



Quality Assurance in Neurosciences and Suitable Standards for Neurosurgical Operation Theatre and Procedural Rooms

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Introduction

Quality is very important concept in Neuroscience especially in Neurosurgery like other medical field's quality concepts were brought intentionally in neurosurgical field as well. Survival of fittest is the dictum of the time. Development of specialty and super specialty hospitals and popularity of neurosurgical centers in international market has brought high competition. The current medical science and neurosurgical scenario emphasize on quality care rather than traditional holistic care only. Public are more aware for health care and now demanding high quality in all specialty, especially super specialty like neurosurgery. Influence of medical insurance also emphasizes the very need of quality in all medical specialties including neurosurgery as in other fields of medical science necessitating significant change in medical practice. Management Guru Deming has further taken the standard from quality management to the extreme of concept of total quality management (TQM) which being applied to all the fields of medicine including Neurosurgery.

Keywords: Neurosurgical; Quality assurance; Procedural rooms; Operation Theatre

Abbreviations: TQA: Total Quality Management; JCI: Joint Commission International; ACP: American College Of Physician; CMA: Canadian Medical Association; PEP: Performance Evaluation Procedure; QA: Quality Assurance; JACHO: Joint Commission on Accreditation of Hospital Organization; JACH: Joint Commission on Accreditation of Hospitals; AHA: American Hospital Association; AMA: American Medical Association; AMH: Accreditation Manual for Hospitals; NABH: National Accreditation Board for Hospitals & Healthcare Providers; NABL: National Accreditation Board for Testing and Calibration Laboratories; ACC: Access, Assessment and Continuity of Care; PRE: Patient Rights and Education; COP: Care of Patient; MOM: Management of Medication; HIC: Hospital Infection Control; CQI: Continuous Quality Improvement; ROM: Responsibility of Management; FMS: Facility Management and Safety; Human Resource Management; IMS: Information Management System; Qi: Quality Improvement; PDCA: Plan, Do, Check, ACT; PCEs: Potentially Compensable Events; CSSD: Central Sterile Supply Department; HEPA: High Efficiency Particulate Aggregate; NSICU: Neurosurgery Intensive Care Unit

Standards

A statement of expectation that defines the structure and process that must be substantially in place in an organization to enhance the quality of care.

Quality

The degree of adherence to pre-established criteria or standards.

Quality assurance

Part of quality management focused on providing confidence that quality requirements will be fulfilled.

Quality improvement: Ongoing response to quality assessment data about a service in ways that improve the process by which are provided to consumers/patients.

Quality assurance programs: are tools used by neurosurgical health organization to establish a quality management system and to improve continually on quality of medical services. Increasing expenditure and disease burden also demands quality control in Medical care.

Definition

Quality assurance (QA) is an activity where the primary objective is to monitor, evaluate or improve the quality of Medical care delivered by Medical care providers. QA should be integral part of all Medical including neurosurgical delivery systems specially that in operation theatres. Health is expected and accepted as fundamental right of human beings in a normal democratic setup Organizations spends huge amount of money, time and man power, to get into quality system process. Many national and international organizations are available for accreditation or certification of hospitals and services in term of quality. Quality is never an accident; but is result of dedicated and intelligent efforts. All humans are entitled with basic right and freedom. It is all about our basic need to live our lives with respect and dignity. The very common human right includes "right to equality" before the law," life and liberty", freedom of thought "and freedom of expression". Apart from all these basic rights, health are also declared as the "fundamental human right" that satisfies the need for physical and mental well-being. The Universal Declaration of human right, adopted by the United Nations in 1948, proclaimed that "everyone has the right to a standard of living, adequate for health and well-being of oneself and one's family including food, clothing, housing and medical care.

Medical Audit

Medical audit is defined as "a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change." There may be different types audit done to improve current standard to the desired state of total quality management (TQM). The types may be Infection control audit, Critical areas audit, Medical record audit, and equipment audit. Medical audit is a cycle that has several procedures. This cycle consists of methodical procedures. They include setting up of best practices, taking necessary action to enhance health system, and monitoring improvements.

