of blood gas instruments can perform lactate analysis automatically along with the conventional blood gas measurements.

When should blood lactate concentration be measured?

Lactate analysis is helpful in evaluating intensive care unit patients, particularly those who are critically ill. It is also very useful in evaluating any patient whose condition is worsening, or who is hypotensive or showing other signs of shock. For patients who have had previous blood gas measurements that revealed metabolic acidosis, blood lactate should be evaluated if the cause of the acidosis is at all unclear. For patients who have been found to have an elevated lactate, the
blood level should be remeasured at intervals until it normalizes.

What treatment is indicated when blood lactate is increased?

There is no specific form of therapy that is indicated when the blood lactate level is abnormally increased. Instead, the focus for most patients is to ensure adequate oxygen availability to the tissues. Thus, if PaO₂ is low, supplemental oxygen is usually indicated, and in many cases mechanical ventilation will be necessary. If cardiac output is low, various measures can be considered to improve systemic perfusion. Depending on the exact cause, this might include administration of intravenous fluids, infusions of drugs that stimulate the heart or affect blood vessel diameter (such as dopamine or dobutamine), or use of the intraaortic balloon pump. In cases of severe anemia, blood transfusions may be required. Pulmonary artery catheterization is frequently implemented in patients with high lactate levels as a means of further assessing cardiac status and the response to the above and other treatments. Obtaining serial blood lactate levels provides the clinician with information as to whether the instituted treatment is having a positive effect. If blood lactate concentration is shown to be decreasing over several hours, it suggests that the treatment being used is ameliorating tissue hypoxia. On the other hand, progressively rising lactate levels are an ominous prognostic finding.

BIBLIOGRAPHY

A Pleasant Surprise

To my surprise, I received a phone call from our main lab manager in May asking if I could help them do a CAP inspection or peer review on another hospital that had the same structure we had, i.e., an independent blood gas lab under the direction of respiratory therapy. How could I refuse such an honor?

I can report to you that it was a very worthwhile experience for several reasons:

• First, I picked up several ideas about how other blood gas labs operate and meet the CAP guidelines. Since this lab was computerized, I got to see how such a system is utilized in a similar hospital setting. It was also helpful to observe how another blood gas lab met some of the more difficult standards, such as Calibration Verification and Supervisory Review.

• Next, the experience strengthened the bond between me and our own lab staff. Normally, I have very little interaction with the lab manager, section chiefs, or the pathologist. After spending the entire day with them, however, I gained a greater appreciation for their expertise and professionalism. They proved that they were truly committed to accuracy and good laboratory practice.

• Finally, I feel the main lab staff has gained a deeper respect for the commitment and skill that we, as RCPs, apply to the operation of our blood gas lab.

If you are asked to join your lab for a peer review of another facility, do not pass it up. The rewards are worth it. However, I do have several tips to ensure success:

1. Study and review the CAP checklists with the accompanying documentation.
2. Review your most recent Deficiency Summary Report and your corresponding responses.
3. Always show respect and courtesy.
4. Ask questions and be as complimentary as possible.
5. If you are unsure about any of the standards, call the CAP office before you inspect. They are very helpful.
6. Be brief and clear in writing your deficiency report.
7. Ask your lab manager to review your comments before the summation conference. They generally have much more experience with the CAP inspections and can provide valuable input.

Perspective on Point-of-Care Blood Gas Analyzers

by Brian E. Jeffreys, RPFT, CPA

Brian Jeffreys is director of the respiratory care services department at The Mt. Sinai Medical Center in Cleveland, OH.

Point-of-care (POC) laboratory instruments have become an important topic in health care journals lately. Individuals quoted in these articles pointedly comment that the most desirable POC instrument is the POC blood gas analyzer. Those remarks make POC testing of particular interest to RCPs. Because of recent advertisements and articles depicting a POC analyzer as a small hand-held device that can be taken directly to the patient’s side, enabling a therapist or lab technician to provide results from analysis immediately after obtaining the sample, we might not realize that there are many instrument configurations that don’t fit this definition, yet still qualify as POC analyzers.

A POC instrument can be anything from a bench-top instrument mounted on a cart to urine dip sticks. POC testing is not something that sprang up recently in the wake of advances in electronic miniaturization and microprocessors. Developments in these fields may have helped to advance the potential of POCs, but the idea of POC testing comes from a long-standing desire to provide better, more efficient care. The small
blood gas/electrolyte instruments that are now entering the market are indeed new and exciting. For RCPs, what could be better than a faster blood gas result? It sounds too good to be true.

Certainly there are things to consider before you take out your purchasing requisition, but most of the information on these instruments is positive. We should strive to get them into our departments and put them to use in a meaningful way. At Mt. Sinai, we have used a POC blood gas analyzer for more than 2 years in our outpatient pulmonary lab. It has performed more than adequately and provided an affordable alternative to a bench-top instrument, so that we can provide blood gas analysis in a low-volume environment (<25 samples in a month). We had previously tried using a bench-top instrument in this environment, but encountered a maintenance nightmare. The first mistake we made then was using an old instrument from our blood gas lab. Without constant use and calibration, the instrument truly acted its age. It was “down” more than it was “up.” We have found the low-volume environment to be an almost perfect use for a POC blood gas analyzer. The devices are inexpensive, and infrequent use has not adversely affected performance. We do miss the CO-oximeter, which is crucial in an outpatient environment to accurately measure SaO₂ and COHb on smokers and non-smokers. To compensate for this, we use a small exhaled CO meter to approximate the COHB percent. Hopefully, we will one day see CO-oximetry in a POC machine.

