



MINISTRY OF HEALTH

INTEGRATED CANCER SCREENING, DIAGNOSIS AND LABORATORY MANAGEMENT

(Breast, Cervical,
and Prostate
cancers)

**CURRICULUM AND
IMPLEMENTATION
GUIDE FOR HEALTH
CARE PROVIDERS**

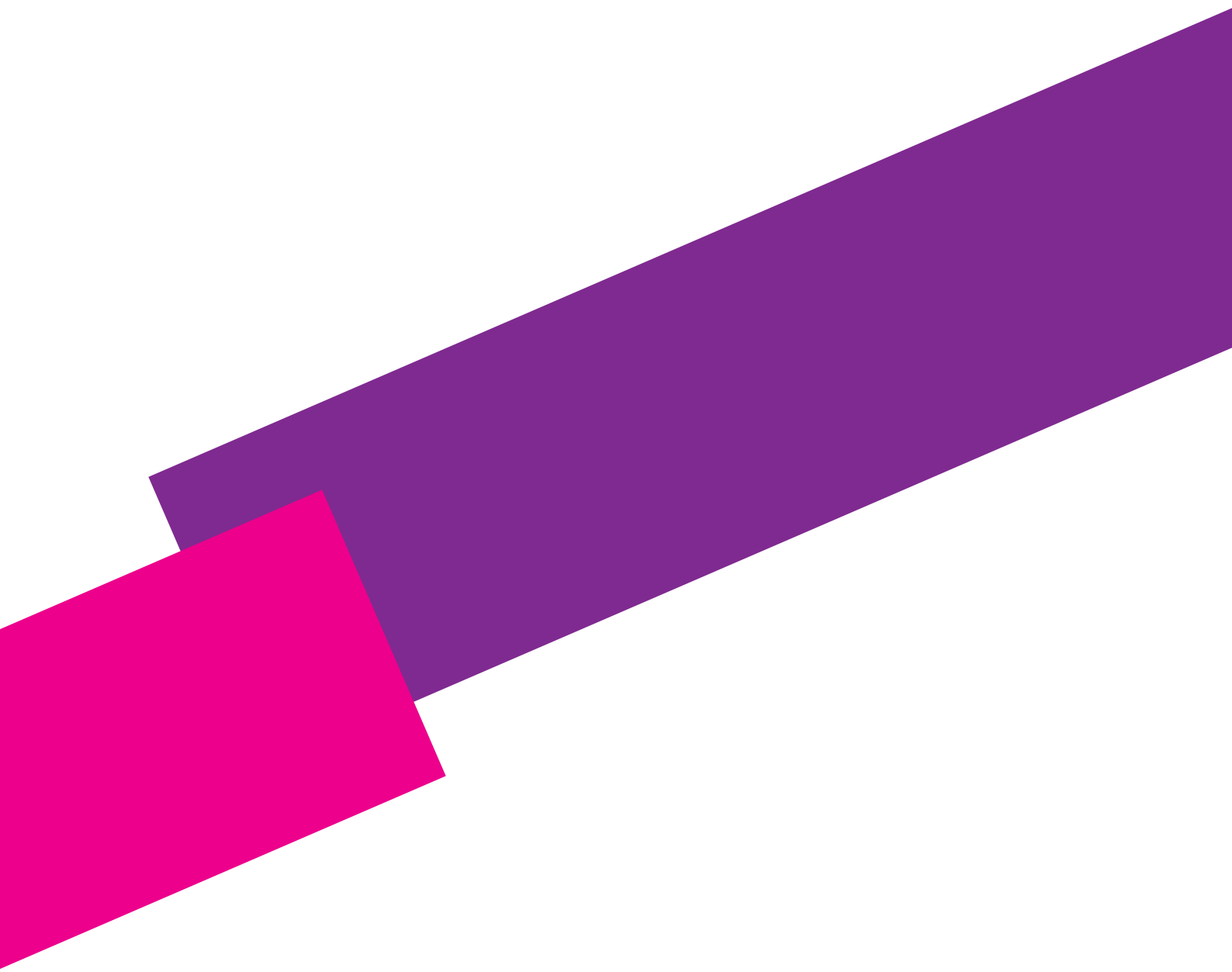


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**EAPHLN
PROJECT**





OVERALL BROAD OBJECTIVES OF THE PROPOSED COURSE

1. Increase knowledge and understanding of the impact of the major cancers and the role team work among health workers can play towards mitigating outcomes of cancer.

2. Improve knowledge and skills in screening and obtaining the right specimen for early

cancer diagnosis.

3. Improve knowledge & skills of appropriate laboratory handling and processing of samples for cancer diagnosis

4. Improve cancer data management and advocacy.

FOREWORD

Cancer is one of the major non-communicable diseases which together with cardiovascular diseases, diabetes and chronic respiratory diseases cause over 60% of global mortality every year. Cancer alone is responsible for an estimated 7.9 million deaths representing close to 13% of annual global deaths.

The cancer burden is rising globally, exerting significant strain on populations and health systems at all income levels. In Kenya, cancer is the 3rd leading cause of death after infectious and cardiovascular diseases. The International Agency for Research in Cancer (IARC) GLOBOCAN report for 2018 estimated 47,887 new cases of cancer annually with a mortality of 32,987. This represents close to 45% increase in incidence compared to the previous report that estimated 37,000 new cancer cases annually with an annual mortality 28,500 in 2012.

