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Original Research Article

Impact of developing and implementing nonconformance management system at clinical biochemistry laboratory section of tertiary care hospital run by Government of Gujarat, India

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ABSTRACT

Introduction: In the era of evidence based medicine, laboratories are in implied need of providing quality services to their stakeholders. Development and implementation of NMS is the most important for laboratory preparing for accreditation.

Aim : The aim of the study is to supplement the knowledge and to provide guidance about development of NMS in accordance with the accreditation requirements.

Materials and Methods: The study was conducted at clinical biochemistry section of NCHSLS, Gujarat, India. Total of 85 NCs retrieved from the nonconformance record for the period of Oct 2011 to Sep 2013. They were analyzed for sources. Analysis was done to know whether they belong to management or technical requirements. Frequency and percentage-wise analysis of NCs related to various procedures of total testing process was also done and RCA for some of the NCs were done using 5 why's or Fish bone technique.

Results and Discussion: Majority of NCs are related to IQC (60%), External audit (14%) and EQAS (12%).

Major NCs occurred in analytical and post analytical procedures and were related to the technical requirements (87%) pertaining to laboratory equipment (35%) and quality of examination procedures (20%).

Conclusion: Development and implementation of NMS, is very useful for identification, record and RCA of NCs. NMS, helps to identify the area of QMS in need of attention as well suggest the corrective and preventive actions. It guides, decision making for developing a robust QMS system. Moreover, correct method of RCA is important in comprehensive evaluation of cause and prevention of the NCs.

1. Introduction

Quality is defined as ability of a service provider to satisfy the needs and expectations of the customer.[1,2] Every industry in the world is focusing on quality of their products or services they provide to sustain the growth of the business. In medical testing laboratories, quality is assessed in terms of accuracy, timeliness of reports and reliability.[3,4] As in the era of evidence based medicine, clinical decision making is done in the light of laboratory results.[5] Errors in the reporting adversely affect the outcome of the patient. Therefore, laboratories

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are in implied need of providing quality services to their stakeholders.[6–8] Automated analysers, training of technical staff and availability of quality control programs has led to great fall in the occurrence of analytical errors and thus non-conformance.[9] Recently, quality improvement has received great attention. Various standards and guidelines are made available by various institutions and organizations like WHO, ISO and CLSI to improve quality of the services provided by the medical laboratories. Rather correcting the immediate problem, laboratories shall work to identify the underlying causes and shall take preventive measures.[10]

In India, National Accreditation Board for testing and calibration Laboratory (NABL) was established, which provides voluntary third party assessment of technical competence and accreditation service to various testing and calibration laboratories in India. Though accreditation is voluntary, many laboratories are applying for NABL accreditation as it increases the confidence of the customer, gives recognition and reputation to the laboratory.[11–13] As on 11/04/2021 1880 medical testing laboratories has been given accreditation by NABL and many laboratories are under process of accreditation in India.[14]

Specific documents named NABL 112 - specific criteria for accreditation of medical laboratories and NABL 117 - Assessment Forms and Checklist (based on ISO 15189:2012) along with many other documents, has been prepared in accordance with ISO 15189 and put in force by NABL to guide the medical laboratories about the accreditation requirements and process.[13–16] Latest version of the same is made available to all in free to download form on official website of NABL.

With availability of advanced, robust and automated analyzers and other equipment's, quality of analytical process of medical laboratories has attained a satisfactory level but quality is a holistic approach and just the good quality of analytical process is not sufficient for accreditation.[17] For medical laboratories, quality of entire process starting from the test prescription by clinicians to the clinical decision making again by clinicians is considered.

For any laboratory preparing for accreditation, most important thing is to develop and implement quality management system (QMS).Once QMS is designed according to the need of the organization and put in to use, routine systemic internal audit drives the further improvement of the QMS. Data management particularly identification and recording of nonconformance, analysis of nonconformance records and actions based on analysis are major fuel for any organization to drive continual improvement.

Various components of non-conformance management system (NMS) include identification, record and correction of the non-conformance. It also includes, grading of non-conformance, analysis of the non-conformance record using various methods like 5 why technique or the fishbone technique to find out root cause and to develop plan of action to make necessary changes in the required area of QMS to prevent the recurrence of the same non-conformance.[18,19]

The aim of the current study is to supplement the knowledge of laboratory personnel about development and evolution of non-conformance management system in medical testing laboratories in accordance with the NABL accreditation requirements. This study will also provide guidance to the medical laboratories currently at various stages of the accreditation process.

2. Materials and Methods

The study was conducted at clinical biochemistry laboratory section of New Civil Hospital, Surat Laboratory Services (NCHSLS) – a tertiary care providing hospital run by the Government of Gujarat, India.

