



Establishment of National Laboratory Standards in Public and Private Hospital Laboratories

****Soghra ANJARANI, Nooshafarin SAFADEL, Parisa DAHIM, Rana AMINI, Saeed MAHDAVI, Siamak MIRAB SAMIEE***

Reference Health Laboratories Research Center, Ministry of Health & Medical Education, Tebran, Iran

***Corresponding Author:** Email: anjarani@health.gov.ir

(Received 23 Sep 2012; accepted 14 Nov 2012)

Abstract

In September 2007 national standard manual was finalized and officially announced as the minimal quality requirements for all medical laboratories in the country. Apart from auditing laboratories, Reference Health Laboratory has performed benchmarking auditing of medical laboratory network (surveys) in provinces. 12th benchmarks performed in Tehran and Alborz provinces, Iran in 2010 in three stages. We tried to compare different processes, their quality and accordance with national standard measures between public and private hospital laboratories. The assessment tool was a standardized checklist consists of 164 questions. Analyzing process show although in most cases implementing the standard requirements are more prominent in private laboratories, there is still a long way to complete fulfillment of requirements, and it takes a lot of effort. Differences between laboratories in public and private sectors especially in laboratory personnel and management process are significant. Probably lack of motivation, plays a key role in obtaining less desirable results in laboratories in public sectors.

Keywords: Standards, Hospital, Laboratory, Iran

Introduction

International organization for standardization (ISO) had published an international standard for medical laboratories, ISO:15189 “Medical Laboratories – particular requirements for quality and competence” (1). It was not feasible to implement the requirements of ISO:15189 all at once in medical laboratories in different sectors and in different provinces, so it had been decided to define the minimal quality requirements that could be mandatory for all clinical laboratories throughout the country. To do so Reference Health Laboratory (RHL) of Ministry of Health organized expert committees, and finally in September 2007 national standard manual was finalized and officially

announced as the minimal quality requirements for all medical laboratories in the country (2, 3).

With the finalization, the explanatory courses were arranged for technical officers throughout the country. More than 20 workshops were performed to train about 400 expert auditors. Trainees were chosen from laboratory departments of medical universities and also scientific societies. The aim of the workshops was training capable and knowledgeable pool of auditors in accordance with national standards and its respective checklists. Apart from auditing laboratories, RHL has performed benchmarking auditing of medical laboratory network (surveys) in provinces. Seasonally, laboratory auditors gather in one selected prov-

ince to audit a noticeable fraction of its total laboratories based on the national standard checklist (3). 12th benchmarks performed in Tehran and Alborze provinces in 2010 (on that time these two provinces were merged as one province named Tehran province). Regarding too many active laboratories in these two provinces, this benchmark performed in three stages:

1) Public hospitals: 84 public hospitals were audited by 60 auditors

2) Private hospitals: 54 private hospitals were audited by 70 auditors

3) Outpatient, private medical laboratories

The results of these audits are the main interest of this study. Through the discussion and analyzing process we try to compare different processes, their quality and accordance with national standard measures between public and private hospital laboratories.

Methods

Reference Health Laboratory conducted this descriptive and comparative study during the 2010. The assessment of the medical laboratories in Tehran and Alborz provinces were performed by the trained auditors and based on the national standard and its respective checklist. Each laboratory had been visited and assessed thoroughly by a team of 3-5 auditors.

The assessment tool was a standardized checklist consists of 164 questions. The questions were categorized based on the requirements in national standard. There were four options for each question: “Yes”, “No”, “Corrective action is required” and “Not applicable”. “Yes” suggested that the requirement is completely fulfilled; “No” showed that the requirement has not been fulfilled yet, “Corrective action is required” showed that an attempt to accomplish the requirements was tried but it is not totally completed and further action is

required, and “Not applicable” showed that the requirement is irrelevant in this precise laboratory. The results obtained from each respective checklist with the laboratory’s informational data were entered in software for further statistical analysis. The reason for this study was to compare the assessment results of 84 public hospital laboratories with 54 private hospital laboratories. The comparison was done on the personnel management, biosafety, equipment management, environment, pre-analytical, analytical and post-analytical processes, quality assurance processes, purchasing and inventory, referral and referee laboratories relations, non-conformity management. We tried to define the weakness and threats in both settings and compare their success ratio. The conclusion would be enlightening the further steps and guide a better implementation rate.

Results

The results of the questionnaire with respecting ethical issues are presented in Tables 1 to 3.

Discussion

Several studies comparing the health service of public and private sector, as some of them are as follows:

A systematic review of comparative Quality of private and public ambulatory health care in low and middle income countries show both public and private sectors, scored low on infrastructure, clinical competence and practice, nevertheless private sector performed better with regard to responsiveness and effort. Synthesis of qualitative components indicates the private sector is more client centered (4).

