Utilization Management in the Clinical Laboratory: An Introduction and Overview

2

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Introduction and Discussion

Health-care systems in developed nations are facing continuing pressure to improve quality and efficiency and to reduce costs. This is particularly true in the USA where health-care expenditures comprise a larger percentage of gross domestic products than any other country. For example, in 2010, the total annual health-care expenditure in the USA was $2.6 trillion dollars or more than ten times the amount spent in 1980 [1]. Advances in medical technologies and therapeutics, combined with an aging population, virtually assures that this trend will continue unless there are major changes to the health-care system. Recent legislation including the Affordable Care Act (Obamacare) will have a major impact on reimbursement for medical care. The formation of accountable care organizations (ACO's) and similar risk-sharing approaches such as the Massachusetts Blue Cross Blue Shield Alternative Quality Contract will progressively eliminate the traditional fee-for-service system of reimbursement in favor of global payments for entire episodes of care and even global payments for entire populations of patients. In addition, quality measures and other metrics are being introduced as part of pay-for-performance systems wherein physicians and hospitals have a portion of their payment withheld pending acceptable achievement of performance goals (e.g., proper management of diabetes care, reducing readmissions, reducing hospital-acquired infections). These so-called "value-based" payment systems will hold providers accountable for both quality and cost [1]. Collectively these developments will only increase pressure on providers to improve outcomes while reducing cost.

Utilization management has been a traditional approach to control costs in health-care systems. This is particularly true for ancillary services such as the clinical laboratory, pharmacy, and radiology. These services are often targeted because they are generally perceived to be significantly over-utilized (or miss-utilized) and because they are usually readily quantifiable. Volume and unit cost data can be easily obtained to estimate the aggregate savings resulting from individual utilization management initiatives. Overutilization of laboratory services has been documented for several decades. For example, in one study from 1982, the authors undertook chart reviews by pathologists and primary care physicians on medical service inpatients. The pathologists identified 26.5 % of tests as being unnecessary and the primary care physicians 42.8 %. The ten most frequently ordered tests showed the worst rate of overutilization [2]. This finding has been consistently confirmed in the literature especially for high-volume automated tests. A number of articles and reviews have appeared in the literature over the years highlighting the need for utilization management in the clinical laboratory and outlining strategies for successful implementation (see [2–11] and supplemental references).

The clinical laboratory usually accounts for approximately 4 % of the typical hospital budget. Therefore, at first glance, it would not appear that much money could be saved by reducing expenditures for laboratory services. However, the operating budgets of most hospital laboratories are still substantial. For example, in our hospital the total operating budget for pathology services is roughly $ 94 million dollars per year divided among the clinical laboratories (50 %), blood transfusion (29 %), and anatomic pathology (21 %). Another important aspect concerning laboratory services is that test results have a major impact on the downstream costs of medical care. It has been estimated that over 70 % of clinical decisions

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(and their attendant costs) are based on the results of laboratory testing [3]. To the extent that a significant percentage of laboratory tests may be unnecessary, the impact of these tests on the overall cost of care is substantial. Furthermore most laboratories define the reference range for common tests as the mean plus or minus 2 standard deviations of the normal population. Therefore 5 % of tests will be abnormal (either low or high) by statistical chance alone. For a laboratory performing five million tests per year, this translates into 250,000 falsely abnormal test results. A significant percentage of these will require time on the part of the physician to assess whether the abnormality is significant and may result in unnecessary follow-up testing and specialist consultations. To the extent that 20–50 % of these tests were unnecessary to begin with, significant downstream costs may be incurred from tests that never should have been ordered in the first place.

Utilization management has other benefits beyond reducing costs in the laboratory. Eliminating unnecessary tests frees up technologists' time allowing these resources to be reassigned to more important duties such as performing STAT testing thus reducing turnaround time for tests on critically ill patients. In addition, the time spent by phlebotomists or nursing assistants collecting blood specimens is also reduced. Finally repetitive blood drawing on hospitalized patients has been associated with hospital-acquired anemia (HAA). For example, Salisbury et al. reported an outcome study in patients with acute myocardial infarction and HAA. They found that patients with HAA had higher mortality rates (hazard ratio 1.82) and a worse health status 1 year after hospitalization [4]. Other studies on HAA have reached similar conclusions.

Utilization management usually implies reducing unnecessary testing as shown in Table 2.1. However, there are tests that have traditionally been underutilized such as cholesterol screening, testing for diabetic management, and human immunodeficiency virus screening. Also there are tests where the appropriate level of utilization is unclear or controversial. A case example is screening for prostate cancer using prostate-specific antigen (PSA). In 2012 the US Preventive Services Task Force recommended against routine screening using PSA and concluded that there is moderate certainty that the benefits of screening do not outweigh the harms (morbidity arising from biopsies and subsequent treatment of low-grade tumors) [5]. In contrast the American Urological Association (AUA) has taken a different perspective. The AUA has recommended against PSA screening in men under 40 years of age, and it does not recommend screening in men between 40 and 54 years of age. However, for men between 55 and 69 years of age, the AUA recommends "shared decision-making for men aged 55–69 years that are considering PSA screening and proceeding based on a man's values and preferences."

Table 2.1 Overutilization versus underutilization: some examples

Overutilization	Routine chemistry panels
	Complete blood counts
	Blood components
	Some esoteric tests
Underutilization	Screening for cervical HPV infection
	Cholesterol screening
	Testing for diabetes and dyslipidemia management
	HIV screening
Controversial utilization	Prostate-specific antigen testing
	High sensitivity C-reactive protein
	Lipoprotein $_{a}$ (Lp(a))

HPV human papilloma virus, *HIV* human immunodeficiency virus

A final goal of utilization management should be to ensure that patients receive the right tests that are needed without necessarily reducing testing costs. For example, we recently banned serologic testing for Babesiosis which is neither optimally sensitive nor specific for diagnosis of this infection. In its place we substituted the thick and thin blood smear as the preferred test.

When deciding how to approach utilization management, it is important to consider the incentives that may be influencing physicians, the hospital, and the laboratory. From the perspective of the laboratory, the incentives may be very different depending on whether the testing is performed on outpatients or inpatients. In the United States, inpatient testing is typically reimbursed using a global payment based on the diagnostic-related group (DRG). The hospital gets a single payment for the entire admission regardless of how many (or few) tests are ordered. There is a strong incentive to reduce inpatient testing as excess tests incur additional costs without generating any revenue. On the other hand, outpatient testing is, for the moment, reimbursed directly. The more tests that are performed, the more revenue is generated. This is one reason many hospitals have set up outreach programs to bring more billable tests into the laboratory. There is little incentive to aggressively target outpatient test utilization. This of course will change dramatically if outpatient testing reimbursement is reconfigured into a single global payment for the entire episode of outpatient care. Likewise physicians may have different incentives depending on the specific situation. For example, some physician practices have set up physician's office laboratories (POLs) where they can bill directly for the tests originating from the practice. There is no incentive to reduce this source of profitable revenue for the practice. Independent practitioners who send their patients to a hospital or commercial laboratory for phlebotomy and testing also have little incentive to control utilization. The practice gets paid for the office visit and is not held accountable for the costs of the testing that they have ordered. With global payment systems, this incentive structure will change dramatically. Physicians who are subject to capitated reimbursement or those in accountable care organizations will have a strong incentive to reduce unnecessary testing as the practice is at financial risk if the cost of care is excessive.

A recurring theme in laboratory utilization management is determining, from an evidence-based perspective, what constitutes overutilization. In many cases there is no consensus on what testing is, or is not, appropriate. Although clinical guidelines exist for some types of testing, often there is no peer-reviewed literature defining appropriate test utilization. For example, how often should a typical patient hospitalized with community-acquired pneumonia have a complete blood count test? Walraven performed a systematic literature review of studies that provided and applied criteria for inappropriate utilization. They concluded that many studies used implicit or explicit criteria that did not meet acceptable methodological standards and that alternative evidence-based standards should be developed for measuring appropriateness [6]. In a follow-on study by Hauser, the authors commented that in the past, many studies used subjective or locally defined definitions of appropriate. However, literature consensus of what is appropriate has improved, and advances in database technologies, as opposed to chart reviews, have facilitated utilization audits [7]. In our experience, determining what is inappropriate utilization is often impossible or, when there is data, it is often inconclusive. In most cases we rely on local clinical experts to provide guidance or meet with clinicians to try to reach a consensus. Invariably this process is based more on intuition and experience rather than true evidence, but we have nonetheless had a number of successes.

A key concept in utilization management concerns who will take overall leadership for the program. Ideally physicians are in the best position to assume leadership as they have the medical knowledge to make judgments about what is in the best interests of patient care. Lacking physician leadership other parties are likely to fill the void such as administrators and third-party payers. Indeed, in some specialties, this is already becoming the case. Recently a number of insurance companies have begun requiring prior authorization before patients can receive expensive genetic and molecular pathology tests. These requirements usually involve multiple administrative barriers that can place a significant burden on the time of the clinician and the patient. An article by Grumet published as far back as 1989 highlighted the onerous strategy often employed by third-party payers with the quote "But another feature has crept into the managed care formula that has been largely overlooked: that of slowing and controlling the use of services and payment for services by impeding, inconveniencing and confusing providers and consumers alike" [8]. In the article he described, eight of these approaches including:

1. Procedural complexity: Requirements for multiple forms and procedure codes
2. Exotic terms: The use of unique or exotic procedures, codes, and terms (e.g., corridor deductibles)
3. Slowdowns: Slowing authorization for procedures and claims
4. Shifting of procedures: Frequent changes to codes, forms, and policies
5. Fail-safe payment systems: Protocols designed to inhibit approving claims where any negative condition will stop fulfilling the claim
6. Overlapping coverage: Systems designed to shift coverage to other payers
7. Fragmentation of transactions: Systems requiring the provider to interact with multiple offices within the insurance carrier
8. Uncertainty of coverage: Ambiguity about whether certain services will be covered

With regard to laboratory utilization management, we believe pathologists and laboratory directors are the most logical individuals to take a leadership role. While many clinicians are interested in improving utilization, they are often consumed with their clinical duties and are not compensated for this activity. However, as described by Zhao et al. [9], there have been historical reasons why pathologists have not been leaders in utilization management. Included among these are:

1. Pathologist contributions not clearly defined
2. Pathologist contributions not compensated (particularly a problem in community hospitals)
3. Lack of recognition of pathologists' role among hospital administrators, managed care, and pathologists themselves

National pathologist professional organizations have recognized these issues and have been encouraging pathologists to redefine their roles in the health-care delivery system. Among these new roles is utilization management. As shown in Table 2.2, pathologists have a number of assets to bring to the table. While it is true that pathologists will not have as good an understanding as medical specialists of the clinical applications of many laboratory tests, this fund of knowledge can be developed over time. Furthermore knowing the intricacies of every test on the menu is not necessary to be a leader of the utilization management program so long as the pathologist has access to clinical advisors in the different medical specialties. Many pathologists have experience directing complex organizations (laboratories) and often serve on hospital and medical staff committees. A number have developed roles as physician executives. In the case of clinical pathologists, most are salaried physicians who are accountable to their hospital and physician's organization. Utilization management is part of their expected professional duties. Finally pathologists understand the cost and reimbursement structure for laboratory tests and have access to test volumes, trends, and ordering patterns through the

Table 2.2 Why pathologists and laboratory directors should take a leadership role in utilization management

Executive leadership experience
• Experience directing organizations (laboratories)
• Frequently serve in role as physician executives
• Frequently serve on hospital and physicians organization committees
Identified professional responsibilities
• Professional duties include utilization management, budgeting, and cost containment
• Accountable to the hospital and health-care system
Knowledge and experience
• Understands the use and limitations of laboratory testing
• Understands laboratory operations
• Understands cost and reimbursement structure for laboratory testing
• Access to laboratory test volumes, trends, and ordering patterns
• Understanding of informatics

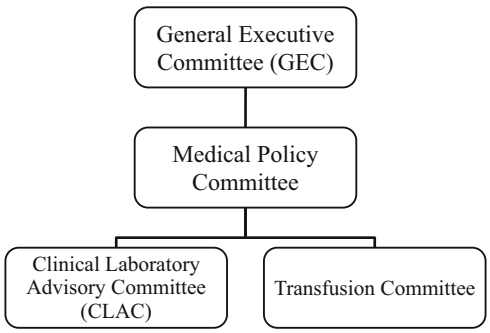

Fig. 2.1 Former organizational structure for Utilization Management at the Massachusetts General Hospital (circa 2008). Committees with pathologist leadership include the Clinical Laboratory Advisory Committee and the Transfusion Committee

laboratory information system. Pathologists by virtue of their role as laboratory directors are thus in a much better position to lead the utilization management program than most clinicians particularly those practicing in narrow specialties. The pathologist can thus serve as the hub of a wheel connecting to physicians across different specialties and coordinating the overall program.

A number of publications have described the organizational structure of hospital utilization management programs [10]. A former organizational structure for utilization management in our hospital is shown in Fig. 2.1 (as described in [10]). The major governing body in the hospital is the General Executive Committee (GEC). Its membership includes clinical chiefs of service (including the Chief of Pathology) and senior hospital administration. The Medical Policy Committee (MPC) reports to the GEC and is responsible for oversight of all clinical activities in the hospital. Its membership includes the Chief Medical Officer, a cross section of clinicians and representatives from nursing and other departments. The Clinical Laboratory Advisory Committee (CLAC) was a subcommittee of the Medical Policy Committee charged with coordinating utilization management and other laboratory-related issues. Membership of the CLAC included representatives from pathology, who chaired the committee, and a cross section of physicians from different clinical specialties. Utilization management initiatives that were approved by the CLAC were forwarded to the MPC for final approval. The Transfusion Committee serves in a similar capacity as the CLAC and is responsible for utilization management and other policies concerning the use of blood components. Initially the CLAC served its purpose and a number of utilization-related initiatives were accomplished. However, as the pace of our utilization management activities expanded, we found that a committee that met once per month was unable to effectively manage the program. We also found that the clinician members were hesitant to make a judgment about tests outside of their specialties. For example, a transplant surgeon would not feel qualified to approve a proposal to eliminate Babesia antibody testing from our laboratory menu. For this reason we reorganized our program to include a core group of clinical pathologists one of whom has advanced informatics training to serve as a coordinating committee. The committee generates utilization management ideas, collects data (e.g., test volumes, test results, ordering providers), and prepares the data for presentations to groups of physicians from the relevant specialty(s). The committee therefore relies on the use of multiple ad hoc specialty group meetings (e.g., infectious disease, transplant, cardiology, medicine house officers) rather than a standing committee with a cross section of physicians. This approach allows multiple issues to be vetted in semi-real time, does not waste the time of the clinicians who only need to review topics in their specialty, and allows the committee to move more rapidly on multiple initiatives.

When starting a utilization management program, it is helpful to establish benchmarking data to determine how your organization compares to other health-care systems and to assess your internal performance over time. External benchmarking data can sometimes be obtained from national professional organizations or by performing a survey of one's peers in other health-care systems. The data should be normalized in some way such as tests per outpatient visit or the number of tests per inpatient discharge. Analysis of test numbers alone is not sufficient as it does not take into account the volume of patients being cared for.

Two key points concerning external benchmarking data are as follows.

First it is important to make certain that the "peer" group to which you are being compared is appropriate. For example, a large academic medical center should not be compared to a mid-sized community hospital as the scope of medical services and patient acuity of the two will be completely different rendering the analysis essentially worthless. Second, all organizations in the peer group should count tests in the exact same way. For example, one organization might report each of the tests in a basic metabolic panel as individual tests whereas other organizations may roll them up into a single panel scored as one test. Molecular diagnostic tests can be reported using a number of individual elements or as reported as a single test. When properly performed, external benchmarking can give the utilization management program a sense of where their organization stands relative to its peers. This may help to assess the scope of opportunity both globally and within specific laboratory specialties. On the other hand, internal benchmarking data allows the organization to evaluate its progress in managing utilization over time. In the past we monitored the total tests per inpatient discharge over time as described in [10]. In doing so we were able to track a 26 % decrease in inpatient tests per discharge over a 6-year period. More recently we have been benchmarking individual services and clinical units within the hospital (e.g., intensive care units, neurology service). This approach allows us to share the information with the individual services so they can see the specific data that is relevant to them.

One of the major reasons to manage utilization is to control costs in the laboratory. For this reason it is important to understand how to calculate cost savings resulting from utilization management activities. The literature contains a number of examples where the cost analysis was not performed correctly. In most cases these studies used laboratory test charges rather than actual costs, or they used average unit costs of tests rather than marginal costs. Charges for laboratory tests often bear little relationship to the actual cost to perform the tests. Charges are often greatly inflated as part of a strategy to improve revenues. The concept of average versus marginal cost is especially important with high-volume automated tests. Assume a laboratory performs a million tests per year with an annual operating budget of $5 million per year. Therefore the average unit cost is $5 per test. Next assume a utilization management initiative eliminates 100,000 tests per year. Using an average unit cost of $5, one could calculate an annual savings of $500,000. But this calculation is completely incorrect. In the laboratory there are two types of cost, fixed and variable. Fixed costs do not change with the volume of tests and include such elements as space, overhead, equipment, and management. Reducing test volumes by 100,000 (2 %) will have no impact on these costs. Then there are variable costs. These change with the volume of tests and include such elements as reagents and other consumables. When automated tests are removed from a preexisting laboratory, only the variable costs are actually saved. In the case of automated testing, the variable costs are typically quite low. In a study by Winkelman, it was shown that it would take an approximate 10 % reduction in automated testing volume to achieve only a 2 % reduction in cost [11]. Therefore, with automated testing, most of the true savings occur from reductions in specimen collection and eliminating the downstream costs of testing as described above. For laboratory tests with a high variable cost, such as molecular diagnostics and many esoteric tests, significant money can be saved by reducing test volumes. A second category concerns reference laboratory testing. Virtually all hospitals send a significant number of tests out to reference laboratories. In this case the hospital gets billed for every test that is performed. Therefore reference laboratory charges are all variable costs and significant savings can be achieved by reducing utilization of these tests. However, laboratories should also be aware of the potential impact of reducing test volumes on revenues. In most cases, tests on hospital inpatients do not generate any revenue because the admission is paid using a global fee such as a diagnostic-related group (DRG). The hospital gets paid the same for the admission regardless of how many tests are, or are not, performed. In most cases outpatient tests generate revenue: reducing the test volume will correspondingly reduce revenues.

A number of medical professional societies are beginning to take an active interest in utilization management. Often this involves the publication of practice guidelines or consensus statements. One of the most visible of these initiatives is the National Physicians Alliance "Promoting Good Stewardship in Medicine Choosing Wisely" campaign [12, 13]. In this program various medical specialties have designated their "Top 5 List" of tests, procedures, and therapies that should not be performed. Predictably a number of these involve laboratory testing. The American Society for Clinical Pathology has summarized the recommendations that relate to the clinical laboratory as shown in Fig. 2.2. In our institution the "Choosing Wisely" recommendations are often cited by clinicians who are working on utilization management. These recommendations represent a good start for guiding utilization management and will no doubt continue to expand. However, there are many areas of laboratory testing that are not covered by the guidelines. For this reason it is important to consult practice guidelines from other professional societies and to develop locally generated consensus standards.

