ጤና ሚኒስቴር - ኢትዮጵያ
MINISTRY OF HEALTH - ETHIOPIA
የዜጎች ጤና ለሃገር ብልጽግና!

ETHIOPIAN HEALTH CENTER REFORM IMPLEMENTATION TRAINING PARTICIPANTS MANUAL.

January 20, 2021
Ministry of Health, Ethiopia
Addis Ababa, Ethiopia

Foreward

Ethiopia, a Sub-Sahran developing country with a population of more than 110 million has been implementing reforms in the health sector since 1991. Four successive Health Sector Development Strategies(HSDP) were implemented, primarily focusing on increasing physical access to health services. Following this the first health sector transformation plan was implemented with the main focus of quality improvement in health care which is also the main focus in the second HSTP. The Ethiopian Health Center Reform Implementation Guide(EHCRIG) has played a pivotal role in realizing the quality improvements efforts particularly in health centers.

The EHCRIG is intended to guide the health system strengthening endeavour of Ethiopia primarily focused on health centers. It guides the health centers leadership and management, transparent handling of health center revenue and expenditure, how to equip the health center with respect to laboratory, pharmacy, maternal & child health as well as other health service outlets. Its proper implementation will ensure the smooth functioning of the health centers at all times. The health center infrastructure including sewerage, CASH, electric power, water access and waste disposal needs are also clearly depicted in this implementation guide.

The Ethiopian Health reform centre implementation manual was started in 2008 EC taking the lessons learnt from the hospital reform implementation manual. Its implementation has resulted in the improvement of health centers readiness for quality health service provision throughout the country as it was possible to improve the average health center performance from the baseline of 40% to 75%.

The current revision of EHCRIG is intended to address the ever increasing demands in quality health service demands that has resulted in institution of new initiatives like EPHCG as well as expansion of the scope existing health services such as emergency obstetric surgical services and obstetric ultrasound.

It is my firm belief that all stake holders supporting health system strengthening among health centres will base their contributions according to this guide to ensure the success of our effort in realizing quality universal primary health care to all.

Dereje Duguma (MD,MPH)
State Minister, Ministry of Health,
Ethiopia

Acronyms

ABC	Classifying drugs into class A, B and C by cost
AIDS	Acquired Immuno-Deficiency Syndrome
ADR	Adverse drug reaction
BOF	Bureau of Finance
CBHI	Community Based Health Insurance
DACA	Drug Administration and Control Authority
DHIS	District Health Information Software
DRG	Diagnosis Related Group
DSM	Drug Supply Management
DTC	Drug and Therapeutics Committee
EC	Ethiopian Calendar
FAMU	Fixed Asset management Unit
FEFO	First expiry, First out
FHT	Family health team
FMHACA	Food, Medicine and Healthcare Administration Control Authority
HC	Health center
HEP	Health Extension Program
HEW	Health Extension Worker
HIV	Human Immune deficiency Virus
HMIS	Health Management Information System
HP	Health Post
HSDA	
HSTP	Health Sector Transformation Plan
GOFAMM	Government Owned Fixed Asset Management Manual
MOF	Ministry of Finance
MOH	Ministry of Health
MOU	Memorandum of Understanding
NACS	Nutrition Assessment and Counselling Service
NGO	Non-Governmental organization
PFSA	Pharmaceuticals Fund and Supply Agency
PHC	Primary Health Care
PHCU	Primary Health Care Unit
PMP	Patient medication profile card
RHB	Regional Health Bureau
SHI	Social Health Insurance
STGs	Standard Treatment Guidelines
TB	Tuberculosis
VEN	Prioritizing drugs as Vital, Essential and None (Less essential)
ZHD	Zonal Health Department

Acknowledgement

The Ministry of health extends its deepest gratitude for Transform PHC for the continuous and humble financial as well as technical support throughout the revision of this guideline. We also recognize the contribution of the expertise and perseverance demonstrated by the following experts:

Dr Zelalem Tadesse……MOH
Dr Wondossen Mengistie……MOH
Mr Meseret Wale…….MOH
Mr Kiflemariam Tsegaye…….MOH
Mr Aklog Getnet……..MOH
Ms Lydia Yohannes……MOH
Mrs Kibura Hassen……..MOH
Mr Kemeredin Shifa……ORHB
Mr Tebibu Solomon…….AARHB
Mr Megersa Abdella……MOH
S/r Meseret Feleke……..MOH
Mr Chala Tesfaye…….JSI/MOH
Mr Kasahun Sime…….JSI/MOH
Mr Woldemariam Hirpa……..JSI/MOH
Dr Mesele Damte……Transform PHCU
Dr Beruhtesfa Bekele……..L10K
Mr Desalew Emaway……..L10K
Mr Wondwossen Shiferaw…..Transform PHC

The ministry also extends its appreciation to the regional experts listed below who have participated in the finalization workshop of the guideline

Ashagre Gebeyehu……...ARHB
Dr Dawit Daniel……..…….SNNP RHB
Mr Selahadin Mohammed……ARHB
Mr Yared Hailu…….DDRHB
Ahmed Yasin…….SRHB

Table of Contents

List of Tables

List of Figures

Introduction to the Manual

The Ethiopian health center reform has been being implemented since 2008 EC. It has contributed in ensuring equitable access to quality health service throughout the country in the Health Sector Transformation Plan I(HSTP-I) implementation. Its implementation has resulted in the improvement of health centers readiness for quality health service provision throughout the country as it was possible to improve the average health center performance from the baseline of 40% to 75%. This was possible as the reform primarily focuses on addressing health center preparedness with regards to infrastructure and health system strengthening. Considering the ever expanding need in quality and breadth of health services as well as new initiatives including EPHCG it was necessary to revise the guideline.

The training of the health care workers and program managers was didactic lecture methodology using the guide and power point slides for each chapter. This approach had resulted in inconsistent quality of cascading trainings at lower levels. Considering the current training material requirements it was necessary to develop a training package that fulfills the minimum in-service training package.

Hence this training manual was produced as a tool to guide the training of health care providers and program managers at all levels in line with the required in-service training standards of Ministry of Health. This will enable trainees implement the program with clear understanding of the implications. The manual will have a participant manual, facilitator guide as well as power point slides for respective chapters. It will also include tools for facilitation of learning during the training.

The training package has the following competences:

- Analyze health center reform status
- Identify health center reform performance gaps
- Synthesize and recommend improvement strategies
- Provide technical support for health center reform
-

Course Syllabus

Course Description: This six days training course was prepared for all health care professionals working in health centers who are engaged in the monitoring, performance management and implementation of health center reform. The training will enable them to technically evaluate, design strategies and implement health center reform performance improvement programs.

Course Goal: To provide participants the knowledge, skill and attitude to technically analyse, evaluate, provide support and suggest improvement interventions in the reform performance of any health center.

Learning Objectives: By the end of this course participants will be able to:

- ✓ utilize effective leadership, governance and health care financing practice guidelines.
- ✓ support and monitor the linkage between health centers and health posts.
- ✓ to suggest optimal organization of various health services in the health center.
- ✓ explain optimal organization of maternal, newborn and child health services.
- ✓ analyze how a health center pharmacy service should be organized optimally.
- ✓ analyse the laboratory service requirements of a health center.
- ✓ program and lead infection prevention and control activities in a health center.
- ✓ analyse the health infrastructure and evaluate facility management.
- ✓ lead the medical equipment management activities in a health center.
- ✓ analyse tools and strategies for human resource management in a health center.
- ✓ use the steps and procedure of clinical governance, patient safety and quality improvement in implementing and monitoring at a health center level.
- ✓ support health information system reform in a health center.

Training /Learning Methods:

- illustrated lectures
- individual and group exercise
- individual reading
- guided practices to develop tools for planning
- Health center visit

Training Materials/aids:

- Flip chart, LCD projector
- Health center reform- participant and facilitator manual
- EHCRIG standards checklist
- Laptop, Markers, plasters, notebooks

Participant Selection criteria: Participants for this training should be health care professionals working in a health center, woreda health office, ZHD, RHB or MOH with a role in the health center reform program implementation at all levels.

Method of Evaluation:

Participant: Pre/post test

Progressive assessment

Course:

- Daily evaluation
- Daily facilitators meeting
- End of Course Evaluation

Certification:

Master TOT participants will be certified if s/he has at least good progressive assessment and post test score of 80% or more.

Participants for basic training will be certified if s/he has at least good progressive assessment and a post test score of 70%.

Trainer's selection criteria:

- Trained on Facilitation skills/Facilitated courses
- Trained on EHCRIG
- Involved in EHCRIG assessment or verification exercises

Course Venue: Accredited training centers with internet service, having at least three nearby health centers.

Course Duration: Six Days

Trainer Composition: 30 participants 4 trainers.

Course Schedule

Day1	Day2	Day3	Day4	Day5
Registration	Maternal and Child Health	Infection Prevention	Human Resources Management	Health center assessment(visit)
Welcome				
Introduction				
Pretest				
TEA BREAK				
Leadership and Governance	Pharmacy Services	Infection Prevention	Clinical Governance ..	Health center assessment(visit)
LUNCH				
Health Center Linkage	Pharmacy Services	Health Center Infrastructure	Clinical Governance ..	Presentation of assesment
TEA BREAK				
Patient Flow	Laboratory Services	Medical equipments	Health information System	Post test and Conclusion

Chapter one: Leadership, Governance and Health Care Financing

Chapter Description: This chapter explains the roles of health center governing board, health center director and health center management committee in exercising effective leadership and governance practices that enables in smooth function of the health center.

Primary Objective: By the end of the sessions you will be able to utilize effective leadership, governance and health care financing practice guidelines.

Enabling Objectives: By the end of the session you will be able to:

- Identify best leadership, governance and health care financing practice guideline
- Describe the procedures of establishing governing board and selecting health center medical director
- Describe the main roles and responsibilities of governing board
- Describe the main roles and responsibilities of health center director.
- Describe the functions of health center management committee.
- Describe health center finance and accounting practice.

Chapter outline

1.1. Introduction

The health policy of the Federal Democratic Republic of Ethiopia aims at increasing access to and coverage of health services and ensuring equity and improving the quality of healthcare. Primary health care, a key driver to achieving universal health coverage, needs to be strengthened through improvements in Health Center leadership and governance among others. Strong practices at health center level leads to effective and efficient Health services delivery which satisfies the evolving needs of the population served. To this effect, Health Center leaders require a unique set of skills to both manage their organization and liaise with external agencies and the local community. Health Center leaders must be able to lead their organizations through change, identifying and solving any challenges that arise.

Historically, public Health Center leadership and governance has been characterized by its inefficiency and lack of community ownership and lack of adequate resources, both financial and non-financial to address some of the pressing issues. To alleviate these leadership, governance and long-standing under-financing problems of the Health Centers, the Federal Government of Ethiopia through the Health Care and Financing Strategy, which was approved by the Council of Ministers in 1998 EC, has established the legislative framework for enhanced Health Center autonomy. The governing board is tasked to lead the process of strategy, planning and budget development exercises at the health center level.

1.2. Operational standards

1. The Health Centre Governing Body is established using clear and transparent systems and processes.
2. The Governing Board approves the Health Centre Head who is appointed/ nominated by the town, sub city or Woreda Health Office.
3. The Governing Board approves an annual and strategic plan for the Health Centre to achieve its goal of improving its community's health and welfare.
4. The Governing Board shall conduct its regular meetings with written minutes at least on quarterly basis.
5. The health centre Head is evaluated biannually, consistent with Regional Legislation to ensure he/she is meeting operational and strategic plans as established by the Board.
6. The health centre shall establish management committee and functioned as per the respective regional health service delivery and administration legal framework.
7. The Health Centre shall post service fee and exemptions using local language(s) in each departments and cash collection points.
8. The Health Centre has a procurement plan, approved by governing board.
9. The health center procurement process is according to regional HSAD.
10. The Health Centre Finance team shall submit reports on monthly basis to the health centre management committee.
11. The Health Centre shall be audited with third party on annual basis and submit report to governing board.

12. The Health Centre shall have a Memorandum of Understanding with Waiver Certificate Granting Authorities and CBHI schemes which provide details on the type of service and mode of payment.
13. The Health Centre shall facilitate reimbursement for waived and credit services.
14. There is a current Health Facility Financial Management manual which establishes all policies and procedures relating to financial management in the facility.

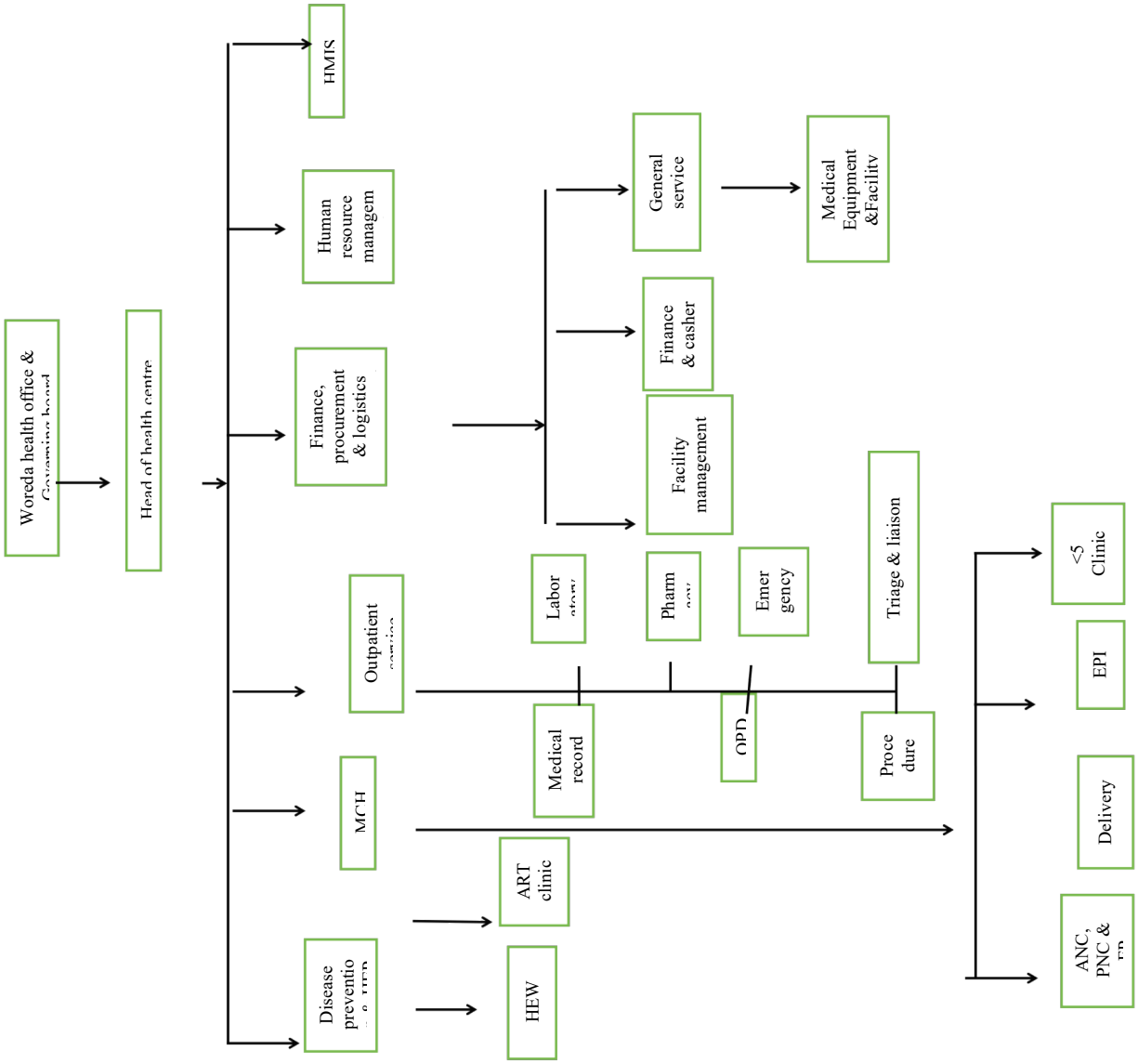


Figure 1.0.1 Organizational structure

Activity 1.1. Group discussion on Health Center governing body
 **Instruction:** • Be in group of 5-6 people • Discuss the below question in your group and report the work in the plenary (share group response to the larger groups using flipchart) **Discussion Question:** - **How is the GB established?** - **What should be its roles and responsibilities?** **Time:** 20 min for group work and 15 minutes for presentation

1.3. Implementation guidance

Guidance 1: Health Center Governing Body

A well-functioning Governing Body, that includes representatives from various public institutions, civil society organizations, neighbourhood community and Health Center's staff, can have a significant impact on the quality and efficiency of the Health Center and its daily performance. The establishment of a Governing Body builds in two essential characteristics of good Health Center: autonomy to do what is necessary to provide good care and accountability to those served for the results of that care.

Governing Body must be committed to creating and maintaining a strong bond between the Health Center and the community it serves and to maintaining a good working relationship with higher authorities such as Sub city, Woreda, Zonal, Regional and Federal Health, Finance and other relevant Government Offices.

The following sections set out the basic principles related to the establishment, responsibilities and operating mechanisms of Governing Board. *More detailed information on the specific powers and duties of Governing Body within each region are described in the Health Service Delivery and Administration Proclamations, Regulations and Directives of each Region*.

1. RESPONSIBILITIES OF GOVERNING BODY

Specific responsibilities of the Governing Body include:

A) Determine the organization's mission, vision and values

It is the Governing Body's responsibility to create and regularly review a statement of mission and vision that articulates the organization's goals and values to enhance the organization's public standing and garner support from the community.

A Mission statement can be defined as 'purpose, reason for being' or simply 'who we are and what we do'.

A Vision statement can be defined as 'an image of the future we seek to create'.

Sample Health Center Vision and Mission and Value Statements are given in Appendix A.

All strategies, plans and policies of the Health Center should be in accordance with the mission, vision and values set by the Governing Body and the Health Center Head.

B) Ensure corporate policies

The Governing Body should ensure the availability and implementation of corporate policies (such as policies for staff recruitment and retention, for income generation and expenditure, for quality assurance etc) the operations of the facility.

C) Ensure effective organizational planning

Governing Bodies must actively participate in an overall organizational planning process. This includes examining and approving the strategic and annual plans of the Health Center, and ensuring that such plans are in accordance with the mission, vision and values of the Health Center and are aligned with local, regional and national health sector priorities and targets.

D) Supervise the overall activities of the Health Center

Governing Body must monitor progress towards the goals and targets of the strategic and annual plans. If the Health Center is not on track to meet its stated plans, the Governing Body must identify the reasons why and should assist the Health Center Head and Health Center Management Committee to identify and implement solutions.

Further guidance on the role of the Governing Body to monitor Health Center performance, including a sample monitoring tool and indicators (the Balanced Scorecard) is presented in *Chapter 10 Quality Improvement and Performance Monitoring.*

E) Provide proper financial oversight

The Governing Body must review and approve the Health Center's annual budget, and implement proper financial controls to follow up on its utilization and ensure that the Health Center operates within its budget. This includes implementation of revenue retention and utilization as per the Sub city or Woreda Health Office financial rules and regulations. Additional responsibilities include ensuring that internal and external financial audits are carried out as required by legislation. The Governing Body should regularly review audit reports and ensure that action is taken on any recommendations made.

F) Ensure adequate resources

The Governing Body must identify what constitutes adequate resources for the organization and ensure the effective means to access these resources. Where necessary, the Body and staff must devise strategies and the means to improve revenues. Such mechanisms could include fee revision, private wing and outsourcing of activities.

G) Oversee fee waiver and exemption systems

Governing Body must ensure the provision of health services to fee waived patients without discrimination, and must ensure the provision of exempted services as described in the Regional financial rules and regulations. Governing Body must ensure the reimbursement of fee waiver expenses from the appropriate Fee Waiver Certificate issuing authorities.

H) **Oversee quality management activities**

The Governing Body must ensure that Health Center services are provided to the highest possible standard. The Governing Body should ensure that systems are in place for monitoring and evaluating the quality and outcome of patient care, customer services and use of resources. The Governing Body should ensure there are appropriate mechanisms and activities to minimize risk, to identify and correct problems, and to identify opportunities to improve patient care and services.

I) I) Approve the appointment of Health Center Head

Governing Body must ensure that the most qualified individual is appointed to the position of Health Center Head, following the processes set out in Sub city or Woreda Health Office Directives. The Health Center Head should be qualified by education and experience appropriate to the position. He/she must be capable of working with diverse groups, such as the Governing Body, various community groups, government officials and Health Center staff, clients/patients and families. He/she should be able to think strategically to provide vision and direction to the Health Center with special attention to professional development. An individual with an entrepreneurial spirit and who is fiscally responsible will be valuable to the organization. He/she should be a results-oriented leader with an eye for understanding how to improve patient quality of care.

J) Support, monitor, and assess the performance of the Health Center Head

The Governing Body should ensure that the performance of the Health Center Head is assessed at least quarterly. If the Health Center Head fails to meet the expectations of the Governing Body with concrete evidences, his/her position should be terminated, following the processes described by regional directives.

K) Provide orientation/training for new Body members and ensure ongoing education for existing members

All Governing Body should participate in ongoing education to assist members to carry out their role in the Health Center. For newly appointed Body members, there should be a planned orientation program that ensures members understand their responsibilities.

(Appendix B presents areas that should be included in a training/orientation programme for Governing Board members.)

L) Ensure legal and ethical integrity and maintain accountability

The Governing Body is responsible for ensuring adherence to legal standards and ethical norms. It ensures that activities of the Health Center are carried out with transparency and accountability and that all required reports are submitted to higher authorities (e.g. Sub city, RHB, BOFED, FMOH, and MOFED) in accordance with government requirements.

M) Ensure community involvement in Health Center service planning and delivery

The Governing Body should ensure that mechanisms are established to enhance the involvement of patients and the public in the planning and delivery of Health Center services and to maintain close consultation with community leadership. Conduct quarterly regular community forums to ensure the participation of the community in identifying challenges and improving quality of services.

N) Review effectiveness of its own performance

The Governing Body should annually and comprehensively evaluate its own performance. A self-assessment checklist for a Governing Body is presented in Appendix C.

2. MEMBERSHIP OF GOVERNING BODY

A) Appointment of Body Members

Rules and procedures for the appointment of Governing Body members are described within the Regional Proclamations, Regulations and Directives. Governing Body members should be residents of the area where the Health Center is established. Additional factors to be taken into consideration when appointing board members include:

- Due consideration to gender and professional mix;
- HP representative, Community and health centre staff representation;
- Professional efficiency, time and experience that will enable the body members to contribute to the improvement of the health sector

A strong Governing Body is comprised of members who:

- act on behalf of the community as a whole;
- are interested and committed to serve as a Body member;
- have a variety of expertise as a collective whole, including finance, administration, health, government bureaucracy;
- maintain high ethical principles, integrity and competence;
- deliver results while using resources wisely;
- give management the full authority to run the Health Center and do not “micro-manage” the Health Center leaders;
- commit the time required for meetings, dialogue, etc;
- subscribe to the principles of accountability for themselves and others;
- are participatory in planning, decision-making, and activities.

B) Tenure of Body membership

The tenure of service of Body members should be amenable to regional directives, and Body members may serve a maximum of two terms, as determined by regional and federal Directives.

C) Revocation of Body membership

The membership of any Body member should be revoked when:

a) The Body member has no interest to continue membership. In such circumstances the Body member should give advance notice as determined by health service deliver and administration (HSDA) Directives and in writing to the governing body Chairperson and Town, Sub-city and Woreda Health office Head.
b) The Body member changes residence address or leaves the office he/she represented;
c) In the case of people's or employees' representative if the Body member loses the faith of his/her constituency and a request is made by the constituency to replace him/her; or
d) The Body member has failed to fulfil the duties of his/her membership. This includes considerations such as:
    i. Repeated absence from Body meetings without sufficient reason
    ii. Proven corruption such as earning benefits in the health facility other than the legally permitted benefits or other corrupt practice
    iii. Repeated failure to follow up on actions agreed by the Body
    iv. Breach of confidentiality

In such cases, the Body should reach consensus that membership should be revoked and should make this recommendation to the Woreda, Town, sub-city Health office Head who will reach a final decision on the matter.

If a Body member leaves office during his/her period of tenure the remaining Body members should select one or more possible replacements and nominate the candidate(s) to the Woreda Health office Head to make the final appointment.

D) Duties and responsibilities of Governing Body members

Body members have a duty to:
a) Attend ordinary and extraordinary meetings, respecting the time;
b) Accept and implement a decision passed by the majority;
c) Prepare for each meeting by reading agendas, minutes of the previous meeting and other documents distributed for consideration;
d) Follow up on any actions agreed by the Body in a timely manner; and
e) Maintain confidentiality on all matters discussed by the Body.

E) Governing Body accountability

Body members have individual and joint responsibility for the decisions they pass and are responsible individually and jointly for any damage caused to the Health Center due to their failure to accomplish the duty entrusted to them. In the event a Governing Body member solely opposes a decision or an agenda for discussion, he/she may explain the reason for his/her unique opposition and make it noted on the minutes. He/she shall not be responsible for any damage occurred due to this decision or agenda item.
Governing Bodies are accountable to their respective Woreda, Town, sub-city, special zone as appropriate and should meet all expectations that the places on the Governing Body.

F) Allowance for Body members

allowances for the governing body chairperson and members should be provided as established by the regional directives.

3. ROLES OF THE CHAIRPERSON OF A GOVERNING BODY

The Governing Body should be led by a chairperson, who is appointed by the ZHD or RHB from among the Body members.
The main responsibilities of the chairperson are to:

A) Preside over the Body

The Chairperson should chair Body meetings and direct the overall functioning of the Body. The Chairperson should take the lead in clarifying the goals of the Governing Body. This helps to build a cohesive group and clarify expectations, while focusing the Governing Body's attention to the connection between its own performance and the success of the Health Center.

B) Convene and facilitate Body meetings and set meeting agendas

The chairperson should ensure that regular governing body Meetings take place in compliance with the periods prescribed in region, City administration and Federal Directives and should convene extraordinary meetings in compliance with these Directives. The Chairperson must ensure that meetings are conducted in a professional manner and are constructive for both the Health Center and the individual Governing Body members. The Chairperson therefore must oversee the development of a well-thought out agenda and supporting materials. The agenda should be a collaborative effort with the Health Center Head. The Chairperson should expect members to arrive at meetings fully prepared to participate in Governing Body meetings. It is important that the Chairperson knows how to clarify, summarize and move Governing Body members to a decision, as well as set aside some time at the end of the meeting for feedback on how the meeting went.

In addition to the above, an effective Chairperson will:

1. Understand the organization
2. Know his/her own responsibilities and authority as Chairperson
3. Create a safe environment for decision making
4. Build good working culture
5. Cultivate future leadership
6. Communicate with the Governing Body through an effective information system
7. Maintain a productive relationship with the Manger and the appropriate government body

4. ROLES OF THE SECRETARY OF THE GOVERNING BODY

The Secretary of the Governing Body is appointed from among Body members. This position could be filled by the Health Center Head.
Perform the following duties;

- The Secretary is responsible for taking minutes of Body meetings. Minutes should be reviewed and approved by the Chairperson before distribution to Body members
- Set agenda with the chairperson and distribute reasonable time ahead of the body meeting.
- Serve as a link between the health center staff and governing body.

5. PROCEDURES OF GOVERNING BODY MEETINGS

The main purpose of Governing Body meetings is to ensure effective governance of the Health Center. This includes developing, debating and approving strategic and annual plans, monitoring implementation, discussing and approving corporate policies and addressing any legal and ethical issues that arise. The Body meetings are also an opportunity to provide structured education sessions for Body members on emerging issues concerning the Health Center and/or the community it serves.

(NB: General guidance/etiquette to ensure that any type of committee or meetings function effectively are presented in Appendix 1D.)

A) Frequency of Governing Body meetings

It is recommended that during the first year of establishment the Governing Body meets once every month to become familiar with its own responsibilities, with the Health Center and the health sector in general. Thereafter the Body should develop a schedule whereby the Body meets no less than the frequency set out in RHB Directives. Extra-ordinary meetings may be convened should a matter of particular importance arise. Such meetings will be convened upon the decision of the Chairperson, or if called for by a minimum of one-third of Body members.

B) Agenda items

The agenda should be set jointly by the Body Chairperson and Health Center Head. All Body members should be invited to nominate agenda items for consideration. The agendas and any documents for discussion at the meeting should be distributed to Body members at least one week in advance of the meeting.

The following should be regular standing items on each and every agenda of the Body:

a) Approval of previous meeting minutes;
b) Governing Body reports;
c) Head's report – providing an overview of Health Center operations, discussion of pressing issues and immediate concerns;
d) Old business – issues unresolved from last meeting;
e) New business – any issues the Body members want to raise; and
f) Next steps – plans for taking action on decisions reached by the Body, with the assignment of follow up responsibilities to individuals as appropriate.

C) Decision making

Decisions by the Body should be made by majority vote. In the case of a tie the Chairperson has the deciding vote. Voting may only take place when a full quorum of Body members is present. A vote passed by less than a full quorum is invalid. The criteria for a full quorum vary from Region to Region (from 50% + 1 of Board members to 2/3rd of Board members).

6. GOVERNING BODY STANDING COMMITTEES

The Governing Body should assign standing committees on a temporary or permanent basis as the need arises to carry out specific functions (for example: Strategic planning committee, quality assurance committee or a committee to address an emerging clinical matter) of the body and report on their activities to the full Body. Regarding the assignment of standing committees as described in the RHB Directives.

When selecting members for each body the following principles should be followed:

a) The Governing Body members should be selected from the current Body members
b) Selection should be transparent and fair, without favouritism of any kind
c) The Governing Body should have chairperson and secretary.

Box 1.0.1: The Seven deadly signs of Poor Health Centre Governance

1. Lack of mission, vision, strategies and community participation/involvement.
2. Resisting change and failure to make strategic investments
3. Making do with irrelevant, useless information
4. Lack of health centre body and management alignment
5. Appointing unqualified or ineffective leaders
6. Failure to spend meeting time on strategic priorities
7. Inability to understand or relate to staff

Activity 1.2. Reflection on Health center Head roles and responsibilities	
	**Instruction:** **Take 2 minutes and write down how a health center head should be selected and reflect in the general discussion** **Time:** 2 minutes for writeup and 5 minutes for discussion

Guidance 2: Health Center Head

Each Health Center should be managed by the Head, who is appointed and approved by the Governing Body. A qualified Health Center Head should have a diverse set of leadership and management skills, as well as considerable healthcare/Health Center experience as either a clinician or management professional.

1. ROLES AND RESPONSIBILITIES OF HEALTH CENTER HEAD

The Head is the highest-ranking management officer in the Health Center and as such, directs and administers the activities of the Health Center in accordance with instructions and plans developed by the Governing Body. The Head must ensure that decisions of the Management Committee are implemented effectively and efficiently throughout the Health Center and must ensure the efficient planning and utilization of all Health Center resources to achieve the organization's goals. This entails the management of human resources, supplies, revenues, and physical and capital assets based on detailed plans developed for all aspects of the Health Center's operations (see Box C).

Responsibility of the Head includes:

- Work with the Governing Body to provide relevant information, facilitate trainings of Body members and support them to work effectively and efficiently.
- Plan, monitor and evaluate Health Center operations and report to relevant bodies
- Prepare budget (treasury and internal revenue) and submit to the Governing Body for approval. In partnership with the Governing Body, the Head is also responsible for designing various mechanisms to increase Health Center revenue.
- The Head should ensure that financial audits are performed in accordance with government requirements and submitted to the Body, and subsequently to the appropriate higher authority in a timely manner.
- Development of Health Center management committee and other structures
- Strive to empower and advance the professional capacity of Health Center staff.
- Establish mechanisms to ensure the quality of care and patients' rights. Further guidance on Quality Management is presented in *Chapter 10 Quality Improvement and Performance Monitoring*.
- Oversee compliance with all relevant regulations.
- Manage Health Center buildings, campuses and physical assets.
- Act as influential leader and chief spokesperson for the Health Center.
- Oversee and Support five satellite health centers.

Box 1.0.2: Summary of the Role of the Head

The Head provides executive leadership to the Health centre and has corporate responsibility for setting the strategic direction, formulating policies, monitoring performance and contributing to the decision making process with fellow Body Members to ensure the future stability and success of the Health Centre, whilst providing the best possible care within available resources.

2. ACCOUNTABILITY AND EVALUATION OF THE HEAD

The Head is accountable to the Governing Body, Sub city or Woreda Health Office, and is the only staff member under the direct supervision of the Governing Body. Evaluations of the Head performance should be conducted at least bi-annually by the Body or appointing authority**.** Evaluation criteria should be based on the job description of the Committee. Annual performance expectations should be spelled out at the beginning of each year in discussion between the appropriate member of the appointing authority, and the Head.

3. RELATIONSHIP BETWEEN HEAD AND GOVERNING BODY CHAIRPERSON

The relationship between the Head and the Governing Body Chairperson must be "managed" well by both individuals in order to galvanize the overall operations of the Health Center to be conducted at their best. It is mostly the responsibility of the Head to ensure that this relationship remains professional, courteous, and informative and defines the leadership of the organization

Activity 1.3. Think pair share	
	**Instruction:** - **Pair with your neighbour and discuss how a health center management committee should be composed and its major roles** - Reflect your discussion in the general discussion. **Time:** 5 minutes for discussion 5 minutes reflection

Guidance 3: Health Center Management Committee

Each Health Center should have a Management Committee that supports the health center Head to oversee the day-to-day operations of the Health Center. The Management Committee provides information and advice to the Head and serves as a forum to share decision making when appropriate, thus strengthening the transparency and accountability of Health Center leadership.

The Management Committee is accountable to and chaired by the Health Center Head.

1. RESPONSIBILITIES OF MANAGEMENT COMMITTEE

The main purpose of the Management Committee is to assist the Head and as such many of the functions of the Management Committee are like that of the Head.

Specific responsibilities include:

A) Assist the Head to prepare Health Center strategic and annual plans for submission to the Governing Body.
B) Provide reports to the Head on implementation of strategic and annual plans, according to each committee member's area of responsibility.
C) Identify areas of concern in the achievement of Health Center plans, and assist the Head to find solutions.
D) Ensure that activities of the Health Center are carried out with transparency and accountability and that all required reports are submitted to higher authorities in accordance with government requirements.
E) Ensure the Health Center complies with all relevant government regulations.
F) Provide financial oversight, advising the Head on mechanisms to generate income and minimize expenses.
G) Ensure proper implementation of fee waiver mechanisms and reimbursement.
H) Ensure proper management of Health Center buildings, estate, equipment and supplies.
I) Resolve departmental or case team problems or disputes when these are beyond the ability of the department head or case team director.
J) Ensure high quality clinical services by establishing and implementing mechanisms to measure and improve the quality of care.

K) Support workforce recruitment and retention, protecting the health and wellbeing of Health Center staff, and creating opportunities for staff development including leadership opportunities.
L) Communicate relevant Head and Management Committee decisions with subordinate employees.
M) Establishes mechanisms to involve patients and the public in the planning and delivery of Health Center services and to maintain close consultation with community leadership.
N) Work to enhance the organization's public standing and strengthen relationships with community, government and professional audiences.

2. MEMBERSHIP OF MANAGEMENT COMMITTEE

The Management Committee should be comprised of senior Health Center leaders such as case team heads senior clinical staff and key administrative personnel. It is also recommended that a staff representative nominated by staff members. This member should serve on the Management Committee for a time limited period as determined by the Governing Body (generally one year) and should then be replaced by another elected representative. The exact membership will be determined by the organization and structure of the Health Center. He/she should recommend the proposed membership to the Governing Body for approval. After approval, specific individuals will automatically be appointed by virtue of their position within the Health Center.

Health Center staff or representatives of appropriate external bodies may be invited to attend Management Committee meetings as non-voting members, to provide reports, information or advice to the Management Committee as the need arises.

3. DUTIES AND RESPONSIBILITIES OF MANAGEMENT COMMITTEE MEMBERS

Management Committee members have a duty to:

a) Attend ordinary and extraordinary meetings, respecting the time;
b) Accept and implement a decision passed by the majority;
c) Prepare for each meeting by reading agendas, minutes of the previous meeting and other documents distributed for consideration;
d) Follow up on any actions agreed by the Governing Body in a timely manner; and
e) Maintain confidentiality on all matters discussed by the Governing Body.

4. PROCEDURES OF MANAGEMENT COMMITTEE MEETINGS

A) Frequency and timing of Committee meetings

Management Committee meetings should be held at least weekly or more often as the need arises. Extra-ordinary meetings may be called by the Head at any time. As far as possible, Management Committee meetings should be held during regular working hours, and committee members should have dedicated time within their work schedule to attend and prepare for committee meetings.

B) Agenda items for Management Committee meetings

The agenda should be set jointly by the Health Center Head. All Management Committee members should be invited to nominate agenda items for consideration by the Head. The agenda and any document for discussion at the meeting should be distributed to Management Committee members in advance of the meeting.

The following should be regular standing items on each and every agenda of the Management committee:

a) Approval of previous meeting minutes;
b) Head's report – providing an overview of Health Center operations, discussion of pressing issues and immediate concerns;
c) Reports from each Management Committee member providing an overview of their department/function and any pressing issues and immediate concerns
d) Old business – issues unresolved from last meeting;
e) New business – any issues Management committee members want to raise; and
f) Next steps – plans for taking action on decisions reached by the Committee, with the assignment of follow up responsibilities to individuals as appropriate.

C) Decision making

Ultimately, the Head is responsible for all Health Center operations and as such has the authority to reach decisions on Health Center management matters. However, he/she may decide to determine specific issues by a vote of the Management committee. In such circumstances decisions of the Management committee should be made by majority vote. In the case of a tie the Head has the deciding vote.

5. SUBCOMMITTEES OF THE MANAGEMENT COMMITTEE

The Management Committee may establish a number of subcommittees to carry out specific duties related to Health Center management. Examples include:

- Quality Committee
- Drug and Therapeutic Committee
- Infection Prevention/ CASH Committee
- Major Incident Committee
- Disciplinary Committee

Guidance 4: Strategic and Annual Planning

Strategic planning is the process of determining what an organization intends to be in the future and how it will get there. The Annual Plan shows how the broader objectives, priorities and targets of the strategic plan will be translated into practical activities. Each Health Center should have strategic and annual plans that are developed taking into consideration the mission, vision and values of the organization and aligned with national, regional and local priorities. Strategic plans should cover a 5-year period and should be ambitious towards reaching the desired outcome. The annual plan should align with this, providing greater operational detail on a year-by-year basis, tied to the annual budget. The Health Sector Transformation Plan (HSTP) and the Regional/Zonal/Woreda Strategic Plans are the source documents for Health Center strategic plans and targets.

Detailed annual plans should have the following features:

- **Scope:** should reflect all activities and budgets, including those implemented by the public sector, donor agencies, NGOs and communities
- **Resource and source of finance:** estimation of the total amount of resources available from all sources (government, specific donors, internal revenue, NGOs etc).
- **Implementation schedule:** a list of major activities, a quarterly/monthly implementation schedule and the responsible body for the implementation of each activity
- **Monitoring framework:** for assessing progress during implementation. This includes key performance indicators, baseline data, annual targets, information sources and collection mechanisms, as well as reporting and feedback mechanisms.

Annual plans should be developed in two stages. The **core plan** is about achieving national targets; the **detailed** plan is the core plan plus other activities of local importance.

Figure 1.2 shows how the planning process works in practice. Health Center should first review Federal, Regional, Zonal and Woreda 'indicative plans', based on which the Health Center should develop its own strategic and annual 'indicative plan'. The draft needs to be reviewed by higher bodies [management and governing boards] for review and approval, with higher bodies amending their own strategic or annual plans to take account of lower level plans or advising amendments to lower-level plans where necessary. This 'top down, bottom up' approach will lead to integration of plans at all levels.

Health Centers should follow the processes established by MOFED/BOFED for budget allocation. This involves preparation of an annual plan and budget using the MOFED/BOFED template and submission of this to the appropriate authority.

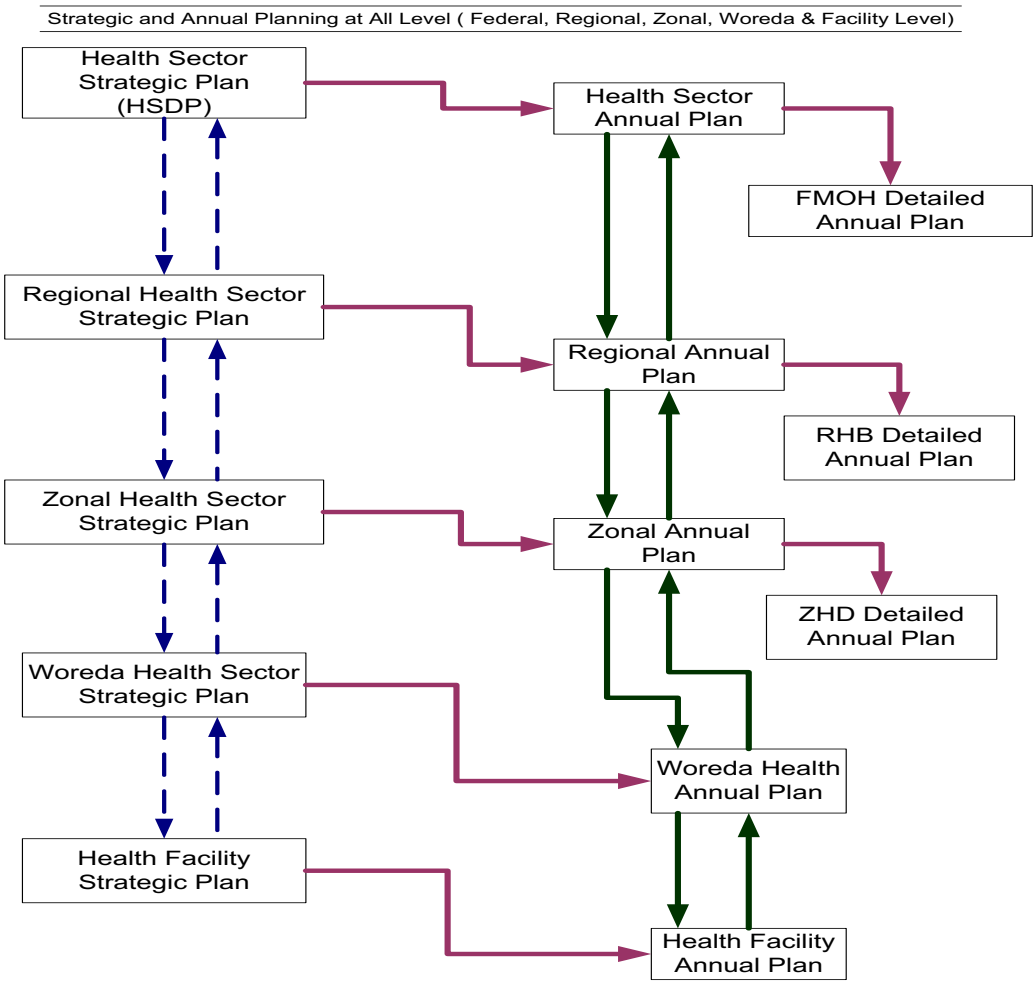


Figure 1.2: Strategic and Annual Planning at all Levels

Activity 1.4. 1 minute paper	
	**Instruction:** **Take a minute to dot down the core activities of health center finance team.** What are the core responsibilities of health center finance team? **Time:** 1 minute for writing and 5 minutes for discussion

Guidance 5: Health Center Finance

1. FINANCE AND PROPERTY CASE TEAM

Each Health Center should establish a Finance and Property Case Team with, as a minimum, the following administrative and financial personnel:

- Finance Head/ Coordinator
- Finance Officer
- Assistant Finance Officer/Cashier
- Daily Cash Collector/s

- Custodian
- Property administration officer
- Procurement Officer

The Finance Case Team Contributes to the Health Center sustainability in a number of key ways:

- Increasing revenue,
- Reducing unnecessary costs and assisting in ensuring that all resources are used appropriately, efficiently and effectively, and
- Improving the quality of services and providing decision makers with timely, accurate and useful programme and financial information.

Duties and responsibilities of key finance personnel are presented in Appendix A.
The management of Health Center property is also a function of this case team. Further guidance on Facilities Management is given in part three of this chapter.

2. HEALTH CENTER BUDGET PLANNING

Health Center budgets should be prepared, approved and appropriated following procedures established by Woreda/Sub City finance. Procedures for planning and budgeting are necessary to ensure that financial resources within the health center spent with proper accountability and in a timely manner according to expenditure guidelines established by the Woreda/Sub City finance. The broad provisions of the legislative framework are common to all Regions, although there are some minor differences from Region to Region, particularly in the Directives governing the implementation. Health Centers should be familiar with and should comply with their own Regional Regulations and Directives when implementing finance reform activities.

As public bodies, government Health Centers should comply with the accounting practices, budgeting and reporting mechanisms established by the regional BOFED or woreda OFED.
The main steps in this process are:
Preparation of work plans: Health Center management, with the active participation of the staff, should prepare work programs following guidelines issued by Woreda.

Preparation of budget: Each Health Center should estimate annual (from July eight up to July seven) budgetary resources from different sources including:

- the amount of retained revenue they expect to collect from different sources
- block grants from government source (both government treasury and foreign)
- other sources (e.g. NGO)

The resources should then be allocated between recurrent expenditure and capital expenditure, in alignment with the work plan.
The annual work plan and budget should be approved by the Governing Board.

Budget call: This is a notification by Woreda to public bodies to prepare a budget request for their expenditure.
Review of work plans and budget: Health Centers should submit their work plans and budget to their woreda/Sub City finance. Each woreda should consolidate all work plans and submit them to the BOFED.

Budget Approval, Appropriation, Notification and Execution: Once the budget has been submitted, Woreda/Sub City finance will review and make recommendations for revision if necessary and will then consolidate all budget submissions. The consolidated budget is submitted to the Regional Cabinet for approval and then presented, with or without adjustment, to the Regional Council for appropriation. After appropriation the woreda/Sub City finance will be notified of the budget which it is authorized to use. The woreda/Sub City finance will, in turn, notify the Health Center of its appropriated budget. Thereafter, the Health Center may utilize the funds.

Budget Execution: Each month the Health Center should submit a monthly disbursement request to Woreda/Sub City finance. Funds will then be transferred to the Health Center bank account.

Reporting: Each Health Center should maintain a book of accounts and formats as prescribed in the Regional financial proclamation and regulation. Monthly reports should be submitted to the Woreda/Sub City health office and finance office.

Budget Adjustment: There are two types of budget adjustment permitted by law:

***Budget transfers* - in** which funds are transferred from one line item to another. Budget transfers from government subsidies should be approved by Woreda/Sub City finance before the funds are spent. The Health Center Head should inform Woreda/Sub City finance from which item(s) in the original approved budget funds will be taken and for what new expenditure categories they will be used. Budget transfers from retained revenue should be approved by the Governing committee. Woreda/Sub City finance do not need to give approval in such cases.

***Supplementary budget* -** this is an increase to the authorized budget. Any supplementary budget must be approved by Woreda/Sub City finance and appropriated by the respective Council. Standardized, approved formats for budget submission, disbursement requests, the book of accounts and accounting formats are contained within the MOFED/BOFED Revised Federal Budget Manual.

3. PLANNING AND BUDGETING FOR RETAINED REVENUE

As part of the budget planning process, the Health Center should estimate the amount of retained revenue it anticipates collecting from different sources in the coming year.

Retained revenue can be estimated on the basis of:

- Trend of past year(s) collections from each source revenue item,
- Total number of visitors and collected revenue from each item of revenue (examination/card, drugs, lab tests, etc),
- Estimated number of service seekers and average collections, and

The retained revenue estimate should be included in the budget proposal.

***Note**:* Expenditure of retained revenue should be budgeted separately from expenditures made from other revenue sources.

All revenue must be appropriated before use. Any unutilized retained revenue should be declared by the Health Center at the end of every fiscal year, so that it can be proclaimed and utilized together with the collections of the following budget year and the appropriated block budget.

4. REVENUE RETENTION

Sources of revenue of Health Centers include:

- Block budget appropriated by the government;
- Fees collected from health care and diagnostic services as well as beds and other services related to medical treatment,
- Sale of drugs and medical supplies,

- Revenue collected from third parties in connection with waiver and health insurance schemes,
- Income from non-medical services and goods such as lease of facilities and other similar activities,
- Direct aid in cash and in kind obtained from domestic and outside sources; and
- Other similar revenue sources

4.1. Health Insurance

The government of Ethiopia has launched two types of health insurance programmes namely social health Insurance (SHI) and community-based health Insurance (CBHI) with multiple objectives of alleviating financial barriers, mobilizing additional resources to the health sector, encouraging community participation, and ultimately improving health service utilization of the population. Social health insurance covers the part of the population engaged in the formal sector, which is constituted by the civil servants, NGO employees, private sector employees, pensioners and police forces. The CBHI programme is designed to address populations that are engaged in the informal sector i.e. the rural population and the people in petty trade in urban settings.

The implementation of health insurance programmes requires the active involvement of different stakeholders with their distinct roles and responsibilities. Health care providers are one of the key stakeholders that have major role for the successful implementation of the programmes. They are expected to provide quality health services that are indicated in the benefit package. The benefit package covers both outpatient and inpatient services, delivery services, surgical services and provision of generic drugs included in the health insurance agency drug list and diagnostic services at health center level. Health centers contracted with the insurance schemes have to be self-contained. In case the services are not available, the health centers are required to sign a contract agreement with private providers to offer the services on their behalf and account. Insurance beneficiaries should not pay any out-of-pocket payment when accessing care, apart from the co-payment and bypass fee if any.

Not all services are covered by the benefit package and there are services excluded due to various reasons, including diagnosis and treatment abroad, cosmetics surgeries, dialysis except acute renal failure, in vitro fertilization, organ transplantation, hip replacement, periodic checkup except key preventive check-up, occupational injuries and traffic accidents, provision of eyeglasses, contact lenses and hearing aids, dentures, crowns, bridges, implants and root canal treatment except those required due to infection.

The health center, prior to service provision identify whether the health insurance beneficiary is an active member. It is expected that the health centers provides all services indicated in the benefit package including supply of drugs, laboratory, and diagnostic services. As per the terms and procedures indicated in the contractual agreement, the health center submit timely, complete and accurate payment requests monthly or quarterly using agreed upon formats and follow up the reimbursement. The purchasing unit or the HI scheme reimburse 75% of the costs of the service immediately within 10 consecutive days and reimburse the remaining 25% after clinical audit report.

The health center is also expected to keep records of all services provided to eligible health insurance beneficiaries and related financial information as appropriate and the information is compiled into reports. These include, service utilization report, fee schedule of the health center issued by the authorized body, standard treatment guidelines and contract document. Apart from HMIS/DHIS formats, the health center utilizes formats developed by health insurance schemes to record and document health insurance activities.

4.2. Fee Waiver

A fee waiver is a right conferred to a household or individual that entitles the household/individual to obtain health services in certain health facilities at no direct charge or at reduced price. Beneficiaries are identified and issued with a 'fee waiver certificate' by a Waiver Certificate Granting Authority (generally Woreda or Sub City Administration). It is implemented in the non-CBHI implementing. Health Centers should enter into a Memorandum of Understanding (MOU) with Waiver Certificate Granting Authorities. This should provide details on the type of service and mode of payment. A sample MOU is presented in Appendix 1B.

The Health Center should maintain a record of expenses incurred for services provided to fee waiver beneficiaries. A sample *Fee Waiver Beneficiary Register* is presented in Appendix C. The Register should be filled by the Accountant, using source information from the patient's medical record, lab order forms, prescription etc.

Additionally, each case team should maintain *Fee Waiver Expense Registration Form* to record services provided to fee waiver beneficiaries (Appendix 1D). This form will provide information for the Health Center Accountant to assist completion of the *Fee Waiver Beneficiary Register*.

Every quarter the Health Center should submit a request to the Waiver Certificate Granting Authority for reimbursement of expenses incurred for services provided to fee waiver patients. A sample *Bill for Reimbursement of Fee Waiver* is presented in Appendix E.

Upon receipt of the bill, the Waiver Certificate Issuing Authority should verify the request and instruct the Woreda, Town or sub-city Office of Finance and Economic Development (WOFED) to make the payment to the health facility.

NB: The Health Center should make all fee waiver reimbursement requests to the Woreda/Sub City in which the Health Center is located. For patients who reside outside that Woreda/Sub City, reimbursement procedures should be established in a third-party arrangement between the the Woreda in which the Health Center is located and the Woreda/Sub City in which the fee waiver beneficiaries reside. Regional agreements should also be reached for reimbursement of certificate holders from different Regions.

4.3. Exempted Health Services

Exempted health services should be provided free of charge to all patients, irrespective of the patient's income. Exempted services are generally those of a public health nature such as:

- TB services
- HIV services
- leprosy services
- family planning services
- prenatal, delivery and postnatal services
- immunization services
- epidemic follow up and control
- Occupational health services for health care workers.

Each Regional Government will approve all list of exempted services in their HSDA legal framework for that Region. Each Health Center should provide exempted services in accordance with the relevant Regional Legislation and should display a list of exempted services at appropriate locations through the Health Center for the information of patients, staff and the public.

The Health Center should finance the costs of exempted services from the appropriated government budget or donations. The Health Center should maintain records of exempted services provided and submit monthly, quarterly and annual reports to the woreda.

4.4. User Fee Setting and Revision

Under the Health Finance Reform, patient fees collected by Health Centers and held by the Health Centers as retained revenue. However, patient fees should be collected on a cost-sharing principle and hence not all costs of providing health services should go into the calculation of user fees. In setting or revising fees what should be considered is charging the user any additional cost (marginal cost) of providing the service. These additional costs are for example costs of drugs, laboratory reagent, cost of any disposable material used to treat the patient, and consumables such as food, bed services, etc. Examples of items that might not be included in fee calculation are costs of buildings, durable assets and staff salary. However, a certain percentage may be added to the user fee to replace these costs bit by bit in the long run.

The process of fee setting is governed by Regional Proclamations, Regulations and Directives and varies slightly from Region to Region. However, the basic principles, common to all Regions are as follows:

- Health Center management can initiate the process for user fee revision,
- The proposed fee structure should be submitted to the woreda,
- The woreda should review, considering the ability and willingness to pay of users,
- The final decision should be made in accordance with regional legislations.

User fees may be revised every 5 years or at appropriate time in accordance with regional legislations.

Health Centers should keep record of expenses and prices to enable fee-setting authorities to periodically revise and set fees. These reports should be part of the management reports submitted by the facilities.

5. UTILIZATION OF REVENUES

Positive Lists

Health Centers may use the retained revenue to meet the manpower and equipment requirements and to improve the quality of health services. Specifically, retained revenue may be used to:

- Improve the services provided under the referral system,
- Improve the supply of drugs, medical equipment and supplies,
- Conduct procurement and carryout construction works to improve the health care services of the Health Center,
- Develop health care information systems and manuals and to improve procedures,

- Conduct on the job training (not exceeding 3 months period) programmes and other similar health related problem-solving research so as to improve the efficiency of employees,
- Strengthen health education activities and undertake disease control and preventive activities,
- Undertake other similar revenue utilization activities in line with the objectives designated by the Region's HSDA directives, and
- Motivate staffs and reduce staff turnover.

Negative Lists

Retained revenue should NOT be used for:

- Any kind of foreign trip and training,
- Long term domestic training programs more than three months,
- Any kind of subsidy given to a third party,
- Payments for hiring consultants,
- Revenue utilization other than those activities designed to meet the objectives therein, nor

  For any expenditure code in the positive list for which there is no approved budget.

Activity 1.5. Reflection on Asset management	
	**Instruction:** - **Reflect your thoughts on asset management guided by the questions raised by you facilitator.** **Time:** 10 minutes

Guidance 6: Asset Management

The Council of Ministers Financial Regulations No 17/1997 categorises government assets into two main categories - fixed assets and supplies.

A fixed asset is "a tangible asset costing Birr 1000 or more that is in operational use and that has a useful economic life of more than one year, such as furniture, computers, equipment, vehicles, buildings".[1] Supplies are all other items owned by the government such as stationary, cleaning supplies, gloves, syringes etc.

The management of assets includes procurement, inventory, storage, maintenance and disposal of assets. Effective asset management ensures that assets are purchased to meet the needs of the heath Center, that assets are maintained in good working order and are disposed of promptly when no longer required or when the end of the useful lifespan has been reached.

[1] FDRE Ministry of Finance and Economic Development. *Government Owned Fixed Assets Management Manual*. December 2007, p.8

The management of Health Center assets is governed by National Legislation as set out in Proclamations, Regulations and Directives related to the procurement, inventory control and disposal of assets. The MOFED has also published the 'Government Owned Fixed Asset Management Manual' (GOFAMM) to provide guidance on the management of assets. Additionally, in 2009 the Procurement Agency (www.ppa.mofed.gov.et) was established. The main role of the Procurement Agency is to ensure the application of fair, competitive, transparent, and non-discriminatory and value for money procurement by public bodies. One specific function of the Procurement Agency is to prepare, update and issue authorized versions of the standard bidding documents, procedural forms and any other documents pertaining to procurement and property administration.

Health Centers should comply with Legislative requirements and with all guidance and forms issued by the Procurement Agency when managing Health Center assets. The guidance below focuses primarily on the management of fixed assets such as medical and non-medical equipment (e.g. generators, vehicles etc) and is consistent with current Legislative requirements. Additional guidance on Facilities Management (including buildings and non-medical equipment) is presented in *Part three of this chapter,* Facilities *Management*; Additional guidance on Medical Equipment Management is presented Chapter 8 of the guide. Guidance on the management of pharmaceuticals is presented in *Chapter 4 Pharmacy Services*.

1. FIXED ASSET MANAGEMENT UNIT (FAMU):

Each Health Center should assign a unit responsible for the management of fixed assets. Full responsibilities of the FAMU are described in the GOFAMM manual and include:

- To establish the fixed asset register,
- To undertake an annual physical count of all fixed assets and reconcile with the register,
- To ensure that all fixed assets are put to appropriate use,
- To calculate depreciation on fixed assets, and
- To identify items for disposal.

2. PROCUREMENT AND MAINTENANCE BUDGET OF FIXED ASSETS

Each Health Center should prepare a 5 year plan for the purchase of major capital. A detailed annual procurement plan should be prepared showing the procurement for the budget year. The costs of procurement should be included in the annual budget. The procurement plan and budget should consider the entire costs related to the purchase including transport, site preparation, installation, staff training, support, supply of consumables, spare parts etc. The procurement plan should be developed taking into consideration the Medical Equipment Development Plan (see Section 3.14), the Health Center annual plan and specific departmental needs.

Health Centers should also budget for the regular maintenance of fixed assets, and for the emergency purchase of any essential assets that it might be necessary to replace unexpectedly during the financial year (for example if equipment is broken and cannot be repaired, or if an item is stolen).

In general, the following guidance gives an estimate of the annual budget required for maintenance and fixed asset replacement costs:

- For medical equipment, each year 5-6% of the 'new' stock value is required.

- For buildings, each year 1-2% of the 'new' construction cost is required.
- For service supplies and plant, each year 3-4% of purchase and installation costs is required

3. REGISTER OF FIXED ASSETS

The Health Center should establish a register of fixed assets that contains information on the date of purchase, description, quantity and cost of each item. A custodian should be assigned for each fixed asset. In general the custodian should be an individual who regularly uses the fixed asset or who is in charge of the department/unit where the item is held. The name of the custodians and the locations of the fixed assets under their custody should be recorded in the register of fixed assets.

An inventory check to physically verify the inventory against records should be undertaken annually, following the procedures described in the GOFAMM manual. Key steps are outlined below:

4. INSURANCE FOR FIXED ASSETS

The Council of Ministers Finance Regulations No 17/1997, Article No 62 provides that "the Heads and employees of public bodies are responsible for the protection and preservation of public property." One of the protection methods for fixed assets is purchasing appropriate insurance policy against unforeseen calamities.

The Health Center Head and the FAMU should also assess which of the assets the Health Center should be included in insurance coverage. Once purchased, the policy should be renewed every year in advance of its expiry date.

5. ACCOUNTING FOR FIXED ASSETS

All fixed assets should be valued and recorded in the Health Center accounting records. The cost at which fixed assests are valued should be the historical cost, i.e. the cost incurred at the time the fixed asset was purchased or constructed. While this is information may be available for new purchases, it may not be known for all assets in the health center, particularly items that were donated or are old. The GOFAMM manual provides guidance on assigning a value to fixed assets in such circumstances.

After the initial valuation, Health Centers should depreciate all items of property, plant and equipment until the item is derecognized. Depreciation is defined as a systematic allocation of the depreciable amount of an asset over its useful life. There are various methods of depreciation. The simplest of all is the Straight-line method of depreciation. Straight-line method of depreciation assumes that the usefulness of the asset is the same over the entire life of the asset.

The following depreciation rates should be used for depreciating Government Owned Fixed Assets.

Vehicle and other vehicular transport	20%
Plant and machinery	12.5%
Buildings – residential	5%
Buildings – non residential	5%
Infrastructure	5%
Furnishings and fixtures	10%
Office equipment	10%
Books	25%

6. DISPOSAL OF FIXED ASSETS

Fixed assets may be disposed when the item becomes unserviceable, obsolete, surplus or abandoned. Government regulations describe three approved methods of disposal:

- Transfer to other public bodies
- Disposal by sale
- Sale by public auction
- Sale through public tender
- Sale as scrap
- Discarding

Whichever method is followed, the description and amount received from all items that are disposed of should be entered in the Health Center acccounts and the Health Center fixed asset register should be amended accordingly.

A Disposal Committee should be established as an advisory body to Health Center management. The Commitee should be comprised of Heads from appropriate Departments/Units such as procurement, finance, legal etc. The Committee should review all recommendations from the FAMU for the disposal of fixed assets, including the method of disposal, and should follow up on any disposals that are approved by Health Centermanagement. *Full guidance on disposal procedures is provided in the GOFAMM manual.*

Guidance 7: Accounting Practice of Health Centers

1. CASH COLLECTION PROCEDURES

A) General issues:

The Health Care and Finance Legislation makes the following stipulations:

- Health Centers should only charge payments at the user fee or bypass fee set by the Health Bureau or the Regional Council,
- Bilingual fee posters should be put up next to each departmental reception desk, in all waiting areas and at all cash points. Each poster should show the fees and exemptions and should advise patients to obtain and keep receipts for all payments,
- collection points should be readily accessible for all patient services (for further guidance see *Chapter 3 Patient Flow*),
- cash should be collected only by personnel who are authorized by the Health Center Head,
- except in emergency cases the fees should be collected after the treatment has been ordered by the clinicians and its availability confirmed, but before the treatment is administered,
- in emergency cases treatment should be administered when needed and the question of payment should be handled when the emergency is under control (for further guidance see *Chapter 3 Patient Flow),*
- Revenue can be collected as cash, cheques or bank transfer. Where a cheque is received the following issues should be considered:
    - Cheques must be made payable to the health facility;

  - Personal or company cheques must be certified by the drawer's bank;
  - Government agency cheques are acceptable without certification;
  - No employee has the authority to cash any cheque made payable to the health facility; and
  - Post-dated cheques shall not be accepted as revenue, and
- Bank transfers must be evidenced by a bank deposit slip or bank advice.

B. Cash Receipt Vouchers

Cash Collectors should collect payments from clients/patients and others by issuing a Cash Receipt Voucher. The Cash Receipt Voucher should be used to acknowledge and evidence the receipt of cash, cheques, the direct deposit of cash into the bank and bank transfers. Only pre-printed sequentially pre-numbered official Receipt Vouchers issued by Regional BOFED (for Health Centers) should be used. A sample Cash Receipt Voucher is presented in Appendix H.

The Cash Receipt Vouchers should be distributed as follows:

- Original copy to the payer as acknowledgment of the cash receipt;
- Second copy to the main Cashier; and
- Third copy is retained in the pad.

On a daily basis each Cash Collector should submit all cash receipt vouchers and cash collected to the main Cashier.

C. Summary Receipt Voucher

The Summary Receipt Voucher is used by the main Cashier to summarize the cash collected and cash vouchers received from each Cash Collector. Upon receipt of the cash receipt vouchers the main Cashier should summarize these on a pre-numbered Summary Receipt Voucher.

The Summary Receipt Voucher is prepared in triplicate:

- original copy is given to the daily Cash Collector as a receipt when the collected cash is remitted;
- second copy is sent to the Accountant attaching the Receipt Vouchers and deposit slips; and
- Third copy is kept in the pad.

A sample Summary Receipt Voucher is presented in Appendix I.

D. Receipt Voucher Summary by Revenue Code

The Receipt Voucher Summary by Revenue Code is a spreadsheet prepared by daily Cash Collectors to summarize receipt vouchers by revenue account code. On a daily basis each Cash Collector should complete a Receipt Voucher Summary by Revenue Code and submit this to the main Cashier together with the issued receipt vouchers and cash collected. The total amount shown on the Receipt Voucher Summary by Revenue Code should be checked with total amount shown on the Summary Receipt Voucher to ensure that the two amounts are the same. A copy of the Receipt Voucher Summary by Revenue Code should be submitted to the Accountant together with the Summary Receipt Voucher and supporting Receipt Vouchers.
A sample Receipt Voucher Summary by Revenue Code is presented in Appendix J.

E. Deposit Receipt Voucher

This is used to acknowledge and evidence the receipt of cash or cheques as a deposit/advance payment from inpatients. The Deposit Receipt Voucher should be prepared by the Cash Collector and submitted to the main Cashier together with the funds deposited. A sample Deposit Receipt Voucher is presented in Appendix K.

The daily Cash Collector should summarize all deposit payments in a *Deposit Cash Book* (see Appendix L).

At the end of the patient stay the total service charge should be calculated:

a) If the service charge is equal to the deposited amount then a *Cash Receipt Voucher (Appendix H)* should be prepared. A copy should be given to the payee and the second copy attached to the *Deposit Receipt Voucher* and submitted to the Accountant.
b) If the service charge is greater than the deposit then the payee should pay the difference and a *Cash Receipt Voucher* should be prepared for the total sum, with a copy given to the payee and a second copy attached to the *Deposit Receipt Voucher* and submitted to the Accountant.
c) If the service charge is less than the deposited amount then a *Cash Receipt Voucher* should be prepared for the total service charge. The balance should be remitted to the payee using a *Payment Voucher* (Appendix M). A copy of both the *Cash Receipt Voucher* and *Payment Voucher* should be attached to the *Deposit Receipt Voucher* and submitted to the Accountant.

F. Cash Register

A Cash Register should be established to record the cash collected each day and the sum deposited in the bank. The Cash Register should be completed by the main Cashier. A sample Cash Register is presented in Appendix N. Credit should be granted for a maximum period of three months. Institutions that have a Credit Agreement with the Health Center may deposit a sum of money at the health center account in advance. That sum can be replenished whenever it is used up. The Health Center Accountant should prepare a monthly report for the Health Center Management with details of credit granted, credit repaid and balance outstanding.

2. HANDLING CASH

In monetary terms ‘cash’ refers to currency, cheques, drafts, cash payment orders and bank remittances.

A) Cash in hand

Cash in hand should be kept in locked safe box under the responsibility of the main Cashier. The cash safe box must be used only for those assets belonging to the Health Center. Personal properties should not be kept in the cash safe box.

Wherever a cash safe box has double or triple keys, the reserve keys should be safely kept in a sealed envelope. The sealed envelope should be signed by the Cashier, Finance officer and Finance Head of the Health Center. When the Cashier requires the reserve key, the sealed envelope should be opened with the presence of two or three signatory persons.

B) Chequebooks

When chequebooks are received from the bank the Cashier should make sure that the leaves of the cheque books are correct and that each leaf in the cheque is stamped. A Register should be

used to record all new chequebooks received and chequebooks issued. Partly used chequebooks should be kept with the Finance officer.

C) Deposit Procedures

All cash and cheques received should be deposited into the Health Center bank account on the date of collection or the next working day if it is not possible to deposit on the same day. If the bank is far from the facility then cash should be kept in a safe box and deposited no less frequently than once a week. If for any reason this is not practical then any different mechanism should be approved by Woreda/Sub City. When revenue is deposited, the Cashier should obtain two copies of the deposit slip – one should be submitted to the Finance officer and the other should remain with the Cashier as evidence. In case of direct deposits by the third party, the Finance officer should collect copies of deposit slips from the bank.

D) Bank Accounts

Health Center bank accounts can only be opened or closed with the approval of Woreda/Sub City OFED. Health Center management should assign, in writing, three named individuals as signatories of each bank account. The bank and Woreda/Sub City OFED should be notified of any changes in the signatories.

Each Health Center should have a bank account specifically for retained revenue. To open the bank account, the Health Center should apply in writing to Woreda/Sub City OFED.

The Health Center should establish a bankbook or bank register record for each bank account that shows the movement of funds indicating the beginning balance, deposits, withdrawals and ending balance at any given time.

Every month the Finance officers should prepare Bank Reconciliation for every bank account and should pass any necessary correcting entries. Correcting entries must be evidenced by the signature of Finance officer and also verified by separate persons, in accordance with the regional government Budget and Accounts Manual.

3. DISBURSEMENT PROCEDURES

Each month and quarter the Finance Head should prepare a cash flow program detailing income and expenditure for each major budget heading. This should be submitted to the Health Center Head for review and approval. A sample Format for Cash Flow Forecast is presented in Appendix Q.

Requests for disbursement (payments) should be made to the Health Center. Finance officer who will prepare a payment voucher and submit, together with supporting documents, to the Head of Finance. The Head of Finance should review and approve the disbursement, taking into consideration funds available, providing the amount of payment is within the limits set by Woreda/Sub City.

After approval the Finance officer will prepare a cheque and submit for signature by assigned signatories. For cash disbursements the approved voucher should be submitted to the Cashier who will effect payment.

Health Centers should present disbursement requests to their respective Woreda/Sub City OFED for operating expenses of all eligible expenditure from the government block grant. Requests for monthly salary will also follow appropriate Woreda/Sub City OFED guidelines.

4. REPORTING PROCEDURES

The Health Center Finance officer should prepare monthly and quarterly reports on revenue, expenditures, receivables, payables, trial balance, the status of budget utilization and others. Reports should be submitted to the Health Center management and Higher Governing Body.

Each identified Health Center cost or profit Center should have a monthly revenue and expenditure report.

A sample report for receivables management is presented in Appendix R.

5. AUDITING

Each Health Center should appoint an Internal Auditor who is responsible to conduct regular internal audit as described in the government *Internal Audit Manual.*

The accounts of the Health Center should be closed on the last day of the financial year. External audit should be conducted by external auditors from the Office of the Auditor General (Federal or regional Audit office) or other authorized private auditors, approved by the Governing body, within six months of the closing of the accounts. The audit should consider the recording and bookkeeping system and the annual retained revenue and expenditure of the Health Center. Audit reports should be submitted to the Health Center Head who in turn will present to the Governing body. Auditors from the Health Bureau, BOFED, Woreda/Sub CIty OFED and Health Offices have the right to access and investigate all accounting records of health facilities as surprise audit or regular audit.

1.4. Implementation /Operational Standards, Checklist and Indicators

1.4.1. Assessment Tool for Operational Standards

In order to determine if the Operational Standards of Health Center Leadership and Governance have been met by the Health Center an assessment tool has been developed which describes criteria for the attainment of a Standard and a method of assessment. This tool can be used by Health Center management or by an external body such as the Sub city or Woreda Health Office to measure attainment of each Operational Standard. The tool is presented in Appendix E of *Chapter 10 Quality Improvement and Performance Monitoring.*

Table 1.0.1: Operational standards for leadership, governance and health care financing

Sta. #	Standard	Method of evaluation	Yes √ No X	met =1 not met =0	Remark
1	The Health Centre Governing Body is established using clear and transparent systems and processes.	Has community representatives.			
		Has staff representatives			
		A focal person for HC-HP linkage is a member.			
		The GB has at least two female members.			

Sta. #	Standard	Method of evaluation	Yes √ No X	met =1 not met =0	Remark
		Members appointment letter issued			
		TOR is defined.			
2	The Governing Body approves the Health Center Head who is appointed/ nominated by the town, sub city or Woreda Health Office	Testimony/ Appointment letter from WorHO/ Mayor/ Governing Body			
		Signed a job description that outlines his/her duties to lead the HC			
		Board approval minute			
3	The Governing Body approves an annual and strategic plan for the Health Center to achieve its goal of improving its community's health and welfare	Minutes of approval of strategic and annual plans			
		Signature of the GB members and stamp of the HC on the documents.			
4	The Governing Body conducts regular meetings with written minutes at least quarterly	The meetings are regularly conducted			
		Minutes and agenda of meetings are available(observe minutes of the current year).			
		Meeting agendas distributed at least one week in advance, and approved by members' signature			
		More than fifty percent of board members attend the meetings.			
		Action plan with defined responsibility developed			
		Action plan implementation status was monitored in subsequent meetings.			
		GB visits the HC before the meeting (check in the minute)			
		Is there an orientation session for new GB members?			
5	The health centre Head is evaluated biannually, consistent with Regional Legislation to ensure he/she is meeting operational plan as approved by the board.	HC report reviewed biannually(check in the minute)			
		Performance appraisal assessment result of the Health Centre Director			
6	The health centre management committee has been established and functioned as per the respective regional	Members nomination is in accordance with the region's HSDA legal framework			
		issued appointment letter to each member of the committee by the HC head			

Sta. #	Standard	Method of evaluation	Yes √ No X	met =1 not met =0	Remark
	health service delivery and administration legal framework.	TOR is defined			
		The committee meets a minimum every week (or as per the region's HSDA legal framework)			
		Agenda of meetings and minutes are available			
		More than fifty percent members attend the meetings			
		Action plan with responsibility developed			
		Action plan monitored during subsequent meetings(Check in the minute)			
7	The health center shall post service fee and exemptions using local language(s) in each department and cash collection premises.	Check presence of posted fee and exempted services			
		Check all exempted services are provided free of charge in the facility (take a sample of 5 eligible mothers and children and verify with interview)			
		Poster that advises patients to obtain and keep receipts posted at cash points for all Out Of Pockets			
8	The Health Centre has a procurement plan, approved by governing board.	Existence of a plan that justifies			
		Approval of the plan by the management committee & GB			
		Approval minute from the board			
		Procurement done according to plan			
9	The health center procurement process is according to regional HSAD.	Take sample procurements and check for bid/proforma			
		Check supplier selection process(purchase committee selection minute)			
		Cross check procured items are in line with approved plan			
10	The health center finance team shall submit reports on monthly basis to the health center management committee	The HC prepares both monthly financial and quarterly performance reports			
		Completeness of the report (include revenue, expenditure, receivables, payables, transfers, cash count , trial balance & bank reconciliation)			
		Monthly financial reports timely reported to WoFED/ WorHO in regular manner			

Sta. #	Standard	Method of evaluation	Yes √ No X	met =1 not met =0	Remark
		quarterly performance reports timely reported to the governing body and SMT management committee on regular bases			
11	The health center shall be audited with third party on annual basis and submit reports to governing body..	Check the audit feedback report			
		Approval of the audit report by the GB			
12	The Health Centre has a Memorandum of Understanding with Waiver Certificate Granting Authorities and CBHI schemes which provide details on the type of service and mode of payment.(CBHI agreement)	Check memorandum of understanding for the current year with CBHI.			
		Check memorandum of understanding for fee waiver of the current year with Woreda council.			
13	The Health Centre shall facilitate reimbursement for waived and credit services.	Presence of updated records of services offered & costs incurred			
		Timely reporting and requesting of the service expenses			
		A report that shows the current status of amount claimed, reimbursed & outstanding balance for the three types of services (waiver, credit)			
14	There is a current Health Facility Financial Management manual.	Observe and confirm presence of the three types of documents at the HC account manual of the regional or Federal			

1.4.2. Implementation Checklist

The following Table can be used as a tool to record whether the main recommendations outlined above have been implemented by the Heath Center. The Table does not measure attainment of each Operational Standard but rather provides a checklist to record implementation activities.

Table 1.0.2: Health Center Leadership and Governance and health care financing checklist

S.No	Activity	Yes	No
1.	A Governing Body has been established		
2.	Terms of Reference for the Governing Body are defined		
3.	The Governing Body meets at a minimum every quarter		
4.	Governing Body members participate in ongoing education		
5.	There is a planned orientation programme for new Governing Body members		
6.	The Health Centre has a Statement of Vision, Mission and Values that has been approved by the Governing Body		
7.	All staff have been oriented to the Health Centre Vision, Mission and Values		
8.	A Health Centre Head has been appointed		
9.	The Head has signed a job description that outlines his/her duties to lead the Health Centre		
10.	The Health Centre Head is evaluated biannually		
11.	A Management Committee has been established. Membership of the Management Committee has been approved by the Governing Body		
12.	The Management Committee meets as a minimum every Week		
13.	The Health Centre has a strategic plan that has been approved by the Governing Body		
14.	The Health Centre has an annual plan that has been approved by the Governing Body		
15.	All staff have been oriented to the Health Centre strategic and annual plans		
16.	An Essential Service Package has been defined for the Health Centre		
17.	There are bilingual fee posters in each service area.		
18.	There is a procurement guideline.		
19.	There is an accounting manual.		
20.	The Finance Case Team prepares and sends monthly reports to appropriate bodies.		
21.	Reconciliation of bank accounts is done.		
22.	External audits are conducted; reports are reviewed by the SMT.		
23.	MOUs with Waiver Certificate Granting Authorities are in place.		
24.	Exempted services are provided and information about services is posted in appropriate places in the Health Centre.		

1.4.3. Indicators

Table 1.0.3: Health Center Governance Leadership and health care financing Indicators

	Indicator	**Formula**	**Frequency**	**Comments**
1.	Number of Governing Body meetings in reporting period	Total number of Governing body meetings in the reporting period	Quarterly	
2.	a) Number of Governing Body meetings cancelled or deferred b) Proportion of scheduled Governing Body meetings cancelled or deferred	a) Total number of Governing body meetings cancelled or deferred in the reporting period b) Total number of Governing body meetings cancelled or deferred in the reporting period ÷ total number of scheduled	Quarterly	

	Indicator	Formula	Frequency	Comments
		Governing Body meetings x 100		
3.	Average attendance rate at Governing Body meetings	∑number of attendees ÷ [total number of Governing Body members x number of meetings] x 100	Quarterly	
4.	Number of Management Committee meetings held	Total number of Management Committee meetings held in the reporting period	Quarterly	
5.	a) Number of Management Committee meetings cancelled or deferred b) Proportion of scheduled Management Committee meetings cancelled or deferred	a) Total number of Management Committee meetings cancelled or deferred in the reporting period b) Total number of Management Committee meetings cancelled or deferred in the reporting period ÷ total number of scheduled Management Committee meetings x 100	Quarterly	
6.	Average attendance rate at Management Committee meetings	∑number of attendees ÷ [number of Management Committee members x number of meetings] x 100	Quarterly	
7.	Share of Government budget allocation	Revenue from Gov. allocation/total revenue *100	Quarterly	HC report/ WFO
8.	Share of Internal revenue generated	Internal revenue generated/total revenue *100	Quarterly	HC report/ WFO
9.	Ratio of health budget utilization to allocation	Budget utilized/Total allocated budget*100	Quarterly	HC report/ IBEX/ DHIS2
10.	Cost per patient-day equivalent	Total recurrent expenditure/[number of inpatient days + (OPD visits/4)]	Quarterly	HC report/ IBEX/ DHIS2
11.	Proportion of persons provided with exempt services	ii) Number of patient attendances provided with exempt services/Total number of attendances *100)	Quarterly	HC report/ IBEX/ DHIS2
12.	Proportion of persons provided with 'fee waiver' service	Number of 'fee waiver' patient attendances /Total number of attendances *100)	Quarterly	HC report/ IBEX/ DHIS2
13.	Proportion of persons provided with insurance service	Number of insurance patient attendances /Total number of attendances *100)	Quarterly	HC report/ IBEX/ DHIS2
14.	a) Operating margin (the % of operating revenue remaining after all operating expenses are paid)	[total operating revenue - total operating expenses]/total operating revenue*100	Quarterly	HC report
15.	b) Proportion of reimbursed amount out of the patient total fees waived	Amount of waived fees reimbursed/Total amount of waived fees*100	Quarterly	HC report
16.	C) Proportion of reimbursed amount out of the insurance patient total expenditure	Amount of insurance expenditure reimbursed/ amount of insurance patient total expenditure *100	Quarterly	HC report

1.5. Additional Reading materials

1. Ethiopian Hospital Reform Implementation Guidelines, Federal Democratic Republic of Ethiopia Ministry of Health, May 2010

Chapter 2: Health Centre linkages

Chapter Description: The second chapter is intended to discuss the linkage of health centres with health posts with the expected support from health centres with respect to strengthening community engagement in health promotion and basic health education.

Primary Objective: By the ned of this session you will be able to support and monitor the linkage between health centers and health posts.