Breast, cervix uteri, oesophagus, prostate and colorectum are the leading types of new cancer cases in both males and females across all ages, with oesophageal cancer being the leading cause of cancer deaths, followed by cervical cancer and then breast cancer. It is sad to note that 70-80% of cancer patients in Kenya are diagnosed at an advanced disease when it is not amenable to cure; this is part of the justification for developing this curriculum for health workers.

In response to this growing challenge, the government has made tremendous progress in developing national policies, strategies and legislation to address cancer control. The enactment of the Cancer Control Act 2012 and establishment of the National Cancer Control Program (NCCP) signified government's commitment to addressing cancer while the Kenya Health Policy 2014-2030, Kenya National Strategy for Prevention of NCDs 2015-2020 and the National Cancer Control strategy 2017-2022 have prioritized cancer control interventions. A key challenge identified in the efforts to address the growing cancer burden is the lack of appropriate diagnostic capacity (HR skills, competence), poor referral networks and long turnaround time. It was thus deemed necessary to develop a curriculum to help health care providers acquire necessary knowledge and develop appropriate skills and attitudes in order to provide quality cancer screening, diagnosis, monitoring and specimen referral for effective patient management.

This curriculum is designed to build the capacity of health care providers who are directly involved in providing care to people suspected of having cancers, particularly cancers of the prostate, breast and cervix. It is particularly suited for medical doctors, clinical officers, nurses and laboratory technologists who are usually directly involved in cancer diagnostic procedures. Development of the curriculum has been a highly consultative process, evidence-based and incorporating recent advances in cancer screening and diagnosis.

It is hoped that implementation of this curriculum will significantly improve cancer management outcomes through screening, early diagnosis and appropriate referral as envisaged by the Kenya National Cancer Control Strategy.

Finally, I would like to recognize the contribution of all partners, experts and reviewers who were involved in the development of this curriculum. In particular, I thank the World Bank through the EAPHLN project for financing the entire process.

Dr. Patrick Amoth



Head, Directorate of Public Health

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The contribution and dedication of all individuals and organizations is highly appreciated.

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Acronyms and abbreviations

AMREF	African Medical and Research Foundation
AHRQ	Agency for Healthcare Research and Quality
AIDS	Acquired Immuno Deficiency Syndromes
ASCUS	Atypical Squamous Cells of Undetermined Significance
BP	Blood Pressure
BPH	Benign Prostatic Hyperplasia
BRCA	Breast Cancer genes
CAP	College of American Pathologists
CIN	Cervical Intraepithelial Neoplasia
CIS	Carcinoma in situ
CLSI	Clinical and Laboratory Standards Institute
CT	Computerized Tomography
DCIS	Ductal carcinoma in situ
DRE	Digital Rectal Examination
EAPHLN	East Africa Public Health Laboratory Network
EQA	External Quality Assurance
EUA	European University Association
FIGO	International Federation of Gynecology and Obstetrics
FISH	Fluorescence in situ hybridization
FNA	Fine Needle Aspiration
GDP	Gross Domestic Product
GOK	Government of Kenya
H&E	Haematoxylin and Eosin
HGSIL	High Grade Squamous Intraepithelial Lesion
HIV	Human Immunodeficiency Virus
HPV	Human Papilloma Virus
HR	Human resource
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
ICAO	International Civil Aviation Organization
IHC	Immunohistochemistry
ILAC	International Laboratory Accreditation Cooperation
ISO	International Organization for Standardization
JICA	Japan International Cooperation Agency
KMTC	Kenya Medical Training College
KEMRI	Kenya Medical Research Institution
KNH	Kenyatta National Hospital
LCIS	Lobular carcinoma in situ
LEEP	Loop Electrosurgical Excision Procedure
LSIL	Low Grade Squamous Intraepithelial Lesion
M&E	Monitoring and evaluation
MEPs	Medical Expenditure Panel Survey
MO's	Medical Officers
MOH	Ministry of Health
MRI	Magnetic Resonance Imaging

MTRH	Moi Teaching and Referral Hospital
NACOSTI	National Commission for Science, Technology and Innovation
NASCOP	National Aids Control Programme
NCCP	National Cancer Control Program
NCDs	Non- communicable diseases
NCI	National Cancer Institute
NPHL	National Public Health Laboratory
OSHA	Occupational Safety and Health Administration
PAP	Papanicolau
PBF	Peripheral Blood Film
PCR	Polymerase Chain Reaction
PET	Positron Emission Tomography
PPE	Personal Protective Equipment
PSA	Prostate specific Antigen
PZ	Peripheral Zone
QSE	Quality System Essential
SHS	Second Hand Smoke
SOP	Standard Operating Procedure
STI	Sexually Transmitted Infection
TAT	Turn Around Time
TDLU	Terminal Ductal Lobular Units
TRUS	Transurethral Ultrasound
TURP	Transurethral Resection of the Prostate
TZ	Transformation Zone
VIA	Visual inspection with Acetic acid
VILI	Visual inspection with Lugol's iodine
WHO	World Health Organization

How to Use This Curriculum

This curriculum is designed in a simple and easy to use format. It is divided into three parts: PART A, PART B, and PART C.

PART A

This part presents the foundation of the Curriculum and Implementation Guide showing detailed front matter, the module titles, objectives, content and the references.

