

Clinical *Audit*
implementation guide

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Health

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Forward

The Ministry of Health has been focusing on improving the quality of health care through designing and developing different policies and guidelines. The HSTP has set out quality improvements as one of its pillars of excellence which are believed to help the sector to accomplish its mission and vision. Based on this strategy the ministry has also developed a five-year National Health Care Quality strategy to aid the execution of the HSTP goals. In line with this HSTQ guidelines developed a different approach to operationalizing the national quality strategy with superior emphasis on clinical audit.

The Health Sector Transformation in Quality (HSTQ) document is developed to facilitate and sustain the implementation of the HSTP, and in particular, the transformation agenda of quality health care services. Accordingly, this guideline is composed of four sections which are; QI Guideline, Quality Structure, Clinical Audit Guideline and Health Service Quality Standards. The HSTQ manual in prepared to be main tools to transform the clinical process of hospital functions and it has been launched a nationwide quality improvement initiative which is going to be operationalized and catalyzed through the EHAQ platform.

Despite, all the efforts, providing acceptable quality of health service in health facilities is a big challenge. The findings from the national core standards performance appraisals that are being conducted in public health facilities and information extracted from provincial reports continuously demonstrate that the implementation of HSTQ and clinical audits are either not done at facility level at all or such audit are only being done in some of the priority health programs and not in all priority health programs. This subsequently leads to an obvious lack of quality improvement projects that are based on the results of clinical audits.

This Clinical Audit implementation guide uniquely designed by the ministry to catalyze the implementation of Health Sector Transformation in Quality (HSTQ) guideline and linking clinical audit findings with existing platforms like morning sessions, seminars, grand round meetings, beside teachings plus quality improvement system then to make clinical audit fundamental component of clinical practice at the facility level.

The aim of this national clinical audit implementation guideline is to support health facilities and health professional to understand both the concept and practice of clinical audit as part of their routine jobs.

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Mr. Yakob Seman	FMOH	Director General/MSGD
Mr. Abase Hassen	FMOH	Director/CSD
Mr. Naod Wendrad	FMOH	Assistant Director/CSD
Sr. Gezashign Denkew	FMOH	Case team coordinator
Mr. Abiy Dawit	FMOH	Senior Officers
Mahlet Asayehegne	FMOH	Senior Officers
Mr. Esayas Mesele	FMOH	Senior Advisor/MSGD
Dr Ashenafi Beza	FMOH	TA/CSD
Dr Tamiru Mebrate	St Peter	CEO
Dr Dawit Yifru	St. Peter	Director/CG & QU
Dr Tigist Mesfine	St. Peter	Quality Officers
Dr Aschalew Worku	AAU/CHS/TASH	Ass. Internist ,PCCM
Dr Ayele Teshome	Yekatit 12 HMC	hospital Provost
Mr. Selahadin Seid	Yekatit 12 hospital	HMC MSIE
Mr.Kokeb Yedeme	St.Peter Specialized Hospital	

Introduction

Clinical audit has been practiced across the globe to ensure the safe and effective delivery of healthcare. Historically, Clinical audit has stretched back to the work of Florence Nightingale (1800s) and Ernest Codman (early 1900s). Both Nightingale and Codman monitored mortality and morbidity rates in their respective institutions and within one-year implementation of clinical audit the mortality rates had reduced from 60% to 2.2%.

Clinical audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit standards/ criteria and the implementation of change. Aspects of structure (input), processes and outcomes of care are selected and systematically evaluated against explicit standards. Where indicated, changes are implemented at an individual, team or service level and further monitoring is used to confirm improvement in health care delivery. Clinical audit should be an integral part of clinical practice and preferably a multi-professional activity. It informs health care providers whether they are providing care that will, (i) yield improved outcomes for patients, (ii) bring about efficiency gains, and (iii) raise patient satisfaction to higher levels.

The Federal Ministry of Health of Ethiopia in collaboration with Regional Health Bureaus, Administrative Cities and developmental Partners has been leading and supporting the health sector for better healthcare provision to all communities. Through designing and implementing the national health sector transformation plan and the different strategies emanated from this national plan, it is well known that improvements have been recorded in most of the services being provided in health facilities through introducing various scientifically proven initiatives and programs in to the health system.

Despite, all the efforts, providing acceptable quality of health service in health facilities is a big challenge. The findings from the national core standards performance appraisals that are being conducted in public health facilities and information extracted from provincial quarterly reports

continuously demonstrate that clinical audits are either not done at facility level at all or such audit are only being done in some of the priority health programs and not in all priority health programs. This subsequently leads to an obvious lack of quality improvement projects that are based on the results of clinical audits.

The aim of this national clinical audit implementation guideline is to support health facilities and health professional to understand both the concept and practice of clinical audit as part of their routine jobs.

