Operational Aspects of a Clinical Decision Support Program

Gary W. Procop, MD, MS[a,*], Allison L. Weathers, MD, FAAN[b], Anita J. Reddy, MD[c]

KEYWORDS

• Laboratory stewardship • Best practice focused • Decision support • Collaborative • Non-intrusive • Functional • Measurable outcomes

KEY POINTS

- Leadership, organization, governance, and support are needed for success.
- Project management improves project completion and time to completion.
- Best practices in care delivery should be the driving force; cost-savings will naturally follow.
- Hard stop clinical decision support tools (CDSTs) are more effective than soft stop CDSTs, but a process to support provider overrides of an electronic blockage should be in place.
- Report generation and outcome measures demonstrate the effectiveness of interventions and are important to continue to foster support.

INTRODUCTION

A clinical decision support program does not usually exist as a stand-alone program. The request for the implementation of clinical decision support is often directed to the individuals overseeing the hospital and/or laboratory informatics services, but requests pertaining to laboratory testing may be directed to the staff of the laboratory. In many instances, these requests are from clinicians who are frustrated by the performance of the hospital or laboratory information system, respectively.[1] Alternatively, a conscientious provider, pathologist or laboratorian may notice over-, under-, or misutilized tests, and seek to use tools within the clinical information system to implement

Disclosure Statement: No disclosures or conflicts of interest.
[a] Molecular Microbiology, Mycology, Parasitology and Virology Laboratories, Enterprise Laboratory Stewardship Committee, Department of Medical Operations, Cleveland Clinic Lerner College of Medicine, Cleveland Clinic, 9500 Euclid Avenue/ LL2-131, Cleveland, OH 44195, USA; [b] Cleveland Clinic Lerner College of Medicine, Cleveland Clinic, 25900 Science Park Drive, AC220 Beechwood, OH 44122, USA; [c] Respiratory Institute, Cleveland Clinic Lerner College of Medicine, Cleveland Clinic, 9500 Euclid Avenue/ G6-156, Cleveland, OH 44195, USA
* Cleveland Clinic, 9500 Euclid Avenue/ LL2-131, Cleveland, OH 44195.
E-mail address: procopg@ccf.org

Clin Lab Med 39 (2019) 215–229
https://doi.org/10.1016/j.cll.2019.01.002 **labmed.theclinics.com**

some type of intervention. In such instances, the leadership of the informatics team, by default, assumes the governance responsibility for implementation and maintenance of these test utilization measures. The scenario described above is highly reliant on self-directed individuals, usually addresses a single problem rather than developing queue of process improvement initiatives, and may founder unless the individual desiring the change has patience, tenacity, sufficient experience, and/or authority to bring the project to a successful conclusion.

The scenario described above is reactive rather than proactive. One of the limitations with this approach is that agreement with the proposed intervention may not have been vetted with all medical staff, or with a group (eg, the laboratory stewardship committee) that has been charged to oversee such implementations. Another common challenge to this reactive approach is that the leadership of informatics, if not particularly dedicated to laboratory stewardship, may implement the requested intervention and then move on to the next task in their queue (eg, system upgrade, interface connections). Although the intervention was made, a determination of the efficacy of the intervention was not performed. This is one of the most significant shortcomings of this approach, because the lack of outcome measures deprives the academic community of evidence for or against such interventions and fails to inform hospital informatics and hospital operations regarding the return on the investment of such interventions, which do incur a cost.

In this article, we propose a collaborative effort between members of Pathology and Laboratory Medicine, clinical service representatives, hospital and laboratory informatics, and administration, as a means to optimize the use of clinical decision support tools (CDSTs) in laboratory stewardship. This approach has also been proposed by others.[2,3]

RECEPTIVENESS

Clinical decision support tools are often viewed as annoyances and, at worse, as impediments to clinical care delivery. The non-judicious use of CDSTs and poor governance of a clinical decision support program may justify such a characterization.[4] Ergo, it is critical that these tools are not implemented in a reactive or haphazard manner. Rather, these should be implemented after thorough consideration as to how these will affect clinical care delivery and how the use of such a tool will improve clinical care. As denoted above, it is the opinion of these authors that these decisions are best made in the context of a laboratory stewardship or similar oversight committee, which has appropriate representation from the laboratory, clinical services, and informatics.

Once a challenge has been identified for which a CDST is recommended, then the receptiveness of the individuals who will be affected by this intervention should be assessed, as well as that of hospital leadership.[2,3] It is best to review the proposal with hospital leadership to assure support before using resources to build and test the recommended intervention. If hospital leadership is not in agreement, then the leaders of the laboratory stewardship committee should meet with them to discuss the reasons for the intervention, the estimate of the impact on clinical services, and an estimate on the impact of the intervention (eg, decreased unnecessary phlebotomy).

