Risk Assessment of the Testing Processes of Access Community Health Network

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Abstract

Purpose: To understand areas of risk within and improve the safety of the testing process within Access Community Health Network's (ACCESS) primary care centers through a comprehensive risk assessment of the management of laboratory testing, imaging studies, and special tests. Additionally, to raise staff awareness about improving quality and safety while contributing to the limited published research on office testing systems.

Scope: Use a multi-methods approach to assess the testing processes across all ACCESS health centers with a detailed assessment in 10 representative centers.

Methods: Use complementary data-gathering methods to assess testing process outcomes: 1) an office systems engineering analysis with direct observation of staff; 2) a chart audit and patient phone survey; 3) an audit of the management of four critical, abnormal test results; 4) event reporting by providers and staff; and 5) a safety culture survey completed by all providers and office staff.

Results: Study data indicates the importance of a consistent practice process for tracking samples, test results, and follow-up; of informing patients of all test results; of increased patient follow-up on abnormal results; and of coordinating the testing process with other office systems.

Key Words: patient safety, ambulatory, practice improvement, laboratory, testing process

Purpose

Like all areas of patient safety in ambulatory care, very little research has been published about ways to improve the reliability and safety of testing in physicians' offices. There is great need for careful study and sharing of testing process improvement methods.

During the past 10 years, investigators have described the errors that occur in the testing process in primary care practices and the reasons these errors occur. However, there are no published studies documenting the actual—as opposed to the reported—rates of errors made during the management of laboratory test results in representative groups of primary care practices. According to data from the Medical Outcomes Study and the National Ambulatory Medical Care Survey (NAMCS) of 2002, the average family physician sees about 100 outpatients per week and orders diagnostic tests on 39% of them.[1] Thus, a four-physician family practice center manages about 30 diagnostic test reports per day, 150 per week, and 7,500 per year, and each test report may contain one to 20 individual test results. Even if errors in the testing process occur infrequently, there is still great opportunity for harm because of the large number of tests ordered by primary care physicians.

The overall goal of this project is to understand and improve the safety of the testing processes of ACCESS' primary care community health centers through a comprehensive risk assessment study of ACCESS health centers' testing processes, including laboratory testing, imaging studies, and special tests. Based on a multi-methods risk assessment that includes input from all important stakeholders, we collaborated with ACCESS managers, staff, and providers to devise and implement improvement strategies.

Scope

The scope of this assessment includes the processing of all lab tests, imaging studies, and special tests ordered on ACCESS patients that, when optimally managed, normally would be returned to ACCESS health centers, posted in a patient's chart, and provided to patients with instructions for follow-up on abnormal results.

ACCESS was established in 1991 and, over the years, has grown into the largest Federally Qualified Health Center (FQHC) in the United States. In 2007, ACCESS provided care at 44 primary care sites, all of which were eligible to participate in this study. ACCESS provided care to about 200,000 unique patients who made more than 600,000 visits. Nearly half of ACCESS patients are African American and just over half are Hispanic.

Virtually all ACCESS patients have incomes under 200 percent of poverty and about one quarter are uninsured. ACCESS is governed by a patient-majority community-based board that reflects the racial and ethnic diversity of its patients. ACCESS' employees at all organizational levels are racially and ethnically diverse, further strengthening bonds with patients, communities, and neighborhoods. ACCESS' mission is to provide high-quality, accessible health care in medically underserved communities in the Chicago area to all who need it without regard to age, race, ethnicity, gender, language, religion, education, sexual orientation, physical condition, or ability to pay.

Because of the large size of the ACCESS organization, and considering the optimal use of grant resources, we assessed 10 ACCESS health centers in detail. These health centers were representative of the organization's primary care sites in terms of number of unique patients, encounters, and clinical staff; geographic location; and the types of lab services offered.

ACCESS has worked to integrate patient safety activities into the organization's quality improvement structure. The Continuous Quality Improvement Council launched a Patient Safety Committee, which is charged with monitoring safety trends, implementing The Joint Commission's patient safety goals, conducting analyses of safety-related occurrences, and making policy recommendations to promote a culture of safety, including recommendations for ongoing staff training and education. This testing process risk assessment study formed a major project for ACCESS and built upon two preliminary studies.

