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



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 preanalytical 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.
- 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.

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					

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2	CLINICAL L SPECIMEN F	ABORATORIES ROBLEM FORM						
	To: At:		Dete:					
	From: Al:	INCOMPANY AND	Phone #: 8					
	6 Specimen Information							
	Petient name: M.		Acc. #:					
	Facility: Dr. name/number		Coll. date:					
	Specimen received:							
	Serum Wholeblood Fluid (specify):	Other (specif	y):					
	I. Probleme Test ordered:							
	Lab accident/lab error (specify):	_ Hemolyzed						
	No specimen received	Serum on clot						
	Wrong type of specimen received	Quantity not sufficient (Q)	NS)					
	Unlabeled specimen	Labei/slip do not match (Microbiology)					
	Mislabeled specimen	Unlabeled slip (Microbiol	Hgy)					
	Leaking specimen container	No allp received (Microbi	ology)					
	Beecimen descrived, request received and decard data	(apacity):						
		Other:						
	III Action							
	Ordering facility/department called Time: D	ete: Person	notified					
	Specimen Problem Form faxed to ordering facility	Specimen Problem Form	forwarded to ordering facility					
	CTS' done Coher (specify):							
	IV. Follow-up							
	Specimen returned to ordering facility Silp returned to	ordering facility 🔲 Specime	visitp destroyed					
	Request for specimen resubmission Request for slip	resubmission D Other:						

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".



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).



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; received and sorted to correct tar automation, lost in routing after i
	Comment is pretext as: TND: Specimen	NOFROZE	Specimen received not frozen insition tote
	Received Unfrozen	THAW	Specimen thawed in error, unable testing
		THAW2	Specimen received not frozen from thawed during transport.

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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).



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.

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Purpo	10		NCC	NL004 Ter	st Not Done Da	ily Report		A REAL PROPERTY.		
This	report list is included	yesterday's	tests that	were resulte	ed as "TND" and is	ncludes the rea	ison test w	ere not pe	rformed.	
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Contribution	Medical C Test Result	Date on 08/31/20	913							
Test				to:	fascorialita, ora	46/01/2013 7:03 an				
EAG Gentral 3	MEDA	PAT NAME	Onler. Physician	ACC Num	Tant	Component	Gallect Data	Result Date	THO Mote	Collector
MOD	12345679	John Dee 1	Taplor Switt	851324118695	OPIATES, UNINE, CONFIRMATORY	CONFIRM, URNE,	8/29/2013	8/31/2013	Text Rol Done; Quartity Not Sufficient	Justin Gua
ANT	91011123	John Doe 2	Marish Carvy	\$61324110321	OPIATE, URINE, CONFIRM (100 NG/ML CUTOFF)	CODEINE CONFIRM, UNINE, GCMS, QUAL	8/29/2013	8/31/2013	Teat Not Dane; Quantity Not Bufficient	Chay Aiken
DRV	14151017	John Dee 3	Randy Jackson	571324319621	LACTATE	LDH	8/31/2013	8010010	Tost Not Dene,Received streaminfactory-	Diana DeGarma
WOR	18102021	Astes Doe 4	Ryan Beacreat	811334111809	CHLAMYDIA/DC, URINE AMPLIFIED PROBE TECHNIQUE	CHLAMYDIA RNA, URINE, AMPLIFIED PROBE, GUAL	8/29/2013	8/31/2013	TEST NOT DONE/ URINE EXCEEDS MAXIMUM VOLUME ALLOWABLE FOR	Do Dice
with	10162021	John Doe 4	Ryan Sentrest	611334111806	CHLAMYDIA/OC, URINE AMPLITIED PROBE TECHNIQUE	NEISSENIA GONORRIOEAE RIAL URINE, AMPLIFIED PROBE, QUAL	8483013	8/31/2013	TESTING TESTINGT DONE/ URINE IN GCCTU TURE EXCEEDS MAXMUM ALLOWABLE VOLUME FOR	Bo Bica
Cast Day OAK	22232435	Jane Doa 1	Karry Underwood	111024111207	ADRENOCONTICOTRO PIC HORMONE	АСТН	6/20/2013	8/31/2013	Test was Lone; Wrong Specimen Type Received 8/31/201	Wate Leas
DAR	16171019	Jaras Dos 2	Kelly Clarkson	111324211643	MICROALBUMIN, URINE, GUANTIYATIVE	ALBUMINICREATIN	6/30/2013	8/31/2013	1 +1-30-20 GRYT Test not done; Specimen is too dilute for assessment (Creatinine lass	Katharine McPhees
GSAA FRE	30313233	Jane Doe 3	Januarillar Logen	161334311347	POTASSIUM, SERUM	POTASSIUM	8/30/2013	8/31/2013	Than or Test Not Dane; Unacceptable Apacimen for Testing;	Adam Lam
FRE	10111211	Jana Doe 8	Jennifier Lopes	101324211240	POTABBIUM, BERUM	POTASSIUM	8/30/2013	8/31/2013	Benam on Glot. Text Not Dana; Unacceptable Bracimen for Texting:	Adam Lam
FRE	34383637	Jana Doa 4	Jessica Banchez	161324211264	CHEM 7 DIA, K. CL., GOZ, BUN, R GLU, CREAD	POTASSIUM	8/30/2013	8/31/2013	Bonam on Clet. Test Not Dane; Unacceptable Specimen for Testing;	Adam Lami
HAY	38394041	John Doe 5	Steven Tyler	141324310418	AST, SERUM	ABT	8/31/2013	8/31/2015	Task Hot Danes	Crystal Rowersos
HAY	38394041	John Doe 5	Steven Tyler	141324310418			8/21/2013	8/31/2013	Tast Not Dane	Crystal
HAY	38394941	John Dos 5	Steven Tyler	141324310418	007	007	8/31/2013	8/31/2013	Laboratory Accident. Test Not Done:	Crystal

