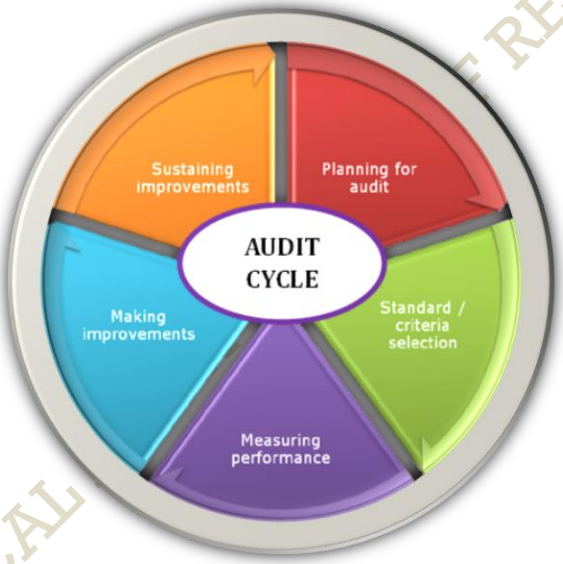
DEDER GENERAL HOSPITAL

CLINICAL AUDIT TERMS OF REFERENCE (TOR)



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Deder, Eastern Ethiopia

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ABBREVIATION

- **DGH**-**D**eder **G**eneral
- **H**ospital GB- **H**ospital **G**overning **B**oard
- **GRC**-GYN Referral Clinic
- **QIC**-**Q**uality **I**mprovement **C**ommittee
- **QIT**- **Q**uality improvement **T**eam
- **SMT**-**S**enior **M**anagement **T**eam
- **SRC**-Surgical Referral Clinic
- **TOR**-**T**erms of **R**eference

1. INTRODUCTION

1.1. Background

In the past six years, the Ministry of health-Ethiopia has been working rigorously to ensure the quality and safety of healthcare. The major undertakings that have been implemented are; the formulation and execution of two national quality strategies, the establishment of a quality management structure across the health system, the extensive capacity building in healthcare quality improvement, and the creation of public awareness of the high-quality healthcare system. Moreover, a common understanding of the importance of high-quality healthcare for the realization of universal health coverage has been created.

During the implementation of the two quality strategies, several large-scale quality improvement initiatives have been launched and encouraging results were noted. The Ethiopian Hospitals Alliance for Quality is one of the initiatives that utilized quality concepts for the improvement of care delivery and outcomes. In the last three cycles, there has been a massive engagement of hospitals and recognition of the best performers. The Maternal and Neonatal Health quality, equity, and dignity (MNH-QED)-WHO-led Global initiative- that mainly operates by networking health facilities in the learning Woredas has been implemented for the last three years.

Within this initiative, forty-eight (48) facilities were networked to reduce maternal and neonatal mortality by half and the QI approach has been employed to achieve the goal. Furthermore, other small-scale initiatives that aimed to improve the HIV and Hypertension quality of care have been undertaken paving the way for more strong initiatives.

To facilitate the learning and knowledge transfer, local and national level learning platforms have been organized. Among them, the National Healthcare Quality and Safety Summit takes a bigger stake bringing healthcare

policymakers, academicians, partners, and professional and patient associations aboard to discuss the improvement strategies, to share the experience, and to take a common stance for improvement of the care delivery.

Although fragmented and not uniformly done, the ministry established a system of producing different clinical guidelines and protocols that can help health care providers treat their patients with evidence-based knowledge. Numerous clinical protocols and treatment guidelines have been developed and disseminated by different bodies within and outside the ministry of health, which paved the way for effective and standardized care across the country.

To help the implementation of HSTP-I, the health services quality directorate (HSQD) prepared clinical audit guidelines incorporated in a document called '*health sector transformation in quality-HSTQ'*. The document guided the quality improvement methods and structure, clinical audit process, and set quality standards on national quality strategy disease priorities and other selected areas like data quality and patient safety and **CRC. 3**

Despite all these efforts, the health systems lack a robust clinical audit system at the hospital level. The recency of the concept, lack of clearly established role and responsibility from ministry to facility level, absence of well-devised clinical audit system, shortage of well-capacitated professionals (on clinical audit) at the facility level, and the complexity and bulkiness of the current audit tools utilized at the facility level are some of the contributing factors to the slow progress toward best practice in clinical audit in the country. Therefore, establishing a solid clinical audit program that uses the available clinical guidelines is highly required to substantiate the improvement efforts.

1.2 Rationale

A growing body of research shows that there is a significant quality gap in the provision of health care along one or more quality dimensions- people-centeredness, safety, timeliness, effectiveness, efficiency, equity, and integration. Actions to improve the quality and safety of care provided require the introduction of a well-organized effective clinical auditing program as one component.

The review of best practices focused on the English NHS(National Health Service) - pioneers in incorporating the clinical audit practice into contemporary healthcare improvement - showed that for clinical audit programs in health facilities to be successful two components need to be fulfilled; i.e., the use of appropriate methodologies and creating a supportive environment.

Accordingly, application of appropriate methods in terms of meticulous planning, designing of easy and workable audit standards and criteria, designing and monitoring of appropriate quality improvement plans based on identified gaps, linking audit findings with quality improvement projects(systematic management of change) together with the absence of appropriate structure that can organize and provide the necessary support for auditors to building their capacity on designing and execution of effective clinical audits are among the prevailing limitation in the clinical audit practice in the Ethiopian Health system. Moreover, the inaccessibility of quality data because of poor data recording practice, the bulkiness of the data set required for audit bearing weight on the staff that is burdened with other priorities are other deficiencies. Also, the absence of a policy and strategy at the ministry level that defines the roles and responsibilities of stakeholders and sets a clear path towards the establishment of an effective clinical audit system made the practice fall far behind the best practices. Nevertheless, encouraging results have been

seen in the practice of clinical audits in hospitals; QI teams are making efforts to regularly conduct audits using the tool and plan actions based on findings. Recognition and acceptance by healthcare providers and QI teams at the facility level are increasing.

