Laboratory Test Utilization Program

Structure and Impact in a Large Academic Medical Center

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Key Words: Health care cost; Laboratory cost; Test utilization; Laboratory formulary

DOI: 10.1309/AJCP4G6UAUXCFTQF

CME/SAM

Upon completion of this activity you will be able to:
- identify the emerging area(s) of laboratory medicine presently having the greatest impact on the rising rate of health care cost.
- list and discuss the roles of the key stakeholders in an effective hospital- or health system–wide laboratory formulary program.
- outline the critical roles of "clinical content experts" in an effective laboratory test utilization program.

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The authors of this article and the planning committee members and staff have no relevant financial relationships with commercial interests to disclose.

Questions appear on p 396. Exam is located at www.ascp.org/ajcpcme.

Abstract

In 2008, the University of Michigan Health System (UMHS) created a Laboratory Test Utilization Program that included the establishment of a Laboratory Formulary Committee under the imprimatur of the Faculty Group Practice, the Office of Clinical Affairs, the Department of Pathology, and UMHS hospital administration. A critical component of the program is UM-CareLink, an order entry system for inpatients and inpatient-like venues. UM-CareLink allows very basic decision support comment prompts. Through the application of peer-reviewed medical evidence, input by medical content experts, excellent cooperation by medical staff, and close oversight by Pathology of the Sendout Laboratory, this program has led to a robust process of test utilization oversight, excellent communication with clinical services, and significant UMHS activity-adjusted reductions in laboratory expense.

For nearly 50 years, the increasing rate of American expenditures for health care has outstripped the growth rate of the US gross domestic product (GDP).[1] Failure to stem this trend will, by the end of the decade, lead to annual costs of more than $4 trillion. This sum is projected to account for as much as 20% of the GDP and to exceed the current economic outputs of every nation in the world, save China, Japan, and, perhaps, Germany![2] This unrelenting and disproportionate rise in costs has become a focal point for intense national political debate, raised concern for American competitiveness in the global economy, and engendered heightened attention within the US health care industry. It is clear that an aggressive, multifaceted approach to more rational use of health care resources is urgently warranted.

Some studies have cogently marshaled evidence that physicians "trigger" the majority of direct health care costs, that the majority of their medical decisions are influenced by laboratory data, and that as many as 94% of their transactions with the electronic medical record include views of laboratory results.[3-6] Based on studies that have revealed no clear-cut correlation between numbers of laboratory tests ordered per patient and clinical outcomes, as well as studies that have revealed significant geographic variations in test usage, also without differences in clinical outcomes, it is clear that "excessive use" and/or "waste" of laboratory resources contribute to the overall cost of health care.[3] Currently, the direct cost of laboratory and pathology testing is believed to account for 4% ($60 billion per year) of health care costs.[7] The rapid emergence of molecular diagnostics and whole-genome sequence-based testing portends an even greater relative contribution to overall health care costs.[7] The economy-crippling

upward trend in health care costs, coupled with an opportunity to more efficiently use laboratory testing resources, create an imperative to address the latter.

A large body of literature addresses tactics and strategies to better "control" laboratory costs. Interest in optimal laboratory test utilization is universal, as evidenced by studies from countries outside of the United States.[8,9] The value of administrative controls (vs purely educational interventions) and the role of pathologists as participants have also been observed to be effective contributors to laboratory test utilization programs.[10,11] Finally, the spate of recent publications in widely read pathology publications further emphasizes the currency and importance of this issue.[12,13]

Faculty members of the Department of Pathology at the University of Michigan (UM), in collaboration with departmental administrative and technical staff and with active participation by the UM Health System (UMHS) administration and clinical colleagues, have engaged for more than 15 years in a systematic and comprehensive approach to effectively rationalize laboratory resources. The overarching structure of this approach includes laboratory organization (transfer of laboratories to Pathology, consolidation of laboratories within Pathology, and maintenance of Pathology-directed laboratory information technology and phlebotomy services), implementation of Lean operations principles, Pathology oversight of UMHS point-of-care testing (instrument selection, training oversight, and quality control), aggressive deployments of technological approaches (eg, automation), systematic "make-buy" analyses with resultant "new test" additions and "old test" discontinuations, aggressive multispecialty focus on the unit cost and utilization of blood products, aggressive price negotiations with commodity and laboratory services vendors, and laboratory test utilization management. (In addition to structural/organizational integration and a disciplined approach to cost control and resource utilization, the Department of Pathology and the UMHS are partners in a complementary revenue enhancement venture, MLabs, a pathology services outreach and reverse reference laboratory program.) The detailed structure and impact of this overarching program are detailed elsewhere.[14]

The focus of this article is specifically the structure, operation, and impact of the UMHS Laboratory Test Utilization Program.

