Efficiency & Streamlining Following Implementation of the Core Laboratory

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Objectives

- Provide a brief overview on the implementation of the Core Laboratory
- Demonstrate how laboratory TAT and FTEs were affected following the implementation of the Total Automation System
- Discuss how the analysis of the TAT data helps identify potential areas for quality improvement.



What is a CORE laboratory?

Consolidation of analytical instruments into a common area

of analytical instruments for various disciplines:

- > Chemistry
- > Hematology
- Coagulation
- Immunology

Automation of specimen processing (pre-post analytics)

- > Transport
- ➢ Processing
- ➤ Reporting
- Archival



How does the CORE laboratory work?

CURRENT MANUAL PROCESSES

Sample tubes received in lab Tubes unpackaged, sorted Bar codes read Tubes examined Tubes put in centrifuge Centrifuge balanced Tubes spun in centrifuge Centrifuge unloaded Aliquots made & labeled Aliquots sorted, bar codes read

Tubes sorted & stored Tubes unloaded ± Samples diluted & re-run Tests run Instrument programmed Loaded into instrument Sorted into test groups Tubes examined Received by technologist Tubes sent to workstations



All of these steps will be automated

1. Improved Patient Care

- Laboratory able to deliver consistent, accurate results in a predictable timeframe to health care providers
- Faster turnaround of test results by standardizing workflow and eliminating many manual steps
- Improved patient safety
 - Reduced errors caused by fatigue
 - > Reduced labelling errors
 - Fewer breakages



2. Sustainability of Laboratory Services

- Impending shortage of MLTs in Nova Scotia
- 146 technical staff at QEII (27%) were eligible for retirement with unreduced pension from 2012-2017.
- Automation allows MLTs to focus on areas requiring skill and experience

>Investigating abnormal results

➤Quality Assurance activities



3. Improved Employee Safety

Minimize exposure of technical staff to blood-borne pathogens using enclosed automated system for:

- > Decapping
- > Aliquotting
- Centrifugation
- > Transportation between instruments
- > Recapping (sealing) for storage





- All routine Chem/Heme/Coag/Immuno testing in Central Core Lab
- Reduction of 29 FTEs system wide (achieved through attrition)
- Operational savings = \$2.2M



Pre Analytical Before





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Pre Analytical After-Aliquotter





Specimen Transport (VTS)



Analytical Before



Automated Track Connects to Analyzers





Sample Storage Before





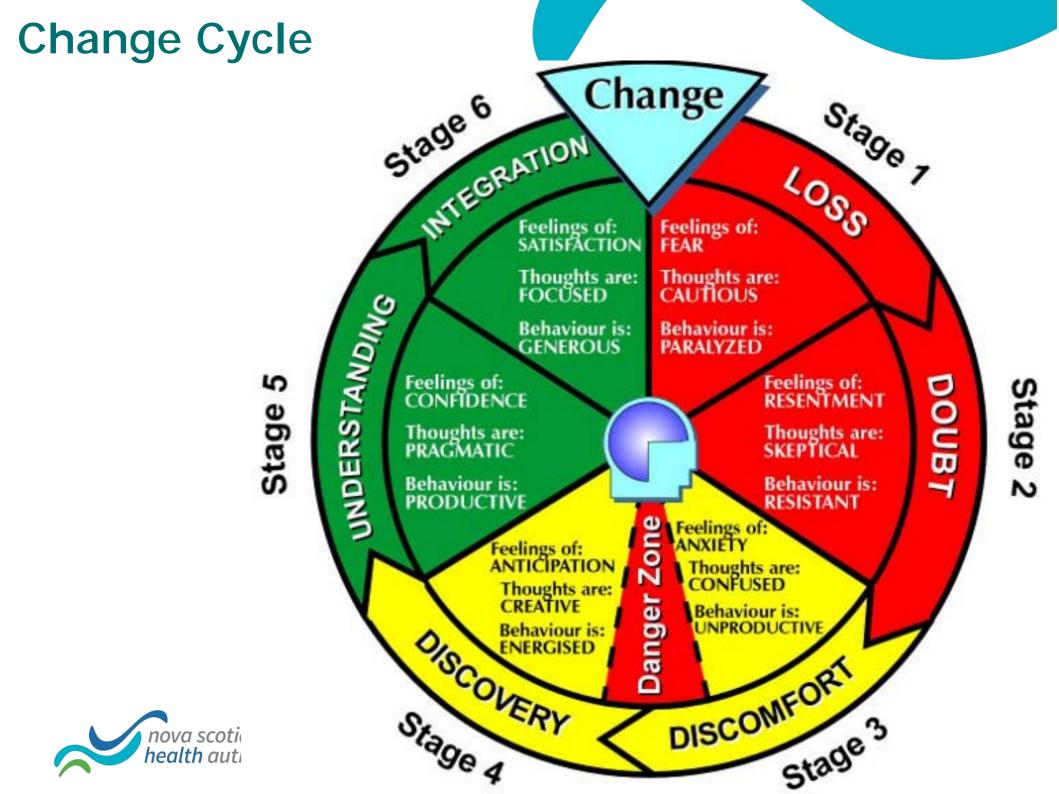
Automated Track Connects to Tube Storage Units



Change Management

- Multi-stakeholder engagement
- Involving end users in planning and design
- Communication
 - Frequent communications/updates
 - ➤ FAQs
 - > Transparency
- Involve end users to implement the changes
- Provide support
- Celebrate milestones!