Rationales

The absence of regular clinical audit practice in health facilities has negative impacts on both on the quality of healthcare delivery in particular and quality medical education at large. The rationales behind developing this clinical audit implementation guide are:

- ❖ Current global evidences show more people are dying because of poor quality of care than lack of care or access. This implies health facilities should pay more attention for the safety and quality of the care that they provide
- ❖ Practice of regular Clinical audits can significantly help health facilities to identify, learn and intervene possible quality gaps to improve their clinical activities continuously
- ❖ Despite the existence of Health Service Transformation in Quality Document, currently in Ethiopia, there is no clearly defined mechanism or enabling environment through which health facilities can practice clinical audit as part of their job
- ❖ Health providers in low-income and middle-income countries (LMICs) often do less than half of recommended or standards evidence based care actions. Poor-quality care resulted in 82 deaths per 100 000 people in LMICs—an annual mortality rate equivalent to that from cerebrovascular disease globally.

Objective

General

- ❖ To create a culture of systematic integration for all public health institutions to fully implement and practice clinical audits as part of their patient safety and quality assurance measures of the routine clinical and academic activities.

Specific

- ❖ To develop self-explanatory and user-friendly clinical audit implementation guide for health facilities
- ❖ To clearly state the rationales behind enforcing public health facilities to practice clinical audits as their routine clinical activities
- ❖ To clearly identify and recommend various mechanisms through which culture of clinical audit practice can be integrated
- ❖ To clearly define and recommend scientifically proven approaches to monitor, support and report performance of clinical audit activities in health facilities
- ❖ To recommend ways of sustainability for health facilities to maximally utilize findings of the clinical audits as part of their evidence-based decision practice for health service improvement
- ❖ To support health facilities linking clinical audit findings with quality improvement activities

Scope

This National Clinical Audit Implementation Guide aims to support hospitals and healthcare professionals in understanding the concept and processes of clinical audit, to support best practice in clinical audit and link findings of clinical audit with quality improve activities as part of their essential and integral component of clinical practice. To this end, this document provides a practical guide to the methodology of clinical audit and it is primarily for hospitals and healthcare professionals involved in or who have an interest in carrying out clinical audit.

Principles of Effective Clinical Audit

If health facilities and clinical departments aspire to conduct effective and successful clinical audit the following guiding principles should be considered:

1. **Confidentiality** should at all times be respected. No information regarding the health status, treatment or stay of a patient in a health facility is to be divulged verbally or in writing without the necessary prior consent. Furthermore, patient data entered into any computer (database) should be protected by a password, access to such computers should be limited to authorized personnel only, and all relevant documentation and material related to the clinical audit must be locked away when not attended to or not in use. Making information anonymous before it is used in audit could also be considered.
2. The **organizational environment** must be supportive towards clinical audit. In practice this means that those who are managing health facilities should ensure policies and procedures are in place to safeguard patient care and they should encourage professional self-regulation, and lifelong learning.
3. A **non-judgmental** working environment should exist, i.e. the search should be for error only. The results that are produced when searching for a deviation from agreed good practices should not be used to denigrate and condemn health care providers.
4. Clinical audit is **data driven**. Clinical audit can only be undertaken if enough data is available to ensure credible results are produced. It is therefore essential that a strong relationship be established between the Health Information system and the Clinical Audit project.
5. Clinical audit should be part of **structured program** to improve quality of care within a facility.
6. Clinical audit is **participatory** in nature. It involves multidisciplinary teams that comprise of health care workers and service users at any level or tier of the health care system. Working in teams ensures that appropriate skills are pooled together from the outset.

Governance of Clinical Audit

In a health facility where clinical audit is structurally integrated with the existing service delivery system, provision of high quality health service and patient safety are ensured. This implies, in order to effectively and successfully conduct clinical audit as part of the routine clinical activity, health facilities should design a mechanism by which clinical audit will be governed.

Role and Responsibilities

Quality and clinical governance directorate/unit

The Quality Unity or Directorate will have the following roles and responsibilities:

- ❖ Coordinate overall clinical audit programs of the hospital
- ❖ Design and implement ToR for clinical audit
- ❖ Support departments in developing clinical audit criteria's and checklist
- ❖ Support the development of a plan and program of clinical audits
- ❖ Ensure departments/ directorates carry out clinical audits regularly
- ❖ Support the analysis, interpretation and design of intervention for clinical audits findings
- ❖ Ensure availability of necessary resources for departments/ directorates to conduct clinical audit
- ❖ Monitor and manage clinical audits progress
- ❖ Link clinical audit findings to QI projects
- ❖ Ensure that departments have taken clinical audit activities as a measure of their performances including their clinical staffs
- ❖ Support and facilitate publication of audit findings in journals, quality bulletin
- ❖ Recognize and celebrate success stories

Quality Council/committee

In the overall efforts to manage and support clinical audit implementation, the quality council of the hospital will be responsible for the following duties:

- ❖ Support quality unit/directorate in the coordination and management of clinical audit activities in the hospitals
- ❖ Establish ad-hoc committees for clinical audit activities if need be there
- ❖ Monitor and evaluate performances of clinical audit activities of the hospital
- ❖ Support the analysis, interpretation and development of change ideas/intervention following clinical audits
- ❖ Support linkage of audit findings to QI activities
- ❖ Ensure clinical audit activities are led and done by multidisciplinary team