The first preliminary study, conducted by Dr. Eder, was a survey of ACCESS health center managers to collect basic information about the process for managing abnormal lab test results in 26 ACCESS health centers. These health centers averaged 1,236 visits per month (minimum average: 423/month; maximum average: 4,986/month). The average number of staff was 16 (n=7 providers, 5 medical assistants, 3 support staff, and 1 manager/team leader). Of the 26 health centers that responded, 21 relied exclusively on Mount Sinai Hospital for laboratory testing, two centers used a single independent laboratory, and three others used multiple laboratories.

The second preliminary study was a Clinic Workflow Analysis Project, conducted by the Quality Improvement Department, to document, analyze, and compare testing processes at four ACCESS health centers. The four health centers were selected for their variability in size, patient encounters, and location. This project documented laboratory testing processes for in-house and off-site testing.

Findings from these two studies pointed to process inconsistencies and issues that could affect the safety and quality of testing processes.

The Risk Assessment of the Testing Process study, which is the subject of this report, involved three classes of research participants: 1) patients who had laboratory or imaging tests at one of the 10 health centers studied whose medical charts were randomly selected for chart audit. A sample of these same patients were contacted and interviewed by phone to provide feedback on their experiences with testing and their understanding of test results; 2) the clinicians and health center support staff at the 10 health centers that were studied intensively; 3) all ACCESS health center staff, because they were asked to complete the Medical Office Survey on Patient Safety.[2] This study was reviewed by an IRB at the University of Chicago and conducted in accord with methods approved by the IRB for protecting all subjects who participated. All research participants either obtained care or worked within urban safety net offices; almost all participants satisfied AHRQ's definition of priority populations.

The lack of published studies makes it impossible to estimate the prevalence of errors within the testing process and the resultant harm to patients. This risk assessment study focused on identifying risks and hazards as the basis for initiating targeted quality improvement activities.

Methods

The comprehensive risk assessment of ACCESS testing processes examined the testing process as a seven-step model that Dr. John Hickner and Dr. Nancy Elder developed. Following Battles' methodological recommendations for studying risks and hazards, we engaged in a broad, multi-methods assessment of the testing process using six complementary data-gathering methods: onsite office systems engineering assessments, chart audits, patient phone interviews, staff-generated event reports, the Medical Office Survey on Patient Safety, and interviews with the testing facilities serving ACCESS. A multi-methods approach combines the strengths of the different methods to identify areas of risk while accommodating variations in testing practices within ACCESS health centers.[3] Most importantly, we studied testing as an office system. We did not study individual performance or the accuracy of ordering tests or interpreting results. The data-gathering methods were conducted as follows:

1. The onsite office systems engineering analysis included direct observation of staff work, key staff interviews, a structured survey of office testing processes completed by the office manager, and process flow mapping in order to document and examine the testing processes, procedures, and policies of ACCESS health centers.
2. An audit of medical charts randomly selected to identify patterns in documenting the process and outcomes of the health centers' testing process. An audit of medical charts for patients with abnormal results to identify patterns in documenting the management of critical abnormal test results, including abnormal pap smears, abnormal mammograms,

abnormal prostate-specific antigen tests, and out-of-therapeutic-range INR values in patients taking coumadin for atrial fibrillation.

3. A phone survey of patients to assess their understanding of tests ordered for them and whether they received test results and instructions on the follow-up of abnormal results.
4. Event reports, completed by providers and staff, to raise staff and physician awareness of safety issues in the testing processes and to identify specific instances of failures in the testing process systems at their own health centers.
5. Medical Office Survey on Patient Safety completed by all providers and office staff to assess the degree to which safety principles are known by employees and practiced in the health centers.

The findings of this multi-methods assessment were shared with each health center, with the patient safety committee, and with ACCESS leadership in order to identify and implement improvements in the health centers' testing processes.

