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Original Research Article

Analysis of Laboratory Critical value Reporting Pattern at clinical biochemistry laboratory of Tertiary health care Center

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Abstract

Objectives: Objective of the study is to analyze critical value reporting data to find frequency of critical reporting, distribution of critical values across reportable range and across hospital segments and reasons for failure in critical reporting.

Material & Method: The critical value reporting data for various analysts were collected from LIS for 1 year. The data were analyzed in computer spreadsheets.

Result & Discussion: Of 548786 test results analyzed, about 10% results were critical. Total Billirubin (20.14 %), Indirect Billirubin (18 %), Glucose (18%) and Sodium (13.6 %),Potassium (11.8%) contributed most to the critical values. 29% of urea, 13.29 % of Glucose, 15.37% of Indirect Billirubin, 13.71% of Sodium, 13.29% of Glucose & 11.6 % of total analyzed potassium were critical. On a per test basis, inpatient tests were 3.6 times more likely to result in a critical callback than outpatient tests. The number of critical values per year per bed was 176.34 for ICU beds and 29.36 for non-ICU beds and 5.0 for Emergency Department.

Conclusion: The high proportion of reported critical value of urea is due to practice of reflex testing in the laboratory whenever Creatinine is in abnormal range. The high proportion of reported critical value of Indirect Billirubin is due to present of PICU, NICU in Hospital. Major reasons for failure of notification of critical alert are incomplete detail on request form, transfer of patient to Ward or ICU, phone is engaged or phone not picked up by care giver.

Keywords: Critical Value, Clinical Chemistry

1. Introduction

Clinical laboratory services are essential to patient care and therefore should be available to meet the needs of all patients and clinical personnel responsible for human health care. Accreditation agencies now require clinical laboratories to list critical limits, formulate notification procedures, document critical results, and notify clinician [1]. This underscores the importance of the notification of critical results and the need to have a continuous improvement process in each laboratory.

Critical result is defined by Lundberg as a result that is so extremely abnormal that it is considered life threatening or that could result in significant morbidity and which, therefore, requires urgent action [2].

Critical limit refers to the upper and/or lower boundary of a result or the change of a result within a critical time scale beyond which the finding is considered to be a medically urgent critical result that warrants prompt action [3].

Critical test refers to a test that requires rapid communication of the result irrespective whether it is normal, significantly abnormal or critical (e.g. Troponin results in all requests from the emergency department)[3]**.**

2. Materials and methods

2.1 Settings

The new Civil Hospital Surat is a 1150 bed tertiary care academic medical center. The clinical laboratories include Clinical Biochemistry, Clinical pathology, and Histopatholaboratory and Microbiology laboratory. In 2013, the Clinical Biochemistry laboratory performed 5, 48,786 tests, of which 82.22% were for inpatients, 15.41 % for outpatients, and 2.37 % for emergency department (ED) patients. Critical values reported from September 1, 2012, to August 31, 2013, were examined. Tests performed in clinical Biochemistry laboratory were included in our critical value analysis.

Table 1: show Critical callback list for Clinical chemistry that was in use at time of study.

Test	Critical value
Glucose(mg/dl)	> 300 or < 55
Creatinine(mg/dl)	> 5
Urea(mg/dl)	> 100
Total Billirubine(mg/dl)	> 15
Indirect Billirubin(mg/dl)	> 15
Sodium(mmlo/L)	>160 or <125
Pottasium (mmlo/L)	> 6 or < 3
Lithium(mmol/L)	> 2
Total Protein(gm/dl)	> 10 or < 3
Amylase(U/L)	> 400
Alkaline Phosphatase(U/L)	> 1000
Calcium(mg/dl)	> 13 or < 6
Uric acid(mg/dl)	> 10
Triglyceride(mg/dl)	> 1000
Albumin(gm/dl)	< 1

All data were obtained from reports generated from the LIS.

