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Use of the Optum Labs Data Warehouse To Assess Test Ordering Patterns for Diagnosis of *Helicobacter pylori* Infection in the United States

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We surveyed national *Helicobacter pylori* diagnostic testing practices and diagnoses using commercial and Medicare medical claims data from Optum Labs (Cambridge, MA). Serologic testing for antibodies to *H. pylori* remains the most commonly ordered diagnostic test despite recent expert recommendations. Changes in reimbursement for serologic testing will likely drive future provider ordering practices.

Helicobacter pylori remains among the most common bacterial infections worldwide. It is estimated that globally one in every two individuals is infected. Local prevalence rates vary, however, with approximately 20 to 40% of individuals in the United States exposed to *H. pylori* by adulthood (1–5). Despite these infection rates, most individuals remain asymptomatic. A number of well-defined clinical syndromes have been associated with infection, however, including dyspepsia, peptic ulcer disease, gastric adenocarcinoma, and mucosa-associated lymphoid tissue (MALT) lymphoma, with the latter two collectively occurring in <1% of individuals (3). Eradication of *H. pylori* through appropriate antibiotic regimens leads to a significant reduction of ulcer recurrence and long-term remission of MALT lymphoma for the majority of afflicted patients (6–8). Therefore, accurate and prompt diagnosis of *H. pylori* infection is essential.

Three noninvasive testing methods are available to detect *H. pylori*, including serologic assays to measure anti-*H. pylori* IgM, IgA, and IgG antibodies, *H. pylori* stool antigen tests (SATs), and urea breath test (UBTs) (9–11). Choosing among these methods requires a thorough understanding of each assay's clinical utility. Serologic testing shows poor sensitivity (74% to 85%) and specificity (79% to 90%) for active infection, although such testing is not affected by prior intake of protein pump inhibitors (PPIs), bismuth compounds, or antibiotics. Additionally, serologic testing should not be used to document *H. pylori* eradication due to demonstrable antibody levels for years following the initial exposure (10). Finally, most serologic assays, aside from certain IgG tests, lack Food and Drug Administration (FDA) clearance. Conversely, detection of *H. pylori* antigen by the SAT or urease activity by the UBT is indicative of active *H. pylori* infection, and either assay can be applied to confirm *H. pylori* clearance following completion of antibiotic therapy (9–11). Both methods also have commercially available, FDA-cleared assays that offer high sensitivities and specificities for *H. pylori* infection (both >95% in pretreatment conditions). Certain drawbacks exist for these two assays, including the generally higher cost compared to that of serologic testing, although this cost is offset by the improved diagnostic accuracy and typically higher reimbursement rates for UBTs and SATs (11, 12). Additionally, due to the specimen collection requirements and assay complexity, UBT availability may be limited to larger hospitals and reference laboratories. Finally, PPIs, bismuth compounds, and antibiotics need to be discontinued 14 to 28 days prior to testing by either the UBT or SAT for result accuracy. Since 2005 and 2007, the American Gastroenterology Association (AGA) and the American College of Gastroenterology (ACG) guidelines have recommended use of either the SAT or UBT as a first-line diagnostic test for suspected *H. pylori* infection in patients with previously uninvestigated dyspepsia who meet specific criteria (10, 11). They also indicate that serologic testing should be avoided entirely due to poor clinical performance characteristics; if used, however, positive serologic findings should be confirmed by a first-line test to document active infection prior to therapeutic intervention.

We conducted a retrospective study of national *H. pylori* diagnostic testing practices and the resulting *H. pylori* diagnoses using medical claims data from the Optum Labs Data Warehouse (OLDW). Briefly, the OLDW is a health care database containing deidentified claims from >100 million individuals enrolled in either commercial insurance or Medicare Advantage plans over a 20-year period (13). For our analysis, we identified first-time tests performed between January 2010 and December 2012 using Current Procedural Terminology, version 4 (CPT-4) codes for *H. pylori* serology (86677: antibody, *H. pylori*; the code does not differentiate among IgA, IgM, or IgG serology), SAT (87338: *H. pylori*, stool), and UBT (83013: *H. pylori*; breath test analysis for urease activity, nonradioactive isotope). Testing by two different methods was considered the same testing event if tests were performed within 14 days of each other. A diagnosis of *H. pylori* infection

Received 5 December 2014 **Returned for modification** 2 January 2015
Accepted 13 January 2015

Accepted manuscript posted online 21 January 2015

Citation Theel ES, Johnson RD, Plumhoff E, Hanson CA. 2015. Use of the Optum Labs Data Warehouse to assess test ordering patterns for diagnosis of *Helicobacter pylori* infection in the United States. J Clin Microbiol 53:1358–1360. doi:10.1128/JCM.03464-14.

