
بسم الله الرحمن الرحيم

“Impact of the critical limits to improve the patient health care”

By

Dr. Rubina Mansoor
Assistant Professor Rawalpindi
Medical College, Rawalpindi.

INTRODUCTION

The term "critical limits" refer to the values (outside the normal range ± 2SD (95% CI) and usually beyond ± 3SD) which are warning or life threatening and require intervention to safe life of the patient hence should be communicated to the clinician urgently.

INTRODUCTION, (Contd)

- The system of critical or panic limits were first formally described and implemented by George .D. Lundberg in 1970.
- The idea of the identifying and notification of critical limits will persist even with increasing laboratory automation and auto verification Although computerized process reduce notification time and estimated errors associated with phone notification and misinterpretation of critical values..Despite of this fact a review by laboratory scientists and pathologist is necessary to counter check errors associated with the instruments or at any step during analysis before release of the test results to the physician.

INTRODUCTION, (Contd)

- For appropriate communication of critical limits consensus should be developed, as various surveys and studies have shown wide variation in the critical limits in various laboratories, hospitals and clinics.

The mechanism and methods of determining critical values include retrograde study of the previous patient data or prospective study assessing the correlation of the patient critical values with the clinical outcome.

INTRODUCTION, (Contd)

- Medical professional groups and Healthcare regulatory committees acknowledge that the failure to report critical test result (CTR) in a timely and reliable way is a threat to patient's safety and quality of health care.
- In 2005 the joint commission in the United States emphasized in their national patient safety goals the requirements to measure, assess and if required take action to improve in time reporting and receipt of critical test results by the responsible licensed caretaker.
- In one of the surveys, it was reported that 36 % hospitals did not meet this hospital safety goals.

INTRODUCTION, (Contd)

- The Canadian council on Health services accreditation [CCHSA]) incorporated as a required organizational practice expectations regarding the verification process for high risk activities such as the communication of critical test results" (CCHSA2007.

QUALITY AND THE TOTAL TESTING PROCESS

- It is essential to produce accurate results for proper interpretation and authenticity.
- Hence improving qualtiy has been a core goal of the laboratory medicine sector for decades, strating from the proficiency testing in 1930s.