If the hospital leadership is supportive of the intervention, then it is important to assess the receptiveness of individuals who will be affected by the intervention (eg, nurses). If the composition of the laboratory stewardship committee is broad, then there should be a sense of the receptiveness, because someone on the committee is from or associated with the affected area. If there is not someone from the area on the standing committee, then ad hoc members may be added for particular

projects. This is an effective way to approach issues when expertise on the committee is lacking.[3]

If hospital leadership is not supportive, then perhaps additional data may be needed. A pilot project could be proposed or the project in question may have to be deferred or abandoned. It is important to recognize that all projects, even very sound projects, will not always be supported. It is important to not become discouraged by a lack of support. In such instances, it is important to reflect on the mission and recent important developments within the health system. Tailoring projects that align with the overall mission of the health system is a strategy to achieve support. For example, if a new cancer center is being constructed, then the use of CDSTs that assists oncologists in chemotherapy selection and prevent mistakes in dosing would likely be embraced.

GOVERNANCE

The PLUGS National Committee for Laboratory Stewardship has listed the key elements of governance as leadership commitment, accountability to a high-level medical executive, committees and subcommittees, laboratory experience, and other key support and networking.[2] Although there is not disagreement with these elements, the Clinical Laboratory Standards Institute's GP49 document, *Developing and Managing a Medical (Test) Utilization Management Program*, reminds us that one size does not fit all with respect to the size, management, and overseeing of test utilization initiatives, and that not having all elements in place should not deter utilization improvement efforts.[3] However, as committees grow beyond the size of one to a few individuals interested in, and performing, test utilization projects, then the governance of the group should become more formalized. This is also important for gaining legitimacy within the institution. The committee should have a Chair or Co-Chairs, who have enough experience and credibility at the institution to be able to promote the initiatives developed by the committee. The committee should also develop a reporting structure. These types of committees often report to Quality or Medical Operations, which go by various but similar names at different institutions. In many instances, there will be a dotted line reporting to Pathology and Laboratory Medicine, because this department is responsible for pathology and laboratory services within the health system.

The Chair may either be a pathologist or a clinician. A strong internal motivation and a dedication to optimizing laboratory utilization is more important than the particular training of the individual holding the position of Chair.

COLLABORATION WITH HOSPITAL INFORMATICS

Hospital information systems are effective vehicles for the implementation of a variety of interventions; a representative from the hospital informatics team should be part of the multidisciplinary laboratory stewardship team.[5,6] Although the focus of this work is on CDSTs, there are several methods or tools that may be used in conjunction with the hospital informatics team to improve laboratory stewardship. The applications, regardless of the complexity subsequently described, are usually maintained by the hospital information team. The CDSTs may come as a predesigned portion of the hospital information system, may be predesigned but require some customization, or may be a fully customized intervention. These 3 options represent increasing levels of complexity for implementation and maintenance. Hospitals with small and less-experienced informatics teams should be able to use the predesigned CDSTs that accompany hospital information systems. A "best practice alert" or some other types

of notification are examples of these types of simple CDSTs. This type of alert may notify practitioners that a test order is a duplicate order, for example, customizing the activation of this type through minor modifications of the contents represents the next level of complexity. An example would be modifying an alert for a renally excreted drug so that it would only be activated if the drug order was placed for a patient with an estimated glomerular filtration rate below a certain threshold. Such an alert would be a tailored modification of an alert that otherwise would always alert the provider when that drug was being prescribed. This would be a mechanism to decrease the number of alerts seen by providers, and the modification makes it so that it is only activated when actually needed (ie, when the patient has decreased renal function). Finally, custom programming is required when desired intervention applications are not in the portfolio of the informatics vendor. The informatics team at the Cleveland Clinic has created or modified most of the interventions presented in this article in an effort to support our laboratory stewardship program. These include embedding data from recent laboratory tests within same-day duplicate test notifications, creating CDSTs that are activated for some providers but not others (ie, electronic privileging), creating alerts that are activated based on length of hospitalization, and creating alerts the fire based on the cost of the test being selected.[7–11]

Given these complexities, it has been our consistent recommendation to foster a strong and collaborative working relationship between the leadership of the laboratory stewardship committee and hospital informatics. This can be done in a variety of ways. A lead member of the hospital informatics team is a member for our laboratory stewardship committee. In this manner, she participates actively in the conversation and can experience firsthand the needs of the group or of the presenting provider. In addition, there is a standing meeting at our institution for the express purpose of monitoring the progress of projects that involve both pathology/laboratory medicine and hospital informatics. Although much of the meeting is devoted to the routine maintenance of the laboratory testing in a major medical center (ie, new test implementation, electronic public health reporting), a portion is devoted to tracking the building and implementation of test utilization initiatives.

PROJECT MANAGEMENT

There are several supporting elements for a test utilization program, the presence of which increase the likelihood of success. The importance of informatics support has already been emphasized. Important components of a successful test utilization or laboratory stewardship program includes active participation with genetic counselors, which is not covered in this article, project management, and the development and reporting of outcome measures, which is discussed below.

