



A prospective tool for risk assessment of sendout testing

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ABSTRACT

Objective: Errors associated with laboratory testing can cause significant patient harm. Sendout testing refers to tests sent by a primary lab to a reference lab when testing is unavailable at the primary lab. Sendout testing is particularly high risk for patient harm, due to many factors including increased hand-offs, manual processes, and complexity associated with rare, low-volume tests. No published prospective tools exist for sendout risk assessment.

Methods: A novel prospective tool was developed to assess risk of diagnostic errors involving laboratory sendout testing. This tool was successfully piloted at nine sites.

Results: Marked diversity was noted among survey respondents, particularly in the sections on quality metrics and utilization management. Of note, most sites had committees who managed rules for test ordering, but few places reported enforcing these rules. Only one site claimed to routinely measure the frequency clinicians failed to retrieve test results. An evaluation of the tool indicated that it was both useful and easy to use.

Conclusions: This tool could be used by other laboratories to identify the areas of highest risk to patients, which in turn may guide them in focusing their quality improvement efforts and resources.

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1. Introduction

Errors in laboratory testing can cause significant patient harm [1]. Though it is well recognized that problems in laboratory testing present important patient safety challenges, there are relatively few published studies, and most of the literature on laboratory errors is retrospective [2]. Few tools exist to help laboratorians prospectively assess risk. To that end, we developed and piloted a prospective tool with the ability to highlight specific areas of risk associated with sendout testing, also known as referral lab testing. While the ultimate goal of this project is to reduce testing-related diagnostic errors (TDE) by encouraging proactive risk assessment and targeted intervention, this paper focuses on development, pilot-testing, implementation, and further extension of the tool. TDE as introduced by Epner et al., denotes diagnostic errors associated with the total testing process, whether from laboratory or non-laboratory sources, that lead to patient harm [3].

Laboratory errors leading to patient harm can be divided into three general categories: pre-analytic, analytic, and post-analytic. Pre-analytic errors include problems in test ordering, specimen collection, and transport to the testing laboratory. Analytic errors encompass problems within the laboratory related to specific test analysis. Post-analytic errors include problems with test reporting, interpretation, and appropriate response by the patient's healthcare provider. Analytic errors have received the most attention by laboratory medicine professionals. This is because the laboratory has control over the entire analytical process from beginning to end, so errors may be easier to identify and remedy. Quality improvement efforts, including standardization, proficiency testing, strict quality control measures and accreditation standards contributed to marked improvement in overall analytic reliability since the initiation of the Clinical Laboratory Improvement Act (CLIA) of 1988. Studies looking at errors from the clinical point of view have revealed that the vast majority of laboratory-related errors now occur in pre- or post-analytical steps [4–6].

Sendout laboratory testing refers to testing sent to a referral lab by a primary lab because the test is not performed in the primary lab. Sendout testing presents additional opportunities for TDE, especially in the pre- and post-analytic phases. In general, there are more manual

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steps and handoffs involved in tests sent to referral laboratories. These additional steps increase the likelihood of errors. As a group, these tests tend to have longer turnaround times increasing the chance that an abnormal test will not be acted upon in a timely fashion. Referral tests are often lower in volume, and in general, the ordering, processing, transporting, and resulting of these tests require many manual steps and therefore are more error prone. In addition, the number of laboratory tests offered by referral laboratories has increased dramatically over the years, which makes it easier for clinicians to mis-order tests or mis-interpret results. One recent study at a major reference laboratory found that up to 1/3 of genetic tests were ordered incorrectly [7].

Based on our assumption and experience that sendout tests are predisposed to pre- and post-analytic errors we decided to focus our risk assessment efforts on this group. This study describes a pilot project at nine sites in which a prospective tool was used to assess risk of diagnostic errors involving laboratory sendout testing. This tool could be used by other laboratories to identify the areas of high risk to patients, and then guide quality improvement.

2. Materials and methods

This study was performed as part of contract research conducted by RTI International on behalf of the Agency for Healthcare Research and Quality (AHRQ, ACTION II Task Order: Proactive risk assessment during the laboratory testing process to reduce diagnostic error; Contract HHS29032001T, Task Order 1). Initially, a systematic review of the medical and grey literature was performed to identify existing tools for prospective risk assessment in the clinical laboratory, and risk assessment approaches used in healthcare settings. This review identified failure modes and effects analysis (FMEA) [8,9] and the derivative version by the Department of Veteran's Affairs National Center for Patient Safety, healthcare failure mode and effects analysis (HFMEA) [10] to be the dominant approaches to prospective risk assessment. These approaches seek to identify all potential hazard modes and then assign a risk score that takes into account the likelihood that a particular mode will be encountered and the severity of harm if it is. Using this information, it seeks to prioritize the hazard modes with the highest aggregate risk for remediation effort.

