Why Didn't I Get My Laboratory Test Results?
Testing Not Performed Due to Pre-Analytical Errors: A Quality Improvement Project

Jeffrey M Schapiro MD, Denise Ja, Keith Ng, Ronald Lualhati, Karl Huang, Laura Peterson and Tasha Morales
Kaiser Permanente Northern California Regional Laboratory, Berkeley, California

Abstract

The Northern California Kaiser Permanente Regional Laboratory provides laboratory testing for 22 Kaiser medical centers and 45 medical offices serving a population of 3.4 million members. Of the over 40 million tests performed each year, approximately 15,000 tests (affecting 10,000 patients) are unable to be performed due to a variety of pre-analytical errors. To reduce such errors, these tests, designated as "Test Not Done" (TND), were assessed in an improvement project as part of our ISO 15189 Quality Indicator Monitoring Program.

The project's goals were to reduce the number of TNDs by more effectively and efficiently identifying the causative errors and to partner with our medical center laboratories to prevent these errors through the development of standardized best practices.

A Cross-Functional Team was formed and using root cause analysis, three major Areas of Focus were identified:

1. Reduce Manual Processes: Medical center laboratories have been notified of TND tests via faxing of paper forms, a labor intensive, time consuming and inefficient workflow that did not support timely follow-up.
2. Standardize Reporting: Assessment of TND results varied by laboratory section with use of different terminology, criteria and explanations as to the cause of the error.
3. Improve Reporting Metrics: Available reports provided to medical center laboratories were manually produced and lacked sufficient specificity to help medical centers efficiently focus on areas of improvement.

Our strategy included the increased use of informatics and reporting tools to capture data into a daily report that could automatically be delivered to medical center laboratories summarizing the previous day's TNDs and reasons for the errors. This eliminated the need for notification faxing and also allowed for standardization of the comments used when communicating the reasons for the TND. This informatics approach provided a way to categorize the pre-analytical errors more comprehensively to produce more meaningful reporting metrics and to generate more useful ongoing quality tracking and feedback reporting with the ability to focus on particular pre-analytical problems.

The outcome of this project has so far produced a region-wide 10% reduction in TNDs for all pre-analytical errors being assessed. We were able to focus on particular problems such as mishandling of frozen specimens with these efforts leading to with a 35% reduction in this type of error overall and a 75% error reduction for Hepatitis C viral load testing in particular. Setting improvement goals based on this experience could potentially realize a savings of over $1.2M while also improving laboratory services and member and physician satisfaction.

Introduction

The Kaiser Permanente Regional Laboratory in Northern California performs over 70% of all laboratory tests for the 22 Kaiser Medical Centers and 45 Medical Office Buildings . Our mission is to process and test each sample and provide accurate and timely results for our clients. However, everyday there are pre-analytic or analytic events that occur resulting in us being unable to perform some tests. Some of the causes for a result of "Test Not Done" (TND) are shown in Figure 1.

When a sample is resulted as "Test Not Done", the process is to notify the medical center by phone notification and faxing a "Specimen Problem Form" (Figure 2) with the patient and test information.

Figure 1. Reasons for Test Not Done (TND)