In 2009-10, policy decision was made by Government of Gujarat, to opt for NABL and NABH accreditation for all tertiary care providing medical laboratories and public hospitals respectively, run by the Gujarat state government to improve the quality of the services provided. While preparing for the NABL accreditation, non-conformance management system was developed and put in to force to respond to non-conformance arising at clinical biochemistry laboratory section of NCHSLS.

Quality system procedures (QSP) was prepared for identification, control, correction, prevention of non-conformance at clinical biochemistry laboratory section of NCHSLS, in accordance with the NABL accreditation requirements.

Based on the QSP in force at clinical Biochemistry laboratory section of NCHSLS, NCs were recorded in the laboratory information system (LIS) as follows.

Whenever any NC is identified, entry of the same is made in the NC entry form, in the LIS. NC entry form can be opened from the quality button of the main menu in the homepage. (Main Menu->Quality ->Non-conformance).Figure 1 Format for recording of Non-conformance at Biochemistry Section NCHSLS. Once the form is open, date and time of NC is recorded first followed by source of the information is selected from the dropdown menu like, Internal Quality Control, External Quality assessment scheme, Internal Audit, External Audit, Feedback, Accidental injury report, turnaround time, critical alert reporting or Unclassified. Then description of event and appropriate control action taken to eliminate or to minimize risk to staff and in the respective fields. Similarly corrective action and preventive actions are recorded and lastly, cross reference of the location is recorded where actual detailed record of the NC is stored. Later improvements, if any, are suggested in corrective, control and preventive measures after performing the root cause analysis using 5 why's and Fish bone diagram techniques.

Accidental Injury Report was maintained in the laboratory, whenever any laboratory personnel is affected by accidental injury like needle injury, sample probe injury, burns due to chemicals. External audit is done by NABL assessor. During the study period, last external assessment was done by NABL assessor in September 2013 and 12 non-conformities were raised. The planned actions and action taken report for all NCs were sent to NABL assessor till closure.

Clinical biochemistry section, NCHSLS, takes part in External Quality Assessment Program, RIQAS every month. RIQAS sends parameter wise detail report of performance in PDF format and CSV formats. Unsatisfactory results undergo root cause analysis and preventive measure are planned and implemented by Clinical biochemistry section, NCHSLS. Complains from laboratory staff and NCs brought to notice by laboratory personnel like technicians, resident doctors or servants are included in the category of "feedback". Two levels of Internal Quality Control (IQC) is done by laboratory twice a day for various parameters and the LJ charts are plotted in the LIS for the same. Laboratory follows certain predefined Westgard rules to accept or reject the run. If these rules are violated by the IQC results, necessary actions taken to control, correct and prevent the non-conformance is documented.

Data of non-conformance was gathered from the non-conformance record of clinical biochemistry section of NCHSLS for the period of Oct 2011 to Sep 2013. During this period, total of 85 NCs were recorded. They were analyzed for sources of NCs as shown inTable 1.

According to Technical clauses of NABL 217, total testing process of a sample is divided in to pre analytical, per analytical and post analytical procedure. Frequency and percentage wise analysis of NCs related to various procedures of total testing process are shown in Table 2.

According to NABL 112 and NABL 217, various requirements related to accreditation process are divided into 2 major clauses: management requirements and technical requirements. NCs related to these major clauses are described in Table 3.

Root cause analysis (RCA) for some of the NCs were done using various RCA methods like 5 why's and Fish bone diagram.

3. Results and Discussion

Initially NC record was being maintained in the physical form as NC register but soon feedback from the technicians and resident doctors were received about the difficulties encountered in management of physicals records of non-conformance. Soon, it was decided by the laboratory management to integrate the non-conformance record into laboratory information system in digital mode so that record keeping, updating, data retrieval and analysis of the record for various purpose in future can be made simple and feasible.

Table 1: Frequency of NCs from various sources

Source of NC	No. of Non-conformance	Percentage (%)
Accidental Injury Report	1	1
External Audit	12	14
External Quality Assessment Program	10	12
Feedback	6	7
Internal Audit	5	6
Internal Quality Control	51	60
Total	85	100

Table 2: Frequency of NCs related to analytical procedure

Type of NCs	No. of Non-Conformance	Percentage (%)
Pre analytical	4	18
Per analytical	9	41
Post analytical	9	41
Total	22	100

Table 3: Frequency of NCs related to major clauses of NABL 112

Type of NC	No. of Non-conformance	Percentage (%)
Management	11	13
Technical	74	87
TOTAL	85	100

Fig. 1: Format for recording of Non-conformance at Biochemistry Section NCHSLS.

