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Technical and Quality Standards and Practices in Healthcare Facilities

Muhammad Tasleem[1*], Nawar Khan[2], Syed Tasweer Hussain Shah[3], Asim Nisar[4]
[1,2&3]National University of Sciences and Technology, Islamabad, Pakistan
[4]Centers of Excellence in Science and Applied Technologies, Islamabad, Pakistan
m.tasleem@ceme.nust.edu.pk[1]
[*]Corresponding author

Abstract - *This paper presents the highlights of many technical standards, as established by International Organization for Standardization (ISO) through International Classification for Standards (ICS) and British Standards (BS), and quality standards and practices as governed by some international, regional or national institutes in promoting patients rights and safety control in medical sciences and healthcare facilities. The paper draws attention to adopt these standards in Pakistan.*

Keywords- *Standards; healthcare; quality; technical; ISO*

1. INTRODUCTION

Quality Control and Management concepts and practices have been rapidly progressed almost in all industrial sectors since last two decades. The one of the major reason is the establishment and expansion of ISO 9000 standards series. ISO 9001 is generic standard and can be adopted by any type of trade. International Organization of Standardization (ISO) has developed many technical standards or specifications as well in parallel to quality guidelines. The standard of each category contributes value in the chain in the form of process efficiency, product or service effectiveness, customer's satisfaction and confidence and system improvement. The other major reason is the effectiveness of international and national quality awards across the world. In the service area, the quality is very superficial and subjective, and thus it is difficult to evaluate precisely or control the service (Yoo, 1996)[12]. According to Parasuraman et al. (1985)[6] quality is an elusive and abstract construct that is difficult to define. Quality can be described in terms of effectiveness and efficiency, and can also refer to characteristics of and the pursuit of excellence (Huber, 2000)[3]. Technical and quality standardization and practices in medical sciences and health care facilities become vital due to intensive caring services. There are number of technical standards as generated by technical committee of ISO, International Classification for Standards (ICS) and British Standards Institute (BSI). The mentioned organizations have introduced very specific technical standards concerning to medical procedures and operations. Some major are highlighted in section 2.

There are other quality standards and guidelines which have been developed and regulated by international, regional or national institutions or agencies (Tasleem et al., 2014)[3] and have been adopted and implemented by medical healthcare facilities to effectively maintain expected level of services and to reduce and control clinical errors. These are introduced in section 3.

This paper sheds light on the introduction and importance of technical and quality standards related to medical and healthcare facilities. In a world undergoing accelerated technological, cultural and socio-economic changes, healthcare organizations have to adopt appropriate organizational improvement policies to be able to fulfill their responsibilities while maintaining an economically viable and sustainable development (Reza et al., 2012)[7]. It has been reported that top quality care and new technology solutions helped Colombian hospital attract patients from all over the world (Agfa HealthCare, 2012).

2. TECHNICAL STANDARDS

There are numerous technical standards concerning to medical procedures, operations and equipments. Some of them are highlighted as established by International Organization of Standardization (www.iso.org) and British Standards Institute (www.bsigroup.com).

2.1 ISO Standards

2.1.1 Anesthetic and Respiratory Equipments

ISO 18082:2014 provides dimensions of non-interchangeable screw-threaded low-pressure connectors for medical gases.

ISO 26825:2008 gives requirements for labels which the user attaches to syringes so that the contents can be identified just before use during anesthesia. It covers the color, size, design and general properties of the label and the typographical characteristics of the wording for the drug name.

2.1.2 Surgery

ISO/TR 11991:1995 provides guidance on airway management during laser surgery of upper airway and intends to minimize the risk of an airway fire when using a laser.

2.1.3 Sterilization and Disinfection

ISO 25424:2009 specifies requirements for the development, validation and routine control of a Low Temperature Steam and Formaldehyde (LTSF) sterilization process for medical devices.

ISO 11135:2014 specifies requirements for the development, validation and routine control of an ethylene oxide sterilization process for medical devices.

ISO 11138-2:2006 provides specific requirements for test organisms, suspensions, inoculated carriers, biological indicators and test methods intended for use in assessing the performance of sterilizers and sterilization processes employing ethylene oxide gas as the sterilizing agent.

