

## FROM THE EDITOR...

I am writing this editor's note just days after the deadly attack on America. I keep thinking that the world and humanity as we have known it, will never be the same. The events of September 11, 2001 will forever alter the course of history. The compassion and unity that have arisen out of this tragedy awe me. I have the deepest admiration and respect for those that have been involved in the rescue and recovery efforts, and for the efforts of healthcare workers who have cared for the injured. We have all been touched by this tragedy. We have been brought together as a nation, as a family of Americans, to stand up against these deplorable acts of violence. Whatever our future holds, we will face it together.

Together we can overcome adversity and move forward to build a better world. It is hard to find things to be happy about at a time of such hurt and anger, but we can rejoice in our togetherness with our family, loved ones, and fellow Americans. We can hope for the beginning of a long healing process for those countless many involved directly with this horrible event. We can move forward with our newly found strength to defeat our foe and given new meaning and purpose to our lives. Our nation is strong because of the strength of its people. Stand strong together. God Bless America! ♦

- Lori Murray

## CLIENT SERVICE SPOTLIGHT



**Deb Neitzel** is a Medical Technologist at Avera St. Luke's Hospital Laboratory. She has worked for Avera St. Luke's for 15 years, and currently works part-time. She is a client service representative and works closely with the outreach facilities in the Avera St. Luke's region. She enjoys getting to know the staff at each of the outreach sites

and although most of her contact is by telephone, she has established great relationships with clients by her friendly voice and helpful attitude.

Deb enjoys working in her yard and loves reading and golfing when she has time. She and her husband, Alan, have two daughters, ages 8 and 5. She grew up in Agar, South Dakota, but has called Aberdeen home for the past 15 years. She received her Bachelor's Degree at SDSU in Brookings. ♦

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## LABORATORY ERRORS CAN HAVE DIRE CONSEQUENCES

Recently officials at St. Agnes Medical Center in Philadelphia reported they had miscalculated the INR's of over 900 elderly patients and that these results may have been responsible for two deaths due to an overdose of coumadin and subsequent complications. An incorrect ISI value was used in calculating the INR 'S between June 4 and July 25, 2001.

In response to this incident the Pennsylvania Department, citing multiple violations of rules designed to catch and prevent errors, announced that it had ordered the laboratory at St. Agnes Medical Center in Philadelphia not to perform Prothrombin Time tests until appropriate corrective actions are taken and documented.

The state said it could not vouch for the lab's ability to produce reliable test results. St. Agnes, which voluntarily stopped performing Prothrombin time testing on August 2, had 10 days to report how it would fix its deficiencies.

Responding to this report the CDC is urging hospitals to change the way they administer the anticoagulant Coumadin (warfarin). In an analysis issued in the Morbidity and Mortality Weekly Report, the CDC notes that warfarin is "one of the most common drugs" associated with medication errors and that correct usage of the drug has been identified as an "important indicator" of quality health care and patient safety (8/24). The agency's recommendations reiterate those

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in a report issued by the Pennsylvania Department of Health, which said laboratories should review package-insert information to verify they are using the correct reagent-specific ISI value in calculating international normalizing ratio (INR). Furthermore, the CDC suggests that "laboratories should report and physicians should consider using" both the INR and the Prothrombin time (used to calculate INR) when considering changing a patient's Coumadin dose.

It is therefore, important to report both the INR value and the Prothrombin Time value in seconds. This will give providers more information and will more likely aid in detecting a lab miscalculation.

Some of the actions taken by St. Agnes to prevent and flag similar mistakes, include:

- implementing a policy for purchasing and introducing a new reagent that requires laboratory staff to document that the correct reagent was shipped by the manufacturer and that the reagent's package insert was reviewed
- expanding performance tests to compare the old reagent with a new shipment
- adding a computer-monitoring system that will flag patients who have significant changes in their INR
- training all lab staff in the new procedures.

Sister Marge Sullivan, St. Agnes President, said that the lab personnel were "well-trained, competent, dedicated employees." No employees have been disciplined. Both state and federal officials plan to alert other laboratories about how this mistake occurred and how it might have been prevented.