As shown in Table 1, majority of NCs are related to IQC (60%), External audit (14%) and EQAS (12%). Thus

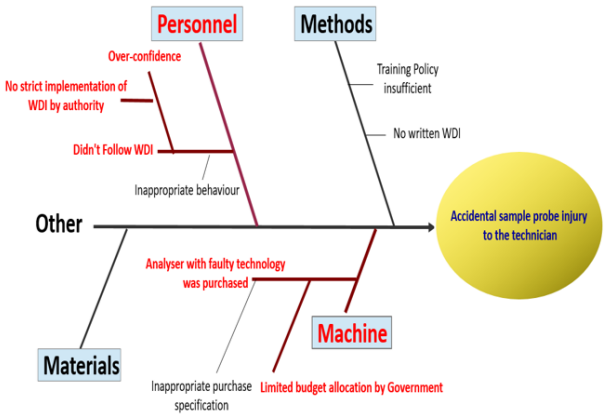

Fig. 2: Fish bone diagram of Feedback NCs

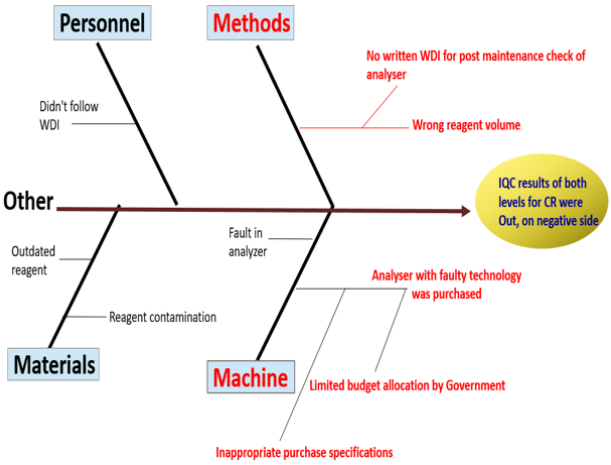

Fig. 3: Fish bone diagram of IQC Non-conformance

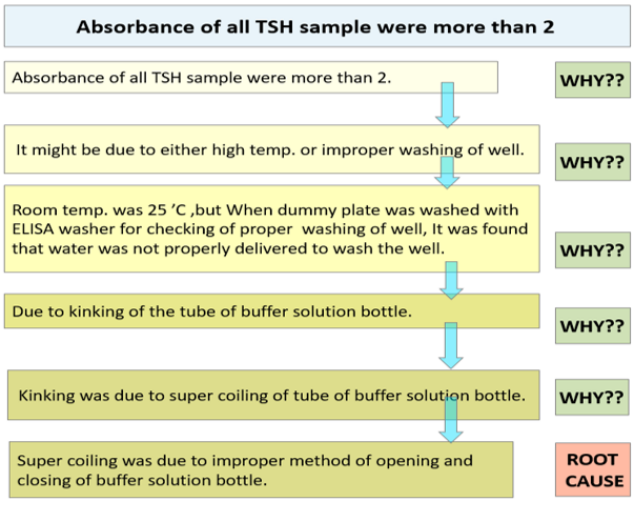

Fig. 4: RCA using 5 why technique for non-conformance - absorbance of all TSH samples was more than 2.

improvement in IQC and EQAS can lead to decrease in total number of NCs. Majority of IQC related NCs can be solved by improvement in automated analyzer quality. Majority of EQAS related NCs can be solved by good quality calibrators and majority of NCs raised by NABL assessor during external audit are related to non-availability of resources from laboratory management committee.

As shown in Table 2, the major NCs occurred in analytical and post analytical procedure. NCs occurring in the pre analytical procedure are, inappropriate and inadequate details in the test request form (TRF), inadequate sample collection, sample and TRF data mismatch, inappropriate transport of samples. NCs occurring in the post analytical procedure are increased turnaround time, lack of informing critical alert. Analytical procedures involved in NCs are related internal quality control and carryover during examination of samples. Thus improvement in analytical and post analytical error will reduce the burden of the total non-conformance.

As shown in Table 3, majority of NCs are related to the technical requirements (87%). From technical clause, most of the NCs are related to laboratory equipment (35%) and quality of examination procedures (20%). If quality of analyzers and related equipment is improved, then total number of non-conformance can be reduced to great extent.

