Evaluation of Inappropriate COVID-19 RT-PCR Test Utilization at an academic medical center

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Abstract

Background: An evolving COVID-19 testing landscape and issues with test supply allocation, especially in the current pandemic, has made it challenging for ordering providers. We audited orders of the Xpert® Xpress SARS-CoV-2 RT-PCR platform—the fastest of several other testing modalities available—to illuminate these challenges utilizing a multidisciplinary laboratory professional team consisting of a pathology resident and microbiology lab director.

Methods: Retrospective review of the first five hundred Xpert® Xpress SARS-CoV-2 RT-PCR test orders from a 2-week period to determine test appropriateness based on the following indications: emergency surgery, emergent obstetric procedures, initial behavioral health admission, and later including discharge to skilled care facilities and pediatric admissions. Our hypothesis was that a significant proportion of orders for this testing platform were inappropriate.

Results: Upon review, a significant proportion of orders were incorrect, with 69.8% (n=349, $p<0.0001$) not meeting indications for rapid testing. Of all orders, 249 designated as emergency surgery were inappropriate, with 49.0% of those orders never proceeding with any surgical intervention; most of these were trauma related (64.6% were orders associated with a trauma unit).

Conclusions: Significant, pervasive inappropriate ordering practices were identified at this center. A laboratory professional team can be key to identifying problems in testing and play a significant role in combating inappropriate test utilization.

Impact statement: In the current pandemic, subject to an evolving testing landscape with frequent changes in recommendations for testing, providers may be especially challenged to order the correct tests. At an academic center, we audited COVID testing of the rapid RT-PCR platform and found that a significant proportion were misordered, suggesting the need for test utilization guidance. Inappropriate laboratory utilization, which has the potential for patient harm and contributes to rising healthcare costs, can be targeted through audits like these that utilize a multi-faceted, physician and laboratory teamwork-based approach.

Introduction

In the US, the "Choosing Wisely" campaign has embodied lab utilization efforts aimed at developing sustainable processes to decrease inappropriate laboratory testing and its downstream effects on patient care and healthcare costs[1,2,3]. The causes of inappropriate testing in laboratory medicine are complex, but can be partially attributed to the rapidly evolving test platforms and guidelines that make appropriate ordering choices challenging for providers[1,4]. The COVID-19 pandemic is an embodiment of these fast-paced changes in testing, and with this in mind, we chose to analyze COVID-19 ordering practices at our academic medical center in an effort to illuminate challenges in ordering practices and contribute to the growing lab utilization management literature.

There are six different COVID-19 testing platforms available at this academic center, among which is the GeneXpert Xpert® Xpress SARS-CoV-2 (Cepheid; Sunnyvale, CA) real-time reverse transcription polymerase chain reaction (RT-PCR) intended for qualitative detection of nucleic acid from SARS-CoV-2 in upper respiratory specimens from individuals suspected of COVID-19 infection. At this academic center, the GeneXpert (GX) assay that has the most rapid turnaround time of the various platforms (1 hour vs 6-24 hours). Testing for COVID-19 is routed between the GX and the five other platforms based on the medical indication selected by the ordering physician. For example, emergent indications routed the specimen to the GX whereas non-emergent indications may route to a batched testing platform with a 24 hour turnaround time. The decision to specifically target the GX platform of testing was based on the following: 1) as the fastest platform, this assay was most susceptible to inappropriate ordering as physicians tried to expedite test results, 2) this platform had a limited supply for testing based on test allocation, and 3) both the laboratory director and pathology residents on service identified frequent physician requests to change their COVID-19 order to this rapid GX platform. The decision was made to review the first 500 tests ordered in a two-week period and determine test appropriateness based on review of the electronic medical record for each patient and hospital consensus guidelines for testing. We hypothesized that there would be a mismatch between the order indication selected that would route to the GX platform and the actual indication for testing.