Materials and Methods

Setting: University of Michigan Health System and Clinical Pathology Laboratories

The UMHS is a comprehensive health care system that encompasses the University of Michigan Hospitals and the University of Michigan Medical and Nursing Schools. The UMHS includes more than 22,000 faculty and staff and more than 120 clinic locations in Michigan and northern Ohio. Fiscal year 2012 was marked by 45,000 inpatient admissions, 1.8 million outpatient visits and procedures, and $4.52 billion in gross charges.

The clinical laboratories operate 24 hours per day, 7 days per week, and 365 days per year and encompass Specimen Processing, Sendout Laboratory, Phlebotomy Service, Blood Bank/Transfusion Medicine, Therapeutic Apheresis, Hematopoietic Progenitor Cell Laboratory, Chemistry, Microbiology-Virology, Hematopathology, Flow Cytometry, Coagulation, and comprehensive Anatomic Pathology Laboratories. Offsite clinical pathology laboratories include Cytogenetics, Molecular Diagnostics, Histocompatibility, Immunology, and nearly 2 dozen limited-function laboratories. The UMHS Clinical Pathology Laboratories produced 5.6 million billable test charges (10.8 million individual results) and $486 million in gross (billed charges) revenue in fiscal year 2012.

Charge and Governance of Laboratory Test Utilization Program

Following a decade of often-frustrated efforts by the Department of Pathology to effectively impact clinical laboratory test utilization, a new Laboratory Test Utilization Program was implemented in July 2008. At the request of Pathology, UMHS leadership charged the Faculty Group Practice (FGP) and Office of Clinical Affairs (OCA) to create a standing Laboratory Formulary Committee. The UMHS FGP, created in 1996, is a nearly 2,000-member faculty-physician organization. The FGP is led by physicians and represents all clinical cohorts within the UMHS. The OCA establishes and maintains UMHS clinical practice policy and is led by the elected chief of clinical affairs and 4 associate chiefs, a permanent administrative staff group, and the Executive Committee for Clinical Affairs, an elected multispecialty physician body that provides advice and oversight. UMHS clinical service chiefs are directly responsible to the chief of clinical affairs in areas germane to UMHS-wide medical policy and practice. It was agreed by consensus among the leaders of the UMHS, FGP, OCA, and the Department of Pathology that the Laboratory Formulary Committee should carry the imprimatur of these groups, be led by an "actively practicing" clinician, and include strong representation by Pathology. The rationale for a major role by Pathology is its overall responsibility for provision of laboratory services, its ability to collect relevant laboratory test utilization and financial data, and its direct responsibility for laboratory testing expense across the UMHS.

Critical Resources

The organizational structure and operating mechanisms for the Test Utilization Program are detailed in the Results. In addition to the creation of a Laboratory Formulary Committee (appropriately charged as described above), critical

DOI: 10.1309/AJCP4G6UAUXCFTQF

components to the success of the program include the UM-CareLink (developed by Eclipsys Corporation, Atlanta, GA; merged with Allscripts in 2010) order entry system for inpatient units and "inpatient-like venues." The first phase of UM-CareLink implementation at the UMHS was completed in 2008. The order entry system was employed primarily as a means to improve patient safety in a manner that would engender user acceptability through the application of order sets and minimization of hurdles that could increase workload for providers. Inpatient-like venues include units that do not serve inpatients per se but function in a similar manner (eg, Medical Procedures Unit). UM-CareLink provides a critical, albeit basic, means for real-time utilization/decision support. The UM-CareLink, deployed in 2008, presents informational "pop-up" boxes that are triggered by selected order requests. Laboratory tests that can be ordered directly through UM-CareLink constitute the "first tier" formulary (see below) and are listed in the online Pathology Laboratory Services Handbook.[15] The great majority of outpatient/offsite laboratory test ordering (until August 2012) was via paper requisitions, most of which was approved by the Department of Pathology.

