

The details of manuscript are as follows:

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Column: Retrospective Study

Title: Assessment of quality control system by sigma metrics and QGI: a roadmap towards preparation for NABL

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Reviewer code: 00068723, 03351479 and 02446387

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Responses to the Editor's comment

We appreciate very much the editor and the reviewers for the constructive comments. We also thank the editor and the reviewers for the effort and time put into the review of the manuscript. Each comment has been carefully considered point by point and responded. Responses to the reviewers and changes in the revised manuscript have been marked as red colour. Short running title and Pin code has been added in the introduction of authors. Aim of abstract has been revised. Core tip and the article highlights have been added. The audio core tip has been uploaded. Table 1 describing QGI has been converted into text. We believe that revised version of manuscript has now been considerably strengthened.

Response to specific Reviewers' Comments

Comment I: The authors investigated the quality control of clinical laboratory test with sigma metrics. They concluded that sigma metrics was satisfactory. Were there any

literatures on sigma metrics on laboratory tests? How were the present results compared with the other data? How were the results compared with ISO standard 15189 in view of quality control? In Introduction, information would be necessary regarding sigma metrics. For example, how it was originally devised, the field of main use.

Response: Yes, there are some articles on sigma metrics on laboratory tests and these have been duly mentioned in the discussion with citation. Already available data was taken into consideration during discussion of our results but statistical analysis was not applied for comparison. Information regarding sigma metrics has been added in the introduction section.

Comment II: This is a good manuscript. However, there are several issues that may kindly be addressed for improvement of the manuscript.

1. The authors have stated as under as per laboratory policy, two levels of controls (level 2, normal and level 3, pathological) were run on daily basis In this context it requires specific mention of the details of the internal quality control material used. Is it purchased from same agency although?

Response: Level 2 and level 3 internal quality controls are run on daily basis, which is purchased from Randox Laboratories Limited and is supplied by its authorized dealer.

2. The instrument (Randox) make and model requires specific mention with its service report with its performance data. A sample service report of the system may be provided in the supplementary.

Response:

Instrument make and model: Rx Suzuka fully automated clinical analyzer (Serial no: S1200800CS0026MA). IQ, OQ and PQ of the equipment along with the sample service report have been attached in the supplementary.

3. NABL accreditation certificate be provided in the supplementary.

Response: Copy of NABL certificate has been attached in the supplementary.

4. The lab specific cut off value including 1sd, 2sd etc one sample chart may be provided in the supplementary with an actual data.

Response: LJ chart of Albumin (one of the parameters) for the month of August, 2017 for QC2, which also shows 1SD and CV%, has been attached in supplementary.

5. How was the data (lab data) stored in the study period?

Response: Hard copy of LJ charts and EQAS report are being stored in separate files. Soft copy of EQAS is available on CMC Vellore site also.

6. How many times Internal quality control was performed. This aspect should be elaborated with details.

Response: 2 levels of controls twice a day were run on daily basis.

7. It must be mentioned that the lab received any complains from end users documenting concerns about the analyses report or not

Response: Time to time feedback is received from the end users (Clinicians of our institute) which is usually positive.

8. The instruments are run by qualified technologists or not and the report is signed by qualified persons as per law or not.

Response: Job has been described for all the members of the laboratory staff. Equipment is run by a team of Senior lab technicians and is signed by authorized signatories (as per criteria laid down by Medical Council of India) approved by NABL team.

9. How often repeat analyses request comes from the clinician? Any such data is maintained or not must be mentioned.

Response: A system is there to keep a record of all repeat analyses but for the period of study no such request was received.

10. To explain the finds the authors have commented as under Strict monitoring as well as increased frequency of IQC run is required. However, it is not mentioned what is the laboratory frequency of IQC in a day in the reporting period. This aspect must be included in the revised manuscript. I recommend for a Major Revision.

Response: As mentioned earlier, 2 levels of controls twice a day were run on daily basis and the same has been included in the revised manuscript.

Comment III: This is a very important paper that advocates the need to develop precise standards or criteria for improving health care quality measures. Most of terms used were clearly defined and used in the application. However, two terms need to be defined: 1) analyses, and 2) outdoor. I assume that authors used the term "outdoor" as outpatient care.

Response:

1) Term Analysis has been used with sigma metrics as sigma metrics analysis which means to quantify the analytical process as defects per million.

2) Term outdoor means outpatient care or Outdoor Patient Department (OPD).