Helicobacter pylori Infections and Recommendations for Its Laboratory Diagnosis

By Paul A. Granato, Ph.D., Director of Microbiology

Helicobacter pylori (H. pylori) remains one of the most common worldwide human infections and is associated with a number of important upper gastrointestinal (GI) conditions including chronic gastritis, peptic ulcer disease (PUD), and gastric malignancy. The prevalence of H. pylori is closely associated with socioeconomic conditions and, accordingly, this infection is more common in developing countries than in developed countries such as the United States. Regardless, it has been estimated that 30 to 40% of the U.S. and over 50% of the world’s populations are infected with H. pylori.

According to the Centers for Disease Control and Prevention, H. pylori causes 75 to 80% of PUD accounting for one million hospitalizations per year and 6,500 deaths. The estimated economic impact of PUD alone for hospitalizations, therapy with proton pump inhibitors, physician office visits, and decreased productivity resulting from days lost from work exceeds $12 billion annually.

Given the widespread prevalence of H. pylori infection and its enormous financial impact on the healthcare industry, the American College of Gastroenterology (ACG) and the American Gastroenterological Association (AGA) have established recommendations and best practice guidelines to assist primary care physicians caring for patients with H. pylori infection.

These best practice guidelines are based upon the use of non-invasive laboratory tests that can clearly establish the presence of active H. pylori. Accordingly, serologic tests that screen for the presence of H. pylori antibodies are no longer recommended by the ACG or AGA because serology does not test for the presence of active disease. In fact, studies have shown that 50% of positive serologic tests are not indicative of active but rather past infection.

Because of this, the ACG and AGA recommends the use of H. pylori stool antigen (HpSA) test or the Urea Breath Test (UBT) as the non-invasive tests of choice for establishing the laboratory diagnosis of active infection. The HpSA test is the preferred method because it is not only highly sensitive but is a more cost effective and less expensive means of establishing the laboratory diagnosis of infection. In addition, the HpSA test is the only test approved by the FDA for use in the initial diagnosis, therapeutic-monitoring, and retesting to confirm eradication of H. pylori infection. Also, HpSA test is the only test approved for use in both adult and pediatric patients whereas the UBT is approved for use only in adults (18 years of age or older).

The AGA and ACG H. pylori test guidelines were developed in 2005 and 2007 respectively. Excellus BlueCross BlueShield (BCBS), in an effort to improve quality of care, increase patient safety, and impact the continued affordability of healthcare, implemented a new non-invasive H. pylori testing policy statement effective Oct. 1, 2011. A portion of the Excellus policy statement is reproduced below for your review:

Excellus BCBS POLICY STATEMENT:

Based upon Excellus BCBS criteria and the assessment of the peer-reviewed literature:

I. Antibody testing (serum, whole blood, finger stick, or urine) does not improve patient outcomes and is considered not medically necessary for either the initial work-up in patients with suspected H. pylori infection or for follow-up testing in patients who have received H. pylori treatment.

II. Testing for H. pylori infection using either the urea breath test (UBT 13C or 14C) or a stool antigen test (HpSA) has been medically proven to be effective and is medically appropriate for the following:

A. Patients, aged 55 years or younger, with uninvestigated dyspeptic symptoms who have no “alarm features” suggestive of cancer or ulcer complications (e.g., bleeding, anemia, unexplained weight loss, vomiting, dysphagia);

Continued on page 3
A Unique Approach to Transfusion Reaction Prevention
Juliane Breh, MT(ASCP), Transfusion Services Manager

Cathy Husted, MT(ASCP), technical supervisor of one of our three Transfusion Services Departments, recently received a phone call from a blood banker in North Carolina. She was calling to thank us and explained how Laboratory Alliance may have prevented a hemolytic transfusion reaction in one of their patients.

She told Cathy that they were about to issue a regular allogeneic unit of red cells for this patient when the patient's wife said to the nurse, "Wait, I have this card!" The wife pulled out one of Laboratory Alliance’s antibody cards and the nurse gave a copy of the card to the blood bank.