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)

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		PERM	ANENTE	£+		-	ALL THE			
		NCRLB013	Test Not Done M	arithly Report						
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RWO	12246678	John Doe1	HO, BETTY H.	371321716370	HEPATITIS C VIRUS RNA PCR QUANTITATIVE	HEP C RNA, BERUM, PCR, QN	8/5/2013	84/2013	Test Not Done; Guardity Not Bufficient, Please extent at least 2.5 cs	Bradley Coope
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RWG	91011121	Jane Doe 2	но, ветту н.	371321516437	VITAMIN D12	VIT 012	6/3/2913	8/5/2013	Test Not Darie: Guardity Not Sufficient.#52013 17-02-24 PDT.MET	Josquin Phoe
AWC	71818202	John Doe 2	CHUANG, ANY I	. 371323616696	ALKALINE PHOEPHATASE	ALKALINE	8/24/2013	8/29/2013	Test Not Done; Quartity Not Bufficland.	Daniel Day Lev
AWG	71818202	John Dos 3	CHERANG, AMY H	371223610096	AST. BERUM	ABT	8/24/2013	8/29/2013	Test Not Done: Quantity Not Sufficient.	Daniel Day Lev
RWC	62427202	Jana Doe 3	ABHYANKAR, STELLA BARANO	371322210619	TISSUE TRANSGLUTAMINA BE RIA, RIG	TISSUE TRANSOLUTAMIN ASE IGA	8/10/2013	8/22/2013	Test Not Dans; Guardity Not Bufficient.	Brad Pill
9999G	53637262	Jana Doe 3	ABHYANKAR, STELLA BARANO	371322210019	TISSUE TRANSGLUTAMINA BE KDA, KDO	TISSUE TRANSGLUTAMIN ASE 100	8/19/2013	6/22/2013	Test Not Dane; Quantity Not Sufficient.	Bred Pdt
SMM	43536373	John Don 3	HO, BETTY H.	331322810088	ALT, BERLIM	ALT	8/16/2013	N18/2013	Test Not Darre; Quartity Not Sufficient.	Garry Oldman
-	43636373	John Doe 3	HO, BETTY H.	331322810088	SOCIUM, SERUM	SODIUM	8/15/2013	8/19/2013	Test Not Done; Quantity	Garry Oldman
SAM	43636373	John Doe 3	HO, BETTY H.	331322810088	CREATININE, SERUM, WITH GLOMERULAR	CREATININE	8/16/2013	8/19/2013	Test Not Dane; Quantity	Garry Oldman
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8MM	*******	Jama Don A	LASH, ALAN D.		C 4 COMPLEMENT	64	8/5/2013	8/11/2013	Test Not Dane; 557 Received; No Presen	Garry Ohlman
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o streamline the data, our team worked on categorizing the various comments associated with "Test Not Done" and ultimately came up with 9 categories:

- Quantity not sufficient (QNS)
- Laboratory accident

- 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.



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.



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



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.

- annual cost savings is \$45,000.
- reduction year-to-date as compared to 2012 (Figure 14).



- Unsatisfactory specimen (UNS)

- Specimen received unfrozen
- No specimen received (NSR)





Results

Figure 12. Total Test Not Done in Parts Per Million

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

The improvement project focusing on samples received unfrozen has shown a 35%



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).





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).



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 preanalytic 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.