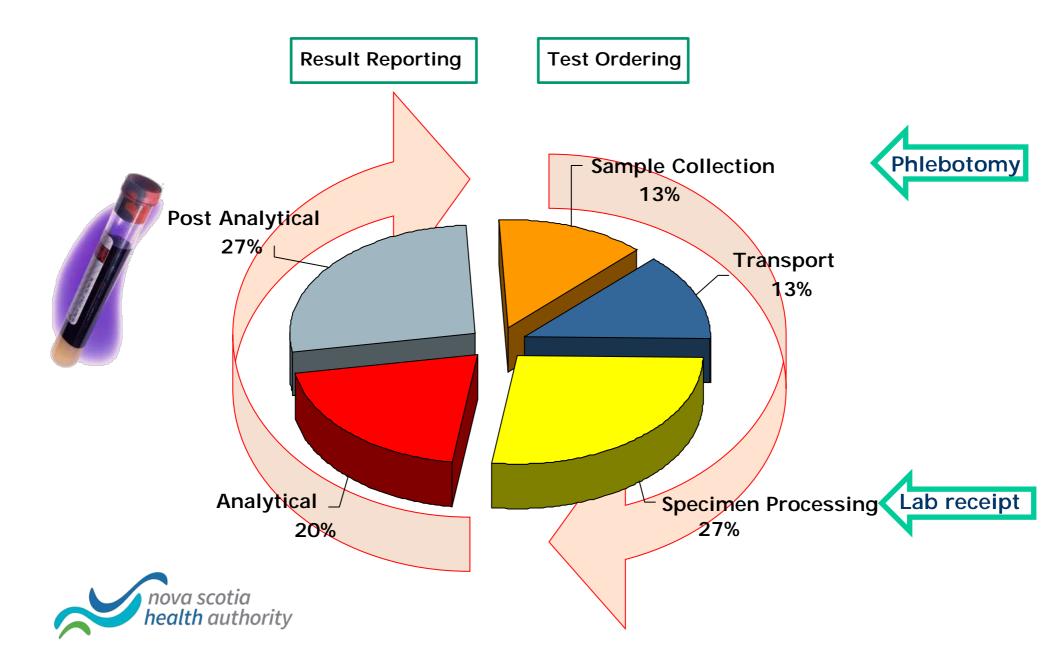


Turnaround Time (TAT)-

a Key Quality Indicator of Laboratory Performance



Turnaround Time- Total Laboratory Testing Cycle



Improving Turnaround Time

- Solutions to improve TAT
 - Pre-analytical
 - Electronic test order entry
 - Specimens transportation by pneumatic tube systems
 - Use of a high speed centrifuge
 - Use of plasma rather than serum specimens
 - Training of laboratory staff to expedite handling of urgent samples
 - Analytical
 - Consolidation of analytical platforms
 - Interfacing instruments
 - Post-analytical
 - Auto-verification of results



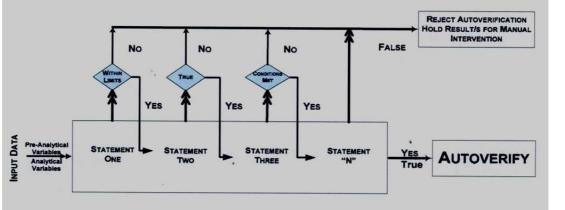
Core Laboratory Establishment Early 2013-May 2015



Pre-analytical: Electric Track Vehicle (ETV) System



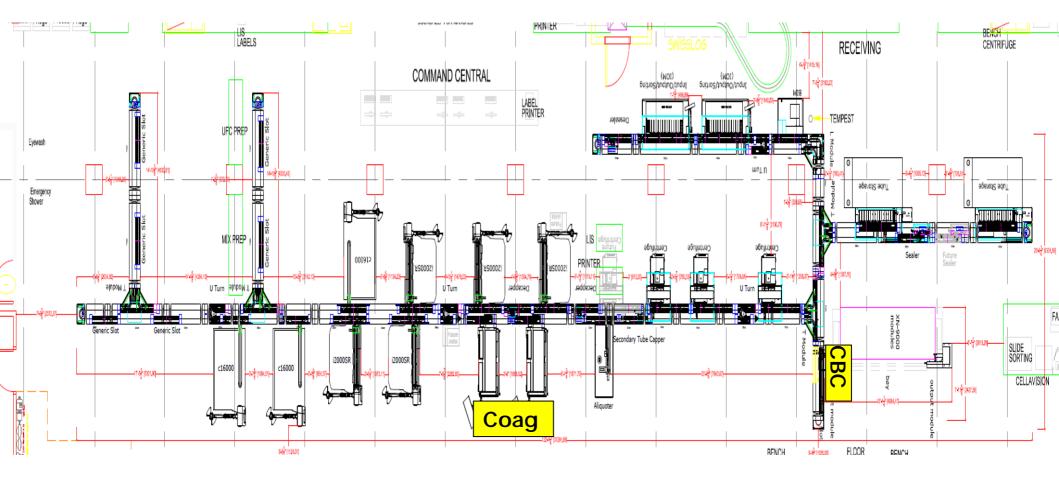
Pre- & analytical: Total Laboratory Automation (TLA)