This unfortunate event is a reminder to us all that we need to be continuously on the alert and review product literature with each new shipment of reagents. We may all see stricter documentation requirements for verification of new lot's or shipments of reagents. ♦

## NEW DEPARTMENT OF TRANSPORTATION (DOT) COMPLIANCE RULINGS

Effective August 1, 2001 the Department of Transportation issued new changes with regards to drug screen collections. Some of those changes include the following:

- The new DOT Chain of Custody (COC) form is revised from a 7 part to a 5 part form. The 5 part form is the only form valid after August 1, 2001
- The Medical Review Officer (MRO) copy of the Chain of Custody (COC) form needs to be faxed directly to the MRO.
- The MRO phone number and fax number need to be pre-printed on the COC.
- The employer's name, phone number and fax number needs to be pre-printed on the COC.
- New Breath Alcohol Test (BAT) forms must be used.
- All new Collectors are required to complete a DOT Drug Screen Collection Certification Course. For those collecting prior to August 1, 2001, they will have until January 31, 2003 to become certified. Refresher training is to be no less frequently than every 5 years.
- All new MRO's are required to complete a MRO Certification Course. For those providing MRO services prior to August 1, 2001, they will have until January 31, 2003 to become certified.

Also, effective November 1, 2001, new DOT Forms and Medical Cards go into effect.

For questions or assistance in complying with the new DOT Rulings, please feel free to contact the following Avera associates:

**Avera McKennan**

Crickett Noll, Substance Abuse Coordinator at Avera McKennan HEALTHworks at (605) 322-5109 or David Darr, Business Development at Avera McKennan, at (605) 322-3856.

**Avera Queen of Peace**

Mari Ascherin, Director of Occupational Health at (605) 995-2443, or Rhonda Baker at (605) 995-5761.

**Avera St Lukes**

Dianne Dell, Outreach Manager, (605) 622-5813

**Avera Sacred Heart**

Warren Erickson, Laboratory Manager, or Rose Smith, (605) 688-8173

## REMINDER

Screening PSA's may only be ordered once every 365 days. Ordering more frequently than that will cause the test to be denied. An ABN must be obtained from the patient for this test before obtaining the sample.

If there are signs, symptoms, or reasons why the physician orders a PSA more frequently than once per year, those should be noted on the requisition and a regular, or diagnostic, PSA should be ordered.

### Food- not an excuse anymore

A new study indicates patients do not need to avoid red meat, dark fish, and certain vegetables for days before and during fecal occult blood testing, though avoiding Vitamin C is still recommended. The study, conducted at the University of North Carolina at

Chapel Hill School of Medicine, finds that test results "are about the same" in patients who do and do not alter their diets. And because dietary restrictions often cause people to avoid the test, the findings may motivate more of the 75 to 80 percent of Americans over age 50 to complete fecal occult blood testing. Lab Line Copyright 2001, Eli Research, Inc.

*"A meaningful life will not be found in the next job or the next car. The way you get meaning in your life is to devote yourself to helping others and creating something that gives you purpose."*

- Morrie Schwartz

## CASE HISTORY

A newborn Caucasian female had an initial hemoglobin of 20.9 and hematocrit of 58.7. The following day, mother and baby were discharged. Three days later the infant was brought to the clinic for jaundice with a total bilirubin of 22.7. She was admitted to the hospital for hyperbilirubinemia and began phototherapy.

A type and direct antiglobulin test were ordered, results were A positive blood type with negative DAT. Family history showed that the mother and a half-brother were affected by hereditary spherocytosis. A CBC on the infant confirmed the presence of spherocytes on the Wright's smear.

Two weeks later, the baby's hemoglobin was down to 8.5, hematocrit 22.0. She was admitted to the hospital for a transfusion of O negative, leukoreduced, irradiated, CMV negative blood. After receiving 60 cc. of blood, her hemoglobin was 14.6, hematocrit 38.4.

This patient is now nearly two years old and still occasionally requires blood transfusions to alleviate the symptoms of her hemolytic anemia.

