Implementing Quality Process in Public Sector Hospitals in India: The Journey Begins

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Introduction
Quality in healthcare is a relatively novel concept in public health in our country. The notion of enforcing quality care in medical profession can be traced back to early 1900s in the form of “Medical Audit” in the United States of America (USA). The medical audit gradually moved to “Hospital Standardization Program” in 1918 and finally took the form of “Quality Assurance activities” (i.e., delivery of relevant and effective medical care in accordance with the standards) with the formation of “Joint Commission on Accreditation of Hospitals” later named as “Joint Commission on Accreditation of Health Care Organizations” in 1960. The Geneva-based International Organization for Standardization (ISO) was raised in 1946. The ISO 9000 series of standards have generated maximum interest worldwide. In India, National Accreditation Board for Hospital and Health Care Providers (NABH), a constituent board of Quality Council of India (QCI), has been set up to establish and operate accreditation program for healthcare organizations.

Quality in Healthcare: What is it?
The quality in healthcare system implies that the patients receive high level of care, have access to a qualified and competent medical staff and to a quality-focused organization, receive understandable education and communication and that their feedback (satisfaction) is evaluated continuously. It also benefits patient through appropriate healthcare decisions and standardization of healthcare processes, focus on patient safety, vulnerable patient, safe transport, and continuity of care, which is paramount.

Role of the Quality System in a Healthcare Facility
The primary role of any quality system is to provide effective means to assuring that the customer (patient) requirements are met fully. Some of the key elements/components of quality that accomplish the patient requirements are patient’s safety, staff behavior toward the patients, correct and timely treatment, compliance to treatment protocols, seeking patient feedback, and adequate response to it, complete record keeping, acceptable quality care at affordable prices, clear communication to the patients with respect to the services, best practices for fixing appointment and service delivery, reliable diagnostic and laboratory support, reliable support services like canteen, ambulance, pharmacy, etc. safe and pleasant environment, technical competence, courtesy, and attitude of staff.

The establishment of a quality system in a healthcare organization facilitates the standardization of the systems and processes (both clinical and administrative). This standardization further ensures improving the performance of the hospital with respect to above-stated key elements/components of quality. The quality system thus acts as a vehicle for healthcare organizations to focus on patient and provider needs and expectations.

Public Health System in India: Quality Issues under National Rural Health Mission
In our country the healthcare setup can be viewed as government and private/corporate organizations. The private/corporate hospitals by the virtue of their objectives typically have an inbuilt quality culture and...
these have been undergoing certification for various accreditation standards. These hospitals have gained importance in recent past due to sheer increase in their numbers and the quality of services they provide.

Still, the governmental setup comprising district hospitals, community health centers, primary health centers and subcenters are the mainstay of healthcare all over the country. Under National Rural Health Mission (NRHM), with accredited social health activist in place, there is bound to be a groundswell of demands for health services and the system needs to be geared to face the challenge. Not only does the system require upgradation to handle higher patient load, but emphasis also needs to be given to quality aspects to increase the level of patient satisfaction.\(^{(5)}\)

Quantitative improvement in services having been achieved in majority of states, the quality needs scrutiny. In fact a disproportionate increase in quantity without a proportionate increase in manpower and physical facility has led to a compromise in quality. One of the biggest challenges under NRHM is to meet the human resource requirement for the services to be delivered. There is deficit of the staff across the board, specialist doctors, male multipurpose workers, and laboratory technicians. The area that lags behind most significantly is the health management information system. Emphasis on interpersonal communication and utilization of the health facility visit for health awareness has been negligible as the time spent by the doctor per patient is limited. The other areas still to be addressed are regular patient feedback and its evaluation, standardization of care processes, patient safety, safe transport, and continuity of care.\(^{(6)}\)

**Quality Standards in India**

Various standards in India that can facilitate the public healthcare facilities to establish quality system are the Bureau of Indian Standards, NABH standards and Indian Public Health Standards (IPHS). In order to ensure quality of services IPHS have been set up for public health facilities so as to provide a yardstick to measure the services being provided there.\(^{(6)}\)

**Why ISO 9001:2008?**

IPHS largely addresses the structural lacunae such as availability of infrastructure, equipment, and manpower; there are a few components that measure processes and none that measure outcomes.\(^{(6)}\) On the other hand ISO 9001: 2008 (earlier version 9001:2000) promotes the adoption of a process approach for developing, implementing, and improving effectiveness of a quality management system (QMS) while enhancing customer satisfaction by meeting customer requirement.