Materials and Methods

Study setting and patients

This study was submitted to and approved by the University of Maryland, Baltimore Institutional Review Board as Exempt under protocol number HP-00094270. The GX test went live for limited testing on 3/29/2020 until the initial algorithm for COVID-19 testing was implemented on 6/1/ 2020, which linked order indications selected for testing to the appropriate test platform. Test orders were part of a check box selection with no free text option in the electronic medical record. Indications that lead to rapid testing on the GX were acute emergency surgery, emergent obstetric procedures, initial behavioral health admissions, and ICU admission, with all other indications deemed non-urgent and placed on high-throughput batched testing. Our study period followed the updated COVID-19 testing algorithm that went live 11/3/2020, which was developed by hospital system incident commend for influenza season. The International Disease Society of America (IDSA) makes no strong recommendations for or against use of rapid tests versus standard or batched RT-PCR testing. The IDSA conditionally recommends RT-PCR testing in symptomatic individuals suspected of having COVID-19; however, testing platforms and turnaround times are determined by the clinical laboratory in conjunction with clinical stakeholders. For this study, the Cerner Millenium laboratory information system database was queried for patients who had GX orders placed between 11/23/2020 to 12/7/2020. Over the two-week study period, the first five hundred tests that routed to the GX were reviewed by a multidisciplinary team consisting of a senior pathology resident and the associate director of the clinical microbiology lab. For each patient, a retrospective chart review was performed and determination of test appropriateness based on hospital-established guidelines for this testing platform. Appropriate indications for testing initially included acute emergency surgery, emergent obstetric procedures, and initial behavioral health admission, but later included orders for discharge to skilled care facilities and pediatric patient admissions (initiated 11/31/2020) as well (see Table 1.); retrospective review included all indications for testing when evaluating test order appropriateness. Descriptive data for these patients was obtained by review of the electronic medical record and included order indication selected, unit associated with the order, and test result. An assessment of the actual indication for the order was then made by chart

review. Discrepancy between indication on the order form and actual indication as well as whether or not the indications met current criteria for GX testing were used to determine appropriateness of testing.

Data collection and analysis

Information pertinent to testing review was collected in a password-protected Excel file (Microsoft, Redmond, WA). Pertinent laboratory data recorded for each request included the order date, patient name and accession number for review in the electronic medical record, ordering unit, order indication, and test outcome. Upon chart review, the actual indication for testing was recorded. For any test where there was a mismatch between the actual and selected order indication, a note regarding the clinical context was made. Differences between order indication and actual indication were analyzed using Chi-square or Fisher's exact test as appropriate. All statistical calculations were performed using SAS software (version 9.4; SAS, Cary, NC).

Results

Of the five hundred tests reviewed over the two-week study period, the majority of indications selected were acute emergency surgery (n=339, 68%), followed by OB emergent (n=78, 16%), behavioral health (n=47, 9.4%), and other [discharge (n=21, 4.2%) and pediatric admissions (n=15, 3%)]. There was a significant discordance between the order and actual indication for testing, with 69.8% tests deemed inappropriate (n=349, $p<0.001$). The majority of inappropriate orders were tests ordered with the indication of "acute emergency surgery" (n=249, see Fig. 1), 49% of which never had any surgical intervention; these orders were mostly from the Trauma or Emergency department units (79%, n=203). These orders placed in anticipation for surgical intervention with no subsequent intervention had no other indication for testing. In a proportion of these inappropriate acute emergency surgery cases that never proceeded to surgery, the patient's had been post a motor vehicle crash (25%, n=30) or other trauma-related event (34%, n=41). Inappropriate ordering was also pervasive in labor and delivery, with "obstetric emergent procedure" indication selected inappropriately in 77% of obstetric-related cases (n=60).

Examples of inappropriate obstetric emergency procedure orders included patient's who were gestational and presenting for a routine obstetric visit with respiratory symptoms or patient's who had no risk factors for cesarean section and proceeded to have an uncomplicated spontaneous vaginal delivery, among others. Behavioral health admissions were also inappropriate in 68% of cases (n=32), and the majority of inappropriate orders were patient's who were being worked up for behavioral health issues but were never admitted. Testing for the indication "discharge to skilled care facilities" was inappropriate in 35% of cases, and the findings in all of these cases was that the patient was not discharged due to ongoing medical or social problems preventing discharge. All pediatric indications selected were appropriate. Most patients ultimately tested negative for COVID (95.8%, n=479).