- ❖ Ensure Presentation of audit findings in the appropriate platforms

Department/unit/directorate quality improvement sub team

The team is preferably led by a senior physician, and depending on the needs, members of the team can be recruited from residents, interns, general practitioners, clinical pharmacists, nurses...etc. the team is expected to conduct clinical audits regularly. The team will be responsible for:

- ❖ Align clinical audit program with the hospital audit program
- ❖ Identify audit checklist which already exist or prepare criteria for the audit topics through engaging relevant experts
- ❖ Lead the development of a plan or program of clinical audits
- ❖ Conduct analysis, interpret, develop and implement QI interventions based on audit findings
- ❖ Facilitate presentation of audit finding in the selected platforms
- ❖ Report audit findings to the quality unit with an improvement plan
- ❖ Take clinical audit activities as a measure of performance of clinical staffs
- ❖ Recognize and celebrate success stories
- ❖ Support and facilitate publication of audit findings in journals, quality bulletin

Frequency of Clinical Audit

Understanding the importance and impacts of quality improvement activities which are designed from the evidences collected through regular clinical audits on patient care, the following key activities should be practiced at hospital level:

- ❖ Ideally every clinical department of the hospital is expected to conduct clinical audit in daily base, but due to several reasons, it is advisable the hospital to conduct in a weekly manner.
- ❖ Each department of the hospital is expected to report its performances of clinical audit to quality units in weekly base.
- ❖ The hospital should compile and report performances of clinical audits to the respective bodies in monthly base.
- ❖ Each clinical department in the hospital is expected to dedicate one day in a week to discuss findings of clinical audits

Process of Clinical Audit

Clinical audit is a cyclical process which has five stages. Each stage of the clinical audit cycle must be undertaken to ensure that an audit is systematic and successful.

Stage-1: Planning for Audit

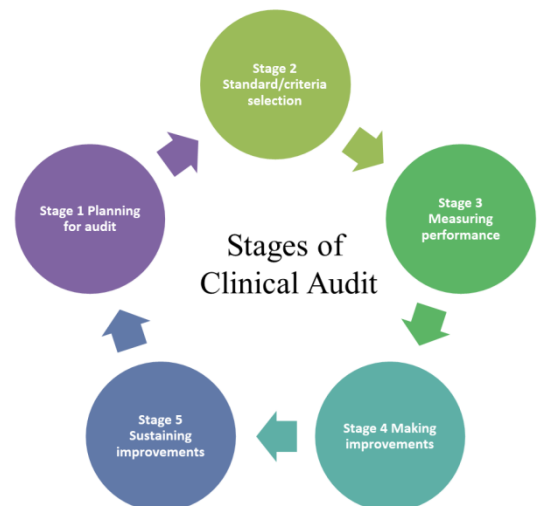
A clinical audit is said to be successful if it helps to identify areas of excellence or areas of improvement. This can be achieved through effective planning and preparation. There are three main steps in the planning process which includes:

1. Involving stakeholders
2. Determining/selecting audit topic
3. Planning the delivery of audit fieldwork

Involving Stakeholders

Ownership relates to involving the right stakeholders in the audit from the phase of planning up to follow up of implementation of change interventions, monitoring improvements and sustaining such improvements. Anyone involved in providing or receiving care can be considered a stakeholder in clinical audit. Identifying the right stakeholders is the first crucial aspect in planning for clinical audit. The stakeholders include the following but not limited to:

1. **Department heads or Quality Focal Persons (seniors)** from all respective departments for Referral/Teaching hospitals. Their involvement could either be direct participation during the audit or overseeing the process which includes:
 - ❖ Leadership role in the audit team
 - ❖ Review of cases that do not achieve the expected level of performance
 - ❖ Provide explanations as to how a care process happens currently
 - ❖ Monitor the implementation of agreed actions
2. **Directors/Directorate Directors** for Referral/Teaching hospitals. Their role can be:



- ❖ Secure resources required to support change
 - ❖ Grant permission to access service user (client) group
 - ❖ Contribute to the analysis of audit findings, including analysis of problems identified
 - ❖ Provide support to the clinical audit team
 - ❖ Monitor the implementation of agreed actions
3. **Chief Resident / Resident focal** assigned for clinical audit- Referral/Teaching hospitals and their role will be :
- ❖ Collection of data, analysis, interpretation and dissemination/presentation of findings
 - ❖ Actively engaged in evidence generation and publication on audit findings
 - ❖ Design quality improvement projects based on audit findings
 - ❖ Provide explanations as to how a care process happens currently
4. **General practitioner** - Referral/Teaching hospitals and Primary hospitals. Their role will be:
- ❖ Collection of data
 - ❖ Contribute to the analysis of audit findings, including analysis of problems, interpretation and identification of potential interventions
 - ❖ Assist in identification of implementation action plan to address areas requiring improvement
 - ❖ Provide explanations as to how a care process happens currently
5. **Clinical Nurse**- all level of health facilities, and their role will be:
- ❖ Collection of data
 - ❖ Contribute to the analysis of audit findings, including analysis of problems, interpretation and identification of potential interventions
 - ❖ Assist in identification of actions to address areas requiring improvement
6. **Clinical Pharmacist** - Referral/Teaching hospitals, and their role will be:
- ❖ Collection of data
 - ❖ Contribute to the analysis of audit findings, including analysis of problems, interpretation and identification of potential interventions
 - ❖ Assist in identification of actions to address areas requiring improvement