It will likely be difficult to convince hospital leadership to hire an individual to support a proposed laboratory stewardship program. Sometimes, as was the case in our institution, we needed to demonstrate effectiveness and cost-savings that could contribute toward the compensation of the project manager before being assigned such a resource. A full-time project manager is likely not needed, except, perhaps, in the largest and most robust of programs. Rather, the project manager could be a shared resource. Optimally, the task would be taken up by an individual who has signified or demonstrated interest in this area or a similar area, such as quality improvement or medical operations. Importantly, as laboratory stewardship management becomes another duty of that individual, in addition to the reason for their primary hire, it is important that they recognize that these are not secondary or optional

assignments. To this end, there should be regular meetings between the project manager and the committee Chair(s) to review the progress of ongoing projects, discuss new projects, set the agenda of upcoming meetings, and any other miscellaneous work of the committee.

The committee Chair(s) is likely a busy physician, with limited time to perform all the necessary tasks for the organization and optimal management of the committee. Project managers are extremely effective in this manner.[3] They schedule meetings, assist with the formation and distribution of the meeting agenda, take and distribute minutes of meetings, and, possibly most importantly, interact with those involved regarding the progress on ongoing projects. The gentle pressure applied through regular and tactful prompting of responsible individuals is particularly important to move projects forward. Many projects will founder without this active management of the individual projects of the committee. Therefore, a project manager is extremely important, especially as the number of ongoing projects increases, because the Chair(s) will have limited capacity to manage these tasks in addition to his/her daily obligations.

OUTCOME MEASURES

It is not uncommon for individual, or groups of, physicians to make requests of the informatics department of a hospital to make changes, such as implementing CDS, that they believe will facilitate care delivery. It is also common that these changes are implemented without any follow-up with regard to the impact of the changes made. The use of CDSTs in modern medicine can irritate providers and hinder care delivery, even when thoughtfully vetted and implemented. Inconsiderate implementation of CDSTs without appropriate discovery, acquisition of clinical champions for the change, appropriate communications, and adequate ability to make rapid modifications should interventions function poorly is a recipe for failure. In addition to appropriately addressing the topics denoted above, the development of outcome reports is important.

It is important that someone or multiple individuals on the team have some expertise with data analysis, basic statistics, and report generation. The assessments of the impacts of test utilization initiatives should be factual with no inflation of the degree or meaningfulness of the impact. This inflation may not be intentional. For example, it is a common novice mistake to use charge information instead of actual cost information when determining the savings associated with an intervention. Charges represent the amount a provider would like to get paid for a service. The amount does not represent the cost of the service and rarely represents the amount actually paid for the service, given the variety of different payers. There is an excellent section Kent Lewandrowski's article, "Integrating Decision Support into a Laboratory Utilization Management Program,") in the Clinical and Laboratory Standards Institute's Developing and Managing a Medical Laboratory (Test) Utilization Management Program, which is recommended.[3]

Each of the interventions we describe below is associated with a unique monthly report that records the activity of each intervention. These reports are subsequently submitted to a dedicated financial officer who reviews and edits the reports for accuracy (ie, report scrubbing). Thereafter, a financial analysis is performed based on the costing and timing study data for each test for which there is a CDS intervention. A cost-savings report is then generated based on materials and labor savings. We have not sought to capture savings associated with stopping unnecessary phlebotomies or the stopping of other untoward events associated with poor test utilization.

These reports are collated annually to produce an annual report that demonstrates the efficacy of the interventions in our health care system (**Table 1**). Such a report is

Table 1
Project summary table

Project	Tests Avoided 2017	Cost-Savings 2017 ($)	Tests Avoided since Inception	Cost-Saving since Inception ($)	Lessons Learned
Best Practice Alert for Same-Day Duplicate Tests	N/A	N/A	N/A	N/A	A simple alert showed promise for highly specialized tests ordered by specialists, but was largely ignored for commonly ordered tests.
Hard Stops for Same-Day Duplicate Tests	4563	54,516	33,949	522,622	Communication with medical staff is essential. Consider a tiered implementation, beginning with a limited number of tests. A workaround is necessary, should the blockaded test be needed.
Extended Hard Stops	13,140	71,718	37,974	205,075	Extended hard stop interventions may help with *C. difficile* rates, and may provide insights into ordering patterns for the management of diabetes mellitus (eg, hemoglobin A1c frequencies).
Soft Stops for Same-Day Duplicate Tests	5507	41,258	26,767	211,800	The ability to override an electronic intervention at the computer order entry terminal will result in decreased compliance with the intervention compared with a hard stop intervention. This intervention, although less effective, still stops approximately half of the duplicate orders, and may be the only solution for settings unwilling to implement a hard stop.

Restricted Testing (Genetic Test Privileging)	57	67,262	565	1,094,659	Building and maintaining a list of privileged providers is an ongoing task. A workaround is necessary, should the blockaded test be needed.
Expensive Test Notifications	131	186,849	654	974,683	Chromosomal microarray studies and other molecular hematopathology tests constituted a large percentage of the tests averted by this intervention.
Three-Day Alerts for Stool Culture/Parasitologic Exams for Patients Hospitalized >3 Days	312	10,545	857	27,497	This intervention demonstrate the feasibility of implementing a classic intervention using an electronic format, which previously required intervention by a human.
Duplicate Constitutional Genetic Testing	350	45,183	940	132,743	Some requests for repeat testing were found to be valid, because exclusion codes were inadvertently not included in the programming (ie, codes to address QNS specimens, broken tubes)
Total	24,060	477,331	135,655	3,169,079	In addition to a substantial cost-savings, false-positive test results were avoided by not testing low-prevalence populations, which improves patient care, and the patient experience was enhanced by decreasing excessive phlebotomies and decreasing the cost of care.