Measures: The project used multiple methods for data collection to facilitate the collection and identification of failures within the testing process from different perspectives. The different methods for data collection provided data that reinforced results of other data collection activities (e.g., there were correspondences between data collected on patient notification of tests results and patient follow-up on abnormal labs from both the chart audits and the patient phone surveys as well as from the audits of all tests and critical abnormal lab results). This study yielded quantitative pilot data on areas in the community health center lab testing process where failures were more or less prevalent. This study also yielded qualitative and observational data on the actual testing process practices and variations as well as on the way responsibilities were distributed among the staff at different sites.

Limitations: Of the 10 potential limitations identified in the proposal, only the following 4 limiting areas were encountered by the research team during the course of this risk assessment project.

1. The extensive scope of the project was realized with minimal exceptions. To study the management of all test results, fewer total charts were audited than originally projected. Unfortunately, the individual hired to audit charts did not devote a satisfactory number of hours to the project in the final 3 months of this phase of the project, and the timing of this performance issue prevented replacement of this person. However, 684 charts containing over 2,000 tests were audited, so sufficient research data was collected to realize the goals of this aspect of the project.

   We proposed and conducted interviews with managers of the testing facilities used by ACCESS health centers to obtain their perspective on the strengths and weaknesses of testing practices at ACCESS sites. The

laboratory managers were able to comment on performance issues generally, but they were not able to provide information specifically about ACCESS health centers.

The proposal indicated a potential issue regarding how representative the 10 health centers were of the entire organization, but feedback on reports shared with health center leaders, organizational leaders, and all clinicians indicated that our findings identified issues common across the organization. The methods utilized proved sufficient to identify the weak links in ACCESS testing processes and served as a foundation for initiating practice improvement activities.

2. Only four sites submitted event reports despite all 10 intervention sites agreeing to complete and being provided an abundance of event reports and staff given the opportunity to complete forms anonymously. Additionally, 14 of the 18 completed reports were submitted by staff from a single site. The lack of reports in combination with responses to the Medical Office Survey on Patient Safety indicated an organizational need to address health center staff perceptions of the punitive nature of organizational culture, communication, and teamwork.

3. We did not audit the number of medical charts originally proposed, and it proved more difficult to reach patients by phone than anticipated. As a result, fewer phone surveys were completed than originally proposed. The following table provides data on project activity related to phone surveys:

Outcomes from phone surveys	Number of Phone Surveys Completed or Attempted	Percentage of Phone Surveys Completed or Attempted/total Number of Charts Audited
Phone surveys completed	144	21
Wrong/Disconnected Phone #	69	10
Answering Machine/No Answer	60	9
Refused	3	0
Other reasons surveys not completed (e.g., patients under 18 years of age, phone numbers unavailable, no response after 2-3 attempts, language issues, individual deceased)	408	60
Total phone surveys attempted to complete	684	100

4. The research team uncovered real problems with real patients while conducting the studies; these were brought to the attention of health center leaders and subsequently addressed in accord with organizational policies. We proposed to do root cause analyses, with the expectation that

real problems would be discovered as a result of our study of the management of critical abnormal labs, but this was not ultimately accomplished due to our failure to uncover cases that were sufficiently recent to allow for a reliable root cause analysis.

These limitations did not impact the overall quality of the study, as the project provided health center staff with data and information on areas of weakness and collaboratively identified strategies for eliminating errors and improving the safety of testing for patients.

Results

Preliminary results are reported here. The analysis of the data is ongoing, with publications in preparation.

Chart audit of all test results. The chart audit provided insights into the maintenance of medical records by clinical and support staff. Charts were audited by the project coordinator, who also helped refine the data collection process. One in seven results was not filed in the chart and about one in 20 results was not signed (the form for onsite waived test results did not have an area for a clinician's signature). Additionally, patients were not notified of one in three tests results, although organizational policy requires patients to be notified face-to-face (communicating PHI via the phone or mail is prohibited).

