



Saint Luke's Regional Laboratories Clinical Laboratory Letter



September 2006

Sad News and Good News

Dr. Marjorie Zucker has practiced as a clinical pathologist at Saint Luke's Hospital (SLH) for the past 16 years. During this tenure she has established a highly respected laboratory hematology consultation service that includes bone marrow interpretation, flow cytometry analysis and coagulation test development and interpretation. She has also served as the medical director of Saint Luke's South and East laboratories. The sad news is that Marge has decided she would like to reduce her office hours to fifty percent beginning this fall.

The good news is that we have recruited two outstanding physicians to continue our hematology pathology consultative service and further expand our clinical pathology coverage throughout the Kansas City region. Dr. Lisa Menninger recently completed her clinical pathology residency at Virginia Commonwealth University Health System and will serve as a clinical pathology consultant throughout the Saint Luke's Healthcare System.

Dr. Sharad Mathur completed his pathology residency and a hematopathology fellowship at SUNY Upstate Medical University in 2000. Currently he is the Chief of Pathology and Laboratory Medicine at the Kansas City VA Medical Center. He will provide hematopathology consultation for Saint Luke's Regional Laboratories.

An Evaluation of Routine Laboratory Screening for Bleeding Risk

It is well established that a detailed clinical history is the most important first step in determining a patient's bleeding risk and the need for coagulation testing. This should include inquiry about excessive bruising, nosebleeds, menorrhagia or other bleeding tendency, excessive bleeding after dental extraction, surgery or childbirth, a family history of a bleeding disorder, presence of liver, renal or hematological disease, and use of medications or herbal supplements that may interfere with

hemostasis. A list of herbs that may interfere with hemostasis was published in the July 2006 edition of Laboratory Letter.

Common laboratory screening tests for hemostasis include APTT, PT, and platelet count. The routine use of these tests to predict bleeding in unselected populations is expensive, and there is evidence in the literature demonstrating that this approach is unwarranted. A recently published review addressed this issue (Ann Intern Med. 2003; 138:W15-W24). Data was extracted from published studies (between 1966 and 2002) of routine coagulation testing in non-surgical hospitalized patients, and surgical patients. In the surgical patients sensitivity and specificity of the APTT in predicting postoperative hemorrhage were calculated.

The authors conclude that patients hospitalized for non-surgical diagnoses do not benefit from routine admission testing of APTT or PT, in the absence of synthetic liver dysfunction or a history of oral anticoagulant therapy. Observational studies have failed to show improvement in clinical outcomes with the use of these tests. Routine admission testing increases costs and the likelihood of false positive results. Two retrospective studies showed that the routine use of these tests has little or no impact on clinical care.

Routine platelet counts in asymptomatic non-surgical patients are also costly and not generally indicated. Monitoring platelet counts is indicated during heparin therapy because of the importance of detecting heparin-induced thrombocytopenia.

In surgical patients, the likelihood of detecting a significant hereditary coagulation factor deficiency in an unselected asymptomatic population is very small (17 per 100,000 in men and 5 per 100,000 in women). Furthermore, the probability of postoperative hemorrhage is exceedingly low (0.22%) among patients considered low-risk for hemorrhage (based on clinical history and

examination). In a study of more than 2000 patients who had preoperative coagulation testing, the APTT had a sensitivity of 33% and a specificity of 84% in predicting postoperative hemorrhage. The likelihood ratio (true positive rate/false positive rate) of the APTT in predicting postoperative bleeding among low-risk patients was less than 1.0, indicating that the test provided no useful information. Even in patients considered high-risk for postoperative hemorrhage the APTT was of limited value in predicting hemorrhage because of low sensitivity and specificity (59% and 68% respectively). In the high-risk group the likelihood ratio of hemorrhage was 1.8, however confidence limits were wide. Several other clinical studies confirmed that preoperative coagulation studies should not be used as a screening test in asymptomatic patients. Such testing does not reliably predict increased or decreased risk for hemorrhage, may be misleading, and may lead to further unnecessary testing.

The authors make the following recommendations regarding the use of screening coagulation tests:

Non-surgical hospitalized patients

- Testing (APTT, PT, platelet count) should be performed only when there are specific clinical indications based on history or physical examination.
- Platelet count monitoring is indicated before and during heparin therapy.

Surgical patients

- Routine preoperative coagulation testing is not recommended.
- Preoperative testing (APTT, PT, platelet count) is warranted for patients with clinical evidence on history or physical examination to suggest a bleeding disorder.

If a platelet function defect is suspected (e.g. use of platelet-inhibitory drugs) a platelet function screening assay (PFA-100) is suggested.

National Coverage Determinations (NCD)

Medicare publishes quarterly updates to the NCDs. In May we referred you to a website that subsequently has been revised. Please note the new website:

cms.hhs.gov/mcd/index_list.asp?list_type=ncd

Periodic review of the updates may decrease the number of ABNs that patients need to sign. Please contact Tammy Thorne (932-3704) or Kristy Gibson (932-3171) with questions.

National Provider Identifier (NPI)

Effective May, 2007, use of the NPI on Medicare fee-for-service claims will be mandatory. When you acquire your number, please contact the laboratory (932-3850) so we may properly submit laboratory claims in the future.

New FluChip Microarray for Influenza Virus

Researchers from the University of Colorado at Boulder and the Centers for Disease Control have developed a new diagnostic microarray to rapidly identify and subtype influenza virus in less than 12 hours. FluChip employs hundreds of nucleic acid probes immobilized onto a microscopic slide. If a patient's specimen contains influenza virus, it will be captured by a complimentary probe. The pattern of captured targets is mathematically analyzed to identify the pathogen.

Although clinical laboratories already use rapid tests that can detect and identify influenza virus as type A or B in less than an hour, these assays cannot determine the particular subtype. More complex testing is necessary for influenza subtyping, which is currently only performed in biosafety level 3 (BSL-3) laboratories. In these laboratories, subtype identification takes four to five days. One advantage of FluChip is that it can be used in BSL-2 laboratories, which includes many clinical laboratories.

In the FluChip study, the CDC provided viral strains from humans, birds, horses, and pigs that included avian influenza, H5N1, and two of the most common seasonal flu subtypes, H3N2 and H1N1. FluChip accurately identified the type and subtype in 72% of samples, the correct type and partially correct subtype in 13%, the correct type only in 10%, false-negatives in 4%, and false positives in 1%. Problems with nucleic acid amplification rather than limitations of the microarray were responsible for the majority of incorrect results.

Researchers hope to improve FluChip's performance and decrease its size to that of a PDA to enable testing for lethal flu strains in remote areas around the world. CDC estimates that it will take at least two years of further development before the FluChip is available commercially.