

Improving the Value of Costly Genetic Reference Laboratory Testing With Active Utilization Management

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• **Context.**—Tests that are performed outside of the ordering institution, send-out tests, represent an area of risk to patients because of complexity associated with sending tests out. Risks related to send-out tests include increased number of handoffs, ordering the wrong or unnecessary test, specimen delays, data entry errors, preventable delays in reporting and acknowledging results, and excess financial liability. Many of the most expensive and most misunderstood tests are send-out genetic tests.

Objective.—To design and develop an active utilization management program to reduce the risk to patients and improve value of genetic send-out tests.

Design.—Send-out test requests that met defined criteria were reviewed by a rotating team of doctoral-level

Increasing health care costs affect everyone in the United States,¹ and laboratory tests are a part of the overall cost increase.² Laboratory tests are an important factor, because they are expensive and can lead to a cascade of other diagnostic tests and interventions, sometimes with equivocal impact on clinical outcome. Appropriate test utilization is an important part of patient care,³ and laboratory medicine staff can help ensure that testing is being performed in ways that maximize benefits for patients. The literature is relatively sparse in this area, especially in regard to pediatric send-out laboratory tests.

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consultants and a genetic counselor in a pediatric tertiary care center.

Results.—Two hundred fifty-one cases were reviewed during an 8-month period. After review, nearly one-quarter of genetic test requests were modified in the downward direction, saving a total of 2% of the entire send-out bill and 19% of the test requests under management. Ultimately, these savings were passed on to patients.

Conclusions.—Implementing an active utilization strategy for expensive send-out tests can be achieved with minimal technical resources and results in improved value of testing to patients.

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Liu et al⁴ reported a successful utilization intervention in the Calgary medical system that reduced the volume of send-out tests by 50%, simply by requiring written clinical justification for any test costing more than \$20 within 2 weeks or the test would be canceled. Although effective, this technique would likely be difficult to implement in many US hospital systems. Instead, send-out test utilization strategies that have been successfully implemented in the United States include the creation of formal utilization committees, pop-up reminders in computerized physician order entry, use of laboratory medicine or pathology residents to review test orders, and implementation of send-out formularies.^{5–7}

Currently, some of the most misunderstood, controversial, and expensive tests are molecular genetic tests. We began by focusing primarily on this group of referred tests. Although genetic tests hold great promise for improving individual patient care, spending on genetic testing in the United States is trending upward at a rate of about 20% per year and the trend is expected to continue.⁸ New tests are being developed at a rapid rate. However, the utility of many genetic tests has yet to be proven. The technology and prices evolve rapidly, making it difficult for busy clinicians to stay current with the costs and benefits of any particular genetic test.^{9,10} Specialists who are not geneticists often find themselves outside their comfort zone when ordering genetic tests, especially when a genetic disease is low on their differential diagnosis. A report by ARUP (Salt Lake City, Utah) showed one-third of genetic tests were ordered in error, and using a genetic counselor in the laboratory decreased errors in genetic test ordering.¹¹

There are other problems associated with genetic testing. Many genetic tests are routinely bundled as mutational analyses of large gene panels, even though only a small subset of these genes account for most instances of a given genetic disease. Bundling promotes overtesting and wasteful expense that can often be reduced with sequential testing strategies. In addition, obscure test names are difficult for clinicians and laboratory personnel to decipher and can lead to errors in test ordering.¹² To add to this complexity, turnaround time for many genetic tests is on the order of weeks to months. Long turnaround times increase the risk that test results are not retrieved, potentially leading to a delayed diagnosis or even misdiagnosis.¹³ All of these factors contribute to poor utilization of these expensive tests.

In this paper, we report strategies that we developed to increase the value of testing for our patients. It is our hope that some of these strategies can be used by other institutions to improve test utilization for larger groups of patients.

