ORIGINAL RESEARCH PAPER
Volume-8 | Issue-11 | November - 2019 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

# ANALYSIS OF CRITICAL VALUES DATA AT A LARGE CLINICAL BIOCHEMISTRY LABORATORY IN A TERTIARY CARE ONCOLOGY CENTRE

**Oncopathology**

**Abhishek Kumar** Senior Resident, Department Of Pathology, Gujarat Cancer Research Institute, Ahmedabad.

**Biren Parikh*** Associate Professor, Department Of Oncopathology, Gujarat Cancer Research Institute, Ahmedabad. * Corresponding Author

**Rachna Shah** Biochemist, Gujarat Cancer Research Institute, Ahmedabad.

## ABSTRACT

**Objectives:** The main objective of the study was to evaluate the critical value data, to analyze the percentage of critical values of each biochemical parameters in our tertiary care oncology based laboratory, and to compare the data with those of other laboratories and hospitals.
**Material and methods:** The critical values data of several biochemical parameters generated from the testing of samples on COBAS 6000 during one year period were obtained from the LIS and results were analyzed.
**Results:** Out of total 887678 Samples tested during one year period, total 2.68% values were found to be in critical range, out of which, Serum calcium had the most frequent critical values (6.65%), followed by serum Potassium (6.13%) and the least common were serum albumin (0.59%) and serum Magnesium (0.62%).
**Discussion:** The frequency of critical values for some parameters were higher than few other laboratories and lower for few parameters than few other laboratories. The higher values might be attributed to biochemical derangements and effect of chemo radiation in our oncology setup.
**Conclusion:** More studies on critical values data analysis should be done in oncology based laboratories to find the frequency of critical values of different biochemical parameters which might prove beneficial to the clinicians in an oncology hospital.

## KEYWORDS

Critical Value, Lab Director, Analytes, Pre-analytical Errors.

## INTRODUCTION

A critical value is defined as "a laboratory test result that represents a pathophysiologic state at such variance with normal as to be life-threatening unless something is done promptly and for which some corrective action could be taken.[1] Currently, the use of the term panic value is discouraged, because it suggests emotional stress, and because it runs against the process of communicating information clearly.[2] One of the most important functions of a clinical laboratory is the clear, accurate, and rapid communication of a critical value to patient care providers.[2]The laboratory accrediting agencies have made critical value reporting part of the requirements for accreditation.[3,4]

How should a laboratory determine which tests to include on a critical value list? Moreover, how should the critical high and low thresholds be established? While ultimately, this determination is the responsibility of the laboratory director, it should be made in communication with the clinicians who use laboratory services, as well as with a medical review board of the institution, if applicable.[3,5]

Defining (and then mandating) a universal set of thresholds for tests, however, would be a difficult task given the scarcity of outcomes-based data on critical value thresholds. Inherent variability in assay-specific reference intervals between institutions is also a complicating factor.

An individual laboratory director can account for this variability by defining critical ranges consistent with his or her own assays and instrumentation. Not every laboratory test should have critical values associated with it. Critical value lists are, by nature, limited to not hinder the clinical effectiveness of notification.[1] Critical lists that are too inclusive (or that have critical value thresholds that require excessive notification) place an unnecessary burden on laboratory staff. Such lists annoy clinicians, create a negative attitude toward important laboratory services, and, most important, provide uncertain additional benefit to patient care. At the other extreme, lists that are too exclusive (or with thresholds that are too high or low) might not prevent adverse clinical outcomes, as a delay in the recognition of life threatening laboratory results by clinicians can be disastrous.

The best place to start when establishing or modifying critical value lists is by comparison with previously published lists, practice parameters, and consensus documents because these sources have been refined with the benefit of time, institutional comparison, and clinical performance.[5,6,]

The 1997 American Society for Clinical Pathology "Critical Values Practice Parameter" (published in the *Journal*) is another outstanding resource.[5] For the critical value reporting process to be effective, the organization must understand and address the variables involved in the process. This information is not readily available in the literature. Most reports have analyzed only a few analytes for short periods or have reviewed a small number of critical values in a number of different institutions.[7-9]

## MATERIAL AND METHODS

The clinical biochemistry lab at Gujarat cancer research institute is accredidated by ISO 15189 since 2010 and it performs on an average approximately Eight lakh samples testing per year by fully automated biochemistry analyzer COBAS 6000.

We performed a Retrospective study of the total blood samples run in one year at clinical biochemistry lab, GCRI, during Jan 2018- Dec 2018, and the total number of critical values data generated by the COBAS 6000 automated analyzer during this period. the percentage of critical values were analyzed for each of those parameters, decided by our lab director to be eligible and crucial to be notified to the clinicians.