Enabling Objectives: By the ned of the session you will be able to:

- Describe the linkage between health center and health post
- Explain how to make Health centers ready for linkage
- Discuss the roles and responsibilities of stakeholders in HC to HP linkage
- Identify the linkage measurement standards with their respective verifications

Chapter Outline:

2.1. Introduction

2.2. Making Health Centers ready

2.3. Guidelines for Merged HEP Services

2.4. Empowering Community with continuous learning.

2.5. Implementation Standards

Activity 2.1. Introducing the chapter	
	**Instruction:** - **Ask participants to reflect their thoughts on HC-HP linkage** - Display PPT and ask participants to read objectives then ask them to read through the introduction and definition of terms. **Time:** 10 minutes.

2.1 Introduction

Ethiopia's primary health care system is designed to provide essential, comprehensive, and integrated health services that are accessible, equitable, and affordable for all. The system is organized by primary health care units (PHCU) with catchment populations of about 100,000-150,000 people, and is comprised of a primary hospital, 4-5 health centers, and five village-(kebele) level health posts linked to each health center. The primary hospital serves as a referral and training center for the health centers and health posts. Furthermore, it provides training, mentoring, and coaching services for health centers and health posts. The health center provides technical (mentorship, supervision, coaching), administrative and logistic support to the health posts under its catchments. It also serves as a referral and training site for HP staffs. The health posts are also directly accountable for health centers.

Ethiopia has registered remarkable achievement in the health sector in the last 15 years by improving access to health information, promotive, preventive and curative services for the community. One of the major contributors to the gains in the health sector is the Health Extension Program (HEP), Ethiopia's flagship community-based primary health care (PHC) delivery platform. Over the last and half decades, HEP has proven to be an effective intervention by serving as the major component of Ethiopia's primary health care delivery system in terms of reach and thus transforming access to health care services. A recurring challenge in the current structure is that the link between HC and HP is generally weak with wide regional and sub-regional variability. A stronger linkage between the primary hospital, HC, HP, and communities enables smooth flow of information and coordinated service delivery. It also enables mentoring, for improved decision making and skill as well as knowledge transfer. HCs/primary hospitals will have full authority and responsibility for HPs under their catchment.

Operational definition

Linkage: The primary hospital, health center, health post, and the community are linked technically and/or administratively and work together to achieve the shared goal of improving the health status of the people.

HEP unit/case team: A HEP unit/case team is established at the health centre and primary hospital to facilitate coordination and implementation of HEP at PHCU level.

Mentorship and coaching: a system of practical training and consultation that fosters ongoing professional development to enhance the knowledge and skills of health care providers to sustainably improve quality of care and health outcomes.

Team-based supportive supervision: A multi-disciplinary team from the health center composed of a health officer/nurse, midwife, pharmacy, laboratory professionals, and others conduct a quarterly supportive supervision to the health posts under its catchment.

Primary health care unit: is comprised of a primary hospital, 4-5 health centers, and five village-(kebele) level health posts linked to each health center.

Family health team: The health workers deployed at urban heath centres are organized as a team also called a "family health team" to provide targeted services to priority populations through home visit or outreach sites. These teams also make referrals for

further care at health centres. This team is composed of leading Medical Doctor/Health Officer/ BSc nurse and 2-3 diploma nurses and 3-4 other members representing environmental health officer, mid-wife nurse and pharmacist.

2.2 Operational standards

1. Health center established functional HEP unit/family health team in urban
2. The HC regularly conducts multi-disciplinary team-based supportive supervision to HPs on quarterly basis
3. Mentorship and coaching is being implemented for HPs/Urban HEps on key prioritized health interventions
4. Health center prepares a joint annual plan with health extension workers/ professionals as a unit
5. The health center collects weekly plan and performance report from each HP/family health team and then provided feedback
6. The HC established learning and experience sharing platform for HC and HP staffs/urban HEps and being in use at least monthly
7. Conduct monthly performance review meeting with health extension workers/urban HEps at PHCU level.
8. All the kebeles under the HC catchment established active and functional community health volunteers (women group, men group, village health leaders, youth health groups, and informal social structures)
9. The health center establish linkage with the catchment primary hospital
10. The health center ensures sustainable supply and logistics management system in all health posts/family health team under its catchment.

Activity 2.2. Making the health centers ready	
	**Instruction:** - **Group participants in to 4-5 people** - **Ask them to work on the question below and present on flip chart** - **How dou make health centers ready for linkage?** **Time:** 20 minutes for group work 15 minutes for discussion.

2.3 Implementation Guidance

Guidance 8: Making Health Centers' ready

1. CAPACITATING THE HEALTH CENTER STAFFS ON COMMUNITY HEALTH

The health center technical staffs need to receive various trainings on community health/health extension program, mentorship, supportive supervision, and other program-

specific trainings to build their capacity and in turn enable them to capacitate the health post staffs. The health center is expected to set up a regular learning and experience sharing platforms to learn and share experiences among themselves on community health and other selected health topics.

2. ESTABLISH HEP UNIT WITH A COORDINATOR AND FAMILY HEALTH TEAM

All health centers will establish HEP unit/family health team at the health center aiming at facilitating the coordination and implementation of community health/HEP. The HEP unit will be composed of a focal person and other multidisciplinary team as deemed necessary. The unit will coordinate and pull technical experts from different case teams of the health center to provide team-based supportive supervision, mentorship, and coaching to the health posts under the catchment of the health center. The HEP unit/ will be entrusted to undertake the following activities:

A. **Develop community health/HEP plan**: The health center together with health posts and community collect basic health, health-related, and key constraints in the implementation of data of kebeles under the health center catchment to develop HEP annual, biannual, and quarterly plan of the PHCU. The comprehensive HEP plan including the community engagement will be articulated to all relevant stakeholders including local administration and community to have a shared understanding on the planned activities and buy-in their support in the implementation of HEP activities.

B. **Coordinate implementation of HEP in the catchment of the HC:** The HEP unit will coordinate the implementation of HEP in the catchment health center through designating teams to mentor, coach, and support HPs, preparing schedules for HC staffs to support HPs, identifying and addressing key bottlenecks in the implementation of HEP, ensuring continuous and sustainable logistic system, and providing administrative support.

C. **Establish/strengthen support systems to HPs:** The community health case team/unit provides or coordinates the provision of various technical supports for basic and comprehensive health posts including team-based supportive supervision, mentorship and coaching, and follow-up and supportive supervision.

    a. **Follow-up and supportive supervision**: The HEP unit/case team is entrusted to coordinate and provide follow-up and supportive supervision to HPs. Besides, the unit identifies and assigns appropriate Health center staffs to render technical and administrative supports to each HP under its catchment. The health center team conducts weekly follow-up and supportive supervision to health posts to provide technical and administrative supports.

    b. Team-based out-reach service and support: The HEP unit identifies and assigns multi-disciplinary technical experts (health officer/nurse, midwife, pharmacy, laboratory, and HEWs) from different case teams to provide comprehensive technical and administrative supports and selected health services for comprehensive and basic health posts. The multi-disciplinary team is expected to visit each health post once in a quarter, but the visit could be more frequent for comprehensive health posts.

D. **Mentorship and coaching:** To capacitate the health center staffs, the primary hospital conducts mentorship and provides different technical supports to the health center. The HEP unit facilitates the health center's case teams to conduct a regular and continuous mentorship and coaching for basic and comprehensive health post staffs based on the knowledge and skill gaps identified after conducting a thorough assessment intended to enhance the knowledge and skills of HP staffs.

E. **Ensure sustainable logistics and supply chain management system**: The health center team provides technical support for HPs to ensure sustainable logistics and supply chain management system is in place. The health center forecasts, quantifies, and procures essential drugs, supplies, and equipment for health posts under its catchment. And, the health center shall allocates budget. The internal revenue of the health center could be used to procure and avail out of stock essential logistics and supplies for HPs to improve the quality of HEP services.

   The health center conducts routine monitoring and regulation to ensure supplies, medicines, and equipment are properly utilized. Besides, to assure appropriate utilization of resources at health post level, the health center should set up a committee (composed of pharmacy department, finance department, HEP unit, and HC director) who have the responsibility to carry out a biannual inventory and report the findings to the health center senior management.

F. **Multi-sectorial collaboration through engaging local administration:** Multi-sectorial engagement in health is very critical strategy to address social determinants of health. In this regard, the health center might play a liaison role between HPs and the kebele administration to ensure multi-sectorial engagement in health at kebele level. The health center also closely works with education, agriculture, women, youth, and children affair, water supply and other sectors to respond for social determinants of health.

Activity 2.3. Merged HEP Services- Think pair-share	
	**Instruction:** - **Pair with your neighbor** - **Discuss how to ensure HC community health services with merged HEP services** - **Reflect your discussions in the general discussion.** **Time:** 5 minutes for discussion 5 minutes for reflection.

Guidance 9: Guideline for merged HEP Services

The HEP optimization roadmap which is planned for the coming 15 years states that the current health posts will be categorized into comprehensive and basic types based on their proximity

to their supervising health centers. As per this roadmap, HPs that are found in the kebeles where the HCs exist will be merged with the HCs with some structural arrangement. These structural arrangements include administrative, technical support, and service delivery approach.

Administrative support: - As indicated on the HEP optimization roadmap there will be no standalone health posts that service as static service provision centers if the health centers and health posts are geographically too close. So the HEWs will be transferred to the health center. Therefore, the following administrative amendments are expected to be implemented:

- The HEP unit head at the health center is responsible for coordinating, and supervising the day-to-day activities of the HEWs. The HEWs are directly accountable to the HEP unit head
- The unit head is expected to facilitate any administrative issues for the HEWs.
- The HEP unit can serve as an office for the HEWs as well where they can organize community health data and reports.
- The HEWs are expected to spend 1-2 days per week at the HC and use the remaining days at the community for community mobilization, outreach services, and home-based care.
- The HEWs have to be considered as HC staff regarding human resource management issues such as individual performance evaluation, annual leave, benefits packages, etc.

Technical support: the health centers staff will continue providing technical support to the HEWs: -

- Capacity building for the HEWs through supervision, coaching, and mentorship.
- The HC staff will conduct regular supportive supervision on community & home-based outreach HEP services.
- Direct involvements of the HC staff are needed on capacity building for the community-based structures, pregnant women conferences, multi-sectoral engagement, campaigns, model kebele creation activities.
- Particularly school health services will be provided jointly with HC staff.
- The HEWs practice the clinical and preventive service (IMNCI/ICCM, FP, EPI) with relatively lesser time (1-2 days in a week) jointly with other dedicated HC staff based on their scope of work.
- During the monthly review meeting of the PHCUs, the HEP performance of that kebele should be equally reviewed against their plan or target mainly focusing on the community-based services.
- The HEWs are expected to develop and submit their respective weekly, monthly, and quarterly plan and reports to their immediate supervisors.

Service delivery approach: -HEP services include health promotion, disease prevention, curative, and rehabilitation. In integrated HEP services, curative services are mainly rendered at the health center. The role of HEWs in curative services at the HC level will be limited (1-2 days per week). They will spend their remaining time providing outreach community and household services and data management and taking part in the review and experience-sharing meetings. As mentioned above, collaboratively with the other staff in the health center, HEWs can provide curative and other preventive services under their scope of practice. The HC staff engagement in community-based services is equally important to provide quality services. Therefore, a team-based approach is greatly encouraged to provide community-level HEP service packages. In general, all of the HEP services must be delivered to the catchment population through the HC, household visit, outreach schedules, and HEWs are mainly required to deal with outreach health activities, and health promotion activities at household and

Activity 2.3. Empowering community forum and countinous learning-2 minute paper	
	**Instruct half of participants to write about the first question and the other half the second question:** - **Write down issues in ensuring regular learning forum?** - **How to empower community forums?** - **Reflect your discussions in the general discussion.** **Time:** 2 minutes for writting 5 minutes for reflection.

community levels and facilitate referrals to HC. Other HEP services such as ICCM/CBNC, family planning, DOTs, etc will be integrated with the HC services.

Guidance 10: Establishing regular learning forum

A. Learning and experience sharing forums: The health center establishes regular learning and experience sharing forums where the health center and HP staffs come together to learn and share experiences among themselves. These forums could be organized at the health center or health post level depending on the health topics and issues identified for learning and experience sharing. These learning sessions could be accompanied by kebele level field visits as deemed necessary.

B. Performance review and improvement platforms: The health center organizes PHCU level monthly performance review and improvement platforms at the health center or HP. The health center and HP teams present their monthly performances and have deliberation on the presentations, undertake root-cause analysis, and develop and implement performance improvement plan. These platforms are guided by a simplified performance review and improvement meeting guide.

C. Report and feedback: In order to monitor the performance of the health extension program in the catchment area, a health center needs to send a regular report to Woreda Health office. The health center is also expected to send a regular oral and written feedback to the health posts based on the report sent and inspection findings. The feedback should clearly indicate the good performing area and the major Gaps and the way forward to fill the gaps. During regular support sessions the health centers staffs should assure the feedbacks are implemented.

Guidance 11: Community engagement and empowerment

Empowering families and communities to produce their own health has been the driving philosophy of the Ethiopian community health system, the HEP. This will be achieved through engaging individuals, families and communities and non-health sectors at ground level in addressing health and its social determinants to achieve good health and wellbeing for all. Even though the current community and multi-sectorial engagement approaches registered tremendous achievement, it is constrained by numerous challenges. In order to address the current strategies, comprehensive community engagement and empowerment strategies with active engagement of the health sectors and multi-sectorial engagement through local administration will be implemented in all kebeles. The community engagement strategies identified for the implementation at kebele and community level include:

A. **Introducing village level Community volunteers (VHLs):** The VHLs bridge the PHCU/HEWs with existing community engagement platforms through revitalization of the stewardship and effective participation of existing community level platforms such as women development groups, men development groups, youth groups and other informal social structures. The VHLs could be organized in teams to coordinate activities in a sub-kebele. As such, three VHL, one man and two women make a team to support 300 households along with WDAs, men groups, youth, and informal social structures.

B. **Optimizing the WDA strategy:** during the last five years, HEP strived to engage large number of WDA networks, its coverage is fall below expectations. Hence, strengthening the WDA approach is expected to sustain the gains health at household level.

C. **Men and youth engagement strategies:** As evidenced by the 2019 national assessment of the HEP and other local studies, men and youth community groups have been barely engaged in health. Developing men and youth engagement strategies, as recommended in the community engagement policy options, is critical to optimizing the existing community engagement strategy through unleashing the potential of these community groups in improving health.

D. **Use existing treasured and trusted social platforms to enhance community engagement:** Tapping of "treasured and trusted" formal and informal community and faith based organizations has been identified as a key intervention in community

engagement policy options to easily reach the community and address key challenges that require societal level responses.

E. **Designing and implementing tailored motivation mechanisms:** Designing and implementing sustainable motivation schemes is imperative to motivate, improve, and sustain the volunteer community health workers' performance.

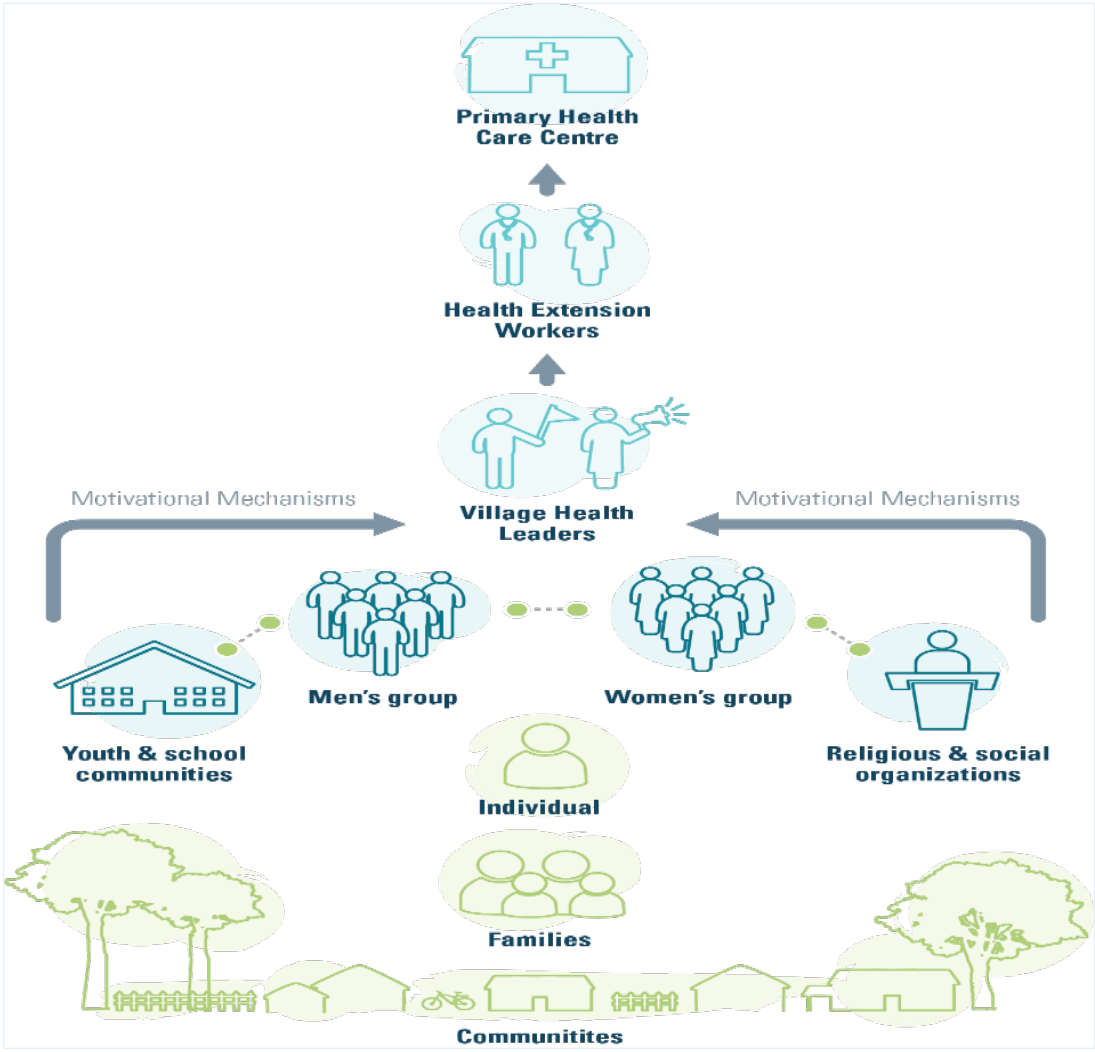


Figure 2.1: Community engagement strategies and their relationships

THE ROLE OF THE HEALTH CENTER IN THE IMPLEMENTATION OF COMMUNITY ENGAGEMENT STRATEGIES

The health center has the responsibility to introduce and/or strengthen community engagement strategies, implementation, monitoring and evaluation of community engagement strategies.

The health center has the following responsibilities in the implementation of community engagement strategies:

- Coordinate and lead the implementation of community engagement platforms at kebele and community level

- Support the revitalization/establishment of men development groups and youth engagement
- Ensure availability and regular use of community engagement implementation guides, training packages, job aids, and tools
- Provide trainings on community engagement approaches for PHCU staffs, kebeles, political leaders, and other sectors
- Provide pre-deployment training, refresher training, and regular thematic training for community engagement platforms
- Regular follow up of the implementation of community engagement platforms
- Regular review of implementation of community engagement platforms during monthly PHCU and kebele level review meetings
- Implement different motivation mechanisms for community volunteers
- Conduct home visits to community volunteers
- Organize experience sharing meeting for community volunteers
- Collaborate with key stakeholders to buy-in support in the implementation of community engagement approaches
- Recording, reporting, and use of data for performance improvement

ROLES AND RESPONSIBILITIES OF DIFFERENT STAKEHOLDERS

Roles and responsibilities of woreda/town/sub-city

- Lead, plan, support, and monitor the implementation of the health extension program, community engagement and empowerment strategies, and family health team
- Lead, plan, support, and monitor the implementation of primary health care linkage (from primary hospital to community level)
- Identify technical and leadership capacity gaps on community health and organize capacity building trainings for PHCU staffs
- Conduct regular performance review meeting and integrated supportive supervision for HCs, HPs, and communities
- Allocate appropriate resources including budget, essential health commodities, human resource, guidelines and manuals, and others for HCs and HPs and assure appropriate utilization
- Collect monthly report, analyze and interpret, and use for informed decision making
- Work closely with the local administration to establish multi-sectorial engagement platform and ensure engagement other sectors (education, agriculture, women, children, and youth affair, finance, and others) in health

Roles and responsibilities of the primary hospital

- Provide overall technical support and guidance in all health program areas for the health center under its catchment
- Plan, implement, and monitor implementation of mentorship and coaching of key prioritized health interventions for HC staffs
- Asses, identify technical capacity gaps of HCs, and organize various capacity building trainings including hands-on training at the hospital
- Serve as a referral facility for the HCs, and implement effective referral system including using referral protocols, tools

- Lead, coordinate, plan, support, implement and monitor the implementation of HEP including linkage between the primary hospital, health posts, and communities in areas where there is no health center
- Provide appropriate supplies, drugs, and equipment for HCs and HPs as deemed necessary

Roles and responsibilities of personnel at health center level

A. **Roles and responsibilities of PHCU director**

- Plans, coordinates, and monitors the implementation of community health/HEP in the PHCU and family health team including the linkage between the health center, health posts, and communities
- Identifies technical capacity gaps of community volunteers, family health team, HC and HP staffs on community health and other health programs, and organize different capacity building trainings
- Provides technical and leadership oversight for the HEP unit to ensure that HEP implementation is well-coordinated, supported, and monitored at the PHCU level
- Ensures annual plan of the PHCU include budget, technical and administrative supports, and essential health commodities plan of the HPs and communities under its catchment
- Ensures the HPs and family health team have the necessary resources including health professionals, essential health commodities, consumable items
- Liaison the health post with local political and administration for the community health systems
- Lead the regular monthly PHCI review meeting with health posts and HC staffs and discuss on identified major bottlenecks and on possible solutions
- Ensure implementation of the Health extension packages in accordance with the implementation guidelines

B. **Roles and responsibilities of HEP unit/case team of the health center**

- Plan, coordinate, and monitor the implementation of HEP and community engagement and empowerment strategies
- Develop a detailed plan on community health to implement the HEP in the kebele and to support health posts for each staffs in the health center and make sure the support is actually delivered
- Identify technical capacity gaps of community volunteers, family health team, HC and HP staffs on community health and other health programs, and organize different capacity building trainings
- Work closely with other case teams of the health center to leverage their technical expertise to build HP staffs technical capacity through multi-disciplinary team-based support, mentorship and coaching, and routine follow-up and supportive supervision
- Provide community-based health promotion and disease prevention services for families and communities in the kebele where the HC is located
- Collect monthly reports, analyze and interpret, and take appropriate measures to improve performances of the HPs
- Organize and co-lead regular monthly PHCU level performance review meeting with HC and HP staffs
- Make sure appropriate resources are allocated to the health posts and assure appropriate utilization

- Ensure implementation of the Health extension packages in accordance with the implementation guidelines

C. **Roles and responsibilities of other health center staffs**

- Each professional will be assigned to one Kebele and technically support Health post staff and volunteer community health workers in the Kebele
- Become part of the multi-disciplinary team to provide team-based support to the HPs
- Conduct mentorship and coaching for HP staffs on key prioritized health interventions
- Identify major bottlenecks (disaggregated into bottlenecks of skill, attitude and logistics) during support session.
- Send feedback to the health posts he/she assigned based on the report collected from health post.
- Report the deliverables of the support to the director of PHCU/HEP unit and participate during the monthly review meeting.
- With health post staff conduct training of community health workers/volunteers for effective community engagement and empowerment

2.4. Implementation /Operational Standards, Checklist and Indicators

2.4.1. Assessment Tool for Operational Standards

Table 2.0.1: Assessment tool for operational standards – Health Center and Health post linkage

S.N	Description of the standards	Verification criteria	Yes √ No X	met =1 not met =0	Remark
1	Health center established functional HEP unit/family health team in urban	HEP unit/ family health team established and has a coordinator			
		Has a detail community health/HEP implementation plan,			
		Has a detail community health/HEP implementation report,			
		The unit has a dedicated office			
		Use standard checklist			
2	The HC regularly conducts multi-disciplinary team-based supportive supervision to HPs on quarterly basis	Supportive supervision plan			
		Supportive supervision report			
		Use standard checklist			
		Supervision finding Feedback			
3	Mentorship and coaching is being implemented for HPs/urban HEps on key	Baseline assessment conducted, key constraints identified, and prioritized for mentorship			
		Mentorship plan developed			

S.N	Description of the standards	Verification criteria	Yes √ No X	met =1 not met =0	Remark
	prioritized health interventions	Mentorship guide and tools/checklist are available			
		Mentorship conducted (review mentorship reports)			
4	Health center prepares a joint annual plan with health extension professionals as a unit.	Shared annual plan			
		Minutes/reports on PHCU plan sensitization workshop			
5	The health center collects weekly plan and performance report from each HP/family health team and then provided feedback	Plan-versus achievement reports			
		Report reviewed and feedback provided			
6	The HC conducts learning and experience sharing platform for HC and HP staffs/urban HEPs and being in use at least annually	Minute for learning and experience shared			
		Documented best practices and lessons learned			
7	Conduct monthly performance review meeting with health extension workers/urban HEps at PHCU level.	Monthly PHCU level performance review meeting minute			
		Root cause analysis conducted for key constraints and performance improvement plan developed			
		Performance improvement action plan developed			
		Documented best practices			
8	All the kebeles under the HC catchment established active and functional community health volunteers(women group, men group, village health leaders, youth health groups, and informal social structures)	Records of community health volunteers of all kebeles are kept at the PHCU level			
		Key performances of community health volunteers of all kebeles are maintained at the PHCU level			
9	The health center establish linkage with the catchment primary/general/specialized hospital	Mentoring plan(copy from hospital)			
		Mentoring feed back			
10	The health center ensures sustainable supply and logistics management system in all health	All HPs/family health teams implement integrated pharmaceutical logistics system (observe HPRRF sent from HPs)			

S.N	Description of the standards	Verification criteria	Yes √ No X	met =1 not met =0	Remark
	posts/family health team under its catchment.	Essential supplies, drugs, and equipment are available and/or functional in all HPs (observe HP/family health team reports of tracer drugs availability and monthly PHCU level performance review meeting minute)			

2.5. Additional Reading materials

1. Health Extension Program Road map

Chapter 3: Patient Flow management

Chapter Desciption: The chapter discusses how the patient flow should be arranged in a health center. This includes setting up triage, emergency health services as well as regular out patient services. It also describes the organization of minor surgical services, liason & referral and in-patient services if there is any.

Chapter objective: By the end of the chapter participants will be able to suggest optimal organization of various health services in the health center.

Enbaling Objectives: By the end of the session you will be able to:

- Describe triage, emergency and liason & referral services arrangement in health centers
- Conceptualize organization of out-patient and minor surgical services in a health center.
- Setup optimal in-patient service in a health center.
- Identify patient flow measurement standards with their respective verification.

Chapter Outline:

3.1. Introduction

Proper patient flow management ensures that health service seekers are provided the services that they require without hardship. Patient flow requires various inputs including human resources, infrastructure, equipment, protocols and pathways. Properly designed patient flow management system helps reduce patient treatment times & grievances, increases provider efficiency, improves staff/client satisfaction, and the overall quality of care.

Emergency Medical Services (EMS) overall are a network of services and resources coordinated to provide aid and medical assistance from primary response to definitive care, involving trained personnel and use of appropriate technologies in the rescue, stabilization, transportation, and advanced treatment of traumatic, obstetric and medical emergencies.

Health Centre based emergency medical services are part of the patient flow in a health Centre setting that includes the processes and procedures needed to ensure the efficient flow of patients between services. Health centre outpatient services management refers to the processes and

procedures needed to ensure the efficient flow of patients between outpatient services and providing quality health care to clients.

Patients enter care into the inpatient service mainly from previous ambulatory care such as referral from outpatients or emergency outpatient department (OPD), home (with an appointment or referred from another facility.) The purpose of the inpatient service is to provide safe, secure, active, energetic, comprehensive, interdisciplinary assessment, stabilization, treatment, initiation and services. The goal of the service is to ensure that the patient can resume normal community living as soon as feasible, thereby maintaining independence. The patient stay should be as short as possible without harming patient outcome. The presence of in-patient service is not a mandatory criterion for health centres but rather optional based on the newly revised health center standard.

This chapter details the inputs and process required to ensure well-organized patient flow at the outpatient department and describes the flow of services from the patient's first encounter with the reception service at the entrance of the health centre until the patient exits the outpatient department and also details the inputs required to ensure well-organized health centre based emergency medical services from the patient's arrival at the entrance of the health centre until the patient is either admitted as inpatient/transferred to outpatient services, referred to other health facilities, discharged home and exits the health centre.

3.2. Operational Standard

1. The health centre shall have an emergency service led by General practitioner or Health officer 24/7.
2. The health Centre shall have ambulance parking area.
3. The health Centre shall have easily accessible emergency room, with ambulance parking area, necessary infrastructure, and with necessary equipment, drugs and supplies needed to provide quality emergency medical services.
4. The health centre shall have a central triage room, with necessary infrastructure, protocol, staffed with appropriately trained personnel and queuing management systems
5. The health centre shall have a liaison service.
6. The health centre shall have an Outpatient Department (OPD) led by a General practitioner or health officer.
7. The health centre shall provide the clinical service based on the Ethiopian primary health care clinical guideline (EPHCG).
8. The health center emergency unit should have updated a documented disaster preparedness and response plan.
9. The health center shall have direction pointers and signage.
10. Health center ensured equitable services are delivered to all.

Activity 3.1 Organization of triage and emergency services	
	**Instruction:** - **Group participants in to 4-5 people** - **Ask them to work on the question below and present on flip chart** - **How should the triage, liaison & referral and emergency services need to be setup?** **Time:** 20 minutes for group work 15 minutes for discussion.

3.3. Implementation Guidance

Guidance 12: Organization of health centres

OVERVIEW

Health centers should have easily identifiable service provision rooms and should provide service in a timely manner without any un-necessary delays. For these, visible room numbers & service labels should be posted on every room, direction indicators should be available & accessible, and rooms that give similar service should be situated as close to each other as possible.

Implementation guidance for Central Triage

The central triage area is the1st contact point for patients with the health center staff (except for patients needing emergency care and laboring mothers). It should be situated at the entrance of the health center with easily recognizable signage for patients and the general public. The triage area should be equipped with the required triage equipment and supplies including pulse oximeter, BP apparatus (adult and pediatric) thermometer, glucometer, weighing scale (adult and pediatric) and triage protocol & staffed by trained professionals.

Staff assigned to the triage area of the health center should be available onsite and ready at all time to receive incoming patients. The health professionals who are assigned in the central triage are responsible for patient support, safe moving, handling, and, preparing wheelchairs/stretchers for use when they are needed. Therefore, health professionals working in central triage need to be trained on basic life support (BLS), infection prevention (IP), triaging protocol, and basic emergency course training (BEC) and communication skills. The waiting room, the Emergency room and the ambulance entrance should clearly be visible from the Central Triage area.

Guidance 13: Implementation Guidance for Emergency service

EMERGENCY UNIT ARRANGEMENT FOR BASIC EMERGENCY SERVICE

The emergency unit should be led by a designated emergency director or case team leader/focal. That person will be responsible for the organization and function of the emergency service.
The Emergency case team leader/focal is responsible for managing all department staff and should ensure that equipment and supplies are available for the patient load. The Emergency unit shall serve as the definitive specialized care area/facility, equipped and staffed to provide rapid and varied emergency care to all people with life-threatening conditions(**Annex 3B**).

Layout of an emergency department/room shall consider key points which include safety, security, access, image & consumer expectations, evolving work practices and the health centers' role. This should allow rapid access to every space with minimum cross traffic. There should be close proximity between the Resuscitation/Acute Treatment areas for non-ambulant Patients and other treatment areas for ambulant patients, as staff may require relocation at times of high workload. Visitor and patient access to all areas should not traverse clinical areas.

HANDLING OF PATIENTS ARRIVING AT EMERGENCY ROOM

Health professionals in the Emergency room will receive, support and direct patients arriving for emergency care and ensure proper handover of patients. They should be easily identified with white uniform (gowns). All Health professional in the Emergency room should be trained in patient moving and handling, basic life support, communication skill and infection prevention & control procedures.

There should be patient support devices in the emergency patient reception area, including: Wheelchairs and stretchers. Patients can arrive at emergency rooms in different ways, including ambulance, public transport or/and independently walking /supported by family and support should be provided as per individual patient needs.

EMERGENCY SERVICE LAY OUT REQUIREMENTS

1) The emergency room should be located on the ground floor for ease of access and should be clearly labelled in a way that is visible from the health centre's gate. Its entrance signage should be clearly illuminated and has multi-lingual labels, preferably red background with white colour labels, that is visible from the street (even at night).
2) There should also be an area dedicated for patient drop-off and ambulance parking. Ambulance parking area should have at least 1 ambulance parking spot and should be close to the emergency room.
3) The floor covering of the emergency room should be a non-slippery surface, impermeable to water, easy to clean; and with acoustic properties that reduce sound transmission and shock absorption to facilitate movement of beds.
4) There should be a dedicated patient registration area co-located with triage.

5) The Triage area should have clear vision to both the waiting room and the ambulance entrance.
6) A decontamination area should be available for patients who are contaminated with toxic substances.
7) There should be an easily accessible resuscitation area with a size that can accommodate at least a single resuscitation bed and room for monitoring and resuscitation equipment.
8) Electrical sockets and hand washing facilities should be available and easily accessible in the Emergency room.
9) There should be an open waiting area for patients as well as relatives/escorts which is clearly visible from the triage and reception areas.
10) There should be a procedure room with hand-washing facilities.
11) There should be staff facilities on the premises with separate Staff changing area, locker, shower and toilet for female and male.
12) There should be dedicated workstation with office furniture.
13) There should a separate patient toilet that is adjacent to the emergency room.
14) There should be clean utility room with sufficient size for the storage of clean and sterile supplies.
15) There should be soiled/dirty utility/disposal mechanism.

ISOLATION ROOMS

Isolation rooms should be provided for the treatment of potentially infectious patients. They should have a room with scrub up facilities, negative ventilation, and be self-contained linen suite facilities. The rooms should be fitted with acute treatment area facilities and located adjacent to patients' reception area, i.e., triage to allow for the immediate isolation of potentially highly infectious based on the health center's standards. Isolation rooms may also be used to treat patients with conditions which require separation from other patients e.g., patients who require privacy for clinical conditions, or who are a source of visual or auditory distress to others. Deceased patients may be placed for grieving relatives to spend time with their deceased ones. These rooms must be enclosed completely from floor to ceiling.

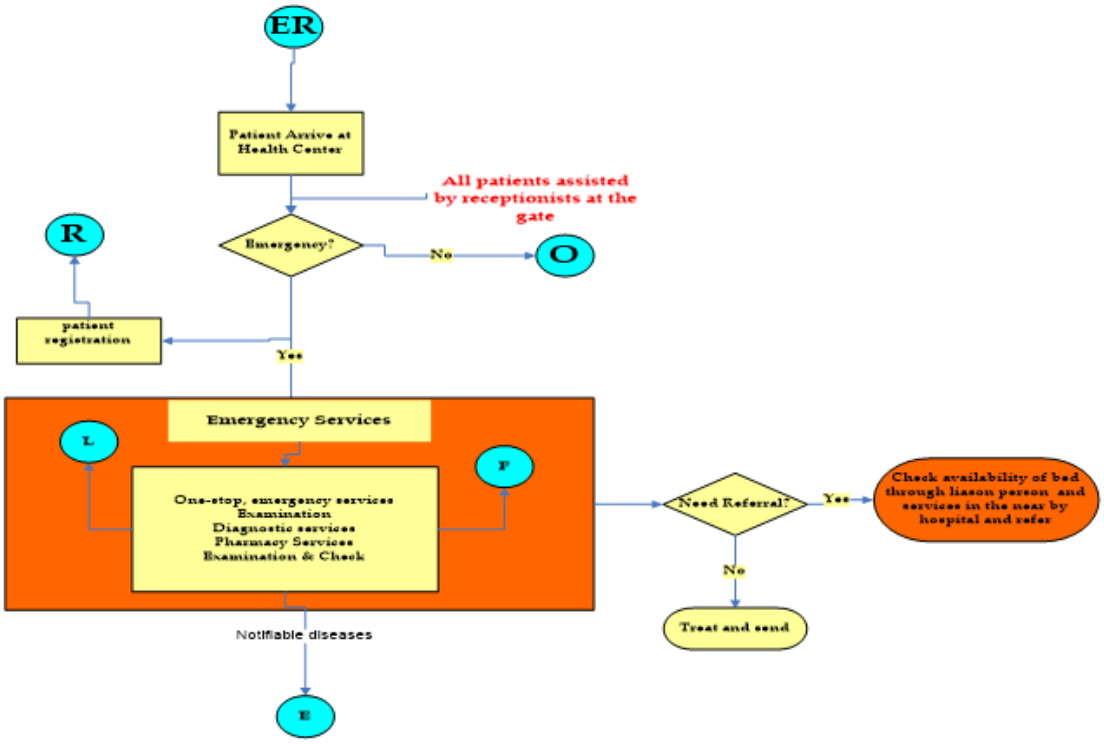


Figure 3.0.1: Emergency service flow in health centers
E: Epidemic notification flow **ER:** Emergency Service flow **F:** Pharmacy service flow **L:** Laboratory service flow **O**: Outpatient service flow **R**: Registration service.
Source: Federal Democratic Republic of Ethiopia Ministry of Health; (2008). Curative, Rehabilitative and Treatment Sub-Business Process.

Guidance 14: Implementation guidance for Liaison and Referral services

Critical to improving the quality of health center care is having an effective networked health care system that strives to deliver quality and efficient health services to the consumer.
Liaison service is vital for effective communication and sustainable smooth flow of patients that need to be operated by liaison officers with special training for the position. Liaison Officer is thus a person that runs the liaison services and liaises between two or more organizations and the public to communicate and coordinate their activities.

Each health center should establish a Referral Protocol that outlines the criteria for making a referral to another facility and the process to be followed when making a referral, including use of the Referral and Feedback Form and any necessary clinical documents that should accompany the referred patient. The protocol should be known and adhered to by all relevant staff.

Each health center should establish a Referrals Service Directory that lists facilities to/from which patients can be referred or received and the services available at each facility (the Referral Network). The contact details of each facility in the Referral Network should be documented. The criteria for receiving/referring patients to each facility should also be documented and agreed between all facilities participating in the Network. Standardized Referral and Feedback formats should be used by all facilities participating in the Network.

- The health centre should establish a liaison office and assign a liaison personnel for referral service facilitation
- The liaison office facilitates referral service, collects and registers referral forms, and provides social services for emergency and out patients, and should have complete and updated service directory.
- The liaison office records, compiles, interprets and reports the referral activities to the health centre management
- The liaison officer takes part in the quality improvement and assurance programs regarding the referral system by participating in regular review meetings within and outside the health facility
- The liaison and referral service should be available 24 hours a day, 7 days a week, and 365 days a year. If it is not possible to have the service 24 hours of the day, the health centre can orient some of the emergency department staffs on referral coordination and may use them on duty hours.
- The suggested qualification of a liaison officer is Diploma or above in health science, social science or information science
- The office should have access to telephone, and a registration system, preferably, computerized registration systems

EMERGENCY REFERRAL OUT

Once the Clinician has decided to refer out a patient the case should be immediately linked to liaison office. Before referring out a patient a liaison officer should:

- Check referral format is completely filed and signed by the physician.
- If there is a command center in the region the liaison should contact the command center to get appropriate receiving facility.
- Use the service directory and the regional referral network to find appropriate facility.
- Send one copy with the patient and attaching one to the patient medical record.
- Before sending any referral out the liaison officer should ensure bed and service availability at receiving facility.
- The liaison office should ensure that the patient has a necessary transport to reach the receiving unit, making use of the facility vehicles/ambulance and professional attendance if it is essential.
- Register the patient on referral register
- If the liaison officer can't find the service or the bed to refer the patient, the patient should stay in the facility with available care until the liaison gets the needed service.
- If the patient is very sick and there are no beds in the receiving institutions the liaison officer has to facilitate online consultation service or has to facilitate communication between referring and receiving doctors/professionals for better management and facilitation.
- If there is any critical or unstable patient that needs admission/stay referral should be made after communication with the referring and receiving physicians (health workers) so that patient transfer is made safely and proper arrangement for the patient management is done.

- Both the referring and receiving health institution liaison officers should make sure critical patients are transported safely and accompanied by professionals who have lifesaving skills.

COLD CASE REFERRAL OUT

After checking all necessary steps listed above and identifying appropriate facility the liaison officer should communicate with receiving facility liaison officer to pass the appointment information to the patient.

Activity 3.2. 2 minute paper on Out patient services	
	**Instruction:** - **Write your ideas on how to organize out patient services and reflect your ideasd in the discussion.** **Time:** 2 minutes for writeup and 5 minutes for discussion.

Guidance 15: Outpatient Department

OUTPATIENT SERVICE LAYOUT

- Outpatient service is linked to the central triage and consists of patient registration and payment, preventive and promotion services (FP, ANC, EPI etc) laboratory and pharmacy, chronic care clinics like ART, VCT, TB/leprosy etc.
- Outpatient Services should be organized in a manner that reduces the length of time that might take a patient to travel from one service area to another.
- Outpatient department consists of the following service areas:
    - Waiting area:
    - Reception and Recording area/desk;
    - Dedicated patient examination rooms; for
        - Adult
        - Under 5
        - AYFS
        - Chronic illness (ART, TB, ANC….)
    - Room for minor procedures (wound care & other)
    - Room for providing dressings and injections
    - Storage place for sterile supplies
    - Utility room for cleaning and storing used equipment

Staff room (for changing cloth)

OUTPATIENT SERVICE ACTIVITY

- The clinical service in OPDs shall have and use the Ethiopian primary health care clinical guideline (EPHCG) for management of communicable and non-communicable diseases for both adult and children above 5 years of age.

- The patient examination chart shall be filled based on the EPHCG requirements.
- The results of any investigations and treatment options should be explained and discussed with the patient and should be clearly documented on the patient card.
- If medication is required, the patient should be directed to the pharmacy dispensing unit to obtain the necessary drugs and appropriate counselling.
- Any minor procedures that are required (such as dressings change or injections) should be carried out in the dressing/injection room of the outpatient department.
- If the patient needs to be referred to other health facility, s/he will be guided to the Liaison office for referral arrangement.

HUMAN RESOURCE NEEDS FOR OUTPATIENT

- The health centre's OPD is led by health officer/GP
- The OPD should be composed of professionals from various disciplines as per the health center standard.

OUTPATIENT DEPARTMENT EQUIPMENT AND SUPPLY NEEDS

- Each case team room should be equipped with equipment and supplies needed to provide care.
- The list of suggested items is found on **Annex3C**

PROCEDURE ROOM AT OUTPATIENT CLINIC

- The outpatient clinic should encompass a procedure room for processing of the medical equipment including standard disinfection procedures.

WAITING AREA AT OUTPATIENT CLINIC

- Waiting area of the health centre should be located closest to the reception and should incorporate the followings:
    - TV area, source for potable water, and gender specific toilet as necessary;
    - Designated, spacious with washable sits and floor
    - Natural or mechanical ventilator
    - Natural or artificial light sources
    - Usher/guide
    - Audio-visual corner with TV for educating patients and their family

Activity 3.4. Think-pair-share on minor surgical and in-patient services	
	**Instruction:** - **Discuss with your neighbors on optimal setup of inpatient and minor surgical services** - **Reflect your discussions to the class.** **Time:** 5 minutes for group work 5 minutes for discussion.

Guidance 16: Minor surgical Service

The Health Centre shall provide minor surgical services for common surgical conditions with clear protocol including patient consent for minor surgical procedures to be done at outpatient level. E.g., Circumcisions, Lipoma excisions, abscess drainages, suturing of soft tissue injuries, external immobilization of closed and open fractures and other minor interventions.

1. Surgical records shall be kept for each patient and it shall be integrated with the patient's over-all health centers record.
2. The pre-operative diagnosis shall be recorded in the medical record for all patients prior to minor surgery.
3. The general medical practitioner or health officer shall explain the disease condition, possible surgical intervention and outcome possibilities in clear, simple and understandable terms to the patient and/or next of kin or family.

   The minor surgical room should be equipped as per the Minor surgical equipment standards of FMHACA.

Guidance 17: In patient department (optional)

IN-PATIENT SERVICES LAYOUT

- Patient wards should be located at close proximity to the emergency and outpatient departments and should be easily accessible for all patients include the disabled patient from elevators, ramps or stairways.
- Each ward should have an adequate number of well-ventilated rooms, functioning set of adequate number of toilets considering the disable, sinks and showers.
- If mixed-sex wards are used there should be separate rooms for male and female Patients.
- Wards should be laid out to facilitate nursing procedure for the patients (i.e.sufficient space around beds, bed screens or curtains to maintain privacy.
- The inpatient service should be composed of the following rooms
  - Wards separate for male and female
  - Nursing Station per ward
  - Physician/HO/BSc Nurse office (consultation room)
  - Bathroom for patients per ward
  - Staff bathroom
  - Duty room
  - Clean utility room

- Soiled utility room
- Mini Store

ADMISSION PROCESS

- The health centre should provide 24 hours, 7 days a week and 365 days a year admission and discharge service, including holidays and weekends. All admissions and discharges should be arranged through the Liaison.
- The health centre should have a written protocol for the admission of patients that includes all steps to be taken in the admission process including how to arrange admission, and the activities to be undertaken when the patient arrives on the ward.
- Upon arrival on the ward the patient should be received by a nurse who will initiate the ward admission process, including orientation to the facilities (such as toilet and showers), instructions for care-givers etc.
- Receiving nurse should assess all patients/clients' conditions on arrival in the ward and informs the on-duty professional for immediate medical assessment for critically ill patients and within 2 hours for patients with stable conditions.

INPATIENT SERVICE ACTIVITY

- The inpatient service includes the following services for admitted patients:
    - Taking comprehensive medical and social history, comprehensive physical examination and performing important laboratory & other medical workups upon admission and when indicated.
    - Nursing care service over the 24 hours of each day of admission until discharge
    - Detailed round visits at least twice a week and daily business round by the attending professional.

DISCHARGE PROCESS

- The health centre should establish a written protocol for the discharge of patients stating all the steps to be followed when arranging discharge, including preparation of a discharge summary and handling of the medical record after discharge.
- Patients ready for discharge should be counselled by the attending professional before discharge. Pre-discharge counselling should include:
    - An explanation of the patient's diagnosis, investigation results and treatments given
    - An explanation of any medications that the patient should continue to take upon discharge
    - Any necessary follow up arrangements
    - Any discussion of any 'warning signs' that the patient has to be aware of and for which he/she should seek medical attention
- The discharge process should be complete in no more than 2 hours (including administrative issues).

PATIENT DEATH

- There shall be a policy or a protocol that states the procedure to be followed for dead body care, including how the staffs informs the next of kin/family members of the deceased, taking all religious and cultural considerations into account.
- A death occurring in the health centre should be confirmed by at least an attending physician or health officer and the nurse giving care.

3.4. Implementation /Operational Standards, Checklist and Indicators

3.4.1. Assessment Tool for Operational Standards

Table 3.1: Assessment tool for operational standards – Patient flow

S.No	Standard	Method of evaluation	Yes √ No X	met =1 not met =0	Remark
1.	The Health centre shall have an emergency services led by General practitioner or Health officer 24/7.	Check presence of standalone ER			
		Check whether the ER unit is labelled properly, visible from the distance, and located near to the gate			
		Check team lead is GP/HO			
		Observe team leader assignment letter			
		Check team leader job description			
		Check whether emergency department team are trained(interview)			
		Check presence of protocols and guidelines			
		Check whether necessary equipment, drugs and supplies are fulfilled based on Ethiopian Emergency Service Labelling Guideline Standard.			
		View triage registration sheet			
		View emergency registration form			
		Sample 5 charts and view whether BEC ESC toolkit attached to patient folder			
2.	The health Centre shall have ambulance parking area	Check the ambulance parking area and confirm that it is accessible for emergency service			
3.	The health Centre shall have easily accessible emergency room, with necessary infrastructure, and with necessary equipment, drugs and supplies needed to provide quality emergency medical services.	Check whether the ER unit is labelled properly & visible from distance,			
		ER is located near to the gate			
		Check whether necessary equipment, drugs and supplies are fulfilled based on Ethiopian Emergency Service Labelling Guideline Standard standards .			
4.	The health centre shall have a central triage	Check availability of central triage			
		Check protocol for triaging and managing queue			

S.No	Standard	Method of evaluation	Yes √ No X	met =1 not met =0	Remark
	room, with necessary infrastructure, protocol, staffed with appropriately trained personnel and queuing management systems	Check availability of basic medical equipment for triage (BP apparatus, temperature measurement, weighing scale, glucometer, pulse oximeter)			
5.	The health centre shall have a liaison service.	Check presence of focal person(assignment letter)			
		Check presence of updated protocol			
		Check availability of revised referral directory			
		Check whether referrals are managed according to the EPHCG (3 sample patient charts)			
		Check the availability of a standard referral sheet and register.			
		Check feedbacks received			
6.	The health centre shall have an Out Patient Department (OPD) led by a General practitioner or health officer.	Check the availability of at least: • Adult OPD, • Chronic disease OPD, • Youth friendly service OPD			
		Check assignment letter for team lead			
		Check team lead JD			
		Check presence of examination coach, BP apparatus and stethoscope			
		Check training on EPHCG of staff at OPD			
		Check the registration book and appointment logbook.			
7.	The health centre shall provide the clinical service based on the Ethiopian primary health care clinical guideline (EPHCG).	Check availability of the EPHCG in all OPD rooms			
		Check 5 sample patient charts on adherence to EPHCG algorithmic approach			
		Check minute on bi monthly clinical forum sessions			
		Check training records for new staffs			
8.	The health center emergency unit should have updated disaster preparedness and	Check the availability at least annually updated documented disaster preparedness and response plan.			

S.No	Standard	Method of evaluation	Yes √ No X	met =1 not met =0	Remark
9.	The health center shall have direction pointers and signage.	Check presence of signage which clearly directs customers to the service they want very easily.			
10	Health center ensured equitable services are delivered to all.	Latrine for handicaps			
		Walkway for handicaps			
		Sign language trained staff			

Chapter 4. Maternal, New-born and Child Health Care

Chapter Description:
This chapter is intended to describe how to organize maternal health care services in health centers. It also outlines how child health and neonatal care services are organized optimally.

Chapter Objective: By the end of the chapter participants will be able to explain optimal organization of maternal, newborn and child health services.

Enabling Objectives: By the end of the session you will be able to:
- Characterize optimal organization for maternal health services in health centers
- Outline service arrangement for new born and child health services
- Identify maternal, newborn and child health services measurement standards with their respective verification criteria.

Chapter Outline:
4.1 Introduction
4.2 Maternal Health Services
4.3 Newborn and Child health Services
4.5 Operational Standards

4.1. Introduction

The time of child birth and the period immediately after birth are particularly critical for maternal, foetal and neonatal survival and well-being. Effective care to prevent and manage complications during this critical period is likely to have a significant impact on reducing maternal deaths, stillbirths and early neonatal deaths. Within this critical period and during antenatal care, quality of care improvement efforts would target essential maternal and new born care and additional care for management of complications that could achieve the highest impact on maternal, foetal and new born survival and well-being.

Additional to maternal and neonatal mortality burden, the high perinatal and under five mortalities require attention and need to be addressed. Health centres need to implement the operational standards contained in this chapter and use the revised standard guidelines, including the establishment and maintenance of new born corners in maternity wards. Health centres should also have separate under 5 OPDs, assign adequate number of qualified health workers in under 5 OPDs with training on revised national guidelines and setting functional vaccination/EPI clinic as essential components of quality paediatric care that address the challenges of high perinatal and U5 mortality rates.

4.2. Operational standards for MNCH care

1. The health centre shall provide MNCH service led by a senior midwife/general practitioner/health officer.
2. The health center avails resources for comprehensive ANC and PMTCT services.

3. The health centre shall establish maternal waiting homes with necessary facilities (optional for urban HCs).
4. The Health Centre shall ensure provision of Basic Emergency Maternal and Newborn Care (BEmONC) services for 24/7.
5. If the HC has OR block, The Health Centre should ensure provision of Comphrensive Emergency obstetrics and New born Care (CEmONC) services for 24/7.
6. The Health Centre shall provide comprehensive postnatal care in the facility as per national standards.
7. The health center should provide comprehensive abortion care service (Safe abortion and Post abortion care) as per the national guideline and protocol.
8. The Health Centre should provide EPI, Growth Monitoring and Promotion services.
9. Health centers shall have established separate under 5 OPD, with necessary facilities.
10. The Health Centres shall ensure provision of family planning services.

Activity 4.1.. Group Work on Maternal care, new born and child health services implementation guidance	
	**Instruction:** - **Guide participants to make groups of 4-6 participants** - Instruct half of the groups to work on one of the topic and the other half on the other - Maternal care service organization in health centers - New Born and child health services organization best practices. **Time:** 30 minutes for group work 20 minutes for discussion.

4.3. Implementation Guidance

Guidance 18: Maternity care implementation guidance

ROLES AND RESPONSIBILITIES

The maternity unit will be led by midwives and she/he will have the following responsibilities:

- Monitor the activities of the maternity unit
- Leads the maternity QI subcommittee (optional) to conduct regular audit meeting and draw action plan depending on the findings
- She/he communicates with the health centre, arrange trainings for all staffs, make sure that there is proper hand over mechanisms, and proper follow up of day-to-day clinical activity.
- The heads of the maternity unit will have roles and responsibilities in each respective unit:

- They prepare and compile monthly, quarterly and yearly report and action plan.
- They should be members of maternal death audit committee/QI committee, should prepare schedule for the unit and make sure that all the necessary materials and supplies are always available.
- They will communicate with the IESO/physician (if available) whenever they have any challenges in their respective units.

RULES AND NORMS

- The maternity unit includes the ANC room, labour & delivery room, and postnatal room.
- The unit should be placed in an easily accessible location and mothers should be treated with respect and dignity.
- Respectful maternity and new born care norms should be applied to all clients and pain should be managed appropriately
- The maternity unit should do audits regularly:
  - Maternity unit audits should be performed every month and client/mom's satisfaction survey should be performed every 3 months.
  - Data should be displayed and updated on a white board at ANC, labour & delivery and postnatal rooms.
- Regular review meetings with in the unit should be held at least every week to discuss unit activity, audit findings, on-going challenges, and way forwards
- Community involvement in the form of pregnant women forum or community forum should be held at least every 3 months.

MATERNITY WAITING ROOMS

Maternity waiting homes are residential facilities in health centres where mothers, especially those living in remote areas can be safely kept at a health facility until the time of delivery, mainly to reduce the maternal morbidity and mortality by avoiding secondary delay. Delays can occur in three ways i.e., primary secondary and tertiary. Primary delay occurs due to delay in decision to seek care and could be due to poor understanding of complications & risk factors in pregnancy and when to seek medical help, poor previous experience in health care facilities, financial implications etc. Primary delays can be prevented through providing communities (men and women) with information on pregnancy, childbirth and new born healthcare so they know when to seek medical help, by facilitating income generation schemes for women to enable them to become financially independent and empowered to make decisions about their own sexual and reproductive health and to become future leaders. Secondary delay occurs because of a delay in reaching healthcare facilities mainly due to distance to health facilities, availability &cost of transportation, poor roads and infrastructure, and geography of the area. Secondary delays can be avoided by construction of maternity waiting homes for pregnant mothers and allowing them to stay in health facilities before the time of labour. It also plays a big role in provision of basic health services, health promotion & disease prevention, as well as helps mothers develop skills on recreational and income generating activities. Tertiary delay

is a delay in receiving adequate health care, due to poor facilities and lack of medical supplies, inadequately trained and poorly motivated medical staff and poor referral systems Tertiary delays can be prevented by training midwives, nurses, doctors and healthcare professionals to provide safe births now and for future generations, ensuring health facilities are suitably equipped to provide safe deliveries and improving referral systems between health centres and hospitals.

- The admission criteria to the maternity waiting homes are:
    - Any mother who resides at distant areas
    - Under-age pregnancy
    - Those with high-risk pregnancy
    - Mothers with nutritional imbalances
    - If there is any risk on the mother from relatives/community, including emotional abuse.
    - Any mother who is pregnant for eight months or more, irrespective of her gravidity, parity, medical and obstetrical history is eligible.
- The services provided in maternity home include:
    - ANC and PNC services
    - Laboratory investigation services
    - 24 hours nursing services
    - Treatment for mothers who are sick, health education, skilled birth attendance, F/P, etc.
- The room should be illuminated, ventilated, clean and should accommodate at least six mothers in one room. In addition, it should have cooking area (kitchen) with full equipment. Furthermore, the room should have bath room, toilet, hand washing facility, electricity and water supply

ANTENATAL CARE (ANC)

- Health centres should provide ANC service throughout working days by skilled health personnel.
- A midwife/senior health care provider in MCH will be the head of the ANC service and all the service providers should be skilled for ANC.
- The ANC room maintains privacy by using curtains / screen
- All ANC services will be provided free of charge including ultrasound where available
- ANC should be provided for all clients according to the national ANC guideline and protocol.
- HIV positive pregnant mothers and their exposed infants should be tested and treated according to the national PMTCT guideline

- A formal and clear communication should exist between the ANC and liaison in order to facilitate proper referral of high-risk pregnancies to higher health facilities (hospitals).
- Iron folate supplementation will be given at least for three months (90tabs) and deworming after first trimester. Drugs should be available and provided on-site free of charge.
- All mothers who come for ANC should be counselled on nutrition, birth preparedness and complication readiness, immunization, breast feeding, family planning, PMTCT counselling and testing, gender-based violence and avoidance of harmful traditional practices.

LABOUR AND DELIVERY

- Labouring mothers should go directly to delivery room without any administrative procedures.
- There should be reception with clear admission criteria.
- The stage of the labour and the status of the foetus will be immediately assessed by skilled health care provider in the delivery room. If the labour is normal, she is allowed to deliver in the health centre.
- If it is abnormal/complicated labour or if the pregnancy is a high-risk pregnancy that couldn't be handled in the health center, the mother should immediately be referred to a higher health facility (hospitals).
- Before referral, the liaison officer should be communicated to facilitate the referral and she should be referred to hospital by an ambulance accompanied by a health care provider.
- The delivery rooms should be clean, well ventilated and with good temperature (neither hot nor cold).
- Delivery room needs to have emergency drug cabinet that has labelled essential drugs.
- It should have all functional essential medical equipment and supplies (see Annex 2 for the list of drugs, supplies and equipment)
- The delivery room should have functional refrigerator with temperature monitoring chart.
- The delivery room should have functional clock, BP apparatus, fetal monitor, newborn weighing scale, stand light and tape meter.
- Privacy must be maintained for first and second stage of labour by screens or curtains and sufficient space should be available for labouring mothers and one companion.

- Mothers are allowed oral fluids and light food during labour. Family member/support person should be allowed to remain with woman constantly during labour and delivery.
- There should be functional bathroom and toilets with hand washing basin and soap accessible to labouring mothers. The delivery room should have hand washing facility for the staff.
- The labour and delivery should have at least four beds for first stage of labour and two delivery coaches for second stage of labour.
- Partograph should be properly and consistently used for active phase of labor and third stage should be managed actively. If a decision has to be made, it should be from the Partograph findings and the action has to be appropriate and timely.
- Vacuum delivery should be based on justified indications and performed timely.
- Delivery coach should be clean, and comfortable with all accessories. Mothers should be allowed to deliver in their preferred position.
- Well-equipped new-born corner for routine essential new-born care and neonatal resuscitation should be available in the labour and delivery room
- The new born corner should include: Radiant warmer, new born sized ambu-bag of sizes 0 and 1, and suction bulb and/or suction machine.
- All health care providers in the labor and delivery should be skilled on essential new-born care and new-born resuscitation.
- Laboratory services that provide essential lab tests for emergency obstetric and new-born care should be available at all times
- Standard protocols, guidelines, algorithms, and job aids should be available in the labour room for the health care provider
- SOPs detailing the roles and responsibilities of staff, admission and discharge criteria, etc should be prepared and consistently used
- Delivery summary should be filled completely on the back of the Partograph.

POST-NATAL CARE (PNC)

- The postnatal room should be clean, ventilated, appropriately illuminated, well equipped and adjacent to the labour room.
- The postnatal beds should be clean and comfortable with accessories and bed sheet.

- The health centre should give postnatal care and stay for at least 24 hours and maternal BP, PR, temperature, uterine tone (contraction), vaginal bleeding checked every 15min for the first 2 hours
- The postnatal room should have at least 8 beds
- Neonates should be monitored for breathing problems, colour; pulse rate, breast feeding and cord care.
- Mother should be counselled for danger signs for both mother (vaginal bleeding, fever, foul smelling vaginal discharge, severe abdominal pain, safe sex, abnormal body movement) and neonate (failure to suck, jaundice, cyanosis, fever, abnormal body movement, difficulty of breathing)

COMPREHENSIVE ABORTION CARE (CAC) SERVICE

- The service should be a woman-centered (comprehensive approach to providing abortion care services that takes into account the various factors that influence a woman's individual needs— both physical and mental—as well as her ability to access services and her personal circumstances).
- The health centre should ensure abortion care services provided to women, as permitted by the national law
- The health centre should manage abortion complications and/or stabilization and referral.
- The health center shall improve women's broader reproductive health by integrating abortion care
- All working staff should have received appropriate training, demonstrate competent skills and the services should be evidence based including use of national guideline and policies.
- The health centre should also ensure availability of safe abortion services & referral as permitted by the law
- The health center should have dedicated room with adequate medical supplies and equipment including pain management and counselling service
- The health center shall integrate family planning service with abortion care

CAESAREAN SECTION (CS) SERVICES

- If the health center has a functioning OR, it should be fully functional operating theatre (one table dedicated for caesarean section) and it should be adjacent to the labour and delivery room.

- Appropriate and adequate caesarean section team members should be available 24/7 (OBY/GYN or IESO, anaesthetist, scrub nurses) with all essential drugs for caesarean section and functional essential equipment.
- Safe surgery check list should be used for all surgeries and documentation should be completed for all caesarean sections.
- Clinical audit to assess completeness of documentation (Indications for C-section, decision to incision time, operation note with the outcome and name with signature of the Surgeon, condition of the mother and the baby, etc with legible hand writing) should be done every three month and rate and indications for C/S should be displayed in white board every month.
- Spinal anaesthesia should be used in the absence of contraindication

FAMILY PLANNING SERVICES

- It is basic right of individual and family to be provided with service, supplies and information how to plan their families. Family planning clients shall receive information, education and counselling on sexual and reproductive health, family planning and STI/HIV/AIDS.
- The health centre should have open access to and availability of full range of family planning services as integral part of basic health services with particular emphasis on long term methods. Services provided should be person-centred, ensuring good communication and client counselling.
- All working staffs should have received appropriate training, demonstrate competent skills and the services should be evidence based including use of national guideline and policies.
- The health centre should ensure availability of all contraceptive methods with particular emphasis on long term methods and the service shall be available at all working hours

Guidance 19: Child health implementation guide

U5 EMERGENCY, TRIAGE AND AMBULATORY (OPD) SERVICE

- Health centres have established under 5 OPD premises.
- Rapid triage for all children presenting to health centres needs to be put in place to identify and manage children with emergency or priority signs.
- Once emergency signs are identified, prompt emergency treatment needs to be given to stabilize the condition of the child.
- Children should be triaged immediately (before any registration or other process) and categorized as emergency, priority and non-urgent cases so as to provide immediate emergency treatment to those with emergency signs, to bring to the front of the OPD queue and to identify non-urgent cases that can wait for their turn at the regular under 5 OPD.

- Appropriate identification codes such as colour coding shall be used to categorize triaged children.
- Emergency treatment room with necessary equipment and emergency drugs should be prepared adjacent to the triage area where children with emergency signs are given emergency treatment such as oxygen administration for children with severe respiratory distress, anticonvulsant treatment for those children who are convulsing etc.
- Professionals with training in ETAT should be assigned in the emergency and triage rooms.

HEALTH CENTRE HAVE AN UNDER 5 OPD SEPARATE FROM ADULT OPD, WITH EMPHASIS ON IMNCI IMPLEMENTATION

Every day, a large number of parents seek health care for their sick children, taking them to hospitals, health centres, pharmacists, doctors and traditional healers. The majority of sick children are treated in OPDs, and in most of them, history and signs and symptoms will determine a course of management that makes the best use of the available resources.

Layout, facility, and staff competence for U5 ambulatory care

- Under 5 OPD & emergency room shall be established in the same building or in very close proximity to each other.
- Well ventilated and illuminated OPD rooms with adequate supplies, guidelines/job aids, drugs and equipment should be set up
- Spacious waiting area in the corridor of the OPD is arranged with chairs/benches for patients/parents.
- Under 5 OPD room shall be clearly labelled and visible to service seekers.
- A physician/HO/BSC nurse or IMNCI trained professional should manage children under the age of 5 years in the under 5 OPDs.
- Children are given priority based on the triage findings (i.e., those with priority signs are given priority in the queue)
- The case management of sick children seen at under 5 OPD should follow national guidelines and recommendations, with reference to standard paediatric textbooks as appropriate.

Components of the under 5 ambulatory care

- ORT corner/room is established within under 5 OPD
- Children aged 5 years and above should be managed based on the Ethiopian Primary Health Care Clinical Guideline (EPHCG) in the regular IPD clinics.

BASIC NEONATAL CARE

The health centre shall be established the new born corners at the maternity ward. All new born at the maternity should have standard identification tags attached to the arm and/or leg of the new born. Rooming in of all new born with their mothers and early initiation (within one hour of delivery) of exclusive breast feeding should always be encouraged. Attention should be given to correct nutrition in sick neonates. No new born shall be discharged from a health centre

in the critical first 24 hours of life, and without receiving basic new born care including birth doses of vaccines.

Triaging sick neonates

Neonates referred from maternity or other health facilities are triaged to identify neonates:

- That need immediate resuscitation
- That can stay with their mothers while receiving treatment
- That should immediately be referred to a higher-level health facility

Mothers'/care givers rights and responsibilities

- Mothers and care givers of new born and children admitted to health centres have the right to know about the health status of their children and should be regularly communicated
- Informative, systematic and regular communication is essential to engage families in the care of their children. Mothers and care givers should be encouraged to be involved in the care of their children and health education in the future care of their children should be given.

EXPANDED PROGRAM ON IMMUNIZATION (EPI)

Immunization is a proven tool for controlling and even eradicating infectious diseases.

EPI Clinic Layout, Facility and Staff Competencies

- Health centres should have a separate functional EPI clinic providing all the routine vaccines within the MNCH unit, open on all days
- All the routine vaccines, diluents, AD syringes and needles, and safety box should be always available in the EPI clinic
- Functional refrigerator, temperature monitoring device, vaccine carriers, and adequate ice packs should be available and cold chains should be maintained in all days
- EPI guidelines and job aids should be readily available and in use
- Standard EPI registers, vaccine ledger book, tally sheets and child immunization cards should be printed and available in adequate quantities
- Registered clinical nurses and/or midwifes with special training on EPI are assigned in the EPI clinic
- EPI clinic is ideal unit for growth monitoring of well infants and for educating mothers on the care of their children

4.4. Implementation /Operational Standards, Checklist and Indicators

4.4.1. Assessment Tool for Operational Standards – MNCH services

Table 4.0.1: Assessment Tool for Operational Standards – MNCH services

S.No	Standard	Method of evaluation	Yes √ No X	met =1 not met =0	Remark
1	The health centre shall avail amenities and resources for MNCH service.	Check rooms for			
		o ANC,			
		o FP,			
		o L & D,			
		o under five OPD,			
		o EPI.			
		Check team lead assigned is MW/GP/HO			
		View job description of the MNCH team lead			
2	The health center avails resources for comprehensive ANC and PMTCT services.	Check availability of :			
		o Dedicated personnel for ANC			
		o Dedicated personnel for PMTCT			
		o BP apparatus			
		o Weighing scale			
		o Fetoscope			
		o Stadiometer			
		o MUAC meter			
		o basic laboratory tests (VDRL, Blood Group &Rh, Hgb & HIV, urine dipstick, RBS…) done			
		o Supply of Iron folate			
		o ART for HIV positive mothers			
		o Supply of TT vaccine			
		o Treatments for HIV exposed baby			
3	The health centre shall establish maternal waiting Homes with necessary facilities and services (optional for urban HCs).	Check availability of separate maternal waiting homes with at least:			
		o Safe water supply			
		o Food			
		o Kitchen			
		o Separate shower and latrine			
		o Adequate electricity			
		o Availability of pairs linen			
		o Audio visual tools			

S.No	Standard	Method of evaluation	Yes √ No X	met =1 not met =0	Remark
		Check pregnant mother's chart for daily clinical check up			
4	The Health Centre should ensure provision of Basic Emergency Maternal and New born Care (BEmONC) services for 24/7.	Trained personnel			
		Separate L & D room			
		New-born corner as per standard			
		Basic supplies			
		o Parenteral Antibiotics			
		o Parenteral Anticonvulsant			
		o Uterotonics			
		o MVA kit			
		o Vacuum extractor			
5	If the HC have OR block, The Health Centre should ensure provision of Comphrensive Emergency obstetrics and New born Care (CEmONC) services for 24/7.	• Fully functional operating theatre (one table dedicated for caesarean section) and it should be adjacent to the labour and delivery room.			
		• Appropriate and adequate caesarean section team members should be available 24/7 (OBY/GYN or IESO, anaesthetist, scrub nurses)			
		• All essential drugs for caesarean section and functional essential equipment should be available.			
		• Check documented Safe surgery check list for all completed surgeries			
		• Check Clinical audit done every 3 month to assess completeness of documentation			

S.No	Standard	Method of evaluation	Yes √ No X	met =1 not met =0	Remark
6	The Health Centre shall provide comprehensive postnatal care in the facility as per national standards	Ensure that the health centre have separate room for PNC			
		Trained personnel			
7	The health center should provide comprehensive abortion care service (Safe abortion and Post abortion care) as per the national guideline and protocol.	• National Technical and procedural guideline for abortion care			
		• MVA			
		• Misoprostol			
		• Pain management for CAC			
		• Trained personnel			
8	The Health Centre should provide static EPI and GMP services.	Ensure that the EPI room is separate and child friendly:			
		o Comfortable chairs			
		o Well ventilated room			
		o Attractive for children			
		Check availability of trained focal person			
		Check availability of functional refrigerator, cold box, vaccine carrier, and ice packs			
		Temperature monitored twice including weekends(check temperature monitoring chart)			
		Check regular availability of all routine vaccines, diluents, AD syringe and needles, and safety boxes			
		Check EPI guidelines and job aids are readily available and in use			
		Ensure availability of GMP assessment tools (weight scale, MUAC meter, Meter/Stadiometer, WHOI standard curve)			
		• Check availability NACS room			

S.No	Standard	Method of evaluation	Yes √ No X	met =1 not met =0	Remark
		• Supply of Supplements (plumpy, BP100..)			
9	Health centres shall have established separate under 5 OPD, with necessary facilities	Check the presence of separate under 5 OPD			
		ORT corner is established within under 5 OPD			
		Check IMNCI implementation:			
		o Check diagnostic facilities (weighing scale, measuring tape)			
		o IMNCI chart booklet			
		o IMNCI registration book			
		Trained personnel			
10	The Health Centres shall ensure provision of family planning services.	Trained health professional			
		Supply of contraceptive methods, including IUDs, implants, injectable, oral Contraceptives & emergency contraceptives			
		EPHCG guide			
		MVA			
		Misoprostol			

4.4.2. Implementation indicators

Table 4.0.2: Indicators related to MNCH Care

No.	Indicator	Formula	Frequency	Source
1	Proportion of pregnant mothers screened for syphilis	Total #of mothers screened for syphilis / Total # of mothers came for ANC follow up	Quarterly	ANC logbook
2	Proportion who had their partners tested for HIV	Total #of partners tested for HIV/Total # of mothers came for ANC follow up	Quarterly	ANC logbook
3	Proportion of mothers with documented Birth planning (place of birth, transport…)	Total #of mothers with documented Birth planning / Total # of mothers came for ANC follow up	Quarterly	ANC logbook
4	Percentage of mothers who have chosen post-partum family planning	Total #of mothers who have chosen post-partum family planning / Total # of mothers came for ANC follow up	Quarterly	ANC logbook
5	Percentage of births followed with completed Partograph	Total #of mothers followed with completed Partograph / Total # of delivery	Quarterly	Partograph review
6	Percentage of birth followed with safe child birth check list	Total #of mothers followed with completed safe child birth check list / Total # of delivery	Quarterly	Delivery register
7	RATE of institutional delivery (from benchmarked number)	Total # of deliveries /Expected number of deliveries by conversion by conversion factor of population	Quarterly	Delivery log book

Chapter 5. Pharmacy Services

Chapter Description: This chapter discusses how a pharmaceutical service should be organized in a health center. Pharmacy service organization in a health center includes provision of drug information services, good dispensing practice as well as monitoring safety of drugs. The new additional services including auditable pharmaceutical services, clinical pharmacy will also be explained in this chapter. Pharmacy waste management is one of the important topics that will be addressed in this chapter. Pharmacy service measurement standards along with their verification will also be discussed.

Chapter objective: By the end of the chapter participants will be able to analyze how a health center pharmacy service should be organized optimally.

Enabling Objectives: By the end of the session you will be able to:

- Discuss pharmacy service organization and management
- Evaluate good dispensing practice
- Audit drug information services
- Analyse an auditable pharmacy service
- Facilitate pharmaceutical waste management
- Discuss antimicrobial stewardship services.
- Identify pharmacy service measurement standards with their respective verifications.

Chapter outline:

5.1. Introduction

Pharmacy service is the last and critical step for client's services in health centers. Since the ultimate health outcome is determined by appropriate selection, quantification, procurement and rational use of pharmaceuticals, pharmacy services should be designed to provide assurance that quality and safety is maintained at all stages of service provision. Following the launching of the Health Sector Transformation Plan (HSTP) and its emphasis to increasing equity and quality of health care, health center pharmacy services are expected to have substantial contributions in realizing this vision by rendering measurable and better-quality services in a more responsible and accountable.

Within the Ethiopian Health Service, a number of reforms are currently taking place that affect pharmaceutical services of Health Centers. Therefore, the standards and guidance set in this chapter are designed to align with and support health center pharmaceutical services to meet the demands of the health sector transformation plan for the nation.

5.2. Operational Standards

1. The Health Center has a functional Drug and Therapeutics Committee (DTC) .
2. The Health Center has a separate pharmacy department comprising dispensaries and medical store directed by a registered Pharmacist /Pharmacy technician respectively.
3. The Health Center develops, utilizes and annually updates a comprehensive list of pharmaceuticals prioritized by VEN
4. The health center implements auditable, transparent and accountable pharmaceutical transactions and services (APTS). (if applicable)
5. The health center provides drug information services to health care providers, patients and the public in order to optimize drug use.
6. The Health Center has policies and standard operating procedures for identifying and managing drug use problems, including: Identifying and reporting adverse drug reactions, and prescription monitoring.
7. The Health Centre has a pharmaceutical supply and inventory management system for drugs, medical supplies and equipment .
8. The Health Center ensures proper and safe disposal of pharmaceutical wastes and expired drugs in line with national guidance.
9. The health centres pharmacy assists and monitors pharmaceutical management activities at the health posts.
10. The Health Centre conducts audits of all drugs, medical supplies and consumable equipment in the store and in each dispensing unit at a minimum bi annually by internal auditor and once a year by external auditor.
11. The health center has functional antimicrobial stewardship program

Activity 5.1. Think-pair-share on Pharmacy service organization and management.	
	**Instruction:** - **Discuss with your neighbours on issues that should be considered in the organization and management of pharmacy services** - Discuss and outline basic concepts in Antimicrobial stewardship services - **Reflect your discussions to the class.** **Time:** 5 minutes for pair discussion 5 minutes for discussion.

5.3. Implementation Guidance

5.4. Guidance 20: Pharmacy Service Organization and Management

RESOURCES NEEDED FOR PHARMACY SERVICES

pharmacy department

Health Center pharmacy services need be effectively managed to provide patient-centered services in a manner consistent with standards outlined in this guideline. To achieve this, the department shall be led by head who is assigned by the health center management. The department head in turn assigns unit coordinators; and team leaders may be formed to execute activities as deemed necessary. The head of pharmacy department performs the following activities (in collaboration with other colleagues):

- Develops implements and monitors annual action plans which are approved by the health center management to fulfill the mission, vision, goals, and scope of services of the health center.
- Follows developments and trends in health center pharmacy practice, and communicates to everyone involved in the provision of pharmacy services
    - Makes sure national service standards and guidelines pertaining to pharmacy practices are availed and implemented
    - Continuously perform workload analysis and alert the health center management for possible action
    - Participate in health center committees and meetings representing the pharmacy department including drug and therapeutics committee (DTC)
    - Makes sure that new staffs are properly oriented and supervised.
    - Designs and implements professional development programs for all staff as appropriate to enhance their knowledge and skills.
    - Regularly evaluates the performance of pharmacy staffs and takes measures accordingly.
    - Communicates and collaborates with other departments and services throughout the health center
    - Produces and communicates performance reports to the health center management and relevant government bureaus and agencies

PHARMACY SERVICE ORGANIZATION

Organization of the pharmacy services should ensure patient's safety, privacy and satisfaction. The pharmacy services of the health center should be organized as outpatient pharmacy services unit, inpatient pharmacy services unit, emergency pharmacy services unit, pharmaceutical supply management unit and drug information services unit. Other units shall also be established depending on the health center demand. The units should be directed by a registered pharmacist.

OPD Pharmacy

can be organized in multiple locations (e.g. ART pharmacy, Adult OPD pharmacy, MCH pharmacy etc.) depending on the arrangement of the OPD clinics, geographical proximity and complexity of the health center so as to improve accessibility and convenience to patients. Patient waiting areas at the OPD pharmacy units should be fitted with appropriate seat and should provide enough safety and protection.

Inpatient pharmacy

Depending on patient load, number of beds, and geographical accessibility, there should be adequate number of inpatient dispensaries located near to the major wards. These dispensaries should be led by pharmacists (preferably clinical pharmacists). Inpatient pharmacy services should function under the unit dose dispensing and work for 24 hours and 7 days a week.

Emergency pharmacy

Should be organized near emergency department. The dispensing process should be organized such that pharmaceuticals should reach to the patient as fast as possible. Besides the routine prescription based dispensing, emergency crash cart system shall be used to avoid delays in availing pharmaceuticals to emergency patients.

Drug Information Services (DIS)

All health centers should provide drug information service (DIS) for health professionals, patients and members of the public. The service generally responds to drug information queries received from the health care team or patients. It also provides education and training to health professionals and/or the public regarding appropriate and safe use of medicines. Regular drug information publications such as drug alerts, newsletters, monographs, therapy updates shall be prepared and distributed to keep the health care team up-to-date. It also notifies availability of pharmaceuticals to the health center staff weekly. The health center shall also provide poison information services. The premise of this service can be either within the pharmacy unit or independently if resources allow.

The DIS should have a dedicated room that has sufficient space and appropriate furniture and equipment including telephone, computer, printer, filing cabinets and internet access. The DIC should be staffed by appropriately skilled drug information pharmacists that are trained in the provision of drug information. The operations of the drug information service should be guided by appropriately formulated standard operating procedures (SOPs)/guidelines prepared in line with national documents. The guidelines/SOPs should be established for receiving and answering drug information queries, developing and distributing educational materials and information publications, documentation activities, education and training activities. The DIS should develop annual action plan on each activities and should be communicated to the head/director of pharmacy department. All services provided should be documented and performance report should be sent to the head of the pharmacy department regularly.