TYPE OF TEST	TEST RECOMMENDATION	RECOMMENDING ORGANIZATION
Immunology	Don't perform unproven diagnostic tests, such as immunoglobulin (IgE) testing of an indiscriminate battery of immunoglobulin E (IgE) tests, in the evaluation of allergy.	American Academy of Allergy, Asthma & Immunology (AAAAI)
	Don't routinely do diagnostic testing in patients with chronic urticaria.	
	Don't test ANA sub-serologies with a positive ANA and clinical suspicion of immune-mediated disease.	American College of Rheumatology
	Don't test for Lyme disease as a cause of musculoskeletal symptoms without an exposure history and appropriate exam findings.	
	Don't order autoantibody panels unless positive antinuclear antibodies (ANA) and evidence of rheumatic disease.	American College of Rheumatology – Pediatric Rheumatology
	Don't test for Lyme disease as a cause of musculoskeletal symptoms without an exposure history and appropriate exam findings.	
	Don't repeat a confirmed positive ANA in patients with established juvenile idiopathic arthritis (JIA) disease activity or systemic lupus erythematosus (SLE).	
	Don't perform immunological testing as part of the routine infertility evaluation.	American Society for Reproductive Medicine
Chemistry	Don't routinely measure1,25-dihydroxyvitamine D unless the patient has hypocalcaemia or decreased kidney function.	The Endocrine Society and the American Association of Clinical Endocrinologists
	Don't order a total or freeT3 level when assessing levothyroxine (T4) dose in hypothyroid patients	
	Don't perform population based screening for 25-OH-Vitamin D deficiency.	ASCP
	Don't routinely screen for prostate cancer using a prostate-specific antigen (PSA) test [or digital rectal exam].	American Academy of Family Physicians (AAFP)
	Don't perform repetitive [CBC and] chemistry testing in the face of clinical and lab stability.	Society of Hospital Medicine (Adult Hospital Medicine)
Toxicology	Don't administer a chelating agent prior to testing urine for metals, a practice referred to as "provoked" urine testing.	The American College of Medical Toxicology and the American Academy of Clinical Toxicology
	Don't perform methotrexate toxicity labs more often than every 12 weeks on stable doses.	American College of Rheumatology – Pediatric Rheumatology

Fig. 2.2 American Society for Clinical Pathology summary of laboratory-related recommendations of the National Physicians alliance promoting good Stewardship in medicine choosing Wisely Campaign. Reproduced with permission

Microbiology	Don't obtain a urine culture unless there are clear signs and symptoms that localize to the urinary tract.	AMDA
	Avoid [antibiotics and] wound cultures in emergency department patients with uncomplicated skin and soft tissue abscesses after successful incision and drainage and with adequate medical follow-up.	American College of Emergency Physicians
Hematology	Don't perform repetitive CBC [and chemistry] testing in the face of clinical and lab stability.	Society of Hospital Medicine (Adult Hospital Medicine)
Blood Banking	Don't administer packed red blood cells (PRBCs) in a young healthy patient without ongoing blood loss and hemoglobin of ≥6g/dL unless symptomatic hemodynamically unstable.	American Society of Anesthesiologists
	Avoid transfusions of red blood cells for arbitrary hemoglobin or hematocrit thresholds and in the absence of symptoms of active coronary disease, heart failure or stroke.	Society of Hospital Medicine (Adult Hospital Medicine)
	Do not transfuse more than the minimum number if red blood cells (RBC) units necessary to relieve symptoms of anemia or to return a patient to a safe hemoglobin range (7 to 8 g/dL in stable, non-cardiac, in-patients).	American Society of Hematology (ASH)
	Do not administer plasma or prothrombin complex concentrates for non-emergent reversal of vitamin K antagonists (i.e. Outside of the setting of major bleeding, intracranial hemorrhage or anticipated emergent surgery).	
	Don't transfuse red blood cells in hemodynamically stable, non-bleeding ICU patients with a hemoglobin concentration greater than 7 g/dl.	Critical Care Societies Collaborative – Critical Care
Coagulation	Don't use bleeding time test to guide patient care.	ASCP
	Don't do work up for clotting disorder (order hypercoagulable testing) for patients who develop first episode of deep vein thrombosis (DVT) in the setting of a known cause.	Society for Vascular Medicine
	Don't routinely order thrombophillia testing on patients undergoing a routine infertility evaluation.	American Society for Reproductive Medicine
	Don't do an inherited thrombophillia evaluation for women with histories of pregnancy loss, intrauterine growth restriction (IUGR), preeclampsia and abruption.	Society for Maternal-Fetal Medicine

Fig. 2.2 (continued)

Cytology	Don't perform Pap smears on women younger than 21 or who have had a hysterectomy for non-cancer disease. Don't screen women older than 65 years of age for cervical cancer who have had adequate prior screening and are not otherwise at high risk for cervical cancer. Don't screen women younger than 30 years of age for cervical cancer with HPV testing, alone or in combination with cytology.	American Academy of Family Physicians (AAFP)
	Don't perform routine annual cervical cytology screening (Pap tests) in women 30-65 years of age.	The American College of Obstetricians and Gynecologists
	Don't perform Pap tests for surveillance of women with a history of endometrial cancer.	Society of Gynecologic Oncology
Molecular Pathology	Don't screen for ovarian cancer [with CA-125] in asymptomatic women at average risk.	The American College of Obstetricians and Gynecologists
	Don't screen low risk women with CA-125 [or ultrasound] for ovarian cancer	Society of Gynecologic Oncology
	Don't perform low risk HPV testing.	ASCP
	Only order Methylated Septin 9 (SEPT9) to screen for colon cancer on patients for whom conventional diagnostics are not possible.	
Pre-Op Battery	Don't perform preoperative medical tests for eye surgery unless there are specific medical indications.	American Academy of Ophthalmology
	Don't obtain baseline laboratory studies in patients without significant systemic disease (ASA I or II) undergoing low-risk surgery – specifically complete blood count, basic or comprehensive metabolic panel, coagulation studies when blood loss (or fluid shifts) is/are expected to be minimal.	American Society of Anesthesiologists
	Avoid routine preoperative testing for low risk surgeries without a clinical indication.	ASCP
Non-Pre-Op Battery	Don't perform routine pre-operative testing before low-risk surgical procedures.	Society of General Internal Medicine (SGIM)
	Don't order diagnostic tests (arterial blood gases, blood chemistries, blood counts) at regular intervals (such as everyday), but rather in response to specific clinical questions.	Critical Care Societies Collaborative – Critical Care

Fig. 2.2 (continued)

Screening Tests	Don't perform routine cancer screening for dialysis with limited life expectancies without signs or symptoms.	American Society of Nephrology
	Don't perform routine general health checks for asymptomatic adults.	Society of General Internal Medicine (SGIM)
	Don't recommend cancer screening in adults with life expectancy of less than 10 years.	
	Do not perform PSA testing for prostate cancer screening in men with no symptoms of the disease when they are expected to live less than 10 years.	The American Society of Clinical Oncology (ASCO)
	Don't recommend screening for breast or colorectal cancer, nor prostate cancer with the PSA test, without considering life expectancy and the risks of testing, overdiagnosis and overtreatment.	American Geriatrics Society (AGS)
	Don't offer noninvasive prenatal testing (NIPT) to low-risk patients or make irreversible decision based on the results of this screening test.	Society for Maternal-Fetal Medicine
Anatomic Pathology	Don't perform sentinel lymph node biopsy or other diagnostic tests for the evaluation of early, thin melanoma because they do not improve survival.	American Academy of Dermatology (AAD)
Fertility	Don't perform advanced sperm function testing, such as sperm penetration or hemizona assays, in the initial evaluation of the infertile couple.	American Society for Reproductive Medicine
Biopsy	Don't perform surgery to remove a breast lump for suspicious findings unless needle biopsy cannot be done.	Commission on Cancer (COC)
CBC (WBC)	Don't use white cell stimulating factors for primary prevention of febrile neutropenia for patients with less than 20 percent risk for this complication.	American Society of Clinical Oncology (ASCO)
Cardiac Markers	Don't perform stress cardiac imaging or advanced non-invasive imaging in the initial evaluation of patients without cardiac symptoms unless high-risk markers are present.	American College of Cardiology
D-dimer	Don't perform chest computed tomography (CT angiography) to evaluate for possible pulmonary embolism in patients with a low clinical probability and negative results of a highly sensitive D-dimer assay.	American College of Chest Physicians American Thoracic Society (ATS)
Hemoglobin	Don't administer erythropoiesis-stimulating agents (ESAs) to chronic kidney disease (CKD) patients with hemoglobin levels ≥ 10 g/dL without symptoms of anemia.	American Society of Nephrology
Hemoglobin A1c	Avoid using medications to achieve hemoglobin A1c<7.5% in most adults age 65 and older; moderate control is generally better.	American Geriatrics Society
Pap Test	Don't perform colposcopy in patients treated for cervical cancer with Pap tests of low grade squamous intraepithelial lesion (LGSIL) or less.	Society of Gynecologic Oncology

Fig. 2.2 (continued)

PSA	A routine bone scan is unnecessary in men with low - risk prostate cancer (patients with newly diagnosed prostate cancer who have a PSA < 20.0 ng/ml and a Gleason score of 6 or less unless the patient's history or clinical examination suggests bony involvement)	American Urological Association
	Don't treat an elevated PSA with antibiotics for patients not experiencing other symptoms.	
Testosterone	Don't prescribe testosterone to men with erectile dysfunction who have normal testosterone levels.	American Urological Association
	Don't prescribe testosterone therapy unless there is biochemical evidence of testosterone deficiency.	The Endocrine Society and American Association of Clinical Endocrinologists
Thyroid Function Tests	Don't routinely order a thyroid ultrasound in patients with abnormal thyroid function tests if there is no palpable abnormality of the thyroid gland.	The Endocrine Society and American Association of Clinical Endocrinologists
Urinalysis/ Urine Culture	Don't use antimicrobials to treat bacteriurua in older adults unless specific urinary tract symptoms are present.	American Geriatrics Society (AGS)
TYPE OF TEST	TEST -RELATED RECOMMENDATION	RECOMMENDING ORGANIZATION
Glucose	Don't recommend daily home finger glucose testing in patients with Type 2 diabetes mellitus not using insulin.	Society of General Internal Medicine (SGIM

Fig. 2.2 (continued)

A Toolbox for Implementing Utilization Management Initiatives

A number of strategies (tools) for addressing utilization management have been described in the literature as shown in Table 2.3. For any given utilization management initiative, it is important to select the right utilization management tool to implement it. A number of factors will influence this decision including:

1. Who is the target audience (e.g., primary care, subspecialty practices, inpatients versus outpatients, residents)? For example, using a gatekeeping mechanism to control utilization of high-volume automated testing will be doomed to fail due to the sheer volume of test requests. Impacting these tests is best approached by physician education coupled with controls built into the order entry system. In contrast testing performed by specialists can often be evaluated by meeting with the physicians during regular staff meetings or with leaders in the specialty practice to develop evidence-based guidelines.
2. What is the test volume (e.g., occasional test, low volume (20–50 per month), moderate volume or high volume (thousands per month)? For example, a low-volume test can be easily subjected to gatekeeping without undue inconvenience for the physicians and the laboratory.
3. What infrastructure is available to assist implementation (e.g., order entry systems, laboratory middleware, requisition design, admission templates, laboratory formulary)?
4. Indications for the test. Some tests should essentially never be ordered (ban), whereas others are useful in certain situations but are overutilized. The latter situation precludes an outright ban but could be subjected to gatekeeping or allowing only certain specialists to order the test.
5. Outpatient versus inpatient testing: Testing on inpatients should be limited to those tests that are required for the management of the patient's acute episode leading to hospitalization. Tests that will not be required for immediate patient management may best be restricted and will not be reimbursed beyond the global DRG payment. On the other hand, outpatient tests generate revenue which will be lost if test volumes are reduced. Although lost revenue should not be a reason to avoid utilization management on outpatients, it is, nonetheless, a factor that needs to be acknowledged.

