

Transforming Laboratory Utilization Review into Laboratory Stewardship: Guidelines by the PLUGS[®] National Committee for Laboratory Stewardship

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Appropriate utilization of clinical laboratory services is important for patient care and requires institutional stewardship. Clinical laboratory stewardship programs are dedicated to improving the ordering, retrieval, and interpretation of appropriate laboratory tests. In addition, these programs focus on developing, maintaining, and improving systems to provide proper financial coverage for medically necessary testing. Overall, clinical laboratory stewardship programs help clinicians improve the quality of patient care while reducing costs to patients, hospitals, and health systems. This document, which was created by a new multiinstitutional committee interested in promoting and formalizing laboratory stewardship, summarizes core elements of successful hospital-based clinical laboratory stewardship programs. The core elements will also be helpful for independent commercial clinical laboratories.

Pathology and laboratory medicine have transformed the practice of medicine by providing tests and services for diagnosis, treatment, monitoring, and prevention of disease and driving advances in all fields of medicine. Laboratory testing is the single highest-volume medical activity with an estimated 13 billion tests performed in the US each year (1). In addition, about 70% of downstream medical decisions are based on pathology and laboratory medicine results (2).

The 3 most significant causes of patient harm related to laboratory services are ordering the

wrong test, failing to retrieve a test, and misinterpreting a test result (3). A number of studies, as well as review of insurance claims, reveal that 10%–30% of laboratory tests performed in the US are either unnecessary or inappropriate (4). About 30% of genetic test orders are inappropriate (5), and about 5% of genetic test orders are frank medical errors (6). About 7% of test results are never retrieved or retrieval is significantly delayed (7). Like all medical interventions, inappropriate laboratory test ordering and interpretation have serious effects, including delayed

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⁸ **Nonstandard abbreviations:** UM, utilization management; PLUGS[®], Pediatric Laboratory Utilization Guidance Services; CPOE, computerized provider order entry.

diagnosis, misdiagnosis, iatrogenic injury resulting from unnecessary treatment or additional studies, unnecessary costs, and more (8).

Laboratory test utilization management is the latest expression of a long trend in healthcare to control costs and improve quality. Examples of this trend in other areas of healthcare services include:

- *Antimicrobial stewardship*, in which healthcare systems work to decrease antimicrobial resistance in the population by limiting the unnecessary use of antibiotics.
- *Pharmacy utilization management*, which encompasses a variety of interventions to improve drug therapy, most notably the use of pharmacy formularies that seek to substitute less expensive, but equally effective, drugs for more expensive drugs.
- *Blood utilization committees*, whose work has led to significant decreases in unnecessary transfusions in the US, as well as motivating the discovery that most patients have better outcomes when more conservative thresholds for red cell transfusion therapy are implemented.
- *Radiology utilization management*, which encompasses a variety of interventions to decrease unnecessary and harmful imaging. This has been a success in pediatrics, for whom restrictive guidelines have led to less cancer-causing radiation without a change in health outcomes, and in adults, in whom unnecessary imaging has decreased, particularly spine imaging for routine back pain and head imaging related to minor trauma or headache.
- *The Choosing Wisely™ campaign* (www.choosingwisely.org) is an initiative of the American Board of Internal Medicine that seeks to provide guidelines for testing and therapy yielding better health while recommending less laboratory testing, fewer procedures, and less expensive treatment across

multiple subspecialties of internal medicine. Choosing Wisely has had a significant effect on reducing unnecessary laboratory services in a number of medical specialties.