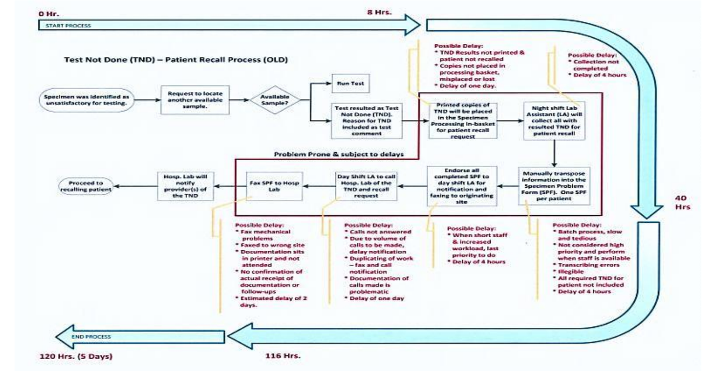
Reason	Definition
Quantity Not Sufficient (QNS)	Specimen does not meet minimum requirement
No Specimen Received (NSR)	No specimen sent from the local facility to Regional Laboratory
Wrong Specimen Type (WST)	Incorrect sample corrected for the test. Example: whole blood sample received instead of serum
Unlabeled Specimen	Specimen received does not have the required patient information
Mislabeled Specimen	Specimen received with incorrect patient information
Leaked in Transit	Specimen received in a container that leaked during transport
Does Not Meet Collection Requirement	As specified. Example: Test ordered as "Fasting" but collected sample is "Random"
Hemolyzed	Serum or plasma received is pale or cherry red in color due to rupturing of Red Blood Cells (RBC)
Specimen Lost	Specimen is lost during transport to the laboratory or testing department
Laboratory Accident	Pre-analytic or analytic accident or error. Example: Spill or specimen contamination
Specimen Integrity Compromised	Specimen was subjected to a condition that rendered specimen non-viable for testing. Example: Prolonged exposure to room temperature instead of refrigerator temperature

Figure 2. Specimen Problem Form (SPF)

Introduction *(continued)*

This notification process (Figure 3) is time consuming, inefficient and subject to delay due to competing priorities, staffing issues, and use of outmoded technologies. Each medical center will then either contact the provider or recall the patient. Due to client feedback related to "Test Not Done", it was becoming apparent that we needed to improve the notification process, standardize the terminology in the reporting of the TND's and to address the root causes of "Test Not Done".

Figure 3. Test Not Done (TND) – Patient Recall Process

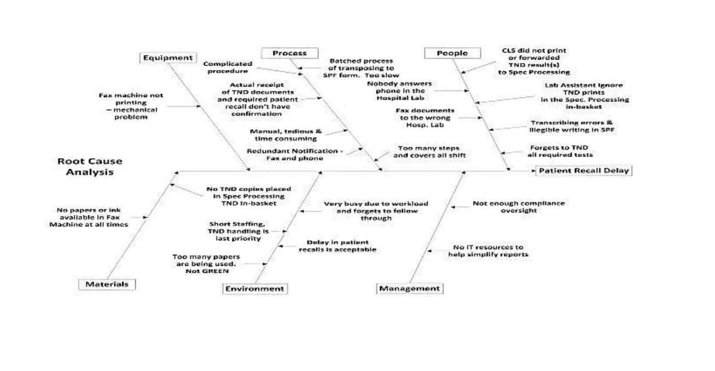


Our goal is to design a process that will reduce the number of "Test Not Done" (TND) by 10% as compared to previous year.

Materials and Methods

To address the inefficiencies of the "TND" workflow, a process improvement team was formed in September 2012 to assess the workflows. "Cause and Effect" Fishbone diagram was used as a tool to help understand the factors contributing to the measured "TND" rates (Figure 4).

Figure 4. Cause and Effect Fishbone Diagram



After performing the Root Cause Analysis (RCA), the process improvement team made the following recommendations:

- Eliminate the manual process of faxing Specimen Problem Form and phoning medical center laboratories.
- Standardize the comments used to communicate the reasons for the "TND" by using templates.
- Use informatics and reporting tools to capture the "TND" data into a daily report that could be automatically delivered electronically to each specific medical center laboratory summarizing the previous day's TNDs and reasons for the errors.
- Develop a monthly "TND" cumulative report categorizing the reasons why we were unable to perform the tests. This report allows each facility to focus on their particular pre-analytic problems.

Actions taken:

To improve reporting metrics, our team worked on standardizing the phrasing of the comments and building standardized canned comments whenever possible.