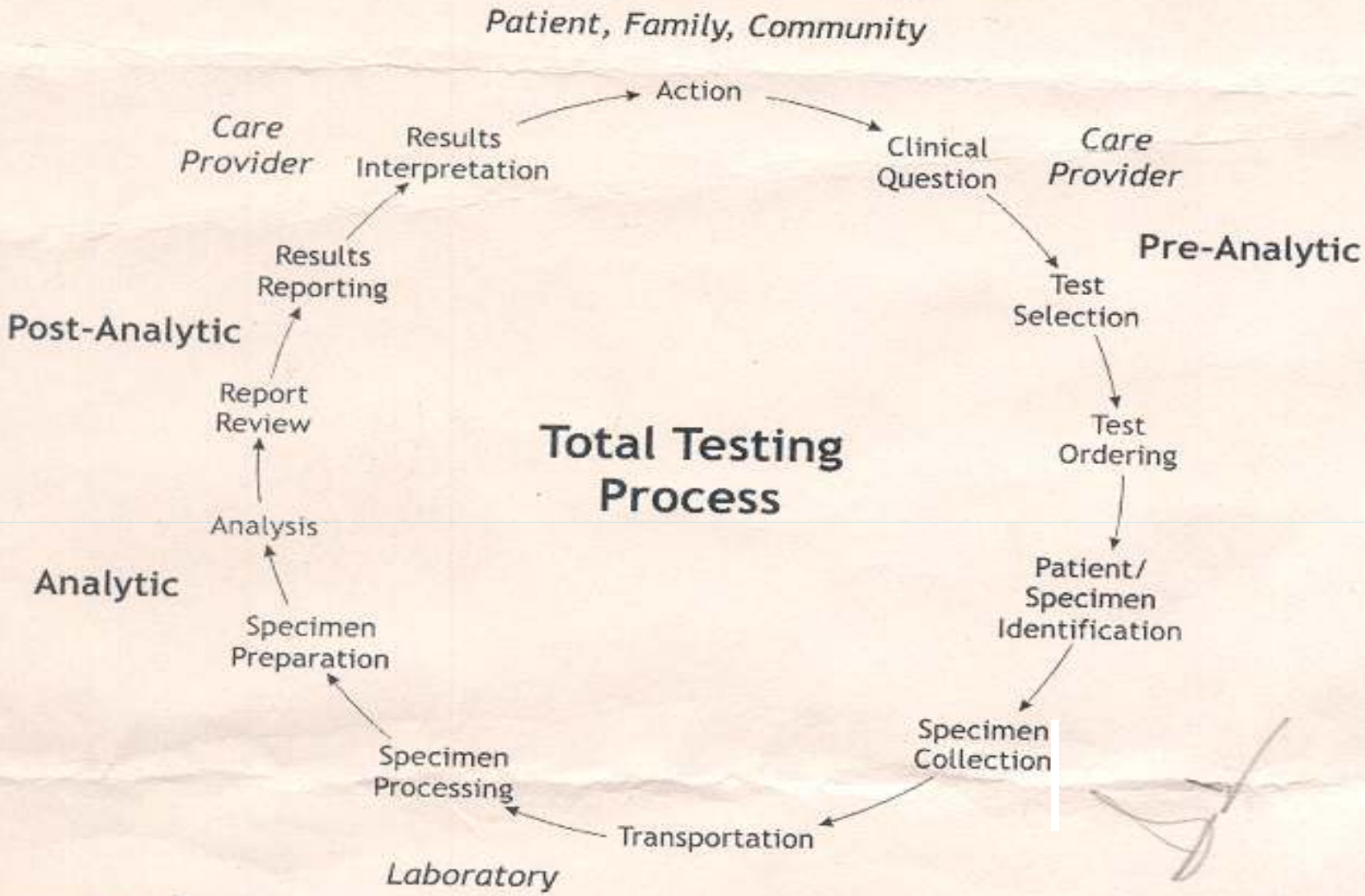
Total Testing Process (TTP) : is a system based frame work for understanding the dynamics of laboratory medicine and has been refined and encompass all components of the that completes the test cycle form the point of clinical question to point of clinical action that can affect the quality of laboratory tests results.

QUALITY AND THE TOTAL TESTING PROCESS, Cond

TTP encloses the following three distinct phases that align with clinical workflow outside and inside the laboratory

- Prenalytic: clinician test selection test ordering patient preparation, specimen collection, patient and specimen identification, and specimen transport
- Analytic: specimen processing and preparation, testing of the specimen, result review and verification, and quality control (QC) checks
- Postnalytic: TAT, critical value reporting, report formatting, general result reporting clinician interpretation and fallow-up, laboratory interpretive consultation services specimen storage and if applicable, daily laboratory shutdown.

Figure 4.1: Phases of the Total Testing Process



Source: Adapted from Boone J. Presentation at the Institute on critical issues in health laboratory practice: managing for better health, September 23-26, 2007. Atlanta, GA: Centers for Disease Control and Prevention.

QUALITY AND THE TOTAL TESTING PROCESS, Cond

Pre-analytical errors

- Various surveys have shown that many laboratory test selection errors arise because clinicians lack adequate knowledge for decision-making when ordering complex testing regimen. Physician knowledge of laboratory test and ability to order appropriately is complicated by following factors.
- (1) rapid proliferation of new tests and tests for additional analytes
- (2) lack of formal education in laboratory testing
- (3) day to day clinician demand leave little time to acquire this intricate knowledge.