Personnel

In order to deliver efficient and quality pharmaceutical services, the health center pharmacy should be staffed by appropriate professional mix and number based on the volume of services and workload. Health center pharmacies should have at least the following positions and professional mix:

- **Pharmacy Services Head**: in charge of overall activities of the pharmacy services
- **Pharmacy Unit Coordinators:** coordinates the overall activity in each unit. When necessary there will be team leaders under coordinators.
- **Pharmacist/druggist:** in charge of managing dispensing and related functions at the following service areas:
    - **OPD pharmacist/druggist**: include evaluators, billers, processors and counsellors. They dispense medicines to patients and manage assigned bins in dispensaries. In addition, chronic care pharmacist/druggist provides pharmaceutical care for patients with chronic diseases.
    - **Inpatient pharmacist**: provides, documents and reports clinical pharmacy service for inpatients. In addition dispenses in ward pharmacies.
    - **Drug Information Pharmacist:** provides up-to-date and unbiased drug information for the healthcare provider and patients
    - **Pharmaceutical supply management pharmacist**: manages the selection, quantification, procurement, storage, inventory and distribution of pharmaceuticals.
    - **Emergency pharmacist/druggist:** provides pharmaceutical services in the emergency department.
- **Pharmacy Accountants**: in charge of aggregating and documenting pharmacy transactions and services.
- **Cashiers**: receives cash from clients and deposits received money in banks and delivers financial documents to accountants
- **Porters:** responsible for loading, unloading, delivering and arranging pharmaceuticals under the supervision of the respective unit coordinators of the pharmacy.
- **Cleaners:** responsible to keep service delivery premises clean and tidy all the time.
- **Patient assistant:** responsible to keep order at dispensing outlets so that patients could be served in an orderly and secure manner

Premises, Equipment and Facilities

The health center should have sufficient space for the storage, compounding, counselling and dispensing of medicines and for the conduct of related administrative activities. Cashiers should

be located within the dispensing room in a cubicle to ensure patient convenience. The pharmacy accountant offices should be stationed adjacent or near dispensaries. The store should be located in an area that is accessible for trucks to facilitate loading and unloading activities. Separate office with office assistant should also be arranged for the head of pharmacy department.

The health center should ensure availability of equipment to deliver proper pharmacy services including: shelves, computers, software, printers, UPS, tablet counters, lockable cabinets, refrigerators, thermometers, dispensing counters, calculators, etc. All service areas should be clearly labelled. Access should be controlled to ensure that only authorized personnel enter the premises and that only designated personnel have access to keys.

All pharmacy service units should have a sink with running water and continuous electricity with power backup (connected to hospital generator). Appropriately located toilet should be available. Telephones and internet services should also be available within each service area.

DRUG AND THERAPEUTICS COMMITTEE

Each Health Center should establish a Drug and Therapeutics Committee (DTC) to promote the safe, rational and cost-effective use of medicines. The health centre DTC must develop annual action plan. To monitor the activities listed in the action plan (example monitoring of prescriptions, continuous supply evaluations, and other drug use related activities) the DTC should have regular sessions.

Membership of DTC

The DTC should be multidisciplinary including but not limited to:

- Health Center manager, or equivalent (Chairperson)
- Pharmacist/druggist (Secretary)
- A representative from each Health Center Case Teams

All DTC members, especially the chair and secretary, should be given sufficient time for their DTC functions, and this should be included in their job descriptions.

Other non-voting, non-executive members may be invited to attend DTC meetings to discuss issues that require their particular expertise.

Procedures of DTC meetings

Steps for the DTC meetings:

- The DTC should meet at a minimum every month, or more often as the need arises.
- Minutes of the previous meeting should be prepared by the secretary and distributed to members for review in sufficient time before the meeting.
- Minutes of all DTC meetings and other related documents should be kept as permanent records of the Health Center.
- The secretary in consultation with chair person should call the meeting
- The agenda and Supplementary materials for the next meeting should be prepared by the secretary in consultation with the chairman.
- Measure Decisions of the DTC should be circulated to medical staff, Health Center management committee/board and all concerned Case Teams.
- The DTC should cooperate and share experiences with other Health Center committees and regional or national DTCs.

Functions of DTC

The DTC of the health centre has several functions that help the facility to improve pharmaceutical services to the community. Its functions include:

- To develop and maintain the Health Centre Specific Medicine List.
- To develop SOPs, policies and guidelines for managing drugs in the facility
- To establishe mechanisms to identify and address drug use problems establish mechanisms to identify, manage and report adverse drug reactions.
- To develop guidelines for generic substitution and therapeutic interchange, on the use of specific medications by the pharmacy personnel
- To serve as a source of information and consulting committee for medical staff about therapy

ANTIMICROBIAL STEWARDSHIP PROGRAM(ASP)

To ensure appropriate use of antimicrobials the right antimicrobial is prescribed at the right time, the right dose, the right route, for the right diagnosis, for the right patient with affordable price and reduce resistance, and to contain an escalating problem that threatens the ability to effectively treat often life-threatening infections; health centers need to implement antimicrobials stewardship programs.

Membership of ASP

The health center should be committed to organize ASP team which will be accountable to the DTC. It is important that antimicrobial stewardship team functions in close collaboration with the quality assurance team, infection prevention and patient safety committee.

Antimicrobial stewardship team is multi-disciplinary (15) including:

- General practitioner
- Clinical pharmacist/clinical oriented pharmacist/pharmacologist or pharmacist with infectious diseases training;
- Clinical microbiologist / medical microbiologist / diagnostic microbiologist / public health microbiologist/clinical laboratory technologist who can provide surveillance data on antimicrobial resistance;
- Nurse representative
- Infection control and patient safety representative
- Environmental Health (Optional)
- Health center epidemiologist/public health officer (Optional)
- IT Professional (Optional)

Roles and Responsibilities of ASP Team

The team is responsible for developing, implementing, and managing the ASP. Major duties and responsibilities include (15);

- Develop Terms of Reference of the ASP Committee indicating the roles of director, secretary and members as well as meeting schedule, norm and related issues.
- Plan the work of stewardship program,
- Secure the support and commitment of the health center management and DTC, to maintain ASP to ultimately acquire adequate authority and expected outcomes for the program.
- Develop and implement antimicrobial drug use policy, formulary restriction and preauthorization deploying evidence-based practical guidelines.
- Incorporate local microbiological profile and resistance pattern data to improve antimicrobial utilization.
- Perform prospective audit of antimicrobial use with direct interaction and feedback to the prescribers and other healthcare providers.
- Organize training on antimicrobial stewardship to health professionals and other concerned staff.
- Organize patient education sessions on the rational use of antimicrobial
- Carry out advocacy, communication and social mobilization on antimicrobial stewardship (Commemorate antimicrobial stewardship and World Antibiotic Awareness Week (WAAW))
- Encourage parenteral (IV) to oral conversion when appropriate
- Promote streamlining or de-escalation of therapy on the basis of culture results
- Negotiate with development partners and other organizations for the implementation of this program in achieving the expected outcomes and for the assurance of its sustainability.
- Keep records, document, report, and Monitor ASP activities

HEALTH CENTRE SPECIFIC DRUGS LIST

The Health Center should have a drug List that contains all drugs, medical supplies, and reagents that can be used in the facility. The List should be reviewed and updated at least annually.

The secretary should prepare the draft from the National Health Center Medicine List
Facility drug list selection should be based on:

- The local disease pattern (Avoid duplication and use limited number of drugs)
- The Ethiopian primary health care clinical guidelines
- The Federal Ministry of Health's Essential Health Services package,
- The National Standard Treatment Guidelines (STGs)
- Drug description using generic names
- The list should be prioritized by VEN (see appendix 5A)

The pharmacy personnel should promote the rational and safe use of drugs and should ensure that all medication prescribed by the Case Teams is included within the facility drug list and is in accordance with Ethiopian primary health care clinical guideline. Any discrepancies should be discussed with the prescriber. Occasionally it is necessary to prescribe from non-facility drug list/or to deviate from facility drug list. Such circumstances should be discussed between the pharmacist/pharmacy technician and Case Team prescriber and should be documented in the patient's medical record.

As a reference, in Annex is the PACK Adult guide 2017: medicines list

CHRONIC CARE MEDICATIONS MANAGEMENT

All patients with a chronic illness like HIV, TB, Leprosy, Hypertension, Diabetes etc. should have a patient medication profile card (PMP). The PMP should be updated by the dispensing Pharmacist/Pharmacy technician whenever drugs are dispensed to the patient. PMPs should be filed sequentially by medical record number or alphabetically by patient name in the dispensing unit.

When a patient presents to the pharmacy for a refill the Pharmacist/Pharmacy technician must assess the patient for signs of compliance, effectiveness and safety of the therapy. The Pharmacist/Pharmacy technician should identify areas for therapeutic modification and should refer to the prescriber when appropriate.

A sample PMP is presented in Appendix 5C.

HEALTH CENTRE-HEALTH POST LINKAGE FOR PHARMACY SERVICES

The health centre pharmacy unit is responsible for the supply of pharmaceuticals, utilization montoring and for provision of technical support to the health post staff regarding pharmaceutical services.

Supply and Utilization Monitoring

All the drugs, vaccines and medical supplies required for health post service provision should be supplied and the utilization should be monitored by the health centre pharmacy department. The consumption reporting and resupply schedules should be established considering the health post service packages, consumption trend, service expansion plans and be in line with the EPSA guidance. Bin cards and Stock cards of the health post should be managed by the health post and pharmacy case team of the catchment area health center.

Technical Support

The health centre pharmacy department is responsible to ensure that the health post staffs are competent enough to manage the pharmaceuticals they handle. The technical support includes but not limited to:

- Product quality inspection skills
- On inventory management and internal auditing skills
- Drug dispensing and counselling skills
- Drug dosing and administration skills
- Pharmaceutical waste management skills
- Adverse drug reactions identification skills

Activity 5.2. :- 2 minute paper and discussion on good dispensing practice.	
	**Instruction:** - **Instruct participants the core concepts in good dispensing practice for 2 minutes** - **Facilitate discussion on the participants writtings.** **Time:** 5 minutes for group work 5 minutes for discussion.

5.5. Guidance 21: Good Dispensing Practice

Good dispensing practice provided by pharmacy professionals has a great contribution to promote rational drug use and ensuring treatment outcomes and hence saving lives. There are many factors that affect good dispensing practice including dispensing standards, professional's knowledge, skill and attitude, human resource (number and mix), dispensing environment and work flow. Therefore, the dispensing practice and environment should be organized in a manner that reduces waiting time and ensures patient convenience safety, confidentiality and ultimately achieve greater patient satisfaction.

DISPENSING AND MEDICATION USE COUNSELLING SERVICES

Dispensing involves six main dispensing steps:

1. Receiving, interpretation and evaluation of a prescription
2. Selection and manipulation of prescription or extemporaneous preparation
3. Labelling of medicines in appropriate container
4. Drug use counselling and supply of the medicine to a patient
5. Recording the transaction and
6. Filing the prescription

Step 1: Receiving, interpretation and evaluation of a prescription:
Dispensers should receive prescription with polite smile and make sure that prescriptions are legible, legal, complete and correct. Orders received by word of mouth or through telephone in case of emergency should later be endorsed by the prescriber and be documented in writing within 48 hours. Receipt of the prescription and confirmation of the integrity of the communication should follow standard procedures for:

a) Identifying the patient, the prescriber and the entity responsible for payment (as applicable);
b) Ensuring the legality/authenticity of the prescription;

c) Interpreting the type of treatment and the prescriber's intentions;
d) Identifying the medicine, and checking the pharmaceutical/ dosage form, strength, appropriate dosage, presentation, method of administration and duration of treatment;
e) Informing the patient about the benefits and implications of the substitution for a branded medicine of an interchangeable multi-source medicine.
f) Helping the patient to resolve the problem when the prescription cannot be dispensed;

The Pharmacist/Pharmacy technician should assess the prescription to ensure the optimal use of the medicine with respect to:
a) Therapeutic aspects
    i. The safety/dose of the medicine,
    ii. Possible contra indications, side-effects/ adverse effects Drug/Drug interactions,
    iii. Drug/Food interaction,
    iv. Drug/disease interactions, and
    v. Treatment duplications.
b) Appropriateness for the individual and the indication for which the medication is prescribed
c) In case of chronic disease like HIV, check the appropriateness of the medication by referring the last patient medication profile/ requesting the patient.
d) Cost of medicine and availability of cheaper alternatives.

Any problems identified should be discussed politely with the prescribers in person and a solution should be worked out in consultation with the prescriber and patient.

Step 2: Preparing items for issue: selection, retrieving, counting/measuring and packaging

1. Retrieve the Medicine.
2. Check three times (while picking, while counting/measuring/pouring and while returning). Select patient-ready packs/pre-packed if available and reading the label and cross matching the drug name and strength against the prescription.

- Select the pack or bottle from the shelf/cupboard and match the following to the prescription
    - Correct medicine
    - Correct strength and concentration
    - Correct dosage form
- Remove the medicines from the pack and confirm the quantity with the client

3. Inspect the removed medication seriously. If any discrepancy is found, do not dispense the medicine to patients.

Measuring liquids:

- Dispense liquid preparations in suitable container
- Liquids must be measured in a clean vessel and should be poured from the stock bottle with the label kept upper side.
- Pour the measured liquid preparation into the container/bottle and label it.

Counting Tablets / Capsules:

- Issue whole packs whenever possible; if not, while counting:
- Do not use fingers to count tablets as this can lead to contamination of drugs
- Use a spoon to put tablets and capsules onto a counting tray
- Count and put them in a labelled drug container or pack
- Close stock containers tightly after dispensing
- Keep the spoon clean at all times
- Do not keep the spoon inside the container

Step 3 Packaging and Labelling:

- Pack the medicine properly. Avoid paper packaging for loose tablets and capsules
- Prepare a label or select the appropriate pre-printed label for the drug preparation to be dispensed.

All medicines to be dispensed should be labelled and the labels should be unambiguous, clear, legible and indelible. If possible lettering should be printed. The following information must be indicated on the label:

- the generic name of the product
- the strength, dose, frequency of administration and total quantity;
- expiry date/ beyond use date
- prescriber's name
- the name of the person for whom the drugs are dispensed;
- the directions for use;
- the name of the prescriber and dispenser;
- date of dispensing; and
- Special precautions as applicable.

Step 4: Drug use counselling and supply of the medicine to a patient:

All drugs should be dispensed with adequate and appropriate information and counselling. Counselling should cover matters that will enhance or optimize medicine therapy and should include:

- Name and description of the medicine used
- Intended use of the medicine and expected action
- Dosage form, dose, route of administration
- Duration of therapy with emphasis given to completing the entire course, e.g. antibiotics
- Expected time to see a response of the medication and instructions on what to do if the medicine appears not to have the desired effect
- The time the drug should be taken in relation to other drugs, food, life style interactions etc
- Clear instructions on measurement and administration of medicine (for example liquid, aerosol, topical preparations or suppositories). If necessary a demonstration such as opening and closing containers or using an aerosol may be necessary
- Techniques for self-monitoring of adherence like alarms, sun sets and sun rise.
- Action to be taken in the event of a dose not being taken
- Explanation of harmless effects of the medication such as urine discoloration
- Common severe side or adverse effects or interactions and therapeutic interactions that may be encountered, including their avoidance and the action that required if they occur
- Storage instructions; keeping medicines out of reach and sight of children
- Beyond use dates, danger of keeping extra doses at home and clarification on the consequences of sharing medication.
- Finally check whether the patient understood the information provided by making him/her repeat the main ideas given
- Give the drug parcel politely

Step 5: **Recording**

Medicines transactions should be recorded and prescriptions should be documented as proof of transaction between the patient and the pharmacy professional. Prescriptions can therefore be traced back if any need arises.

Prescriptions for narcotic and psychotropic drugs should be registered by EFDA registration form and prescriptions for chronic illnesses should be registered using patient medication profile card. A computerized dispensing and registration system may also be used, but should always be supported by paper back up. The registration book should be completed at the time of dispensing.
For a prescription which is returned to a patient because all the items in the original prescription could not be filled, the drugs that have been dispensed from the pharmacy should be copied on a blank prescription and the prescription should be filed appropriately. On the original prescription, which is retained by the patient, the word "**dispensed**" should be stamped adjacent to those items which have been dispensed.

For prescriptions which are to be refilled on a later date, the dispensing information should be entered into the registration book before returning the prescription to the patient. The official seal of the pharmacy, name and signature of the dispenser, the date of dispensing and the next refill date should be written on the back /side of the prescription.

Step 6.: Filing
Each prescription should be signed and accountability accepted by the Pharmacist/Pharmacy technician or other authorized person for the correctness of the dispensing of the medicine and confirming that the medicine was supplied.

1. At the close of each day all dispensed prescriptions should be organized into ordinary or special (e.g. Narcotic and psychotropic drugs and chronic care prescriptions like ART, Hypertension) prescriptions and filed
2. Prescriptions should be filed sequentially by day in a single container/carton for each month. The container should be labelled with the month and year
3. Containers of prescriptions should be arranged on a monthly basis
4. Narcotic and psychotropic prescriptions should be filed securely for 5 years and other prescriptions for two years
5. At end of the day, the number of patients served at each dispensing units should be recorded with the price of drugs dispensed and reported at the end of the month.

Prescriptions, patient and medication related records and information should be documented and kept in a secure place that is easily accessible only to the authorized personnel.

Activity 5.3. Think-pair-share on Auditable pharmaceutical Services
 **Instruction:** • Pair with your neighbour • Discuss your experiences and expectations on APS and reflect your discussion during the general discussion **Time:** 5 min for reading and discussion 5 min for presentation

5.6. Guidance 22: Auditable Pharmaceutical Transactions and Service

APTS is a data driven package of interventions designed to establish accountable, transparent and responsible pharmacy practice. It enables health facilities to optimize utilization of medicines budget, improve access to medicines, and decrease wastages. APTS continuously monitors the number, mix & performance of pharmacy workforce. It also improves pharmacy premise design and workflow. Through improving recording and documentation, it generates reliable and consistent information for decision making. As a result, APTS improves overall quality of pharmacy services thereby increasing patient knowledge and satisfaction. Ultimately it contributes to better health outcomes. APTS has five result areas: efficient budget utilization, transparent and accountable transactions, reliable information, effective workforce development and deployment, and improved customer satisfactions. In order to achieve these results, health centers are expected implement selected interventions. The following list provides guidance on what needs to be done to achieve each of these results.

Efficient budget utilization

- All health centers should develop facility specific drug list prioritized by VEN and enforce its use
- Regular ABC value analysis should be conducted and reconciled with VEN categorization and results should be used for guiding decisions during subsequent procurements
- Procurement should be conducted only from health center medicines list
- Regular stock status and consumption to stock analysis is conducted to identify medicines at risk of expiry
- The health center should measure wastage rate of medicines on monthly basis. The health center identifies medicines having near expiry date and take preventive measures to reduce wastage/expiry.
- Establish effective mechanisms for managing sales of medicines and/or increasing revenue by increasing turnover rate, improving availability and reducing misappropriations.

TRANSPARENT AND ACCOUNTABLE TRANSACTIONS

The process of receiving, issuing and dispensing pharmaceuticals in health center should be transparent and accountable. Pharmaceuticals are received at the pharmaceuticals store from EPSA and other sources. The pharmaceuticals received by the store are issued to dispending outlets. From the dispensing outlets medicines are dispensed to patient on cash, for free or on

credit. All transactions should be conducted using legally approved and pharmaceuticals-specific models, sales tickets, and dispensing registers. The flow of pharmaceuticals from distributers to end users in the health center shall include:

Receiving

All pharmaceuticals (medicines, lab reagents, medical supplies, and equipment) should be received and managed by the health center Pharmaceuticals Store. Receiving is an important step for proper inventory management. At this step pharmaceuticals must be assessed for quality and quantity and added into the inventory of the store. Hence pharmaceuticals need to be physically inspected before receiving. In physical inspection, the store manager and supply management officer make sure that the products received are as per the list, quantity ordered and expected quality. Once pharmaceuticals are received, inventory records are immediately updated. Pharmaceuticals should be requested using standard format (RRF) from EPSA every two month.

Issuing

Each dispensing unit should have an agreed list of pharmaceuticals including the maximum (one month) and minimum (two weeks) quantity to be stocked in the dispensing unit. The stock list of each dispensing unit should be approved by pharmacy head. Each dispensing unit should maintain Bin Cards for all pharmaceuticals in the unit with shared responsibility by bin owners.
Dispensary transactions and billing
The provisions of Health Care Finance Reform Legislation enable facilities to raise and retain revenue. The sale of pharmaceutical products is an important source of health center income. With the exception of exempted health programs (Immunization, TB, Leprosy, ART and MNCH) pharmaceuticals can be sold at a price that covers the actual cost of the medicine plus a service
charge. Transparent and uniform procedures should be established for setting the sale price of each pharmaceutical and for recording sales.

The retail price of each pharmaceutical should come from the store in issue vouchers (model 22/health). Each dispensing unit should sell pharmaceuticals at the stated price. All pharmaceuticals should be dispensed/sold using a standard sales ticket designed for the purpose and approved by Federal Ministry of Finance and economic development or respective regional finance bureaus.

The pharmacy professional is responsible to record each medicine with full descriptions, uniquely identifying codes, retail prices in the intended sales tickets or free registers. The pharmacist also has to record all service provided, DTP identified by prescription evaluators, and counselling made for clients. The pharmacy accountant summarizes all transactions (financial value, dispensed medicines and services) on daily basis and prepares report on monthly basis as per the APTS guideline. Auditors in collaboration with pharmacy professionals and DTC members should use the document for auditing of the above transactions and improving the service.

EFFECTIVE WORKLOAD ANALYSIS AND MANPOWER DEPLOYMENT

The level of effort for each pharmacy service provision units should be measured and workload should be calculated. Based on the workload analysis result, the health center's human resource

focal/management will deploy the required professionals. Key assumptions used for workload analysis:

- For dispensaries 1000 prescription (or 1500 counseling episodes) per pharmacists per month;
- for clinical pharmacy services in wards, 35 beds per pharmacist per day for primary health care settings
- for chronic pharmacies, 30 prescriptions per day per pharmacist
- other services units shall deploy staffs as per their workload

RELIABLE INFORMATION FOR DECISION MAKING

Product, services, financial related performance reports should be produced consistently and communicated timely. The report of the pharmacy should be linked to the serial numbers of financial tools for ease of documentation, reference and validation. Information concerning the financial values includes value of medicines sold on cash, credit and for free.

Service related information includes the total number of patients served per health facility, per dispenser per month segregated by service type which may include services rendered for paying, credit and free patients; outpatients, inpatients and emergency patients; mothers and children; patients with chronic illnesses, patients taking medicines for OIs and so on.
Product related information includes consumption to stock ratio analyses, availability of medicines for top ten diseases, rate of expiry and affordability to take subsequent measures for improving services. Managers and service providers should use this information for decision making.

CUSTOMER SATISFACTION

The eventual success of health center pharmacy service is to meet clients demand and improve their satisfaction through improving availability of medicines with quality pharmaceutical services. Dispensing workflow arrangement and provision of one-stop-shopping service enhances client convenience and reduces waiting time. Regular workload analysis and human resource deployment enables efficient manpower use and reduces patient waiting time. This and the other aforementioned create the environment whereby patients are empowered to properly adhere to prescribed medicine by improving their knowledge and satisfaction.

DRUG INFORMATION SERVICES

Due to the vast number of medicines and the information related to them, it would be very difficult for the health professional to search for all credible sources of information and use it in routine practice. Hence access to authoritative, unbiased and well-referenced drug information is fundamental for the rational and effective use of drugs.

All health centers should provide drug information service (DIS) for health professionals, patients and members of the public. The service generally responds to drug information queries received from the health care team or patients. It also provides education and training to health professionals and/or the public regarding appropriate and safe use of medicines. Regular drug information publications such as drug alerts, newsletters, monographs, therapy updates shall

be prepared and distributed to keep the health care team up-to-date. It also notifies availability of pharmaceuticals to the health center staff weekly. The health center shall also provide poison information services. The premise of this service can be either within the DIC or independently if resources allow.

The DIC should have a dedicated room that has sufficient space and appropriate furniture and equipment including telephone, computer, printer, filing cabinets and internet access. The DIC should have a current collection of national and international authoritative reference materials such as books, journals, guidelines, formularies, and databases. The DIC should be staffed by appropriately skilled drug information pharmacists that are trained in the provision of drug information.

The operations of the drug information service should be guided by appropriately formulated standard operating procedures (SOPs)/guidelines prepared in line with national documents. The guidelines/SOPs should be established for receiving and answering drug information queries, developing and distributing educational materials and information publications, documentation activities, education and training activities. It needs also to guide monitoring and evaluation activities, participation in other clinical pharmacy services, supporting DTC activities and conducting research. The center is a resource for the DTC in formulary preparation and revision. The DIC should be open during normal working hours. The services provided by the center should be documented on standard formats prepared for the purpose.

Educating patients on the rational use of medicines through different mechanisms is a crucial activity of the DIC. Patients need be given appropriate information about the medicines they use to achieve optimum adherence that results in better treatment outcomes. Medicine use education is needed so that people have the skills and knowledge to make informed decisions about how to use and store medicines and to understand the role of medicines in health care, with their potential benefits and risks. All relevant staffs of the pharmacy department should be involved in the provision of education for the patient as appropriate. Under the health center health education program, the unit will have weekly breakdown of topics assigned to responsible pharmacists.

The DIC should develop annual action plan on each activities and should be communicated to the head/director of pharmacy department. All services provided should be documented and performance report should be sent to the head of the pharmacy department regularly.

Activity 5.4. Group work on Drug supply management and inventory
 **Instruction:** • Be in group of 5-6 people • Work on one of the following topics as guided by the facilitator • Present your work using flip chart at the end of group work • After 30 minutes facilitate group presentation and discussion **Time:** 60 min for reading and discussion 30 min for presentation

5.7. Guidance 23: Drug Supply Management

Effective drug supply management ensures the uninterrupted availability of quality, registered, safe and effective pharmaceuticals. Drug supply management involves six basic functions: selection, quantification, procurement, storage, distribution and use. The Health Center should have a Pharmacist/druggist as a drug supply manager and Pharmacy technician as a store keeper.

SELECTION

All Health Centers should have a facility drug list that lists all drugs, medical supplies and consumable equipment that can be used in the Health Center. The Facility drug list should be approved by the DTC of the facility and be based on the Ethiopian primary health care clinical guideline.

QUANTIFICATION

After selection is performed, the quantity of each product required by the Health Center for a given period of time should be determined. To guide this process, a quantification Policy in line with EPSA guidance should be developed and approved by the DTC of the Health Center. The Quantification Policy should indicate:

- The methodology for quantification
- Techniques for prioritization (VEN and ABC analysis)
- The annual schedule for procurement

Note: use morbidity method whenever there is new programs, program changes, outbreaks, Use consumption method in normal situations and in established facility using past consumption data.
See box A and box B as guides for quantification using consumption and morbidity methods respectively.

Box 5.0.1: Quantification Steps Using the Consumption Method

Step 1: Prepare list of pharmaceuticals to be quantified
Step 2: Determine the period of time to be reviewed for consumption
Step 3: Enter consumption data for each pharmaceutical
Step 4: Calculate average monthly consumption
Step 5: Calculate the quantity of each drug required for the next procurement period
Step 6: Adjust for expected changes in consumption patterns
Step 7: Adjust for safety stock requirements and estimated losses

Step 8: perform stock analysis
Step 9: Adjust for safety stock requirements and estimated losses and expiry
Step 10: Estimate costs for each pharmaceutical and total costs
Step 11: Compare total costs with budget and make adjustments

Box 5.0.2: Quantification Steps Using the Consumption Method

Step 1: Specify the list of health problems
Step 2: Establish standard or average treatments for each health problem
Step 3: Establish the list of drugs to be quantified
Step 4: Collect morbidity data for each problem
Step 5: Calculate the number of treatment episodes for each health problem
Step 6: Calculate the quantity of drugs for each health problem
Step 7:Combine the estimates for each drug from the various health problems into a master procurement list
Step 8: Adjust quantities to cover other health problems
Step 9: Adjust for current stock position and expected losses
Step 10: Estimate costs for each drug and total cost
Step 11: Compare total costs with budget and make adjustments

As resources are always limited, the DTC should review and approve all forecast /quantifications with their respective annual budget prior to procurement/purchase order to EPSA. To make rational reduction of the quantified products different prioritizing mechanisms can be used (see appendix 5A).

PROCUREMENT

The Pharmacy services coordinator should be responsible for the purchase of all pharmaceutical aspects of the facility. A Procurement Policy, approved by the DTC should be established. General principles and procedures that should be addressed in the procurement policy include:

- Procurement by generic name and/or by brand only when circumstances compel to do so.
- procurement limited to products specified in the Health Center Medicine List
- procurement in bulk
- procurement based on quantification and available funds
- flexibility to respond to emergency situations
- compatibility with the regional and national procurement laws
- product quality assurance;
    - The Pharmacy services coordinator/head must not purchase any medicinal product where she/he has any reason to doubt its safety, quality or efficacy.
    - The Pharmacy services coordinator/head must ensure that both the supplier and the source of any medicine purchased are reputable and registered by the regulatory body.

Procurement through EPSA

Health Centers should procure preferentially through **EPSA**. A contract agreement should be signed between **EPSA/ EPSA** hubs and the Health Center. Health center can buy drugs on credit according to the agreement made with PFSA and on cash or on credit from private suppliers.

Procurement through Private Suppliers

If pharmaceuticals are not available from **EPSA**, they should be purchased from private suppliers. The Pharmacy services coordinator should have an out of stock confirmation from **EPSA** prior to purchasing from private suppliers. Purchases should only be made from private suppliers that are registered with EFDA. To improve efficiency and minimize costs while procuring from private suppliers, open bidding and biannual contract agreement is preferred, with every two month - deliveries.

RECEIVING OF PROCURED PHARMACEUTICALS

Generally, when receiving drugs, medical supplies and equipment, the following inspection check list should be considered by the pharmacy services coordinator.

All shipments

- Compare the items with the supplier's invoices and original purchase order.
- Note discrepancies on the receiving report.
  Check that:
  - No of containers delivered is correct
  - No of packages in each container is correct
  - Quantity in each package is correct
  - Drug is correct (don't confuse generic and brand names , country of origin etc)
  - Dosage form is correct(tablet liquid, other form)
  - Strength is correct (milligrams, percent concentration, other measurement)
  - Unique identifiers are present if required (example: article code , ministry of health stamp, not for sale stamps, only for promotion stamps, specific facility stamps)
  - if there is visible evidence of damage.
  - Counterfeit/ fake/ products may not be labelled by uniform spell, logos, label layouts, etc
- Counter fit products may have variation in one of the above points

Tablets / Capsules

Check that:

- Tablets/capsules are identical in size and in shape
- Tablets/capsules are identical in colour (variation of shade of colour from batch to batch may be normal. However, if it is within the same batch it may indicate poor quality)
- Tablets/capsules markings are identical (example : scoring , lettering , numbering, etc)

- There are no defects (check for coloured spots , hollows, fragments/ breaks, /friability behaviour / , uneven edges , cracks , embedded or adherent foreign matter, stickiness
- There is no odour when a sealed bottle is opened except for flavoured tablets and those with active ingredients normally having a characteristic odour
- There is no odour after tablets have been exposed to room air for 20 -30 minutes
- Counterfeit/ fake/ products may not be labelled by uniform spell, logos, label layouts, etc

Parenterals (IV liquids, ampoules , dry solids for reconstitution, suspension for injections)

Check that:

- Solutions are clear (solutions should be free from un dissolved particles)
- Dry solids for use in injections are entirely free from visible foreign particles
- There are no leaking containers (bottles, vials, ampoules, bags etc)
- Counterfeit/ fake/ products may not be labelled by uniform spell, logos, label layouts, etc.
- Counter fit products may have variation in one of the above points.

Oral liquid/semisolid dosage forms

- Oral liquid /semisolid dosage forms are syrups/solution, powder for reconstitutions, suspensions, emulsions, gels etc

  Check that:
  - If the bottle size/shape is the uniform
  - If there is no gas evolving when sample bottles are opened that indicates fermentation
  - If there is no leakages, breakages, label deformities
  - If there is no any colour changes in the same batch
  - If there is no foreign particles
  - Counterfeit/ fake/ products may not be labelled by uniform spell, logos, label layouts
- Counter fit products may have variation in one of the above points. so, professionals should be careful during the whole process of procurement.

STORAGE

Storage is the safekeeping of pharmaceuticals to protect the shelf life of products and avoid damage (Damage by sunlight, flammable chemicals, polluting chemicals & dusts, oxygen, moisture, temperature, physical pressures like sharps, insects and rodents etc.), expiry, and theft (see table 5.1*)*

The Pharmacy services coordinators/head is responsible for the overall management of pharmaceuticals in the Health Center.

Table 5.1. Guideline for storage of pharmaceuticals

Activities		Justification
1.	Store pharmaceuticals in a dry, well-lit, well- ventilated storeroom - away from direct sunlight. Temperatures in the storeroom should not exceed 25ºC.	Extreme heat and exposure to direct sunlight can degrade pharmaceuticals and dramatically shorten shelf life. Direct sunlight raises the temperature of the product and can reduce its shelf life or may damage the product by other mechanisms.

2.	Clean and disinfect the storeroom regularly. Keep food and drink out of the storeroom.	Pests are less attracted to the storeroom if it is regularly cleaned and disinfected. The outside of the store should also be kept clean, and any garbage should be stored in covered containers. Water should not be allowed to stagnate near the building. Would should be varnished or painted to discourage pests. If possible, a regular schedule for extermination will also help eliminate pests.
3.	Protect storeroom from water and moisture.	Moisture can destroy both supplies and their packaging. If the packaging is damaged, the product is still unacceptable to the patient even when the pharmaceutical is not damaged.
4.	Keep fire safety equipment available, accessible, and functional, and train employees to use it.	Stopping a fire before it spreads can save expensive supplies and the storage facility. The right equipment should be available; water is able to put out paper fires, but is ineffective on electrical and chemical fires. Place well-maintained fire extinguishers at suitable positions in the storeroom. If a fire extinguisher is not available, keep sand or soil in a bucket nearby.
5.	Store latex products away from electric motors and fluorescent lights.	Latex products can be damaged if they are directly exposed to fluorescent lights and electric motors. Electric motors and fluorescent lights create the chemical ozone which can rapidly deteriorate latex products. Keep latex products in paper Boxes and cartons.
6.	Maintain cold storage, including a cold chain, as required.	Cold storage (2 to 8 degrees Celsius or 36 to 46 degrees Fahrenheit) is essential for maintaining the shelf life of certain pharmaceuticals including vaccines. These items are irrevocably damaged if the cold chain is broken. If electricity is unreliable, the use of cylindered gas or kerosene-powered refrigeration is recommended. Many drugs require storage below 25 ^{o}C. There may also be products that should be stored at a temperature below 0^{o}C and hence the required storage condition should be maintained for these products.
7.	Limit storage area access to authorized personnel. Drugs which need an access-controlled environment such as narcotics, psychotropic, etc should be stored under lock and key separate from the rest of stock preferably a locked wire cage within the storage facility or a lockable cabinet.	To prevent theft and pilferage, lock the storeroom and/or limit access to personnel other than authorized staff, and track the movement of pharmaceuticals.
8.	Stack cartons at least 10 cm off the floor, 30 cm away from the wall and other stacks, and no more than 2.5m high for heavy cartons.	Pallets keep the products off the floor so they are less susceptible to pests, water and dirt damage. Stack pallets 30 cm away from the walls and each other to promote air circulation and to ease movement of stock, cleaning and inspection. Do not stack cartons more than 2.5m as the weight of the products may crush the cartons at the bottom. This will reduce potential injury to warehouse personnel. If cartons are particularly heavy, stack cartons less than 2.5m. Where feasible, strong well-organized shelving is preferred.
9.	Store medical supplies away from insecticides, chemicals, old files, office supplies and other materials.	Exposure to insecticides and other chemicals may affect the shelf life of pharmaceuticals. Old files and office supplies may get in the way and reduce space for medical supplies or make them less accessible. "De-junking" the storeroom regularly makes more space for storage.

10.	Store flammable products separately from other products. Take appropriate safety precautions. Storage areas and cabinets should be clearly marked to indicate that they contain highly flammable liquids and should display the international hazard symbol. Corrosive or oxidant products, laboratory chemicals and reagents should be stored away from flammables, ideally in a separate steel cabinet to prevent leakage.	Some medical procedures use flammable products, such as alcohol, cylindered gas, or mineral spirits. Such products should be stored in the coolest possible place, away from electrical appliances and other products and near a fire extinguisher.
11.	Store pharmaceuticals to facilitate FEFO procedures and stock management.	FEFO (First Expiry, First Out) is a method of managing drugs in a storage facility where the drugs are managed by their expiry date. Drugs that will expire first are issued first, regardless of when they were received at the health facility.
12.	Store drugs in their original shipping cartons. Arrange cartons with arrows pointing up, and with identification labels, expiry dates, and manufacturing dates clearly visible.	Drugs should not be opened to repackage them. Store supplies in their original shipping cartons. Items should be stored according to manufacturer's instructions on the cartons; this includes paying attention to the direction of the arrows. Identification labels make it easier to follow FEFO, and make it easier to select the right product.
13.	Separate unusable pharmaceuticals from usable pharmaceuticals and dispose of damaged or expired products without delay.	Do not dispense expired drugs to the patients. Designate a separate part of the storeroom for damaged and expired goods.

DISTRIBUTION

Drugs, medical supplies and equipment should be managed centrally by the Health Center Medical store. All products should be received into the Health Center Medical store, and should be stored there until they are issued to the dispensing units or other consumption areas (laboratory, ward, delivery and etc.) in the facility.
A procedure approved by the DTC, should be established for:

- Obtaining supplies from the medical store
- Action to be taken in the case of incomplete documentation or other enquiries
- Return of expired, damaged, leftover and empty packs from the dispensing unit and other areas to the Central store.

The store manager should establish a resupply schedule for each of the dispensing units and other consumption areas. Generally between one week to one month. Each receiving unit should have a designated day to receive its resupply (for example every Monday for weekly supply or the first Monday of every month for monthly supply) unless in emergency situations.

USE

All of the above steps are to deliver appropriate drugs for clients/patients, which require rational prescribing, rational dispensing and good adherence to treatment by patients. Rational use of drugs involves that patients receive medicines appropriate to their clinical needs, in dose that meet their own individual requirements, for an adequate period of time and at lowest cost to them and their community.

Rational use of drugs requires that a particular patient with a specific health problem receives drugs according to the following:

- Appropriate dose,
- Appropriate dosage form,
- Appropriate route of administration,
- Appropriate frequency of administration,
- Appropriate duration of treatment,
- Appropriate information to the patient,
- Adequate follow up.

Box 5.0.3: Temperature & Humidity Control for Pharmaceuticals

1. The store should be designed store to moderate internal temperatures. The use of trees for shade and shelter, correct building orientation for natural lighting and ventilation, and appropriate building materials can moderate internal temperature.
2. Ceilings should be at least 2.6 m high to allow adequate ventilation.
3. The following procedures can be implemented to moderate the temperature inside the store.
    - In hot, dry climates, good construction and night time ventilation can maintain daytime temperatures several degrees below ambient. In hot, humid climates, effective cross-ventilation is required.
    - In cold climate areas the storage buildings should be well insulated.
4. Moisture sensitive products should be stored at a relative humidity less than 60%. For this purpose:-
    - It is advisable to open the windows or air vents of the store room to allow air circulation. Ensure that all windows have screens to keep out insects and birds before opening.
    - Put Boxes on pallets and ensure that there is sufficient space between the pallets and the walls of the store room for proper air circulation.
    - Never open a new container unless necessary.
    - Use ceiling mounted ventilator or standing fans as appropriate.
    - Installing Air Conditioners when the need arises.
    - Depending on the climate condition and the financial capacity of the health center, installation of a dehumidifier can also be considered.
5. Some drugs are photosensitive and can be damaged if exposed to direct sunlight. To protect products from sunlight:
    - Shade the windows or use curtains, if they are in direct sunlight.
    - Keep products intact in cartons.
    - Maintain trees on the premises around the facility to help provide shade.
6. Heat affects many products. Ointments and creams that can easily melt and heat can cause degradation. The above stated points about sunlight and humidity control will also help protect such products from heat. It is important to have a wall thermometer in various parts of the pharmacy/store to monitor temperature.
    - Some drugs may be affected by flammable chemicals : Don't keep flammables with pharmaceuticals
    - Some chemicals are pollutants : Don't keep poisons and pollutants with pharmaceuticals
7. Oxidation reduction may be aggravated for some drugs if their container is opened
   Re- Label the 'beyond use date' by professionals if once the package of pharmaceuticals are opened because drugs may start to be oxidized

5.8. Guidance 24: Inventory Control System

The purpose of an inventory control system is to maintain appropriate stock levels to meet the needs of patients. A well designed inventory control system informs personnel when and how much of a pharmaceutical to order and helps to reduce shortages, oversupply, and expiry of drugs and medical supplies.

The most important points for controlling of inventory are:

1. The ***maximum months of stock*** is the largest amount of each pharmaceutical a facility should hold in the store at any one time. If a facility has more than the maximum for a pharmaceutical, it is 'overstocked' and risks having drugs and medical supplies expire before they are used.
2. The **Reorder level:** is level of a specific item just before ordering and set by considering lead time and average monthly consumption.
3. The ***minimum months of stock/Emergency Order Point*** is the approximate level of the 'stock on hand' at the time of the expected arrival of the next delivery from the supplier. This stock level of a specific item is used as a reserve /safety stocks and can be utilized only when lead time is longer than the expected. When the reordered level didn't arrive at the point of minimum stock levels/the lead time is longer than expected , then the level becomes emergency order point; a second order should be initiated i.e emergency order
4. The ***emergency order point***: is the level where the risk of stocking out is likely and levels become a bit lower than minimum, but there is still time to receive an emergency delivery to avoid the stock-out.
5. The **Lead Time** is the amount of time elapsed from the time of order /request to the arrival of an an item in the facility.
6. The **Average Monthly Consumption**: is the average consumption of an item calculated by considering days out of stock in months, total consumption & duration covered in months.

For most essential pharmaceuticals, the Health Center should adopt the national system for pharmaceuticals inventory management and transaction systems (formats, recording, reporting, ordering, inventory control procedures, delivery schedules, etc.) in cooperation with the Pharmaceutical Fund and Supply Agency (**EPSA)**

Standardized forms for inventory management are described below:

1. **Bin Card** (See Appendix 5E)

A Bin Card should be prepared for each product in the Pharmaceutical Store. The Bin Card should be kept with the product inside the store. All transactions of the product to or from the store should be recorded on the Bin Card. The Bin Card should also include a column for the loss/adjustment of stock and a column for the stock balance. The stock balance should be updated after each and every transaction or adjustment.

2. **Stock Card** (See Appendix 5F)

The Stock Card is similar to the Bin Card but is used to track stock based on issuing and receiving orders. The Stock Card should be handled by the Pharmacy services coordinator but

not by the store keeper. Whenever Stock Cards are updated the totals should be checked against those on the Bin Card and any discrepancies should be investigated.

A combined Bin/Stock Card System provides a measure of internal control that helps to minimize leakages of stock due to theft or loss, to trace stock turn over, to minimize expiry and stock outs.
Paper based or electronic Stock Cards can be used. If an electronic system is installed there should be regular back up of data.

3. **Internal Facility Report, and Requisition (IFRR)**
   a) The IFRR Voucher (model 20/1) is used to report the internal calculated consumption of items and request items from store to Dispensing Units. The IFRR also calculates the quantity of each item that should be provided to the Dispensing Unit to reach maximum stock levels.
   b) Stock status analysis: This can be defined as analyzing stocks at hand & stock on order in order to determine whether the stock is: active, nonmoving (dead), slow moving or expired, and then to select, quantify, request, purchase, or transfer & avoid expired once. (See Appendix 5H)
   c) Facility Combined 'Report and Requisition Form' (RRF) (See Appendix 5I)

4. **Transfer/exchange or donation of overstock and unwanted Drugs and medical supplies between health facilities using model 22/1**

Transfer/exchange or donations of supplies/medicines is made between one public health facility where it is over stocked or unwanted to another public health facility where it is needed; up on an agreement made between the two facilities. Transfer/exchange/or donation of drugs should not only be made between facilities, but also within units of the specific facility. If drugs that come through donations are over stocked, these can also be exchanged either in monetary value or item wise. However, whenever drugs are transferred to any facility, including returning to EPSA, it should be recorded in financial issuing and receiving vouchers (model 22-1 and model 19-1).

PHYSICAL INVENTORY (PHYSICAL COUNT)

A Physical Inventory (also called Physical Count) is an actual count of each pharmaceutical in stock at any given time. A Physical Inventory should be done regularly in the store and each dispensing unit, at a minimum of once per year. If the facilty decides and need arises, the Physical Inventory could be done every two months to coincide with **EPSA**'s planned delivery schedule. Bin Cards and Stock Record Cards should be updated at the end of each physical count.

Each facility should adopt an SOP providing details on how the Physical Inventory should be conducted.

Box 5.0.4: Preparation for Physical Inventory

Set a date for the physical count. Select the physical count team. Participants should be selected from the facility.

- Do not issue pharmaceuticals during the physical count or count receipts on the day of the physical count, except in an emergency. Receipts during the physical count will be recorded on

the *Bin Cards* and the *Stock Record Cards* the following day and counted in the next physical count.

- Make sure that the *Bin Cards* and the *Stock Cards* for the pharmaceuticals are updated to the day of the physical count. If the *Bin Cards* and the *Stock Cards* are not completed, complete them.
- Make sure that the Bin cards are with store man and the stock cards either in the hands of the DSM officer /or finance officer
- Prepare the store, making sure all cartons are neatly stacked and partial cartons are clearly visible.
- Reorganize pharmaceuticals by FEFO before counting. Mark expiry dates clearly, with large, dark numbers, on each Box or carton. This step should have been taken during routine receipt and management of supplies.
- Visually inspect pharmaceuticals as you organize them for counting.
- Separate any expired or damaged drugs and medical supplies.
- Be sure to have the *Bin Cards* for each pharmaceutical to be counted.
- Register all drugs in full description (name, dosage form, strength, and brand, expiry date, unit selling price and retail price(for the dispensary), and code number) in the inventory sheet.
- Crosscheck the list in the inventory sheet against drugs on the shelves
- Reorganize if identical items found in different places
- Count item by item and fill the physical quantity on the corresponding column.
- Deliver to the account section and pharmacy case team coordinator for the columns of unit cost, total cost, stock card quantity and reconciliation of overage and shortages (see Appendix 5L)

5.9. Guidance 25: Clinical pharmacy services

Clinical pharmacy services are patient-oriented services developed to promote the rational use of medicines, and more specifically, to maximize therapeutic benefits, minimize risk, and reduce cost. Clinical pharmacists assume responsibility for managing medication therapy in direct patient care settings (inpatient, outpatient and emergency). They assess patients, identify drug therapy needs and problems, propose care plan, recommend choices and hence contribute to therapeutic decisions thereby improving treatment outcomes. The service should be well integrated with all clinical departments.

MAJOR STEPS IN CLINICAL PHARMACY SERVICES

Clinical pharmacy services are provided based on pharmaceutical care principles. The delivery of pharmaceutical care involves the following logical processes:

- Assess the patient's medicine therapy needs and identify actual and potential drug therapy problems (DTP)
- Develop a care plan to resolve and/or prevent the DTPs
- Implement the care plan
- Evaluate and review the care plan

A) Assess the patient's medicine therapy needs and identify actual and potential drug therapy problems (DTP)

A drug therapy problem is any undesirable event experienced by a patient, which involves or is suspected to involve, medicine therapy, and which interferes with the achievement of the

desired goals of therapy. Through assessment the pharmacist establishes the existence of any therapy needs or problems with the drug therapy by interpreting information collected from patient, caregivers, medical records and other healthcare professionals.

B) Develop a care plan to resolve and/or prevent the DTPs

At this step, the pharmacist determines how to manage the patient's medical conditions successfully with pharmacotherapy. The pharmacist establishes goals of therapy by negotiating and agreeing upon endpoints and timeframe for pharmacotherapies. Then appropriate interventions are determined to resolve DTPs, achieve goals, and prevent new problems by considering therapeutic alternatives and selecting patient-specific pharmacotherapy, patient education, and other nondrug interventions. Finally a schedule is established for follow-up evaluation that is clinically appropriate and convenient for the patient. The responsible clinician should be informed and agree on the plan before implementation. In developing the care plan the pharmacist should ensure that the patient is well informed on the process being undertaken.

C) Implement the care plan

The pharmaceutical care plan is implemented with the agreement of the patient and within the context of the overall care of the patient, in cooperation with other members of the health care team.

D) Evaluate and review the care plan

At this step of the pharmaceutical care process the pharmacist evaluates effectiveness and safety of pharmacotherapy and judgment is made as to the clinical status of the condition being managed with pharmacotherapy. Patient compliance is also assessed and new DTPs are identified, if any. Finally next follow-up evaluation is scheduled. Although all patients benefit, it is necessary to select patients that would benefit most from a pharmaceutical care plan. Hence the following group of patients should be considered:

- Those with multiple conditions/drugs,
- Those whose age, weight or clinical state may affect drug PK and PD
- Patients taking medicines known to have a high risk of toxicity
- Patients taking medicines with a narrow therapeutic index
- Patients taking medicines which may interact
- Patients whose therapy is changed frequently
- Patients who have advanced disease state and/or develop complications
- Patients who failed to respond with initial therapy and continue to deteriorate

CLINICAL PHARMACY SERVICES IN THE INPATIENT SETUP

During the provision of clinical pharmacy services in the inpatient setup, the following activities need to be performed:

A) Admission medication history taking

Using an In-patient Medication Profile Form (Annex 8), a pharmacist working in a specific ward will be responsible in taking admission medication history either together with the admitting physician or independently. The information collected during the process will be documented in a patient chart so that it will be an input for subsequent decision making for the MDT.

Admission medication history includes but not limited to:

- ✓ Pertinent patient demographics
- ✓ Past or current medications (Prescription drugs, over the counter drugs, herbal medicines or supplements)
- ✓ Any known drug allergy (KDA)
- ✓ Adverse drug reactions
- ✓ Overall patient adherence to therapy
- ✓ Social habits
- ✓ Immunization status, for a child and pregnancy status for women

B) Patient monitoring and follow-up

The pharmacist shall be responsible to monitor the outcome of drug therapy from effectiveness and toxicity perspectives for admitted patients based upon relevant laboratory data, radiological findings, physical findings, subjective findings, and document it on pharmaceutical care progress note recording form (Annex 9) in a patient chart. These include:

- ✓ Assess whether goals of therapy are achieved or not
- ✓ Identify existing or potential adverse reactions and/or treatment failures and recommend management approaches.
- ✓ Identify drug incompatibilities and interactions having clinical significance and discuss potential solutions.
- ✓ Apply pharmacokinetic dosing principles in dosing of selected drugs such as IV to PO switch

C) Ward rounds, morning sessions and seminars

The pharmacist should actively engage in ward rounds, morning sessions and seminars to contribute to patient care decisions. These activities are performed both as part of the multidisciplinary team (MDT) and as pharmacy only activities. In pharmacy only rounds, the pharmacists are also expected to communicate patients and provide patient medication counselling. They will participate in grand rounds and death reviews, if applicable.

D) Medication reconciliation services

Medication reconciliation is the standardized process of obtaining a patient's best possible history and comparing it to admission, transfer or discharge medication orders to prevent errors of transcription, omission, duplication, interactions and other medicine-related problems. It involves documenting discrepancies identified between the medication history and current medication orders and how these discrepancies were resolved. All patients should have their medication reconciled as soon as possible after admission or presentation. If medication reconciliation cannot be completed for all patients, prioritize patients most likely to obtain maximum benefit. The service should be documented using Medication reconciliation form.

E) **Drug information provision**

As part of the routine clinical pharmacy service provision in the inpatient setup, pharmacists should provide verbal and/or written drug information timely. The service is given proactively or when posed by the healthcare team it should be recorded appropriately.

F) **Discharge medication counseling**

Pharmacists need to involved in discharge planning and provide medications counseling to ensure continuity of care after patients are discharged from health center. Using in-patient

medication profile form, the pharmacist will record discharge medications and counseling provided.

DOCUMENTATION OF CLINICAL PHARMACY SERVICES

Clinical pharmacy services should be properly documented on standard formats and relevant reports should be produced. Documentation ensures continuity of care and failure to document clinical pharmacy activities adversely affects the quality of care provided to the patient. The formats include:

- Inpatient Medication Profile Form
- Pharmaceutical Care Progress Recording Form
- Medication Reconciliation Form
- Clinical Pharmacy Intervention Daily Summary Form
- Clinical Pharmacy Intervention Monthly Summary and Reporting Form

The first three forms should be part of the permanent medical record (patient chart) of the patient. All patients with chronic illness and having a follow-up in the health center should have a patient medication profile form (PMP) for documentation. The PMP should be retained in the pharmacy and updated by the dispensing pharmacist whenever drugs are dispensed to the patient. The PMP can be in hard copy or computerized with hard copy back up and should contain the following information:

a) Name of the health center,
b) Patient medical record number
c) The full name, sex, age and weight of the patient,
d) The address of the patient and next of kin (if appropriate)
e) Diagnoses and any concomitant diseases
f) History of adverse drug reactions
g) Description of all medicines (prescription and non-prescription) used by the patient
h) Reason for any changes made in the regimen of the patient
i) Name or initial of prescriber and prescription number
j) Dispensing and / or prescription date
k) Appointment / Refill date, and
l) Signature of the dispenser

PMPs should be filed sequentially by medical record number or alphabetically by patient name in chronic care pharmacies. When a patient presents to the pharmacy for a refill, the pharmacist must assess the patient for signs of compliance, effectiveness and safety of therapy. The pharmacist should identify areas for therapeutic modification and should refer to the prescriber when appropriate.

5.10. Guidance 26: Monitoring Medication Use and Safety

Medication use involves a multistep process including prescribing, transcribing, dispensing, administering, and monitoring. It is crucial to ensure patient safety through the implementation of safe medication use practices. Each health center should implement medication safety programs including adverse drug event (ADE) monitoring

and reporting, performing medication reconciliation activities, identifying high alert medications, and implementing new and existing national standards and systems. The DIS is responsible for monitoring medication use and safety, presenting the findings and recommendations to the DTC, following interventions proposed by the DTC, and measuring outcomes.

Monitoring Medication Use

To monitor the use of medications in health centers, the pharmacy department in collaboration with the DTC should implement the following activities periodically.

- Monitoring of prescriptions
- Aggregate data methods (ABC, VEN)
- Indicator study methods
- Drug use evaluation methods

Prescription Monitoring

Prescriptions should be regularly monitored to identify prescribing trends and problems and to promote proper prescribing and dispensing practices in the health center. The monitoring schedule should be set at a frequency suitable for the patient mix and prescribing practice in the health center. The results should be communicated to the DTC for proper implementation and follow-up.

Prescriptions should be monitored for:

- Legality, legibility and completeness of prescription
- Appropriateness of prescription papers used (NPS)
- Appropriateness of the medication for the diagnosis
- Compliance with the health center formulary or applicable treatment guidelines
- The appropriate dose and route of administration
- The appropriate duration of therapy
- Significant interactions (drug-drug, drug-disease and drug-food)
- Duplication of therapy

ABC-VEN Analysis

ABC and VEN analysis are aggregate data methods that are used to identify medication use problems. Each health center should employ these methods annually to monitor drug use and

take interventions accordingly.

ABC Analysis is a method for determining and comparing pharmaceutical costs within the formulary system. It follows the Pareto principle "separating the vital few from the trivial many". ABC analysis can be explained in terms of budget consumed and number of drugs in the budget list as follows:

Category	Percentage of Budget Share	Percentage of Drugs
"A" Drugs	70-80%	10-20%
"B" Drugs	15-20%	10-20%
"C" Drugs	5-10%	60-80%

"A" medicines:
- High percentage of funds spent on large-volume or high-cost items
- Greatest potential for savings
- Greatest potential for identifying expensive medicines that are overused

"B" medicines:
- Moderate cost and moderate number of items; important items

"C" medicines:
- Small amount of funds spent on the majority of the inventory

Steps in performing ABC analysis:

Step 1. List all items purchased and enter the unit cost.

Step 2. Enter consumption quantities for each item.

Step 3. Calculate the value of consumption for each item.

Step 5. Calculate the percentage of total value represented by each item.

Step 6. Calculate the cumulative percentage of total value for each item.

Step 7. Choose cut-off points for A, B, and C.

Note: The results of ABC should be reconciled with that of VEN.

VEN Analysis is a method to prioritize for medicine purchase. This analysis is used to identify high priority medicines for procurement and low priority medicines that the DTC should analyze carefully for deletion from the formulary.

VEN stands for:

V = Vital: potentially lifesaving and crucial to providing basic health services.

E = Essential: effective against less severe but significant illness; not vital.

N = Non-essential: effective for minor illness but have high cost and low therapeutic advantage.

Steps for conducting VEN analysis:

Steps for conducting a VEN analysis are as follows:

Step 1. Classify all medicine on the list as V, E, or N

Step 2. Analyze the "N" items. Where possible, reduce quantities to purchase or eliminate them.

Step 3. Identify and limit therapeutic duplications.

Step 4. Reconsider proposed purchase quantities.

Step 5. Find additional funds if needed or possible.

Indicator study methods

In indicator studies, a selected indicator is set and performance against this indicator is measured. Indicators can be developed to assess prescribing, patient care or facility practices. The following table presents possible indicators that could be used for an Indicator Study.

Selected indicators to assess prescribing, patient care and facility practices

Table 3: Selected indicator to assess prescribing, patient care and facility practices

Prescribing Indicators	Patient Care Indicators	Facility Indicators
• Average number of medicines per encounter • % of medicines prescribed by generic name • % of encounters with an antibiotic prescribed • % of encounters with an injection prescribed • % of medicines prescribed which are from the essential medicines list or formulary list	• Average consultation time • Average dispensing times • % of medicines actually dispensed • % of medicines that are adequately labeled • % of patients who know how to take their medicines	• Availability of essential medicine list or formulary • Availability of key set of indicator medicines • Availability of standard treatment guideline (STG)

Table 4: Steps to be taken when conducting a drug use indicator study

Step 1: Determine objectives of study, Step 2: Define indicators and data collection procedures, Step 3: Determine study design and sampling methods, Step 4: Pilot test, Step 5: Train data collectors, Step 6: Collect data as per the time line, Step 7: Compile and analyze data, Step 8: Prepare report and recommendations based on findings of study, Step 9: Present report and recommendations to DTC and relevant health center staff, and implement recommendations arising from study, repeat study to assess impact

Drug Use Evaluation (DUE)

Drug Use Evaluation studies can be undertaken to measure the use of a specific drug and/or adherence to standard treatment guidelines (STGs). DUE studies are particularly important to investigate:

- Perceived overuse or underuse of medications
- Problems identified by indicator and aggregate methods
- High numbers of ADRs
- Excessive amounts of non-formulary medicines used
- Use of high-costs medicines when less expensive alternatives exist
- Use of excessive numbers of medicines within a therapeutic category.

Table 5: Steps to be undertaken in conducting a DUE study

Step 1: Define appropriate medicine use (for example medicine use described in national or local STGs)
Step 2: Audit actual prescribing practice against the set criteria
Step 3: Analyze data, prepare report and recommendations based on findings
Step 4: Present report and recommendations to DTC and relevant staff
Step 5: Implement recommendations arising from study, repeat study to assess impact

Problems identified by aggregate methods, Indicator Study and DUE studies may be further investigated using the following qualitative methods: In-depth interviews, Focus Group Discussions, Structured Observations, and Structured Questionnaires.

5.13.2. **Monitoring Medication Safety**

Adverse Drug Event Monitoring and Reporting

The pharmacy department shall coordinate, in cooperation with medical and nursing staff an adverse drug event (ADE) program. The program shall include: prevention, identification and reporting of ADR, medication errors and product defects.

Vigilance is required to detect ADRs. Individuals susceptible to an ADR include:

- Those with multiple diseases
- Those on multiple drug therapy
- Geriatric or pediatric patients
- Those receiving medicines that are known to be associated with serious adverse effects
- Those receiving drugs with a low therapeutic index or potential for multiple interactions
- Those with organ impairment that may alter drug pharmacokinetics, and
- Those who have had a previous ADR

An ADR focal person should be appointed by the DTC. He/she will be part of the drug information services unit and will be responsible to:

- Ensure that all health professionals are involved in detecting, assessing, managing and reporting potential ADRs
- Ensure that ADR report forms are readily available in all clinical areas and that health professionals are familiar with the form and how to complete it
- Receive ADR report forms from clinical staff
- Investigate potential ADRs
- Analyze ADR data and compile reports
- Provide regular reports to the DTC/and health center Management on ADRs in the facility
- Report all ADRs to the Regulatory Body

The DTC should receive regular reports from the ADR focal person and make any necessary decisions regarding the use of medicines in the health center. Where necessary the health center formulary should be amended to take account of detected ADRs.

Suspected ADEs should be investigated, managed and reported as follows:

1. **Assess suspected ADR with respect to**:
    a) ***Patient details***: age, gender, organ function, height, weight; diagnosis and other relevant co-morbidities prior to reaction; previous exposure to suspected drug(s) or related drug(s).
    b) ***Medicine details***: non-prescription drugs, alternative treatments, recently ceased medicines; name, dose, route of administration, manufacturer, batch; date and time commenced; date and time discontinued (if applicable); indication.

c) ***Comprehensive adverse reaction details***: description of the reaction; time of onset and duration of reaction; complications and sequelae; treatment and outcome of treatment; relevant investigation results or autopsy report.

2. **Perform causality assessment:** to assess likelihood of the drug causing the observed reaction.

A literature review may be undertaken to assess the likelihood that a suspected ADR was caused by a particular drug and/or the advice of other health professionals may be sought.

The ADR should be classified as:

- **Certain**: a clear temporal association is established between medicine administration and the reaction; and/or the results of investigations confirm that there is a relationship between the administration of the medicine and the reaction; and/or the reaction recurs upon re-exposure to the drug; and/or the reaction is commonly known to occur with suspected drug;
- **Probable**: the reaction is known to occur with the suspected drug, and there is a possible temporal association between the reaction and medicine administration; and/or the reaction resolves or improves upon withdrawal of the suspected medicine and other medicine therapy remains unchanged; and/or an uncommon clinical event occurs in the absence of other potentially causative factors;
- **Possible**: an alternative explanation for the reaction exists; and/or more than one medicine is suspected; and/or recovery follows withdrawal of more than one drug; and/or the temporal association between the reaction and administration of the medicine is unclear; or
- **Doubtful**: another cause is more likely to have accounted for the clinical event, e.g. underlying disease.

3. **Make recommendations on treatment options**; including possible alternative treatments taking into consideration:

- The likelihood of the suspected drug(s) having caused the reaction
- The clinical significance of the reaction
- The condition of the patient
- The requirement for therapy
- The risks and benefits associated with continuing therapy
- The relative efficacy and safety of other therapeutic options, and

- The prophylactic use of other medicines to prevent future adverse reactions.

4. **Document the ADR and provide follow up advice:**

All ADRs should be clearly highlighted in the patient's case notes. Any patient who has experienced an ADR should receive advice about the drug and reaction, should be advised to avoid the drug in the future and should be given an 'alert card' that states the drug involved and nature of the reaction. He/she should be advised to show this card at any future clinical consultation to prevent the same drug being prescribed again.

5. **Report ADR reporting mechanism;**

The health center Pharmacy department should avail reporting form, retain the necessary documentation and also mail the ADE report to regulatory authority (FMHACA).

A standardized form should be used to record and report ADRs. This should include:

- Patient name, sex, age, medical record number
- Clinical diagnosis
- Current medication
- History of previous ADR if any
- Details of adverse reaction
- Causality assessment
- Recommendations given

A sample of the reporting form is presented in Annex 16.

High alert medications

High-alert (or high-hazard) medications are those that are most likely to cause significant harm to the patient, even when used as intended. Although mistakes may not be more common in the use of these medications, when errors occur the impact on the patient can be significant. Some medications that have been considered as high-alert medications include: anticoagulants such as heparin and warfarin, narcotics and opiates, insulins, and sedatives.

General Principles for Reducing Harm from High-Alert Medications

Health centers and other care settings should employ the following principles of a safe system:

1. Methods to *prevent* harm include:
    - Develop preprinted order forms and protocols to reflect a standardized approach to treat patients with similar problems, disease states, or needs.
    - Minimize variability by standardizing strengths

- Include reminders and information about appropriate monitoring parameters in the order forms and protocols
- Consider protocols for the elderly, pediatric, and pregnant patients.

2. Methods to *identify* errors and harm include:
   - Include reminders and information about appropriate monitoring parameters in the order forms and protocols
   - Ensure that critical lab information is available to those who need the information and take action.
   - Implement independent double-checks where appropriate.
   - Instruct patients on symptoms to monitor and when to contact a health care provider.
3. Methods to *mitigate* harm include:
   - Ensure that antidotes and reversal agents are readily available.
   - Have rescue protocols available.

5.11. Guidance 27: Pharmaceutical Waste Management

Pharmaceutical Waste Disposal Guideline of EFDA should be taken into account for every activity in relation to Pharmaceutical Waste management in Health Centers.
Pharmaceuticals which are eligible for disposal include the following:

- All expired/damaged pharmaceuticals
- All syrups or eye drops (expired or unexpired) found unsealed while received from supplier or in the store
- All cold chain products not stored as per appropriate storage guidelines or manufacturers' recommendations (e.g.: insulin, hormones, gamma globulins and vaccines)
- All bulk or loose tablets and capsules with containers which are not sealed, properly labelled or within broken blister pack.
- All unsealed or damaged tubes of creams, ointments, lotions and related products.
- Any counterfeit pharmaceuticals

Each Health Center should establish a pharmaceutical waste disposal committee comprised of representatives from pharmacy, finance/audit, and sanitation services to ensure the proper disposal of pharmaceutical wastes in accordance with the EFDA directives.

Each Health Center should establish an SOP for the management of pharmaceutical waste. The SOP should include the schedule, methods, materials and equipment required for disposal and the responsible person. The SOP should be in line with Pharmaceutical Waste Disposal Guideline of EFDA and needs approval from the Health Center DTC. Disposal of pharmaceutical wastes should be supported by proper documentation, including the price of the products for audit and other legal requirements and may require presence of representative of concerned regulatory body at the place and time of disposal.

The Health Center should obtain disposal certificate from the regulatory body for pharmaceuticals properly disposed as per the guideline of EFDA.

STEPS FOR DISPOSAL OF PHARMACEUTICAL WASTES

Basic steps to be adhered for the disposal of pharmaceutical wastes are:

- ***Step 1:*** Pharmaceuticals that are expired/damaged or unfit for use should be counted, recorded and placed segregated from the other pharmaceuticals in the Health Center.
- ***Step 2:*** List of pharmaceuticals expired or unfit for use should be submitted to the responsible body for disposal and should be reported to the regulatory body.
- ***Step 3:*** The pharmaceuticals should be sorted out based on the pharmaceutical dosage form and chosen disposal method.
- ***Step 4:*** The pharmaceuticals should be disposed of in accordance with the appropriate method and in the presence of delegates from the responsible body.
- ***Step 5:*** Signed and stamped certificate of disposal should be issued by the authorized body entitled to oversee proper disposal of the pharmaceuticals.
- ***Step 6:*** Adjustments for each disposed pharmaceutical waste should be made in the available inventory management system.

Health Center pharmacy and cleaning staff should be oriented about the potential risks of hazardous pharmaceutical wastes and their management. Cleaners and others handling hazardous pharmaceutical wastes should wear protective devices like apron, plastic shoes, gloves, head gears, eye glasses, and goggles.

5.12. Implementation Checklist and Indicators

5.12.1. Operational standard assessment checklists for pharmacy services

The following Table can be used as a tool to record whether the main recommendations outlined above have been implemented by the health center. This tool is not meant to measure attainment of each Operational Standard, but rather to provide a checklist to record implementation activities.

Table 5.2. Operational standards for pharmaceutical services

S.No	Standard	Method of evaluation	Yes √ No X	met =1 not met =0	Remark
1	The Health Center has a functional Drug and Therapeutics Committee (DTC).	Presence of official letter of assignment for members			
		Presence of terms of reference (TOR)			
		Presence of DTC annual plan for the fiscal year			
		Presence of at least 6 signed meeting minutes in the last 12 months			
		Presence of performance report of DTC activities of the last fiscal year			
2	The Health Center has a separate pharmacy department comprising dispensaries and medical store directed by a registered Pharmacist and Pharmacist/Pharmacy technician respectively.	Presence of pharmacy services nearby outpatient, inpatient (optional) and emergency departments			
		Presence of pharmaceutical supply management unit (DSM officer)			
		Presence of drug information service unit			
		Presence of store for medical supplies, lab reagents, and medical equipment			
		Check the dispensary is guided by a pharmacist/druggist			
		Check store is led by a druggist/pharmacist(check assignment letter)			

S.No	Standard	Method of evaluation	Yes √ No X	met =1 not met =0	Remark
		Availability of 24/7 hours pharmacy services			
3	The Health Center develops, utilizes and annually updates a comprehensive list of pharmaceuticals prioritized by VEN	Availability of annually updated pharmaceutical list as per EPHCG drug list			
		The list is prioritized by VEN			
4	The health center implements auditable, transparent and accountable pharmaceutical transactions and services (APTS). (if applicable)	Workflow organized as: Evaluator ➔ Biller ➔Casher➔ Counselor (Entrance and Exit)			
		Presence of properly recorded and filed vouchers[2] at store			
		Presence of properly recorded and filed prescriptions, sales tickets and registers at dispensaries			
		Adequate human resource is deployed in each pharmacy services units[3] *(hint: based on workload analysis:number of prescriptions and bed size)*			
		Pharmacy premises are arranged so as to keep patient safety and privacy			
		Implementation of coding to uniquely identify medicines			

[2] Vouchers include: model 19/health and 22/health

[3] Human resource: pharmacists at OPD pharmacy, Inpatient pharmacy, emergency pharmacy, drug information services, and Pharmaceutical Supply Mgmt. unit; Pharmacy accountants, cashiers, porters, admin assistant and cleaners

S.No	Standard	Method of evaluation	Yes √ No X	met =1 not met =0	Remark
		Presence of survey report on patient satisfaction of overall pharmacy services			
		Bin ownership is implemented			
		Presence of monthly reports for products, finance and services			
		Presence of audit report (internal)			
		Presence of annual report on ABC and VEN analyses			
		Presence of survey report on patient satisfaction of overall pharmacy services			
		The health center has patient medication profile card in use for recording of medications for chronic disease such as ART			
5	The Health Center provides access to drug information to both health care providers and the public	Presence of dedicated room for drug information services			
		Dedicated assigned pharmacy professional for DIC			
		Presence of properly filled query receiving and answering forms *(see the previous month records*			
		Presence of recently prepared sample drug alert/newsletter, therapy update, drug monograph			
		Presence of updates on stock availability, new arrivals to the health center community *(ask health care team or see records or posts)*			

S.No	Standard	Method of evaluation	Yes √ No X	met =1 not met =0	Remark
		Presence of medicine use education for patients *(ask the appropriate unit and* Presence of yearly and weekly plans *(see the plan)*			
6	The Health Center has policies and standard operating procedures for identifying and managing drug use problems, including: Identifying and reporting adverse drug reactions, and prescription monitoring. (if applicable)	The health center has ADR reporting form.			
		Presence of semi-annual prescription monitoring report			
		Presence of annual DUE Report			
		The health center clinical staffs knows where/how to report ADR(ask clinical unit)			
		Presence of WHO drug use indicator study report			
7	The Health Centre has a pharmaceutical supply and inventory management system for drugs, medical supplies and equipment.	Presence of procurement policy			
		Presence of annual pharmaceutical quantification and supply plan (check with DTC)			
		Report that shows percentage of procured items from the health center list.			
		Presence of updated bin card (check randomly selected 10 bin cards)			
		Availability of IFRR to distribute pharmaceuticals (ask other units ways of distribution)			
		Availability of paper based or electronic inventory management tool			
		The facility has done regularly (monthly) stock status analysis			

S.No	Standard	Method of evaluation	Yes √ No X	met =1 not met =0	Remark
		Availability of vital drugs of the health facility at any time.			
		Conducts physical inventory minimum once a year for dispensaries and store (check report)			
		Good storage practice is being followed [4] (refer table 5.4)			
		Check for cold chains are stored in refrigerators/cold room			
		The health center uses the report of physical count of drugs for financial reconciliations/auditing and decisions.			
8	The Health Center ensures proper and safe disposal of pharmaceutical wastes and expired drugs in line with national guidance.	List of disposable drugs			
		Committee approval for disposal			
		Check presence of guideline			
		The health centre disposes expired and unusable drugs in accordance with FMHACA guideline(check report).			
9	The health centres pharmacy assists and monitors pharmaceutical management activities at the health posts.	The health center pharmacy section:			
		Gives continuous supplies to the catchment area health posts(Check HPMRR))			
		Provides technical support on drug use to the catchment area health post team(checklist and Support feedback)			

[4] See storage areas for cleanliness, proper arrangement, use of pallets, adequate shelves, ventilation and presence of thermometer on the wall and in the refrigerator

S.No	Standard	Method of evaluation	Yes √ No X	met =1 not met =0	Remark
10	The Health Centre conducts audits of all drugs, medical supplies and consumable equipment in the store and in each dispensing unit at a minimum bi annually by internal auditor and once a year by external auditor.	Presence of audit report of drugs, medical supplies and consumable equipment that are audited at least once a year by internal and external auditors			
11	The health center has functional antimicrobial stewardship program	Presence of official letter of assignment for members of ASP			
		Check for availability of AMR training trained personnel			
		Presence of terms of reference TOR			
		Presence of meeting minute			
		Presence of latest action plan (check for the plan)			

5.12.2. Indicators

In addition, the following indicators may be monitored on a regular basis to assess the effectiveness/outcomes of implementation of the recommendations provided in this chapter.

Table 5.3. Pharmaceutical services indicators

S/N	Indicators	Formula	Frequency	Comments
1.	Percentage availability of national tracer drugs at Health Center	$\frac{\sum \text{tracer drugs } x \sum \text{months available}}{\sum \text{tracer drugs } x \sum \text{total number of months in time per}}$	Quarterly	HMIS
2.	Average stock out duration for national tracer drugs at Health Center	∑ of stock out days of tracer drugs throughout reporting period/total number of tracer drugs	Quarterly	HMIS
3.	Percentage Availability of vital drugs of the health facility drug list	% available vital drugs = (# of available vital drugs) / (# of selected vital drugs) *100	Monthly	
4.	Actual drug expenditure as % of budget allocated to drugs	(Actual expenditure on drugs) / (total budget allocated to drugs) *100	Quarterly	

5.	Drug expenditure from EPSA as proportion of total drug expenditure	Actual expenditure on drugs from EPSA /total expenditure on drugs x 100	Quarterly	
6.	a) Percentage of drugs prescribed from the facility drug list	% Drugs from the list = (#Drugs from the list in the sample (30 prescriptions)) / (total # drugs in all sample (30 prescriptions)) *100	Annually	
7.	a) % of expired and damaged drug in value (%ED)	(% ED) = (Monetary value of total expired drugs) / (monetary value of total drugs available in that physical year) * 100 Note: it should be less than 2 %	Quarterly	
8.	Proportion of drug budget out of the total recurrent budget	Proportion of budget allocated to drugs/total recurrent budget * 100	Quarterly	HMIS
9.	Attrition rate of pharmacy staff	Number of pharmacy staff leaving/total number of pharmacy staff at beginning of reporting period * 100	Quarterly	HMIS
10.	a) Cumulative number of pharmacy staff who have undergone in-service training b) Cumulative proportion of pharmacy staff who have received in service training	a) Total number of pharmacy staff trained from beginning of year until end of reporting period b) Cumulative number of staff who received training/total number of staff at beginning of period *100	Quarterly	HMIS
11.	In patient satisfaction survey : % of respondents who answer 'always or usually' to the following questions "Before giving you any new medication, how often did staff describe possible side effects in a way you could understand?"	Total number of inpatients who respond 'always or usually' to the questions listed/ Total number of inpatients respondents.	Biannual	
12.	Out patient satisfaction survey : % of respondents who answer 'yes' to the following questions "The staff described the medications possible side effects/ and the dosage who knows the dosage of their medication in a way I could understand?"	% out patient satisfaction survey = Total number of outpatients who knows the dosage and respond 'yes' to the questions listed / (Total number of outpatients respondents.)	Biannual	
13	Consumption Ratio : Indicates the amount of used drugs in every month compared to the stocks available during the period; indicator for access to essential medicine, greater consumption indicates availability of needed (vital and essential) drugs	cost of drugs dispensed per month /[Cost of stock available for use (dispensary +store)]100%	Monthly	HMIS
14	Presence of Functional DTC	DTC which have action plan and minute		
15	Presence of drug list prioritized by VEN and is in use	presence of drug list prioritized by VEN and distributed to prescribers	Annually	
16	Physical Inventory in monetary value (PI)	PI= presence of inventory report used for decision makers	Annually	
17	Pharmaceutical waste Disposal	Report of disposed pharmaceuticals according to EFDA guidance	Annually	
18	Case load analysis report for human resource development (CLA-HRD)	(CLA-HRD) = Report of pharmaceutical caseload analysis	Annually	

		and measures taken for human resource development		
19	Pharmaceutical transactions are transparent	all transaction of the pharmacy are auditable	Annually	
20	presence of pharmacy services premises that satisfies the patient in terms of dispensing and counselling	presence of dispensing and counselling cubicles	Annually	

5.13. Additional Reading Materials

1. Ethiopian primary health care clinical guideline, (****)
2. EHSTG, 2016 Ethiopia
3. Ethiopian Minimum Standard for Health Center prepared by FMHACA
4. Ethiopian Hospital Reform implementation Guidelines, volume 1, may 2010. By federal ministry of health, Addis Ababa, Ethiopia.
5. Standard Operational Procedures for ALERT Center pharmacy Service, 2009, Addis Ababa, Ethiopia.
6. Management Sciences for Health & World Health organization, Managing drug supply, Kumar Ian press 1997), USA
7. Auditable Pharmaceutical Transactions and Services (APTS); Amhara Region; May 2012

Chapter 6: Laboratory Service

Chapter Description: This chapter will describe the reforms needed to setup an optimal laboratory service in a health center. The topics covered will include organization and management of lab services, lab equipment and reagent supplies management, standard operating procedures and quality assurance requirements. The chapter also discusses the measurement standards of the chapter with their respective verification.

Primary Objective: By the end of the chapter participants will be able to analyse the laboratory service requirements of a health center.

Enabling Objectives: By the end of the session you will be able to:

- Setup laboratory service organization and management
- Identify laboratory equipment management needs
- Manage laboratory reagent supplies and inventory
- Assess laboratory services quality assurance activities.
- List laboratory service measurement standards with their verification

Chapter Outline:

6.1. Introduction

Medical Laboratory services are essential in the practice of modern medicine by providing information to clinicians to accurately assess the status of a patient's health, make accurate diagnoses, formulate treatment plans, and monitor the effects of treatment. Laboratories are a major source of health information used as a raw data for research, epidemiological and surveillance purposes, moreover; laboratories are often the first sites for the detection of disease outbreaks. To provide such functions laboratory data must be recorded and reported through the appropriate channels in an accurate and timely manner.

The current laboratory service in Ethiopia is organized in a structure that follows the general health care delivery system of the country, incorporating specialized, general and primary hospitals in addition to health centres and health posts. At the apex of this system, there are Regional Laboratories and a National Referral Laboratory at the Ethiopian public Health institute(EPHI) A detailed description of the responsibilities of laboratories at different tier levels in Ethiopia is presented in **Appendix 6A**. As part of the Ethiopian laboratory network, HCs may refer specimens to a higher-level facility, and also from the same level of facilities in accordance with agreed protocols and guidelines between facilities (MOU).

These standards and guidelines are mainly based on ISO15189 and WHO standards to ensure the establishment of standardised, efficient, productive, service-oriented laboratories that can produce accurate, timely and reliable test results that helps health centres to provide individual

patient care, using the referral network where appropriate, and in addition provide data for the surveillance of population health and wellbeing. Effective laboratory management ensures that equipment, supplies and competent staffs are available to produce quality result, at all times to perform agreed tests with minimal 'down time' in service provision.

6.2. Operational Standards

1. The health centre provides laboratory service with optimal infrastructure and resources.
2. The health centre has functional laboratory management information system.
3. The health centre laboratory posts updated list of laboratory tests as per EPHCG recommendation.
4. The Health center monitors laboratory service satisfaction biannually (client and providers).
5. The Health centre has a functional laboratory supplies management system.
6. The Health centre laboratory has standard operating procedures.
7. The laboratory has established safety facilities.
8. The laboratory shall design a backup laboratory service.
9. The health centre laboratory shall implement quality control activities.
10. The health centre Laboratory participates in the National As well as international accreditation body (ENAO/SLIMTA/ISO.

Activity 6.1. Group work with gallery walk

Instruction:

- Be in group of 5-6 people
- Your facilitator will assign topics for each group
- Present your work using flip chart as a gallery walk
- After 40 minutes facilitate gallery walk discussions

Time: 40 min for group work 50 min for galler walk presentation

6.3. Implementation Guidance

Guidance 28: Organization and Management of lab services

LABORATORY MANAGEMENT STRUCTURE

The laboratory shall have its own organizational structure that enables the laboratory to communicate internally and externally with vendors, other health institutions to create collaboration and partnership and EQA program providers by working under the organizational umbrella of the health center. Each laboratory must have an organizational chart (organogram) that describes the management and supervisory arrangements in the laboratory.

