QUALITY MANAGEMENT IN MEDICAL LABORATORIES: EN ISO 15189 REQUIREMENTS FOR IMPLEMENTATION
Tıbbi Laboratuvarlarda Kalite Yönetimi: EN ISO 15189 Uygulama Şartları

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Summary: *With each passing day, it is required to use the Total Quality Management and quality standards in the diagnostic laboratories because of the increased number of clinical diagnostic laboratories and technological developments on this subject. In this context, medical laboratories are at the hub of the information flow. Laboratory analysis results affect the clinical decisions at a rate of 75%. Thus, it should be an indispensable policy to deliver the correct and reliable test results. There are some quality standards to be fulfilled in order to implement this policy and to deliver the test results that have the same validity everywhere. To this end, accreditation is an important tool. A medical laboratory should warrant a high quality service to the patients and clinicians during the process which include withdrawing blood from the patients and delivering their results.*

ISO 15189 is an international standard used by the medical laboratories to enhance their quality management systems and to evaluate their efficiency. This standard is used by the accreditation organizations to recognize and confirm the efficiency of the medical laboratories.

In this review, this subject is taken into consideration by reviewing the literature and applying the secondary resources, and aims to provide a theoretical framework for the future studies.

Keywords: *Medical laboratory, accreditation, ISO 15189.*

Özet: *Klinik tanı laboratuvarlarının sayısının her geçen gün artması ve bu alandaki teknolojik gelişmeler, toplam kalite yönetimi ve kalite standartlarının tanı laboratuvarlarında kullanımını gerekli hale getirmiştir. Laboratuvar testleri klinik tanının neredeyse vazgeçilmez bir parçası haline gelmiştir. Bu bağlamda tıbbi laboratuvarlar sağlık sistemindeki bilgi akışının tam merkezinde bulunmaktadırlar. Laboratuvar analiz sonuçları da klinik kararları %75 oranında etkilemektedir. Çünkü klinisyenler hastalardan istedikleri analizlerin sonuçlarına dayanarak, teşhis ve tedavilerini gerçekleştirmektedirler. Bu nedenle verilen test sonuçlarında hata yapmamak ve güvenilir sonuçlar vermek tanı laboratuvarlarının vazgeçilmez politikası olmalıdır. Bu politikayı gerçekleştirmek ve geçerliliği her yerde aynı olan test sonuçları verebilmek için bir takım kalite standartlarının yerine getirilmesi zorunludur. Akreditasyon da bunu gerçekleştirmede önemli bir araçtır. Bir tıbbi laboratuvar, kan alımından laboratuvar sonuçlarının hastaya bildirilmesine kadar olan süreçte, hastalara ve klinisyenlere yüksek kalitede bir hizmet sağlamalıdır.*

ISO 15189 uluslararası bir standart olup, tıbbi laboratuvarların kalite yönetim sistemlerini geliştirmeleri ve yeterliliklerini değerlendirmeleri içindir. Akreditasyon kuruluşları tarafından, tıbbi laboratuvarların yeterliliğinin tanınması ve teyit edilmesi amacıyla kullanılmaktadır.

Bu derleme ikincil kaynakların araştırılmasına ve literarür taramasına bağlı olarak ele alınmakta ve daha sonra yapılacak olan çalışmalara kuramsal bir alt yapı teşkil etmesi hedeflenmektedir.

Anahtar kelimeler: *tıbbi laboratuvar, akreditasyon, ISO 15189.*

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Accreditation is not about who the best is, but who has a system of standard procedures. Accreditation is an instrument rather than aim, which increases the quality with high standards of services for clients – patients, physicians (1, 2). Laboratory certification and accreditation are the minimum standards which a laboratory needs for the quality and which regulate the local, regional and national rules in order to make the tests with the patient samples. Regular controls are performed to fulfill the purpose of guaranteeing to obey the rules and the institutional standards which are the parts of the certification/accreditation process (3). Especially in health services, accreditation systems are more convenient rather than a certification (4). In terms of the laboratories, quality service is defined to interpret the correct tests accurately which are taken on time from the correct patients with an adequate performance. In this context, accreditation is an effective tool for the quality evaluation and management (5). This publication has stimulated the development by ISO of the Final Draft International Standard (FDIS) 15189 "Quality Management in the Medical Laboratory". The accreditation process generally consists of a self-assessment, an on-site survey, and follow-up action for improvements, conducted periodically and for-cause. Although there are procedural and programmatic differences between the various inspection and accreditation options, the assessment examines topics covering many areas in the provision of laboratory service. These include environment (space, design, and environmental conditions), staff (quantity and quality of laboratory staff), purchase and inventory, instruments (procedure manual, maintenance), supplies and reagents (preparing, handling, labelling, and storing), process control (validation of processes, internal quality control and external quality assessment), safety, documents and records, laboratory information management and compliance with legislation, regulations and ethical principles (6).