Currently, we are considering another potential use for a POC blood gas analyzer, this time as a backup instrument. In our facility, the use of noninvasive monitoring (pulse oximetry and capnography) in the care and weaning of the ventilator patient has reduced the need for blood gas analysis tremendously. In our busiest years in the blood gas lab, the intensive care units were sending us thousands of blood gas samples per month. Our total workload is about 35% of what it was in our busiest period. Yet we are still the main blood gas service in our institution, so we must provide a 24-hour/7-day-a-week service to serve those patients who still need arterial blood gas analysis, as well as to validate the hospital’s noninvasive monitors.

To maintain a 24-hour service, a backup instrument is obviously required. Even if you ignore the reliability problem in backup instruments, they are expensive to keep in readiness. A backup instrument has the same inventory of reagents and electrodes, and the same maintenance and repair costs as a main instrument. You must run QC every day, do proficiency tests thrice yearly, do linearity testing, and incur other costs to meet regulatory requirements. After all the expense, there is no guarantee that, when your main instrument fails, the backup instrument will not also be in need of service.

In such a situation, how nice it would be to reach to the shelf, take down your backup instrument (a POC blood gas analyzer), flip it on, and get back to work. This is the way that I envision the use of a POC analyzer as a backup instrument. The instrument would be inexpensive to buy, would generate costs only when it was used, and would be reliable and ready when needed.

All of the POC blood gas analyzers that we have evaluated have a guarantee on their measurement cells or sample measurement packs. In our use of the POC analyzer, when a measurement pack fails to pass QC or calibration, we simply open another one. We then call customer service and the company replaces the failed measurement pack at no charge. There are limits, of course. When we first acquired the instrument, we had some problems with failing measurement packs. All the faulty packs were replaced, but we also received more on-site training from the customer support department.

One negative aspect of POC testing is that the cost-per-test on POC analyzers is much higher than it is for the bench-top instruments.² Our own evaluation showed that one of our bench-top instruments
instruments has a cost-per-test of approximately $1.75, whereas the POC analyzer we use has a cost-per-test greater than $10. The current difference between instruments in cost-per-test is substantial, and it was a major factor in preventing us from using a POC analyzer as backup. But we expect that competition and technology will make instrumentation cheaper. As the cost-per-test comes down, the use of POC as backup will become more feasible. In addition, costs of using a POC as a backup are limited by the expectation that your main instrument will be out-of-service infrequently and for no more than 24 hours at a time.

There are other points of concern related to general use of POC blood gas analyzers. There is concern over who should be allowed to use the instrument, how it will be controlled, and how competency is to be checked. Studies have shown that POC analyzers correlate closely with bench-top instruments, but experience has taught us that there are measurement differences between the two modalities in patient samples, quality control, and proficiency testing. The differences in measurement must be acceptable to your medical staff or you will quickly lose credibility. Finally, the expectation of improved outcomes from rapid analysis may be good material for copy in slick marketing brochures, but has little basis in reality. Still, POC analyzers have great potential for forward-thinking respiratory care departments—if put to the right use.

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1. Anonymous. Point of care lab testing. SCCM Symposia Highlights; 1996:33-34

Thanks to Lawrence Martin, MD, for proof-reading.

CONVENIENCE VS. QUALITY
by Cheryl P. Morgan, RRT, RPFT
Cheryl Morgan is pulmonary laboratory coordinator at St. Vincent’s Medical Center in Bridgeport, CT.

Point-of-care testing (POCT) has become the new medical buzzword of the 90s. But are we sacrificing quality for convenience? We’re all trying to respond to cost-cutting initiatives while preserving patient care, but perhaps we need to keep in mind that faster isn’t always better.

It seems to me that we need to be careful when new technology crops up in response to a fad or a trend. The CLIA ’88 regulations, for example, have stipulated certain requirements for the technology long used in blood gas analysis occurring within the pulmonary lab. Yet many of these rules don’t seem to apply to technology generated for POCT, even though both are considered moderately complex. The two blood gas systems I’ve looked at for POCT have cartridges with everything you need to analyze your sample, including electrode sensors, but neither corrects for changes in barometric pressure. The partial pressures of blood gases will change with changes in barometric pressure—at least that’s what I’ve always been taught according to Boyle’s Law. My pulmonary lab analyzers correct for barometric pressure. How do the POCT analyzers justify the non-compensation? I’m not quite sure how the College of American Pathologists can allow these systems to pass the accreditation standards, when there are a lot of standards these systems can’t meet.

According to the National Committee for Clinical Laboratory Standards (NCCLS)
In Vitro Diagnostic (IVD) Testing: Proposed Guideline, March 1995, there are a number of aspects to consider. Included among the crucial points made in the document is the following: “Because of the enormous consequences of unreliable test results, it is vital that high quality and reliable results be maintained as tests are transferred from the clinical laboratory to the point of care.” I’m cautious about POCT because oftentimes nurses and residents are involved in analyzing samples, but they just don’t have the training to pay attention to the minute details of all of the things that could go wrong during analysis. That’s not a comment about their nursing or physician skills, which may be exemplary. I just find it hard to believe that our years of experience and training can be so easily dismissed and replaced by someone who has 1 hour of training. Whose life are we affecting if there’s a mistake or, worse yet, a mistake that may not even be recognized?