7. **Intern representative/ Intern focal** assigned for clinical audit- Referral/Teaching hospitals, and their role will be:
 - ❖ Collection of data
 - ❖ Contribute to the analysis of audit findings, including analysis of problems, interpretation and identification of potential interventions
 - ❖ Design implementation plan
8. **Case team managers and Coordinators**- all levels of hospitals, and their role will be:
 - ❖ Grant permission to access service user (client) group
 - ❖ Contribute to the analysis of audit findings, including analysis of problems identified
 - ❖ Secure resources required to support change
 - ❖ Provide support to the clinical audit team
9. **Clients**: Act as a source for data, and their role will be:
 - ❖ **Direct**- interview, client forum/focus group
 - ❖ **Indirect**- Complaint box, analysis of feedback/comments made at service user forums
10. **Donor organizations**- all levels of health facility, and their role will be:
 - ❖ Secure resources required for audit and support change
11. **Hospital management (medical director/ CED)**- all levels of health facility, and their role will be:
 - ❖ Secure resources required for audit and support change
 - ❖ Grant permission to access service user (client) group

Determining the Audit Topic

This is a very important step that must be given careful consideration. Subjects for clinical audit should be selected with a view to improving the quality or safety of care or of service provision. The following points need to be considered while selecting topic

1. **National**: - audit where participation is required due to government or regulatory requirements or as part of an accreditation scheme or national priority area.

For example: - maternal and child health, non-communicable diseases/ HTN, DM/ are Ethiopian national priority areas. As a result, these audits can have a priority over the other topics

2. **Internal / hospital management:** - audit where audit topics are based on hospital management team priorities in response to
 - a. Either top ten or five Morbidity and mortality data of the hospital
 - b. Incidents
 - c. Risk management
 - d. Complaints from patients
3. **Department /service directorate/ case team priorities:** - where audit topics are based on
 - a. Department /service directorate/ case team concern
 - b. Department /service directorate/ case team policies/ procedures
4. **Clinician interest** – locally initiated audits not covered by the above but which will contribute to the overall work of the service

Audit Topic prioritization matrix:

Selection of the audit topic needs careful thought and planning, as clinical staff and service providers have limited resources with which to deliver clinical audits. Mandatory audits will take resource priority and this can be justified using prioritization matrix

Score 3- High level, Score 2- Medium level, Score 1- Low level, Score 0- No importance

No	Criteria	Topic 1	Topic 2	Topic 3
1.	It is among the top ten/five morbidity or mortality case			
2.	Topic is national/regional priority or high interest of the hospital			
3.	Local evidence suggests unwanted variation in practice			
4.	There has been a high level of investment in new			

	equipment/intervention requiring effectiveness to be measured			
5.	The topic concerned of high cost, volume or risk to staff or users			
6.	Suggested in morning session, grand round, seminar, death audit, journals...			

Planning the Delivery of Audit Fieldwork

The audit is planned to be carried out on a regular basis every weekly by the clinical audit team. The team should select the appropriate platform depending on the level of the health facility to ensure the engagement of all responsible stakeholders involved in the provision of healthcare. Below are possible platforms /but not limited to/ health facilities can consider for discussion on plans, audit findings and change idea generation for improvement as well as update on implementation progress and follow up

Morning meeting

- ❖ Brief stakeholders on aims and objectives of the clinical audit
- ❖ Discuss on current nationally endorsed disease specific standards and criteria for audit (revise if the need arises)

Grand round

- ❖ Discuss on current health care practice and standards set for such practices
- ❖ Dissemination of audit findings

Seminar

- ❖ Teaching/ updating stakeholders to improve current healthcare practice based on the gaps identified during audit
- ❖ Discuss on methodologies of clinical audit
- ❖ Present and discuss on quality improvement projects designed based on audit findings
- ❖ Discuss on current nationally endorsed disease specific standards and criteria for audit

- ❖ Dissemination of audit findings

Death audit presentation

- ❖ Discuss on current nationally endorsed disease specific standards
- ❖ Dissemination of audit findings

Journal presentation

- ❖ Teaching/ updating stakeholders to improve current healthcare practice based on the gaps identified during audit
- ❖ Dissemination of audit findings

Case team forums

- ❖ Brief stakeholders on aims and objectives of clinical audit(for each weekly selected audit topic)
- ❖ Present audit findings
- ❖ Present and discuss on quality improvement projects designed based on audit findings
- ❖ Present improvements achieved after conducting a clinical audit

Performance Monitoring Team Meeting

- ❖ Ensure all clinical audit reports are timely submitted to the respective bodies such FMOH, RHBs...
- ❖ Ensure data quality, specially timeliness and completeness

Stage-2: Standard and Criteria Selection

Criteria and standard selection is one of the core steps in clinical auditing after topic selection. This is a phase where by the clinical audit team review available evidences to find standards and audit criteria's against which the audit will be conducted.

