2.6

Continuous Quality Improvement (CQI)

2.6 Continuous Quality Improvement (CQI)

Continuous Quality Improvement (CQI) has been used in the manufacturing world more extensively than in the healthcare field. However, the underlying foundation of medicine is in fact quite closely tied to the principles of CQI. This includes the observation of a phenomenon, isolating variables and changing the process, observing the results and taking action. If the results are beneficial, continue with the change and look for the next area to improve. If the results are adverse, discard them and try something else. Continue to observe the results until a pattern of foreseeable positive results emerges from performing certain actions.

CQI is easy for healthcare professionals to learn since it is based on this basic scientific model of discovery. As healthcare professionals learn the concepts and strategies behind CQI, they will infuse their scientific background and experience into the program. Innovative measures and positive results follow quickly. These results include higher quality of service delivered, satisfied patients and customers, and lower costs. Quality Control (QC) has been proven time and again to cut costs dramatically.

These standards focus on a systematic approach of using data to measure, assess and improve current performance. This continuous process focuses on outcomes of care, and must include reducing actual and potential risks to patient safety. To achieve this goal, the standards emphasize processes, systems and individual behaviours that reduce the likelihood of unanticipated adverse events. Physicians should be involved in all stages of improvement. They can help design patient care processes, identify the data necessary to measure performance, help analyze this data, and suggest and implement the process improvements.

STANDARD-16. CQI-1: THERE IS A STRUCTURED QUALITY IMPROVEMENT AND CONTINUOUS MONITORING PROGRAMME IN THE ORGANIZATION

IND.93 THE QUALITY IMPROVEMENT PROGRAMME IS DEVELOPED, IMPLEMENTED AND MAINTAINED BY A MULTI-DISCIPLINARY COMMITTEE

Institutionalization of QI Program

Quality Improvement (QI) refers to a philosophy and approach to examining work processes to make them better, effective, efficient and responsive, etc. The principles of QI include:

i. Patients and their family/caregivers are at the center of improvement efforts.

ii. Focus on work processes.

iii. Involvement of interdisciplinary teams to identify issues and make improvements.

iv. Use of data and team knowledge to guide changes.

The QI Committee comprises of the following individuals:

a. CEO of the HCE,
b. Representative from the Hospital Board of Directors
c. MS of the HCE,
d. Director/s of Clinical Care departments as appropriate for your facility.
e. Managers/Directors, Ancillary Services
f. Nursing Managers/Director of Nursing,
g. QI Manager,
h. Head of Pharmacy Department,
i. Infection Control Nurse,
j. Any co-opted member.

The QI Committee is responsible for[42]:

1. Prioritizing issues referred to the QI Committee for review.
2. Assuring that the review functions outlined in the plan are completed.
3. Assuring that the data obtained through QI activities are analyzed, recommendations made, and problem resolution is appropriately followed.
4. Incorporating internal and external sources of benchmarking data, utilizing the Clinical Outcomes Measurement System (COMS) data.
5. Identifying other sources of Patient Safety Goals such as the PHC's MSDS, for incorporation into the hospitals overall quality improvement efforts.

[42]Model Quality Improvement Program CAH Hospital Network.

6. Reporting the ongoing findings, studies, recommendations and trends, quarterly and annually, to the Board of Management/Directors.
7. Reporting to the HCE Management/Medical Staff monthly, or as appropriate.
8. Identifying Continued Professional Development/educational needs and assuring that staff education for quality improvement takes place.
9. Appointing sub committees or teams to work on specific issues, as necessary.
10. Assuring that the necessary resources are available.
11. Coordinating activities with the PHC as and when required.

IND.94 THE QUALITY IMPROVEMENT PROGRAMME IS DOCUMENTED

Quality Improvement Plan

Quality services are services that are provided in a timely, safe, effective, equitable, and recovery-oriented and recipient-centered approach.

The following QI Plan serves as the foundation of the commitment of this hospital to continuously improve the quality of the treatment and services it provides. The concerned Hospital is committed to the ongoing improvement of the quality of care its clients receive, as evidenced by the outcomes of that care. The organization continuously strives to ensure that:

i. The treatment provided incorporates evidence based effective practices.

ii. The treatment and services are appropriate to each client's needs, and are available when needed.

iii. Risk to clients, providers and others is minimized, and errors in the delivery of services are prevented.

iv. Clients' individual needs and expectations are respected; clients or those whom they designate, have the opportunity to participate in taking decisions regarding their treatment and services are provided with sensitivity and care.

v. Procedures, treatments and services are provided in a timely and efficient manner, with appropriate coordination and continuity across all phases of care and all providers of care.