Another point the NCCLS guideline makes is that POCT is expensive. It is more costly than testing done in the laboratory setting, so each hospital or non-hospital site must perform a cost analysis to see if the rapid response of results warrants or justifies the expense. It is possible that costs can be saved in other areas to offset the added cost, such as a decreased length of stay by patients in POCT areas, more positive patient outcomes, or less additional ancillary services. POCT does not make much sense if it does not result in a cost savings somewhere down the line. The need for rapid response of test results otherwise does not seem to make much difference.

According to NCCLS, the cost analysis should address the following in-hospital considerations: turn-around-time; length of stay (within department/within institution), patient comfort, clinical decisions based on rapid results, STAT testing requirements, follow-up testing, laboratory staffing levels, non-laboratory staffing levels, therapeutic/pharmacy utilization, blood product utilization, and physician convenience.

NCCLS recommends that all CLIA recommendations be adhered to, just as in a laboratory setting. However, non-laboratory personnel oftentimes see all of this detail and paperwork as a waste of time, and it’s hard to get compliance in a non-laboratory setting. The question often comes up as to why are we doing all of this when it doesn’t seem to make a difference either way. Non-laboratory personnel would rather spend their time on direct patient care, and they don’t have the background to understand your explanation. You could say that the Clinical Laboratory Improvement Act of 1988 is a law, and if we don’t do this we’re breaking the law. However, then people feel that they are being intimidated. It is recommended that POCT devices have the capability of downloading patient data to a Laboratory Information System to provide a permanent record and to facilitate billing. Critical values should also be defined. However, in my opinion, these critical values mean nothing if the sample results are potentially inaccurate.

NCCLS recommends that a Hospital Point-of-Care Testing Coordinator be appointed to advise and assist POCT site directors, supervisors, and testing personnel in the following: selecting testing methodologies, verifying of methods and test procedures performed, establishing a QC program, enrolling and participating in a proficiency testing program, establishing acceptable levels of analytic performance and ensuring that these levels are maintained, resolving technical problems and ensuring that actions are taken whenever test systems deviate from the laboratory’s established performance specifications, ensuring that each person performing tests receives regular in-service training and education, and evaluating the competency of all testing personnel and ensuring that staff maintain their competency to perform test procedures. This represents a lot of work, and perhaps it makes more sense to leave the analysis where it belongs—in the laboratory with the skilled practitioners.

I may be one of the few people saying this, but I do think that POCT is a phase that medicine is
D I A G N O S T I C S  S E C T I O N  B U L L E T I N

going through as it downsizes. At some point we’ll realize that this just isn’t working, and we’ll go back to the way things were. Maybe not completely, because people will still be very aware of being cost-effective, but we’ll move back toward the middle once again. There have been many specialized industries that have come into existence to meet a perceived at-the-moment need, but that have not withstood the test of time. Market forces have a way of changing direction quickly, just like the wind. In my opinion, we have a better chance of withstanding strong market forces if we adhere to the tried-and-true aspects of our profession rather than fostering change just for the sake of change. Sometimes it seems the more things change, the more they remain the same, and at some point in time we realize that we’ve already been here before.

VENDOR RESPONDS TO QUESTIONS ABOUT POC TESTING

Editor’s Note: One vendor responded to our request to comment on the previous article. The following is that response.

The i-STAT System measures or calculates the level of 16 different substances in blood using a variety of unit-use test cartridges. Among these measurements are the traditional arterial blood-gas parameters: pH, PCO$_2$, and PO$_2$.

The system measures the blood-gas parameters at 37°C as per common practice. It directly heats the biosensor chips and fluids within the cartridge to achieve thermal. Each unit-use cartridge also includes a calibration fluid so that every sensor is calibrated before measuring the sample. The oxygen calibration is dependent upon the environmental barometric pressure as is common on traditional bench-top blood gas analyzers. The i-STAT analyzer measures the barometric pressure using a set of redundant solid-state pressure sensors.

The performance of the i-STAT System is equal to that of the traditional laboratory or bench-top equipment. By exploiting biosensor technology to package the sensors in a unit-use format, the i-STAT System achieves this performance while eliminating the need for calibration and maintenance.

POC VS. LAB:

**BOTH MAY BE BEST IN BLOOD GAS ANALYSIS**

by Karen Titus

Editor’s Note: The following article is reprinted with permission from the College of American Pathologists from CAP TODAY, June 1996.

The matter of bedside behavior is no longer an issue solely for clinicians. Those with a stake in the blood gas analyzer field now face a bedside question of their own: How big a role will point-of-care testing play in laboratory operations?

Just as users of cellular phones are able to take and make calls almost anywhere, health care workers may soon be running blood gas analyzers in any number of locales. And while it’s unlikely that laboratory technologists will run arterial pH tests while driving down the highway, critical care testing could be used in bedside and near-patient settings, either in the hospital or in the home, in both centralized laboratories and reference labs, during emergency transport, and even at the site where a person is injured or first contacted by medical personnel.

