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DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE UPDATE

Rochester General Hospital • Newark-Wayne Community Hospital

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5. File: Clinical Lab Manual

HIV Testing Update

Governor Patterson signed a law in September, which is now in effect, authorizing significant changes in New York State's HIV testing practices. The updating of these laws will increase opportunities for people to be screened for the virus and improve linkages with care and treatment services for individuals diagnosed with HIV. Implementing this legislation is critical, since approximately 20 percent of HIV-positive New Yorkers are unaware of their infection status and 33 percent of persons newly identified with HIV are diagnosed with AIDS within one year.

Key provisions of the legislation include:

- HIV testing must be offered to all persons between the ages of 13 and 64 receiving hospital or primary care services, with limited exceptions noted in the law. The offering must be made to inpatients; persons seeking services in emergency departments; persons receiving primary care as an outpatient at a clinic; or from a physician, physician assistant, nurse practitioner or midwife.
- Standardized model forms for obtaining informed consent and providing for disclosure will be developed by the New York State Dept. of Health and posted on the Department's website.
- Consent for HIV testing can be part of a general durable consent to medical care, though specific opt out language for HIV testing must be included.
- Consent for rapid HIV testing can be oral and noted in the medical record.
- Prior to being asked to consent to HIV testing, patients must be provided the seven points of information about HIV required by the Public Health Law.
- Health care and other HIV test providers authorizing HIV testing must arrange an appointment for medical care for persons confirmed positive.
- HIV test requisition forms submitted to laboratories will be simplified.
- Deceased, comatose of persons otherwise incapable of providing consent, and who is the source of an occupational exposure, may now be tested for HIV in certain circumstances without consent.

Confidential HIV information may be released without a written statement prohibiting re-disclosure when routine disclosures are made to treating providers or to health insurers to obtain payment.

For additional information, please go to the NYSDH website www.nyhealth.gov.

Based on the above information we are in the process of updating all lab requisitions to include our HIV 1/2 antibody screen. We are also making adjustments for HIV to be ordered online if you have access to electronic ordering. In the mean time you can continue to use our existing HIV requisition. We will no longer accept requisitions that request results by code. As reflected in the law, all results should be part of the patient's medical record in their own name. True anonymous testing is still being offered through the NYSDOH.

Testing Algorithm for Toxigenic *Clostridium difficile*

The Microbiology Laboratory at Rochester General Hospital has changed the testing algorithm for toxigenic *Clostridium difficile* in order to increase the sensitivity of detection. Stool specimens are now tested by an enzyme immunoassay (EIA) which simultaneously detects *C. difficile* toxins A and B and an antigen specific to all *C. difficile* called glutamate dehydrogenase (GDH). Specimens which are positive for toxin by this assay will not need any further testing. Specimens which are negative for toxin but positive for *C. difficile* common antigen (GDH) by EIA will be assayed for the toxin B gene by PCR. The pairing of *C. difficile* toxin and GDH detection by EIA has a sensitivity of 96% and a negative predictive value of 99% when compared to PCR. This new combination test will be performed on a routine basis throughout the day, evening and night shifts and will have a turn-around-time of approximately 4 hours from the time the specimen is received in microbiology. The test will also be available as a STAT. Any specimen requiring PCR testing, which we expect will happen about 10% of the time, will be forwarded to our reference lab with a turn-around-time of approximately 48 hours. We intend to bring the PCR assay in-house in the near future.

Important points to remember:

- Please follow Infection Control protocols for suspected cases of toxigenic *C. difficile*.
- Submit only 1 specimen per patient per diarrheal episode. Routine orders should be written as "stool x 1".
- Test only at-risk patients having at least 3 stools per day for 1 to 2 days.
- A repeat specimen from patients negative for toxigenic *C. difficile*, but with persistent diarrhea and no other diagnosis, may be submitted > 3 days after the initial negative specimen.
- Specimens from patients < 1 year old are not routinely tested due to high colonization rates in infants.
- Only non-formed stools will be accepted for testing.

For additional information or for questions, contact Microbiology at 922-4555.

Successful Joint Commission Survey

Over the past month, The Joint Commission (TJC) completed rigorous, unannounced surveys at Rochester General Hospital (RGH) and Newark Wayne Community Hospital (NWCH), to evaluate our performance against national quality and patient safety standards. The health System is extremely pleased to report that the results were extraordinary and each facility was fully re-accredited! This means that both RGH and NWCH have not only met, but in many cases far exceeded the stringent patient care standards and CMS requirements for our industry.

The Joint Commission was so impressed with many of the initiatives and processes in place throughout our system that they've asked us to submit them as industry best practices. Beyond our well maintained facilities and equipment, and our effective clinical processes, what most impressed the surveyors were our people and our culture. They commented often on the passion, pride, commitment to learning, and sense of purpose consistently displayed by each and every one of our team members, physicians and volunteers. We will continue to pursue excellence in everything we do to improve clinical quality and the patient experience for *every patient, every encounter, every time*! The growing strength and evolution of our culture and our people position us well as we continue our work to deliver unparalleled service and to build One Great Health System – adaptive, innovative, and ready for health care reform and the many challenges and opportunities ahead.