Table 2.3 Strategies to approach laboratory utilization management: a toolbox

Physician education and feedback
Presentations at medical conferences
Distributing literature on test guidelines
Develop an electronic laboratory handbook with recommended laboratory workups
Practice guidelines
Identify and monitor "sound alike" tests (e.g., 25OH and 1–25OH vitamin D)
Posting test costs or charges
Retaining a laboratory-based genetic counselor
Physician profiling and variation analysis
Post "pending" tests to the electronic medical record
Restrictions on testing
Discontinue obsolete tests (banning)
Use of gatekeepers or prior authorization systems
Restrict selected tests that can only be ordered by specific specialists
Develop a list of tests that should never be ordered more than once (e.g., genetic tests)
Restrict inpatient sendout tests that are not relevant to the current hospitalization
Capture and eliminate same-day duplicate tests
Restrict the use of automatic orders for daily laboratory testing
Establish a laboratory formulary
Requisition design
Validate and refine reference intervals to eliminate falsely abnormal tests
Develop admission templates
Order entry design[a]
Decision support
Use of "pop-ups"
Develop algorithms and reflex testing protocols
Benchmarking against peer organizations
Clinical pathology consultative and interpretive services
Financial motivation including risk sharing and pay-for-performance

[a]Order entry systems may be used to support many of the strategies listed in this table

6. Testing that is ordered predominantly by one or a few physicians but not by others in the same area of medical specialty. This situation is not uncommon and can pose significant challenges. In some cases this reflects the unique patient population that is seen by the specialist. For example, one neurologist may specialize in seeing patients with seizure disorders whereas other neurologists may see other types of patients (e.g., movement disorders, Alzheimer's disease). This alone could explain what initially might appear to be a peculiar test ordering pattern. In other cases a particular physician may be the only one ordering a certain test with no clear explanation. In our experience these physicians are often uncooperative or outright obstinate. There are a variety of approaches to dealing with this situation. These include forcing the physician to justify the test to a laboratory utilization committee (or medical policy committee), enlisting assistance from the physician's chief of service or the chief medical officer, having the physician develop his/her own guidelines followed by ongoing monitoring and feedback, or subjecting the test to a gatekeeping mechanism or a prior approval strategy. An alternative approach is simply to wait out the physician until testing strategies change or the physician leaves the health-care organization either through retirement or by moving to a different practice. In our hospital this has actually occurred on a number of occasions.

In the discussion that follows, we will review some of the utilization management tools listed in Table 2.3 and provide specific examples where these tools were used to implement utilization management initiatives. Many of these tools are discussed in detail in other chapters of this book and will not be further described here. These include:

1. Retaining a laboratory-based genetic counselor
2. Physician profiling
3. Establishing a laboratory formulary
4. Order entry design: decision support
5. Benchmarking
6. Clinical pathology consultative services
7. Prior authorization

Physician Education Physician education to control utilization management has frequently been regarded as a weak intervention, and its impact is often of limited duration. However, depending on the specific educational objective, physician education can be very effective in a number of situations. There are many venues in which physician education can be delivered depending in part on the target audience, the complexity of the presentation, and the need to allow for discussion and feedback. Physician turnover can limit the longevity of the educational intervention especially in hospitals with large numbers of resident/fellow trainees or in services that rely on locum tenens coverage. Some of the available approaches to providing education include:

1. National medical conferences, hospital grand rounds, or morbidity and mortality rounds
2. Continuing education webinars and podcasts (includes internal webinars and those offered nationally)
3. Web-based written guidelines
4. Distributing literature and guidelines on subject areas
5. Developing websites with recommended approaches to laboratory testing
6. Emails sent to target physicians
7. In-person discussions such as attending resident hospital rounds or peer-to-peer discussions
8. Use of order entry pop-ups with educational content

The key is to first decide whether the utilization initiative can reasonably be expected to be successful using education alone and to plan on mechanisms to ensure its longevity. It is also necessary to develop metrics to monitor the effectiveness and persistence of the intervention. In most cases physician education involves developing practice guidelines or evidence-based approaches to clinical problems with the educational component being to disseminate and gain acceptance of the recommendations. In most cases it is best for the laboratory to enlist the aid of local clinical experts who are recognized by their peers. Educational materials arising exclusively from the laboratory will usually be regarded with skepticism. In one study, Thakkar et al. reported on the results of an educational intervention targeting the frequency of daily blood test orders in hospitalized patients [14]. The intervention involved education through flyers placed in providers' offices and email communications. They documented a mean decrease in complete blood counts from 1.46 to 1.37 tests per day and a decrease in basic metabolic panels from 0.91 to 0.83 tests per day. They did not report on the effectiveness of the intervention over the long term. In our hospital we attempted a similar intervention in which we required medical house staff to specifically decide which tests were needed each day as opposed to writing orders for tests as "daily until discontinued." We observed a significant decrease in test orders, but the number of orders rapidly returned to baseline after we stopped active management of the intervention. Similar issues with recidivism were also reported by May et al. [15].

Another approach we have used to educate physicians for selected esoteric tests (e.g., testing for tick-borne infections) employs personalized email communications to the providers. Many esoteric tests have a limited number of physicians who order the test with any frequency. First we do a computer search to identify the providers and the volume of tests that they order. We then send them an email with educational content. An example of a recent email is shown below.

Email to individual providers. Good day. You are probably aware that the hospital is facing significant budget challenges. The clinical laboratories have been working with a number of medical services to identify tests of low or marginal clinical utility that can be eliminated from the test menu. One such test is serology IgG and IgM for Babesiosis. You are receiving this email because you have ordered two or more Babesia serologies based on a recent audit. Infectious disease specialists have concluded that the most appropriate test to detect active infection with Babesia is the thick and thin blood smear. Serologic tests cannot differentiate current from past infection and suffer from false negative and positive results. For this reason Babesia serology will no longer be offered by the clinical laboratory as the blood smear is the preferred approach. The MGH Medical Policy Committee has approved this change to the testing menu. We recognize that there may be occasional situations where the serologic test offers clinical value. The Pathology Core Laboratory resident on-call is available to approve these requests. The MGH Core Lab resident on call can be reached by paging 2–1827.

Physician Feedback Physician feedback provides an interactive method to educate physicians about their test ordering patterns and may allow opportunities for one-on-one interactions. Typically the term "physician feedback" implies physician profiling (see chapter on physician profiling). However, this is not always the case. Feedback can take many forms such as posting test costs (or charges), gatekeeping of tests, creating order entry pop-ups with an educational component, performing physician-blinded variation analysis, or even simple interventions such as posting pending tests in the electronic medical record to alert the physician that the test has already been ordered. For example, Fig. 2.3a shows an electronic order entry pop-up screen that appears whenever a physician orders testing for creatine kinase MB isoenzyme (CK-MB). Note that the pop-up includes educational information on the updated rule out of myocardial infarction protocol. If the clinician decides to order the test anyway, a second screen pops-up requiring a reason for the test request. The success of the pop-up screen was monitored along with the reason given for the test by the clinician. Over time we observed an 80 % decrease in orders for CK-MB. Figure 2.3b shows the impact of the pop-up on CK-MB test orders over time. Inappropriate test orders could be monitored and individualized education provided to the physician.

Another example of physician feedback is shown in Fig. 2.4. In this case we were attempting to determine which physicians were ordering genetic tests and their medical specialty. As shown in Fig. 2.4, there was significant variation in the dollar amount of genetic test orders among different providers. In addition, most of the top test ordering physicians by dollar volume were in pediatric genetics. The "profiling "data was provided to the pediatric genetics physicians with the identities of the individual providers blinded from the data set. We arranged a meeting with the pediatric genetics group to develop guidelines for appropriate test orders in different clinical scenarios. The result was an approximate $ 10,000 per month decrease in expenses for these tests.

Posting Laboratory Costs or Charges

Physicians are often unaware of the cost (or charges) for laboratory tests that they order. Posting the cost of laboratory tests may be complicated because laboratories often do not know their true unit costs for many of the tests that they offer. Also when tests are eliminated, the laboratory does not save the average unit cost but rather only the variable cost as described earlier. An alternative approach is to post laboratory charges in the provider order entry system. In a study by Feldman