Far-fetched? Not according to Charles R. Handorf, MD, PhD, chair of the CAP Alternative Site/Point-of-Care Testing Committee. “This is definitely an area where point-of-care testing is probably having more of an impact on the central laboratory than any other area,” he says.
“With a lot of POC testing, the devices duplicate testing done in a central laboratory,” he explains. “For example, a bedside glucose analyzer generally doesn’t replace the glucose analyzer in the central lab; it’s merely additive. But in many instances, distributed or POC blood gas analysis can replace blood gas instrumentation in the central laboratory. It represents a real change in the way we’re thinking about blood gases, and it makes a big difference to clinicians, who are able to make decisions on a real-time basis. That’s a real value.”

“POC has really come of age with blood gas and electrolytes, because that’s where the highest need is and is the easiest to justify,” agrees Robert A. Dorsher, U.S. product leader for Mallinckrodt Sensor Systems.

Despite this apparently limitless potential for POC blood gas testing, however, laboratory-based analyzers don’t appear to be going the way of the rotary phone any time soon, say many observers. For both manufacturers and users of blood gas analyzers, the more immediate challenge is cutting laboratory and hospital costs. The solution, most agree, could fall on either or both sides of the POC/central lab testing fence.

Location, location, location!

“People in the field are constantly asking me, ‘what do you think is going to happen? Do you think eventually all blood gas analyzers are going to be sitting next to everyone’s bed?’” reports Donald L. Baker, director of marketing and regulatory affairs at Radiometer America. “The issue is predominant in customers’ minds.”

Not surprisingly, manufacturers are equally obsessed. “There are competing visions out there,” acknowledges Dorsher. “If you talk to the traditional (blood gas analyzer) companies, You’ll find that many discount POC almost entirely. If you talk to the POC companies, they’ll tell you the whole world is going to go POC.”

Baker contends that some mixture of POC and laboratory-based blood gas analysis is the most likely scenario. “I don’t think the field is going to go all in one direction,” he says. “I think we’ll see a combination of a number of different segments.

What we’re seeing so far is that the handheld bedside analyzers are not really used at bedside,” he continues. “If you have an ER or ICU that has 15 beds, you don’t see 15 hand-held (devices), because they’re very expensive, and they disappear sometimes. What they’re doing is really using them in a near-patient setting, the same as with other analyzers, with one unit in the ICU, for example.

“At the same time, you’ll continue to see some analyzers located in the central lab,” he adds. “And then you may see a very, very small number that are actually used at bedside, say in a 5-bed ICU.”

Large university hospitals, for example, may perform blood gas analysis in several locations, including a centralized laboratory with a traditional analyzer and a satellite blood gas lab in an outpatient clinic, where near-patient testing is the norm.

Smaller hospitals, by the same token, may also find that a mixed approach works best. They could run a traditional, laboratory-based blood gas analyzer during the day, and a POC device during the off-hours, when volumes are lower but the criticality of individual results remain high.

“Community hospitals may opt to go POC and traditional because of labor issues, coverage, and volume,” says Dorsher. “And certainly on the high end there’s enough niche for production-type processing as well as POC processing. We’re seeing a lot of mix in a lot of hospitals. “So what you’re going to find is a happy medium, based on the appropriateness of the delivery systems within individual hospitals,” he continues. “Although people are touting extremes, I think these two marketplaces will coexist. There may be friction between them, but it’s really based on what the hospital is trying to accomplish.

“Both marketplaces are based on fulfilling the hospitals’ needs to streamline their services and
make them cost-effective. Sometimes the traditional configuration is going to work, and sometimes the POC is going to work, and more often than not it’s going to be a mix of both.”

That trend should continue as laboratories become more sophisticated at determining cost-effectiveness, he adds. “The shift is away from, ‘Your disposables cost X percent of my disposables.’ Hospitals are looking at the cost-effectiveness of delivery systems, including which blood gas technology to use.”

Hospitals traditionally have looked at the cost of their analyzers’ reagents and compared that to a POC test cartridge, explains Maria E. Grant, product manager, i-Stat Corp. “Now hospitals are comparing the overall costs by looking at the entire process of delivering blood analysis results.”

“There are two components to the blood analysis process,” Grant continues, “and they compose the annual operating budget for a particular test panel.” One is the “floor” component (materials and labor associated with, for example, drawing the sample, preparing it to be transported, transporting it) and the other is the laboratory component (for example, equipment maintenance, and depreciation, supplies, and the labor associated with receiving, accessioning, spinning, and analyzing the specimen and reviewing the results). “You analyze your point-of-care process the same way,” Grant says, “and you tie it all into volume.”

Mary M. Audette, RN, director of marketing at Diametrics Medical, suggests that while some tests will always be best suited to centralized testing, stat tests most likely will move to the bedside—particularly with patients in the operating room, the intensive care or cardiac care unit, and the emergency department—as part of the overall patient-focused care trend in hospitals.

POC blood gas analyzers may have even bigger potential use outside the hospital.

“When you talk about bringing testing to the patient, you now have the opportunity to do immediate testing of home care patients,” Audette notes. “Think of the respiratory therapist in the hospital who now has to drive out to the home, draw a sample, label the sample, drive back to the laboratory, and have it tested—and if there’s a change required in the patient’s care, someone has to go back and make whatever adjustments are needed. Compare the expense of doing that versus taking a (POC analyzer) into the home and having the results immediately, with the ability to make a therapeutic change right away.”

Emergency care represents another possible arena for POC blood gas analysis. “It brings the capability of immediate testing to patients who haven’t had that access before,” says Audette.

New developments

Expanding along with their POC potential are blood gas analyzers’ menus, say industry representatives.