Discussion

Identifying inappropriate laboratory ordering practices is a crucial part of modern laboratory utilization and management efforts to optimize patient care and control healthcare costs. Laboratory order errors have been increasingly documented in the primary literature, described as a source of not only wasted healthcare resources but as a possible source of patient harm through unnecessary phlebotomy or diagnostic error leading to invasive procedures[1,4-6]**.** Inappropriate orders are not a surprise given the rapid introduction of new and emerging diagnostic testing modalities, which makes it challenging for physicians to follow best ordering practices[4]**.** The range of errors include those ordered mistakenly, redundantly, or inappropriately, with the latter defined generally as tests ordered that violate a guideline produced by a professional society[6,7]. Prior large scale auditing data has revealed significant variation in ordering practices that encompasses both under and over-utilization of tests that do not follow current guidelines[7]. This has significant implications not only in terms of cost-effectiveness, but in equity of access to laboratory testing and broader public health outcomes.

At our tertiary medical center, audit of COVID-19 GX ordering practices was performed in order to determine order appropriateness and understand physician-ordering practices. Our medical center has various COVID-19 nucleic acid testing platforms that have been added over the course of the pandemic to deal with the increased volumes of testing, changing test

recommendations, and limited supply of testing reagents and materials. Among these platforms is the GX platform that is attractive because of its short turnaround time but is one of the most limited in available testing resources in comparison to other testing platforms. A single cartridge is used per test, and test cartridges are allotted to the hospital at a set frequency because of national supply allocations. To deal with the high demand for this testing option and in anticipation of influenza season, hospital incident command developed a COVID-19 algorithm that went live November 3, 2020 that linked order indications selected for testing to the appropriate test platform. Patient indications that were linked to the GX, for both symptomatic and asymptomatic patients, included the following: acute emergency surgery, obstetric emergent procedure, and initial behavioral health admission, which later also included pediatric patient admissions and inpatients awaiting discharge to skilled care facilities. The clear consequence of overutilization of this testing platform was the limitation in resources for other patients who met criteria for the faster test; however, unlike other instances of inappropriate ordering, there was no clear direct patient harm that would result from misordering. The purpose of this study was to evaluate ordering practices of this RT-PCR testing platform and gain insight into ways to optimize lab management.

Over the two-week study period, a significant proportion of tests were found to be inappropriately ordered, and most often for an acute emergency surgery indication. A majority of these inappropriate “acute surgery” indication cases were ordered in the trauma or emergency department units, with the latter also responsible for the majority of inappropriate “behavioral health admission” indications. Although we did not explore specific reasons for inappropriate ordering, primary literature has established various contributing factors such as feelings of insecurity or lack of awareness and knowledge of testing by ordering providers[1-3,8]. In our study, reasons for incorrect test order indication may have included foreshadowing need for emergent surgery, as many of these cases were patients in the emergency department or trauma center post motor vehicle accidents or gunshot wounds; however, following the guidelines outlined by the hospital, these patients should not have had COVID orders placed until patients were definitively heading to the OR. Some informal physician feedback included not being able to distinguish “priority” or acute emergency cases from “non-priority” cases. While these concerns are valid, they do not account for the 49% of patients with “acute surgery” selected as the indication in our

cohort who were discharged without any surgery. Inappropriate ordering was not only prevalent in the ED or trauma units, but was also pervasive in labor and delivery, where the indication of "OB emergent" was selected for scheduled cesarean sections in addition to routine gestational visits and induction of labor cases with low risk of cesarean section. Even order indications that seem straightforward (e.g., discharge), were often inappropriate.

Identifying misordering practices can broadly illuminate problems with test ordering design elements and the steps necessary to eliminate inappropriate ordering. For instance, in inappropriate "acute emergency surgery" or "obstetric emergency surgery" situations, the initial design of the orderable could have included the need for a case associated with the patient to be posted prior to being eligible to select this order indication. In the case of "initial behavioral health admission," the orderable could similarly be linked to an admission note or some other evidence to support selecting this indication. These examples highlight what is well established in the lab utilization literature, which is that the electronic health record can be utilized in a lab stewardship manner[8-10]. Utilization of computerized efforts to streamline lab management in addition to audits like this study as well as provider education and feedback regarding ordering practices could result in positive changes[11], although data is lacking regarding long-term order practice changes following similar interventions[3,9].