Editor: K. C. Carroll

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doi:10.1128/JCM.03464-14

TABLE 1 Comparison of the number of ordered *H. pylori* diagnostic tests and the number of *H. pylori* diagnoses using the Optum Labs Data Warehouse[a]

Test name[b]	CPT code	Total no. of patients tested	Normalized patients tested per 10,000 member-months[c]	Patients with a *H. pylori* diagnosis[d]		Patients without a *H. pylori* diagnosis[d]	
				No.	% total	No.	% total
Serology[e]	86677	366,846	4.58	15,495	4.2	351,351	95.8
UBT	83013	81,887	0.75	12,183	18.0	67,141	82.0
SAT	87338	58,841	1.02	7,666	13.0	51,175	87.0
Serology + SAT	86677, 87338	4,711	0.06	612	13.0	4,099	87.0
Serology + UBT	86677, 83013	3,451	0.04	932	27.0	2,519	73.0

[a] Limited to the first testing event for each individual between 2010 and 2012 (i.e., multiple testing events by the same assay for the same individual were excluded).
[b] SAT, stool antigen test; UBT, urea breath test.
[c] The normalized testing rate was calculated by applying yearly OLDW enrollment criteria to the database population from which the study cohort was extracted.
[d] Based on documentation of the ICD-9-CM 041.86 diagnosis code for *H. pylori* infection.
[e] Serologic testing includes individual or any combination of anti-*H. pylori* IgM, IgA, and/or IgG antibody testing.

during the observation period was identified using the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnosis code 041.86. Study data were accessed in compliance with the Health Insurance Portability and Accountability Act of 1996, and, because this study involved analysis of preexisting, deidentified data, it was exempt from institutional review board approval.

Despite the ACG and AGA recommendations, we found that serologic testing remains the most commonly ordered assay for evaluation of *H. pylori*, with 366,846 serologic tests performed between 2010 and 2012 compared with 81,887 and 58,841 UBT and SAT assays, respectively (Table 1). *H. pylori* diagnosis codes were observed in 4.2% (15,496/366,846) of patients tested by serology (none of whom were examined by SAT or UBT within the 14-day window) versus 18.0% (12,183/81,887) and 13.0% (7,666/58,841) of patients tested by UBT and SAT, respectively. Finally, 8,162 individuals were tested by both serology and either the UBT or SAT, although the ACG and AGA only recommend confirmatory testing of positive serologic results (Table 1).

Certain limitations to this data set exist, including the absence of qualitative results for each testing scenario, the lack of inpatient testing data, and the unavailability of comparative data for *H. pylori* ordering practices prior to the 2005/2007 AGA/ACG guidelines. Additionally, the 14-day testing window may have precluded the inclusion of UBT or SAT tests performed to confirm positive serology following that time period. Despite this, a number of significant conclusions can be drawn. First, there is minimal provider adherence to the AGA/ACG recommendations to avoid serologic testing for *H. pylori*. While certain patient scenarios may warrant serologic evaluation (e.g., an inability to discontinue PPI or antibiotic use, epidemiologic exposure studies, etc.), it is unlikely that these scenarios account for the 4.5-fold and 6.2-fold higher ordering rates of serologic assays compared to the UBT and SAT, respectively. Second, >15,000 individuals were diagnosed with *H. pylori* infection based on serologic evaluation alone. As indicated by the ACG and AGA, the positive predictive value of a positive serologic result approaches only 50% (10, 11). Therefore, approximately 7,500 individuals may have been misdiagnosed with inappropriate initiation of antibiotic therapy, propagating the dilemma of global antibiotic resistance. Finally, use of UBTs or SATs is associated with a significantly higher rate of *H. pylori* diagnoses than serologic testing ($P < 0.005$), further supporting the use of these assays as accurate biomarkers for active *H. pylori* infection.

What can be done to encourage proper test utilization for detection of *H. pylori*? While tailored education regarding the clinical utility of the different methods should continue and target providers who routinely order *H. pylori* testing, this method alone is unlikely to suffice. A more drastic incentive to alter ordering practices is likely to be changes to test reimbursement rates by insurance providers. Currently, while the Centers for Medicare and Medicaid Services reimburses all three methods (e.g., CPT 86677 at $19.80, CPT 83013 at $91.89, and CPT 87338 at $19.62) (12), an increasing number of private insurers, including Cigna, Geisinger Health Plan, and Aetna indicate that serologic testing is "not medically necessary" and no longer provide reimbursement for such testing.

In conclusion, we show that the OLDW is a powerful tool for examining claims data and have applied it to quantify both *H. pylori* testing practices and the resulting *H. pylori* diagnoses at a national level. We confirm that despite current ACG and AGA recommendations, appropriate test utilization for *H. pylori* remains substandard. Utilization of such databases should be considered an additional means to monitor test utilization, diagnoses, and treatment decisions beyond the local level.

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