Postanalytical : Auto-Verification



Total Laboratory Automation System Layout



Module	Number	Module	Number
Input/output module	2	Aliquoter	1
BIM (bulk Input	1	Architect c16000	3
module			
Centrifuge module	3	Architect i2000	5
De-capper module	2	Sysmex XN1000	3
Re-sealer	1	ACL TOP 700 (IL)	2
De-sealer	1	Tube storage module	2

- Processing 3600 tubes per hour
- Total distance traveled from IOM to Storage is 96.6 meters
- Total time traveled: 9.5 minutes.
- Total Track Footprint is about 3000 feet²
- The largest and most complex system in North America !!

Outlines of the Studies

- Evaluation of the TAT in VG Core Lab
 - Study I: Comparison of Total TAT (PR-TAT) between the pre- and post- core lab eras
 - Study II: Impact of ETV & TLA Systems on Total TAT
 - Delivery TAT (PI-TAT)
 - In-lab TAT (IR-TAT)
 - Study III: Impact of the Auto-Verification (AV) on In-lab TAT
- Impact of the Core Lab on other labs across the Central Zone



Study I: Evaluation of Total TAT (PR-TAT)

- Five representative analytes were selected:
 - General Chem: Potassium, Urea
 - Immunoassay: TSH
 - Hematology: CBC
 - Coagulation: Prothrombin Time (PT)
- Pre-core period:
 - October 2013 for Hematology
 - March 2014 for Chemistry
- Post-core period: March 2016
- Retrospective data (1 month) was extracted from LIS
 - The time of blood collection
 - The time that results were released by the LIS.

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Goals of Total TAT (PR-TAT) in Our Department

• Priorities of Test Requests

- STAT 1 hr
- Urgent 3 hrs
- Routine 8 hrs
- Outlier percentage rate < 10% for each type of priorities



Sample Processing Protocols Post-Core Laboratory

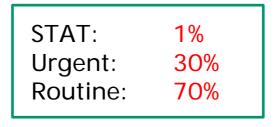
Protocols	STAT	Urgent	Routine	
Applied Analytes	•STAT Chem: K and urea	•STAT Coag: PT	•All routine requests	
	•STAT CBC	•All urgent requests	•TSH	
Registration at the main floor	yes	yes	yes	
Delivery through ETV	Immediately	Quick	when available	
Sample check-in at core lab (2nd floor)	Manually Scan	automated online	automated online	
Offline Centrifugation	yes	No, online centrifugation	No, online centrifugation	
Sample introduction to the IOM on track	priority lanes CBC loaded on ins.	priority lanes	routine lanes	



Increase in Test Volumes from 2014 to 2016

Analyte	January -	January -	% increase in	Routine samples	% referred-in
	March 2014	March 2016	2016 (naturally)	referred-in to VG	samples to
				in Apr. 2015	total numbers
Potassium	44139	47983	8.7%	18962	28.3%
Urea	33973	36194	6.5%	12844	26.2%
TSH*	45886	47897	4.4%	NA	NA
CBC	52791	58971	11.7%	23733	28.7%
РТ	14383	15938	10.8%	4819	23.2%







		Pre-core laboratory				Post-core laboratory			
Priority type	Analyte	potassium	urea	CBC	РТ	potassium	urea	CBC	PT
	Sample number (n)	146	108	221	103	188	124	243	115
	Mean (min)	73.5	74.7	43.1	57.9	72.8	74.9	51	74.6
	SD	48.9	53	34.9	25.5	34.7	37.7	28.9	31.4
	Median (min)	63.1	63	33.5	50.4	63.2	67.8	45.6 *	68.9 *
Stat	90% percentile TAT (min)	105.1	100.2	72.5	80	106.4	102.3	82.6	112.7
	OP-TAT 60min %	55.5%	55.6%	17.6%	28.2%	57.4%	63.7%	25.9%	66.1%
	OP-TAT 90min%	15.8%	13.9%	6.3%	5.8%	18.1%	16.1%	8.6%	23.5%

- PR-TAT was comparable for chemistry analytes, but delayed by 15 min for hematology tests
- 90% completion time for STAT requests was 1.5-2 hours!
- Outlier rates were worse and did not meet our goals