2.1.4 Medical Laboratory

ISO 15189:2012 specifies requirements for quality and competence in medical laboratories. This standard can be used by medical laboratories in developing their quality management systems and assessing their own competence. It can also be used for confirming or recognizing the competence of medical laboratories by laboratory customers, regulating authorities and accreditation bodies.

ISO 15190:2003 specifies requirements for safe practices in the medical laboratory.

ISO/TR 22869:2005 provides guidance to medical laboratories describing how a medical laboratory can meet the specific technical and quality requirements in ISO 15189:2003.

ISO/TS 22367:2008 characterizes the application for reducing laboratory error and improving patient safety by applying the principles of risk management, with reference to examination aspects, especially to pre- and post-examination aspects, of the cycle of laboratory medical care.

ISO/DTS 17518 provides guidance for users of reagents for staining in biology in medical laboratories.

2.1.5 Dentistry

ISO 1942:2008 provides definitions for a number of concepts specific to dentistry in the interest of facilitating development and comprehension of standards.

ISO 3950:2009 provides a system for designating teeth or areas of the oral cavity using two digits.

ISO/CD 18845 provides guidance on test methods and marking for the accuracy of machined indirect restorations.

2.1.6 Hospital equipment

IEC 60601:2009: applies to the basic safety and essential performance of medical beds intended for adults.

IEC 80601:2009: establishes particular basic safety and essential performance requirements, which minimize hazards to patients, and operators for heating devices using blankets, pads or mattresses and intended for heating in medical use and specifies tests for demonstrating compliance with these requirements.

2.1.7 Medical Textiles

ISO 10282:2014 specifies requirements for packaged sterile rubber gloves intended for use in surgical procedures to protect the patient and the user from cross-contamination.

ISO 11193-1:2008 specifies requirements for packaged sterile, or bulked non-sterile, rubber gloves intended for use in medical examinations and diagnostic or therapeutic procedures to protect the patient and the user from cross-contamination.

ISO 22609:2004 describes a laboratory test method for measuring the resistance of medical face masks to penetration by a splash of synthetic blood.

2.1.8 Medical Devices

ISO/IEC Guide 63:2012: provides guidance to include safety aspects in the development of medical device.

ISO 10781:2009 describes the content and means of functioning of the electronic health record system of the HL7 EHR Work Group.

2.1.9 Medical Plastic wares

ISO 12771:1997 specifies requirements for the development and use of disposable serological pipettes.

ISO 8362-4:2011 specifies the shape, dimensions and capacities of glass vials for injectable preparations. The standard applies to colourless or amber glass containers moulded from borosilicate or soda-lime glass, with or without an internal surface treatment, and intended to be used in the packaging, storage or transportation of products intended for injection.

ISO 8536-1:2011 specifies the dimensions, performance and requirements of infusion glass bottles necessary to ensure functional interchangeability. It is applicable only to infusion bottles for single use.

ISO 11418-1:2005 specifies the design, dimensions, material and requirements of drop-dispensing glass bottles. Drop-dispensing glass bottles are applicable to primary packs used in direct contact with a drug.

ISO 11418-1:2005 is applicable to drop-dispensing glass bottles used in pharmacy. Together with the corresponding closure systems, they serve for packaging of pharmaceutical preparations which are not intended for parenteral use.

2.1.10 Blood transfusion, infusion and injection

ISO/ASTM 51939:2013 outlines irradiator installation qualification, operational qualification, performance qualification and routine product processing do symmetric procedures to be followed in the irradiation of blood and blood components by the blood-banking community.

ISO 1135-4:2011 specifies requirements for single-use transfusion sets for medical use in order to ensure their compatibility with containers for blood and blood components as well as with intravenous equipment.

In some countries, the national pharmacopoeia or other national regulations are legally binding and take precedence over ISO 1135-4:2011.

ISO 21649:2006: applies to safety and performance and testing requirements for single-use and multiple-use needle-free injection systems intended for human use in clinics and other medical settings and for personal use by patients.
The dose chamber of the injection system is often disposable and intended to be replaced after either a single use or a limited number of uses. It is sometimes separable from the injection mechanism and often termed a "cartridge", "ampoule", "syringe", "capsule" or "disc". In contrast, the dose chamber also may be a permanent internal chamber designed to last through the claimed life of the device.
ISO 8362-2:2008 specifies the shape, dimensions, material, performance requirements and labeling of closures for injection vials covered by ISO 8362-1 and ISO 8362-4.
ISO 28620:2010 specifies essential requirements and related test methods for non-electrically driven portable infusion devices. It applies to devices designed for continuous (fixed or adjustable) flow and/or for bolus application.