Analytical error

It includes

- proper specimen processing and preparation
- proper testing of the specimen
- result review and verification
- and quality control (QC) checks

QUALITY AND ERRORS

Post analytical phase require proper interpretation communication and documentation

1. Communication is defined as the effective transmission of knowledge or information from one individual to another. It requires clear and concise formulation of data, transformation of the data into useful information and an agreed method of communication understood by the sender and receiver

2. Poor communication between laboratory professional and clinicians is generally cited as the chief issue affecting quality of laboratory services during the preanalytic and postanalytic phases

3. Throughout the health care system communication failures are a leading cause of shortfalls in quality particularly of preventable errors that harm patient

QUALITY AND ERRORS, Cond

4. Widely overlooked in training of health care providers is that few clinicians or laboratory professionals receive formal training in effective communications

5. Most quality initiatives in laboratory medicine have focused historically on the analytic phase of testing however root cause analyses and other medical error studies confirm that more errors occur in the preanalytic and postanalytic phases testing. The distribution of these errors by phase varies among setting and institutions.

6. An extensive review of reported errors in laboratory medicine published from 1992 to 2001 found great heterogeneity in study designs and reporting of errors. The distribution of errors was 32-75% in the preanalytic phase, 13-32% in the analytic phase and 9-31% in the postanalytic (administration) phases.

QUALITY AND ERRORS, Cond

7. in a larges study of errors detected in blood banks the distribution was 41% in the preanalytical phase 4% in the analytic phase and 55% in the postanalytical phase

8. One of the studies whole laboratory estimated the 8% of errors had the potential for serious harm

9. Preanalytic communication involves discussion between the clinician and the laboratory to select an appropriate test or set of tests and the communication of appropriate patient information on requisition slips. These communications may involve and extensive set of medical professionals including physicians nurses pathologists medical technology laboratory technicians and clerical staff they may communicate about test orders patient identification information and specimen adequacy

QUALITY AND ERRORS, Cond

10. Postanalytic communication entails laboratory professionals communication with the clinician about critical values and interpretation of laboratory findings.

11. Breakdowns in pre-and postanalytic communication lead to errors patient safely events and inefficient and ineffective use of health care resource

Table 1. Communicating CRT: safe practices, vulnerability and proposed changes

Ideas and changes	Identified vulnerabilities in Processes	safe practices recommendations
Identify who should receive the results	Medical trainees and advance practitioners set stage for complexity in determining who to call l	Determine short-and long –term goals for who should receive results (ideal to contract the ordering provider for all CRT)
		1. Maintain nursing staff as intermediary to receive in –patient 2..Review ED protocol in place for handing discharged patients" CTR

Identify who should receives the results when the ordering provider is not available	communication for CTR to clerical staff nurses and other regulated health professionals accepting CTR not aware of what to do with results (I.e." action and time frame to relay) and/or not supported by written protocols unclear ownership for accepting ambulatory patients, CTR" off hours	Enforce and monitor compliance with policy rule not to communicate CTR to a non-regulated health professional or team member (e.g., clerk) Articulate clear escalation steps and time frames if first contract not available
Define which test results requires timely and reliable communication	Lists for different laboratories, critical values found in laboratory based documents no formal process involving laboratory and clinical leadership to review and revise lists for critical values to be called	Consult extensively with clinical services and laboratory leadership to approve parameters for communicating CTR consolidate lists of all laboratories' critical values within one hospital-wide policy Educate clinical teams and laboratory staff on CRT call parameters. Customize LIS to identify individual results requiring a call based on the defined list

Ideas and changes	Identified vulnerabilities in Processes	safe practices recommendations
Identify when test result should be actively reported to the ordering provider and establish explicit time frames for this process	Laboratory- based policies directed laboratory staff that "critical values are telephoned immediately upon verification of accuracy no explicit time frames were set if unable to reach care provider	Articulate explicit steps and time frames for repeating and escalating calls if first call page unsuccessful address unique challenges posed by ambulatory- based results and off hours CRT
Identify how to notify the responsible provider	Adverse events identified in safety reports due to use of voicemail to communicate CRT specific physicians requested laboratory call by phone rather than pager	Establish rules and monitor infractions for calls left on voicemail and / or communicated to non- regulated health provider