Documentation Failures in Patient Medical Records	n=2008 tests
Test result not in chart	14%
No provider signature on test result	6%
Test result signed but not dated	27%
No documentation of provider response	13%
No documentation that patient was notified	36%
No documentation that patient acknowledged the follow-up plan *if test results were abnormal*	42%

The chart audit data may overestimate deficiencies in communicating test results to patients; failure to document does not mean that it did not happen.

Patient phone survey. The patient phone survey was used to evaluate communication regarding test results. We found that many phone numbers in patients' records were incorrect or disconnected. Almost all patients whom we could contact participated in the survey, and approximately 15% of the patients whose charts were audited participated. The responses to two questions were particularly relevant for their correspondence to the chart audit data. Two-thirds

of patients (68%) who had lab tests reported receiving their results. One of every two patients reported receiving instructions or information about their results.

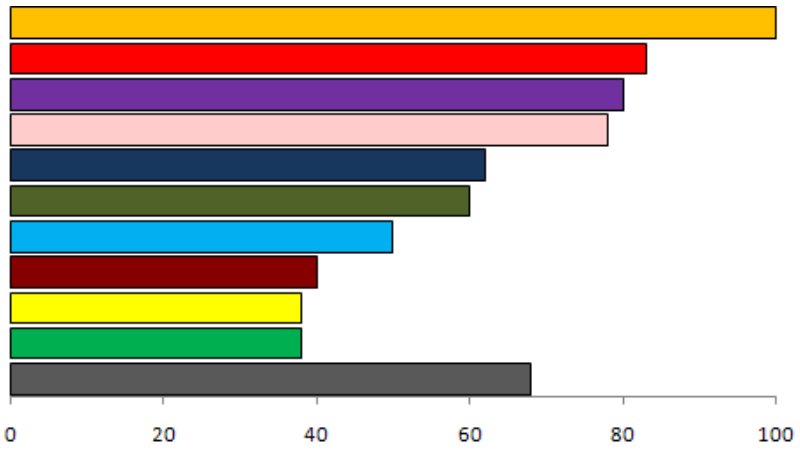
Question	Test Type	Blood (n=64)	Non-Blood (n=65)	Imaging (n=11)
Did you know why you were having this test (s) done?	Yes	89	92	100
Have you received the result of the test(s)?	Yes	65	73	82
If yes, how did you receive the results?	In office	86	88	66
	Other	14	12	34
How soon did you receive your test result?	<2 weeks	84	88	89
	>2 weeks	16	12	11
Were you given any instructions or information about your results?	Yes	57	52	75

Audit of abnormal test results. Data from the audit of charts with critical abnormal test results indicate that about 10% of patients were put at risk by not being notified of their test results within an appropriate time frame. The number of patients not monitored through follow-up varied across the four tests; there were additional failures in monitoring patients through follow-up on their abnormal results for three of the four tests, suggesting an increased risk and potential for harm. More patients were not monitored through follow-up than were not notified of their results for three of the four tests.

Number of cases in which there was one or more documentation failures	Test Type			
Testing step where the first failure occurred	Pap Smear (n=110)	Mammogram (n=87)	PSA (n=99)	INR (n=65)
Test results not returned to clinician	0	3	7	2
Clinician did not document response to test result	2	4	4	3
Patient not notified of test result	8	3	6	10
Patient not monitored through follow-up	42	10	36	7

Total patients for which there was at least one documentation failure	52	20	53	22

Medical Office Survey on Patient Safety. Staff at all clinical sites were asked to complete the Medical Office Survey on Patient Safety (developed by Westat under contract to AHRQ). Overall, approximately 50% of the community health center staff and physicians completed the survey, with a response rate of about 75% in the 10 sites that were the main participants in the risk assessment study. In the written reports to each health center and to ACCESS leadership, we provided a summary of the responses to a subset of questions that were most pertinent to the testing process. Summarized responses to a different subset of questions was provided to the patient safety committee. An example of the how the survey data were presented is provided below. The percent of staff responding agree or strongly agree to the question: "*After this office makes changes to improve the patient care process, we check to see if the changes worked*" is shown below. The grey bar on the bottom was the average of all respondents; every stripe of color represents a health center.