Quality Improvement Principles. QI is a systematic approach to assessing services and improving them on a priority basis. The HCE's approach to Continuous Quality Improvement (CQI) is based on the principles that follow.

a. **Client Focus**. High quality organizations focus on their internal and external clients and on meeting or exceeding needs and expectations.

b. **Recovery-oriented**. Services are characterized by a commitment to promoting and preserving wellness and to expanding choice. This approach promotes maximum flexibility and choice to meet individually defined goals and to permit client-centered services.

c. **Employee Empowerment**. Effective programs for QI involve people at all levels of the organization.

d. **Leadership Involvement**. Strong leadership and direction/support for quality improvement activities by the governing body/Hospital Committee and CEO/MS are key to performance improvement. This involvement of organizational leadership assures that quality improvement initiatives are consistent with the provider's mission and/or strategic plan.

e. **Data Informed Practice**. Successful QI processes create feedback loops, using data to inform practice and measure results. Evidence-based decisions are likely to be correct decisions.

f. **Statistical Tools**. For continuous improvement of care, tools and methods are needed that foster knowledge and understanding. CQI organizations use a defined set of analytic tools such as flow charts, cause and effect diagrams, Pareto charts, histograms, and control charts to turn data into information.

g. **Prevention Overcorrection**. CQI entities seek to design good processes to achieve excellent outcomes rather than designing processes after the event.

h. **Continuous Improvement**. Processes must be continually reviewed and improved. Small incremental changes do make an impact and providers can always find an opportunity to make things better.

Continuous Quality Improvement Activities: CQI activities emerge from a systematic and organized framework for improvement. This framework, adopted by the hospital leadership, is understood, accepted and utilized across the organization, as a result of continuous education and involvement of staff at all levels. QI involves two primary activities:

1. Measuring and assessing the performance of hospital services through collection and analysis of data.
2. Conducting quality improvement initiatives and taking action where indicated, including the:

   A. Design of new services

   B. Improvement of existing services

The QI Plan described previously may be documented as per the following format;

Table 17: Sample Format for QI Plan

Name of Hospital_____

Date of the Current Plan_____

Introduction : Mission, Vision, Scope of Service*(Describe briefly the hospital program that will be covered by this Plan, including the HCE's mission and vision, the types of services provided, its relative size etc.)*

_____

_____

_____

_____

_____

IND.95 THERE IS A DESIGNATED INDIVIDUAL FOR COORDINATING AND IMPLEMENTING THE QUALITY IMPROVEMENT PROGRAMME

QI Program Coordinator

i. The Director/Manager QI is a professional who works collaboratively with the CEO/MS, committee members and departments to coordinate and facilitate the activities of the CQI program throughout the organization.
ii. He/she is responsible for identifying quality indicators, collecting and analyzing data, developing and implementing changes to improve service delivery, and monitoring to assure that improvement is made and sustained.
iii. The ultimate goal is to improve the quality of care that is routinely provided to the patients in the HCE.

IND.96 THE QUALITY IMPROVEMENT PROGRAM IS COMPREHENSIVE AND COVERS ALL THE MAJOR ELEMENTS RELATED TO QUALITY IMPROVEMENT AND RISK MANAGEMENT

Comprehensiveness of QI Program

The QI Program includes the following activities;

i. All services directly or indirectly affecting patient care and safety

ii. Medication therapy
iii. Utilization management e.g. Payment Error Prevention Program (PEPP)[43]/Hospital Payment Monitoring Program
iv. Nosocomial infections
v. Professional staff credentialing
vi. Surgical case review
vii. Blood usage review
viii. Medical record review (includes active and closed record reviews)
ix. Risk management activities
x. Patient/Staff/Physician satisfaction surveys
xi. Morbidity/Mortality Review
xii. Implementation of the PHC's MSDS

(List other activities as appropriate to your facility, such as the SSIC).

Here are 10 tips to help HCEs get QI programs off the ground and poised for success[44].

a. **Make it an organizational priority:** Make sure QI is part of the hospital's mission statement and strategic plan. It should also be embedded into the culture so that everyone in the organization bears responsibility.

b. **Create a non-punitive culture**: Hospitals need to support QI in a non-punitive environment. This kind of leadership should come from the top and permeate down throughout the whole organization. For example, change "incident" reporting to "opportunity for improvement."

c. **Promote teamwork:** Hospitals need to make teamwork a central part of their work culture. Develop small quality action teams and promote stronger staff relationships.

d. **Start with national measures:** Start with the kinds of measures that are being taken nationally. Cases of Ischemic heart disease, diarrhea and pneumonia are some of the conditions with a good sample size that hospitals can start analyzing. Hospitals should also make sure they can meet the reporting requirements of third-party payers, government agencies and organizations that are studying quality.

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[43] Bitonte D.A, Butler P., Curry P., Feigenbaum R.A, Jean-Baptiste R., Nowak M.J. (2001).*The Payment Error Prevention Program (PEPP): Reducing Medicare Payment errors in prospective payment system hospitals*. Retrieved from www.ncbi.nlm.nih.gov/pubmed/11378983.