Strengthening and intensifying the efforts of clinical audit practice initiated at a hospital level to excel from a mediocre stage to an optimal level and serve as a means for quality improvement is of paramount importance. 4

Informed by the best practice, this document outlines the concept of clinical audit, steps in conducting a clinical audit, roles, and responsibilities of involved stakeholders, and methods to evaluate the effectiveness of the clinical audit program. Moreover, based on the available clinical guidelines and protocols utilized in hospitals by involving relevant stakeholders, simplified clinical audit tools on selected topic areas are developed and included to facilitate the regular conduction of clinical audits in hospitals. The audit tools comprise standards and criteria that can be used to assess the appropriateness of the clinical service delivered in hospitals. Therefore, this guide and tools will direct, standardize, and improve the effectiveness of the clinical audit practice in the Ethiopian health system.

2. DEFINITIONS

2.1. Quality Improvement

Quality improvement (QI) is a continuous process whereby organizations iteratively test and measure changes in work routines, set and achieve ambitious aims, shift whole system performance, and spread best practices for rapid uptake at a larger scale to address a specific issue or set of issues they have determined to improve (1).

2.2. Clinical Audit

''A quality improvement process that seeks to improve patient care and outcomes through a systematic review of care against explicit criteria and the implementation of change'' (2)

It involves the assessment of structure, process, and outcome of care against agreed explicit standards where changes are introduced based on identified gaps and further monitoring made to ascertain improvements (2).

2.3. Quality Committee/Counsel

A committee that is composed of department heads and selected experts in the hospital that oversees the quality improvement efforts of the hospital and mainstreams the QI concepts and activities in all departments.

2.4. Quality unit/directorate

A formally organized structure that is responsible for the coordination and guidance of all QI activities in a hospital. This unit or directorate involves in devising the hospital QI strategy, annual QI plan, providing capacity building trainings related to QI, coordinating the formation of quality improvement teams (QITs), coordinating regular clinical audit projects, providing coaching support to QITs, lesson documentation, selection of key performance indicators related to service quality, involving in research, planning and conducting learning sessions etc…

2.5. Quality improvement team

Is a team that works in the specific unit/ward responsible for designing, implementing, monitoring, and reporting quality improvement activities. This team functions as an audit team. This team carries out the day-to-day QI activities and should be composed of representatives of different professionals involved in the care process within the department. The roles and responsibilities of the QIT and members, meeting frequency, and quorum need to be defined in a term of reference.

3. OBJECTIVES

The objectives of this guide are to:

- Strengthen the clinical audit system in hospitals across the country.
- Standardize the clinical audit practice in such a way that it's an integral part of mainstream QI activities.
- Help hospitals to effectively conduct a clinical audit on the services they deliver.
- Guide the development of audit standards and criteria for local audit priorities.

4. SCOPE

This document is intended to guide healthcare workers, quality improvement teams, and unit leaders practicing in a hospital setup to understand the concepts and methodologies of clinical audit and conduct clinical audits as an integral part of mainstream clinical and QI activities. It promotes awareness on clinical audit and guides to the achievement of best practices in clinical audit in hospitals.

5. Conducting clinical audit

An effective clinical audit requires a structured system with competent leadership, involvement by all staff, and stress on team working and support (3). Therefore, hospitals should integrate the healthcare clinical audit to the larger improvement effort (if it exists) or develop a clinical audit program.

6. Stages of clinical audit

A typical clinical audit has five stages: planning, standard selection, and criteria setting, measuring performance against a standard, making improvement, and sustaining improvement.

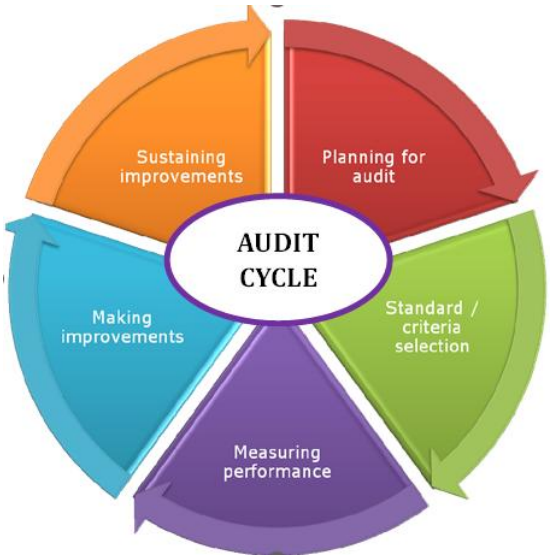

Figure 1: Stages of clinical audit

6.1 Planning

Although the amount of **preparation** depends on the circumstance, whether it is a small audit conducted by an individual or a large audit involving multiple disciplines effective planning and preparation is key for a successful audit (3).

Preparation involves **three main components**: **involving stakeholders**, **determining audit topic**, and **planning the delivery of audit field work** (3).

Step 1: involving stakeholders

Three questions can guide to determine who should be involved in clinical audits: ***who is involved in the delivery of care***, ***who receives, uses, or benefits from the care or service***, ***who has the authority to support the implementation of any identified changes*** (3).

Since clinical audits evaluate the effectiveness of clinical care practices and the majority of these involve multi-disciplinary teams, the involvement of representatives of all clinical and managerial practices contributing to the audit topic area is crucial. Everyone involved should be made clear of the aim of the audit and their specific role and responsibilities. An agreement for the leadership and ownership should be reached and where possible commitment

for change by all involved should be ascertained (3).

Departments within the facility should establish a **QIT** (which will also serve as an **audit team**) that consists of all relevant stakeholders for the improvement of the care within the unit. It may be composed of representatives of all involved in the care provision i.e., clinicians (physician, midwife, nurse, laboratory, and pharmacy professionals) and unit leaders/coordinators, administration staff, and other health personnel.

The primary concerns of those receiving care might differ from those delivering care therefore the audit team should give careful thought to the possible benefits of **involving service users** in the clinical audit process and which methods to use if they are to be part of the audit. Service users can be directly involved in the audit or indirectly through focus group discussion, interviews, surveys, collecting feedback, and the likes. Where service users are directly involved in clinical audit programs, their roles need to be clearly defined and appropriate support and guidance provided to enable the delivery of the audit (3).