METHODS

Hospital Setting

Seattle Children's Hospital (Seattle, Washington) is a 250-bed care center and a teaching hospital associated with the University of Washington, School of Medicine. The Department of Laboratories performs more than 600 different clinical laboratory tests and processes more than 1 million requisitions per year. Tests not performed in-house account for an additional 40 000 tests per year, and these are sent to more than 100 reference laboratories across the country. Three full-time staff members are responsible for receiving, ordering, packaging, and processing results for all tests that are sent to other reference laboratories. The majority of these tests (82%) are sent to 2 major reference laboratories that have electronic interfaces for ordering and resulting tests.

Design

We designed a rotation of 3 doctoral-level faculty (2 clinical pathologists and 1 clinical chemist) and 1 genetic counselor to review send-out requests that met predefined criteria shown in Table 1. They include tests costing the laboratory more than \$1000, multiple genetic tests on the same requisition, requests to nonpreferred laboratories, requests to international laboratories, and tests that are normally performed in-house. The \$1000 cutoff was arbitrarily chosen because the volume of tests costing more than \$1000 was deemed to be manageable given the current resources dedicated to this study. Tests that met the criteria were labeled "UM," short for "utilization management," in the laboratory information system so that they were automatically flagged by the send-out processing team to review. The send-out team forwarded the request to the on-call consultant for adjudication. The on-call consultant used a time-out process that included the following: confirming that the correct test was ordered,¹⁴ checking that there was documentation of medical necessity, encouraging of insurance preauthorization, and suggesting sequential test strategies when appropriate.^{15,16} This process was achieved either by chart review or by direct discussion with the ordering provider. A template was created to e-mail the provider or guide verbal conversations. A brief chart review (less than 5 minutes) was performed with each case to determine if the intended test had been ordered, if the provider had documented medical necessity in the record, and if preauthorization had been attempted or was required. For example, many gene names are very similar and may differ by only one letter, so we checked for typographic errors. If a provider orders *SCA1* gene testing, we asked whether the provider intended to order *SCN1A* testing. If it was not clear that these steps were complete, a conversation was initiated with the provider using the standard communication template. Because we recognized the complexity of care in our

Table 1. Criteria for Tests Under Management

Tests costing the laboratory >\$1000
Multiple genetic tests on same requisition
Requests to send to nonpreferred laboratory
Requests to send to international laboratories
Requests to send tests that are performed in-house

pediatric population, we did not attempt to strictly determine medical necessity by asking if the testing would directly change patient management, and instead we asked only that the provider's rationale and discussion with the family be documented in the record. Ultimately, it was the ordering provider's decision to proceed, modify, or cancel the test.

Each case was documented in a Microsoft Access (Bellevue, Washington) database to ensure consistency in case adjudication. Time to review a case ranged from 5 minutes to 2 hours of consultant time, with an average time of 15 minutes. The most time-consuming step was identifying and reaching the appropriate care provider(s) to have the discussion. In more complex cases, conversations might also occur with the performing laboratory to get more information about a test, or arrange for sequential testing. All cases were adjudicated within a week of the order date. This was considered acceptable for most molecular tests, for which the average turnaround time is approximately 4 to 6 weeks. Any specimens with stability issues (eg, Fanconi anemia breakage studies) were handled within 1 day. We handled stat and clinically urgent requests on an individual basis (eg, neonatal intensive care unit requests for multiple gene tests for surfactant deficiencies were sent simultaneously instead of sequentially). This study was approved by the Seattle Children's Hospital Institutional Review Board.

RESULTS

In all, 251 cases met the defined criteria during an 8-month period and were reviewed by the utilization management committee. This committee met weekly to discuss cases and come to a consensus on how to manage certain types of cases in a uniform manner. Policies and procedures were created to help guide these efforts. Table 2 summarizes the cases. Seventy-six percent of the cases were approved without modification. A combined total of 24% of the genetic test requests were modified in the downward direction, either through sequential testing (11%) or cancellation (13%). This corresponds to a savings of \$118 952 (19% of the total cost of requests, \$610 456) for the laboratory, resulting in an average savings of \$463 per test request under management (Table 3). The exact savings

Table 2. Modification Rate of Cases Reviewed Under Management

	All (n = 251)	Genetic (n = 199)
Approved, % (No.)	76 (190)	76 (152)
Sequential, % (No.)	8 (21)	11 (21)
Cancelled, % (No.)	16 (40)	13 (26)

Table 3. Financial Effect of Utilization Management

	Amount, \$
Total cost of requests	610 456
Cost saved ^a	118 952
Total spent	491 504
Average savings/test request	463

^a Cost saved is 19% of total cost of requests.