[44] Carrie Vaughan for Health Leaders News, September 27, 2006.

e. **Institutionalize the measures:** It is important for hospitals to institutionalize quality measures beyond what is required at the national level. For example, a HCE that serves a large elderly population would require tracking quality indicators related to respiratory and pulmonary conditions. That is how you can get buy-in at all levels of the hospital: from the board, the CEO, the administration and clinical staff.

f. **Utilize the right data:** HCEs often collect a lot of information and send or store it somewhere, and never use it in decision-making processes. Hospitals should not only evaluate what they are currently collecting, but they must also ensure collecting crucial information and then actually using that information for critical decisions.

g. **Collect and report information regularly:** Improving quality means measuring, analyzing and reporting information. HCEs need to institutionalize and report regularly.

h. **Invest in information systems:** HCEs need to invest in statistical analysis tools and MIS that support QI cost effectively. However, HCEs should continue to upgrade their internal capabilities and capacities so that they can switch to Electronic Medical Record System (EMRS) down the road. In the meantime, make sure all the key clinical and administrative players have regular access to computerized information from the pharmacy and other areas of the facility.

i. **Establish networks:** One of the best strategies for HCEs, especially critical access hospitals, is to develop partnerships with other facilities rather than taking on quality initiatives by themselves. These networks enable HCEs to share their experiences and pool resources to facilitate QI activities in a cost effective manner.

j. **Ask the experts:** HCEs should take advantage of the assistance available from other QI Organizations including hospitals, the PHC, the Health Department etc. which can offer expertise along with educational and analytical tools to assist Quality Improvement initiatives.

A typical Temporal and Cyclical sequence of factors resulting in quality change is depicted ahead[45];

[45] Alteras, T., Silow-Carroll,S., Meyer, J.A. (2007). *Hospital Quality Improvement: Strategies and Lessons From U.S. Hospitals.*

Figure No. 23

1. A ***Trigger*** serving as a "wake-up call" that prompts the HCE to begin or renew an emphasis on Quality Improvement, marking the beginning of cultural shift and leading to . . .

2. ***Organizational and Structural Changes*** such as the establishment of quality-related councils and committees, empowerment of nurses and other staff, and investments in new technology and infrastructure that facilitate . . .

3. ***A New Problem-Solving Process,*** involving a standardized, systematic, multidisciplinary team approach to identify and study a problem area, conduct root cause analysis, develop action plans, and hold team leaders accountable, resulting in the establishment of . . .

4. ***New Protocols and Practices,*** including evidence-based policies and procedures, clinical pathways and guidelines, error-reducing software, and patient flow management techniques, leading to . . .

5. ***Improved Outcomes*** in process and health-related measures (e.g., patient flow, errors, complications, and mortality), satisfaction and work environment, and "bottom line" indicators such as reduced length of stay and increased market share. Experiencing such positive results serves as a motivation to hospital staff to expand their efforts, thus turning the above sequence into a self-sustaining cycle. That is, the improved outcomes led to further impetus to change, accelerated change, and a spreading of the "change culture" to other parts of the institution. This entire sequence reflects the establishment, growth, and reinforcement of a culture of quality.

IND.97 THE DESIGNATED PROGRAMME IS COMMUNICATED AND COORDINATED AMONGST ALL THE EMPLOYEES OF THE ORGANIZATION THROUGH A PROPER TRAINING MECHANISM

Communication of QI Program

All staff is assigned the responsibility and authority to participate in the Hospital's QI Plan. To fully accomplish this, all staff shall be provided education regarding the QI Plan during their initial orientation and on an annual basis thereafter.

This education shall include a description of the QI Plan and how they fit into the plan, based on their particular job responsibilities. It shall also include education regarding the QI methodology utilized by the HCEs.

IND.98 THE QUALITY IMPROVEMENT PROGRAMME IS A CONTINUOUS PROCESS AND UPDATED AT LEAST ONCE IN A YEAR

Annual Review of QI Program

The QI Plan shall be evaluated on an annual basis for effectiveness in achieving the goal of assuring that the most appropriate quality of care has been provided to patients. A summary of activities, improvements made, care delivery processes modified, projects in progress, and recommendations for changes to this QI Plan, shall be compiled and forwarded to the Board for action.

STANDARD-17. CQI-2: THE ORGANIZATION IDENTIFIES KEY INDICATORS TO MONITOR THE CLINICAL STRUCTURES, PROCESSES AND OUTCOMES WHICH ARE USED AS TOOLS FOR CONTINUAL IMPROVEMENT

IND.99 MONITORING INCLUDES APPROPRIATE PATIENT ASSESSMENT

Monitoring of Patient Assessment

The hospital shall develop appropriate Key Performance Indicators (KPIs) suitable to it. The following, however, is mandatory;

i. Time for initial assessment of indoor and emergency patients.
ii. Percentage of cases (in-patients) wherein care plan with desired outcomes is documented and counter-signed by the clinician.
iii. Percentage of cases (in-patients) wherein screening for nutritional needs has been done.
iv. Percentage of cases (in-patients) wherein the nursing care plan is documented.

IND.100 MONITORING INCLUDES SAFETY AND QUALITY CONTROL PROGRAMS OF THE DIAGNOSTIC SERVICES

Monitoring of Diagnostic Services

The hospital shall develop appropriate KPIs suitable for all diagnostic services. The following, however, is mandatory;

i. Number of reporting errors/1000 investigations.
ii. Percentage of re-dos.
iii. Percentage of reports co-relating with clinical diagnosis.
iv. Percentage of adherence to safety precautions by employees working in diagnostics.

Interpretation(s): Reporting errors need to be captured. It is better if the organization captures these errors as errors picked up before dispatching the reports and errors picked after the dispatch of reports. This includes transcription errors also.

Re-dos include tests which needed to be repeated in view of poor sample or improper positioning and in case of radiology also includes film wastage.