The parameters which were choosen by the lab director to be notified for critical values were serum creatinine, blood urea nitrogen, serum sodium, potassium, calcium, chloride, uric acid, total bilirubin, amylase, albumin, phosphorus, magnesium and plasma glucose levels.

Laboratory staff is notified of the presence of a critical value by the LIS. The result is then checked for analytical reliability, Then after checking and ruling out the pre- analytical errors as a potential cause of critical values, the sample is run again. Once the result is validated, the result is considered as a true critical value and then the person responsible for the patient's healthcare is notified by the laboratory technical staff telephonically.

The list of critical values and their biological limits are presented in table 1. These limits were designed based on world literature study and by consultation of the clinicians of our hospital.

**Table 1: Critical value limits range in our laboratory**

| TEST | UNITS | LOWER LIMIT | UPPER LIMIT |
|---|---|---|---|
| Glucose (Adult) | Mg/dl | ≤ 50 | ≥ 350 |
| Glucose (pediatric) | Mg/dl | < 50 | ≥ 150 |

| | | | |
|---|---|---|---|
| Urea nitrogen (adult) | Mg/dl | - | ≥ 80 |
| Urea nitrogen (pediatric) | Mg/dl | - | ≥ 40 |
| Creatinine (adult) | Mg/dl | - | ≥ 5.0 |
| Creatinine (pediatric) | Mg/dl | - | ≥ 2.5 |
| Sodium (Adult) | Mmol/l | ≤ 120 | ≥ 150 |
| Sodium (infant) | Mmol/l | ≤ 130 | ≥ 146 |
| Potassium (adult) | Mmol/l | ≤ 2.8 | ≥ 6.2 |
| Potassium (infant) | Mmol/l | ≤ 3.0 | ≥ 6.0 |
| Chloride | Mmol/l | ≤ 80 | ≥ 120 |
| Calcium (adult) | Mg/dl | ≤ 6.0 | ≥ 13.0 |
| Calcium (infant) | Mg/dl | ≤ 5.9 | ≥ 12.5 |
| Uric acid | Mg/dl | - | ≥ 10 |
| Albumin | Gm/dl | ≤ 1.7 | ≥ 6.2 |
| Magnesium (adult) | Mg/dl | ≤ 1.0 | ≥ 4.7 |
| Magnesium (infant) | Mg/dl | ≤ 1.2 | ≥ 13.0 |
| Phosphorus (adult) | Mg/dl | ≤ 1.0 | ≥ 8.9 |
| Phosphorus (infant) | Mg/dl | ≤ 1.0 | ≥ 9.0 |
| Total Bilirubin | Mg/dl | - | ≥ 10 |
| Amylase | U/L | - | ≥ 500 |

## RESULTS

Total 887668 patient samples were analyzed during the study period and 23800 critical alerts were generated by the Cobas 6000 analyzer in total during this period. Both lower critical values and higher critical values of all the eligible parameters were recorded separately and total percentage of critical values for each parameters were recorded.

**Table 2: Critical values of different parameters tested**

| TEST | TOTAL | CRITICAl VALUES | LOWER CRITICAL | HIGHER CRITICAL | PERCENTAGE (%) |
|---|---|---|---|---|---|
| Creatinine | 137747 | 1109 | -- | -- | 0.81 |
| Uric acid | 23566 | 1427 | -- | -- | 6.06 |
| Glucose | 57996 | 1511 | 469 (31%) | 1042(69%) | 2.61 |
| U-BUN | 55499 | 634 | -- | -- | 0.66 |
| Bil- T | 96440 | 1802 | -- | -- | 1.87 |
| Amylase | 1560 | 76 | -- | -- | 4.87 |
| Albumin | 74220 | 436 | 384 (88%) | 52(12%) | 0.59 |
| Sodium | 101974 | 4122 | 2679(65%) | 1443(35%) | 4.04 |
| Potassium | 101805 | 6243 | 1462(23%) | 4781(77%) | 6.13 |
| Chloride | 102586 | 3046 | 2741(90%) | 305 (10%) | 2.97 |
| Calcium | 40336 | 2684 | 403 (15%) | 2281(85%) | 6.65 |
| Phosphorus | 26325 | 539 | 178 (33%) | 361 (67%) | 2.05 |
| Magnesium | 27614 | 171 | 169 (99%) | 02(1%) | 0.62 |
| **TOTAL** | **887668** | **23800** | **--** | **--** | **2.68** |

## DISCUSSION

Our study comprised of total 887668 sample received during one year period.Studies from other laboratories had sample size ranging from 548786 done by sarita et al [10] to 5105336 studied by Anand Dighe et al. [11]

It is evident from our study that the incidence of critical values in our lab varies from as low as 0.59% for serum albumin to as high as 6.65% for serum calcium. Critical values of serum creatinine is 0.81% and it is 0.66% for U- BUN.