### Hereditary Spherocytosis

Spherocytes are RBC's with decreased surface area: volume ratio. The cells have a smaller diameter than normal RBC's with a concentrated hemoglobin content. There are several conditions which can cause spherocytes to form:

- 1) final stage of normal RBC life span
- 2) complement activation and antibody coating (immune hemolytic anemia)
- 3) severe burns
- 4) hypersplenism, post-splenectomy
- 5) Clostridium welchii septicemia
- 6) spider, bee, and snake venom
- 7) hereditary spherocytosis (HS)

Hereditary Spherocytosis (HS) is the most common form of hereditary hemolytic anemia in the Caucasian population, occurring in about 1 out of 5000 people. HS is an inherited autosomal dominant condition in which a RBC membrane defect causes the cells to be prematurely captured in the spleen. The majority of cells seen in HS are stomatocytes and stomatospherocytes indicating a gradual loss of cell membrane as the RBC's circulate and are conditioned by the spleen. It is believed that a spectrin deficiency is a major contributor to the pathology of HS. Spectrin makes up the "skeleton" of the RBC membrane and a decrease in the surface density of spectrin directly affects the elastic properties of the membrane.

HS can present at any age. The clinical manifestation consists of a classic triad of jaundice, anemia, and hypersplenism. About 25% of HS patients have a mild, compensated anemia; 66% have a mild, uncompensated anemia with the classic symptoms; and the remaining 10% have a severe hemolytic anemia that may require transfusion therapy. Other indicators of RBC destruction include polychromasia, increased reticulocyte count, presence of nucleated RBC's, increased total bilirubin, increased LDH, and the presence of urobilinogen in the urine.

The osmotic fragility test is useful for the diagnosis of HS. RBC's are incubated in a series of hypotonic sodium chloride solutions. As the NaCl concentration decreases, the red cells take up water in an effort to achieve osmotic equilibrium. In HS, there is a decreased surface area: volume ratio so the cells are unable to expand as much as normal RBC's and lyse at higher NaCl concentrations.

Splenectomy is the treatment of choice for the severe form of HS. After splenectomy, the spherocytic cells exist with a normal or near-normal life span. It is recommended to wait until the patient is at least 6 years of age to perform the surgery to decrease the risk of post-splenectomy sepsis. In young children there is a higher risk of infection, especially from Streptococcus pneumoniae. A pneumococcal vaccination is advised to be administered to children prior to splenectomy surgery.

## Important facts to know about HIPAA HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 (HIPAA) INCLUDES:

- Insurance portability: Ensures individuals moving from one health plan to another will have continuity of coverage and not be denied coverage under pre-existing condition clauses.
- Fraud enforcement(accountability): Increases the federal government fraud enforcement authorities
- Administrative simplification: Responsible for standardizing of electronic formats for certain transactions, ensuring the privacy of certain patient information, and ensuring the security of electronic health information and electronic signatures

### Impact on providers and payers:

1. Adapt all electronic claim submissions and related systems to a new format for electronic transmission in order to get paid.
2. Assess all electronic information systems and implement protocols to ensure secure and confidential transactions
3. Assess all operators related to patient information and adapt and implement policies and procedures to ensure privacy and security during operations.
4. Accomplish steps 1-3 in 24 months or face civil monetary penalties

### The Administrative requirements of HIPAA

1. Designation of a privacy official whose responsibilities include making sure an organization has policies and procedures for the use and disclosure of information, making sure an organization obtains patient authorization, receiving and addressing complaints, coordinating training of employees, and coordinating functions with the security officer.
2. Training and certification of work force: The higher the level of access to protected health information, the more in-depth training they need. But all employees need a general level of training to make them aware of their privacy obligations.
3. Safeguard procedures: Formal procedures are needed to ensure that only authorized, trained personnel can gain access to private health information.
4. Complaint process: There needs to be a procedure in place to take complaints and respond by either doing what you can to fix the situation or to explain it.

5. Sanctions for violations: Once employees are trained they need to know what they can and can not do and what will happen if the rules are violated.
6. Mitigation procedure: Must have procedures in place to deal with an incident or violation when it occurs
7. Business partner or vendor contracts: You are responsible for information accessed by third parties so you need appropriate contracts following HIPAA rules.
8. Notice of Information practices: Patients have a right to know what information you have collected on them, how you collected it, and why information is needed. Policies are necessary on disclosing only the minimum necessary data, how you define minimum necessary data, and your procedure for identifying that data if identified data is appropriate for disclosure. There also needs to be written policies for validating the requestor and reason, and then deciding whether the identified data will suffice or, if not, what is then the minimum necessary data to be used or disclosed.
9. Audit trails: This is a system for tracking when, from where, and by whom electronic health information is accessed.

In July of this year a 48-page document was issued from the Department of Health and Human Services regarding clarifications to issues sought after by CAP earlier in the year. The guidance document states that health care providers who have indirect treatment relationships with patients, such as laboratories, can use and disclose private health information for treatment, payment, and health care operations without first obtaining patient consent.