Traditionally, these initiatives have been referred to inside healthcare systems and insurance companies as utilization management (UM)⁸. A better term, and one that is gaining credibility, is stewardship, which refers to “the careful and responsible management of something entrusted to one's care” (Merriam-Webster). Stewardship focuses on the value of a healthcare service, which is the quality of the service provided relative to its cost. Stewardship approaches value from the perspective of the individual patient, as well as from that of the entire population. The word stewardship avoids some of the negative connotations associated with the term utilization management, which sometimes has been used to emphasize cost cutting without considering quality. The cost cutting of UM has often been perceived as thoughtless—for example, when it is used across the board rather than focused and evidence-based—and even viewed as cruel by both patients and healthcare providers. For our purposes, we use the terms laboratory test utilization management (or UM for short) interchangeably with clinical laboratory stewardship, acknowledging the likelihood that stewardship will come into more common use.

Stewardship programs are dedicated to the following 2 primary goals: (a) improving the ordering, retrieval, and interpretation of appropriate laboratory tests and (b) developing, maintaining, and improving systems to provide proper financial coverage for medically necessary testing. A growing body of evidence shows that stewardship programs can optimize the diagnosis, treatment, and monitoring of disease and reduce downstream adverse events associated with errors in test ordering, retrieval, and interpretation. At the same time, stewardship programs can protect patients against financial harm. Overall, stewardship programs help clinicians improve the quality of patient

care while reducing costs to patients, hospitals, and health systems.

The complexity of medical decision-making surrounding laboratory use and the variability in the size and types of care among US hospitals require flexibility in implementation. However, experience shows that stewardship programs can be implemented effectively in a wide variety of hospitals and that success is dependent on defined leadership and a coordinated multidisciplinary approach. In recognition of the need to improve laboratory utilization, the National Committee for Laboratory Stewardship recommends that integrated health systems and independent hospitals implement laboratory stewardship programs. This committee was commissioned by the national collaboration PLUGS® and consists of 10 members from 7 academic institutions. The committee members are laboratory medical directors, clinical chemists, and medical technologists in a consulting role. This committee supports stewardship initiatives within commercial clinical laboratories and encourages commercial laboratories to align with the stewardship programs of integrated health systems and independent hospitals. This document summarizes core elements of successful hospital-based laboratory stewardship programs. It complements existing guidelines from organizations including the Clinical Laboratory Standards Institute, *Choosing Wisely*, and others. The core elements will also be helpful to independent commercial clinical labs. There is no single template for a program to optimize laboratory testing.

SUMMARY OF KEY COMPONENTS OF LABORATORY STEWARDSHIP PROGRAMS AND BASIS FOR UM CHECKLISTS

An institution's laboratory stewardship program is one important component of a hospital's overall utilization review plan. Such a plan is a Centers for Medicare and Medicaid Services condition of par-

ticipation in Medicare and Medicaid programs (9) and helps meet The Joint Commission and other accreditation standards pertaining to utilization review.

Laboratory stewardship programs have the following 4 basic elements, which are modeled after the antibiotic stewardship programs (10): (a) governance, (b) interventions, (c) data extraction and monitoring, and (d) review of data coupled with strategies and tactics for improvement.

Governance

The elements of governance are: (a) leadership commitment; (b) accountability to a high-level medical executive; (c) committees and subcommittees; (d) laboratory expertise and other key support; and (e) networking.

Leadership commitment. Leadership commitment involves ensuring that laboratory stewardship efforts have the necessary human, financial, and information technology resources required to succeed. Commitment from leadership will help determine the size and impact of the laboratory stewardship program. Stewardship programs will usually have a significant return on investment through better insurance reimbursement and savings from avoiding unnecessary and uncompensated laboratory tests. Laboratory stewardship programs will usually produce direct positive impact to patient safety initiatives and to initiatives that improve the patient experience. Leadership support can take a number of the following forms:

- Formal statements that the health system or facility supports efforts to improve laboratory stewardship. The laboratory stewardship program should be conducted with approval from and oversight by a high-ranked executive, such as the institution's chief medical officer, who is highly visible and empowered in the organization, or should obtain its authority from a high-ranking leadership committee, such as the executive medical board.