An additional critical resource is the Department of Pathology Sendout Laboratory. The Sendout Laboratory resides in Pathology, is directed by a pathologist (J.S.W.), and is staffed by a specifically trained cohort of medical technologists and rotating pathology residents. The Sendout Laboratory is allocated a line-item annual laboratory test expense budget. Esoteric laboratory specimens and orders, whether requested through UM-CareLink or manually, are prepared, packaged, and sent to Clinical Laboratory Improvement Amendments–licensed reference laboratories via this service. Sendout Laboratory personnel also play a major role in reference laboratory procurement and utilization management (see below).

Finally, it should be acknowledged that the entire program has required significant time commitments by Laboratory Formulary Committee members, Pathology administrative and informatics support personnel, invited physician experts (see Results), Sendout Laboratory personnel, and Medical Center Information Technology (MCIT) personnel. The latter are responsible for both maintenance and implementation of changes in the UM-CareLink test order process that result from Laboratory Formulary Committee decisions.

Results

Laboratory Formulary Committee: Structure and Operation

The Laboratory Formulary Committee, established in July 2008, was modeled after the UMHS Pharmacy and Therapeutics Committee. The committee is chaired by a practicing clinician (internal medicine, rheumatology) who is also a member of the FGP Clinical Practice Committee and an associate chief of clinical affairs. Standing members include 3 additional internal medicine subspecialists (oncology, infectious diseases, and gastroenterology); 1 pathologist who is the clinical laboratory director and director of the Sendout Laboratory; the senior associate hospital director, whose domain of oversight includes Pathology; the Pathology Department director of operations; administrative support staff from Pathology; and, since August 2011, a pediatric neurologist. Two health care economics fellows participated as ex officio members between August 2011 and May 2012.

The Laboratory Formulary Committee meets monthly. The major order of business typically includes the vetting of current or proposed new laboratory tests. Discussions regarding medical utility and evidence-based practice are led by invited clinical "content experts." Content experts are prospectively selected and invited by the committee. Every attempt is made to identify individuals who possess extensive topic-specific clinical experience and are institutionally recognized authorities. (Examples include a neurologist who specializes in multiple sclerosis–cerebrospinal fluid oligoclonal bands and myelin basic protein, a gastroenterologist who specializes in inflammatory bowel disease [inflammatory bowel disease serology panel], and an oncologist who specializes in breast cancer [quantitative circulating breast carcinoma cell assay].) Peer-reviewed literature germane to the clinical utility and operating characteristics of each test is distributed in advance of each meeting. The invited clinical expert is asked to provide any additional publications that he or she considers germane to the discussion. Data that pertain to test volume, cost, reimbursement, and utilization patterns are provided by Pathology **Figure 1**. In many instances, clinical content experts engage in dialogue with UMHS physician colleagues who practice in the area under discussion. After an individual test has been vetted by the committee, policy changes, including ordering recommendations and restrictions, are communicated by memo to clinical services deemed likely to be affected **Figure 2**. In addition, change orders that alter test availability (eg, no longer available, available only to specific services, or available only to outpatients) are forwarded to MCIT UM-CareLink personnel and, where appropriate, to the Sendout Laboratory. The currently deployed UM-CareLink system can display pop-ups that contain brief statements such as "recommend one test X per admission" or "test X should be ordered in consultation with a neurologist." The system has no capacity for specific test-directed linkage to previous laboratory results and does not have the capacity to regulate access to order placement at login or upon placing a specific test order. These limitations are addressed further within the Discussion.

Follow-up surveys of utilization data are scheduled in 6-month intervals. The Laboratory Formulary Committee

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Laboratory Formulary-Testing Activity Cost (SAMPLE)

Test Name	Myelin basic protein
Reference Lab	X
Charge per test	$61.00
Number of tests ordered	162 annual
Specialty/Subspecialty who order	NEU = 51.3%
	O/P = 48.2%
CPT Code	83873
Financial Impact; Current Charges =	$9,882.00/year (annualized)

X = Name of reference laboratory

NEU = Neurology

O/P = Outpatient orders

Figure 1 Laboratory formulary activity and cost. This data template example provides test name, locations of test performance (reference laboratory or University of Michigan Health System), annual volumes, origins of test orders, proportions of outpatient vs inpatient orders, and cost data.