We have not yet completed the entire analysis of the patient safety survey data.

Outcomes

In the following section, we give the principal findings of the risk assessment study followed by the recommendations for improving the testing process that we shared with organizational and health center leaders.

Finding: The management of testing in Access Community Health Network primary care centers has significant variation both within and between health centers. Variation in the health center testing processes is one source of uncertainty and error.

Recommendations:
1) All health center staff must be trained (and regularly retrained) to use one method for maintaining Lab, Referral, and Abnormal Logs.

2) Managing the testing process is a time-consuming activity. Medical Assistants must have dedicated time to effectively allow them to manage the testing process accurately.

3) Medical Assistants must regularly audit and update all test tracking, test results, and follow-up logs. We recommend that a comprehensive review of all logs be done at least once each week.

Finding: Patients do not consistently receive notification of test results, nor do patients consistently follow up on abnormal results.

Recommendations:
1) To avoid misplacing the paper record of the result, all test results should be placed immediately into the medical chart, with the chart made available for clinician review and response.

2) Health center staff must regularly monitor and confirm that patients with abnormal test results are provided those results and that the patients keep their follow-up appointments.

3) Many patients are not informed of normal test results due to organizational concerns with HIPAA and the organizational policy that restricts staff from using the phone, mail, or email to inform patients of test results, so this policy must be reviewed and changed. Evidence suggests that this policy may also adversely shape patient expectations about test results and adversely affect patient notification and follow-up on critical abnormal results.

Finding: Testing processes cannot be improved without careful coordination with other office systems.

1) The community hospital that processes a majority of laboratory tests often cancels tests but does not notify health center staff when a test is cancelled; therefore, test results are not available at patients' follow-up visits. Cancellation of a test should result in the electronic generation of a report that immediately notifies the health center staff of a test's cancelled status.

2) Health center staff should pull and prepare charts before the day of the appointments.

3) Organizations should rapidly expand its recently launched "Good Catch" program to expand the number of health centers and staff involved in this campaign to raise awareness of error prevention and patient safety.

4) Organizations should develop a “Just Culture” program to address communication issues identified by the Medical Office Survey of Patient Safety.

5) Clinicians must keep patient charts and progress notes up-to-date, with charts returned and filed within an agreed amount of time so that staff time is not wasted looking for “missing” charts.

Discussion

Although this study was conducted within medical offices of a single organization, variation in the systems for managing tests was observed both within and between sites. The lack of standardization in testing processes results in inefficiencies and errors. For example, those sites that did not maintain or review tracking logs at regular intervals demonstrated worse performance in both the time it took to return results to patients and in the percentage of patients who returned and obtained their test results. In addition, the intersection of test management with other office system problems, such as delayed physician documentation of clinic visits, contributed to variation in the testing process and the risk of testing process failures.

Because of this risk assessment, leadership and employees of the health centers are beginning to make the connection between other quality issues and patient safety. The health centers previously participated in quality improvement activities focused on the delivery of medical services for prevention and chronic disease management. This risk assessment highlighted failures to notify patients of important test results related to chronic disease management (diabetes testing) and prevention (pap smears, PSA, and mammograms), so patient safety is being recognized as an important element of all clinical activities.

The steps in the testing process that require coordination between the primary care office and lab—transformation of specimens into results—and the primary care office and patients—transformation of data into information—appear to be areas of high risk and areas for targeted improvement. Consistently throughout the study sites, physician and staff communication with patients about tests, test results, and follow-up instructions constituted an area with the greatest number of errors and failures.

Standardizing the testing process, diligent test tracking, staff training, and dedicated time for staff to manage the testing process are among the recommendations for practice improvements to reduce errors within the testing process. Additionally, assessing a practice’s testing process can identify areas of risk and potential for causing harm to patients.

It is not evident from study observations that practices had previously recognized the connection between reducing errors in the testing process and patient safety.

