EVALUATION OF MICROBIOLOGY LABORATORY QUALITY CONTROL BASED ON QUALITY MANAGEMENT SYSTEM IN GOVERNMENTAL AND PRIVATE HOSPITALS OF TEHRAN

Seyedeh Afroz Azimi 1*, Nooshafarin Safadel 2

1-MSC Microbiology, Department of Microbiology, Islamic Azad University – Urmia Branch.
2-MD.AP.CP. Assistant Professor, Quality Management and Accreditation Office, Reference Health Laboratory, Ministry of Health and Medical Education.

ABSTRACT: The importance of quality management system as a basic level, error reduction and prevention of duplication in addition to expenses decreasing and profitability of organizations resulted to the public interest in the settlement of laboratory standard version (ISO 15189) in Iran since 2006 but it is still a new project. Using national and international standards and organizing implementation programs based on these standards, is a promising way to improve the quality of health care.

The goal of this study was to practically find out the condition of ISO 15189 administration and screening in microbiology laboratories, as a main part of every clinical lab, in a variety of Tehran hospitals. In order to assess the standard implementation in the volunteered laboratories a multi section questionnaire were designed containing all the standard section with the possibility of defining the answer. The main sections were derived from ISO 15189 and approved by the Ministry of Health and Medical Education. Extracted data from the questionnaires showed that paying attention to the principles of quality management system and ISO 15189 standard were well agreed among all of laboratories. Although the rate of standard implementation were different in each area, all of them showed considerable improvement from 2006 to 2011. In conclusion, further evaluation by the Health Reference Laboratory would be more concentrate on the weak points which are basically in areas of “controlling nonconformities”, “quality control” and “documentation”. Therefore, a multi stage reassessment of comparable data in shorter intervals and careful inspection of the situation would be an effective step toward the full settlement.

*Corresponding Author: Correspondence should be addressed to Seyedeh Afroz Azimi, MSc Microbiology, Islamic Azad University Urmia Branch, Iran. s_afroz_a@yahoo.com
INTRODUCTION

Consistent with the global approach to the quality improvement in a variety of fields such as industry, manufacturing, trade and services, pioneers in science and technology moved rapidly towards standardizing all of their activities. However, despite rapid progress of standardization in the field of industry, it is a more recent discussion in the field of health and treatment. Considering the importance of medical laboratories’ test results and the crucial role of such services for clinicians, patients and public health, multiple attempts have been done to provide a standard quality assurance approach [1]. Therefore, the final version of standardization requirements, ISO 15189, were developed based on ISO 9001 standard and published in 2003 by the International Organization for Standardization by name of “medical laboratories- particular requirements for quality & competence”[2].

This standard was minor revised and republished in 2007 with the aim of introducing a quality management system that guarantee the quality of all system outputs and the final results of medical laboratory tests in addition to technical activities necessary to achieve this goal[3]. ISO 15189 is a structured standard containing five main sections which includes every single affair in a nominated laboratory such as examinations, equipments and personnel. The most important and detailed parts of this standard are the fourth and fifth sections which contain management and technical requirements respectively. The brief constituents of ISO 15189 were depicted in figure 1.

To date, compliance with ISO 15189 is becoming progressively accepted as the optimal approach to assuring quality in medical testing which includes accuracy, reliability and timeliness of reported test results [4]. The accreditation of medical laboratories is currently converting from a ‘recommendation’ to a ‘requirement’ in many countries all over the world [5]. Therefore, in our country, Iran, dramatic changes have been made recently in administrators’ policy with regard to the Quality Management System (QMS) which shows a high rate of interest in order to improve the quality of results and standardizing all medical testing affairs. As a result, a domestic version of the mentioned standard was described as “ISO 15189.ir” by the National Standard Organization of Iran and it becomes the reference for accreditation of quality management system of all clinical laboratories.

Additionally development and declaration of the mentioned local laboratory standard has been performed by the Health Reference Laboratory in Ministry of Health and Medical Education of Iran and the requirements for establishment of such standard in all organizations and laboratories has been predicted. Accordingly a number of surveillance programs have been carried out by the Health Reference Laboratory specialists since 2006 to monitor the performance of all medical laboratories of the country. The experts provided particular and distinct checklists for each of laboratory sections such as biochemistry, hematology, microbiology, genetics and etc. Afterwards, evaluation based on provided checklists has been made primarily in 2006 by the Reference Laboratory (unpublished data) and re-achieved after five years (in 2011, the present investigation) with the aim of continuous following up of “ISO 15189.ir” implementation in every section of medical laboratories all over the country.

