Managed care organizations are shifting from traditional utilization management programs to focus on initiatives that improve the health of an insured population. This strategy requires sophisticated data integration to identify at-risk individuals and track outcomes. Laboratory data are becoming increasingly valuable tools for managed care organizations and healthcare providers. The HEDIS Effectiveness of Care measures have incorporated laboratory data into several key performance indicators. By building a comprehensive repository of laboratory data that includes both procedure codes and laboratory values, managed care organizations can realize substantial savings by avoiding the costly medical record reviews required when administrative data are incomplete. In addition to tracking clinical outcomes, laboratory data provide the ability to risk-stratify a population to target high-risk individuals for case management and disease management interventions. Healthcare organizations face several challenges in the integration of laboratory data into medical databases and practice management software. Confidentiality is a key consideration in view of recent healthcare regulations. Providers of laboratory services should work collaboratively with organizations setting standards for healthcare informatics to facilitate the pooling of data for quality improvement and outcomes research.

Population health improvement, which encompasses disease management, complex case management, and clinical quality improvement, follows the same format as continuous quality improvement as illustrated in Fig. 1. Laboratory data can play a key role in each of these steps, including the identification of the target population, risk stratification, implementation of targeted interventions, and tracking clinical outcomes. Laboratory data are valuable because they are objective and clearly documented. Because many clinical practice guidelines set well-defined standards using laboratory values, the results are ideally suited to tie clinical interventions to evidence-based guidelines.

Over the past decade, there has been substantial progress toward defining objective methods to measure the importance of sophisticated data integration to identify target populations and track clinical outcomes. Laboratory data are becoming increasingly valuable for healthcare organizations seeking to promote population health improvement.

Traditional utilization management methods have focused on the authorization of healthcare services deemed medically appropriate. These interventions have contributed to public resentment toward managed care and strained relationships between MCOs and contracted providers. Both MCOs and their customers have questioned the value of traditional utilization management activities in the setting of today’s healthcare industry. Health plans have also been under increasing pressure from both customers and regulators to demonstrate the quality and value of the healthcare services being purchased. Improving clinical outcomes can translate into cost savings through avoided hospital admissions, fewer adverse events, and a reduction in morbidity related to chronic illnesses.

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Over the past decade, there has been substantial progress toward defining objective methods to measure
the quality of healthcare (1). In the managed care industry, several data sources are used to measure healthcare outcomes. The most frequently used sources include administrative records (e.g., claims data), medical records, and patient or provider surveys (2). Administrative data, which have traditionally been limited to claims and encounters, offer the advantage of being readily available and inexpensive to collect. Despite the limitations of these data, they been valuable tools in population health improvement.

Data from outpatient laboratory services have the potential to transform population health improvement and outcomes research. Laboratory claims data reflect process-oriented outcomes related to appropriate laboratory services. Administrative data that include the results of diagnostic laboratory tests can provide outcomes that are comparable to those gleaned from abstracting medical records at a fraction of the cost.

The value of outpatient laboratory data has been substantially enhanced by the Health Plan Employer Data and Information Set (HEDIS®). HEDIS is a set of standardized performance measures designed to give healthcare purchasers and consumers outcomes data to compare managed healthcare plans (3). HEDIS is routinely used by large employer groups and consultants to select and evaluate health plans. The Health Care Financing Administration requires Medicare health maintenance organizations to report selected HEDIS measures, and several states require HEDIS reporting for commercial health maintenance organizations and Medicaid health maintenance organizations. As the HEDIS standards continue to evolve, laboratory data are playing an increasingly critical role in the measurement of clinical outcomes. Most of the HEDIS Effectiveness of Care measures relate to ambulatory care services. The administrative data for health plans that reimburse providers on a capitated or prepaid basis are often incomplete with respect to outpatient care. Laboratory data represent a cost-effective method for health plans to supplement existing administrative data.

