Identification of Performance Measures of Importance for Quality in Laboratory Medicine

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Introduction

Quality measurement in healthcare is shifting from a focus on quality assurance to transparency and accountability for patient care outcomes. Public reporting of performance data and the advent of "pay for reporting"–as well as pay for performance in some regions–has sharpened the focus on quality. With hospital-level reporting of data already under way, a nascent movement in physician-level reporting is now taking shape. In 2004, the National Quality Forum (NQF) endorsed 23 priorities for healthcare quality measurement and reporting.[1] These practices, published in the report *National Priorities for Healthcare Quality Measurement and Reporting*, build on the Institute of Medicine's (IOM's) 2003 report, *Priority Areas for National Action: Transforming Health Care Quality*. These priorities are organized into 2 infrastructure priorities, 5 process of care priorities, and 15 healthcare condition priorities (tables 1A and 1B).[2] (All tables and figures are presented at the end of the paper.)

Process and outcome measures developed by the Joint Commission, the Centers for Medicare and Medicaid Services (CMS), and the American Medical Association Physician Consortium for Performance Improvement (AMA PCPI) are in use for several of these priority areas. For example, use of beta blockers and aspirin after an acute myocardial infarction (AMI) are among the 17 measures now publicly reported by hospitals under the auspices of the Hospital Quality Alliance (HQA). A number of these measures include laboratory tests, which focus on either performance of the test or achievement of a specified target. A systematic framework for laboratory quality measurement, however, does not exist today. Laboratory testing is an essential component of clinical diagnosis and therapeutic decisionmaking. Significant costs related to laboratory tests are incurred by various stakeholders.

NQF recently convened 23 key stakeholders in laboratory medicine to participate in a workshop on defining laboratory quality and value. The workshop revealed several issues in undertaking national laboratory medicine quality measurement and reporting efforts. These issues included the vast number of areas that laboratory medicine covers and concerns about implementing a consensus standard in which many factors are largely out of laboratories' control.[3]

Little information is thus available on how to demonstrate whether service provided by laboratories–and whether the *use* of these services–is safe, timely, efficient, effective, equitable, and patient centered. This question forms the central thesis that is explored further in this research document. In Part I, the current landscape of quality measurement is examined with special attention to the scope of laboratory medicine measures and practices and what laboratories are currently implementing. Using the national priority areas endorsed by NQF as a foundation, a crosswalk of existing measures and guidelines as well as works-in-progress will be developed. A conceptual framework for a multidisciplinary, integrated view of laboratory quality measurement will be presented. In Part II, gaps in current measurement and research related to laboratory quality are identified. Issues related to feasibility of measurement, the burden of data collection, and actionability will be discussed. The paper concludes with specific recommendations for furthering the quality measurement agenda for laboratory medicine.

Part I. The Evidence Base and the Current Landscape of Laboratory-Based Quality Measurement

The priority conditions (table 1A) have been the subject of several guidelines developed by professional societies and healthcare agencies. Recommendations presented in these guidelines are typically rated by class and level of evidence. In this section, the focus is on laboratory tests recommended in the condition-specific guidelines. The strength of evidence is listed with each recommendation below if it was provided in the cited guideline.

Professional societies such as the American Diabetes Association (ADA), the American College of Cardiology, and the American Heart Association are the primary sources of disease-specific guidelines in their respective specialties. A number of healthcare organizations have developed performance measures that are based in these guidelines. The Joint Commission Core Measures, now included in the HQA set of publicly reported hospital-based measures, cover common conditions such as heart failure (HF) and pneumonia. The Ambulatory Care Quality Alliance–now known as the AQA Alliance–identifies performance metrics suitable for the ambulatory setting. The National Committee for Quality Assurance (NCQA) measures and reports performance of managed care organizations on specific measures of clinical and administrative performance. The AMA PCPI is developing similar metrics for physician-level reporting of performance data. The Physician Voluntary Reporting Program (PVRP) was developed by CMS. NQF provides an independent mechanism for evaluation and endorsement of performance measures.

Diabetes

Diabetes leads to significant morbidity and mortality and affects quality of life. More than 1.5 million new cases of diabetes were diagnosed in 2005. The prevalence of diabetes in the United States is estimated to be 20.8 million, which represents 7 percent of the population.[4]

Evidence-Based Laboratory Testing: The ADA recommends the following tests as part of comprehensive diabetes evaluation and lists a grade based on the ADA evidence grading system for clinical practice recommendations:[5] glycosylated hemoglobin (HbA1c), low density lipoprotein (LDL)-C, high density lipoprotein (HDL)-C, triglycerides, liver function, serum creatinine, thyroid stimulating hormone (for type 1 diabetics), urine microalbumin, urinary ketones, protein, and sediment. For initial diagnosis of diabetes in children and non-pregnant adults, use of fasting

plasma glucose is recommended (E). The use of HbA1c for *diagnosis* of diabetes is not recommended (E). Regular *monitoring* of HbA1c to evaluate glycemic control is recommended (E), with a target HbA1c of less than 7 percent for patients in general (B). In individuals without overt cardiovascular disease, LDL goal of <100 mg/dl is recommended (A); in those with known cardiovascular disease, a 30 to 40 percent reduction in LDL (A) and a target of <70 mg/dl is recommended (B). A triglyceride goal of <150 mg/dl and HDL goal of >40 mg/dl (>50 mg/dl in women) is recommended (C). An annual test for the presence of microalbuminuria in type 1 diabetic patients with diabetes duration of >=5 years and in all type 2 diabetic patients, starting at diagnosis and during pregnancy is recommended (E). Measurement of serum creatinine at least annually for the estimation of glomerular filtration rate (GFR) in all adults with diabetes is suggested. The serum creatinine alone should not be used as a measure of kidney function but instead used to estimate GFR and stage the level of chronic kidney disease (E).

Laboratory-Based Performance Metrics: A number of organizations, including AMA, AQA, CMS, and NCQA, have developed process and outcome measures for diabetes and related complications. The laboratory tests that are explicitly included in these measures include performance of HbA1c, LDL- cholesterol, HDL cholesterol, and triglycerides. The CMS PVRP starter set includes measures for LDL and HbA1c control. The NCQA measures similarly include a target threshold to be achieved for HbA1c and LDL; these laboratory-related measures also are supported by the AQA as part of a "starter set."

