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# Root Cause Analysis of Absurd results of Serum Potassium - Need for verification of vacuum tube quality

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## Abstract

**Objective:** The study aims at performing root cause analysis of absurd results of serum potassium observed at biochemistry laboratory of new civil hospital Surat, Gujarat. 5-why technique is used to find root cause of the absurd results.

**Methods:** Fishbone diagrams for root cause analysis of absurd potassium results were developed. During analysis of each of possible causes results of July and August 2018 for serum potassium were exported from LIS. For each absurd report, serum potassium was analyzed in duplicate with QC samples. Calcium was also measured in such samples. Person collecting samples were interviewed for process of collection. Plain Vacuum tubes from supply department were checked for its potassium contamination.

**Results and Conclusion:** Calcium in serum with absurd potassium was very low, indicating EDTA contamination. $K^+$ in some of the plain vacuum tube was unacceptably high. Fishbone diagrams are powerful technique for Root Cause Analysis, as it notes down even rarest cause in its fish bone. Such rare cause, as in current case of $K^+$ contamination of plain vacuum tube during manufacturing, can be overlooked if such extensive cause listing is not done. $K^+$ contamination of plain vacuum tube during manufacturing highlight need for developing protocols for routine testing of quality of vacuum tube before lot is put in to use.

**Keywords:** Root cause analysis, Fishbone diagrams, absurd results, potassium.

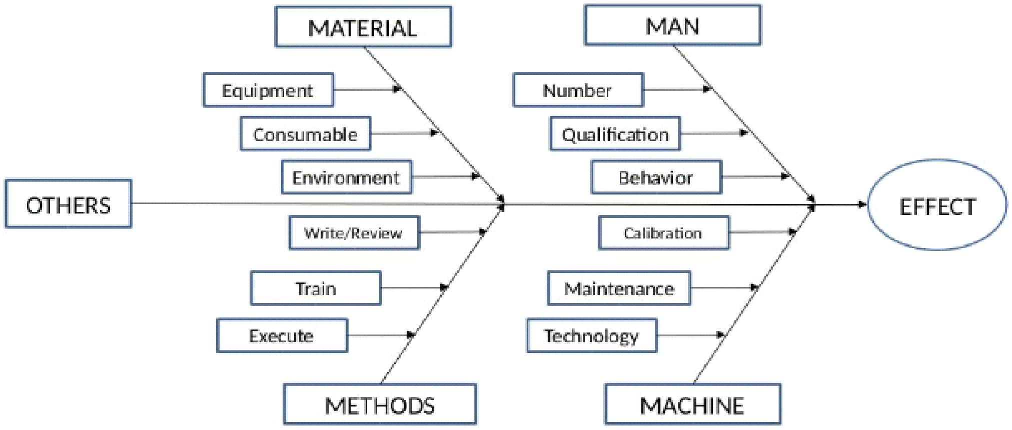
## 1. Introduction

Modern clinical laboratory have many challenges. One of the challenges is to use modern technique of problem solving in day to day laboratory practice. ISO 15189: 2012 have published standards requiring laboratory to use modern technique in identification, control, correction and prevention of nonconformity. 5-why and fishbone diagrams are used by industries to the effect of root cause analysis. The study shows its usefulness in day to day clinical laboratory practice for problem solving.

Fishbone diagram and 5-why are frequently used method for root cause analysis. Ishikawa diagrams, shown in Figure 1 (also called fishbone diagrams, herringbone diagrams, cause-and-effect diagrams, or Fishikawa) are causal diagrams created by Kaoru Ishikawa that show the causes of a specific event. Common uses of the Ishikawa diagram are product design and quality defect prevention to identify potential factors causing an overall effect. Each cause or reason for imperfection is a source of variation. Causes are usually grouped into major categories to identify and classify these sources of variation.

The Fishbone diagram is an analysis tool that provides a systematic way of looking at effects and the causes that create or contribute to those effects. Because of the function of the Fishbone diagram, it may be referred to as a cause-and-effect diagram. [2]

