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THE ISSUE OF TEST UTILIZATION WITHIN THE CLINICAL LABORATORY

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ABSTRACT
Healthcare costs in the United States continue to rise, consuming nearly 20% of the nation's gross domestic product (GDP), with sustained projected increases in the foreseeable future. Diagnostic testing accounts for 3% of this total, one third of which is deemed unnecessary. Under the current fee-for-service (FFS) model, physicians have been incentivized to order more testing and provide more treatment because payment is dependent on the quantity of care rather than the quality of care, thus doing little to inspire patient involvement, patient education, or preventative care in a system that already shields patients from the true cost of care. By identifying the contributing factors for improper test utilization within the clinical laboratory, including genetic testing, healthcare organizations can reduce overall costs for all stakeholders by implementing changes outlined in this paper, including electronic medical record restrictions and consulting specialists in diagnostic and genetic testing such as the Doctorates in Clinical Laboratory Sciences (DCLS).

Key Words: Free for service model, electronic medical record DCLS practitioners

INTRODUCTION

In today's hospitals and healthcare facilities, many organizational challenges must be overcome for facilities to succeed in the ever-changing United States healthcare system. Led by the enormous growth in healthcare spending, with ongoing projected increases (Centers for Medicare & Medicaid Services, 2018; Centers for Medicare & Medicaid Services, 2019), governmental regulations and pressure to contain costs for all stakeholders continue to move in the direction of decreasing reimbursements, restrictive coverage, and higher premiums for at-risk patients, requiring the improvement in the quality of care by means of measuring key performance indicators within healthcare facilities. In their efforts to optimize performance while decreasing costs, healthcare facilities are faced with significant operational challenges, including: supply chain disruptions and back-orders resulting in expediting charges and increased chances for erroneous drug conversion mistakes due to relying on back-up medications; misfiling claims to payers leading to innately lower reimbursements; attracting and retaining productive staff to decrease turnover rates and costs associated with hiring,

training, and on-boarding; and, properly utilizing organizational resources to maximize key performance measures tracked by overseeing governmental agencies. This paper will focus on one of these challenges—the issue of properly utilizing organization resources—discussing effective test utilization within the clinical laboratory, reviewing current best practices that have been trialed by other organizations, and proposing a broad solution that healthcare facilities could implement to achieve their goals of stronger financial strength and the provision of higher quality patient care. The issue of efficient test utilization spans the entire available test menu and affects patient safety overall; however, this paper will emphasize modern genetic testing, which has gained accelerated attention due to its significant costs and the unprecedented benefits for patients compared to other laboratory assays available to providers.

CONTRIBUTING FACTORS AND IMPACTS OF IMPROPER CLINICAL LABORATORY TEST UTILIZATION

Clinical laboratory test utilization is the summation of physicians and other healthcare providers selecting the correct laboratory test at the correct time for their patients and then correctly interpreting that test result before administering the correct treatment or ordering subsequent testing to achieve the correct diagnosis. Ineffective or inappropriate test ordering has been classified as "pre-pre" analytical errors, referring to improper test selection before a patient sample has even been collected (Laposata & Dighe, 2007). Also identified, but on the opposite end of the assay-ordering spectrum, are "post-post" analytical errors, where an incorrect interpretation of a laboratory test results in a provider misdiagnosing or inaccurately treating the patient in a manner that is excessive or needless (Laposata & Dighe, 2007). As previously mentioned, the overall financial impact of diagnostic testing, representing just 3% of all healthcare spending, is fairly low, even when considering expensive genetic assays (e.g. next-generation full genome sequencing); however, the downstream testing and procedures based on those laboratory findings (or lack of) can be tremendously pricey giving rise to the aforementioned unmanageable costs.

In recent studies, nearly one-third of all laboratory testing was deemed to be unnecessary, with multiple factors contributing to the issue of improper test utilization by physicians (Jones, 2017; Wertman, Sostrin, Pavlova & Lundberg, 1980). Perhaps one of the most challenging contributing factors is the lack of evidence-based recommendations. As payers move towards an outcome-based model, evidence-based best practices have led to efficiencies in the provision of many healthcare services. In the world of laboratory testing, however, there have been limited studies towards improving test utilization methods. The lack of resources available to hospital and healthcare administrators hinders their ability to implement progressive change when they are forced to withstand the trial and error process themselves. Add in the technological limitations of big data mining, compilation, and understanding, and the goal of superior test utilization is all but

lost in the endless list of priorities that organizations must balance with dwindling resources.