Criteria of Audit focuses on decisions regarding the overall purpose of the audit, what question you want the audit to answer, written as a series of statements or tasks that the audit will focus on. These criteria are explicit statements that define what is being measured and represent elements of care that can be measured objectively.

The standards define the aspect of care to be measured, and should always be based on the best available evidence. For Criteria to be sound and lead to improvement it should be consistent with smart Guidance: (Specific, Measurable, Achievable, and Relevant, Timely)

Integration of Standard and Criteria Selection with system

- ❖ Once a Clinical Audit team is selected at Department level Comprising of Consultants, Residents, Gp's and Interns they will Select and prioritize a problem list based on the tool mentioned above.
- ❖ The team then sets a criteria entailing the three Classifications (Structure, Process, outcome)
- ❖ The Experts then set standards based:
 - ❖ Reference to Local Guideline
 - ❖ Reference to National Guideline
 - ❖ Literature Review
- ❖ Lastly a check list is made comprising of:
 - ❖ Standard Title: which summarizes area of focus for standard
 - ❖ Standard Statement: Which explains level of performance to be achieved
 - ❖ Standard Criteria: Provides the details of what needs to be achieved for the standard to be met

Guidance for Setting Criteria & Standard

If the selected clinical audit topic is found in the national audit tool (HSTQ), every audit criteria and standard mentioned in the HSTQ must be followed accordingly. Whereas, the audit topic is new which is not in the HSTQ, then the following recommendations should be considered. All audit projects must have agreed criteria to measure against. These criteria should be derived from evidence – either from good quality guidelines, reviews of the literature or where this is not available national or local consensus. The next step involves agreeing the standards which in most cases should be 100% or 0% with exceptions listed. Once a topic has been chosen, valid criteria for evaluating against and the level of performance (standard) must be chosen. Criteria can be classified into those concerned with:

1. Structure (what you need) Examples of criteria relating to structure include the numbers of staff and skill mix, the provision of equipment and physical space.
2. Process (what you do) Process criteria refer to actions and decisions taken by practitioners and users. Examples include assessment, education, documentation, prescribing, surgical and other therapeutic interventions.

- Outcome (what you expect) Outcome criteria are typically measures of the physical or behavioral response to an intervention, reported health status and level of knowledge and satisfaction. Sometimes surrogate or intermediate outcome indicators are used instead.

N.B. The use of an objective criterion with an agreed standard of performance is a hallmark of clinical audit. Sample of Criteria Vs Standard

Criteria	Target Standard Met
Administration of Diuretics to pts with heart failure (Process)	100% of patients to achieve this level of care
Adequate Facilities for hand hygiene are available. i.e. one wash basin per 6 beds (Structure)	100% of areas

The criteria and the level of performance must be measurable and acceptable to all the stakeholders involved in an audit. These criteria are explicit statements that define what is being measured, for example: The date, vaccine batch and number of a vaccine administered should be entered in the patient's notes' (HSE e-learning Centre)

Poorly defined criteria can be misleading. There are four requirements for good and valid criteria. It should be Relevant, Clearly defined, easily measured and based on evidence (NICE 2002).

The table shows the relationship between criteria and standards in clinical audit:

Criteria	Standard
The date, vaccine batch and number of a vaccine administered should be entered in pts note (Process)	100%

Sourcing criteria

- ❖ Professional Associations e.g. Internal Medicine Society, ESOG
- ❖ Literature
- ❖ Guidelines
- ❖ National and international literature.
- ❖ National, and Local policies and procedures.

- ❖ Statutory requirements and regulations
- ❖ Clinical guidelines.
- ❖ Clinical pathways.
- ❖ Develop your own:

N.B. Criteria should be based on the latest available research and evidence. Your literature search gives an idea of what criteria and standards are recommended or achieved internationally and nationally. If criteria are not available, it is acceptable to develop criteria based on a local consensus. In any event all standards must be agreed by members of the team.

Stage-3: Measuring Performances

Data collection must be precise and only essential data collected, i.e. only the minimum data required by the objectives of the audit. It is strongly recommended that data that already exists be used. To ensure only essential data are being collected, certain details about what is to be audited must be established from the outset. This stage may be described in steps as follows:

- ❖ Step 1: Data collection
- ❖ Step 2: Data analysis
- ❖ Step 3: Drawing conclusions
- ❖ Step 4: Presentation of results

The overall objective of conducting clinical audit is to improve the quality of care and outcomes by measuring current practice against the set standards. After standards against which the audit will be conducted have been identified, the next step in the audit process is the collection of relevant data about current practice in order to facilitate quality gap identification. During data collection and analysis, there should be involvement of the user group in the process.