3. Results

Proportions of critical values were calculated for each analytes, for various hospital sites, for various limits of test results and call status:

3.1 Critical Values by Test:

Table -2 Critical Values by Test [2]

Test	Critical Test Results	Yearly Test Volume	Percentage of Test Volume with critical result	Percentage of all critical test results
TG	18	10522	0.17	0.03
ALB	39	21546	0.18	0.07
TP	73	24297	0.3	0.14
LI+	5	1059	0.47	0.01
ALP	85	15816	0.54	0.16
UA	53	3320	1.6	0.10
AMY	551	16274	3.39	1.05
CAL	458	8658	5.29	0.87
CRE	4804	72872	6.59	9.16
TBIL	9486	123720	8.54	20.14
K+	6202	53443	11.6	11.82
GLU	9486	71359	13.29	18.08
NA+	7133	52016	13.71	13.60
IBILL	9486	61721	15.37	18.08
UREA	3501	12163	28.78	6.67
TOTAL	52462	548786	--	100

During the period of the study (12 months), the clinical biochemistry laboratory reported 52,462 (10.46 %) critical values out of total reported 5, 48,786 test results.

The high proportion of reported critical value of urea is due to practice of reflex testing in the laboratory whenever Creatinine is in abnormal range. While in case of glucose and potassium, sodium, high propitiation of Critical reporting is due to it's lower critical range. The high proportion of reported critical value of Indirect Billirubin is due to present of PICU, NICU in Hospital.

3.2 Critical value by sites

Results for inpatients (which account for 82.22 % of all tests) constituted.78.38 % of critical callbacks; for Emergency patients (2.37% of all tests), constituted 0.11% of critical callbacks; and for outpatients (15.41% of all tests), constituted 21.51 % of critical callbacks Thus, on a per test basis, inpatient tests were 3.6 times more likely to result in a critical callback than outpatient tests.

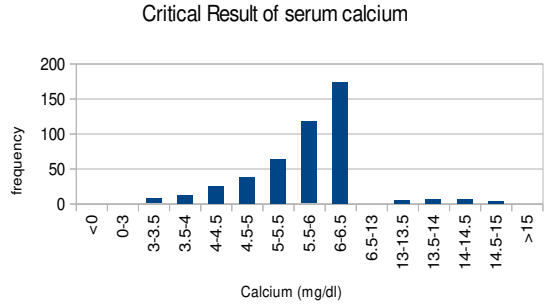
Table-3 Critical value by sites[2]			
Location	**No(%) of Critical test result**	**No. of Beds**	**Critical values per year per Bed**
Inpatient(ICU)	8817(21.44)	50	176.34
Inpatient(Non-ICU)	32301(78.56)	1100	29.36
Inpatient (Total)	41118(100)	1150	35.75
Outpatient	11284(21.51)	----	----
Emergency Department	60(0.11)	12	5.0
Total	52462(100)	----	----

The intensive care units (ICUs; medical, surgical, neonatal, , burn, and pediatric) were frequent locations for inpatient critical callbacks, contributing 21.44% of all critical callbacks, despite representing only 4.35 % of the total Inpatient population (50/1150 beds). The number of critical values per year per bed was 176.34 for ICU beds and 29.36 for non-ICU beds and 5.0 for Emergency Department.

3.3 Examination of Critical Value Limits:

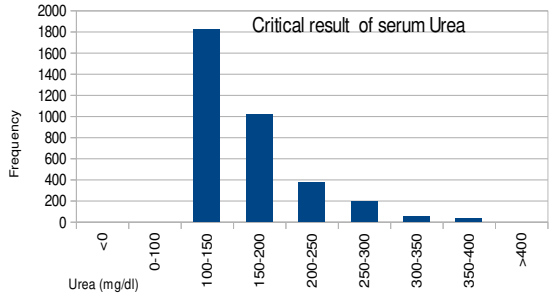
To better understand our present upper and lower value limits for critical callbacks (e.g., the limits for potassium of <3 and >6.0 mmol/L, we plotted the number of critical callbacks for each analytes versus. the result. This enabled us to examine the potential effect of changing the limits of critical callback would have on call volumes.

Figure 1 : Critical Result of Serum Calcium



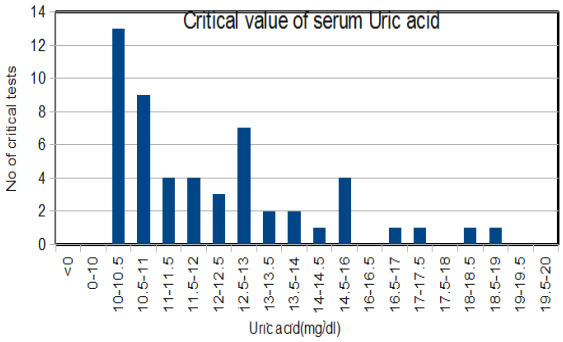
Above graph shows maximum frequency of Serum Calcium critical level in the range 6.0-6.5 mg/dl.