Table 1: Comparing the result of auditing public hospital laboratories and private hospital laboratories in Personnel Management, Biosafety, Equipment Management and Environment processes in Tehran and Alborz provinces

	Personnel Management (14 questions)				Biosafety (26 questions)				Equipment Management (15 questions)				Environment (36 questions)			
	Yes	No	Corrective action is required	Not applicable	Yes	No	Corrective action is required	Not applicable	Yes	No	Corrective action is required	Not applicable	Yes	No	Corrective action is required	Not applicable
Public H.L. ¹ (84 cases)	65.58	13	19.8	1.6	63.35	17.19	18.81	0.65	61.20	14.7	23.3	0.8	74.19	11.62	11.27	2.92
Private H.L. ² (54 cases)	76.28	6.71	16.86	0.14	76.15	7.77	15.77	0.31	72.93	6.93	18.93	1.2	85.55	5.78	6.83	1.83

Table 2: Comparing the result of auditing public hospital laboratories and private hospital laboratories in Pre-analytical, Analytical, Quality Assurance and post-analytical processes in Tehran and Alborz provinces

	Pre-analytical (12 questions)				Analytical (11 questions)				Quality Assurance (15 questions)				Post-analytical (10 questions)			
	Yes	No	Corrective action is required	Not applicable	Yes	No	Corrective action is required	Not applicable	Yes	No	Corrective action is required	Not applicable	Yes	No	Corrective action is required	Not applicable
Public H.L. ¹ (84 cases)	68.3	12.95	17.85	0.9	53.71	17.87	25.5	2.91	36.39	30.28	32.37	0.96	71.08	13.37	15.54	0
Private H.L. ² (54 cases)	80	6.33	13.17	0.5	61.45	12.36	24.36	3.45	35.87	20	25.33	0.8	80.2	4.8	15	0

1- Public hospital laboratories
2- Private hospital laboratories

Table3: Comparing the result of auditing public hospital laboratories and private hospital laboratories in Purchasing and inventory, Referral and referee laboratories and Non-conformity management in Tehran and Alborz Provinces

	Purchasing and inventory (13questions)				Referral and referee laborato- ries (6questions)				Non-conformity management (6questions)			
	Yes	No	Corrective action is required	Not appli- cable	Yes	No	Corrective action is required	Not appli- cable	Yes	No	Corrective action is required	Not appli- cable
Public H.L ¹ (84 cases)	54.03	21.97	22.8	1.2	22.72	5.51	7.74	64.03	48.19	26.75	24.58	0.48
Private H.L ² (54 cases)	70.08	8.92	17.08	0.92	70.28	3.43	10.57	15.43	60.4	16.4	23.2	0

Other study in South Korea revealed public hospital workers were stereotyped as lazy and incompetent, and public hospitals were portrayed as poorly managed and of low quality, unlike the claims made by the government (5).

In a study in Bangladesh about public and private hospitals, private hospitals were evaluated better on responsiveness, communication, and discipline (6).

In combination with other evidence on health service delivery in China, it was suggested that changes in ownership type alone are unlikely to dramatically improve or harm overall quality (7).

Comparison of different processes in two sectors:

- *Personnel Management*

Private sector shows a 10% better implementation ratio in comparison to the public sector. During discussion with the public laboratory directors it was noticed that they encounter certain managerial restrictions, which has affected their field of action as the laboratory director. In some of the laboratories in the public sector, the directors were supposed to only supervise the technical issues and the personnel management was not one of their responsibilities. This issue had apparently affected many aspects of the personnel management such as trainings or related corrective actions. Due to our observation the training was one of the most affected areas.

On the other hand as some of the legal regulations such as the permit requirements do not include the public sector, the directors did not feel the necessary responsibility toward the standard implementation.

WHO in one of its reports brought highly trained individuals tend to move to more stable (and available) jobs in the private sector (8).

- *Biosafety*

No regulation or guideline can ensure safe practices. Individual and organizational attitudes regarding safety will influence all aspects of safe practice, including willingness to report concerns, response to incidents, and communication of risk (9).

Private laboratories showed 12% better implementation rate. The detailed analysis of the questions showed that the public laboratories problem area rests in waste management and providing the personnel protective equipment. Waste management in hospitals is the responsibility of the central management. We concluded that this part is more due to the budget.

- *Equipment Management*

Public laboratories showed less achievement in this field. The problem could be traced back to the weak documentation skills in all personnel. The personnel are neither well convinced to the importance of documentation nor have received the required sufficient training. The failure is most apparent at usage of

control material and also at generating the records of all procedures.

- *Environment*

One series of five papers shows the private sector performs significantly better than public sector institutions. This series examines this variation in performance with the objective of identifying successful approaches to the management of medical equipment (10).

Public laboratories showed 10% less achievement in environment requirements. This was mainly due to the old structure of a few hospitals that has affected the total percentage dramatically.