The hospital’s antibody screen test was negative and therefore protocol had not required the longer antiglobulin crossmatch. The North Carolina blood bank had no idea the patient had a history of antibodies until they received a copy of our antibody card. The card stated this patient had a history of Anti-Jk b and Anti-K. The patient could have had a delayed hemolytic transfusion reaction if it were not for the antibody card.

The blood banker called to thank us and to request a copy of the patient’s results.

This scenario is proof that the efforts on behalf of our Antibody Letter Program are valuable. We go above and beyond regulation requirements for reporting results by providing our patients who develop clinically significant blood group antibodies with a letter and antibody ID card for their wallet.

The letter explains why they are getting the card, and the importance of presenting it to the hospital whenever they are admitted for care. We also send a letter to the physicians, explaining why it will take additional time to provide blood products for their patient. We hope this will eliminate patient care delays and improve communication with the practitioners.

The goal of the program is to prevent transfusion reactions, shorten the turn-around time for receiving blood products when the patient has blood group antibodies, and to help our fellow blood bankers identify the reactivity they may be seeing in their workups.

Laboratory Alliance’s antibody letter process is a combined effort by the supervisory team (managers, technical supervisors and lead techs), special projects manager and medical advisors. An overview of the process is outlined below:

1. Staff perform the antibody workup.
2. Supervisors perform review of the workup for accuracy.
3. Supervisors check the patient’s historical file to see if they have ever received an antibody letter for this antibody(ies).
4. Supervisors print a copy of the antibody ID results. The patient’s address is recorded and the physician’s address is confirmed for accuracy.
5. Supervisors enter the patient’s demographic information, antibody results, physician's name and address into a mail merge spreadsheet.
6. The special projects manager generates the patient and physician letters from the spreadsheet.
7. The draft letters are reviewed for syntax errors, grammar, etc.
8. The technical supervisor completes an antibody ID card, collates the draft letters, envelopes and a copy of the patient’s results and gives them to the transfusion service medical advisor.
9. The transfusion service medical advisor reviews all documents for accuracy and clinical appropriateness.
10. Edits are made to the letters if necessary and final copies are printed on letterhead paper.
11. The technical supervisor gets the pathologist signature on the official letters.
12. The supervisor places the antibody card and patient letter in one envelope and the physician letter in another, and mails both.

This process was in place years ago at one of our three hospital locations. Rachel Elder, M.D., medical advisor for our Transfusion Services Department, recently resurrected this project with Barb Gonnella, MT(ASCP), manager of Transfusion Services Special Projects, and Patricia Spizuoco, M.D. and Michael Graber, M.D., assistant medical advisors. Together, with our Medical Advisors Committee, the program was implemented in all three of our hospital Transfusion Service sites in 2010.

We apply Lean Initiative principles to add the patient information to the spreadsheet daily, making the process more manageable. The recent call from North Carolina reaffirmed that our commitment to this program is making a difference in patient care.
B. Determining eradication after antibiotic therapy in any of the following circumstances:
1. Patients with active peptic ulcer disease (PUD) or who have received treatment for *H. pylori* PUD;
2. Patients with persistent dyspeptic symptoms after an appropriate course of treatment;
3. Patients with associated mucosa-associated lymphoid tissue (MALT) lymphoma; or
4. Patients who have undergone resection for early gastric cancer.

C. As part of the preoperative work-up for patients undergoing a bariatric procedure.

It is important to emphasize to physicians and other health care providers that the Excellus BCBS policy committee has determined that *H. pylori* serology testing is **NOT** medically necessary. Consequently, Excellus BCBS will no longer provide insurance reimbursement for this test but will audit and hold accountable all health care providers who continue to order the serologic test. The only *H. pylori* tests that Excellus BCBS will continue to reimburse for are the HpSA test and the UBT.

If you have any questions about this new policy statement for non-invasive *H. pylori* testing, please contact your local Excellus BCBS representative.
Compliance Corner
By Nancy Sniffen, Director of Billing and Compliance

Diagnostic Information
Medicare laws dictate that clinicians should only order tests that are medically necessary for the diagnosis or treatment of the patient. Medicare may deny payment for a test even though the physician believed it was appropriate if the test did not meet Medicare’s definition of medical necessity.