The health centre laboratory should have functional central, laboratories. The laboratory should provide services 24/7.

LABORATORY MANAGEMENT ROLE

The laboratory shall be managed by an experienced laboratory professional or persons with the competence in their field and in management. The duties and responsibilities of the laboratory manager, quality officer and safety officer should be documented. The laboratory manager (or designate/s) shall:

1. Provide effective leadership of the medical laboratory service, including planning, budgeting and overall financial management, in accordance with organizational assignment.
2. By representing the Health Center, liaise and work effectively with applicable regulatory authority and accrediting agencies, appropriate administrative officials, the healthcare community, and the patient population served.
3. Ensure that there are appropriate number of staff with the required education, training and competence to provide medical laboratory services that meet the needs and requirements of the users
4. Ensure the implementation of laboratory quality policy
5. Implement a safe laboratory environment in compliance with good practice and applicable requirements
6. Develop Health canter laboratory specific annual plan and ensure that adequate budget is allocated
7. Ensure the provision of clinical advice with respect to the choice of examinations, use of the service and interpretation of examination results
8. Provide professional development programs for laboratory staff and opportunities to participate in scientific and other activities of professional laboratory organizations
9. Define, implement and monitor standards of performance and quality improvement of the medical laboratory service or services
10. Maintain strong communication/relationship among clinical and non-clinical staff.

COMPETENCY ASSESSMENT

Competency assessment is a tool to check the knowledge and skill of the professionals on a given or scheduled time. Competency assessment can include theoretical, practical or both at a time Competency assessment should have a Plan and systematically given after every training and on regular scheduled bases.

CUSTOMER SERVICES

Each laboratory should develop a system to collect and measure data on how much the laboratory services and products satisfy the costumer (the patients and clinical staff) and should take steps to address any problems identified. This could be done through suggestion boxes, suggestion books and/or satisfaction surveys as part of or additional to the overall health center's clinical governance and quality improvement programme.

The laboratory should have a mechanism to record complaints from patients, staff and clients. All complaints and problems reported to the laboratory as well as corrective action taken should

be documented and the handling procedure should be part of the overall health center's complaint handling and management system.

Tests available

The Laboratory Manager, in collaboration with the Finance Department, should produce a list of all tests that are provided by the laboratory, including the fee per test. The list should be updated on an annual basis (or more often as required) and should be posted on cashier desk and, in sample collection areas and readily available to all clinical staff and patients/clients.

Laboratory Handbook/information manual

Laboratory Handbook/information manual should be prepared by each laboratory for the benefit of clinical staff ordering diagnostic tests. The user manual should be distributed to all sample collection areas including inpatient room, emergency room, procedure room, labour and delivery room, outpatient department etc.

The user manual should include:

- A list of all tests available at the laboratory and average turn-around time for each
- A list of tests that may be taken by the laboratory and referred to a higher tier for analysis and turn-around time for each.
- For each test:
    - Type of sample
    - Volume of sample required
    - Sample collection procedure and materials
    - Reference range
    - Critical Value
    - Test interference or procedure limitations
    - Sensitivity and Specificity
    - Accuracy and Precision
    - Any other pertinent test characteristics
    - Interpretation

CLINICAL ADVICE SERVICE

The laboratory should provide a service to clinical staff to assist with the interpretation of results and to advice on the need for additional tests. To achieve this laboratory staff may make comments on the result report form, either commenting on the interpretation of the results and/or suggesting additional investigations that might aid the diagnosis. Laboratory personnel should be available to answer queries from clinical staff about individual test results or the need for further investigation. Additionally, the laboratory should establish '**panic results'** (i.e. a result which should be communicated immediately to the physician for urgent action) for each investigation and processes by which such results are communicated immediately to the ordering clinician.

Information sharing

The Health centre should have a process to update clinical staff on areas such as newly started or discontinued tests and in interpreting laboratory results etc. There should also be a forum

through which laboratory staff can discuss individual patient care with clinicians when necessary. Possible mechanisms include:

a)'In house' education sessions at which all laboratory staff members who attend workshops/trainings share this knowledge with their laboratory and other clinical colleagues.

b) Clinical review meetings of all clinical staff or of each clinical case team. These meetings should provide clinical advice/up to date information about laboratory services to clinical staff.

Customer service Satisfaction

Each lab should develop a system to collect and measure data on how much the laboratory services and results satisfy patients/clients and clinical staff in order to take measures on any problems identified. This could be done through suggestion boxes or satisfaction surveys.

The laboratory should have a mechanism to record complaints from staff and clients. All complaints and problems reported to the laboratory as well as corrective action taken should be documented.

For further discussion on ways to ensure a patient centred service please see Sections *Chapter 10 Quality Management and Monitoring and Reporting*.

TESTS TO BE PROVIDED BY A HEALTH CENTRE LABORATORY

The following diagnostic tests should be provided by Health Centre Laboratory
The list are Annexed

Table 6.1. Essential laboratory services in a health center

Haematology
Haemoglobin
Full Blood count
Total WBC count
Differential white cell count
Peripheral blood film
ESR (Erythrocyte sedimentation Rate)
Haematocrit
Protrombine Time(PT)
Partial Thromboplastic Time (PTT)
International Normalised ratio (INR)
Clinical Chemistry
RBS (Random blood sugar)
Aspartate Aminotransferase (AST)
Alanine amino Transferase (ALT)
ALP
Urea,creatinine
Bilirubin Total
Bilirubn Direct
Uric Acid
Total cholesterol
Triglyceride
Sodium (Na)
Potassium (K)

Magnesium
Chloride (CL)
Bicarbonate
Microbiology
AFB Smear
Xpert MTB/RIF assay for tuberculosis
Gram Stain
India Ink Stain
Wet Mounts
Mycology
•KOH Test
Serology
Rapid HIV Test
RF
RPR
Salmonella typhi-O
Salmonella typhi-H
Prouteus-OX_{19}
Blood group anti-A, Anti-B, Anti-D,
TPPA/ TPHA/ RPR
H.pyloriAb test
COVID -19 Ag/Ab test
Hepatitis B surface Ag (HBs)
Hepeetites C surafaseAb Test (HCV)
Hepetites C antibody test (HCV)
C- reactive protein (CRP)
Cryptococal Ag test
Parasitology
• Malaria Rapid Test/RDT
• Blood Film
• Stool examination: Direct microscopy and concentration techniques
• Occult blood
• Stool Ag Test
Urine analysis
• Urine Dipstick with Microscopy
• Urine Pregnancy Rapid Test(HCG)
ImunoHematology
• CD4 test

REFERRALS AND TRANSPORTATION OF LABORATORY SAMPLES

Within Health centres, trained support staff should be used to transport samples and results between the laboratory and clinical areas. The transport between the Health centre and external facilities is handled by the Sample Transfer Service (STS). The STS is a system that outlines the process of referring and transporting laboratory samples in a coordinated, timely, and effective manner. The quality of laboratory results is dependent upon the quality of the

specimen received. Therefore, the STS are designed to minimize the time from when the specimen is collected to when it is delivered.

There should be an assigned contact person to oversee the referral and transport process and a trained courier (preferably a non-technical staff member) for the transportation of samples. Transport should be arranged in accordance with the SOP of each test taking into account any special requirements (e.g. maintenance of the cold chain). All relevant personnel (runners, couriers, laboratory staff, clinicians and Health officer) should be trained in the collection, preservation and transport of specimens as appropriate.

The Health centre should establish linkages with other facilities for the receipt and referral of samples. There should be a policy, agreed between relevant facilities, that specifies:

- The other facilities from which samples may be received,
- The type of samples and tests that will be conducted for other facilities,
- The turnaround time for each test and process by which results will be reported back to the referring facility,
- The higher level facility(s) to which samples may be referred,
- The type of samples and tests that will be conducted at the higher level facility(s), and
- The turnaround time for each test and process by which results will be reported back to the Health centre.

Laboratory samples may also be received from external private health facilities. The Health Centre may decide to charge a higher fee for the testing of these samples.

A system should be established to track referred and received samples to ensure that no samples or results are lost and to keep a record of test results.

ORGANISATION OF LABORATORY WORKING ENVIRONMENT

The physical structure of the laboratory should be of an appropriate size, location, and layout to ensure safety to staff, patients, and others. Since facility design has direct impact on the efficiency, diagram of the layout of the laboratory department should be given an emphasis and clearly displayed on the wall of the central laboratory.

The laboratory space should be sufficient to accommodate:

- Patient registration and sample collection
- Administration and clerical functions
- Instrument storage
- Refrigerators and other storage space for reagents and supplies.
- Washing and disinfection room
- Mini store

Ideally, laboratory samples should be collected from patients within the service area where they are receiving clinical carein ER, on the ward etc). The sample and test request form should be taken to the laboratory by a support staff member. A process should be in place to ensure that all necessary testing equipment (e.g. tourniquet, blood collection tubes etc) and sample request forms are always available in all testing areas. For further discussion on the

organization of Laboratory Services and sample collection, including BPR recommendations, see *Chapter 3 Patient Flow*.

If it is necessary to collect samples within the laboratory department then there must be a covered waiting area for patients, a patient reception and/or a sample collection room. The laboratory test area should be well lit, have good ventilation and a minimum of two sinks – one for washing hands and the second for laboratory purposes. The laboratory work space should be organized by the type of department/test performed (i.e. haematology, clinical chemistry, microbiology etc).

Strong, built-in benches with levelled tops and covered with a surface that can be disinfected (such as Formica) or painted with oil based paint should be there. Benches should be at least 0.9m high and 0.5m wide. There should be an adequate number of lab stools. These should be at least 0.6m high to enable staff to sit while performing lab work. Stainless steel or plastic stools are preferable for the ease of cleaning and disinfection.

Laboratory floors should be made of materials that are resistant to acids, alkalis and salts (e.g. not wood). Alternatively the floors may be plated or painted with such materials. Ceilings should be of materials that can easily be cleaned and disinfected and should provide a continuous seal to prevent contaminants from seeping through. Internal and external walls should be maintained in good condition.

A mini-store for reagents and supplies should be located within the laboratory department. There should be sufficient power outlets for all electrical equipment within the laboratory and the use of extension cords should be minimized. Laboratory equipment, including refrigerators, should be protected by Uninterrupted Power Supply (UPS) devices. Essential equipment should be connected to the backup power supply in the event of power failure.

Access to the laboratory should be restricted to authorized personnel. Laboratory buildings should be secured with window locks or burglar bars, door and cupboard locks as necessary. Keys should be held by authorized personnel only.

LABORATORY SAFETY

Everyone in the laboratory is responsible for safety in the laboratory. But there should be someone to oversee health and safety activities. The Laboratory Manager could fill this position if necessary. Responsibilities include:

1. conducting regular risk assessments of laboratory premises
2. maintaining a safe working environment
3. ensuring adequate safety equipment is available at all times
4. ensuring the safe disposal of laboratory waste
5. preparing the laboratory health and safety manual
6. preparing the department-specific Major Incident Plan
7. training laboratory staff on health and safety procedures
8. establishing mechanisms to report laboratory accidents or injuries
9. ensuring that remedial action is taken in response to any accidents or injuries

1. Risk assessment

A regular risk assessment of laboratory premises should be conducted at a minimum every quarter. A standard assessment tool should be used. A sample Laboratory Risk Assessment Form is presented in Appendix F. Based on the findings of the risk assessment appropriate steps should be taken to minimize risk.
Copies of all risk assessments and a description of remedial action taken should be maintained in the laboratory.

2. Laboratory environment

Laboratories should be adequately signed and clearly indicate:

- Entrances to areas where bio-hazardous materials are kept,
- Fire exits and fire extinguishers,
- First aid kit,
- Eye wash station, and
- Safety shower.

Bio-hazardous materials should be stored in secure and clearly demarcated.

Walkways, doors and fire escape routes should be unobstructed at all times and all areas of the laboratory should be adequately lit.

General safety rules, such as standard precautions, should be laminated and posted in an open and visible space within the laboratory.

3. Safety equipment

a) Personal Protective Equipment (PPE): this should be available in sufficient quantities for the use of laboratory staff and visitors at all times. PPE includes:
    a. Goggles, gloves, coats, plastic aprons and face shields
    b. Cryogenic/heat resistant gloves
b) First Aid Kit: there should be a first aid kit in each laboratory testing area. This should be checked and restocked weekly.
c) Eye wash station: there should be an eye wash station in each laboratory testing area. The water should be changed weekly or after each use.
d) Safety shower: there should be a safety shower available to all laboratory staff in the event of chemical exposure. This should be tested weekly.

4. Waste disposal

Laboratory waste should be regarded as ‘hazardous’ and disposed of accordingly. Further guidance on waste management, including the management of spills of hazardous materials is presented in Section 3.4.1.1 of *Chapter 7 Infection Prevention.*

All staff who handles laboratory waste (including those undertaking repairs of drainage systems) should follow standard infection prevention measures and wear PPE. (For further guidance on the use of PPE please see Section 3.2.2 of *Chapter 7 Infection Prevention*).

LABORATORY HEALTH AND SAFETY MANUAL

The laboratory should have a health and safety manual that:

a) Establishes general safety principles such as:
    i. The implementation of 'Standard Precautions' for infection prevention (see section 3.2 of *Chapter 7 Infection Prevention.*
    ii. The use of personal protective equipment and proper clothing (e.g. close-toed shoes, clothing that minimized skin exposure, hair tied back etc.)
    iii. Prohibition of eating, drinking or smoking in the laboratory
    iv. The use of equipment by appropriately trained personnel only
    v. Decontamination of equipment
b) Establishes procedures for the storage of and access to hazardous materials
c) Establishes procedures for the disposal of laboratory waste
d) Describes action to be taken in the event of an accident or injury such as fire, chemical spill, inoculation accident etc.
e) Reporting and monitoring of accidents and incidents
5. Training of laboratory staff on safety

All laboratory staff should be trained on each of the areas covered in the health and safety manual and on the health center Major Incident Plan, including each staff member's role in a major incident.

6. Report of accidents or injuries

A standard report form should be used to record all accidents and incidents including spills of chemical or bio-hazardous materials, accidental needle stick injury etc. The Incident Officer should investigate the incident in collaboration with the Laboratory Manager and take any necessary action.

LABORATORY STAFF MANAGEMENT

The health centre of which the laboratory is a part is responsible to organize laboratory management.

Laboratory management staff must have a plan to be successful, that includes:

- Describe management's roles and responsibilities regarding personnel management.
- Establish a program to verify employee competency
- Improve employee's competency
- Identify potential sources of employee performance problems
- Insure fair and non-biased system for recognition and staff reward

And in addition the laboratory management has a responsibility to

- Implement and maintain personnel records
- To prepare job description (Assignment of duties and responsibilities to each staff person)
- Creation of a rotation schedule
- Career paths that allow the opportunities for progression and career advancement, including further training and research. Priority for career

advancement should be given to those with longer lengths of service and good performance evaluations
- Regular staff meetings
- Staff performance reviews

In addition to technical staff the laboratory should have sufficient clerical staff for registration of samples, documentation of lab results and archiving of materials.

Further guidance on the above is presented in *Chapter9 Human Resource Management*.

INFORMATION MANAGEMENT

Complete and detailed information management must include complete, legible, accurate, timely, secure and confidential information which is a key to improve the efficiency and quality of laboratory services. In addition, an organized information management system allows for easy coordination between sites and helps reduce costs. The information management may be of paper-based and/or computer- based, but has to ensure confidentiality and privacy of patient information.

DOCUMENT MANAGEMENT

Documents must be clear, concise; user friendly, accurate, up-to-date and explicit written document helps in communicationof the quality management system.
The following documents should be present in the laboratory:

- Policy Manual
- SOPs
- Quality assurance manual
- Health and safety manual
- Approved laboratory test request and report forms (Samples are presented in *Appendix B,Chapter 3 Medical Records Management)*
- Laboratory registration books
- Specimen referral form
- Report form (monthly, quarterly)
- Stock inventory form
- Refrigerator/Freezer charts
- Equipment Maintenance Logs
- QA Charts and External QA Records
- Error logs
- Accident and occurrence management Logs

These documents should be organized through an established system of documentation and record handling, which includes:

- Document Identification and version control
- Master File

  - The master file should contain a copy of every version of every document, thereby serving as an archive of all previous versions of the document, including the current version.
- Master Index
  - The master index should have a list of all the documents currently in use.
  - It should contain the document name, number, version designation, effective date, and document location.
  - The master index should be changed every time a new version of a document is released.
  - The master index allows staff to ensure that they are using the appropriate version of a document.
- Document Distribution
  - The master file and master index should list the locations of all copies of a particular document.
- Document Review
  - To ensure that the latest versions of all documents are being used the Quality Assurance Officer should be responsible for overseeing the entire system, monitoring version identification, revision control, the master file, the master index, and the distribution of documents.
  - A review should be performed annually in order to ensure that all documents and procedures are up to date.

RECORD MANAGEMENT

Records are the collected information produced by the laboratory in the process of performing and reporting a laboratory test. Characteristics of records are that they: Need to be easily retrieved or accessed; contain information that is permanent, and does not require updating.

Records are essential for:-

- Continuous monitoring of quality system
- Sample tracking throughout process
- To identify inherent problems

Laboratory record includes but not limited to:

- Patient test report
- Sample accession log
- Work sheet
- Instrument print out
- Maintenance data
- Quality control data
- EQA/PT records

There must be a system or procedure for record control, has to be easily accessible and up-to-date and have to be stored in the facility for a limited duration

Guidance 29: Laboratory Equipment Management

The following sections provide an overview of the management of laboratory equipment. For more detailed guidance please see *Chapter on Medical Equipment and Facilities Management*.

EQUIPMENT REQUIRED IN A HEALTH CENTRE LABORATORY

To perform the tests described in above Health Centre laboratories must have minimum of at least one from each laboratory equipment, instruments, reference materials, consumables and reagents which are important to accomplish the above listed tests to be performed in the laboratory.

The laboratory should be connected to a back-up power supply (generator) in cases of interruption to the mains electrical supply. Each laboratory material and equipment has to be uniquely labelled, marked or otherwise identified.

PROCUREMENT OF EQUIPMENT

A junior technologist or senior laboratory technician should be a member of the health centre management Committee that is responsible to approve the procurement of all medical equipment including laboratory equipment. Prior to ordering or accepting equipment there must be a check to ensure that the laboratory has adequate room size and access for the equipment, together with an adequate electrical system, plumbing and ventilation, as required.

For all new equipment there must be an agreement with the vendor for installation, calibration, maintenance, reagent supply, service and repair and training of staff for a specified time period. All new equipment should be supplied with a user manual. All procurement decisions must ensure availability of continuous reagent supply. There should be a sustainable supply of reagents, and as far as possible required reagents should be integrated across systems.

All donated equipment must be assessed by laboratory management before acceptance. This assessment should include the need for the item and any maintenance and reagent requirements to ensure that any necessary spare parts or reagents are readily available in the country.

INVENTORY CONTROL

Every lab should have an inventory of all equipment and instruments that includes:

- Name of manufacturer,
- Name of supplier
- Model and serial number,
- Date of purchase or acquisition,
- Purchase cost,
- Record of contracted maintenance, and
- Record of equipment breakdowns.
- Record of equipment calibration

Manufacturers' manuals should be attached to, or stored beside, each instrument. Laboratory equipment should only be used by appropriately trained staff. An equipment SOP which is prepared in the laboratory must be read and signed by laboratory staff to indicate they can operate the equipment with basic knowledge.

EQUIPMENT MAINTENANCE

There should be a service for preventive maintenance, calibration and monitoring of equipment function that is documented and at a minimum follows manufacturer's recommendations. The Quality Assurance (QA) Officer (see section 6.11) is responsible to produce the required schedule of maintenance, calibration and control following manufacturer's inserts and basic QA procedures to ensure that instruments in the laboratory are maintained properly, daily maintenance, calibrations and controls are run, and maintenance logs are kept up to date.

There should be close follow up of instruments' functional abilities such as temperature of refrigerators, incubators, rotation of centrifuges etc. Log books or standard forms should be stored near or attached to the instrument and should be completed on a regular basis by the laboratory staff. The QA officer is responsible to review the log books or forms to ensure that the required checks have been done.

All preventive maintenance should be documented in a computer/log book and kept in each laboratory. All records of corrective actions taken, repair and services should be documented and kept in the laboratory. For instruments that are not functioning properly an ' OUT OF ORDER' label should be attached on an easily visible part of the instrument body until corrective maintenance is done. Instrument down time should be recorded.

Good maintenance practices minimize instrument repair costs and limit instrument downtime and workflow interruptions. There are two types of maintenance: planned preventive maintenance and corrective maintenance. For each item of equipment a check-list or log should be kept of all maintenance activities.

Only individuals who have taken appropriate training or professionals thoroughly read and signed on specific SOP on specific piece of equipment should undertake maintenance activities. For some equipment this will require a certified service engineer.

Preventive Maintenance

Periodic maintenance prior to equipment failure will prevent accidental breakdown and increase performance. Systematic Preventive Maintenance includes adjusting, calibrating, changing spare parts, following shut down procedures, and performing general cleaning procedures (such as blowing, rinsing, wiping, flushing). Cleaning procedures should adhere to Standard Operating Procedures that apply to each instrument.

The Operator (user) should perform daily, weekly, monthly and/or quarterly preventive maintenance for each type of equipment in the laboratory. All preventive maintenance activities should be recorded in a maintenance log for each piece of equipment. A sample Preventive Maintenance Log is presented in Appendix 6B.

Service engineers from the appropriate company or EPHI should perform semi-annual or annual preventive maintenance on the larger more complex instruments. A log must be completed with copies held on site and by the service engineer.

Corrective Maintenance

Corrective maintenance involves equipment repair and replacement of parts. Instrument operators can perform simple corrective maintenance such as replacing blown out fuses and removing blockage from the fluidics system by using troubleshooting charts from instrument user manuals. However, most corrective maintenance must be performed by a qualified service engineer. All corrective maintenance activities should be recorded in a maintenance log for each piece of equipment.
A sample Corrective Maintenance Log is presented in Appendix 6C.

Engineers, aside from those sent by the supplier, can perform corrective maintenance on instruments still under warranty.

Guidance 30: Control of Laboratory Reagents and Supplies

Health centre Laboratories may require reagents, controls calibrators and supplies for: Clinical chemistry, Haematological tests, Microbiological tests, Serology, Parasitology, and Others.

In the procurement of reagents, the supplier should provide a certificate of suitability of the reagents for the intended test. Laboratories should only purchase reagents that have been approved by the Food Medicine and Healthcare Administration and Control Authority (FMHACA). Reagents should be stored according to manufacturer's recommendations.

All reagents and other supplies should be:

- catalogued and stored accordingly to aid retrieval,
- properly stored according to manufacturer's instructions,
- discarded when the shelf life is expired, with standard procedure
- labelled to indicate identification and, when applicable, significant titre strength or concentration,
- Marked with date of preparation or expiration.
- marked with the date opened:
- The date that the reagent was first opened must be written on the container with a standard plastic laminated form. If reagents are dispensed from intact stock containers by dilution or any other treatment, the date of preparation as well as the duration should be written,
- The components of reagent kits of different lot numbers should not be interchanged unless otherwise specified.

REAGENT AND SUPPLY INVENTORY CONTROL

Laboratory management should have control over the purchase, storage and distribution of laboratory reagents and supplies. If another department (for example finance or pharmacy) is responsible for the purchase of laboratory reagents and supplies this should be done in

consultation with the Laboratory Manager must be consulted for stock order a system through which the Laboratory Manager can order stock when necessary.

The laboratory should establish a control system and register purchasing and supply of reagents and supplies with its expiry date through a log book or an electronic system and supplies should be recorded. This will allow laboratory staff to compare the current stock in the laboratory and in the warehouse to avoid unpredicted stock out.

Laboratory reagents and supplies should be stored in a mini-store that is managed by the Laboratory Manager.

Guidance 31: Standard Operating Procedures

Standard Operating Procedures (SOPs) are created for regularly recurring work or processes that are conducted in the laboratory. This is done to ensure that activities are performed consistently and in a manner that achieves results of the highest quality, and that the laboratory is run as efficiently as possible. All laboratory staff should participate in the creation of SOPs. Each SOP should be approved by the Laboratory Manager and Quality Assurance Officer prior to implementation.

SOPs should be available for:

- Specimen management (collection, processing, rejection, retention and disposal)

All SOPs for specimen management should include:

Action upon receipt of a sample:

Upon receipt each laboratory should check the availability of the requested test in that laboratory, including the turnaround time for results. If the service is not available, the laboratory should notify the customer and refer the sample to a different laboratory capable of performing the request test (see section 3.7). If the service is available, the sample must be checked according to the acceptance and rejection criteria. A specimen can be rejected if:

- it is received without a request form,
- it is unlabelled, incompletely labelled or if the name on the label does not match the name on the request form,
- it is leaking,
- it is collected in a broken and inappropriate container,
- it is the wrong type of specimen for the requested test,
- it was not transported according to requirements,
- the time since collection is too long(depending on the type of test),
- it is haemolysed
- there is insufficient volume of a specimen, or
- there is bacterial overgrowth present

Documentation of sample receipt:

A log book should be used to record the receipt of samples. This should include:

- the name of the patient and identification number,
- the source of the specimen,
- the name of the submitter, and
- The date of collection.
- Tests to be performed

- All testing procedures:

All SOPs for individual tests should include:

a) The full test name, including the full name of the methodology used (commonly used abbreviations should be listed at the beginning of the SOP),
b) The types of reactions, specimens, or organisms involved in the test,
c) Guidelines for the storage of specimens to ensure their integrity until testing is complete,
d) The clinical reasoning for performing the test,
e) Any calculations and formulas needed to obtain a result,
f) The methodology used, including the limitations of procedures and reagents,
g) Standards by which a sample is accepted or rejected,
h) Safety issues related to that particular test,
i) The test procedure, including:
    - A complete set of instructions
    - Detailed descriptions such as measuring units, etc.
    - How to prepare slides, solution, calibrators, control, reagents, stains, etc. for use
j) The criteria for what to do if a test system becomes inoperable,
k) A corrective action guideline (when necessary),
l) Interpretation of results, including:
    - Reportable ranges
    - Critical or panic values
m) Methods of disposal for specimens and other products used,
n) References to relevant and pertinent materials,
o) Criteria for the referral of specimens to and from other health facilities, and
p) Transport requirements (e.g. cold chain) if the specimen is to be transferred to another laboratory.

A sample SOP for haemoglobin estimation is presented in Appendix 6D.

a) SOPs should also be available for:
b) Testing algorithms (The procedure for analyzing a sample that has more than one test request)
c) The maintenance and monitoring of each piece of equipment (see section 3.4)
d) Sample collection, rejection, retention, referrals and transportation (see section 3.7)
e) Safety procedures and waste management, including proper specimen disposal (see section 3.9)
f) Quality assurance procedures (see section 6.11)

Each SOP should be reviewed on a regular basis (for example annually). The level of revision and due date for the next review should be stated on each SOP. The national SOP template, developed by EPHII is presented in Appendix 6E.

Guidance 32: Quality Assurance

Quality Assurance (QA) is a process of actions and tests designed to ensure that specific standards are adhered to, and that laboratory testing is as accurate and efficient as possible. QA begins when the laboratory test is first requested and ends at the point where the test results are returned to the patient's folder. When problems are identified, they should be documented and corrected in an appropriate manner.

Quality assurance should be undertaken for all tests performed by the laboratory. Both internal and external quality assurance processes can be applied. Internal QA is when the health centre itself undertakes QA activities. External QA is when an external body (such as the Regional Laboratory, EPHI) performs QA testing of the laboratory.

A full-time laboratory quality assurance officer should be assigned to oversee all laboratory QA activities. This includes the QA of all tests undertaken outside the laboratory (for example PIHCT, PMTCT). The QA Officer will be responsible to oversee all internal QA activities and to liaise with, facilitate and maintain records of all external QA activities.

EXTERNAL QA

Laboratory EQA programs are implemented in the form of:

- Proficiency panel testing
    - A number of proficiency panels are sent to a laboratory by the regional laboratories or other bodies
    - Analysis tests are performed
    - Results are compared between labs
- Blind re-checking
    - A random selection of samples are collected from the routine work load and sent to a laboratory
    - Any errors detected reflect the reality of everyday performance in that lab
- On-site assessments

In due course external QA processes will be developed for other laboratory tests. Health centres must comply with all national external QA requirements. Additionally Health centre may establish external QA mechanisms with other accredited agencies or may develop inter-institutional QA processes.

INTERNAL QA

The Health centre laboratory has to have an internal laboratory QA which involves Pre-analytical Analytical and Post-analytical steps to insure the quality of patient/client result, if problem is identified somewhere in the procedure, the problem has to be properly documented with the corrective action taken.

ACCREDITATION OF LABORATORY

Accreditation of health laboratories is the process by which an independent and authorized agency accredits the quality system and competence of a laboratory on the basis of certain pre-defined standards. Accreditation is done at regular intervals to ensure maintenance of standards and reliability of results generated to support clinical and public health activities by the laboratories.

The Health centre Management with the Laboratory Facilitates the implementation and maintenance of an effective quality management system to meet the required National& international predefined standard.

Benefits of a quality system/accreditation

- Gives confidence to users in availing the service& confidence to the laboratory for the results generated
- Provides national/international recognition of technical competence
- Helps in defending laboratories while dealing with legal disputes pertaining to laboratory results
- Reduces the operating costs of the laboratories by getting results right the first time and every time
- Helps in national and international acceptance of results
- Meets purchase or regulatory specifications
- Increases competitiveness and market share.

6.4. Implementation Checklist and Indicators

6.4.1. Assessment Tool for Operational Standards

In order to determine if the Operational Standards of Laboratory Services have been met by the health centre an assessment tool has been developed which describes criteria for the attainment of a Standard and a method of assessment. This tool can be used by health centre management or by an external body such as the RHB or FMOH to measure attainment of each Operational Standard.

Table 6.2. Assessment toll for operational standards - Laboratory services

Std. #	Standard	Method of evaluation	Yes √ No X	met =1 not met =0	Remark
1	The health centre provides laboratory service with optimal infrastructure and resources.	Laboratory has adequate space as per standard			
		Staffed according to standard			
		Has equipment as per EPHCG			
2	The health centre has functional laboratory management information system.	Check lab register			
		Lab request forms			
		Annual plan and performance			
3	The health centre laboratory posted updated list of laboratory tests as per EPHCG recommendation.	Check posted list of laboratories tests in OPD, ER, MNCH			
		Verify laboratory list is as per EPHCG			
4	The Health center monitors laboratory service satisfaction biannually(client and providers).	Collected survey data			
		Check report of client satisfaction survey			
		Check report of providers satisfaction on survey			
5	The Health centre has a functional laboratory supplies management system.	Check bin card			
		Check storage area			
		Check RRF			
6	The Health centre laboratory has standard operating procedures.	**Check SOP for**:			
		○ Sample collection, acceptance, transport, storing and disposal			
		○ Lab testing SOPs			
		○ Safety and medical waste disposal			
		○ Lab equipment maintenance and follow-up SOP			
		○ Quality assurance SOP			

Std. #	Standard	Method of evaluation	Yes √ No X	met =1 not met =0	Remark
7	The laboratory has established safety facilities.	Presence of water			
		Fire extinguisher			
		Safety kit			
		Waste segregation			
8	The laboratory shall design a backup laboratory service.	Check backup plan			
		Check MOU for lab backup service			
9	The health centre laboratory shall implement quality control activities.	IQA plan			
		IQA report			
		IQA sample			
		EQA plan			
		EQA report/feedback			
10	The health centre Laboratory participates in the National As well as international accreditation body (ENAO/SLIMTA/ISO.	Check recognition certificate			

6.4.2. Laboratory Service indicators

Table 6.3. Laboratory Services Indicators

	Indicator	Formula	Frequency	Comment
1.	Total number of samples received by laboratory services	Total number of samples received by laboratory services (inpatient, outpatient and emergency) during the reporting period	Quarterly	
2.	a) Number of samples rejected b) Proportion of laboratory samples rejected	a) Total number of samples rejected by laboratory services (inpatient, outpatient and emergency) during the reporting period) b) Total number of samples rejected by laboratory services (inpatient, outpatient and emergency) ÷ Total number of samples received (inpatient, outpatient and emergency) x 100	Quarterly	
3.	a) Number of samples referred into laboratory services from another facility b) Proportion of laboratory samples that were referred by another facility	a) Total number of samples referred into laboratory services from another facility during the reporting period b) Number of samples referred into laboratory services ÷ total	Quarterly	

	Indicator	Formula	Frequency	Comment
		number of laboratory samples x 100		
4.	a) Number of samples referred by laboratory services to another facility b) Proportion of laboratory samples that were referred to another facility	a) Total number of samples referred to another facility laboratory services during the reporting period b) Number of samples that were referred to another facility ÷ total number of laboratory samples x 100	Quarterly	
5.	Average turnaround time per laboratory discipline (chemistry, haematology, urine, stool etc)	∑ turnaround time for each discipline ÷ number of tests conducted in that discipline	Quarterly	
6.	Test availability	[∑tests x ∑days available] ÷ [∑tests x ∑total number of days in time period] x 100	Quarterly	
7.	Average number of tests per laboratory employee per day	Total number of tests conducted ÷ [number of laboratory staff x number of working days in reporting period]	Quarterly	
8.	Attrition rate laboratory staff	Number of laboratory staff who left during reporting period ÷ total number of laboratory staff at beginning of reporting period x 100	Quarterly	HMIS
9.	Cumulative proportion of laboratory staff who received in service training	Total number of laboratory staff who received in service training from beginning of year to end of reporting period ÷ number of staff at beginning of year x 100	Quarterly	HMIS
10.	Cumulative proportion of laboratory staff who underwent performance evaluation	Total number of laboratory staff who underwent performance evaluation from beginning of year to end of reporting period ÷ number of laboratory staff at beginning of year * 100	Quarterly	
11.	Number of complaints received against laboratory services	Total number of complaints against laboratory services	Quarterly	
12.	a) Number of complaints against laboratory services upheld b) Proportion of complaints against laboratory services upheld	a) Total number of complaints against the laboratory upheld b) Number of complaints upheld ÷ number of complaints received x 100	Quarterly	

6.5. Additional Reading Materials

1. Ethiopian Health centre Reform Implementation Guide lines, Federal Democratic republic of Ethiopia Ministry of health, May 2010
2. ETHIOPIAN HOSPITAL SERVICES TRANSFORMATION GUIDELINES Volume 1, September 2016
3. CLSI/NCCLS. Application of a Quality Management System Model for Laboratory Services; Approved Guideline—Third edition. CLSI/NCCLS document GP26-A3. Wayne, PA: NCCLS; 2004. www.clsi.org.

Chapter 7: Infection Prevention and Control (IPC)

Chapter Description: The chapter is intended to discuss and explain the minimum infection prevention and control standards that has to be met by a health center in order to provide safe health care service to customers and safe work place for health care providers. It also describes the arrangement for IPC program management at health center level.

Primary Objective: By the end of the chapter participants will be able to program and lead infection prevention and control activities in a health center.

Enabling Objectives: By the end of the session you will be able to:

- Identify health center Infection prevention and control activities of health centers
- Explain how to organize IPC committee and its responsibilities
- Analyze health center standard precaution requirements
- Assess the IPC infrastructure and supplies of health center
- Discuss worker safety and environmental hygiene in a health center.

Chapter Outline

7.1. Introduction

Infection Prevention and Control (IPC) refers to scientifically sound practices aimed at preventing harm caused by infection to patients, health workers and the community. It is a systematic effort or process of placing barriers between a susceptible host (person lacking effective natural or acquired protection) and infectious agents. The goal of Infection Prevention and Control is to make healthcare facilities safe for all, including patients, clinical and non-clinical staff of healthcare facilities, and the community. [5] The potential for the transmission of infections in the health care setting is high. Both those receiving and providing care in a health centre are at risk of acquiring and transmitting infections through exposure to blood, body fluids or contaminated materials. These infections are termed as healthcare acquired infections (HCAIs). HCAIs are defined as an infection occurring in a patient during the process of care in a hospital or other health-care facility which was not present or incubating at the time of admission. This includes infections acquired in the hospital or other health care facility but appearing before or after discharge, and also occupational infections among staff of the facility.

The patient population is often sick, immune-compromised and more susceptible to infections. They are also more likely to transmit infections to others. Healthcare workers may be exposed

[5] National infection prevention and control (IPC) reference manual for health care service VOL. 1

to infection through the provision of care. Poor compliance to standard procedures by healthcare workers can cause the transmission of infections among patients.
Establishing an infection prevention and control program with the aim of stopping the transmission of infectious agents is the only way to reduce the occurrence of HCAIs and demonstrates a health centre's commitment to the well-being of patients and staff by assuring a clean and safe environment.

The prevalence of infectious diseases such as tuberculosis, HIV, Hepatitis B (HBV), Hepatitis C (HCV) and other infectious diseases in Ethiopia heightens the urgency for health centres to implement a comprehensive infection prevention and control[6] program which includes:

- Effective management support
- Staff engagement and involvement
- Patients/ clients and care providers engagement and involvement
- Provision of necessary equipment and supplies
- Availability of guidelines & SOPs
- Monitoring and surveillance and
- Training

7.2. Operational Standards

1. Health center established functional IPC/CASH committee.
2. The health center conducts quarterly CASH/IPC audit
3. The health center shall avail the necessary equipment, supplies and infrastructure necessary for IPC/CASH are available.
4. The health center shall ensure that all staff are trained using standard infection prevention and control training manual.
5. The health center ensures housekeeping activities.
6. The health center ensures hand hygiene facilities are available at all service points.
7. The health center has a functional laundry service.
8. The health center ensures standardized instrument processing practice.
9. The health center ensures all the post exposure and preventive interventions, and procedures are in place in case of occurrence of occupational risks.
10. The health center provides health education to patients/clients, caregivers and visitors.
11. The health center shall ensure proper health care waste management.
12. The health center provides IPC/CASH support to its satellite health posts

[6] Infection Prevention and Control (IPC) is used interchangeably with clean & safe health facilities (CASH) in this guideline.

Activity 7.1. Think-pair share
 **Instruction:** • Be in pair with your neighbour • Discuss how to manage IPC program in a health center and share your thoughts in the general discussion **Time:** 10 min for reading and discussion 10min for discussion

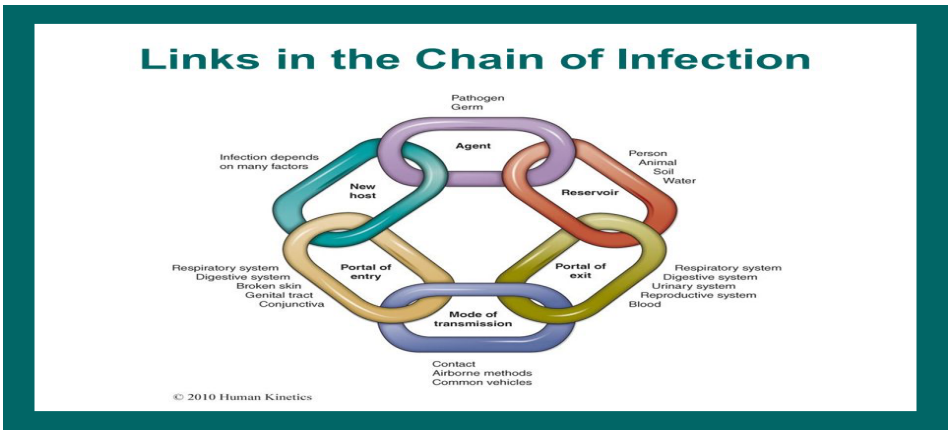
7.3. Implementation Guidance

Guidance 33: Management of Infection Prevention Activities

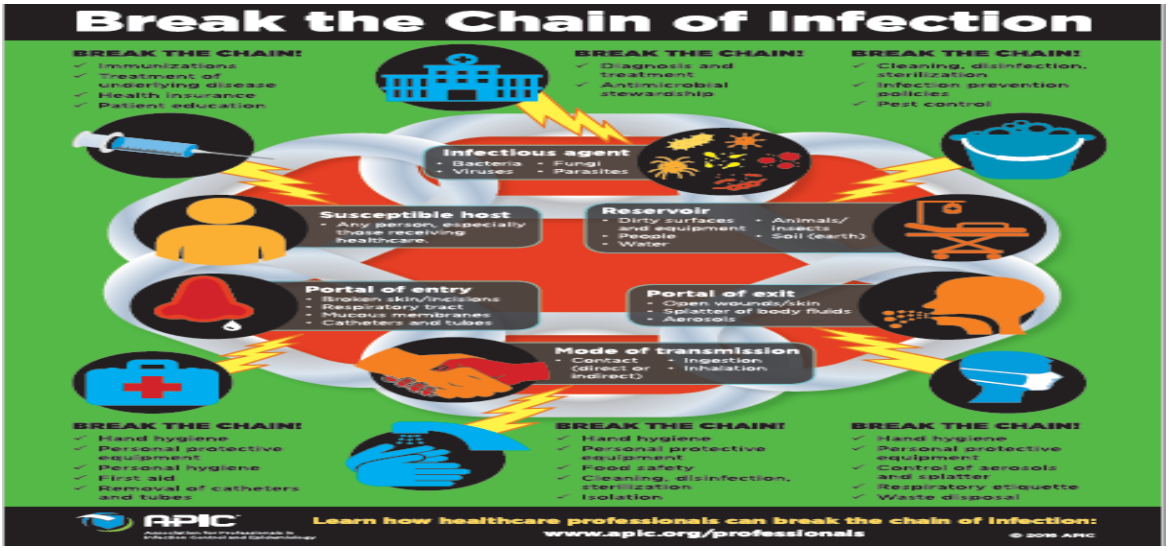
Why infection prevention?

- ☞ To protect patients from nosocomial infections
- ☞ To protect the healthcare providers and support staff from occupational hazard
- ☞ To protect visitors
- ☞ To protect students practicing in the healthcare facilities
- ☞ To protect communities and environment

Chain of infection for IPC



How to break chain of infection



The goal of infection prevention would be;

- ☞ To make healthcare facilities safe place for all, including
  - Patients,
  - Clinical and
  - Non-clinical staff of healthcare facilities, and
  - The community.

The 8 WHO core components of IPC

1. IPC programmes
2. Evidence-based guidelines
3. Education and training
4. Health care-associated infection (HAI) surveillance
5. Multimodal strategies
6. Monitoring and audit of IPC practices and feedback
7. Workload, staffing and bed occupancy (facility level)
8. Built environment, materials and equipment for IPC (facility level)

Why do we need to manage IPC activities?
Effective management is essential in creating an effective infection prevention and control (IPC) program. There are two tiers of management of an IPC program: direct management of infection prevention activities by a designated individual(s) and by the health center infection prevention and control committee.

Health centers should have a designated person or persons to oversee day to day infection prevention and control activities with roles and responsibilities in relation to IPC/CASH activities clearly described in their job descriptions, and sufficient time allocated in their work schedule to fulfil their duties. It is recommended that one person (nurse, environmental HW, or any staff trained in IPC/CASH) is designated to coordinate overall activities as his/her primary job responsibility. Besides, health centers need to have an IPC/CASH Committee charged with overall coordination and monitoring of the health center's IPC work. The committee should be multi-disciplinary and representative of the health centre staff and should have no more than 5-8 members. Committee members should be individuals who are interested and engaged in IPC activities and are able to direct health center staff to implement the program and incorporate IPC/CASH strategies into their daily work responsibilities.

Health center staff from the following key areas should be represented on the IPC/CASH committee:

- Head of Health Center (PHCU)
- Outpatient, inpatient and emergency case teams
- Environmental Health Worker
- Administration (finance/procurement)
- Pharmacy
- Laboratory
- QI focal

The Health Center management should support the committee's efforts by:

- Monitoring the IPC/CASH committee's overall activities
- Ensuring that equipment and supplies needed for IPC/CASH activities are available
- Reviewing committee action plan, reports (e.g. on healthcare acquired infections prevalence) and acting on actionable items
- Encouraging staff adherence to and involvement in the IPC activities

IPC COMMITTEE'S SCOPE OF WORK

The IPC committee and infection prevention designate(s) are responsible for the development of an operational plan and coordination of the health center's overall IPC activities. If there is a person selected to work on IPC activities full time, his/her responsibilities should be clearly delineated in a job description. The committee should also have a Terms of Reference (TOR) that outlines the roles and responsibilities of all members. The TOR should include the frequency of meetings as well as the process for recording and reporting information. It is recommended that the committee meets regularly, at least once a month. The team should select a chairperson who will be responsible for coordinating the IPC committee's activities (calling meetings, disseminating minutes etc) and a secretary to record meeting minutes. The committee's main responsibilities are to:

1. Define and prepare the health center's annual IPC/CASH plan
2. Monitor and evaluate the performance of the program by assessing implementation of the plan and adherence to standard practices
3. Establish a program for the surveillance of HCAIs and regularly review HCAI surveillance data
4. Report findings on HCAIs surveillance and performance of the IPC/CASH program to management and other staff and identify areas for intervention.
5. Ensure, in collaboration with relevant staff, appropriate staff training in IPC guidelines, the consistent and adequate supply of personal protective equipment and other IPC supplies and equipment
6. Create a sense of individual responsibility for IPC amongst all staff and patients/clients

INFECTION PREVENTION & CONTROL PLAN

The IPC/CASH plan should outline all of the activities to be included in the health center's IPC/CASH program. At a minimum the plan should address the health center's guidelines and procedures for:

- Standard precautions
- Transmission based precautions
- Equipment and supplies for IPC activities, including personal protective equipment
- Monitoring and evaluation of IPC activities
- IPC training

MONITORING AND SURVEILLANCE

An IPC/CASH program must include routine monitoring and surveillance. The Health Center must assess the success of its infection prevention program by measuring adherence to IPC guidelines as well as identifying and tracking HCAIs quarterly, at a minimum.

Monitoring

Health centers should measure the effectiveness of all components of the IP&PS program including inputs, processes and as per the IPC action plan of the respective health center.
For example:

Inputs: IPC inputs would include equipment and supplies for health center staff. Input data can be used to assess the availability, quantity and quality of supplies and equipment needed for IPC practice. In addition, data can be used to conduct cost analysis.

Process and Outcomes:

This data can be used to assess the safety and effectiveness of a Health Center's operations and can be collected through the following methods:

- Performance indicators: The IPC Committee must develop and monitor performance indicators to assess the progress of the IPC program. Targets should be set for each indicator based on improvements using a percentage scale. For example, a key target may be a 50% improvement in the number of staff observed using proper infection prevention techniques within a given day; or rate of healthcare facility acquired infection. This will allow the IPC committee to work towards continual improvements, rather than reaching a particular benchmark.
- Qualitative methods for assessing quality include clinical vignettes and consultation observation. Clinical vignettes involve providing staff with hypothetical cases and recording their response on how they would handle the given cases. Consultation observations involve observing staff as they interact with patients and adhere to national IP guidelines.
- Surveys: Often used to collect data on facility procedures, for example, hand hygiene procedures being used by facility staff. A checklist can also be used to assess adherence to IP guidelines.
- Surveys are more common as they can be used to collect a large amount of data at once and is easier to implement than continuous reporting.

- Observation: The IPC Committee also can conduct unannounced site visits to various case teams on a monthly basis. These site visits would ostensibly be carried out to determine what is working and what is not. This approach could provide a strong incentive for the case teams to maintain a high level of IP practices. It would also act as an indicator which the IP Committee could use to determine the efficacy of the IP program and implement changes where necessary.

SURVEILLANCE OF HCAIS

Monitoring and measuring healthcare acquired infections can provide valuable information on the effectiveness of the Health Center's infection and patient safety prevention program. Tracking the number of HCAIs or rate of HCAIs allows Health Centers to assess quality of care and patient safety. In addition, data can reveal areas for improvement or gaps in practice that need to be revised or strengthened. HCAIs should be included as one of the indicators in the Balanced Scorecard that is monitored regularly by the senior management team

In devising a surveillance program the IPC committee should consider the following:

- Patients and units to be monitored
- Type of infections and relevant information to be collected
- Frequency and duration of monitoring
- Methods of data collection
- Methods for data analysis, feedback and dissemination
- Methods to ensure confidentiality of information

The methods to be used and staff responsible for coordinating and conducting surveillance should be clearly outlined in the Health Center's HCAIs surveillance protocol. In addition, staff involved in coordinating or collecting HCAIs data should include someone trained/oriented in IPC/CASH practice and knowledgeable in data collection and analysis techniques.

Either prevalence or incidence of HCAIs can be tracked. Prevalence studies would be conducted at one point in time and would measure infections that exist on the day the survey is done. Incidence surveys measure number of infections that occur in patients over a defined period of time. For an incidence survey, patients would be tracked throughout the course of their stay in the Health Center and the incidence of an infection would be recorded.

Conducting surveillance of HCAIs can be a time consuming and costly undertaking. Therefore, when resources are limited, facilities can choose to focus on specific units or specific types of infections.

Considering the definition of HCAIs, the disease condition arises more than 72 hours after admission to a healthcare facility. The minimum health center regulatory standard specifies 10 beds admission capacity for emergency and delivery services only. At present collecting routine surveillance data on HCAIs from all health centers is not practically possible as patient

admission and inpatient services are provided by very few health centers (urban/rural highly populated areas). While these facilities can serve as sentinel HCAIs surveillance sites, periodic prevalence/incidence surveys are to be conducted to determine more reliable information to show the rate of HCAIs at a national level.

Guidance 34: Standard Precautions

This are set of guidelines designed to create physical, chemical and mechanical protective barrier between microorganism and person to prevent the spread of infection (the barrier serves to break the diseases transmission cycle). Example of barriers:

- Physical Barrier – PPE
- Mechanical Barrier – HLD and Sterilization
- Chemical Barrier – Antiseptic and Disinfectant

Standard Precautions are first level precautions. The aim of standard precautions is to reduce the risk of transmitting micro microorganism from known or unknown sources of infection (e.g. respiratory droplet, contaminated object) within health care settings. Applying Standard Precautions while providing patient care is based on the anticipated interaction HCW will have with blood, body fluid or potential pathogen exposure from patients. They provide a rationale for appropriate utilization of limited IPC resources.

Key Components of Standard Precautions

1. Hand hygiene

Activity 7.2. Group discussion on IPC
 **Instruction:** • Be in group of 5-6 people • Discuss the topics below in your group and report the work in the plenary (share group response to the larger groups using flipchart) **Discussion Topics:** - **Standard precautions** - **Environmental hygiene** - **Worker Safety** **Time:** 45 min for reading and discussion 15 min for presentation

2. Use of PPE
3. Safe work practices (such as safe injection practice, safe practice in the procedure room)
4. Health center Cleanliness and Housekeeping
5. Environmental cleaning
6. Instrument Processing

7. Processing of linens/Laundry services
8. Healthcare Waste Management

HAND HYGIENE

Hand hygiene is one of the most important measures for infection prevention. Studies have shown that effective and consistent hand hygiene practice among healthcare staffs can reduce the occurrence of HCAIs by 15%-30%. However, studies show that compliance to hand hygiene among healthcare workers remains very low; to a level below 50% even in settings with optimal conditions. Hand hygiene generally refers to hand washing, hand antisepsis (with alcohol based hand rub) and surgical hand scrub. Hand hygiene should be practiced by all healthcare providers before and after contact with a patient/client regardless of their health status. To achieve the greatest compliance in hand hygiene, all staff should be trained or correctly oriented on proper hand hygiene techniques as part of infection prevention training program. Hand hygiene facilities such as functioning sinks, soap and water should be in place in all patient care areas. The health center should provide a consistent supply of clean water for all patient care areas. This can be achieved by short term provision of water using containers with improvised sinks (buckets with faucets fixed to it) and/or temporary storage tankers or long term provision of water from reliable supply designed for the health center.

The health center should also provide plain soap, in the form of bar or liquid, antiseptic soap, and/or alcohol and glycerine (for preparation of waterless antiseptic hand rub) for all patient care areas on a regular basis. If bar soap is used, provision of small bars and draining soap racks is recommended to prevent accumulation of contaminated liquid which harbors microorganisms. When the soap dispensers are reused they should be thoroughly cleaned before refilling; adding soap to a partially empty soap dispenser is not recommended as it leads to bacterial contamination of the soap. The minor operation rooms should be provided with plain soap, antiseptic soap, 2-4% chlorohexidine and 7.5-10% povidone iodine, alcohol, non-contaminated glycerine, and nail cleaners/soft brushes for surgical hand scrubs.
Hand hygiene involves HCWs cleaning their hands before, after, and at specific moments during patient care and when performing health care tasks. Hand hygiene is the single most important intervention for preventing transmission of infections (e.g., person to person or contaminated object to person). It must be performed consistently at the recommended moment during patient care using soap and water or alcohol-based hand rub (ABHR) and with a technique that effectively removes microorganisms from hands.

USE OF PPE

It relies on an HCW‘s assessment of the likely risk of contact with potentially infectious materials during each task. The appropriate PPE should be chosen by the HCW according to the assessed risk. The risk is not based on the appearance, characteristics, or diagnosis of the patient, but rather the potential for the HCW coming into contact with blood, body fluids, non-intact skin, mucous membranes, or items that have been in contact with these. The risk may be re-assessed during the task (e.g., if the patient starts vomiting) and PPE added as needed.

Table 7.1. Personal Protective Equipment: Uses

Type of PPE	Who should wear PPE?	What is Protected?	When PPE should be worn
Gloves Surgical (normal and elbow length) Examination Nitrile Latex Heavy duty	Medical, nursing staff (including students) Runners/transistors Cleaning, laundry staff	Hands	When there is direct contact with exposed wounds, blood, body fluids, or any type of lesion. When drawing blood or handling medical instruments involved with invasive procedures (catheters, IV insertion, probes, etc.). During surgical procedures When handling waste items or other contaminated surface When cleaning patient areas.
Protective eyewear	Medical, nursing staff (including students) Runners/ transitors as needed Cleaning, laundry staff as needed	Eyes	When splattering of blood or body fluids to the face is possible, When handling bio-hazardous, soiled linens, When performing waste collection for hazardous or non-hazardous waste.
Masks Surgical mask	Medical, nursing staff (including students) Porters Runners/transitors Cleaning staff as needed, laundry staff as needed	Mouth, nose	To protect mucous membranes of mouth and nose when splattering of blood, body fluids, secretions or excretions is possible
Particulate respirators	Medical, nursing staff, cleaning staff, any person entering isolation rooms	Mouth and nose	When entering the room of airborne infectious agents such as TB
Face shields	Medical, nursing staff (including students)	Face, mouth, nose and eyes	To protect mucous membranes of eyes when splattering of blood, body fluids, secretions or excretions is likely
Plastic aprons Gowns	Medical, nursing staff (including students) Runners/transitors Cleaning, and laundry staff as needed	Skin, clothing	To protect skin and clothing when splattering of blood, body fluids, secretions or excretions is likely

Synthetic long sleeve aprons, goggles and masks should be provided to all staff involved with conducting invasive procedures. Synthetic long sleeve aprons, goggles and masks should be consistently used when splashes are anticipated.

SELECTING THE APPROPRIATE PPE

When selecting what PPE should be worn, the health care worker should assess:

I. Type of exposure anticipated
   a. Splashes or contact - the health care worker should assess the type and volume of body fluid or blood that he/she may potentially encounter in caring for the patient and select appropriate PPE accordingly.
   b. Type of isolation precaution (airborne, contact or droplet) - the health care worker should also consider the level or type of isolation precaution that the patient is on.

II. Durability and appropriateness for the task

III. Correct fit of the PPE

DECONTAMINATING, CLEANING AND HLD/ STERILIZATION OR DISPOSAL OF PPES

Table 7.2: Personal Protective Equipment: decontaminating, Cleaning and HLD/Sterilization or Disposal of PPEs and Disposal Methods

Equipment	Standard procedure
Apron	If reusable: clean with detergent and water, dry, disinfect with 70% alcohol If disposable: discard in appropriate waste container according to the health care facility waste management guidelines
N 95 or standard surgical mask (Use disposable mask only)	Discard in appropriate waste bag according to the health care facility guidelines
Eye protector/goggles/face shield	If reusable: clean with detergent and water, dry, and disinfect with 70 % alcohol or soak in 1% hypochlorite solution for 20 minutes and rinse and dry. If disposable: discard in appropriate waste bag according to the health care facility guidelines
Gown	If reusable: launder as per the health care facility guidelines for soiled linen. For example: launder in hot water (70° - 80° C) if possible OR Soak in clean water with bleaching powder 0.5% for 30 minutes. Wash again with detergent and water to remove the bleach. Dry in a cloth drier or in the sun
Cap (Use of disposable cap is recommended)	If reusable: launder as per the health care facility guidelines for soiled linen. For example: launder in hot water (70° - 80° C) if possible OR Soak in clean water with bleaching powder 0.5% for 30 minutes Wash again with detergent and water to remove the bleach. Caps should be dried in a cloth drier or in the sun. If disposable: discard in appropriate waste bag: Seal the bag.
Gloves (Use disposable gloves only)	If gloves are disposable, it is advisable to decontaminate (by Soaking and rinsing before disposal. Gloves should be changed and disposed of properly after contact with every patient or contaminated item.

Equipment	Standard procedure
	Surgical gloves can be reused after reprocessing using sterilization or high level disinfection (HLD) techniques. Surgical gloves should not be reprocessed more than three times. Gloves are *not* reusable if the glove has been torn, punctured, or broken. Housekeeping staff should wash the exterior of their utility gloves after cleaning each patient area/room to prevent the spread of infectious agents. Gloves should be discarded in the appropriate waste container according to the waste management guidelines.

Source: Adapted from Practical Guidelines for Infection Control in Health Care Facilities, WHO, 2003

Safe work practices: are those that do not harm the patient, do not expose the HCW to any risks, provided by skilled person, using appropriate injection equipment and do not result in waste that is dangerous for the community.

Health center Cleanliness and Housekeeping: Maintain a clean and safe health facility is essential to provide quality care for patients. Proper cleaning will reduce the number of microorganisms in patient care areas and will help to minimize the risk of exposure to infectious agents to patients, families, caregivers, visitors and health center staff. Health center may provide the housekeeping service through its own staff or, may contract out services to an outside vendor. However, regardless of how the service is provided and by whom, the health center must ensure that standards are met and the guidance adhered to.

Environmental Cleaning: of noncritical care equipment, instruments, devices, and environmental surfaces. Clean patient care equipment between each use on patients to prevent cross-contamination between patients.

Instrument Processing: processing instruments and other items (before reuse) so as to reduce the transmission of infection during clinical procedures and patient care by cleaning and sterilization or HLD.

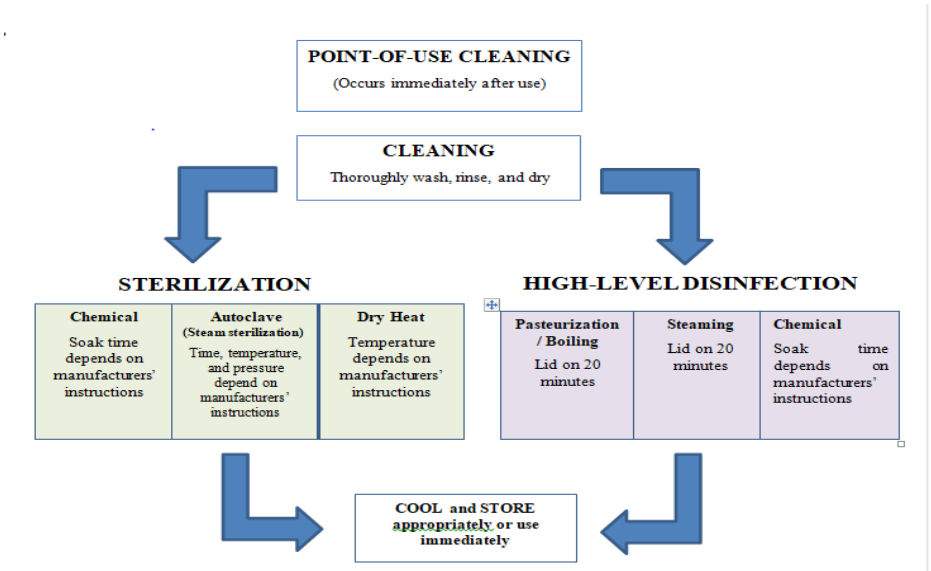
Spaulding classified instruments and patient care devices into three categories, based upon how the device is used. Items are classified as:

- Non-critical — come in contact with intact skin but not mucous membranes
- Semi-critical — come in contact with mucous membranes or non-intact skin
- Critical — come in contact with sterile areas of the body including the vascular system

Table 7.1: Spaulding's Risk Classification and Level of Processing

Risk category	Level of disinfection/sterilization	Examples
Critical	Sterilization	Reusable surgical instruments
Semi-critical	High-level disinfection	Respiratory instruments, specula used for vaginal examination, endoscopes
Non-critical	Cleaning	Blood pressure cuffs, stethoscopes

Workflow for instrument processing and other medical devices



Effectiveness of Methods of Processing Instruments

METHOD	EFFECTIVENESS (Kill or remove microorganisms)	END POINT
Cleaning (soap and rinsing with water)	Up to 80%	Until visibly clean
High-Level Disinfection	95% (does not inactivate endospores)	Boiling or chemical for 20 minutes
Sterilization	100%	High-pressure steam, dry heat or chemical for the recommended time

Effect of soaking instruments in chlorine solution

Soaking of instruments in disinfectant prior to cleaning

According to the WHO and PHAO, soaking of instruments in 0.5% chlorine solution or any other disinfectant prior to cleaning is not recommended for the following reasons:

- It may damage/corrode the instruments
- The disinfectant may be inactivated by blood and body fluids, which could become a source of microbial contamination and formation of biofilm
- Transportation of contaminated items soaked in chemical disinfectant to the decontamination area may pose a risk to health care workers and result in inappropriate handling and accidental damage May contribute to the development of antimicrobial resistance to disinfectants.

Processing of linens/Laundry services: is a manner that:

- Removes pathogens from the linens and protect them from reintroduction of pathogens.
- Reduces risk for transfer of pathogens to HCWs, other patients, and the environment.

Health care Waste Management: Healthcare Waste (HCW) is a key issue to control and reduce HAIs in Health-Care Facilities (HCF) and to ensure that the environment is well protected. Healthcare Waste Management (HCWM) should be part of the overall management system of a HCF and reflect the quality of the services provided by the facilities.[7]

TRANSMISSION-BASED PRECAUTIONS

Transmission-based precautions are sets of extra precautions that need to be employed when routes of the transmission are not interrupted with the use of Standard Precautions alone. Each of these precautions should be used in conjunction with Standard Precautions.

There are three main types of Transmission-based Precautions namely:

- Airborne Precaution
- Droplet Precaution
- Contact Precaution

Note: For some diseases that have multiple routes of transmission, more than one Transmission-Based Precautions category may be used (e.g., influenza, Middle East Respiratory Syndrome, corona virus [MERS-CoV], varicella)

Airborne Precautions

Airborne Precautions prevent transmission of infectious agents that remain infectious over long distances (particles which are 5μm or less in size and can remain in the air for several hours and be widely dispersed). This transmission can occur either through airborne droplet nuclei or dust particles containing the infectious microorganisms, which can be produced by coughing, sneezing, talking, or by procedures (e.g. bronchoscopy or suctioning). Special air handling and ventilation are needed to ensure prevention of airborne transmission of infectious agents. Airborne particles do not land on and contaminate surfaces. These precautions are effective in preventing infections like Mycobacterium tuberculosis, Chicken pox and measles. They are

[7] National infection prevention and control (IPC) reference manual for health care service VOL. 1 & Ethiopian Hospital services Transformation Guidelines (EHSTG) VOL.2

recommended for patients with either known or suspected infections that could be transmitted by airborne route.

Droplet Precautions

These precautions reduce the risks of transmission of pathogens spread wholly or partly by droplets larger than 5µm in size (e.g. *Bordatella pertussis, H. influenza* & *N. Meningitides*, *M. pneumonia*, flu, mumps, and rubella viruses). Other conditions include Diphtheria, Pertussis, Pneumonic Plague and *S. pharyngitis*. These remain in the air briefly and can travel about 1 meter (3 feet) or less. Droplet transmission requires close proximity or contact between the source and the susceptible host. Droplets may also land on surfaces and then be transferred by contact transmission.

Contact Precautions

Patients are placed on Contact Precautions when they have suspected or known infections that are spread directly or indirectly from an infected or colonized individual by touch or contact with the patient or the patient‘s environment (surfaces and equipment). Contact is a common way that germs spread in health care facilities. Organisms that require Contact Precautions include Cholera, Varicella-Zoster (shingles); neonatal or mucocutaneous Herpes simplex virus; Enterovirus meningitis; patients infected or colonized with enteric pathogens, hemorrhagic fever viruses, multidrug-resistant organisms such as and Carbapenem-Resistant Enterobacteriaceae (CRE); and C. Difficile. Chicken pox is spread both by the airborne and contact routes at different stages of illness. Contact precautions should be implemented for patient with wet or draining infection that may be contagious (e.g. draining abscesses, herpes zoster, impetigo, conjunctivitis, scabies, lice and wound infection).

EMPIRIC /SYNDROMIC USE OF TRANSMISSION-BASED PRECAUTIONS

Every effort should be made to diagnose the microorganism responsible for infection; however, laboratory diagnosis is not immediately available and not always available. In these circumstances, precautions must be based on empiric/syndromic findings. If there is any question about whether a patient without a known diagnosis has a specific infection, implement Transmission-Based Precautions based on the patient‘s signs and symptoms until a definitive diagnosis (i.e., laboratory test results) can be made. A complete listing of clinical syndromes or conditions warranting the empirical use of Transmission- based precautions is presented in table.

Table 7. 3: Empiric use of Transmission –Based Precaution (based on sign and symptoms) for isolation of patient in health center[8]

Contact	Droplet	Air born
Acute diarrhea in an incontinent or diapered patient Diarrhea in an adult with a history of recent antibiotic use or hospitalization (in settings with *C. difficile*) Upper respiratory infections in infants and young children (wear mask as per Standard Precautions) History of infection/colonization with multidrug-resistant organisms (use Airborne Precautions for tuberculosis [TB]) Abscess or infected draining wound that cannot be covered with bandages Instrument processing Skin or wound infection with excessive drainage in a patient with recent hospitalization (in settings where multidrug-resistant microorganisms are prevalent)	Symptoms of upper respiratory infection; cough, runny nose, sore throat, congestion. Severe during periods when pertussis is present in the community Suspected meningitis: fever, vomiting, and stiff, persistent cough neck Hemorrhagic rash with fever Generalized rash of unknown cause	Chronic cough/fever/weight loss/night sweats and upper lobe chest findings Cough or fever and chest findings in a person who is infected with HIV or at high risk for HIV Rashes (vesicles or pustules) suggestive varicella Acute respiratory distress syndrome when new respiratory organisms are a risk in the community Vesicular rash (suspected varicella) (wear gown, gloves and eye protection also)

Adapted from: Siegel et al. 2017; WHO 2008.

Guidance 35: Environmental Hygiene

WASTE MANAGEMENT

Healthcare facilities produce waste that is potentially harmful to the health of the public and the environment. Healthcare workers, patients, waste handlers, waste pickers, and the general public are exposed to health risks from infectious waste (particularly contaminated sharps), chemicals, and other special health care wastes HCW. Improper disposal of special health care wastes including open dumping and uncontrolled burning increases the risk of spreading infections and of exposure to toxic emissions from incomplete combustion. Proper management of health care wastes through an integrated, effective waste management system can minimize the risks both within and outside healthcare facilities.

[8] National infection prevention and control (IPC) reference manual for health care service VOL. 1

WASTE MANAGEMENT PROCEDURES

Waste management is a multi-step process involving:

- Waste minimization
- Segregation
- Handling
- Collection
- Storage
- Transportation
- Treatment & disposal

Waste Minimization

In a proper HCW management system, the first step is waste reduction or minimization. It helps to ensure good sanitation of the health facility and the safety of workers and communities by reducing the quantity of wastes generated. Waste minimization also reduces the environmental impact by decreasing air pollution and the landfill capacity needed for disposal. Significant reduction of waste generated in health care facilities may be encouraged by implementing:

- source reduction such as by avoiding or reducing unnecessary injections
- improved waste reuse/recycling practice,
- good management and work control practices (rational use of different reagents, medical equipment and materials, etc)
- proper waste segregation system

Segregation

Segregation denotes the separation of waste into a range of classes according to its character. Waste separation reduces the quantity of waste that requires specialized treatment and care. Generally, facility waste is classified into 3 categories of waste: non-infectious, sharps waste and infectious waste.

Non-infectious waste is waste that is non-hazardous and under normal circumstances poses no health risk. It includes paper, packaging, left-over foods, boxes, glass, plastic, etc.

Sharps waste includes sharp materials and equipment that are disposed after being used. For example: used syringes, needles, lancets, blades, scalpels, broken glass, etc.

Infectious waste is a waste material that has, in part or in whole, been in contact with blood and/or body fluids. Due to the presence of blood and body fluids, such wastes are regarded to be infectious waste and can potentially transmit microorganisms to susceptible people. It includes contaminated gauze, dressings, cultures, IV lines, used gloves, anatomical wastes, placenta, tissues and the like.

Segregation must:

- Take place immediately and at the source where the waste is generated; waste must never be re-sorted.
- Ensure that proper segregation techniques are used and that infectious HCW is not mixed with non-infectious waste.

The 3 categories of HCW shall be segregated into colour coded containers as follows:

Table 7.4: Segregation of wastes into the color coded containers

Segregation Category	Color-coded container	Non-color coded bins
Non-infectious waste/ General waste	Black bin	Bins should be labelled non-risk waste
Infectious waste	Yellow bin	Bins should be labelled infectious waste
Sharp waste	Yellow safety box	The box should be labelled biohazard waste.

Note that in the absence of colour coded bins, it is possible to place waste segregation system using labelled waste bins with an infectious and non-infectious symbol or text on the side of the bins. However, such bins should not be used for liquid waste. To maximize efficiency and safety, these three waste categories must be handled and disposed of separately throughout the main steps of: segregation, collection, handling, storage, transport, treatment, and disposal.

Location of segregation containers

- Safety boxes
  - A safety box should always be located within arm's reach of any place where an injection is given. Safety boxes may be transported on a trolley with injection equipment in patient wards.
  - Safety boxes should not be placed in high traffic areas (ex. corridors outside patient rooms) where people could bump into them or be stuck on someone carrying sharps to be disposed of.
  - Don't place containers on the floor or anywhere where they could be knocked over or easily reached by children.
- Infectious waste bins.
  - Yellow infectious waste bins should be located in all rooms where infectious waste is generated.
  - Infectious waste bins should not be located in public areas.
- Non-infectious waste garbage bins
  - Black garbage bins should be located in all rooms where waste may be generated.
  - Garbage bins should be located in all public areas.

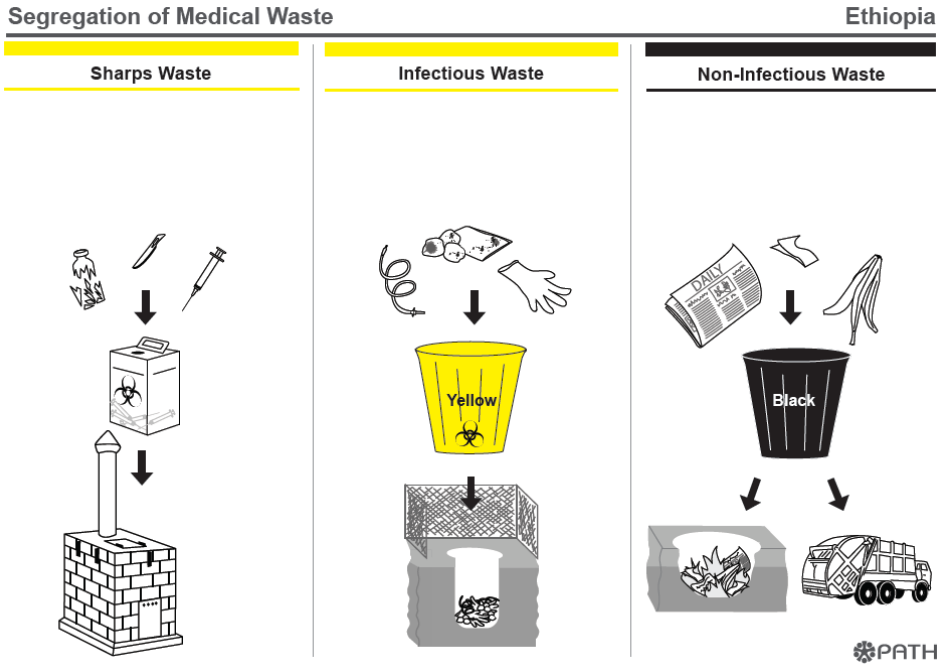


Figure 7.0.1 Segregation of health care waste by waste type

Source: Path, 2005.

Handling

When handling waste, waste management staff should wear protective clothing at all times. Wearing PPE reduces risk from sharps and protects against exposure to blood and other bodily fluids, and splashes from chemicals. PPE that is recommended to be worn when handling waste includes:

- Dust mask
- Face shield
- Heavy duty gloves
- Plastic apron
- Cloths that cover the body
- Head cover
- Goggle

Handling sharps

- Place the syringe in a safety box immediately after use
- Do not recap, bend, or remove needles from syringe.

Handling safety boxes

- Safety boxes must be fully and properly assembled before use.
- Safety boxes must be sealed and collected when they are ¾ full.
- Safety boxes must never be emptied or opened.
- Put sharps containers as close to the point of use as possible and practical, ideally within arm's reach.
- Mark or label safety boxes so that people will not unknowingly use them as a garbage container or for discarding other items.
- Don't shake a safety box to settle its contents and make room for more sharps.

Handling infectious waste bins

- Infectious waste bins should be covered before collection,
- Bins should be cleaned and disinfected by using 0.5% chlorine solution for 10 minutes after emptying.

Collection

Schedule

- At a minimum, the infectious waste bins should be collected each day.
- Safety boxes should be collected when ¾ full or daily.
- Garbage bins should be collected each day.
- No infectious bag or bin should be collected unless it is labeled with its point of production and content.

Rotating bins

- A rotating bin system must be used if bins are collected during patient hours. When a bin or safety box is collected, an empty bin or safety box must immediately be put in its place. This practice is not necessary if bins are collected when the facility is closed, however emptied bins and new safety boxes must be in place when the facility opens.

Storage

- Each Health Center should have a specially designated room for waste storage.
- The room should be used only for storage of safety boxes and infectious waste until final disposal.
- Infectious waste should not be stored for more than two days before being treated or disposed of.
- Safety boxes may be stored for up to one week before incineration or transport. The frequency of incineration should be based on the amount of sharps waste produced and on incinerator capacity.
- The storage room should be totally enclosed and locked.
- The storage room should be inaccessible to the public, animals, rodents, birds and insects.
- There should be good lighting and ventilation of storage room.

Transport

On-site transport

- A trolley, bin, or wheel barrow may be used for transporting safety boxes and bins
- The collected waste should not be left even temporarily anywhere other than at the designated storage room
- Containers should be covered with lids during storage and transport
- Carts should be used for transporting bags of infectious waste within the facility

Transport to Off-site Disposal

- The waste should be placed in rigid, leak-proof containers before being loaded
- Containers should be covered with lids during transportation

- When transporting plastic bags of infectious waste, care should be taken to prevent tearing the bags
- Vehicles used for transporting infectious waste should be disinfected (0.5% chlorine solution) prior to use for any other purpose
- The vehicles should carry adequate supply of plastic bags, standard protective clothing, cleaning tools and disinfectants to clean and disinfect in case of any spillage
- Records should be kept to document all transport of medical waste

Disposal

Options listed in decreasing order of preference.

- Sharps waste:
  - Incineration using either properly built brick incinerator or another incinerator
  - Transport to off-site incinerators, if there is centralized treatment service
  - On-site burial
- Infectious waste:
  - On-site burial
  - On site incineration provided that the incinerator is standard incinerator and capable of destroying such wastes
- Non-risk waste:
  - Collection by municipal truck for landfill disposal
  - On-site secured burning

Incineration

All incinerators should be inspected and maintained by an environmental health professional on a regular basis, and report of the inspection should be provided to Health Center management. Incineration must follow standard operating procedures, including proper loading, preheating, and control, according to the design of the incinerator. Dangerous materials must not be incinerated, including PVC plastics, mercury thermometers, batteries, x-ray materials, aerosol cans and glass vials. Incinerator operators must remove ash from the ash chamber and grate before using the incinerator. Ash should be put in an ash pit or waste pit.

Operator

Incinerator operators must wear protective equipment when loading and operating the incinerator. Proper equipment includes heavy duty gloves, boots, apron, and goggles. Protective equipment should be made of materials that do not easily burn or melt.

Burial of infectious waste

Burial pits must be properly constructed and protected. Pits must be above the water table (the bottom of the pit should at least be 1.5 meter away from the ground water table) and fenced to prevent access by animals and the community. Non-risk waste must not be dumped into infectious waste burial pits.

Waste Spills

Despite the implementation of preventive measures, waste spills can occur. Outlined below are procedures to manage waste spills according to type. All those managing waste spills should wear personal protective equipment such as protective gloves, goggles and masks.

A) Infectious Waste Spills

A bleach (Sodium Hypochlorite) solution should be poured over waste and be allowed to stand for 15 minutes. After the allotted time has passed, using a dustpan and broom, the waste should be carefully brushed off the ground and into an infectious waste bag or bin. Ensure no waste remains in the broom. After waste has been removed, cover the area with bleach solution.

B) Sharps Waste Spills

A bleach (Sodium Hypochlorite) solution should be poured over waste and allowed to stand for 15 minutes. After the allotted time has passed, using a dustpan and broom, the waste should be carefully brushed off the ground and into a puncture proof container. Do not allow hands to contact sharps. Ensure no sharps fragments remain in the broom. After waste has been removed, cover the area with bleach solution.

C) Managing spills of broken thermometer and blood pressure equipment

Those handling spills of broken thermometer and blood pressure equipment should wear examination gloves on both hands. All droplets of mercury should be collected with a spoon (or similar utensil), and placed in a small, closed container for disposal or reuse. Wash or clean the area with a bleach (chlorine) solution. When process is complete, examination gloves that were used should be removed carefully and hands washed properly.

Guidance 36: Worker safety

In addition to the procedures outlined above, the health post should ensure that mechanisms are in place to identify and address occupational health and safety risks to staff. The health post should also ensure that staff can access services in the event that they are exposed to infectious agents.

INJECTION SAFETY

The use of injection materials in the health post setting exposes healthcare personnel to needle stick injuries and potentially to infectious materials. The WHO estimates that "contaminated injections caused annually 21 million HBV infections, two million HCV infections and 260,000 HIV infections. These infections led to 49,000, 24,000 and 210,000 deaths respectively. 40% of the global burden of HBV and HCV among health workers is attributable to occupational exposure."[9] It is imperative that health posts establish an injection safety plan as part of infection prevention and control program.

The injection safety plan should include the health post's procedures to address the following areas:

- Needle and syringe usage and disposal:
  - Every injection is given using a single sterile syringe and needle combination
  - Syringes are not reused
  - No recapping, manual detaching or manipulation of used needles

[9] WHO, Technical Guidance for Global Fund HIV Proposals, 2008. http://www.who.int/hiv/pub/toolkits/Injection%20safety.pdf

    - After each use, the needle and syringe are safely disposed of in a puncture proof container
- Needle stick injuries:
    - There is a reporting and tracking mechanism for needlestick injuries
    - HIV Post exposure prophylaxis plan (see below)

HIV POST EXPOSURE PROPHYLAXIS

The risk of HIV infection after a needle stick injury or other exposure to HIV-infected blood is estimated to be 0.3% (3 in 1000 or 1 in 300). However, several cases of seroconversion among healthcare workers exposed to HIV via mucous membrane or non-intact skin have been documented. Implementation of standard precautions (as described in section 3.2) will significantly reduce occupational exposure of health post staff (both healthcare workers and support staff) to HIV and other blood borne pathogens. In the event that healthcare personnel (HCP) are exposed, health posts staff should immediately contact the nearby health centre to identify and assess staff need for PEP and provide care and treatment.

NB: The following guidelines only address the management of occupational exposure among healthcare workers. In addition to PEP for occupational exposures, health posts should link clients to the nearby health centre which provides PEP services for non-occupational exposure to HIV, such as sexual assault. The recommendations provided in this section are based on the national PEP protocol.

PEP Procedures

If an occupational exposure occurs, the following procedures for PEP should be followed:

Step 1 Treat exposure*:*

- Use soap and water to wash areas exposed to potentially infectious fluids as soon as possible
- Flush exposed mucous membranes with water
- Flush exposed eyes with water or saline solution

Step 2 Report exposures*:* Report and document the exposure. The incident should be reported to the healthcare personnel's immediate supervisor

Step 3 Determine the level of risk*:* It is important to determine risk of HIV transmission to the HCP associated with the HCP's exposure. A number of criteria that should be used to determine the level of risk are described in detail in the PEP decision-making tool presented in Appendix D. This tool should also be used to determine the need for PEP, to decide if PEP is indicated and whether or not a 2-drug or 3-drug regimen is required.