PART B

This part presents the sample pretest and post test questions for the course.

PART C

This part presents power-point used for all modules of the course. The facilitators will need to use teaching methods that are appropriate for adult learners, including brainstorming group discussions, over-view lectures and participant presentations, role plays, cases studies, group activities, exercises and practicum(s).



**INTERGRATED
CANCER
SCREENING,
DIAGNOSIS AND
LABORATORY
MANAGEMENT**

(Breast, Cervical,
and Prostate
cancers)

PART A

Curriculum and Implementation Guide

INTERGRATED CANCER SCREENING, DIAGNOSIS AND LABORATORY MONITORING: (Breast, Cervical and Prostate cancers)

1. INTRODUCTION

Cancer is one of the major non-communicable diseases which together with cardiovascular diseases, diabetes and chronic respiratory diseases cause over 60% of global mortality every year. Cancer alone is responsible for an estimated 7.9 million deaths representing close to 13% of annual global deaths. Cancer is the third leading cause of death in Kenya, after infectious diseases and cardiovascular diseases. It causes 7% of total national mortality every year.

In response to this growing challenge, the government has made tremendous progress in developing national policies, strategies and legislation to address cancer control. The enactment of the Cancer Control Act 2012 and establishment of National Cancer Control Program (NCCP) signified government commitment to addressing cancer while the Kenya Health Policy 2014-2030, Kenya National Strategy for Prevention of NCDs 2015-2020 and the National Cancer Control strategy 2017-2022 have prioritized cancer control interventions.

A survey conducted in three counties in Kenya revealed that cancers of the breast, cervix and prostate constitute a major burden. Other gaps identified include lack of appropriate diagnostic capacity (HR skills, competence), poor referral networks, and long turnaround time. These challenges have led to late diagnosis with poor treatment outcomes. It is therefore necessary to take steps towards addressing these gaps.

2. PURPOSE OF THE COURSE

The purpose of this curriculum is to help health care providers to acquire necessary knowledge and develop appropriate skills and attitudes required to provide quality cancer screening, diagnosis, monitoring and specimen referral for effective patient management.

3. TARGET GROUP- MULTIDISCIPLINARY TEAMS

The course is designed for health care providers who are directly involved in providing care to people suspected of having cancers, particularly cancers of the prostate, breast and cervix. The course is particularly suited for medical doctors, clinical officers, nurses and laboratory technologists who are usually directly involved in cancer diagnostic procedures. Each cohort of trainees' will be not more than 18 representing different cadres. For practical sessions each cadre will proceed to the respective practical area.

4. COURSE DURATION

This course is designed in a modular format to be implemented over a period of 6 consecutive days which ensures there is minimal disruption to service delivery at the health facilities.

5. CERTIFICATION

Upon successfully attending all the modules and successful assessment of the participants, participants will be awarded a certificate and will be eligible to earn continuous professional development points with their relevant regulatory body.

6. COURSE ORGANIZATION

Module 1: OVERVIEW OF THE CANCER BURDEN

Unit 1: Epidemiology, causes, and risk factors: global and regional

Unit 2: Cancer intervention measures (National guidelines and standards)

Module 2: OVERVIEW OF CANCER SCREENING AND DIAGNOSIS

Unit 1: Cancer screening and diagnostic standards

Unit 2: Cancer screening situation

Unit 3: Cancer screening, diagnostic and monitoring methods

Module 3: BREAST CANCER

Unit 1: Epidemiology

Unit 2: Anatomy, Pathology and Clinical presentation of breast cancer

Unit 3: Specimen collection and handling

Unit 4: Processing, reporting of FNA and histology specimens

Module 4: CERVICAL CANCER

Unit 1: Epidemiology

Unit 2: Anatomy, Pathology and Clinical presentation of cervical cancer

Unit 3: Specimen collection and handling

Unit 4: Processing, reporting PAP smears and histology specimens

Module 5: PROSTATE CANCER

Unit 1: Epidemiology

Unit 2: Anatomy, Pathology and Clinical presentation of prostate cancer

Unit 3: Specimen collection, handling and laboratory diagnosis

Unit 4: Digital rectal examination

Module 6: OTHER CANCERS

Unit 1: Top ten adult neoplasms in Kenya

Unit 2: Top five childhood neoplasms in Kenya

Unit 3: Screening and laboratory diagnosis of other adult neoplasms

Unit 4: Screening and laboratory diagnosis of childhood neoplasms

Unit 5: Types of Specimen and handling

Module 7: SPECIMEN REFERRAL AND NETWORKING

Unit 1: Specimens referral pathways

Unit 2: Documentation associated with specimens' referral

Unit 3: Specimen acceptance and rejection criteria

Unit 4: Code of conduct and ethics in handling laboratory specimens

Module 8: QUALITY MANAGEMENT SYSTEM IN CANCER SCREENING AND DIAGNOSIS

Unit 1: Quality management systems

Unit 2: Quality assurance measures for cancer screening and diagnosis

Unit 3: Biosafety and Biosecurity

Unit 4: Problem solving techniques

Module 9: COMMUNICATION ADVOCACY, AND SOCIAL MOBILIZATION

Unit 1: Communication, advocacy and social mobilization.

Module 10: MONITORING AND EVALUATION

Unit 1: Monitoring and evaluation in cancer prevention and control.

7. TRAINING, FACILITATION AND SITES

This curriculum will be used to train the trainers (TOTs) and subsequently will be used to facilitate future training programs.