Obesity

Obesity is recognized as a driver of increasing prevalence of metabolic syndrome in the United States. Metabolic syndrome, which is a collection of risk factors for atherosclerotic cardiovascular disease, is increasingly prevalent. The development of these metabolic risk factors in individuals is a harbinger of overt diabetes, dyslipidemias, hypertension, and ischemic heart disease.[6]

Evidence-Based Laboratory Testing: As specified in the AHA/National Heart, Lung, and Blood Institute statement on the metabolic syndrome, laboratory tests that can–in conjunction with other clinical findings–help establish a diagnosis of the metabolic syndrome include LDL and HDL cholesterol, triglycerides, and fasting blood glucose. The U.S. Preventive Services Task Force did not find sufficient evidence for use of specific screening interventions including laboratory tests for overweight children and adolescents.[7]

Heart Failure

There are approximately 550,000 new cases of HF diagnosed each year in the United States. More than 5 million people in the United States have HF; these patients account for more than 1 million hospital admissions annually (where HF is the primary diagnosis). The HF DRG carries the highest total Medicare expenditure in diagnosis and treatment costs.[8]

Evidence-Based Laboratory Testing: The ACC/AHA 2005 guidelines[8] recommend specific laboratory tests as part of the initial evaluation (Class I, (C)): complete blood count, urinalysis, serum electrolytes (including calcium and magnesium), blood urea nitrogen, serum creatinine, fasting blood glucose (glycohemoglobin), lipid profile, liver function tests, and thyroid stimulating hormone. Screening for hemochromatosis, HIV, rheumatologic disorders, amyloidosis, and pheochromocytoma may be appropriate in selected patients (Class IIa, (C)). Measurement of serum B-type natriuretic peptide (BNP) level is suggested for patients in urgent care settings in whom the diagnosis of HF is uncertain (Class IIa, (A)), while value of serial measurements of BNP is not established (Class IIb, (C)).

Laboratory-Based Performance Metrics: The AMA PCPI measure set for HF includes initial laboratory evaluation of patients over the age of 18 years. The measure requires documentation of complete blood count, serum electrolytes, blood urea nitrogen, serum creatinine, blood glucose, and thyroid stimulating hormone. A

related NQF-endorsed™ consensus standard for use of warfarin among HF patients who also have atrial fibrillation implies monitoring of laboratory test for prothrombin time and International Normalized Ratio (PT/INR), although none of the metrics directly measures it.

Ischemic Heart Disease

Ischemic heart disease is the leading cause of mortality in the United States. The current prevalence of coronary artery disease is estimated at 13 million.[9]

Evidence-Based Laboratory Testing: The ACC/AHA guidelines for *secondary prevention* among patients with atherosclerotic heart disease have established specific treatment targets for LDL-C (target < 100mg/dl Class I (A), target <70 mg/dl Class IIa (B)), non-HDL-C, triglycerides, and HbA1c (target <7 percent Class I (B)).[9] For patients undergoing percutaneous coronary intervention (PCI), all patients who have signs or symptoms suggestive of myocardial infarction (MI) during or after PCI and those with complicated procedures should have creatine kinase (CK-MB) and troponin I or T measured after the procedure (Class I, (B)). The ACC/AHA/Society for Cardiovascular Angiography and Interventions guidelines further recommend routine measurement of cardiac biomarkers (CK-MB and/or troponin I or T) in all patients undergoing PCI 8 to 12 hours after the procedure (Class IIa, (C)).[10] A new rise greater than five times the upper limit in these biomarkers constitutes a clinically significant periprocedural MI.[10]

Laboratory-Based Performance Metrics: The AMA PCPI measures for chronic stable coronary artery disease include laboratory assessment of LDL-C, HDL-C, triglycerides, and a fasting blood glucose. For patients with an acute coronary event, lipid measurement is recommended within 24 hours of hospitalization. The Joint Commission and CMS core measure sets for AMI do not explicitly focus on laboratory tests (with the exception of a CMS test measure for LDL measurement). Timely measurement of cardiac markers of acute injury such as troponin is implicit in performance measures.

Stroke

There are an estimated 700,000 cases of stroke each year in the United States. Of these 200,000 are recurrent strokes. More than 70,000 strokes are attributable to atrial fibrillation per year.[11, 12]

Evidence-Based Laboratory Testing: The AHA/ASA guideline for stroke prevention in patients with prior stroke or a transient ischemic attack recommends a goal of HbA1c <7 percent (Class IIa (B)) among diabetics and a cholesterol goal for patients with existing coronary heart disease of LDL <100mg/dl and <70 mg/dl for high-risk patients (Class I (A)).[12] For patients with stroke or a transient ischemic attack (TIA) who have persistent or intermittent atrial fibrillation, the guideline recommends anticoagulation with warfarin to achieve a target INR measurement between 2.0 and 3.0 (Class I (A)). For patients with an ischemic stroke or TIA caused by an AMI in whom left ventricular mural thrombus is identified by echocardiography or another form of cardiac imaging, oral anticoagulation should be considered to achieve an INR of 2.0 to 3.0 for at least three months and up to one year (Class IIa,(B)). Similarly, for patients with ischemic stroke or TIA who have rheumatic mitral valve disease, long-term warfarin therapy is reasonable, with a target INR range of 2.0 to 3.0 (Class IIa (C)). Other clinical subsets that require identification via laboratory tests such as antiphospholipid syndrome, inherited thrombophilia, hyperhomocysteinemia, and sickle cell disease are discussed in the guideline, and these tests may be ordered in appropriate clinical settings.[11,12]

Laboratory-Based Performance Metrics: The Joint Commission Standardized Stroke Measure Set includes laboratory assessment of lipids during the hospitalization. This measure set was developed as part of the Joint Commission Certification program for Primary Stroke Centers. At this time, the AMA PCPI is developing performance measures for stroke. None of these proposed measures specifies laboratory measurements.