The Best Practice Alert was used as a pilot. Although the number of tests averted was collected for pre-/post-comparison studies, this intervention was not retained.

Abbreviations: N/A, not applicable; QNS, quantity not sufficient for testing.

useful in a variety of ways. Foremost, the report should be shared with the leadership, who have supported the initiatives, and team members, who have brought the interventions to completion. The former demonstrates the competency of the group, which builds trust. The development of a reputation of a team that works for positive change within the institution in a collaborative way and accomplishes tasks will help secure future support. Sharing the annual report with team members provides an opportunity to genuinely thank them for their work and to demonstrate the larger view of the initiative to some who may have only seen their part of it. As more and more initiatives are added to the laboratory stewardship portfolio, analogies, and extrapolations can be made from previous experiences to new projects, which will facilitate implementation. Finally, although improvements in quality and patient care are the primary drivers of laboratory stewardship initiatives, the associated cost-savings are also important and should be reported. This savings should be collated for the projects implemented within the year, as well as year over year. Even initiatives with small savings add up over time. These cost-savings are appreciated by leadership and can also be used to garner support for new initiatives, and may be used to justify a new position (eg, project manager or genetics counselor).

EXAMPLES AND ASSOCIATED STUDIES

The Test Utilization Committee of the Cleveland Clinic, now re-branded as the laboratory stewardship committee, has been using CDSTs since 2011. Brief explanations and our experience with 8 CDS interventions, and any associated studies that have resulted from these projects follow.

Best Practice Alert for Same-Day Duplicate Tests

One of our earliest interventions at the Cleveland Clinic was using Best Practice Alerts or simple "Pop-up" notification for same-day duplicate testing. We first initiated this to study the effect of the intervention, with quantitative cytomegalovirus (CMV) testing and quantitative Epstein-Barr virus (EBV) testing. We selected these tests, because, through evidence, experience, and consensus between Infectious Diseases and Laboratory Medicine leadership, it was decided that same-day repeat testing for these viruses was not warranted.

The alert that was designed simply notified the provider that a same-day duplicate test was being ordered, and relied on the ordering provider to discontinue the order. We studied the same-day duplicate ordering of this test for 3 months before and 3 months after the intervention. To our pleasant surprise, there was a significant decrease in the number of duplicate orders placed after the intervention (data not shown; $P<.001$). We repeated the intervention in the same manner for same-day duplicate *Clostridium difficile* testing. To our unpleasant surprise, the results were opposite those we found for quantitative CMV and EBV testing. There was essentially no impact of the intervention for this test (data not shown; $P = .21$).

We have hypothesized on these stark differences. We believe, but did not definitively prove, that because quantitative CMV and EBV testing is usually only performed on a select group of patients by a select group of providers that the alert was read by, agreed to, and acted on appropriately. Conversely, because every intern, resident, and fellow in their busy day commonly consider the possibility of *C difficile*-associated diarrhea, the alert was likely ignored or, to use the colloquial "clicked through," and the duplicate order was placed. The reason for these differences remains conjecture, but we have subsequently performed timing studies regarding when the next order is placed after an electronic blockade, and have demonstrated that it is highly unlikely

that the provider actually read the order (data not shown). Interestingly, Swimley and colleagues[12] demonstrated similar findings for *C difficile* testing, finding that, although some providers adhered to recommendations from the alert, the alert was often overridden resulting in no overall effect on *C difficile* testing rates.

These initiatives suggest that simple Best Practice Alerts or notifications may be used to curtail certain duplicate tests, possibly highly specialized tests ordered by highly specialized providers. These alerts are likely not regularly read and are less effective for commonly used tests; this behavior has been described for similar pharmacy-associated alerts.[13] This initiative provided our test utilization committee with the data needed to convince leadership to support the development of a hard stop for certain same-day duplicate tests.

Hard Stops for Same-Day Duplicate Tests

The introduction of the Same-Day Hard Stop CDST to avoid unnecessary same-day duplicate testing was undertaken in a tiered manner. This measured implementation was undertaken because this type of intervention (ie, a hard stop CDST) had never been used with providers at our institution. The leadership of our institution also required that we develop a mechanism by which the provider could obtain the test if they truly thought the duplicate test was medically necessary (ie, a bypass mechanism). We devised a process by which the ordering provider could work with our Laboratory Client Services, which is staffed 24/7, to place the desired order and effectively override the electronic blockade.

We began with a small number of tests that the test utilization committee agreed were not needed more than once per day. The list of 13 tests that were to be included in the Same-Day Hard Stop CDS trial was first shared with and approved by institutional leadership, and then shared with all medical staff via the hospital computer system. An opportunity for feedback concerning the tests on the list, as well as the initiative itself, was offered. One provider requested one of the tests to be removed, as he reported that, although rarely, he occasionally needed that particular test more than once per day in certain clinical scenarios. His request was granted, which reflected the philosophy of the test utilization committee of working to find areas of agreement and minimize academic arguments to move projects forward.