Ideas and changes	Identified vulnerabilities in Processes	safe practices recommendations
Establish a shared policy for uniform communication of all types of test results to all recipients	Rapid response laboratory TDM and microbiology laboratory had individual policies directing staff CRT processes	Create single hospital –wide policy available electronically on policy and procedure database standardize processes across laboratories roll out new policy
Design reliability into the system	No data available to track timeliness and appropriateness of communicated CRT	Install lis call back module to provide data reports for daily review and monitoring of CRT calls implement read back as a required function with LIS upgrade establish laboratory call centre Mon –Fri day shift
Support and maintain systems	Pitfalls gaps identified within different patient information systems	Identify requirements for upgrades and functionality of new systems
Support infrastructure development	Lack of transfer of patient and service information between hospital information systems	Investigate laboratory use of online on-call schedules adapt for use by laboratories

IMPLEMENTING CHANGE INITIATIVES: EXECUTION

Changes Were Focused In The Following Areas:

- Defining lists of critical values to be communicated
- Identifying who to call
- Establishing explicit time frames for calls

Table NO. 2 factors identified as barriers

Information systems	Laboratory	Clinical teams
1. Inability to identify patient location 2. Inability to identify patients primary service in LIS complexity of online on call schedule is difficult for laboratory staff to navigate health professional unable to acknowledge CTR reviewed electronically	1. Not escalating calls within set time frames 2. First call delayed due to other work role commitments 3. Poor availability of call centre staff 4. Attempting to find ordering physician via informal channels forgetting of check outstanding CTR calls in callback module	1. Inaccurate of incomplete information on submitted laboratory requisition 2. Not responding to pages if busy with patient care of teaching rounds 3. Trainee not familiar with patient or call processes (i.e. backup role) 4. Calls not picked up by in patient unit ,or laboratory staff left on hold 5. Routine laboratory requisition sent in early morning which effect workflow due to limited resources

LESSONS LEARNED FROM VARIOUS SURVEYS AND ASSESSMENTS

1. There is great value in reviewing a complicated process such as the communication of CTR as a series of interdependent sub-processes. In the past change strategies for the communication of CTR were tackled only from the perspectives of laboratories or individual clinical services with limited success
2. There are merits of an inter-professional team (I.e. Laboratory and clinical leaders) working together to address mutually important issue
3. There is value in learning from failures (i.e. CTR cases where calling targets were not met).
4. Higher cost but higher leverage approaches can be pivotal such as the customization of the LIS callback module and the establishment of a call centre which provided data for ongoing monitoring and was a key to sustainable long term improvement
5. Regular (e.g. daily and monthly reporting) monitoring and vigilance are needed to make sure that practices are sustained and to ensure the early identification of issues and problems

BIOCHEMISTRY – CRITICAL RESULT

ANALYTE	CRITICAL VALUES	FREQUENCY
Glucose - Hi	20	Once / 72 hrs.
Glucose - Lo	2.2	Each Event
Potassium (Infants <2 mos.)	< 2.5 / > 7.0	Each Event
Potassium (Adults &children > 2 mos.)	< 2.5 / > 6.5	Each Event
Potassium (dialysis patients*)	< 2.8 / > 6.5	Each Event
Sodium	< 120 / > 160	Once / 72 hrs.
Urea (infants)	> 25	Once / 72 hrs.
Uric acid	> 800	Once / 72 hrs.
Calcium, Corrected	< 1.75 / > 3.0	Once / 72 hrs.
Calcium, Ionized	< 0.75 / > 1.63	Once / 72 hrs.
Ammonia	>100 (<16 yrs)	Once / 72 hrs.
Lactate	> 5	Once / 72 hrs.
Iron	> 50	Once / 72 hrs.