Kidney Disease

In 2004, the incidence of end-stage renal disease (ESRD) was 104,000 new patients receiving treatment. The prevalent dialysis population reached 336,000 while the prevalent renal transplant population increased to more than 136,000. Both prevalent populations have more than doubled since 1988. The number of Medicare patients age 75 and older and with chronic kidney disease, a precursor to ESRD, more than doubled between 1997-1998 and 2003-2004, reaching nearly 1 million patients.[13]

Evidence-Based Laboratory Testing: Patients who are found to have persistent elevated creatinine or proteinuria should have the following laboratory measurements performed: urinalysis, complete blood count, serum electrolytes, blood urea nitrogen (BUN), serum creatinine, glucose, albumin, total protein, glomerular filtration rate (GFR), and cholesterol. Additional tests such as HIV may be required in selected populations. These and other tests including serum calcium, magnesium and phosphate may be required for monitoring response to treatment, which includes dialysis.[14]

Laboratory-Based Performance Metrics: The CMS PVRP measure set specifies hematocrit (or hemoglobin) target level as one of the metrics for ESRD. The AMA PCPI measures for ESRD do not specify laboratory measurements.

Hypertension

The National Health and Nutrition Examination Survey estimated that more than 50 million people in the United States have high blood pressure requiring treatment.[15] Hypertension is a risk factor for cardiovascular disease, including MI and stroke, and for both chronic and ESRD.

Evidence-Based Laboratory Testing: The JNC7 Guidelines for Hypertension recommend that the following laboratory tests are obtained prior to initiation of therapy: blood glucose, hematocrit, potassium, creatinine and estimated glomerular

filtration rate, calcium, LDL-C, HDL-C, triglycerides, and urinalysis. Tests for urinary albumin excretion or albumin/creatinine ratio are considered optional.[16]

Laboratory-Based Performance Metrics: Laboratory-related performance measures for hypertension are not specified in the AMA PCPI, the NQF National Voluntary Consensus Standards for Ambulatory Care, or the CMS PVRP measure sets.

Depression and Mental Illness

The prevalence of major depression ranges from 4.8 to 8.6 percent in primary care settings.[17]

Evidence-Based Laboratory Testing: The American Psychiatric Association practice guideline for psychiatric evaluation of adults suggests the following laboratory studies in appropriate patients as part of the initial evaluation: complete blood count, blood chemistry including glucose, electrolytes, calcium, and kidney and liver function tests, blood alcohol level, measurement of vitamin B12 level, Lyme serology, syphilis serology, thyroid function tests, and determination of erythrocyte sedimentation rate.[18]

Laboratory-Based Performance Metrics: Laboratory-related performance measures for depression are not specified in the AMA PCPI, the NQF National Voluntary Consensus Standards for Ambulatory Care, or the CMS PVRP measure sets.

Pneumonia

Although not included in the IOM Priority Areas, pneumonia accounts for more than 700,000 hospitalizations among Medicare patients and 5.6 million cases overall. More than 90 percent of deaths due to pneumonia occur among patients age 65 years and older.[19]

Evidence-Based Laboratory Testing: The 2003 update of the Infectious Diseases Society of America guideline for treatment of community acquired pneumonia in an immunocompetent host recommends the following laboratory tests for those hospitalized:[20] CBC, BUN, glucose, electrolytes, liver function, and oxygen saturation (strength of evidence B-II); screening for HIV is recommended in patients age 14-54 (B-II). Two pretreatment blood cultures are recommended (A-II), as well as Gram stain and culture of expectorated sputum (B-II). Testing of induced sputum is established only for *M. tuberculosis* and *P. carinii* (A-I). Infectious agent specific tests include: Legionella in the setting of enigmatic pneumonia (C-II) or pneumonia requiring intensive care (A-III); C. pneumoniae IgG or IgM (B-III); S. pneumoniae Gram stain and culture of sputum and blood culture (B-II), or pneumococcal urinary antigen assay (B-II). In a Clinical Position Statement developed by the American College of Physicians, guidance is provided for management of patients with community acquired pneumonia at home.[21] A complete blood count, chemistry panel, and blood culture are suggested in selected patients. All patients should have an assessment of oxygen saturation by pulse oximetry or an arterial blood gas. For patients that are not low risk based on history and physical exam, calculation of a risk score is suggested. If performed, the score requires measurement of pH, BUN, sodium, glucose, hematocrit, and pO2.

Laboratory-Based Performance Metrics: The Joint Commission and CMS measures require two laboratory tests – blood culture for bacteria and arterial blood gas (or pulse oximetry) to assess oxygenation. These measures also are endorsed by NQF. The AMA PCPI includes assessment of oxygenation in the measurement set. AQA does not include any laboratory measures in the starter set.

Cervical and Colon Cancer

Colorectal cancer is the third leading cause of cancer death among women and second among men. More than 150,000 new cases of colorectal cancer and approximately 55,000 deaths due to colorectal cancer were expected to occur in

2006. More than 9,710 new cases of cancer of the uterine cervix and 3,700 deaths related to it were expected to occur in 2006.[22]

Evidence-Based Laboratory Testing: The American Cancer Society recommends annual screening for colorectal cancer among men and women at age 50 with fecal occult blood test (FOBT) or fecal immunochemical test (FIT). Non-laboratory tests are acceptable alternatives to FOBT or FIT when performed regularly on a specified time basis. Screening for cervical cancer should be performed with a regular Pap test every year or with a liquid-based test every two years. Screening with HPV DNA testing and Pap test may be performed every three years as an alternative.[22] Screening and diagnostic tests for malignancy include cytology and surgical pathology where a sample of cellular materials or a tissue specimen must be interpreted correctly. Findings from a study conducted by the Association of Directors of Anatomic and Surgical Pathology[23] suggest a lack of uniformity and consistency in terminology and definitions used by the 41 laboratories surveyed. Variations in what is considered an error in documentation or reporting as well as mechanisms to track such errors were notable. Interobserver and interlaboratory reproducibility of cervical cytology interpretation was reported as suboptimal in separate studies.[24,25] A lack of consensus and guidelines in identifying what constitutes critical values in surgical pathology and cytology requiring urgent notification of clinicians is notable.[26] The potential for error in anatomic pathology and a need for systematic measurement and improvement is well recognized.[23,27,28,29]

Laboratory-Based Performance Metrics: Performance of Pap testing as a screening test for cervical cancer and fecal occult blood test for colon cancer is included in the AQA starter set. The AMA PCPI includes the FOBT test in the Preventive Care and Screening measure set.