2.2 British Standards

BS 8432:2005 gives guidance on the design of spinal orthoses.
BS 13779:2008 specific to implants for surgery, chemical analysis and characterization of crystallinity and phase purity.
BS 25539:2009 is specific to cardiovascular implants, endovascular devices and vascular stents.
BS 7206:2008 specific to implants for surgery of partial and total hip joint prostheses and provides classification and designation of dimensions.
BS 5832:2007 is specific to implants for surgery with use of metallic materials and wrought stainless steel.
BS 8835:2010 is specific to inhalational anesthesia systems and transfer and receiving systems of active anesthetic gas scavenging systems.
BS 10651:2009 is specific to lung ventilators for medical use and defines particular requirements for basic safety and essential performance.
BS 8185:2009 specifies guidance on respiratory tract humidifiers for medical use and specifies requirements for respiratory humidification systems.
BS 8359:2009 specifies safety requirements for oxygen concentrators for medical use.
BS 18778:2009 defines particular requirements for respiratory equipment and infant monitors.
BS 5366:2009 specifies tracheostomy tubes and connectors for use in anesthetic and respiratory equipments for adults.
BS 60601:2008 specific to medical electrical equipments and particularly specify requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source
BS 55011:2009 defines limits and methods of measurement of radio-frequency disturbance characteristics of medical equipments

3. QUALITY STANDARDS

3.1 ISO Standards

ISO 9001:2008: An ISO 9000 implementation gives a basic road map for integration of all functions involved in total health care services, for ensuring a better quality of service to the patients. The last version, the ISO 9001:2008, is very relevant to the Healthcare Services Sector as it focuses on fulfilling customer (patient) expectations, improving the quality of an organization's business and management processes, so that when a job is done it is done well, first time, every time.
ISO 9001 is based on famous Deming's Plan-Do-Check-Act (PDCA) cycle. The major clauses include clause 5.0 - management responsibility, clause 6.0 - resource management, clause 7.0 - product realization (service provision) and clause 8.0 - monitoring, measurement and analysis (customer satisfaction and continual improvement).

3.2 Joint Commission International Accreditation (JCIA)

Joint Commission International Accreditation is a division of Joint Commission on Accreditation of Healthcare Organization (JCAHO) in U.S.A. Joint Commission International (JCI) is contributing to improve patient safety and quality of health care in the international community through standards and evaluation. It offers different types of programs , for example, education, publications, advisory, and international accreditation and certification services including of primary care, medical transport and ambulatory care in more than 100 countries (www.jointcommisioninternational.com).

Figure 1. Gold Seal of Approval® by JCI

The healthcare standard established by JCI is comprehensive comprising 323 total standard numbers and 1134 measurable elements and majorly focuses on environment safety and infection control. A hospital with an accreditation from JCI means that it provides patient-centered quality care, focuses on patient safety, and ensures patients' rights. There is only one hospital, Agha Khan University Hospital Karachi, accredited from JCI in Pakistan.

3.3 The International Society for Quality in Health Care (ISQua)

ISQua is the International Society for Quality in Health Care. The society provides standards, principles and solutions covering entire continuum of care, ranging from system and processes to quality and patient care and performance and exchange through global network (www.isqua.com). ISQua is involved in the accreditation of national and regional health care facilities and is an essential resource for policy makers, leading patient safety agencies, health care workers and professionals around the world.

3.4 International and National Quality Awards

Almost all of the countries in the world have established and implemented their own national quality awards which are dated from different times. Mostly these award systems have been established by some governmental institution or other regulatory agency to lay down upmost performance standards with fundamental principles and values of quality and results. Malcolm Baldrige National Quality Award (MBNQA) and European Foundation Quality Management (EFQM) systems and criteria are the most famous in the world.