Clearly, the pervasiveness of inappropriate ordering at this institution demonstrates an opportunity for laboratory stewardship, which could mean laboratory professionals working with ordering providers to audit the appropriateness of a test request, physician ordering practice feedback, or redesigning test elements. Information technology and the electronic medical record system can be utilized to direct tests appropriately and flag or stop inappropriate orders before they even reach the laboratory[7,12]. The literature supports a multifaceted approach[1,3,8,13], but with the commonality that physicians work together with laboratory professionals so that the issues inherent to laboratory testing issues are approached in the context of meeting the clinical care needs of the patient. Inappropriate GX ordering at this medical center has not yet been formally addressed on a systems-level due to a lack of dedicated data management resources. However, physicians who place COVID-19 orders and wish to switch to the GX platform have had to

negotiate test appropriateness with the microbiology lab directors on a test-by-test basis. In these instances, the lab director has utilized the aforementioned ordering algorithm and provided physician education concerning appropriate test ordering. In addition, clear disregard for the testing algorithm (when identified) was addressed with hospital risk management in an effort to increase provider education. This retrospective audit regarding the inappropriate use of the platform will be informative for future decisions regarding test order design.

There are obvious limitations to our study. First, this was a retrospective single-center investigation of only two weeks duration. However, the issues in ordering were uniform over that period, and we have observed ongoing issues in ordering of this testing platform since the onset of the pandemic due to the evolving test landscape and recommendations for testing. Second, we did not investigate reasons for inappropriate ordering apart from speculation; it could be that there was an element of the ordering process that made selection of a different order indication impossible. However, this finding would also support the need for better design elements and clinical-lab interface that is the overall recommendation from our findings. Additionally, retrospective chart review of real time decisions made for test ordering does not necessarily take into account the rationale of the provider. Medical decisions for ordering are complex, and extrapolation of that decision making from the electronic medical record is somewhat limited. However, review of test orders by a pathology resident—given their background medical knowledge and training—in addition to the expertise of a clinical laboratory professional allows for increased accuracy in final assessment of test appropriateness. Finally, physician feedback regarding ordering was only provided in limited circumstances as described previously. Our data have identified the need for additional systems-level interventions, which may include changing design elements in the electronic health record or the way physicians are educated regarding ordering, in order to tackle inappropriate lab utilization.

Conclusions

Inappropriate laboratory testing for the COVID-19 GX platform was pervasive at this academic medical center, reflecting growing literature highlighting similar findings in laboratory medicine in general. Although this is a single-institution study, these findings suggest that multi-

institutional investigation of similar testing platforms may be warranted. Lab utilization literature emphasizes a combined effort in tackling inappropriate testing that includes tasks such as lab feedback regarding physician ordering practices, audits, and physician ordering education in addition to computerized systems that facilitate appropriate order choices. Like in our study, where physician-based knowledge of patient care was bridged with a laboratory professional in order to determine test appropriateness, it is through a laboratory-clinical interface that we can improve lab utilization with downstream clinical and financial implications.