- If PEP is not indicated, the health centre personnel will advise the HCP accordingly and the exposure case is considered closed at this point.

- If PEP is indicated outside regular working hours then the HCP should be given a 'PEP starter pack'. PEP starter packs should contain sufficient drugs for three days medication and should be available in the pharmacy.

***Step 4 Counseling and Testing**:* All healthcare personnel who have been exposed and have PEP indication should be provided with HIV counselling and testing. Counselling and testing can either be provided by a trained member of the health centre or at the ART clinic.

***Step 5 Provide PEP treatment**:* Begin appropriate drug and PEP treatment.

- Exposed individuals who test negative for HIV, should receive comprehensive counselling on PEP and receive follow-up care according to the standard PEP protocol, including the completion of the one month treatment and subsequent HIV tests at 3 and 6 months post-exposure.
- Individuals who test positive for HIV should be enrolled in chronic HIV care and receive standard HIV/ART services.

***Step 6 Follow-up testing**:* Follow-up laboratory testing should be done at 3-months and 6-months post-exposure.

***Step 7 Maintain records**:* Keep records of all exposed staff. These records should be maintained securely to ensure confidentiality.

Activity 7.3. Reflection on IPC equipment, supplies and infrastructure	
	**Instruction:** - **Actively engage in the discussion to the following question** **Discussion Question** **What are theequipment, supplies and infrastructures required for optimal IPC?** **Time:** Facilitate reflection discussion for 10 minutes

Guidance 37: Equipment, Supplies and Infrastructure

The IPC Committee should conduct needs assessment to identify:

- Current stock of supplies (personal protective equipment and cleaning supplies such as gloves, soap, towels, linens, alcohol, etc)
- Availability and functionality of sinks, toilets
- Availability and functionality of incinerator and other waste disposal equipment
- Availability and functionality of laundry equipment
- Availability and quality of water supply

The assessment should be done periodically (at a minimum annually) to ensure that any new needs are identified. Conducting an evaluation not only permits the IPP committee and Health Center management to estimate needed supplies and equipment for implementing IPC guidelines, but also allows staff to identify their own needs. Health Center management can also use information from the evaluation to properly plan and budget for purchase/maintenance

of IPC related supplies and equipment. The need for IPC supplies and equipment can be assessed on a department/service area basis as outlined in Table 4 below:

Table 7.5: IPC/CASH Supplies and Equipment Needs Assessment

Case Team	Hazard	PPE need
Washing room	Blood contaminated linens	Gloves Apron Boots Masks etc.
Delivery and procedure room	Blood splash	Apron Goggles Face shield Drapes Boots etc.

IPC supplies should be purchased regularly to ensure that there is an adequate supply available. If IPC supplies are purchased through a bidding process, clear specifications should be given to the bidding committee or unit responsible for purchasing the IPC supplies that outline the desired quality and type of materials to be purchased.

In addition to assessing supply needs, the IPC committee should also assess infrastructural needs required to support infection prevention and patient safety activities. The IPC committee should assess the availability, functionality of infrastructure as well as quantify the cost of repair/replacement. The assessment could include plumbing and sewage, sinks, incinerator for waste disposal and laundry equipment.

WATER, SEWAGE AND PLUMBING

The Health Center should ensure that safe water is available 24 hours a day. Provisions should be in place to ensure that when water outages/shortages occur that water supply is not interrupted. Tankers or other water storage containers should be in place. They should be cleaned regularly and the quality of water should be sampled periodically to check for contamination.

SINKS, TOILETS

It is important that all rooms within a Health Center have properly functioning sink and toilet facilities. At a minimum, there should be a sink in each patient care area. Facilities should be accessible to patients, staff and visitors.

ELECTRICITY

The Health Center should ensure that electricity is available 24 hours a day. In particular, procedure rooms and operating rooms should have adequate lighting. A generator or other energy supply should be available for use when power supply is interrupted.

VENTILATION

Proper ventilation of patient care areas can reduce trapping of air, promote air circulation and help to minimize the transmission of infections.

LAY OUT OF PATIENT BEDS

Patient rooms should be organized in a way that will reduce transmission risk. In wards rooms with an open layout, spacing between beds should be 1-2 meters.

Guidance 38: Infection Prevention and Control Training

TRAINING AND MOTIVATION OF HEALTHCARE WORKERS

Successful adoption of infection prevention and patient safety standards requires periodic Infection Prevention training for all staffs. In order to effectively implement IPC practices, staff must first be informed and educated on current IPC/CASH principles.

The Infection Prevention team should assess training needs of the staff and provide required training in collaboration with woreda health office. Trainings should include general information on IPC practice and principles as well as practical skills tailored and appropriate to staff job functions. Health centers can contact partner organizations to provide standardized IPC/CASH trainings for members of the IPC committee who will then train/orient the rest of Health Center staffs. Materials should be adopted from standard training materials and trainers should be trained in IP&PS. Health centers should provide periodic re-orientation for staff and review the impact of trainings. Further IPC/CASH information can be given to staff through awareness programs and campaigns.
A motivated and encouraged health center workforce is essential to ensuring the sustainability of IP&PS guidelines. As such, successful adoption of infection prevention standards requires that Infection Prevention and Patient Safety trainings not only educate health center staff on IPC guidelines, but also motivate the staff to adhere to the IPC guidelines. Staff ownership can be cultivated by:

- Involving staff by asking their input on IP&PS guidelines
- Assigning a staff member of each case team a role in coordinating and monitoring staff on infection prevention and patient safety guidelines
- Providing orientation and sensitization on the importance of IPC

The following are additional recommendations on what elements should be included in a comprehensive IP training to support implementation of an IPC/CASH program.
Establish the importance of IPC with staff: To facilitate staff investment in implementing IP&PS guidelines, the IPC committee should ensure that all staffs understand that the IPC guidelines they are being trained in:

- Prevent the spread of unnecessary infections
- Improve the quality of patient / client care
- Promote a safe environment for both patients and staff,

Use appropriate training techniques: It is necessary that infection prevention and patient safety guidelines are clearly understood by all Health Center staff. This can be accomplished by using group-based training and demonstrative techniques to ensure that all staff, including low-literate staff should sufficiently informed on IPC.

Foster Staff Motivation: To maximize the benefits of infection prevention and patient safety training, the following items are suggested to maintain a motivated staff:

- The Health Center manager and case team leaders should be role-models in following infection prevention guidelines. They show due diligence in adhering to infection prevention and patient safety guidelines.
- Make and award certificates of achievement following the IPC training
- Suggest letters of recommendation shall be written and placed on file for staff after good performance evaluations are achieved
- Publicly recognize staff as individuals or in case teams that exemplify "excellence in infection prevention and patient safety practice". For example, a "wall of recognition" or "employee of the month" award can be used to create positive reinforcement for staff.

Distribute IPC guidelines throughout Health Center: Once training has been completed, materials relating to IPC guidelines should be posted in both public and private spaces throughout the Health Center. The IP guidelines should be strategically located in places where IPC must be practiced, for example, hand hygiene posters should be posted in all Health Center bathrooms, as a reminder to staff to wash their hands.

EDUCATING PATIENTS, CAREGIVERS, AND OTHER VISITORS REGARDING IPC GUIDELINES

Family members/caregivers are integral in the health delivery process, as they may assist in the care of the patient. Therefore, it is critical that family members and other caregivers are informed and educated on IPC guidelines. Since caregivers and visitors are not trained Health Center staff, special attention is needed in educating all visitors on appropriate IPC guidelines.

Involve the nursing staff in training patients and visitors. The nursing staff is responsible for educating patients and visitors about IPC practices within the Health Center. Nurses should be held accountable for effectively communicating proper IPC guidelines to both patients and visitors. Since some patients may be illiterate, it is necessary that representatives from the nursing staff recite the roles and responsibilities to all patients and visitors who enter the site.
Educate patients and visitors on IPC guidelines using illustrative pamphlets. The nursing staff can educate patients and visitors in either a group or an individual basis. The Health Center should have pamphlets and/ or brochures that highlight the IPC practices and that the patients, caregivers and visitors are expected to abide by. For example, educational pamphlets should address hand hygiene procedures and visiting hours. Brochures, pamphlets, or other educational materials should be illustrative in nature. This enables all visitors and patients regardless of education or literacy level to quickly grasp the concepts of IPC guidelines. Wherever possible, posters detailing IPC practices also should be posted in patient/ clients care areas.

Implementation Checklist and Indicators

7.3.1. Assessment Tool for Operational Standards

In order to determine if the Operational Standards for Infection Prevention and patient safety have been met by the Health Center, an assessment tool has been developed which describes criteria for the attainment of a Standard and a method of assessment. This tool can be used by Health Center management or by an external body such as the RHB or FMOH to measure attainment of each Operational Standard.

Table 7.6: Assessment Tool for Operational Standards - IPC/CASH

Std #	Standard	Method of Evaluation	Yes √ No X	met =1 not met =0	Remark
1.	Health center established functional IPC/CASH committee.	Check member assignment letter			
		Focal person assignment letter			
		Check IPC committee TOR			
		Current annual plan			
		Minutes of regular IPC meetings			
		Used IPC/CASH audit tool in ensuring IPC/CASH activities regularly			
2.	The health center conducts quarterly CASH/IPC audit	Check presence of audit plan			
		Check assessment checklist/audit tool			
		Action plan based on audit result			
		Implementation of action plan			
3.	The health center shall avail the necessary equipment, supplies necessary for IPC/CASH.	**Check availability of**:			
		disinfectant			
		detergents supplies			
		PPE,			
		Sweeping & mopping tools,			
		trollies for waste transport			
4.	The Health center shall	Check availability of the revised IPC guideline, 2019			

Std #	Standard	Method of Evaluation	Yes √ No X	met =1 not met =0	Remark
	ensure that all staff are trained using standard infection prevention and control training manual.	Training plan			
		Check separate training materials are prepared for clinical and supportive staffs			
		Training Attendance, minute and photos			
		Interview 5 sampled staff(3 providers & 2 support) on training			
5.	The health center ensures housekeeping activities.	Adequate cleaners as per standard			
		Observe visibly cleanliness of sampled rooms(eg delivery, toilet			
		Compound cleanliness(inside and around)			
		Check rooms are well ventilated			
6.	The health center ensures hand hygiene facilities are available at all service points.	Observe presence and functionality of hand hygiene stations in all service outlets			
		Hand hygiene job aids posted at all stations			
		Observe hand hygiene practice of 3 staffs			
		Check presence of sanitizers in all service outlets			
7.	The health center has a functional laundry service.	Check presence of designated laundry room			
		Check presence and functionality of laundry machine			
		Presence of water at all times			
		Use of PPE during laundry machine operation			

Std #	Standard	Method of Evaluation	Yes √ No X	met =1 not met =0	Remark
8.	The health center ensures standardized instrument processing practice.	Presence of SOPs based on revised IPC manual(2019)			
		Check instruments are processed based on the revised IPC guideline			
		Presence of sterilizer/high level disinfection setup			
		Separate Storage area for sterilized and cleaned supplies			
9.	The health center ensures all the post exposure and preventive interventions and procedures are in place in case of occurrence of occupational risks.	Annual plan HBV/COVID vaccinations for staff			
		Presence of PEP for HIV & HBV			
		PPE including:			
		o Mask			
		o Face shield			
		o Boots			
		o Heavy duty gloves			
		o Head cover			
		o Goggles			
10.	The health center provides health education to patients/clients, caregivers and visitors.	Annual plan			
		Posted monthly schedule			
		HE Logbook/report			
		EPHCG included in all HE sessions			
		IPC HE topics included in monthly schedules			
11.	The health center shall ensure proper health care waste management.	Check proper segregation of wastes			
		Fenced Placenta pit, Incinerator, ash pit and Burying pit			
		Disposal is proper(check the right wastes are disposed in the right place and no wastes found/disposed outside places mentioned above)			
12.		Annual plan for support			

Std #	Standard	Method of Evaluation	Yes √ No X	met =1 not met =0	Remark
	The Health center provides IPC/CASH support to its satellite health posts	Support checklist and feedback			
		Training report			
		IPC/CASH supplies provided			

7.3.2. Indicators

In addition, the following indicators may be monitored on a regular basis to assess the effectiveness/outcomes of implementation of the recommendations provided in this chapter.

Table 7.6: Infection Prevention and patient safety Indicators

S/N	Indicators	Formula	Frequency	Comment
1.	Healthcare acquired infection rate	Total number of patients with an infection arising 72 hours after admission during reporting period /total number of admissions during reporting period *100	Quarterly	
2.	a) Number of occupational exposures reported in the Health Center, categorized by type of exposure b) Number of non-occupational exposures reported in the Health Center, categorized by type of exposure	a) Total number of occupational exposures during reporting period, categorized by type of exposure b) Total number of non-occupational exposures during reporting period, categorized by type	Quarterly	
3.	The number of people that started PEP treatment	Total number of people started on PEP treatment during the reporting period	Quarterly	
4.	% of people that completed the PEP treatment	Total number of people that completed PEP treatment during the reporting period/ Total number of people who should have completed PEP treatment during the reporting period*100	Quarterly	

S/N	Indicators	Formula	Frequency	Comment
5.	a) Number of days when incinerator was not working b) % of total days	a) Total number of days that the incinerator was not working during the reporting period b) Total number of days that the incinerator was not working during the reporting period/total number of days in reporting period *100	Quarterly	
6.	Inpatient satisfaction survey: % of respondents who answered 'always' or 'usually' to the question "During this health facility stay, how often was the room you were sleeping in kept clean?"	Total number of patients who responded 'always' or 'usually' to the listed question/ Total number of s respondents*100	Biannual	Survey tool presented in Chapter 10 Quality Management and Monitoring and Reporting.
7.	Outpatient satisfaction survey: % of respondents who answered 'agree' or 'strongly agree' to the question "The outpatient department was clean	Total number of outpatients who respond 'agree' or 'strongly agree' to the listed questions/ Total number of outpatients respondents*100	Biannual	Survey tool presented in Chapter 10 Quality Management and Monitoring and Reporting.

7.4. Additional reading materials

1.

Chapter 8: Health Centre Infrastructure and Facility Management

Chapter Description: The health center infrastructure and facility management chapter describes the infrastructure requirements of a health center including service organization, building layout, maintainance procedures, safety to workers and customers. It also discusses the electricity supply, water supply , policy in transportation and vehicle management. The health center staff training on safety and fire prevention and procedures and preparedness for emergency response is discussed in this chapter as well.

Primary Objective: By the end of the chapter participants will be able to analyse the health infrastructure and evaluate facility management.

Enabling Objectives: By the end of the session you will be able to:

- Identify health center facility management organization and service layout
- Assess the electricity and water supply of health centers
- Evaluate the emergency preparedness of health center
- Ascertain health center has policy in transportation
- Ensure health centers use transparent vehicle management

Chapter outline:
8.1 Introduction
8.2 Organization of facilities management service
8.3 Vehicle Management
8.4 Health center infrastructure standards

8.1. Introduction

The primary health care infrastructure has made huge expansion in terms of potential coverage reaching more than 90% in 2019. The health infrastructure index of Ethiopia (composite of amenities, equipment and HF to population coverage and readiness), per the WHO Africa 2018 report, was 0.46 which is better than the WHO Africa regional average of 0.39. With this huge scale of expansions, ensuring continued functionalities of facilities and basic amenities (water, electricity, communication technologies, …) are important to improve the provision of quality health services.

8.2. Operational Standards

1. The health center has documents verifying ownership of land.
2. Health center has maintenance officer / delegate to oversee maintenance.
3. The health center floors are inspected on weekly bases, maintained and when appropriate improved to ensure cleanliness of grounds and safety of patients, visitors and staff.
4. Potable water is available 24/7 through regular or alternate sources to meet essential patient care.

5. Electrical services are available 24/7 through a regular or alternate sources to meet essential patient care.
6. The health centre conducts quarterly preventive and corrective maintenance for all facilities and operating systems(e.g. electrical, water, sanitation, sewerage and ventilation) to ensure patient and staff safety and comfort.
7. There is a notification and work order system for facility and operating system(e.g. electrical, water, sanitation, sewerage and ventilation) repairs.
8. The health center has a transport policy for the use of and access to health center vehicles.
9. The health center has a policy addressing access to health center premises.
10. The health center has a fire safety plan that addresses both the prevention and response to fire.
11. The health center has a plan for responding to likely community or health center emergencies, epidemics and natural disasters.
12. Health center staff members are trained and knowledgeable about their roles in the plans for fire safety, security, hazardous materials and emergencies.
13. The health center ensures the availability of functional toilets, hand washing sinks and showers.
14. The Health centre compound are regularly inspected, maintained, and, when appropriate, improved to ensure cleanliness of rooms and compound's safety of patients, visitors and staff.

Activity 8.1. Group discussion on Organization of facilities management

Instruction:

- Be in group of 5-6 people
- Discuss the topics below in your group and report the work in the plenary (share group response to the larger groups using flipchart)

Discussion Topics:

- **Health center renovation**
- **Layout of patient services and facility cleanliness**
- **Utilities and sewerage**
- **Health center security and safety**

Time: 45 min for reading and discussion 15 min for presentation

8.3. Implementation Guidance

Guidance 39: Organization of facilities management service

Each health centre should hire a maintenance officer /delegate maintenance officer to oversee the overall facility management who is accountable to the finance and property case team leader. The health center should develop inspection and/or reporting formats for specific

infrastructure management process including the inspection and maintenance process communications. The Facilities Manager should support the maintenance officer to sufficiently fulfil the functions described below.

The maintenance officer is responsible for:

- Planning for renovation and expansion
- Layout of patient/client services
- Gardening
- Utilities and sewerage management
- Security and safety
- Infrastructure for disaster and outbreak response

PLANNING FOR RENOVATION AND EXPANSION

The services provided by a health centre and the number of patients attending a health centre are rarely static. To accommodate changes in services or patient load it may be necessary to undertake significant renovation of existing buildings, to construct new buildings and/or to redesign the layout and functions of the health centre. Careful planning for new construction must be performed according to the laws and regulation (Ethiopian Building Codes). The planning is best carried out through a dedicated committee, with members from a range of backgrounds including staff who are well versed with the new service to be provided. Adequate consideration should be given to the effects of the construction process on existing services. Factors to consider that may interrupt normal facility operation include noise, vibrations, water or electricity needs or interruptions, access to large equipment or machinery, storage of construction materials, facilities for construction staff, excess dust etc. Therefore construction activities should be planned to minimize the effect on daily health center operations.

The following key steps as described in Table 8.1 below need to be addressed during the construction or renovation.

Table 8.0.1: Steps to be taken for planning construction or renovation

Step	Description
One	Establish the need for renovation or construction: • What services will be provided? • What is the demand and/or population health need for those services? • Can these services be provided using existing buildings or is renovation or new construction required? Stakeholders such as woreda, health center staff and the community should be involved at this stage.
Two	Preparation of a Design Brief. • The Design Brief is a basic framework for the design of the building or facility and should provide sufficient detail for construction engineers to prepare construction plans. Health center and woreda health office should be engaged during this process.
Three	Tender announcement and consideration of bids received • The Design Brief should be put to competitive tender • Bids received should be considered by the planning committee

	• Explicit criteria should be used to assess or score each bid received. Criteria could include: o Cost of construction o Time to completion o Closeness of plan to Design Brief
Four	Construction of the building or facility. As far as possible construction activities should be planned to minimize the effect on daily facility operations.
Five	Purchase of all furniture, equipment, and supplies needed for the building or facility Appointment and training of all staff

LAYOUT OF PATIENT SERVICES

The buildings are the most fundamental component of a health centre and their layout and design contribute significantly to the smooth operation of patient services and other activities. The use of buildings should be organized to:

- Allow for patients to be easily visible by staff for supervision purposes,
- Include all the needed clinical and non-clinical areas, avoiding unnecessary redundancies and making efficient use of space,
- Provide an efficient system for the handling of storage of supplies and the removal of waste, and
- The health centre should be organized such that patient services are easily accessible and located in close proximity to each other.
    - Clients should get a one stop shopping in medical records, laboratory and pharmacy that each should have its own cashiers. The laboratory and the pharmacy should be in proximity to the OPD.
- The Emergency Department should be easily accessed from the adjacent main road and should have a separate entrance that is labelled in a way that is visible from the street.
- The Outpatient Department (OPD) should have enough space and seating available for the expected number of daily arrivals.
- The Health centre triages should be clearly labelled and easily accessible.
- Areas that are restricted to staff only should be clearly marked with “No entry” or “Restricted entry” signs to prevent unwanted visitors from entering.

COMPOUND CLEANLINESS AND SAFETY

Patient and community perceptions of a health centre and staff satisfaction with their workplace can be enhanced by clean and pleasant health centre grounds. Buildings should be linked by covered and paved walkways, where possible. Recreation areas should be established including areas for sitting and for walking. Grass, trees and flowers should be planted wherever possible and special features such as fountains may be installed as a focal point. Health centre grounds should be free from litter, including old equipment or construction materials, and should be regularly inspected to ensure a safe and comfortable environment for patients, visitors and staff.

Grounds keeping staff should have access to all necessary tools, equipment and machinery necessary to maintain and enhance the health centre ground. These materials should be budgeted to ensure that there is a consistent supply of materials.

UTILITIES AND SEWERAGE

Electricity

A reliable source of electricity is essential for essential primary health care services. As regular supplies may be erratic, every healthcare facility must have a backup system in place, such as a diesel generator. Alternatively, solar panels might be a more cost-effective backup option. Regular(quarterly) inspections of the back-up electricity system should be conducted, with particular attention given to potential causes of malfunction. Health centre should have access to a professional qualified technician with appropriate training, tools and equipment to perform maintenance and repair of electrical back-up installations. Up-to-date plans and manuals should be kept by each facility to ensure easy access when troubleshooting or maintaining the equipment.

Water supply

All health centres should have access to a safe and reliable water supply. Water in health centre must be:

- Free of disease-causing organisms and any other hazardous substances,
- Clear, colourless, odourless, and tasteless,
- Not too highly concentrated with calcium, magnesium, manganese, iron, or carbonates,
- Without any corrosive substances, and
- At a relatively low temperature.

A backup water supply such as water tanks, a reservoir or dedicated well should be available in case the main supply is interrupted. Water tanks should hold sufficient water to supply the health centre for three days. Backup supplies should be cleaned weekly and water checked to ensure the quality and safety of the water being brought to the facility. A filter should be used to make the water safe and potable. Filters must be cleaned on a regular basis, as they tend to get clogged.

Sewerage and toilets

Proper sewage facilities are essential to any healthcare facility to ensure cleanliness and minimize the spread of infections. Flushing toilets should be available wherever possible and when an adequate amount of water is available ideally adjacent to each clinical care area. Otherwise, pit latrines are recommended. Covered walkways should be used to link health centre buildings to any external toilet facilities. It is important that all rooms within a Health Center have properly functioning sink and toilet facilities. At a minimum, there should be a sink in each patient care area. Facilities should be accessible to patients, staff and visitors. The health center should conduct inspection of toilets, sinks and sewerage facilities on weekly basis with corrective maintenance accordingly.

Plumbing

Health centre plumbing should be checked on a week days to ensure that all components are functional and there are no leaks in the system. Unnecessary water loss (due to leaks, running toilets etc) can be costly and can cause damage to a building or equipment if left unattended. Water pumps, if present, should be regularly checked and maintained.

Pest and rodent control

Rodents and insects can spread disease and cause damage to buildings and equipment, for example by chewing electrical wires and soft tubing. The presence of pests and rodents can be minimized by keeping the facility clean and free from waste materials.

Inspections should be performed quarterly to detect the presence of rats, rodents or other pests, paying particular attention to store rooms. Proper extermination methods should be undertaken when pests are suspected. Extermination techniques should be performed in accordance with local rules. Patients and staff should be temporarily removed from areas if there is a risk of exposure to toxic chemicals or substances.

HEALTH CENTRE SECURITY AND SAFETY

Security for the staff, patients, property, and information located within the health center is critical. Potential security threats include theft – by an employee or visitor, and threats against patients or staff. Security personnel play a vital role in ensuring that the health center is welcoming and accessible but also a safe environment for patients, visitors and staff. Security personnel need a thorough knowledge of the premises in order to protect buildings and valuable equipment. Security personnel should know when and how to diffuse potentially difficult situations and should be able to react appropriately in an emergency. The security team should provide 24 hour coverage, with security officers stationed at all entry and exit points of the health centre. The security staff also should conduct regular rounds of the premises.

The health center should have a policy to control access to the health center addressing all relevant areas. Access to the health center should be limited to staff, patients, caregivers and visitors with legitimate business. All staff should wear staff ID badges which they must present on entry to the facility. In addition, staff should wear uniforms appropriate for their positions at all times within the health center.

Health center Safety

Hazardous materials

Exposure to hazardous chemicals can produce a wide range of adverse health effects. The likelihood of an adverse health effect occurring, and the severity of the effect are dependent on the toxicity of the chemical, route of exposure, and the nature and extent of exposure to that substance.

Material safety data sheets (MSDSs) should be available for all chemicals found at the health center. These should include information about the substance, safe handling, precautions, first aid, etc. MSDSs should be held at all sites where hazardous materials are stored or utilized, and a full set of all MSDSs should be held by personnel in the materials management/central supply department and by health center management. The health center should ensure that reasonable stocks of personal protective equipment are held at all times, and that these form part of recurrent

budgets. Basic personal protective equipment includes gloves, masks, eye protection, protective clothing, etc.

Fire safety

A fire in a health facility risks the safety, health, and lives of patients and providers. Health centers should have a fire safety plan that addresses both the prevention(electric safety, flammable storage, smoking/open flame restrictions and fire inspections) of and response(fire warning, emergency notifications, firefighting equipment, water sources, access to building and evacuation) to fires.

All employees should be trained in fire prevention and response and should be familiar with the fire safety plan. Training should include the operation of firefighting equipment, evacuation, and the specific responsibilities of each staff member. Update training should be conducted at least annually through "Fire and evacuation Drill".

Activity 8.2. Reflection on Vehicle management	
	**Instruction:** **Engage actively in the discussion of vehicle management in a health center during session facilitation** **Questions:** **How should be vehicle management should be organized?** **What principles should be addressed in health center vehicle management?** **Time:** 15 minutes

Guidance 40: Vehicle management

Health centers may have one or more vehicles, including ambulances, depending on the size and location of the facility. Such vehicles should be organized under finance and property management unit. All drivers must have valid driving licenses for the type of vehicle used and must be sufficiently trained to undertake basic repairs (for example burst tyres, overheating etc.). All vehicles should be equipped with at least one spare tyre and preferably two for vehicles used in remote locations, and these should be checked on a regular basis to ensure they are intact and filled with air. All vehicles should be fitted with functioning seat belts in both front and back seats and these should be used by drivers and passengers at all times. All vehicles must be insured against accident and theft.

Routine services should be undertaken for each vehicle in accordance with manufacturer's recommendations. Routine and repair services should only be undertaken by a qualified mechanic. A log book should be kept for each vehicle that describes the mileage undertaken and maintenance record for the vehicle.

A transport policy should be established that specifies:

- The appropriate use of ambulances and regular vehicles,
- The process by which vehicles are issued for use,
- Control of vehicle keys,
- Storage of vehicles,
- Fuel consumption policy,

- Use of seatbelts,
- Use of mobile telephone by driver,
- Use of alcohol, chat or other substances by driver,
- Action to be taken in the event of an accident or breakdown, and
- Action to be taken in the event of misuse of the vehicle.

10.1. Implementation Checklist and Indicators

8.4.1. Assessment Tool for Operational Standards

Table 8.2. Assessment Tool for Operational Standards – Health Centre Infrastructure and Facility Management

s.no	Standard	Verification	Yes √ No X	met =1 not met =0	Remark
1	The health center has documents verifying ownership of land.	blue print			
		ownership certificate			
2	Designated Health center maintenance officer is hired for facility maintenance functions.	Employment letter			
		Job description			
		Annual plan			
3	The health center floors are inspected on weekly bases, maintained and when appropriate improved to ensure cleanliness of grounds and safety of patients, visitors and staff.	Reports of weekly inspections			
		Inspect floors for safety and cleanliness			
4	Potable water is available 24/7 through regular or alternate sources to meet essential patient care.	Check the availability of water [inspect and interview]			
		water quality test report			
5	Electrical services are available 24/7 through a regular or alternate sources to meet essential patient care.	Check the availability of electiric power [inspect and interview]			
6	The health center conducts quarterly preventive and corrective maintenance for all facilities and operating	[inspect]			

s.no	Standard	Verification	Yes √ No X	met =1 not met =0	Remark
	systems (e.g. electrical, water, sanitation, sewerage and ventilation) to ensure patient and staff safety and comfort	maintenance reports			
7	There is a notification and work order system for facility and operating system(e.g. electrical, water, sanitation, sewerage and ventilation) repairs.	Notification form			
		Maintenance request form			
		Maintenance report form			
8	The health center has a transport policy for the use of and access to health center vehicles.	Observe policy			
		Check/interview processes are according to policy			
9	The health center has a policy addressing access to health center premises and traffic flow.	Observe policy			
		Availability of guards			
		Observe traffic flow management			
10	The health center has a fire safety plan that addresses both the prevention and response to fires.	Observe plan			
		Updated Fire extinguisher / Sand			
		Report on Fire safety drill exercise during last year			
11	The health center has a plan for responding to likely community or health center emergencies, epidemics and natural disasters.	Assigned surveillance officer			
		Observe plan			
12	Health center staff members are trained and knowledgeable about their roles in the plans for fire safety, security, hazardous materials and emergencies.	Check presence of training material			
		Observe training report and/or list			
		Interview staff whether they are trained			
13		Observe			

s.no	Standard	Verification	Yes √ No X	met =1 not met =0	Remark
	The health center ensures the availability of functional toilets, hand washing sinks and showers.	○ toilets (labelled for men and women) as per standard			
		○ handwashing stations			
		○ showers			
14	The Health centre compound are regularly inspected, maintained, and, when appropriate, improved to ensure cleanliness and safety of compound.	Observe compound for cleanliness			
		Separate entrance gates and exit for cars as well as people			
		Observe functional fence			
		Dedicated green areas			
		Inspection reports			

8.5. Additional Reading Materials

Chapter 9: Medical Equipment Management

Chapter Description: The Medical equipment management chapter is intended to illustrate the human resource needs for medical equipment management together with training needs for equipment management. It also describes standard practices of medical equipment inventory, medical equipment development plan as well as caliberation, inspection, testing maintainance and disposal(decommissioning) of medical equipments.

Chapter Objective: By the end of the chapter participants will be able to lead the medical equipment management activities in a health center.

Enabling Objectives: By the end of the session you will be able to:

- Identify human resource needs for medical equipment management
- Synthesize medical equipment development plan
- Explain medical equipment calibration, inspectio, testing, maintenance and disposal
- Identify Training needs for medical equipment use and maintenance
- Suggest budgeting for medical equipment management

Chapter Outline:
9.1 Introduction
9.2 Human resource need for medical equipment management
9.3 Medical equipment inventory
9.4 Medical equipment development plan
9.5 Caliberation, inspection, testing, maintenance and Disposal of medial equipments
9.6 Training in Medical equipment use and maintenance
9.7 Medical equipment budgeting

9.1. Introduction

Ensuring availability of a functional medical equipment at health centre level help the health system to offer a safe and quality to the standard essential services to beneficiaries. However, a study in Ethiopia documented that about 39% of medical equipment were found to be non-functional in health centers. The rising number of these non-functional equipment are due to poor equipment handling and utilization, frequent power surges, lack of operator training, lack of preventive maintenance, lack of spare parts and maintenance capacity. In addition, a system capable of supporting and managing the medical technology must be in place. It is very crucial to implement Medical Equipment Management in the health centre to manage and coordinate the planning, procurement, training, operation, maintenance, decommissioning and disposal.

During the last five years (2015-2020), the ministry of health adapted and implemented health centre reform guidelines. The medical equipment and facility management chapter was implemented in over 90% of the health centres. This chapter was one of the difficult chapters to successfully meet over 80% against its minimum standards. Despite that, the implementation exercises help the health leadership and manager to dedicate resources and enhance service quality. This chapter outlines standards that health centre should adhere to appropriately

manage their medical equipment, allowing for the provision of services while ensuring the safety of its patients.

9.2. Operational Standards

1. The Drug and Therapeutic Committee (DTC) should be responsible to oversee the entire Medical Equipment Management.
2. The health centre has an active medical equipment maintenance work order system and ensure functional work relationship with workshops available within zone health department or nearby Primary Hospital.
3. The health centre has a paper-based or computer-based current equipment history file documentation.
4. All new equipment's are installed and commissioned in accordance with the manufacturer's specifications and undergoes acceptance testing prior to its initial use to ensure the equipment is in good operating condition.
5. All equipment operators and personnel are trained on proper application, safety, and maintenance of medical equipment.
6. The health centre ensures decommissioning including relocation, uses as spare, donation.
7. Health center conducts proper disposal of medical equipment according to national and regional legislations.

Activity 9.1. Two minutes paper	
	**Instruction:** **Write down considerations for human resource needs for medical equipment management and share your ideas on general discussion** **Time:** 10 minutes

9.3. Implementation Guidance

Guidance 41: Human resource needs for medical equipment management

MAINTENANCE OFFICER

A health centre should be staffed with a maintenance officer.

INCIDENT OFFICER/FOCAL PERSON

The health centre should establish a process to report and investigate all critical incidents, including incidents that arise from the use of medical equipment. An Incident Officer should be assigned to investigate all incidents and to ensure that any required follow up action is implemented. Further guidance on Incident Reporting and a sample Incident Report Form are presented in *Quality Management & Clinical and Patient Safety Chapter*.

DRUG AND THERAPEUTIC COMMITTEE (DTC)

Each health centre should have a maintenance officer and established a Drug and Therapeutic Committee (DTC), with the following activities;

- Prepare a written agreement with the nearby Medical Equipment Maintenance workshop and facilitate a regular testing, calibration, measuring instruments, and oversee the overall medical equipment management services
- Support in establishing and maintaining paper or computer based medical equipment inventory.
- Develop and maintain equipment history files for all equipment
- Prepare/adopt SOPs for equipment use, and safety
- Facilitate acceptance testing and installation of new equipment
- Facilitate staff in-service training on the correct and safe use of equipment and basic troubleshooting and preventive maintenance measures
- Drug and Therapeutic Committee DTC ensures the health centre allocates sufficient budget for regular and incident-based maintenance budget.
- The DTC establishes paper- based or automated and centralized documentation system that tracks all equipment for planning, budgeting, requisition, reporting and other purposes.
- The DTC participates on equipment planning, purchase, installation, maintenance, and troubleshooting.

NEAR-BY MEDICAL EQUIPMENT MAINTENANCE WORKSHOPS

A health centre should closely work with the nearest medical equipment maintenance workshops. Hence, simple preventive and corrective maintenance and sophisticated or more complex equipment should be linked with the referral system to get services from the next high-level primary hospital medical equipment maintenance workshop and seek technical support from zone Healthy Department. Bio-medical engineers and experts of the medical equipment maintenance from the partnered workshop should oversee the condition and operation of all medical equipment, be the contact point for all equipment and maintenance matters, be responsible for finding the correct solution (calling in technical support from external service providers) and possibly undertake PPM and repair themselves (if properly trained).

The maintenance officer of the health centre should be a member of the health centre DTC.

Guidance 42: Medical Equipment Inventory

An inventory of medical device is a detailed itemized list of medical equipment held by the health centre and:

- Must be continually maintained and updated to reflect the current status of each medical equipment
- Medical equipment inventory is a list of the technology on hand, including details of the type and quantity of equipment and the current operating status
    - Accessories, consumables and spare parts inventories are directly correlated with the main medical equipment inventory

Data included in health centre medical equipment inventory are: -

- Inventory identification number
- Type of equipment/item
- Brief description of item
- Manufacturer
- Model/part number
- Serial number
- Power requirement
- Physical location within facility
- Condition/operating status
- Operation/service requirements
- Date inventory updated
- Maintenance service provider
- Purchase supplier
- Year of Manufacturing and purchased
- Equipment risk classification
- Estimated life span
- Availability of trained user and technicians
- Other information as needed

Before establishing a medical equipment inventory the DTC should determine which items should consult the inclusion and exclusion criteria presented in Box 9.1. However, the DTC may decide to exclude smaller, less expensive and easily replaceable items from the medical equipment inventory and program (for example sphygmomanometers, stethoscopes, etc.) since the effort required to record, maintain and repair these smaller items may not be worth the required manpower and financial resources. The Medical Equipment Strategy should give a clear definition of medical equipment that should be included in the medical equipment inventory and program and should also state exclusion criteria for items that should not be included. The inventory team is responsible to visit every department and record every item of medical equipment. A sample Inventory Data Collection Form is presented in **Appendix 9A**.

Box 9.0.1: Definition of Medical Equipment

Medical equipment can be defined as "any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article that is used for:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease or injury,
- Investigation, replacement, modification, or support of the anatomy or of a physiological process,
- Supporting or sustaining life,
- Control of conception,
- Disinfection of medical devices,
- Providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body, *and* which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means."

Source: GHTF/SG1/N29R16:2005, Global Harmonization Task Force, 2005.

Items that are obsolete, that cannot be repaired or that are not of use to the health centre should be removed and transferred to a storage area at the time of the inventory and the formal disposal process should be started. An inventory code number should be assigned to each piece of equipment. This can be done sequentially from number 1 upwards. Each new item is assigned the next number, with no regard to type of equipment, location etc. Alternatively, a 'speaking numbers' inventory system can be used. This system indicates the location, the type of equipment and the individual number of the equipment. With a 'speaking number' system each room/department in the health centre is assigned a location code and each type of equipment is assigned an equipment type code – for example "OPD1 99 02" where OPD1 is Outpatient department number 1 , 99 indicates the item is suction pump and 02 is the individual number of machine. Although the 'speaking numbers' inventory system is more complex to establish, it has the advantage that it is easy to identify the location of each item and to organise the equipment inventory by each department.

An inventory database should be established to record and manage all items of equipment. This can be paper based or computerized, with paper back up.
Information gathered as part of the inventory of medical equipment should be included in the overall fixed asset inventory of the health centre. Further guidance on the fixed asset inventory process is provided in Chapter 1.3.1.6 Leadership and Governance.

The inventory should be reviewed and checked biannually, with regular updates during the year when new equipment arrives or is removed from service. Additional inventory checks may be conducted at shorter time intervals throughout the year, as determined by the DTC and health centre management. All equipment should be labelled with its inventory number preferably using a waterproof PVC sticker. When an item is discarded it should be removed from the inventory database. A record should be kept in a separate file of all discarded equipment for future reference and audit purposes. Health centre policy should prohibit use of medical equipment without inventory tags/stickers. This is to ensure that all equipment in use has undergone 'acceptance testing' and receives regular preventive maintenance, hence minimizing risks to patients and staff from faulty equipment.

EQUIPMENT RISK CLASSIFICATION

As part of establishing an inventory system, an assessment should be undertaken to classify each medical equipment as 'high', 'medium' or 'low' risk. This level of risk determines the priority with which equipment should be repaired and maintained or replaced if no longer operable. For example, if a 'high risk' item (such as an anaesthesia machine) is broken this should generally be repaired before a 'low risk' item even if the 'low risk' item has been broken for longer..
Additionally, when implementing the guidance in this chapter (such as developing standard operating procedures (SOPs), setting maintenance schedules, training staff in equipment use etc.) the 'high risk' items should be dealt with first.

The assessment of risk should be done based on:

- Function of the equipment: For example whether the equipment is used for life support, routine treatment, diagnosis or monitoring
- Risk which may be associated with equipment failure
- Preventive maintenance requirements: The frequency with which preventive maintenance is required to minimize breakdown and ensure safety
- Main area of equipment uses: For example use in anaesthesia or surgical areas, use in general care areas etc.
- Likelihood of equipment failure: This is measured as the 'mean time between failures' calculated from previous use or service records

Appendix 9C presents a Sample Medical Equipment Risk Assessment Form for assigning the risk category to medical equipment.

A medical equipment risk assessment form should be completed for all items in the equipment inventory. The risk category should be entered on the Inventory Index Card, and the Risk Assessment Form should be filed in the Equipment History File (see Section 8.3.5 below). Any new item of equipment should be assigned a 'risk category' when it is received by the hospital and entered into the inventory.

SPARE PARTS INVENTORY

The pharmacy department should maintain a stock of the most commonly replaceable spare parts for the different types of equipment in the health centre. Items should be kept in a locked room with a stock control system in place. Spare parts should be stored according to manufacturer's instructions and should not be used beyond the expiration date. The inventory of spare parts should be managed using a 'stock and bin card' system.

Bin Card

A Bin Card should be prepared for each spare part stored in the pharmacy department. The Bin Card should be kept with the product inside the store. All transactions of the product to or from the store should be recorded on the Bin Card. The Bin Card should also include a column for the loss/adjustment of stock and a column for the stock balance. The stock balance should be updated after each and every transaction or adjustment.

Stock Card

The Stock Card is similar to the Bin Card but is used to track stock based on issuing and receiving orders. The Stock Card should be maintained by pharmacy department head. Whenever Stock Cards are updated the totals should be checked against those on the Bin Card and any discrepancies should be investigated.

A combined Bin/Stock Card System provides a measure of internal control that helps to minimize leakages of stock due to theft or loss. Paper based or electronic Stock Cards can be used. If an electronic system is installed, there should be regular back up of data. Sample Bin and Stock Record Cards are presented in **Appendices 8D and 8E**.

EQUIPMENT HISTORY FILE

An individual file/folder should be established for each item of equipment. This file should be held in the pharmacy department. The file should contain:

- Inventory Data Collection Form (**Appendix 9A**)
- The address of the manufacturer
- The address of the supplier and local agents
- Details of any maintenance contract and maintenance contractor (if relevant)
- Copy of warranty (if relevant)
- Price paid/Copy of invoice
- List of consumables required to run machine and recommended spare parts
- Acceptance test log sheet (**Appendix 9H**)
- Medical Equipment Risk Assessment Form (**Appendix 9C**)
- SOPs for operation and maintenance of the item
- Planned preventive maintenance schedule
- Corrective maintenance reports (**Appendix 9K**)

Operator, service and other relevant manuals for all equipment items should be stored in the information center. Copies should be made and distributed to users and other interested parties as necessary.

ESSENTIAL MEDICAL EQUIPMENT LIST

Each health centre should establish an essential medical equipment list that describes the number and types of equipment required by the standard. A multi-disciplinary team brought together from across all the departments/case teams should develop an outline of the Essential Service Package for the health centre that describes the core functions and services provided. This Essential Service Package will determine the corresponding essential equipment list of all items that are necessary to provide each service. Each discipline will decide the type of equipment required to provide the healthcare interventions described in the **essential service package**. National health centre standard for medical equipment, should be the minimum requirements of the essential equipment list, but these may be expanded upon as determined by the multi-disciplinary team. The Essential Medical Equipment List should be approved by the DTC.

Activity 9.2. Guided Practice	
	**Instruction:** **Using the template on Table 9.1 develop a medical equipment development plan for your health centers:** **Time:** 30 minutes.

Guidance 43: Medical Equipment Development Plan

The Equipment Development Plan (EDP) is a plan to define goals for acquisition, maintenance, and replacement of equipment in the short term and long term. The equipment development plan should be developed taking into consideration the current equipment inventory and the 'essential equipment list'.

The medical equipment development plan (EDP) brings attention to:

- Current stock and condition of equipment: which pieces need to be replaced or maintained, which pieces need to be disposed
- Shortfalls in equipment: missing equipment that needs to be purchased
- What action is needed to maintain, replace or purchase equipment
- Short-term (1 year) and long-term (2-5 year) goals to ensure that the health center has all necessary equipment for current and future services

The EDP should be developed by the DTC and approved by health centre management. The plan is the basis for the annual equipment budget. The maintenance officer and Head of pharmacy department is responsible to implement the plan, with the assistance of other departments where relevant (for example administration and finance). He/she should present quarterly reports to the health centre management on the status of implementation of the EDP plan.
The plan should be updated annually. A sample template for an EDP is presented in Table 1 below.

Table 9.0.1: Sample Template for Equipment Acquisition Plan

Department/Room:					
Equipment (type and inventory number)	**Condition** For example age and expected life; working condition (good, fair, poor, needs repair, damaged beyond repair, obsolete)	**Short Term Action (1year)** For example: repair needed; replacement needed; user training needed; first time purchase needed	**Short term cost estimate**	**Longer Term Action (2-5 years)** For example: replacement needed; first time purchase needed	**Long term cost estimates**

A. Existing equipment					
Suction machine					
B. Additional equipment required *(based on Model Equipment List)*					
Chemistry machine					

ACQUISITION /PROCUREMENT OF MEDICAL EQUIPMENT

The acquisition / procurement of medical equipment should be undertaken in accordance with the Ethiopian government/ MOFED/BOFAD directives. Medical Equipment may enter into the health centre through one of the following means.

1. Purchasing
2. Donation
3. Leasing and Renting
4. Cluster based equipment sharing

In Medical equipment procurement processes the following steps should be considered.

- Need assessments and justifications
- Planning and budgeting
- Technology assessment, preparation of technical specification and selection
- Cost of ownership (Maintenance, Spare part, consumable etc)
- After purchase services arrangemment
- Human resource
- Procurement

When purchasing new equipment enough spare parts and accessories for at least 2 years should also be purchased. Further guidance on the procurement process and development of a procurement policy is presented in Financial and Asset Management Chapter 1.

Equipment Donation

The health centre DTC should strictly follow National Medical Equipment Donation Directive for the receipt of donated medical equipment. The directive describes the conditions under which donated medical equipment will be accepted by the health centre. For example:

- Donated equipment must be in good working order
- Equipment will only be accepted if the item is needed by the health centre and is described in the essential equipment list and associated annual equipment management Plan
- Instruction manuals, in English, should be supplied with the donation
- Supplies, consumables and spare parts for the equipment should be readily available in Ethiopia. If that is not possible, at least 1 year of needed consumables and spare parts should be supplied by the donor with the donated equipment
- Expertise for the maintenance and repair of the equipment should be available in Ethiopia
- The equipment must be compatible with other medical equipment system in the health centre

- The equipment must not require any special storage or operating conditions that the health centre cannot provide (for example air conditioning, humidity control etc.)
- The donor should provide training in the regular use and preventive maintenance of the equipment, if relevant, and
- The donor should provide follow up support regarding use of the equipment, where necessary.
- When items are donated the health centre and donor must agree who is responsible for customs clearance, including approval of the item by the regulatory authority if necessary.

The DTC should establish a list of desired equipment that is based on the Model Equipment List and associated Equipment annual Plan. The list of desired items and donation policy should be given to all individuals/organizations that are willing to make a donation to the health centre. All equipment donations should be reviewed by DTC and approved by the health centre management before acceptance.

PREPARING FOR EQUIPMENT DELIVERY AND COMMISSIONING

When an order has been placed to purchase a new equipment, or a donation has been accepted, preparations must be made for receipt of the item. This is to ensure quick and efficient installation, commissioning, training, and eventually placement into service. Pre-installation work involves the following:

A) Site Preparation

Site preparation is often required to ensure that the location where the new equipment to be installed is suitable. This may require new connections for electricity, water, drainage, gas or waste and may even require construction work.

Preliminary considerations to think about include:

- Is there sufficient access to the room/space (door entry)?
- Is the room/space large enough?
- Is the position and layout of the room/space suitable?
- Are the required work surfaces and service supply points available?
- Is the environment adequate for the purpose? (Is it dust-free? Is it Away from running water? Is Air conditioned necessary?)

Site preparation tasks may include:

- Disposing of the existing item that is to be replaced if there is any.
- Extending pipelines and supply connections to the installation site
- Upgrading the type of supply, such as increasing voltage or pipeline diameters
- Providing new surfaces, such as laying concrete or providing new worktops
- Creating the correct installation site, such as digging trenches, building a transformer house or a compressor building

Appendix 8F presents a list of Common Site Preparation Steps to follow when preparing a site to receive a new piece of equipment.

B) Organizing Lifting Equipment

Large or heavy items will need to be lifted and moved upon arrival. Plans should be made ahead of time to arrange proper lifting/moving equipment before the new equipment arrives.

C) Organizing Warehouse Space
If goods need to be stored before they can be unpacked or installed, space should be made available for these items before they arrive.

D) Preparation for acceptance testing and installation
Any preparations that need to be made for acceptance testing and installation, including ensuring that appropriately trained personnel to do the testing are available, gathering or acquiring materials, working/storage space and/or test instruments should be done before the item arrives.

E) Preparation for user training
The details of training should already have been decided when drawing up the purchase contract or donation acceptance document. During delivery time, any preparations that need to be made (including preparation of training materials, training space, equipment, etc.) should be finalized in order to ensure training can commence when the equipment is delivered.

ACCEPTANCE TESTING AND INSTALLATION

All medical equipment, purchased or donated, should be inspected upon delivery and tested prior to initial use. This is known as acceptance testing and ensures that delivered medical equipment is complete, undamaged, in good operating condition, accompanied by manuals and spare parts, satisfies safety criteria, and meets specifications of the purchase order. A competent individual must assess the functionality of the equipment to prevent any harm to the operator or patient upon use. Guidance for unpacking and inspecting equipment is presented in **Appendix 8G**.

The main steps in the Acceptance Testing process are described below:

1) Determine what personnel should be involved by asking the following:
   - **How complex is the equipment?** The more complex the device, the more likely the manufacturer will need to be involved.
   - **Do the health centre staffs have the necessary technical skills?** If the staff cannot perform the job, then an outside vendor should be contracted.
   - **Are you buying a single item or in bulk?** If purchasing in bulk, it is often worthwhile to contract the manufacturer to perform this process on all the equipment. For a single unit, the in-house staff may be able to manage with guidance from the manufacturer.

2) Isolate the equipment until it has undergone acceptance testing

Once equipment arrives, set it aside by isolating the equipment in a special holding area and by labelling it as “not for use” to ensure that the equipment will not be used. The only exception is for large items that may be delivered to where they will be installed but should still be clearly marked as “not for use” until the acceptance process is completed.

3) Undertake acceptance testing and complete Acceptance Test Log Sheet (**see Appendix 9H**)
Acceptance testing should include:
   - Checking the delivered equipment matches as per the details of the purchasing order (model, vendor, quantity, technical requirements, etc)

- Checking the equipment is accompanied by operation and service manuals and necessary paperwork (e.g. warranty, if applicable) as per the purchase order.
- Checking that appropriate spare parts and consumables are included as per the purchase order

4) Accept the equipment and Establish Equipment History File

If the equipment passes the safety, calibration and function tests and commissioned then the health center can officially accept the equipment. An Acceptance Test Log Sheet (**Appendix 9H**) should be completed, signed and filed in the Equipment History File.

5) Enter equipment into the equipment inventory

After the item has undergone acceptance testing and commissioned it should be entered into the health centre inventory. The assigned inventory number should be marked onto the item of equipment.

6) Prepare Standards Operating Procedures and assign Planned Preventive Maintenance Schedule(see sections 9.3.12 and 9.1. 3 below)

7) Provide training for equipment users and maintainance officer as appropriate.
User training should be provided by an application specialist, especially training for sophisticated or complex devices.

STANDARD OPERATING PROCEDURES

To ensure that equipment is used correctly and safely Standard Operating Procedures (SOPs) should be developed and attached to each item of equipment. The SOP should be a simple 'how-to' guide that describes how to use the equipment, instructions for care of the equipment, and basic safety and troubleshooting procedures. The SOP should be based on the manufacturer's user manual (if available). SOPs should be kept attached or adjacent to the item and a copy should be included in the Equipment History File that is stored in the pharmacy Department.
All staff, including maintenance officer, should be trained to follow the SOPs and infection prevention procedures when handling medical equipment. (For further guidance on infection prevention see *Infection Prevention and Patient Safety Chapter*).

Guidance 44: Calibration, Inspection, Testing, Maintenance and Disposal

Medical devices may cause life threatening problem if it is not managed properly. Therefore, it is important to have a well-planned and managed maintenance program to ensure medical equipment are reliable, safe and available all time when it is needed for diagnostic procedures, therapy, treatments and monitoring of patients. In addition, such activities prolong the useful life of the equipment and minimize the repair related cost of equipment.

PLANNED PREVENTATIVE MAINTENANCE

All medical equipment should be inspected and tested prior to use (acceptance testing) and thereafter should undergo regular planned preventative maintenance (PPM) to ensure that the equipment is working properly and to prolong its expected lifetime. Safety and calibration

testing should also be performed regularly to ensure the equipment is safe to use and is operating within expected specifications (or to adjust if it is not).

Preventing equipment failure is more efficient than repairing equipment after breakdown occurs. PPM should be carried out by both equipment users (for simple, easy, everyday tasks) as well as biomedical technicians from the nearest hospital/zone medical equipment maintenance workshop (for more complex tasks requiring special skills and/or tools). For some equipment PPM should only be carried out by certified service engineers.

SOPs for each item of equipment should include instructions on simple PPM and troubleshooting that can be performed by users of the item. For each item of equipment there should be a plan for preventive maintenance, safety and calibration testing that is documented and at a minimum follows manufacturer's recommendations. If the manufacturer's manual is not available then inspection, testing and preventive maintenance should be conducted at a minimum every six months.

The preventive maintenance plan should include:

- A description of and guidelines for the tasks to be conducted
- A statement on who is expected to perform each of the above tasks
- The frequency with which each of the tasks should be conducted

For each item of equipment, a timetable/schedule for each of the tasks above should be established together with a log file to document all maintenance activities. The maintenance plan and schedule should be developed collaboratively between the DTC and each core process owner. The maintenance plan, schedule and log sheet should be attached or kept adjacent to the equipment item. A copy of the plan and schedule should be kept in the Equipment History File that is held in the pharmacy head or DTC.

A sample Preventive Maintenance Log Sheet is presented in Appendix 9I.

The DTC should establish a system to check all Maintenance Log Sheets to ensure that all PPM tasks are conducted in accordance with the schedule for each item of equipment, and should address any instances where PPM is not conducted in accordance with the schedule.

CALIBRATION

Some medical equipment, particularly those with therapeutic energy output needs to be calibrated periodically. This means that energy levels are to be measured and if there is a discrepancy from the indicated levels, adjustments must be made until the device functions within specifications. Devices that take measurements also require periodic calibration.

SAFETY INSPECTIONS

These are performed to ensure the device is electrically and biomechanically safe. These inspections may also include checks for radiation safety or dangerous gas or chemical pollutants. When these inspections are done, the results are compared to country or regional standards as well as to the manufacturer's specifications. The frequency of safety inspections may be different than planned

Maintenance and performance inspections are usually based on regulatory requirements periodic calibration to ensure accuracy compared to known standards.

CORRECTIVE MAINTENANCE

Corrective maintenance involves equipment repair and replacement of parts. Instrument operators can follow SOPs to perform simple corrective maintenance such as replacing blown out fuses or simple troubleshooting. However, most corrective maintenance must be performed by a qualified technician. A 'Good Practice Checklist' for corrective maintenance technicians is presented in **Appendix 9J**.

Whenever corrective maintenance is performed a Corrective Maintenance Report should be completed and stored in the Equipment History File. A sample Corrective Maintenance Report is presented in **Appendix 9K**.

NB: Only engineers that are certified by the supplier can perform corrective maintenance on instruments still under warranty.

If a large piece of equipment requires major maintenance an assessment should be done to determine whether it is worthwhile repairing the item or whether it would be better to purchase a new one. Generally, if purchasing separately all the parts that make up a piece of equipment it would cost 3-4 times the price of the equipment. Maintenance may be cheaper in the short term, but if this only adds a short additional lifespan to the item or if it is continually necessary to replace different parts, then it may be more cost effective to purchase a new item.

Work Orders and Reports

Whenever an item of equipment is faulty this should be reported immediately to the maintenance officer or DTC using a Service Request/Work Order Form. Requests for maintenance to be undertaken by technicians should also be documented on a Work Order Form. In urgent cases the request for repair can be made by a telephone call or other verbal means of reporting, however this must always be backed up with a written request on the Work Order Form. A sample Work Order Form is presented in **Appendix 9L**.

Three copies of the Work Order Form should be prepared (using carbon copy paper):

- The first copy should be kept by the user department and filed in a 'Maintenance Pending File'. This file is best organized by date submitted, with the most recent request at the top. The 'Maintenance Pending File' should be checked regularly by the DTC to ensure that Work Orders are being carried out in a timely manner. When the work is completed, and the item is returned to service the Work Order Form should be signed by the user and the Work Order Form should be transferred to a 'Maintenance Completed File'.
- The second two copies of the Work Order Form should be submitted to the bear by Equipment Maintenance workshop together with the broken item (if it is feasible to move the item). Whenever a Work Order is received by the Equipment Maintenance Department this should be reviewed by the Department Head and the duty should be assigned to the appropriate individual (or outside service provider). The name of the person who is assigned to undertake the repair should be written on both copies of the Work Order Form. In the event that several items required repair at the same time then 'High priority' equipment should be repaired before 'Medium' or 'Low Priority' equipment.

- Within the Equipment Maintenance Department one copy of the Work Order should be entered into a 'Work Order Pending' File held by the Head of Equipment Maintenance. This file is best organized by date submitted, with the most recent request at the top. When the work is completed the Work Order should be transferred to a 'Work Order Completed' File and kept as a permanent record of the work undertaken.
- The final copy of the Work Order Form should be given to the responsible medical equipment technician who is assigned to undertake the repair. Upon completion of the task the final section of the Work Order Form and a Corrective Maintenance Log should be completed. The item should be returned to the user. The completed Work Order Form and Corrective Maintenance Log should be filed together in the Equipment History File.

Outsourcing of Technical Services

When the equipment maintenance department is unable to perform PPM or corrective maintenance of a particular item of equipment, support from external maintenance contractors will be required. Work may be outsourced to the Ethiopian public health institute for laboratory devices, the manufacturer's local agent, the manufacturer, private maintenance companies, individuals such as electricians or plumbers. The Ethiopian Biomedical and Laboratory Equipment Engineers Association could be a good source for finding qualified individuals or companies. Support may also be provided by the relevant Regional Health Bureau.
When making the decision to outsource a service, the maintenance workshop must consider the task at hand and the qualifications needed to perform the task. In order to do this, the Medical Equipment Committee should register all potential individuals and companies that they would consider as a supplier of maintenance services. The MEMU should prepare a list of requirements that each company should meet in order to be contracted by the maintenance workshop and a team of suitable staff chosen to visit these registered suppliers when possible to ensure that the suppliers meets the requirements and are qualified to provide the services they offer.

Once the appropriate companies or individuals have been identified and registered, the DTC should determine the type of arrangement they would like to have with the particular organization. The arrangement used depends on the sophistication of the equipment and the number of maintenance options available.

The most common arrangements encountered are:

1. Agents' Maintenance Contracts – typically for sophisticated equipment that is covered by a warranty for a certain period of time. The contract would be for service post-warranty and negotiated at the time of equipment purchase.
2. Annual Contracts – for particular types or groups of equipment that can be maintained by an external company for a period of one year. A formal tendering process should take place to select the best company to provide these services.
3. Annual Standby Registration – these companies or individuals can be called upon as needed to provide maintenance services for certain equipment although they must submit tenders at the time a job becomes available
4. One-off Jobs – in this case, the expertise needed may not be on the registered list and the MEMU must look for individuals or companies that might be able to undertake this one-time only task.

Having such arrangements allows the workshop to gain from the benefits of bulk purchasing (e.g. one company can cover many different maintenance jobs), gain from the benefit of fixed

period contracts; ensure that appropriate contractors are chosen and that the quality of work is high. Therefore, when a repair requiring external support becomes necessary, the Head of the Equipment Maintenance Department can refer to the registered list of companies and/or contracts to outsource the work.

The DTC should follow national guidelines for the use of outside contractors including:

- Staff from the maintenance department must accompany outside consultants at all times
- Contractor must provide feedback on progress of job
- Contractor must sign-out after each service visit
- Contractor will provide a report at the completion of the service to be placed in the equipment file

Workshops may also collaborate together to enter joint service contracts in order to minimize costs and benefit from bulk purchasing.

DISPOSAL OF MEDICAL EQUIPMENT

The health centre should establish Medical Equipment Disposal Committee to oversee the disposal of all medical equipment that are no longer required by the health centre, including medical equipment. Items may be disposed when they are no longer required by the health centre, cannot be repaired, or have reached the end of their useful lifespan (see **Appendix 9B**). A policy for the disposal of fixed assets should be established by the health centre and approved by health centre management.

Whenever an item of medical equipment is disposed it should be removed from the health centre inventory and a record should be entered into the Equipment History File to indicate that the item has been disposed. The Equipment History File should then be moved to a separate storage location for 'inactive' equipment items.

Further guidance on the disposal of health center assets, including medical equipment is presented in *Financial and Asset Management Chapter 1.*

Activity 9.3. Guided Practice	
	**Instruction:** **Using the guide on Table 9.2 develop medical equipment training plan for your health centers:** **Time:** 30 minutes.

Guidance 45: Training in equipment use and maintenance

Proper use of medical equipment is essential to maintain optimal performance of medical devices and preserve the safety of patients as well as the staff operating the devices. Given the variation in technical characteristics of medical equipment, all clinical staff should be trained to operate each medical device that they use. The DTC is responsible for overseeing all user training for medical devices, whether in-service or conducted by suppliers/external parties.

Training should be conducted at various times throughout a staff member's career:

- Induction training – when staff are newly placed in post, move to a new department or facility, or to a new location with different responsibilities
- Training at the commissioning of equipment – when new equipment first arrives
- Refresher training – to update and renew skills throughout the working life of staff

The health centre plans annually at least one-week long in-house refresher training program for its staffs. Participation in such refresher programs is mandatory and is part of the annual performance evaluation.

User training should cover:

- Equipment capabilities
    - Purpose and capabilities of device
    - Awareness of different models and operational differences
    - Awareness of the expected life of medical device and need for replacement
    - Knowledge of where/how to access user manuals and receive equipment updates
- Operating procedures
    - How to assemble the device and connect accessories
    - How to operate the device effectively and safely
        - How to link device to patient safely, causing minimal discomfort to patient
    - How to set/change controls
- Protocol for equipment failure
    - How to recognize malfunction (or correct if possible)
    - Who to contact to report damage and adverse incidents and to do so promptly
- Emergency and safety procedures
    - How to safely shut down/dissemble
    - How to clean/decontaminate device and maintain equipment in good operating condition
    - Basic safety protocol:
        - Always visually inspect equipment before each use.
            - Check for signs of damage or incorrect settings
            - Make sure all necessary parts are in place
        - Do not use equipment unless properly trained
        - Ask senior staff or other trained personnel when in need of assistance
- Maintenance procedures
    - How to perform basic, routine maintenance (if applicable)
    - How to request equipment maintenance (work order)
    - How to keep track of consumables and reorder when necessary

The DTC should establish an Equipment Training Plan that describes the training needs of health centre staff for the use of medical equipment. Table 2 describes the steps to develop an Equipment Training Plan.

Table 9.0.2: Steps to Develop an Equipment Training Plan

Process	Activity
The DTC (or its training sub-group):	
Identify existing needs	Refers to:

Process	Activity
	• Any record the DTC made when analyzing the Equipment Inventory that training was required • Any prompts, triggers or requests for training reported/submitted
Identify new needs	Study the Equipment Development Plan (EDP) and identify the training required to handle: • Planned equipment replacements • Planned new equipment purchases/donations or additional services • Problems with equipment operation, maintenance or management
Determine the range of training that will satisfy the needs	Consider: • The eight different areas for equipment-related skill development: basic handling, operation, application, care and cleaning, safety, user PPM, PPM and repair for maintainers, associated skills (procurement, stock control, financial management, etc.) • The three types of training required at different times in the working life of staff (induction, at commissioning and refresher training)
Determine the source that will provide the needs	Consider: • The various sources of training which provide the option for on-the-job or external courses • Any initiatives organized and provided by the central health service provider organization and donor programs
Prioritize across the needs	Prioritize the short-term and long-term actions
Prepare an overall Equipment Training Plan	Cover all aspects listed above for equipment-related skill development.

Training can be provided either on site or off site. When purchasing new medical equipment, the health centre can request that suppliers provide in-service training for equipment use, maintenance, and repair. The health centre can also send staff to the primary hospital maintenance workshop. The DTC should assess the quality of the manufacturer's user training to ensure it is practical and provides adequate training for equipment use. The health centre can also send staff to be trained at other facilities where employees are already trained and using the particular item of medical equipment.

The health centre can hold in-service trainings if it has staff that are professionally trained to operate and repair the specified medical equipment and has other needed resources to conduct the training (see below).
For in-service trainings the health centre should provide:

- Trainer (professionally trained expert in use, maintenance, and repair of medical equipment)
- Training materials specific to the piece of medical equipment
- Adequate space to conduct the training
- Sample equipment and supplies to practice/conduct the training

- Test and calibration instruments to test performance and safety
- Spare parts for maintenance training
- User and service manuals
- Formal method of testing and method of certifying trainees (e.g. give exam and issue certificate)

The Human Resource Department and DTC are responsible for keeping records of all user trainings. Training records should specify the name of the person trained, the trainer, the date of the training, the medical device for which training was conducted, its manufacturer and model. If possible, the content of the training should be appended or briefly described in the user training form. A sample User Training Verification Form is presented in **Appendix 9M**

Activity 9.4. Guided Practice	
	**Instruction:** **Based on the medical development plan & training plan you have worked on activity 9.2&9.3 develop a medical equipment budget plan for your health center** **Time:** 30 minutes.

Guidance 46: Budgeting for Medical Equipment Management

To effectively manage all medical equipment careful planning and budgeting is essential. As illustrated in Figure 2 below, there are a variety of costs to medical equipment. It is essential that entirety of costs for all medical equipment existing and planned purchases are considered when planning and budgeting.

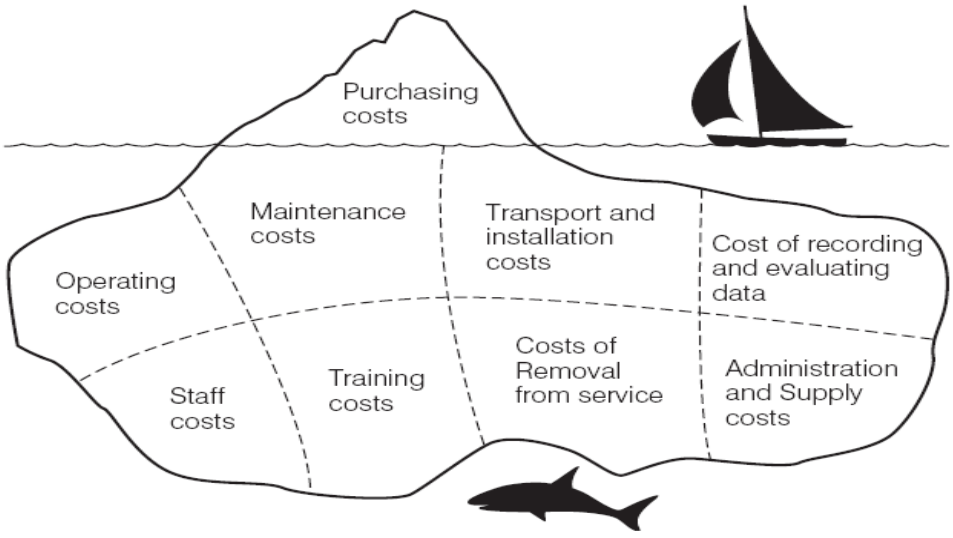


Figure 9.0.1: Hidden costs of medical equipment purchase

Source: Temple-Bird, C., KaurManjit, LenelAndreas,andWilliKawohl. (2005). *Guide 2: How to Plan and Budget for your Healthcare Technology.* In 'How to Manage' Series for Healthcare Technology.*p.58* Hertfordshire, UK: TALC.

The first step in preparing a budget for the management of medical equipment is to determine the value of existing stock. This is known as the 'Stock Value Estimate'. This should indicate the up-to-date replacement cost of all items in the Equipment Inventory. The up-to-date replacement value can be estimated from purchase contracts, supplier information, data from service contracts, manufacturer's websites etc. With the above information it is possible to calculate an annual equipment budget. This should be based on the Equipment Development Plan and should include:

- Replacement costs for current equipment
- Maintenance and repair costs
- Costs for new purchases for expansion of services
- Installation costs of new equipment
- Training costs

Replacement costs for current equipment

An annual replacement budget covers equipment likely to reach the end of its usefulness by the end of the year. A quick estimate of an annual replacement budget can be made using the Stock Value Estimate as follows:

Annual replacement budget = Stock Value Estimate/ average lifetime of all equipment
Further guidance on the calculation of replacement costs is presented in **Appendix 9N**.

Maintenance and repair costs

As an approximation, maintenance and repair costs for medical equipment are generally between 5-6% of the 'new' stock value. Hence the Stock Value Estimate can also be used to estimate the budget required for maintenance and repair.

Costs for new purchases for expansion of services

The Equipment Development Plan guides the purchase of new equipment for the health center. The cost of items that are due to be purchased in the Financial Year should be calculated and included in the Medical Equipment Budget.

Installation costs of new equipment

As described above, there may be costs associated with the installation of new items such as renovation, installation of plumbing etc. The equipment development plan should include a description of any installation work that is required. These costs should be estimated and included in the budget.

Training costs

The equipment training plan is the basis for the estimate of training costs associated with medical equipment use and maintenance.

BUDGET SUBMISSION

The equipment management budget that is prepared by the DTC should be submitted to the

health centre management for inclusion in the health centre's annual budget plan. The health centre should allocate items to capital or recurrent budget lines as appropriate.

9.4. Implementation Checklist and Indicators

9.4.1. Implementation Checklist

Table 9.3. Standards checklist for medical equipment

Std. #	Description of the standard	Verification Criteria	Yes √ No X	met =1 not met =0	Remark
1	The Drug and Therapeutic Committee (DTC) should be responsible to oversee the entire Medical Equipment Management.	Verify DTC TOR address medical equipment			
		○ Commissioning			
		○ Maintenance and history file documentation			
		○ Disposal			
2	The health centre has an active medical equipment maintenance work order system and ensure functional work relationship with workshops available within zone health department or nearby Primary Hospital.	MOU with ZHD/primary hospital workshop			
		Maintenance request form			
		Maintenance report form			
3	The health centre has a paper-based or computer-based current equipment history file documentation.	Users guide attached in file			
		Verify paper/computer based documentation is current			
		Preventive maintenance reports			
		Electronic/paper based medical equipment history update form-containing maintenance requests, reports and other documentations			
4	All new equipment's are installed and commissioned in accordance with the manufacturer's specifications and undergoes acceptance testing prior to its initial use to ensure the	Acceptance testing report			
		Installation report in line with manufacturer's guide			

Std. #	Description of the standard	Verification Criteria	Yes √ No X	met =1 not met =0	Remark
	equipment is in good operating condition(evaluate this standard if there is new equipment procured).				
5	All equipment operators and personnel are trained on proper application, safety, and maintenance of medical equipment.	Training plan			
		Training report			
6	The health centre ensures decommissioning including relocation, uses as spare, donation or selling.	Decommissioning plan			
		Decommissioning report			
7	Health center conducts proper disposal of medical equipment according to national and regional legislations.	Disposal plan			
		Disposal report			

9.5. Additional Reading Materials

1

Chapter 10: Human Resource Management

Chapter Description: The chapter describes the tools that need to be used by human resource team of a health center in human resource management. It also describes the procedures of recruitment, placement and employee retention stretegies. Finally the chapter explains the human resource standards to measure and continually reform your health centers.

Primary Objective: By the end of the chapter participants are expected to analyse tools and strategies for human resource management in a health center.

Enabling Objective: By the end of the session you will be able to:

- Identify tools for human resource management
- Discuss recruitment, placement and retention of human resource in health centers
- Evaluate human resource performances using reform standards

Chapter outline:
10.1 Introduction
10.2 Human resource team and tools
10.3 Recruitment, placement and retention of human resource
10.4 Implementation standards

10.1. Introduction

The most important asset of a health centre is the people who work there. Each employee is responsible for carrying out the health centre's duty to care for patients. A well-performing health workforce is one that works in ways that are responsive, fair and efficient to achieve the best health outcomes possible, given available resources and circumstances.

The main objective of the Human Resource Management (HRM) function is to ensure that the facility attracts, develops, retains, and motivates employees who are critical for achieving the organization's objectives of delivering high quality and safe patient care. The HRM undertakes these responsibilities based on established policies and procedures of civil service.
This chapter sets standards and provides guidance for the establishment of a human resource management function that contributes to the advancement of the vision, mission and guiding principles of the health centre.

10.2. Operational Standards for HRM

1. The Health Center (HC) has a HRM personnel staffed as per standard.
2. The HRM case team maintains a personnel file for each and every HC employee.
3. The health centre establishes and institutionalizes Human Resources Information Management System (HRIS) that enhance the HR management function.
4. The HC has annual plan that also addresses Human Resource Development (HRD), staff numbers, skill mix and staff training and development.
5. The Health Center adopted and implemented benefits and motivation packages to ensure satisfactory productivity.

6. The HC has a performance management process in which all employees are formally evaluated at least two times per annum.
7. The HC has an HR policy and procedure related to human resource management and code of conduct that is known, and adhered to, by staff.
8. The HC regularly conducts a staff job satisfaction survey and exit interview to assess staff opinions about their workplace.
9. Health centre established occupational health and safety system to identify and address health and safety risks to staff.
10. Health center has grievance management system

10.3. Operational guidance

Activity 10.1. Reflection on human resource team and tools	
	**Instruction:** Reflect your ideas on "What are the minimum tools an HRM team need to work on? **Time:** 5 minutes

Guidance 47: Human resource team and tools

HUMAN RESOURCE DEVELOPMENT PLAN

The health centre will have human resources management team that keeps employees profile. It should develop human resource development plan and get approval of the management committee. As part of the management committee the HR team lead should utilize the management committee for evidence-based decision making in achieving optimal human resources in the health center.

BENEFIT AND MOTIVATION PACKAGE

Health center should have a clear staff benefit and motivational package approved by governing body in order to retain a qualified and experienced staff, so as to enable fully motivated towards achieving the facility mission and vision. In addition to the basic salary, pension, opportunities for duty, risk allowance, uniform allowances and employees may be provided with additional benefits or opportunities as determined by governing body. This form of compensation add to the overall cost of labour for the health centre, so decisions regarding fringe benefits must be evaluated to maximize employee satisfaction and minimize costs, motivates staff to improve performance, retain staff and attracts new employees to the health centre. The HRM Case Team should strive to establish good employer-employee relationships that contribute to satisfactory productivity, motivation and moral. Employee relations are directed toward preventing and resolving problems involving individuals that arise out of or affect work situations.

The possible staff benefits and motivation packages to be considered in the HC may include: Library access, access to recreational service (cafeteria, break room, green area etc), refreshment programs (study visit), risk free environment, performance based private wing

participation, creating smooth employee/employer relation, objective based training and carer development opportunities, performance based recognition program (rewards: certificate, thank you letter etc) and others are some of the benifits and motivators of an employee working in the health center which is thought as enablers to retain them.

CODE OF CONDUCT

The health center should have a code of conduct and professional ethics manual which should be known by all employees. In addition the HR should ensure that all employees are aware of existing national and regional proclamations as well as directives. Health centre ensures that all employees wear badges and appropriate uniforms at all times.

Each health centre should ensure that employee works as per the standards that governs employee conduct. The standards should include what is expected from the employee in their work, their interactions with patients, caregivers, visitor and other staff, confidentiality etc.

Badge and uniform Dressing code and identification: The health centre should ensure guideline which clearly and strictly define dress codes for all employees. Such guidelines should explicitly list each article of clothing, the colour, and condition which is acceptable in health centre settings. The health centre should also have a guideline to ensure that all staff wear their identification badges at all times in work premises**.**

EMPLOYEE JOB DESCRIPTION

Job description is a short statement that includes information about an employee's assigned duties and responsibilities. This should be derived from the position's objectives, skills and trainings required to perform the positions tasks. The job description should be developed by the HR team in consultation with the medical director of the health center. Each employee's responsibilities are defined in a current job description, which has been signed by the employee and filed in their personal file. It should be kept under review and amended if the need arises based on the template Job descriptions from MoH or RHB of each profession. If an employee is promoted or transferred to another position then a new job description should be signed for the new position.

Job description should contain at least the following information:

- Job Title,
- Reporting to,
- Department/case team,
- Employment type,
- Job Summary,
- Responsibilities,
- Qualifications,
- Licenses,
- Experience, Other required skills Physical Demands,
- Description of job site and work environment,
- Occupational Exposure Salary and Benefits,

- Date, Employee Name and Signature.

PERSONNEL RECORDS

The health center shall have a unit or focal person who carries out the major functions of Human Resource Management (HRM). Each health center shall maintain a current employment record for each staff. The record shall contain, at a minimum, information on credentials, health examination (fitness for duty), work history, current job description, and evidence of orientation, in-service education/training and copies of annual evaluation. The health center also shall have summary of health care providers profession, gender and number. For organizational and legal purposes, health centres should maintain and regularly update a file on each employee that includes information such as credentials for hiring, ongoing performance evaluations, and any documentation concerning performance improvement action. Employee files are also the repository of documents defining the mutual understanding between the employee and employer concerning workplace policies and performance expectations. Health centres should choose to install a computerized database to manage selected human resource information where it provides easy retrieval of information for audit and planning purposes. The health center should ensure employee records are private and confidential.

The health centre establishes and institutionalized Human Resources Information Management System (HRIS) that enhance the HR management function.

Guidance 48: Recruitment, placement and Retention

The human resource team in coordination with the management need to ensure that the required number and mix of professionals are in place. In cases of recruitment need the following points have to be noted to ensure transparency and equal opportunity for all.

- 1) Recruitment: vacancy announcement, screening of applicants
- 2) Job applicant interviews
- 3) Reference checks
- 4) Employment offers
- 5) New staff induction/Orientation
- 6) Promotion, secondments and transfers

RECRUITMENT, HIRING AND ORIENTATION

Recruitment involves searching for and attracting prospective employees, either from outside or inside of the health centre. The HC should recruit based on national or regional civil service proclamation and directives or procedures of recruitment. The HC ether receive already recruited or assigned staff by concerned body and also process each remaining activities or recruit by its own as per the proclamation.

HRM case team or case worker should prepare new-hire orientation session to all new employees. The orientation provides information about the health centre's mission, vision and values – and helps build the employee's sense of identification with the organization. The orientation should include an overview of the job expectations and performance skills needed to perform the job functions and an explanation of reporting structures and mechanisms. The

Employee Code of Conduct and Statement of Employee Rights and Responsibilities should be introduced to the worker at this stage.

HRM Case Team or case worker should also provide regular (at least yearly) recurring orientations or inservice orientation to all staff in order to familiarize new policies and procedures and refresh the basic civil service rules and regulations.

PERFORMANCE MANAGEMENT

The health center should have a performance management process and reward policies in which all employees are formally evaluated at least semi-annually, higher performers are recognized and rewarded, and action plans for improvement are documented. Performance management is an on-going process focused on reinforcing high performance or improving substandard performance to enhance the knowledge, skills and behaviours of all employees in order to achieve organizational goals. The HC should improve the performance of staff through supportive supervision, performance-based evaluation and performance improvement for the overall success of the facility.

Supportive supervision is a continuous and participatory process, where a supervisor or leader accepts shared responsibility for an employee's professional development to get the best possible performance from the employee.

Performance-based evaluation (PBE) is the practice of periodic review and evaluation of an individual's or team's performance against specified goals or expectations. The evaluation should be conducted using the framework of 'Balanced Score Card' (BSC).

The Performance Improvement Process (PIP) is designed to identify, communicate, and intervene when job performance is below expected standards. Performance improvement interventions should be initiated as soon as it becomes apparent that an employee is not meeting expected performance standards. Supervisors should not wait until the end of the review period to communicate the need to improve performance if the need to improve is identified earlier in the period. The HC should have PIP in order to improve the performance of employee through coaching and counselling. In all cases of poor performance, the supervisor should consult with the HRM case team or case worker and other management committee as necessary for advice and decision making about any actions necessary.

All PBE results and any Performance Improvement measures should be documented in the employee personnel file for follow up and future reference.

TRAINING AND DEVELOPMENT

Continuing Professional Development (CPD)

Health professionals and their employing organization will identify their learning needs based on their performance appraisal and ability to accomplish annual plans. Then the identified CPD needs shall be revised and approved by the immediate supervisor. The immediate supervisor will send compiled needs in the unit/Directorate to the responsible unit or directorate in the facility or organization. Eventually, compiled CPD needs will be present at the facility, Woreda health office, zonal heath department and regional level.