The Same-Day Hard Stop CDS was implemented for the 12 remaining tests, and to the surprise of many the implementation of the intervention was uneventful; requests to override the intervention, all of which were granted, were minimal. Therefore, the second tier of the rollout proceeded promptly, which included 77 additional tests; the addition of these tests was similarly uneventful. Finally, for the full-scale rollout, the physicians on the test utilization committee reviewed all tests on the test menu to determine which met the criteria of not being needed more than once per day. Only those for which there was consensus were targeted for inclusion. Over 1200 tests were included for the final phase of implementation of the Same-Day Hard Stop intervention.

Not surprisingly, there were a small number of instances wherein the subtleties of test use was not considered by the test utilization committee members. This occurred only 6 times and, in each instance, the provider requesting that a test be removed from the Same-Day Hard Stop list gave a valid reason. In addition, because of the excellent working relationship between the committee and the members of the hospital information technology group, the tests were able to be removed promptly (ie, within 24 hours). Feedback to the provider that their request had been heard and granted, and the test in question had been removed, helped team building with our clinical colleagues.

The details of the first 2 years of the Same-Day Hard Stop CDS intervention have been described previously.[9] Particularly interesting in this study was the documentation of the

number of additional attempts to place the order after the electronic blockade was active, the language of which clearly stated that the provider needed to call Laboratory Client Services if they wanted to override the electronic blockade. This was interpreted as indirect evidence that the alert was not being read. In addition, the authors reviewed all the notifications of patient adverse events after the first year of implementation, and discovered no untoward events associated with this intervention. This finding, in conjunction with the fact that the provider was always given the right to override the intervention, brought the authors to the conclusion that this intervention was safe.

We reported that 11,790 unnecessary same-day duplicate test orders were prevented in the 2 years of this intervention, which saved the institution US$183,586 in materials and labor.[9] From 2011, when this intervention was implemented, through 2017, 33,949 unnecessary same-day duplicate test orders were stopped, saving the institution $522,622, and saving the patients a lot of unnecessary blood loss and pain.

Similarly, Dalal and colleagues[14] used a hard stop CDST to stop Free T3 (FT3) and Free T4 (FT4) orders placed on patients who had normal thyroid-stimulating hormone (TSH) levels. They reported a decrease in the ratio of FT4:TSH orders of 35.2% and a decreased FT3:TSH ratio of 55.2%. Furthermore, they found that the percentage of FT4 ordered due to abnormal TSH results increased by 126.1%. This intervention demonstrated a decrease in unnecessary testing, while increasing the appropriate use of the test. Hard stop CDSTs also have significant applications in the pharmacy domain to prevent dose-related patient safety issues.[15,16]

Extended Hard Stops

The success of the Same-Day Hard Stop CDST resulted in the recognition that some tests could be stopped for longer time periods. We initially examined an Extended Hard Stop CDST for hemoglobin A1c, hepatitis C genotyping, and *C difficile* testing. Hemoglobin A1c testing was limited to 30 days; it was recognized that this could be extended beyond 30 days, but, as previously stated, we favored achieving consensus and implementing the intervention, rather than risking a stalemate secondary to disagreements. Hepatitis C genotyping was slightly more controversial because of the recognized possibility of reinfection, but was retained because the same override mechanism as described above was in place. *C difficile* polymerase chain reaction testing was limited to one per week, and submitting stools for a test of cure was discouraged. This latter intervention has been useful in decreasing false-positives due to testing in a low-prevalence population (ie, individuals who have already tested negative). Others have also demonstrated the efficacy of using CDSTs as one of the tools to control inappropriate testing for *C difficile.*[17,18]

Subsequently, 30-day extended hard stops were added for 2 molecular hematopathology assays. Unlike the Same-Day Hard Stop CDST database, in which tests could be added or removed relatively easily, the addition of new tests for this intervention required an entirely new informatics build, which has significantly limited the ability to add new tests to this intervention. The Extended Hard Stop CDST was implemented at our institution in 2014. The process to override the electronic blockade from this CDST is the same as that described above. Since the implementation of the Extended Hard Stop CDST, this intervention has stopped 37,974 unnecessary tests and saved the institution $205,075.

Soft Stops for Same-Day Duplicate Tests

It was requested that we develop an intervention to address same-day duplicate testing at the regional hospitals of the Cleveland Clinic health system. There were several challenges that made the implementation of the Same-Day Hard Stop CDST

unfeasible in the regional hospitals at that time. The intervention design consisted of an alert similar in configuration to that of the hard stop CDST, except that the ordering provider did not have to call Laboratory Client Services to override the intervention. The provider could simply bypass the electronic blockade at the point of computerized order entry and proceed with placing the order.