The process includes following steps

- i. There cognition of problem or issue.
- ii. Set criteria and standard for the purpose.
- iii. Data Gathering is done accurately.
- iv. Compare performance with criteria and standards set already.
- v. Applying changes when outcome is satisfactory or as desired. The same is circulated for universal adoption.
- vi. Re Audit: The auditare repeated after specific time period. It validates whether changes applied have the intended result.

Quality Management Systems and Accreditation Authorities

Some of the bodies for accreditation are as follows

Today hospitals practice various quality management systems through accreditation. Several accreditation bodies at national and international level have been established quality management systems through various standards specific to patient care and safety.

Joint commission International (JCI)

JCI was formerly known as joint commission on accreditation of hospital organization (JACHO) and joint commission on accreditation of hospitals (JACH). JACH is a US based non-profit organization formed in 1951 with mission to maintain and elevate the standards of health care delivery system through evaluation and accreditation of health care organizations. The American college of physician (ACP), the American hospital association (AHA), the American medical association (AMA), and the Canadian medical association (CMA) joins with the ACS to create the JCAH. JCAH started hospital standardization through establishing a

standard process. In 1970 publication of accreditation manual for hospitals (AMH) made the transition from minimum standard to optimal achievable standards. In 1972 the JCAH required the holding of medical audits and developed a retrospective outcome oriented method, the performance evaluation procedure (PEP) designed in objectively reviewing and evaluating care service. In 1985 they included specific Quality assurance chapter in the manual. In 1986 it stimulated to create a situation of focused improvement of quality continuously with clinical and administrative means. In 1987 JACH changed its name to JACHO and the standards published by it in 1992 began the careful transition from quality assessment to a quality improvement approach. 1994 it implemented several important changes that included revised survey process applying performance standards around patient care. It also started indicate or measurement system for initial data collection. It also started accreditation for health care networks and organization specific performance reports. 1997 JACHO launched ORYX, an evaluation in outcome and other performance measures into the process. 1998 Ernest A Codman Award was instituted for recognizing outstanding achievement by the hospital and individuals. 2000 the JACHO published international quality standards for hospitals and presented its first accreditation award. 2002, the JACHO established its first annual national patient safety goals and associated requirements for it 2002 itself it launched Disease specific care certification. 2005, the WHO assigned joint commission and joint commission international, a collaborating centre for patient safety solutions. In the year 2007 joint commission was renamed as joint commission international. JCI is pioneer in accreditation and throughout the world various hospitals got accreditation from it.

Patient safety goals established by JCI (2007)

- i. To improve accuracy of patient identification.
- ii. To improve the effectiveness of communication amongst care giver.
- iii. Improve the safety of using medications.
- iv. Reduce the risk of healthcare-associated infections.
- v. Measures to prevent medication errors.
- vi. Reduce the risk of patient harm resulting from fall.
- vii. Reduce the risk of influenza and pneumococcal disease in hospitalizes old patient.
- viii. Reduce the risk of surgical fires.
- ix. Implementation of applicable national patient safety goals in the hospitals.

- x. To encourage patients' active involvement in their own care as a patient safety strategy.
- xi. To prevent health-care associated pressure ulcers (bedsores).
- xii. The hospital to identify safety risk inherent in its patient's population.

The Quality Council of India and Accreditation Board for Hospitals (NABH) and Laboratories (NABL)

The national accreditation board for hospital and healthcare providers is part of quality council of India, setup to establish and operate accreditation program for health care organization. The board has structured its program in a way to set bench marks for the progress of the health industry. Standards for hospitals have been drafted by technical committees of NABH and contain a complete set of standards for evaluation of hospitals for accreditation. These standards provide "framework for quality assurance and quality improvement" for hospitals. The standards focus on patient safety and quality of care. The standards focus on continuous monitoring of any sentinel events. And exhaustive corrective actions ultimately leading to quality culture at all levels and across whole system and functions. The standards are equally applicable to hospitals and nursing homes in private as well as in government sector.