National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs) list specific CPT codes for covered tests, as well as the Medicare-approved ICD-9 codes (diagnosis codes) for those laboratory tests that are reasonable and necessary for the diagnosis or treatment of the ICD-9 codes provided by the ordering clinician. ICD-9 codes supporting medical necessity must be included on the laboratory requisition. The diagnosis must be present for the procedure to be paid and there must be documentation within the patient’s medical record.

Providing our laboratory with accurate and essential diagnostic information is critical to the efficient operation of our laboratory. Without appropriate diagnostic documentation, the laboratory is not reimbursed for the tests performed.

Additionally, diagnostic information can determine whether or not an ABN should be signed. Laboratory Alliance clients may provide either an ICD-9 code or a written diagnosis in the space provided on our requisitions.

Providing diagnostic information when ordering a test not only helps the laboratory operate efficiently and receive payment for its services, it eliminates the time and expense the physician office may incur when responding to requests from the laboratory.

National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs)
NCD is a national policy statement for a diagnostic laboratory test. It indicates which diagnoses, signs or symptoms are payable for specific tests.

Following is a list of tests covered under a NCD:
- CA 15-3
- CA 19.9
- CA 27.29
- CEA
- Collagen Crosslinks (N-Telopeptide)
- Digoxin
- GGTT
- Glucose
- Glycated Hemoglobin
- Hepatitis Panel
- HCG, Quantitative
- HIV (Diagnostic and Prognostic)
- Serum Iron Studies (Iron, TIBC, Ferritin, Transferrin)
- Lipids (Lipid Panel, Cholesterol, Triglycerides, Direct LDL, HDL, Lipoprotein Fractionations)
- Occult Blood
- Partial Thromboplastin Time (PTT)
- Prothrombin Time (PT)
- PSA (Screen and Diagnostic)
- Thyroid Testing (T4, TSH, Free T4, T3 Resin Uptake)
- Urine Culture

Local Coverage Determination (LCD)
An LCD is a local policy statement by the local Medicare carrier or fiscal intermediary that indicates which diagnoses, signs or symptoms are payable for specific tests.

Following is a list of tests covered under the LCDs:
- Acid Phosphatase (Total and Prostatic)
- Beta-2-Microglobulin
- B-Type Natriuretic Peptide (BNP)
- Calcium, Ionized
- CRP, High Sensitivity
- Drug Screen
- Erythrocyte Sedimentation Rate (ESR)
- Flow Cytometry
- Hepatic Function Panel
- Hepatitis Tests
- Homocysteine
- HPV
- Immunocytochemistry
- Magnesium
- Parathyroid Hormone (PTH)
- RAST Tests
- Syphilis Tests
- Vitamin D, 25 OH

Purpose of the ABN is to give the patient advance notice that Medicare may not pay for the test ordered. When payment is denied as not medically necessary, Laboratory Alliance can only bill the patient if we have received a valid ABN.

You can review the NCD and LCD policies by visiting our website at www.laboratoryalliance.com and selecting ‘Healthcare Providers.’

Reflex Testing
Reflex testing is testing that is performed as a result of initial test results. The reflexively ordered test is used to further identify significant diagnostic information required for appropriate patient care.

A list of the reflex tests performed by Laboratory Alliance, when appropriate, is found in our Directory of Services as well as on the back of our test requisitions.

Panels
Organ or disease panels will only be billed and reimbursed when all test components are medically necessary. If only some components are medically necessary, or if the physician wishes to order other tests not included in the panel, those tests should be ordered individually.

A list of tests included in the American Medical Association acceptable panels is printed on our requisitions and is found in our Directory of Services.

The Medicare reimbursement for these tests can be found at www.cms.gov/clinicalLabFeeSched/02_clinlab.asp. Medicaid reimbursement will usually be equal to, or less than, the Medicare reimbursement.

Custom Panels
Use of custom panels is not generally encouraged by Laboratory Alliance. If a physician requests us to customize a panel of tests, a signed acknowledgement is required from each physician who will be ordering the custom panel. The acknowledgement needs to be signed annually.