Pregnancy and Childbirth

Evidence-Based Laboratory Testing: The American Pediatrics Association and the American College of Obstetrics and Gynecology recommend in the collaborative Guidelines for Perinatal Care that every pregnant patient should receive the following laboratory tests on the initial visit: Blood and Rh type with antibody screen, hematocrit or hemoglobin, Rubella immunity, syphilis serology (RPR), hepatitis B surface antigen, HIV, Chlamydia, and Pap test. Repeat testing for HIV is recommended in the third trimester for patients at high risk of acquiring HIV, those in high prevalence areas, and those that declined the test earlier. For selected patients at high risk for specific conditions, the following tests are recommended: N. gonorrhea, tuberculosis skin test, red cell indices (MCV) for thalassemia screen, hemoglobin electrophoresis for hemoglobinopathies such as sickle and thalassemia, hexosaminidase A for Tay Sachs disease, DNA analysis for Canavan disease, cystic fibrosis carrier state, serum phenylalanine level, toxoplasmosis screen, and hepatitis C antibody. Patients at high risk for sexually transmitted diseases should be retested in the third trimester.[30]

Laboratory-Based Performance Metrics: The AMA PCPI measure set for Prenatal Testing includes the performance of ABO and Rh typing and antibody tests, oral glucose tolerance test, HIV, urinalysis and culture, serum alpha-fetoprotein (women under 35 years of age only), and cervical cytology.

Asthma

In 2000, asthma accounted for 10.4 million outpatient visits, 1.8 million emergency department visits, 465,000 hospitalizations, and 4,487 deaths nationally. More than 5 percent of children reported having an asthma attack in the previous year.[31]

Evidence-Based Laboratory Testing: The Expert Panel Report: Guidelines for the Diagnosis and Treatment of Asthma does not specify laboratory tests that should be routinely used for diagnosis or monitoring of asthma.[32]

Laboratory-Based Performance Metrics: Diagnosis and monitoring of asthma is primarily by use of spirometry and pulmonary function tests. Routine laboratory measurement for asthma is not indicated in the absence of comorbid conditions.

Patient Safety

As a complex process with multiple handoffs during the testing process, laboratory measurement is susceptible to errors. The total testing process is depicted in figure 1. Estimates of distribution of errors show that most of the errors occur due to pre-analytical factors (46 to 68.2 percent of total errors), while a high error rate (18.5 to 47 percent of total errors) has also been found in the postanalytical phase.[33] The error rate within the analytic phase ranges from 13 to 32 percent.[34] Patient identification errors,[35] communication gaps,[36] and anatomic pathology discrepancies[37] have been reported.

The Joint Commission has recently released the 2007 National Patient Safety Goals Laboratory Version. The four primary goals are to 1) improve the accuracy of patient identification; 2) improve the effectiveness of communication among care providers; 3) reduce the risk of healthcare associated infections; and 4) encourage patient involvement in their own care as a patient safety strategy.

Activities of the College of American Pathologists

The College of American Pathologists (CAP) is a medical society serving nearly 16,000 physician members and the laboratory community throughout the world. The nearly 16,000 pathologist members of the College represent board-certified pathologists and pathologists in training worldwide. More than 6,000 laboratories are accredited by CAP, and approximately 23,000 laboratories are enrolled in the College's proficiency testing programs.[38] The College conducts periodic surveys

and benchmarking studies. Q-PROBES are short-term studies that provide a one-time comprehensive assessment of key processes in the laboratory. Topics for recent Q-PROBES include utilization of BNP test in the emergency departments, microscopic urine sedimentation rate examination, completeness of surgical pathology reports, and order accuracy of send-out laboratory tests. Q-TRACKS monitors reach beyond the testing phase to evaluate the quality of processes both within and beyond the laboratory that can impact test results and patient outcomes. The current assessments include:

- patient identification accuracy;
- blood culture contamination;
- laboratory specimen acceptability;
- in-date blood product wastage;
- gynecologic cytology outcomes: biopsy correlation performance;
- satisfaction with outpatient specimen collection;
- stat test turnaround time (TAT) outliers;
- morning rounds inpatient test availability;
- critical values reporting;
- TAT of troponin;
- corrected results; and
- outpatient order entry error rate.

Performance indicators for these studies are listed in table 2.

<u>The Institute for Quality in Laboratory Medicine</u>

The Quality Indicators Workgroup of the Institute for Quality in Laboratory Medicine (IQLM) proposed an initial set of 11 performance metrics for laboratory quality. The group categorized the indicators as system, pre-analytic, analytic, postanalytic, infrastructure, and system/general.

- System
    - Diabetes monitoring
    - Hyperlipidemia screening

- Pre-analytic Phase
    - Patient identification
    - Test order accuracy/appropriateness
    - Blood culture contamination
    - Adequacy of specimen information
- Analytic Phase
    - Accuracy of point of care testing
    - Cervical cytology/biopsy correlation
- Postanalytic Phase
    - Critical value reporting
- Infrastructure
    - TAT
    - Clinician satisfaction
- System/General
    - Clinician follow up

The Workgroup conducted preliminary evaluation of the indicators in terms of scientific importance, acceptability, feasibility, and usefulness. A comprehensive evaluation of quality of evidence, generalizability, and applicability was not conducted. The participants also identified important limitations including lack of strong evidence to link these performance indicators to health outcomes, and limited relevance of the indicators to national health priorities.[3]

Towards a Comprehensive, Multidisciplinary Measurement and Reporting Framework

There are clearly multiple stakeholders involved in development, measurement, and application of performance measures relevant to laboratory medicine. A crosswalk of professional association guidelines with national priorities is presented in table 3. At a more practical level, patients, providers, laboratory

professionals, IT specialists and other ancillary staff routinely deal with test specimens and test results. From the payers and policy perspective, appropriateness and efficient utilization of laboratory resources is an important consideration. A multidisciplinary framework grounded in national health priorities is required to systematically measure, report and improve laboratory-related quality. The framework should align with the six domains of quality care proposed by IOM: safe, effective, patient centered, efficient, equitable, and timely. In the recent IOM report, *Performance Measurement: Accelerating Improvement*, specific design principles are identified that are important to consider. These include 1) comprehensive measurement that advances all six aims identified in *Crossing the Quality Chasm*; 2) longitudinal measurement that spans care settings over time; 3) individual patient-level, population-based, and system-level measurement instead of a provider-specific or silos of care focus; and 4) shared accountability instead of focusing on one individual's actions.