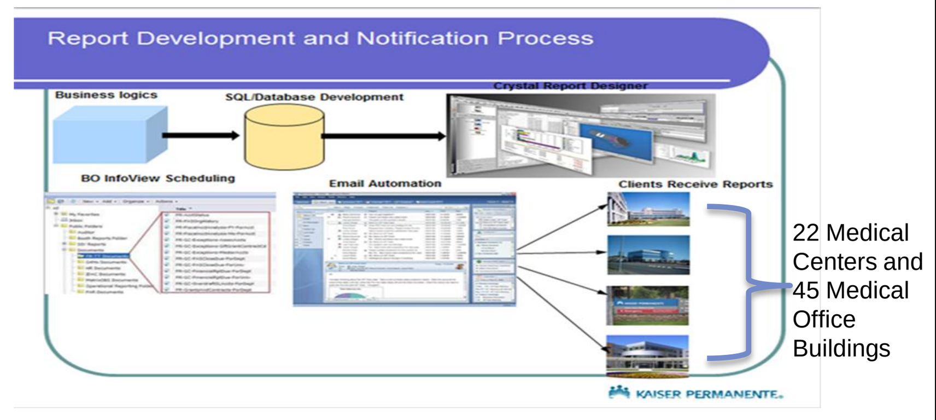
Table 1: Examples of how "canned" comments were standardized

Old Comment Process	New Canned Comment Code	New Comment
Comment is pretext as: TND: Specimen is lost	LOST	TND: Unable to locate specimen; specimen received and sorted to correct target in automation, lost in routing after initial sort.
Comment is pretext as: TND: Specimen Received Unfrozen	NOFROZE	Specimen received not frozen inside transport tote ___________.
	THAW	Specimen thawed in error, unable to perform testing
	THAW2	Specimen received not frozen from courier, thawed during transport.

Materials and Methods *(continued)*

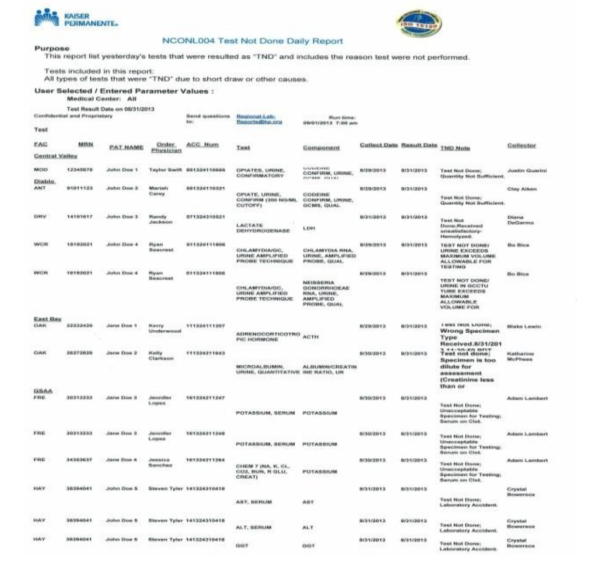
By November of 2012, our Data Informatics analyst developed a daily and monthly Crystal report that automatically grouped together a list of tests resulted as "Test Not Done" by searching for key words or canned comments associated with the result. (Figure 5).

Figure 5. Test Not Done (TND) Crystal Report Development



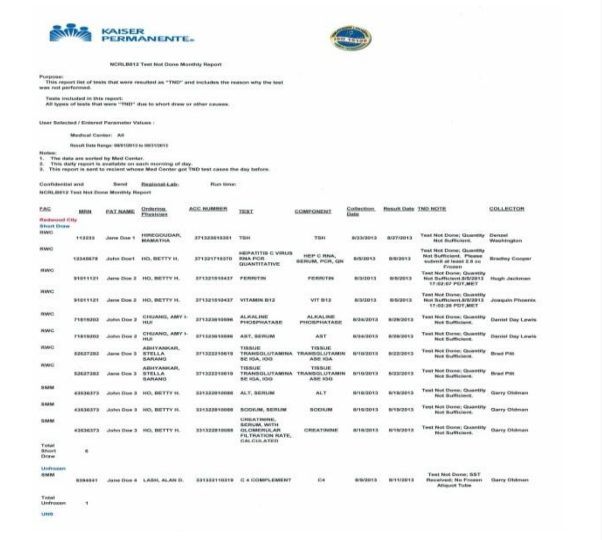
By mid-January 2013, the automated Daily "Test Not Done" Report was ready for electronic distribution to each medical center for follow up (Figure 6), with the report being automatically generated and distributed 7 days a week.