After implementation, we received and reviewed the monthly reports for the Soft Stop for Same-Day Duplicates at the regional hospitals. It became evident that the efficacy of the Soft Stop intervention was substantially less effective than the Same-Day Hard Stop CDST at the main campus. Therefore, we studied this intervention after a year and performed a comparison between the Same-Day Hard Stop CDST. This comparison is informative, because all of the tests that are on the Same-Day Soft Stop list are also on the Same-Day Hard Stop list. The Same-Day Hard Stop CDST was found to be 92.3% effective with respect to stopping the initially blockaded tests, whereas the Same-Day Soft Stop CDST was only 42.6% effective during the year in which both CDSTs were studied.[7] The cost-saving associated with the Same-Day Hard Stop CDST was $16.08/initial alert activation, whereas for the Same-Day Soft Stop CDST the saving was only $3.52/initial alert activation. These data demonstrated the superior efficacy and cost-savings associated with the Same-Day Hard Stop CDST compared with the Same-Day Soft Stop CDST. However, as noted above, there may be local issues that preclude the use of a hard stop CDST, so a soft stop may be the only option, which is better than no intervention.

The Soft Stop CDST for same-day duplicate tests has been in operation in our regional hospitals since 2013. It has stopped 26,767 unnecessary same-day duplicate orders and saved the institution $211,800.

Restricted Testing (Genetic Test Privileging)

Two initiatives were undertaken at the Cleveland Clinic to assure the appropriateness of molecular genetic test orders. These included the employment of a laboratory-based genetics counselor and the implementation of a Restricted Use CDST. Only the latter is discussed here, given the focus of this article, but the efficacy of both have been described.[10]

Our Restricted Use CDST intervention sought to limit molecular genetic testing to those individuals who used this testing routinely in their practice (ie, deemed users). We cited the precedent of limiting the use of certain therapeutic agents to certain groups of physicians (eg, certain antibiotics are restricted to infectious diseases practitioners and chemotherapy is largely limited to oncologists). Similarly, we explained to the leadership the great complexity of many of these assays, as well as the subtleties of these tests, which, if not appreciated during interpretation, pose a real possibility of misinterpretation and possible patient harm. These proved effective points to receive approval by senior leadership to move forward with this program.

Individuals who have received the Restricted Use CDST alert received language in the alert that notified them that if they believed the patient needed the molecular genetic test, then it could be obtained through a consultation with Medical Genetics or other deemed users. The implementation, apart from the construction of the deemed users list, was uneventful. Subsequently, we performed a focused review of patients for whom the Restricted Use CDST was activated. Three-quarters of inpatients for whom the Restricted Use CDST was activated did not receive a consultation, whereas for 25% a Medical Genetics consultation was placed. In the outpatient setting, the split was closer to 50:50. These data suggest that from 50% to 75% of the orders that were originally being placed by individuals not deemed to be experts in that area of testing (ie, not a deemed user) were not needed (ie, the ordering provider who was blocked

did not obtain a consult). Conversely, we are pleased that between 25% and 50% of patients who may not have been scheduled to see an expert in the field necessary had a consult placed. The restricted use initiative was implemented in 2011, and although only 565 have been stopped by the Restricted Use CDST, these usually expensive tests have resulted in a cost-savings of $1,094,659.

A full assessment of CDS with respect to the diagnosis and management of patient with a genetic component to their health care issue is beyond the scope of this text. This field, however, is extensive. In addition to stopping unnecessary genetic testing, CDS has been used to more effectively guide providers in the optimal diagnosis and treatment of patients with a wide variety of diseases.[19–21]

Expensive Test Notifications

The listing of the cost of testing as a deterrent of excessive testing has been reviewed by several groups and the results are mixed. In our intervention, we decided to intervene for only the high-cost tests. We devised an alert that notified the provider that the test being ordered had a cost of $\geq$$1000. This was initially done in $1000 increments and then the range was expanded to include tests that cost $\geq$$500. The language in the alert notified the provider that the charges of the tests exceed the cost and that charges not covered by insurance would be the responsibility of the patient. The intervention was not a hard stop, so the provider could bypass it and continue to place the order at the computer terminal without calling the laboratory.

We studied the efficacy of the Expensive Test CDST over a 3-year period.[11] The efficacy of this intervention was particularly interesting. If the absolute number of tests stopped by the Expensive Test CDST (ie, 654) was the indicator of success, then the intervention would be deemed ineffective, because only 12.5%, 12.9%, and 14.3% of the tests for which the CDST was activated were abandoned. However, if the cost-saving was the measure of the effectiveness of the intervention, then it would be considered successful, because the cost-savings for these 3 years was $696,007.

Sedrak and colleagues[22] undertook a randomized controlled trial examining the impact of displaying Medicare-allowable fees for inpatient tests. They found that displaying fees had no significant impact on overall clinician ordering behavior or associated fees. Schmidt and colleagues[23] also performed a randomized controlled trial to determine the impact of displaying the maximum Medicare reimbursement rate on test ordering behavior. This group, however, expanded the study to include both inpatients and outpatients, as well as different insurance categories (ie, government, commercial, and self-pay). They, like Sedrak, found that displaying this cost information had no impact on ordering behavior. Interestingly, they also assessed the charge awareness of residents and found that residents overestimated the charges of these tests. Horn and colleagues[24] studied the impact of the real-time cost display of the test commonly used by primary care physicians. In contrast to the previous 2 studies, they did find a significant relative decrease in 5 of the 21 tests for which the intervention was included. Considering that only 5 of the 21 tests were positively affected with respect to decreasing the ordering of laboratory tests, this group concluded that the real-time display of cost information could result in a modest reduction in laboratory testing.