NABH Standards are included in following broad 10 areas:

- i. Access, assessment and continuity of care (ACC)
- ii. Patient Rights and education (PRE)
- iii. Care of patient (COP)
- iv. Management of Medication (MOM)
- v. Hospital Infection Control (HIC)
- vi. Continuous quality improvement (CQI)
- vii. Responsibility of management (ROM)
- viii. Facility management and safety (FMS)
- ix. Human resource management (HRM)
- x. Information Management system (IMS)

Three Quality Improvement (Qi) Methods and Models

Plan, Do, Check, ACT method (PDCA method)

It is one of the widely used QI method developed in 1920 by Walter Stewart and Deming. This method in health covers following aspect:

- i. Establish goals and objectives.

- ii. Develop policies and procedures to guide workers.

Six steps method

It is a continuous quality improvement approach presented by Krousel Wood with focus on health care application. The six-step methodology used by this, these steps is as follows

- i. Record adverse or other outcomes of interest.
- ii. Use statistical techniques to determine variation randomness.
- iii. Suggestions to reduce adverse outcomes.
- iv. To implement the suggestion on trial basis and monitor results in due course of time.
- v. If improvement occurs implement the suggestion and standardize.
- vi. To seek further suggestion for improvement.

Benchmarking

It is a process of comparing a hospital's performance against that of organizations that have been identified as excellent. There are three types of benchmarking.

Internal benchmarking: It compares performance between functional areas or departments within an organization. For example infection rate in department of Neurosurgery and department of paediatric surgery.

Competitive benchmarking: Used to close the gap between organization performances with that of its industry competitors. It is also called performance benchmarking. For example infection rate in department of neurosurgery of one hospital with that of other standard hospital with best result.

Comparative benchmarking: Exercises examining a process in another industry to apply the principles that makes it effective to a similar process. For example success rate in hospital industry with any other successful industry.

Quality assurance include the parameter of quality care assurance programme in facility

- i. Reducing avoidable deaths
- ii. Reducing avoidable complications.
- iii. Reducing unnecessary surgeries or invasive procedures.
- iv. Identify omissions of necessary services.
- v. Reducing unnecessary readmissions.

Risk Management

Medical services including Neurosurgical services are prone to various risks. Risk is an event or situation that could potentially result in any event,

or situation that could potentially result in an injury to an individual or financial loss to the hospital/organization. Effectively managing those is a major activity in any quality assurance program. The objective are

- i. Minimize the potential for injuries occurring.
- ii. Minimize the potentially compensable events (PCEs)
- iii. Respond appropriately to the injured patient.
- iv. Anticipate and plan for ensuring liability when injuries occur.
- v. Prevent or reduce financial loss.

To effectively risk management program should perform the following steps

- a. Risk identification-Identify risks usually by incident reporting. For example needle stick injuries, patient or employee falls, Medication errors (wrong drug, wrong dose).
- b. Risk analysis- Analyse the risk (rate of incidence, how and why it so happened and by whom and where).
- c. Risk valuation- Evaluates the risks in work areas where it is likely to happen.
- d. Risk reduction/mitigation/elimination -Try to reduce or all together mitigate or eliminate by taking appropriate actions.

Sentinel Events

A relative infrequent unexpected incident related to system or process deficiencies, which leads to death or Major and enduring loss of function (at least for 2 weeks or more) for a recipient of health care service.

Surgical events

- i. Surgery performed on the wrong body parts
- ii. Surgery performed on wrong patient
- iii. Wrong surgical procedure performed on the wrong patient.
- iv. Retained instrument sin patients discovered after surgery/procedure.
- v. Patient death during or immediately post-surgical procedure
- vi. Anaesthesia related event.