“As we continue to broaden the functionality of these analyzers, the term ‘blood gas analyzer’ will fade and will be replaced by the concept of a critical care analyzer,” says Howard Deahr, Nova Biomedical’s vice president of sales for North America.

“In the area of acute care, there are a number of analytes that are needed by the attending physician that are not offered today,” says Deahr, who declined to discuss specific analytes under development at Nova.

Diametrics Medical will be adding hematocrit to its new product, scheduled to be released later this year, and plans to add several additional critical-time tests down the road, Audette reports.

According to Radiometer’s Baker, “It used to be that people only thought of pH, pCO₂, and pO₂; now when they talk about blood gas analyzers, they’re thinking more of whole blood critical care parameters.”

While pH, pCO₂, and pO₂ remain at the core of these parameters, CO-oximetry parameters and measured saturation also come into play, largely because organizations such as the National Committee for Clinical Laboratory Standards
have recommended against the use of calculated saturation, Baker notes. In addition, he says sodium, potassium, calcium, and chloride, as well as glucose, have become widely available in the last 5 years.

Baker draws an analogy to the chemistry laboratory, where one analyzer with multiple parameters has replaced five or six different analyzers, all with different functions. “We’re starting to see more of that in the blood gas market: One system that has a fairly small sample volume, deals in whole blood, and gives you some flexibility.”

Economic constraints doubtless will temper menu development. Additive, rather than replacement, tests are more difficult to justify. “Even if we have a great idea, if we can’t show that it actually saves money, then it won’t fly,” says Dr. Handorf. “I don’t think that the menu of bedside testing is going to get a whole lot bigger than it currently is. That’s my opinion, although others would disagree.”

While blood gases weigh in heavily on the benefit scale, the clinical advantage of other, high-cost bedside tests is questionable, he says. “You could certainly have bedside liver enzyme tests—but the question is, WHY? What would you get that you couldn’t get by waiting 45 minutes for the central laboratory test?”

First and foremost, says Mallinckrodt’s Dorsher, manufacturers—and users—need to define whether an instrument is a POC or a traditional laboratory-based analyzer. “You can’t cross back and forth between POC and traditional analyzers based on menu alone. Adding glucose or lactate to a traditional analyzer doesn’t make it a POC piece of equipment. Likewise, just because I can get a glucose on a POC system doesn’t mean it’s now a production analyzer capable of cranking out glucoses cheaply.”

The interface between blood gas analyzers and laboratory and hospital information systems is another area of concern to users and manufacturers.

Most traditional blood gas analyzers feature large, integrated internal data management systems, explains Baker. “People want to see a lot of data when it comes to blood gases,” he says. “They want to quickly verify all the quality control aspects, they want to look at patient data, and they may even want to be able to do trending. This is an area that POC will have to look at closely; it’s difficult without the data management component.”

Grant predicts that POC information will be integrated into patient monitoring systems, and from there into the LIS or HIS. “It’s going to provide a quick, seamless, paperless process,” she says. Moreover, such a system “will reduce physicians’ decision cycle times, enabling them to improve their critical pathways.”

As promising as all these developments may be, future technological advances may propel the field far beyond the current POC and laboratory-based framework. While good bedside analyzers are “very helpful” from a clinical standpoint, Dr. Handorf says, “This is probably only a phase that we’re going through.”

Devices now in development—and in some cases already available, although not widely used—will allow percutaneous measurement of blood gases and other values that don’t require an arterial stick, Dr. Handorf explains. The future, he says, could bring not only real-time analysis of real blood gases but serial evaluation of a patient’s values over any period of time.

“That’s what oximetry has tried to do, but technologically that’s not at all where we’re going to end up. I think we’re going to go much further than that. It’s going to be very exciting.”

With POC devices in, traditional QC is out

Using a variation on the “you-can’t-teach-an-old-dog-new-tricks” argument, proponents of alternative quality control methods have set out to prove that conventional QC methods are not the most viable approach for the current generation of laboratory tests.

At a meeting of the National Committee for Clinical Laboratory Standards’ subcommittee on
unit-use testing in late March, members launched an effort to develop new QC techniques that would be deemed more suitable for point-of-care devices. And though the task appears daunting, the subcommittee’s chair, Boehringer Mannheim’s David L. Phillips, reports that a tentative document may be available early next year.

The issue has become a lightning rod for manufacturers in particular, says Phillips. “Traditional quality control is not appropriate for nontraditional or unitized test devices. We need to develop something else,” Phillips says.

In a presentation at the March 29 meeting, subcommittee member James O. Westgard, PhD, noted that QC has yet to move beyond its second generation of development, which is widely considered to consist of the rules and trending techniques developed by Dr. Westgard in the mid-to late 1960s. In the meantime, he said, technological advances have pushed analyzers into their fourth or fifth generation of development, moving from the auto-analyzer to random and discrete testing.

“Essentially, the committee has to make a decision: Do we want to leapfrog from the second generation of QA/QC to where we are now, or do we want to start from scratch and do something different?” Dr. Westgard asks.

Even traditional QC methods used in the central laboratory have their limitations, Phillips continues. “If you look at the statistics of QC now, it doesn’t assure that you’re not reporting out bad results. So if we’re taking the QC system out of the central lab and applying it to unit use, then we’re taking a flawed system and applying it to another method.”

Charles R. Handorf, MD, PhD, chair of the CAP Alternative Site/Point-of-Care Testing Committee, concurs.