Current HEDIS measures that require administrative claims data from laboratory services include Cervical Cancer Screening, Chlamydia Screening in Women, and Prenatal Care in the First Trimester (4). In the latter measure, documentation of a prenatal laboratory panel is counted as evidence of the initiation of prenatal care. This is a key factor because billing practices for global obstetric professional services do not readily identify the date of the first prenatal visit.

Two HEDIS measures introduced within the past few years reflect specific outcomes related to clinical laboratory results. Cholesterol Management After Acute Cardiovascular Events reflects results of LDL-cholesterol (LDL-C) testing 60–365 days after discharge for an acute myocardial infarction, coronary artery bypass graft, or percutaneous transluminal coronary angioplasty (4). The Comprehensive Diabetes Care measures evolved from the accountability measures proposed by the Diabetes Quality Improvement Project (5). These indicators include both hemoglobin A1c (HbA1c) testing and results, the latter reflecting the portion of the diabetic population with poor control. Other diabetes care measures relying on laboratory data include LDL-C screening, LDL-C results, and screening for microalbuminuria.

The costs of data collection for HEDIS reporting are becoming an increasing burden for MCOs. The availability of a database with diagnostic laboratory test results has significant implications regarding the costs of data collection for HEDIS. Most health plans use a hybrid method of sampling for the HEDIS Effectiveness of Care measures. After a random sample of the subpopulation is identified using the HEDIS data specifications, medical record review is required to document the results of laboratory-related quality measures when the data are not available in an electronic format. Such data collection is costly because it is typically spread over a geographic area and the reviews are generally performed by a healthcare professional. A database that includes electronic laboratory results can potentially save a large managed care plan millions of dollars by reducing the volume of medical record reviews.

Because health plans and practitioners are held increasingly accountable for healthcare outcomes through the reporting of performance measures such as HEDIS, there is growing interest in the design and implementation of clinical quality improvement programs and disease management interventions. There are several types of targeted interventions that have demonstrated a favorable impact on clinical outcomes. These include reminder systems to prompt practitioners and patients to complete routine periodic diagnostic testing or screening, tracking systems to reflect when key recommended services are due, and practitioner-specific feedback regarding outcomes (6, 7). Laboratory data, including both claims data and laboratory results, are well suited for each of these categories of interventions.

In any insured population, the majority of healthcare resources are used by a small percentage of the covered
individuals, most of whom have chronic illnesses. Typically, chronic disease accounts for ~80% of hospital days and ~70% of hospital admissions (8). Claims data, even with their limitations, can be used by health plans to identify some high-risk individuals who may be appropriate candidates for case management or disease management programs. Such programs generally work collaboratively with treating physicians to engage the patient and caregiver(s) to actively participate in the treatment plan.

Disease management and care management programs typically implement a variety of interventions tailored to the needs of specific groups of affected individuals. To ensure the financial viability of these programs, costly interventions need to be directed to the frailest individuals. A valid risk-stratification model can identify those individuals who have a high risk of complications and thus have the greatest potential to impact outcomes and lower healthcare costs. For asthma, risk stratification can be accomplished using claims data reflecting emergency room and hospital utilization and pharmacy utilization patterns (9). For most other disease processes, however, claims data alone do not provide effective risk stratification. Health risk appraisals can augment administrative data to help identify high-risk individuals. However, these are expensive and cumbersome to administer to an entire population. The integration of laboratory data into claims data offers a more efficient alternative. It also creates a database suitable for data mining to identify patterns of resource utilization and laboratory results that predict unfavorable outcomes. These high-risk individuals may respond to proactive intervention using a care management approach.