ANALYTE	CRITICAL VALUES	FREQUENCY
Acetaminophen	>50mg/L	Once / 72 hrs.
Amikacin	Trough >10 mg/L Peak>30mg/L	Each Event
Amitriptyline & Notriptyline	>1000µg/L	Once / 72 hrs.
Bilirubin, Total (neonates)	>300	Once / 72 hrs.
Beta –0H-Butyrate	>5	Once / 72 hrs.
Carbamazepine	>20 mg/L	Each Event
Carboxyhemoglobin	> 40%	Once / 72 hrs.
CSF Glucose	> 500	Once / 72 hrs.
CSF Protein	< 2.0	Once / 72 hrs.
Desipramine	> 2.0	Once / 72 hrs.
Dioxepin & N-Desmethyldoxepin	> 1000µg/L	Once / 72 hrs.
Ethosuximide	> 200 mg/L	Once / 72 hrs.
Ethylene Glycol	Present	Once / 72 hrs.
FT3	> 9.0	Once / 72 hrs.
Gentamicin	Trough > 4 mg/L	Each Event
Imipramine & Desipramine	> 1000 µg/L	Once / 72 hrs.
Isopropanol	Present	Once / 72 hrs.

Lithium	> 2.0	Once / 72 hrs.
Magnesium	< 0.5 / >2.0	Once / 72 hrs.
Maprotiline	> 1000 µg/L	Once / 72 hrs.
Methanol	Present	Once / 72 hrs.
Nortriptyline	> 1000 µg/L	Once / 72 hrs.
Phenobarb	> 60 mg/L	Each Event
Phenytoin	> 40	Once / 72 hrs.
Phosphate	< 0.4 / > 5.0	Once / 72 hrs.
Primidone	> 24 mg/L	Once / 72 hrs.
Salicylate	> 700 mg/L	Once / 72 hrs.
Total CO_2	< 15.0/ > 40.0	Once / 72 hrs.
Theophylline (adults)	> 25	Once / 72 hrs.
Theophylline (children <1 month)	> 15	Once / 72 hrs.
Thiocyanate	> 100 mg/L	Once / 72 hrs.
Tobramycin	Through > 4 mg/L	Once / 72 hrs.
Trimipramine & N-Desmethyltrimipramine	> 1000 µg/L	Each Event
Troponin T	> 0.01 µg/L	Firs Positive**
Valproic Acid	> 200 mg/L	Once / 72 hrs.
Vancomycin	Through > 20 mg/L	Once / 72 hrs.

Test	Low	High
Serum total dioxide	< 10 mEq/L	> 45 mEq/L
Serum sodium	< 120 mEq/L	>160 mEq/L
Serum potassium	< 2.7 mEq/L	> 6.5 mEq/L
Serum potassium (hemolyzed)	< 2.7 mEq/L	> 8.0 mEq/L
Serum glucose	< 40 mg/dL	> 700 mg/dL
Serum calcium	< 6 mg/dL	> 13 mg/dL
Lonized calcium	< 0.78 mmol/L	> 1.57 mmol/L
Serum phosphate	< 1 mg/dL	None

Serum salicylate	None	> 70 mg/dL
Serum magnesium	None	> 8.0 mg/dL
Troponin1	None	> 0.5 ng/ml
Fibrinogen	< 50 mg	None

TDM drugs	< Therapeutic Range	> Therapeutic Range
pO_2	≤ 40mm Hg	None
pCO_2	≤ 20mm Hg	≥ 70 mmHg
pH	≤ 7.2 units	≥ 7.6 units
CK-MB	None	See not

Conclusion

- The consensus on the critical values is of paramount importance to establish the uniform policy for the critical limits. In addition proper protocols needs to be formulated for the effective and timely communication of critical values which is crucial and require collaboration of laboratory staff and clinicians and should be followed to decreased mordantly and mortality and to improve patient outcome as whole.


THANKS