This will be a hospital based training conducted by trainers who have undergone trainers of trainees' course.

Trainers and facilitators for the course will be drawn from a pool of subject-matter experts with the relevant practice, teaching experience and attitude in cancer screening, diagnosis and Laboratory management.

7.1. PERFORMANCE ASSESSMENT

Assessment of the participants will be through pre- and post-tests, continuous assessment through question and answer sessions and attendance for all the modules will be mandatory. Assignments and group activities will also be assessed and feedback given.

7.2. IMPLEMENTATION

This is an intensive 6-day course with a practical component in a hospital clinical and laboratory setting. The course should begin at 8.30am on a Monday and stretch through to 5.00 pm every day. This implies that participants travelling from far-out districts will have to arrive at the training venue on the Sunday preceding the week of training to be in time for the starting of the course on Monday morning. Participants will depart from the workshop venue on Saturday.

The recommended number of participants per training is eighteen (18). The training mix of participants will be determined from time to time by the organizers on the basis of need and circumstances.

The learning methods that will be used for this course will be appropriate for adult learners and will include: overview lectures, demonstrations, group discussions, case studies, assignments, role plays and practical sessions in clinical and laboratory settings.

In every training, participants will fill in a course evaluation tool that will be used for periodic review.

7.3. CURRICULUM REVIEW/ CHANGE

Continuous monitoring and evaluation will be done by the participants and the facilitators and the observations recorded. After five course implementation cycles, a review workshop will be planned to incorporate all the recommendations.

7.4. REFERENCES AND RECOMMENDED READINGS

These are appended at the back of each module

7.5. APPENDICES

- Tentative Pretest/Post-test
- Tentative Course Timetable
- Tentative letter to experts seeking for document improvement
- Course evaluation questionnaire (Develop form)

COURSE DESCRIPTIONS

Module1: OVERVIEW OF THE CANCER BURDEN

Objectives: by the end of this module participants should be able to:

1. Describe epidemiology, causes, and risk factors of cancer
2. Discuss various cancer intervention measures

Outcome:

A health worker capable of applying the knowledge on overall cancer burden to advance the agenda of cancer screening diagnosis and laboratory management.

Content

- **Epidemiology, Causes, and Risk factors of cancer:** Global, Regional, incidence, prevalence. Causes and Risk factors including: Biological, environmental, behavioral.
- **Social-economic impact of cancer:** Social including direct and indirect.
- **Cancer intervention measures:** Preventive, Curative, Palliative. Policy, Legislation, guidelines.

Module 1: Implementation guide

STEP	CONTENT	LEARNING METHODS	TIME
UNIT 1	Epidemiology, Causes, and Risk factors of cancer	Lecture discussion	1 hours
UNIT 2	Cancer intervention measures	Lecture discussion & hospital visit	3 hour

Total time: 4 hours

References and recommended readings

Tools, equipment and materials

- Publications

Module2: OVERVIEW OF CANCER SCREENING AND DIAGNOSIS

Objectives: by the end of this module participants should be able to:

1. Describe Cancer screening and diagnostic standards
2. Explain Cancer screening situation
3. Discuss Cancer screening, diagnostic and monitoring methods

Outcome:

A health worker capable of applying the knowledge on cancer screening and laboratory diagnosis to advance cancer prevention and control.

Content

- Cancer screening and diagnostic standards: evolution of screening, diagnostic standards and methods: international and regional.
- Cancer screening situation: screening and diagnosis including accessibility, expertise and resources distribution.
- Cancer screening, diagnostic and monitoring methods: screening methods including HPV, VIA/VILI, diagnostic methods including cytological techniques and monitoring methods including biochemical and molecular techniques.

Module 2 implementation guide

STEP	CONTENT	LEARNING METHODS	TIME
UNIT 1	Cancer screening and diagnostic standards	Lecture discussion	30 min
UNIT 2	Cancer screening situation	Lecture discussion/illustrations	30 min
UNIT 3	Cancer screening, diagnostic and monitoring methods	Lecture discussion	2 hour

Total time: 3 hours

References and recommended readings

1. MoH- Kenya (2013) National guidelines for cancer management
2. MoH- Kenya (2012) National guidelines for prevention and management of cervical, breast and prostate cancer
3. MoH- Kenya (2017- 2022) National Cancer Control Strategy
4. GLOBOCAN (2018) IARC, Lyons France
5. MoH- Kenya (2018) Kenya National Cancer Screening guidelines

Tools, equipment and materials

- Posters and charts
- Video

Module 3: BREAST CANCER

Objectives:

1. Describe the epidemiology, causes and risk factors of breast cancer
2. Explain the anatomy, pathology and clinical presentation of breast cancer
3. Describe the processes of specimen collection and handling
4. Perform, process and report FNA and histology specimen

Outcome:

A health worker capable of applying the knowledge on cancer screening, diagnosis and laboratory management in the prevention and control breast cancer.