Risk stratification of a diabetic population represents a major challenge. The increasing incidence of diabetes and the demonstrated ability to reduce morbidity through aggressive diabetes management increase the importance of a validated risk-stratification model using laboratory data. Diabetic control can be quantified through HbA1c results, and end-organ disease can be identified through proteinuria or increased serum creatinine concentrations. A database including these key laboratory results offers a powerful risk-stratification tool for diabetes management. Individuals with poorly controlled blood sugars can be targeted for intense diabetes education. In the presence of diabetic nephropathy, programs can promote the initiation of angiotensin-converting enzyme inhibitor therapy. Timely referral to a nephrologist can prevent or delay end-stage renal disease (ESRD).

Risk stratification in hypertension is also a challenge, particularly in view of the high incidence among the elderly. Epidemiologic studies of hypertension have indicated that the condition usually occurs in conjunction with a separate metabolically defined risk factor, with <20% occurring in isolation (10). Several of these risk factors can be quantified with laboratory data. Dyslipidemia, glucose intolerance, and renal insufficiency are key comorbid conditions that can be well defined with laboratory data to identify high-risk individuals.

Laboratory data provide a powerful adjuvant to risk stratification in coronary artery disease. Patients with coronary artery disease who have increased LDL-C concentrations can be targeted for improved lipid management, which can slow or reverse the progression of their heart disease. Cardiac patients with diabetes can be identified if glycemic control is poor or unknown. Electronic laboratory results may represent a cost-effective method for health plans to address primary prevention of coronary artery disease. Individuals with increased LDL-C concentrations can be targeted for risk factor modification, including lipid management, smoking cessation, and weight control.

Laboratory data are an integral part of the quality improvement measurements in chronic renal disease and ESRD. The National Kidney Foundation has developed a set of quality standards as a component of its Dialysis Outcomes Quality Initiative (11). Nutritional status is reflected by several laboratory measures, including albumin and prealbumin concentrations, creatinine index, and serum cholesterol. Blood urea nitrogen sampling occurs pre- and postdialysis, and serum bicarbonate concentrations are routinely monitored on a monthly basis. The evaluation and monitoring of anemia requires both hematocrit concentration and iron studies. Hematocrit concentrations also guide the appropriate administration of epoetin therapy, a key driver of pharmacy costs in ESRD.

A database with electronic laboratory results also provides a cost-effective method to define a pre-ESRD population. This high-risk group is not readily identified with claims data. A systematic method to identify individuals with pre-ESRD provides the opportunity to delay the onset of dialysis through aggressive diet management, blood pressure control, and angiotensin-converting enzyme inhibitor therapy, when appropriate. Early identification also facilitates timely vascular access in anticipation of dialysis. Failed vascular access is a major cause of morbidity in ESRD patients, representing one of the most common reasons for hospital admission (12, 13). One of the goals of the National Kidney Foundation’s Diabetes Quality Improvement Project program is to promote the placement of native arteriovenous fistulae, which are associated with fewer complications than polytetrafluoroethylene grafts (14). With the use of serum creatinine results, a disease management initiative can facilitate early specialty referral for pre-ESRD patients to promote optimal vascular access, improving clinical outcomes and quality of life.

It is widely believed that the use of electronic medical records has the potential to improve efficiencies and reduce medical errors. Decision support models can be incorporated into such databases to promote evidence-based medical therapies and recommended diagnostic testing. The integration of comprehensive laboratory data into a practice management system has enormous poten-
tial to improve care. Automated reminders can prompt recommended laboratory services related to routine health screenings or disease-management protocols. Such systems can also ensure appropriate follow-up of abnormal laboratory test results. In the context of electronic prescribing, medical errors can be prevented by identifying relative and absolute contraindications. Alerts can be triggered if the selection or dosing of a medication is affected by a disease process identified through a diagnosis code or abnormal test result. Practitioners with such systems also have the ability to track their aggregate outcomes such as diabetes management (HbA1c), lipid management (LDL-C), and chronic anticoagulation (prothrombin time/international normalized ratio).

The integration of laboratory data into claims data also provides an enhanced method to profile practitioners. Physicians can be given useful feedback regarding their adherence to practice guidelines in comparison to peers in the same specialty. With the Internet creating informed consumers who will likely take a more active role in their healthcare decisions, some health plans are already releasing practice-specific quality measures to help members in the selection of a primary care provider.