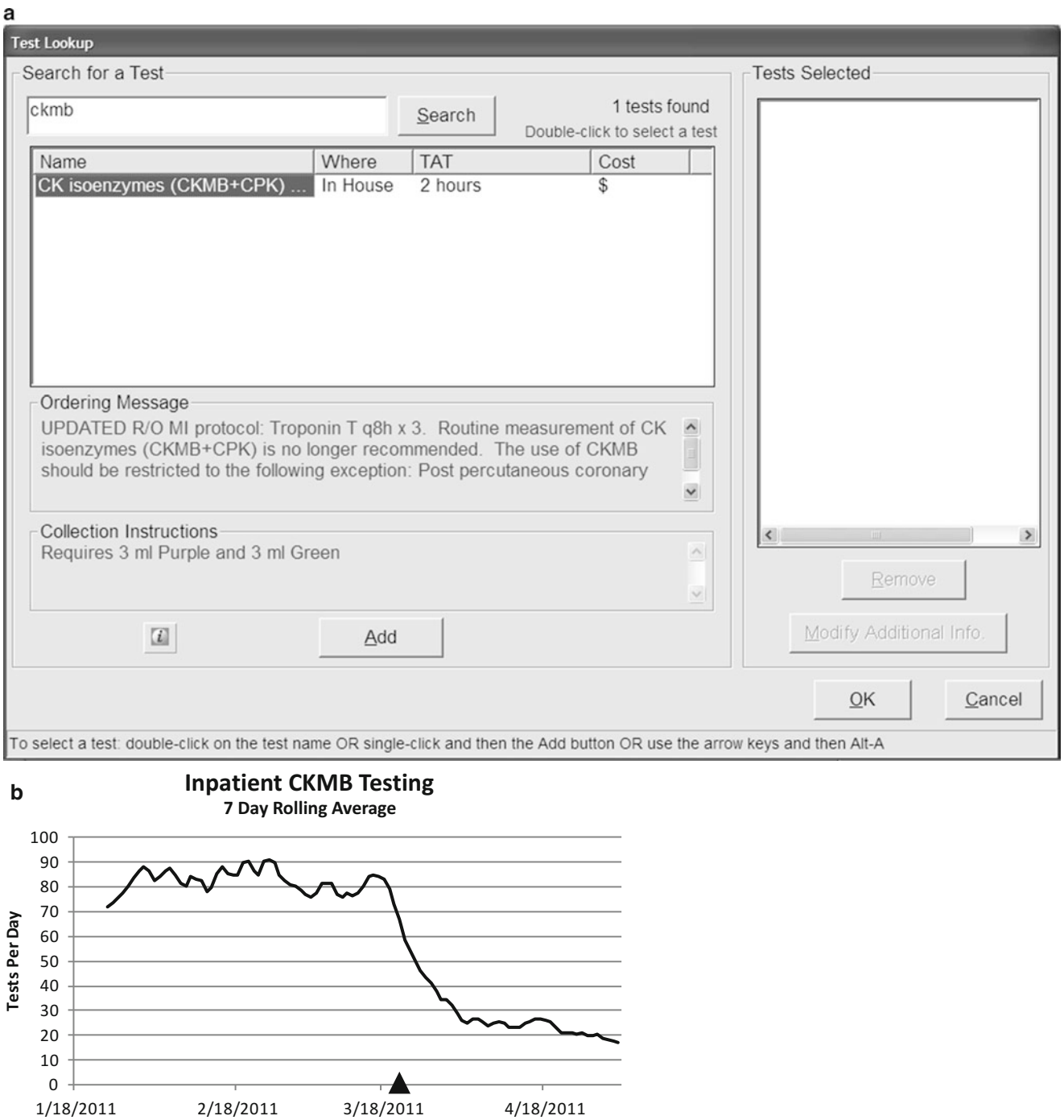

Fig. 2.3 (**a**) Order entry pop-up screen that appears when a physician requests testing for creatine kinase MB isoenzyme. When the test is requested, an ordering message is displayed describing the new rule out myocardial infarction (R/O MI) protocol and reminding the clinician that creatine kinase MB isoenzyme (CK-MB) and total creatine kinase enzyme (CPK) is no longer recommended. (**b**) Volume of creatine kinase MB isoenzyme test orders over time after implementation of an order entry pop-up screen. The pop-up was implemented in late March of 2011. The graph shows a significant decline in the test volume following implementation of the intervention

et al., the authors reported the results of posting laboratory charges for 60 randomly assigned tests [16]. Following posting of the charges, there was a modest reduction in testing from an average of 3.72–3.40 tests per patient day. In our hospital we implemented a somewhat simpler strategy in which we post relative costs as $, $$, or $$. We have not evaluated the impact of this on test ordering patterns.

Requisition and Order Entry Screen Design

It has long been known that the design of a laboratory requisition (or order entry test screen) can have a significant positive or negative impact on laboratory test utilization. This may include:

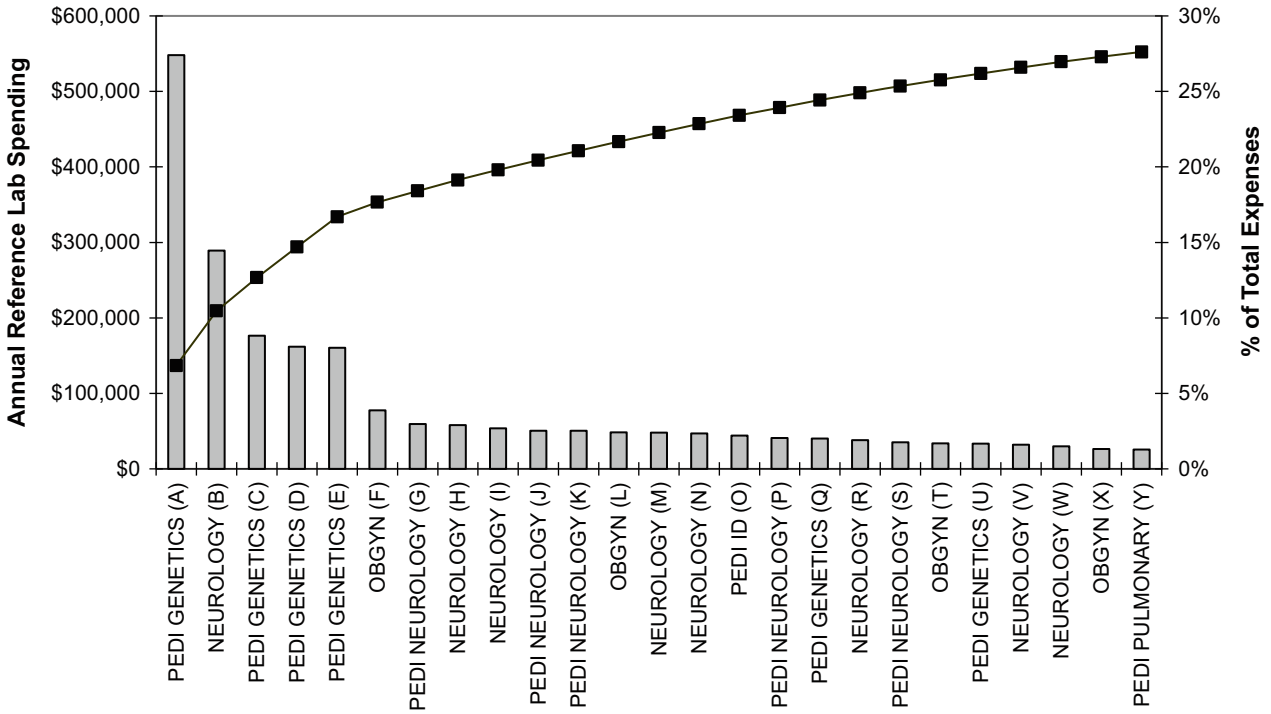

Fig. 2.4 Genetic testing ordered by different providers and their medical specialty. The graph shows the annual expense of genetic tests ordered by different providers and the *line* with *boxes* shows the cumulative expense across all providers. *Key*: individual providers are designated by letters A–Y, *Pedi* pediatric

1. Removing a test
2. Adding a test
3. Grouping of tests in a logical order
4. Adding an opportunity to order an automated algorithm (e.g., thyroid algorithm)

For example, several years ago we were receiving a number of test requests for celiac disease including anti-tissue transglutaminase, anti-gliadin, and anti-endomysial antibodies. Working with our clinical immunologists and gastroenterologists, we developed a celiac disease screening algorithm comprised of sequential testing of total IgA and tissue transglutaminase (IgA and/or IgG) levels. Gliadin antibodies would sometimes be added depending on the results of the TTG testing. Of note, endomysial antibody was an expensive test that had been sent out to a reference laboratory. A box for checking the new celiac algorithm was added to our outpatient order requisition. The gliadin and endomysial antibodies could still be requested as "write-in" tests but were not specifically listed on the requisition. The impact on total testing volumes for celiac disease is shown in Fig. 2.5. Over time there was a significant reduction of testing for endomysial and gliadin antibodies without a corresponding increase in tissue transglutaminase antibodies.

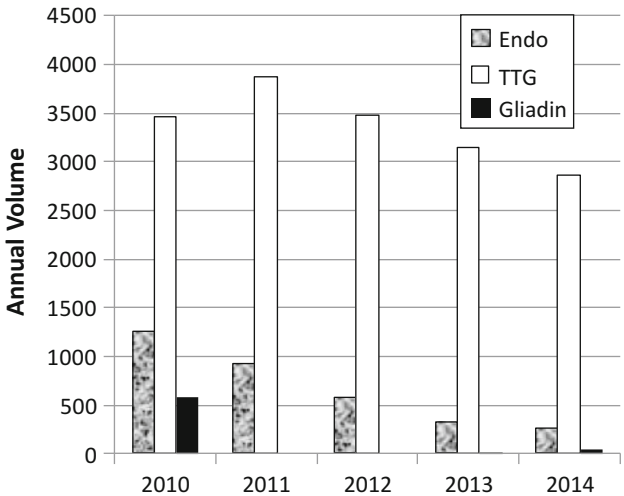

Fig. 2.5 Annual test volumes for celiac disease tests. *Key*: *Endo* anti-endomysial antibody, *TTG* anti-tissue transglutaminase antibody

In 1998 van Walraven reported the results of a multi-prolonged intervention strategy combining requisition changes, clinical guidelines, and changes to funding policy (Canada) that targeted testing for erythrocyte sedimentation rate, urine microscopic examination, renal function, iron stores, and thyroid function testing. They observed significant decreases in requests for these tests following the intervention [17].