“I absolutely agree with people who say that we need to take a different approach to quality control, especially for these new devices and new ways of testing. The way we’re doing quality control now, in my view, is antiquated. We’re trying to apply old testing paradigms to many of these new devices, and it doesn’t make sense. We don’t have a good statistical basis for a lot of what we do.”

From the subcommittee’s standpoint, says Phillips, the challenge will be to create a flexible system that identifies sources of error and ways to manage—but not necessarily eliminate—them.

“To provide a simplistic example, let’s say the committee is able to identify ten components that make up a ‘quality system.’ Some manufacturers may be able to build a system that can control five of those,” he says. “The other five are then the operator’s responsibility to check. Another manufacturer may be able to build in nine of the components, so the operator only checks one. As long as the operator knows what part of the quality system can be verified by the manufacturer, the operator can manage the rest. In both instances, the manufacturer can assist with the operator-managed portion.”

Once the subcommittee develops a list of all sources of error, says Phillips, it will try to construct a guideline managing the error sources. The group’s next meeting is scheduled for June 24; in addition, it appears that the American Association for Clinical Chemistry will address the topic of alternative QC at its fall Forum, to be held in San Francisco Oct 24-25. “This Forum should provide us data to demonstrate if there is value in doing more or less QC,” says Phillips. “Can we assure quality without spending as much as we have historically spent?”

Although the subcommittee’s efforts have officially been designated as a “fast-track” project by NCCLS, the issue of alternative QC may take time to be resolved in the minds of users and manufacturers.

While alternative QC has a reasonable basis for use with distinct analytes, it has no place as a blanket application, argues Robert Dorsher, of Mallinckrodt Sensor Systems. “It has its place in coag and well-characterized, stable chemistries, but I believe it really needs to be thoroughly investigated for blood gases,” he says.
Nova Biomedical’s Howard Deahr suggests that budget considerations, rather than good laboratory practices, are helping to propel the move toward alternative QC. “Some of the approaches to POC or near-patient testing are very costly, so alternative QC is often used as a compromise to that.”

Furthermore, the electronic simulators used to perform alternative QC don’t satisfy all QC requirements, including trends and operator proficiency, says Deahr. “Quality control should monitor the entire testing process, and an electronic simulator is nothing more than a test of the electronics of the instrument. We believe that traditional QC is very important, especially in near-patient testing. POC is often performed on the hospital’s sickest patients, at the most critical time of their hospital stay—but it’s often performed by POC personnel who may not be the best laboratory personnel.”

Dr. Handorf agrees—to a point. “I think the electronic QC has a place, but I don’t think electronic QC is the whole answer,” he says. “I think we will get to a rational point on QC at some point, but it sure is hard to change old habits and attitudes.”


HCFA Inspection Reminder
by Pauline H. Wulbrecht, RPFT

Pauline H. Wulbrecht, RPFT, is from the Scott & White Clinic in Temple, TX.

In regard to personnel standards for labs performing moderate complexity testing (i.e., pulmonary function labs performing ABGs), the Federal Register states in two separate paragraphs (493.1423) that for moderate complexity testing an individual may be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course etc.; or have earned an academic high school diploma or equivalent. HCFA inspectors do not recognize NBRC credentials.

Nothing is said, however, about what happens if the high school education occurred on foreign soil. It is the responsibility of the laboratory director to ensure that documentation of all education credentials for testing personnel meets the regulation requirements. So be aware that even though your staff may have NBRC credentials, when your personnel records are evaluated during inspection, all high school education obtained in foreign countries can be questioned. The inspector can require you to provide a transcript of high school courses or may request an equivalency evaluation by one of the organizations listed in the interpretative guidelines for surveyors (see below).

This process can cost your technician anywhere from $80 to $200, depending on which documents are needed for the evaluation and how fast you need them back. It usually takes a minimum of 20 working days if everything is satisfactory the first go-round. This requirement is important for laboratories that have long-time technicians who “trained on the job,” but advanced through the credentialing process over the years. Quite frankly, it would be faster and cheaper to go and get a GED (HCFA will accept this) at the local high school.

Interpretive Guidelines—Laboratories

Equivalency evaluations for foreign academic credentials will be performed by an organization that is a member of the National Association of Credential Evaluations Services, Inc. (NACES). The following are members of NACES as of the publication of these guidelines:

(Note: the prices vary, so shop around)
REQUEST FOR INFORMATION:  
“ICING” BLOOD FOR ABGS  
by Jerome L. Eisenberg

I’m looking for facts, experiences, etc., concerning “icing” blood for ABGs versus running the samples directly from the patient to the lab. We are thinking about changing our procedure from immediately doing the analyses, which the RCPs normally do themselves, to letting the samples sit iced until the lab techs are free to do them. The only time the analysis would be done right away would be when there is a STAT order involved.

Our RCPs are not concerned about which method we adopt. In fact, it might be easier for us if we did not have to be concerned with finding someone to palpate the patient until certain that bleeding had stopped. What we are really concerned about is determining which method would assure the most accurate readings.

If you have any information regarding this topic, please contact me at:  
4227 Susan Dr., Williamsville  
NY 14221  
e-mail: JLRMEISENB@AOL.COM.
One of the goals of the Diagnostics Section is to gain more information about the expertise of our members and the primary way we have of accomplishing that goal is through short surveys published in the Bulletin. Please take a few minutes out of your day to fill out the following survey on cardiac stress testing and mail/fax it to Susan Blonshine at the address/number listed on the back page of this issue.