Content

- **Epidemiology, causes and risk factors of breast cancer:** Global, Regional incidence, prevalence. Causes and Risk factors including: Biological, environmental, behavioral.
- **Pathology and clinical presentation of breast cancer:** Anatomy and physiology of the breast, pathogenesis, types, grading and staging of breast cancer. Signs and symptoms of breast cancer. Overview of treatment and outcome of breast cancer.
- **Screening and laboratory diagnosis of breast cancer:** Screening methods, laboratory investigations, interpretation, reporting, and pathological staging of breast cancer. Tumour markers.
- **Process of sample collection and handling:** Sample types, collection procedures, handling and preparation. Laboratory processing of samples, archiving of reports and samples. Turn-around time.
- **Perform an FNA and biopsy specimen:** Perform an FNA procedure practically in a clinical setting.

Module 3: Implementation guide

STEP	CONTENT	LEARNING METHODS	TIME
UNIT 1	Epidemiology, Causes, and Risk factors of breast cancer	Lecture discussion	1 hour
UNIT 2	Pathology and clinical presentation of breast cancer	Lecture discussion /illustrations	1 hour
UNIT 3	Sample collection, processing and handling	Lecture discussion & practical	2 hours
UNIT 4	Outlining the processing and reporting of FNA and biopsy specimen	Practical demonstration	2 hours

Total time: 6 hours

References and recommended readings

1. MoH- Kenya (2013) National guidelines for cancer management
2. MoH- Kenya (2012) National guidelines for prevention and management of cervical, breast and prostate cancer
3. MoH- Kenya (2017- 2022) National Cancer Control Strategy
4. GLOBOCAN (2018) IARC, Lyons France
5. MoH- Kenya (2018) Kenya National Cancer Screening guidelines
6. Demay R.M. (1999) The Art & Science of Cytopathology

Tools, equipment and materials

- Gloves
- Glass slides, coverslips and slide holders
- Fixatives
- Assorted Stains
- Core biopsy gun and needles
- Hypodermic syringes
- Slide racks
- Disinfectants/ antiseptics/Gauze
- Reporting template for breast cytology
- (Booked patients, clinic and laboratory space)

Module 4: CERVICAL CANCER

Objectives:

1. Describe the epidemiology, causes and risk factors of cervical cancer
2. Explain the anatomy, pathology and clinical presentation of cervical cancer
3. Describe the processes of specimen collection and handling
4. Perform, process and report a PAP smear and histology specimen

Outcome

A health worker capable of applying the knowledge on cancer screening ,diagnosis and laboratory management in the prevention and control of cancer of the cervix.

Content

- Epidemiology, causes and risk factors of cervical cancer: Global, Regional incidence, prevalence. Causes and Risk factors including: Biological, environmental, behavioral.
- Pathology and clinical presentation of cervical cancer: Anatomy and physiology of the uterine cervix, pathogenesis, types, grading and staging of pre-cancer and cervical cancer. Signs and symptoms of cervical cancer. Primary and secondary prevention. Overview of treatment and outcome of pre-cancer and cervical cancer.
- Screening and laboratory diagnosis of cervical cancer: Screening methods, laboratory investigations, interpretation, reporting, and pathological staging of pre-cancer and cervical cancer.
- Process of sample collection and handling: Sample types, indications, collection procedures, handling and preparation. Laboratory processing of samples, archiving of reports and samples. Turn-around time.
- Performing, processing and reporting a PAP smear and a biopsy specimen: Perform a PAP procedure practically in a clinical setting
- Quality assurance in cervical cancer diagnosis: Quality assurance in screening and diagnosis, laboratory processes and reporting.

Module 4: Implementation guide

STEP	CONTENT	LEARNING METHODS	TIME
UNIT 1	Epidemiology, Causes, and Risk factors of cervical cancer	Lecture discussion	1 hour
UNIT 2	Anatomy, Pathology and clinical presentation of cervical cancer	Lecture discussion/illustrations	1 hour
UNIT 4	Specimen collection, processing and handling	Lecture discussion practical	2 hours
UNIT 5	Outlining the processing and reporting of PAP smear and histology specimen	Practical demonstration	2 hours

Total time: 6 hours

References and recommended readings

1. MoH- Kenya (2013) National guidelines for cancer management
2. MoH- Kenya (2012) National guidelines for prevention and management of cervical, breast and prostate cancer
3. MoH- Kenya (2017- 2022) National Cancer Control Strategy
4. GLOBOCAN (2018) IARC, Lyons France
5. MoH- Kenya (2018) Kenya National Cancer Screening guidelines
6. Demay R.M. (1999) The Art & Science of Cytopathology

Tools, equipment and materials

- Gloves
- Glass slides, coverslips and slide holders
- Fixatives
- Pap Stains
- Slide racks
- Disinfectants/ antiseptics/Gauze
- Speculum
- Pap smear collection kit
- Charts
- Bethesda template for reporting pap smears
- [Booked patients, clinic and laboratory space]

Module 5: PROSTATE CANCER

Objectives:

1. Describe the epidemiology, causes and risk factors of prostate cancer
2. Explain the anatomy, pathology and clinical presentation of prostate cancer
3. Describe the processes of specimen collection, handling and laboratory diagnosis
4. Perform and report a Digital rectal examination

Outcome:

A health worker capable of applying the knowledge on cancer diagnosis and laboratory management in the prevention and control of cancer of the prostate.