Results for Study I- Urgent

		Pre-core laboratory				Po	Post-core laboratory				
Priority type	Analyte	potassium	urea	CBC	РТ	potassium	urea	CBC	РТ		
	Sample number (n)	4165	3585	4464	2097	4569	4152	4674	1785		
	Mean TAT (min)	141.1	141.2	117.5	139.8	121.1	119.6	103.6	116.6		
	SD	61.8	56.5	61.2	63.2	49.9	47.5	59.1	50.5		
Urgent	Median TAT (min)	133.1	133.8	108.3	127	111.2*	110.8 *	91.2 *	106 *		
	90% tile TAT (min)	201.2	202.3	182.3	211.6	174.7	107.4	166	175.7		
	OP-TAT 2 hrs (%)	62.8%	63.3%	41.4%	55.9%	40.0%	38.8%	25.7%	36.1%		
	OP-TAT 3 hrs (%)	16.3%	16.4%	10.6%	19.1%	8.8%	8.0%	7.6%	9.4%		

- PR-TAT was improved by 25 min for all urgent tests
- 90% completion times were < 3 hours
- Outlier rates at 3hrs <10% and reduced by 50%

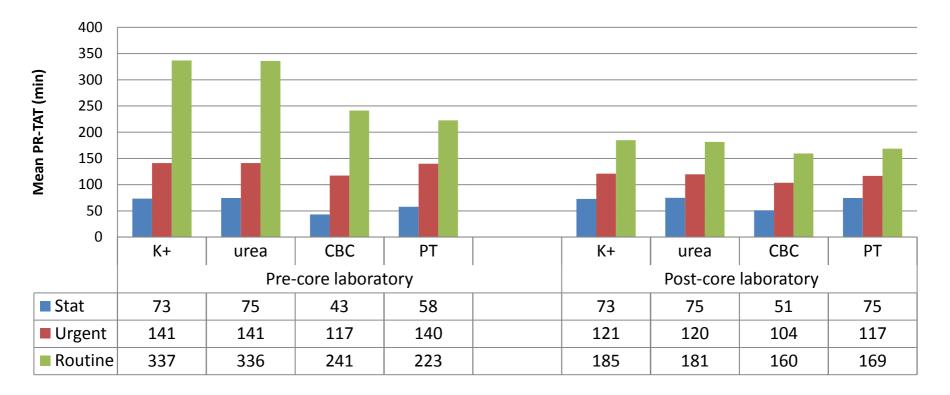
Results for Study I- Routine

		Pre	-core la	ooratory		Post-core laboratory				
Priority type	Analyte	potassium	urea	CBC	PT	potassium	urea	CBC	РТ	
	Sample number (n)	10477	7669	15274	3625	11304	7801	14629	3395	
	Mean TAT (min)	337	336	241	223	185	181	160	169	
	SD	139	139	132	176	101	100	98	162	
Routine	Median TAT (min)	314	313	201	177	157 *	154 *	133 *	138 *	
	90% tile TAT (min)	523	523	413	387	316	311	286	289	
	OP-TAT 6 hrs (%)	39.5%	39.6%	19.4%	14.6%	5.6%	5.0%	3.8%	4.7%	
	OP-TAT 8 hrs (%)	22.0%	16.5%	4.1%	3.3%	1.2%	0.9%	0.4%	0.7%	

- The PR-TAT were improved by 50-150 min (30-50%) for all routine tests
- 90% completion time was < 6 hours and outlier rates < 10%!



Summary for Study I



- The PR-TAT were significantly improved for urgent and routine requests, given the volume were about 35% higher post-core laboratory.
- For STAT requests, mean PR-TAT has no change for chemistry analytes while it is delayed significantly for hematology testing.



Study II: Impact of ETV & TLA Systems on Total TAT

- PR- TAT was divided into
 - PI TAT (phlebotomy to in- lab, delivery) : Efficiency of the ETV system
 - IR- TAT (in- lab to reporting, in-lab): Efficiency of the TLA system
- Representative analytes were grouped:
 - Hem: CBC and PT
 - Chem: Potassium, Urea, TSH
- Pre-core period:
 - Hem tests: received, then processed in Hem lab
 - Chem tests: were centrifuged in ACS and then received in Chem lab
- Post-core period
 - Hem+ Chem samples were delivered through ETV
 - All samples are received, then processed in the core lab
- Retrospective data was extracted from LIS

Study II: Impact of ETV on PI- TAT (delivery)