Clinical Consultation Services
Appropriate test usage and test ordering may be discussed with Laboratory Alliance’s Chief Executive Officer and Director of Laboratories Michael R. O’Leary, M.D. He may be reached by contacting our Customer Service Department at (315) 461-3008.
Pap smears and Endocervical/Transformation Zone Dilemmas

By Janet Miller, Cytopathology Manager, in collaboration with John Fazio, M.D., Pathologist and Medical Advisor for the Cytology Department

Laboratory Alliance has a challenging caseload of Pap smears from family practice clinicians, gynecologists, hospital based clinics and, on rare occasion, from migrant worker clinics and even from Haiti. In the past year, we have diagnosed five cases of cervical cancer. This is after years of seeing no cases of cervical cancer in Pap tests.

A frequent concern of our clinicians is whether they are taking a diagnostic Pap smear. The quality indicator we rely on for an adequate Pap test in a cycling patient with a cervix is the presence of endocervical or transformation zone (EC/TZ) material. Numerous studies have been done to study the frequency of cervical disease in patients who have EC/TZ in their previous Paps or patients who did not have EC/TZ material in their Paps. Some cytology labs have dropped the adequacy comment for their Pap test reporting. Laboratory Alliance believes this adequacy comment is an important part of a Pap test report.

Studies have shown the probability of EC/TZ not being present in a Pap smear increases if the patient is post-menopausal, pregnant or taking oral contraceptives. Fortunately, studies have also shown that there is no increase in squamous lesions in patients who have not had EC/TZ reported in their Pap.

We are adding an additional comment to our adequacy area of our Pap smear reports. For post-menopausal patients the comment may read:

Satisfactory for evaluation: Endocervical/transformation zone cannot be assessed due to atrophic changes.

This comment will also help address the difficulty of identifying EC/TZ in atrophic patients. In atrophic Paps or atrophic vaginitis it is very difficult to distinguish between sheets of atrophic parabasal cells and atrophic endocervical cells. The option to use such a sign out is included in the Bethesda System for Reporting Cervical Cytology, but has not been used by Laboratory Alliance’s Cytology Department in recent years.

In terms of endocervical cells and adequacy of Pap tests, there has been a shift in thinking over the past 20 years. Experts in the field have downplayed the significance of endocervical cells in the Pap test, so that the current recommendations no longer deem Pap tests that lack endocervical cells as “unsatisfactory.”

It is also important to note that some women have repeated Pap tests that lack EC/TZ cells despite good collection technique and use of appropriate sampling devices. Because the literature is conflicted concerning the significance of this finding, a repeat Pap test in 12 months is now the recommended management for a woman with a satisfactory Pap lacking EC/TZ component. This represents a compromise position, as the literature is unclear as to the significance of this finding.

Indications for considering an early (less than 12 months) repeat Pap test include:

1) Previous squamous abnormality without two subsequent negative Pap tests or a negative HPV test,
2) A previous Pap with unexplained glandular abnormalities;

Managing women with negative Paps lacking endocervical/metaplastic cells or other quality indicators

<table>
<thead>
<tr>
<th>Negative but lacking endocervical/metaplastic cells</th>
<th>OR borderline cellularity</th>
<th>OR obscuring blood/inflammation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior abnormal or CIN*</td>
<td>HPV positive</td>
<td>HPV negative/unknown</td>
</tr>
<tr>
<td>Prior glandular abnormality</td>
<td>Repeat Pap in 6 months</td>
<td>Repeat 12 months</td>
</tr>
<tr>
<td>HPV+ within 12 months</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td>Cervix not see OR endocervix not sampled</td>
<td>Repeat HPV test in 6 more months</td>
<td></td>
</tr>
<tr>
<td>Prior obscured Pap</td>
<td>If Pap or HPV test is positive, manage per ASCCP guideline</td>
<td></td>
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<tr>
<td>Repeat Pap in 6 months</td>
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</tbody>
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*Unless 2 prior negative Pap tests or a negative HPV test

ASCCP recommendations
Sari Reikes Named Controller

Laboratory Alliance welcomes Sari Reikes who was hired as controller in July. Sari comes to us from Hospitals Home Health Care, Inc., where she served as chief financial officer at the certified home health care agency serving Oswego County. Hospitals Home Health Care, Inc., owned by Oswego Health and a partner with St. Joseph’s Hospital Health Center, was listed by Homecare Elite as a “Top 100” homecare agency in the nation. As chief financial officer, Sari was responsible for financial and strategic planning, business expansion, accounting and financial operations, budget development and management, and human resource management.