- Ensuring participation from the many medical and administrative groups that can support stewardship activities. This is detailed in the Laboratory expertise and other key support section.
- Including stewardship-related duties in job descriptions and annual performance reviews for pathologists, other doctoral-level laboratory positions, genetic counselors, and direct care providers, including physicians, nurses, and physician assistants.
- Ensuring staff from relevant departments are given sufficient time to contribute to stewardship activities.
- Supporting training and education in laboratory stewardship.

Accountability to a higher-level medical executive. A key element of accountability is the appointing of a physician or other doctoral-level leader who is responsible for the program outcomes. This person may or may not be the head of the institutional laboratory stewardship committee, and is often available to settle disagreements as part of the escalation plan.

Committees and subcommittees. Committee work is essential for governance. This starts with establishing a multidisciplinary laboratory stewardship committee with broad high-ranking representation from medical and administrative leadership; it is essential that the chief medical officer and the chief financial officer participate or provide appropriate, visible, empowered designees.

Subcommittees should form around particular topics that need more detailed policy and procedure work. These may form along medical topics, such as cancer genomic profiling or cardiovascular disease management. Alternatively, subcommittees may form around particular programs or process issues, such as distinguishing research from clinical testing or creating policies and procedures around preauthorization. Subcommittees

work best when they have both medical and administrative participation, and when the participants have sufficient expertise, reputation, and authority.

Laboratory expertise and other key support. Optimal laboratory involvement starts with appointing laboratory leaders responsible for improving appropriate test utilization. It is essential that a high-ranking pathologist or other doctoral-level laboratory leader participates on the overall laboratory stewardship committee and be active and visible. In addition, other laboratory leaders can lead or participate in subcommittees and subspecialty teams within their areas of expertise. Formal training in pathology and laboratory medicine is beneficial for the laboratory leaders in the stewardship program. Pathologists and other doctoral-level laboratorians are ideal candidates to lead laboratory utilization improvement efforts given their laboratory training and familiarity with technical aspects and clinical implications of tests. Such activities fit well with overall accreditation standards and existing laboratory quality improvement requirements.

The overall laboratory stewardship program requires support of a number of key groups throughout the institution. These include:

- *Clinicians and department heads.* Tests are ordered by clinicians outside the laboratory setting, and it is vital that clinicians are fully engaged in and supportive of efforts to improve laboratory utilization. Department chairs are often engaged in implementing cost-savings initiatives for the hospital, as well as working on implementing standard best practices in their field. They can prove strong advocates for stewardship initiatives.
- *All clinical specialties* may assist on a multidisciplinary utilization committee or subcommittees as needed and can coordinate facility-wide laboratory utilization strategies, bringing their skills to auditing, analyzing, and reporting data.

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They can also assist with educating staff on the importance of appropriate laboratory utilization and with implementing strategies to optimize the use of laboratory tests.

- *Finance leadership.* It is important to have the chief financial officer or his or her designee to help make decisions using real financial data rather than financial assumptions. Decisions to approve, certain kinds of medically necessary, expensive testing that might be poorly reimbursed by insurance will not move forward without backing from finance and other administrative leadership.
- *Quality improvement staff* can also be key partners given that optimizing laboratory use is a medical quality and patient safety issue.
- *Laboratory staff* at all levels can guide the proper use of tests and the flow of results. They can guide clinicians to current test information including algorithms, facilitate consultations with pathologists and doctoral-level staff, and expedite testing as necessary. Laboratory staff at all levels can work collaboratively with clinicians to ensure that laboratory results are retrieved and laboratory reports present data in a clear and logical way, supporting optimal clinical care.
- *Evidence-based practice experts* can be key partners in guiding the use of laboratory tests on the basis of clinical outcomes instead of the more traditional practice of routine daily orders.
- *Clinical informaticists and information technology staff* are useful in analyzing lab utilization data, comparing it with external peer group data if available, and helping to select the interventions with the highest impact. They are also useful in measuring the effectiveness of interventions. Examples include implementing clinical decision support for appropriate laboratory use, creating prompts for action to retrieve and review test orders in key situations, and facilitat-

ing the collection and reporting of laboratory utilization data. Advanced programming is usually necessary to embed algorithmic testing to facilitate best practices. When the program grows and a number of different tests are being targeted, each with different interventions at different levels, a good project manager becomes useful in getting all parties to deliver as expected.