DATE: December 12, 2011 (SAMPLE)

EFFECTIVE: Immediately

TO: Internal Medicine; Family Medicine; Pediatrics; Neurology; Gastroenterology

CC: Dr. X, M.D., Director, Clinical Pathology

FROM: Lab Formulary Committee; Faculty Group Practice; Office of Clinical Affairs; Dr. Y, M.D. (Chair)

SUBJECT: Lab Formulary Change: Inflammatory Bowel Disease (IBD) Serology Panel to be replaced by new Inflammatory Bowel Disease Serology Panel

The Lab Formulary Committee was created in July 2008 to enhance UMHS cost effectiveness by developing principles, standards, and guidelines for the high-cost of laboratory tests. Recently XXX Laboratories released a new inflammatory bowel diagnostic test: "New Serology". This panel combines serologic, genetic and inflammation markers to help tailor therapy. The "Old Serology" will be phased out and replaced by "New Serology". At this time the Formulary Committee believes that the restrictions for "New Serology" should remain the same as the current test "Old Serology".

Thus, the "New Serology" will be restricted to the following:

- It is non-orderable on inpatients.
- It should be restricted on an outpatient basis, but orderable with justification.
- The patient with a high clinical suspicion of IBD should be referred to a GI Specialist.

Please feel free to contact Dr. Y, M.D. or any of the following members should you have any questions regarding the lab formulary change.

Lab Formulary Committee Members: Drs. X, Y, A, B, C, D, E, and F

The principles of the Lab Formulary include:

- To assure highest quality of patient care
- To promote the ideal patient care experience
- To assure the appropriateness and the right sequencing in the utilization of lab tests
- To assure the appropriate utilization using the medical evidence based test analysis
- To maximize productivity and fiscal soundness

Figure 2 Laboratory Formulary Committee memorandum. Test change notices are distributed to faculty of clinical services deemed most likely to be affected. The sample memo identifies the test in question, briefly reviews the charge of the Laboratory Formulary Committee, provides a bullet-point list of explicit recommendations and/or changes in test usage and availability, and invites questions.

also devotes periodic agenda time to follow-up assessments and potential new policy areas (eg, test order cascades and enhanced decision support). Follow-up assessments have been precipitated both by changes in medical practice and infrequent situations in which a Laboratory Formulary Committee recommendation has been "appealed." An example of the former is vitamin D orders for which in July 2009, the committee concluded that utilization was appropriate, and no changes in the formulary were implemented. In October 2012, the committee revisited vitamin D order recommendations and recommended that this assay only be ordered in patients "at risk" of vitamin D deficiency. References to more recent US Public Health Service guidelines were provided along with commentary by a clinical "content expert." An example of "appeal" occurred when a physician requested that the committee revisit the December 2008 recommendation to restrict growth assessment testing orders on inpatients and for the Sendout Laboratory to use a less expensive reference laboratory. The committee decided to maintain its 2008 recommendation.

It should be emphasized that conscious effort is made to promulgate a "tone" of decision support, education, and careful use of resources rather than one of "restriction."

The overarching position of the Laboratory Formulary Committee is to regulate availability of clinical laboratory tests based on medical evidence. As noted above, candidate tests are first reviewed to determine whether there is sufficient volume and cost to justify the attention (and time) of the committee (Figure 1). (It should be noted that several tests that have been "low to moderate" in volume and cost have been vetted on an ad hoc basis on the recommendations of either a committee member or on outside party.) Candidate laboratory tests are prospected by a systematic review of expensive and/or high-volume sendout tests wherein the UMHS directly pays the performing reference laboratory its full (or discounted) charge; by the identification of very esoteric or unusual sendout tests in which the volume of orders appears to exceed likely true clinical needs or in which such tests are frequently ordered by physicians who do not specialize in the particular area; by poll of clinical laboratory directors; and, in the case of requests, by clinicians that a new laboratory test be made available. In addition, several complex algorithmic testing cascades have been vetted. In the latter case, the goal has been to streamline complicated multistep testing sequences.

Impact of Laboratory Test Utilization Program

The overall impact of the Laboratory Test Utilization Program falls into 5 general areas. The first 3 can be quantified, albeit with caveats, whereas the last 2 areas are not easy to quantify but nonetheless are important to the ongoing and future success of the program. Areas of impact include

DOI: 10.1309/AJCP4G6UAUXCFTQF

numbers and categories of vetted tests, sendout costs, changes in volumes (and costs) of vetted individual tests, UMHS laboratory test utilization structure and Sendout Laboratory operation, and potential to influence both ongoing and "next-generation" utilization control efforts.