However this five year evaluation needs more prompt surveys according to a specific checklist that would be capable of analyzing the outcome information in order to extract all valuable and informative data specially comparison between the competence of different laboratories to the standard measures.

Basically, microbiology section is one of the fundamental units of a medical laboratory which is concerned with the prevention, diagnosis and treatment of infectious diseases. Due to the sensitivity of microbiology unit performance in terms of helping to improve treatment procedure and control of infectious agents, both in community and hospitals, proper implementation of quality management system in this part is one of the most important tasks of every laboratory [6].

Regarding the services which are delivered by microbiology section, the ISO 15189 standard in this unit refers to all different affairs such as arrangements for requisition, patients’ identification and preparation, sample collection, transportation, storage, processing and examination of clinical samples in addition to subsequent validation, interpretation, reporting and advice together with consideration of safety and ethics in medical testing. Other technical affairs that are considered in the standard
include facility and material providing (i.e. equipments and kits) and also educational opportunities offering for professional staff.

Laboratory Quality Management System (Lab QMS) in Microbiology has evolved in western countries in the past 40 years [7], but this aspect has not received its full credit in Iran, to date. Although many laboratories had excellent achievements in quality control division, these activities are without any frame or standards.

The aim of the present investigation was to evaluate the establishment of Lab QMS in the various processes of active microbiology laboratories in Tehran healthcare settings, Tehran, Iran. In other words Lab QMS was considered as the basis for standardizing and concordance between the eight sections of Lab QMS and the five main divisions and other subdivisions of ISO 15189, as the appropriate standard for clinical laboratories, were used as reference for further inspections.

An additional goal of the present exploration is to compare the present situation with the primary screening of microbiology Lab QMS which was discovered in 2006 to inspect the standard trends in the country and the Process of improvement were measured over a 5-year period. The assessment was taken in Tehran hospitals as a primary phase while the next phases will be extended to the whole country after removal of deficiencies and gaps. The results of this study would support laboratories towards the accurate understanding of quality assurance and to find deficiencies in order to improve the situation in way of accreditation. Furthermore, focusing on the outcomes would make sure the administrating system and physicians to the acceptance of lab results to complete the treatment process.

MATERIAL AND METHODS

Sample collection:

The present study was carried out in microbiology laboratories located in the governmental, private and charity hospitals of Tehran, Iran in a one year period from May 2011 until May 2012. The participated health care settings were consisted of 36 charity and governmental plus 50 private sector hospital laboratories in Tehran (totally 86 healthcare centers).

Assessment of ISO 15189 compliance:

To access the rate of ISO 15189 implementation and restoration in mentioned laboratories, a comprehensive questionnaire were designed containing all the standard section as a yes/no question with the possibility of defining the answer [8]. The questionnaire comprised of 90 questions (74 main and 16 complementary questions) divided into ten main subdivisions reflecting the various activities of a microbiology department of a hospital laboratory, as well as eliciting information by the attitude of Quality Management System as the basis and key infrastructure which leads to better practice of ISO 15189.

The main sections derived from ISO 15189 were as follows; 1. physical situation and infrastructure of a microbiology laboratory 2. Documentation requirements 3. Pre-analytical procedures 4. Analytical procedures 5. Post-analytical procedures and reporting, 6. control of nonconformities, 7. Quality control, 8. Equipment availability, maintenance and application, 9. Health, safety and waste management and 10. Staff training. The main requirements of each section were extracted from ISO 15189 and approved by the Ministry of Health and Medical Education.

Prior coordination had made with the technical officer and supervisor of all mentioned hospitals and therapeutic centers, thereafter the questionnaire were presented in addition to a referral letter from the Health Reference Laboratory, Ministry of Health and Medical Education. The forms were completed by at least one of the microbiology laboratory staff and technical officer or supervisor of the laboratory in all 86 centers, subsequently content of assembled checklists were verified using random check and according to QMS certification and traceability methods.

It should be mentioned that reassessment of several ambiguous responses or inquiring further necessary questions were performed in case of need.

Data analysis:

Extracted records from all questionnaires were ordered and imported in Microsoft Excel software. The answers to each sections of the questionnaire were separated in to 3 groups; the “Yes” answer to all questions of a section considered as “Acceptable Settlement” of ISO 15189, conversely No answer to
some or all of the questions of a subdivision regarded as “Require Corrective Action” and “Lack of Settlement” respectively.