Attaining the buy-in of those with authority to approve changes arising from audit recommendations is also important, especially in circumstances where the changes need a resource or have implications for other services areas (3).8

Step 2: Determine the audit topic

Careful thought should be given when selecting audit topics as hospitals have limited resources with which they can execute clinical audits. The audit teams should do this with the view of improving the quality and safety of care. Apart from mandatory audits (national audits prioritized by MoH), all other audits should be prioritized in a way resource can be utilized efficiently (3).

The following factors should be taken into account when prioritizing audit topics:

- Costly practice areas
- Areas with a frequent patient complaint
- High-volume practice areas
- Risky practice areas
- Areas that show variation in clinical practice,
- Have evidence of poor quality (high rate of complication and adverse outcome)
- Have a reliable data source
- Likely to improve process and outcome care

It is also good to consider whether there is good evidence to inform audit standards and if data can be collected in a reasonable time (3).

Audits that are part of national audits should be a top priority. The hospital/department will then prioritize other topic areas using a scoring system taking into account the above points. It should be noted that there is also room for carrying out audits on the clinical interest of practitioners (3).

After topic selection, audit proposal should be prepared and submitted to the QI unit (Annex 2: Audit proposal form), QI unit/ committee approves the proposed audit after thorough review. Approved proposals should be registered using the registration form to facilitate monitoring of progress. (Annex 3: Clinical audit project registration and monitoring form)

Step 3: Planning the audit delivery

Planning the audit execution is a very crucial step for a successful audit. **The following issues should be well considered in this step**.

A. Set the aim/objectives of the audit: Carrying out an audit with no clear objective will bring little to no improvement. Detailed statements can be used to describe the different aspects of quality that will be measured to show how

the aim of the clinical audit will be met (3).

Assure all team members are aware of the purpose: All Health workforce involved in the subject of the audit must understand the aim of the audit and their role in it. This needs to be clarified at the outset and may be expressed in terms of the reference document (3).

B. Equip the audit team with the necessary knowledge and skills: Involving the right people with the right skill will be a crucial aspect of the planning process ensuring the task will be accomplished effectively and efficiently. The audit team should have a great depth of understanding of clinical audit processes. Members should know the concept of clinical audit, and clinical guidelines utilized in clinical care. They have to be familiar with setting criteria, data collection, templates used in clinical audit (**audit proposal form, chart abstraction forms**….), **data analysis methods, and methods for improving.** The QI unit will be responsible for building the capacity of the QIT in the aforementioned areas; it will also provide technical support whenever necessary.

6.2 Selecting Quality Standards and Setting Criteria

For the selected national disease and condition priorities, use the audit standards and criteria attached in the second section of the document. These standards and criteria are developed after considering the current context of health care delivery in hospitals across the country. The working committee has thoroughly discussed and weighed the quality culture, the structure in place, and lessons learned from the implementation of HSTQ. Over and above that, great efforts were made to make the audit criteria suitable for all tier levels.

Once a department/hospital meets these standards, the QIT can devise audit standards and criteria that are more advanced or prioritize other audit topics, develop standards and criteria for the identified topics, and continue with the

process of clinical audit and improvement. The QIT can formulate evidence-based and relevant criteria using the guide below.

The quality standards or criteria developing process should take the internationally validated methodology and these should be included in the audit proposal for approval by the quality committee.

Skills required in clinical audit process (3)

- Leadership, organizational and management skills
- Clinical skills
- Project management skills
- Change management skills
- Audit methodology expertise
- Understanding of data protection requirements
- Data collection and data analysis skills
- Facilitation skills
- Communication skills
- Interpersonal skills

Adapted from A practical guide to clinical audit August 2013 Dublin 11

6.2.1 Defining standards and criteria

6.2.1.1 Standard

"An **objective** with guidance for its achievement given in the form of criteria sets which specify required resources, activities, and predicted outcomes" (Royal College of Nursing, 1990) (4).

6.2.1.2 Criteria

"An **item or variable** which enables the achievement of a standard (broad objective of care) and the evaluation of whether it has been achieved or not" (Royal College of Nursing, 1990) (4).

Within clinical audit, **criteria** are used to assess the **quality of care** provided by an individual, a team, or an organization. These criteria are explicit statements that define what is being measured and represent elements of care that can be

measured objectively (5).

Criteria can be classified in to three- *structure criteria, process criteria, outcome criteria (2).*

6.2.1.2.1 Structure criteria

Structure criteria refer to the resources required. They may include the numbers of **staff and skill mix, organizational arrangements, the provision of materials, drugs, equipment, and physical space** (2).

6.2.1.2.2 Process criteria

Process criteria refer to the **actions and decisions** taken by practitioners together with **users**. These actions may include **communication, assessment, education, investigations, prescribing, surgical**, and other **therapeutic interventions, evaluation, and documentation** (2).

6.2.1.2.3 Outcome criteria

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, a proxy, or intermediate outcome criteria are used instead. These relate to aspects of care that are closely linked to eventual outcomes but are more easily measured (2).12

6.2.1.3 Developing valid criteria

Once a topic has been chosen, appropriate criteria that are explicit, evidence-based, measurable, and related to important aspects of care must be developed (2).

Methods for developing criteria

1. **Using guidelines:** criteria can easily be drawn out from recommendations of up-to-date clinical practice guidelines. A literature search of the specific journal can also be used to develop criteria when national or locally endorsed guidelines are unavailable (2).
2. **Prioritizing the evidence method**: start by conducting systematic

reviews to identify key elements of care. Then carry out focused systematic literature reviews about each key element of care to develop, when it is justified by evidence, one or more criteria for each element of care. This is followed by prioritization of the criteria into 'must do' or 'should do' based on the strength of research evidence and impact on outcome. Present the criteria in a protocol including data collection forms, and instructions to external peer review (2).