Given the absence of published tools with demonstrated applicability for TDE associated with sendout testing, we created a *de novo* instrument. Faculty members at three academic institutions partnered with RTI International to create, evaluate, revise, and pilot a prospective tool for risk assessment of sendout testing using a process of rapid-cycle development. This group of laboratory medicine professionals all had experience with errors related to referral laboratory testing. We aimed to keep the tool simple enough to be completed by key laboratory personnel within 1 h. Also, we wanted the results to be easy to interpret and decided to display results as a color-coded heat map. Heat maps provide quick visual display of results, highlighting hazard modes of concern, without the use of complicated algorithms or scoring methods. For this tool, green was associated with a low risk of diagnostic errors, yellow answers were cautionary, and red represented areas with a high risk of problems. A hard copy version of the tool consisted of a spiral bound notebook listing questions followed by a list of 2–4 potential answers. After circling responses, users could simply flip a color-coded transparency over the answers to indicate the color/score of that particular response. After the first draft of the tool was created, a diverse team of laboratorians at a second academic institution was asked to complete the assessment. Following that activity, the team carefully critiqued each item of the instrument. Additionally, an RTI employee conducted usability interviews as part of a cognitive assessment of the tool to ensure that the tool was comprehensive, well-organized, and clear. A revised tool was created and taken to a third academic institution. The process was repeated. Finally, representatives of all three academic institutions and RTI reached consensus on a final revision. A table of items included in this tool can be found in the Supplementary Material.

That version, consisting of 52 items, was then shipped to the nine participating hospitals recruited for this study. Instructions indicated that the tool was to be completed collaboratively by laboratory personnel involved in sendout testing, including but not limited to clinical laboratory scientists, laboratory information system (LIS) coordinators, billing and compliance officers, and medical directors.

These nine participating sites included academic centers and reference laboratories. The risk assessment questions were broken up into seven main sections: context/laboratory demographics, test selection by clinician, sample processing and transport by the lab, utilization management, results reporting, clinician result retrieval and interpretation, and quality measures. Utilization management refers to interventions to help physicians order the correct test or panel of tests. A follow-up usability survey was also completed at each site immediately after completing the risk assessment. This survey included appraisal of the tool's content, format, application, implementation, and overall impressions.

3. Results

3.1. Prospective risk assessment tool

Of the 52 questions, only 11% (6) were given a single rating by all 9 sites, 38% (20) of questions had two of the three color ratings, and 50% (26) of questions had all three colors represented in the results. Two demographic items were not color coded. Laboratories in this study varied to some extent in size, with three sites reporting between 500,000 and 1,000,000 billable tests per year and six sites reported >1,000,000 billable tests per year. No sites reported less than 500,000 billable tests per year. Four laboratories sent out <5% of these billable tests to referral laboratories, three sent out 5–10% of tests, and two sent out >10% of their tests. Laboratories varied greatly in the number of referral laboratories used, with one lab using <10 referral laboratories, three using 11–50 laboratories, two reported using 50–100 laboratories, and one site sent specimens to >100 different referral laboratories. The areas deemed to be of highest risk, where four or more sites rated red, included utilization management, non-interfaced orders or results, and a lack of quality measures.

The test utilization management section includes four items related to rules influencing appropriate test ordering behavior (Table 1). These items reveal who determines what the test ordering rules will be, how the rules are enforced, and how intensively tests are actively managed. Responses varied considerably. One site had no test utilization rules, while two had daily intensive test utilization review by doctoral level laboratory medicine staff. The other laboratory responses fell in between. Five sites rarely or never actively intervened in test management while four sites had at least some degree of daily management. Daily management activities included creation of computerized physician order entry (CPOE) prompts and reflex testing algorithms, limiting the ability of clinicians to order certain tests, and requiring review of undefined or miscellaneous tests. Four laboratories had multidisciplinary committees of clinicians and laboratory medicine MD/PhDs that generated test ordering rules, one institution relied on a clinician committee, and three sites had rules made by laboratory MD/PhDs only.

Although eight of nine sites had a committee charged with making rules about test ordering practices, only four sites reported enforcing these rules. Two sites reported that clinician orders that violated rules were flagged for review by laboratory medicine MD/PhDs. Two other sites reported that orders that violated rules were detected and processed by laboratory technicians. Tests were rarely or never modified at five sites. One site modified tests daily, two weekly, and one modified tests monthly. One other item included in this section is related to delays in specimen transport to reference laboratories resulting from laboratory test review. Those who responded stated that specimens were rarely or never delayed.

Table 1

Utilization management questions. In answering these questions green represented low risk responses, yellow answers were cautionary, and red represented areas with a high risk of problems leading to diagnostic errors.