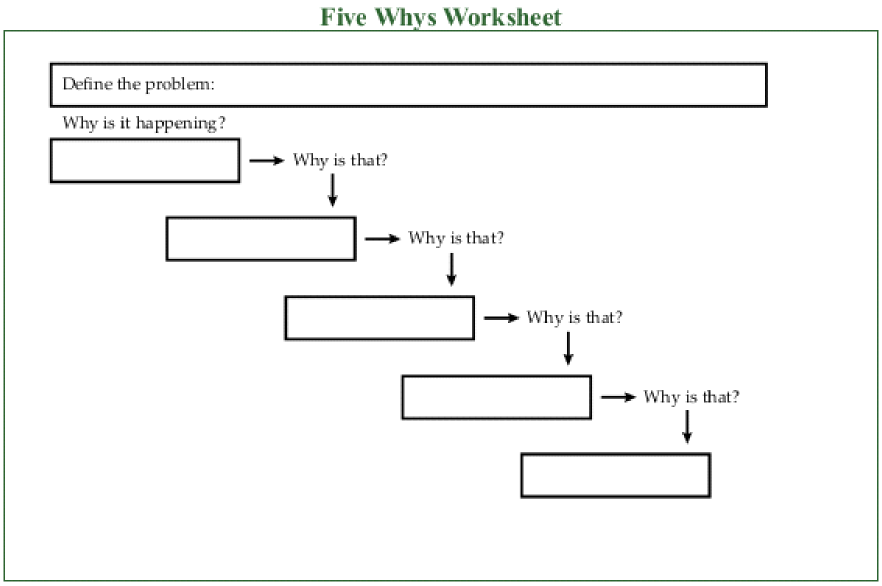
**Figure 1: Fishbone diagram for root cause analysis**




The defect is shown as the fish's head, facing to the right, with the causes extending to the left, the ribs branch off the backbone for major causes, with sub-branches for root-causes, to as many levels as required.

5-Whys are an iterative interrogative technique used to explore the cause-and-effect relationships underlying a particular problem. The primary goal of the technique is to determine the root cause of a defect or problem by repeating the question "Why?" Each answer forms the basis of the next question. The "5" in the name derives from an anecdotal observation on the number of iterations (repetitions) needed to resolve the problem. When looking to solve a problem, it helps to begin at the end result, reflect on what caused that, and question the answer five times. This elementary and often effective approach to problem solving promotes deep thinking through questioning, and can be adapted quickly and applied to most problems. Most obviously and directly, the Five Whys technique relates to the principle of systematic problem-solving: without the intent of the principle, the technique can only be a shell of the process. [3]