In the earlier days of clinical laboratory sciences, a finite test menu was offered to clinicians due to limited testing methodologies. Today, technological advancements within the realm of diagnostic assays have cultivated the rise of testing platforms that offer insight to nearly every biochemical aspect of human beings, from simple enzymatic and antibody/antigen reactions down to exact sequences of genetic material to identify mutations in single nucleotides or genes along with entire human genomes. Hospital testing menus can range from one to a few hundred tests; then, add in the upwards of several thousand other tests offered through reference laboratories and it becomes difficult for any single healthcare provider to know not only which test would provide the patient information most expediently, but, to also know how to interpret those results within the clinical context of their patient's diagnosis and health history. The enormity of tests available has convoluted these decision-making issues that providers face on a daily basis.

Given the degree of innovative assay development in recent years, the issue of ineffective test utilization and high risk of result misinterpretation is compounded when modern genetic testing is involved. Medical schools fail to properly educate student physicians on diagnostic testing and interpreting results, and, the vast majority of schools rarely explore genetic testing if their curriculum does include clinical laboratory sciences (Laposata, 2007). The lapse in didactic coursework is caused primarily from a profuse shortage in clinical molecular biologists and geneticists who are knowledgeable enough about cutting-edge genetic testing to educate providers, including those enrolled in medical schools as well as experienced physicians already in the workforce (Riley, 2015).

Another contributing factor to improper test utilization is the over-bundling of test panels, which has evolved from two differing influences: (1) facilities that make it easier for physicians to order more tests in order to generate increased revenue under the FFS model, and (2) as healthcare organizations diversify to encompass more of the patient share within the market and offer specialized treatment options for more diseases and injuries, more order sets are generated that are tailored to each new treatment (e.g. stroke, chest pain, and wound care). The creation of order sets fosters redundancy as the same tests might be included in multiple panels.

Along the same lines of over-bundling test panels, but restrictive to repeat testing of specific tests, are standing orders. Easy to use, and easier to lead to waste, standing orders rarely have scenarios where it is beneficial to continuously monitor particular analytes over periods of time. One such scenario that benefits from standing orders is therapeutic drug monitoring while patients receive pharmaceuticals; however, far too often, these ordering practices span longer than

the essential time period or the information sought could have been achieved from simpler or fewer repeated analyses.

The new environment of healthcare within the United States depicts aggressive legislature focusing on turning the current FFS reimbursement models into value-based models in an attempt to be prohibitive on the ever-growing costs of care (Committee on Quality of Health Care in America, 2001). While the FFS model has been in place, unsustainable healthcare costs have caused the country to spend nearly 20% of its GDP on healthcare, resulting in part from tempted physicians and other healthcare providers to habitually over-utilize clinical laboratory resources and testing aiming for higher reimbursement from payers (CMS, 2018). This number will continue to creep upwards until the conversion towards outcome-based payments has been fully achieved and integrated into society. This issue, in particular, is one that compounds an earlier contributing factor – the lack of education and training older physicians face because these providers have been embedded with the sense that facility resources, in terms of diagnostic testing, is unlimited and not an opportunity for improvement when administrators are attempting to contain costs.

When genetic testing is isolated as a part of the test utilization problem, the effects of increasing wastes and costs are amplified due to their significantly higher costs as compared to all other traditional diagnostic assays apart from imaging procedures. Most physicians are unaware of the costs of testing, much as patients are oblivious to the true cost of healthcare. Bates (1997) observed that when physicians are provided with the cost per test their patients would be charged, no significant change in test ordering occurred from the price transparency thus suggesting that providers either do not care about the costs patients accrue or they see the charge as potential revenue for services rendered. Also worth mentioning is that patients might overlook the costs of tests as well due to increased demand for genetic and genomic testing resulting from enhanced public awareness and public perception of its benefits (Kotzer, 2014). Moreover, patients will often pay the cost of additional tests if they believe, or have been informed by their doctor, that there is added benefit from the result for higher probabilities of improved treatment as money is generally not a factor when their or a loved one's health is in jeopardy.