Prior to joining Hospitals Home Health Care in 2001, Sari was a senior cost accountant at Crouse Hospital, where she was in charge of budgeting, responsible for the maintenance and integrity of the decision support system, supported hospital operation improvement programs and assisted with financial analysis projects.

Earlier professional experience included Boston’s Children’s Hospital and Partners Healthcare (Brigham and Women’s Hospital and Massachusetts General Hospital).

Sari earned her Bachelor of Science in Finance from the University of Connecticut and a Master’s in Public Administration/Healthcare from Suffolk University in Boston. She relocated from Boston to Manlius in 1999.

Sari is a member of Healthcare Financial Management Association.

She and her husband, Peter, have three children: Michael, 8 years old, Philip, 6 years old, and Sam, 5 years old. She enjoys attending and participating in sporting events with her family.

Rita Romano Newly Appointed Manager

Laboratory Alliance is pleased to announce the appointment of Rita Romano as the manager for the Rapid Response Laboratory at Upstate University Hospital at Community General.

Rita joined Laboratory Alliance in August, coming to us from St. Joseph’s Hospital Health Center where she was the environmental health and safety officer and the director of environmental services. She had regulatory responsibilities for physical environment compliance with the Joint Commission and DNV.

Rita has more than 22 years of experience in the field since beginning her career as a medical technologist at Community General Hospital in 1988.

She worked as a local operations manager for LabCorp, where she was one of the principal investigators for research trials conducted through Merck Pharmaceuticals, including clinical trials for one of the first HIV vaccines.

Rita served as the laboratory manager and compliance officer for Northern Syracuse OB/GYN Associates. In this role, she was one of the founding members of the Physicians Office Laboratory Organization, a network organization formed to support physician office laboratories through the Central New York region.

Prior to that, she worked at North Medical Laboratory Services and had a major role in the initial set up of the laboratory.

Rita earned her bachelor’s degree in Medical Technology from St. Bonaventure University and is certified by the American Society of Clinical Pathologists as a medical technologist. She is a graduate of the Ahern & Murphy Associates Leadership Course.

She is an active member of the Clinical Laboratory Management Association Central New York chapter, previously serving as a member of the Education Committee. She currently serves as a board member for the Advancement Committee at Bishop Ludden High School.

Rita resides in Liverpool with her husband Michael and their two children, Angela and Ralph.

Pap smears

Continued from page 5

3) A positive high risk HPV test within 12 months;
4) Clinical inability to clearly visualize the cervix or sample the endocervical canal;
5) Lack of EC/TZ component in consecutive pap tests; and
6) Insufficient previous screening.

For more information or to have questions answered about this topic or any other aspects of Pap or HPV testing, contact Janet Miller, cytology manager at (315) 410-7211, or John Fazio M.D., Onondaga Hill Pathology, medical advisor, Cytology Department, at (315) 492-5096.

Welcome New Client
Anthony Grasso Jr., M.D.
Syracuse, N.Y.
New Employees
Please welcome our new employees
At our Corporate Office
Rhys Brigida – Information Systems Analyst
At our Operations Center
Stephen Champlin, Jr. – Phlebotomist
Nathan Brzostek – Laboratory Office Assistant
Mark Giordano – R & D Specialist
Kelly Hill – Phlebotomist
Lori LeClair – Medical Technologist
Aaron Page – Laboratory Office Assistant
Benjamin Robedee – Technical Processing Assistant
At our Rapid Response Laboratory at Upstate University Hospital at Community General
Jo-Ann Floridia – Medical Technologist
At our Rapid Response Laboratory at Crouse Hospital
Samantha Lovelace – Medical Lab Technician
At our Rapid Response Laboratory at St. Joseph’s Hospital
Wanda Salem – Medical Technologist