ACCREDITATION

The terms of certification and license can usually be confused with the term of accreditation as meaning. These three terms are compared on the basis of three titles (definition, involves and delivered by) in Table I (1, 7).

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A global study for WHO in 2000, 14 identified 36 nationwide accreditation programmes and their rapid growth since 1995, especially in Europe. A survey of the WHO European Region in 2002 identified 17 such programmes focusing on whole hospitals. Mandatory programmes have recently been adopted in Croatia, France, Italy and Scotland. There is growing worldwide demand and concern for quality in health care, and for effective mechanisms – such as accreditation, ISO certification, and technology assessment –to promote it (9).

Table I. Definitions and comparison of accreditation, certification and licensing

	Definition	Involves	Delivered By
Accreditation	Procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks	Formal recognition by an independent body of technical competence, as well as compliance to a QMS	The 'authoritative body' is the national accreditation body of the country concerned.
Certification	Procedure by which a third party gives written assurance that a product, process or service conforms to specific Requirements	Assurance of compliance to a QMS, most commonly ISO 9001. The scope is variable but (in contrast to accreditation), there are no formal requirements for technical competence	A country may have many 'third parties' able to provide certification
Licensing	The permission, permit from a governmental agency to operate a laboratory	Licensing of health-care facilities is distinct from accreditation and certification and does not necessarily require any evaluation of quality management or technical competence	Usually mandatory and government-imposed

Source: (8).

QUALITY IMPROVEMENT IN THE MEDICAL LABORATORIES

Health services have a special place because of their indispensability in the service sector. Health services' high risk processes and their feature that gives the people an opportunity to use the health services at the time they are provided. That's why, quality systems in the health services organizations are gaining importance every other day (10). The quality control applications applied in the clinical chemical laboratories have also provided first, the adaptation of the total quality management concepts into the laboratory sector, second, the development of the application discipline and the third, the adaptation of the understanding of the coordinated audits. Furthermore, having better analytical quality in medical laboratories gave rise to cost reduction by eliminating the recurring sample studies and claim repeats which means a loss to medical laboratories. In order to reduce the mistakes in laboratory applications, to provide patient safety and to improve the quality, the methods such as quality control processes, quality programs, certified education programs, giving a permission to the jobs related to the laboratories, accreditation of the laboratories and managing the laboratory applications are used. Building quality systems in the laboratories will play an important role so as to reduce the medical errors. There is also need for a culture in which everybody takes up seriously as a responsibility to prevent the risks and damages in health system (11). Error reductions in laboratories over time is partially related to the increased quality level of education and personnel, adopting specific rules in order to determine the mistakes which can be allowed in the quality control procedures and applying the proficiency tests (12).

ISO 15189 benefits to a hospital system laboratory; **Quality of Healthcare (**Decrease Errors, Patient Returns, Patient Complaints), **Safety of Employees and Patients (**Infectious Diseases, Nosocomial Infections), **Cost of Care(**Cost Reductions, Budget, Constraints, New Methodologies, Instrumentation),**Delivery of Care (**Patient Waiting Time, Provider Waiting Time) (13).

ISO 15189 AND ACCREDITATION PROCESS

The publication has stimulated the development by ISO of the Final Draft International Standard (FDIS) 15189 "Quality Management in the Medical Laboratory". This standard seems better suited for the needs of the laboratories. ISO has produced also the new IEC 17025 "General Requirements for the Competence of Testing and Calibrating Laboratories" for general laboratories, the successor of ISO guide 25 and EN 45000. Both ISO 15189 and 17025 cover the requirements of ISO 9000:2000, which make them easily acceptable for the public (14, 15). For the medical laboratories, the most important product of these committees is EN ISO 15189 (16). White (2002) suggests that ISO 15189 series compared with ISO 9000 will reduce the errors effectively in every stage of the medical laboratories. Kubono (2004) also indicates that ISO 15189 will form a framework in order to design and improve the quality of the process based management systems in the medical laboratories (17, 18).

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ISO 15189 requirements are mainly composed of 6 parts, namely, (1) Scope, (2) Normative references, (3) Terms and definitions, (4) Management requirements, (5) Technical requirements, and (6) Annex. Especially, (4) and (5) are main parts.

CONCLUSION

Health services have a special place because of their indispensability in the service sector. In this sector, medical laboratories are at the hub of the information flow. Laboratory analysis results affect the clinical decisions at a rate of %75. In order to reduce the mistakes in laboratory applications, to provide patient safety and to improve the quality, the methods such as quality control processes, quality programs, certified education programs, licensing the jobs related to the laboratories, accreditation of the laboratories and managing the laboratory applications are used. Thus, accreditation is an important tool. In India only 0.17% of laboratories have achieved accreditation. The situation in Pakistan is similar. And ın Turkey only 0.02% of laboratories have accreditation (19). In developing countries accreditation is a new concept and needs to be encouraged and improved. Particularly, this is of vital significance when developing countries are considered.

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