3. **RAND/UCLA appropriateness method:** The method applies presenting findings of a literature review to a panel of clinicians, chosen for their clinical expertise and professional influence, who are asked to rate the appropriateness of a set of possible criteria for the particular procedure on a 9-point scale from 1 (extremely inappropriate) to 9 (extremely appropriate). The first round of ratings is undertaken without allowing any discussion between the panelists, and a second-round is undertaken after a structured panel meeting (2).
4. **Criteria based on professional consensus:** criteria can also be developed based on the views of professional groups, applying methods of formal consensus. However, different consensus groups are likely to produce different criteria. A checklist is useful to ensure that an explicit process is used to identify, select, and combine the evidence for the criteria and that the strength of the evidence is assessed in some way. Such criteria have the advantage of taking local factors such as the concerns of local users into account (2).
5. **Involving users:** Service users can also become usefully involved in developing criteria that take account of the needs of people with their particular condition, from specific age groups, or ethnic or social backgrounds. Audit teams can collaborate with users to establish their experience of the service and the important elements of care from which criteria can be developed. If the criteria selected by clinicians and those

selected by users relate to different elements of care, both sets of criteria may be included. If clinicians and users have different views about the same element of care, an open approach is required to achieve consensus (2).

While developing standards or criteria it should be noted that the criteria/ standards should be in line with the SMART protocol. Each criterion should be clear, easy to understand (un- ambiguous), specific (not open to interpretation). They also should be measurable- feasible 13

to attain the data for, achievable- of a level of acceptable performance agreed with stakeholder, Relevant (related to important aspects of care), and theoretically sound (evidence-based). Acceptable evidence-based guidelines that are going to be used to formulate the criteria should be identified ahead.

6.2.2 Setting target

Audit criteria should consist of quantifiable performance levels. These performance levels or targets: a defined level or degree of expected compliance with the audit criterion may be expressed as percentages (**0% to 100%**). **Clinical importance, practicability, and acceptability** should be taken into account and assessed when **setting targets**. Where a criterion is **critical to the safety of service users**, targets may be **set at 100%.** However, where clinical importance is **not as significant**, **resources required to fulfill the target performance level** should be considered and an acceptable performance level (one which is seen as both reasonable and attainable by those delivering and receiving care) should be identified. Setting an ideal target also requires identifying the best possible care that lies between the minimally acceptable level of care and the highest possible level of care (3).

6.2.3 Inclusion criteria/exclusion criteria

To make the data collection purposeful and ascertain the representativeness of the target population, it is advised to set inclusion and exclusion criteria. Inclusion criteria are statements describing the "target population to whom a clinical guideline is intended to apply", While exclusion criteria are used to "Define areas outside the remit of the clinical guideline" (3).

6.2.4 Exceptions

Refers to a group of cases **within the target population** for which the **criterion is not applicable**. There will be acceptable circumstances in which the identified sample may not comply with a specific criterion. These samples will not be included in the data analysis for that specific criterion. It should be noted that an agreement should be reached on exception before the audit commence (3).

6.3 Measuring Performance against Standards

This stage has the following **four steps**: ***data collection, data analysis, drawing conclusions, and presentation of results (3)***. 14

6.3.1 Data Collection

This is the collection of relevant data about the current practice to facilitate comparison. Before data collection commences, a structured approach should be taken to the identification of relevant data and to ensuring that the data collection process is efficient, effective, and accurate. Details that need to be established from the outset include, the user group to be included, inclusion/exclusion criteria, the consent required to access user group information, the healthcare professionals involved in the service user's care, the period over which the criteria apply, the analysis to be performed (2).

The type of data required 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. **Data types** can be of **categorical (nominal/ordinal) and quantitative or numerical (discrete/continuous)** (3).

6.3.1.1 Data items

Data collected must be relevant to the aims and objectives of the audit. It is equally important that each data item is adequate and not excessive for the purpose of measurement of practice against the relevant audit criteria. Collection of data which is not required for the purposes of measurement provides little or no benefit, is more time consuming and may infringe compliance with information governance requirements and practices (3).

Points to be considered before data collection begins

- What type of data do I need to collect (quantitative and/or qualitative)?
- What data items will need to be used to show whether or not performance levels have been met for each standard?
- What data sources will be used to find the data?
- Will a data collection tool need to be designed?
- Will I need to collect data prospectively and/or retrospectively?
- What size is the target population and will I need to take a sample?
- How long will data be collected (manually and/or electronically)?
- How long will it take to collect the required amount of data?
- Who will be collecting the data?
- How will I ensure data quality?

Adapted from Ashmore, Ruthven and Hazelwood (2011b).

6.3.1.2 Sources of data

The source of data for an audit should be specified and agreed by the audit team. The source specified should provide the most accurate and complete data as readily as possible. As much as possible data that is relevant and routinely collected and can be found in existing sources should be used for auditing. In times where the data in question is not documented in existing source a method of tracing the data from other far reached sources can be attempted (3).

6.3.1.3 Data collection methods:

Can be retrospective/ cross sectional / prospective. Retrospective data is collected after the completion of care to the service use while prospective data is collected in real time during the care provision (3).

Sample selection methods

More often than **not clinical audits** involve the **technique of sampling** as it is **not necessary or even feasible** to take data on **all target population** identified. One major factor that should be taken in to account when sampling is that, the sample should be representative of the target population. There are various methods of sampling but the commonly used are **random sampling and convenience sampling** (3).

- **Random sampling** is a **simple method** of sampling where service users are selected randomly for instance every **3rd, 6th case seen** (3).
- **Convenience sampling** uses the approach of selecting the **nearest** and most **convenient persons** to act as respondents; it therefore does not produce findings that can be taken to be representative (3)

Sample size

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** (2).

6.3.2 Data analysis Step

Data collection is only part of the process of measuring performance, in order to compare actual practice and performance against the agreed standards, the clinical audit data must be collated and analyzed.

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 (3).

The basic requirement of an audit is to identify whether or not performance levels have been reached. This requires working out the percentage of cases that have met each audit criterion. In order to calculate the percentage, it is necessary to identify both the total number of applicable cases for a criterion (the denominator) and the total number within the denominator group that met the criterion (the numerator) (3).