**Table 3: critical values of serum creatinine (comparative study)**

| STUDY | Critical values CREATININE | Critical values U-BUN |
|---|---|---|
| Sarita et al 10 | 6.59% | 28.78% |
| Present study | 0.81% | 0.66% |

As we can see, the frequency of critical values of renal function tests are much lower in our laboratory, which might be attributed to lesser number of renal patients in an oncology set up.

**Table 4: Critical values of Electrolytes (a comparative study)**

| Study | Sodium | Potassium | Chloride | Calcium | Magnesium | Phosphate |
|---|---|---|---|---|---|---|
| Sarita et al 10 | 13.71% | 11.6% | - | 5.29% | - | - |
| A.Dighe et al 11 | 0.2% | 1.8% | - | 0.8% | 0.3% | 0.4% |
| AA-Roca et al 12 | 0.2% | 0.9% | - | 1.3% | - | 0.2% |
| **Present study** | **4.04%** | **6.13%** | **2.97%** | **6.65%** | **0.62%** | **2.05%** |

It is evident from the comparative study that the critical values of electrolytes are lower than study of sarita et al [10] but it is much higher than study done by A.Dighe and AA-Rocha et al.[12] Since our study group comprised entirely of oncology patients with different disease spectrum and metabolic profile than general patients and also comprises of large percentage of post chemo-radiation patients, the prevalence of critical values might be attributed to these factors.

These results also points towards the need of further studies in oncology care hospitals to see the prevalence of critical values of serum electrolyte parameters in these patients to observe a pattern of serum electrolyte values in oncology patients.

It was observed that the critical levels of hyponatremia was more common (65%) than hypernatremia (35%) while the hyperkalemia rates were more common (77%) than hypokalemia (23%).

The critical values for hypercalcemia was more common (85%) than hypocalcemia (15%).

Critical values of Serum total Bilirubin was 1.87% in our study and it was 8.54% in the study done by sarita et al.[10]

The incidence of critical values of serum uric acid, which is very important for an oncology centre was 6.06% in our study while it was 1.6% in the study done by sarita et al.[10] This can be attributed to the high cell death and turnover in cancer patients. This highlights the need for study of frequency of critical values in oncology centres to know the tumor burden, cell death in cancer patients both in pre chemotherapy and post chemotherapy states.

## CONCLUSION

It is evident from our study that the frequency of critical values for some parameters like serum Potassium, Uric acid are higher in the patients of an oncology centre than other non oncology patients. These values show that these critical biochemical values can be detrimental to these patients and timely notification to the clinician is very important so that necessary actions could be taken to correct them. Further studies of critical values in oncology based labs might be beneficial to observe certain trends and in understanding the effects of drugs/ radiation or the effects of tumor on the biochemical profile of these patients.

## REFERENCES


1. Lundberg GD. When to Panic over Abnormal Values. Med Lab Observer 1972;4:47-54.
2. Genzen JR, Tormey CA. Pathology consultation on reporting of critical values. Am J Clin Pathol. 2011; 135: 505-13.
3. College of American Pathologists. Laboratory Accreditation checklist. Available at: http://www.cap.org/apps/cap.portal. Accessed January 18th 2018.
4. Joint Commission on Accreditation of Healthcare Organizations. International Patient Safety Goals 2007. Available at: http :// www. jointcommission. org/PatientSafety/ National- PatientSafetyGoals. Accessed January 8th 2018.
5. Emancipator K. Critical values: ASCP practice parameter. Am J Clin Pathol. 1997;108:247-253.
6. Burtis C, Ashwood E, Bruns D, eds. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics. 4th ed. St Louis, MO: Elsevier Saunders; 2006
7. Lum G. Assessment of a critical limit protocol for point-ofcare glucose testing. Am J Clin Pathol. 1996;106:390-395.
8. Howanitz PJ, Steindel SJ, Heard NV. Laboratory critical values policies and procedures: a College of American Pathologists Q-Probes study in 623 institutions. Arch Pathol Lab Med. 2002;126:663-669.
9. Kuperman GJ, Boyle D, Jha A, et al. How promptly are inpatients treated for critical laboratory results? J Am Med Inform Assoc. 1998;5:112-119.
10. Sarita Jagdishbhai Mangukiya et al / International Journal of Biomedical and Advance Research 2015; 6(08): 617-622.
11. Anand S. Dighe et al, Analysis of Laboratory Critical Value Reporting at a Large Academic Medical Center, Am J Clin Pathol 2006;125:758-764.
12. Ariadna Arbiol-Roca, Analysis of laboratory critical values at a referral Spanish tertiary university hospital, Biochem Med (Zagreb). 29(1): 010704.