3.4.1 MBNQA

It is U.S.A based quality award system established since in 1987. There are five categories of the sectors including a separate one for healthcare. Since 2002 there have been 17 healthcare facilities which won MBNQA in healthcare category (www.nist.gov). The award criteria are non-prescriptive and address following seven elements;

- Leadership and governance
- Strategic planning
- Health care and processes and operations,
- Customers
- Workforce
- Finance and markets
- Knowledge Management

The Health Care Criteria items and the scoring guidelines can be used as competitive strategy in external assessments or for identification of opportunities for improvement in self-assessment.

Figure 2.Baldrige Healthcare Criteria Framework

3.4.2 EFQM

EFQM framework and criteria is European based established since 1994. Hospitals, outpatient services, acute care, rehabilitation clinics, primary care centers and specialized services have used this approach (Moeller, 2001)[4]. Studies have shown that the EFQM approach provides a broader framework for evaluation and improvement of quality. In Germany 10-15% of total hospitals are using EFQM approach (EFQM, 2003).[2]

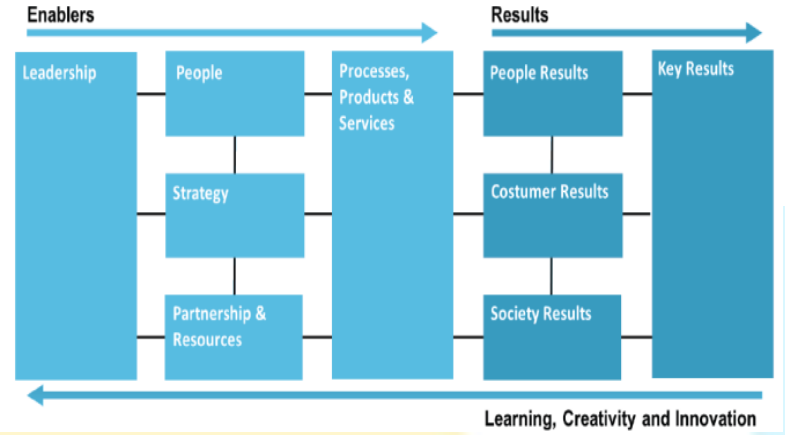

Figure 3. EFQM Criteria Framework

3.4.3 Prime Minister Quality Award (PMQA)

PMQA is based on MBNQA criteria has been prepared and is under implementation by National Productivity Organization (NPO) Pakistan.

3.5 Pakistan Standards

Pakistan's governmental and institutions and regulatory bodies are marching to meet international benchmarks. There have been initiatives to cope the advanced requirements through Pakistan standards and the same is true in standardizing healthcare practices in medical facilities.

The formulation and or adoption of Pakistan Standards is carried out in Technical Committees and endorsed by National Standards Committee which include Pakistan Standards and Quality Control Authority (PSQCA) experts, intellectuals from related scientific institutions, technical experts from relevant production units and consumers.

Figure 4. Pakistan Standard Mark

Drafts of Pakistan standards for primary healthcare and secondary have been prepared and are under scrutiny for finalization and implementation in Pakistan.

3.5.1 Primary health care facility

Primary healthcare facility standard covers following requirements;

- Primary care management committee
- Patient information
- Notifiable diseases
- Provision of utilities facilities and monitoring of equipment
- Water supply
- Waiting area
- Latrine Facility
- Work area
- Operability of the procedures and guideline
- Availability of Staff
- Health and Safety
- Emergency cases
- Privacy
- Patient feedback
- Complaint Handling
- Continual Improvement

3.5.2 Secondary health care facility

Secondary healthcare facility standard covers following requirements;

- Patient Rights
- Care Continuum
- Operation Theatre Department
- Casualty Department
- Intensive Care Unit
- Resuscitation
- Maternity Services
- Laboratory Services

- Radiology
- Pharmacy Services
- Infection Control
- Sterile Supplies
- Cleanliness and Sanitation
- Waste Management
- Health and Safety
- Safe and Appropriate Facilities

Each requirement area covers service management, procedures and policy, facilities and equipments and measurable criteria to establish.

4. CONCLUSION

As many technical and quality standards and practices have been introduced and implemented across the world, there is constant need to adopt and cope with the benchmarks by medical sciences and healthcare facilities in Pakistan. These standards are important in better patient care, safety control and continual improvement.

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