Networking. Networking is the last element of governance. Laboratory stewardship leadership at all levels should promote links to local and national groups and initiatives that are either dedicated to laboratory stewardship or have a strong stewardship component. These groups include the AACC, Association for Molecular Pathology, College of American Pathologists, American Society for Clinical Pathology, PLUGS[®], Choosing Wisely, and others. In addition, laboratory stewardship programs need to have strong working relationships with third-party payers, which include the health insurance industry and the specialty benefits management industry, as well as government at the federal and state levels. Reference laboratories can play a useful role in laboratory stewardship initiatives by providing peer comparison data that identify over- or underutilization of a particular test by a hospital. Such tests can then be specific targets for the stewardship committee. Stewardship initiatives that help to ensure appropriate testing can be shared with payers in an effort to decrease denials and facilitate reimbursement.

Interventions

Interventions to improve laboratory utilization. Stewardship interventions are listed in the following 3 categories based on the strength of the intervention: gentle, medium, or strong. The strength of the intervention refers to its overall

Table 1. Stewardship intervention examples by strength.

Gentle	Medium	Strong
Posting guidelines on the requisition	Utilization report cards	Utilization report cards with peer or leadership review
Computerized reminders regarding utilization guidelines	Changes to manual requisitions	Privileging specific tests to specialty providers
Educational lectures	Hiding tests in CPOE systems	Laboratory formulary including send-out formulary
Consensus reference laboratory preselection for specialized testing	Periodically reviewing and updating physician preferences	Requirement for high-level approval or consultation
Providing relative cost information in CPOE		Rules requirement CPOE: Hard stops

success that is usually achieved in stopping an unwanted behavior. Stronger interventions tend to be more difficult to accomplish.

Gentle interventions are usually educational and do not require systematic changes or hard stops. Medium-strength interventions include systematic changes but allow for navigation around them. An example of a medium-strength intervention would be removing tests from the requisition or hiding tests in computerized provider order entry (CPOE) but allowing the same test to be ordered if specifically requested. Finally, strong interventions use different mechanisms to produce hard stops. It should be emphasized that these interventions are not mutually exclusive; using >1 intervention allows customization for each institution and situation and increases the impact on behavior. Examples for each intervention type are outlined in Table 1 (11, 12).

Gentle interventions. Gentle interventions include both passive efforts, such as posting of guidelines or cost of tests, and active educational efforts, such as targeted presentations and communications. To sustain the impact of an educational intervention, repeat educational efforts are almost always required. Laboratory stewardship programs should provide regular updates on laboratory diagnostic capabilities, the appropriate use of emerging diagnostic tests, tests approaching obsolescence, testing algorithms, and evidence-based

testing strategies. Sharing facility-specific information on laboratory utilization is a tool to motivate improved testing strategy, particularly if wide variations in the patterns of use exist among similar patient care locations. There are many options for providing education on laboratory utilization, such as formal and informal didactic presentations and messaging through posters and flyers and newsletters or electronic communication to staff groups. Reviewing de-identified cases with providers, in which appropriate changes in laboratory testing could have been made, is another useful approach. A variety of web-based educational resources can help facilities develop education content. Education can be effective when paired with corresponding interventions and measurement of outcomes.