Content

- Epidemiology, causes and risk factors of prostate cancer: Global, Regional incidence, prevalence. Causes and Risk factors including: Biological, environmental, behavioral.
- Pathology and clinical presentation of prostate cancer: Anatomy and physiology of the prostate, pathogenesis, types, grading and staging of prostate cancer. Signs and symptoms of prostate cancer. Overview of treatment and outcome of prostate cancer.
- Screening and laboratory diagnosis of prostate cancer: Screening methods, laboratory investigations, interpretation, reporting, and pathological staging of prostate cancer. Tumor markers.
- Process of sample collection and handling: Sample types, indications, collection procedures, handling and preparation. Laboratory processing of samples, archiving of reports and samples. Turn- around time.
- Process and report a Digital rectal examination.
- Quality assurance in prostate cancer diagnosis: Quality assurance in screening and diagnosis, laboratory processes and reporting.

Module 5: Implementation guide

STEP	CONTENT	LEARNING METHODS	TIME
UNIT 1	Epidemiology, Causes, and Risk factors of prostate cancer	Lecture discussion	1 hour
UNIT 2	Anatomy, Pathology and clinical presentation of prostate cancer	Lecture discussion / illustrations	1 hour
UNIT 3	Specimen collection, processing and handling	Lecture discussion & practical demonstration	2 hours
UNIT 4	Perform and report digital rectal examination	Practical demonstration	2 hours

Total time: 6 hours

References and recommended readings

1. MoH- Kenya (2013) National guidelines for cancer management
2. MoH- Kenya (2012) National guidelines for prevention and management of cervical, breast and prostate cancer
3. MoH- Kenya (2017- 2022) National Cancer Control Strategy
4. GLOBOCAN (2018) IARC, Lyons France
5. MoH- Kenya (2018) Kenya National Cancer Screening guidelines
6. Demay R.M. (1999) The Art & Science of Cytopathology

Tools, equipment and materials

- Gloves
- Glass slides, coverslips and slide holders
- Fixatives
- Disinfectants/ antiseptics/Gauze
- Charts
- Trucut biopsy kit
- Proctoscope
- (Booked patients, clinic and laboratory space)

Module 6: OTHER CANCERS

Objectives

1. List top ten adult neoplasms in Kenya
2. Outline top five childhood neoplasms in Kenya
3. Explain the screening and laboratory diagnosis of other adult neoplasms
4. Explain the screening and laboratory diagnosis of childhood neoplasms
5. Discuss specimen types and handling of these neoplasms

Outcome:

A health worker capable of promoting awareness of the importance of screening and laboratory diagnosis of childhood and other cancers.

Contents

- **The top five other adult and childhood cancers:** Include esophageal, gastric, Kaposi's, colorectal, hepatic cancers as well as common childhood malignancies
- **Screening and laboratory diagnosis:** Serological, hematological, exfoliative cytology, Fine needle aspirate, surgical biopsies, bone marrow aspirate and biopsy, tumor and prognostic markers.
- **Sample Types:** Blood, body fluids, scrapings, imprints, Brushings, washings, bone marrow and trephines biopsy, surgical biopsies.

Module 6: Implementation guide

STEP	CONTENT	LEARNING METHODS	TIME
UNIT 1 & 2	Top adult and childhood cancers	Lecture discussion	½ hour
UNIT 3&4	Screening and laboratory diagnosis of common pediatric and other adult cancers	Lecture discussion & practical /video clip	2 hour
UNIT 5	Specimen types	Lecture discussion	½ hour

Total time: 3 hours

References and recommended readings

1. MoH- Kenya (2013) National guidelines for cancer management
2. MoH- Kenya (2012) National guidelines for prevention and management of cervical, breast and prostate cancer
3. MoH- Kenya (2017- 2022) National Cancer Control Strategy
4. GLOBOCAN (2018) IARC, Lyons France
5. MoH- Kenya (2018) Kenya National Cancer Screening guidelines
6. Demay R.M. (1999) The Art & Science of Cytopathology
7. Dacie and Lewis (2012) Practical Haematology

Tools, equipment and materials

Module 7: SPECIMEN REFERRAL NETWORKING

Objectives:

1. Develop referral pathways
2. Identify documents associated with specimen referral
3. Apply acceptance and rejection criteria for specimens
4. Apply code of conduct and ethics in handling laboratory specimens

Outcome:

A health worker capable of participating in the utilization of specimen referral systems in support of cancer screening diagnosis and laboratory management.

Content

- **Referral networks:** Including vertical, horizontal, referral points, and associated logistics.
- **Mapping, selection and developing of referral networks:** including definitions, selection criteria, methods and strategies of developing of referral networks
- **Sample referral pathways:** including telemedicine, packaging and shipment processes, acceptance and rejection criteria
- **Code of conduct and ethics:** including communication, handling of laboratory samples and of result.

Module 7 implementation guide

STEP	CONTENT	LEARNING METHODS	TIME
UNIT 1	Develop Referral pathways	Lecture discussion	1 hour
UNIT 2	Identify documentation associated with specimen referral	Lecture discussion/illustrations	1 hour
UNIT 3	Apply acceptance and rejection criteria for specimens	Lecture, discussion, demonstrations	30 min
UNIT 4	Code of conduct and ethics	Lecture, discussion	30 min

Total time: 3 hours

References and recommended readings

1. Standards ISO15189, OSHA Kenya 2007.
2. MoH (2013) National guideline for cancer management Kenya: MoH Kenya
3. National guidelines for laboratory specimen referral networks 2012
4. MOH- Kenya (2012): National Guidelines for Laboratory Referral Networks.