**Figure 2: 5-Whys technique for root cause analysis**



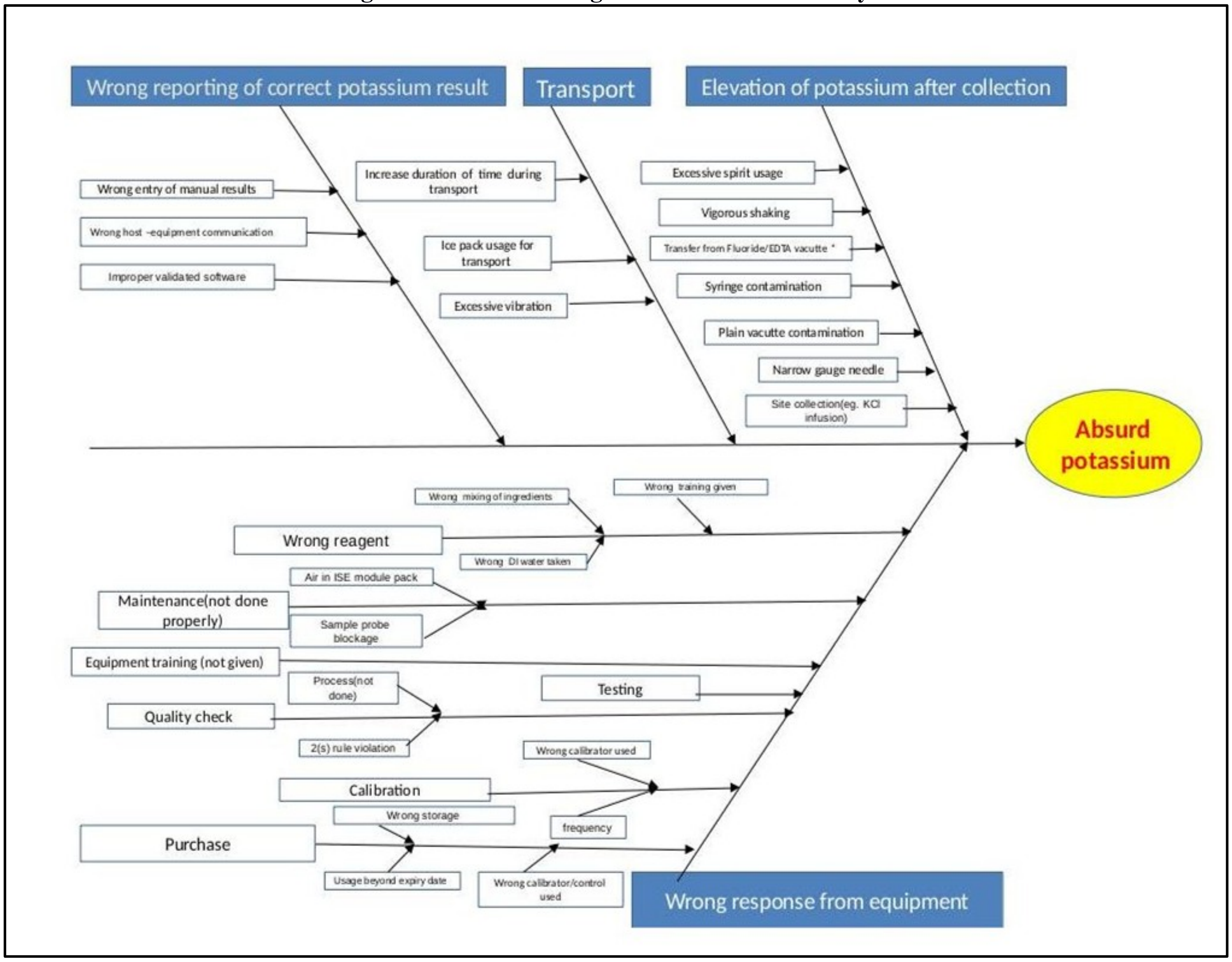

## 2. Method

For absurd potassium results, fishbone diagram was constructed. For each fishbone, various possible causes of absurd potassium were enlisted. Each cause was evaluated to reach possible cause of absurd potassium in the current case.

## 3. Result and discussion

Through discussion among faculties, and exhaustive list of possible causes for absurd potassium were drawn as fishbone diagram. Instead of traditional man and material type of fishbone, laboratory processes were used as major fish bone. This allowed detailed look-in to possible causes of absurd potassium. Figure 3 shows the result.

**Figure 3: Fish bone diagram for root cause analysis**




As post-examination and examination process are easy to analyze they were examined first.

**3.1 Wrong reporting of correct Potassium results (Post-examination process)**

The laboratory uses automated analyzers and LIS. The LIS do not require manual entry by technicians and LIS was validated for correctness of data transfer and Host-equipment communication. Observed absurd potassium was verified to be same in equipment and LIS. The laboratory samples were transported in stipulated duration and there was no evidence of increase in duration of time during transport for samples with absurd results. Samples were not transported in ice pack. They were transported by humans within hospital; excessive vibration during transport was unlikely. Such samples were checked if ever they were hemolyzed or not and found to be not hemolysed. Thus, post-analytical phase was not responsible for absurd potassium.

**3.2 Wrong response from Equipments (Examination process)**

Calibrators and controls usage beyond expiry was not found. Equipment calibration and maintenance were as per manufacturer's instruction. IQC, EQA of were in acceptable range. Samples with absurd $K^+$ were analyzed in duplicate. As shown in Table 1, results showed that replicates confirmed absurd $K^+$ in sample.

**Table 1: Duplicate $K^+$ results and $Ca^{2+}$ in same sample**

| | K+ mmol/L | | Calcium |
|---|---|---|---|
| Sample id | 1st value | 2nd value | |
| 2448 | 17.3 | 17.3 | Undetectable |
| 2467 | 13.9 | 14.1 | Undetectable |
| 2534 | 73.4 | 73.7 | Undetectable |
| 2627 | 10.09 | 10.09 | 0.2 |
| 2672 | 84.7 | 82.6 | Undetectable |

Acceptable IQC, EQA and analysis of replicate samples helped the laboratory to conclude that examination process is not responsible for absurd $K^+$ observed in samples.

**Problem with elevated potassium results after collection (pre-examination process)**

The residents and interns who draw the sample were interview both personally and telepathically and also through the faculties. Orders of draw and collection technique were asked. Order of draw was correct, vigorous shaking; sample collection by a narrow gauge needle was not done.

Specimens for determining $K^+$ concentrations in serum or plasma must be collected by methods that minimize hemolysis, because release of $K^+$ from as few as 0.5% of erythrocytes can increase $K^+$ values by 0.5

mmol/L. An increase in $K^+$ of 0.6% has been estimated for every 10 mg/dl of plasma hemolglobin (Hb) caused by hemolysis. Thus, slight hemolysis (Hb= 50 mg/dl) can be expected to raise $K^+$ values by approximately 3%, marked hemolysis (Hb>200 mg/dl) by 12%, and gross hemolysis (Hb> 500 mg/dl) by as much as 30%). Samples were observed for hemolysis, but, not gross hemolysis was evident. [1]

History of KCl infusion history was absent.