To capture co-relation it becomes mandatory that all investigation forms have a provisional diagnosis/relevant clinical details written on them. The organization could decide which tests will be monitored. However, in case of laboratory, errors shall be captured for all histo-

pathological tests and in case of radiology they shall be captured for CT and MRI. The form can have the differential diagnoses also written on them.

To capture adherence to safety precautions, the organization needs to do a random check of all employees per month (working in these areas and including all categories of staff) and capture data.

IND.101 MONITORING INCLUDES ALL INVASIVE PROCEDURES

Monitoring of Invasive Procedures

The hospital shall develop appropriate KPIs suitable to it. The following, however,is mandatory;

i. Percentage of unplanned invasive procedures.
ii. Percentage of rescheduling of invasive procedures.
iii. Percentage of cases where the organization procedures, to prevent adverse events like wrong patient and wrong procedure, have been adhered to.
iv. Percentage of cases who received appropriate prophylactic antibiotics within the specified time frame.

Interpretations: Unplanned procedure shall be captured only during the same admission. Re-scheduling of patients include cancellation and postponement (beyond four hours) of the procedure because of poor communication, inadequate preparation or inefficiency within the system.

Prophylactic antibiotics should be administered ideally within 30-60 minutes but certainly within two hours of the time of incision.

IND.102 MONITORING INCLUDES ADVERSE DRUG EVENTS

Monitoring of Adverse Drug Events

The hospital shall develop appropriate KPIs suitable to it. The following, however, is mandatory;

i. Percentage of medication errors (Prescribing, dispensing, administration)
ii. Incidence of adverse drug reactions (ADRs).
iii. Percentage of admissions with adverse drug reaction/s.
iv. Percentage of medication charts with error prone abbreviations.
v. Percentage of patients receiving high risk medications developing adverse drug event.

Interpretations: The organization shall document a list of approved abbreviations for medication charts. This shall be based on best national and international practices. For example, "ISMP list of Error-Prone abbreviations, Symbols, and Dose Designations".

ADR monitoring and reporting programs encourage ADR surveillance, facilitate ADR documentation, promote the reporting of ADRs, provide a mechanism for monitoring the safety of drug use in high-risk patient populations, and stimulate the education of health professionals regarding potential ADRs. A comprehensive, ongoing ADR program should include mechanisms for monitoring, detecting, evaluating, documenting, and reporting ADRs as well as intervening and providing educational feedback to prescribers, other healthcare professionals, and patients. Additionally, ADR programs should focus on identifying problems leading to ADRs, planning for positive changes, and measuring the results of these changes. Positive outcomes resulting from an ADR program should be emphasized to support program growth and development.

A comprehensive ADR-monitoring and reporting program should be an integral part of an organization's overall drug use system.

An ADR-monitoring and reporting program should include the following features;

a. The program should establish:
    1. An ongoing and concurrent (during drug therapy) surveillance system based on the reporting of suspected ADRs by pharmacists, physicians, nurses, or patients.
    2. A prospective (before drug therapy) surveillance system for high-risk drugs or patients with a high risk for ADRs.
    3. A concurrent surveillance system for monitoring alerting orders. Alerting orders include the use of "tracer" drugs that are used to treat common ADRs (e.g., orders for immediate doses of antihistamines, epinephrine, and corticosteroids), abrupt discontinuation or decreases in dosage of a drug or stat orders for laboratory assessment of therapeutic drug levels.
b. Prescribers, caregivers, and patients should be notified regarding suspected ADRs.
c. Information regarding suspected ADRs should be reported to the pharmacy for complete data collection and analysis, including the patient's name, the patient's medical and medication history, a description of the suspected ADR, the temporal sequence of the event, any remedial treatment required, and outcomes.
d. High-risk patients should be identified and monitored. High-risk patients include but are not limited to paediatric patients, geriatric patients, patients with organ failure (e.g., hepatic or renal failure), and patients receiving multiple drugs.
e. Drugs likely to cause ADRs ("high-risk" drugs) should be identified, and their use should be monitored. Examples of drugs that may be considered as high risk include

aminoglycosides, amphotericin, antineoplastics, corticosteroids, digoxin, heparin, lidocaine, phenytoin, theophylline, thrombolytic agents, and warfarin.

f. The cause(s) of each suspected ADR should be evaluated on the basis of the patient's medical and medication history, the circumstances of the adverse event, alternative etiologies, and a literature review.

g. A method for assigning the probability of a reported or suspected ADR (e.g., confirmed or definite, likely, possible, and unlikely) should be developed to categorize each ADR. Algorithms may be useful in establishing the causes of suspected ADRs. Subjective questions and the professional judgment of a pharmacist can be used as additional tools to determine the probability of an ADR. Questions might include the following:

   1. Was there a temporal relationship between the onset of drug therapy and the adverse reaction?
   2. Was there a de-challenge; i.e., did the signs and symptoms of the adverse reaction subside when the drug was withdrawn?
   3. Can signs and symptoms of the adverse reaction be explained by the patient's disease state?
   4. Were there any laboratory tests that provide evidence for the reaction being an ADR?
   5. What was the patient's previous general experience with the drug?
   6. Did symptoms return when the agent was re administered?

h. A method for ranking ADRs by severity should be established.

i. A description of each suspected ADR and the outcomes from the event should be documented in the patient's medical record.

