

Low enrollment has forced many laboratory education programs to close across the country. 15 programs closed last year, leaving 273 programs to serve the entire country. It is estimated that approximately 30 percent of programs in the U.S. have closed in the last 5 years.

The BOR annual survey of Accredited Medical Laboratory Science Programs reports for the last two years shows that nearly 100% of the graduates who sought employment in a laboratory immediately found employment.

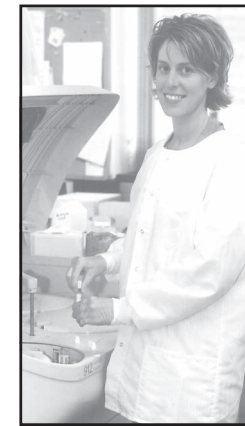
Based on demographic information available through ASCP, over 72% of the current laboratory workforce is over the age of 40, with the majority nearing retirement age. Concern has been expressed that there are not enough people entering the profession at a time when many in the workforce will be retiring, and the demand for laboratory services is expected to triple. This is moving professional organizations to take the personnel shortage issue to the national policy arena.

The 2002 survey results also showed that rural communities still have a difficult time filling vacancies in the laboratory, especially cytotechnologists and histotechnologists. Many labs have had to utilize temporary staff to fill positions, along with an increase use of non-certified personnel to fill positions. Salaries do appear to be rising, although just ahead of inflation.

There are modest improvements, but not enough to make anyone feel comfortable. Credit must be given to the grass roots activities of medical laboratory professionals to increase the public awareness of the shortage and to grab the attention of Congress.

ASCP June 23, 2003 ♦

Client Service Spotlight



Michelle Friesen has been an employee of Avera Sacred Heart Hospital for 7 years. She is a medical technologist (ASCP) from Menno, SD. She received her bachelor's degree in Clinical Laboratory Science from SDSU and completed her internship at Sioux Valley Hospital. She and her husband Lee have two children: Seth, age 5, and Aidan, age 2. Their pets include 2 cats (on a regular basis) and whatever her boys bring home...frogs, snakes, worms, butterflies, etc.!

Michelle enjoys listening to books on tape during her 45 minute commute to ASHH, going for walks, decorating birthday cakes, and "researching" on the internet. Her favorite aspect of lab work is the challenge of keeping up with the constantly changing instrumentation and methodology. She also works for a temp agency (Lewis and Clark Health Education and Services) in Yankton. Michelle appreciates the exposure she receives when working in different laboratory environments and gains new perspectives on laboratory practices and instrumentation ♦

Case Study

A six-year-old Caucasian female presented to the emergency room with episodes of abdominal pain and occasional fever. The symptoms had been occurring over several days. Approximately one year earlier, she had gone to the ER with the same complaints. Nothing unusual was noted at that time.

Laboratory Work:

The CBC revealed a hemoglobin of 10.0 g/dl, a WBC of 169.6×10^3 , and a platelet count of 545,000. The manual differential showed 54 segmented neutrophils, 19 bands, 13 lymphocytes, 4 monocytes, 2 eosinophil, 1 basophil, 5 metamyelocyte, and 1 promyelocyte. Calcium and AST were increased on the metabolic panel. The urinalysis contained 2+ leukocyte esterase.

The patient was referred to a pediatric oncologist for a bone marrow aspirate. In conjunction with the bone marrow aspirate, flow cytometry and cytogenetic studies were obtained. The Philadelphia chromosome translocation abnormality was revealed upon chromosomal analysis of the bone marrow. The abnormality is an indication of Chronic Myelocytic Leukemia (CML). Approximately 90% of CML patients will have the Philadelphia chromosome. A FISH (fluorescent in situ hybridization) study was performed and 95.8% of 500 nuclei had fusion of the BCR and ABL signals. Fusion of these two genes leads to the leukemogenic process. CML is predominantly found in adults. It is very rare in children.