Medium-strength interventions. Medium-strength interventions involve system changes that fall short of putting a hard stop on an order. These changes should be designed to make it easy for the provider to do the “right thing”. CPOE systems give providers automatic access to thousands of laboratory tests and the ability to customize order frequency, which increases the potential for confusion among similarly or misnamed tests. One approach to reduce inappropriate testing is implementation of testing cascades, algorithms, and best practice recommendations in CPOE to guide

behavior at the time of the order. Some examples include:

- *Standard workflow processes to reduce commonly misordered test orders.* In many situations, commonly misordered tests are inadvertently ordered by clinicians. For example, clinicians may inappropriately order tests such as 1-25 dihydroxy Vitamin D instead of 25 hydroxy Vitamin D. Red blood cell folate is often ordered instead of serum folate. Confirmatory genetic testing for factor V Leiden is frequently ordered without first performing activated protein C resistance testing. In these cases, the laboratory should create systems to notify clinicians with pop-ups or prevent misordering using order sets, hiding tests, or other methods. This improves patient safety by reducing the need for repeat venipuncture and ensuring optimal turnaround time for the correct test. These interventions often also decrease costs because many nonmolecular tests are less expensive than the molecular counterpart, for example, activated protein C resistance testing is less expensive than factor V Leiden PCR. In addition, once the test order is discovered to be incorrect, as in the Vitamin D example above, the cost of testing has already been incurred, and additional cost for the appropriate test must subsequently be incurred.
- *Automatic alerts in situations for which testing might be unnecessarily duplicative,* including simultaneous orders for blood cultures, cardiac troponin levels, lactic acid, reference send-out tests, and others. This may also be used to stop duplicate test orders (13).
- *Time-sensitive automatic stop orders* for specified daily laboratory test draws, such as daily complete blood counts, daily basic metabolic panels, and similar orders.
- *Provider feedback* regarding provider ordering patterns in a collegial and nonblaming environ-

ment is another method used to influence appropriate testing behavior. The ability to fairly compare ordering patterns between peers is a powerful tool to standardize test utilization (14).

Strong interventions. Strong interventions are designed to eliminate unnecessary and unintended laboratory testing. Removal of obsolete or antiquated tests from the laboratory formula is one effective approach that is frequently implemented for nongenetic tests. Other forms of strong interventions include privileging to specialists, implementing hard stops in CPOE (e.g., duplicate testing rules), and using diagnostic management teams to guide a provider to the most effective testing plan. Some examples include:

- *Establishing a laboratory formulary.* A wide spectrum of appropriate clinical laboratory tests is available for use on hospitalized and ambulatory patients. However, given the rapid growth of tests available to today's clinicians, providers often cannot keep up with advances in laboratory medicine or new testing strategies or algorithms. Given the huge number of tests available, the creation of a laboratory formulary is critical for ensuring appropriate laboratory utilization. In addition to providing clinicians with a concise list of appropriate laboratory tests to ensure quality and safety, the formulary assists in ensuring (a) the right test is ordered at the right time; (b) tests on the formulary have appropriate turnaround times; (c) identification of tests requiring consultation before ordering, such as complex genetic tests; (d) applicable collection instructions are provided to ensure specimen integrity; and (e) recommended uses for individual tests.
- *Hard stops in CPOE.* Different than a pop-up, hard stops give an alert that a specific test cannot be ordered under certain criteria, such as duplication or requirement for privileging to

specific providers. It is important to institute an escalation strategy for one-off cases that require exception handling.

- *Requirement for higher-level approval.* This strategy is often reserved for high-resource and complex testing for which the risk of misordering is high (6). The most common examples are genetic testing for inherited diseases and cancer genomic profiling. Considerations for review include assessing the correct order, appropriate and documented medical necessity; reviewing the best technique and performing laboratory; and obtaining prior authorization. This intervention requires dedicated resources and expertise in the clinical area, and as such, a separate document outlining the appropriate elements of a case management program can be referenced.

Monitoring and tracking using accurate data

Measurement is critical to identify opportunities for improvement and assess the impact of interventional efforts. Therefore, an effective laboratory stewardship program requires the accurate extraction and analysis of data. Ideally, stewardship programs monitor:

- Appropriateness of laboratory test orders.
- Retrieval of test results.
- Appropriateness of test interpretation.
- Impact of each stewardship intervention.