**CARDIAC STRESS TESTING SURVEY**

Name _________________________________
Address _______________________________
City, State, Zip __________________________
Phone _________________________________
FAX __________________________________
E-mail _________________________________

1. Are you performing cardiac stress testing in the respiratory care department?
   - □ yes
   - □ no
2. Is a physician present for the exercise?
   - □ yes
   - □ no
3. Who attends the exercise in addition to a physician?
   - □ RCP
   - □ RN
   - □ Other (please specify) _________________
4. Is ACLS required for attendance at the exercise?
   - □ Physician
   - □ RCP
   - □ RN
   - □ Other

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**FOR YOUR INFORMATION**

**NCCLS Schedules Managed-Care Congress**

Concerned that rapid developments in the area of managed care are occurring without a solid consensus from all participants, the National Committee on Clinical Laboratory Standards (NCCLS) has scheduled a major congress for the spring that will address key quality-related factors. “Consensus: The Key to Real Value in Managed Care” will be designed to elicit agreement from a broad range of professionals and organizations on issues that affect all aspects of health care today. The AARC will be playing an active role in the discussions through the participation of Diagnostics Section Chair Susan Blonshine, BS, RRT, RPFT.

Participants in the congress, which will take place in Arlington, VA, April 18-20, are expected to focus on the determination of medical necessity and medical “niceties,” patient satisfaction, provider satisfaction, employer cost, and outcomes assessment. In addition, the congress will examine existing problems within the system and identify areas where consensus on various issues could help to meet the expectations of managed-care systems, improve administrative processes, and achieve quality-related goals.

To facilitate the discussion of these topics, the congress will be broken down into three “issue tracks.” Track A will focus on “The Delivery of Quality Medical Care Within a Managed-Care System.” Track B will deal with “The Fair, Efficient, and Effective Administration of a Managed-Care System.” Track C will address “Effective Quality Assurance in the Managed-Care Environment.”

NCCLS has a 30-year history of developing standards through the consensus process and includes a diverse membership that reflects the majority of the types of organizations involved in the development of managed care. For more information about the upcoming congress, con-
A study that compared 2,184 critically ill patients who underwent right heart catheterization within 24 hours of being admitted to an ICU with a control group of patients who did not receive the test has raised serious questions about the safety and effectiveness of the procedure.

According to researchers from Case Western Reserve University in Cleveland, OH, patients who had the test had a 24% higher 30-day mortality rate and stayed in the ICU an average of 1.8 days longer than those who did not. Their hospital bills averaged $49,300—a third higher than those for patients who did not undergo the procedure. More than 1.2 million right heart catheterizations are done every year in the U.S.

These dismal results, which confirm the findings from five previous studies that found an association between the test and increased risk of complications, higher mortality rates, and added costs, have led the American Medical Association to call for a nationwide study of the procedure. If a study is not forthcoming, the AMA says the Food and Drug Administration should consider a moratorium on the test. The study was published in the September 18 issue of JAMA. (Source: Reuters, 9/17/96, USA Today, 9/18/96)

The groundbreaking Guidelines on the Treatment of Asthma published by the National Institutes of Health in 1991 recommended major changes in the diagnosis and treatment of asthma. Now the NIH group responsible for those guidelines has published a new report that speaks to the cost and quality issues related to asthma care. The National Asthma Education and Prevention Task Force Report on the Cost Effectiveness, Quality of Care, and Financing of Asthma Care provides a comprehensive overview of the issues that must be addressed for successful implementation of the guidelines nationwide. The report, which is included as a supplement to the September issue of the American Journal of Respiratory and Critical Care Medicine, is must-reading for every RCP involved in the diagnosis of this condition.

Physicians battling the HIV virus are finally chalking up some victories. Using a mixture of antiviral drugs in a “cocktail” approach, they have been able to remarkably lower the amounts of HIV in the systems of infected individuals — sometimes to the point where it can no longer be detected by standard tests. If they can begin treating a patient soon enough — before the virus devastates the immune system — they believe they may be able to hold the virus at bay over the long term.

But what about patients whose immune systems are already severely compromised by the disease? New research being conducted at New York Hospital-Cornell Medical Center suggests there may be hope for them as well. In an attempt to see if the immune system could be stimulated (something yet to be accomplished by medical science), they administered small doses of the hormone interleukin-2 to AIDS patients with CD4 counts that were below normal but not indicative of full blown AIDS. The idea was to see if the hormone, which is used against several cancers known to cause severe side effects in large doses, might still have a positive effect if given at doses that could be tolerated. Patients were taught to self-administer the treatment through injections.
Researchers started their subjects out with doses measuring 125,000 IU, but found they were too low to make a difference in CD4 counts. Doses of 500,000 IU made a difference, but caused side effects like low-grade fever, muscle aches, and general malaise. When patients were given doses of 250,000 IU, however, CD4 counts began to rise, adding a mean of 27 or 28 cells a month, and there were no side effects.

Since the study group contained only 16 patients who received the therapy for 6 months, the researchers say more work must be done to establish the efficacy of this treatment. However, they believe it holds promise, not only for patients who have yet to develop full blown AIDS but also for those who are already suffering from the disease. The “cocktail” approach could be combined with the interleukin-2 therapy, they say, to reduce the amount of the virus in the person’s system and boost his/her immune system at the same time.