Tools, equipment and materials

Module 8: QUALITY MANAGEMENT SYSTEM IN CANCER SCREENING AND DIAGNOSIS

Objectives:

1. Describe quality management systems
2. Describe quality assurance measures required for cancer screening and diagnosis
3. Discuss bio safety and biosecurity measures
4. Describe problem solving techniques

Outcome:

A health worker competent in applying a quality management system for cancer screening, diagnosis and laboratory management.

Content

- **ISO 15189 standard:** including its evolution, purpose, and scope.
- **Management requirement:** including organization management responsibility, Quality management systems, document control, service agreement, and evaluation of referral laboratories.
- **Technical responsibility:** including personnel, accommodation and environmental conditions, laboratory equipment, reagent and consumable.
- **Laboratory safety and biosecurity:** including risk group classification, design for safety, identification of hazards, personnel and management responsibility.

Module 8 implementation guide

STEP	CONTENT	LEARNING METHODS	TIME
UNIT 1	Describe quality management systems	Lecture discussion	1 hour
UNIT 2	Describe quality assurance measures required for cancer screening and diagnosis	Lecture discussion/illustrations	1 hour
UNIT 3	Discuss bio safety and biosecurity measures	Lecture, discussion,	1 hour
UNIT 4	Describe problem solving techniques	Lecture, discussion demonstrations	1 hour

Total time: 4 hours

References and recommended readings

1. Standards, ISO15189,15190,9001,17025
2. OSHA Kenya 2007
3. National laboratory safety manual

Tools, equipment and materials

Module 9: COMMUNICATION, ADVOCACY, AND SOCIAL MOBILIZATION

Objectives: By the end of this module participants should be able to:

1. Discuss communication , advocacy, and social mobilization
2. Describe steps and principles in advocacy and social mobilization
3. Describe communication channels and Components for effective communication
4. Discuss myths, beliefs, stigma and demystification

Outcome

- A health worker who is competent in advocating for and mobilizing resources cancer diagnosis, screening and laboratory management.

Content

- **Communication, advocacy, and social mobilization:** including definition of community, Advocacy, communication and social mobilization.
- **Advocacy and social mobilization:** including concept of advocacy, rationale for advocacy, steps in advocacy, concept of community mobilization, rationale for community mobilization, steps involved in community mobilization, community participation, and rationale for community participation.
- **Communication channels and Components:** including principle and types of communication, barriers to effective communication, and communication skills.
- **Myths, beliefs, stigma and demystification:** including effects of stigma, myths and believes, concept of demystification, mystification and reality.

Module 9 implementation guide

STEP	CONTENT	LEARNING METHODS	TIME
UNIT 1	Discuss communication , advocacy, and social mobilization	Lecture discussion	1 hour
UNIT 2	Describe steps and principles in advocacy and social mobilization	Lecture discussion /illustrations	30 MIN
UNIT 3	Describe communication channels and Components for effective communication	Lecture, discussion	30 MIN
UNIT 4	Discuss myths, beliefs, stigma and demystification	Lecture, discussion, case scenarios and studies	1hour

Total time: 3 hours

References and recommended readings

1. Meseret Yazachew Yihene Alem (2004) Introduction to Health Education by Jimma University
2. National Open University of Nigeria School of Health Sciences Course Code: National Open University of Nigeria 2008

Tools, equipment and materials

Module 10: MONITORING AND EVALUATION

Objectives

1. Define concepts of monitoring and evaluation in cancer prevention and control
2. Outline cancer indicators
3. Discuss cancer data collection tools including cancer registry

Content

- Concepts of monitoring and evaluation in cancer prevention and control i.e. evaluation and its importance, need for reliable data, characteristics of data, key evaluation issues, monitoring and its importance. Data collection, analysis, presentation and use.
- Cancer indicators and data collection tools and methods, steps/process and mechanisms. Data sources including cancer registries and surveillance. Measurements/indicators importance, types, and characteristics of a good indicator. Monitoring tools for data collection, completeness and accuracy, timeliness, and methods used for analysis. Utilization of M & E information for service delivery, communication, decision making and operational research.

Tools, equipment and materials

Module10: Implementation guide

STEP	CONTENT	LEARNING METHODS	TIME
UNIT 1	Define concepts of monitoring and evaluation in cancer prevention and control	Lecture, small group discussions, plenary	1 hour
UNIT 2	Outline cancer indicators	Lecture, small group discussions, plenary, exercises	1 hour
UNIT 3	Discuss cancer data collection tools including cancer registry	Lecture, small group discussions, exercises, case studies	1 hour

Total time: 3 hours

References and recommended readings

1. Ministry of Social Development- ME division (2003)- a Training manual on monitoring and evaluation, concepts tools and strategy for social sector programs.
2. Peter Rossi et al, (1999), Evaluation: A Systematic Approach, 6th edition.
3. World Bank. (2002), Operations and evaluation Department. Monitoring and evaluation: Some tools, Methods and approaches.
4. International Planned Parenthood federation (2000), Guide for designing Results Oriented projects and writing successful proposals. Western Hemisphere Region Inc.
5. AMREF, MoH, JICA. (2012). Training Curriculum on Governance, Leadership and Management for Health Systems Strengthening.

Tools, equipment and materials



**INTERGRATED
CANCER
SCREENING,
DIAGNOSIS AND
LABORATORY
MANAGEMENT**

(Breast, Cervical,
and Prostate
cancers)

PART B

Pretest - Post test questions

PRETEST (30min)**MODULE1: OVERVIEW OF THE CANCER BURDEN**

INSTRUCTIONS:

Answer TRUE (T) or FALSE (F) in the boxes provided below, indicating T for True and F for False.