Step One: Data Collection

Before data collection commences, we have to know the type of data to be collected (Quantitative Vs Qualitative), Data sources, and data collection tool, standard, sampling mechanism and duration of data collection should be clarified. The following steps need to be considered while data collection

1. **Data type:** - The type and required data is dependent on the audit question and objectives. The aim of data collection is to enable comparison of current practice against the audit standard; therefore, the type of data collected must facilitate this comparison
2. **Data items:** - Data collected must be relevant to the aims and objectives; data item also should be adequate and not excessive for the purpose of measurement of practice against the relevant audit criteria. These identified items should be including in the data collection tool. Data collection tools should derive from the standard selected for audit.
3. **Sources of data:** - source of data should be identified and agreed by the team. Same data source should be also used for re-audits to identify improvements.
4. **Data collection methods:** - can be retrospective , prospective or cross-sectional
5. **Sample selection methods and sample size:** - It is often not possible or necessary to gather data on all service users, events or items for audit purposes; therefore, sampling is often required. It is important that any sample selected is representative of the population under examination. Simple random sampling and convenience sampling tend to be the most commonly used methods in clinical audit. Clinical audit is not research. It is about evaluating compliance with standards rather than creating new knowledge, therefore sample sizes for data collection are often a compromise between the statistical validity of the results and pragmatic issues around data collection i.e. time, access to data, costs. The sample should be small enough to allow for speedy data collection but large enough to be representative. In some audits the sample will be time driven and in others it will be numerical

Data collection planned should come first on the audit team meeting. The team should determine the data items that need to be collected, source of data, and sampling methods. After this the data collection can be carried out using a checklist either individually or as group using a standardized checklist derived from the standards set. Usually residents and interns should take the primarily responsibility for data collection.

Step-Two: Data Analysis

The basic aim of data analysis is to convert a collection of facts (data) into useful information in order identify the level of compliance with the agreed standard. Collation of data involves the

gathering together of all data collected during the period of the audit. This may involve transferring the data collected from the data collection tool onto summary sheets (manual data collection) or onto a spreadsheet or database (manual or electronic data collection) for interpretation. The main aim of data analysis is to answer the questions posed by the audit objectives; highlighting areas of good practice and areas that require particular attention or improvement. The type of data analysis depends on the type of information collected. This can range from simple averages and percentages to sophisticated statistical techniques.

The data analysis should be done as a team. Presence of the senior professional is must in the data analysis and interpretation. Data feeding can be conducted with the same professional that collected the data. An excel database is recommended for the checklist so that it will be easier for that analysis and also to compare findings during the re-audit.

Step-Three: Drawing Conclusion

After results have been compiled and the data has been analyzed against the standards, the final step in the process (where applicable), is to identify the reasons why the standard was not met. In order to understand the reason for failure to achieve compliance with clinical audit criteria, the audit team should carefully review all findings.

Cases of unacceptable care should then be reviewed in order for the team to:

- ❖ Clearly identify and agree on areas for improvement identified by the clinical audit.
- ❖ Analyze the areas for improvement to identify what underlying, contributory or deep-rooted factors are involved. Tools like process mapping, fishbone diagrams, and 5 whys can be used to explore root causes.

Step-Four: Report Writing and Presenting Results

The aim of any presentation of results should be to maximize the impact of the clinical audit on the audience in order to generate discussion and to stimulate and support action planning.

An audit report should be written as soon as all audit data has been analyzed. Graphical analysis should be used to visually demonstrate audit results. The audit report should outline the purpose of the audit, the criteria measured, the actual performance achieved and a comparison of actual

performance against the selected best practice benchmarks or high quality evidence based standards of care. The report should clearly identify:

- ❖ Areas for improvement, for example, unrecorded practice, practice not occurring, poor levels of service user satisfaction.
- ❖ Causes, for example, poor documentation, inadequate staffing, training and practice issues.
- ❖ Needed improvements, for example, the introduction of a structured assessment proforma for service users with asthma so that all relevant service user data and examination findings are checked.
- ❖ Information explaining why some cases do not meet the required standards.
- ❖ Relevant, meaningful and useful information that will help to identify and address issues arising from the audit.

The following points can be used as a guide while writing a clinical audit report for documentation

- ❖ Title of the clinical audit
- ❖ Background to the clinical audit, that is, reason for selection of the subject
- ❖ Design of the clinical audit including:
 - ❖ Aim and/or specific objective/s to express clearly the intention of the audit
 - ❖ Time period for data collection
 - ❖ Data collection strategy, that is, retrospective, concurrent or prospective
 - How data were collected
 - ❖ Quality-of-care measures used in the audit
 - ❖ Analysis of the findings including:
 - ❖ Score
 - ❖ Problems or shortcomings in patient care identified
 - ❖ Root causes of the problems
 - ❖ Specific improvements needed

Data graphics are a good way of communicating this information to others. The most commonly used form of data graphics in clinical audit are tables, graphs and charts. The team should

prepare 30-45 minutes brief presentation on the audit findings according to the above outline. The presentation should be conducted on the existing platform like morning sessions as mentioned on the planning part. Time for discussion and improvement plan should be adequate.