In another example we reviewed our inpatient provider order entry (POE) system for opportunities to reduce unnecessary utilization. One feature of the POE system is a "quick

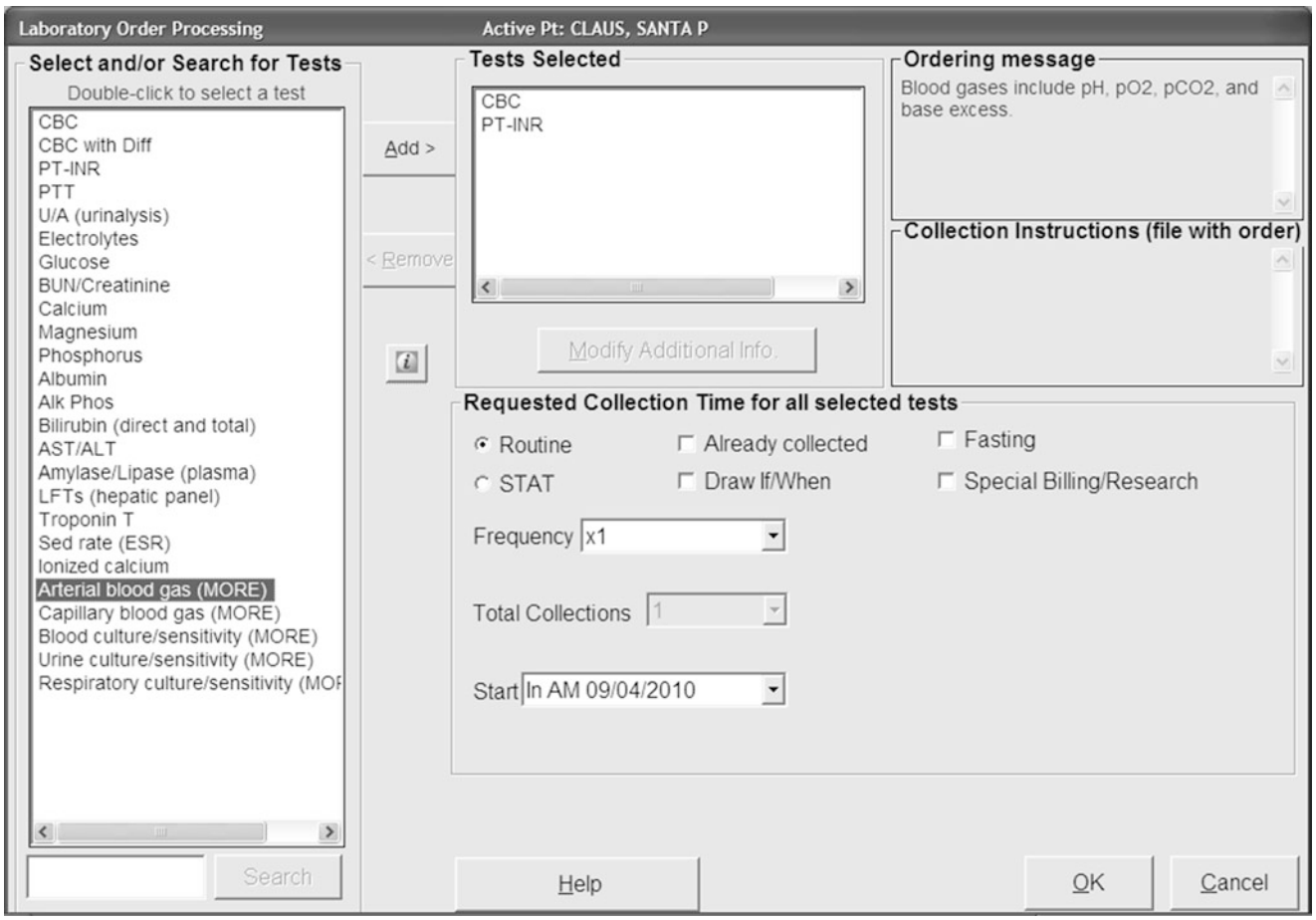

Fig. 2.6 Provider order entry "quick pick" screen: common tests that are ordered are displayed in the *box* on the *left*. Selected tests appear in the *center box*. Other ordering information is displayed in other locations on the screen

pick" screen where common laboratory tests are displayed to make test ordering more convenient for the provider (Fig. 2.6). However, this also creates opportunities for overutilization as tests are easy to order and are visually presented to the clinician. We removed several tests from the quick pick screen that we thought were being overutilized including lactate dehydrogenase (LDH) and total creatine kinase (CPK). In the case of LDH, there was a 54 % decrease in test orders following removal of the test from the screen.

Develop an Electronic Laboratory Handbook

In the past many laboratories printed laboratory handbooks that could be distributed to physicians and staff. These books contained various information including the test menu, normal reference ranges, expected turnaround time, and specimen collection requirements. Although useful in their time, these books rapidly become out of date and are therefore unreliable. They also lack a user interface such as a search function to find test information and look for guidance in test selection and interpretation. Several years ago we developed an electronic online laboratory handbook that could be easily updated to incorporate changes in our laboratory services (Fig. 2.7). Because the handbook is readily available online in our hospital applications menu, it provides convenient access to testing information throughout our health-care network. Through the use of a search function, the clinician cannot only find test information but also guidance on what is the most appropriate test to order. For example, if the clinician types "CMV" into the search box, all of the related tests on our menu are shown along with which test is recommended in different clinical situations. This function eliminates unnecessary testing and also helps to ensure that the patient gets the right test.

"Sound Alike" Tests Another use of the online handbook is to identify "sound alike" tests. For example, if the clinician types "vitamin D" into the search box, the following message appears.

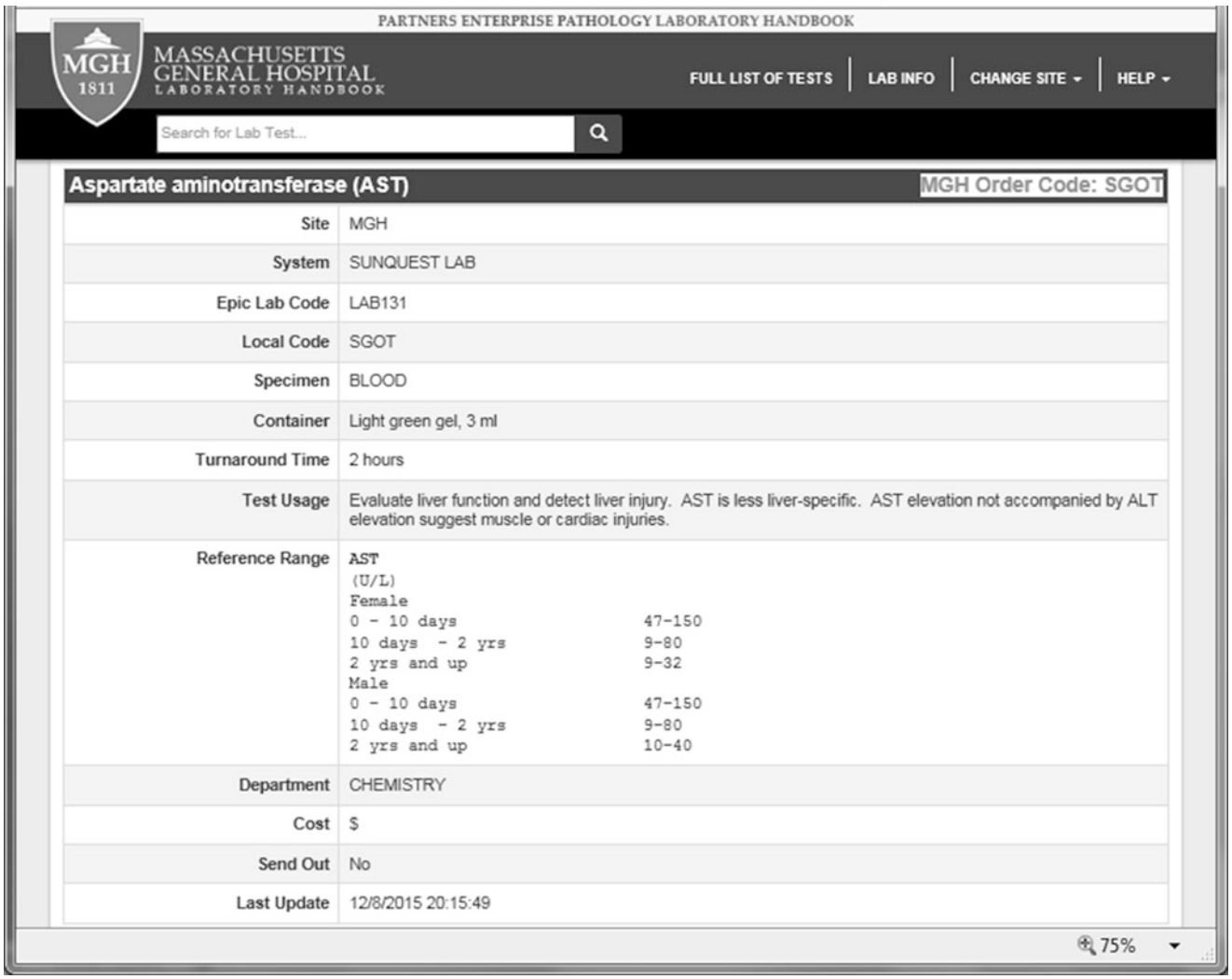

Fig. 2.7 Screen shot of the Massachusetts General Hospital On-Line Laboratory Handbook. Various information can be accessed from the screen such as critical values, reference ranges, reflex protocols, and laboratory policies

Test Name	Lab	Comment
1–25-OH Vitamin D	*Chemistry* (*Sendouts*)	Please note that 1,25 OH vitamin D is in general NOT the test of choice for assessment of vitamin D deficiency. Please order 25-OH vitamin D if that is the intent
25-OH Vitamin D	*Core Lab*	25-OH vitamin D is the test of choice for evaluation of vitamin D deficiency. Test measures total 25-OH vitamin D (D2 and D3) by tandem mass spectrometry

In most situations 25-OH vitamin D is the preferred test to evaluate vitamin D status. However, clinicians often get confused by the "look alike" test, 1–25 OH vitamin D. The decision support function aids clinicians in test selection and also provides educational content at the time of the test order. This approach is much more effective than "after the fact" education once an error in test selection has already occurred.