6.3.3 Drawing conclusions

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. Individual cases where care is not consistent with criteria should be reviewed to find any cases which may still represent acceptable care. 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 (3).

There must be a clear understanding of the reasons why performance levels are not being reached to enable development of appropriate and effective solutions. There are a number of tools that can be utilized to facilitate a root cause analysis, including process mapping, the 'five whys', and cause and effect diagrams (fishbone diagramming) (2, 3).

6.3.4 Presentation of 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. There are various methods for the presentation of clinical audit results including visual presentations, for example, posters which are useful ways of reaching as many stakeholders as possible. Data can also be presented visually using tables, charts and graphs in both written and verbal presentations (for example, through using presentation software like Microsoft PowerPoint), Written reports (Annex 4: Audit finding reporting template) for submission to the relevant clinical lead, directorate or governance committee and Verbal presentations at relevant meetings (3).17

6.3.5 AUDIT METHODOLOGY FOR SELECTED NATIONAL DISEASE PRIORITIES

The description below illustrates the methodology that should be followed while auditing the selected topics in a hospital setup. The hospital clinical audit tools are designed for selected priority topics within a thematic area. The sub-teams tasked with the development were guided to use a prioritization matrix for the topic selection process. The audit tools were developed through successive consultative workshops involving experts with subject matter knowledge and programmatic experience in selected topic areas. Where available, the developing committee attempted to find and stick to the latest version of national guidelines while synthesizing the criteria, as these guidelines dictate the service provision in a hospital setup. International guidelines targeting low and middle-income countries (LMICs) are utilized where it was difficult to find national or local recommendations.

The audit tools are structured in a way that can make the audit process easy. An audit tool for a specific topic includes the general aim of the audit- "to improve

the quality of clinical care on that specific topic", which is further broken down into multiple objectives covering the steps in the clinical care process. "Aim" and "objectives" will create a uniform understanding among the audit team as to why the audit is being conducted. Following these, "inclusion" and "exclusion" criteria, which the auditors will use to determine the study populations from the source population, are identified. The instruction section that outlines additional points the audit team should follow is also described.

The "**Standards**" -are labeled in a light green color and describe and assess the critical clinical steps a client passes through, from evaluation to treatment to monitoring to counseling and discharge at the point of care. "Criteria" which quantify a specific standard are listed under each standard.

Some of these criteria will have "sub-elements"-which quantify the criterion under which they are listed. These "sub-elements" are shaded in blue and are requirements for fulfillment of a criterion.

The **last standard** (which is found at the bottom of the audit tools) is an **outcome standard** that measures the result of the clinical care. It is found in most audit topics, **except** those without an **immediate outcome** (ANC, postnatal care, CAC, initial care aspects of DM, HTN, Asthma, TB and HIV/AIDS and HEI).

Each outcome and process standard is followed by a target, which denotes the expected level of performance. These targets, expressed in percentage), serve as a reference point against which the actual performance is compared.**18**

6.3.5.1 Data collection methods

- The data collection source is mainly the client chart. Registry review may be appropriate when assessing some criteria in some audit topic areas like ENC, TB, and HIV/AIDS…). The specific data source the auditor must look for within a client chart or registry is identified in the data source section of the table.

- A **total of 19 medical records** (**client chart**) of the **last reporting quarter** should be **sampled** for the audit. The **individual client charts** can be withdrawn by **systematic random sampling** (**total number of cases seen in the last completed quarter divided by 19** will give the **"Nth value;"** take medical record number **(MRN)** of charts every **"Nth value"**).

- Use the **available client charts drawn** for the **last reporting quarter** as **100%** even if the number of client charts found for the reporting quarter **is less than 19.**

- For **follow-up care audit topics**, **unless specified** on the standard/criterion, assess the care provided during the **three-month period**. For instance, if the patient had **three visits in the quarter**, assess the care provided during **all three visits**. If a time period is specified on the standard or criterion, assess the care provided during the specified time period.

- Use the data abstraction tool and identify the data element for the audit.

- To verify whether a criterion, a sub-element, or an outcome standard is met or not, look for the data element in the specified data source and confirm whether the step is completed or not.

- Absence of documentation is taken as the service was not provided.

- **On multiple occasions**, triangulation of data from multiple data sources is needed to make verification that the step stated in the criterion or a sub-element is fulfilled. The descriptions provided in the data source section of the table indicate which data to triangulate and which data sources to look for in the patient chart or registry. If the triangulations reveal inconsistencies the **criterion or a sub-element** will be considered **unmet and will be scored "NO" and "0" respectively**.

- To ease the burden on the auditing team, for audit topics with monitoring components of **admitted or kept patient care**, a review of a **couple of days'** data will be considered sufficient to assess the clinical care. The instruction section (top of the table) of the audit tools describes the **specific days** that will be reviewed during the audit.

- **Each standard will be scored from 100%.** The percentage will be calculated based on the number of criteria **met out of the expected**. For instance, the standard will be scored 100% if all criteria under it (excluding the NA) are fulfilled. It will be **scored 50%** if two of the criteria out of the four are fulfilled and it will be scored 75% if three out of four criteria are met.

- The **outcome standard**, which is the last standard within the audit tools assessing the result of the clinical care, will be scored "**YES" or "NO**". N.B. some audit topics do not have an outcome standard (ANC, postnatal care, CAC, initial care aspects of DM, HTN, Asthma, TB and HIV/AIDS and HEI).

- In the soft copy version of the audit tools, the score for a standard per chart is automatically calculated. If the audit team is using a hard copy, they need to determine the score for a standard using the above explained method.

- If all requirements for a criterion are met, score "YES", if any requirement is unmet score "NO", If the criterion does not apply for the specific patient, record it as NA (not applicable).

- For a criterion that has sub-elements under it, give "1" if the sub-element is fulfilled, and give "0" if it is not fulfilled or give NA if it does not apply for the particular patient. **The criterion will be scored "YES" if all sub-elements (excluding the NAs) are scored "1"** otherwise it will be **scored "NO"**

- Use the remark section to document any additional information or reminders during data collection.