Summary table for the four steps

Step 1: Data collection	Step 2: Data analysis	Step 3: Drawing conclusions	Step 4: Presentation of results
Collection of relevant data about current practice in order to facilitate comparison.	Convert a collection of facts (data) into useful information in order to identify the level of compliance with the agreed standard.	Identify the reasons why the standard was not met.	Maximize the impact of the clinical audit on the audience in order to generate discussion and to stimulate and support action planning.

Stage-4: Linking Clinical Audit Findings with the Quality Improvement

Change is often the most difficult part of the audit. When the audit teams have developed the recommendations, decisions should be made on how changes can be introduced and monitored. Results should be used in conjunction with feedback and local consensus to change clinical practice and to improve standards.

Priorities for action should be identified and these should be clearly documented. All audits should be accompanied by a quality improvement plan in order to achieve the required improvements in practice.

After finishing all the clinical auditing activities, the findings of the audit must be taken to the next level which quality improvement cycle. Each clinical department is required to refer steps of QI cycles for them to link findings of the audit to QI activities of the hospital.

- Develop the team charter
- Set clear aim statement
- Put measures
- Develop change ideas
- Test the change ideas
- Implement the change ideas

- Scale up the experience

Stage-5: Sustaining Improvement

The main components that should be considered when sustaining, spreading and Scaling up change ideas:

Monitoring the quality improvement plan: Clinical departments and/or managers are accountable for the delivery of quality improvement plans and sustaining quality improvement.

The following key issues should be addressed while monitoring performance:

- ❖ A summary report of progress should be submitted through the appropriate lines of responsibility at regular intervals.
- ❖ The quality improvement team is responsible for monitoring and reporting the progress of implementation through the reporting structure.
- ❖ The progress of any quality improvement plan associated with an audit should be formally assessed at regular intervals of 3-6 months and appropriate actions to be taken should be determined where progress is not being maintained
- ❖ Where plans have not been implemented, a rapid re-audit is recommended to ensure that changes have indeed improved practice and to ascertain whether further audit procedures are required in the short term.

Performance indicators: Performance indicators can be used to monitor improvements as a result of quality improvement activities. A small number of key performance indicators may be developed for each quality improvement program to monitor implementation of the improvement plans. A **red**, **amber** and **green** traffic light system can be used to monitor implementation status. The same system can also be used to measure the impact of change on practice when performing rapid re-audits.

Evaluating audit quality: It is recommended that the quality of an audit program is evaluated as part of the wider quality and risk management agenda (NICE, 2002). Service providers should assess their structures, processes, outcomes and resources for audit activities. All clinical audits should be conducted in a manner that complies with legislation, guidance and service provider policies relating to confidentiality and data protection.

Dissemination and celebrating success: Completion of an audit cycle will usually result in improvements in practice. This should be communicated to all stakeholders. A successful audit in one service may be transferable to other parts of the service. Completed audits should be shared locally via the most appropriate mechanisms, including department quality and safety meetings, journal club meetings, the intranet, newsletters and local conferences and seminars. Consideration should also be given to sharing clinical audit work regionally and nationally through relevant journals, conferences and other media.

Remember to close the loop by re-auditing: Audit is a continuous cycle. If following an initial audit it is found that desired performance levels are not being reached, and a program of change activity has been put in place; then the audit should be repeated to show whether the changes implemented have improved care or whether further changes are required. This cycle is repeated until the desired performance levels are being achieved.

Standardization: Establish or update specific recognized policies, procedures, standards that act as a model or guidelines for the changed process. Make it hard not to follow the new process by building in constraints (e.g. no longer stocking the old), affordances (e.g. the new system guides us in doing the right things) and differentiation (e.g. color coding).

Remove the old system: Remove the old system and incorporate the new/changed system. Build in **structures to ‘foolproof’ change**, so that it is difficult, if not impossible for Providers to revert to old ways of doing things: Standardization, Documentation, Training/orientation and developing a ‘tool kit’ that has all the aids needed to successfully apply and Measure the intervention/change.

Monitoring and Evaluating Clinical Audit

Monitoring and Evaluation of a clinical audit program should be done by all relevant stakeholders including the institution management, RHBs and FMOH. Monitoring should basically focus on the implementation of the clinical audit program while the evaluation assesses the effectiveness of the programs to bring about improvement in clinical outcome indicators and client satisfaction.

The implementation of action plans will be monitored by the Clinical Audit lead and reported to the quality council and Senior Management Team (SMT) via a standing monthly and quarterly report. All actions should include target dates for completion, and reporting may therefore be by

exception. There should be an agreed process for following up any actions that have not been implemented by the target date. The clinical audit policy/TOR of the institution should set out clear lines of reporting for monitoring the clinical audit program. Each clinical audit project on the program would be better to have a CLINICAL AUDIT LEAD that is ultimately responsible for the conduct of the audit. However in order to ensure that the organization as a whole benefits from the program, it must be monitored by the Senior Management Team (SMT).