Test result interpretation is another challenge that is becoming increasingly complicated when genetic tests are ordered and also when numerous, very detailed and focused assays are ordered concurrently. Due to the underwhelming understanding of the vast data we can obtain from amplifying a patient's genetic code, the risk of doctors inaccurately treating patients not comprehending the "big picture" of mutations within whole and exome genomes is virtually guaranteed. Without highly trained and specialized genetic counselors available for consultation, physicians are simply ordering tests with the mindset of "why not?" rather than "why?" and subsequently are unable to efficiently diagnose or treat

their patients due to the lack of knowledge regarding these tests. Kotzer (2014) recognized that as the demand for genetic testing in healthcare continues to increase and become more complex, the need for genetic counselors that can increase genetic testing utilization also increases. Limited training and limited time to address complexities surrounding these uniquely specialized tests further support the need for trained personnel.

The core motivating goal of utilization management is cost savings. Lowered costs within healthcare organizations have been achieved through various measures, including decreased length-of-stay (LOS), fewer days on antibiotics, fewer tests ordered and resources used, reduced chances for patient harm resulting from improper treatment, optimized staffing productivity, and decreased readmission rates. When monitoring departmental costs attributed to clinical laboratory testing, all direct and indirect costs, including pre-analytic and analytic, variable, semi-variable, and fixed costs, must be accounted for in order to derive the true overall cost (MacMillan, 2013). Knowing the true cost is imperative in order to determine downstream savings that can be achieved through utilization efforts. These costs cannot always be directly measured due to the volatile nature of patient outcomes and clinical presentations within the same patient populations with matching diagnoses; therefore, cost accounting becomes even more important in analyzing laboratory costs and the impacts of improved utilization management.

SUGGESTED MEASURES TO IMPROVE TEST UTILIZATION

Measures to improve test utilization, including genetic tests, begins with the difficult clinical decision to define the patients that do and do not need a test (Baird, 2014). Once this step has been completed, the process to develop physician tools for test ordering and interpretation can be created. Clinicians are often compelled to order more tests initially for myriad reasons, including (1) an assumption that the initial visit might be the only opportunity to get the desired information; (2) patients' requests resulting from information they obtained online; or, (3) the practice of defensive medicine that causes doctors to over-utilize tests in order to avoid potential malpractice litigation, or worse, patient harm. Because of this tendency to order unnecessary tests, proper planning and implementation of tools are imperative and should lay the foundation for improved diagnostic testing utilization.

The most significant tool available to healthcare administrators and providers to improve laboratory testing utilization is the facility's electronic medical record (EMR),with its three main subsystems of clinical decision support system (CDSS), computerized physician order entry system (CPOE), and health information exchange (HIE) (Aziz & Alshekhabokakr, 2017). Today's leading EMR's have been developed with a plethora of functionalities that can customize the software to tailor the needs of the organization. One example of those functionalities is "hard-stops" which are alerts embedded within the EMR to alert professional healthcare staff of errors that have been made or are about to be made. Hard-stops

integrate the idea of stewardship interventions categorized into 3 varying strengths consisting of gentle, medium, or strong in order to stop an unwanted behavior with strong interventions designed to eliminate unnecessary and unintended laboratory testing (Dickerson, et. al, 2017). Tailoring hard-stops to alert nursing and clinical staff that specific tests cannot be ordered on particular patient populations is one way to cease ordering errors. Another hard-stop might be created to alert ordering personnel of duplicate test orders within specific timeframes where repeated analyte testing is not necessary or beneficial until a specified amount of time has passed.

Another functionality within EMR's that can be harnessed once patient populations have been identified to benefit the most from specific diagnostic tests is reflexed testing. Reflexed testing, simply the sequential ordering of downstream tests based on the results from the previous test results, has enormous potential for streamlining patient care. Creating and modifying these types of testing formularies generates gained benefits for all healthcare stakeholders for multiple reasons: ease-of-use for physicians who are untrained or lacking education about downstream testing and interpretation, cost savings for the facility and patient since only appropriate testing will be performed based on the results of the previously order test or test panel, and time saved for providers who are already juggling high patient volumes and hectic schedules. Many reflex testing panels and formularies include complex result interpretations by pathologists and clinical laboratory technical directors to assist care providers receiving the result information by explaining the findings and suggesting treatment approaches based on the clinical presentation of the patient in conjunction with their other symptoms.

Along the lines of EMR functionalities, but for an organizational health system with multiple care sites and less useful to stand-alone facilities, is standardization. Identifying, creating, and implementing new testing formularies, reflex testing, and alerting ordering personnel of duplicate testing orders can be spread throughout the organization as a whole allowing for larger scales of efficiency to be achieved. Standardization cannot be achieved without physician buy-in and input to avoid hindering their abilities to treat their patients. Physicians are most commonly the end-users in standardization efforts so success rides on their input and willingness to accept new processes. One such example of physician buy-in and achieving successful genetic test utilization is human papillomavirus (HPV) DNA testing. By developing ordering criteria and identifying which patients would benefit from HPV DNA tests, providers could prevent costs without benefit and potential over-treatment of women (Solomon, 2009).