Overall evaluation and grading of health centers were scored by 1 to 4 according to the rate of QMS implementation in every participated laboratory. A score of 4 represents the best possible establishment of standard model comparing to the other laboratories; conversely, a lower score suggests an area for improvement. Quality Management System standard as the basic infrastructure and further strict implementation of ISO 15189 has been taken into consideration.

Extraction of data from the questionnaires was performed and the answers imported to Microsoft Excel and SPSS version 16 for frequency analyses and cross-tabulation. Frequencies and percentages were described in proceeding tables.

RESULTS AND DISCUSSION

All the 86 microbiology laboratories from the Capital were successfully filled the questionnaire and further information was extracted from answered questions. Overview questions showed that each laboratory had at least 20 patients daily where the numbers of patients were varying from 20 to 300 cases every day in assorted hospitals. Initially the most frequent biological samples which were collected daily in microbiology laboratories were defined to be urine, stool, sputum, blood, wound and other samples respectively.

Evaluation of “ISO 15189” Implementation

In the current evaluation, paying attention to the principles of quality management systems and ISO 15189 standard were found to be well agreed among all of laboratories.

The standard situations of participated hospitals relating to various sections of ISO 15189 based on Lab QMS, were assessed in 10 separate classification and more or less progressed parameters were defined in form of a questionnaire (Table 1). In every one of studied sections, the majority of hospitals were in need of improving the situation and corrective actions were required to justify the field according to the standard. Therefore, the most variable category of this investigation were considered “require corrective action” group, which showed the most fluctuation values from 2006 to 2011, the two years that standard accreditation were performed (discussed later in results).

The most well developed areas which proved to be in full settlement of standard were “in microbiology laboratories and “physical situation and infrastructure” that were completely established in 20.9% and 16.3% of hospitals respectively (table 1). However, low percentage of these parameters might show the urgent need of a supplementary program in order to improve such percentages.

As mentioned above, further comparisons has been made regarding the hospitals competence to ISO 15189 and according to the rate of microbiology laboratories which were requiring counteractive actions, the weak points of organizations were in the areas of “controlling nonconformities”, “quality control” and “documentation” (Table 1).

Controlling of the nonconformities refers to affairs of a laboratory which are not defined in the framework of the standard that must be document, follow up and take corrective actions to be removed. This parameter in addition to the documentation and record keeping in laboratories did not well agreed and settled yet since these are new topics of Lab QMS in Iran; therefore the importance of these sections should be explained to all organizations.

Another section that should be improved is quality control of the laboratories. Many laboratories overlook quality control measures. This is mainly due to financial issues since a number of laboratories would like to decrease the cost of their tests to attract more clients and this might led them to ignore some high charge quality control requirements. In this situation accurate monitoring of quality control implementation would be very useful to improve such situation.

Comparison of the standard implementation between 2006 and 2011

As mentioned above, acquired results of this evaluation were compared to the same results which had been achieved by the Health Reference Laboratory of Ministry of Health and Medical Education in 2006. The most uneven category of this comparison was in “require corrective action” group (figure 2).
The most increased percentages were defined in physical situations and all stages of clinical testing (consisted of pre-analytical, analytical and post-analytical phases), such percentages were at least 30% lower in 2006, while this amount were belonged to the “lack of settlement” category on that time point. This means that nearly one third of participated laboratories tried to improve their situation from lack of standard establishment to the compliance of it and partial implementation of its requirements.

The only section of the questionnaire which has not shown considerable improvement was staff training (figure 2). Previous studies have shown the effect of personnel training both on the quality of test results and physicians trust [9]. Therefore this topic requires more attention in future planning.

**Establishment of laboratory QMS, based on hospital types:**

After the inspection for the establishment of laboratory QMS, the percentage of that were determined with respect to the type of health centers (table 2). Present finding shows that the laboratory QMS among the microbiology laboratories of Tehran hospitals are more acceptable in private hospitals comparing governmental centers. In private sector no sample were found to have the first grade of QMS implementation while 5 governmental hospitals were found in this score (the weakest score). Additionally considerable percentages of private centers were in the third grade comparing governmental ones while no governmental center were defined in the best grade (see details in table 2).