Figure 6. Test Not Done (TND) Daily Report Example



By April 2013 the Monthly "Test Not Done" Report was developed as a comprehensive report for the medical centers to use for quality tracking and feedback reporting (Figure 7).

Figure 7. Test Not Done (TND) Monthly Report Example



To streamline the data, our team worked on categorizing the various comments associated with "Test Not Done" and ultimately came up with 9 categories:

- Unsatisfactory specimen (UNS)
- Quantity not sufficient (QNS)
- Laboratory accident
- Specimen received unfrozen
- No specimen received (NSR)
- Wrong type of specimen received
- CO_2 specimen decapped
- Specimen clotted
- Other reason

Materials and Methods *(continued)*

Our team continues to work in collaboration with the Region-wide Quality and Compliance (LQC) group and hospital laboratory staff in an effort to reduce the "Test Not Done". In addition to distributing flyers to all medical centers (Figure 8 and 9), our Outreach Coordinators plan on making site visits to train and educate staff on proper specimen collection, handling and transport.

Figure 8. Frozen Flyer

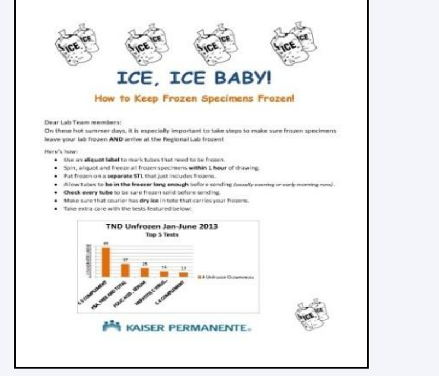
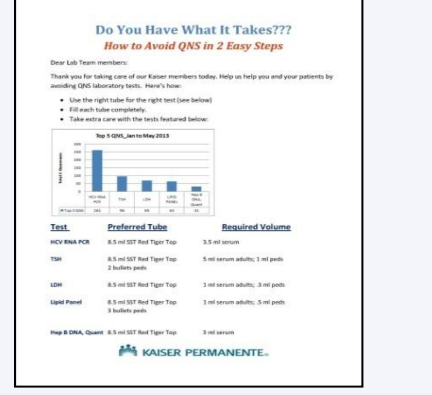


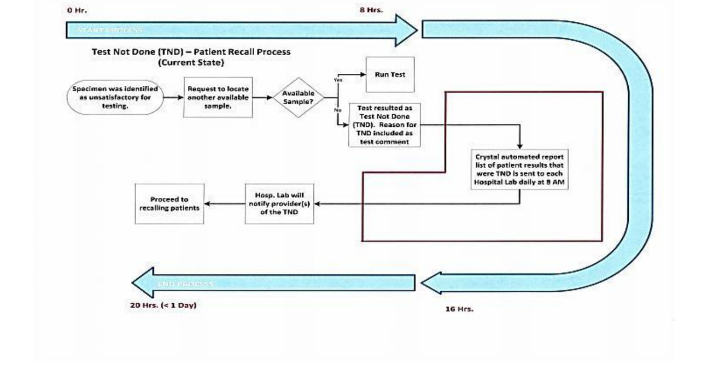
Figure 9. QNS Flyer



Results

The automated "Test Not Done" Daily Report simplified the overall notification workflow by eliminating the wasted steps that often lead to errors and time delays in sample processing (Figure 10). Eliminating the wasted steps allows us to reallocate our staff to perform other tasks. The turnaround time to recall patients has been reduced from 3 - 5 days to less than 24 hours, improving patient management.

Figure 10. Current State TND Workflow



The trending data from the automated Monthly Test Not Done Report (Figure 11 and 12) allows each medical center to assess which problem areas to focus on. Overall, the top 3 contributing causes of unperformed tests at the medical centers are: 1) Unsatisfactory (hemolysis), 2) Quantity Not Sufficient and 3) Unfrozen. These 3 categories account for 44% of the overall Test Not Done. This led to more than 4,200 patient recalls this year.