The lab also suspected if the sample after collection was kept in fluoride or EDTA vacuum tubes and poured in to plain vacuum tube, but after cross questioning by their faculties it was clear that they followed proper order of draw of vacuum tubes for blood collection [4].

All answers from the junior doctors were proper and did not violate any norms. The laboratory was at this point clueless.

In one sample, collected within the laboratory, under observation by teaching staff, showed absurd result, despite all analytical care. It was hypothesized that tube or syringe may be contaminated with EDTA or some chelating agent.

To immediately confirm such possibility, serum calcium were measured in such samples. As shown in Table 1, serum calcium was very low or undetectable; confirming the hypothesis that K2/K3 EDTA contamination.

As, there was no evidence of wrong order or draw, contamination of syringe and plain vacuum tubes by $K^+$ was suspected as last possibility. Several lots of vacuum tubes were checked for its potassium by adding 1 ml DI water in it and measuring its potassium. Results are shown in Figure 3 to 6 for various lots tested. Note that Y-axis is logarithmic in Figure 2 and 3 to accommodate very high $K^+$ in certain samples.

**Figure 4: $K^+$ in Plain Tubes of LOT#1805079c**

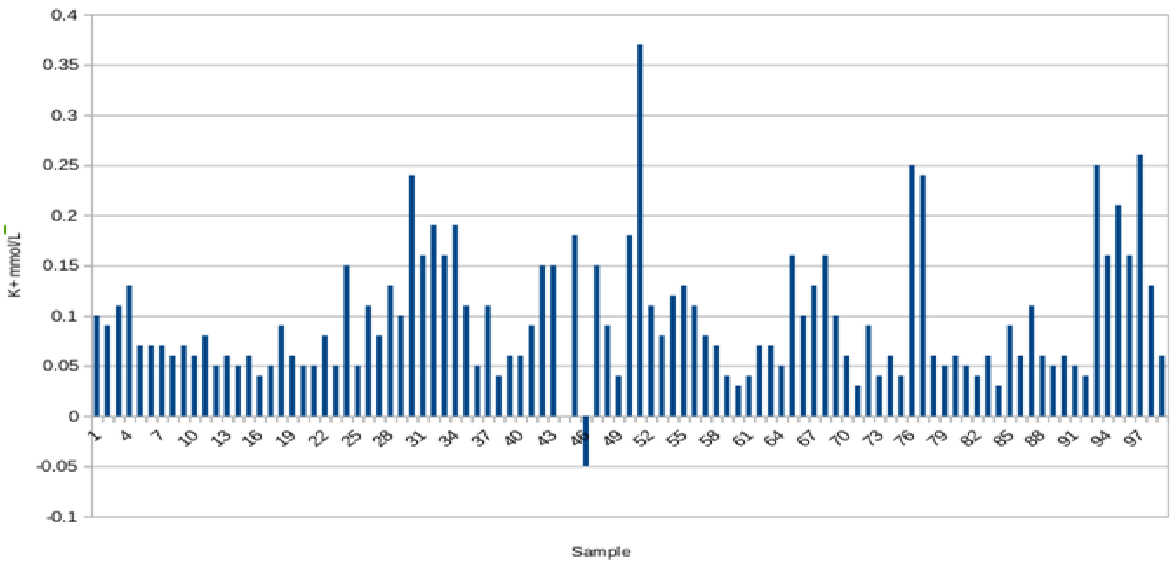



**Figure 5: $K^+$ in Plain Tubes of LOT#1805028c**

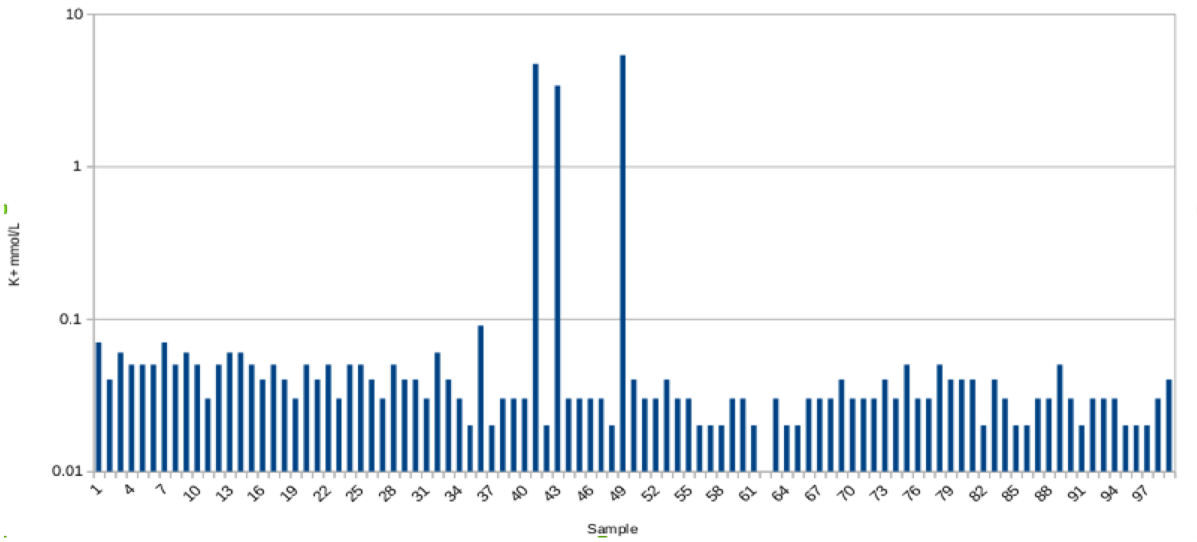
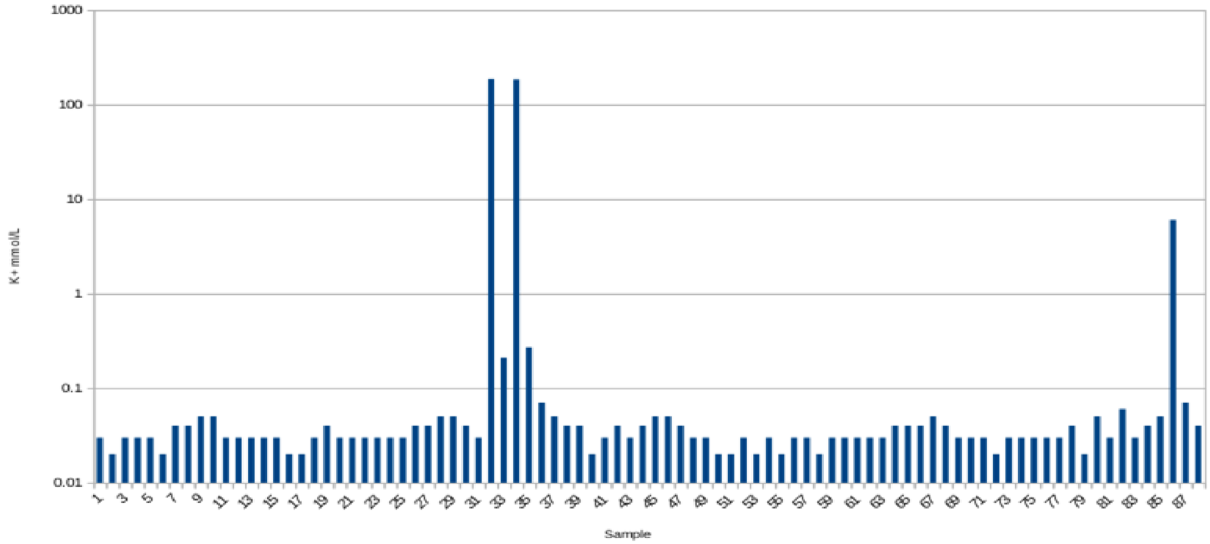


**Figure 6: $K^+$ in Plain Tubes of LOT#1805079c**




The graph shows that certain tubes in certain lots had very high $K^+$. Such occasional $K^+$ contamination was responsible for absurd potassium. Poor manufacturing system is likely to be resulting in such contamination. As, most laboratory uses vacuum tube without any in-house verification of quality, such contamination of vacuum tube may go unnoticed.

## 4. Conclusion

Fishbone diagrams are powerful technique for Root Cause Analysis, as it notes down even rarest cause in its fish bone. Such rare cause, as in current case of $K^+$ contamination of plain vacuum tube during manufacturing, can be overlooked if such extensive cause listing is not done.

Moreover, the $K^+$ contamination of plain vacuum tube during manufacturing highlight need for developing protocols for routine testing of quality of vacuum tube before lot is put in to use.

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