How often do you actively manage and intervene in test utilization using processes/tools <u>such as, but not limited to</u> , the ones shown next: 1. Establishing a formulary of approved tests 2. Creating custom order sets that are each designed for a specific specialty 3. Creating electronic prompts (clinical decision support) that guide test ordering based on the patient's history, chief complaint or the suspected diagnosis 4. Creating clinician-approved sequential testing protocols (reflex testing) 5. Limiting the ability of clinicians to order specific tests based on criteria such as obsolescence, a price threshold or because a test is deemed to require highly specialized knowledge? 6. Requiring review of any miscellaneous or hand-written or "system-undefined" test	Daily	Weekly	Monthly	Rarely or never
Who determines the rules for implementing utilization management? (choose the option that most closely describes your situation)	Multi-disciplinary committee of clinicians and laboratory MD/PhD's	Clinician committee	MD/PhD laboratory personnel only or non-doctoral level laboratory personnel only	There are no utilization management rules
How are the utilization management rules enforced for sendouts (choose the best option):	Clinician orders that violate rules can be entered, but are electronically flagged for laboratory review	Clinician orders that violate rules are electronically prevented from being entered	Clinician orders that violate rules can be entered, but are manually detected and flagged for laboratory review	Rules are not enforced or not used
How often are orders cancelled or modified as a result of a laboratory review?	Daily	Weekly	Monthly	Rarely or never

Quality measures included the following nine items: the volume of miscellaneous/undefined/manually entered test orders, the volume of results/orders left un-entered after 8 h, the number or percent of samples that miss their expected pick-up time, the number or % of samples that exceed their expected referral lab turn around time, the percent of results not retrieved, sendout test volume by analyte, utilization management impact, measures of sample quality (e.g. aliquot QNS), and corrected results rate by referral lab (Table 2). These items were rated as green if the attribute was measured with thresholds for corrective action, yellow if measured without a threshold for corrective action, and red if the attribute was not measured. All nine items had a mixture of responses from green to red among the various sites. The percent of results not retrieved was only measured by one of the nine laboratories. Similarly, the volume of results/orders left un-entered after 8 h was only monitored by the same one of nine laboratories. No lab scored all green, yellow, or red. The lab utilizing the most quality metrics scored seven greens, one yellow, and one red, while the two laboratories with the least number of measured quality metrics scored eight reds and one yellow each. The other five laboratories had a mixture of reds and yellows.

3.2. Follow-up survey of usability

Results from the usability survey indicated that all participants agreed that the tool was educational and useful (Table 3). Survey respondents had a favorable impression of the tool with all nine strongly agreeing that the items included in the assessment and the time to

complete it were appropriate. One question in the usability survey asked respondents to indicate the top 2–3 issues addressed by this tool that were not otherwise on their priority list to address. The top responses all pointed to the quality metrics. Other problem areas focused on utilization management, documentation problems, long turnaround times for entering results, and clinician results retrieval. Only one respondent stated that he or she already knew all the flawed areas in their laboratory.

Though the time taken to complete the survey was not formally measured, all respondents strongly agreed that the number of questions included and the length of time required to complete the assessment was appropriate. Informal discussions indicated that the tool could be completed by groups of laboratory personnel in less than an hour. No single individual had the breadth and depth of knowledge to complete the whole survey alone; a group effort was required. All agreed that the color overlay and scoring mechanisms were user-friendly and that the assessment was informational, educational, and useful to clinical laboratory personnel in hospitals of all types. One person commented that the tool would work best on a computer.

4. Discussion

This prospective tool is a novel instrument developed to assess the risk of diagnostic error and harm associated with laboratory sendout testing. Based on a consensus of faculty and staff at the three institutions involved in creating this risk assessment, sendout testing has been acknowledged as particularly high risk, due to many factors including

Table 2

Quality measures. Responses for this section are scored “green” if this aspect is measured with thresholds for corrective action, “yellow” if measured with no threshold for corrective action, and “red” if the attribute is not measured.

Quality measures
Are the following quality measures routinely tracked and do unsatisfactory results drive corrective action?
Volume of miscellaneous/undefined/manually entered test orders, i.e., not selectable from menu
Volume of results/orders left unentered after 8 h
Number or percent of samples that miss their expected pick-up time
Number or percent of sendout samples that exceed their expected referral lab turnaround time
Percent results not retrieved
Send out test volume by analyte
Utilization management impact (e.g., percent orders modified—tests added, deleted, changed)
Measures of sendout sample quality, e.g. aliquot QNS
Corrected result rate by referral lab

increased hand-offs, the manual nature of many sendout processes, and the complexity associated with rare or low-volume tests. All of these issues increase the probability of errors which can cause patient harm. Unlike most risk assessment tools, this one is prospective in nature, and enables laboratories to prevent errors before they lead to patient harm. It does this by helping laboratories identify the areas of highest risk to patients, which in turn gives guidance on where laboratories should focus their quality improvement efforts and resources. In addition, while designed for sendouts, many of the items in the tool are general enough that they can be applied to testing performed within the laboratory.