The first step towards developing a measurement system is a conceptual framework that addresses the needs of multiple stakeholders and design considerations discussed above. Such a conceptual framework for laboratory performance measurement is presented in figure 2. The framework incorporates each of the design principles identified in the IOM report. Evidence-based laboratory tests are linked to priority health conditions, which in turn link to individual patients. Patients can be "rolled up" into populations, and populations into the system. Thus, instead of focusing simply on the provider or the laboratory, the conceptual framework allows measurement and reporting that is at the patient level, population based, and at system level. Because a test may be performed at a site different than the ordering provider (e.g., send-out tests), the laboratory is identified as the "analysis" site. Therefore, the framework allows laboratory as the fourth locus for performance measurement. It is important to monitor specific laboratory values over time (e.g., LDL-C), regardless of the laboratory or provider site. The well-established total testing process is utilized to outline the key dimensions of a test: order, specimen, analysis, reporting, and follow-up. There are two other design

principles that need to be elucidated. Comprehensiveness is shown in table 4 and the accompanying example, where the six aims of quality (safe, effective, patient centered, efficient, equitable, and timely) are applied to the *total testing process* (as well as to each key dimension). By highlighting the total testing process–which requires multidisciplinary input–the remaining principle of shared accountability is reinforced.

Part II. Gaps and Priorities for Further Research

The preceding sections comprehensively describe the current landscape of quality measures that focus on laboratory tests, and are anchored by the national health priorities. For each priority area, national guidelines are described, again in the context of laboratory testing. Recent and ongoing initiatives of the IQLM and CAP are succinctly presented. The two products of prior sections are a) a comprehensive crosswalk of national health priorities with established guidelines, and b) a conceptual framework for measurement and reporting of laboratory performance. These two tools are next utilized to identify gaps in measurement and priorities for further research.

Gaps in Measurement: A review of the crosswalk in table 3 shows that there are few if any measures available for children with special needs, frailty due to old age, mental illness, self management, care coordination, care at the end of life, and pain management. The second observation is that there are no measures to evaluate overuse or misuse of laboratory tests. Whether any laboratory tests that are appropriate for pain management and care at the end of life are available can be debated. A third observation can be made that of all the laboratory tests considered evidence-based (i.e., Class I or IIa), relatively few are part of existing performance measures. Fourth, systematic and standardized measurement of errors in anatomic pathology is needed. Finally, nearly all of the existing laboratory performance measures are based in effectiveness. The remaining five aims, safe, timely, efficient, equitable, and patient-centeredness, are not addressed.

Starter Set for Performance Measurement: CAP's Q-PROBES and Q-TRACKS represent a promising set of measures for internal process improvement within laboratories. Measurement of the service aspect of laboratory performance includes patient/provider satisfaction, turn around time, and critical value reporting. Accuracy of patient identification is a common goal across the continuum of care and has implications for patient safety as well as coordination of care. It is important to note that none of these CAP measures were designed for the purpose of accountability and public reporting. Although further testing to ascertain reliability of these measures is needed, the CAP studies have established face validity of the measures and feasibility of data collection. In addition, many of these measures are shown to be actionable.[39,40] These measures can thus be considered for inclusion in a starter set of laboratory performance measures. Well-specified and reliable measures of performance in anatomic pathology are not available and should be the focus of future development.

Priorities for Further Research: There are at least three aspects of laboratory performance where further research is urgently needed: a) patient safety; b) timeliness; and c) care coordination. Most of the current research and measurement has focused on one or the other isolated aspects of performance such as patient identification or turn around times. It is not apparent, for instance, how improving timeliness will affect error rates. Future research should produce practical insights to help ensure that the total testing process for clinical chemistry and anatomic pathology is highly reliable, efficient and free of error. The role of information technology and the science of informatics in improving multiple aspects of laboratory quality should be explored.[41]

Timeliness standards for urgent tests need to be established. A recent Q-PROBES study of TAT for biochemical markers of myocardial injury highlighted the mismatch between expectations of emergency physicians and those of laboratory personnel.[42] The TAT standards should take into account achievable performance

and needs of the patients and the clinicians. A multidisciplinary approach to establishing such standards is recommended.

Further research in the role of laboratory testing in medication safety should be considered a high priority. Commonly performed tests for drug levels (e.g., aminoglycoside, digoxin level) and monitoring of drug effectiveness (e.g., INR for monitoring warfarin effectiveness in anticoagulation) are reasonable targets. Methods to measure and improve errors in gynecologic cytology and surgical pathology need to be developed. Laboratory information systems are underutilized as repositories of clinically meaningful, readily available patient-specific data that can be used for both process and outcome measures. Methodologies to identify and disseminate best practices in laboratory performance management need to be developed.

Finally, a national measurement system for laboratory quality is viable only as part of a larger, overall national framework for healthcare quality. The proposed conceptual framework (figure 2), which is consistent with the four design principles outlined in the recent IOM report *Performance Measurement: Accelerating Improvement* can serve as a blueprint for a structured schema (e.g., XML) for storage and aggregation of performance data. The crosswalk (table 3) represents the condition-test pairings within the measurement framework. The "6-Aims X Total-Testing-Process" matrix (table 4) may be used as a guide to ensure that the testing process is error-free, responsive to patient acuity, based in evidence and standards, without misuse and overuse, free of disparities, and respectful of patient preferences. This, ultimately, is how laboratories and providers will have to demonstrate value to patients and to society.

Table 1A. Priority Areas – Healthcare Conditions

Healthcare Conditions
Diabetes
Ischemic heart disease
Heart failure
Acute myocardial infarction
Stroke
Hypertension
Kidney disease
Asthma
Cancer
Depression
Mental illness
Pregnancy, childbirth
Children with special healthcare needs
Frailty associated with old age
Tobacco dependence
Obesity

Source: NQF. *National Priorities for Healthcare Quality Measurement and Reporting: A Consensus Report*; 2004.

Table 1B. Priority Areas – Infrastructure and Processes of Care

Priority areas
Infrastructure:
Information technology
Patient safety
Processes of care:
Care coordination and communication
Care at the end of life
Immunizations
Pain management
Self-management

Source: NQF. *National Priorities for Healthcare Quality Measurement and Reporting: A Consensus Report*; 2004.