Peculiarities

The audit tool for malaria should be utilized in areas where malaria is endemic. If the audit team was not able to find a single case of admission due to malaria during the audit period, they can skip the audit for malaria.

On **adult health and child health themes**, when conducting the audit on **pneumonia**, the **target population** is the patients who have been admitted and cared for in the **ED initially** and **then transferred to the inpatient ward**. The **upper section** of the audit tools assesses the **immediate care** that should be provided in the ED, while the **latter focuses** on the **follow-up care** that is provided in the **inpatient department**.

On the adult health section, when auditing the topic **TB follow-up care**, the audit team should review the care provided for the patient starting from the **end of the second month till end of six month**. The patient is expected to be evaluated **weekly by the provider** in this phase.

An audit on **TB follow-up care** should be conducted if the facility provides a follow-up service for TB patients. If the facility doses not have a follow-up service for TB patients, this section can be **skipped. N.B. this does not include the audit on TB initial care**. The audit on **TB initial care** should be done by **all hospitals.**

Whenever there is a description next to a criterion or standard, the auditor must give attention to the description and score the criterion or standard accordingly. For instance, whenever the auditor comes across a description saying "only for primary hospitals" it means that criterion or standard only applies to primary hospital context; the criterion or standard will be scored "NA" for General and tertiary hospitals.

When analyzing clinical audit findings and designing QI projects on emergency topics (**Poisoning, Burn, and Trauma**), the audit team should keep the **national target for emergency room mortality in mind** (which **is 0.2%).** In addition to comparing the score of the outcome standard for each topic with the outcome target, the audit team should also calculate the **aggregate ER mortality rate of the hospital** from all **emergency causes and identify the degree of contribution of the three causes toward the aggregate mortality rate.** The audit team can then design QI projects with interventions that can help decrease the **total emergency mortality rate** by focusing on the **three causes.** This ideology is based on the fact that, in an emergency room, the initial components of the care for most cases are similar and interrelated. Therefore, having a holistic view of the care provided in ED is crucial to improve the overall outcome.21

6.3.5.2 Data Analysis

- Each process standard will be scored from 100%. The percentage will be calculated based on the number of criteria met out of the expected. For instance, the standard will be scored 100% if all criteria under it (excluding the NA) are fulfilled. It will be scored 50% if two of the criteria out of the four are fulfilled.

- Once the score of the standard for each chart is determined, calculate the actual performance (**average score**) of the 19 charts or total number of charts audited. This is calculated by adding the score of the standard for **each chart** and dividing it by 19 or total number of charts audited. Again, in the soft copy version of the audit tools the score is calculated automatically. When using the hardcopy version, one has to calculate the score manually.
- Compute the difference between the performance (**average score**) and target in terms of **percentage**. This is calculated as (**100%*actual**

performance)/Target.

- Calculate the **average score** for the outcome standard by dividing the number of charts that are **scored 'YES'** to the total number of charts audited, if the outcome standard is in the form of positive statement or by dividing the number of charts that are **scored 'NO'** to the total number of charts audited, if it is stated in negative form. N.B some topic areas do not have an outcome standard.

- The **"total"** at the bottom of the table on the X-axis denotes the total number of process standards met per chart. N.B. The outcome standard should not be included in this count. Calculate the percentage on the X-axis for a single chart by counting the number of process standards that are met (meaning achieving the target) by a single chart divided by the number of process standards expected to be met by a single chart (excluding the outcome standard). A standard is considered met when the chart scores a point that is equal or above the target set for the standard.

- The **general average** (of the all-reviewed charts) on far right of the X-axis can be computed by the summing average score of each chart and dividing it by the number of charts audited.

- In the soft copy version of the audit tools, each of the above discussed scores are calculated automatically (the excel sheet generates the results automatically). When using the hardcopy version, one has to calculate the scores manually using the method described above.

6.3.5.3 Drawing conclusion

- Identify the standards on which there is significant difference between set target and actual performance. These are the areas which need to be addressed first.

- Do problem analysis using five whys and fishbone analysis and other tools.

- Identify the root cause of the gap.
- When the difference between the performance and set target continues to be more than 100%, it indicates that a revision of the set target is needed.

6.3.5.4 Presentation of results and writing report

- Present the findings to staff and relevant stakeholders.
- Write a report (Annex 4: Audit finding reporting template) and submit it to the responsible body (facility manager, case team leaders, process owner, QI unit, etc.)
- Regular summary clinical audit reports, together with recommendations, should be communicated to all relevant areas of the organization. An effective audit carried out in one area of the institution may be transferable to other parts of the organization. Once a round of data collection has been completed and the data has been analyzed, the results and findings should be presented at **quality meetings**, for **discussion, agreement of interventions**, and a **commitment** to complete another audit cycle within a designated timeframe. The **quality committee** will review all summary clinical audit reports on completion.

6.4 Making improvements

The ultimate goal of conducting clinical audits is, understanding the degree to which care provided comply with the expected level of care and identify poor areas of performance to make improvements in those areas (

Data analysis and interpretation, which lead to a conclusion, will answer the question of degree of compliance, thereby pointing to areas of excellence and areas of poor performance. QIT should interpret the data and discuss the findings to identify areas of poor performance that need improvement action (3).

After a thorough analysis of **root causes** the next step is to come up with possible changes or recommendations that can address the areas which need improvement. The audit team is expected to develop such changes and these should be presented to all relevant stakeholders where a thorough discussion regarding the feasibility, urgency, impact on clinical care and service users, and resource implication of proposed changes can be made to decide on priority actions. These change ideas must be documented and tested using the principles of quality improvement to identify which ones are actually linked to improvement. A detailed quality improvement plan on how the priority changes will be tested should be **devised** (**P part of PDSA**). The quality improvement plan should include a detailed task for each prioritized change ideas, assigned responsible persons, a reasonable time scale for completing the tasks along with how and when progress will be measured (3). Once proposed changes are put in place, their **implementation progress** should be monitored regularly to ensure they are being implemented as agreed plan and time frame (**D part of PDSA)**. The responsible bodies that are identified in the quality improvement plan will be accountable for the execution of the changes in accord with the plan. The progress made in the implementation, the difficulties faced and actions taken to address them should be studied, documented and reported in a summarized form to the appropriate body regularly (**S part of PDSA**). Developing or identifying a small number of indicators to monitor the status of implementation and improvements made would make the tracking effective and help identify difficulties early. The audit team will run **multiple small scale PDSA cycles** for each of the prioritized change ideas and decides based on the findings of the cycles to adapt, adopt or abandon **(A part of PDSA).**

6.5 Sustaining the improvement

The change ideas that have brought on the desired improvement will be incorporated to the system. A new way of doing things is identified and these ways should be standardized while removing the old methodologies. To make sure whether these changes have affected the other parts of the clinical process, a second audit or re-audit will be conducted making the process continuous. This cycle is repeated until the desired performance is achieved in the overall clinical process for the specific topic.