Figure 2: Critical Result of Serum Urea



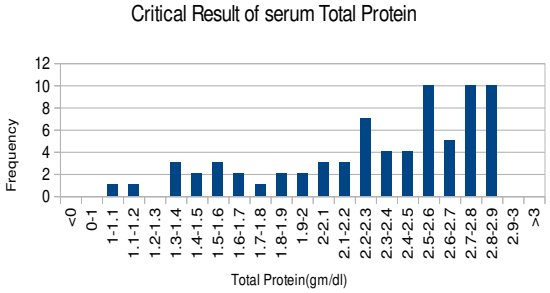
Above graph shows maximum frequency of Serum Urea Critical level in the range 100-150 mg/dl. There will be almost 50% reduction in Urea critical alert call if the critical range is increased from >100 mg/dl to >160 mg/dl.

Figure 3: Critical Result of Serum Uric acid



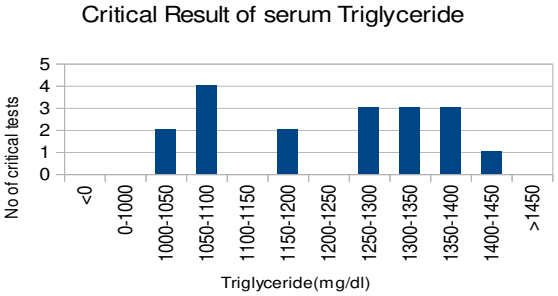
Above graph shows maximum frequency of Serum Uric acid Critical level in the range 10-10.5 mg/dl. Critical limit for Uric acid is >10 mg/dl.There will be almost 50% reduction in Uric acid critical alert call if the critical range is increased from >10 mg/dl to > 13 mg/dl.

Figure 4: Critical Result of Serum Total Protein



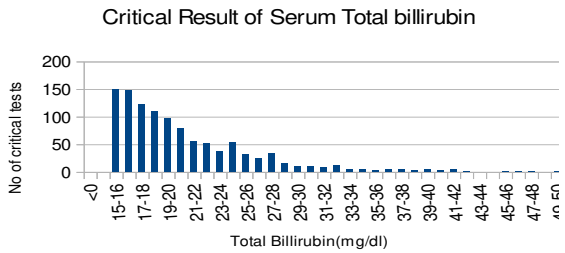
Above graph shows maximum frequency of serum total protein critical level in the range 2.5-2.9gm/dl.

Figure 5: Critical Result of Serum Triglyceride



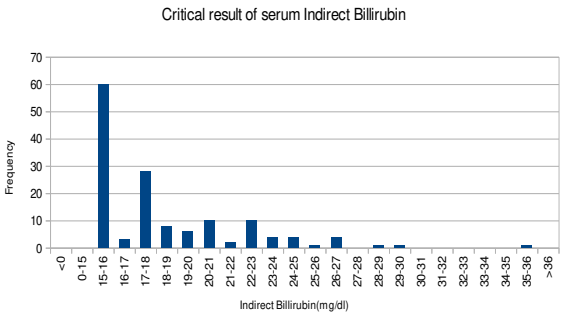
Above graph shows maximum frequency of Serum Triglyceride critical level in the range 1050-1100 mg/dl.

Figure 6: Critical Result of Serum Total Billirubin



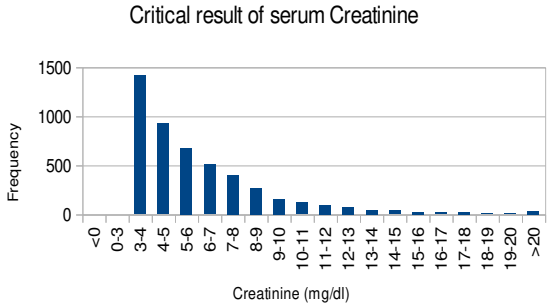
Above graph shows maximum frequency of Serum Total Billirubin Critical level in the range 15-18 mg/dl.

Figure 7: Critical Result of Serum Indirect Billirubin



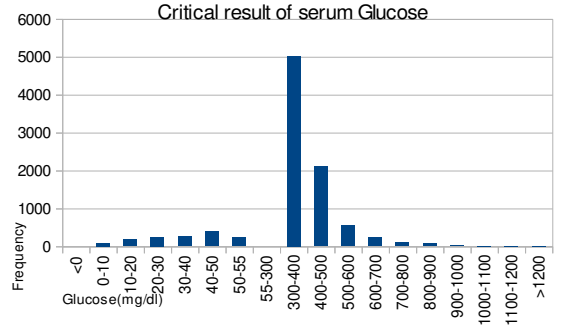
Above graph shows maximum frequency of Serum Indirect Billirubin Critical level in the range 15-16 mg/dl.