Table 2. The College of American Pathologists Q-TRACKS

Q-TRACK	Performance Indicators
Patient Identification Accuracy	• Wristband Error Rate (%) • Breakdown of Wristband Error Types (%)
Blood Culture Contamination	• Total Contamination Rate (%) • Neonatal Contamination Rate (%) • Other Contamination Rate (%)
Laboratory Specimen Acceptability	• Specimen Rejection Rate (%) • Breakdown of Rejection Reasons (%)
In-Date Blood Product Wastage	• Overall Wastage Rate (%) • Other Blood Components Wastage Rates (%) • Breakdown of Wastage Reasons (%)
Gynecologic Cytology Outcomes: Biopsy Correlation Performance	• Predictive Value of a Positive Cytology (%) • Sensitivity (%) • Screening/Interpretation Sensitivity (%) • Sampling Sensitivity (%) • Percent Positive for ASC-US Interpretations • Percent Positive for ASC-H Interpretations • Percent Positive for AGC Interpretations
Satisfaction With Outpatient Specimen Collection	• Patient Satisfaction Score • Percentage of Patients “More Than Satisfied”

Stat Test Turnaround Time Outliers	• Stat TAT Outlier Rate (%) • Breakdown of Outliers by Shift (%) • Breakdown of Outliers by Day of Week (%)
Morning Rounds Inpatient Test Availability	• Morning Rounds Reporting Compliance Rate (%)
Critical Values Reporting	• Total Critical Values Reporting Rate (%) • Inpatient Critical Values Reporting Rate (%) • Outpatient Critical Values Reporting Rate (%)
Turnaround Time (TAT) of Troponin	• Median TAT of troponin measured from the time troponin is ordered to the time the result is made available to ED personnel • Percentage of troponin results reported by each institution's established reporting deadline
Corrected Results	• Test Result Correction Rate (%)
Outpatient Order Entry Error Rate	• Outpatient Order Entry Error Rate (%) • Order Entry Error Rates by Category (%)

Source: www.cap.org. Last accessed August 2006.

Table 3. Crosswal of National Health Priorities with Guidelines and Other National Measures That Include Laboratory Tests

Priority Areas	CMS 8th SOW and PVRP / Joint Commission Core Measures	NQF	AQA	AMA PCPI	Guideline/Laboratory test(s)
Asthma	None	None	none	none	NHLBI: No laboratory tests specified
Cancer screening	None	Colorectal cancer screening *(Ambulatory Care)*; Cervical cancer screening *(Ambulatory Care)*	Colorectal - FOBT; Cervical - Pap	FOBT	ACP: Cervical - Pap; Colorectal - FOBT
Children with special needs	None	None	none	none	No specific laboratory tests
Diabetes	HbA1c, lipid (CMS PVRP)	Hemoglobin A1c Testing *(Ambulatory Care);* Hemoglobin A1c management *(Ambulatory Care);* Hemoglobin A1c Test for Pediatric Patients *(Ambulatory Care);* Urine protein screening *(Ambulatory Care);* Lipid Profile *(Ambulatory Care);* Lipid Profile Paired Measure: Lipid management : LDL-C < 130, Lipid Management: LDL-C < 100 *(Ambulatory Care)*	HbA1c; LDL	HbA1c, LDL-C, HDL-C, Tot-C, TG, urine microalbumin, creatinine clearance	ACP: LDL-C, HDL-C; ADA: HbA1c, LDL-C, HDL-C, triglycerides, liver function, serum creatinine, thyroid stimulating hormone (for type I diabetics), urine microalbumin, urinary ketones, protein and sediment.
Kidney disease	Hematocrit (CMS PVRP)	Post-operative Renal Failure *(Cardiac Surgery)*	none	none	Urinalysis, complete blood count, serum electrolytes, blood urea nitrogen (BUN), serum creatinine, glucose, albumin, total protein, glomerular filtration rate (GFR), and cholesterol. HIV, Ca, PO4, Mg (as needed)

Frailty due to older age	None	None	none	none	No specific laboratory tests
Heart failure	None	None	none	CBC, electrolytes, Ca, Mg, BUN, Cr, glucose, TSH, LFT, urinalysis	ACC/AHA: CBC, UA, serum chemistries, Ca, Mg, HbA1c, lipids, TSH, renal, hepatic profile, transferrin, BNP. Monitoring: Potassium, renal function, sodium, hematocrit, BNP (urgent care)
Hypertension	None	None	none	none	JNC7: blood glucose, hematocrit, potassium, creatinine, calcium, LDL-C, HDL-C, triglycerides, and urinalysis. Tests for urinary albumin excretion or albumin/creatinine ratio (optional)
Ischemic heart disease	None	IVD: Complete Lipid Profile and LDL Control <100 *(Ambulatory Care);* CAD: Percentage of members who have optimally managed modifiable risk *(Ambulatory Care)*	LDL-C, HDL-C, TG	LDL-C, HDL-C, TG, FBG	ACC/AHA: Secondary prevention -- LDL-C, non-HDL-C, TG, HbA1c, INR; ACC/AHA/SCAI (PCI cases): CKMB, Troponin I or T
Major depression	None	None	none	none	APA: complete blood count, blood chemistry including glucose, electrolytes, calcium, and kidney and liver function tests, vitamin B12 level, syphilis serology, thyroid function tests, erythrocyte sedimentation rate.
Mental illness	None	None	none	none	Condition-specific testing
Obesity	None	None	none	none	AHA/NHLBI (Metabolic syndrome): LDL and HDL cholesterol, triglycerides, and fasting blood glucose

Pneumonia	Blood culture; oxygenation	Oxygenation assessment *(Hospital Care)*; Blood cultures performed in the emergency department prior to initial antibiotic received in hospital *(Hospital Care)*	none	oxygenation	IDSA: CBC, BUN, glucose, electrolytes, liver function, and oxygen saturation, HIV, blood and sputum culture, Gram stain of sputum
Pregnancy and childbirth	None	Screening for Human Immunodeficiency Virus (HIV) *(Ambulatory Care)*; Blood Groups (ABO) and D (Rh) Type *(Ambulatory Care)*; Blood Group Antibody Testing *(Ambulatory Care)*	HIV	Urine protein, ABO & Rh type and antibody, cervical cytology, HIV, urine culture, urine leuk est, glucose test, serum AFP	ACOG: Blood and Rh type with antibody screen, hematocrit or hemoglobin, Rubella immunity, syphilis serology (RPR), hepatitis B surface antigen, HIV, Chlamydia, and Pap test.
Stroke	Lipid profile (Joint Commission Stroke)	None	none	(pending)	AHA/ASA (Secondary prevention): HbA1c, LDL-C, HDL-C, INR; homocysteine, APL antibody
Care coordination	None	None	none	none	
Self-management	None	None	none	none	