Three-Day Alerts for Stool Culture/Parasitologic Examinations for Patients Hospitalized greater than 3 Days

There is a tenet in clinical microbiology that, for patients who have been hospitalized for greater than 3 days who develop diarrhea, that the diarrhea is not usually secondary to routine bacterial pathogens (ie, *Salmonella*, *Shigella*, *Campylobacter*, Enterohemorrhagic *E. coli*) or enteric parasites. Although there are recognized exceptions, for

most individuals routine stool cultures or stool polymerase chain reaction, and ova and parasite examinations, are discouraged if diarrhea develops after 3 days of hospitalization.

We developed a CDST that determined the length of hospitalization at the time of order entry for stool culture and/or ova and parasite examinations. If the hospitalization was $\geq$3 days, then a hard stop alert was activated and the order could not be placed electronically. Similar to the Same-Day Hard Stop, the provider could override the electronic blockade, if they called Laboratory Client Services. We performed a pre-/post-analysis evaluating the ordering patterns for these tests 11 months before and after the implementation. After this intervention, there was a 54.1% reduction in ova and parasite microscopic morphologic examination (P<.0001), a 22.6% reduction in the *Giardia* and *Cryptosporidium* enzyme immunoassay (P = .28), and a 49.1% reduction in stool cultures (P<.0001).[8,25]

The cost-saving associated with this intervention is small, with only 857 unnecessary tests stopped since the implementation in 2014, with a cost-savings of $27,497. This serves as a reminder that these programs are about implementing best practices, rather than solely for the purpose of reducing health care costs.

Duplicate Constitutional Genetic Testing

It is recommended that genetic tests are not duplicated unless there is a good reason (eg, phenotype/genotype mismatch or concern over an erroneous result).[26] However, repeat constitutional genetic testing is not uncommon. We believe that this, in part, may be because of the unawareness of the practitioner that the test had previously been ordered, similar to our experience with the same-day duplicate hard stops. To address this issue, we devised a Duplicate Constitutional Genetic Test CDST, which placed a hard stop on any duplicate orders for 42 unique constitutional molecular genetic tests. As with previous interventions, the same procedure was used (ie, calling Laboratory Client Services) to override the electronic blockage, if the provider decided that a repeat test was medically necessary.

We studied the impact and efficacy of Duplicate Constitutional Genetic Test CDST over 3 years.[27] During this timeframe the CDST blocked 793 individual constitutional molecular genetic test orders; override requests were received and granted by Laboratory Client Services for 10.5% of the electronically blocked tests. A medical records review by our laboratory-based genetics counselor demonstrated that 81.9% of these were justified requests. Unfortunately, during the construction of this intervention, exclusion codes were not included for tests that were rejected for insufficient quantity of specimen, broken tube, and so forth. This resulted in justified override requests and has been remedied. The Duplicate Constitutional Genetic Test CDS intervention, which was implemented in 2015, has stopped 940 unnecessary tests and resulted in a $98,597 cost-savings for our institution. Similarly, Krasowski and colleagues[5] included duplicate alert notification in their overall strategy to improve test utilization.

SUMMARY

Although there have been substantial advances made in applications available in clinical information systems, additional progress is needed because most of the interventions described in this article required customized programming.[28,29] We have demonstrated the challenges and opportunities of operationalizing CDSTs of laboratory stewardship to improve medical care in a tertiary care medical center and the associated regional hospitals in our health system. The interventions described, as well as one not covered, which prevents excessive blood cultures, have, in aggregate,

since their implementation, stopped 120,384 unnecessary tests and saved our institution $3,170,699.

Simple alerts are minimally effective and often not read because of alert fatigue and other factors. Hard stop CDSTs are more effective, but these must be used judiciously, so as to not interrupt care delivery. Furthermore, if these are used, a process by which the provider can bypass or override the alert should be developed. Current hospital information systems are lacking with respect to being able to provide advanced or custom CDSTs at present, so custom programming is necessary. Clinical decision support tools will remain a part of the hospital information system for the foreseeable future. When used carefully, these can assist in the appropriate delivery of care, while decreasing health care costs through the elimination of unnecessary testing and the sequelae thereof.