RCA of accidental sample probe injury to the index finger of right hand of senior technician, reported on 1st October 2012, using fish bone technique was done. Figure 2. Accident happened because, technician tried to load the urgent sample in the sample tray during the run. As technician was senior and experienced, technician's confidence turned to overconfidence and he disregarded the WDI stating not to open the lid of the analyzer till the run is completed and authority did not reinforced strict implementation of the WDI, despite knowing that technicians are violating the instructions of the WDI. Moreover, analyzer was not equipped with the sensor that senses the opening of lid during run and immediately stops the movements of probe. So that, such accidents can be prevented. It might be due to limited budget to purchase analyzer from government or the specifications might not be appropriately drawn during purchase or both.

RCA using fish bone technique was done for another NC pertaining to IQC. Figure 3. Creatinine (CR) results for both levels of IQC were obtained on negative side on 2nd October 2012. Same results were obtained on repeat run. Upon further investigation, it was found that, IQC values of CR were out of range on negative side due to change in reagent volume by engineer during the repair of analyzer but original volumes were not restored after repair. Engineer and technician forgot to restore the original reagent volumes. It was due to no written WDI for post maintenance check of analyzer. So, the root cause of the NC was lack of WDI for post maintenance check for analyzer.

Moreover, if the analyzer had bar-coding system for reagent and its parameters, then any changes done manually during repair would be overwritten by reading of barcode present on the reagent bottle, but barcode scanner is not present in analyzer, might be due to limited budget from government to purchase analyzer or inappropriate purchase specification drawn during purchase or both.

Another RCA was done for a feedback non-conformance in which the absorbance of all TSH samples run in a single batch were more than 2.0 on 31st January of 2013. Figure 4. RCA was done using 5 WHY's technique and root cause found was improper washing of wells of the ELISA plate which was cross checked using dummy ELISA plate which might be due to wash solution was not properly delivered to wash the well might be due to either pump failure or blocking of tube. On physical inspection, kinking and blockage in the tubing was found. Kinking occurred due to super coiling of tubing due to improper method of opening and closing of buffer bottle. A WDI was prepared mentioning correct method for loading of buffer by keeping the lid fix and rotating the bottle from bottom and training for the same was conducted.

At the time of analysis of NC data, it was understood that nature of NC varies greatly with the time period. NCs recorded for initial period of about 2 years, were quite primitive as the concept of QMS was totally new for entire staff of NCHSLS but experience gain from developing and implementing various components of QMS and from critically evaluating QMS in terms of breach in the conformance, had tremendous and long lasting impact on the understanding of the criticality of the every component of the QMS.

While analyzing NC record, it was found that many NCs were related to increase in turnaround time (TAT). An effort was made to find out the root cause for increase in the TAT. TAT starts from test request by clinicians to interpretation of the results by clinicians which includes various sections or departments of the hospital like out-patient department, sample collection section, sample processing section and report dispatch section. To find out accurate and correct root cause of the increase in the TAT, the information chain needs to be intact throughout all the sections and departments. It was difficult to find all the root causes correctly and accurately as the information chain was broken at many places, still some primary conclusions from the available data were made and necessary corrections in the system were planned. Later, newly admitted MD pursing resident doctor was assigned the TAT related dissertation topic which helped the laboratory a lot in finding the areas that were in need of changes. Some changes were made in the like sensitization of clinicians, nursing staff and ward attendants, changes in the laboratory information system, purchase of new computers, printers and barcode readers for various departments and sections of the hospital to develop of a robust system to provide the results in stipulated TAT.

During the pandemic of the Covid-19, to provide the good and timely diagnostic services a new fully automated biochemistry analyzer was to be purchased for the Clinical Biochemistry Section, NCHSLS. When specifications were being drawn as a part of procurement procedure, it was recommended that the analyzer should have sensor that detect the opening of the lid of the analyzer during run, ring an alarm and immediately abort the movement of sample and reagent probes, so accidental probe injuries can be prevented. Similarly, in built barcode scanner facility in the analyzer was also recommended so that sample detection and reagent management can be done efficiently and accurately with minimal manual efforts.

4. Conclusion

Developed and implementation of Non-conformances management system, in accordance with NABL 112 and NABL 217, at Clinical Biochemistry Laboratory of New Civil Hospital and Government Medical College Surat as a part of accreditation process was very useful identification, record and root cause analysis based on local needs of the laboratory and were the same was done.

Learning from these experiences has also provided guidance, for better future decision making like purchasing of new biochemistry analyzer or developing a robust system to provide reports in the stipulated TAT.

The studies found that majority of non-conformances are related to EQAS, NABL assessment and IQC. Moreover, correct method of root cause analysis is important in comprehensive evaluation of cause and prevention of the NCs. The Fishbone technique of RCA is better than 5 Why's for correct planning of preventive strategy.