FMHACA's Continuing Professional Development (CPD) Guideline for Health Professionals define Continuing Professional Development (CPD) 'as a range of learning activities through which health professionals maintain and develop throughout their career to ensure that they retain their capacity to practice safely, effectively and legally within their evolving scope of practice'. This definition emphasizes the need for health professionals to maintain, update and enhance their knowledge, skills and attitude in order to adequately deliver quality health care. Health professionals need to cope up with the changing disease pattern in which diseases that had been eradicated are now reemerging, as well as an increase on non-communicable diseases.

CPD helps to maintain professional competence in an environment of numerous challenges, rapid organizational changes, information technology, increasing public expectation and demand for quality and greater accountability. CPD is an ethical obligation for all health professionals to ensure their professional practice is up- to- date and can contribute to improving patient outcomes and quality of care. It is also a mandatory for health professionals practicing in Ethiopia. Health professionals should accumulate the mandatory credit hours or certificates of training attendance for relicensing their profession every five years.

According to the FMHACA's Continuing Professional Development (CPD) Guideline for Health Professionals, some of the features of CPD applicable to the context of health centers are:

- Continuing professional development refers to all activities health professionals
- undertake formally so as to maintain, update and develop their knowledge, skills and attitudes in response to the health service needs of the public
- Continuing professional development denotes to the period of education and training of health professionals commencing after completion of basic or post graduate health professional training
- Continuing professional development is a broad concept referring to the continuing development of the multi-faceted competencies inherent in health services covering wider domains of professionalism needed for high quality professional performance.
- It aims to maintain and develop competencies of individual health professionals essential for meeting the changing needs of patients and the health service system and responding to the new challenges of scientific development
- Continuing professional development must serve the purpose of enhancing the professional development (what is relevant to current practice and the future profession) of health professionals

Renewal of licensure

No health professional shall practice his/her profession in the health center without having professional license from the appropriate organ. The health center shall ensure that all health professionals recruited by the health center are licensed as per the registration and licensing requirement of the appropriate organ. Each health center shall ensure and maintain evidence of current active licensure, registration, certification or other credentials for employees and contract staff prior to staff assuming job responsibilities and shall have procedures for verifying that the current status is maintained.

A license, unless suspended or revoked or under consideration in pending case, should renewable annually and the Health center should submit an application for license renewal to the appropriate organ no later than sixty (60) days before the expiration date of the current license.

OCCUPATIONAL HEALTH AND SAFETY (OHS)

Each person involved in direct patient care shall have an occupational health screening by a physician or other qualified health professional prior to entering active status and at least once every five (5) years thereafter. A health professional shall not conduct health examination for himself/ herself. Each health screening shall include a medical history, physical examination, and any indicated laboratory work and investigations. A report, signed by an examining physician or other qualified health professional, shall be made of each examination. The report of each examination shall be kept on file in the health center and shall be open to inspection by the appropriate organ.

Immunization against communicable disease shall be required of all employees and all other persons who routinely come in contact with patients or patient areas. Immunizations shall be in accordance with current national immunization guidelines.

Every health professional shall report to the health center whenever he/she is infected with contagious diseases. The health professional shall not practice his/her profession during the period of such infection and his/her rights provided under the relevant employment law and the health center's HR manual shall be respected.

Occupational health and safety deals with the overall working environment suitability for employees so as to enables to increase efficiency and effectiveness of the health center. Maintaining a safe work environment for health centre employees is essential for the provision of quality care and for promoting staff satisfaction. Both the health centre and employees play a role in ensuring occupational health and safety. The health centre should ensure that a work premise does not cause hazards and personal protective equipments are provided. Employees once provided with necessary information, should properly use safety devices and materials, and report any problems or defects of materials/equipment, as well as report any situation which they feel presents a hazard at the facility.The HC should have a work place hazard reporting mechanism both within the facility and external body. The health centre management committee should assess the risks that might occur in the work place like Needlesticks, Slips, trips and falls, Violence and aggression (from patients and/or other staff), Hazardous substances (chemicals, drugs etc), Harassment (from patients and/or other staff), Stress etc through work place inspection.

The health center management should focus on initiating staff to report occupational hazards and immediate remedial actions.

EMPLOYEE SATISFACTION

Health Centre provides services to employees to ensure satisfactory productivity, motivation, and morale as evidenced by effective policies and procedures for personnel retention, compensation and benefits, training and development and employee recognition. The HC regularly conducts a staff job satisfaction survey and exit interview to assess staff opinions about their workplace.

GRIEVANCE MANAGEMENT

A grievance is a concern or complaint that an employee has about his/her job, for example his/her employment terms and conditions, work environment, contractual or statutory rights or the way he/she is being treated at work. Grievances can often be avoided by good communication between employees and senior managers such that problems are identified and corrective action taken at an early stage. Grievances are more likely when employees feel that their views are not being heard or their concerns are not being addressed. Grievances are more likely to be settled when employees perceive that the process is transparent, fair and without retribution for the employee. The health center should handle grievance based on the proclamation as early as possible to prevent further crises.

TERMINATION OF EMPLOYMENT

Whenever a licensed health-care professional is terminated as a result of a job-related incident, the health center shall refer a report of the incident to the appropriate organ.
A worker's employment may end through retirement, resignation, termination by the employer or death. Whenever an employee leaves the workplace an exit interview should be conducted to gather information about the employee's experience and any lessons that could be learned for future employees. The exit interview should be reviewed by the HRM case team coordinator or case worker to identify areas for follow up and action, and thereafter should be documented and filed.

10.4. Implementation Checklist and Indicators

10.4.1. Assessment Tool for Operational Standards

In order to determine if the Operational Standards of HRM have been met by the health centre an assessment tool has been developed which describes criteria for the attainment of a Standard and a method of assessment. This tool can be used by health centre management or by an external body such as the RHB or MoH to measure attainment of each Operational Standard.

Table 10.0.1: Assessment Tool for Operational Standards - Human Resources Management

Std. #	Description of the standard	Verification Criteria	Yes √ No X	met =1 not met =0	Remark
1	The Health Center (HC) has a HRM personnel staffed as per standard.	Employment or assignment letter			
		Check Letter of assignment of HR lead to Management committee			
2	The HRM case team maintains a personnel file for each and every HC employee.	Randomly select five files and check the following points.			
		Employment or assignment letter			
		Job description			
3	The health centre establishes and institutionalizes Human Resources Information Management System (HRIS) that enhance the HR management function.	Electronic/paper based employee profile including:			
		- Socio-demography			
		- Employment history			
		- Trainings & CPD			
		- Family			
		- Profession			
4	The HC has annual plan that also addresses Human Resource Development (HRD), staff numbers, skill mix and staff training and development.	Current annual plan			
		Reports on HRD			
5	The Health Center adopted and implemented benefits and motivation packages to ensure satisfactory productivity.	Motivation plan			
		Identification and recognition of best performers			
6	The HC has a performance	Select 5 files and check :BSc based plan			

Std. #	Description of the standard	Verification Criteria	Yes √ No X	met =1 not met =0	Remark
	management process in which all employees are formally evaluated at least two times per annum.	BSC based performance appraisal			
7	The HC has an HR policy and procedure related to human resource management and code of conduct that is known, and adhered to, by staff.	Check presence of policy			
		Interview 3 staff on knowledge of policy			
		All staff wear			
		○ ID badges			
		○ gown			
8	The HC regularly conducts a staff job satisfaction survey and exit interview to assess staff opinions about their workplace.	Survey checklist			
		Survey report			
		Filled Exit interview tool in files of employees left the HC			
		Action plan based on results			
9	Health centre established occupational health and safety system to identify and address health and safety risks to staff.	Employees safety need assessment			
		Employees safety plan			
		Employees safety implementation report			
10	Health center has grievance management system	Grievance management committee			
		Grievance collection forms, registration, box			
		Weekly grievance management action plan/reports/minute			

10.4.2. Indicators

In addition, these indicators may be monitored on a regular basis to assess the effectiveness/ outcomes of implementation of the recommendations provided in this chapter.

Table 10.0.2: Human Resources Management Indicators

S/N	Indicators	Formula	Frequency	Comment
1.	% of posts filled as per the regional standard	Total number of posts filled ÷ total number of posts as per regional standard x 100	Quarterly	HMIS indicator
2.	a) Total number of health officers	a) Total number of health officers at end of reporting period	Quarterly	HMIS indicator

S/N	Indicators	Formula	Frequency	Comment
	b) Attrition rate	b)Total number of health officers who left during reporting period/total number of health officers at beginning of reporting period * 100		
3.	a) Total number of nurses b) Attrition rate	a) Total number of nurses at end of reporting period b) Total number of nurses who left during reporting period /total number of nurses at beginning of reporting period * 100	Quarterly	HMIS indicator
4.	a) Total number of other clinical staff b) Attrition rate-	a) Total number of other clinical staff at end of reporting period b)Total number of other clinical staff who left during reporting period/total number of other clinical staff at beginning of reporting period * 100	Quarterly	HMIS indicator
5.	a) Total number of - non clinical staff b) Attrition rate	a) Total number of non clinical staff at end of reporting period b)Total number of non clinical staff who left during reporting period/total number of non clinical staff at beginning of reporting period * 100	Quarterly	HMIS indicator
6.	Cumulative number (%) of staff who underwent performance evaluation	Total number of staff who underwent performance evaluation from beginning of year to end of reporting period ÷ total number of staff at beginning of year * 100	Quarterly	
7.	a) Number of staff with performance that is less than satisfactory b) Proportion of employees with less than satisfactory performance	a) Total number of staff with performance that is less than satisfactory b) Total number of staff with performance that is less than satisfactory/ Total number of staff who underwent performance evaluation*100	Quarterly	
8.	a) Cumulative number of staff who received in service training b) % of staff who received in service training	a) Total number of staff with in-service training from beginning of year to end of reporting period b) Cumulative number of staff who received training/total number of staff at beginning of period *100	Quarterly	HMIS indicator
9.	a) Number of new staff who received new hire orientation during reporting period b) % of new staff who received new hire orientation	a) Total number of new staff who received a new hire orientation b) Total number of new staff who received a new hire orientation / total number of new staff *100	Quarterly	

S/N	Indicators	Formula	Frequency	Comment
10.	Number of grievances received	Total number of grievances recorded by the HR department	Quarterly	
11.	Number of occupational injuries reported	Total number of occupational injuries reported	Quarterly	

10.5. Additional Reading Materials

- Ethiopian Hospital Reform Implementation Guidelines, Federal Democratic Republic of Ethiopia Ministry of Health, Ethiopian hospital services transformation guidelines, Volume 2, September 2016
- Health center standard (ETHIOPIAN STANDARD)

Chapter 11: Clinical Governance, Quality improvement and safety

Chapter Description: This is a new chapter included in the health center reform guide. It is intended to organize and address patient afety and quality improvement activities of a health center. The chapter guides through the principles of quality governance, methodoligies of quality improvement and regular related interventions including clinical audit, root cause analysis and quality improvement design. It also addresses the roles and responsibilities of all stakeholders involved in ensuring the quality of health services in a health center.

Primary objective: By the end of the chapter participants are expected to use the steps and procedure of clinical governance, patient safety and quality improvement in implementing and monitoring at a health center level.

Enabling Objectives: By the end of the session you will be able to:

- Discuss the principles of clinical governance
- Identify quality improvement models
- Explain the relationship between EPHCG, clinical audit and quality improvement
- Explain patient safety standards that need to be met by a health center
- Assess the clinical governance, patient safety and quality improvement practices of helath centers
- Synthesize and provide feedback for improvement to health centers

Chapter Outline:

11.1. Introduction

According to MOH of Ethiopia, **Health governance** is defined as the process of "competently directing health system resources, performances, and stakeholder participation toward the goal of saving lives and doing so in ways that are open, transparent, accountable equitable, and responsive to the needs of the people. *(*Health Facility Governance in the Ethiopian Health System *2020)*

The Ethiopian National Quality Strategy defined **quality** to be "care that is measurably safe, of the highest standard, evidence-based, uniformly delivered, with the appropriate utilization of resources and services."

Governance for Quality can also be defined as "Competently directing health system resources, performances, and stakeholder participation toward the goal of saving lives and doing so in ways that are open, transparent, accountable, equitable, and responsive to the needs of the people (LMG facilitator guide)

Clinical Governance is the system through which health facility are accountable for continuously improving the quality of their services and safeguarding high standards of care, by creating an environment in which clinical excellence can flourish. It is essentially a quality control system that helps health facility monitor the quality of care they deliver. (EHSTG II ,2016)

Achieving sustainable changes to quality and safety is not easy and requires a strategic, consistent and evidence informed approach at all levels in the organization. Governance for quality is important to address the following areas of consistent failure (Hall, 2012):

- **Leadership of quality is weak**: It may include lack of awareness of quality indicators, lack of discussion among various actors in the system and inability to challenge the existing practices and not adequately prioritizing quality in the system.
- **Failure to recognize a problem:** Information provided to the board is insufficient to enable action (particularly proactive action).
- **Lack of assurance:** Check and challenge of frontline compliance, the board has taken sensible actions but has no assurance process to check they are being complied with; the board has no mechanism to independently assure quality governance.
- **Inadequate risk management:** Inability to identify risks and put in place proper actions, too much reliance on third parties, ineffective risk management, lack of clinical engagement with some or all staff.
- **Inadequate implementation of policies, procedures, protocols and guidelines:** a focus on availing policies, procedures, protocols and guidelines rather than appropriate use.

11.2. Operational Standards

1. The health center has a functional multidisciplinary team that leads clinical governance, quality and safety.
2. The health center has operational plan disaggregated by quarter for clinical governance, quality and safety.
3. The health center implement citizen charter for the services they render.
4. The health center ensured adherence to Primary Health Care Clinical Guideline (EPHCG) to provide standardized clinical care and ensure quality and safety.
5. The health center implemented quarterly clinical audit (using EPHCG ,health center clinical audit) and use the findings for quality improvement and assurance
6. The health center identified priority problems on quality services and implemented quality improvement projects (Kaizen, Models for improvement)
7. The health center conducted quarterly community score card and town hall meetings with the community to monitor service quality and ensure accountability.
8. The health center participates quarterly in collaborative learning and experience sharing platform of Ethiopian Primary Health Care Alliance for Quality (EPAQ).

9. Health center conducts Patient satisfaction survey bi -annually
10. Procedures are established to asses and minimize risk to patients during health care service.
11. Health center conducts quarterly good governance index assessment.

Activity 11.1. Group discussion

Instruction:

- Be in group of 5-6 people
- Discuss one of the topics below in your group and report the work in the plenary (share group response to the larger groups using flipchart)

Discussion Question:

- Principles of clinical governance
- National Quality framework
- Clinical governance, patient safety and quality improvement committe

Time: 30 min for reading and discussion 15 min for presentation

11.3. Implementation guidance

Guidance 49: Principles of good governance

Effective governance is increasingly recognized as pivotal to improvements in healthcare quality and patient experiences. Clinical governance is the main vehicle by which health care facilities are held accountable for safeguarding high standards of health care, continuously improving the quality of their services, and creating and maintaining an environment in which clinical excellence can flourish. Therefore, clinical governance can bridge the gap between managerial and clinical approach to quality care. There are a variety of conceptual frameworks that seek to identify the attributes of good governance. This section draws on the attributes of good governance identified by the United Nations Development Program (UNDP).

Stewardship: Stewardship refers to the "careful and responsible management of something entrusted to one's care". Those who exercise the authority to make policy – the minister of health and others who work to reform public health laws – must exercise stewardship, putting aside personal desires and working to maximize the health interests of the people they serve.

Transparency: Transparency is "built on the free flow of information". It requires that, as far as possible, the process of developing, implementing and enforcing the law should be open and visible to the public. Transparency helps to build public understanding about the law, and confidence that legal powers will be exercised for the benefit of society as a whole.

Participation: In cases where the law is intended to influence and alter behaviour, it is important that those who are directly affected by the law should be aware of it, understand it and also appreciate the goals.

Fairness: the principle of fairness makes a significant contribution to good governance because it encompasses the related human rights of equality and non-discrimination. Article 26 of the International Covenant on Civil and Political Rights states: *the law shall prohibit any discrimination and guarantee to all persons equal and effective protection against*

discrimination on any ground such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status.

Accountability: Accountability means taking responsibility for the success and failure of laws and policies, and putting processes in place to ensure that changes are made to improve decision-making and the performance of public health functions in future. In the context of public health law reform, accountability requires that legislation should set out the responsibilities and functions of public health officials so that it is clear who is accountable for enforcing the law and for exercising powers to protect the public's health.

The rule of law: The principle of the rule of law means that all persons, officials and institutions, including the State itself, are accountable under laws that are publicly disseminated, equally enforced, independently adjudicated, and consistent with international human rights standards. *(Advancing the right to health: the vital role of law,)*

Guidance 50: National Framework for quality

As per the national quality and safety strategy of Ethiopia, Quality is defined as comprehensive and integrated care that is measurably safe, effective, people-centered, and uniformly delivered in a timely way that is affordable to the Ethiopian population and appropriately utilizes resources and services efficiently. It has seven generally accepted dimensions: Table 11.1

Table 11.1. Dimensions of health service quality

Quality dimensions	Definitions
Safe	avoiding injuries to patients from the care that is intended to help them; the WHO defines "patient safety" as the prevention of errors and adverse effects to patients associated with healthcare.
Effective	the care is based on evidence-based knowledge and evidence-based guidelines
People-centred	It must consider the people's needs, preferences and values while delivering health care, characterized by respect and dignity of the users. Health care driven by people-centeredness shifts the power from the health care system and providers to patients/users of the system. The health system should aspire a vision of providing people centred care. People-centred care has the following attributes: • Continuity: from illness prevention to palliation; between services (example maternity and paediatrics); and between levels of care (example primary to specialist care). • Coordination: across different care settings, in ways that meet the particular needs of the individuals and carers; • Comprehensiveness: that broadens the range of service the individuals and communities can use: from health promotion through to palliative care.
Timely	reducing waits and sometimes harmful delays for both those who receive and those who give care
Efficient	avoiding waste, including waste of equipment, supplies, ideas, and energy
Equitable	providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status

Integrated	care provided to the patients are coordinated across the health platform and individual care providers. It ensures continuity—both system's ability to retain users; and users could see a physician who is familiar with their medical history—and integration of care—complementarity and coherence of care across the health platforms. This characteristic is especially highly needed in treating non-communicable and other chronic diseases like HIV/AIDS

Table 11.2 High-quality health systems should be informed by four values

Values	Value components
They are for people	• Health systems must reach people (Access) • The emphasis on people-centeredness (Information &power asymmetry)
Equitable	• High-quality health care needs to be available and affordable for all people • Quality improvements should explicitly include poor and vulnerable people to redress existing inequities.
Resilient	• Respond to routine challenges • Requires accountable leaders who respect and motivate their frontline staff.
Efficient	• Aim to avoid waste and • Achieve the maximum possible improvement in health outcomes with the investment received

QUALITY PERSPECTIVES

In healthcare, key stakeholder's expectations of quality

- Health managers at different levels (Ministry, Regional, Zonal, woreda Facility etc.) may focus on the image of the facility or the health system, human resources, efficient use of resources, performance in key health indicators, cost recovery etc.
- Healthcare provider's expectation may be availability inputs, an enabling environment, staff motivation, outcomes of morbidity and mortality etc.
- Client's expectation will be staff attentive listening, friendliness, privacy, confidentiality, waiting time, technical competence, clean environment, availability of drugs, good clinical outcomes, providing information and obtaining feedback etc.
- Community's expectations are access to care, affordability, societal norms etc.

Overall, the pursuit of quality is a fundamental requirement in the health sector.
Patients generally look at quality from three perspectives. They are,

- Don't harm me
- Heal me
- Be nice to me

CORE COMPONENTS OF QUALITY MANAGEMENT IN HEALTH CARE

There are three core components of quality management in Healthcare, namely quality planning, quality improvement, and quality control. They all go hand in hand. It just like a three-leg stool. If one of the legs is not there you cannot sit on it. Leveraging all three pillars (namely quality planning, quality control and quality improvement) in a holistic way is one of the key foundations of Ethiopia National Healthcare Quality Strategy.

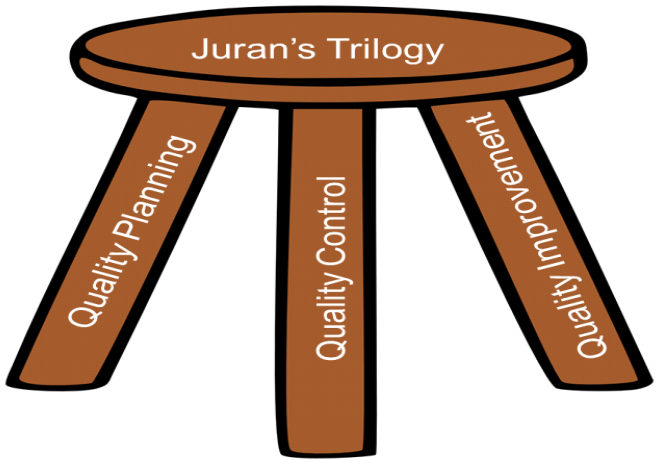


Figure 11.0.1: Juran's trilogy(Quality planning, quality control and quality improvement

Quality Planning: as outlined in the HSTQ, it is a systematic process that:

- Brings systems thinking to the highest levels of leadership and governance:
    - Priorities
    - Structures (e.g.: quality directorate)
    - Data systems
    - Building capability
    - safety
- Responds to the measured gap between what the population needs and what is currently being delivered in the health system
- It then establishes the goals, policies and strategies to close this gap, and ensures that the resources are allocated to do this effectively
- Involves designing a structure that delivers the right care to patients at the right time, every time

In the facility level, quality planning can include the following but not limited to:

- Establishing and strengthening quality structure.
- Adopt/adapt/develop service standards.
- Regular performance monitoring activities.
- Institutionalize the principles and practice of QI.
- Undertake regular capacity development programme.

Quality Control: is defined as *"the regulatory process through which we measure actual quality performance, compare it with quality goals, and act on the difference"* (Juran, 1988). Quality assurance (QA) measures compliance against certain necessary standards. Quality control also includes the following;-

- Seeks to ensure that quality is maintained or improved, and errors are reduced or eliminated.

- Programs evaluate current Healthcare quality, identify problem areas, create a method to overcome issues, and monitor the method taken to improve quality.
- Processes consist of both internal quality assurance and external quality assurance (for instance, these monitoring and improvement activities may be internally motivated (problems are identified and addressed from within a Healthcare facility by a facility based QI team) or externally required (standards are set, and problems are identified through inspection by government agencies (woreda, zone, region, federal)).
- Internal monitoring – continuous measurement.
- External inspection – intermittent inspection.
- Internal and external regulations – professional oversight, accreditation.

Quality Improvement (QI): is defined as *"the organized creation of beneficial change; the attainment of unprecedented levels of performance"* (Gibbons, 1994). Steps of quality improvement includes;-

- Set aims.
- Introduce change
- Set measurement for improvement
- Test intervention
- Measure changes in work routines.
- Observation ,testing and feedback
- Spread best practices for rapid uptake at a larger scale to address a specific issue or suite of issues they have determined to improve.
- Observation, testing and feedback

Quality improvement is focused on improving the different components of health service quality and is linked to measuring the level of quality and utilizing this measurement for improving the service quality. The process of performance and quality improvement involves every individual and unit and is the day to day responsibility of everybody involved in the service provision. Outcomes of health service need to be the focus for improvement. The processes that lead towards the outcomes and the inputs required to conduct the processes are also key components in the performance and quality improvement process.

ORGANIZATION CULTURAL ELEMENTS OF QUALITY

Culture change within organizations is fundamental to health services to be able to deliver continually improving, high quality and compassionate care. Organizational cultures in health care must be nurtured in parallel with changes in systems, processes and structures. The following five key cultural elements are necessary for sustaining cultures that ensure high quality and compassionate care for patients.

Five Key Cultural Elements for Sustaining High-Quality Care

1. Inspiring visions operationalized at every level
2. Clear, aligned objectives for all teams, departments and individual staff
3. Supportive and enabling people management and high levels of staff engagement
4. Learning, innovation and quality improvement embedded in the practice of all staff
5. Effective team working

INTERVENTIONS TO IMPROVE QUALITY OF CARE

1. Changing clinical practice at the front line (Service re-design)
2. Setting standards
3. Engaging and empowering patients, families and communities
4. Information and education for health care workers, managers and policy-makers
5. Use of continuous quality improvement programs and methods
6. Establishing performance-based incentives (financial and non-financial)
7. Legislation and regulation

Guidance 51: health center clinical governance, quality and safety committee

The health center should establish a multidisciplinary team that leads clinical governance, safety and quality improvement initiatives. The team will also be the main facilitating body to ensure adherence to quality standards at the health center.

TEAM COMPOSITION

The team will be chaired by the health center head and will have 6 additional members including (but not limited to) MCH, OPD/+IPD, HEP Coordinator, pharmacy & laboratory professionals, HIT officer and administrative staff and admin.

ROLES AND RESPONSIBILITIES OF THE COMMITTEE

- Develops operational planning on health service quality,
- Ensures implementation of patient rights and responsibilities,
- Monitors adherence to primary health care clinical guideline in the diagnosis and management of patients,
- Conducts clinical audit using EPHCG and other audit tools and ensure the findings to be used for quality improvement.
- Designs and implements quality improvement cycles using quality improvement models.
- Monitors the implementation of community score card and town hall meetings with the community and ensure the feedback from the community will be used for service quality improvement.
- Ensures continuous learning on primary health care service quality through collaborative learning and sharing experiences through EPAQ platform.
- Ensures engagement of all staffs of the health center and senior management team to ensure adherence to the standards for clinical governance and quality improvement.
- Outlines indicators and use these indicators to regularly monitor health center performance, analyze under-performances & lower level of quality, and responsible to design interventions & strategies for improving priority problems.
- Monitors each case team/service unit to conduct chart review, run PDSA cycle, act for identified problems, document best practices and report to the performance and quality team.

- Provides formal report to next level health office.
- The focal person of performance and quality improvement team will be a secretary of the performance and improvement team
- Ensure regular data review and data use
- Ensure the implementation of Safety and clinical governance activities

HEALTH CENTER GOVERNING BODY IN QUALITY OF CARE

In this context governing body includes both the governance board and management committee of the health center, since they both contribute for the delivery of quality health service. Desired Characteristics of Governing Board members to achieve quality and safe health care are:

- Skills or Expertise
- Commitment
- Volunteer
- Diversity
- Serve the needs of the organization first
- Be objective

Characteristics of an effective Governing body to achieve high quality care

- Mission-Centered
- Strategic Planning
- Governing body with 'Diversity'
- Training and Development
- Professionalism
- Self-Evaluating
- Collaborative

Roles of Health Center Governing Body in assuring High-Quality Care

Health Center Governing Body have an essential role in promoting a culture of quality and safety of care through their own behaviors and actions by:

- Setting one large goal for quality and safety for the organization
- Making quality and safety of care a core part of the board's meeting agenda
- Reflecting the core values of the organization in the decisions of the board
- Supporting the provider in becoming a learning organization
- Ensuring effective systems exist for evaluating and improving the delivery of high-quality care
- Mainstreaming quality in all aspects
- Ensuring a reliable data capturing, analyzing and interpreting system in place
- Make sure improvement as a day-to-day task of all health care providers
- **Use of evidence for decision making**
    - Encouraging all activities and plan based on the evidence generated
    - Use evidence as in put for quality improvement
    - Sharing service user stories at board meetings
    - Fostering a culture of transparency and honest communication

- Encouraging and supporting the executive to identify resources for staff education on improving quality and safety
- Supporting the executive in developing the provider's program for improving quality and safety
- Integration

The governing body is also responsible for assuring the design of quality program to:

1. Adequately monitor the delivery of care and services
   - Activities that could create risk or harm are easily identifiable.
2. Easily identify opportunities to drive improvement into existing systems and activities.
3. Assure effective linkages between the different activities in an organization are designed to protect patients from harm and
4. Assure compliance with current standards of care
5. Assure that changes for improvement remain in place over

Monitoring performance

Evidences show that facility governing boards often fail to set goals, monitor progress, and to hold staff accountable for performance related to the quality care. In addition, a significant number of facility managers and governing boards do not prioritize quality of care in their agendas. In their efforts of monitoring of performances, the needs to pay attention to the following:

- Data are very vital for continuous quality improvement
- Set goals/planning quality
- Make facility walk-through visit
- Regular review of performance
- Quality performance should be on the agenda at every governing body meeting
- Regularly reviews quality dashboard/KPI dashboards and client satisfaction surveys
- Hear community's concerns
- Motivate staff

Activity 11.2. One minute paper	
	**Instruction:** - Write down two common quality improvement models with their main features and reflect your idea in a discussion **Time:** 5 minutes

Guidance 52: Quality improvement models: Kaizen, Models for improvement

The two selected QI Models to be used in the Ethiopian healthcare are:

1. **Kaizen:** Engine driving improvement or the entry point of all QI activities
2. **Model for Improvement:** Vehicle that provides structure for improvement

KAIZEN

- It focuses on improving efficiency and lowering cost
- The key feature of the Kaizen Model is big results come from many small changes accumulated over time.

Steps of implementation

- 5S is the part of the Kaizen system that establishes a workplace that can be ideal for continuous improvement. It is a philosophy and a way of organizing and managing the workspace and work flow with the intent to improve efficiency of work. 5S shall be conducted systematically with full participation of all staff serving the institution**.**

Figure 11.0.2: 5s steps in quality improvement

1. **Sort (seri):** remove unused stuff from working place by:
   - Categorizing and color code the items.
   - Developing inventory list for all categorized items.
   - Storing (keep) "may be needed" items.
   - Regularly sorting of unused items.
   - Developing culture of returning items to where they belong.

2. **Set in order (seiton):** organize all necessary items in proper order for easy services provision (proper orderliness) by:
   - Organizing cabinets with labeling/numbering.
   - Keeping items at their respective areas and label them accordingly.
   - Directional arrows leading to services areas.
   - Labeling of service rooms.

- Updating stock/equipment inventories.

Note: the rules and regulation must be written and well known to all Staff.

3. **Shine (seiso): maintain high standards of cleanness.**
   - Routine cleaning and mass cleaning campaign.
   - Clean not only the place that comes into your view but also behind, under furniture or equipment.
   - Clean and attractive environment will be appreciated by internal and external clients.

4. **Standardize (seiketsu):** the first three components set the stage for the facility to develop and implement standard operating procedure to maintain good working environment.
   - Set up the sort, set and shine as a norm in every section of the health facility.
   - Work instruction.
   - Standard operating procedures (SOPs).
   - Standard and regulation for both administrative and technical staff.

5. **Sustain (shitsuke):** train and maintain discipline of the health care workers engaged (consistent practice of 5S).
   - To train and main discipline of the health workers engaged.
   - Apply regular self-assessment.

THE MODEL FOR IMPROVEMENT

The model of improvement asks three questions that are fundamental to making improvements
- What are we trying to accomplish?
- What change can we make that will result in improvement?
- How will we know a change is an improvement?

What are we trying to accomplish?

This encourages us to think about our aim. This should be:
- **Specific –** we can describe it clearly and precisely who will benefit, what will be achieved**?**
- **Measurable –** we need to be able to use data to tell us whether our aim has been achieved
- **Ambitious -** when we set our aim we may not know how we are going to achieve it but this shouldn't stop us declaring a bold target if we know that it is what our customers need or expect yet achievable
- **Relevant –** if we need resources or support to achieve our aim, it will need to be meaningful to others
- **Time-bound – we need to be clear about when we expect to achieve our aim**

"What change can we make that will result in improvement?"

This question directs us to thinking about changes we could make that may help us achieve our aim. We often call these change ideas. We know we have to make a change to see an improvement. However, not every change will be an improvement. There are lots of different techniques and tools we can use to help us identify changes that are likely to be successful.

We can:

- Compare ourselves with others who are doing better than we are and work out what they are doing differently. This is called benchmarking
- Study and ask experts to find out what is known best practice
- Use root cause analysis tools to try and discover the underlying cause of us not achieving our aim. These include 5 whys and fishbone
- Use creativity tools such as provocations and random words to help us think more innovatively about what changes might lead to improvement
- Consult lists of change concepts6 (e.g "task shifting", "reducing waste") to see if they offer any hints as to what we could do differently
- Map key steps in the processes associated with our aim to help us see where process improvements could be made

"How will we know the change is an improvement?"

This question in the Model for Improvement speaks to measurement. In order to know our change led to an improvement we have to find a way of measuring something that would demonstrate we've achieved our aim; for example, the amount of money we have saved, the distance we can run. This is known as our outcome measure. Before we start making any changes we need to find out how we are currently doing against our outcome measure – how much money have I already saved, how far can I run now? This is known as our baseline. We then need to observe what happens to our outcome measure as we introduce different changes. We also want to be sure we are making the changes we planned so we need to introduce a process measure that will tell us. The process measure relates to the change and tells us how well we are doing that change or step in the process.

> **In combination with the Plan-Do-Study-Act (PDSA) test cycle, model for improvement is the foundational framework for successful improvement activity**

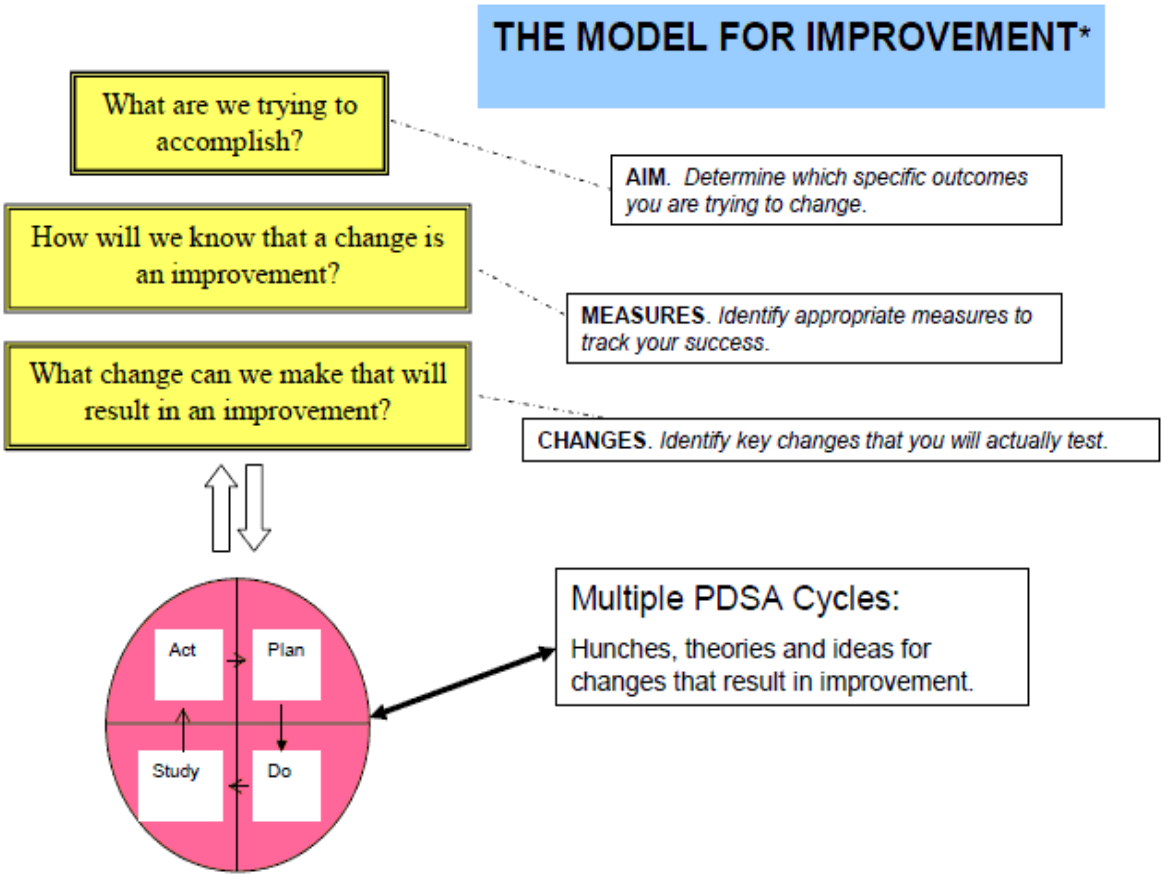


Figure 11.0.3: Plan, Do, Study and Act(PDSA) cycle

Plan – Do – Study – Act cycle (Deming cycle)

Step 1: Plan

- Plan the test or observation, including a plan for collecting data.
- State the objective of the test.
- Make predictions about what will happen and why.
- Develop a plan to test the change. (Who? What? When? Where? What data need to be collected?)

Step 2: Do

- Try out the test on a small scale.
- Carry out the test.
- Document problems and unexpected observations.
- Begin analysis of the data.

Step 3: Study

- Set aside time to analyze the data and study the results.
- Complete the analysis of the data.
- Compare the data to your predictions.
- Summarize and reflect on what was learned.

Step 4: Act

- Refine the change, based on what was learned from the test.
- Determine what modifications should be made.
- Prepare a plan for the next test.

PRINCIPLES OF IMPROVEMENT

Fundamental to the success of any improvement effort is the understanding that improvement requires change. Change is when you alter how work or activity is done, produce visible, positive differences in results relative to the desired goals and having a lasting impact. It is important to note that not all changes result in improvement. (eg burnt out light, fixing door handle….), but some of the changes simply reset things back to where they were. Doing more of the same, more people, more time, more money, more equipment don't /may not bring change.

> "Insanity: doing the same thing over and over again and expecting different results"
> Albert Einstein

TYPES OF CHANGES

Reactive change: change that are needed to keep the system of interest running day to day at the current level of performance

Fundamental change: changes that are needed to create a new system of performance (design or redesign, fundamentally alter how the system works….

Fundamental changes that result in improvement

- Alter how work or activity is done or the makeup of a product
- Produce visible, positive differences in results relative to historical norms
- Have a lasting impact

Improvement is defined by characteristics such as faster, easier, more efficient, more effective, less expensive, safer, cleaner and so on. The Extent of improvement is directly related to the nature of the changes that are developed and implemented.

DRIVERS OF IMPROVEMENT IN HEALTH CARE

The drivers of Improvement are:

- Will: Having the ***Will*** (desire) to change the current state to one that is better.
- Ideas: Developing ***Ideas*** that will contribute to making processes and outcome better.
- Execution: Having the capacity to apply QI theories, tools and techniques that enable the ***Execution*** of the ideas.

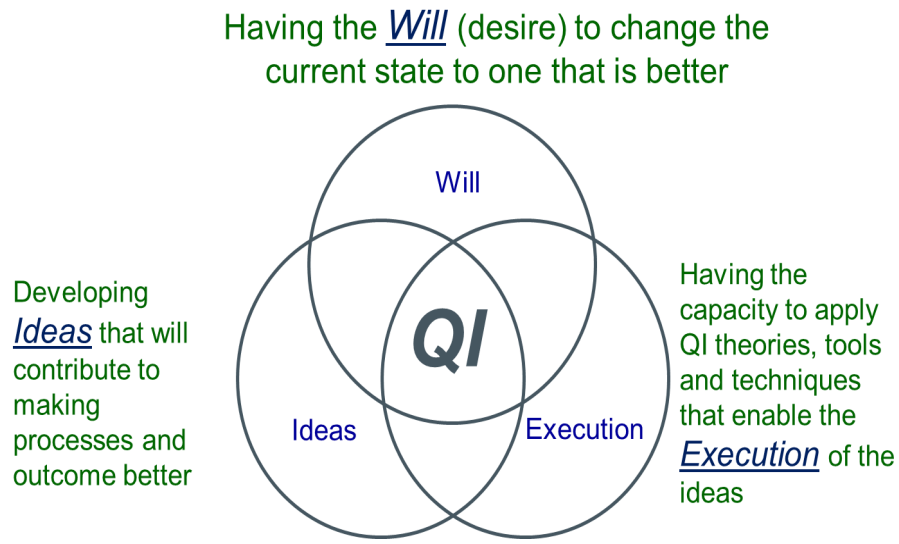


Figure 11.0.4: Drivers of quality improvement in health care

QUALITY PLANNING AND MONITORING

All successful quality improvement programs include four key elements:

1. The Problem
   - Start with an in-depth understanding of the problem
   - System-wide buy-in for the quality improvement initiative and the problem it targets
2. The Goal
   - Target improvements based on a return on investment (ROI) and cost-benefit analyses
   - Ask several key questions when defining their quality improvement goals:
     - How does this tie into our organization's strategic improvement objectives?
     - What will have the biggest impact on patients?
     - What areas have the largest variation?
     - What will have the biggest impact on costs?
3. The Aim
   - Aims break up the work of achieving the goal into manageable pieces.
4. The Measures
   - Measuring baselines and actuals
   - Determine if there is an improvement; and if and how the improvement is correlated to intervention.

Guidance 53: Implementing improvement cycle

Health center performance and quality needs to be improved continuously all the time. The improvement process mainly involves the following steps in a cyclic manner.

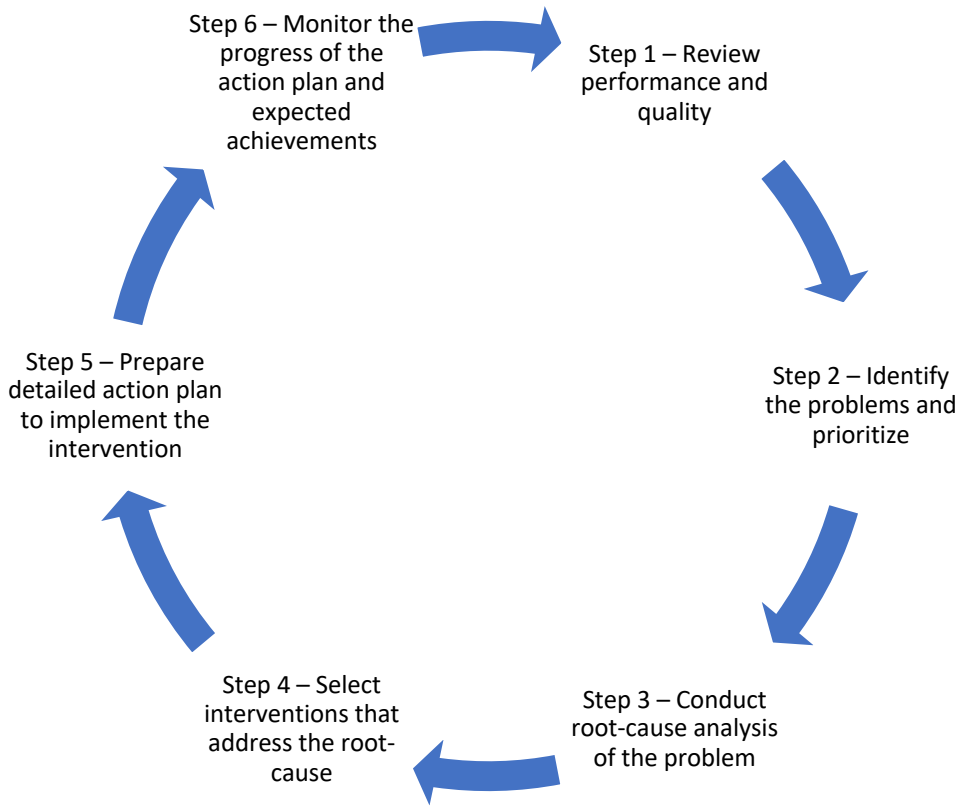


Figure 11.0.5 Quality improvement implementation cycle

REVIEW PERFORMANCE AND QUALITY

In this step the following activities will be carried out:

- HMIS officer will bring the HMIS indicators after comparing with the target for the period
- More indicators or issues from Clinical/quality audit, chart review, satisfaction survey, observations, staff or clients' complaints, findings from supportive supervision, performance review meetings and government board meetings will be organized and presented to the team by responsible bodies assigned by the management committee or health center head.
- The performance monitoring team will critically evaluate and interpret the indicators (both HMIS & non-HMIS) whether they are within the planned limit or reflect a poor performance or quality by comparing the current figure with the period target
- This activity will be carried out monthly, quarterly, bi-annually and annually by the performance monitoring team.

IDENTIFY THE PROBLEMS AND PRIORITIZE

Based on the review of the indicators and issues in step 1, list-out problems that need improvement. From the bigger list select manageable size of problems to be addressed in the month. Improving every service area at a time may not be possible for various reasons, so the health center needs to select priority areas of improvement for a specific time period and then gets into the actual improvement actions.

The first priority will be given to problems solved with little resource followed by problems that are more complex and expensive to solve. However, it might be necessary to address more difficult area first if its effect is significant. Performances and quality related to national & regional priority areas (especially TB, Malaria, HIV, Maternal and Child health) should be taken as priority considerations.

CONDUCT ROOT-CAUSE ANALYSIS OF THE PROBLEM

Understanding the causes of the problem helps to develop the most appropriate intervention for improvement. Knowing the cause of the gap/variation and targeting the changes to these causes will enable the improvement effort to be more sustainable than addressing the superficial part of the problem by giving symptomatic treatment. Fishbone analysis and flowcharting are among the commonest techniques to identify root causes of a problem.

Fishbone analysis steps

1. Place the problem (to be analyzed & improved) in a box at the end of a horizontal arrow
2. Categorize major cause areas (example as: policy, process, people, environment, infrastructure) and connect them with the backbone arrows using diagonal arrows
3. To find secondary, tertiary, etc causes ask the question "why this has happened" under each category or reason
4. *Repeat the step till you get the root cause*

Below is a sample fishbone diagram to analyse the root cause of "Low skilled birth attendance in our catchment area"

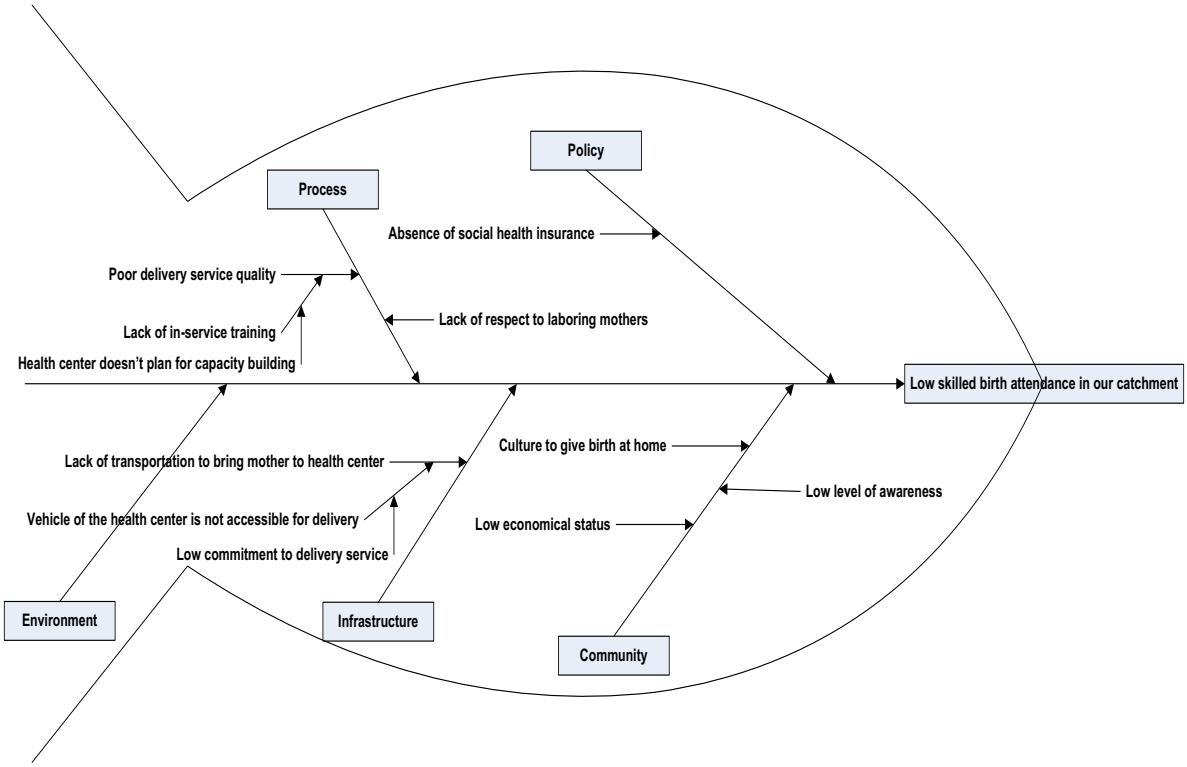
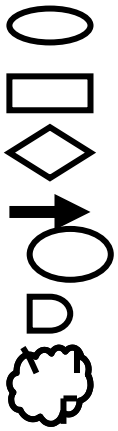


Figure 11.0.6 Fishbone analysis of root causes in quality problems

Steps to prepare flow chart

1. Decide on the beginning and end points of the process to be flowcharted
2. Identify the steps of the process
3. Link the steps with arrows showing direction. The following symbols may also be used for the appropriate drawing.



Begin or End

Step

Decision

Flow Lines

Connectors

Delays

SELECT INTERVENTIONS THAT ADDRESS THE ROOT-CAUSE

Following the root cause analysis, design an intervention which will address the root cause directly so that the problem will be solved from its root and not superficially. When selecting the intervention the team needs to consider its cost and feasibility for implementation.

PREPARE DETAILED ACTION PLAN, IMPLEMENT THE INTERVENTION, MONITOR THE PROGRESS AND EXPECTED ACHIEVEMENTS

In this step, the team will prepare an action plan to implement the selected interventions as well as collecting data relevant to monitor progress using PDSA cycle. The team should discuss on the implementation status of the interventions in the action plan. The discussion should also address an evaluation of the intervention if it is leading towards improvement or not based on which the intervention might be continued as it is, modified to some extent or dropped from being implemented. Then the cycle continues.

Improvement action plan template – annex xxx

MEASURING CHANGE, COMMUNICATING FINDINGS, DOCUMENTING AND RECOGNIZING ACHIEVEMENTS'

Along with the implementation of quality improvement strategies, the level of quality of care needs continuous measurement to track changes towards the set goals. Measurement should be done using the selected indicators in step 3. Findings from quality measurement after analysis are the tools for advocacy to take further actions for quality improvement. This can mobilize resources; create a competitive environment among health care providers and increase awareness of beneficiaries on quality of health care.

CONCLUSON - QUALITY IMPROVEMENT PROJECT

The products of the above-mentioned steps may end up having a quality improvement project for the specific facility/facilities. The development and implementation of health care quality improvement project is important process to address deficiencies of quality through strategic approach. The process of quality improvement project involves quality assessment that compares performance with expectations, standards, or goals; identification of the root cause for the quality gaps; and designing and implementation of best interventions to address the gaps within the framework of locally available resources; and continuous monitoring and evaluation of the outcomes.

Activity 11.4. Think pair share Patient right…	
	**Instruction:** - **Pair with your neighbour** - **List down main issues to address in patient right** - **Share your discussions in the general discussion** **Time:** 10 minutes

Guidance 54: Patient right, Grievance handling, Patient/client centered care

HEALTH CARE SAFETY

There 10 key areas a health center should give attention to introduce safety culture in the health center

1. Governance for Safety and Quality in Health Service Organizations
2. Partnering with Consumers
3. Preventing and Controlling Healthcare Associated Infections
4. Medication Safety
5. Patient Identification and Procedure Matching
6. Clinical Handover
7. Blood and Blood Products
8. Preventing and Managing Pressure Injuries
9. Recognizing and Responding to Clinical Deterioration in Acute Health Care
10. Preventing Falls and Harm from Falls

THE GOVERNANCE FOR SAFETY AND QUALITY IN HEALTH SERVICE ORGANIZATIONS

Health service organization leaders implement governance systems to set, monitor and improve the performance of the organization and communicate the importance of the patient experience and quality management to all members of the workforce. Clinicians and other members of the workforce use the governance systems.

Criteria to achieve the Governance for Safety and Quality in Health centers

- **Governance and quality improvement systems:** There are integrated systems of governance to actively manage patient safety and quality risks.
- **Clinical practice:** Care provided by the clinical workforce is guided by current best practice.
- **Performance and skills management:** Managers and the clinical workforce have the right qualifications, skills and approach to provide safe, high-quality health care.

- **Incident and complaints management:** Patient safety and quality incidents are recognised, reported and analysed, and this information is used to improve safety systems.
- **Patient rights and engagement:** Patient rights are respected and their engagement in their care is supported.

PARTNERING WITH CONSUMER

Leaders of a health service organization implement systems to support partnering with patients, careers and other consumers to improve the safety and quality of care. Patients, carers, consumers, clinicians and other members of the workforce use the systems for partnering with consumers.

Criteria to achieve the Partnering with Consumers Standard

- **Consumer partnership in service planning:** Governance structures are in place to form partnerships with consumers and/or cares.
- **Consumer partnership in designing care:** Consumers and/or carers are supported by the health service organisation to actively participate in the improvement of the patient experience and patient health outcomes.
- **Consumer partnership in service measurement and evaluation:** Consumers and/or carers receive information on the health service organization's performance and contribute to the ongoing monitoring, measurement and evaluation of performance for continuous quality improvement

THE PREVENTING AND CONTROLLING HEALTHCARE ASSOCIATED INFECTION

Clinical leaders and senior managers of a health service organization implement systems to prevent and manage healthcare associated infections and communicate these to the workforce to achieve appropriate outcomes. Clinicians and other members of the workforce use the healthcare associated infection prevention and control systems.

Criteria to achieve the Preventing and Controlling Healthcare Associated Infections

- **Governance and systems for infection prevention, control and surveillance:** Effective governance and management systems for healthcare associated infections are implemented and maintained.
- **Infection prevention and control strategies:** Strategies for the prevention and control of healthcare associated infections are developed and implemented.
- **Managing patients with infections or colonization:** Patients presenting with, or acquiring an infection or colonization during their care are identified promptly and receive the necessary management and treatment**.**
- **Antimicrobial stewardship:** Safe and appropriate antimicrobial prescribing is a strategic goal of the clinical governance system.

- **Cleaning, disinfection and sterilization:** Healthcare facilities and the associated environment are clean and hygienic. Reprocessing of equipment and instrumentation meets current best practice guidelines.
- **Communicating with patients and careers:** Information on healthcare associated infections is provided to patients, careers, consumers and service providers.

THE MEDICATION SAFETY

Clinical leaders and senior managers of a health service organization implement systems to reduce the occurrence of medication incidents, and improve the safety and quality of medicine use. Clinicians and other members of the workforce use the systems to safely manage medicines.

Criteria to achieve the Medication Safety

- **Governance and systems for medication safety:** Health service organizations have mechanisms for the safe prescribing, dispensing, supplying, administering, storing, manufacturing, compounding and monitoring of the effects of medicines**.**
- **Documentation of patient information:** The clinical workforce accurately records a patient's medication history and this history is available throughout the episode of care.
- **Medication management processes:** The clinical workforce is supported for the prescribing, dispensing, administering, storing, manufacturing, compounding and monitoring of medicines.
- **Continuity of medication management:** The clinician provides a complete list of a patient's medicines to the receiving clinician and patient when handing over care or changing medicines.
- **Communicating with patients and careers:** The clinical workforce informs patients about their options, risks and responsibilities for an agreed medication management plan.

PATIENT IDENTIFICATION AND PROCEDURE MATCHING

Clinical leaders and senior managers of a health service organization establish systems to ensure the correct identification of patients and correct matching of patients with their intended treatment. Clinicians and other members of the workforce use the patient identification and procedure matching systems.

Criteria to achieve the Patient Identification and Procedure Matching

- **Identification of individual patients** At least three approved patient identifiers are used when providing care, therapy or services**.**
- **Processes to transfer care** A patient's identity is confirmed using three approved patient identifiers when transferring responsibility for care**.**
- **Processes to match patients and their** care Health service organizations have explicit processes to correctly match patients with their intended care.

THE CLINICAL HANDOVER

Clinical leaders and senior managers of a health service organization implement documented systems for effective and structured clinical handover. Clinicians and other members of the workforce use the clinical handover systems**.**

Criteria to achieve the Clinical Handover

- **Governance and leadership for effective clinical:** handover Health service organizations implement effective clinical handover systems**.**
- **Clinical handover processes:** Health service organizations have documented and structured clinical handover processes in place.
- **Patient and career involvement in clinical handover:** Health service organizations establish mechanisms to include patients and carers in clinical handover processes.

BLOOD AND BLOOD PRODUCTS SAFETY

Clinical leaders and senior managers of a health service organization implement systems to ensure the safe, appropriate, efficient and effective use of blood and blood products. Clinicians and other members of the workforce use the blood and blood product safety systems.

Criteria to achieve the Blood and Blood Product safety

- **Governance and systems for blood and blood product prescribing and clinical use:** Health service organisations have systems in place for the safe and appropriate prescribing and clinical use of blood and blood products.
- **Documenting patient information:** The clinical workforce accurately records a patient's blood and blood product transfusion history and indications for use of blood and blood products.
- **Managing blood and blood product safety:** Health service organisations have systems to receive, store, transport and monitor wastage of blood and blood products safely and efficiently.
- **Communicating with patients and carers:** Patients and carers are informed about the risks and benefits of using blood and blood products, and the available alternatives when a plan for treatment is developed.

PREVENTING AND MANAGING PRESSURE INJURIES

Clinical leaders and senior managers of the health service organization implement evidence-based systems to prevent pressure injuries and manage them when they do occur. Clinicians and other members of the workforce use the pressure injury prevention and management systems

Criteria to achieve the Preventing and Managing Pressure Injuries

- **Governance and systems for the prevention and management of pressure injuries:** Health service organizations have governance structures and systems in place for the prevention and management of pressure injuries.

- **Preventing pressure injuries:** Patients are screened on presentation and pressure injury prevention strategies are implemented when clinically indicated.
- **Managing pressure injuries:** Patients who have pressure injuries are managed according to best practice guidelines**.**
- **Communicating with patients and carers:** Patients and carers are informed of the risks, prevention strategies and management of pressure injuries.

RECOGNIZING AND RESPONDING TO CLINICAL DETERIORATION IN ACUTE HEALTH CARE

Health service organizations establish and maintain systems for recognizing and responding to clinical deterioration. Clinicians and other members of the workforce use the recognition and response systems.

Criteria to achieve the Recognizing and Responding to Clinical Deterioration

- **Establishing recognition and response:** systems Organization-wide systems consistent with the National Consensus Statement3 are used to support and promote recognition of, and response to, patients whose condition deteriorates in an acute health care facility**.**
- **Recognizing clinical deterioration and escalating care:** Patients whose condition is deteriorating are recognized and appropriate action is taken to escalate care.
- **Responding to clinical deterioration:** Appropriate and timely care is provided to patients whose condition is deteriorating**.**
- **Communicating with patients and carers:** Patients, families and carers are informed of recognition and response systems and can contribute to the processes of escalating care.

THE PREVENTING FALLS AND HARM FROM FALLS

Clinical leaders and senior managers of a health service organization implement systems to prevent patient falls and minimize harm from falls. Clinicians and other members of the workforce use the falls prevention and harm minimization systems.

Criteria to achieve the Preventing Falls and Harm

- **Governance and systems for preventing falls:** Health service organizations have governance structures and systems in place to reduce falls and minimise harm from falls.
- **Screening and assessing risks of falls and harm from falling:** Patients on presentation, during admission, and when clinically indicated, are screened for risk of a fall and the potential to be harmed from falls.
- **Preventing falls and harm from falling:** Prevention strategies are in place for patients at risk of falling.
- **Communicating with patients and careers:** Patients and careers are informed of the identified risks from falls and are engaged in the development of a falls prevention plan.

Guidance 55: Clinical audit

Clinical audit is measuring clinical process or outcome against well-defined standards set best on the principles of evidence based medicine. The main objective of conducting clinical audit is to identify the discrepancies between the actual clinical practice and expected standard in order to identify the changes needed to improve quality of care. In Ethiopian primary health care system clinical audit can be conducted using Ethiopian Primary Health Care Clinical Guideline (EPHCG), standards for maternal and child health (BEmONC standards, partographs, IMNCI protocols, etc) and health center clinical audit tool. The findings of clinical audit can be used for problem solving, standardizing clinical practices, improve culture of clinical practice and other interventions that improve quality of care for patients.

ETHIOPIAN PRIMARY HEALTH CARE CLINICAL GUIDELINE

The Ethiopian Primary Health Care Clinical Guideline (EPHCG) is a guide for clinicians to provide primary care of older children and adults at health center level. The EPHCG has an integrated symptom-based algorithmic approach to address the common presenting symptoms and priority chronic conditions in the country. The adult content is a comprehensive guide to the adult presenting to primary health care facilities. The pediatric content addresses priority conditions in children aged 5-14 years presenting to primary care and is intended to complement the Integrated Management of Childhood Illness which addresses children younger than 5 years old. The scope covered in chronic conditions for adults, and long-term health conditions for older children includes: cardiovascular diseases; diabetes; chronic respiratory diseases; mental health, musculoskeletal disorders; and women's health. The Guideline provides basic management principles to deal with these diseases at a health center level in an integrated user-friendly way to support health workers to provide care that is evidence-informed, compliant with local guidelines, comprehensive, compassionate and respectful. The adherence to this clinical guide in the health centers will standardize the care given at this level, will improve the quality of service and in effect will improve the health outcomes of the country.

HEALTH CENTER CLINICAL AUDIT

Health center clinical audit is a quality improvement and clinical governance initiative that aims to strengthen quality improvement activities in a health center. It has its own procedure and process using a standardized checklist.

The main objective of conducting clinical audit is to identify the discrepancies between the actual clinical practice and expected standard in order to identify the changes needed to improve quality of care. In Ethiopian primary health care system clinical audit can be conducted using Ethiopian Primary Health Care Clinical Guideline (EPHCG), standards for maternal and child health (BEmONC standards, partographs, IMNCI protocols, etc) and health center clinical audit tool. The findings of clinical audit can be used for problem solving, standardizing clinical practices, improve culture of clinical practice and other interventions that improve quality of care for patients.

Guidance 56: Ethiopian Primary Health Care Alliance for Quality (EPAQ)

EPAQ is a collaborative quality improvement approach that brings about improvement in service delivery of primary health care institutions through creating networks which facilitate learning, information sharing and technical and other support. The EPAQ approach foster a collaborative learning and experience sharing platform for primary health care facilities with a goal of improving service quality and patient experience in primary health care system. The primary health care facilities within a woreda will create a network for collaborative learning, experience sharing, quality improvement and improving patient outcome.
A detailed guidance on the process and implementation of EPAQ is provided on the national guideline.

Guidance 57: Community Score Card

A community score card is a community-led governance tool which brings primary health care facilities, local government structures and the community together to promote accountability and responsiveness to community needs. A community score card can add value to already existing community engagement mechanisms by providing quantifiable and actionable data on community perceptions on primary health care service quality. The community score card is conducted quarterly at each kebele under the health center catchment using six indicators – caring, respectful and compassionate health professionals, health center waiting time, availability of medicine and diagnostic services, health center infrastructure, availability and management of ambulance services and cleanliness and sanitation of the health center. The findings from the community score card will be used for improving quality of primary health care service delivery and setting structured agenda for discussion and feedback to the community during town hall meetings.

Guidance 58: Catchment based clinical mentorship (primary hospital)

Clinical mentoring is a critical component of a comprehensive in-service training program, as it provides a bridge between didactic training and independent clinical practice. Clinical mentoring enables health care workers (HCW) to practice new skills in clinical settings with the support and guidance of a more specialized and experienced clinician. Intensive, practical training is especially important in RMNCH training.

ROLES AND RESPONSIBILITIES OF VARIOUS FACILITIES

Primary Hospitals

- Identify and designate a focal point for RMNCH mentorship program.
- Allocate budget for RMNCH mentorship program.
- Assess, plan, and prepare schedule for catchment health centers.
- Ensure all health facilities are enrolled in catchment RMNCH mentorship linkage
- Ensure availability of SOP, job aids and checklists in the hospitals and distribute to catchment health centers

- Organize regular catchment review meetings
- Conduct supportive supervision to support the implementation of the catchment program.
- Support the selection of mentees and mentors
- Support staff capacity enhancement activity.
- Collect and analyze the overall activity report submitted by the mentors.
- Provide feedback on outcome of patients referred to the hospitals from catchment health centers.
- Make logistics, including transportation and appropriate forms, are available for mentors

Health centers

- Allocate resource for RMNCH mentorship program
- Monitor implementation of the mentoring program
- Maintain communication with mentor and mentee
- Actively participate in regular review meeting of mentorship program
- Create smooth working environment for mentorship program
- Support the selection of mentees.
- Collect and analyze the overall activity report for mentorship program on regular review meeting.
- Document changes in RMNCH outcomes of mentorship programs.

11.4. Implementation checklist and indicators

11.4.1. Clinical governance, safety and quality implementation checklist for operational standards with verification criteria

Table 11.1: Assessment Tool for Operational Standards - Clinical governance, safety and quality

No	Standards	Verification criteria	Yes √ No X	met =1 not met =0	Remark
1	The health center has a functional QI committee that leads clinical governance, quality and safety initiatives.	Members from each case team assigned with official letter			
		Review TOR and list of Team established comprise of different case team			
		Regular meeting minute documented			
		Health center have assigned QI focal person with official letter			

No	Standards	Verification criteria	Yes √ No X	met =1 not met =0	Remark
2	The health center has operational plan disaggregated by quarter for clinical governance, quality and safety	Check quality and safety plan			
		Check quality and safety plan is integrated with annual health center plan			
3	The health center implement citizen charter for the services they render	The patient right and responsibility developed with local language and posted			
		check updated charter is posted			
		check standardized TAT from registration book			
		Check needed pre conditions are posted when patients come to health center.			
		Measure services are performed according to the standard			
		Check action plan after performance review of the charter			
4	The health center ensured adherence to Primary Health Care Clinical Guideline (EPHCG) to provide standardized clinical care and ensure quality and patient safety.	Review EPHCG training records			
		availability EPHCG in all OPD rooms			
		review continued forum minutes			
		check advocacy of EPHCG in the HE sessions/public forums			
		observe EPHCG is included in the HC plan			
		check EPHCG mentoring docs			
		observe 2 HW-patient interactions			
		take randomly 3 charts from d/t departments and audit			
		pick randomly 3 referrals and compare referral reason with EPHCG			
5	The health center implemented quarterly clinical audit	review conducted audit docs			
		Review identified problems			

No	Standards	Verification criteria	Yes √ No X	met =1 not met =0	Remark
	(using EPHCG, health center clinical audit) and use the findings for quality improvement and assurance	review if audit findings are used for quality improvement interventions(QI projects)			
6	The health center identified priority problems on quality services and implemented quality improvement projects (Kaizen, Models for improvement)	review problem priority doc			
		review QI project docs			
		review run charts			
		observe /check changes after project implementation			
7	The health center conducted quarterly community score card and town hall meetings with the community to monitor service quality and ensure accountability.	review quarterly CSC reports			
		review town hall meeting minute			
		check if key quality indicators are discussed /presented			
		Check community concerns are addressed (number of raised concerns against number of addressed) in narration form (chapter 2)			
8	The health center participates quarterly in collaborative learning and experience sharing platform of Ethiopian Primary Health Care Alliance for Quality (EPAQ).	check if the HC is member/lead in the cluster			
		check minute/photos/video of EPAQ participation in the last quarter			
		Action plans based on EPAQ participation			
9	Patient satisfaction should be done bi - annually and use it for improvement	check bi annual survey docs			
		check analysis of survey docs			
		check action plan based on survey findings for performance improvement			
10	Procedures are established to asses and minimize risk to	Check risk assessment of ER, delivery, laboratory ,injection room and OR if available (annex tools)			

No	Standards	Verification criteria	Yes √ No X	met =1 not met =0	Remark
	patients during health care service.	Check risk assessment was performed last 6 month and reviewed			
		Action plan based assessment findings			
		Check incident reports collected and investigated analysed and monitored for improvement			
		Neonate identification system should be in place (arm band card number)			
		Emergency care Clinical Skill drill annually			
		Safety protocols posted in emergency care settings (ER, L &D, Laboratory, Pharmacy) etc			
11	Health center conducts quarterly good governance index assessment	Filled GGI assessment of last quarter			
		Analysis of GGI assessment			
		Action plan based on assessment			
		Intervention report of action pplan			

11.4.2. Clinical governance, safety and quality monitoring indicators

Table 11.0.2: Clinical governance, safety and quality monitoring indicators

S.no	Indicator	Formula	Assessment period	Data source
1	Percentage of graduated QI projects	No. graduated QI projects/total available *100	Bi annual	Project docs
2	Client satisfaction Percentage score	No. survey rating scores achieved/total rating score expected if achieved full*100	Bi annual	Survey doc/report
3	Percentage of monthly performance review meetings conducted	No. conducted meetings/no expected *100	Monthly	Admin. report/Minute

4	percentage of QI projects designed	No. QI projects designed /no. of planned QI projects *100	Bi annual	Admin. report/Minute
5	Proportion of maternal deaths	Number of maternal deaths/total number of deliveries*100	Quarterly	HMIS
6	Percentage of clinical audits conducted	Number of clinical audit reports submitted/ no. of expected audits to be conducted *100	Quarterly	Clinical audit assessment report
7	Proportion of incident report	Number of Incidents reported/ Total no. of outpatient visits *100	Quarterly	Incident reports
8	Proportion of OPDs adherence to the EPHCG	No. of OPDs currently using EPHCG/ Total no. of OPDS *100	Quarterly	EPHCG assessment report

11.5. Additional Reading Materials

1. Ethiopian Primary health care Guideline
2. Catchment based clinical mentorship guide

Chapter 12: Health Information System

Chapter Description: This chapter explains the health information system practices in a health center. The chapter includes discussion on Medical redord and documentation of patient information. Data quality improvement is discussed in the chapter aiming to introduce common quality issues and remedies. Using DHIS2 application for data analysis and reporting is also discusse. The composition, roles and responsibilities of performance monitoring team is also addressed in the chapper before the standards and verifications were explained.

Primary Objective: By the end of the chapter participants will be able to support health information system reform in a health center.

Enabling Objective: By the end of the session you will be able to:

- Explain a medical record
- Narrate documenting oatient information
- Use DHIS2 application for data analysis and reporting
- Describe use of quality data
- Establish performance monitoring team with the right composition and clear roles and responsibilities.

Chapter Outline:

12.1. Introduction

Health Information System refers to system that captures, stores, manages or transmits information related to the health of individuals or the activities of organizations, which will improve health care management decisions at all levels of the health system (WHO, 2017). Health Information System provides the underpinnings for decision making and has four key functions: Data production, compilation, analysis, synthesis, and communication and use. Health Information system serves multiple users and data from different sources are used for multiple purposes at different levels of the health system. A well-functioning health information system is one that ensures the production, analysis, dissemination and use of reliable and timely information on health determinants, health systems performance and health status. This document is mainly addressing Health Management Information System (HMIS); Information Revolution; and Functional Medical Record.

Health Management Information System (HMIS) is a system whereby health data are recorded, stored, retrieved, and processed to improve decision-making. HMIS is one of the six core building blocks of the health system and provides data needed for other components (service delivery, health workforce, access to essential medicines, financing, and leadership). Ethiopia has introduced different health reform agenda to improve the performance of country Health Management Information System (HMIS), such as, Information Revolution, Data quality and Use of Data for Decision Making.

Information Revolution

Information Revolution is crosscutting agenda described in Health Sector Transformation Plan II (HSTP II), which mainly deals with improving culture of data use at all levels of the health system; to digitalize priority Health Information System (HIS) to improve access and quality of service, to improve HIS governance. In addition, it is a strategy to maximize the availability, accessibility, quality, and use of health information for decision making processes through the appropriate use of ICTs to positively impact the access, quality, and equity of healthcare delivery at all levels. Different strategies were also introduced by federal ministry of health to support information revolution agenda primary health care level called Connected Woreda Program.

Connected Woreda Strategy

Connected Woreda Program is a platform to introduce the concept of information revolution at PHCU level. It is also a collaborative learning platform through information sharing and mentorship. Connected woreda strategy helps to improve use of quality data for planning, monitoring and evaluation at PHC level. "Connected Woreda" operationalizes data-use innovations through instituting a tiered pathway for facilities and woredas to achieve the highest standards in data quality and use. Connected Woreda creates a plan to realize these innovations at the woreda and primary health care unit (PHCU) level. This ensures that data-use interventions target facilities and health care workers at the level where primary care is delivered. This pathway begins with an assessment where facilities are evaluated and scored against a common set of criteria related to M&E infrastructure, data quality, and administrative and clinic data use.

12.2. Operational Standards

1. The Health Center shall have a single unified health information system department
2. The Health Center shall have/establish a single standardized medical record room
3. The Health Center should avail and utilizes all standard set of formats for medical record registration
4. The Health Center should have medical records management auditing system
5. The Health Center has ensure proper handling and confidentiality of medical records
6. The Health Center have a capacity building platform to improve health information system quarterly bases and eHealth literacy.
7. The health center should establish a functional Performance Monitoring Team (PMT).
8. The health center needs to prepare strategic plan, annual quarterly and monthly plan

9. The health center needs to collect and report reportable indicators to the respective body as per the HMIS standard and should utilize the report for internal service quality improvement
10. The health center needs to implement Data quality audit selected priority problems
11. The health center should have fulfilled all the requirements of Information Revolution.
12. The health center performs QI projects to improve identified data quality gaps

12.3. Implementation Guidance

Guidance 59: Medical record

Medical record is "a collection of facts about a patient's health history, including past and present illness(es) and treatment(s) written up by the health care professional treating the patient" (WHO, 2003). The goals of recording information in medical records are to support the delivery of good care, clinical decision-making, communication between healthcare workers, continuity of care, scientific research, quality assurance and transparency of the delivered care (Zegers M et al, 2011). It is also important for measuring and improving the quality and coverage of health services and policy directions and promote equity, to detect and control emerging and endemic health problems and for empowering individuals and communities with timely and understandable information.

HUMAN RESOURCES FOR THE MEDICAL RECORDS DEPARTMENT

All personnel that work in the Medical Records Department should be qualified to conduct their jobs, which require reading, keyboarding, and organizational skills. Depending on the size of the facility and volume of patients, the number of personnel working in the Medical Records Department will vary. However, there should be enough staff to cover the following duties, particularly during the prime hours:

- Patient registration
- Authorization of free and credit services
- Development and maintenance of the MPI
- Retrieving and filing MRs
- Delivering files to various locations of the health center
- Recording chart location
- Collection of MRs from individual service units
- Checking and ensuring completion of MRs after discharge or death
- Filing reports generated by the Medical Records Department
- Handling of medico-legal issues relating to releasing patient information and other legal issues.

All MR personnel should undergo MR orientation and subsequent annual training on all departmental policies. Professional mix of the staffs of medical record unit should incorporate MRU head, Information Technology professional, Health Information Technology (HIT) workers, runners, and cashers.

MEDICAL RECORD GENERATION AND RETRIEVAL

The health center medical registration unit (MRU) identify the patient/Client is a new or recurring before registering and giving a medical registration number (MRN). Each patient should have one MRN for all visits to the specific health facility i.e. the MRN generated during the registration process at the patient's/ Client's first visit to the specific health facility. Subsequently, the same MRN should be used for all other visits, including outpatient, inpatient and emergency visits and other services.

Master Patient Index

The Master Patient Index (MPI) is a record of patient's/client's full name, address, registration dates, and the MRN. The MPI is an essential element of existing, retrieving and generating new MRNs. Each health care facility should have a MPI. The MPI can be paper-based or computer-based with paper based back up. MPI relies on the use of an individual index card. Each MPI card should include the following information: Patient's/Client's first name, Patient's/Client's father name, Patient's/Client's grandfather name (if available), Date of Birth (DOB)/Age, Sex (Male/Female), Address, MRN, Date of registration and Phone number. The index cards should be filled alphabetically by first name. When the health center learns that, a patient has changed his/her name legally, a cross-index file should be made to identify the initial record with the previous name. The MRN of the original registration should be recorded on the cross-index card.

If a patient changes any other contact details (such as address or telephone number) a new MPI card shall be prepared to replace the original. The patient's name, MRN, date of registration and any other unchanged information should be transcribed exactly as written on the original onto the new card. The old card should be scored through with the signature of the individual preparing the new card. The new card should be stapled to the top of the old card and both should be filed together so that, the updated information is readily available without losing any prior information. In a computer based MPI, the contact details can be amended directly in the appropriate computer fields.

Manual Paper-Based System: Health Centers that use a paper-based MPI may purchase vertical file cabinets for filing index cards. The paper based MPI should be monitored by the MRU, at a minimum, every quarter to ensure that the MPI is filed correctly. Each facility must establish a procedure for this activity. Sub-headings may be added in the alphabetized system for common names ("Me" for Meskerems', "Mo" for Mohammed's', etc.).

Computer-Based System: The use of a computerized MPI permits faster retrieval of patients' MRN. Electronic Health Management Information System (E-HMIS) is being rolled out across Ethiopian health centers that include a computerized MPI component. However, a paper-based card file should also be maintained in case of computer technical failure/downtime. Interruptions in the system can be caused by a variety of factors, including electrical outages or hardware/software problems. Therefore, health centers should maintain a back-up, paper-based system in order to ensure no interruption in MRN retrieval. If a computer-based system is used in addition to a manual system, similar procedures should be followed for both MR management

systems to ensure optimal patient care. Both systems are effective when implemented and used correctly.

Patient/Client Registration

Patient/Client registration is the process of recording the patient's/client's identification and assigning a MRN. When the patient arrives at registration, the clerk should ask the patient's full name (first name, father's and grandfather's name) and then search for an existing MRN in the paper-based MPI (i.e., set of index cards) or in the computerized MPI. This should be done to protect from providing more than one MRN for one patient/client.

If there is an existing MRN for that patient/client, the registration clerk should facilitate the retrieval of the existing MR stored in the record room. The MRU worker should retrieve the patient's MR and then, a runner will take the MR to the area where the patient is to be treated as per the request of health care provider. If the patient/client new or have no MRN, the registration clerk should generate a new MRN. New MRNs should be issued in straight numeric sequence, without skipping any numbers. Each MRN should be assigned to one and only one patient/client. Reissuing a MRN to another patient should never occur. Registration staffs should have to create both a service card and an MPI card for a specific attending patient/client simultaneously and the MPI card have to be placed in the MPI box. Registration of patients/client regardless of which service they will access and whether it is electronics or manual it should be networked within the facility.

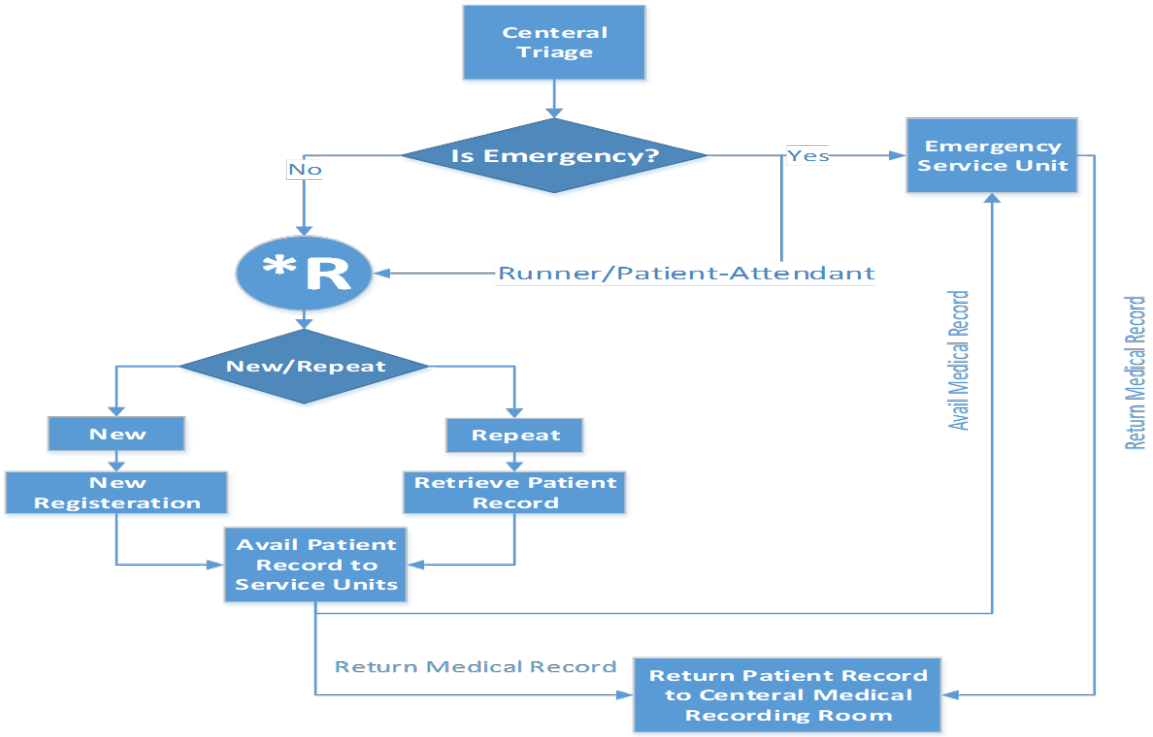


Figure 12.1: Patient registration process and patient card path in a health center

*R - Registration

Starting a Medical Record for a New Patient/Client

After the MRN is generated (i.e., the next number in the sequence is assigned to the selected patient/client), an individual health center -approved folder should be assigned to the patient/client. Any patient information generated by health center staff during the period of care should be kept in this folder. A paper fastener or metallic fastening tool can be used to keep all pre-approved clinical documents/forms in the folder. The MRN should be clearly displayed on the folder as a form of identification.