Numbers and Categories of Vetted Tests

Through June, 2012, 43 Sendout Laboratory tests or panels, 9 UMHS in-house (tests), and 5 new test requests had been evaluated by the Laboratory Formulary Committee. Table 1 summarizes Sendout Laboratory tests vetted since 2008,

Table 1
Sendout Laboratory Tests Vetted by the UMHS Laboratory Formulary Committee

Test	Review Date	Formulary Changes
Aspergillus antigen (S)	August 2008	Only patients *not* receiving antifungal therapy *unless* high
Multiple myeloma FISH	September 2008	Restricted to 1 analysis per patient
Chronic lymphocytic leukemia FISH	September 2008	No order for inpatients Outpatient orders accepted
Inflammatory bowel disease panel (S) (proprietary)	October 2008	No order for inpatients Outpatient orders accepted Recommend referral to Gastroenterology
TMPT (genotype)	October 2008	Restricted to 1 analysis per patient
TMPT enzyme (phenotype)	October 2008	Preferable to TMPT genotype, not both
Thiopurine metabolites	October 2008	Appropriately utilized No change in formulary
Infliximab/HACA	November 2008	Appropriately utilized No change in formulary
Celiac disease panel (S) (proprietary)	November 2008	Removed from formulary Standard celiac disease assays are sufficient
Celiac disease HLA typing (proprietary)	November 2008	Appropriately utilized No change in formulary
Growth assessment panel V (IGF1; IGFBP3) (proprietary)	December 2008	No order for inpatients Changeover date for new, less expensive reference laboratory
Histoplasma antigen (U)	December 2008	Appropriately utilized No change in formulary
Alkaline phosphatase isoenzymes (S)	December 2008	No order for inpatients
Hereditary nonpolyposis colorectal cancer genetic analysis: *MLH1*, *MSH2*, *MLH1/MSH2*, *MSH6*	February 2009	Outpatient orders only Genetics Clinic only One analysis per patient unless permission
Parvovirus B19 DNA	April 2009	No more than 1 order/wk
BK virus DNA	April 2009	No more than 1 order/wk
Adenovirus DNA	April 2009	No more than 1 order/wk
Human herpesvirus-6 DNA	April 2009	No more than 1 order/wk
MTHFR-C677T mutation analysis	June 2009	Removed from formulary
Plasminogen activator inhibitor 4G/5G genotyping	June 2009	Removed from formulary
Paraneoplastic antibody panel (S)	September 2009	Inpatient orders require approval of attending physician
Thyroid-stimulating Ig	September 2009	Appropriately utilized No change in formulary
Circulating tumor cells	November 2009	In-sourced by UM Pathology in 2010 Outpatient orders only Patients with metastatic disease Oncology Clinic only
Histoplasma antigen (S)	November 2009	Appropriately utilized No change in formulary
CFTR full-gene analysis	December 2009	Appropriately utilized (only by Cystic Fibrosis Clinic) No change in formulary
Herpes simplex, type 1 antibody; herpes simplex, type 2 antibody	January 2010	Appropriately utilized No change in formulary
Epstein-Barr virus PCR	April 2010	Appropriately utilized No change in formulary
Crohn disease prognostic test (proprietary)	October 2010	Outpatients only Gastroenterologists only One time only
Red blood cell folate	January 2011	Removed from formulary
Esoteric neurogenetics tests (proprietary-single vendor)	March 2011	Outpatients only Neurologists only
Cancer antigens (S): CA 125, CA 15-3, CA 27-29	March 2011	Removed CA 27-29 from formulary No more frequent than once every 3 weeks One order/admission
Myelin basic protein	August 2011	Remove MBP from formulary
ADAMTS13	September 2011	One order/wk only No recheck until more than 1 month
Hepatitis E serology: IgM and IgG	October 2011	Pop-up box comment: "HEV antibody testing is not part of routine hepatitis testing."