Figure 11. Test Not Done (TND) YTD – Jan to Aug 2013

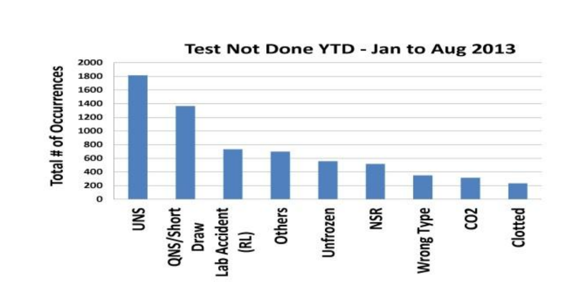
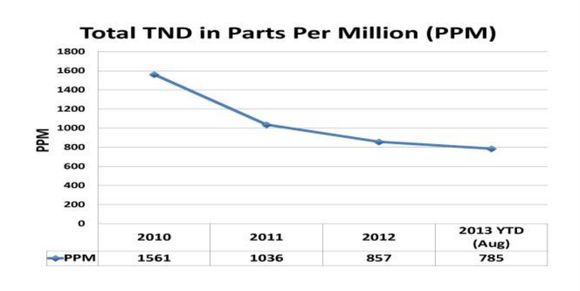


Figure 12. Total TND in Parts Per Million (PPM)



As part of an outreach project, the Regional Laboratory Quality team is working in collaboration with the medical center Quality leaders throughout this year to address all 3 issues.

- To date, we have seen an overall 10% reduction in the number of patient recalls as compared to 2012 (Figure 13). This translates to approximately 950 fewer patients that need to return to the medical center laboratories for a redraw. The estimated annual cost savings is $45,000.
- The improvement project focusing on samples received unfrozen has shown a 35% reduction year-to-date as compared to 2012 (Figure 14).

Figure 13. Test Not Done Comparison

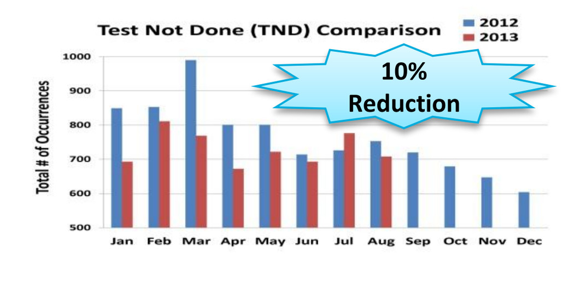
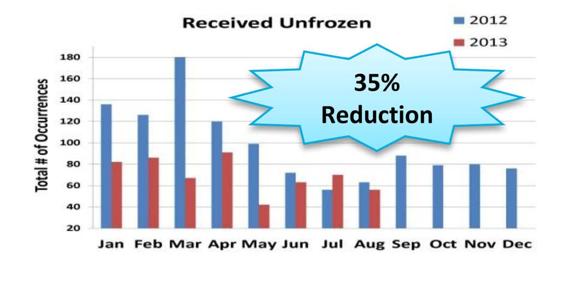


Figure 14. Sample received unfrozen



Results *(continued)*

- Addressing the root causes for "quantity not sufficient" (QNS) for Hepatitis C Virus RNA PCR samples in May has shown remarkable, sustained improvement, resulting in 75% reduction in "Test Not Done" (Figure 15). Overall QNS for 2013 is showing a downward trend (Figure 16).