CBC	pre-core (Oct-Dec 2013)			post-core (Jan-Mar 2016)			
	stat	urgent	routine	stat	urgent	routine	
n	526	12460	40177	682	13997	44292	
Mean (min)	29	73	136	38	84	152	
SD	42	50	270	39	56	97	
Median (min)	20	61	120	32*	74*	123	
90% tile (min)	48	140	227	58	132	293	
OP 60min	7.6%	50.9%	88.9%	8.5%	67.3%	92.5%	
OP 120min	2.3%	17.1%	50.4%	1.9%	13.8%	51.9%	
РТ	pre-	core (Oct-Dec 20)13)	post-core (Jan-Mar 2016)			
	stat	urgent	routine	stat	urgent	routine	
n	259	5730	9670	322	5322	10294	
Mean	25	74	137	38	84	140	
SD	20	73	166	23	59	120	
Median	21	58	114	34*	73*	112	
90% tile	43	139	245	59	131	274	
OP 60min	6.2%	48.3%	84.8%	9.6%	66.3%	87.2%	
OP 120min	0.4%	16.0%	45.4%	1.2%	13.6%	44.6%	

• Median PI-TATs were delayed by 12 min for STAT and urgent, but comparable for routine

• 90% tile post-core delivery time was 59min (1hr), 131 min (2hrs) and 280 min (4hrs) for stat, urgent and routine respectively and no improvement for the outlier rates

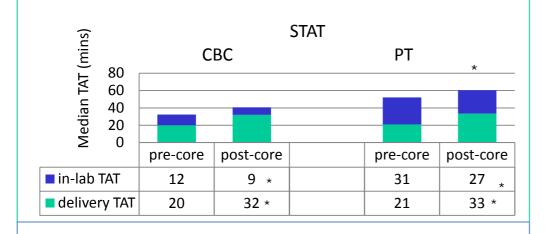
Study II: Impact of TLA on In-Lab TAT of Hema Analytes

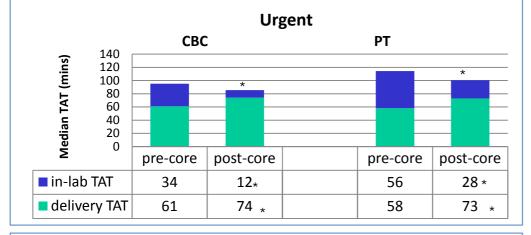
Analyte	Parameters	Pre-TLA				Post-TLA			
Analyte	r arameters	STAT	Urgent	Routine	STAT	Urgent	Routine		
CBC	Sample number (n)	526	12464	40177	682	13997	44292		
	Mean TAT (min)	20	43.2	95	16.4	21.5	16.8		
	SD	23.6	40.3	111	33	27.7	26.4		
	Median TAT (min)	12.4	34.1	43.5	8.7*	11.6*	11.3*		
	90 th percentile (min)	43.2	90.4	257.4	36.7	50	26.5		
	OP-TAT 30 min (%)	15.6%	54.5%	59.1%	15.0%	18.3%	8.0%		
	OP-TAT 60 min (%)	4.6%	25.8%	42.4%	3.1%	7.5%	2.6%		

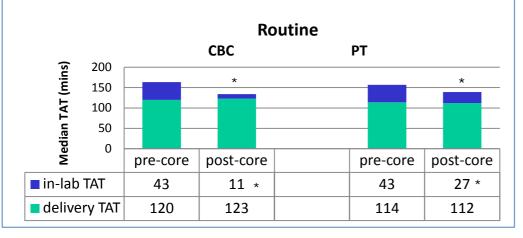
Apolyto	Doromotoro		Pre-TLA			Post-TLA	<u> </u>
Analyte	Parameters	STAT	Urgent	Routine	STAT	Urgent	Routine
РТ	Sample number (n)	259	5730	9670	322	5322	10294
	Mean TAT (min)	35.4	64.3	80.9	34.3	34.4	31.9
	SD	14.6	40.3	98.2	24.2	22.1	19.4
	Median TAT (min)	31.1	56.4	42.8	26.9*	27.6*	27.1*
	90 th percentile (min)	49	106	217.6	50.8	53.8	43.4
	OP-TAT 30 min (%)	54.8%	87.3%	80.8%	38.2%	35.3%	29.5%
	OP-TAT 60 min (%)	5.4%	45.6%	33.2%	6.5%	7.6%	4.8%

- All parameters for TAT were improved dramatically
- Median TAT reduced by 5min, 25min and 20 min for STAT, urgent and routine
- 90% completion time was <60min for both tests on all priorities
- OP TAT exceeding 60 min <10%

Summary for Study II on Hematology Testing







- Generally, delivery TAT > in-lab TAT
 - •More remarkable in post-core lab
- ETV negatively impacted on delivery TAT
 STAT: 12 min (60%)
 Urgent: 14 min (23%)
 Routine: no change
- TLA system significantly improved In-lab TAT
 STAT :

•CBC- 3 min (25%) •PT- 4 min (13%)