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References

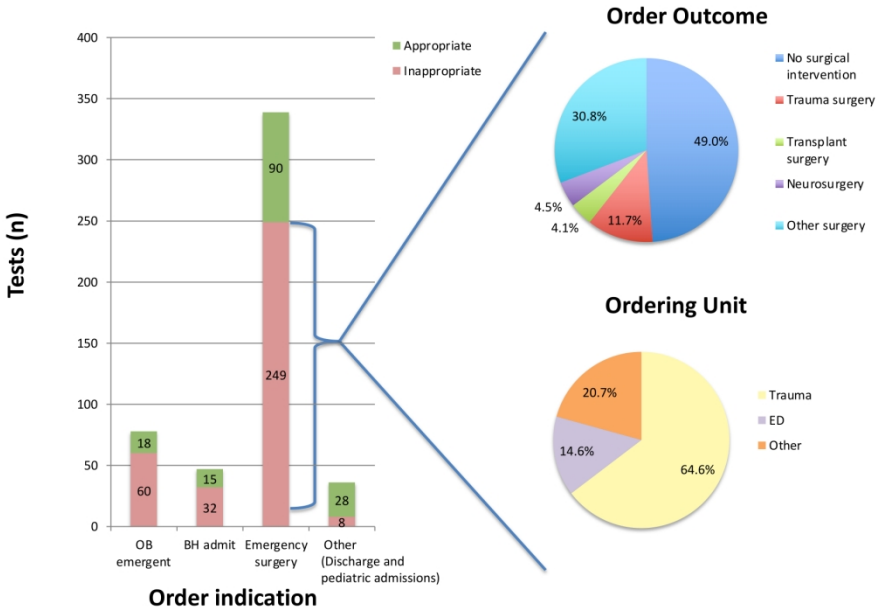
1. Freedman DB. Towards Better Test Utilization - Strategies to Improve Physician Ordering and Their Impact on Patient Outcomes. *EJIFCC*. 2015;26(1):15-30.
2. Bodley T, Kwan JL, Matelski J, et al. Self-reported test ordering practices among Canadian internal medicine physicians and trainees: a multicenter cross-sectional survey. *BMC Health Serv Res*. 2019;19(1):820.
3. Vrijsen BEL, Naaktgeboren CA, Vos LM, et al. Inappropriate laboratory testing in internal medicine inpatients: prevalence, causes and interventions. *Ann Med Surg.* 2020;51:48–53.
4. Naugler C. A perspective on laboratory utilization management from Canada. *Clin Chim Acta.* 2014;427:142-4.
5. Chami N, Simons JE, Sweetman A, et al. Rates of inappropriate laboratory test utilization in Ontario. *Clin Biochem.* 2017;50(15):822-827.
6. Lundberg GD. The need for an outcomes research agenda for clinical laboratory testing. *JAMA.* 1998;280(6):565-6.
7. Ferraro S, Panteghini M. The role of laboratory in ensuring appropriate test requests. *Clin Biochem.* 2017;50(10-11):555-561.
8. Dine CJ, Miller J, Fuld A, et al. Educating physicians-in-training about resource utilization and their own outcomes of care in the inpatient setting. *J Grad Med Educ.* 2010;2(2):175–180.
9. Qavi A, Szymanski J, Jackups, R. A Clinical Decision Support Alert Prevents Inappropriate Repeat Laboratory Testing Ordered Within the Same Admission on Inpatients. *Am J Clin Pathol.* 2018;149(suppl 1):S172.
10. Zare S, Meidani Z, Shirdeli M, et al. Laboratory test ordering in inpatient hospitals: a systematic review on the effects and features of clinical decision support systems. *BMC Med Inform Decis Mak*. 2021;21(1):20.
11. Kiechle FL, Arcenas RC, Rogers LC. Establishing benchmarks and metrics for disruptive technologies, inappropriate and obsolete tests in the clinical laboratory. *Clin Chim Acta.* 2014;427:131-6.
12. Hauser RG, Shirts BH. Do we now know what inappropriate laboratory utilization is? An expanded systematic review of laboratory clinical audits. *Am J Clin Pathol.* 2014 Jun;141(6):774-83.
13. Dhanani JA, Barnett AG, Lipman J, et al. Strategies to reduce inappropriate laboratory blood test orders in intensive care are effective and safe: a before-and-after quality improvement study. *Anaesth Intensive Care.* 2018 May;46(3):313-320.

Table 1. 2020 Fall COVID-19 testing algorithm

	Test indications	
Platform	**Asymptomatic Patients**	**Symptomatic Patients**
GX (TAT=1 HR)	Acute emergency surgery Emergent obstetric procedures Initial behavioral health admission Pediatric admissions**	
BD (TAT=3-5 HR)	Ambulatory oncology or transplant same-day surgery	
	Discharge to nursing home, skilled nursing facility, jail, or acute care facility*	
Roche/Abbott (TAT=24 HR)	Asymptomatic screening for inpatient admission	PUI admission
	Pre-op 24-96 hour	
	Ambulatory oncology or transplant surgery in >24 hrs	Ambulatory oncology or transplant infusion PUI
	Obstetric scheduled c-section in >24 hrs	
		Repeat inpatient testing
Reference Laboratory (TAT=3-5 days)	Routine, ambulatory	ED discharge home Ambulatory office visit PUI
BioFire (TAT=3 HR)		Acute respiratory failure, active oncology or transplant inpatient

*Discharged patients were later routed to the GX platform instead of BD. **Pediatric patients were added as an appropriate indication for GX testing beginning 11/31/20. Abbreviations: TAT=Turnaround time, GX=Cepheid GeneXpert®, BD=BD MAX™ System, PUI=Patient under investigation, ED=Emergency department

Figure 1. All GX orders during study period, with pie graphs of the outcome and unit associated with the inappropriate emergency surgery orders. Abbreviations: OB=Obstetric, BH=Behavioral health, ED=Emergency department



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