Clinical Chemistry 63:7
1299–1304 (2017)

Letters to the Editor

Laboratory Formulary: A Model for High-Value Evidence-Based Medicine

To the Editor:

Health systems across the US have struggled to meet the value proposition of healthcare reform: to provide high-quality, low-cost, accessible care *(1)*. While laudable efforts have been undertaken to reduce hospitalizations, readmissions, imaging, and pharmaceutical costs, less attention has been given to managing the costs of diagnostic laboratory testing. In addition, while the number of diagnostic tests available to clinicians has grown enormously, many of these tests are expensive, have limited clinical utility, and require nuanced interpretation *(2, 3)*.

At the University of Rochester Medical Center (URMC),[1] we approached this challenge by developing a laboratory formulary, a mechanism to classify diagnostic tests into different categories with the goal of aligning clinical utility with the medical expertise of ordering physicians to minimize inappropriate and/or unnecessary testing. This model has gained much attention recently and been implemented in several institutions *(4, 5)*. Successful implementation, however, is not an easy undertaking. Herein we describe how our Laboratory Diagnostics Committee (LDC) developed a laboratory formulary for our academic and community provider–based health system.

In 2008, it became apparent that the ordering behaviors of URMC physicians required a cultural transformation for proper use of laboratory diagnostics. The LDC was established to provide both strategic guidance and a solution to this issue.

The LDC included the Chief Medical and Chief Operations officers. The Chair of the Internal Medicine Department took a lead role in the LDC, working with the Department of Pathology and Laboratory Medicine and key subspecialty clinical leaders to develop a process to critically evaluate our diagnostic test menu and develop a laboratory test formulary. Each test on our menu was classified into Tier 1, Tier 2, or Tier 3 (Table 1) based on LDC recommendations.

Tier 1 consists of common tests with clear and well-proven clinical utility that are available to all providers. Tier 2 tests have a more specialized, narrow clinical indication. With rare exceptions, these tests are restricted to subspecialists with faculty appointments or privileges at URMC and its affiliated hospitals. The URMC electronic medical record includes the physicians' subspecialties, and Tier 2 tests are automatically available for physicians to order. Tier 3 tests are considered "nonformulary" and include tests that have unclear, controversial, poorly proven, or very limited clinical indications. Ordering of Tier 3 tests requires approval from the LDC.

Providers can order Tier 3 tests by submitting a medical necessity request. The request includes information on the patient's medical condition and how the proposed test would contribute to medical decisions and treatment outcomes. Typically, this request is for a one-time authorization for an urgent medical need. Less commonly, a provider may request that a Tier 3 test be formally reviewed by an appropriate LDC subspecialty committee and, if approved, changed to a Tier 2 test. This data-driven LDC review process ensures that the laboratory formulary remains up to date with clinical evidence. The LDC oversight structure provides a mechanism that facilitates primary care provider access to subspecialist expert advice without having to send patients for formal in-office consultation. It also ensures alignment of clinical utility, test performance, and provider interpretative skills.

Although not the primary motivation of this program, substantial financial benefits have resulted from improved utilization of diagnostic testing. During the first year of implementation in 2011, inpatient and outpatient send-out test volumes were reduced 48% and 18%, respectively, resulting in about $500 000 in savings. Ordering of Tier 1, 2, and 3 tests was reduced by 22%, 14%, and 21%, respectively, at the end of year one. The unexpected decrease of Tier 1 tests suggests that in test utilization alone, the initiative contributed to a global decrease in test ordering. After 2 years, Tier 1, 2, and 3 tests had 7%, 23%, and 52% reductions in volume, respectively, compared to test volumes before implementation. These results indicate that a laboratory formulary can provide long-term, sustainable changes for test utilization. Additional costs have been limited to an additional staff member in the send-out division and one-half faculty effort overseeing the ordering process.