As mentioned above, doctors are not typically taught how to interpret molecular and genetic assay results prior to completing medical school and must learn on-the-job during residencies and fellowships. Physicians who are nearing retirement are often the least trained and knowledgeable in understanding the complex methodologies integrated into genetic testing. These physicians would benefit

greatly from geneticists and molecular biologists. Laboratory leaders at the Cleveland Clinic sought to correct this shortfall by requiring providers without specialty training in genetics to use genetic counselors and molecular genetic pathologists to assist in test selection. By requiring untrained ordering personnel to use genetic counselors and molecular genetic pathologists, Cleveland Clinic generated a gross cost savings over $1.5 million dollars in two years as a result of test utilization management efforts alone (Riley, 2015). Laboratory genetic counselors are able to increase genetic test utilization through review and assessment of the appropriateness of the ordered testing, developing protocols, and by increasing communication with ordering providers (Kotzer, 2014). Genetic counselors are also available to obtain detailed family histories that are crucial to interpreting genetic test results which can prove burdensome to standard physicians.

Diagnostic management teams (DMT) are a possible solution for both lack of education and training as well as understanding expanding test menus, and, they would be cost-neutral since they would be comprised of already employed hospital staff (Laposata, 2007). Each member of the team would stem from their own specialty as the subject-matter expert for that field, including the pathologists and clinical technical directors mentioned above but also the medical laboratory scientists performing the tests since they are the most knowledgeable about testing limitations and interferences. One emerging resource with high promise to bridge the educational gap between non-laboratorians and clinicians are the Doctorates in Clinical Laboratory Sciences (DCLS). Medically trained, these DCLS offer insight to diagnostic test result interpretation and proper test utilization. Along the lines of DMT's, leaders at the University of Michigan Health System (UMHS) created a laboratory test utilization program that included the establishment of a Laboratory Formulary Committee and through the application of peer-reviewed medical evidence, input by medical content experts, and excellent cooperation by medical staff, the utilization program led to a robust process of test utilization oversight, ideal communication with clinical services, and significant UMHS activity-adjusted reductions in laboratory expense (Warren, 2013).

Proposed implementation plan

To begin implementing a test utilization effort, data must be gathered and analyzed within the organization. Trends and ordering patterns within physician specialties and related diagnosis populations should be compared to medical knowledge and literature to ensure doctors are practicing relevant testing configurations and avoiding archaic methodologies (e.g. erythrocyte sedimentation rate versus C-reactive protein). Trends and inconsistencies amongst evidence-based practices should then be shared with key providers to initiate physician buy-in. Test utilization programs would benefit most from having clinical pathologists, DCLS practitioners, or the laboratory medical director lead dialogue as they can be the physician champion bridging the clinical laboratory to patient providers. Successful collaboration between doctors and the laboratory is vital for developing

guidelines and algorithms that encourage proper test usage. Testing formulary changes would include eliminating obsolete tests, implementing frequency limitations so that certain tests might only be orderable once per day or even once per admission, and supporting physician ordering tiers so that only highly-skilled personnel would be able to order specialized testing. Diagnostic management teams could also be created to assist providers with efficient test ordering and interpretation in conjunction with EMR tactics. Utilization improvement opportunities should then be implemented and monitored for process improvement and performance outcomes. Even if test utilization processes were only rolled out as small-scale changes localized to one physician practice, documented success could then be spread throughout the organization as the new standard for diagnostic test ordering.

CONCLUSION

When challenged with scarce resources and dwindling reimbursements, healthcare organizations and facilities must identify opportunities for cost containment. Efficient diagnostic test utilization, particularly genetic testing, is a rising area of interest to healthcare administrators given that downstream patient testing and treatment can equate to poor resource allocation and time management. Physicians must ensure that they are diagnosing and treating their patients correctly and quickly in order to meet recent governmental standards and receive maximum reimbursement for their services. To generate cost savings in the form of shorter length-of-stay, lower readmission rates, and higher staffing productivity, hospitals must identify outdated and uneconomical physician ordering behaviors and implement new strategies for reducing waste. Strategies can include creating DMT's composed of highly trained personnel and/or EMR regulations to assist providers in ordering the right tests at the right time in order to administer the right treatment.

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