Service Card

Each new patient registered for outpatient or inpatient services should be issued a service card. This card is a small pocket-sized card used as an identification card for each patient, which should be shown to the MR staff whenever the patient attends the health center. All the necessary registration information should be recorded on the card. Contents of the patient service card include: Name of the Facility, Date of Registration, Medical Record Number, Name of client, DOB or age at registration, Sex, Client's address, Phone number and free service stamp space.

STORAGE OF MEDICAL RECORDS

All active MRs should be filed in a single, centralized file room, i.e., the Medical Records Department or Card Room. MRs should be filed numerically according to MRN. If more than one room is needed for file storage, files should be stored numerically (e.g. MRN 1,000-5,000 in one room 1; MRN 5,001 – 10,000 in room 2). Health center should audit the files periodically (quarterly or as per health center policy) to ensure correct filing. All patient files should be stored together, using one MPI, including those from specialized clinics (Eg. ART, EPI etc). If separate record numbers and/or filing systems exist, the health center should integrate these within a single system.

RETRIEVING EXISTING MEDICAL RECORD FOR A RETURNING PATIENT

Retrieving MR using MRN

If the patient knows his/her MR number or brings his Service Card, then the MR number can be used to find the patient's MR. The MR is filed numerically in the MR room and hence can be easily retrieved from the shelf.

Retrieving MR by name

If the patient does not remember their MRN or does not have their service card, then MPI can be used to search for the patient information. The patient's index card is filed alphabetically by first name in the MPI. When the Index Card is located the MR number can be read from the card and used to retrieve the MR then a new service card will be prepared and provided to the client with the appropriate education on the benefit.

APPOINTMENT CARD

An appointment card should be given to the patient stating the date and time of planned outpatient visits or admission.

ELECTRONIC MEDICAL RECORD (EMR)

Electronic Medical Record (EMR) is a systematic collection of electronic health information about individual patients or populations for planning, budgeting, and decision-making process to ensure evidence-based practice. EMRs may include a range of data, including demographics, medical history, medication and allergies, immunization status, laboratory test results, radiology images, vital signs, personal statistics like age and weight, and billing information. Ethiopian Ministry of Health recognize the benefit of Digital Health and introduced information revolution road map and eHealth architecture to ensure interrogability and standards for successful implementation of EMR applications in the country. EMR implementation in Ethiopia were characterized as fragmented, with identified duplicated efforts, inadequate ICT infrastructure or planning, and insufficient enabling environments to support eHealth standards, skills, and knowledge as well as limited e-health coordination at multiple layers of the health sector.

Guidance 60: Documenting Patient Information

MR documentation is essential to ensure quality of care for every patient. All information regarding the patient and his/her course of care at the health center should be recorded in the MR. This includes his/her presenting symptoms and medical history, any diagnostic test orders and results, all documentation from care providers and consultants, interventions, diagnostics, medications, therapy, and information and instructions at discharge. Any subsequent return visits to the health center should be recorded in the same MR. The MR provides each clinician responsible for patient care with access to a record of the patient's health status, medical history, investigation procedures (lab tests, etc.), treatments and outcomes.

HOW AND WHEN TO DOCUMENT

The health care professional responsible for administering clinical event, intervention, instruction or observation, as soon as possible after the occurrence, should document each clinical event, intervention, instruction or observation. MRs of discharged patients should have all documentation completed by the discharging physician before the patient is discharged from the health center and the record should then be returned to the medical record room.

- All entries should be dated and authenticated with full signatures. Professional designation (i.e. MD, RN, etc.) should also be included.
- This information is to be filed in one folder divided in separate sections for each visit/admission in chronological order.
- If the patient/client has a chronic disease and regularly attends a Specialized Clinic (e.g. HIV, TB etc) then a separate section may be created in the MR folder to record all visits to the Specialized Clinic.

GENERAL RULES IN CLINICAL DOCUMENTATION

The patient's name and MRN should appear on each page.

- All handwriting should be in permanent ink that is legible when photocopied. Pencil entry in any part of the record is not permitted.
- All entries should be dated and authenticated, including signature and title of the author.
- Each clinician should sign those portions of the MR containing documentation of care for which he/she is responsible.
- Transcription of verbal orders or other information should be accurate and complete. It should be signed by the person who transcribed the verbal order or other information and co-signed by the person giving the verbal order within one working day of the verbal order.

STANDARDIZED DOCUMENTATION AND FORMS

Only approved and standard clinical forms (approved by government agencies or health center management) should be used in the MR. A standardized format should be used throughout the health center 's to facilitate the entry, review, and retrieval of information. The following criteria can be applied to ensure standardization.

- All forms should be of the same size, usually maximum of A4.
- Key identifiers such as the name of the form, patient's name and medical record number should be located in the same place on all medical record and clinical documentation forms.

KEY COMPONENTS OF CLINICAL DOCUMENTATION & MEDICAL RECORD FORMS

The MR should contain the following components, filed in the following order:

Demographic sheet
Function: A page recording all patient demographic and contact information for all clinicians to reference (patient name, date of registration, date of birth/age, sex, address, emergency contact information).
Location: Front of MR.
Work process: When the patient is first registered, a demographic sheet will be put in the patient's MR.

Summary sheet of all visit dates
Function: To capture patient visits to the facility.
Location: Inner side of the front page of medical folder
Work process: All visit dates, for both inpatient and outpatients, will be recorded on the summary sheet.

History and physical examination assessment
Function: To record patient history and physical examination assessment findings.

Location: MR
Work process: When a patient is admitted as an in-patient a full history and physical examination should be conducted by the attending physician.

Progress notes
Function: To record clinical findings and progress.
Location: MR
Work process: When the patient is seen by a clinician, the information obtained will be recorded with date, clinical details, and signature of the attending clinician.

Consultation request sheet
Function: When a different specialty opinion is sought, the form serves as a communication tool for the different consulting parties.
Location: MR as a permanent record.

HANDLING OF MEDICAL RECORDS

A comprehensive MR management system encompasses the handling the MR from time of patient registration, during active care delivery, through patient discharge, and ongoing filing/storage of the MR, until removal/destruction of old MRs from storage. The flow of MRs/charts is important to ensure a balance between availability of clinical information and patient confidentiality. A well-designed system minimizes the loss of MRs.

TRACKING THE LOCATION OF MEDICAL RECORDS

A MR location tracking system should be established in order to find MRs. The system varies depending on whether or not a paper-based or computerized patient registration system is used. Manual Paper-Based System: A check in/out logbook should be used by Medical Record Unit. Entries on the log should include the following information:

Table 12.1. Tracer card sample

MRN	Date dispatched from MRU	Name & signature of person dispatched	Location MR taken to & Name of care provider	Date returned to MRU

On a daily basis, assigned MR staff should refer to the logbook and ensure that all MRs are returned to the card room. The only exception is for admitted inpatients whose treatment is ongoing. This step is important, as it prevents loss and misuse of MRs. In addition, when a MR is removed, one can put in its place a tracer card, which is a card the size of the MR, on which is written the patient name, the MRN, where the MR is going, and the date it was removed from the file. This can help track where records are outside the Medical Records Room. When not in use the tracer card should be stored in the back of the MR. A sample tracer card is included in (Appendix A).

Computer-Based System: In a computerized patient registration system, a MR tracking feature should allow an easy and effective method to locate MRs.

MEDICAL RECORDS HANDLING

Only authorized personnel should have access to MRs, and only on a "need to know basis." Selected employees who have been designed by health center management to handle MRs and who have received MR training should only access the Medical Records Unit (MRU). When other health center employees need access to MRs, a request should be made to the MR staff. Patients should never handle MRs without staff assistance. Health center should develop strict procedures based on these principles and ensure that all staff members are properly informed and trained for proper implementation practice.

MEDICAL RECORDS AT DISCHARGE

The MR of discharged or deceased patients should be returned to the Medical Record Case Team within 24 hours of discharge. The Medical Record Case Team should review the MR to see if all forms have been properly signed, particularly the discharge summary. If they are not signed, the MR Department should alert the physician on record or case team leader to complete and sign the discharge summary.

ARCHIVING MEDICAL RECORDS

Inactive files (i.e., MRs with no clinical activities for a pre-defined period of time (i.e., 2 years) may be archived by MR staff in order to regain shelving space. Individual health center should establish an archiving policy. When archiving, these files should be numerically stored in a separate area, according to their MRNs. The corresponding MPI index card of the patient should be labelled "archived". NEVER create another file numbering system for archived files. If archived files needed to be retrieved, the same MR retrieving mechanism should be used.

DESTRUCTION OF INACTIVE MEDICAL RECORDS

The MOH "Health center Patients/Clients/Records Retention Schedule" guideline details the length of time a MR is retained in inactive status. In general, a facility is required to retain a MR for up to 10 years after the patient's last episode of care at that facility. After the pre-defined retention period, the MR should be destroyed by burning, shredding or another method that is certain to maintain the patient's confidentiality. Destruction of the medical record should also be supervised by the head of the MR department. If medical records are destroyed, the following key information should be maintained permanently: Medical record name, Full name, Sex and Date of birth, Last visit/Admission/Discharge date, Patient first date of visit, Diagnosis/Patient status, Name of the attending doctor(s), Investigations and operations/Procedures performed and Discharge summary for each admission if more than one.

Table 12.2: Registration logbook for retaining vital patient information while destroying

Medical record number (MRN	Full name	Sex/Date of birth	Last visit/Admission/Discharge date	Patient first date of visit	Diagnosis/Patient status	Name of the attending doctor (s)	Investigations and operations/Procedures performed	Discharge summary

A note should be included with the retained documents stating that the records have been destroyed according to the retention policy. The MR Department should establish a folder to collate the information above for all MRs that are destroyed.

ACCESS TO MEDICAL RECORDS FROM THE HEALTH CENTER

MRs should be accessed from the facility only upon an order from the appropriate jurisdiction bodies. The health center should establish its own policy regarding MR removal from the premises, and this policy should comply with federal and regional health policies. If a patient seeks health care from another health center and has consented to the release of his/her clinical information to the new health center, only a photocopy should be given to the requesting health center. The original MR should never be transferred out of the health center.

CONFIDENTIALITY

MRs should be maintained in the strictest confidence, as they contain personal and private information about patients, including their health status, personal, family and contact information. MRs should be stored in a secure area, and there should be clear policies regarding confidentiality and the release of patient information. Particularly for the medico legal cases, a separate locked MR store should be available on place. The content of a MR should only be used for providing patient care or in the course of supporting patient care activities (for example evaluation of services, clinical audit etc.). Access to the content of MRs should be granted only to personnel who are undertaking the above activities. Other supporting staffs that are granted access to MRs but are not involved in delivering patient care (e.g., porters, runners) should not read and/or disclose the content of the records. All employees should sign a 'Code of Conduct' that includes a statement regarding the confidentiality of patient information.

Guidance 61: Data Quality and Information Use

DATA QUALITY

Data quality is often defined as "fitness for use". Good quality health is dependent on the access to and use of good quality data. It is starting point for health care information, whether maintained manually or electronically. Availability of quality data is at the heart of a functioning evidence-based decision making in the health sector. It is widely recognized that quality data leads to better clinical and health admin decisions that results in better health outcomes for the country. Data quality is important for service users, for healthcare organizations and for researchers.

Symptoms of data quality problems

Different people supply different answers to the same question.

- Data are not collected in a standardized way or objectively measured.
- Staff suspect that the information is unreliable, but they have no way of proving it.
- There are parallel data systems to collect the same indicator.
- Data management operational processes are not documented.
- Data collection and reporting tools are not standardized; different groups have their own formats.

Activity 12.3. Think-pair-share	
	**Instruction:** **Be in pair with your neighbor** Discuss on the question below-write your discussion on your note book. Share your points in the general discussion. Discussion Question: How do you check for data quality problems? **Time:** 5 minutes

- Too many resources (money, time, and effort) are allocated to investigate and correct faults after the fact.
- Mistakes are spotted by external stakeholders (during audits).

Possible solutions to problems of data quality

Standardization and simplification of guidelines and recording and reporting formats across the health system.

- Integration and institutionalization of health data
- Build capacity of health work force from data generation to information use
- Staffing of health institutions with necessary skilled human power to support the HIS
- Strengthen the Performance Monitoring Team (PMT) at each level of the health system

- Enhance culture of information use at each level of health system

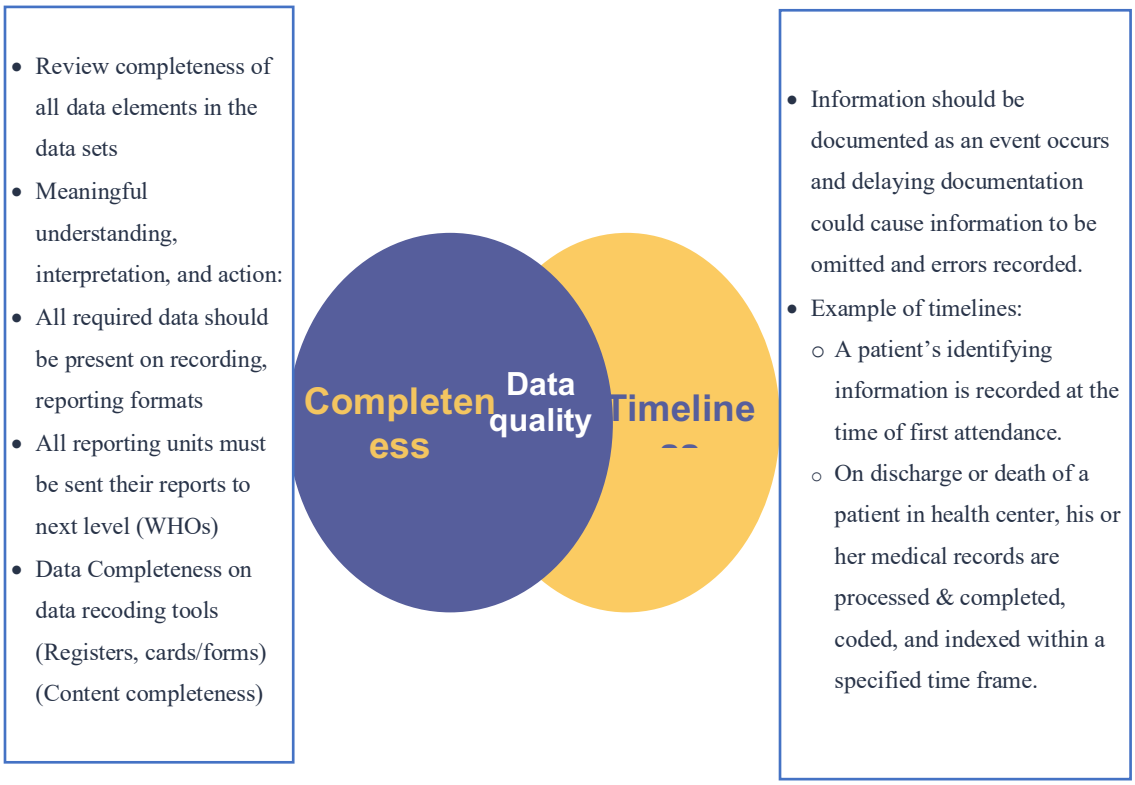


Figure12.2: Most commonly used data quality dimensions identified by MOH

DATA QUALITY ASSURANCE

Data quality assessments help to improve data quality by uncovering hidden problems in data collection, aggregation, and transmission of priority indicator/data. Knowing about these problems allows health professionals and managers to develop data quality improvement plan. There are different techniques used at facility and administrative levels to show the level of data quality and to take corrective measures.

Techniques of data quality assurance

The following methodology shall be applied to assure data quality at service delivery and intermediate health administration units. A desk review of the data that have been reported to national level whereby the quality of aggregate reported data for recommended program indicators is examined using standardized data quality metrics.

Health facility assessment

Data Quality Checks using LQAS method: Other health facility assessments to conduct data verification and an evaluation of the adequacy of the information system to produce quality data (system assessment).

Lots quality assurance sampling (LQAS) is a technique useful for assessing whether the desired level of data accuracy has been achieved by comparing data in relevant record forms (i.e. registers or tallies) and the HMIS reports at Health Facility level.

Box 12.1: Basic Principles of LQAS

1. A method for testing hypothesis, e.g. desired level of HMIS data quality is achieved (or not)
2. Small random sample for a lot/supervisory area is used
    a. The optimal sample size is 19
    b. A sample size of 12 also serves well, particularly if it is consistently used over time for studying the same supervisory area
    c. Testing only two possibilities i.e. Yes or No; Present or Absent
3. If the number of sampled items not meeting the standard exceeds a pre-determined criterion (decision rule), then the lot is rejected or considered not achieving the desired level of pre-set standard
4. "Decision rule" table is used for determining whether the pre-set criterion is met or not
5. Aggregating LQAS data from multiple supervisory areas can give us mathematical percentage of the level of achievement.
6. Comparing LQAS results over time can also indicate if there is any change or not.

Source: Ministry of Health, Health data quality training manual (source)

USE OF DATA FOR DECISION MAKING (UDDM)

The term data /information use refers to the use of data in the decision-making process. A decision maker uses information if he/she is aware of the decision make or question to be answered and relevant information is explicitly considered in the decision-making process, even if the quality of data is suboptimal.

CULTURE OF INFORMATION USE

The perceived value of individuals and organizations on the role of information for informed decision making. Information use at the Health Facility level – facilities need information on the coverage or amount and quality of services, resources availability including human resources, patients' satisfaction with the service etc. These kinds of data inform facilities in planning and managing health services, program's performance, and resources. Information use at the administrative levels – need information on service coverage, burden of disease, disease occurrences, staff performance, resource availability etc. for planning, policy formulation,

performance measurement and improvement, designing interventions, developing strategies, and formulating policies etc.

MAJOR PLATFORMS AND FORUMS FOR INFORMATION USE

The major platforms in the health sector for use of information are the Woreda-based annual planning, regular Performance Monitoring Meetings, and participatory review meetings. These platforms use information to monitor progress vis-à-vis performance targets set at the time of strategic planning (HSTP) and the Woreda-based annual planning. Within this Performance Improvement framework, results are achieved through a process that considers the institutional context, describes desired performance, identifies gaps between desired and actual performance, identifies root causes, and selects interventions to close the gaps and measures changes in performance.

Guidance 62: Data analysis and reporting using DHIS2 application

The District Health Information System (DHIS 2) is a health information system that supports local governments at various levels (Federal, Region, Zone, Woreda, health facility) to efficiently carryout three core categories of health information management activities. Collecting, capturing, validating, and forwarding raw health data. Processing of data which entails analysis, extraction, format manipulation, production and dissemination of statistics, reports, graphs, maps, and similar health information. Using data/information for daily management, budget allocations and long-term planning which have traditionally been done to a very limited extent by most managers and decision makers.

Activity 12.4. Reflection on XX	
	**Instruction:** **Share your thoughts on the question below.** **Discussion Question:** **What are the activities during data analysis and reporting using DHIS2 app.** **Time:** 10 minutes

To address the growing need for timely, complete, and accurate reporting across the various health networks, the FMOH developed the DHIS 2 system. The DHIS 2 is an information system that enables health facilities, Woreda Health Offices (WorHO), Zonal Health Departments (ZHD), and RHBs to electronically compile weekly and immediately reportable diseases, out-patient department (OPD), inpatient-department (IPD), and service delivery data for Public Health Emergency Data and electronically receive and submit them to the next level. Reports are submitted and received electronically through secure web based DHIS 2 system working both offline and online modality. The data and data elements also can also be exported via removable

media such as USB flash drives, and CD/DVD where internet/network connectivity is not available.

The core objectives of the application software are to ensure reporting completeness, accuracy and timeliness to ultimately foster local data analysis and information use. In addition to that, by facilitating the evidence-based decision-making process and culture of information use for the successful implementation of information revolution agenda including other agendas in HSTP II.

OVERVIEW OF DATA QUALITY CHECKS USING DHIS2 APPLICATION

Ensuring data quality is a key concern in building an effective HMIS. Data quality has different dimensions including:

- **Correctness:** Data should be within the normal range for data collected at that facility. There should be no gross discrepancies when compared with data from related data elements.
- **Completeness:** Data for all data elements for all health facilities should have been submitted.
- **Consistency:** Data should be consistent with data entered during earlier months and years while allowing for changes with reorganization, increased workload, etc. and consistent with other similar facilities.
- **Timeliness:** All data from all reporting org. units should be submitted at the appointed time.
- **Data quality checks:** data quality checking can be done through various means, including; at point of data entry, the software can check the data entered to see if it falls within the min-max ranges of that data element (based on all previous data registered).

Defining various validation rules, which can be run once the user has finished data entry. The user can also check the entered data for a particular period and Organization Unit(s) against the validation rules and display the violations for these validation rules. Analysis of data sets, i.e. examining gaps in data. Data triangulation which is comparing the same data or indicator from different sources.

RUNNING VALIDATION RULE ANALYSIS

A validation rule is based on an expression which defines a relationship between a numbers of data elements. The expression has a left side and a right side and an operator which defines whether the former must be less than, equal to or greater than the latter. The expression forms a condition which should assert that certain logical criteria are met. For instance, a validation rule could assert that the total number of vaccines given to infants is less than or equal to the total number of infants.

The validation rule analysis function will test validation rules against the data registered in the system. Validation violations will be reported in cases where the condition defined through the validation rule expression is not met, i.e. the condition is false.

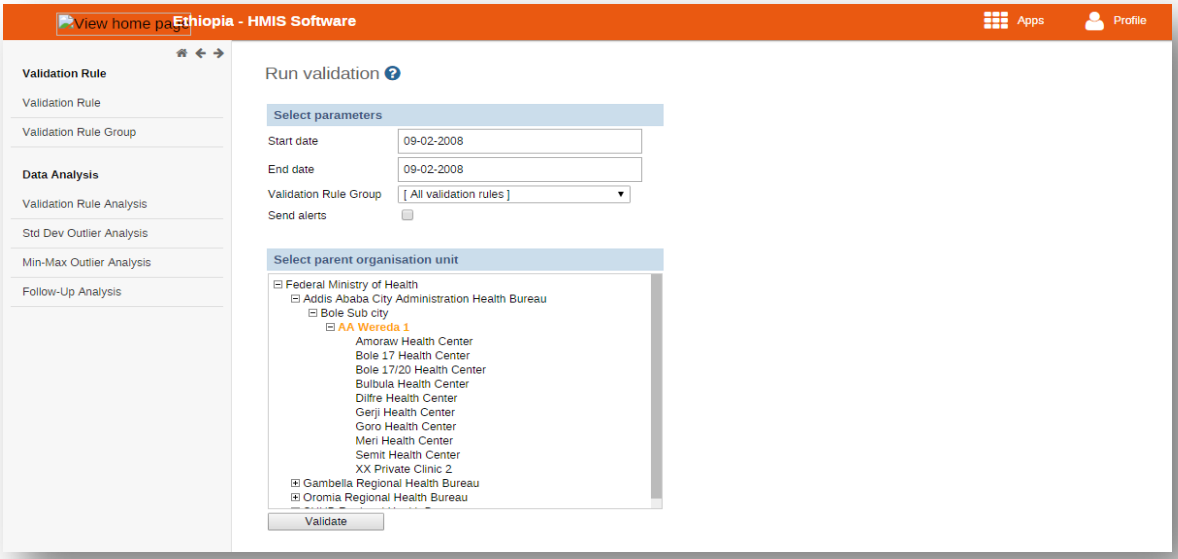


Figure 12.3: Data Validation Check using DHIS2 Application

Validation results

The analysis process will run for a while depending on the amount of data that is being analyzed. If there were no violations of the validation rules a message saying validation passed successfully is displayed. If validation violations were found, they will be presented in a list. The organization unit, period, left side description and value, operator, and right-side value and description for each validation violation are displayed. The show details icon can be clicked in order to get more information about a validation violation. This will open a popup screen that provides information about the data elements included in the validation rules and their corresponding data values. This information can be used in order to fix incorrect data. The validation violations can be exported to a PDF document by clicking on the Download as PDF button, and to a Microsoft Excel workbook by clicking on the Download as Excel button.

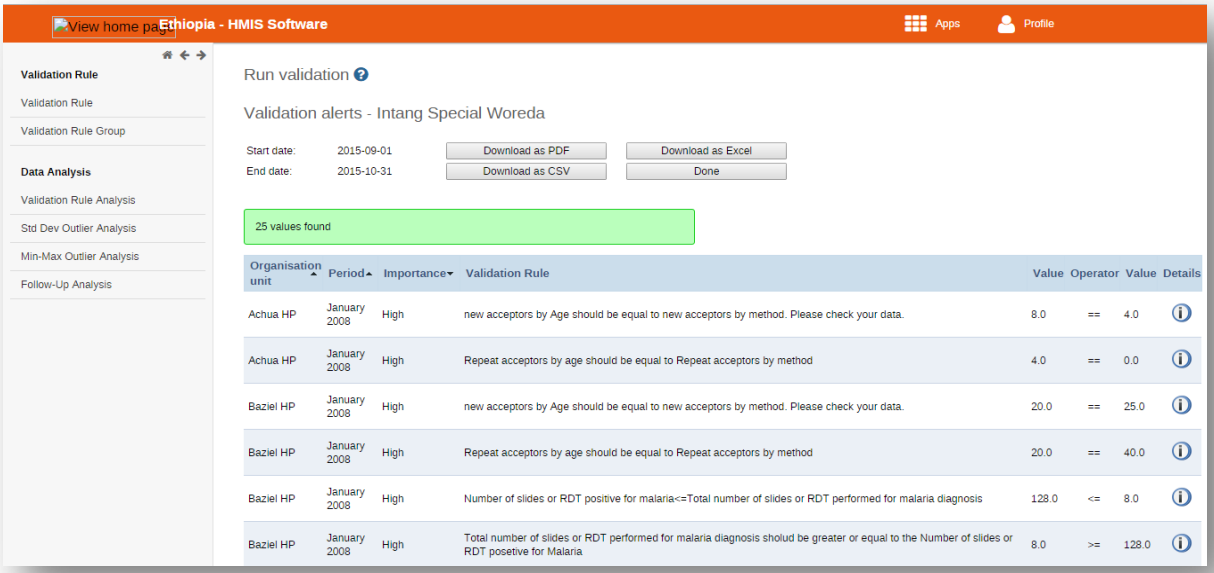


Figure 12.4 Data validation result using DHIS2 application

STANDARD DEVIATION OUTLIER ANALYSIS

You can access Outlier analysis from the Services → Data Quality menu. The standard deviation-based outlier analysis provides a mechanism for revealing values that are numerically distant from the rest of the data. Outliers can occur by chance, but they often indicate a measurement error or a heavy-tailed distribution (leading to very high numbers). In the former case one wishes to discard them while in the latter case one should be cautious in using tools or interpretations that assume a normal distribution. The analysis is based on the standard normal distribution. Select what data to analyse:

- First, select the form and to date for the data to include in the analysis.
- Second, select the data set from which to pick data elements from.
- Third, select all or some of the data elements in the data set by double-clicking or marking them and clicking the add/ remove buttons.
- Fourth, select the parent organization unit to use. All children of the organization unit will be included.
- Fifth, select the number of standard deviations. This refers to the number of standard deviations the data is allowed to deviate from the mean before it is classified as an outlier.

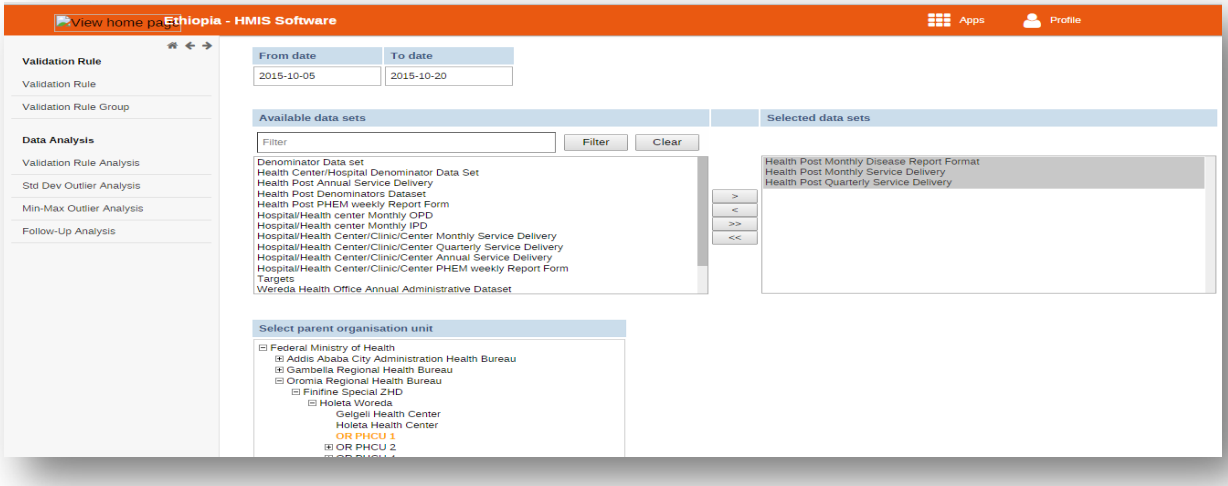


Figure 12.5: Data Validation rule check using DHIS2 Application

Analysis result

The potential outlier values discovered will be presented in a list after the analysis process is finished. The data element, organization unit, period, minimum value, actual value, and maximum value will be displayed for each outlier. The minimum and maximum values refer to the border values derived from the number of standard deviations selected for the analysis. Each outlier value can be modified directly in the analysis result page. The value can be modified by clicking inside the corresponding field in the value column, entering a value and then navigate away from that field either by clicking tab or anywhere outside the field. The system will provide an alert if the value is still outside the defined minimum and maximum values, but the value will be saved in any case. The field will have a red background color if the value is outside the range, and a green if inside. Each outlier value can be marked for further follow-up by clicking the star icon.

MINIMUM - MAXIMUM OUTLIER ANALYSIS

The min-max value-based outlier analysis provides a mechanism for revealing values that are outside the pre-defined minimum and maximum values. Minimum and maximum values can be custom defined or automatically defined by the system in the data administration module. See the section about Std dev outlier analysis for further details on usage.

REPORTING (DHIS2) SYSTEM

DHIS2 to has several features that can help the work of improving data quality; validation during data entry to make sure data is captured on the right format and within a reasonable range, user-defined validation rules based on mathematical relationships between the data being captured (e.g. sub totals vs totals), outlier analysis functions, as well as reports on data coverage and completeness. More indirectly, several of the DHIS2 design principles contribute to improving data quality, such as the idea of harmonizing data into one integrated data warehouse, supporting local level access to data and analysis tools, and by offering a wide range of tools for data analysis

and dissemination. With more structured and harmonized data collection processes and with strengthened information use at all levels, the quality of data will improve. The most basic way of data quality check in DHIS2 is to make sure that the data being captured is on the correct format. The DHIS2 will give the users a message that the value entered is not on the correct format and will not save the value until it has been changed to an accepted value. E.g. text cannot be inputted in a numeric field. The different types of data values supported in DHIS2 are explained in the user manual in the chapter on data elements. To stop typing mistakes during data entry (e.g typing '1000' instead of '100') the DHIS2 checks that the value being entered is within a reasonable range. This range is based on the previously collected data by the same health facility for the same data element and consists of a minimum and a maximum value. As soon as the users enter a value outside the user will be alerted that the value is not accepted. In order to calculate the reasonable ranges, the system needs at least six months (periods) of data.

Guidance 63: Performance Monitoring Team (PMT)

Performance Monitoring Team is a team of multidisciplinary health workforce that is primarily responsibility to improve data quality and use information regularly to monitor progress and improve performance at all levels. Ensuring data quality and continuous use of information will result in improvement in access, utilization, coverage and quality of health services.

Group of the Performance Review Team at the Health Facility level

1. Health center and PHCU Director or official delegate chairs the PMT
2. All case team coordinators serve as a team members
3. The PMT at health center level may invite the HEWs to participate in the meeting on need basis
4. HMIS focal person serves as secretary and responsible for:
    - Ensuring data accuracy, timeliness, and completeness of HMIS reports
    - Supports the case team coordinators to review and interpret the data analysed to help them make a decision and take action.
    - Ensuring recording of the meeting minutes; archive the minutes and circulate them to all concerned in a timely manner.
5. The PMT evaluates the overall performance accordingly
6. The Performance Review Team meets on monthly basis and assess/evaluate the overall performance of the Health center or the Primary Health Care Unit (PHCU), develop improvement action plan, and track the implementation

12.4. Implementation checklist and indicators

12.4.1. Implementation checklist

Table 12.3. Assessment Tool for Operational Standards - HIS

S.No	Standard	Verification criteria	Yes √ No X	met =1 not met =0	Remark
1	The Health Center shall have a single unified health information system department.	Availability of Card room			
		Have MR registration Officers including runners			
		Have HIT Units/HIT experts			
		Have data managers for electronic data entry.			
2	The Health Center shall have a single standardized medical record room	Total of 5-10 shelves for storing medical records.			
		Each shelves should be labelled			
		Have MPI boxes			
		Have Computers and UPSs for electronic patient registration.			
		Have adequate furniture's (1 table, 1 chair, and accessories) and office materials			
3	The Health Center should avail and utilizes standard set of formats for medical record registration	**Card room:** patient Individual Folder, Patient ID, Tracer cards, MPI card, patent history sheets,			
		OPD Room: OPD Abstract, Tally sheet, Progress Notes, Lab orders, referral, prescription, etc			
		HIT Room: Reporting formats (OPD, IPD and Service), updated version of DHIS2 app, NCOD, etc			
4	The Health Center should have medical records	Audit bi-annually to identify passive and active cards.			

S.No	Standard	Verification criteria	Yes √ No X	met =1 not met =0	Remark
	management auditing system.	Consistency check b/n electronic and manual system though auditing [Check redundant cards, duplication, incomplete, etc) by selecting 10 individual patient cards from MPI check consistency]			
		Review utilization of formats (Randomly sample 10 individual patient cards seen in the previous quarters, and confirm that each has a minimum, data elements (demographic data, clinical and administrative information)			
5	The Health Center has ensure proper handling and confidentiality of medico legal patient- medical records.	Have assigned focal person for medico-legal issues at card room.			
		Identify medico legal cards			
		Prepare lockable box for medico-legal cards			
		Ensure Medico legal cards should register when they submitted and returned to medico-legal box			
6	The Health Center have a capacity building platform to improve health information system.	Regular gap identification on data management			
		Have regular bi-monthly meeting b/n HIT and medical record.			
		Provide training for all staffs working in medical record management			
		Have trained HIT professionals			
7	The health center should establish a functional PMT team	Have a PMT team comprise of different case teams.			
		Have regular monthly meeting with documented minute			

S.No	Standard	Verification criteria	**Yes √ No X**	**met =1 not met =0**	**Remark**
		Have avail and utilize standard PMT and data quality Logbook			
8	The health center needs to prepare strategic plan, annual quarterly and monthly plan	Have documented five years strategic plan			
		Have documented annually plan that is disaggregated quarterly and monthly,			
		Cascaded plan up to each unit/case team of the health center which is agreed and signed by each unit leader			
9	The health center needs to collect report and utilize findings for internal service quality improvement	Availability of copy of the report /monthly, quarterly, bi-annually, and annually/			
		Prepared improvement plan of action based on the identified gaps			
		Perform plan vs achievements (by chart, table, graphs, map, etc)			
		Display performance both internally and external to the community (by chart, table, graphs, map, etc)			
10	The health center needs to implement Data quality audit selected priority problems	Self-assessments of health center performance conducted using LQAS			
		Have functional DHIS 2 application with updated data			
		Major indicators selected for follow up where the health center has poor performance			
		Developed action plan			
11	The health center should have fulfilled all the requirements of Information Revolution.	Have plan to improve the implementation of Connected Woreda strategy (CWS).			
		Assign enough budget for HIS activity			

S.No	Standard	Verification criteria	Yes √ No X	met =1 not met =0	Remark
		regularly monitor the implementation of Connected Woreda strategy (CWS).			
12	The health center performs QI projects to improve identified data quality gaps	Quality improvement project is developed for identified gaps during data evaluation by the PMT and Quality unit			
		Action plans are implemented			
		Charts are plotted to measure progresses			

Appendices

Appendix 1A Sample Health Center Mission, Vision and Values Statements

A Mission can be defined as 'purpose, reason for being' or simply 'who we are and what we do'.
A Vision can be defined as 'an image of the future we seek to create'.

Mission statement

The mission of [ ] Health Centre is to provide health promotion, diseases prevention, curative and rehabilitation services for all people in its catchment area through community engagement, empowerment, mobilization and ownership.

Vision Statement

To see a model [ ] Health Centre in [ ] administrative zones by the year 20 [- -].

Values of [ ] Health Center

Respect and dignity. We value each person as an individual, respect their aspirations and commitments in life, and seek to understand their priorities, needs, abilities and limits. We take what others have to say seriously. We are honest about our point of view and what we can and cannot do.

Commitment to quality of care. We insist on quality and striving to get the basics right every time: safety, confidentiality, professional and managerial integrity, accountability, dependable service and good communication. We welcome feedback, learn from our mistakes and build on our successes.

Compassion. We respond with humanity and kindness to each person's pain, distress, anxiety or need. We search for the things we can do, however small, to give comfort and relieve suffering. We find time for those we serve and work alongside. We do not wait to be asked, because we care.

Improving lives. We strive to improve health and well-being and people's experiences of our health center. We value excellence and professionalism wherever we find it – in the everyday things that make people's lives better as much as in clinical practice, service improvements and innovation.

Working together for patients. We put patients first in everything we do, by reaching out to staff, patients, caregivers, families, communities, and professionals outside the health center. We put the needs of patients and communities before organizational boundaries.
Everyone counts. We use our resources for the benefit of the whole community, and make sure nobody is excluded or left behind. We accept that some people need more help, that difficult decisions have to be taken – and that when we waste resources we waste others' opportunities. We recognize that we all have a part to play in making ourselves and our communities healthier.
Adapted from The NHS Constitution for England. DOH, London, Jan 2009.

Appendix 1B Sample content of Governing Body training programme

Governance:

- What is health center governance?
- What are sub-city or Woreda Health Office expectations of Governing Bodies?
- Roles and responsibilities of Governing Body
- Jurisdiction and Power of Health Center Governing Body
- Leadership and Code of Conduct for Governing Body Members
- Role of Chairman, Members and Health Center Manager
- Disclosure of Gifts and Loans
- Register of Interests
- Conflict of Interest
- Meeting Agendas and Rules
- 8 Deadly Sins of Health Center Governance
- Policies, Guidelines and Protocols
- Health Center Management Committees
- Complaints Management
- Adopting the Code of Conduct
- Public Interest vs. Private Interest
- Dealing with Material Personal Interest and Conflict of Interest
- Dealing with Official Misconduct

Performance monitoring:

- Health Center Reporting System to the Governing Body
- Benchmarking

Patient and community involvement:

- Patients' Rights and Responsibilities
- Involving the community
- Community score card

Business and Financial Management:

- Planning Cycle
- Health Center Corporate Plan
- Health Center Operational Business Plan
- Annual Budget
- Annual Report
- Revenue and Expenditure
- Raising Revenue
- Commercial activities

- Health center enterprises
- Private Wing
- Fees and Charges
- Grants and Subsidies
- Borrowings
- Developer Contributions/Infrastructure Charges

Planning and Development

- Planning and Development
- Land Use Planning

Appendix 1C Sample Self-Assessment Checklist for Governing Body

1. Legal Structure of the Health Center and Background Information	
a. Is there documentation relating to the role and reporting responsibilities and appointment of the Governing Body (GB) and its members	Yes/No If yes, list and provide copies of documentation available:
b. Are there any special issues or challenges facing the health center (i.e. member communication, resources, stability)	Describe:
c. Date of most recent governance review	State date:
2. Role of Governance Body and Accountabilities	
a. Is there approved strategic plan.	List and provide copies of objects/purpose, mission, vision, values, strategic directions etc
b. Does the strategic plan cover more years of activity?	Start dates: End Date:
c. Does the board facilitate health center-community interface meeting? d. If yes, what is the date of the last review?	Yes/No If yes, state date:
3. The Governance Board's Role	
a. Define the role of the Body	Define:
b. Is there a statement of the Board's role? If yes, date of last review	Yes/No If yes, date: Provide copies of statement if available
c. Does the board has annual work plan?	Yes/No If yes, provide copy
d. Provide an outline of how the Body performs its responsibilities for the following areas of Body performance: • Strategic planning development • Oversight of the Health center overall management • Closely follow quality of health services (risk identification and management) • Composition of health center governance board in line with legal framework	Describe:
4. **Duties, Obligations and Expectations of Individual Body Members**	
a. Is there a Board Code of Conduct that describes the rules of fiduciary conduct (avoid conflict of interest, corporate obedience –	Yes/No If yes, provide copy.

solidarity, board speaks with one voice – confidentiality, loyalty)?	
b. Describe expectations regarding the level of attendance and participation at the Board and Committee meetings. How are these expectations communicated?	Describe:
c. Describe individual board member evaluation (self-evaluation and/or peer review)	Describe:
5. Governance Board members	
a. Describe the following: • Board members composition and qualification • Term • Termination • Role • Voting rights	Yes/No If Yes state date of last review: Provide copy of available
b. Do all members have written mandates/TOR	Yes/No If yes, provide copies
c. Are members' mandates/ TOR reviewed periodically?	Yes/No Describe:
d. How are Members established?	Describe:
e. How are Members reports dealt with the Board?	Describe:
f. Is the Audit Committee comprised of independent directors?	Describe:
g. Is there an Executive Committee? What is its role? Describe decision making role.	Yes/No If Yes describe:
6. Governance Board Orientation, Education and Evaluation	
a. Is the Board orientation mandatory? How is orientation conducted?	Yes/No Describe and provide index of orientation manual if available
b. Is there a written manual for new Board members?	Yes/No If yes, provide index
c. Is an annual Board retreat held?	Yes/No If yes, state date of last retreat, attendance and agenda

d. Is there an annual evaluation of the performance of individual board members and the board as a whole?	Yes/No If yes, provide copy of the evaluation tool and describe process for providing feedback and action on results

Appendix 1D Guidelines/etiquette for effective committees and meetings

When a new committee/group is established it is important to:

1) Determine group membership:
    - Consider which departments/people are most involve and should be on team
    - Include all points of view, including conflicting ones
2) Assign a Chair and Secretary

3) Establish Terms of Reference for the group including:
    - Function/duties of the committee
    - Description of outputs expected
    - Realistic timeline for completion of project (if relevant)
    - Statement of who the group/committee is accountable to (if relevant)
    - Frequency of meetings

4) Set schedule for meetings, ideally at a fixed frequency, day and time. (For example, the first Monday of every month at 4pm; or every Wednesday at 3pm). A fixed schedule makes it easier for committee members to plan their schedule and remember to attend the meetings.

For each meeting:

5) The Secretary and Chair should circulate an agenda, the minutes of the previous meeting, and papers for discussion in advance of the meeting. These should be circulated to all committee members in advance (ideally one week before the meeting).

6) All committee members should review the agenda, minutes and items for discussion BEFORE the meeting so that they have full information for discussion at the meeting. If the meeting is spent reviewing items for the first time then much time will be wasted and the meeting will be unproductive.

7) Begin and end the meeting ON TIME. Do not wait more than a few minutes for members who are late.
8) Be concise and stay on topic. If the agenda is long, a time limit should be set for each agenda item.

9) Begin the meeting by reviewing the minutes of the previous meeting and obtaining an update report on any action points that were assigned from the previous meeting.

10) For each item on the agenda agree any action points that need to be followed up after the meeting. For each action assign a specific individual to complete the task and a deadline for completion (for example prior to next meeting, or within one month etc)

11) Prepare minutes of each meeting. These should include a summary of discussions and all action points should be clearly stated with the name of the responsible individual.

Appendix 1E Duties and Responsibilities of Key Finance Personnel

Finance Head

a. Plans, manages and controls the accounting functions in the health center and manages the work of Accountants and cashiers. Maintains the current Health center Accounting Manual.
b. Manages the health center cash at Bank and accounts and cash in safe

c. Monitors level of cash in safe, Suspense Payment Vouchers and cash in bank
d. Signs cheques and all vouchers in accordance with the financial delegations approved by the CEO and the Governing Board.
e. Ensures that the work of accounts are up to date, the monthly reports are produced accurately and delivered to concerned authorities/institutions on a timely basis
f. Ensures that financial formats, registers and ledgers are available to execute the accounts work
g. Cheques and verifies:
    - The hands budget/ledger cards to all source of funds and prepared source documents and enters transaction on Transaction Register
    - The posting of the entries from the Transaction Register to the General Ledger, Budget/Expenditure subsidiary Ledger Card and Subsidiary Ledger Cards
    - All accounting records are maintained up to date
    - All monthly reports and bank reconciliation statements

The Accountant

a. Prepares a cash receipt voucher in triplicate for every receipt of cash or cheques in the name of the Health center and maintains receipt vouchers
b. Keeps the cheque book and prepares cheques
c. Prepares source documents for retained revenue and government budget
d. Maintains Budget/Expenditure Subsidiary Ledger Cards
e. Prepares appropriate monthly reports for all sources of finance (donors fund, retained revenue and government budget)
f. Prepares bank reconciliation statements for all bank accounts maintained by the health center for retained revenue and government budget accounts
g. Maintains vouchers and cheque books of accounts of the health center
h. Keeps all financial documents after registration in chronological order
i. Provides financial documents to auditors (both internal and external) when required

Cashier

a. Collects the health center cash receipts, cheques, and draft and cash payment orders by issuing an official pre-printed receipt voucher for the sums received revenue
b. Collects or receives the cash from other revenue collectors or assistant cashiers and deposits into the bank
c. Withdraws cash from the bank when endorsed by the assigned signatories
d. Handles the petty cash at the health facility level where authorized by appropriate officials
e. Handles the cash in safe and suspense payment vouchers
f. Pays employees salary and operating expenses
g. Issues cash receipts voucher to cash collectors
h. Prepares summary receipt voucher and distribute to cash collector and Accountant
i. Keeps unused cheque in locked safe box
j. Keeps all original documents of bid bond performance guarantees, cheques and payment orders.
k. Collects new chequebooks from the bank when authorized by the CEO.
l. Transfers source documents to the Accountant after filling and signing Financial Document Transitory Forms (Model 42).

Daily Cash Collector(s)

a. Collects or receives cash from clients/patients and others by issuing an official pre-printed receipt voucher for the sums received

b. Remits collected cash daily to the main cashier
c. Prepares daily cash collection/receipts summary by revenue code

Internal Auditor

a. Advises the head of the health facility on the effectiveness of the internal control systems within the facility and assists in establishing an efficient, effective control system.
b. Ensures that all health facility resources are used only for the proper and approved purposes, and that they are used in the most economical, efficient and effective way through conducting internal audit at specific intervals, and submits reports to the head of the health facility and a copy to respective Finance Office.
c. Ensures compliance of the facility management with established policies, procedures, laws and regulations, including behavioral and ethical expectations.
d. Safeguards the Health facility's assets from losses of all kinds, including those arising from fraud, irregularity or corruption.
e. Monitors the achievement of the health facility's objectives and assess and identifies the risks in achieving the objectives.
f. Ensures the integrity and reliability of the health facility's financial information, accounts and data including internal and external reporting and accountability processes.

Other staffs

Health centers shall have other staffs that are necessary to carry out their day-to-day activities. These other staffs include procurement officer, storekeeper, archive staffs and statistician.

Appendix 1F Sample Memorandum of Understanding for Fee Waiver

Memorandum of Understanding
Between
"Fee Waiver Issuing Authority" and "[name] Health Institution"
Regarding

Financing of Health Services Rendered to Fee Waiver Certificate Holders

WHEREAS the resources mobilized and allocated for health sector in Ethiopia are by far less than the required level of basic health service delivery;

WHEREAS the Federal Council of Ministers endorsed a health care and financing strategy, which is serving as a basis for formulating various health finance reform measures in the country;

WHEREAS the main aims of the strategy are to increase efficiency in the use of available resources and promote sustainability of health care financing to improve coverage, equity and quality of health services;

WHEREAS some of the changes suggested by the Strategy were, among other things, allowing facilities to retain user fees, rationalize and tighten rules for fee waivers, and steps to revise user fees;

WHEREAS no one should be excluded from use of health services because of increased user feed;

WHEREAS no health service shall be completely free and some one has to pay for it;

Now, therefore, the two parties have entered into this Memorandum of Agreement dated ---------- ---------- for Financing of Health Services Rendered to Fee Waiver Certificate Holders residing in ----------Woreda/Kebele.

1. Purpose and framework of the agreement

The overall purpose of the agreement is to ensure equity and efficiency in Health Service delivery by the health institution. It is drawn within the framework of expanding equitable and quality basic health service delivery system and provide efficient and sustainable health services.

2. Scope of agreement

This agreement is applicable to health service rendered by health facilities for free to holders of fee waiver certificate issued by the fee waiver issuing authority, which has entered into this agreement. It applies to all types of health services provided by the health institution.

3. Obligations of the two parties

3.1. Duties of the health institution

The health institution has the following duties and responsibilities:

a) Render all types of health services within its capacity to all persons demanding and deserving those services without making any distinction between waived and paying patients;

b) Ensure that the poor are able to utilize health services rendered by the health institution;

c) Record services rendered to fee waiver certificate holders in a format provided for this purpose and submits periodic reports, in line with the established norms for reporting, to the next higher level of authority;

d) Request reimbursement for services rendered freely at the end of each quarter of the budget year;

e) Shall not provide unnecessary services and shall not charge higher fees for services given to waiver certificate holders than to the paying patients;

f) Post the fee payable and the conditions under which health services are provided free of charge and conduct educational programmes to make the public aware of this fact;

g) Collect and deposit payments made in reimbursement of costs incurred for health services provided to patients entitled to waiver;

3.2. Duties of fee waiver certificate issuing authority

a) Certificate granting authorities have full obligation to reimburse the fees that the health facilities would have received had the service would not have been rendered freely to certificate holders.

b) Verifies and disburses payments received from health facilities within one week of the receipt of request for disbursement by the health institution;

c) Submits list of fee waiver certificate holders and copies of each of the fee-waiver certificates issued to the health institution;

d) Make payments to referral health facilities for services given to fee-waiver certificate holder through referral letters issued by the health institution, which has signed this agreement.

e) Ensure that those issued with fee waiver certificates are indeed those who deserve it.

f) Allocate budget to cover for the fee-waiver certificates issued by it.

4. Duration/ Tem of this Agreement

This agreement is valid for one budget year, starting from Jul 1 to June 30 of the next Ethiopian Fiscal Year.

5. Monitoring and evaluation of this agreement

The two parties shall convene and discuss the implementation of this agreement twice per year: one at the end of the first six months and one at the end of the budget year.

In witness whereof, the parties hereto execute this agreement

Health Institution [NAME]	Fee waiver certificate issuing authority [NAME]
Name of signatory: _____	Name of Signatory ----------
Title: ----------	Title ----------
Date: ----------	Date _____

Witnesses

1.
Name:_____

Address:_____

2.Name:
_____

Address:
_____

3.Name:
_____

Address
_____

Appendix 1G Sample Fee Waiver Beneficiary Register

No	Date of service rendered	Full name	Age	Sex	Occupation	Address			Waiver certificate #	ID number	Medical card #	Category (Inpatient /Outpatient)	Cost of services provided				
						Woreda	Kebele	House #					Exam.	Lab test	Drugs	Others	Total

Appendix 1H Sample Departmental Fee Waiver Expense Registration Form

_____Regional Gov't,_____Woreda, _____Health Center

Fee Waived Patient Charge Form

No	Date	Name of Waived Patient	Card Number	Type of Service Provided	Fee Charged in Birr		Name and Signature of Accountant
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							
Total							

Appendix 1I Sample Bill for Reimbursement of Fee Waiver

From: [Name of Health Facility]

To: [Name of Reimbursing Institution]

No	Name of Patient	Fee-Waiver card Number	Woreda	Kebele	Date Service is provided	Total Requested Reimbursement	Name and signature of the beneficiary
Total							

_____ _____

Prepared by [Name and Signature] Approved by [Name and Signature]
Accountant Finance Officer

Note: The Bill is prepared in three copies. 1st and 2nd copy will be sent to the waiver certificate issuing authority (retains 1st copy and sends 2nd copy to WOFED for payment), 3rd copy is retained in the Health Facility for record.

Appendix 1J Sample of fee calculation for public patients

The Health Care Reform and Financing strategy stipulates that user fees should be set on a cost sharing basis. Accordingly, some expenditure items may not go into the calculation. For practical considerations it is useful to limit the user fees to costs that can easily be attributed to a given service for example:

- medical examination (card) fee
- laboratory tests
- X ray
- drugs
- consumables such as gloves and syringes

Example to Set Examination (card) fee

In setting the examination fee the elements that should be considered are direct and indirect costs of printing the card and a certain percentage of the salary of medical personnel who are deployed to provide medical examinations.

a. Total cost of printing cards (paid to printing house) plus total transportation plus loading and unloading cost divided by the total number of cards printed = the average cost of printing a card, which is unit cost of a card that should go into the calculation of examination fee.
b. A given % of costs of total salary of medical personnel (to be determined by an appropriate authority)
c. Add the above a+b to arrive at Examination/Card Fee to be charged

Example to Set the Cost of Drugs

To set the cost of drugs one should consider the purchase price of drugs from the distributor, transportation cost, loading and unloading cost and other direct costs. After considering all the costs the total cost divided by the by the number of tins, pills, capsules, bottles, etc will give the unit cost of the drug.

a. Direct purchase price of the drug
b. Transportation and associated costs such as loading and unloading to be divided equally among all types of drugs procured
c. Per diem associated and other costs related with procurements will be divided among the types of the drugs
d. Profit to be calculated as a given percent of purchase price to be decided by appropriate authority
e. The Price of a Particular unit of drug = Purchase price + Transportation cost + loading and unloading cost + Per Diem and other related costs DIVIDED by the number of units (number of tin, pills, capsules, bottles, etc) PLUS a certain %, say 25% to calculate PROFIT of the Health facility.

Example to Set Laboratory Test Fees

To determine the cost of lab tests, we need to have information on the purchase price of reagents, the number of tests that we can make with a unit of reagent and the total cost of laboratory equipment.

a. Add total purchase price + transportation cost + per diem and any other direct cost related to the acquisition of the reagent and DIVIDE the sum by total reagent units to arrive at the cost of a unit reagent.
b. Estimate or get data from past experience on the number of tests that can be conducted using one unit/volume of reagent to arrive at cost of a given reagent per test

c. Determine % of profit to be calculated per test (to be decided by appropriate authority)
d. Then Laboratory test fee = Cost of one unit reagent DIVIDED by NUMBER of Tests that we can make by a unit of reagent TIMES a given % equals laboratory fee to be charged for that particular test.

Example to Set Bed Fee

The bed fee can be estimated by considering the cost of housekeeping, (which can be calculated by taking into account the detergents per month, number of beds or bed sheets) purchase price of bed sheets and blankets, wage of cleaners, or, by taking the cost of acquiring the materials and by calculating outsourcing cost per unit of bed into account. To set fee for bed per day:

a. Estimate cost of bed sheets and blankets (calculate the duration of service in terms of days and divide the cost by number of days); take the quotient you get to calculate the bed fee
b. Consider cost of detergents for washing the bed sheets and blankets (take total cost of detergents used per month and divide by the total number of bed sheets)
c. Take wage of cleaners/ janitors (divide monthly salary by number of bed rooms); and take some %, say 5% of the unit wage cost for the calculation of bed fee
d. Or instead of (b) and (c), take outsourcing cost for housekeeping divided by the number of bed rooms
e. Add some %age to cover part of the fixed costs and/ or profit on (a + b + c), or on (a + d)
f. Add (a + b + c)+(e), OR, add (a + d + e) to set fee per bed

Daily Inpatient Fees

The daily inpatient fee is meant to cover bed, food, theatre, and drug and doctor fees. Laboratory and x-ray fees also should be collected from inpatients according to the number and type of investigations performed.

Outpatient Fees

An outpatient treatment fee is chargeable for each treatment received by the patient. The health facility manager is responsible for having the most recent list of chargeable treatments and the correct fee. This list should be distributed to all relevant staff at the facility and posted in waiting areas.

Non-Ethiopians

Since Health center are subsidized from government treasury, tax payers resource or the public fund, foreigners are required to pay double for all fees. Note that the cost of health services for refugees are often covered though agreements with United Nations or other agencies responsible for refugee assistance. Billing arrangements should be investigated.

No treatment-no fee.

If treatment is not provided because the treatment is not available, e.g. drugs, then there is no charge. If the patient purchases materials privately the treatment fee should not be charged for applying the treatment.

Appendix 1K Sample Receipt Voucher

The [NAME OF HEALTH FACILITY], hereafter called [HEALTH FACILITY], and [NAME OF THE SIGNATORY], hereafter called "the subscriber" have entered into this agreement as of [date] [month] [year] in [PLACE]

A. Telephone number of the Subscriber ----------
B. Address of the Subscriber (Location: Region/Zone/Woreda) ----------
C. Name and signature of higher official of the Subscriber ----------

Areas of agreement

The health facility shall be obliged to provide all medical services on credit, unless otherwise it is expressly stated that the services, which includes [LIST THEM HERE], cannot be provided on credit.

1 The customer shall receive medical treatment if admitted as an emergency case or if s/he presents a referral letter;

2 No medical service is granted to a person demanding medical service unless s/he produces a medical form especially prepared for this purpose, which is signed by officials, whose sample signatures are already deposited with the health facility;

3 The letter/referral authorizing the bearer to receive medical services on credit shall be valid for a single episode of illness;

4 If a person receiving medical treatment is laid off from work while receiving medical services from the health facility, the Subscriber shall have an obligation to notify the health facility to discontinue provision of medical service on credit. The Subscriber, however, shall be obliged to settle the total value of medical services provided to the employee of the Subscriber before notification;

5 The Subscriber shall be obliged to go to the credit services section of the health facility and collect invoices on or before the 5th day of the every month and settle within 15 days the total value of medical services granted to all of its employees on credit. After making the payments, the Subscriber should make sure that the payment is recorded by appropriate section of the health facility. No further request for medical services on credit shall be entertained if the Subscriber fails to make the payments for services granted on credit basis as per the terms of this agreement.

6 The health facility shall have the authority to terminate this agreement without further notice if the Subscriber fails to honor the terms of this agreement and fails to settle its bills. The health facility shall have the authority to claim unsettled bill at a court of law.

7 The persons who have received medical services upon credit based on credit agreement should ask for a medical certificate immediately after s/he received the services. The Subscriber shall have no right whatsoever to ask for medical certificate at a later date. If, for some reason, the Subscriber doubts the genuineness of medical certificates, it shall have the right to demand clarifications by writing official letter to the health facility.

8 This agreement shall be valid for a period of one year;

9 If the Subscriber who entered into this agreement with the health facility is transferred to another location, sold, changed, becomes bankrupt, closed, dissolved, etc., it shall have the obligation to settle its bills beforehand and request for termination of this agreement. Transferring the obligation to a third party shall not be allowed and hence not acceptable.

10 If the Subscriber fails to act in accordance with the terms an conditions indicated above, the health facility shall have the authority to terminate this agreement without any further notice. The health facility shall have the right to claim any unsettled bills in a court of law if the Subscriber fails to pay the total value of medical services granted to the employees of the Subscriber on credit basis.

11 We, the undersigned, representing our respective institutions have correctly understood all the terms and conditions indicated above from 1-10 have entered into this agreement.

On behalf of the health facility:	On behalf of the Subscriber
_____	_____
Name and Signature	Name and Signature
[OFFICIAL STAMP]	[OFFICIAL STAMP]

Witnesses:

1 Name _____ Signature _____
2. Name _____ Signature _____
3. Name _____ Signature _____

Copy:
(As appropriate)

Appendix 3A

Assessment checklist for basic emergency services			
S.no		Yes	No
1.	Does the facility provide emergency service 24 hours a day and 7 days a week?		
2.	Is the EU clearly labelled and visible?		
3.	Is there ambulance parking area close to the emergency unit?		
4.	Does the EU have a separate:		
	Triage area		
	Resuscitation area		
	Procedure area		
	Examination area		
	Short stay area		
	Waiting area		
5.	Does the emergency unit have a dedicated director or case team leader?		
6.	Is the emergency department led by an MSC/BSC nurse, health officer or physician trained in emergency and critical care?		
7.	Has the clinical staff received short course in-service training?		
8.	Does the EU have 24 hrs access to these services?		
	Laboratory service		
	Radiology service		
	operation theatre		
	pharmacy service		
	blood product service		
9.	Is there a written documented disaster preparedness plan?		
10.	Is there a disaster equipment storage area?		
11.	Is there HC liaison and referral service?		
12.	Is Liaison and Referral Officer has been assigned?		
13.	Are there personnel trained in Liaison and referral communication		
14.	Does your HC have a record-keeping system to keep track of Referral out		

Appendix 3B: The basic equipment and supplies needed for effective running of the Emergency Department or Unit are listed below:

A. Airways/Breathing

- Bag valve mask:
- Laryngeal Mask Airway
- Nasal prongs
- Nasopharyngeal airways
- Nebulizers
- Oropharyngeal airways
- Oxygen cylinder with a flow meter
- Suction machines and tubes
- Tongue depressor
- Tracheostomy set
- Transport Ventilators
- Ventilator (ICU)- optional for primary hospital
- Ventury airway mask/ poly mask
- Yankeur suction

B. Circulation/Hemodynamics

- 12 lead ECG machine
- Blood and fluid warmer
- Central venous catheters
- Cut-down set 1 (phased out)*
- Defibrillator/ Automated External Defibrillator (AED)
- Foley's catheter
- High-capacity catheters
- Infusion pumps
- Intraosseous Needles
- IV cannula 14, 16 18 20 and 22
- Syringe pumps

C. Splints

- Bandages
- cervical collar –soft/hard collar
- POP
- Spine board
- Splints (specify the types needed)
- Trac 3 traction kit*

D. Monitoring Devices

- Pulse oximeter
- Patient Monitors (invasive and noninvasive)
- Glucometer
- Blood gas electrolyte analyzer
- Spirometer/ peak flow meter
- Thermometer
- Diagnosis set

- Stethoscope
- Sphygmomanometer (Digital & Android)

E. Other Emergency Equipment

- Bradlow tape measure (for children)
- Weighing scale
- Telephone and directory
- Pedal operated color-coded waste bins
- Safety box for sharps
- Blood fridge
- Cabinets
- Computer and accessories and appropriate software
- Consumable cabinet
- Drug cabinet
- Examination couch
- Examination lamps
- Hoist
- Instrument trays
- Office furniture
- Refrigerator
- Resuscitation trolley/tray
- Rollers
- Stretchers
- Suction machine
- Telephones
- Trolleys
- Wheel chairs

F. Diagnostic

- Blood gas/electrolyte analyzer
- Mobile X-ray machine
- Diagnostic set
- Diagnostic Peritoneal Lavage set
- Glucometer
- Laboratory sample set
- Lumber puncture set
- Minor surgical set
- Fetal heart monitor
- Hand held Doppler machine
- Suprapubic catheter sets
- Ultrasound machine

G. Medicines

Essential medicines needed for effective running of Emergency are listed below:

- 50% Dextrose
- Adrenaline
- Nor-adrenaline
- Anti-snake venom serum
- Aspirin
- Atropine
- Anti-Tetanus Serum
- Dextran/ voluven
- Diazepam
- Dobutamine
- Etomidate
- Fresh Frozen Plasma
- Gelofusin
- Group O negative whole blood
- Heparin
- Hydralazine

- Hydrocortisone
- Glucagon, IM
- Insulin
- IV calcium Gluconate
- IV Dopamine
- IV Fluid - all type
- IV Frusemide
- IV KCl
- IV Vit K
- Labetalol
- Lignocaine
- 10% xylocaine spray
- Magnesium Sulphate
- Mannitol
- Midazolam
- Morphine
- Naloxone
- Nitroglycerine
- Oral Rehydration Salt (ORS)
- Oxygen supply
- Pethidine
- Phenylephrine
- Propofol
- Salbutamol
- Sodium bicarbonate
- suxamethonium

Appendix 3C: The list of equipment required in OPD

- Stethoscope
- Sphygmomanometer
- Thermometer
- Weighing scale
- Infant meter and height scale
- Otoscope
- Dressing set
- Specula of different sizes
- Stand lamp/ torch
- Reflex hammer
- Fetoscope
- Snellen's chart
- Ophthalmoscope
- Pickup forceps with jar
- Sterilization drum
- Infusion stand
- Instrument tray
- Instrument trolley
- Sterilizer (steam and dry)
- Kidney basin
- ENT set, mobile
- Tuning forks , 500Hz
- Packing nasal forceps,
- Patient forms:
    - History and examination sheets
    - Consultation request form
    - Referral form
    - Laboratory request form
    - Prescription pads
- Sample collection supplies
- Dressing supplies
- Personal protective equipment

No	ITEM	Yes/No
1.	Functional Sphygmomanometer (BP apparatus)	
1.	Stethoscope	
2.	Suction machine portable	
3.	Pinnard stethoscope (Fetoscope)/doppler	
4.	Ultra Sound	
5.	Thermometer	
6.	Filled oxygen tank with flow meter	
7.	Nasal prongs for oxygen administration	
8.	Catheter for oxygen administration	
9.	5 delivery sets, at least two sterile	
10.	Sterile suture kit	
11.	Forceps	
12.	Vacuum extractor	
13.	Urinary Catheter	
14.	HIV test kits (KHB, Stat pack)	
15.	Stand lamp	
16.	Speculum for vaginal examination	
17.	Craniotomy set	
18.	Sterilizer (Steam or dry)	
19.	Ambu-bag with sterile mask	
20.	Bed with accessories	
21.	IV stand	
22.	Mask for oxygen administration	
23.	Cord cutting/clumping set	
24.	Radiant Warmer	
25.	Towels for drying and wrapping new-born babies	
26.	weighing scale for baby	
27.	Tape to measure baby length and Head circumference	
28.	Functioning clock	
29.	Two Episiotomy set	
30.	Suction bulb for NB resuscitation	
31.	Long sleeve glove for removal of retained placenta	
32	NASG	
33	MVA set (at least two)	
34	E & C set (at least two)	

Appendix 4A: Essential drugs that must be available in emergency drug cabinet of L& D ward

No	In the emergency drug cabinet on the L&D ward or refrigerator	Yes/No

1	Uterotonic medication (Oxytocin, Misoprostol Po and/ or Ergometrine)	
2	Magnesium sulphate	
3	Diazepam	
4	Antihypertensive medication (Nifedipine and Hydralazine)	
5	40% glucose	
6	IV Cannula	
7	Lidocaine	
8	Syringe & needle	
9	IV fluids (crystalloids)	
10	Tetracycline eye ointment	
11	Sterile gloves	
12	Atropine	
13	Vitamin K	
14	Adrenaline	
15	Ampicillin IV	
16	Calcium Gluconate	
17	TDF/3TC/EFV (ARV drugs)	
18	Nevirapine syrup	
19	Aminophylline	
20	Hydrocortisone	

Appendix 4B: Medical equipment in labour and delivery ward and operation theatre (equipment must be functional at the time of assessment)

Appendix 4C: List of drugs and equipment that should be available in operating theatre

S. no	In operation theatre	Yes	No
1.	Ketamine injection		
2.	Oxygen inhalation		
3.	Thiopental iv		
4.	Halothane		
5.	Muscle relaxant (Suxamethonium and Vecronium)		
6.	Lidocaine injection and or Bupivacaine		
7.	Lidocaine + epinephrine injection		
8.	Ephedrine injection		
9.	Dexamethasone im		
10.	Diazepam /iv/		
11.	Suction		
12.	Oxygen		
13.	Ambu bag (Adult)		
14.	Ambu bag (Neonatal)		
15.	Spinal Needle		
16.	3 Caesarean section sets at least one ready		
17.	2 Laparotomy sets with at least one ready		

Appendix 4D: Facility, Supplies and Equipment for Under 5 OPD

No	Equipment/Facility/supply	Yes	No
1	Functional hand washing basins		
2	Examination beds with clean sheets		
3	Table and chair for the physician (clinician)		
4	Weight and height measuring scales for infants and children		
5	MUAC tapes		
6	Thermometers		
7	Otoscopes and torches		
8	Paediatric BP apparatus (different sizes)		
9	Disposable and sterile gloves and alcohol swab		
10	Syringes and needles as required		
11	Printed papers such as prescription papers, lab request forms, X. ray and U/S request forms, referral papers		
12	HMIS/IMNCI registers		

Appendix 5A: ABC and VEN analysis for reviewing of Health Centre Medicine List and purchase prioritization

ABC analysis is a method for determining and comparing pharmaceutical costs within the formulary system. It follows the Pareto principle "separating the vital few from the trivial many". ABC Analysis can be explained in terms of budget consumed and number of drugs in the budget list as follows:

VEN Analysis

If funds are limited, **VEN** analysis is a method to prioritize for medicine purchase. This analysis is used to identify high-priority medicines for procurement and low-priority medicines that the DTC should analyze carefully for deletion from the Medicine List.

VEN stands for:

V = Vital:

- Potentially lifesaving :
- Crucial to providing basic health services; without which it is impossible to deliver the service
- It is mandatory 24 hours of a day and 12 months of a year

E = Essential: Effective against less severe but significant illness, not vital; it is between Vital and less essential

N = Non essential/less essential: Effective for minor illnesses but have high cost and low therapeutic advantage

Steps for conducting a VEN analysis are as follows:

- ***Step 1.*** Classify all medicine list of the health facility as V, E, or N
- ***Step 2.*** Analyze the "N" items. Where possible, reduce quantities to purchase or eliminate them.
- ***Step 3.*** *Perform ABC analysis*
- ***Step 4.*** *Reconcile the ABC analysis with the VEN*
- ***Step 5.*** Perform stock analysis for items that create discrepancy between ABC and VEN See appendix J
- ***Step 6.*** Identify and limit therapeutic duplications.
- ***Step 7.*** Reconsider proposed purchase quantities.
- ***Step 8***. Find additional funds if needed or possible.

ABC Analysis

Applications of ABC analysis:

See steps of ABC analysis below

- Measures the degree to which actual consumption reflects public health needs and morbidity
- Reduces inventory levels and costs by arranging for more frequent purchase or delivery of smaller quantities of class A items

- Seeks major cost reductions by finding lower prices on class A items
- Reduces inventory of items that have limited use in the system, but costs the system large amounts of money
- Provides information for choosing the most cost-effective alternatives and finding opportunities for therapeutic substitution and gathers information for pharmaco-economic analysis

Method of Categorization

Category	Percentage of Budget	Percentage of Drugs Orders
"A" Drugs	70-80%	10-20%
"B" Drugs	15-20%	10-20%
"C" Drugs	5-10%	60-80%

"A" medicines:

- High percentage of funds spent on large-volume or high-cost items
- Greatest potential for savings
- Greatest potential for identifying expensive medicines that are overused

"B" medicines:

- Moderate cost and moderate number of items.

"C" medicines:

- Small amount of funds spent on the majority

Steps of ABC analysis:

Step 1: The group should take each drug, reagents and medical supplies from the purchase receiving model (model 19) or equivalent with their unit and total price for the intended years

Step 2: Crosscheck the price of drugs, medical supplies and reagents that is found in our model19 does exactly correlate with that of the finance section file

Step 3: Add drugs and medical supplies that might be purchased through pity cash, and money paid for loading and unloading from the drug budget.

Step 4: Cross check the total amount paid is exactly the same as the budget allocated

Step 5: Categorize each supply with A, B or C.: sort all of the items by alphabetical order

Step 7: Add all same drugs / supplies purchased on different days or price

Step 8: Sort out again in descending manner so that the largest amount being on the top and decreasing down.

Step 9: Calculate percentage of each item from the total budget of that particular year. This value tells us the amount of each drug or medical supply that took from total budget. Then as indicated earlier the summation of percentage of the items up to 70-80% should categorize under grade A. And the rest (15%-20%) should be taken as category C

Step 10: Crosschecking of drug order system with cost percentage system. This categorization should be crosschecked by creating drug order and using percentage of drug order as a cut point instead of using the percentage of budget

Step 11: Percentage of drugs order should be taken 10-20%, 10-20%, 60-80% as a cut point as shown below.

Category	Percentage of Budget	Percentage of Drugs Orders
"A" Drugs	70-80%	10-20%
"B" Drugs	15-20%	10-20%
"C" Drugs	5-10%	60-80%

Step 12: The results of both systems should be compared and one should gate comparable results

Appendix 5B: Patient Medication Profile Card

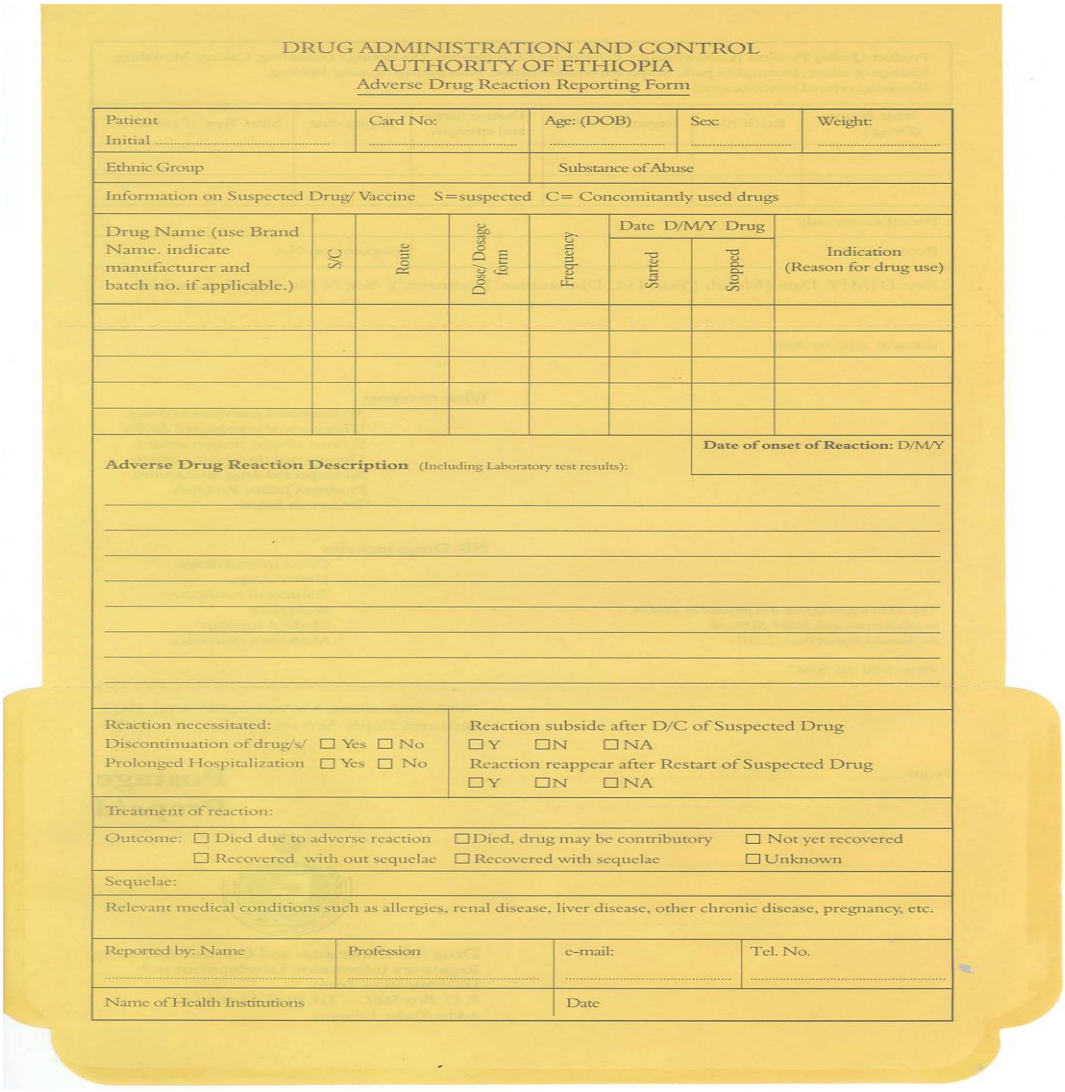
PATIENT MEDICATION PROFILE CARD

Name of Health Institution: _____

Patient Information			**Clinical Information**					
Card No: _____			**Type of Chronic Illness: _____**					
Name: _____			Current Status: □ On active treatment □ Transferred-out □ Lost for Follow-up □ Deceased					
Sex: □ Male □ Female Date Started: _____	Age: _____ years Wt. on Start: ___ Kg		**History of ADR or Side Effects**		**Concomitant Diseases**		**Reason for Change in Regimen or other remarks**	
			Date	Description	Date	Description	Date	Description
Patient Source: □ Inpatient □ Outpatient								
Address	Patient's: _____ _____ Tel:	Support Person's: _____ __						

Drug Dispensing Information																															
Date	Reason for Visit		Weight in Kg	In/Outpatient (I/O)	Prescriber	**Drugs Dispensed**																Other Drugs	Date of Next Visit								Signature	
	Start	Refill			Initial	Drug No	Drug One				Drug Two						Drug Three															
							Drug Name	Strength	Brand	Quantity	Drug Name	Strength	Brand	Quantity	Drug Name	Strength	Brand	Quantity														

Appendix 5C: Sample Adverse Drug Reaction Reporting Form



DRUG ADMINISTRATION AND CONTROL AUTHORITY OF ETHIOPIA

Adverse Drug Reaction Reporting Form

Patient Initial	Card No:	Age: (DOB)	Sex:	Weight: .....
Ethnic Group		Substance of Abuse		
Information on Suspected Drug/ Vaccine S=suspected C= Concomitantly used drugs				

Drug Name (use Brand Name. indicate manufacturer and batch no. if applicable.)	S/C	Route	Dose/ Dosage form	Frequency	Date D/M/Y Drug Started	Date D/M/Y Drug Stopped	Indication (Reason for drug use)

Adverse Drug Reaction Description (Including Laboratory test results):

Date of onset of Reaction: D/M/Y

Reaction necessitated: Discontinuation of drug/s/ ☐ Yes ☐ No Prolonged Hospitalization ☐ Yes ☐ No	Reaction subside after D/C of Suspected Drug ☐ Y ☐ N ☐ NA Reaction reappear after Restart of Suspected Drug ☐ Y ☐ N ☐ NA
Treatment of reaction:	
Outcome: ☐ Died due to adverse reaction ☐ Died, drug may be contributory ☐ Not yet recovered ☐ Recovered with out sequelae ☐ Recovered with sequelae ☐ Unknown	
Sequelae:	
Relevant medical conditions such as allergies, renal disease, liver disease, other chronic disease, pregnancy, etc.	

Reported by: Name	Profession	e-mail:	Tel. No. .....
Name of Health Institutions		Date	

Product Quality Problem (Colour change, Separating of components, Powdering / crumbling, Caking, Moulding, Change of odour, Incomplete pack, Suspected contamination, Poor packaging /poor labeling, Receiving expired medicines,etc)					
Trade Name (Drug)	Batch No.	Registration No.	Dosage form and strength	Expiry date	Size/ Type of container
For office use only					
Received On:				Registration No.	
Key: D|M|Y Date |Month |Year; D/C Discontinue Treatment; Y Yes; N No; NA Not available					

መጀመሪያ አዚህ ሳይ አጠፍ

What to report

All suspected reactions to drugs
Unknown or unexpected ADRs
Serious adverse drug reactions
Unexpected therapeutic effects
All suspected drug interactions
Product Quality Problem
Treatment failure

NB. Drugs includes

Conventional drugs
Herbal drugs
Traditional medicines
Biologicals
Medical supplies
Medicated cosmetics

This ADR reporting form was prepared by DACA in collaboration with MSH-SPS and the financial support from USAID.

ቀጥሎ አዚህ ሳይ አጠፍ

የጉዳይ መልስ መስጫ አገልግሎት ፈቃድ ቁጥር HQ2
Business Reply Service Licence No. HQ2

From .....