j. Serious or unexpected ADRs should be reported to the Drug Regulatory Authority (DRA) or the drug's manufacturer (or both).

k. All ADR reports should be reviewed and evaluated by a designated multidisciplinary committee (e.g., a pharmacy and therapeutics committee).

l. ADR-report information should be disseminated to healthcare professional staff members for educational purposes. Good topics for medical staff education include preventing ADRs and appropriate and effective care for patients who experience ADRs. Educational programs can be conducted as morning "report" discussions, newsletters, algorithms for treatment, and multidisciplinary reviews of drug-use evaluations. Patient confidentiality should be preserved.

m. In settings where it is possible, a pharmacy-coordinated ADR team or committee, consisting of a physician, nurse, QI leader, an administrator, and a pharmacist is recommended. The team should be charged with adopting a definition for the organization, promoting awareness of the consequences of ADRs, establishing

mechanisms for identifying and reporting ADRs, reviewing ADR patterns or trends, and developing preventive and corrective interventions.

n. Continuous monitoring of patient outcomes and patterns of ADRs is imperative. Findings from an ADR monitoring and reporting program should be incorporated into the organization's ongoing Quality Improvement activities. The process should include the following:
    1. Feedback to all appropriate healthcare staff.
    2. Continuous monitoring for trends, clusters, or significant individual ADRs.
    3. Educational efforts for prevention of ADRs.
    4. Evaluation of prescribing patterns, patient monitoring practices, patient outcomes, and the ADR program's effect on overall and individual patient outcomes.

An overall goal of the ADR process should be the achievement of positive patient outcomes[46].

IND.103 MONITORING INCLUDES USE OF ANAESTHESIA.

Monitoring Use of Anaesthesia

The hospital shall develop appropriate KPIs suitable to it. The following, however, is mandatory;

i. Percentage of modification of anaesthesia plan
ii. Percentage of unplanned ventilation following anaesthesia
iii. Percentage of adverse anaesthesia events
iv. Anaesthesia-related mortality rate.

Interpretation(s): Anaesthesia plan is prepared at the time of pre-anaesthesia assessment. The same shall be reviewed during the immediate pre-operative re-evaluation. Modifications done in the plan based on this assessment shall be captured.

Adverse anaesthesia events include events, which happen during the procedure like hypoxia, arrhythmias, cardiac arrest, etc.

[46] Society of Health-System Pharmacists. (1995). *AHSP guidelines on adverse drug reaction monitoring and reporting*. American Journal of Health-System Pharmacy. 52:417–9.

IND.104 MONITORING INCLUDES USE OF BLOOD AND BLOOD PRODUCTS

Monitoring Use of Blood and Blood Products

The hospital shall develop appropriate KPIs suitable to it. The following, however, is mandatory;

i. Percentage of transfusion reactions.
ii. Percentage of wastage of blood and blood products.
iii. Percentage of blood component usage.
iv. Turnaround time for issue of blood and blood components.

Interpretation(s): Wastage includes blood products found unfit for use.

Every Blood Transfusion Service (BTS) should develop an effective quality system to ensure the implementation of these strategies. The quality system should cover all aspects of its activities and ensure traceability, from the recruitment and selection of blood donors to the transfusion of blood and blood products to patients. It should also reflect the structure, needs and capabilities of the BTS, as well as the needs of the hospitals and patients that it serves.

Key elements of quality systems include:

a. Organizational Management
b. Standards
c. Documentation
d. Training
e. Assessment.

Selective elements are discussed as below:

Organizational Management

Commitment and support from the management at all levels is central to an effective quality system, including;

1. Clearly defined organizational structure that defines accountability, authority and responsibility.
2. Designation of a quality manager, with the necessary skills and expertise, in each blood centre and hospital blood bank.
3. Formation of a quality section or identified work area in the hospital blood bank from which quality activities can be coordinated.
4. Development of a culture of quality through a management focus on building quality into all activities.
5. Motivation of staff to ensure their commitment and support for the quality system.
6. Identification of specific processes and procedures and their critical control points.

Documentation

An effective and accurate documentation system, that ensures traceability of all BTS activities, is the foundation of good quality management. Important activities include;

1. Development of a quality manual: a document describing the quality system, including the organization's quality policy, standards and procedures.
2. Production and use of appropriate, comprehensive documents for all activities, including standard operating procedures, forms, labels and any other documents required.
3. Generation and maintenance of complete and accurate records.
4. Development of a system to manage the issue, use and retrieval of documents.

Assessment

Ensuring quality is a continual process; ongoing assessment of the effectiveness of the quality system is essential and can be achieved through:

1. Validation of all processes, procedures, equipment and reagents.
2. Ongoing collection and analysis of data generated from key activities and their use in QI.
3. Establishment of haemovigilance through a system of monitoring, reporting and investigation of adverse incidents related to all blood transfusion activities.
4. Regular review of all activities to assess the overall effectiveness of the quality system and ensure CQI.
5. Programme of regular internal and external audits of the quality system.
6. Reporting and analysis of errors with effective corrective and preventive action.
7. Active participation in appropriate external quality assessment schemes to improve laboratory performance[47].