CLINICAL LABORATORIES UPDATE

Leppert/Cramer MMH NIH 2010 Abstract

This past year, two students in the Rochester General Hospital School of Medical Technology, working under the supervision of Dr. Stewart Cramer in Pathology, and Hal James, Supervisor of Histology, did a project entitled "Prospective Study of Myometrial Hyperplasia in Hysterectomies for Benign Disease". This project was done in collaboration with Dr. Phyllis Leppert, Director of ObGyn Research at Duke University Medical School. Dr. Leppert was Chairman of ObGyn at Rochester General Hospital in the 1990's, before leaving for a stint at NIH, and then Duke. On behalf of the group, this work is being presented at the 3rd NIH Symposium on Advances in Leiomyoma Research in Bethesda, Maryland on November 22-23, 2010, by Dr. Leppert.

This is the 5th NIH Symposium presentation from The Myoma Project at RGH. Presentations at the first 2 NIH Symposia were done by Dr. Patricia Newcomb of RGH ObGyn.

Category: Clinical Pathology

Myometrial Hyperplasia (MMH), a Precursor of Fibroids, in Hysterectomies for Benign Disease

SF Cramer, T Ng, P Paulot, PC Leppert, (Duke University).

Objective: We evaluated 50 consecutive hysterectomies for benign disease (HBD) to determine the presence of MMH, and correlated its presence to gross pathology and clinical symptoms.

Methods: MMH is characterized by irregular zones of hypercellularity and increased nucleus/cell ratio. H&E slides of HBD specimens were reviewed for MMH. Trichrome stains for collagen and elastic stains were performed in ten cases because H&E was non-diagnostic. HBD specimens were photographed for presence of gross bulges (BU), pale firm myometrium (PFM), subserosal ridges (SR), and vascular ectasia (VE: an indication of increased pressure). Myoma Index (MI) was calculated for each specimen utilizing the number and diameters of fibroids. Microscopic findings were correlated to gross pathology and recorded symptoms.

Results: 21(42%) hysterectomies were performed for clinically diagnosed fibroid uteri (CFU), 18(36%) for abnormal pain and/or bleeding (PBU), 11(22%) for prolapse (PU). MI was high for six, moderate for 11 in hysterectomies performed for CFU. In four CFU, MI indicated a lack of clinically significant fibroids. MMH was microscopically apparent in all specimens with observed fibroids. BU due to MMH were observed in 18 specimens while PFM was seen in 30 specimens. VE due to MMH was seen in 19 specimens. Trichrome stains demonstrated less collagen in MMH than in normal myometrium. However, focal fibrosis and focal cell hypertrophy within MMH was found. Elastic stains showed that in PBU with SR, VE was seen in inner myometrium with associated elastosis.

Conclusions: We demonstrate for the first time that VE is associated with MMH. We suggest that MMH may be responsible for signs and symptoms leading to HBD and might simulate fibroids on pelvic exam and sonograms.

Support: Rochester General Hospital Myoma Fund

Changes to the Laboratory Requisitions

We will begin printing many of Rochester General Health System Laboratory requisitions on white paper with black print and the tri-colored RGHS logo.

The process and change will allow us to make timely adjustments to the test menu as well as print in house. We anticipate that this will give us better control of our inventory with the ability of giving our providers and patients the most current test options and Laboratory Collection Station information.

Requisitions that will remain the same color are: Non GYN and Thyroid FNA (purple), OB/GYN Cytology (green), and Pathology (gold).

Requisitions printed off IDX or our Website will also have the most current updates. The process for ordering and delivery of requisitions through our Courier Department (585) 922-4526) will not change. Please call Maureen Ryan at (585) 922-4570, Jeanne Kurzik at (585) 922-4875, or your Laboratory Representative, if there are questions or comments.

MASSIVE TRANSFUSION PROTOCOL

William Fricke, MD

Massive blood loss is a relatively rare event, even at major trauma centers, but when it occurs, it is stressful for everyone involved in the patient's care. For caregivers at the bedside or in the OR, the bleeding is usually only one of the acute problems that must be addressed. For laboratory and blood bank staff, there are often difficulties providing blood products for the affected patient in a timely fashion, maintaining an adequate inventory of blood products, and continuing to serve other patients.

There is little about treatment of massive hemorrhage that is standardized. The definition varies from loss of an entire blood volume in 24 hours to loss of 30% of blood volume in 2 hours. Similarly, there is often confusion about how to treat patients with massive blood loss. Clearly, replacement of lost blood is important, but which blood products - red cells, platelets, or plasma - when, and in what quantities, is not validated by well controlled studies. As a result, much blood product ordering is based on tradition rather than evidence-based literature.