Figure 8: Critical Result of Serum Creatinine



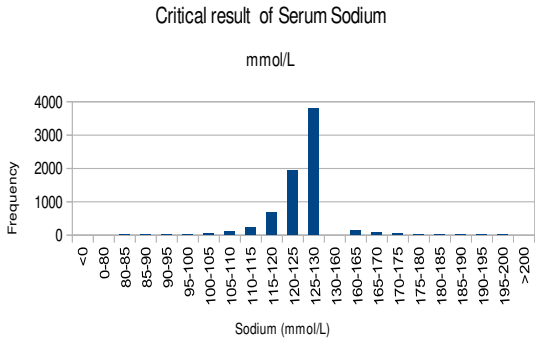
Above graph shows maximum frequency of Serum Creatinine Critical level in the range 3.0-4.0 mg/dl. There will be almost 50% reduction in Creatinine critical alert call if the critical range is increased from >3 mg/dl to >5 mg/dl.

Figure 9: Critical Result of Serum Glucose



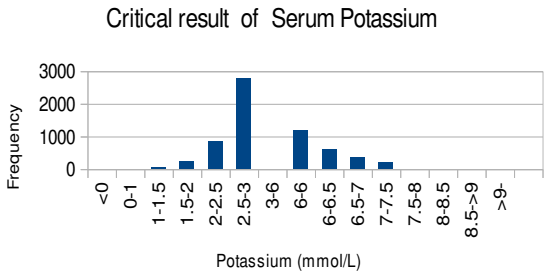
Above graph shows maximum frequency of Plasma Glucose Critical level in the range 300-400 mg/dl. There will be almost 65% reduction in Plasma Glucose critical alert call if the critical range is increased from >300 mg/dl to >450 mg/dl.

Figure 10: Critical Result of Serum Sodium



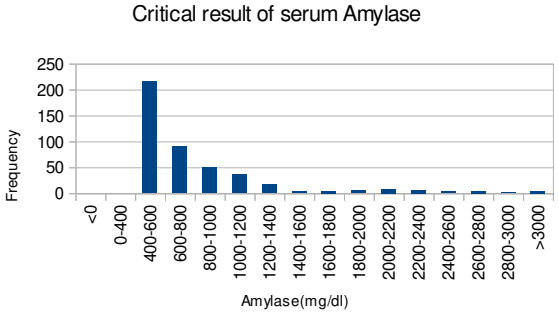
Above graph shows maximum frequency of Serum Sodium Critical level in the range 125-130 mmol/L.

Figure 11: Critical Result of Serum Potassium



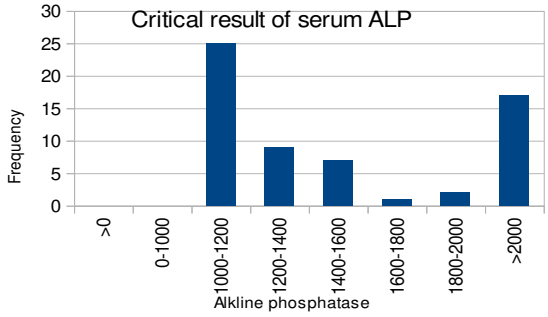
Above graph shows maximum frequency of Serum Potassium Critical level in the range 2.5-3 mmol/L.

Figure 12: Critical Result of Serum Amylase



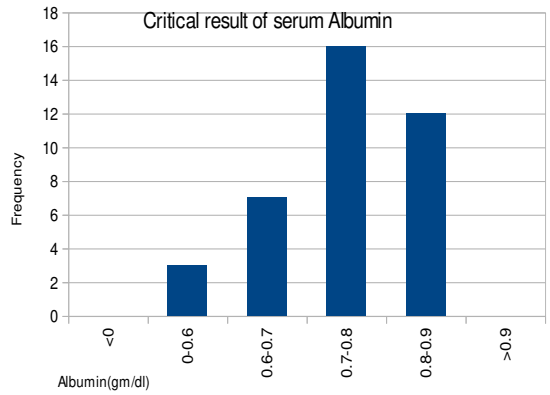
Above graph shows maximum frequency of Serum Amylase critical level in the range 400-600 mg/dl. Critical limit for Serum Amylase is >400 IU/l,

Figure 13: Critical Result of Serum ALP



Above graph shows maximum frequency of Serum ALP critical level in the range 1000-1200 mg/dl. Critical limit for Serum Total ALP is >1000 IU/l.