The exchange of laboratory results in an electronic format and the pooling of such data from multiple sources favor the adoption of a standardized language and format. For the communication of laboratory tests and results, the Logical Observation Identifier Names and Codes (LOINC®) appears to be the best suited framework to meet this need. LOINC offers a set of universal identification codes and nomenclature to identify laboratory procedures and test results (15). Because LOINC does not convey all the necessary information regarding an individual laboratory service, it is intended to be used in the context of a message format such as Health Level Seven, Inc. (HL7), the American Society for Testing and Materials (ASTM), CEN TC251, or DICOM.

Regenstrief LOINC Mapping Assistant (RELMA) is the name of the program that maps existing internal laboratory test codes and observation names to LOINC codes and nomenclature. For inpatient laboratory data, there can be significant variation in how individual hospitals code laboratory tests into LOINC (16). Although some discrepancy in coding can be expected with outpatient reference laboratory vendors, matching common laboratory tests should be less problematic. LOINC is already in use by several large reference laboratories, and there is increasing support for universal adoption. Both LOINC and RELMA can be downloaded from the Internet and are not associated with licensing fees (15).

Systematized Nomenclature of Medicine (SNOMED) is a broader and more detailed system of medical terminology developed by the American College of Pathologists. It is both multiaxial and hierarchical. One chapter is dedicated to laboratory procedures. LOINC and SNOMED are supporting a collaboration that will integrate the strengths of both systems, preventing overlap (17).

Confidentiality is a major consideration in the use of laboratory data. MCOs wishing to use laboratory data with test results must ensure that member consent regarding access to medical records does not limit the health plan to information necessary to pay claims. Under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the impending regulations related to protecting the privacy of patients' health information do recognize quality improvement and population-based activities such as disease management and care management as legitimate components of healthcare operations (18). Thus the exchange of data for these purposes should be covered under the appropriate patient consent as long as proper security measures are followed.

For data that include electronic laboratory results, CLIA and state laws must also be taken into consideration. Unless otherwise defined by state law, CLIA (42 USC 263a) specifies that diagnostic test results must be released only to “authorized persons or the individual responsible for utilizing the test results” (19). Confidentiality is further complicated if test results relate to conditions such as HIV infection or mental illness, which have unique protection from disclosure. Consultation with legal counsel is advised if data containing diagnostic test results are used for health improvement purposes in a setting other than the physician's practice.

Another potential barrier affecting the use of electronic laboratory results is the lack of standardization for some laboratory services. In today's environment, most healthcare entities that have access to comprehensive laboratory data are likely to have an exclusive arrangement with a contracted laboratory vendor. This lessens concerns regarding variability as well as potential discrepancies in the translation of internal test codes to LOINC nomenclature. For the purposes of population health improvement, HbA1c is the most relevant indicator. Even when data are combined from more than one source, the expected variances across vendors should not preclude meaningful risk stratification. When other factors are equal, the highest risk individuals will have markedly increased HbA1c values. If improvement in the measure is tracked over time, the change in values can be analyzed on an individual basis because most patients will be matched to a specific laboratory vendor.

Laboratory data have become a powerful tool to improve clinical outcomes in the healthcare industry. Laboratory vendors that recognize this and format data for such use may have a competitive advantage. The growing interest in using laboratory data for health improvement has the potential to prompt MCOs to pursue exclusivity agreements or closer working relationships with a limited number of vendors for outpatient laboratory services. The implementation of HIPAA regulations for electronic data transmission will help promote standardization within the industry. However, the exchange and integration of laboratory data with test results requires collaboration far beyond specifications for HIPAA. Leaders in the labora-
tory services industry, perhaps in cooperation with an academic medical center, should consider the promotion of a standardized format for the use of laboratory data in population health improvement and outcomes research.

References