Postage Prepaid

Drug Administration and Control Authority
Regulatory Information Development and Dissemination Team
P. O. Box 5681 - Tel. 0115-52 41 22/23
Addis Ababa, Ethiopia

Appendix 5D: Sampl Bin Card

Name of health facility _____

Product name, strength and dosage form_____

Unit of issue_____

Date	Doc.Number (Receiving or Issuing)	Received from or Issued to	Quantity				Batch No.	Expiry Date	Remarks
			Received	Issued	Loss/Adj	Balance			

Appendix: 5E

Sample Stock Card

Name of Health Facility _____
Product name, Strength and dosage form_____
Unit of Issue _____Bin Location _____
Maximum stock level_____
Reorder level_____
Minimum stock level/ Emergency order point_____
Average Monthly /last month consumption if regular increase/_____

year	Jan	Feb	March	April	May	June	July	August	Sept	Oct.	Nov	Dec.	Total	Los/ adjustment
2011														
2012														
			Average				Average				Average			

Appendix: 5F

Stock Status Analysis Chart

Ser. No	**Description:** Name of drug, Dosage form, Strength, bran if any	Unit	Total Stock at hand & ordered	Expiry Date	Average Monthly or last month Consumption if increasing	Months of Stock (MOS) Stock could be enough for months	Until expiry, the amount of stock that could be consumed
			A	***B***	***C***	***D***	***E***
Key: A = Stock Dispensing Units + Other Service Units + Pharmacy Store +SO		C = Quarter Consumption / 3 - DOS in Months			D =A/C ,	E = (C x Shelf life in month), or = (A) when no over stock, Note: *S.L	

Note:- If column G is negative number, then divide that number by column C ; the result is the amount of stock available that can be used for extra months (more than 4 month), extra months than the 4th month are indicated as negative H .And out of stock months before the 4th month are indicated as positive **H**. When calculating **D,** the shelf life of a drug is very much important. *S.L. stands for "shelf **life"** of a drug should be considered in calculating consumption ". SO=stock ordered, DOS=days out of stock in months. When ABC/VEN analysis is performed and when **A**. Class items are in discrepancy with VEN, then A class should be subjected to Stock Status Analysis. When a drug has near expiry, it should be analysed with this Stock Status Analysis Form

Appendix 5G: Model 20/1- Internal Facility Report and Requisition (IFRR)-Voucher

SN	Internal Drug Code	**Description:** (Drug/Reagent/ Supplies / Name Strength, Dosage Form	**Completed by Dispensing Units**				**Completed By Store**			**Qty to be Approved**	**Remark**
			Beg Stock	**QTY Received**	**Loss /Adj.**	**End stock**	**Calculated Consumption E=A+B±C-D**	**Max F=E*2**	**Qty to Max G=F-D**		
			A	**B**	**C**	**D**	**E**	**F**	**G**	**H**	

Reported/Requested by Name …… Signature & date: …….. Approved by Name ……Signature & Date

Note: *Original to the store, second copy to pad. The information in the carbon copy may serve as a beginning balance for audit and second round request.*

Appendix 5H: Facility Combined- Report and Requisition Form (FC-RRF)

Health Facility_____ **Region**_____
Zone_____ **Woreda**_____
Reporting period: From _____**to** _____
(Month/day/year) (Month/day/year)

SN	Item Code	Item Description	Unit of Issue	**Report Part**						**Requisition**
				Beginning Balance in Store	Quantity Received	Losses/ Adjustments	Ending Balance in Store	Days Out of Stock	Calculated Consumption	Maximum Stock Quantity
				A	**B**	**C**	**D**	**E**	**F= A + B +/- C – D**	**G = F * 2**

Remarks:
Completed by: _____ signature: _____
date: _____

Approved by: _____ signature: _____
date: _____

Appendix 5I: Sample Store Inventory Form (SIF)

Name of Health facility_____ Section (unit) store Page number _____ Date_____

SN	To be Filled Before the Physical Inventory						To be Filled During Inventory		To be Filled After Physical Inventory			Remark
	Drug code	Description (Drug name, dosage form, strength and brand)	Unit	Batch No	Expiry date	Unit cost	Physical QTY	Stock card Balance	Total cost		Discrepancy	
Sum Total												

Inventory Registered by Name _____Counted by Name _____Recounted by Name _____

Signature_____ Signature _____ Signature _____

Responsible Persons Name_____,_____,_____ _____

Signature's _____,_____,_____ _____

Appendix 5J: Sample Sales Ticket

Name of Patient_____sex_____age_____

Sales Ticket **Seri. No**

Name of the pharmacy (printed) **Date**

Full Name of patient

Drug Code	Description (drug name , dosage form, brand if any,)	Unit	Quantity	Retail Price		Tota Pric
			Sum Total			

Signature of dispenser **Signature of casher**

Tele: xxxxxxxx (printed) **stamp**

Paid stamp
ተከፍሏል

Annex 5K

Major category	Medication	Dossage form	checked with PHCG

Anaesthetics	**local Anaesthetics**	**lidocaine**	Injection: 1%; 2% (hydrochloride) in vial•	
			Topical forms: 2% to 4%	
Medicines for pain and palliative care	**Non-opioids and non-steroidal anti-inflammatory drugs (NSAIDs)**	**aspirin**	Tablet: 100mg to 500mg	
		Diclofenac Potassium	Injection, 25mg/ml in 3ml ampoule, 75mg/m	
			Tablet, 25mg, 50mg	
		ibuprofen	Tablet: 200mg; 400mg	
		Paracetamol	Tablet: 500mg	
	Opioid analgesics	**Codeine**	Tablet 30mg	
		morphine hydrochloride	Injection: 10mg in 1mL ampoule	
			Tablet (immediate release): 10mg	
		Morphine sulphate	Oral Solution, 5mg/5ml, 10mg/5ml, 20 mg/ml, 50mg/ml,	
		Tramadol HCL	Injection, 50mg/ml	
			Tablet/Capsule, 50mg,75mg,100mg	
	Medicines for other common symptoms in palliative care	**diazepam**	100 mg/ml	
			Tablet: 5mg; 10mg	
		docusate sodium	Capsule: 100mg	
			Oral liquid: 50mg/5mL	

		loperamide	Solid oral dosage form: 2mg	
		Senna	Oral liquid: 7.5mg/5mL	
		Metoclopramide	Tablet: 10mg	
		Chloropheniramine	**Tablet, 2mg, 4mg, 6mg**	
		Epinephrine	Injection: 1mg in 1mL ampoule	yes
		hydrocortisone	Powder for injection: 100mg in vial	yes
		PromethazineHydrochloride	**Injection, 25mg/ml in 1ml and 2ml ampoules**	yes
		Cetrizine	**Oral solution, 1mg/ml,**	
			Tablet, 5mg, 10 mg	
		loratadine	Tablet: 10mg	
		prednisolone	Tablet: 5mg; 25mg	
Antidotes and other substances used in poisonings	**non specific**	**charcoal, activated**	Powder	
	Specific	**atropine**	Injection: 1mg (sulfate) in 1mL ampoule	
		naloxone	Injection: 400mcg (hydrochloride) in 1mL ampoule	
Anticonvulsants/ antiepileptics		**diazepam**	Injection: 5mg/mL	
		Gel or rectal solution	5mg/mL in 2mL; 4mL tubes	
		lorazepam Parenteral formulation	2mg/mL in 1mL ampoule; 4mg/mL in 1mL ampoule	

		magnesium sulfate	Injection: 0.5g/mL in 2mL ampoule; 0.5g/mL in 10mL ampoule	
		midazolam	• Ampoule: 1mg/mL; 10mg/mL	
			Solution for oromucosal administration: 5mg/mL; 10mg/mL	
		Phenobarbitone	Tablet,15mg, 30mg, 60mg,100 mg	
		phenytoin	Injection: 50mg/mL in 5mL vial	
			Tablet: 50mg	
		valproic acid	Tablet: 200mg	
Anti-infective medicines	**Intestinal anthelminthics**	**albendazole**	Tablet: 400mg	
		mebendazole	Tablet: 100mg	
		praziquantel	Tablet: 150mg; 600mg	
		pyrantel	Tablet: 250mg	
	Antischistosomals and other antitrematode medicines	**praziquantel**	Tablet: 600mg	
	Beta-lactam medicines	**amoxicillin**	Solid oral dosage form: 250mg; 500mg	
		amoxicillin + clavulanate	Tablet: 500mg + 125mg	
		ampicillin	Powder for injection: 1g in vial	

		benzathine benzylpenicillin	Powder for injection: 900mg benzylpenicillin (=1.2 milliomIU) in 5mL vial; 1.44g benzylpenicillin (=2.4 millionIU) in 5 mL vial	
		Crystaline pencillin	Injection, 1 MIU, 10 MIU, 20 MIU In Via	
		cefalexin	Solid oral dosage form: 250mg	
		cefazolin	Powder for injection: 1 g (as sodium salt) in vial	
		ceftriaxone	Powder for injection: 250mg; 1g in vial	yes
		cloxacillin	Capsule: 500mg	
		phenoxymethylpenicillin	Tablet: 250mg	
		procaine benzylpenicillin	Powder for injection: 1g (=1 millionIU); 3g (=3 millionIU) in vial	
	Other antibacterials	azithromycin	Capsule: 250mg; 500mg	
		ciprofloxacin	Tablet: 250mg	
		Chloramphenicol	Injection(sodium succinate), 1gm in via;Oily suspension for injection, 0.5gm (as sodium	

			succinate)/ml in 2 ml ampoule	
		clindamycin	Injection: 150mg/mL	
			Capsule: 150mg	
		co-trimoxazole	Tablet: 160mg/800mg	
		dapsone	Tablet: 25mg; 50mg; 100mg	
		doxycycline	Solid oral dosage form: 100mg	
		erythromycin	Solid oral dosage form: 250mg	
		gentamicin	Injection: 40mg/mL in 2mL vial	
		metronidazole	Injection: 500mg in 100mL vial	
			Tablet: 200mg to 500mg	
		nitrofurantoin	Tablet: 100mg	
		Tetracycline HCL	Capsule, 250mg	
		Tindazole	Tablet, 250mg, 500mg	
		vancomycin	Powder for injection: 250mg in vial	
	Antituberculosis medicines	isoniazid	Tablet: 300mg	
		rifampicin + isoniazid + pyrazinamide + ethambutol	Tablet: 150mg + 75mg + 400mg + 275mg	
		rifampicin + isoniazid	Tablet: 150mg + 75mg; 300mg + 150mg	

	Antifungal medicines	clotrimazole	Vaginal cream: 1%	
			Vaginal tablet: 500mg	
		fluconazole	Capsule: 50mg	
		griseofulvin	Solid oral dosage form: 125mg; 250mg	
		nystatin	Tablet: 100 000IU; 500 000IU	
	Antiherpes medicines	**aciclovir**	Tablet: 200mg	
	Nucleoside/nucleotide reverse transcriptase inhibitors	**abacavir (ABC)**	Tablet: 300mg	
		lamivudine (3TC)	Tablet: 150mg	
		tenofovir disoproxil fumarate (TDF)	Tablet: 300mg	
		zidovudine (AZT)	Tablet: 300mg	
	Non-nucleoside reverse transcriptase inhibitors	**efavirenz (EFV)**	Tablet: 600mg	
		nevirapine (NVP)	Tablet: 200mg	
	Protease inhibitors	**atazanavir**	Solid oral dosage form: 300mg	
		lopinavir + ritonavir (LPV/r)	Tablet (heat stable): 200mg + 50mg	
		ritonavir	Tablet (heat stable): 100mg	
	Fixed-dose combinations	**tenofovir + emtricitabine + efavirenz**	Tablet: 300mg + 200mg + 600mg	
		emtricitabine + tenofovir	Tablet: 200mg + 300mg	
	Antimalarial medicines	**artesunate + amodiaquine**	Tablet: 25mg + 67.5mg; 50mg + 135mg; 100mg + 270mg	
		artemether + lumefantrine	Tablet: 20mg + 120mg	

		Artemether	**Oral Suspension, 40mg/0.5ml, 80mg/ml Injection, 20mg/ml, 40mg/ml, 80mg/ml**	
			Suppository, 40mg	
		artesunate	Injection: ampoules, containing 60mg anhydrous artesunic acid	
		artesunate + mefloquine	Tablet: 25mg + 55mg; 100mg + 220mg	
		sulfadoxine pyrimethamine	Tablet: 500mg/25mg	
		Chloroquine	Injection, 50mg/ml (equivalent to 40mg/ml base)	
			Syrup, 50mg base/5ml	
			Tablet, 250mg, 500mg(equivalent to 150mg, 300 mg base)	
		Primaquine	Tablet, 7.5 mg, 15mg base	
		quinine sulphate	Tablet: 300mg	
	Antipneumocystosis and antitoxoplasmosis medicines	**co-trimoxazole**	Tablet: 800mg + 160mg	

Antimigraine medicines	**For treatment of acute attack**	**paracetamol**	Tablet: 500mg	
Antiparkinsonism medicines		**biperiden**	Injection: 5mg (lactate) in 1mL ampoule	
Medicines affecting the blood	**Antianemia medicines**	**ferrous sulphate**	Tablet: equivalent to 65mg iron	
		folic acid	Tablet: 400mcg	yes
		iron + folic acid	Tablet: equivalent to 60mg iron + 400mcg folic acid	
Blood products of human origin and plasma substitutes	**Plasma-derived medicines**	**anti-D immunoglobulin**	Injection: 250mcg in single-dose vial	
		hepatitis B immunoglobulin	Injection: 100IU/mL sterile solution	
		rabies immunoglobulin	Injection: 150IU/mL in vial	
		Tetanus anti-toxin	Injection, 1500 Units, 3000Units	
		tetanus immunoglobulin	Injection: 500IU in vial	yes
Cardiovascular medicines	**Antianginal medicines**	**metoprolol**	Tablet: 50mg; 100mg	
		glyceryl trinitrate	Tablet (sublingual): 500mcg [0.5mg]	
		isosorbide dinitrate	Tablet (sublingual): 5mg	
	Antihypertensive medicines	**amlodipine**	Tablet: 5mg	
		metoprolol	Tablet: 50mg; 100mg	
		enalapril	Tablet: 2.5mg; 5mg	
		hydralazine	Powder for injection: 20mg in ampoule	

		hydrochlorothiazide	Solid oral dosage form: 12.5mg; 25mg	
		methyldopa	Tablet: 250mg	
	Medicines used in heart failure	**carvedilol**	Tablet: 3.125mg; 6.25mg; 12.5mg	
		enalapril	Tablet: 2.5mg; 5mg	
		furosemide	Injection: 10mg/mL in 2mL ampoule	
			Tablet: 40mg	
		hydrochlorothiazide	Solid oral dosage form: 25mg	
		spironolactone	Tablet: 25mg	
	Anti-platelet medicines	**aspirin**	Tablet: 100mg	
	Thrombolytic medicines	**streptokinase**	Powder for injection: 1.5 million IU in vial	
	Lipid-lowering agents	**simvastatin**	Tablet: 20mg; 40mg	
Dermatological medicines (topical)	**Antifungal medicines**	**miconazole**	Cream: 2%	
		selenium sulfide	Detergent-based suspension: 2%	
		terbinafine	Cream: 1% or ointment: 1%	
		Ketoconazole	2% cream	Not in essential drug list
		Clotrimazole	1% cream	
	Anti-infective medicines	**Clindamycin**	1% topical gel	Not found in essential list
		mupirocin	Cream: 2%	
			Ointment: 2%	

		potassium permanganate	Aqueous solution: 1:10 000	
		silver sulfadiazine	Cream: 1%	
	Anti-inflammatory and antipruritic medicines	**betamethasone**	Cream or ointment: 0.1%	
		calamine	Lotion, 5%	
		hydrocortisone	Cream: 1%	
	Medicines affecting skin differentiation and proliferation	**benzoyl peroxide**	Cream: 5%	
		podophyllum	Solution: 15%	
		salicylic acid	Solution: 5%	
	Scabicides and pediculicides	**Benzyl benzoate lotion**	25% lotion	
		permethrin	Lotion: 1%	
			Cream: 5%	
Disinfectants and antiseptics	**Antiseptics**	**chlorhexidine**	Solution: 5%	
		povidone iodine	Solution: 10%	
Diuretics		**hydrochlorothiazide**	Solid oral dosage form: 25mg	
		spironolactone	Tablet: 25mg	
Gastrointestinal drugs	**Antiulcer medicines**	**omeprazole**	Solid oral dosage form: 10mg; 20mg	
		ranitidine	Tablet: 150mg (as hydrochloride)	
	Antiemetic medicines	**metoclopramide**	Tablet: 10mg	
	Laxatives	**Bisacodyl**	Tablet, 5mg, 10mg	
		docusate sodium	Capsule: 100mg	
		senna	Tablet: 7.5mg	
	Medicines used in diarrhoea	**oral rehydration solution**		
	Antihaemorrhoidal Agents	**Bismuth compound**	Suppository, 59mg + 24mg + 49mg +296mg +10mg + 33mg	

Hormones, other endocrine medicines and contraceptives	**Oral hormonal contraceptives**	**ethinylestradiol + levonorgestrel**	Tablet: 30mcg + 150mcg	
		ethinylestradiol + norethisterone	Tablet: 35mcg + 1mg	
		levonorgestrel	Tablet: 30mcg; 750mcg; 1.5 mg	
	Injectable hormonal contraceptives	**medroxyprogesterone acetate**	Depot injection: 150mg/mL in 1mL vial	
		norethisterone enantate	Oily solution: 200mg/mL in 1mL ampoule	
	Intrauterine devices	**copper-containing device**		
	Barrier methods	condoms		
	Implantable contraceptives	**etonogestrel-releasing implant**	Single-rod etonogestrel-releasing implant, containing 68mg of etonogestrel	
	Estrogens	**oestradiol**	Tablet: 0.5mg; 1mg	
		conjugated oestrogens	Tablet: 0.3mg	
	Insulins and other medicines used for diabetes	**gliclazide**	Solid oral dosage form: (controlled-release tablets) 80mg.	
		basal insulin	Injection: 40IU/mL in 10mL vial	
		metformin	Tablet: 500mg	
	Progestogens	**medroxyprogesterone acetate**	Tablet: 5mg	
Immunologicals	**Diagnostic agents**	**tuberculin, purified protein derivative(PPD)**	Injection	
	Vaccines	diphtheria vaccine		
		hepatitis b vaccine		

		influenza vaccine		
		pertussis vaccine		
		rabies vaccine		
		rota virus vaccine		
		Tetanus toxoid	injection 0.5 ml. 1 ml	
		tetanus vaccine	combination	yes
Ophthalmological preparations	**Anti-infective agents**	Chloramphenicol	Eye ointment, 1%, 5%	
			Eye drops, 0.4%, 0.5%, 1%, 5%	
		Erythormycin eye drop		Not in essential drug list 2014
		azithromycin	**Solution (eye drops): 1.5%**	
		Gentamicin	Eye drops, 0.3%	
		Oxymetazoline Hydrochloride	Eye drops, 0.025%, 0.05%	
	Miotics and antiglaucoma medicines	**acetazolamide**	**Tablet: 250mg**	
		pilocarpine	**Solution (eye drops): 2%**	
		timolol	**Solution (eye drops): 0.5%**	
Oxytocics and antioxytocics	**Oxytocics**	**ergometrine**	Injection: 200mcg in 1mL ampoule	
		misoprostol	Tablet: 200mcg	
		oxytocin	Injection: 10IU in 1mL	
	Antioxytocics (tocolytics)	nifedipine Immediate-release	capsule: 10mg	
Medicines for mental and	**Medicines used in psychotic disorders**	**chlorpromazine**	Tablet: 100mg	

behavioural disorders			Injection, 25mg/ml, 25mg/2ml, 50mg/2ml in 1ml, and 2ml ampoules	
		fluphenazine	Injection: 25mg in 1mL ampoule	
		haloperidol	Injection: 5mg in 1mL ampoule	
			Tablet: 2mg, 5mg	
		risperidone	Solid oral dosage form: 0.25mg	
	Medicines used in depressive disorders	**amitriptyline**	Tablet: 25mg; 75mg	
		fluoxetine	Solid oral dosage form: 20mg	
	Medicines for disorders due to psychoactive substance use	nicotine replacement therapy (NRT)	Chewing gum: 2mg; 4mg	
			Transdermal patch: 7mg to 21mg/24hours	
Medicines acting on the respiratory tract	**Antiasthmatic and medicines for chronic obstructive pulmonary disease**	budesonide	Inhalation (aerosol): 100mcg per dose; 200mcg per dose	
		ipratropium bromide	Inhalation (aerosol): 20mcg/metered dose	
		salbutamol	Metered dose inhaler (aerosol): 100mcg per dose	

			Respirator solution for use in nebulizers: 5mg/mL	
		theophylline	Tablet, extended-release: 100mg, 200mg	
	Antitussives/expectorants	Dextromethorphan Hydrobromide	Syrup, 5mg, 7.5mg, 15mg/5ml	
		Diphenhydramine Hydrochloride	12.5mg/5ml	
		Hyoscine	njection, 20mg/ml Tablet, 10mg	
Solutions correcting water, electrolyte and acid-base disturbances	**Oral**	oral glucose		
		oral rehydration solution		
	Parenteral	**glucose**	Injectable solution: 5%; 10%; 40%,50%	yes
		sodium chloride	Injection, 0.9% (Normal Saline) 500ml, 1000ml	yes
		sterile water	2mL; 5mL; 10mL ampoules	
		ringer's lactate	Injectable solution	
Vitamins and minerals		**calcium**	Tablet: 500mg (elemental)	
		calcium gluconate 10%	Injection: 100mg/mL in 10mL ampoule	
		pyridoxine	Tablet: 25mg	
		thiamine	Injection: 100mg/mL in 2mL via	yes
			Tablet: 50mg (hydrochloride)	

		Vitamine B1+B6+B12	Tablet/Injection, 100mg +200mg+1000 mcg	
Ear, nose, mouse and throat medicines		**acetic acid**	Topical: 2% in alcohol	
		beclometasone	Nasal spray: 50mcg per dose	
		ciprofloxacin	Topical: 0.3% drops	
		Gentian violate	solutions 1%	Not available in essential drug lists 2014
		Hydrogen peroxide	solutions, 1.5%,3%	
		lidocaine hydrochloride	4% spray	
		Miconazole	Oral gel, 25mg/ Vial	
		Triamcinolone acetonide	o.1 % paste, 5gm tube	
		Tetracaine HCL	solution 0.5 %	
Specific medicines for neonatal care	**Medicines administered to the neonate**	co-trimoxazole	Oral liquid: 200mg/40mg per 5mL	
		nevirapine (NVP)	Oral liquid: 50mg/5mL	
		zidovudine (AZT)	Oral liquid: 50mg/5mL	
	Medicines administered to the mother	dexamethasone	Injection: 4mg/mL	
Medicines for diseases of joints	Medicines used to treat gout	allopurinol	Tablet: 100mg	
	***Total(N)**			
	***Total(%)**			

Appendix 6A The Laboratory Network: Responsibilities of Laboratories at Different Tier Levels in Ethiopia

A tiered laboratory network is an integrated system of laboratories organized in alignment with the public health delivery network in a country. There should be four levels of laboratories in the national network:

1. **Level I-Primary:** Health post and health center laboratories that primarily serve outpatients.
2. **Level II- Secondary:** Laboratories in intermediate referral facilities (e.g., district hospitals).
3. **Level III-Tertiary:** Laboratories in a regional referral hospital that may be part of a regional or provincial health bureau.
4. **Level IV-National Reference Laboratory**: The national public health reference laboratory for the country.

The tiered levels of a laboratory system and the testing performed at each level may vary depending on the population served (e.g., infants, adults), physical infrastructure, electricity, water, road conditions, and the availability of trained technical personnel in-country.

Level I Laboratories

Level I laboratories would consist of health post or health center laboratories that would primarily serve outpatients. Essential infrastructure, such as clean water, refrigeration and electricity, may or may not be available. These laboratories would serve as peripheral branches of Level II laboratories, which would be the center or hub. Health posts may refer specimens to health center laboratories. Diploma level staff at Level I laboratories would be very limited, with usually no more than one trained laboratory assistant or nurse providing services. The laboratory would offer diagnostic and monitoring services for HIV/AIDS, TB and malaria. If essential infrastructure were lacking, then the on-site test menu would be restricted to manual tests. Sites with reliable power and water would perform certain automated chemistry tests required for antiretroviral therapy (ART) monitoring. Same day performance and delivery of results must be available while the patient is present for immediate counseling, treatment and regimen modification.

When required testing exceeds the scope of services available from Level I facilities, the "parent" Level II laboratories would provide a range of consultant services, including receipt of referral specimens and patients.

Level II Laboratories

Level II laboratories would consist of district hospitals or primary hospital laboratories that perform tests beyond the capabilities of Level I facilities. Health posts may refer specimens to Health Center Laboratories under Level I. Serving inpatients; these laboratories would have dedicated laboratory space, formally trained personnel, UPS systems, and a consistent source of reagent grade water. The laboratory would be staffed by a minimum of three formally trained technologists or technicians. One staff member who has managerial skills would serve as the senior or supervisory technologist.

The Level II laboratories would have more extensive test menus for diagnoses and treatment. Consolidating testing at the district level for certain tests provides necessary volumes for automated equipment platforms. The Level II laboratories would coordinate the services of Level I laboratories in the district as well as serve as reagent and supply reservoir/back-up repositories for these laboratories. In addition, Level II laboratories would provide the following consultant services and support for Level I laboratories:

- Managerial oversight of an outreach program of peripheral primary laboratories (World Health Organization [WHO], 2003a)
- Referral laboratory services with a more extensive test menu
- On-site quality assessment visits
- Assistance with resolving technical problems
- Data management support with a strong paper-based laboratory information system (should be part of a national system of data collection by the Ministry of Health [MOH])
- Development and implementation of quality assurance (QA) activities (including, but not limited to, QC, QI and EQA/PT)
- Periodic review of QC
- Information and training for adequate specimen collection
- Coordination of EQA
- Collection of data for assessment of quality indicators
- Approval and annual review of SOPs and policies to ensure alignment with current practices
- Assistance with development of SOPs and safety procedures
- Staff development/training, performance management, competency assessment, and retraining
- Coordination of courier/transport services
- Assistance with results reporting and record retention
- Equipment maintenance and service support including review of maintenance logs
- Follow-up on laboratory incident and accident reports
- Assessment of safety management practices

Level III Laboratories

Level III laboratories would consist of laboratories in tertiary referral facilities such as regional or provincial hospitals. These laboratories would perform a complete menu of testing for HIV/AIDS, TB and malaria as well as testing for many other diseases. Level III laboratories would complete the more sophisticated tests that Level II laboratories were not able to perform. These facilities must have dedicated laboratory space that would include a separate microbiology space, a Biosafety Level 3 designated area, and UPS systems. Reagent grade water would also be required. Formally trained, diploma level technologists who are able to meet workload demands would staff Level III laboratories. One technologist who has managerial skills would serve as the laboratory

supervisor. Level III laboratories would act as laboratory resource groups for the facilities in their regions.

In addition, Level III laboratories would provide the following services:

- A more comprehensive test menu than that provided at Level II laboratories
- Coordinate laboratory services and information management with other Level III laboratories
- Perform assessments of laboratories in the region; evaluate the QA data from laboratories in the region
- Coordinate surveillance data collection from lower levels in an effort to obtain country-wide statistics
- May collect and report inter-laboratory comparisons and EQA data for the region
- Develop training programs and coordination of continuing education
- Assure adequate requisition and reporting mechanisms as well as record retention procedures
- Standardize units, methodologies and reference ranges based on national reference laboratory recommendations
- Determine the amount of patient history/clinical presentation required for tests referred to other levels
- Provide logistical and management support to their service areas

Level IV Laboratories (National Reference Laboratories)

Level IV national reference laboratories are recommended to strengthen laboratory capacity for diseases of public health concern. Ideally, they would provide linkages with clinical trials and other public health laboratories, forming integrated laboratory networks. Senior program employees, laboratory management and senior laboratory technologists/scientists would staff these laboratories. Level IV laboratories would possess the infrastructure, equipment, information systems, and logistical capabilities of sophisticated reference laboratories. In some countries lacking a unique national reference laboratory, Level III laboratories may serve as national reference laboratories.

Level IV National Reference Laboratories would:

- Perform all testing performed at the other levels
- Perform molecular and esoteric testing beyond the technical capabilities of Level III laboratories (e.g., nucleic acid assays, HIV drug resistance studies, TB drug susceptibility studies)
- Develop laboratory standards and processes for laboratory accreditation
- Develop monitoring and evaluation activities for laboratories
- Serve as the national coordinator for HIV, TB, and malaria laboratory programs
- Maintain national database of equipment and maintenance in country
- Participate in international EQA programs and develop/oversee national EQA programs
- Provide input on national laboratory policy development

- Determine what information needs to be supplied with the test result to better interpret the test
- Provide courier and logistics management support for the regions
- Develop and implement testing algorithms and reflex protocols for laboratory utilization
- Establish standards for quality management and assist with policy and procedure development
- Provide assistance with reference range validations and development of national reference ranges specific to equipment/methods used
- Coordinate the collection of surveillance data to obtain and monitor country-wide statistics
- Introduce and implement new technologies, appropriate for each level, to reflect current best practices
- Select and evaluate diagnostic tests
- Define sensitivity and specificity requirements in order to select methods that would be evaluated with a method validation plan

Appendix 6B SamplePreventive Maintenance Log

Equipment Type	**Inventory Number**
Model	**Serial No.**

Preventive maintenance performed:

1.	
2.	
3.	
4.	

Spare parts changed and other materials used:

No.	**Item**	**Quantity**

User comments		
Date	**Signature**	**Date**

Service engineer comments and required follow-up	
Preventive maintenance performed by	
Signature	**Date**

Appendix 6C Sample Corrective Maintenance Log

Equipment type	**Inventory Number**
Model	**Serial No.**
Description of equipment failure	
Cause of equipment failure (if known)	
Part of machine / equipment to be maintained	

Corrective action **Time required**		
Spare parts replaced **1.** **2.** **3.** **4.** **5.** **6.**		
Engineer 1	**Signature 1**	**Date**
Engineer 2	**Signature 2**	**Date**

User comments		
Date	**Signature**	**Date**

Appendix 6D Sample SOP for Haemoglobin Estimation

Purpose:

The measurement of haemoglobin is useful for the detection of anaemia, its severity, and the patient's response to treatment as well as the quality of a donor's blood before donation.

Method

Cyanmethemoglobin method. This involves the use of Drabkins solution, which contains Potassiumferricyanide and potassium cyanide.

Principle

When whole blood is diluted 1 in 201 in Drabkins solution, it is haemolysed and the haemoglobin is oxidized to methemoglobin by the ferricyanide. The methemoglobin formed is converted to stable hemiglobicyanide by the cyanide. The absorbance of the HiCN solution is read at 540 nm and compared with that of a reference HiCN standard solution.

Sample

Whole blood mixed with EDTA or capillary blood.

Reagents

1) Drabkins solution
2) Potassium ferricyanide (hexacyanoferrate III)
3) Potassium cyanide
4) Potassium dihydrogen phosphate
5) Non-ionic detergent (e.g. Nonidet)
6) Distilled or deionised water.

This solution must be stored in an opaque brown glass container or plain glass with silver foil wrapped around it. It is pale, yellow and clear and should be discarded if turbid.

Equipment

Spectrophotometer with 540nm wavelength

Procedure

1) Measure out 0.02ml of capillary or venous blood well mixed with EDTA and dispense into 4ml of Drabkins solution.
2) Stopper the tube, mix well and let stand for 4 –5mins away from sunlight.
3) Using the 540 nm wavelength in the spectrophotometer, zero with Drabkins fluid and read the absorbance of test solution.
4) Read off the haemoglobin value from the calibration graph already prepared.

Note. Daily control tests are necessary to ensure that the Drabkins solution and spectrophometer are functioning adequately. This can be done using a control haemolysate, preserved whole blood control or use of HiCN reference standard. Also the Drabkinssolution can be visibly examined for turbidity or measured against a water blank at 540 nm at which the Drabkins should give a 300 reading.

Calculation

This is done by directly reading off the value from the already prepared graph.

Avoiding errors

a) Ensure that the blood collected is well mixed
b) The Drabkins solution used must be clear and without any signs of turbidity and at room temperature before use.
c) The volume of blood collected in the pipette must be exactly 0.02ml.
d) Ensure that the cuvette surfaces are clean and dry without finger prints.
e) Avoid using unmatched or scratched cuvettes or chipped pipettes.

f) Do not allow air bubble in the solution.

Normal values

Men	14 – 16 g/dl
Women	12 – 14 g/dl
Children	11 – 13 g/dl

Appendix 6E National SOP Template

Department of Infectious and Non Infectious Diseases
Ethiopian Public Health Institute
Addis Ababa

TITLE:	**Revision Date:**
Document Number: 01	**Status:**
Section: Documents and Records	**Page:**

Purpose

Abbreviations

Materials

Reagents

Reagents preparation:

Reagents stability and storage:

Supplies

Sample

Sample type	**Amount required**	**Transport and Storage**	**Stability**

Limitations:

Special Safety Precautions

Quality Control	Control	Level	Stability	Frequency	Preparation (y/n)

Control preparation:
Note:

Maintenance

Use table if necessary

Step	Action
1	
2	
3	

Prepared by:	Authority:

NOTE: This is a CONTROLLED document for internal use only. Any documents appearing in paper form are not controlled and should be checked against the electronic version prior to use.

Department of Infectious and Non Infectious Diseases
Ethiopian Public Health Institute
Addis Ababa

TITLE:	**Revision Date:**
Document Number:	**Status:**
Section: Documents and Records	**Page:**

Procedure

Step	Action

Calculation	
Result Interpretation	
Expected Values	
Principle	
Clinical Utility	
Reference	

Prepared by:	Authority:

NOTE: This is a CONTROLLED document for internal use only. Any documents appearing in paper form are not controlled and should be checked against the electronic version prior to use.

Appendix 6F Sample Laboratory Risk Assessment Form

Laboratory/ Department: _____

Name of Institution: _____

Inspected by: _____ Month/Year: _____

	ITEM	YES	NO
1.	**LABORATORY SIGNS**		
a.	Entrance to biohazardous areas clearly marked		
b.	Emergency contacts listed (First-Aid, Fire etc.)		
c.	Emergency signs posted (Fire exit. Eye wash station etc.)		
d.	Emergency telephone numbers (Fire, ambulance etc.)		
2.	**SAFETY EQUIPMENT**		
a.	Safety manual present/ read by all		
b.	Material Safety Data Sheets (MSDS) available		
c.	Safety Shower		
1.	Unobstructed and labelled		
2.	Tested within past one month		
d.	Eye wash station present		
1.	Unobstructed and labelled		
2.	Water changed weekly		
e.	First-Aid Kit available and labelled		
1.	Fully stocked		
3.	**PROTECTIVE CLOTHING**		
a.	PPE present (goggles, gloves, coats, face shield etc)		
b.	Visitor coats and safety glasses available		
c.	Proper heat resistant/cryogenic gloves available		
d.	Appropriate personal clothing and footwear		
4.	**HAZARDS**		
a.	Walkways, doors and fire escape routes unobstructed		
b.	Adequate lighting in all areas		
c.	Work benches and floors cleaned daily		
d.	Storage areas accessible, clean and dry		
5.	**SPILL PROCEDURE**		
a.	Spill kits available (biological/chemical/radioactive)		
b.	Clearly posted with instruction for use		
c.	Chemical spills documentation present		
6.	**ELECTRICAL**		
a.	Power distribution board clearly labelled		
b.	Extension cords only for temporary use		
c.	Multiplugs used only on computers		

d.	Surge protection (UPS) present		
e.	Electrical cords not frayed		
f.	Electrical plugs in good condition		
g.	Earth leakage system in good working condition		
7.	**GAS CYLINDERS**		
a.	Properly and individually chained to the wall		
b.	Labelled empty or full		
c.	Labelled as to cylinder contents		
d.	Safety caps on cylinders not presently in use		
e.	“No smoking” & “Danger of explosion” signs present		
8.	**REFRIGERATORS/FREEZERS**		
a.	“No Food or Drink” signs posted on doors		
9.	**CHEMICAL STORAGE**		
a.	Chemicals stored by reactive class (flammables, acids etc)		
b.	Incompatible chemicals physically separated		
c.	Chemicals properly labelled		
d.	Chemicals dated on receipt and when opened		
e.	Inspected monthly for leakage, cracked stoppers, etc.		
f.	Storage areas labelled with hazard stickers		
g.	Acids/corrosives/solvents stored in compatible trays		
h.	No chemicals stored on bench tops/in fume hoods/under sinks		
i.	Flammable liquid storage cabinet present and labelled		
j.	List of chemicals available present with MSDS		
10.	**FIRE EQUIPMENT**		
a.	Fire extinguishers present, clearly labelled in working order		
b.	Fire blankets present and clearly labelled		
c.	Fire hose present, clearly labelled, and in working order		
d.	Fire alarm system present		
e.	All equipment serviced within the last year		
11.	**BIOHAZARD WASTE**		
a.	Appropriate containers available and clearly marked		
b.	Containers sealed and stored correctly before disposal		
c.	Regular disposal system in place & records kept		
12.	**BIOHAZARD CABINETS/EXTRACTION HOODS**		
a.	In good working condition		
b.	Inspected and serviced within last year		
c.	Smoke test done regularly (minimum once a week)		
d.	Cleaned daily		

13.	**SAFETY PROCEDURES & DOCUMENTATION**		
a.	In-house training up to date		
b.	Risk assessment procedures up to date		
c.	Medical surveillance records up to date		
d.	Fire drill practiced		
e.	Safety meetings held regularly & records kept		
f.	Injury on-duty reports up to date		
g.	Standard operating procedures up to date		
14.	**AUTOCLAVE**		
a.	In good working condition		
b.	Inspected and serviced within the last year		
c.	Pressure tested within the last two years		
d.	Log book for daily temperature and pressure recording And quality control indicators present		
15.	**ACCOMODATION**		
a.	Building adequate		
b.	Receiving office adequate		
c.	Staff facilities adequate		
d.	Laboratory space adequate		
e.	Bench space adequate		
f.	Other rooms (Phlebotomy, Office, night duty, etc.)		
16.	**LABORATORY EQUIPMENT**		
a.	Clean and in good working order		
b.	Properly guarded		
c.	Proper electrical connections		
d.	Staff adequately trained in use		
17.	**VENTILATION & NOISE**		
a.	Temperature control systems adequate		
b.	Dust and fumes minimized		
c.	Noise level acceptable		

General observations: _____
_____
_____
Action to be taken: _____
_____
_____
Signed by: _____
Laboratory Manager: _____
Date: _____

Appendix 6G List of Modifiable Diseases

The FMOH declares the following conditions to be of concern to the public health and reportable as required by law:

a. Acute Flaccid Paralysis (AFP)/Polio
b. Avian Human Influenza
c. Cholera
d. Dysentery
e. Measles
f. Malaria
g. Meningococcal meningitis
h. Neonatal Tetanus
i. Plague
j. Relapsing fever
k. Rift Valley Fever (RVF)
l. SARS
m. Smallpox
n. Typhoid Fever
o. Typhus
p. Viral Hemorrhagic Fever
q. Yellow Fever
r. Any unusual occurrence of infectious or communicable disease or any unusual or increased occurrence of any illness that may indicate public health hazard, including any single case or multiple cases of a newly recognized, emergent or re-emergent disease or disease-producing agent, including newly identified multi-drug resistant bacteria or a novel influenza strain such as a pandemic influenza strain.
s. Any outbreak, epidemic, or unusual or increased occurrence of any illness that may indicate an outbreak or epidemic. This includes suspected or confirmed outbreaks of foodborne disease, waterborne disease, disease caused by antimicrobial resistant organisms, any infection that may indicate a bioterrorism event, or of any infection that may indicated a public health hazard.

In addition to the reportable conditions the FMOH requires the following reportable emergency illnesses or health conditions to be of concern to the public health and reporting

i. Clusters of Respiratory illness (including upper or lower respiratory tract infections, difficulty breathing and Adult Respiratory Distress Syndrome);
ii. Clusters of Gastrointestinal illness (including vomiting, diarrhoea, abdominal pain, or any other gastrointestinal distress);
iii. Influenza-like constitutional symptoms and signs;
iv. Clusters neurologic symptoms or signs indicating the possibility of meningitis, encephalitis, or unexplained acute encephalopathy or delirium;
v. Cluster of Rash illness;
vi. Haemorrhagic illness;
vii. Botulism-like syndrome;
viii. Sepsis or unexplained shock;
ix. Febrile illness (illness with fever, chills or rigors);
x. Non traumatic coma or sudden death; and

Reports should be submitted to the Woreda Health Office, Regional Health Bureau or Federal Ministry of Health using a Standard Report Form.

Source: National Notifiable Diseases and Conditions Reporting Rule and General Control Measures for the Control of Public Health Threats. FMOH, Ethiopian Public Health Institute. April 2009.

ANNEX 6H

PACK **Adult guide2017:**testlist

	Specimen	Testname
Point-of-care	Blood	Glucose
		Haemoglobin
		HIVrapidtest
		Malariarapid diagnostictest
		Rapidsyphilistest
		Rapidrhesus
	Urine	Pregnancytest
		Urinalysisforblood,glucose,ketones,leucocytes, nitritesandprotein
	Stool	Examination forblood/occultblood
Laboratory	Nailclippings	Microscopyandcultureforfungus
	Blood	Alanineaminotransferase[ALT]
		Alkalinephosphatase [ALP]
		Aspartate aminotransferase[AST]
		C-reactiveprotein[CRP]
		Calcium
		CD4count
		Cholesterol
		Creatinine
		Cryptococcalantigen
		Culture
		ErythrocyteSedimentationRate[ESR]
		Estimatedglomerularfiltrationrate[eGFR]/creatinineclearance
		Fullbloodcount
		Gamma-glutamyltransferase[GGT]
		Glucose
		Glycatedhaemoglobin[HbA_{1c}]
		Haemoglobinanddifferential
		HepatitisBsurfaceantibody[HBsAb]
		HepatitisBsurfaceantigen[HBsAg]
		HepatitisCantibody
		HIVELISAtest
		HIV PCR(polymerasechainreaction)
		HIVviral load[VL]

		International NormalisedRatio[INR]
		Lactate
		Magnesium
		Parasiteslidemicroscopyformalaria
		Potassium
		Prothrombintime
		RapidPlasmaReagin[RPR]
		Rheumatoid factor[RF]
		Sodium
		Thyroid stimulating hormone[TSH]
		Triglycerides
		Urate
		Urea
	CervicalSmear	Papanicolaou(Pap)smear
	Lymphnodeaspirate	Microscopy, cultureandsensitivity
	Sputum	Cultureanddrugsusceptibilitytestingfortuberculosis
		Smearfortuberculosis
		XpertMTB/RIFassayfortuberculosis
	Stool	Culture
		Microscopyforova,cystsandparasites
	Urine	Albumincreatinineratio
		Microscopy, cultureandsensitivity

Appendix 9A: Sample Inventory Data Collection Form

Inventory # _____

Type of Equipment: _____

Manufacturer: _____

Model: _____ Serial #: _____

Country of Origin: _____ Year of Manufacture: _____

Power Requirement: ☐ 220V ☐ 110V

Current State/Condition:
☐ Operable and in service
☐ Operable and out of service
Reason out of service: _____
☐ Needs maintenance
☐ Not repairable
Needs to be discarded? ☐ Yes ☐ No

Spare parts available? ☐ Yes ☐ No
If yes, what, how many, and where are they located? _____
_____

Manuals Available:
☐ User manual # of copies _____ Location _____
☐ Service manual # of copies _____ Location _____
☐ Other (specify) # of copies _____ Location _____

Equipment Users:

☐ Doctors ☐ Nurses ☐ Lab Technicians
☐ Students ☐ Residents ☐ Other (specify) _____

Equipment owner (department), if any: _____

Contact Person and Telephone numbers: _____

Current location of equipment: _____

Will it move from here? ☐ No ☐ Yes If so, where? _____

Other notes (use back of paper if more room is needed: _____
_____
_____

PHCG list of supplies

1 3-5% acetic acid for cervical screening
2 70% alcohol disinfectant
3 Adhesive tape
4 Adjustable light source/examination lamp
5 Alcohol-impregnated sterile swab
6 Artery forceps
7 Bag valve mask 8 Cervical collar or neck brace
9 Cervical smear brush
10 Cotton strips/swabs
11 Curette
12 Curved forceps and clamp
13 Cytology spray
14 Defibrillator
15 Elastic bandages
16 Electrocardiograph
17 Endotracheal tube
18 Face mask, surgical
19 Gauze
20 Gloves (examination)
21 Gloves (sterile)
22 Gloves (sterile long, for manual removal of placenta)
23 Glucose meter/glucose analyser/glucose monitor
24 Gowns/aprons
25 Haemoglobinometer
26 Heater/warming device
27 Ice pack
28 Intravenous cannula [G-14 (orange), G-16(grey), G-18(green), G-20(pink)]
29 Intravenous tubing
30 Lancet

31 Laryngoscope
32 Litmus paper
33 Lubricant
34 Microscope for malaria parasite slide microscopy
35 Microscope slides
36 Millimetre ruler
37 N95 respirator
38 Nasogastric tube
39 Nasopharyngeal airway
40 Nebulizer
41 Needle driver
42 Non-pneumatic anti-shock garments
43 Oropharyngeal airway
44 Otoscope
45 Oxygen mask and tubing
46 Oxygen source (cylinder or concentrator)
47 Paper towel or absorbent cloth
48 Peak expiratory flow meter
49 Pen torch for eye examination
50 Penis model
51 Permanent marking pen for labelling
52 Povidone iodine to clean skin before lymph node aspiration
53 Pressure bandages
54 Pulse oximeter/oxygen saturation machine
55 Rapid HIV antibody testing kit (2 types)
56 Rapid malaria diagnosis test kit
57 Rapid non-treponemal syphilis test: Rapid Plasma Reagin (RPR) kit
58 Rapid pregnancy test kit
59 Rapid treponemal syphilis test kit
60 Reflex hammer
61 Refrigerator [for storing PPD]
62 Romanowsky staining for smear [malaria test]
63 Scalpel with blades
64 Scissors
65 Sharps bins
66 Spacer
67 Specimen bottles for blood collection: potassium EDTA, fluoride oxalate, lithium heparin, plain
68 Specimen bottle for sputum collection
69 Sphygmomanometer/blood pressure monitor
70 Spine board
71 Splint equipment
72 Stadiometer
73 Sterile towels/drapes
74 Stethoscope
75 Suction pump (manual or electric) with catheter
76 Suture materials

77 Syringes with needles (disposable) (18- to 27-guage needles)
78 Tape measure
79 Tenaculum to hold the cervix during insertion of IUD
80 Thermometer
81 Tongue depressor
82 Tourniquet
83 Urethral catheter
84 Urine bag
85 Urine dipstick
86 Uterine sound
87 Vaginal speculum 88 Visor/glasses/eye protection
89 Weighing scale
90 X-ray machine

Appendix 9B Typical Equipment Lifespan

The following is a list of typical equipment lifetimes developed by Hospital Associations from another country. The list reflects how equipment lasts. While this may not be directly applicable to the Ethiopian context, it is useful to have and use as a reference.

Diagnostic and Treatment Departments

Item	Years
Accelerator	7
Alternating pressure pad	10
Amino acid analyzer	7
Amplifier	10
Anaerobe chamber	15
Analyzer, haematology	7
Anatomical model	10
Anesthesia unit	7
Ankle exerciser	15
Apnea monitor	7
Apron, lead-lined	47
Arthroscope	5
Arthroscopy instrumentation	3
Aspirator	10
Audiometer	10
Autoclave	10
Autoscaler, ionic	10
Bacteriology analyzer	8
Baci incinerator	5
Balance	
Analytical	10
Electronic	7
Precision mechanical	10
Basal metabolism unit	8
Bath	
Fluidotherapy	7
Paraffin	7
Serological	7
Water	7
Biochemical analysis unit	7
Biochromatic analyzer	7
Biofeedback machine	8
Biomagnetometer	7
Bipolar coagulator	7
Blood cell counter	5
Blood chemistry analyzer, automated	5
Blood culture analyzer	8
Blood gas analyzer	5
Blood gas apparatus, volumetrics	8
Blood transfusion apparatus	6
Blood warmer	7
Blood warmer coil	7
Bone surgery apparatus	3
Breathing unit, positive-pressure	8
Bronchoscope	
Flexible	3
Rigid	3
Carbon monoxide recorder/detector	10
Cardiac monitor	5
Cardioscope	8
Cart	
Emergency-isolation	10
Medicine	10
Caspar ACF instrument and plate system	7
Cassette changer	8
Cautery unit	
Dermatology	7
Gynecology	7
Cell freezer	7
Cell washer	5
Centrifuge	7
Centrifuge, refrigerated	5
Cerebral function monitor	7
Child immobilizer	15
Chloridiometer	10
Chromatograph, gas	7
Clinical analyzer	5
Clopay wrapping machine	10
Coagulation analyzer	5
Cold-pack unit, floor	10
Colonoscope	3
Colorimeter	7
Colposcope, with floor stand	8
Computer, clinical	5

Item	Years
Computer-assisted tomography (CT) scanner	5
Conductivity tester	5
CO-oximeter	10
Cryoopthalmic unit, with probes	7
Cryostat	7
Cryosurgical unit	10
Cyclotron	7
Cystic fibrosis treatment system	10
Cystometer	10
Cystometrogram unit	10
Cystoscope	3
Decalcifier	10
Deionized water system	7
Densitometer, recording	5
Dental drill, with syringe	3
Dermatome	10
Diagnostic set	10
Diathermy unit	10
Digital fluoroscopy unit	5
Digital radiography unit	5
Diluter	10
Dispenser, alcohol	10
Distilling apparatus	15
Doppler	5
Dose calibrator	5
Dryer, sonic	10
Duodenoscope	3
Echocardiograph system	5
Echoview system	5
Electrocardiograph	7
Electrocardioscanner (Holter monitor scanner)	7
Electroencephalograph	7
Electrolyte analyzer	5
Electromyograph	7
Electrophoresis unit	7
Electrosurgical unit	7
Ergometer	10
Evacuator	10
Evoked potential unit	10
Exercise apparatus	15
Exercise equipment, outdoor	10
Exercise system, computer assisted	5
Exerciser, orthotron	10
Eye surgery equipment (phacoemulsifier)	7
Fibreoptic equipment	5
Fibrometer	7
Film changer	8
Film viewer	10
Flow cytometer	5
Fluid sample handler	5
Fluorimeter	10
Fluoroscope	8
Frame, turning	15
Furnace, laboratory	10
Gamma camera	5
Gamma counter	7
Gamma knife	10
Gamma well system	7
Gas analyzer	8
Gastroscope	3
Geiger counter	10
Generator	5
Gloves, lead-lined	3
Hand dynamometer	10
Heart-lung system	8
Heat sealer	5
Hemodialysis unit	5
Hemoglobinometer	7
Hemophotometer	10
High-density mobile film system	10
Holter	
Electrocardiograph	7
Electroencephalograph	7
Homogenizer	10
Hood, exhaust or Bacti	10
Hydrocollator	10
Hydrotherapy equipment	15
Hyfrecator	10
Hyperbaric chamber	15
Hypothermia apparatus	10
Image analyzer	5

Item	Years
Image intensifier	5
Immunodiffusion equipment	10
IMX analyzer	7
Incubator, laboratory	10
Inhalator	10
Intraarterial shaver	10
Iontophoresis unit	8
Isodensitometer	7
Isolation chamber	12
Isotope equipment	7
Isotope scanner	7
Kiln	10
K-pads	5
Kymograph	10
Lamp	
Deep-therapy	10
Infrared	10
Mercury quartz	10
Slit	10
Laparoscope	3
Laryngoscope	3
Laser, coronary	2
Laser, surgical	5
Laser positioner	5
Laser smoke evacuator	5
Lifter, patient	10
Linac scalpel	5
Linear accelerator	7
Lithotripter, extracorporeal shock-wave (ESWL)	5
Magnetic resonance imaging (MRI) equipment	5
Mammography unit	
Fixed	5
Mobile (van)	8
Marograph	7
Mass spectrophotometer	7
Microbiology analyzer	8
Microscope	7
Microtome	7
Microtron power system	7
Mirror, therapy	15
Muscle stimulator	10

Item	Year
Nebulizer	
Pneumatic	10
Ultrasonic	10
Nephroscope	7
Neurological surgical table headrest	10
Neutron beam accelerator	8
Noninvasive CO2 monitor	7
Optical readers	5
Orthotron system	10
Orthourological instruments	10
Oscilloscope	7
Oven	
Paraffin	10
Sterilizing	10
Oximeter	10
Oxygen analyzer	7
Oxygen tank, motor, and truck	8
Pacemaker, cardiac (external)	5
Pacing system analyzer	7
Panendoscope	10
Parallel bars	15
Pelviscope	7
Percussor	5
Perforator	10
Peripheral analyzer	10
pH gas analyzer	10
pH meter	10
Phonocardiograph	8
Photocoagulator	10
Photography apparatus, gross pathology	10
Photometer	8
Physioscope	10
Pipette, automatic	10
Plasma freezer	10
Platelet rotator	20
Positron emission tomography (PET) scanner	5
Proctoscope	3
Prothrombin timer, automated	8
Proton beam accelerator	7
Pulmonary function analyzer	8

Item	Years
Pulmonary function equipment	8
Pulsed oxygen chamber	10
Pulse oxymeter	7
Pump	
Infusion	10
Stomach	10
Suction	10
Surgical	10
Vacuum	10
Radiation meter	8
Radioactive source, cobalt	5
Radiographic duplicating printer	8
Radiographic-fluoroscopic combination	5
Radiographic head unit	5
Rate meter, dual	10
Refractometer	10
Refrigerator, blood bank	10
Resuscitator	10
Retractor	5
Rhinoscope	3
Rinser, sonic	10
Rotoosteotome unit	10
Saw	
Autopsy	10
Neurosurgical	10
Surgical, electric	10
Scale	
Bed	10
Chair	10
Clinical	10
Scale, metabolic	10
Scintillation scaler	8
Sensitometer	10
Seriograph, automatic	8
Shaking machine (vortexer)	8
Sharpener, microtome knife	10
Sigmoidoscope	3
Signal-averaged EKG	5
Simulator	5
Single-photon emission computed tomography (SPECT) Scanner	5
Sinuscope	7
Skelton	10
Slide stainer, laboratory	7
Spectrophotometer	8
Spectroscope	10
Sphygmomanometer	10
Spirometer	8
Stand	
Basin	15
Intravenous	15
Irrigating	15
Mayo	15
Steam-pack equipment	10
Stereo tactic frame	5
Sterilizer, movable	12
Steris sterilization system	7
Stethoscope	5
Stress tester	10
Stretcher	10
Hydraulic	7
Surgical shaver	5
Tank	
Cleaning	10
Full-body	15
Hot-water	10
Therapy	15
TDX analyzer	7
Telemetry unit, cardiac	5
Telescope, microlens	10
Telescopic shoulder wheel	15
Telethermometer	10
Tent	
Aerosol	8
Oxygen	8
Thyroid uptake system	5
Tissue-embedding center	8
Tissue processor	7
Titrator, automatic	10
Tonometer	10
Totalap	10
Tourniquet, automatic	10
Tourniquet system	7
Traction unit	10
Transcutaneous nerve stimulator system	5
Transesophageal transducer	5

Item	Years
Treadmill, electric	8
Tube dryer	10
Tube tester	10
Ultrasound, diagnostic	5
Ultrasound unit, therapeutic	7
Vacuvette	10
Ventilator, respiratory	10
Vial filler	10
Vibrator	10
Video	
Camera	5
Light source	5
Monitor	5
Printer	5

Item	Years
Wheelchair	5
X-ray equipment	
Developing tank	10
Film dryer	8
Film processor	8
Furniture	15
Image intensifier	5
Intensifying screens	5
Silver recovery unit	7
X-ray unit	
Fluoroscopic	5
Mobile	5
Radiographic	5
Superficial therapy	5
Tomographic	5
Wiring	5

Nursing Departments

Nursing departments consist of cardiac care, chemical dependency, intensive care, medical/surgical care, neonatal intensive care, nursery, pediatrics, pediatric developmental disabilities, and psychiatric units.

Item	Years
Bassinet	15
Bath	
Sitz	10
Whirlpool	10
Bed	
Birthing	15
Electric	12
Flotation therapy	10
Hydraulic	15
Labor	15
Manual	15
Orthopedic	15
Bench, metal or wood	15
Bin, metal or wood	15
Blood pressure device, electronic	6
Bookcase, metal	20

Item	Year
Cabinet	
Bedside	15
File	15
Instrument	15
Metal or wood	15
Pharmacy	15
Solution	15
X-ray	15
Central supply furniture	15
Chair	
Blood drawing	10
Dental	15
Executive	15
Folding	10
Geriatric	10
Hydraulic, surgeon's	15

Item	Years
Chair (continued	
Kinetron	15
Podiatric	15
Shower/bath	10
Specialist's	15
Chart rack	20
Chart recorder	10
Clothes locker	
Fibreglass or metal	15
Laminate or wood	12
Computer, caridial output	5
Credenza	15
Crib	15
Croupette	10
Defibrillator	5
Desk, metal or wood	20
Doppler	5
Dresser	15
Food service furniture	15
Frame, turning	15
Housekeeping furniture	15
ICU and CCU furniture	15
Infant care center	10
In-service education furniture	15
Insufflator	5
Labor and delivery furniture	15
Laboratory furniture	15
Lamp	
Bilirubin	10
Emergency	10
Lawn and patio furniture	5
Light	
Delivery	15
Examining	10
Portable, emergency	10
Natural childbirth backrest	10
Nursing service furniture	15
Operating room furniture	15

Item	Years
Operating stool	15
Ophthalmoscope	10
Osmometer	7
Otoscope	7
Ottoman	10
Patient monitoring equipment	10
Phototherapy unit	10
Physicians' in-and-out register, portable	10
Physiological monitor	7
Pump, breast	10
Scale, baby	15
Settee	12
Shelving, portable, steel	20
Sofa	12
Stall Bars	15
Table	
Anaesthetic	15
Autopsy	20
Electrohydraulic tilt	10
Examining	15
Folding	10
Food preparation	15
Fracture	15
Instrument	15
Light	15
Metal	15
Obstetrical	20
Operating	15
Orthopedic	10
Overbed	15
Pool	10
Refrigerated	10
Therapy	15
Traction	10
Urological	15
Wood	15
Telemetry unit, cardiac	5
Thermometer, electric	5
Ultrasonic fetal heart monitor	7
Work station	10

Appendix 9C Sample Medical Equipment Risk Assessment Form

All medical equipment should be assessed to determine the risk associated with equipment use and failure. This guides the priority that should be assigned to each item for maintenance and repair and replacement when the item can no longer be repaired.

Step 1 Assign a score to each item of equipment

Each item of equipment should be scored in each of 5 categories:

Category A Equipment function
Category B Risk associated with equipment failure
Category C Preventive maintenance requirements
Category D Main area of equipment use
Category E Likelihood of equipment failure (mean time between failures)

Note: Category E, the 'mean time between failures' can be calculated based on equipment service and incident history. If this is not known then an estimate should be made.

Step 2 Calculate Total Score and Risk Category

The most important categories in the assessment are (A) Equipment Function and (B) Risk Associated with Equipment failure. Because these are the most important categories these are given greater weight when the total score is calculated. Hence the total score is calculated as follows:

Total score = A + B + (C+D+E)/3

The total score will range from 3 to 20.

Medical equipment should be categorized as follows:

High risk (score 18 – 20):
Equipment should be tested at least twice per year and should be given highest priority for repair and routine testing and calibration.

Medium risk (score 15 – 17):
Equipment should be tested at least annually and should be repaired or undergo routine testing and calibration after this has been done for 'high priority' equipment.

Low risk (score 12 -14):
Equipment should be tested at least annually and should be repaired or undergo routine testing and calibration after this has been done for 'high and medium risk' equipment.

Hazard surveillance (<12):
Equipment in this category should undergo annual inspection.

Appendix 9D Sample Bin Record Card for Spare Parts

Item Description: Item Code Number:

Date	Doc. No. (Receiving or Issuing)	Received from or Issued to	Quantity				Batch No.	Expiry Date	Remarks
			Received	Issued	Loss/Adj	Balance			

Appendix 9E Sample Stock Record Card for Spare Parts

Item Description: Item Code Number:
Unit pack size: Maximum stock level:
Minimum re-order level: Lead time:
Order quantity:

Date	Doc. No. (Receiving or Issuing	Received from or Issued to	Quantity				Price		Expiry Date	Remarks
							Unit Price			
			Received	Issued	Loss/Adj	Balance	Birr	Cent		

Appendix 9G Guidance for Unpacking and Inspecting Equipment Orders

Checks	Activities
For damage	□ systematically open one crate at a time □ check the boxes/packages inside each crate for possible damage □ systematically open one package at a time and note what you find on the relevant documents (see Appendix H) □ Keep all packaging, supports, labels and booklets, as you may have to re-pack the equipment to return it for repairs. □ unpack the equipment carefully □ ensure that the equipment and its associated supplies do not appear to be damaged □ if anything appears damaged, take a photograph if possible, and notify the supplier
Against documentation	□ check that the delivery matches the packing list(s) □ check that the contents comply with the specifications in the purchase order – in other words, check the type and model of all equipment and supplies □ check that the quantities are according to the purchase order
Technical requirements	□ ensure that the voltage shown on the packing list (or on the packing case) for electrical equipment is compatible with your power supply □ check that the equipment data plate matches your order and the packing case/list and, for electrical equipment, that the voltage stated is correct □ for electrical equipment, ensure the mains lead and battery charger, where applicable, is included
The 'package'	□ check that all the necessary consumables, accessories and spare parts have arrived as per the purchase contract □ keep these equipment-related supplies together in a dry, cool and safe place until you can issue some and register the rest into the Stores system □ check that the operating manual, service manual (including a wiring/circuit diagram), and any assembly and installation instructions have arrived as per the purchase contract □ keep the manuals together in a dry, cool and safe place until you can make copies and issue/store them □ notify the supplier if any documentation is missing or seems unacceptable (e.g. in another language than requested)

Appendix 9H Sample Acceptance Test Log Sheet

Only when this form has been satisfactorily completed should the Registration Box be filled in by the trained health worker.

REGISTRATION BOX

ALLOCATED INVENTORY NUMBER . . . .

EQUIPMENT TYPE . . . .

DESTINATION LOCATION . . . .

ACCEPTANCE DATE . . . .

WARRANTY EXPIRY DATE . . . .

MAINTENANCE CONTRACT WITH . . . .

HEALTH FACILITY . . . .

NAME OF EQUIPMENT . . . .

TYPE/MODEL . . . .

ORDER NUMBER	SERIAL NUMBER . . . .
COST.	DATE RECEIVED . . . .
MANUFACTURER	SUPPLIER/AGENT . . . .
ADDRESS	ADDRESS . . . .
. . . .	. . . .

. . . .

. . . .	. . . .
PHONE	PHONE . . . .
FAX	FAX . . . .

DETAILS OF ALL ACCESSORIES, CONSUMABLES, SPARE PARTS AND MANUALS RECEIVED ARE LISTED ON THE FOLLOWING PAGE OF THIS FORM.

ACCEPTANCE CHECKS

1. DELIVERY

Undertaken by: . . . . . .

Witnessed by: Name . . . . . Position . . . . . Date . . . . . .

	Yes/done	**No/not done**	**Corrected if applicable**
a) Representative of supplier present?	. . . . .	. . . . .	. . . . .
b) Correct number of boxes received?	. . . . .	. . . . .	. . . . .
c) After unloading, visible damage to the boxes?	. . . . .	. . . . .	. . . . .
d) If damaged, has this been stated on the delivery note and senior management informed?	. . . . .	. . . . .	. . . . .

Comments . . . . . .
. . . . . .
. . . . . .

2. UNPACKING (refer to invoices and shipping documents)

Undertaken by: . . . . . .

Witnessed by: Name . . . . . Position . . . . . Date . . . . . .

	Yes/done	**No/not done**	**Corrected if applicable**
a) Visible damage to the equipment?	. . . . .	. . . . .	. . . . .
b) Equipment complete as ordered?	. . . . .	. . . . .	. . . . .
c) User/operator manual as ordered?	. . . . .	. . . . .	. . . . .
d) Service/technical manual as ordered?	. . . . .	. . . . .	. . . . .
e) Accessories as ordered?	. . . . .	. . . . .	. . . . .
f) Consumables as ordered?	. . . . .	. . . . .	. . . . .
g) Spare parts as ordered?	. . . . .	. . . . .	. . . . .

Comments . . . . . .
. . . . . .

3. ASSEMBLY (refer to manuals)

Undertaken by: . . . . . .

Witnessed by: Name . . . . . Position . . . . . Date . . . . . .

	Yes/done	**No/not done**	**Corrected if applicable**
a) Are all parts available?	. . . . .	. . . . .	. . . . .
b) Do they fit together?	. . . . .	. . . . .	. . . . .
	. . . . .	. . . . .	. . . . .

c) Mains lead with plug included?			
d) Do all the accessories fit?	. . . . .	. . . . .	. . . . .
e) Are markings and labels OK?	. . . . .	. . . . .	. . . . .
f) Any damage?	. . . . .	. . . . .	. . . . .

Comments . . . . . .
. . . . . .
. . . . . .
. . . . . .

4. INSTALLATION (refer to manuals)

Undertaken by: . . . . . .
Witnessed by: Name . . . . . Position . . . . . Date . . . . . .

	Yes/done	**No/not done**	**Corrected if applicable**
a) Was the work carried out satisfactorily?	. . . . .	. . . . .	. . . . .
b) Were technical staff present as learners?	. . . . .	. . . . .	. . . . .

Comments . . . . . .
. . . . . .

5. COMMISSIONING/TESTING

Undertaken by: . . . . . .
Witnessed by: Name . . . . . Position . . . . . Date . . . . . .

	Yes/done	**No/not done**	**Corrected if applicable**
a) Were electrical, mechanical, gas, radiation safety tests and performance checks carried out in accordance with the test sheets on pages 7 to 9 of this form?	. . . . .	. . . . .	. . . . .
b) Was the work carried out satisfactorily?	. . . . .	. . . . .	. . . . .
c) Were technical staff present as learners?	. . . . .	. . . . .	. . . . .
d) Were operators present as learners?	. . . . .	. . . . .	. . . . .

Comments . . . . . .
. . . . . .

6. ACCEPTANCE – to be certified by the Head of Equipment Maintenance only

	Yes/done	**No/not done**	**Corrected if applicable**
a) Is the equipment accepted?	. . . . .	. . . . .	. . . . .
b) If rejected, have the shortcomings been summarized on page 10 of this form	. . . . .	. . . . .	. . . . .

c) If so, has a report gone to senior management and formal complaints procedures started?	. . . . .	. . . . .	. . . . .
d) Should payment be withheld pending corrections?	. . . . .	. . . . .	. . . . .
e) Is payment approved?	. . . . .	. . . . .	. . . . .

Comments . . . . . .
. . . . . .
. . . . . .

Page 5

7. TRAINING

Undertaken by: . . . . . .

Witnessed by: Name . . . . . Position . . . . . Date . . . . . .

	Yes/done	**No/not done**	**Corrected if applicable**
a) Were the expected training courses given?	. . . . .	. . . . .	. . . . .
b) Were the training courses satisfactory?	. . . . .	. . . . .	. . . . .
c) Were suitable operators present?	. . . . .	. . . . .	. . . . .
d) Were suitable technical staff present?	. . . . .	. . . . .	. . . . .

Comments . . . . . .
. . . . . .

8. REGISTRATION – to be undertaken by the Head of Medical Equipment Maintenance

	Yes/done	**No/not done**	**Corrected if applicable**
a) If accepted, has an inventory number been allocated?	. . . . .	. . . . .	. . . . .
b) Has the Registration Box on Page 1 of this form been filled in?	. . . . .	. . . . .	. . . . .
c) Has the Stores Controller been provided with the location for the equipment and all necessary data, so that the Stores Receiving Procedure can be followed and a Goods Received Note completed?	. . . . .	. . . . .	. . . . .
d) Have the accessories, consumables, spare parts, and manuals all been issued to the correct holding authorities?	. . . . .	. . . . .	. . . . .

NAME. . . . . .
SIGNATURE . . . . . .
DATE . . . . . .

NOW PLACE THIS FORM AS THE FIRST RECORD IN THE EQUIPMENT FILE/SERVICE HISTORY

Page 6

Describe and quantify all items received, and complete a Register of New Stocks form:

ACCESSORIES RECEIVED

1. 2.
3. 4.
5. 6.
7. 8.

CONSUMABLES RECEIVED

1. 2.

3. 4.
5. 6.
7. 8.

SPARE PARTS RECEIVED

1. 2.
3. 4.
5. 6.
7. 8.

MANUALS RECEIVED

1. 2.

3. 4.

Page 7

COMMISSIONING/TESTING PROCEDURES (see manuals and relevant technical standards)

i. ELECTRICAL INTEGRITY TESTS

Undertaken by: . . . . . .

Witnessed by: Name . . . . . Position . . . . . Date . . . . . .

Classification (applies to medical equipment only)	**Fill as applicable**
a) Class I - II - III?	. . . . .
b) Type B - BF - CF?	. . . . .
c) Type AP - APG?	. . . . .

	Yes/done	**No/not done**	**Corrected if applicable**
Mains Connection			
a) Are cables and plugs intact?	. . . . .	. . . . .	. . . . .
b) Is cable color code correctly connected?	. . . . .	. . . . .	. . . . .
c) Are connectors intact?	. . . . .	. . . . .	. . . . .
d) Are the fuses correct?	. . . . .	. . . . .	. . . . .
e) Is equipment protection correct?	. . . . .	. . . . .	. . . . .
f) Is voltage setting correct?	. . . . .	. . . . .	. . . . .
g) Is there an earth terminal?	. . . . .	. . . . .	. . . . .
Electrical Measurements with Safety Tester			
a) Is protective earth continuity correct?	. . . . .	. . . . .	. . . . .
b) Is insulation resistance correct?	. . . . .	. . . . .	. . . . .
c) Are the leakage currents correct?	. . . . .	. . . . .	. . . . .
d) Is the voltage measurement correct?	. . . . .	. . . . .	. . . . .

Comments . . . . . .
. . . . . .

Page 8

ii. MECHANICAL INTEGRITY TESTS

Undertaken by: . . . . . .

Witnessed by: Name . . . . . Position . . . . . Date . . . . . .

	Yes/done	**No/not done**	**Corrected if applicable**
a) Are knobs and switches intact?	. . . . .	. . . . .	. . . . .
b) Do the wheels/castors move?	. . . . .	. . . . .	. . . . .
c) Are the handles intact?	. . . . .	. . . . .	. . . . .
d) Are the mechanical movements okay?	. . . . .	. . . . .	. . . . .

Comments . . . . . .
. . . . . .
. . . . . .

iii. GAS INTEGRITY TESTS

Undertaken by: . . . . . .

Witnessed by: Name . . . . . Position . . . . . Date . . . . . .

	Yes/done	No/not done	Corrected if applicable
a) Are the cylinders full?	. . . . .	. . . . .	. . . . .
b) Are appropriate gauges available?	. . . . .	. . . . .	. . . . .
c) Is there a cylinder key?	. . . . .	. . . . .	. . . . .
d) Is the pressure reading correct?	. . . . .	. . . . .	. . . . .
e) Is the cylinder colour code correct?	. . . . .	. . . . .	. . . . .
f) Are the hoses and fittings correct?	. . . . .	. . . . .	. . . . .
g) Is the system leaking?	. . . . .	. . . . .	. . . . .

Comments . . . . . .
. . . . . .

Page 9

iv. RADIATION INTEGRITY TESTS

Undertaken by: . . . . . .
Witnessed by: Name . . . . . Position . . . . . Date . . . . . .

	Yes/done	No/not done	Corrected if applicable
a) Is the kV calibration correct?	. . . . .	. . . . .	. . . . .
b) Is the mAs calibrated correctly?	. . . . .	. . . . .	. . . . .
c) Was the line voltage compensation performed?	. . . . .	. . . . .	. . . . .
d) Was the exposure test correct?	. . . . .	. . . . .	. . . . .
e) Were the step wedge test results correct?	. . . . .	. . . . .	. . . . .
f) Were the small and large focus calibrations done?	. . . . .	. . . . .	. . . . .

Comments . . . . . .
. . . . . .
. . . . . .

v. PERFORMANCE TESTS (see manuals for manufacturer's recommendations)
Undertaken by: . . . . . .

Witnessed by: Name . . . . . Position . . . . . Date . . . . . .

	Yes/done	No/not done	Corrected if applicable
Note: carry out all operational tests as specified by the manufacturer			
a) Are the function verification tests correct?	. . . . .	. . . . .	. . . . .
b) Is the equipment calibration acceptable?	. . . . .	. . . . .	. . . . .

Comments . . . . . .
. . . . . .
. . . . . .

Page 10

FAULT REPORT (describe any shortcomings with the equipment or services provided)
. . . . . .
. . . . . .
. . . . . .
. . . . . .
. . . . . .
. . . . . .
. . . . . .

. . . .
. . . . . .

NAME . . . . . .
SIGNATURE . . . . . .
DATE . . . . . .

Appendix 9I Sample Planned Preventive Maintenance Log Sheet

Equipment:							**Inventory #:**							**Location:**							**Month:**		
Task	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**
Daily Tasks																							
Daily Task 1																							
Daily Task 2																							
Daily Task 3																							
Daily Task 4																							
Daily Task 5																							
Weekly Tasks																							
Weekly Task 1																							
Weekly Task 2																							
Monthly Tasks																							
Monthly Task 1																							
Monthly Task 2																							
Quarterly Tasks																							
Quarterly Task 1																							
Quarterly Technical PM																							
Semi-Annual Tasks																							
Semi-Annual Technical PM																							
Annual Tasks																							
Annual Technical PM																							

Appendix 8J Good Practice Checklist for Corrective Maintenance

Step 1
Resist the temptation to dive straight in. Do not immediately open up the machine and plunge in with a screwdriver.

Step 2
Listen to the equipment users. Talk to the user – they can help you to discover the symptoms of the fault. Ask the users lots of questions – they often don't realize how much they know.

Step 3
Look up the equipment's service history. Each individual piece of equipment should have a record of its service history. Use this to make yourself aware of the particular machine's past fault.

Step 4
Check the main incoming supply. Ensure that the electricity/gas/water supply is reaching the wall outlet/socket – if it isn't, check the relevant main circuit breakers/valves/taps controlling the service supply.

Step 5
Inspect the main incoming connection. Check the plug, connector, and mains/incoming lead to see if electricity (or other supply) is reaching the machine.

Step 6
Inspect the machine's external supply connection point. Check the main external fuses/taps/regulators for the machine.

Step 7
Refer to the operator's manual. Familiarize yourself with the instructions on how the equipment is meant to work.

Step 8
Check the accessories. Ensure that the correct accessories are attached to the correct inlets.

Step 9
Watch the machine in operation. Ask the users to describe what steps they usually take to put the machine through a normal operational cycle. Watch them do this, and observe what happens.

Step 10
Refer to local sources of advice. Consult the service manual, training resources, PPM schedules and any other technical personnel. Take note of any possibility of remote diagnostics where, for complex equipment such as CT scanners, the manufacturer's computer may be able to log into the equipment and diagnose the fault.

Step 11
Only at this point, consider opening the machine. Decide whether it is best to take the machine back to the workshop before opening it.

Step 12
Inspect the machine's internal supply connection points. Check the main internal fuses/taps/valves for the machine, and then check the on/off switch.
Step 13
Go through the troubleshooting or fault-finding steps provided in the service manual. BEWARE: It is very common for maintainers to guess the problem and act on it without verification. This leads to frustration when the diagnosis turns out to be incorrect. Thus, always take steps in the following order:

1. Determine the problem to a high degree of certainty by testing
- Alter and adjust the equipment as little as possible during this stage
- Never guess a problem or make an alteration that cannot be reversed
- Always record adjustments as the work progresses (for example, on a notepad)
2. Correct the problem.

Step 14
Contact more experienced colleagues. Ask the in-house team of another health service provider (for example at a neighbouring public or private hospital), or ask the national service provider (National Scientific Equipment Center).

Step 15
Ask the manufacturer or their representative for help. Contact them for discussions and fault-finding by phone, fax or email. Email is the cheapest and often the most effective way to get in contact with the manufacturer. Try to get some hints, but be sure to clarify whether you are being charged for this advice.

Step 16
Call in support from the private sector when the work is beyond your capabilities. Call in the private maintenance contractor, if there is one, for faults that cannot be handled by the in-house team. Ensure that the hospital management or Medical Equipment Service has the funds to cover this.

Step 17
If the work is within your capabilities, only at this point consider taking corrective action. When a fault is found that the in-house team has the skills and authority to pursue, follow the corrective action or parts replacement steps provided in the service manual.

Step 18
Use the correct materials. Select only the correct maintenance materials and spare parts relevant to the machine.

Step 19
Work carefully. Handle the spare parts and maintenance materials carefully so as not to damage them or the machine.

Step 20
Make a record of your work. Fill in the Work Order form to record the problem reported, fault found, corrective action taken, parts used, time taken, etc.

Step 21
Ensure the equipment is safe to use. Always safety test the equipment with the correct test equipment before returning it to the users.

Step 22
Repeat step 9. Ensure that the operators can make the equipment function properly during a normal operational cycle.

Step 23
Reduce the likelihood of problems in the future. Ensure in the future that planned preventive maintenance (PPM) is carried out on the equipment.

Appendix 8K Sample Corrective Maintenance Report

Work order number:

Equipment type	**Inventory Number**
Model	**Serial No.**

Description of equipment failure
Cause of equipment failure (if known)
Part of machine / equipment to be maintained

Corrective action **Time required**		
Spare parts replaced **1.** **2.** **3.** **4.** **5.** **6.**		
Engineer 1	**Signature 1**	**Date**
Engineer 2	**Signature 2**	**Date**

User comments		
Date	**Signature**	**Date**

Appendix 9L Sample Work Order Form

<table>
<tr><td colspan="2">Note: this is a triplicate form
• 1st sheet is the User File copy
• 2nd sheet is the Maintenance Progress File copy
• 3rd sheet is the Equipment History File copy</td></tr>
<tr><td colspan="2">SECTION A: To be completed by user</td></tr>
<tr><td>Equipment Type:</td><td>Inventory Number:</td></tr>
<tr><td>Item Location:</td><td></td></tr>
<tr><td>Name of person making request:</td><td>Date:</td></tr>
<tr><td colspan="2">Description of Problem:</td></tr>
<tr><td colspan="2">Troubleshooting performed (if relevant):</td></tr>
<tr><td colspan="2"></td></tr>
<tr><td colspan="2">SECTION B: To be completed by Head of DTC</td></tr>
<tr><td>Date request received:</td><td>Work order number:</td></tr>
<tr><td>Priority of task (high/medium or low):</td><td>Task allocated to:</td></tr>
<tr><td colspan="2"></td></tr>
<tr><td colspan="2">SECTION C: To be completed by Maintenance Technician</td></tr>
<tr><td colspan="2">Was item repaired?
Yes ☐ No ☐</td></tr>
<tr><td>If Yes, complete Maintenance Report Form. Return Item to User.

Equipment returned to_____

Date returned _____</td><td>If No, state reason work not completed and return Work Order Form to Head of Equipment Maintenance for follow up and completion of Work Order (by assigning another technician or outsourcing):</td></tr>
<tr><td colspan="2">Name of Maintenance Technician _____
Signature: _____</td></tr>
<tr><td colspan="2">After corrective maintenance is completed the Work Order Form and Corrective Maintenance Log Form should be filed together in the Equipment History File.</td></tr>
</table>

Appendix 9M Sample User Training Verification Form

Name:	Position:
Department/ward:	Date employment commenced:

Medical Device	Manufacturer/ Supplier	Model	Trained By	Date of training	Assessment/ Review date	Comments

Appendix 9N Principles behind Replacement Cost Calculations

A. Basic Principle

Assuming	Your equipment stock value is, for example, US$2,500,000 (Note: This is not based on what is purchased each year, but upon the value of all the items already owned.)
And	All the equipment only had a 'life' of one year
Then	US$2,500,000 would be needed each year to replace equipment

B. Taking Equipment 'Life' Into Account

But	If the 'life' of the equipment is, in fact, five years
Assume	The equipment will **not** all reach the end of its life at the same time
Then	The replacement budget can be spread over the lifetime of the equipment, as follows:

Replacement budget **each year** = value of stock
Lifetime

For example: Replacement budget per annum = $2,500,000/5 = $500,000 p.a.

C. Averaging Across All Stock

In fact, stock will actually be made up of different types of equipment with different lifetimes – some 5 years, some 10, some 15, etc. Based on such lifetimes, an **average** lifetime is often taken to be 10 years. Thus, a **rough estimate** of the replacement budget will need to be 10% of the equipment stock value each year:

Replacement budget **each year** = total stock value
Average lifetime

For example: Replacement budget per annum = $2,500,000/10 = $250,000 p.a.