CFTR, cystic fibrosis transmembrane conductance regulator; FISH, fluorescence in situ hybridization; HACA, human antichimeric antibody; HEV, hepatitis E virus; HLA, human leukocyte antigen; Ig, immunoglobulin; IGF1, insulin-like growth factor 1; IGFBP3, insulin-like growth factor binding protein 3; MBP, myelin basic protein; *MLH1*, MutL homolog 1 (hereditary nonpolyposis colon cancer); *MLH1/MSH2*, MutL homolog1/Mut5 homolog 2; *MSH2*, MutS homolog 2 (hereditary nonpolyposis colon cancer); *MSHG*, Mut5 homolog 6; MTHFR, methylenetetrahydrofolate reductase; PCR, polymerase chain reaction; S, serum; TMPT, thiopurine methyltransferase; U, urine; UM, University of Michigan; UMHS, University of Michigan Health System.

DOI: 10.1309/AJCP4G6UAUXCFTQF

Table 2 summarizes vetted UM Pathology (in-house) tests, and **Table 3** lists proposed new tests that have been vetted. In addition, a "platelet refractoriness" testing algorithm that is required for orders of human leukocyte antigen–matched platelets was vetted in July 2011 (not shown in tabular form).

Examination of the dates upon which the Laboratory Formulary Committee evaluated various laboratory tests reveals that there was a particular effort to address very expensive sendout tests early in the program. As noted earlier, the chief rationale for this prioritization has been that Sendout Laboratory tests are direct cost items. Also, given that the UMHS clinical laboratories are full service and comprehensive, sendout tests are nearly always low to moderate volume, expensive, and "superesoteric." In results not shown, the temporal lag between committee decisions and implementation of restrictions and notices in the formulary made apparent by UM-CareLink has decreased from 3 to 5 months (early in the program) to less than 2 months. (Early in the program, test order modifications in UM-CareLink were placed at the end of lengthy MCIT work queues.)

Impact on Cost of Sendout Testing Expense

As noted previously, the great majority of laboratory tests vetted by the Laboratory Formulary Committee have been sendouts. As summarized in **Table 4**, there has been a modest but largely consistent absolute annual decline in laboratory sendout expenses since fiscal year (FY) 2008, the year of the establishment of the committee. The sendout cost data shown are from UMHS patients and do not include MLabs sendout costs (which are fully reimbursed by MLabs clients). (MLabs client tests are ordered by non-UMHS physicians who practice outside of the OCA and FGP.) The financial impact of the focus by the Laboratory Formulary Committee on sendout test expenses is even greater when overall UMHS and associated clinical laboratory testing growth data are used to normalize the data. Not shown is the 4-year (FY 2008-2012) upward trend in overall UMHS activity as reflected in annual gross charges and overall annual expenses.

Table 3
Proposed New Tests Vetted by the UMHS Laboratory Formulary Committee

Test	Review Date	Formulary Changes
Cylex Immuno Know assay (proprietary)	August 2010	Not added to formulary
Helicobacter pylori sensitivity	August 2010	Added to formulary
IL-28B genetic polymorphism assay	September 2010	Outpatient only One time/patient
Peripheral nerve fiber morphometric analysis	February 2012	Not added to formulary

UMHS, University of Michigan Health System.

Changes in Volumes and Costs of Vetted Individual Tests

As reflected in Tables 1, 2, and 3, 43 individual laboratory tests or panels have been vetted by the Laboratory Formulary Committee since its inception in 2008. Thirty-two tests were sendouts at the time of evaluation, 5 were assays performed within the UMHS, and 4 were new test requests. It should be noted that more than 50 new tests have been implemented by the Department of Pathology since July 2008. Decisions to add these assays were made by laboratory directors in the Department of Pathology, based on UMHS and/or MLabs clinical demand, and were thus not vetted by the Laboratory Formulary Committee. Among the 43 tests and panels evaluated by the Laboratory Formulary Committee, decisions to not offer or to restrict in some fashion occurred in 27 instances. The circulating tumor cell assay was vetted and restrictions imposed, but the assay was subsequently set up within UM Pathology. Follow-up of individual tests vetted by the committee are conducted at 6-month intervals following the initial assessment.