IND.105 MONITORING INCLUDES AVAILABILITY AND CONTENT OF MEDICAL RECORDS

Monitoring Availability and Contents of Documentation

The hospital shall develop appropriate KPIs suitable to it. The following, however, is mandatory;

i. Percentage of medical records not having discharge summary.
ii. Percentage of medical records not having codification as per International Classification of Diseases (ICD).
iii. Percentage of medical records having incomplete and/or improper consent.
iv. Percentage of missing records.

[47] WHO. *Essential Health Technologies*. Retrieved from www.who.int/bct

Interpretation(s): Missing records include records within the retention time only.

The content, completion, timeliness and accuracy of medical record (documentation) have a direct impact on the evaluation of the quality of assessment, planning and delivery of quality services. Documentation has a universal effect on organizational operations, evaluation of care and services, reimbursement, and survey compliance. The quality and type of care and services delivered to the patient are determined in part through documentation. On-going planning and assessment rely heavily on the quality and accuracy of the documentation in the chart.

Proactive concurrent monitoring of the completion, timeliness and accuracy of the medical record documentation is critical. Both the need for good documentation and risk factors hindering quality, support the importance of an on-going, scheduled audits and monitoring for every patient's medical record. Some of the alerts and Quality Assurance (QA) monitors may be included in the clinical and administrative software used. The quality monitoring process will focus on the combination of using manual and computerized clinical and billing data as well as standards/requirements.

Establishing the qualitative and quantitative monitoring process is expected to be tailored to the HCE, their needs, the services they provide, workflow issues, survey findings and overall management of the facility.

a. **Internal Qualitative vs. Quantitative Audits and Monitoring**

There are various types of audits/monitoring systems – qualitative, quantitative and self-monitoring including manual and automated methods. Qualitative audits look at the quality of documentation assessing adherence to clinical practice guidelines, evaluating consistency in charting, and adherence to regulations, standards and interpretations. This type of audit is usually completed by a staff member or consultant who has professional training, education or experience. Qualitative audits adhere to the SOPs on qualitative patient care protocols, both internal and those prescribed by the regulatory agencies. Qualitative protocols include increased knowledge and skills of the reviewer to evaluate documentation that focuses on the clinical practice and standards. The results or findings from the qualitative monitoring provide the data for QA reviews of the quality of care, in relationship to the standards, clinical practices and the regulatory requirements.

The HCE staff can be trained and internal systems can be established for self-monitoring to complete quantitative audits which focus on whether a document is complete (all sections of a form), authenticated, or timely. This type of audit is more objective than a qualitative audit.

Increased **self–reliance and self-monitoring** is within reach of the clinical staff documenting, using the following methods:

1. Self-auditing; before you put the pen down, look for those clinical interventions, observations or assessment that would demonstrate the quality of care you just provided or planning for the future.
2. Look at the automated edits or warning/alerts for inconsistencies of documentation based on the software criteria.
3. Set an expectation to periodically run reports to identify areas of deficiencies or information to evaluate the documentation, examples, un-noted orders report, alerts for individuals – to check against the charting planned or just completed
4. **Establish 'shift to shift' or 'person to person' monitoring of documentation with a "sign-off" either manual/or electronic to indicate self-monitoring.** Some examples are medication and treatment, ADL monitoring etc.

On an on-going basis, facilities should have quantitative and qualitative monitoring in place to assure complete and timely records. Admission, current and discharged, record monitoring assures that analysis is completed throughout the patient stay. The goal to continuous monitoring throughout a patient stay is to identify problems or omissions when correction is possible. Analyzing the record on discharge makes it virtually impossible to legally and ethically address or correct documentation problems when it can still impact the patient during their stay while maintaining the integrity of the medical record. For example, if an assessment is not completed on admission nothing can be done on discharge, but if it is found during an admission audit, the assessment can still be completed in order for the facility to provide appropriate care and services for the patient. Signatures for manual systems shall meet the requirements for a full signature, initials that are referenced by the clinician's full name, including title.

b. **External Qualitative and Quantitative Audits**

Audits of health record information may be performed for the licensing and certification process, for legal reviews from licensing boards and for billing reviews.

Assessing the Quality of Documentation

When completing a qualitative audit, the reviewer should have the ability to assess the following issues, identify strengths and weaknesses, and provide suggestions to correct future documentation discrepancies;

1. Consistency in documentation between progress notes, assessments, care plans, etc.
2. Duplication or redundancy in documentation.

3. Contradiction in documentation without a clear reason for the differences. This may occur between two disciplines or within one discipline such as nursing where multiple staff members document on a similar issue.
4. Documentation that is missing key elements for the proper assessment or planning of a problem.
5. Documentation reflects application of appropriate practice guidelines, standards, regulations, reimbursement rules, and clinical protocols across all disciplines.
6. Understanding of the reason for all types of documentation in a long term care record and the underlying guidelines, standards, regulations, or clinical practice protocols.

A health information consultant should have the ability to provide a qualitative and quantitative analysis of the documentation content of the medical record, identify potential workflow issues and provide feedback and suggestions for resolution.

c. **Routine Audits/Monitoring (Criteria and Timeframes)**

Every long term care facility should have systems in place for monitoring completion of their documentation on an on-going basis. At a minimum, records should be reviewed on admission and hospital return, concurrently on a monthly/quarterly basis, and upon discharge/death. Not all audit findings will be correctable. For findings that cannot be corrected, the information should be gathered for training/retraining, system evaluation and improvement. The QA process should incorporate the findings into their overall quality management program[48].