Once the desired level of performance is achieved, targets can be revised (if set for less than 100%), and the audit process will continue to meet the new targets, or the QIT can devise audit standards and criteria that are more advanced or prioritize other audit topics, develop standards and criteria and continue with the process of clinical audit and improvement.

It is important to note that documenting and disseminating successful audits is part of sustaining improvement. The **QI unit** together with the **QIT** should document audits that have brought on improvement and share it with all stakeholders. Using the existing learning platforms, the knowledge obtained should be communicated to other departments and units within and outside the institution (3).

7. AUDIT MONITORING PROCESS

The recommended time to complete a clinical audit is three months, but this might depend on the problems the audit team prioritized to address in one cycle. The audit team should assign an estimated time of completion of the project at the beginning of the audit. The audit team should notify the QI unit if a need for extension arises during the implementation of the clinical audit project and this

should be with sufficient justification (5).

Three phases along with an estimated period are identified to help track the status of the audit and make the monitoring easy.

- **Phase 1**- comprises ***team establishment***, ***planning*** the delivery of audit, and ***data collection***. The estimated time is **two weeks.**
- **Phase 2-** comprises ***data analysis*** and ***interpretation***, ***problem prioritization, root cause analysis, drawing a conclusion, developing change ideas, presentation of findings,*** and ***writing reports***. The estimated time is **three weeks.**
- **Phase 3**- comprises ***designing*** and ***implementing QI projects***, including ***testing change ideas (PDSA***) for each **prioritized problem**. The remaining period from the estimated date of completion will be used **for this phase**. It is best to complete the phase-in seven weeks period.

Reaudit will be conducted at the **end of the clinical audit project** (ideally **three months** but could be more depending on the **length of QI project implementation).**

7.1 Audit status indicator definition

- **On track**- project is progressing according to schedule
- **Delayed**- project is running but falls behind schedule
- **Completed**- each phase is completed according to the schedule
- **Abandoned**- the project is not completed within the initial estimated period or the extension period allowed.

8. ROLES AND RESPONSIBILITIES

8.1 Health facility

- Establish audit teams/QIT
- Monitor the implementation of audits regularly
- Integrate clinical audit as a regular activity
- Ensure change is achieved as per the action plan
- Ensure capacity building of their respective staff
- Ensure availability of guidelines, protocols, and audit tools to service delivery unit

8.2 Healthcare Providers

- Involve actively in clinical audit
- Perform regular audit with the audit team
- Recording and documentation of audit
- Identify topics for clinical audit
- maintain client privacy and confidentiality

8.3 Quality Improvement team

- Plan for clinical audit
- Support the quality unit in the coordination of clinical audit
- Ensure the audit guideline is implemented
- Undertake analysis, interpretation of clinical audit
- Design the implementation of change as per the audit finding (support linkage of audit activity with quality improvement activity)
- Ensure clinical audit is implemented by a multidisciplinary team
- Ensure presentation (dissemination) of clinical audit finding
- Monitor and evaluate the performance of clinical audit

8.4 Quality unit/directorate

- Support clinical audit team in planning clinical audit
- Support clinical audit team in the coordination of clinical audit and support for overall quality improvement
- **Makes approval of audit projects**
- Register clinical audit projects and follow the execution as per the schedule
- Facilitate in the dissemination of audit findings using different platform
- Coordinate in analysis, interpretation of clinical audit
- support the implementation of change as per the audit finding (support linkage of audit activity with quality improvement activity)
- Facilitate clinical audit to be implemented by a multidisciplinary team
- Support in monitoring and evaluating clinical audit performance

GENERAL RULES

CLINICAL AUDIT AND QUALITY IMPROVEMENT TEAM STRUCTURE

Leadership:

- **Departments/Case Teams with Specialists:** The most senior specialist shall be the Clinical Audit/Quality Improvement (QI) team leader.
- **Departments/Case Teams without Specialists:** The most senior member shall be the Clinical Audit/QI team leader.

Secretariat:

- The department/case team head shall be served as the team secretary.
- In their absence, a designated representative chosen by the head shall be serve as the secretary.

Team Participation:

- The clinical audit team member of each case team shall be automatically the member of any quality improvement projects undertaken by their respective team/department

CLINICAL AUDIT FREQUENCY

- All clinical departments shall be conducting the clinical audit **quarterly**
- The audit frequency can be modified by the hospital quality improvement Committee depending on the overall facility audit findings of the same period.

REVIEW AND AMENDMENTS OF TERMS OF REFERENCES

- Any section or part of the TOR is subject to change at any time based on the decision or recommendation of Quality Committee or Senior Management Team.

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2. Federal Ministry of Health. National Quality strategy 2016-2020.
3. NICE. Principles for Best Practice in Clinical Audit. Oxford, Radcliffe Medical Press, 2002.
4. Quality & Patient Safety Directorate Dr. Steevens Hospital Dublin (2013). A Practical Guide to Clinical Audit.
5. Royal College of Nursing (1990) Quality Patient Care: The dynamic standard setting system. Harrow: Scutari Press.
6. Lincolnshire Community Health Services NHS Trust. Clinical Audit Policy and Procedures 2018-2021.