The differential distinction of participated microbiology laboratories which confirmed the better implementation of ISO 15189 in private hospitals that might be due to higher financial integration and brief funding process in such laboratories.

**CONCLUSION**

This study attempts to clarify the concept of ISO 15189 based on Laboratory Quality Management System (lab QMS) in microbiology laboratories of Tehran, Iran.

The overall trend of the standard principals and Lab QMS were relatively desirable in the participated laboratories. The comparative findings have been endorsed upgrading and improving of whole parameters of microbiology Lab QMS since 2006. The best degree of enhancement in 2011 assessment was seen in the field of physical situations and infrastructures plus to the analytical procedures, while the weak points of organizations that should be considered by the Health Reference Laboratory for further follow up, were in areas of “controlling nonconformities”, “quality control” and “documentation”.

In this study, more than half of private hospital microbiology laboratories had grade 3 and 4, which showed suitable settlement of standard requirements along with the aim of Health Reference Laboratory (Ministry of Health and Medical Education in Iran).

Although the descriptive result shows promising trend of standardization among the Capital hospitals, the next step evaluation by the Health Reference Laboratory would be more concentrating on the weak points. Consequently, a multi stage reassessment of comparable data in shorter intervals and careful inspection of the situation would be an effective step toward accomplishment.

The present results will be submitted to the Health Reference Laboratory of the Ministry of Health and Medical Education to be considered for further evaluations in Capital and other hospitals of the country to enable a more accurate judging of the current ISO 15189 implementation in the country.

**ACKNOWLEDGMENT**

This study was supported by the Ministry of Health and Medical Education, Tehran, Iran.

**REFERENCES**

3. International Organization for Standardization. Medical laboratories: particular requirements for quality and competence,
Figure 1: The brief constituents of ISO 15189 standard.
### Table 1. The standard situations of participated hospitals relating to various sections of ISO 15189 based on Lab QMS.

<table>
<thead>
<tr>
<th>Questionnaire Subdivisions</th>
<th>Lack of Settlement</th>
<th>Require Corrective Action</th>
<th>Adequate Settlement</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>%</td>
<td>No.</td>
<td>%</td>
</tr>
<tr>
<td>Physical situation and infrastructure</td>
<td>0</td>
<td>0</td>
<td>72</td>
<td>83.7</td>
</tr>
<tr>
<td>Pre-analytical procedures</td>
<td>9</td>
<td>10.5</td>
<td>69</td>
<td>80.2</td>
</tr>
<tr>
<td>Analytical procedures</td>
<td>0</td>
<td>0</td>
<td>68</td>
<td>79.1</td>
</tr>
<tr>
<td>Post-analytical procedures and reporting</td>
<td>13</td>
<td>15.1</td>
<td>64</td>
<td>74.4</td>
</tr>
<tr>
<td>Health, safety and waste management</td>
<td>14</td>
<td>16.3</td>
<td>61</td>
<td>70.9</td>
</tr>
<tr>
<td>Equipment availability, maintenance</td>
<td>18</td>
<td>20.9</td>
<td>57</td>
<td>66.3</td>
</tr>
<tr>
<td>Staff training</td>
<td>36</td>
<td>41.9</td>
<td>47</td>
<td>54.7</td>
</tr>
<tr>
<td>Documentation</td>
<td>38</td>
<td>32.7</td>
<td>46</td>
<td>53.4</td>
</tr>
<tr>
<td>Quality control</td>
<td>40</td>
<td>46.5</td>
<td>43</td>
<td>50</td>
</tr>
<tr>
<td>Control of nonconformities</td>
<td>41</td>
<td>47.7</td>
<td>42</td>
<td>48.8</td>
</tr>
</tbody>
</table>

### Table 2. The rate of QMS implementation with respect to the hospitals type (governmental or private).

<table>
<thead>
<tr>
<th>Grades</th>
<th>Governmental Hospitals</th>
<th>Private Hospital</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>%</td>
<td>No.</td>
</tr>
<tr>
<td>1</td>
<td>5</td>
<td>13.9</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>22</td>
<td>61.1</td>
<td>25</td>
</tr>
<tr>
<td>3</td>
<td>9</td>
<td>25</td>
<td>23</td>
</tr>
<tr>
<td>4</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>36</td>
<td>100</td>
<td>50</td>
</tr>
</tbody>
</table>
Figure 2. Comparison of the standard implementation between 2006 and 2011 (the comparison made exclusively on the “Require Corrective Action” groups).