Patient safety	*Patient identification; communication among providers; hospital-acquired infections; patient involvement in own care*	Read back the complete order or test result for verbal or telephone orders or for telephonic reporting of critical test results *(Safe Practices)*; Implement a standardized protocol to prevent the mislabeling of radiographs, laboratory specimens, or other diagnostic studies *(Safe Practices);* Ensure that care information is transmitted in a timely and clearly understandable form to all of the patient's healthcare providers *(Safe Practices)*; Monitor every patient on long-term oral anticoagulants *(Safe Practices)*; Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products (Serious Reportable Events); Patient death or serious disability associated with hypoglycemia (Serious Reportable Events);Death or serious disability associated with failure to identify and treat hyperbilirubinemia in neonates (Serious Reportable Events)	*none*	*none*	*Joint Commission: 1) improve the accuracy of patient identification; 2) improve the effectiveness of communication among care providers; 3) Reduce the risk of healthcare associated infections; and 4) encourage patient involvement in their own care as a patient safety strategy.*
Information technology	n/a	Implement a computerized prescriber order entry (CPOE) system *(Safe Practices)*	n/a	n/a	

Care at the end of life	None	none	none	none	No specific laboratory tests identified
Pain management	n/a	none	n/a	n/a	No specific laboratory tests identified
HF: Screening for hemochromatosis, HIV, rheumatologic disorders, amyloidosis, pheochromocytoma may be appropriate in selected patients (Class IIa, Level of Evidence C)					
Stroke: Other clinical subsets that require identification via laboratory tests such as antiphospholipid syndrome, inherited thrombophilia, hyperhomocysteinemia, and sickle cell disease are discussed in the guideline, and these tests may be ordered in appropriate clinical settings.					

Table 4. Comprehensive Measurement to Foster Improvement in All Six Aims of Healthcare (IOM Design Principle 1). Emphasis on the total testing process is conducive to the concept of shared accountability (IOM Design Principle 7). ***Examples are for illustration purpose only.***

	Safe	**Timely**	**Effective**	**Efficient**	**Equitable**	**Patient-centered**
Test order	Legible; complete	Acuity of condition	Evidence-based; underuse	Overuse, misuse	No bias	Patient preferences; end of life
Specimen acquisition	Identification; contamination; adequacy	STAT	Scientific e.g., timing of drug-level	Waste, re-draws	Special needs, culture	Access, comfort, satisfaction
Analysis	Process control	TAT	Standards based	Re-work		
Reporting	Interpretation	Critical values	Standards based	Corrected results	Language; literacy	Interpretable
Follow up	Appropriate	Delays	Evidence based	Waste	No bias	Patient preferences
TOTAL TEST PROCESS	Error free	Responsive to acuity	Evidence and standards based	No misuse or underuse of resources	Free of disparities	Respect for patient preferences