APPENDIX: DGH DEPARTMENT LEVEL CLINICAL AUDIT TEAM ESTABLISHEMENT

GYN/OBS DEPARTMENT CLINICAL AUDIT TEAM MEMBERS:

S/N	Full Name	Status/position	Role	Signature
1.	Dr.Taju Abdi (MD, Senior)	OR & GYNOBS Director	D/chairperson	
2.	Dr.Anwar Sham (MD, Senior)	Staff	Member	
3.	Addisu Wondimu	Staff	Secretory	
4.	Abdella Mohammed	Staff	D/Secretory	
5.	Maruf Abdisha	Staff	Member	
6.	Alfiya abdella	Staff	Member	
7.	Tsion Tolesa	Staff	Member	
8.	Getahun Beleta	Staff	Member	
9.	Naima Abdo	Staff	Member	
10.	Shukriya Hassen	Staff	Member	
11.	Hanan Abduselam	Staff	Member	
12.	Safiya Amin	Staff	Member	
13.	Hanan Mamud	Staff	Member	
14.	Wazira Mohammed	Staff	Member	
15.	Tuji Dawud	Staff	Member	
16.	Dine Ahmed	Staff	Member	

EOPD CASE TEAM CLINICAL AUDIT TEAM MEMBERS:

S/N	Full Name	Status	Role	Signature
1.	Dr. Samuel Shimelis	Emergency Director	Chairperson	
2.	Jabir Mohammed	Emergency Head	Secretary	
3.	Bayan Shafi	Staff	Member	
4.	Laliftu Abdurhman	Staff	Member	
5.	Zabib Abrahim	Staff	Member	
6.	Alamudin Sufiyan	Staff	Member	
7.	Yosef Tesfaye	Staff	Member	
8.	Mohamed Sakin	Staff	Member	
9.				

ICU CASE TEAM CLINICAL AUDIT TEAM MEMBERS:

S/N	Full Name	Status	Role	Signature
1.	Dr. Dawit Seifu	Impatient Director	Chairperson	
2.	Numeyri Badru	Adult ICU Head	Secretary	
3.	Lencho Jabir	Staff	Deputy Secretary	
4.	Kadir Yusuf	Staff	Member	
5.	Jabir m/d Abrahim	Staff	Member	
6.	Mebratu Debru	Staff	Member	
7.	Mohamed Ahmednur	Staff	Member	
8.	Bayan Mohammednur	Staff	Member	
9.	Murad Amin	Staff	Member	

MEDICAL WARD CASE TEAM CLINICAL AUDIT TEAM MEMBERS:

S/N	Full Name	Status	Role	Signature
1.	Dr.Dawit Seifu	Inpatient Director	Chairperson	
2.	Dr.Rastem Abdella	Ward Head	Secretary	
3.	Moheemed Abdella	Staff	Member	
4.	Ibsa Abrahim	Staff	Member	
5.	Shame Ahmed	Staff	Member	
6.	Buzu Siyum	Staff	Member	
7.	Muluqan Tasfaye	Staff	Member	
8.	Kadir Yusuf	Staff	Member	
9.				
10.				
11.				
12.				

NICU CLINICAL AUDIT TEAM MEMBERS:

S/N	Full Name	Status	Role	Signature
1.	Dr. Taju Abdi (MD, Senior)	Team Coordinator	Chairperson	
2.	Ismael Abrahim	NICU Head	Secretary	
3.	Abdurhaman Bakri	Staff	Deputy Secretary	
4.	Mikael Aliyi	Staff	Member	
5.	Maserat Megarsa	Staff	Member	
6.	Abdi Bakar	Staff	Member	
7.	Derartu Abdulaziz	Staff	Member	
8.				
9.				
10.				
11.				
12.				

OPD CLINICAL AUDIT TEAM MEMBERS:

S/N	Full Name	Status	Role	Signature
1.	Dr.Bahar Abdi (MD)	OPD Director	Chairperson	
2.	Chala Abdusemad	OPD Coordinator	Secretary	
3.	Midhaga Badru	OPD2 f/p	D/ Secretary	
4.	Dr.Gutu	OPD1	Member	
5.	Dr.Frezar	OPD2	Member	
6.	Iliyas Ahmed Umer	OPD3 f/p	Member	
7.	Abdi Aliyi	Pedi OPD f/p	Member	
8.	Farahan Johar	Surgical OPD f/p	Member	
9.	Faiza Sufiyan	Gyn OPD f/p		
10.	Yonis Seifudin	Outpatient Pharmacy f/p	Member	
11.	Amire lab	Outpatient lab f/p	Member	
12.	Balisa	Outpatient Radio f/p	Member	
13.	Kedir	Ophthalmology Clinic head	Member	
14.	Arafat	Psychiatric Clinic head	Member	
15.	Wubeshet	Dental Clinic head	Member	
16.	Iftu Sani	ART Clinic head		
17.	Jafer Dine	TB clinic head		
18.	Balisa Seyfudin	Health literacy unit f/p		

PEDI WARD CASE TEAM CASE TEAM CLINICAL AUDIT TEAM MEMBERS

S/N	Full Name	Status	Role	Signature
1.	Dr.Dawit Seifu	Inpatient Director	Chairperson	
2.	Dr.Tsegaye	Ward physician MD	D/Chairperson	
3.	Mohamed Aliyi	Pedi Ward Head	Secretary	
4.	Calaa Abrahim	Staff	Member	
5.	Sabit Mohamed	Staff	Member	
6.	Nujoma Dine	Staff	Member	
7.	Jabir Mohammed	Staff	Member	
8.	Amir Adem	Staff	Member	

SURGICAL WARD CASE TEAM CLINICAL AUDIT TEAM MEMBERS

S/N	**Full Name**	**Status**	**Role**	**Signature**
	Dr. Isak Abdi (Senior)	Surgery dept coordinator	Chairperson	
	Kalifa Jamal	Surgical Ward Head	Secretary	
	Dr.Meron	Staff	Member	
	Endalkachew Mokonin	Staff	Member	
	Wardi Usman	Staff	Member	
	Wubishet Tamirat	Staff	Member	
	Fuad Abdella	Staff	Member	
	Nagash wogayo	Staff	Member	