Develop Practice Guidelines

Practice guidelines may be developed by national physician's organizations, government agencies, or at the local level within an individual hospital or practice. Locally developed guidelines (even if modeled on national guidelines) tend to be the most effective as the relevant stakeholders will have provided input. The problem with guidelines is that they are usually voluntary and they may also fail to capture the nuances of real-world clinical practice. One of the earliest guidelines developed for laboratory testing is the now near universal thyroid screening algorithm as shown in Fig. 2.8. This screening guideline was highly effective because, in most cases, the

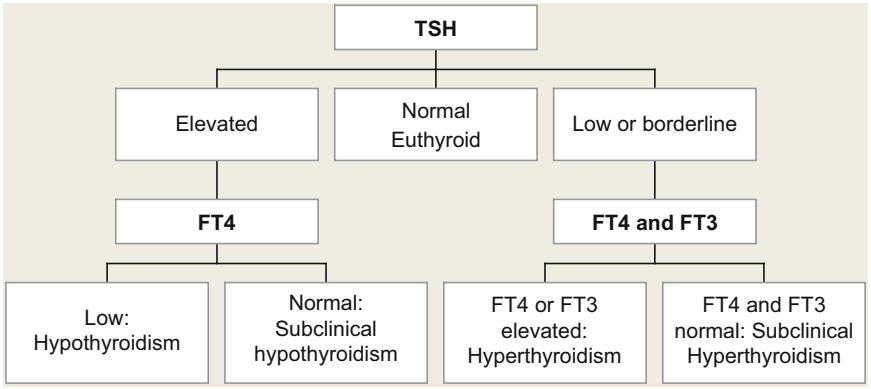

Fig. 2.8 Example of a thyroid screening algorithm. When a thyroid screen is ordered, only the initial test (TSH) is performed. Based on the result of the TSH test, other tests may be added. In most cases the TSH is normal and no further testing is required. *Key*: *TSH* thyroid-stimulating hormone, *FT4* free T4, *FT3* free T3

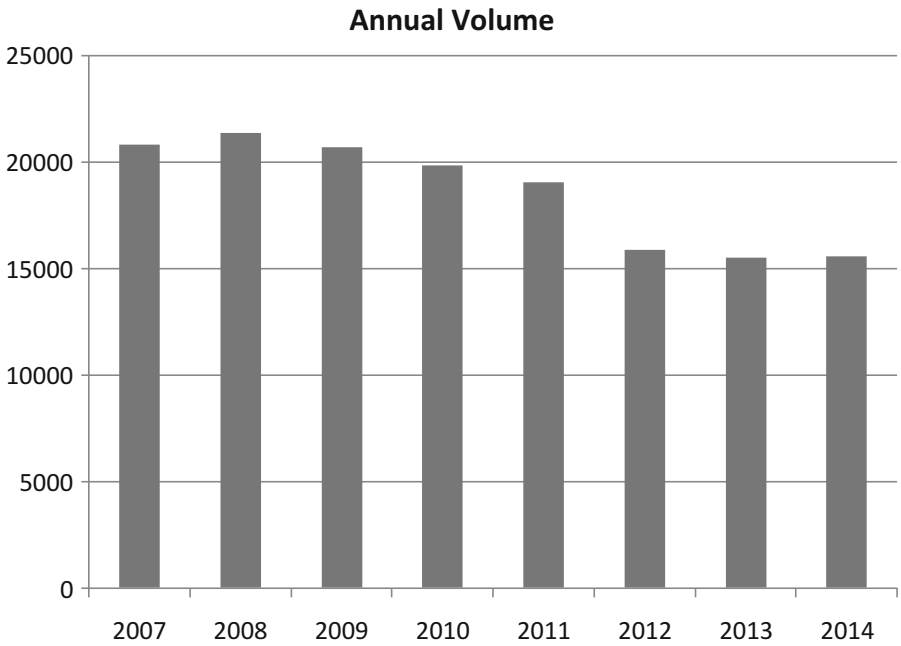

Fig. 2.9 Annual test volume for prostate-specific antigen. A modest decline in the test volume was observed over time

patient only requires one test (thyroid-stimulating hormone). In the absence of the guideline, many physicians ordered multiple tests up front to ensure that all of the necessary results would be available with one blood draw. The algorithm is managed within the laboratory and can be automated on most immunoassay platforms. Over the years a large number of guidelines have been published. For example, in 1995 Kelly reported that more than 1700 clinical practice guidelines by national organizations were available [18]. That number has increased substantially since that time. He also noted that many complex issues occur in the development, dissemination, and implementation of guidelines. The most notable recent example of a practice guideline is the "Choosing Wisely" guidelines discussed earlier. However, other guidelines are potentially controversial, or there may be disagreement between different organizations as described above for screening for prostate cancer using prostate-specific antigen. Following the prostate screening guidelines issued by the United States Preventative Services Task Force, we began monitoring our PSA test volumes over time as shown in Fig. 2.9. Clearly there has been some decrease in the test volume but nowhere near as much as we had initially expected. This example illustrates the major problem with guidelines in that, for various reasons, physicians may choose not to follow them, or they may be unaware of them. Requiring physicians to search online for guidelines is inconvenient and is usually ineffective. To help solve this problem, our hospital maintains an intranet website that lists a large number of practice guidelines and suggested approaches to various clinical problems. The site is called the Primary Care Office Insite (PCOI). Most of our physicians are aware of the website. The Department of Veterans Affairs and Department of Defense has employed a similar approach which can be accessed on their website (http://www.healthquality.va.gov/). As one final example, our blood transfusion committee developed guidelines for the appropriate use of blood components

including red blood cells, platelets, fresh frozen plasma, and cryoprecipitate. The guidelines contain a lot of detail and are impossible for the average physician to remember. The solution was to print plastic cards that could be attached to a physician's identification badge holder which made them readily available. Subsequently our blood bank set up a computer algorithm that can pull laboratory data to determine if individual transfusions were meeting the guidelines. In cases that they do not meet the guidelines, an email is sent to the ordering provider reminding them of the guidelines and provides ongoing education.

Regardless of their source, the keys to practice guidelines include the following:

1. They must be convenient to access during the course of clinical care.
2. They must be endorsed by key local clinicians and/or national physician's organizations.
3. Physicians must be made aware of them.
4. They must be clear, simple, and easy to understand.

Capture and Eliminate Same-Day Duplicate Tests

In most hospitals, especially academic medical centers, the medical team caring for the patient may inadvertently order duplicate tests on the same day. In one study Bridges et al. evaluated the rate of duplicate orders for six tests (acute hepatitis panel, antinuclear antibody, vitamin B12 and folate, thyroid-stimulating hormone, and ferritin with iron/TIBC) [19]. The overall rate of duplicate tests was 7.7 %. In another study May et al. [15] described an intervention to reduce redundant test ordering utilizing the laboratory information system to capture duplicate orders and cancel them. They reported a 12 % decrease in inpatient tests.

Gatekeeping

Gatekeeping has long been utilized by third-party payers to restrict access to medical services [20]. In the past this activity rarely involved laboratory testing. However, the recent availability of high-cost genetic and molecular testing has led to a number of payers setting up prior approval requirements (gatekeeping) for these tests. However, gatekeeping has also been employed for the purpose of physician education by laboratory directors as a means to control utilization as described earlier in this chapter. In most cases this involves moderate- to high-cost tests that are requested in relatively low volume. Attempts to gatekeep higher-volume tests by direct human interaction will be logistically impossible. Electronic order entry can be employed in this situation. The gatekeeping strategy is basically an extension of what many hospitals currently do to control the use of expensive antibiotics which is usually managed by infectious disease physicians. Reports of gatekeeping initiatives in the clinical laboratory go back several decades. For example, in 1987 our hospital set up a mandatory laboratory approval for requests for lactic dehydrogenase isoenzyme analysis (LDH isoenzymes), a marker for myocardial infarction that was being supplanted by assays for creatine kinase MB isoenzyme. The gatekeeping effort reduced requests for LDH isoenzymes from approximately 2000 per month to 7 per month (>99 %). A number of studies have reported on similar successes. For example, Fryer et al. reported an 83 % decrease following a gatekeeping initiative for toxicology screens [21] and Hutton et al. an 85 % reduction in C-reactive protein testing [22]. Gatekeeping is an effective approach to utilization management on two fronts: first it imposes a barrier to ordering the test and, second, it creates an opportunity for physician education. Over time if the gatekeeping strategy with education is effective, the number of tests that need to be reviewed should decline.

Restricting Inpatient Sendout Tests

A number of tests that are sent out to reference laboratories will not reasonably be expected to have a result during the time of the patient's hospital admission or will not contribute actionable information to impact treatment. This is particularly true for molecular genetic tests. Hospitals are beginning to gatekeep these tests or even ban their use on inpatients altogether. The test can then be deferred to the outpatient setting if it is truly needed. In another example, tests may be ordered up front in the context of the working differential diagnosis without knowledge by the physician of the turnaround time. However, once the diagnosis becomes clear, some of these may, in retrospect, not have been necessary. Kyle et al. reported an intervention targeting a paraneoplastic panel with a unit cost of $ 1757.50 and an expected turnaround time of 14–21 days. Panels that were requested on inpatients were reviewed with the ordering physician who frequently was unaware of the turnaround time. Overall 60 % of the requests were canceled [23].

Develop Admission Templates

A number of hospitals have implemented admission templates. Usually these are developed by interdisciplinary teams to specify physician's orders based on the admitting diagnosis. For example, we have templates for a variety of diagnoses such as heart failure, acute myocardial infarction, and pneumonia. The templates include nursing orders, pharmacy,

laboratories, and other orders. The main purpose of the templates is threefold:

1. To standardize patient care across the hospital
2. To ensure that required tests, drugs, etc. are ordered and not forgotten
3. To assist in utilization management

In our hospital the laboratory and pharmacy reviews all templates to ensure good practice and assess opportunities for utilization management. On a number of occasions, we have removed unnecessary tests and made other modifications to the templates.

Validate and Refine Reference Intervals

Many physicians, especially interns and junior residents, place considerable faith in the normal reference values published by their laboratories. Frequently values that are even slightly outside of the reference range prompt a clinical response which may include repeat or additional testing, specialist consultations, or other maneuvers. In some cases clinical laboratories have not made an adequate effort to ensure the accuracy of their reference ranges including considerations such as gender, ethnicity, and age. In other cases reference ranges are determined in a sloppy manner such as carrying over historical ranges to new assays or performing only a limited normal value study. For example, a laboratory might take 20 samples from volunteers in their lab. Given the current demographics of the medical technologist labor force, this approach will usually result in a sampling of a generally older population with a greater representation of females. It also assumes that all of the volunteers are indeed normal and healthy. Another approach that has been used is to take samples from presumptively healthy blood donors, but this also introduces certain population biases. If a reference range is not properly established, normal patients will exhibit abnormal laboratory values which may prompt further testing and intervention. Also, truly abnormal test results may be inappropriately designated as normal. As one illustration of this, we had long experienced a higher than expected rate of borderline hypokalemia. As a result, many fruitless clinical workups were occurring on an ongoing basis. Despite our best efforts, we could not identify the source of the problem. Eventually we were notified that the manufacturer was recalibrating their assay which would add 0.2 mol/L to each potassium result. The problem was immediately solved. As one follow-up we checked with the pharmacy who reported a significant decrease in potassium supplementation in our hospitalized inpatients. While this was a calibration issue and not a reference range issue, it does demonstrate the impact of reporting erroneous abnormal results. In another example, the reference range for our plasma chloride was not properly set with the lower end of the range set at 100 mmol/L. A number of clinicians complained about seeing too many patients with low chloride values compelling them to figure out what next steps to do. This represented a significant waste of the physician's time. A survey of other hospitals using the same instrument as ours showed a different reference range prompting us to reassess our range and change it.