Treatment:

Typically, Interferon and Cytarabine are used to treat CML patients. However, this patient was given Gleevec, a new gene-targeting drug. Gleevec is a tyrosine-kinase activity inhibitor that slows white blood cell growth. It was approved for pediatric use five days prior to the patient's diagnosis of CML. In early June, the patient was started on Gleevec. After one week of treatment, her white blood cell count was down to 10.8×10^3 . She is also scheduled to have a bone marrow transplant. ♦

The New CLIA Regulations and How Labs Will Be Surveyed Under These New Guidelines

Speaker: **Connie Richards**

October 21, 2003
8:30 - 12:00

Orthopedic Institute Auditorium

Avera Laboratory Network *Lab News* is published every other month to provide the latest updates on services from labs of the Avera Laboratory Network.

Editors: Lori Murray

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Security Compliance & What Does It Mean To Us?

Now that the HIPAA compliance regulations on Privacy Standards have been implemented, it's time to take a look at the next phase of the regulations: Security Compliance.

HIPAA's security regulations have been released and a two-year time deadline to meet the requirements has been given. Two years may seem like a long time, but as we all remember a few years ago when the words "HIPAA Privacy Compliance" were introduced, we thought we had a long time until we had to meet those regulations and how fast the time came, so it's important not to wait, but to start getting a plan formulated.

So what is "Security Compliance" and what does it mean to us? "This final rule adopts standards for the security of electronic protected health information to be implemented by health plans, health care clearinghouses, and certain health providers. The use of the security standards will improve the Medicare and Medicaid programs, and other Federal and private health programs, the effectiveness and efficiency of the health care industry in general by establishing a level of protection for certain electronic health information. Compliance dates are two years for most entities except for the small health plans which have three years to comply."

The security rule mandates that organizations do the following:

- Train all workforce members in security awareness
- Conduct risk analysis to determine information security risks and vulnerabilities
- Establish policies and procedures that allow access to electronic PHI on a need to know basis
- Implement audit controls that record and examine who has logged into Information systems
- Limit physical access to facilities
- Establish and enforce sanctions to all workforce members who do not follow Security policies and procedures.

While all the standards are required for organizations to safeguard the confidentiality, integrity, and availability of electronic protected health information that it creates, receives, maintains, or transmits, the implementation of the standards varies. To distinguish between strict guidelines and recommendations, the rule sites implementations specifications as "required" or "addressable". The rule has 42 implementation specifications, of which only 20 are "required" and the remaining "addressable". If listed as required, you must implement it. If listed as addressable,

you don't have to implement it unless it's reasonable and appropriate for your organizations own situation. Alternative solutions should be implemented for addressable items when you do not use their recommendations.

Meeting these requirements may involve technical solutions that may take time to research, evaluate, and integrate into existing systems. If your facility does not have it's own compliance team or office, please feel free to contact ALN for all your HIPAA compliance questions or educational needs.

Summary of Standards

Administrative Safeguards

- Security Management Process - *required*
- Assigned security responsibility - *required*
- Workforce security - *addressable*
- Information access management - *required*
 - Access authorization - *addressable*
 - Access establishment & modification - *addressable*
- Security awareness and training - *addressable*
- Security incident procedures - *required*
- Contingency plan - *required*
- Evaluation - *required*
- Business associate contracts and other arrangements - *required*

Physical Safeguards

- Facility access controls - *addressable*
- Workstation use - *required*
- Workstation security - *required*
- Device and media controls - *required* (disposal & reuse)
 - Addressable (accountability, backup & storage)

Technical Safeguards

- Access control – unique user ID - *required*
- Emergency access procedure - *required*
- Automatic logoff - *addressable*; encryption and decryption - *addressable*
- Audit control - *required*
- Integrity - *addressable*
- Person or entity authentication - *required*
- Transmission security - *addressable*

Organizational

- Business associate contracts or other arrangements - *required*
- Group health plan sponsor - *required*