Collecting data for a second time, after changes have been introduced, is central to both assessing and maintaining the improvements made during clinical audit. The same procedures of sample selection, information collection, and analysis (see 5.3 above) should be used throughout the process, to ensure that the data are valid and comparable with each other. If performance targets were not reached during implementation, modifications to the plan or additional interventions will be needed. Systems for long-term monitoring of indicators should be set up and only the minimum number of essential indicators should be included. Data collection can be minimized if monitoring is based on routinely available or easily collected indicators. However, if no data source is available and the performance indicator is a key measure, systems for providing data must be created.

Whenever possible, authoritative, evidence-based sources of guidance on selecting performance indicators and advice on audit criteria should be used. When local indicators are required and subsequently developed, care should be taken to ensure these indicators are valid and reliable. It is important to ensure that data are collected accurately and analyzed and interpreted appropriately when performance indicators are used to monitor sustained improvement. Findings should be reviewed regularly and any decline in performance should be investigated through more detailed audits. The subsequent results should inform the development and implementation of new improvement strategies. By so doing, monitoring is linked to an overall quality strategy, thus making it a routine part of managing the service.

Other sources of information, such as errors, adverse incidents, mortality and morbidity reviews, and comments from users can also be included for continued monitoring of performance, but these mechanisms depend largely on a non-judgmental environment.

Checklist to Monitor a Clinical Audit Program

Health facilities may use the following list of criteria to monitor the key components of the clinical audit program in their facility set ups.

Input	Yes	No
The hospital has clinical audit plan and program		
The hospital availed the required resources for clinical audit program		
The hospital has clearly stated ToR for Clinical Audit		
All clinical departments of the hospital have received orientation on how to conduct clinical audits		
Clinical audit practice is integrated with the existing clinical governance platforms		
All clinical audit teams are composed of multidisciplinary health professions		
Process		
Clinical audit topics are selected based on agreed criteria		
Existing platforms such as morning sessions, grand round, case team forums, and other discussed clinical findings		
All clinical departments have done weekly clinical audits		
Clinical audit activities are taken as a measure of performances of the department and clinical staffs		
One day in a week is dedicated to discuss findings of clinical audits in each clinical departments of the hospital		
Output		
All clinical audit findings linked with quality improvement projects		
Audit score get improved compared to the previous audit score		
Client satisfaction score gets improved compared to the previous audit score		
Timeliness and completeness of clinical audit report is 100% achieved		
Best performing Departments and staffs are recognized		

Annex: Sample Check List Design for prioritization

N.B. Score 1 if compliant to Criteria and 0 if Non-Compliant to criteria

Facility Name			XYZ Hospital		
Name of Auditor			Dr. XY		
Audit Topic			Clinical Record Audit for HTN		
Aim/Objective of Audit			Assess facility setup for HTN, Assess Adherence to proper Guidelines		
Exclusion Criteria (If Applicable)			Patients with single follow up at facility, poor adherence		
Period Of Audit: (including Cycle)					
No	Sample of structure Criteria	Standard	Chart 1	Chart 2	Chart 3
1	Availability of Chronic Follow Up clinic i.e. PHC 1 chronic Follow up Clinic, if General / referral Minimum 2 chronic follow up Clinic and if specialized Hospital Designated Cardiovascular Follow Up Clinic	100%			
2	Availability of Trained manpower in the Follow up Clinic for Dx & Mx of HTN i.e. 1 Consultant, 1 GP, 1 Nurse	100%			
3	Availability of Guideline & Job Aids for the Management of HTn in the follow up clinics	100%			
No	Sample of Process criteria	Standard	Chart 1	Chart 2	Chart 3
1	Proper base line investigation prior to start of treatment, that is OFT, Serum e-, ECG	100%			

2	Patients started on Rx as per the guideline. That is for stage 1 = x medication, Stage 2 = y & Z medication	100%			
3	Proper follow up investigations done, that is A, B & C investigations	100%			
4	Proper adherence counseling and support given. That is evidence of support and adherence counseling documented on charts.	100%			
No	Sample of Outcome criteria	Standard	Chart 1	Chart 2	Chart 3
1	Patients with controlled HTN during follow up. That is BP less than a specific no with specific disease condition	100%			
2	Patients with any adverse drug reactions while on treatment. Eg. ADR A, ADR B	100%			
Total results					

Reference

1. University of Gonder, Health science College, clinical audit guideline, 2018
2. Copeland, G. A practical Handbook for Clinical Audit. Clinical Governance Support Team, March 2005.
3. Department of Health. The Policy on Quality in Health Care for South Africa. Abbreviated version, April 2007.
4. National Audit Office. A safer place for patients: learning to improve patient safety. London: The Stationary Office, 2005.
5. National Institute for Clinical Excellence (NICE). 2002. Principles for Best Practice in Clinical Audit.