Figure 14: Critical Result of Serum Albumin



Above graph shows maximum frequency of Serum Albumin critical level in the range 0.7-0.8 mg/dl. Critical limit for Serum Albumin is <1gm/dl.

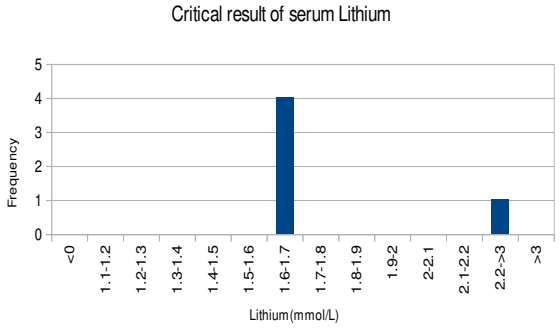


Figure 15: Critical Result of Serum Lithium

Above graph shows maximum frequency of Serum Lithium Critical level in the range 1.6-1.7 mmol/L. Critical limit for Serum lithium is >2 mmol/l.

There is 50 % reduction of critical callback, if critical limit of urea, uric acid, creatinine, Glucose is changed.

3.4 Critical alert by analysis of calls:

Table-8 Critical alert by call status

Category	Total No	Percentage of each category
Phone is engaged, Phone is not picked up	1131	6.5
Indoor patient Critical alert is successfully informed	4726	26.9
OPD alert is not informed	3475	19.8
Location of patient is wrong; patient is transfer to other ward or ICU.	85	0.48
Indoor patient alert not informed	8094	46.2
Total	17527	100

In the study ,it was found that major reasons for failure of notification of critical alert are incomplete detail on request form which include details about patient location, patient is transfer to Ward or ICU(0.48%), phone is engaged or phone not picked up by care giver (6.5%) ,OPD patients are routinely not informed about critical results(19.8%).

4. Discussion

Critical limits must be established by each laboratory, since sample types, analytical platforms, patient population and clinician's perception may differ in different laboratory.

Critical test and limit lists vary grossly across laboratories. While differing patient populations, settings and laboratory methods may explain these variations, many critical limits are simply different because there is a lot of subjective element and traditional practice behind compiling these lists.

Critical limits are clinical decision thresholds that should trigger appropriate actions. Therefore critical limit lists should neither be too inclusive nor exclusive. Critical limits that are too conservative may put unnecessary burden on both laboratory staff and clinicians and may lead to annoyance or inertia at the end-user level, which can result in truly critical results being ignored and thus fatal outcomes.

Separate lists are needed for neonatal, pediatric and adult care as well as for various ward or outpatient settings (e.g. there is no need to phone a high Troponin result to the cardiac surgery unit in a post-operative case; or a high Creatinine to a renal ward or dialysis unit, or repeatedly elevated liver enzymes which are already known to the doctors). Rapid or unexpected changes in patient results may also qualify for urgent communication and thus could be added as a rule to the critical limit list. For example, a result that rapidly became normal should ring alarm bells and generate rapid communication as it could signal the deterioration of or harm to patients (e.g. a rapidly falling sodium concentration in a chronic hypernatraemic patient due to overzealous fluid therapy).

Accreditation agencies now require clinical laboratories to list critical limits, formulate notification procedures, document critical results, and notify clinicians. This underscores the importance of the notification of critical results and the need to have a continuous improvement process in each laboratory.

Accreditation according to international standards can decrease differences regarding the management of critical values across laboratories of different countries. The issues concerning critical limits should be debated and a consensus critical values list should be considered.

Apart from seeking agreement with clinicians, there is no specific guidance given for managing critical results and thus heterogeneous practices are observed in different laboratories.

The high proportion of reported critical value of urea is due to practice of reflex testing in the laboratory whenever Creatinine is in abnormal range. The high proportion of reported critical value of Indirect Billirubin is due to present of PICU, NICU in Hospital. Major reasons for failure of notification of critical alert are incomplete detail on request form, transfer to Ward or ICU, phone is engaged or phone not picked up by care giver.

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