Extraction and monitoring. The interventions previously discussed require data on the ordering patterns of clinicians and how those patterns compare with benchmarks and peer behavior. It is imperative that our clinical partners have confidence in the accuracy and validity of the data we share with them regarding their ordering patterns. Otherwise, they will be less likely to consider changing their behavior. However, generating

these data and converting them into actionable information can be challenging. Part of the challenge stems from the institution's laboratory information system. Some institutions choose an enterprise-level electronic medical record system that has a built-in laboratory information system module, whereas others choose a separate vendor for its laboratory information system and build and maintain an interface between the 2. The latter arrangement adds a level of complexity that should be investigated before creating a data extraction plan.

Data extraction can also be complicated by personnel limitations on who can extract the data. An electronic medical record vendor may have extensive certification requirements for individuals wishing to perform queries of the database(s). Some pathology departments have their own informatics division that can manage the data extraction process, whereas other pathology departments depend on their institutional information technology department for such support. In the latter situation, laboratory leaders may need to galvanize the institutional leadership commitment discussed earlier in this document to ensure data extraction needs are prioritized among the many competing institutional information technology demands.

Another challenge to anticipate and manage is the sheer volume of data that will be available through an electronic medical record/laboratory information system database. Prudent project management suggests the coordinating body take a narrow focus at the beginning of the initiative—for example, extracting data for a single test from a particular hospital unit ordered by a specific clinician cluster—and build more complex and insightful queries through a series of iterative cycles.

Information on these ordering patterns is only valuable if it can be provided in real time and on a regular ongoing basis. Therefore, it is important that the successful queries be converted into reports that can be automated and pushed out to

key stakeholders in a timely fashion. It is best to clarify beforehand whether there will be different staff who will be writing the queries vs building the reports. It is also important to build the most user-friendly report design to increase the likelihood that they will be read by the key stakeholders.

Review and improve

Once the right governance is established, an effective laboratory stewardship program will need to establish how the leadership committee will solicit and vet opportunities. The initial candidates for interventions should not reflect individual pet projects but rather should be based on institutional priorities. Therefore, it is important that the leadership committee establish prioritization criteria. To do so, the committee may want to consider opportunities identified through the *Choosing Wisely* programs and other published research, or from internal data related to patient safety incidents. It is unlikely that the committee will struggle with too few opportunities. A more likely challenge will be in prioritizing many worthwhile improvement opportunities. Data will play a key role in helping the committee determine where the greatest opportunities lie. Prioritizing will also help ensure project teams commissioned by the leadership committee have the necessary resources and focus to deliver the desired benefits expeditiously.

The committee will also need to establish expectations regarding updating the project team's progress and barriers. The committee should leverage its senior medical and administrative membership to address organizational issues and structures impeding the project team's efforts. The committee's expectations should also include who

will monitor data after an intervention implementation to assess the degree of success and future actions. Over the long term, a laboratory stewardship program should take a strategic approach for identifying opportunities that align with institutional and departmental needs. Otherwise, a reactive approach will take root and the project teams' hard work will be diluted by fragmented focus and competing demands.

CONCLUSION

Appropriate stewardship of laboratory resources improves patient care by ensuring the correct tests are performed at the appropriate time. Excessive and unnecessary tests are not only costly but also, more importantly, may result in harm, which is a quality and patient safety issue. Evidence-based, patient-centered efforts to improve test utilization are justified, beyond being cost-effective, because they increase patient safety and satisfaction. Groups that undertake and sustain test stewardship programs should be recognized and rewarded. It is the intention of the National Committee for Laboratory Stewardship to devise a tiered recognition program and provide certificates of recognition, depending on the degree of participation. The rewards, we believe, will follow naturally through the promotion of a culture of quality and continuous improvement, possibly improved Hospital Consumer Assessment of Healthcare Providers and Systems scores, and more streamlined reimbursement with fewer denials, as payers recognize the ongoing and active engagement of institutions in laboratory stewardship.

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