Policies, Procedures and Documentation

- Policies and procedures - *required*
- Documentation - *required* ♦

BNP VS. proBNP

It has been estimated by the American Heart Association that approximately 4.8 million Americans have congestive heart failure, with 550,000 new cases occurring each year. Congestive heart failure is a condition in which the heart cannot pump blood efficiently to the rest of the body. Symptoms of CHF are shortness of breath, fluid retention, and respiratory distress. Brain-type natriuretic peptide is a hormone secreted into the circulation by the left ventricle in response to increased blood pressure. BNP dilates the vessels and promotes water and sodium loss, which in turn reduces fluid load on the heart and improves cardiac performance.

BNP was first discovered in pig brain tissue (hence the term *brain-type*). The precursor form of BNP is proBNP, which contains 108 amino acids. When proBNP is secreted it is cleaved into the active BNP, and the inactive N-terminal fragment, NT-proBNP. NT-proBNP has a longer half-life and is more stable in laboratory specimens. There are assays available to test for both types of BNP. Naturally-occurring BNP and a drug called nesiritide (Natrecor®) are chemically identical and the BNP test cannot differentiate between the two. Natrecor® is used as a treatment for patients with acutely decompensated congestive heart failure who have shortness of breath at rest or with minimal activity.

BNP Method

Biosite has a single-use fluorescent immunoassay for BNP. The Triage BNP method uses EDTA whole blood or plasma. If the specimen cannot be tested within 4 hours of collection, the plasma must be separated and frozen at – 20. EDTA plasma results are about 7% lower than whole blood results. Testing time is approximately 20 minutes. The linearity of the assay is from 5-1300 pg/ml and the manufacturers recommended normal range is <100 pg/ml. The Triage BNP test offers point-of-care capability, no centrifuge is required, and is an economical method of screening for heart failure.

Pro-BNP Method

Roche has developed the first fully automated method for measuring NT-proBNP. Serum or plasma samples can be used although EDTA plasma yields 10% lower values. The methodology is a double antibody electrochemiluminescent (ECL) immunoassay. TAT is about 18 minutes. The ECL method provides linear results from 5-35,000 pg/ml. Reference ranges provided by the manufacturer are <125 pg/ml for patients <75 years of age and <450 pg/ml for patients 75 or older. The automated platform reduces technologist time and decreases human errors. Probably the biggest advantage of the NT-proBNP method is that it is not affected by Natrecor® therapy. Compared to the BNP assay, NT-proBNP is more sensitive but less specific. It may be most useful as a method of ruling out CHF due to its negative predictor value of greater than or equal to 98%.

Whether your testing facility uses the BNP assay or the NT-proBNP assay, they both can offer valuable information for diagnosing and treating congestive heart failure when used in conjunction with the clinical presentation of the patient. ♦

Sources:

Biosite Triage BNP product insert, Roche Elecsys proBNP product insert, www.natrecor.com, www.dlslab.com, www.medicalautomation.org, www.aruplab.com

2002 Wage & Vacancy Survey Results

The American Society for Clinical Pathology (ASCP) released on June 23, 2003, its report on the state of the clinical laboratory workforce today. This is the 12th survey in a series of biennial studies done by ASCP Board of Registry (BOR). A full report will be available in the September 2003 issue of Laboratory Medicine

These initial findings were reported at a press briefing in Salt Lake City at the CLMA-ASCP Conference. The BOR has been documenting declining numbers of lab professionals since the mid 1990's. At the same time, the U.S. Department of Labor Bureau of Labor Statistics tracked the increasing demand for laboratory services, which reached 10 billion tests performed in 2001 and continues to climb.

It is estimated that from 2002 through 2010, a total of 13,200 new Medical Technologists and Medical Laboratory Technicians will be needed each year to meet the demand for laboratory services as the population in the U.S. ages. The average number of graduates from accredited programs is less than 5000 per year, indicating an annual shortage of 8,200 professionals.

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