**Quality Beyond Accreditation**

**Dr Bushra Fiza**

**Professor, Biochemistry; Director, Central Laboratory**

**Mahatma Gandhi Medical College & Hospital**

**Jaipur, India**

[**bushrafiza786@gmail.com**](mailto:bushrafiza786@gmail.com)

**ABSTRACT**

Quality assurance has become an integral part of healthcare services. Patients and the community at large, look forward to any hospital or laboratory as a service provider expecting quality of services in all respects. Quality accreditations are looked upon as a necessity for various empanelment and a preferred organization. However, the actual intent of attaining accreditations is lost as the focus shifts from genuine quality assurance to generation of manipulated documents as evidence of compliance to the quality standards.

Some key aspects can help the healthcare team attain quality beyond accreditation certificates. Understanding and implementation of system-based approach and formulating policies and procedures as per institutional needs is of utmost priority. A continual training program along with regular monitoring of compliances through regular internal and external audits is further necessity to sustain the quality of services. Effective communication and documentation are the backbone for any quality management system (QMS). Any QMS can only be strengthened by involving all personnel and designating them responsibilities as per their position and identified role in the health care team. Besides audits, lean analysis is recommended to eliminate unnecessary steps and hence to streamline the entire work flow. Above all, the focus of each teammate as well as QMS at large should be staff safety and patient benefit. Regular hazard identification and risk assessment should be conducted to minimize the sources of errors that impose risk to staff or patients.

All the above measures along with compliance of standards can help the healthcare organization sustain as well as continuously improve and assure quality of services to patients as well as society at large.

**Key words: Quality management system, system-based approach, lean analysis, risk assessment, audits**

**INTRODUCTION**

Quality is the need of the hour. Like any other industry, healthcare industry is also expected to follow certain quality standards and deliver quality services. Nowadays, healthcare industry is looked upon more as a paid service rather than a noble cause for patient wellbeing. Moreover, owing to the privatization of healthcare services and increasing demand of insurance agencies and other beneficiary bodies, the need for attaining accreditation has immensely increased. This has resulted in an outburst of consultancies which claim to ensure accreditations. Many hospitals and laboratories hire such consultancies and on the basis of manipulated documents attain quality accreditations. Unfortunately, in the process of attaining accreditations, most of the healthcare providers tend to miss upon the basic purpose of these certifications. Instead of actual quality assurance, the entire process gets deviated to generation of false documentary evidence and under-reporting of errors.

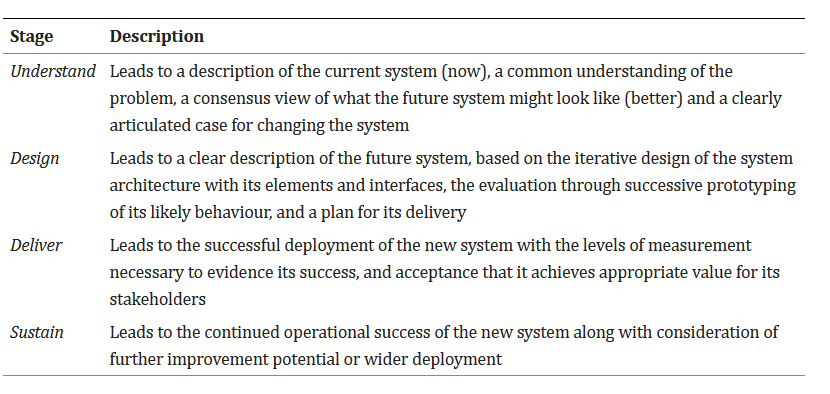
In the above context, there is immense need to understand the actual meaning of quality assurance and to strive for maintaining quality beyond the accreditations. The consultants may draft templates for any organization or can make the data presentable as per the referring standards viz NABH or ISO 15189 etc, but delivering reliable quality services demand far more involvement and commitment of the entire team. This chapter deals with some basic concepts and protocols which can help attain actual quality beyond accreditations.

**System based Approach**

“A systems approach involves integrating the necessary disciplines into a team who then use a structured process to deliver a system, working from needs to requirements and from design to delivery” 1-3.