Significance and Implications

The main reason for malpractice suits against primary care physicians is failure to diagnose, which frequently involves failure to appropriately follow up on abnormal test results. Our study illustrates the high and unacceptable error rates in test notification follow-up in a group of community health centers. From our informal discussion with physicians from other community health centers, we believe that this is a widespread problem. Our prior studies have documented the many errors that occur in management of testing in primary care offices. Although it has not been possible to quantify this risk in terms of volume and percent of tests, mistakes in testing represent a large risk to patients. Beyond documenting the problem, we were able to pinpoint specific weaknesses in the testing processes of these 10 primary care health centers. We were able to demonstrate the interdependency of testing processes and other office processes; problems in other office systems, such as poor recordkeeping, can cause errors in testing.

This risk assessment study is among the few to collect data in primary care offices and is unique in looking at error rates in Federally Qualified Community Health Centers. According to the National Association of Community Health Centers, about 1,200 organizations operate about 7,000 community health centers; 18 million individuals received medical care in community health centers in CY08. The majority of community health center patients are minorities and have a low socioeconomic status. Thus, even if one believes that our findings are typical only of community health centers, our findings have great importance.

For primary care practices interested in improving their performance, the testing process can be a good place to start, as there is likely to be room for improvement in all primary care offices. Finally, our findings highlight the importance of involving patients in testing process improvement. As we move forward with our next project, which is the development and testing of a toolkit for testing process improvement, one of our tools will focus on patient communication and empowerment so that patients can be fully engaged as partners in the safety of office-based testing.

List of Publications and Products

<u>Presentations</u>

Hickner J. Improving the Testing Process in Primary Care Practice. Harvard Quality Colloquium, Boston, MA, August 21, 2008.

Chen E. Assessment of the Management of Critical Abnormal Test Results. Pritzker School of Medicine Summer Research Program Symposium, August 27, 2008.

Hickner J. Improving the Testing Process in Primary Care Practice. Primary Care Patient Safety and Health Information Technology Meeting (sponsored by AHRQ), Washington, DC, October 2, 2008.

Chen E. Quality Assessment of Abnormal Test Results in Community Health Centers. University of Chicago Medical Center Quality Fair, October 15, 2008.

Chen E, Eder M, Hickner J. Quality Assessment of Abnormal Test Results in Community Health Centers. North American Primary Care Research Group, November, 2008, Puerto Rico.

Eder, M. Evaluating Testing Processes. Chicago, IL, November 7, 2008. ACCESS all staff breakfast (800 attendees), poster provided risk assessment study data and explained its relevance for JCAHO patient communication and patient safety goals; 100 copies of the poster were distributed.

Hickner J, Eder M. Staff Perceptions of ACCESS Testing Processes: Responses from the Medical Office Safety Culture Survey. ACCESS Patient Safety Committee, November 13, 2008, Chicago, IL.

Upcoming Presentations

Hickner J, Elder N, Eder M. Studying and Improving Testing Processes in Primary Care Offices; workshop selected for AHRQ's 2009 PBRN Research Conference, June 24-26, 2009, Bethesda, MD.

Eder M. A Multi-Methods Risk Assessment of Testing Processes in Urban Community Health Centers, Academy Health 2009 Annual Research Meeting June 29, 2009, Chicago, IL.

Publications (in process)

The following manuscript titles were proposed to characterize work currently in progress:

1) You Can't Improve Testing When the Office is in Chaos.

2) Issues within Patient/Office Communications Around Testing Processes: What Your Patients Don't Know Can Kill Them.

3) Testing Processes: Out of Sight, Out of Mind.

References

1. Woodwell D., Cherry D.K. National Ambulatory Medical Care Survey; 2002 Summary. Advance Data from Vital and Health Statistics. National Center for Health Statistics, Hyattsville, MD. No. 346, August 26, 2003.

2. Medical Office Survey on Patient Safety Culture. (Prepared by WESTAT, under Contract No. 233-02-0087). Rockville, MD: Agency for Healthcare Research and Quality; December 2008. AHRQ Publication No. 08(09)-0059.

3. Battles, JB, Lilford RJ. Organizing Patient Safety Research to Identify Risk and Hazards. *Qual Saf Health Care* 2003:12 (Suppl II):ii2-ii7.