Figure 15. Hepatitis C Virus RNA PCR QNS

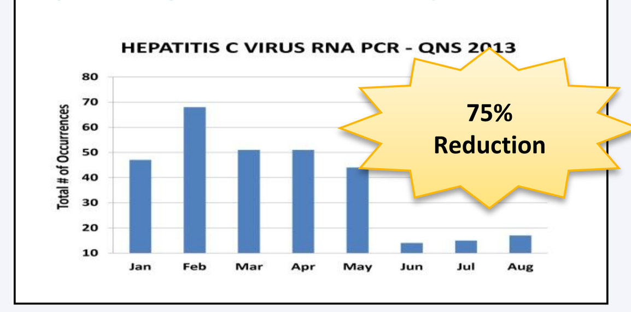
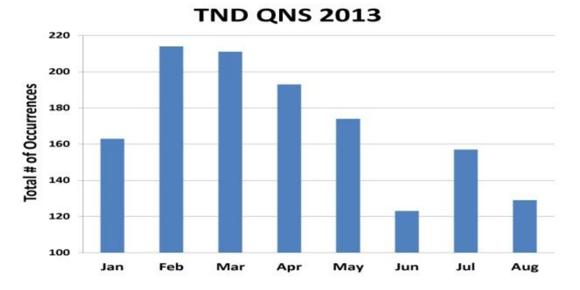


Figure 16. Test Not Done (TND) Due to QNS



To measure the effectiveness of the Daily and Monthly "Test Not Done" Reports, a survey was sent out to the medical center laboratories for feedback. The survey results indicate that the reports are an effective tool for providing feedback to the phlebotomists and for quality tracking and quality improvement (Figure 17 and 18).

Figure 17.

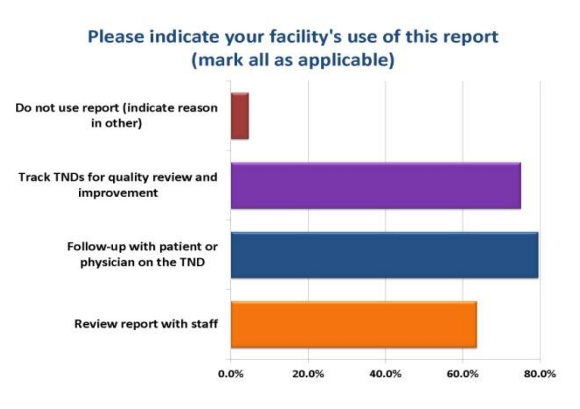
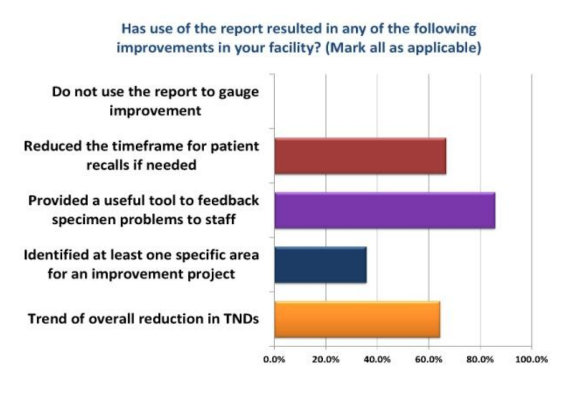


Figure 18.



Conclusion

Replacing the manual faxing process for notification of a "Test Not Done" by an automated daily electronic report has shown to be not only a more efficient and time saving process, but using this tool has also provided all the following improvements:

- ✓ Meeting the goal of reducing "Test Not Done" by 10% (approximately 950 patient recalls) as compared to 2012 with cost savings of approximately $45,000.
- ✓ Allows us to effectively track and monitor the causes for the "Test Not Done" in a much more timely manner.
- ✓ Medical Center leaders can provide timely feedback to the phlebotomist on pre-analytic problems.
- ✓ Identifies the problematic pre-analytic issues at the medical center laboratories that warrant root cause analysis and corrective actions.
- ✓ Standardization of the comments used when reporting tests as "TND".
- ✓ Allows us to identify where to strategically place resources so as to maximize resolution of pre-analytical problems.
- ✓ Allows us to eliminate the wasted steps in the workflow that causes delay in the notification process.
- ✓ Allows us to be "greener" by eliminating the use of paper as a means of documentation and communication.

Since implementing this on-going quality improvement project, we have made substantial improvements to our pre-analytical processes. Our efforts in reducing "Test Not Done" have improved quality, service and patient care, as well as producing significant cost savings.