5. Limitation of the study

The study was conducted at Clinical Biochemistry section of NCHSLS, Surat. For generalizability of data, evaluation of NCs data need to be done with the NCs data of other sections of the NCHSLS as well as with the clinical biochemistry laboratory sections of other NABL accredited laboratories of tertiary care hospitals run by Government of Gujarat.

6. Conflict of Interest

There are no conflicts of interest in this article.

7. Source of Funding

None.

References

1. Modi K, Shaherawala J. Turnaround time for common clinical chemistry examinations and root cause analysis for its delay. *Int J Clin Biochem Res*. 2019;6(4):596–600.

2. Chauhan KP, Trivedi AP, Patel D, Gami B, Haridas N. Monitoring and root cause analysis of clinical biochemistry turnaround time at an academic hospital. *Ind J Clin Biochem*. 2014;29(4):505–9.
3. World Health Organization. Laboratory quality management system: handbook [Internet]. France: World Health Organization; 2011. [Cited 2021 April 11]. Available from: https://www.who.int/publications/i/item/9789241548274.
4. Westgard JO, Westgard SA, Serrano L, Wildermuth C, Migliarino G, Fernandez E, et al. Basic Quality Management Systems: Essentials for Quality Management in the Medical Laboratory [Internet]. Medison WI: Westgard QC, Inc; 2014. Available from: https://www.westgard.com/images/stories/BQMS-Preview.pdf.
5. Badrick T. Evidence-Based Laboratory Medicine. *Clin Biochem Rev*. 2013;34(2):43–6.
6. Zima T. Accreditation in clinical laboratories. *Biochem Med*. 2010;20(2):215–20. doi:10.11613/BM.2010.026.
7. Zima T. Accreditation of medical laboratories - system, process, benefits for labs. *J Med Biochem*. 2017;36(3):231–7. doi:10.1515/jomb-2017-0025.
8. Roy AD, Das D. An evaluation of the errors occurring in pathology and microbiology laboratories of a tertiary care teaching hospital and their root cause analyses. *J Health Res Rev*. 2019;6(3):102–6. doi:10.4103/jhrr.jhrr_38_19.
9. Goswamia B, Singha B, Chawla R, Mallika V. Evaluation of errors in a clinical laboratory: a one-year experience. *Clin Chem Lab Med*. 2010;48(1):63–6.
10. Technical Criteria for Laboratory Accreditation (Medical Laboratories) [Internet]. Hong Kong: The Government of the Hong Kong Special Administrative Region 2010; c2010 [Forth Edition: February 2010; cited No 2013]. Available from: www.itc.gov.hk/en/quality/hkas/doc/hoklas/HOKLAS015-Abridged.pdf.
11. Dahiya K, Ghalaut VS, Verma M, Kumari A, Dalal D. Hurdles Faced in Getting a Clinical Biochemistry LaboratoryAccredited by NABL in Government Setup: Our Experience. *IJMB*. 2020;24(1):1–3. doi:10.5005/jp-journals-10054-0136.
12. Wadhwa V, Rai S, Thukral T, Chopra M. Laboratory quality management system: Road to accreditation and beyond. *Indian J Med Microbiol*. 2012;30(2):131–40. doi:10.4103/0255-0857.96647.
13. Kanagasabapathy AS, Rao P. Laboratory accreditation-Procedural guidelines. *Indian J Clin Biochem*. 2005;20(2):186–8.
14. National Accreditation Board for Testing and Calibration Laboratory. [Accessed April 11 2021]. Available from: https://nabl-india.org/nabl/index.php?c=searchlab&m=index&Itemid=177.
15. National Accreditation Board for Testing and Calibration Laboratory, NABL 112: Specific criteria for accreditation of medical laboratories; 2019. [Accessed April 11 2021]. Available from: https://nabl-india.org/nabl/index.php?c=publicaccredationdoc&m=index&docType=both.
16. National Accreditation Board for Testing and Calibration Laboratory, NABL 217: Assessment Forms and Checklist (based on ISO 15189:2012); 2021. [Accessed April 11 2021]. Available from: https://nabl-india.org/nabl/index.php?c=publicaccredationdoc&m=index&docType=both&per_page=25.
17. Bonini P, Plebani M, Ceriotti F, Rubboli F. Errors in Laboratory Medicine. *Clin Chem*. 2002;48(5):691–698.
18. Guidance for the Identification and control of non-conformity [Internet]. UK: The All Wales Pathology Quality Managers Forum; c2010 [updated 2013 Nov 11; cited 2013 Nov 19]. Available from: www.nliah.com/portal/microsites/Uploads/Resources/GHcVK6iMa.doc.
19. Jordarian accreditation system; c2011. *Policy on grading of Non-conformities*. 2011;.

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