Figure 1. Composite case of test request modification after review by utilization management program.

The patient is a 2-year-old boy with developmental delay, hypotonia, and failure to thrive. The provider requested a congenital myasthenic panel, which includes 10 genes and costs the laboratory \$7000. The patient or insurance company will be billed a 20% markup (\$8400). Our intervention included sending the provider our e-mail template, suggesting that he consider sequential testing. The most frequent gene associated with congenital myasthenic syndrome is *CHRNE* (\$730). The provider agreed with this approach. The patient was found to have a disease causing mutation in *CHRNE*, preventing further workup and saving several thousand dollars.

to patients are difficult to calculate because of the variety of payers involved. We estimate that the impact to patients is significant because of the high cost of each test and markup on send-out tests. We reviewed a number of individual cases to evaluate the true cost to patients, which is represented in the composite case (Figure 1).

We hypothesized that nongeneticists would use the majority of our utilization management service. Figure 2 shows the breakdown of genetic test orders by specialty. More than half (55%) were ordered by nongenetic providers. Not surprisingly, the nongenetic providers also required more of the consultant's time. Although 46% of all cases were adjudicated with a simple chart review, the majority (75%) of the test requests from genetic providers were handled in this manner. In contrast, 66% of the requests from nongenetic providers were handled with an e-mail or phone discussion with the ordering provider.

COMMENT

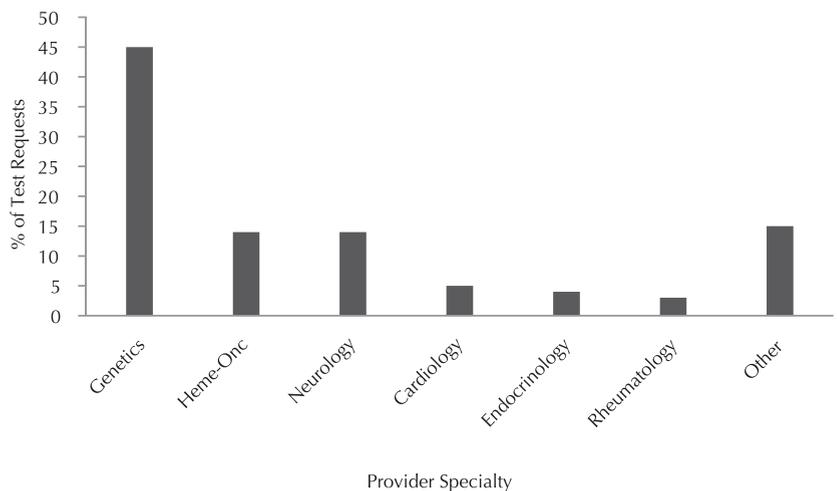
Active utilization management benefits patients by decreasing the total cost of testing, and ultimately increasing the value of the test. This intervention included encouraging providers to obtain insurance preauthorization before ordering the test. Preauthorization increases the likelihood that a test will be covered by private insurance, and also provides incentive for the provider to document rationale and clinical necessity in the electronic medical record. Ultimately, this helps to reduce unnecessary testing, or "curiosity" testing practices. To support this process, we implemented a DNA banking and sample hold policy to limit redraws while waiting for preauthorization. Nearly a quarter of the tests under management were modified or canceled; these patients likely had the most benefit. Reduction or elimination of the laboratory bill could be viewed as an immediate financial benefit to the family.