The first and foremost requirement for improvement of the process of any service provider is to switch from a person-based approach to a system-based approach. This implies that all components of the organization including organogram, job responsibilities, policies and standard operating procedures should be well defined. No matter how well-scripted templates may be available through consultants or online platforms, this being the very first step of attaining quality should be personalized as per the needs of the concerned hospital or laboratory. Moreover, it should involve inputs of various team members and should be reviewed and refined to be as practical and as feasible as possible.

Table 1: Stages of Improvement/ systematic Approach4



* For a system to become more reliable, it is recommended that a backup plan should be also in place. This means that all posts mentioned in the organogram should have a predefined alternative in case of his/ her absentia. Similarly, back up of each process and/ or equipment in case of any technical failure should be identified beforehand.

**Robust training program**

“The healthcare industry is a very competitive environment, and clinical institutions have to deliver a higher quality of care – while staying within budget. A skilled and motivated staff that’s always up-to-date with the latest developments in techniques and technologies is a huge competitive advantage. There is a need to raise awareness that education doesn’t come to an end once people are in the middle of their professional career. Because the healthcare industry is continuously evolving and hence health care providers have to regularly keep up with new techniques and technologies and expand their knowledge and skills – which means continuous education is not a nice-to-have but an absolute necessity for any healthcare professional who wants to provide high-quality patient care” 5.

Once the policies and procedures have been defined, it is important to train the staff. The first step of this process is to identify the training needs. It is advisable to first define the minimum basic knowledge and level of competency that is desired from concerned personnel. Although some basic trainings can be evident in the certificates any personnel possesses but to make them competent, we need to have a continual training plan in place. Since conducting trainings may require additional resources like time, human resource and space, the training plan needs to be well aligned with the routine course of work.

* Some measures recommended to make the training plan effective include preparation of training modules along with pre & post-tests to ensure that the objectives of training are attained. A feedback mechanism in place will also help to improve the modules further. The training calendar should be prepared in advance and compliance to attend it should be ensured.
* Organizing trainers’ training is another suggested measure to ensure more controlled and effective trainings. The persons with good teaching or communication skills can be trained as trainers who can then conduct continual training of the ground team.

**Internal Audits**

“Clinical audits consist of measuring a clinical outcome or a process, against well-defined standards set on the principles of evidence-based medicine. Aim of the audit is to highlight the discrepancies between actual practice and standard in order to identify the changes needed to improve the quality of care” 6.

Once the policies and processes have been defined, it is important to check whether they are being complied with. The most appropriate method of self-evaluation can be through conduction of internal audits. To become an auditor, basic awareness and training is required. Auditors can be identified from the team itself. Next, appropriate checklists need to be prepared so that all aspects of the clause or selected area can be audited. It has been observed that the staff tends to avoid audits. Instead, audits should be welcomed and conducted at regular intervals. Internal audits can help us identify the areas of improvement. Any non-compliance identified should be closed and necessary corrective action should be taken in a stipulated time.

* One should always keep in mind that audits should be an informed event. This will help us identify areas which have been neglected during initial planning or processes which need to be improvised. On the other hand, surprize checks help us evaluate the compliance of laid down processes.
* It is always advisable that audits should be interdepartmental i.e. auditor from one department audits some other department. This helps make the process more bias free.

**External Audits**

Besides internal audits, external audits should also be planned at fixed intervals. An independent external person/ agency can provide a more critical analysis of the processes. The audits of accreditation agencies are also a type of external audit. But any hospital or lab should look out for more such audits which are focussed on actual quality assurance rather than certification or accreditation.

**Lean analysis**

**“**Lean is a set of operating philosophies and methods that help create a maximum value for patients by reducing waste and waits” 7. “Originally derived from the Toyota car company production, lean utilises a continuous learning cycle that is driven by the 'true’ experts in the processes of health care, being the patients/families, health care providers and support staff” 8.