Example: Patient with an Acute Condition and a Chronic Disease

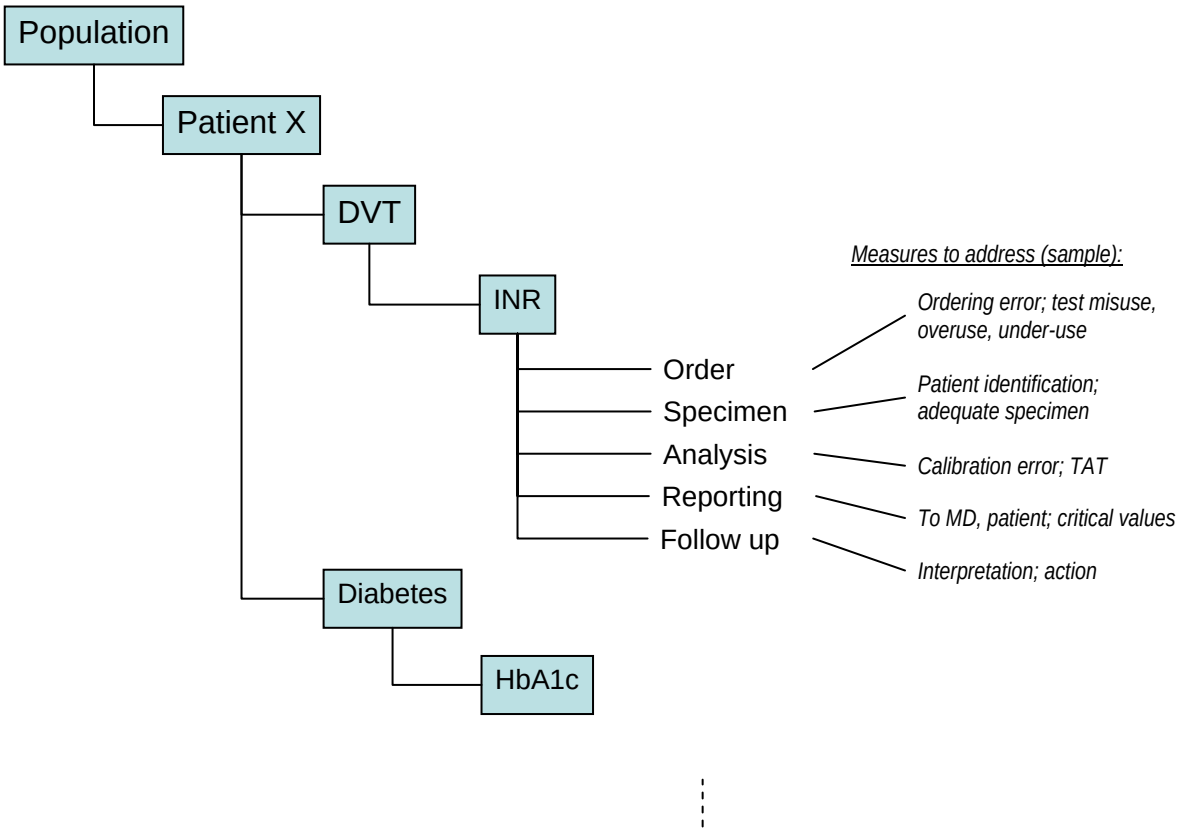
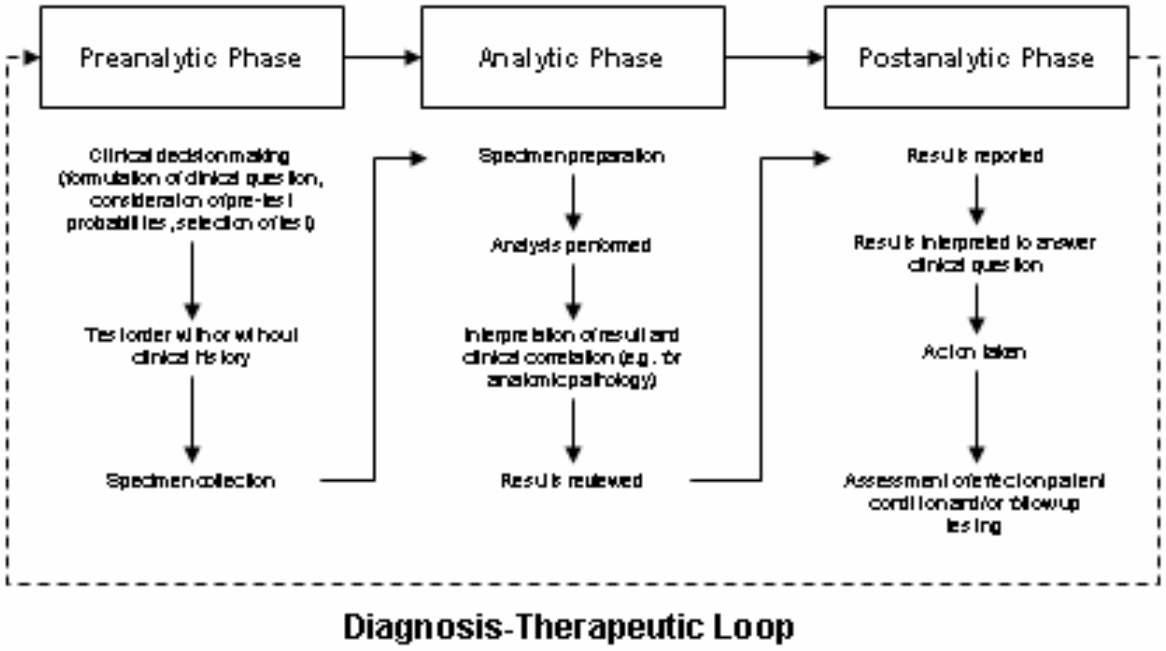
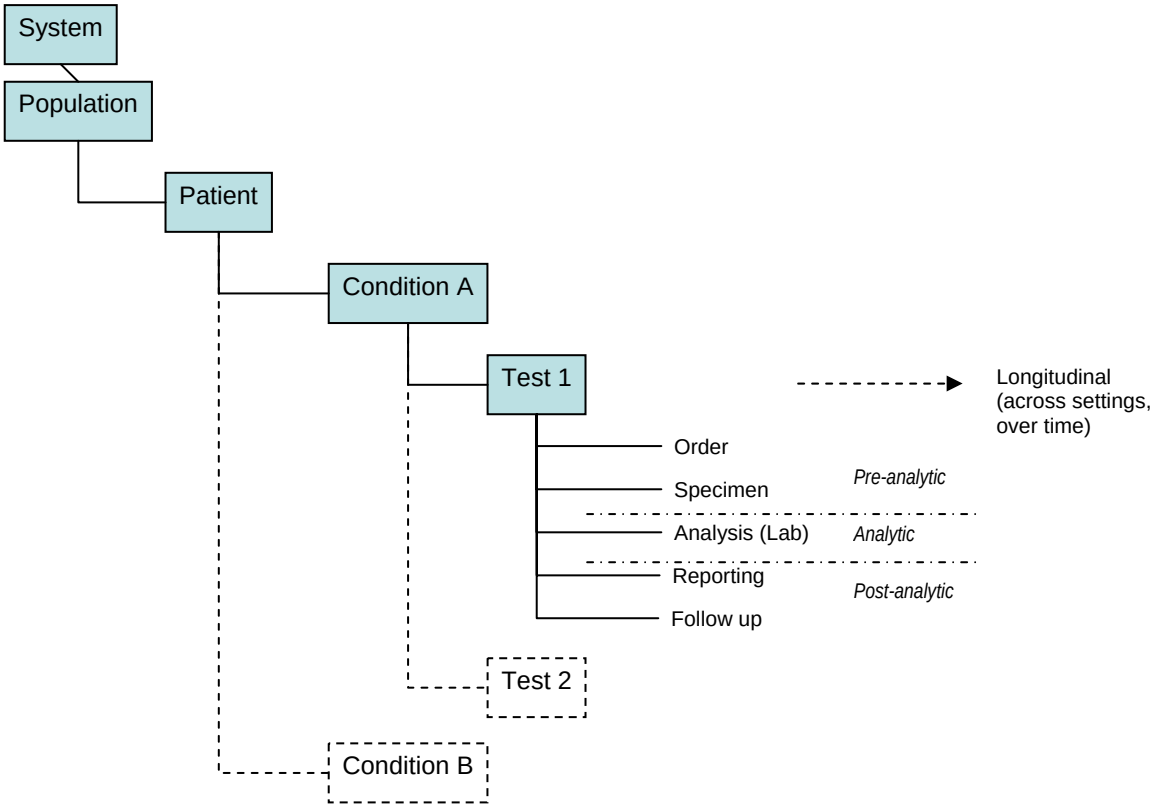


Figure 1. Total Testing Process in the context of clinical decision making and treatment (modified from Barr 1994).



Reference: Barr JT, Silver S. The total testing process and its implications for laboratory administration and education. Clin Lab Manage Rev 1994;8:526–42.

Figure 2. Conceptual Framework for Laboratory Medicine Performance Measurement. All four design principles proposed in the IOM report *Performance Measurement: Accelerating Improvement* are addressed. Specific laboratories may be identified by analysis site.



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