Develop Algorithms and Reflex Testing Protocols

In our hospital we have implemented over 200 reflex testing protocols. Some of these represent basic standards of practice (e.g., a negative rapid strep A test is reflexed to a throat culture), whereas others were designed with utilization management in mind. In some cases the optimal laboratory workup of a clinical problem is beyond the scope of knowledge of the typical clinician. In a study by Laposata et al., the authors reviewed the rate of inappropriate test orders in groups of physicians who either did or did not have access to our special coagulation testing algorithms. Physicians who did not have access to the algorithms averaged 3.56 test ordering errors per laboratory requisition compared to 1.62 errors for those who did [24]. In addition a significant percentage of physicians stated that the algorithms and laboratory interpretations saved them time, reduced the number of tests ordered, and helped prevent a misdiagnosis.

Often a physician is faced with a differential diagnosis that may require a number of laboratory tests. However, based on the results of an initial test, the differential diagnosis is narrowed thereby eliminating the need for many of the other tests. Algorithms ensure that the correct tests are performed and eliminate those that are not, even though this could not be foreseen in advance. Another example is the anemia algorithm described in the chapter on utilization management in hematology.

Restrict Orders for "Daily Until Discontinued" Laboratory Testing

In many hospitals, especially academic medical centers, physicians (interns and residents) order laboratory tests as "daily until discontinued." Usually this includes a complete blood count (CBC), basic metabolic panel, and calcium/phosphorus/magnesium. There are several reasons for this practice:

1. Many hospital patients are very ill and may require frequent monitoring.
2. The resident may be afraid of criticism if laboratory values are not available during patient rounds.

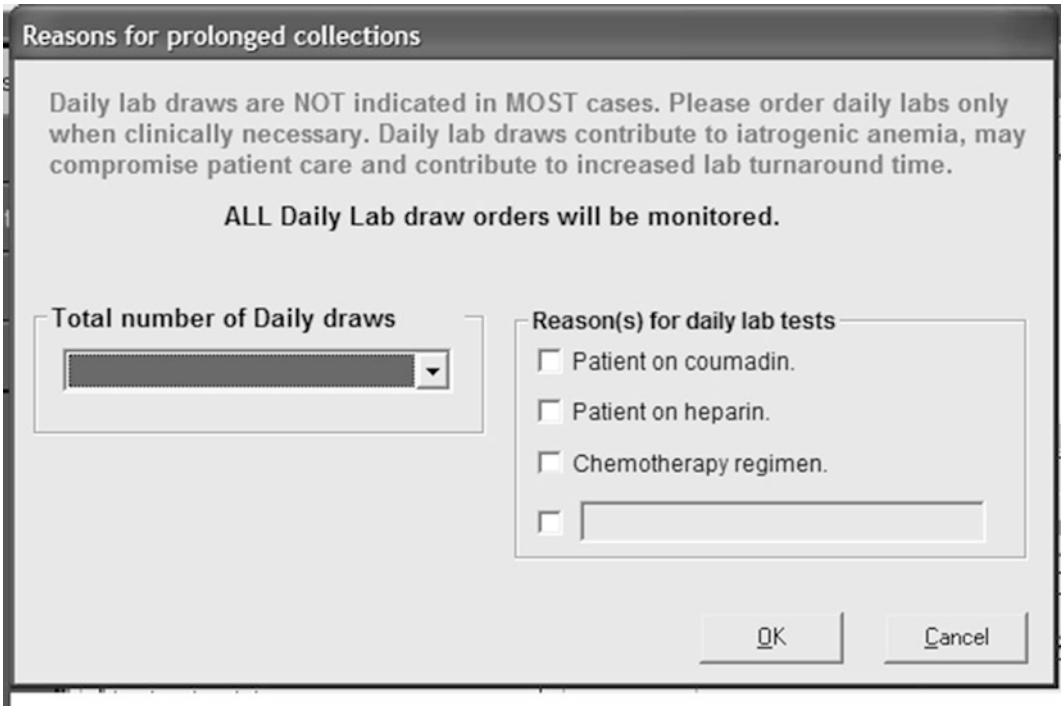

Fig. 2.10 Order entry "pop-up" screen for "daily labs." If a request is made for "daily labs," a pop-up screen appears stating the hospital policy and a reason for the request is required

3. Convenience: Most residents are very busy and must work within required duty hours. By putting the common laboratory tests on "autopilot," there is one less item to have to think about.

This practice is obviously wasteful and contributes to iatrogenic anemia. In the past we attempted to reduce this practice with the exceptions of the CBC in oncology patients, immunosuppressant drug levels, and coagulation testing on patients on heparin or Coumadin. In most cases the preferred approach is to assess each patient on a regular basis and determine what tests will be required for that day. We attempted various educational activities at house officer conferences and performed a short pilot project (described above) with little long-term success. Subsequently we implemented an order entry pop-up screen as shown in Fig. 2.10 and began an audit of who was ordering "daily labs." Any physician who ordered four or more "daily labs" in a 1-week period received an email as shown in below:

> You are receiving this e-mail because during the past week, you placed 4 or more orders for recurrent daily labs without an apparent approved indication.
>
> Inappropriate use of recurrent laboratory orders can inadvertently lead to unnecessary testing. Excess laboratory testing places patients at increased risk for hospital acquired anemia. Moreover, unneeded testing can also reduce patients' experience of care, waste nursing and laboratory resources and lead to increased turnaround-time for needed laboratory tests.
>
> Per MGH ordering guidelines, orders for recurrent daily labs should only be used in the following five situations:
>
> 1. To monitor PTT in patients receiving heparin
> 2. To monitor PT/INR in patients receiving Coumadin
> 3. To monitor labs needed to safely manage or treat chemotherapy patients
> 4. For immunosuppressant monitoring
> 5. For reasons included on approved MGH order templates, if tests are ordered using the template
>
> This policy has been approved by the MGH Medical Policy Committee.

Over time we have achieved a significant reduction in "daily lab" orders as shown in Fig. 2.11. The progress we observed suggests a slow but steady culture change is occurring among the residents who order the majority of the testing on hospital inpatients. In the future we plan to block all daily orders in our order entry system with the exception of the indications mentioned above.

Restrict Which Physicians or Specialists Can Order Expensive Tests

A number of hospitals have set up systems where only certain physician specialists can order expensive tests. In most cases these restrictions target tests in genetics, neurology, and infectious disease. The strategy recognizes that these tests may be important for some patients but that most

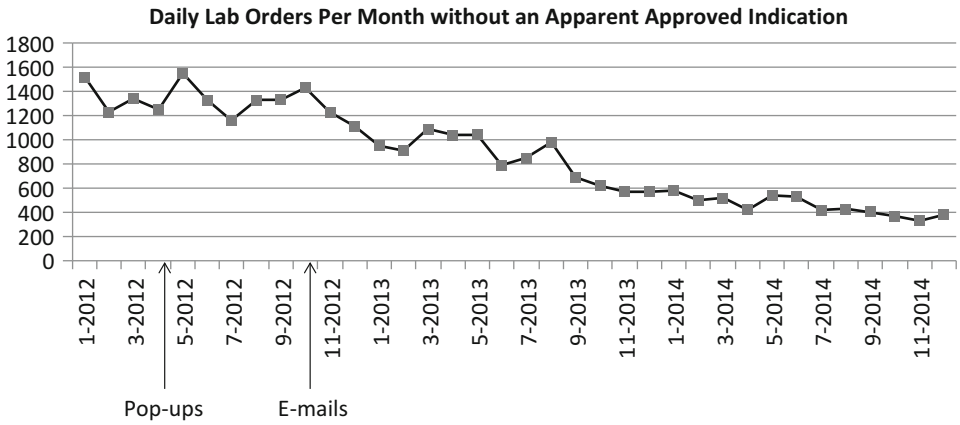

Fig. 2.11 Number of "daily lab" orders per week without an apparent approved indication. Over time following multiple interventions the number of non-approved requests for "daily labs" showed a significant and steady decline

nonspecialists lack an adequate understanding of when the tests are appropriate or should be avoided. For example, a patient with a complex presentation may generate a long differential diagnosis that would require many diverse tests to be ordered. However, a specialist can often narrow the differential diagnosis and select only those tests that are most likely to be informative. This strategy can be built into hospital laboratory formularies as discussed in a subsequent chapter.

Restrict Orders for Tests That Should Never Be Ordered More Than Once

Delivery of care is often fragmented across a health-care network. A test may be ordered by one physician, but the result may not be widely available or may be difficult to find in the electronic medical record. In addition, many physicians may fail to look at what tests are already available resulting in duplicate orders. For obvious reasons genetic tests should never be ordered more than once on an individual patient. However, some nongenetic tests should also not be ordered more than once in the course of a patient's workup for a given clinical problem. When a patient is seen by multiple clinicians and specialists, duplicate tests may be ordered. The laboratory can use the order entry system or the laboratory information system to identify and cancel redundant orders for tests that should only be ordered once during a given clinical evaluation. At a minimum, tests that are already pending in the system should be identified clearly in the electronic medical record so that clinicians are aware that the test is in the system awaiting a result.

Conclusion

Increasing pressures to contain costs in the American health-care system will continue to drive efforts to manage the utilization of medical resources including the clinical laboratory. Physicians should be leaders in this process to ensure that the quality of patient care is not compromised. In the case of laboratory medicine, clinical pathologists are ideally suited to lead the utilization management program while working in collaboration with clinicians and administrators. Many examples of utilization management initiatives have been described in the literature. Successful implementation of such initiatives can be accomplished using a variety of strategies (tools) so long as the most appropriate strategy is selected to match the individual initiative. More detail concerning many of the topics described in this manuscript can be found in the chapters that follow.

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