•Urgent

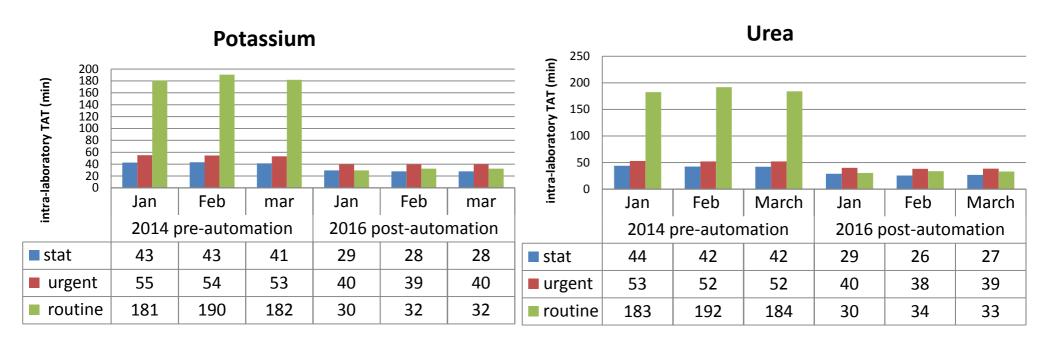
•CBC- 22 min (65%) •PT- 28 min (50%)

•Routine

•CBC- 32 min (74%) •PT- 17 min (40%)

• Total TATs were improved for both urgent and routine, but not for STAT requests due to the longer delivery TAT after the core

Impact of TLA on In-Iab TAT of Chem Analytes

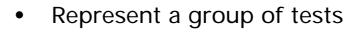


 Compared to pre-automation TAT excluded the centrifugation time, postautomation TATs were still reduced by

- STAT: 10min (24%)
- Urgent: 14 min (26%)
- Routine: 150 min (81%)

Impact of TLA on In-lab TAT of TSH Testing

TSH	2014 pre- TLA	2016 post- TLA		
Sample number (n)	45886	47897		
Mean TAT (min)	855	62		
SD	976	55		
Median TAT (min)	453	52 *		
90% til (min)	1715	82		
OP TAT 90 min (%)	98.0%	7.9%		



- Run during the day shifts, weekdays
- Treated as routine tests by lab
- TLA changes the running pattern
 - Randomly and 24/7
- Median TAT reduction: 400 min (6.5 hrs)
- 90% completion: <90 min



Lessons Learned and Followup Actions Made

• ETV system

- When under the limit of the capacity of the ETV system, dedicated staff should be arranged for timely loading and unloading of the cars to achieve fast TAT.
 - Applied in June 2016
- When over the capacity, ie peak time, manually delivery of super STAT samples should be considered to meet the required shorter TAT



Lessons Learned and Followup Actions Made

- TLA system
 - Efficiently manage substantial amount of samples at a reasonable TAT no matter what types of priorities
 - To reach the shortest TAT, samples should be offline centrifuged and directly front loaded on to the analyzers
 - There are no benefit with the current practice for STAT Chem tests (off-line centrifugation then loading onto the IOM)
 - Practice has been changed for STAT Chem since Oct. 2016



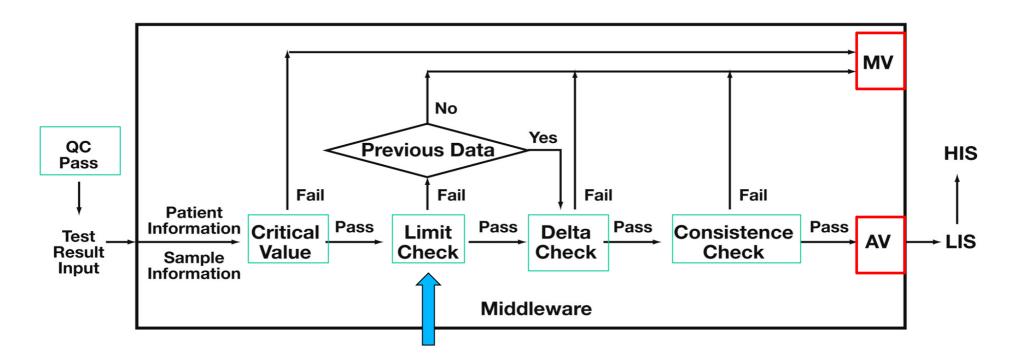


Study III: Impact of the Auto-Verification (AV) on In-Iab TAT for Chemistry Analytes

- Efficiency of the entire TLA track system
 - Pre-analytical
 - Streamlining sample processing
 - •
 - Analytical
 - Consolidating multiple instruments onto the track system
 - Post-analytical
 - Auto-verification- efficiency of result reporting



Introduction of Auto-Verification (AV)



- AV is a process of using computer-based rules to verify lab results without manual intervention
- Free up staff
- Improve the quality by standardizing the process of resulting
- Detect lab errors

Study III Approach

- Representative Analytes
 - Potassium and Urea
- Study periods
 - 1. Pre-AV period: before TLA
 - 2. AV-RR (Initial AV rules based on reference ranges):
 - Potassium RR: 3.4-5.0 mmol/L
 - Urea RR: 2.5-9.2mmol/L
 - 3. AV-advanced
 - AV cutoffs- Potassium: 3.2-5.3 mmol/L
 - AV cutoffs- Urea: 2.5-36 mmol/L
- Retrospective data was extracted from the LIS
 - the time that samples were loaded onto the IOM,
 - the time that results were released by LIS