1. *Maintaining a Unit Record*

A unit record and unit numbering system is recommended for long term care facilities. With a unit record, the patient is assigned a medical record number on the first admission to the HCEs. This number is retained for each subsequent admission/readmission, and is used for both paper and electronic portions of the record. Though there may be multiple volumes, folders and formats, the patient's entire medical record is filed as a unit under one number.

In long term care, the record(s) from previous admissions should be brought forward and filed in the same area as the current admission. Bringing previous records forward provides the most comprehensive picture of the resident's medical history and therapy. The previous records should be readily accessible to staff for use in the assessment and care planning process.

When a resident is readmitted, all records from previous admissions should be pulled forward and maintained in the overflow files. Records from previous admissions should be separated from other discharged/closed records to prevent the inadvertent destruction of the record(s) prior to the required medical records retention period (Refer to Government/Statutory

[48]American Health Information Management Association (AHIMA), 2012

requirements). The medical records from previous stays remain in their original file folder and are retained, chronologically, with other records for residents currently in the facility. The records from one discharge to another are not combined into one folder.

If the previous records cannot be brought forward and kept in the same area as the current record, the facility must have a process in place to ensure that previous records are not inadvertently destroyed prior to the required retention period for the record.

2. *Defining What is Part of the Medical Record*

The medical record in a long term care facility reflects the multi-disciplinary approach to assessment, care planning and care delivery. The medical record includes, but is not limited to, the following types of information: patient identification, admission/readmission documentation, advance directives and consents, history and physical exams and other related hospital records, assessments, care plan, physicians orders, physician and professional consult progress notes, nursing documentation/progress notes, medication and treatment records, reports from lab, X-rays and other diagnostic tests, rehabilitation and restorative therapy records, social service documentation, nutrition services documentation, and other miscellaneous records including correspondence and administrative documents.

HCEs policy should specifically be outlined in the format of a chart order, the exact documents and records that will be considered part of the medical record.

3. *Maintenance of the Medical Record*

It is critical that both the active record and the overflow records are maintained in a systematically organized fashion. This means that all records have an established chart order or order of filing that is followed. All records (records on the nursing station, overflow records, and discharge records) should be readily accessible, maintained in an organized chart order, filed in an easily retrievable manner, and maintained in folders or chart holders sufficient in size for the volume of the record. The chart holders and folders should be kept neat, clean and orderly. Products are available for cleaning/disinfecting the chart holders (binders). Cleaning is recommended periodically during the stay and upon discharge.

4. *Identification (Name and Number) on pages of the Medical Record*

From a legal perspective, each page or individual documents in the medical record should contain the patient identification information. At a minimum, both the patient name and medical record number should be on each form. If labels/label paper is used, the patient identification information must be included on the label. The patient name and number should be placed on both sides of a two-sided form/page because records are frequently copied. Identification information appearing on both sides of a form helps to ensure that the copy is not lost or misplaced. If the back of the form is blank, no identification information is

required on the blank side. There should not be documentation on the back of a one-sided form. If, for any reason, documentation is placed on the back of a one-sided form, a label or identifying information must be added and any blank space on the form lined or X'd out to prevent further documentation that may be out of sequence.

Patient identification information can be noted on forms by methods such as writing on the page in permanent ink, stamping by an addressograph, or affixing a printed or manually completed label. Regardless of the method used, identification information should not obscure any content on the form. Patient specific documents printed from a computer system to be filed in the medical record, such as physician orders, care plans, etc., should include patient identification information on each page.

STANDARD-18. CQI-3: SENTINEL EVENTS ARE INTENSIVELY ANALYSED

IND.106 THE ORGANIZATION HAS DEFINED SENTINEL EVENTS

Sentinel Events

A sentinel event is defined as "An unexpected occurrence involving Death or Serious Physical or Psychological Injury, or the Risk thereof".Serious Injury specifically includes loss of limb or function. The phrase, 'or risk thereof' includes any process variation for which a recurrence carries a significant chance of a serious adverse outcome."

Such events are called "SENTINEL" because they signal the need for immediate investigation and response.

The real tragedy is that most of these medical mistakes are preventable. They are most often caused by systems that break down and don't support the highly qualified and dedicated hospital caregivers the way they should.

While significant and attracting attention, medication errors aren't the only types of medical errors that hospitals need to pay attention to.

Sentinel events also include the following, even if the outcome was not death or major permanent loss of function:

i. Newborn abduction, or discharge to the wrong family.

ii. Unexpected death of a full term foetus.

iii. Severe neonatal jaundice (bilirubin over 30 milligrams/deciliter).

iv. Surgery on the wrong individual or wrong body part.

v. Surgical instrument or object left in a patient after surgery or another procedure.

vi. Rape in a continuous care setting.