UMHS Laboratory Test Utilization Program Structure and Sendout Laboratory Operations

The establishment of the Laboratory Formulary Committee and attendant policies to effect changes in test ordering

Table 2
UM Pathology Tests Vetted by the UMHS Laboratory Formulary Committee

Test	Review Date	Formulary Changes
Vitamin D (S)	July 2009	Appropriately utilized No change in formulary
Antinuclear antibody (S)	July 2009	Restricted in patients with positive ≥1:320 for 5 years
Bleeding time	September 2010	Removed from formulary
Westergren sedimentation rate	September 2010	Inpatients only No more than twice/wk
Anti-HLA class I and class II	January 2011	High-risk patients By approved protocol

HLA, human leukocyte antigen; S, serum; UM, University of Michigan; UMHS, University of Michigan Health System.

DOI: 10.1309/AJCP4G6UAUXCFTQF

Table 4
Sendout Laboratory Test Expense: 4-Year Trend

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Sendout expense (in $ millions)[a]	5.07	5.05	4.91	4.78	4.98
Percentage change[b]		–0.010	–0.026	–0.028	+0.042
Clinical lab testing expense (in $ millions)[c]	27.9	29.7	31.6	34.0	35.4
Percentage change[b]		+0.06	+0.06	+0.08	+0.03
Sendout expense normalized to clinical lab testing expense[d]	18.2	16.9	15.5	14.1	13.1
Percentage change[b]		–0.07	–0.08	–0.09	–0.05
UMHS activity: adjusted discharges	79,883	82,235	85,797	90,075	93,003
Percentage change[b]		+0.03	+0.04	+0.05	+0.03

FY, fiscal year; UMHS, University of Michigan Health System.
[a] UMHS patients only.
[b] Percentage change from prior year.
[c] Clinical laboratory testing expense excludes blood bank testing, blood product expenses, specimen collections, and direct information technology (Pathology Informatics budget) expenses.
[d] Annual sendout expense normalized to clinical laboratory testing expense (and expressed as a ratio) for the corresponding year.

through UM-CareLink and, in the case of sendout tests, in the function of the Sendout Laboratory has had several major impacts. The lag time between Laboratory Formulary Committee decisions and updates in the UM-CareLink test ordering, where changes have been implemented, has decreased from 3 to 5 months to approximately 6 weeks. Although data were not collected until FY 2010, the number of real-time requests discussed between Sendout Laboratory personnel (laboratory staff, Pathology residents, and the laboratory director) and a care provider has averaged 33 per month.

Overarching Operational and Cultural Impact of the Laboratory Testing Utilization Program

Finally, and importantly, the Laboratory Test Utilization Program has established an operating structure that includes an institutionally credible Laboratory Formulary Committee, a close functional relationship with Pathology (data collection and Sendout Laboratory), a robust connection to UM-CareLink via MCIT, and a UMHS culture of laboratory test utilization vetting. The committee has hosted 17 different content experts at meetings, and the addition of a pediatric neurologist in 2011 to the committee was the direct result of interest in the program by the neurologist and the chairperson of the Department of Pediatrics.

Discussion

The rapidly rising cost of American health care is a serious challenge. An overarching solution for health care cost reduction is well beyond the scope of this article but doubtlessly will be multifaceted and include better application of evidence-based medical practice; improved communication; attention directed toward diagnostics, therapeutics, and preventative care; improved resource distribution and allocation; and changes in reimbursement structure. Laboratory testing cost is a relatively small but important component.[7] The importance of laboratory testing cost is much more significant when one considers the importance of test results in medical decision making and when one considers the "downstream" impact of accurate, timely, and clinically useful test results.[3-6]

The present study provides a description of the structure and operation of an institutionally based Laboratory Test Utilization Program and provides quantitative data that suggest that this program has had a positive financial impact. It should be emphasized again that this study pertains to clinical laboratory test utilization, a single facet of a broader approach to control clinical laboratory expenses. (For instance, in FY 2011 and FY 2012, the UMHS spent $15.2 million and $13.3 million, respectively, on blood products alone.) A description of the overarching systematic and comprehensive approach to control UMHS laboratory costs is detailed elsewhere.[14]

At the center of the UMHS Laboratory Test Utilization Program is the Laboratory Laboratory Formulary Committee, which was fashioned after the UMHS Pharmacy and Therapeutics Committee. Important aspects of the committee are that it has the imprimatur of the FGP, OCA, Department of Pathology, and UMHS administration. The committee is led by a clinically active physician and composed of practicing physicians in addition to UMHS administration and Pathology. The responsibility linkage between the chief of clinical affairs (director of the OCA) and all UMHS clinical service chiefs is a critical structural component of this program. The structure and operation of the Sendout Laboratory within Pathology and its direction by a pathologist are also important structural aspects of this program.