Results: Impact of Auto-Verifications on In-lab TAT

Amelates	Damanatana	AV - RR (Nov. 2015)			AV –advanced (Mar. 2016)		
Analytes	Parameters	STAT	Urgent	Routine	STAT	Urgent	Routine
Potassium	Sample number (n)	159	4365	11434	165	4396	11229
	Mean TAT (min)	44.4	46.5	40.1	27.7	39.4	32.4
	SD	98.1	33.5	82.0	17.1	27.4	44.6
	Median TAT (min)	30.7	37.6	29.3	23.6 *	34.7 *	27.3
	90 th percentile (min)	66.4	73.5	56.5	42.3	54.0	48.8
	OP-TAT 60 min (%)	14.5%	15.4%	8.5%	4.3%	7.6%	5.3%
Urea	Sample number (n)	116	3961	8117	124	4152	7801
	Mean TAT (min)	35.4	46.3	40.0	26.8	38.5	33.2
	SD	23.3	39.7	52.5	24.7	20.0	49.9
	Median TAT (min)	28.9	37.4	30.5	22.3 *	33.4 *	29.1
	90 th percentile (min)	59.8	71.3	58.9	40.9	50.4	49.2
	OP-TAT 60 min (%)	10.3%	15.0%	9.4%	2.4%	6.3%	5.3%

- Median TAT were reduced by 6 and 4 min for STA and urgent
- 90% tile TAT were reduced by avg. 22, 20 and 9 min for STAT, Urgent and Routine
- OP-TAT 60 min for both tests were reduced from 38-77% for different priorities, indicating improvement of reporting consistency .

Impact of the Core Laboratory on the Community Hospitals - DGH

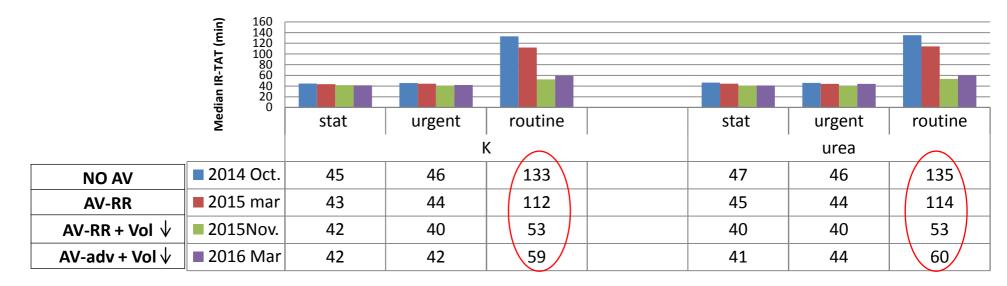
- What has been changed in other sites
 - Auto-verifications
 - Reduced routine test volume- referred to the core lab (65%)
 - Reduced FTEs- 1x tech-II and 2.5x tech-I (25% reduction)
- Impact of the changes on the in-lab TAT in DGH?
- Study periods

1.	Pre-AV period:	Oct. 2014
2.	AV-RR:	Mar. 2015
3.	AV-RR + reduced test volume:	Nov. 2015
4.	AV-advanced + reduced test volume:	Mar. 2016

Volume Changes in DGH

Volume	priority	2014 Oct. (pre-core)	2015 Mar (post-core+ AV-RR)	2015 Nov. (refer VG+ AV-RR	2016 Mar. (refer VG + AV-Adv.)	% diff Mar15-14	%diff Nov.15 -14	%Diff Mar.16-14
K	stat	77	93	102	82	17%	32%	6%
	urgent	2290	2277	2134	1848	-1%	-7%	-19%
	routine	5608 (70%)	4852	1322	1324	-16%	-76%	-76%
urea	stat	62	61	83	58	-2%	34%	-6%
	urgent	2168	2144	2034	882	-1%	-6%	-59%
	routine	4110 (65%)	3450	982	888	-19%	-76%	-78%
K+Urea	Total monthly	14238	12784	6555	5000	-11%	-54%	-65%

Median IR-TAT in DGH Site



- 1. AV-RR improved TAT by 21 min for routine requests!
- 2. Decreased routine test volume shorten the TAT further by 1 hr

Lessons Learned and Followup Actions Made

- Auto-Verification
 - Beneficial in
 - Free up staff
 - Improve the quality by standardizing the process of resulting
 - Reduce TAT
 - Troponin and other tests run on other platforms under the progress for auto-verification
 - AV rules should balance the error detection and fast TAT
 - Impact of AV rules on error detections under the progress