The study was published in the Proceedings of the National Academy of Sciences last September. (Source: Reuter, 9/16/96)

NEW WEAPONS BEING DEVELOPED AGAINST DRUG-RESISTANT BACTERIA

The increasing drug resistance of bacterial infections like *Streptococcus pneumoniae*, *Staphylococcus aureus*, and enterococci has been a growing concern in hospitals for quite some time. As resistant strains of these bacteria gain ground, however, many are now leaving the hospital for other areas of the community. Particularly vulnerable are those in high-risk populations, such as the elderly, young children, and those with underlying medical conditions that leave them with compromised immune systems. Health officials estimate, for example, that resistance to penicillin — the first defense against *S. pneumoniae* — currently stands near 40% and other drugs, such as cephalosporins and non-beta-lactam agents, are catching up fast. Says Robert C. Moellering, MD, chair of the department of medicine at New England Deaconess Hospital in Boston, “While resistance was once found primarily in the hospital setting, we’re beginning to see more and more evidence of resistant pathogens in the community.”

Clearly, new drugs are needed to curtail the spread of these deadly bacteria. Rhone-Poulenc Rorer believes it has a couple of possible replacements. The company is currently awaiting approval from the FDA for an injectable streptogramin antibiotic called Synercid® (quinupristin/ dalfopristin), and an oral antibiotic called Zagam® (sparfloxacin) that appears to provide comprehensive coverage of community acquired infections, particularly those involving the respiratory tract. “Based on extensive clinical trials, Synercid and sparfloxacin show promise in treating several important antibiotic resistant strains,” says Moellering. “New agents, combined with infection control measures and judicious antibiotic use, will help us win the war against microbes.”

Moellering’s comments were made during a satellite symposium aired prior to the 36th Interscience Conference on Antimicrobial Agents and Chemotherapy held last fall. (Source: PRNewswire, 9/16/96)

SMOKING STEALS THE YEARS AWAY

Since cigarette smoking causes life-threatening diseases like lung cancer, heart attacks, and stroke, it only stands to reason that smokers have shorter average life spans than nonsmokers. According to a British study involving 7,735 men, that’s exactly right. They found that 78% of the men who had never smoked were still alive at age 73. Only 42% of those who had started smoking before the age of 20 and continued smoking throughout their lives could say the same. The 15-year study was conducted at London’s Royal Free Hospital School of Medicine and funded by the British Heart Foundation. (Source: Reuter, 10/11/96)
RESOURCE PANEL UPDATE

A
n updated version of our Resource Panel appears in this issue, but we are still looking for additional qualified members to add to the list. If you would like to participate in the panel, fill out the form below (we ask that you limit yourselves to 10 topics or less) and return it to one of the Bulletin editors at the addresses listed on the last page of this issue. Another update will be coming soon.

☐ New Panel Member    ☐ Returning Panel Member w/Changes    ☐ Please drop my name from the panel

Name: ________________________________________________________________

Title: ________________________________________________________________

Institution: __________________________________________________________

Complete address(es) (work and/or home): ______________________________________

________________________________________________________

________________________________________________________

Phone(s): __________________________________________________________

Fax: __________________________________________________________________

E-mail (if available): __________________________________________________

TOPICS

Pulmonary Diagnostics
☐ Spirometry
☐ Lung volumes
☐ Airway Mechanics
☐ Diffusing Capacity
☐ Steady State Diffusing Capacity
☐ Blood Gas, Electrolyte and Hemoximetry Analysis
☐ Point-of-Care Testing
☐ Bronchoscopy
☐ Sweat Chloride Testing
☐ Conscious Sedation
☐ Cardiopulmonary Exercise Testing
☐ Airways Challenge Testing
☐ Pulmonary Mechanics and Occluding Pressures
☐ Sleep Disorders
☐ High Altitude Simulation
☐ Ventilatory Drive

Critical Care Pulmonary Diagnostics
☐ Indirect Calorimetry
☐ Noninvasive Cardiac Diagnostics

Pediatric and Neonatal Care
☐ Neonatal, Infant, Toddler, and Pediatric
☐ Pediatric Bronchoscopy

☐ Research

☐ Occupational Health

☐ Administrative Management

☐ Rehabilitation & Education

☐ Patient-Focused Protocols

☐ Clinical Practice Guidelines
OUTSTANDING SECTION MEMBER OF THE QUARTER: NOMINATION FORM

Don’t forget to make your nominations for the Diagnostics Outstanding Section Member of the Quarter award. The winner of each Outstanding Section Member of the Quarter award will be featured in an article in the Bulletin and our Specialty Practitioner of the Year will be chosen from these four winners. The winner of the Specialty Practitioner of the Year award will be honored during the Awards ceremony at the AARC Convention.

The recipient of this award will be determined by the Section Chair or a selection committee appointed by the Chair. Each nominee must be a member of the AARC and a member of the Section.

Use the following form to send in your nominations for this important award.

I would like to nominate _______________________________ for Diagnostics Outstanding Section Member of the Quarter because ________________________________________________________________

Nominee _______________________________ Your Name _______________________________

Hospital _______________________________ Hospital _______________________________

Address _______________________________ Address _______________________________

City __________________ State, Zip City __________________ State, Zip

Phone _______________________________ Phone _______________________________

Mail or FAX this form to the Section Chair at the address/number listed on the last page of this issue.