Device or product events

Patient death or serious disability associated with, the use of contaminated drugs, device, products supplied by the organization/the use or function of device in a manner other than the device's intended use/the failure or break down of a device

or medical equipment/the intra vascular air embolism.

Environmental events

- i. Patient death or serious disability while being cared for in a healthcare facility associated with
- ii. A burn in cured from any source/a slip, trip, or fall/an electric shock/the use of restraints or bed rails.

Care management events

Patient death or serious disability associated with a haemolytic reaction due to the administration of ABO- incompatibility blood or blood products. Medication errors leading to the death or serious disability of patient due to incorrect administration of drugs for example omission error/dose error/ dose preparation error /wrong time error/wrong rate of administration error/ wrong patient error. Patient death or serious disability associated with an avoidable delay in treatment or response to abnormal test results.

Criminal events

- i. Any care ordered or provided by impersonating a clinical member of staff.
- ii. Abduction of patient.
- iii. Sexual assault on a patient with in or grounds of health care facility.
- iv. Death or other injury of a patient or staff member resulting from a physical as saultor other crime that occurred within or the ground of the health care facility.

Standard Precautions

- a. A method of infection control in which all human blood and other body material or fluid are considered infectious for HIV,HBV and other blood borne pathogens, regardless of patient history. It encompasses a variety of practice to prevent occupational exposure, such as the use of personal protective equipment (PPE), disposal of sharp sand safe house keeping.
- b. Set of guidelines protecting first aiders or health care professional from pathogens. The main message is “don’t touch or use anything that has the victim’s body fluids on it without a barrier.” It also assumes that all body fluid of a patient is infectious, and must be treated accordingly.
- c. Standard precautions apply to blood, all body fluids, secretions and excretions (except sweat) regard less of whether or not they contain visible blood, non-intact skin and mucous membranes.

Quality Indicators

Percentage of medication errors

(Total no of medication error in given period of time/total no of discharge and deaths in that period) x100

Percentage of transfusion reactions

(Total no of transfusions in a given period/ total no of transfusions in that period) x100

Urinary tract infection rate

(No of urinary catheter associated UTI sin a given period/ No of urinary catheter days in that period) x1000

Respiratory infection rate

(No of ventilator associated pneumonia sin a given period/no of ventilator days in that period) x1000

Intra vascular device infection rate

(No of central line associated blood stream infection in a given period/ No of central line days in that period) x1000

Surgical site infection rate

(No of surgical site infection in a given period/ no of surgeries performed in that period) x100

Incidence of bed sore after admission

(No of patients who developed new/worsening of pressure ulcer in a given period/No of discharges and deaths in that month) x100

Bed occupancy rate and average length of stay

Bed occupancy rate: (No of inpatient days in a given period/No of available bed days in that period) x100

Average length of stay (combined and specialty wise): (No of inpatient days in a given period/No of discharges and deaths in that period of time)x100

Incidence of needle stick injuries(injury due to sharp needles): (No of parental exposure in a given period of time/total number of in patient days in given period of time) x100.

The above points are symbolic only. Idea of quality is very stand involves each and every step we take in the profession which is called as total quality management (TQM). Quality should be inherent in every walk of work, Areas of the organization what

may be called a sin stitutionalization of quality. It should come in day to day practice involuntarily to become successful.

Guidelines for Surveillance of the Operation Theatre Environment

It is important that proper environment is created and maintained in surgery operation theatre area for prevention of hospital acquired infections and optimal outcomes in all neurosurgical cases. For meeting this requirement following should be done:

- i. The operation theatre should have the proper zoning concept Care should be undertaken to avoid crisscrossing of traffic between the zones. It is ensured that there is unidirectional flow of work and materials.
- ii. Air conditioning should be planned to support a clean and optimal environment at all places in the operation theatre. There may be a laminar flow with central air-conditioning and HEPA filters with positive pressure environment in all operating suits.
- iii. Entry to protected and sterile zones is restricted and due care is taken that only authorized persons enter these areas and they are properly clothed as per the requirements.
- iv. Any member of staff suffering from contagious infections is for bidden entry to these areas till he is clinically cured.
- v. Regular washing and sterilization of operation theatre should be carried out and these activities are done in a planned manner and are cord of these is maintained by the operation theatre nurse in charge.
- vi. Regular fumigation of operating suits should be carried out and a record of these is maintained by the operation theatre nurse in charge.
- vii. It is ensured that OT change clothes, slippers/foot wears, caps, masks, plastic gown, sterile rape sand gowns etc. Should be available in adequate quantity as per the requirements.
- viii. Personnel in OT should be properly trained and educated in proper maintenance of the OT Environment and are provided with logistic sand materials.
- ix. Cultures wabs should be regularly taken from the operation theatre area for surveillance of hospital acquired infections. This should be done by the Hospital Infection Control (HIC) nursing sister. The results are documented and a record of this is maintained and findings discussed with all those involved in OT operation management.
- x. All statutory provisions with regard to Bio-medical waste management should be

complied in Operation Rooms Structural considerations as follows

- a. Primary structure of any hospital which includes main structure with floor columns and walls should be built to have 50-60 years of life span.
- b. Secondary structure including steam, ventilation, cooling, water supply, gases, waste-water systems, electric lines, fire extinguishing system, IT net with optic cables supply and disposal pipelines, elevators, heating, radio net, etc. Should be built to have a 15-20 years of life span.
- c. Tertiary Structure should be built to have 10-15 years of life span. The tertiary structure includes all decoration, furnishing, wall panelling, paint colours, lighting, floor mats etc. It also includes all flooring, wood fitting, furniture, sanitary equipment, false ceiling etc.

Neurological Operation Theatre Complex

The operation theatre complex consists of operating rooms, pre-medication room, post-operative room, and reception, Neurosurgeons room, nursing rooms, male/female changing rooms and other ancillary areas. The neurosurgery operation theatre is a high cost area to the hospital management hence proper utilization of theatres is essential. The facility within the neurosurgery operating room requires presence of high end operating equipment, sterile operating room condition, and good light condition with proper ventilator systems. It is preferred to go in for grouping of operation theatres for being effective and for cost effectiveness of resources and for from removing duplication of resources.

Design consideration of operation theatres

Neurosurgery operation theatre should be located on 1st floor (Ideal) in vertical unit. It should be away from general movement of public and near to neurosurgical post-operative rooms, neurosurgical ICU and neurosurgical wards. Central sterile supply department (CSSD) should be close and easily accessible to neurosurgery operation theatre. It is preferred to have Dum-waiters, (sterile and dirty) for movement of sterile and unsterile surgical items to and from the theatres respectively. There should be unidirectional flow of OT materials. In planning operation theatres the following criteria may be considered.

Functional criteria: Zoning concept should be in corporate while considering the functional criteria's.

Ultraclean Zone: this covers 1meter around the operating site.

Sterile Zone: This area covers the operation rooms/suite; scrub room; gowning area; sterile line area.

Clean Zone: This includes drugstore; sterile store; staffroom; an aesthetist's room; pre medication room.

Protective Zone: these are the area through which patient are wheeled into; personal movement; lifts; OT Reception, Waiting area; change rooms; all forms part of this zone.

Disposal Zone: This is outer most zones and comprise of the dirty corridor around the OT complex. Soiled linen and unsterile instruments are taken out of the operating through the hatch, and then moved out of OT complex through this corridor.

A septic zone: Put step had coined this term to represent the site of incision.

Size of operation theatres (Table 1)

S. no	Type of operation theatres	Size(ft)	Areas (Sq feet)	Remarks
1	Minor OT	18X16	288	Minor neurosurgery OT
2	Major specialty OT	18x18	324	Surgery, orthopaedics etc.
3	Super specialty OT	25x25	625	Neurosurgery, cardiac surgery etc.