Employee Anniversaries
October, 5 years:
Garland Blanch
Kathy Calarese
Jeremy Fuller
Brenda Jetty
Sara McCabe
November, 5 years:
Christina Remillard
December, 5 years:
Megan Galeazza
Teri Lee Gillett
Robert Gutierrez

October, 10 years:
Janet Kerfien
November, 10 years:
Jennifer Fiacchi
Kimberly Hayes
William Miller
December, 10 years:
Tammy Short

Take a closer look at our anatomic pathology services
You’ll see why Laboratory Alliance is the right diagnostic partner for your practice.

A growing number of Central New York doctors put their trust in our network of more than 20 affiliated pathologists and specialty consultants.
Combined with our Histology and Cytology Departments, we offer
• a team of 250 technical support members spanning all areas of laboratory medicine
• unsurpassed accuracy standards
• personal attention combined with decades of experience and expertise
• prompt services with timely routine Pap and biopsy turnaround
• a comprehensive test menu that ensures accurate diagnosis and aids in the prognosis
• rapid and reliable courier and billing services

For more information or to learn more about our anatomic pathology services, call (315) 461-3008 or visit www.laboratoryalliance.com

LABORATORY ALLIANCE of Central New York, LLC
www.laboratoryalliance.com

You’re Invited
Employees and a Guest
Join us for the Laboratory Alliance Holiday Party
Saturday, January 7
Holiday Inn Electronics Parkway
6 p.m.-midnight
Another Reason to Know Your Vitamin D Level

The Syracuse Post-Standard ran an article titled “Sunlight and food alone often don’t provide enough vitamin D,” by Health Editor Kathleen Poliquin. View the article online by searching the article’s title at syracuse.com.

We ran the following article in an earlier edition of LabLines. During the winter months people who live north of the mid-Atlantic states do not get enough vitamin D from the sunlight.

While it’s been known for some time that vitamin D deficiency contributes to the development of osteoporosis and weakened immunities, a recent report says that vitamin D plays a role in the prevention of age-related macular degeneration, a disease associated with aging that gradually destroys vision.

“In women younger than 75 years, having 25(OH)D concentrations higher than 38 nmol/L was significantly associated with a 48% decreased odds of early age-related macular degeneration,” reported the study, performed at the University of Buffalo and detailed in the medical publication Arch Ophthalmol. 2011;129(4):481-489.

When we don’t replace vitamin D daily, our body will meet its needs by stealing calcium from our bones, weakening them over time — a process that can contribute to the development of osteoporosis and weaken our immunities. Vitamin D deficiency may also increase the risk of heart disease and colon and prostate cancer.

Testing provides important information.

A vitamin D deficiency is diagnosed by measuring the concentration of a specific form of vitamin D in blood. Unfortunately, many tests do not measure the supplemental form of vitamin D. It is imperative to request a total vitamin D test (25-OH vitamin D) in order to assess your true status — a total test that measures vitamin D$_2$ and D$_3$ levels in the blood.

Laboratory Alliance recommends that you ask your doctor if you should be tested.

If you live in Central New York, it’s likely you are vitamin D deficient. Do you know your vitamin D level?

Why worry?

When we don’t replace vitamin D daily, our body will meet its needs by stealing calcium from our bones, weakening them over time — a process that can contribute to the development of osteoporosis and weaken our immunities. Vitamin D deficiency may also increase the risk of heart disease and colon and prostate cancer.

Testing provides important information.

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Ask your doctor if you should be tested. To learn more, visit www.laboratoryalliance.com or call (315) 461-3008.

LABlines is a quarterly publication by LABORATORY ALLIANCE of CNY.

Comments, suggestions or inquiries should be directed to Anne Marie Mullin, Vice President of Business Development and Marketing, (315) 461-3036, or by email to annemariemullin@lacny.com.