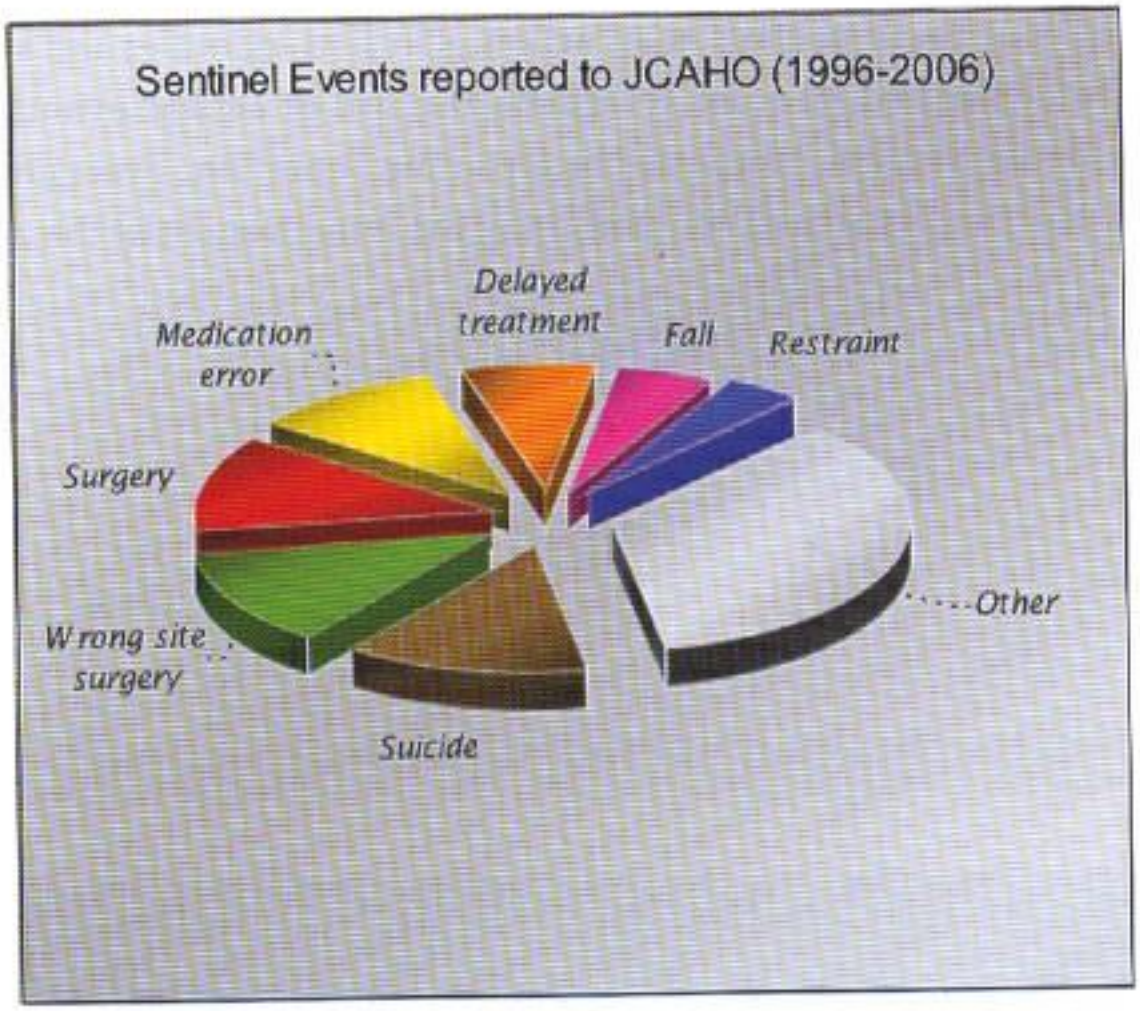
vii. Suicide in a continuous care setting, or within 72 hours of discharge.

viii. Haemolytic transfusion reaction due to blood group incompatibilities.

ix. Radiation therapy to the wrong body region or 25% above the planned dose.

In addition to the list above, The PHC will require each Licensed/Accredited Organization to define sentinel events for its own care system and put into place monitoring procedures to detect these events and a procedure for root cause analysis.

Figure No. 24



IND.107 SENTINEL EVENTS ARE INTENSIVELY ANALYZED WHEN THEY OCCUR.

Analysis of Sentinel Events

HCEs are expected to identify and respond appropriately to all sentinel events occurring in the hospital or associated with services that the hospital provides, or provides for. Appropriate response includes conducting a timely, thorough, and credible root cause analysis; developing an action plan designed to implement improvements to reduce risk, implementing the improvements, and monitoring the effectiveness of those improvements.

Root Cause Analysis and Action Plan are described as follows:

Root Cause Analysis

Root cause analysis is a process for identifying the factors that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event. A root cause analysis focuses primarily on systems and processes, not on individual performance. The analysis progresses from special causes in clinical processes to common causes in organizational processes and systems and identifies potential improvements in these processes or systems that would tend to decrease the likelihood of such events in the future or determines, after analysis, that no such improvement opportunities exist.

Action Plan

The product of the root cause analysis is an action plan that identifies the strategies that the hospital intends to implement in order to reduce the risk of similar events occurring in the future. The plan should address responsibility for implementation, oversight, pilot testing as appropriate, time lines, and strategies for measuring the effectiveness of the actions[49].

[49]Centre for Addiction and Mental Health (CAMH), Refreshed Core, January 2011.