This is an exercise where steps of any process are scrutinized for their authentic utility. The workflow is microscopically reviewed in this analysis to see which step of the process is time consuming yet unnecessary. Once identified, such steps can be omitted, thereby making the process leaner. Eg there may be duplicity of a step like sample receiving both through the LIS as well as manually, hence one of the steps should be removed. This lean analysis can be conducted through an external agency or as an inhouse activity. However, during inhouse process, it is always advisable to involve persons who are not directly part of the department or team.

* For a laboratory, this process can be easily conducted when the auditors themselves move along with a patient/ sample and record all events with duration and non-conformities. The auditor during this entire process shall be a silent observer. They shall conduct a sample audit across few days as well as at different times of the day. This exercise can give a deep insight into the entire process and help us identify areas of concern and ultimately to plan improvement.

**Involve & delegate duties**

“In delivering health care, an effective teamwork can immediately and positively affect patient safety and outcome. The evolution in health care and a global demand for quality patient care necessitate a parallel health care professional development with a great focus on patient centred teamwork approach. This can only be achieved by placing the patient in the centre of care and through sharing a wide based culture of values and principles” 9.

Usually, ensuring quality is considered as responsibility of a dedicated team who will prepare documents and manipulate data to make it as impressive as possible. This mindset needs to be strongly addressed. Each and every person involved in the team should be made aware of the laid down policies and procedures. Moreover, their inputs should be documented and taken into consideration. In simpler words, all team mates should be involved in the quality drive. The team leader should delegate duties to each teammate. This will make each member answerable and also ensure compliance of quality standards.

According to Mitchell P et al., 201410, the personal values that are desired from members of an effective and high-functioning health care team are: Honesty, Discipline, Creativity, Humility and Curiosity

**Effective documentation & communication**

The strongest pillar of a good system is effective documentation & communication. This means that on one hand, all policies and procedures should be well documented, all records should be up to date and on the other hand, all what is documented should be well communicated. It is always a good practice to “*document what you communicate and communicate what you document*”. The organization should develop a work culture that emphasizes on both documentation as well as communication.

* The lab or hospital can maintain a “Read & Understood Record” for all its key documents including Quality Manual, Quality System Procedures, Standard Operating Procedures etc. This implies that all concerned give a declaration that they have read as well as understood the documents. This may sound hypothetical and unnecessary. However, it has been observed that when one signs this declaration, he/ she becomes answerable and hence would make sure to read the document.

**Risk assessment**

**“**Risk management is defined in the literature as “all the activities connected with hazard identification, assessment, selection of appropriate responses and risk monitoring”11. “Risk assessment involves specific steps: identifying hazards, analyzing and evaluating all possible risks”12.

Though risk assessment is recommended rather a necessity as per all quality standards, it is the most neglected and manipulated activity in the accreditation process. In fact, the team members are usually unaware of any such requirement and its compliance. Hence, this needs to be addresses by training the staff as well as involving them in the process. The more appropriate term for this concept is ‘Hazard Identification and Risk Assessment (HIRA)’.

Once the concept and its intent are understood, the process becomes easier as well as beneficial. HIRA stands for identification of various types of hazards at all stages of the work flow. These include any hazard that may cause risk to the patient as well as the staff. Once the hazards are enlisted, their risk is assessed based on their severity (mild, moderate and severe) and the likelihood of occurrence (rare, less likely and very likely). The grades are converted into scores and each hazard is scored based on both the above criteria. Next the corrective actions for each identified hazard/ risk are implemented and documented. Effective implementation of HIRA minimizes the risks and errors that may harm the patient, staff or organization.

**Conclusion**

Attaining quality is not a one-time procedure. Instead, it is a continuous process and is much more than simply preparing evidence which justify compliance of quality standards. Any Quality Management System can be considered an effective system only if there is active involvement of all team members. A clear understanding of quality standard and effective use of various quality tools can ensure actual quality beyond accreditations. A system based, problem solving approach of the core team is recommended for development of the healthcare services. Patient well-being should be focussed at all stages of work and should not be compromised at any cost. Basic understanding and stepwise implementation of various quality initiatives can help an organization attain a quality management that is much more effective and efficient.

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