Table 1: Size of operation theatres.

Work flow in operation theatre

The flow of material and work should be from clean to dirty zone in one direction only. The corridors leading to the surgical operation room should be 2.85-3.2sqmeter. The direction flow should be unidirectional and it should not criss-cross.

Equipments

The technology is rising. The requirement of equipment will be according to the choice of the surgeons and the type of cases being dealt with. They may include electronic- hydraulic operation table, high speed drill, ultra sonic aspirator, cautery machine, operation suit, navigation, stereotactic frame or even frameless stereotactic surgery etc. these are symbolic each surgical discipline will decide specific equipment as required at that place depending on need.

Space requirement

Space required for an operating room is about 625 square feet (25x25feet) for super specialty operation theatre (see detailsintable1). The ceiling height should be at least 3.1to3.2 meters to a maximum height of 3.6meter.

Environmental Criteria

The operation theatre should be well ventilated, there should be adequate lighting and a good lighting and a good infection control protocol should be adopted to decrease the risk of infection and related morbidity and mortality.

Temperature

The temperature should be maintained between 210 -230. However 22-26 0 C may be used in Neurosurgery ICU.

Humidity

The humidity of 45-55% should be ideal for OT while 30-60% may be used in neuro surgery ICU.

Air changes

Air changes should be 15-20/hour is accepted norm in OT while even 6 air changes suffice in NSICU. The exhaust should be placed at ground level. HEPA (high efficiency particulate aggregate) filters which have the filtration capacity between 0.3-0.5 microns may be used in case of operating room staking up neurosurgeries requiring ultra-sterile environment while even HEPA or Millipore filter (0.5micron) can be used in neurosurgery ICU. A continuous positive pressure should be maintained. 15-20 mm of positive pressure should be in OT while 15mm of hg may be ideal in ICU (Neurosurgery-intensive care) unit as well.

The wall may be metallic in modular OT with anti bacterial paint. However wall may be plain and green and easily washable. The colour of the wall should be glare free; shades of green, blue, violet are preferred. The corners should be rounded to prevent bacteria from harbouring in sharp corners. The terrazzo tiles or mosaic may be used for flooring. Sliding doors are ideal for the operation theatres. Proper grounding is essential. Electrical switches should be of high quality, spark proof. There should be a minimum of 4sockets with two of them 15amps; all sockets should be placed at 4 feet height within the theatres or outside. Ventilation flow types: The ventilation system is essential within the OT, both to maintain the desired temperature and also to maintain the air changes. Different flow pattern have been used.

Turbulent flow: In this type there is uniform mixing of air in the room. This method uses continuous turbulent flow diluting the clean incoming air, with the contaminated operating room air exhausted through the exit with same rate as inflow.

Laminar flow: In this type of, is most preferred where there is high velocity air flow. These are further classified into vertical, horizontal and others (tunnel type, cross-flow pattern).

The exponential flow: This gives a trumpet shaped air flow pattern. In this type there is down ward and out ward flow of air. This type of air flow has the facility of moving the sterile air centrally down ward over the operation table and operating team, and then curves progressively out ward towards the periphery of the clean (vertical, horizontal and others (tunnel type, cross-flow pattern)).

Noise level: Noise level should be below than 30-40 decibel in OT while sit should be below 40 decible in NSICU.

Hazards in Operation Theatres

The theatre is also subjected to multiple hazards, which may be as below.

- i. Electrical hazard: Due to accumulation of static charges, inflammable anaesthetic gases, use of electric cautery etc.
- ii. Infection hazards: due to improper planning and design of OT, lack proper ventilation systems.
- iii. Cardiac arrest: team should be alert; crash cart maintained and readily available.
- iv. Identity: Proper identification of patient, limb /operating site, gas cylinder etc.
- v. Transfusion hazards: Fire hazards, Falls etc.