The privacy rule does not require clinical laboratories that are also covered health care providers to provide an individual access to information if CLIA prohibits them from doing so. It is stated that "CLIA permits clinical laboratories to provide clinical laboratory test records and reports only to authorized persons. The privacy rule includes an exemption to individuals' general right to access personal health information about themselves if providing this information is in conflict with CLIA.

The July 6th guidance can be accessed at [www.hhs.gov/orc/hipaa](http://www.hhs.gov/orc/hipaa).

## ONLINE USERS GUIDE

We are proud to announce our On-Line Catalog. This catalog is available online to search test requirements, testing frequency, specimen requirements, etc. Just click onto [www.averalabnet.com/catalog.asp](http://www.averalabnet.com/catalog.asp) and you can search alphabetically or by test name. You can access the Catalog for information regarding Turn-around times, Consultation services, policies, supplies, etc.

While you are there, click onto ARUP Interpretive Guide. Did you ever wish you had more information as to why a doctor has ordered a certain test, how it pertains to disease states, or what the results mean? Here is the place to find many of those answers here.

While you are looking at the catalog, be sure to check out the rest of our website for information regarding ALN or your Service Center, FAQ's, or search some of the links provided. Grab your mouse and do some browsing!!

Our LabNet Newsletter has taken on a new look. We are excited about the changes. It is part of our effort to keep our services progressing into the future.

The Avera Laboratory Network continues to grow, evolve, and meet new challenges. We are responding to the needs of our clients with the type of information we provide and the ways in which we provide it. Client feedback is very important to us, and helps guide us when developing articles, programs, and services.

Check out our Website and the LabNet News at [www.averalabnet.com](http://www.averalabnet.com).



## A "BLACK HOLE" IN CLIA

WASHINGTON, DC, Sept. 6 (Eli Digital) Centers for Medicare & Medicaid Services inspectors soon will be conducting random, on-site visits to labs certified as waived or provider-performed microscopy facilities under the Clinical Laboratory Improvement Amendments.

In a new inspection report, the HHS Office of Inspector General pokes holes in existing CLIA controls over waived and provider-performed microscopy testing, noting that labs who only do such tests typically don't get surveyed at all, while surveyors who inspect moderate and high complexity labs don't evaluate waived and PPM test procedures.

Indeed, one state agency official told the OIG that the lack of site visits for waived labs is "a huge black hole in the integrity of the CLIA program. ... If no one ever checks on them ... they can essentially do whatever they want."

That hole likely will soon be filled, however. In a response to the OIG's findings, CMS says it is planning to undertake random onsite inspections of some waiver and provider-performed microscopy labs each year - not just on the basis of the OIG's recommendations, but also "as a result of [its] own studies." CMS also plans to initiate reviews of how moderate and high complexity labs handle those tests.

Titled "Enrollment and Certification Processes in the Clinical Laboratory Improvement Amendments Program" (OEI-05-00-00251), the report also suggests that CMS' policy of relying on labs to self-identify for enrollment may not be working. More than 40 states reported finding labs conducting tests without a CLIA certificate, the OIG says.

To see the report, go to: <http://www.hhs.gov/oig/oei/reports/a537.pdf>

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## CMS RE-ENDORSES CAP FOR CLIA ACCREDITATION

The Centers for Medicare & Medicaid Services Sept. 12 renewed the College of American Pathologists as a laboratory accreditation organization under the Clinical Laboratory Improvement Amendments. CMS determined that "the accreditation process of this organization provides reasonable assurance that the laboratories accredited by it meet the conditions required by CLIA statute and regulations," the agency says in a Federal Register notice. Therefore, labs that secure CAP accreditation - and maintain that status - in lieu of direct federal oversight are considered to have met CLIA condition-level requirements and are thus not "subject to routine inspection by State survey agencies to determine compliance." The agency notes, however, that CAP-accredited labs still are subject to federal validation and complaint investigation surveys. This notice is effective for the period September 12, 2001 through September 30, 2007. To see the notice, go to [www.access.gpo.gov/su\\_docs/fedreg/a010912c.html](http://www.access.gpo.gov/su_docs/fedreg/a010912c.html). Lab Line Copyright 2001, Eli Research, Inc.