Survey respondents reported that the tool was useful and easy to use. Importantly, the considerable diversity in question responses among our nine respondents indicates that there is considerable variation in practices between individual sites and that this instrument was sensitive to those variations. The main limitation of this pilot study is its small sample size. We also have no independent confirmation that respondents interpreted the questions or chose their responses accurately, and this reflects a generic limitation of all prospective risk assessment approaches; results can vary depending on who completes the assessment and their individual experience, perspective, and knowledge. Another limitation is that the tool assesses laboratory practices that are less than desirable as deemed by the tool developers, but no firm statement can be made about the TDEs or patient harms that result from the less than desirable practices even though a heat map populated predominately with red and yellow may be cause for concern by reasonable laboratorians at a given facility. Despite these limitations, this tool identifies several interesting trends, particularly in the sections related to utilization management and quality measures.

There is increasing interest among laboratories in utilization management, which is defined as strategies and tactics to ensure that the

right test is ordered on the right patient at the right time. This is an area with clear opportunities for improvement, and there are many different ways that test ordering can be managed. In this study, there was substantial variation amongst the nine sites surveyed on how they manage their sendout tests. Even though eight of nine sites reported to have a committee involved in utilization management, about half of the sites reported that no utilization management rules were enforced. There are a number of possible reasons for this apparent discrepancy. It may reflect the difficulties all institutions have in implementing best practices in complex medical systems. Individuals charged with rule enforcement may be understaffed or may be culturally resistant to suggesting to physicians that their test orders could be improved. There also may be technical barriers in implementing rules such as lack of programmers who could implement CPOE prompts. Regardless of the reason, each site had some yellow or red responses, indicating that every site identified at least some areas of risk. Though our sample size is small, this suggests that many laboratories will have opportunity for substantial improvement in utilization management. A recent paper by several authors describes one way a utilization management committee successfully improved sendout genetic test orders [11].

Quality measures are increasingly important for laboratories. In this study, quality metrics for sendout tests varied dramatically among survey sites. Some laboratories measure nothing but sendout test volume, while other laboratories measure and have thresholds for corrective action for everything from number of QNS (quantity not sufficient) samples to referral lab turnaround times. There was one metric that only one of the nine laboratories routinely measured, the number of test results not retrieved by a clinician. Failure to retrieve results is a major cause of harm as it can lead to delayed or missed diagnoses [12]. In legal cases involving laboratory testing, failure to retrieve a result is one of the top three reasons clinicians are sued [6]. It may be difficult for laboratory medicine professionals to know if a test result was noted and acted upon without doing in-depth chart reviews, which is not practical for most tests. This tool has the potential to help hospital laboratories proactively identify areas to focus their error prevention efforts. By focusing on areas of greatest risk, laboratories will be better able to achieve our ultimate goal: decreasing the risk of harm related to diagnostic errors for patients everywhere.

Since this pilot study showed promising results, we are working on two logical extensions of this work. The first is to make an online version of the survey. This will enable wider use of the survey and facilitate easier analysis. Using this online edition, we then plan to do a much larger survey to assess prospectively the risk associated with sendout testing in the United States and Canada.

In conclusion, managing sendout testing will remain challenging for laboratories. More tests are being developed each year, and by necessity many hospital laboratories will send these tests out to referral laboratories. The inherent complexity increases patient risk for testing-related diagnostic errors and has profound financial implications for patients and the healthcare system. This sendout risk assessment tool may

Table 3

Follow-up usability survey results. The numbers listed correspond to the number of individuals who responded with that particular answer. Overall, people thought that the tool was user friendly and useful.

Item	Disagree	Somewhat disagree	Neutral	Somewhat agree	Strongly agree	Comments
This tool is best completed collaboratively by a small group of 2–3 people.				2	7	
The number of questions included and the length of time required to complete the assessment are appropriate.					9	
The color overlay and scoring mechanism are user-friendly and appealing.				4	5	
This assessment is informative, educational, and useful to clinical laboratory personnel in hospitals of all types.				4	5	
This assessment helped us identify risk areas that were not otherwise on our priority list of issues to address. [Please indicate the top 2–3 issues in the comments section].			1	5	3	Topic #1: Topic #2: Topic #3:
As a result of completing this assessment, it is likely that our laboratory will take action to remediate some of the identified risk areas.		2	2	4	1	
This assessment tool will reduce the likelihood of missed, delayed, or incorrect diagnoses resulting from laboratory test ordering.	2	2	2	2	1	

prove to be a powerful instrument for laboratories that need to find high impact areas on which to focus their quality improvement efforts.

Conflict of interest

None.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <http://dx.doi.org/10.1016/j.cca.2014.03.028>.

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