Thoughtful test ordering also decreases the risk of false positives and false negatives, especially in low-prevalence populations. Ordering a test when the chance of false positives is high can lead to a diagnostic testing cascade, incurring unnecessary costs and anxiety for the family. Conversely, ordering the wrong test and getting a negative result can be falsely reassuring.

An unintended benefit of our intervention was discovered in our case documentation using an Access database. We tracked results for sequential test requests in order to facilitate efficient sequential testing. This allowed us to communicate results to providers and to decrease the risk of unacknowledged results.

Although the ultimate goal of this intervention was to increase value to patients, we also saw a benefit to our institution. The policy at Seattle Children's is to pay for all reference laboratory testing by institutional billing and then seek reimbursement from the patient's insurance company or use donated uncompensated care funds for qualifying families. Some of the reasons for this policy include contractual obligations with insurance payers and billing requirements of reference laboratories. This practice to not pass on patient billing information to reference laboratories is common among hospitals because of the difficulty in separating ambulatory patients from inpatients, which would be necessary to achieve billing compliance. The end result is that Seattle Children's, like many hospitals, pays the total price billed by the reference laboratory for reference testing on every patient, independent of insurance coverage. The cases involved in this intervention represented only 0.6% of our annual send-out test volume, but disproportionately represented 10% of the total send-out bill. To date, we have saved 2% of the entire send-out bill. Any savings allows the laboratory to redirect resources to in-house testing and specimen processing.

Figure 2. Genetic test requests by provider specialty. Abbreviation: Heme-Onc, hematology oncology service.



Overall, the implementation of the utilization intervention was a relatively simple process that can be implemented in a variety of hospital settings. It is low-tech, requiring limited laboratory information system involvement by adding "UM" to defined test names. Dedicated resources are required, but can be managed with just a few faculty and staff, which could include a mixture of pathologists, clinical chemists, clinical microbiologists, genetic counselors, and residents or fellows. The 3 doctoral-level consultants each dedicated a maximum of 0.1 full-time equivalents to the utilization management project and the laboratory genetic counselor devoted 0.4 full-time equivalents, which is a total of 0.7 full-time equivalents. This time includes development of the process (ie, training), development of the communication tools and database, and data input and analysis. On average, a doctoral-level consultant costs our hospital \$192 000/y in salary and benefits, and a genetic counselor costs \$98 000/y. Weighted appropriately, this accounts for a total of \$96 800/y devoted to utilization management. Our study took place in an 8-month period, which corresponds to approximately \$64 533. With the savings of \$118 952 in testing not sent, we can justify the time spent to achieve this, especially with the understanding that this initial investment built the foundation to expand the intervention in the future without proportionally increasing the costs.

We also found that our providers were generally appreciative and happy with the service. Because we focused the conversations on the patient's best interest, and stressed that the final decision was the provider's, we did not encounter significant negative feedback. Many providers were, in fact, relieved to learn of review, especially when we discovered duplicate orders or orders made in error. We also used this utilization process to strengthen interdepartment relationships and capitalize on specialty expertise. Collaboration with the Division of Genetic Medicine was key to the success of this intervention, and it has been instrumental in cowriting policies. We plan to expand our collaborations with other divisions, including cardiology and neurology.

This pilot study was limited in its scope by focusing on expensive genetic tests in a pediatric population. Although we didn't encounter the new wave of molecular testing during this pilot (eg, whole-exome and next-generation sequencing), we plan to develop a multi-department collaboration to address appropriate testing and utilization strategies. Future directions also include expanding the utilization management criteria by lowering the cost

threshold and studying the impact of implementing the same interventions at more than one institution. In addition, the intervention could be applied to in-house testing. Finally, there are other tools we can use to improve utilization management of laboratory tests; multiple interventions are stronger than one. These include (1) privileging, which limits the ordering of certain tests to specialists; (2) defined send-out formularies, (3) pop-up computerized physician order entry reminders with best-practice guidelines for specific tests¹⁷; and (4) provider report cards.¹⁸ It is our plan to implement some of these tools in the future.

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