The coagulopathy that develops in association with massive blood loss is due to acidosis, hypothermia, and dilution of coagulation factors and platelets, which becomes part of a vicious cycle that exacerbates the hemorrhage. The goal of blood product support is to prevent or interrupt this cycle by providing oxygen carrying capacity, replacing coagulation factors and platelets, and restoring intravascular volume.

In the ideal situation, real time information on tissue oxygenation and hemostasis would be available and would guide blood product use. In the absence of this information, an assessment of the amount of blood loss and likely compromise of hemostasis should be done. Unfortunately, this generally relies on a "best guess" of estimated blood loss and likely continuing blood loss. Usable information on hemostasis is infrequently available.

Replacement of lost blood involves red cells for oxygen carrying capacity, plasma for coagulation proteins, and platelets for primary hemostasis. The hemoglobin or hematocrit is used as a surrogate for tissue oxygenation and should be at least 7 or 8 gm/dL. It is generally not necessary to raise the hemoglobin to greater than 9 gm/dL. Dilution, loss, and consumption of coagulation factors requires replacement with plasma, which contains all the necessary factors. Hemorrhage with moderate blood loss does not usually require plasma transfusion, whereas massive blood loss is more appropriately treated with plasma and red cells in a 1:1 ratio. Platelet transfusion may also be necessary due to platelet loss, dilution, and consumption. Cryoprecipitate is useful for rare patients with isolated fibrinogen deficiency who do not need replacement of other coagulation factors.

The massive transfusion protocol was developed at RGH in order to facilitate the ordering and supplying of blood products for massively bleeding patients. It can be activated by the attending physician when a bleeding patient has received 6 units of red cells in 2 hours and has ongoing bleeding or if the patient is likely to bleed this much. The blood bank may also contact the clinical unit when 6 units of red cells have been released in 2 hours for a patient. When it is activated, the blood bank will prepare and send to the clinical unit packs of 4 units of red cells, 4 units of plasma, and a unit of pooled or apheresis platelets. The packs will continue to be sent until the protocol is discontinued by the clinician. Selected hematology and coagulation tests are to be done after each pack has been transfused and the results used to guide additional blood product use.

The protocol has several benefits. First, it is based on published literature that indicates that aggressive replacement of hemostatic factors concurrent with replacement of red cells helps reduce shock, coagulopathy, and death in massively bleeding trauma patients. Second, it provides a rational framework for blood product replacement in massively bleeding patients. Third, it allows the clinical staff caring for bleeding patients to focus on other aspects of patient care. And, fourth, it simplifies blood product preparation for the blood bank staff such that the products will be available in a more timely manner.

For more information, please contact the Transfusion Service (922-4083) or Dr Fricke (922-4576 or e-mail).

CLINICAL LABORATORIES UPDATE

Health Fair in Wayne County

Newark-Wayne Community Hospital Laboratory, in conjunction with the Newark Rotary Club, held its annual Community Health Blood Screen on Saturday November 13, 2010. This marks the 20th year that the blood screening has been offered to the public. The screening was attended by more than 145 Wayne County residents. This is a great opportunity for individuals to obtain a preliminary review of their general health status through a variety of blood tests including liver, kidney, metabolic, lipid, and hematological functions.

Results of the lab test are sent to the patient's primary care physician. If the patient does not have a primary care physician at the time of testing, results are forwarded to William Fricke MD, Laboratory Director. He will review and make recommendations to the patient to seek medical attention if needed. Laboratory team members that participated in this event included: Brandie Salisbury, Rhonda Richter, Yomalis DeJesus, Nancy Rutt, Carol Raes, Terry McIntryre, Mary Gooden, Ruth Olschewske, and Larry Bean.

ZIP IT !

Drivers are collecting specimen bags and samples are falling out because the zip tops on specimen bags are not fully zip closed.

PLEASE CHECK YOUR SPECIMEN BAGS TO BE SURE THEY ARE FULLY CLOSED TO REDUCE ERRORS AND RE-DRAWS.

CLINICAL LABORATORIES UPDATE

Registration Process Changes

In preparation for electronic medical records (EMR) and to comply with payment requirements for laboratory claims, we made changes to our registration process at our Patient Service Centers. Our new process will allow us to positively identify patients and assure that insurance information is accurate. Because of this new process, we are experiencing longer wait times at some patient service centers. In an effort to improve, we are piloting various staffing models and work-flow processes.

As providers, please help us minimize wait times by doing the following:

- Making sure that your patient's full legal name, date of birth, address and phone number, insurance information, and diagnosis for all tests being requested is accurate and complete.
- Ensuring that handwriting is legible.
- Remind your patient that they must present ID and insurance information at each visit.
- Encourage patients to visit the lab during non-peak hours, typically late mornings and afternoons.