Continue Monitoring TAT Across the Central Zone Following the Core Laboratory

- Review the goals
- Recommendations

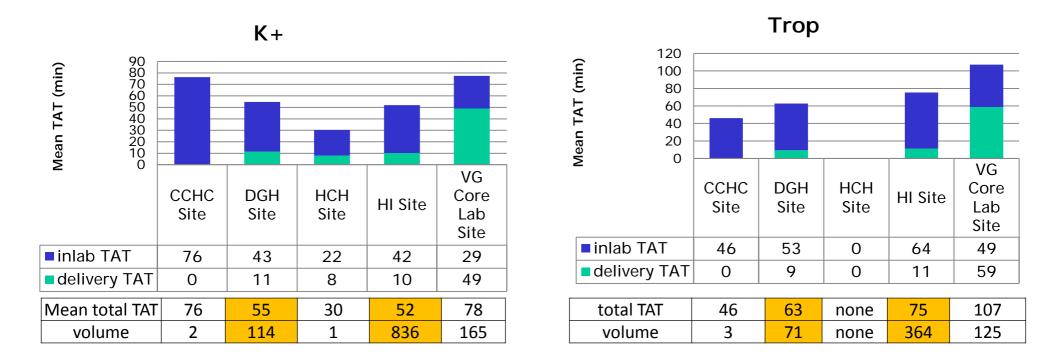
Test volumes for all the labs in the Central Zone (June, 2016)

Volume	S	TAT	Ur	gent	% Urgent		
	K +	Trop	K +	Trop	K +	Тгор	
CCHC Site	2	3	1166	372	100%	99%	
DGH Site	114	71	1898	773	94%	92%	
HCH Site	1	0	298	123	100%	100%	
HI Site	836	364	7365	1512	90%	81%	
VG Core Lab							
Site	165	125	4707	276	97%	69%	

1. All routine requests is under the control of the VG Core lab with the TLA

- 2. TAT for STAT request HI site
- 3. TAT for urgent requests should be the focus for all the sites

TAT review for **STAT requests** across the Central Zone (June 2016)

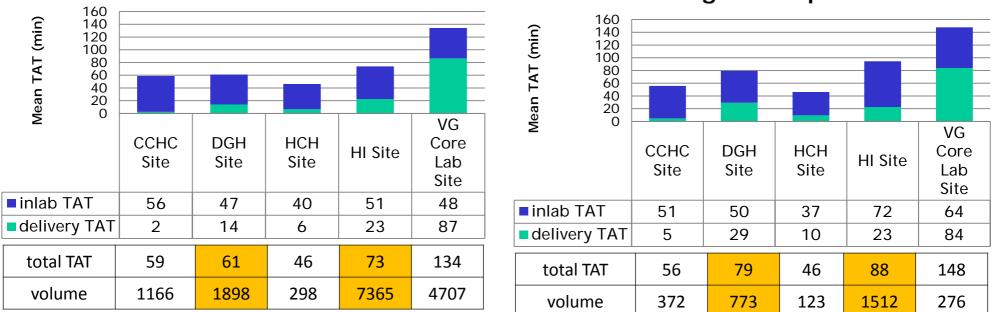


- Mean delivery TAT was only 10 min across all sites with the pneumatic system
- In lab TAT of HI site (ER) can be improved to reach the possible shortest mean total TAT.



TAT Review for Urgent Request Across the Central Zone

Urgent K+



Urgent Trop

- HI site shows the longest delivery, in-lab and total TAT for both K and Trop, which can be associated with the highest volume.
- By comparing the TAT across the sites, each lab should determine its own goals



Recommendations:

Set new goals of TAT-Clinical needs & laboratory capabilities

•For VG

- •Do not service emergency; no pneumatic tube system; TLA implementation
- •One goal for all requests
 - •Inlab-TAT: 1hr
- •Reduce outlier rate

•For HI & DGH & other sites Pneumatic tube system •STAT for HI •Delivery TAT: 15 min •Inlab TAT: 1hr •Total: 1:15 •Urgent for all sites •Delivery TAT: 20min •Inlab TAT: 1:15 hr •Total: 1:30 hr



General TAT goal: 90% completion time for in-lab TAT of <60 min for common laboratory tests!

Summary

- Significant positive impact of Core Lab on the laboratory service as a whole.
 - Improvement of total TAT across all the labs in the Central Zone
 - Reduced workload on other community labs
 - Cost savings in FTEs
 - 25% reduction in the community labs
 - 13% reduction in the QEII
- Change in workflow has driven new considerations in monitoring TAT
 - Setting new goals of TAT based on the clinical requirements and the laboratory capabilities/limitations
 - 90% completion time and outlier rate of TAT are more effective measurements of TAT and can be a marker of greater value for lab services and related clinical outcomes.
 - Analysis of the different phases of TAT helps identify potential areas for continuous quality improvement







Questions

- 1. For STAT requests, mean PR-TAT has no change for chemistry analytes while it is delayed significantly for hematology testing, WHY ?
- 2. Inlab -TAT for Urgent is longer than that of Routine although urgent samples were loaded on the priority lanes and routine samples were loaded on the routine lanes, why?
- 3. AV-RR is improved in DGH but not in HI, why?

