



Challenges of Implementing Iranian National Laboratory Standards

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Abstract

After four years of publishing the Iranian National Laboratory Standard and following a strategic plan to implement its requirements, it was decided to review the taken actions, evaluating the achievements and the failures, as well as analyzing the gaps and planning the interventional activities to resolve the problems. A thorough evaluation revealed that the progress of implementation process varies considerably in different provinces, as well as in laboratories in different public and private sectors. Diversity and heterogeneity of laboratories throughout the country is one of unresolvable problems. Although we encounter shortage of resources in the country, improper allocation or distribution of resources and budgets make the problems more complicated. Inadequacy of academic training in laboratory sciences has resulted in necessity of holding comprehensive post-graduate training courses. Revising academic curriculum of laboratory sciences could be mostly helpful, moreover there should be organized, training courses with pre-determined practical topics. providing specific technical guidelines, to clarify the required technical details could temporarily fill the training gaps of laboratory staff. Inadequate number of competent auditors was one of the difficulties in universities. Another important challenge returns to laboratory equipment, developing the national controlling system to manage the laboratory equipment in terms of quality and accessibility has been planned in RHL. At last cultural problems and resistance to change are main obstacles that have reduced the pace of standardization, it needs to rationalize the necessity of establishing laboratory standards for all stakeholders.

Keyword: Laboratory, Standards, Reference, Health, Iran

Introduction

There is a specific hierarchy of laboratory services in Ministry of Health (MOH), Iran. Although there are 31 provinces In Iran, MOH has divided the country to 49 regions each of which is under supervision of its dedicated medical university. There is an office of laboratory affairs in each university that is responsible for supervising the laboratories in that province. There are nearly 5000 laboratories throughout the country in different public and private sectors with different range of activities and capabilities and different levels of quality performance. Each of them had

their own policy to maintain and improve their quality (1). Moreover, there are fundamental differences in domestic situation and limitations in different provinces of Iran (2). After four years of publishing the national standard, it was necessary to evaluate the achievements and failures of implementation of standards throughout the country, as well as analyzing the gaps and planning the interventional activities to resolve the problems (3).

In this article, the challenges of establishment of the laboratory standard in Iran will be discussed

and strategy of Reference Health Laboratory (RHL) to overcome the obstacles will be presented.

Methods

Assessing the achievements and failures of the laboratories, all around the country, in implementing standard requirements carried out through several different methods. The most effective source of data gathering was analysis of the results obtained by benchmarking programs. This program has been the best opportunity to assess the challenges of implementation of laboratory standards in different provinces (4), in this program the laboratory auditors from all around the country gather together in one province to inspect almost all of the medical laboratories there. The final report is sent out to the dean and deputies of the host university in order to take appropriate actions.

Another important means of investigating the condition at district levels is random inspection of performance of the universities (3). To do so, expert teams from Reference Health Laboratory carry out on-site evaluation to monitor the tasks that the universities have been required to perform. The cumulative analysis of the laboratory inspection's reports by office of the laboratory affairs provides valuable information about the performance of laboratories over a period of time in different provinces.

The External Quality Assessment Schemes (EQAS) was extended in terms of covering parameters and the frequency of holding the program. Analyzed information of this countrywide program is utilized for policy-making in different fields such as quality of laboratory equipment and assessing training needs, it could also be used to overall estimation of laboratory performances (5).

Results and Discussion

A thorough evaluation revealed that the progress of implementation process varies considerably in different provinces. This fact is resulted from

several factors. Probably the most important and affective factor is intent and willingness of cooperation in the offices of laboratory affairs in respective universities. The responsibility of establishment of standards in each province is laid on the dedicated university, which supervises the laboratories there. According to local situation each university must have its own schedule for implementation and certainly it should be stepwise, flexible, practical and feasible within specified time frames. It is shown where the university authorities desire to cooperate in establishing the standard, they usually succeed to remove the barriers and proceed.

Financial problems and shortage of resources such as personnel, equipment, supplies and facilities are highly prominent obstacles in implementing laboratory standard. In many cases the problem is not the lack of resources but the allocation or distribution of resources and budgets make serious troubles. Taking appropriate policies for resource management could resolve many problems.

Diversity of laboratories as well as laboratories in many different public and private sectors and at different level of quality development make it nearly impossible to set a same plan or follow a same approach for implementing the standards in all these heterogeneous laboratories throughout the country. Even the best laid national plan may go awry; there would be many different plans and approaches according to domestic situation in each province and laboratories in different sectors (6). The universities and the subsidiary laboratories should be considered free to choose where to start and how to move forward.

Lack of knowledge or skills of technical staff reduce the pace of implementation process. Insufficiency of academic training in laboratory sciences has resulted in necessity of holding pervasive and comprehensive post-graduate training courses for laboratory personnel. Adjoining the principles of quality management system in academic curriculum of laboratory sciences could be mostly helpful. Until then it is necessary to fix an organized, training courses with pre-determined practical topics (6). Cascading training

programs were held throughout the country, although evaluating the effectiveness of these training courses is very difficult and challenging.

National laboratory standard addresses general concept of quality requirements. In some areas it seems necessary to provide specific technical guidelines, clarifying the required technical details in some processes such as specimen management, waste management and preventive maintenance of laboratory equipment (7). It also would be helpful for less competent personnel to follow through the instructions.

Shortage of human resources and inadequate number of competent auditors in many provinces led to ineffective tracking of the implementation process in the laboratories, there should be sufficient number of laboratory auditors to monitor accomplishments and failures of the laboratories in this process. It definitely requires arrangements to get the trained and qualified auditors to work-force (2).

Reviewing the overall results of External Quality Assessment Schemes in the country give us a valuable idea about status quo. Evaluating the EQAS results revealed that an important challenge we encountered is related to laboratory equipment. To develop a national controlling system to manage the laboratory equipment in terms of quality and accessibility is really crucial (8) and it is one of the RHL priorities.

The last but not the least barrier to implement the laboratory standard is cultural problems and resistance to change that make it difficult to enforce a new discipline (2). It takes time and needs to rationalize the necessity of establishing laboratory standards, and bring up the subject repeatedly in related seminars and forums.

Conclusion

Naturally enforcement of a new regulation may come up against certain barriers and reluctant reactions. Establishment of National Iranian Laboratory Standard was confronted some difficulties that reduce the pace of implementation process, but the problems are potentially resolvable

through revision of the strategies and rearrangement of resources.

Full cooperation of universities' authorities plays a key role, especially in designing a stepwise plan to implement the standard in laboratories in different sectors in a timely manner, concerning the local situation in their province, as well as efficient resource management could solve many problems. Revising academic curriculums and organized post graduate training courses improves the knowledge of laboratory staff, as the most common cause of laboratory errors. Providing supplementary technical guidelines is also beneficial. To improve the quality of laboratory equipments is crucial for quality performance of laboratories, upgrading the related regulation is important.

In order to trace the implementation process in the laboratories, there should be sufficient number of auditors and formation of laboratory auditor pool is necessary.

Finally the most challenging part of laboratory standardization is to overcome the cultural problems and reluctance to change.

Ethical considerations

Ethical issues (Including plagiarism, Informed Consent, misconduct, data fabrication and/or falsification, double publication and/or submission, redundancy, etc) have been completely observed by the authors.

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The authors declare that there is no conflict of interest.

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