Finally, the implementation of UM-CareLink, the UMHS inpatient and inpatient-like venue order entry system, has been vital. Orderable laboratory tests constitute the de facto laboratory formulary, and the capacity to place restrictions and limitations into UM-CareLink test ordering is a critical component of the program. (A higher level and more

DOI: 10.1309/AJCP4G6UAUXCFTQF

comprehensive decision support–backed order entry system might create greater impact.) The rudimentary decision support capacity of UM-CareLink is a shortcoming of the current program. As noted earlier, UM-CareLink was implemented to improve patient safety. To garner user acceptance, there was a conscious decision to minimize "regulatory controls." Clearly, the capacity to reference previous laboratory results, to tailor ordering by physician specialty, and to limit test order frequency per admission would be major enhancements. The committee is currently exploring its potential role in a UMHS laboratory test order decision support initiative. Given UMHS test volumes (5.6 million billable charges and 10.8 million individual tests in FY 2012), it would be practically impossible to effect any meaningful laboratory test utilization program without a significant ability to "automate" (via UM-CareLink) a major portion of the communication to ordering care providers.

One of the most important, and certainly the most scrutinized, metrics that can be used to assess laboratory test utilization as well as effectiveness of this program is aggregate annual sendout expense. Although it is tempting to rely solely on absolute annual sendout cost, this measure encompasses overall UMHS growth in patient volume. In addition, overall Pathology Sendout Laboratory expenses include some MLabs testing that is paid for in full by the referring hospital, medical practice, or reference laboratory and then sent by the Sendout Laboratory to an "up-the-chain" reference laboratory. In this case, no actual incremental expense (beyond packaging and shipping cost) is incurred. (It is commonplace that sets of laboratory tests, often esoteric, from a single patient are received from an MLabs client. Several of the tests are performed in UMHS Pathology, whereas a single test or small subset of tests that are not offered at UMHS is sent on to an external reference laboratory. These tests are booked as Sendout Laboratory costs.) In Table 4, overall clinical laboratory testing expense and UMHS clinical activity (adjusted discharges) are shown. (Adjusted discharges represent a summation of discharged inpatient and outpatient visits in which 58 outpatient visits are counted as equivalent to a single inpatient discharge.) A potential pitfall in the application of adjusted discharges as a valid measure of overall activity is that many superesoteric expensive laboratory tests are ordered in outpatients. One could envision a scenario in which the inclusion of inpatients in this metric might overstate the apparent effectiveness of the program because inpatient costs, which are very high, have an undue impact on the overall institutional expense as compared with sendout expense. UMHS patient sendout expense is shown in absolute terms and normalized to overall clinical laboratory testing expense as a means to account for UMHS growth. Normalization of sendout expense to overall clinical laboratory testing expense has the added analytical benefit of fully capturing the financial impact of insourcing testing since in-house testing expense is reflected in the clinical laboratory testing expense line. The major shortcoming of direct or normalized testing cost is that new, often expensive testing cannot be easily measured (or controlled).

An important means of testing the impact of the Laboratory Test Utilization Program is to examine cause-and-effect linkages between utilization of tests before vetting by the Laboratory Formulary Committee and subsequent to any changes in test availability or the posting of new test-ordering recommendations or restrictions. Ongoing utilization of this type of analytical system will require data links between individual requested tests, test-specific order entry decision support, subsequent placement of the test request (or not), capture of cost data for each test, and specialty-specific and/or case mix–adjusted changes in overall growth.

This study outlines the structure and impact of a laboratory test utilization program in a large academic medical center. Key elements of the program include the broad-based mandate under the imprimatur of the administration, physician groups, and Pathology. Critical components include expert clinician participation and visibility in the Laboratory Formulary Committee, the functionality of the order entry system (including information technology support), and Pathology leadership and responsibility for the Sendout Laboratory.

The overall impact of the Laboratory Test Utilization Program falls into 5 areas. These include categories and numbers of tests vetted, sendout test costs (normalized for institutional growth), changes in volumes (and costs) of individual tests, robust institution-wide laboratory test utilization structure (and Sendout Laboratory operation), and impact on institution-wide culture.

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