REFERENCES

1. Guo U, Chen L, Mehta PH. Electronic health record innovations: helping physicians - one less click at a time. Health Inf Manag 2017;46(3):140–4.
2. Dickerson JA, Fletcher AH, Procop G, et al. Transforming laboratory utilization review into laboratory stewardship: guidelines by the PLUGS National Committee for Laboratory Stewardship. J Appl Lab Med 2017;2(2):259–68.
3. Procop GW, Daley AT, Baron J, et al. GP49 developing and managing a medical laboratory (test) utilization management program. 1st edition. Wayne (PA): Clinical Laboratory Standards Institute; 2017.
4. Elwyn G, Scholl I, Tietbohl C, et al. "Many miles to go …": a systematic review of the implementation of patient decision support interventions into routine clinical practice. BMC Med Inform Decis Mak 2013;13(Suppl 2):S14.
5. Krasowski MD, Chudzik D, Dolezal A, et al. Promoting improved utilization of laboratory testing through changes in an electronic medical record: experience at an academic medical center. BMC Med Inform Decis Mak 2015;15:11.
6. Wilson ML. Decreasing inappropriate laboratory test utilization: controlling costs and improving quality of care. Am J Clin Pathol 2015;143(5):614–6.
7. Procop GW, Keating C, Stagno P, et al. Reducing duplicate testing: a comparison of two clinical decision support tools. Am J Clin Pathol 2015;143(5):623–6.
8. Procop GW, Nikolic D, Asamoto K, et al. Reply to Beal et al., 'The "3-Day Rule" for stool tests may not apply when using PCR panels. J Clin Microbiol 2018;56(4).
9. Procop GW, Yerian LM, Wyllie R, et al. Duplicate laboratory test reduction using a clinical decision support tool. Am J Clin Pathol 2014;141(5):718–23.
10. Riley JD, Procop GW, Kottke-Marchant K, et al. Improving molecular genetic test utilization through order restriction, test review, and guidance. J Mol Diagn 2015;17(3):225–9.
11. Riley JD, Stanley G, Wyllie R, et al. The impact of an electronic expensive test notification. Am J Clin Pathol 2018;149(6):530–5.
12. Swimley K, Olsen R, Long SW, et al. Failure of best practice alerts to affect *C. difficile* test utilization. Am J Clin Pathol 2018;150:S143–68.
13. Cho I, Lee Y, Lee JH, et al. Wide variation and patterns of physicians' responses to drug-drug interaction alerts. Int J Qual Health Care 2018. https://doi.org/10.1093/intqhc/mzy102.
14. Dalal S, Bhesania S, Silber S, et al. Use of electronic clinical decision support and hard stops to decrease unnecessary thyroid function testing. BMJ Qual Improv Rep 2017;6(1) [pii:u223041.w8346].

15. Grissinger M. Small effort, big payoff: automated maximum dose alerts with hard stops. P T 2016;41(2):82–128.
16. Martin DB, Kaemingk D, Frieze D, et al. Safe implementation of computerized provider order entry for adult oncology. Appl Clin Inform 2015;6(4):638–49.
17. Friedland AE, Brown S, Glick DR, et al. Use of computerized clinical decision support for diagnostic stewardship in *Clostridioides difficile* testing: an academic hospital quasi-experimental study. J Gen Intern Med 2018;34(1):31–2.
18. Madden GR, German Mesner I, Cox HL, et al. Reduced *Clostridium difficile* tests and laboratory-identified events with a computerized clinical decision support tool and financial incentive. Infect Control Hosp Epidemiol 2018;39(6):737–40.
19. Freimuth RR, Formea CM, Hoffman JM, et al. Implementing genomic clinical decision support for drug-based precision medicine. CPT Pharmacometrics Syst Pharmacol 2017;6(3):153–5.
20. Graham MM, James MT, Spertus JA. Decision support tools: realizing the potential to improve quality of care. Can J Cardiol 2018;34(7):821–6.
21. Hasnie AA, Kumbamu A, Safarova MS, et al. A clinical decision support tool for familial hypercholesterolemia based on physician input. Mayo Clin Proc Innov Qual Outcomes 2018;2(2):103–12.
22. Sedrak MS, Myers JS, Small DS, et al. Effect of a price transparency intervention in the electronic health record on clinician ordering of inpatient laboratory tests: the PRICE randomized clinical trial. JAMA Intern Med 2017;177(7):939–45.
23. Schmidt RL, Colbert-Getz JM, Milne CK, et al. Impact of laboratory charge display within the electronic health record across an entire academic medical center: results of a randomized controlled trial. Am J Clin Pathol 2017;148(6):513–22.
24. Horn DM, Koplan KE, Senese MD, et al. The impact of cost displays on primary care physician laboratory test ordering. J Gen Intern Med 2014;29(5):708–14.
25. Nikolic D, Richter SS, Asamoto K, et al. Implementation of a clinical decision support tool for stool cultures and parasitological studies in hospitalized patients. J Clin Microbiol 2017;55(12):3350–4.
26. Choosing wisely: smart decisions about genetic testing. 2015. Available at: http://www.choosingwisely.org/patient-resources/making-smart-decisions-about-genetic-testing/. Accessed October 12, 2018.
27. Riley JD, Stanley G, Wyllie R, et al. An electronic strategy to eliminate duplicate genetic testing using clinical decision support (Poster No. 152). CAP18 The Pathologists' Meeting. October 20–24, 2018. Chicago, IL.
28. Islam MM, Poly TN, Li YJ. Recent advancement of clinical information systems: opportunities and challenges. Yearb Med Inform 2018;27(1):83–90.
29. Rubinstein M, Hirsch R, Bandyopadhyay K, et al. Effectiveness of practices to support appropriate laboratory test utilization: a laboratory medicine best practices systematic review and meta-analysis. Am J Clin Pathol 2018;149(3):197–221.