Class II Biological safety cabinet only existed in 40% of laboratories irrespective of the group that they belong to. Class II Biological safety cabinet is mandatory for the laboratories that are supposed to perform blood culture. Reference Health Laboratory should pursue this issue for dedication of necessary budget.

- *Pre-analytical, analytical and post analytical procedures*

Public laboratories showed less achievement in these fields. Fortunately the weakness was not at the technical aspect of the laboratories but as mentioned earlier it was on documentation management.

- *Quality assurance*

At this category, which we believe is one of the most fundamental and essential parts for assuring the quality of the results, unfortunately both groups showed weaknesses in these areas and achieved almost 35%. This ratio is much beneath what is desired. The personnel were not able to analyze the result of quality control procedures and implement the corrective action.

We also find out that to empower our assessing tool, we should increase the number of our questions in this field.

- *Purchasing and inventory*

Due to the centralized purchasing department in hospital, laboratory director had minimal

say in choosing the supplier. This problem was more highlighted in public hospitals.

- *Referral and referee laboratories*

We noticed that only a handful of public laboratories were a referral laboratory with full capacity. In other cases though the laboratory was not capable of performing all the desired tests but they do not participate in sending the samples. Patients' samples were sent out of the hospital without laboratory involvement. It should be noted that this issue is not in accordance with national standards, and may cause serious problems especially in terms of biosecurity. It also may affect the quality of specimen because of improper condition of specimen transport. It is strongly recommended that there should be determined policy and documented procedures concerning the test performing and their turnaround times in hospital laboratories. Requests of clinicians of different wards of the hospital should take in to the account. The president of hospital should approve the list of performing tests and provide the needed resources.

If for any reason the laboratory could not perform a certain groups of tests, the specimen could be sent to a referral laboratory according the related documented standards.

- *Non-conformity management*

None of the groups were able to show any credibility in management of non-conformities and also corrective and preventive actions. Since management of the nonconformities is considered as a more mature step in establishing quality management system, the results of evaluation indicated that all laboratories in public and private sectors had difficulties in detecting the nonconformities and take proper corrective and preventive actions. Training in this field and performing internal audit as well as documentation of the detected nonconformities and taking corrective actions should be strongly considered.

Conclusion

Although in most cases implementing the standard requirements are performed in the private laboratories, there is still a long way to absolute fulfillment of the requirements.

Probably lack of motivation, plays a key role in obtaining less desirable results in laboratories in public sectors. In public laboratories there is no financial competition, and no need for licenses renewal through accreditation process, so the pace of progression toward implementation of standards are much slower than what it is in the private sector. Taking in to account that public laboratories are providing service to a large number of people, it is strongly recommended that motivation, responsibility and commitment of laboratory directors and technical staff should be increased through incentive programs.

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.

Acknowledgement

We would like to express our gratitude to all auditors and laboratory specialists in medical universities for their cooperation in improving the quality of laboratory services throughout the country. I would also like to thank my dear colleagues Ms. Tavakoli and Ms. Saleh Hosseini for their great efforts in performing the benchmarking programs and analyzing the results. The authors declare that there is no conflict of interest.

References

1. ISO 15189:2007. *Medical Laboratories –Particular requirements for quality and competence.*
2. *Iranian National Laboratory standards* (September 2007). Reference Health Laboratories, Ministry of Health & Medical Education.
3. Dahim P, Amini R, Safadel N, Rashed Marandi F, Khodaverdian K, Rahnamaye Farzami M (2009). Implementation of Quality Management System in Iranian Medical Laboratories. *Iranian J Publ Health*, 38 (Suppl. 1): 150-152.
4. Berendes S, Heywood P, Oliver S, Garner P (2011). Quality of private and public ambulatory health care in low and middle income countries: systematic review of comparative studies. *PLoS Me*, 8(4): e1000433.
5. Oh J, Lee JS, Choi YJ, Park HK, Do YK, Eun SJ (2011). Struggle against privatization: a case history in the use of comparative performance evaluation of public hospitals. *Int J Health Serv*, 41(2): 371-88.
6. Andaleeb S (2000). Public and private hospitals in Bangladesh: service quality and predictors of hospital choice. *Health Policy and Planning*, 15(1): 95–102.
7. Eggleston K, Lu M, Li C, Wang J, Yang Z, Zhang J, Quan H(2010). Comparing public and private hospitals in China: evidence from Guangdong. *BMC Health Serv Res*, 23: 70-76.
8. World Health Organization(WHO), available from: www.who.org.
9. *Guidelines for Biosafety Laboratory Competency*. CDC and the Association of Public Health Laboratories (2011). Supplement / Vol. 6.
10. Rimmelzwaal Bl(1997). *The effective management of medical equipment in developing countries*. FAKT, Stuttgart.