The successful implementation of a laboratory formulary has challenges that require an ongoing, multidisciplinary approach. It was essential to have institutional leadership with buy-in from URMC faculty physicians to make this strategy successful. It was also crucial to have effective communication, information technology support, and rapid (24-h) turnaround time to adjudicate Tier 3 exception requests.

While healthcare reform has placed new pressures on provider organizations, it has also created opportunities to more closely examine our daily operations. The laboratory formulary developed for our health system has proven to be a successful program for overseeing and improving laboratory test utilization. It allows laboratory professionals to collaborate closely with clinical providers to redefine high-value patient care and the future of laboratory testing.

[1] Nonstandard abbreviations: URMC, University of Rochester Medical Center; LDC, Laboratory Diagnostics Committee.

Table 1. Tiered test features and ordering process in laboratory formulary.

	Tier 1	Tier 2	Tier 3 (nonformulary)
Type	Common	Specialized	Uniquely subspecialized/rare
Clinical utility	Well-proven clinical utility	Limited or narrow clinical utility	Unclear, controversial, poorly proven, or very limited clinical utility
Requirements for provider access/ordering	No restrictions; available to all providers	Subspecialty faculty appointment or privileges at URMC and affiliated hospitals	Subspecialty faculty appointment or privileges at URMC and affiliated hospitals and LDC[a] approval
Percent of test ordering volumes	87%	11%	2%
Examples	1. Most in-house testing	1. 1,25-Dihydroxy Vitamin D	1. Inflammatory bowel disease panel[b]
	2. Cystic fibrosis 32 mutations	2. Fecal pancreatic elastase	2. Pancreatitis panel[b]
	3. TSH receptor antibody	3. Disaccharidase analysis	3. α_1-Antitrypsin genotype
	4. Serum-free cortisol	4. Insulin antibodies	4. Hepatitis C RIBA
	5. Zinc	5. BMT Panel[b]	5. β-Thalassemia gene
			6. Biotinidase

[a] LDC, Laboratory Diagnostic Committee; TSH, thyroid-stimulating hormone; RIBA, recombinant immunoblot assay; BMT, bone marrow transplant.
[b] Panel test components vary by institution. The inflammatory bowel disease panel includes *Saccharomyces cerevisiae*, immunoglobulin A (IgA) and IgG antibodies, and neutrophil-specific antibodies. The pancreatitis panel includes next generation sequencing of *PRSS1*, *SPINK1*, *CTRC*, and *CFTR*. The BMT Panel includes hepatitis B surface antigen with reflex to confirmation; Hepatitis B core antibody; HIV 1/2/0 antibody; human T-lymphotropic virus (HTLV) 1/2 antibody with reflex to immunoblot; CMV total antibody; Epstein-Barr virus (EBV) IgG; varicella zoster virus (VZV) IgG; herpes simplex virus (HSV) 1/2 antibody; syphilis IgG; HIV/HBV/HCV NAT (HIV/hepatitis B virus/HCV nucleic acid amplification testing); hepatitis C antibody and Chagas antibody (Ab) IgG.

Author Contributions: *All authors confirmed they have contributed to the intellectual content of this paper and have met the following 3 requirements: (a) significant contributions to the conception and design, acquisition of data, or analysis and interpretation of data; (b) drafting or revising the article for intellectual content; and (c) final approval of the published article.*

Authors' Disclosures or Potential Conflicts of Interest: *No authors declared any potential conflicts of interest.*

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Previously published online at
DOI: 10.1373/clinchem.2016.270819

Large Variation in Measured Cardiac Troponin T Concentrations after Standard Addition in Serum or Plasma of Different Individuals

To the Editor:

During acute myocardial infarction (AMI),[1] cardiac troponin T (cTnT) is released from the damaged myo-

[1] Nonstandard abbreviations: AMI, acute myocardial infarction; cTnT, cardiac troponin T; CK-MB, creatine-kinase MB isoenzyme; hs-cTnT, high-sensitivity cTnT; LoD, limit of detection; CV_g, intersubject CV.