Furthermore ISO 9001: 2008 can act as a stepping stone for implementation of more resource intensive and stringent standards such as NABH.

When a hospital is certified as complying with ISO 9001: 2008 standards it implies that it is able to provide services that meet patient’s requirements and complies with statutory and regulatory requirements applicable to the services and aims to enhance patient satisfaction through effective application of the quality management system and through processes for continual improvement.\(^{(7)}\)

**The Indian Initiative**

National Health System Resource Centre (NHSRC), a technical support group with NRHM, has taken up an initiative to facilitate the improvement of service delivery in the public healthcare facilities to meet the laid down quality process in line with ISO 9001: 2008 standard requirements, and also to develop a methodology of quality improvement as applicable to public health facilities.\(^{(5)}\)

**The Methodology for Quality Improvement**

At commencement of the project, a survey is carried out to create a baseline document called the “As-Is Situation Analysis” which includes the infrastructure, manpower, and equipment survey of the facility as per quality standards such as the IPHS. Thereafter, analysis and evaluation of gaps are carried out and an action plan is developed to fill the gaps. The next step is the preparation of QMS documents which involves preparation of the “To be” process documents. The “To be” documents entail the processes which are intended to be implemented in the facility. These include the quality manual, procedure manual, forms and format manual and standard operating procedures.\(^{(5)}\)

A basic orientation and training is provided to the hospital managers and to the existing staff at the healthcare facilities for facilitating the implementation of action plan. The development of QMS documents follows in coordination with hospital, local, and state agencies which also support the effective implementation of documented processes.

After reviewing the status of process implementation, internal audits (IA) are conducted to elucidate remaining gaps. This is followed by measures/actions for closing these gaps and ensuring consistency in performance. The efforts are made to improve the processes and service quality aimed at improving the quality of treatment and end-user-related parameters such as patient satisfaction, waiting time for registration and
examination, indoor illumination levels, promptness of care, cleanliness of toilets and surroundings, complaint resolution time, establishment of sturdy admission and discharge process, institution of system for medical and death audits, timely reporting of investigation results, compliance to statutory rules such as bio-medical waste (management and handing) rule and regulatory guidelines such as AERB (atomic energy regulatory board) norms, calibration of measuring equipments, establishment of the verification system of results of the laboratory test, sterilization and infection control measures, maintenance of records and documents, review of internal process for continual improvement, stores and inventory management functions, etc. Efforts are also made to improve internal process parameters such as timely and adequate availability of equipments and optimization of store inventories, managerial, administrative, and technical capacity.

After a robust implementation of QMS, a final audit (for certification) is carried out by external certifying agencies. Once the hospital is certified as ISO compliant, it undergoes yearly surveillance audit for assessing the compliance to the standards and a 3 yearly recertification audit for retaining the certificate.

In the journey so far the hospitals facilitated by NHSRC and their certification status are as follows:(8)
1. Korba District Hospital, Chhattisgarh, certified to ISO 9001:2000 and successfully completed first surveillance audit.
2. Duffrin Hospital, Allahabad, U.P, certified to ISO 9001:2000 and surveillance audit completed.
3. Doon Hospital, Dehradun, Uttarakhand, certified to ISO 9001:2008.
4. Deoghar Hospital, Deoghar, Jharkhand, certified to ISO 9001:2008.
5. Karauli District Hospital, Karauli, Rajasthan, certified to ISO 9001:2008.
6. Puri District Hospital, Puri, Orissa, certified to ISO 9001:2008.
7. Ara District Hospital, Bihar, Pending certification.
8. Katni District Hospital, Madhya Pradesh, Pending certification.

Conclusion
Effective implementation of the QMS will address the major quality issues such as the staff deficit; implementation of the health management information system, interpersonal communication, and other important unaddressed areas such as regular patient feedback and its evaluation, standardization of care processes, patient safety, safe transport, and continuity of care and will thus facilitate improvement in public sector hospital as envisaged under NRHM. Once the hospital is certified, it is important that it focuses on maintaining the quality and that the hospital staff is continuously motivated for continual and ongoing quality enhancement to higher levels of quality of healthcare.

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How cite this article: Sharma KD. Implementing quality process in public sector hospitals in India: The journey begins. Indian J Community Med 2012;37:150-2.

Source of Support: Nil, Conflict of Interest: None declared.