Q1	Cancer is the second most important cause of death in Kenya?	
Q2	Kenya has a National Cancer Control Strategy	

MODULE 1 ANSWERS:

Q1 F

Q2 T

PRETEST**MODULE2: OVERVIEW OF CANCER SCREENING AND DIAGNOSIS**

INSTRUCTIONS:

Answer TRUE (T) or FALSE (F) in the boxes provided below, indicating T for True and F for False.

Q1	Ultra sound is the first screening method for breast cancer	
Q2	Histology is the gold standard for diagnosis of breast, cervical and prostate cancers	

MODULE 2 ANSWERS:

Q1 F

Q2 T

PRETEST**MODULE 3: BREAST CANCER**

INSTRUCTIONS:

Answer TRUE (T) or FALSE (F) in the boxes provided below, indicating T for True and F for False.

Q1	Lobular carcinoma is the most common type of breast cancer	
Q2	Stage 1 breast cancer is the commonest presentation in Kenya	

MODULE 3 ANSWERS:

Q1 F

Q2 F

PRETEST**MODULE 4: CERVICAL CANCER**

INSTRUCTIONS:

Answer TRUE (T) or FALSE (F) in the boxes provided below, indicating T for True and F for False.

Q1	Human papillomavirus (HPV) is the primary cause of 99.7% of all cervical cancers	
Q2	HPV vaccination and male circumcision are recommended strategies for primary prevention of cervical cancer	

MODULE 4 ANSWERS:

Q1 T

Q2 T

PRETEST**MODULE 5: PROSTATE CANCER**

INSTRUCTIONS:

Answer TRUE (T) or FALSE (F) in the boxes provided below, indicating T for True and F for False.

Q1	Mass screening by PSA is recommended for prostate cancer	
Q2	Digital Rectal examination has no value in screening	

MODULE 5 ANSWERS:

Q1 F

Q2 F

PRETEST**MODULE 6: OTHER CANCERS**

|

INSTRUCTIONS:

Answer TRUE (T) or FALSE (F) in the boxes provided below, indicating T for True and F for False.

Q1	Oesophageal cancer is the leading cause of cancer deaths in men	
Q2	Overall Stage of a cancer is the most important indicator of treatment outcome	

MODULE 6 ANSWERS:

Q1 T

Q2 T

PRETEST**MODULE 7: SPECIMEN REFERAL NETWORKING**

INSTRUCTIONS:

Answer TRUE (T) or FALSE (F) in the boxes provided below, indicating T for true and F for false.

Q1	Laboratory referral systems are purely market driven	
Q2	Adherence to packaging and shipment standards is necessary for quality results.	

MODULE 7 ANSWERS

Q1 F

Q2 T

PRETEST**MODULE 8: QUALITY MANAGEMENT SYSTEM IN CANCER SCREENING AND DIAGNOSIS**

INSTRUCTIONS:

Answer TRUE (T) or FALSE (F) in the boxes provided below, indicating T for true and F for false.

Q1	The most serious errors occur in the analytical phase	
Q2	Waste segregation is not a necessary step in bio-safety and bio-security	

MODULE 8 ANSWERS

Q1 F

Q2 F

PRETEST**MODULE 9: ADVOCACY, COMMUNICATION AND SOCIAL MOBILIZATION**

INSTRUCTIONS:

Answer TRUE (T) or FALSE (F) in the boxes provided below, indicating T for true and F for false.

Q 1	For effective communication to occur the audience must remove their own barriers	
Q2	It is not necessary to understand the structure of the community for effective social mobilization	

MODULE 9 ANSWERS

Q1 T

Q2 F

PRETEST**MODULE 10: MONITORING AND EVALUATION**

INSTRUCTIONS:

Answer TRUE (T) or FALSE (F) in the boxes provided below, indicating T for True and F for False.

Q1	A hospital-based cancer registry can be used for formulation of cancer policies	
Q2	A catchment population must be defined when establishing a population-based cancer registry	

MODULE 10 ANSWERS:

Q1 T

Q2 T



MODULE 1

OVERVIEW OF THE CANCER BURDEN

OBJECTIVES

By the end of this module participants should be able to:
Describe epidemiology, causes and risk factors for cancer;
Discuss various cancer intervention measures

Cancer Epidemiology, causes and risk factors

Unit outline

Epidemiology, causes and risk factors

Social-economic impact

Cancer intervention measures:

Given ten minutes...

In your view, what is the significance of cancer as an NCD in Kenya?

INTRODUCTION

Cancer is a major NCD and among the leading causes of death worldwide.

NCDs are estimated to cause more than 60% of annual global mortality (ref).

It is estimated that cancer kills over 7.9 million people (13%) globally every year (ref).

Communicable diseases remain the leading causes of death in many developing countries, but the incidence and mortality from NCDs is also rising rapidly.

CANCER IN KENYA

Many cancers are preventable. However, cancer remains a public health concern and ranks third as a cause of death after infectious and cardiovascular diseases.

It annually accounts for 7% of total national mortality.

Over 60% of affected patients are below 70 years.

Majority of cancer cases present in late stages due to low awareness, capacity to diagnose and treat cancer.

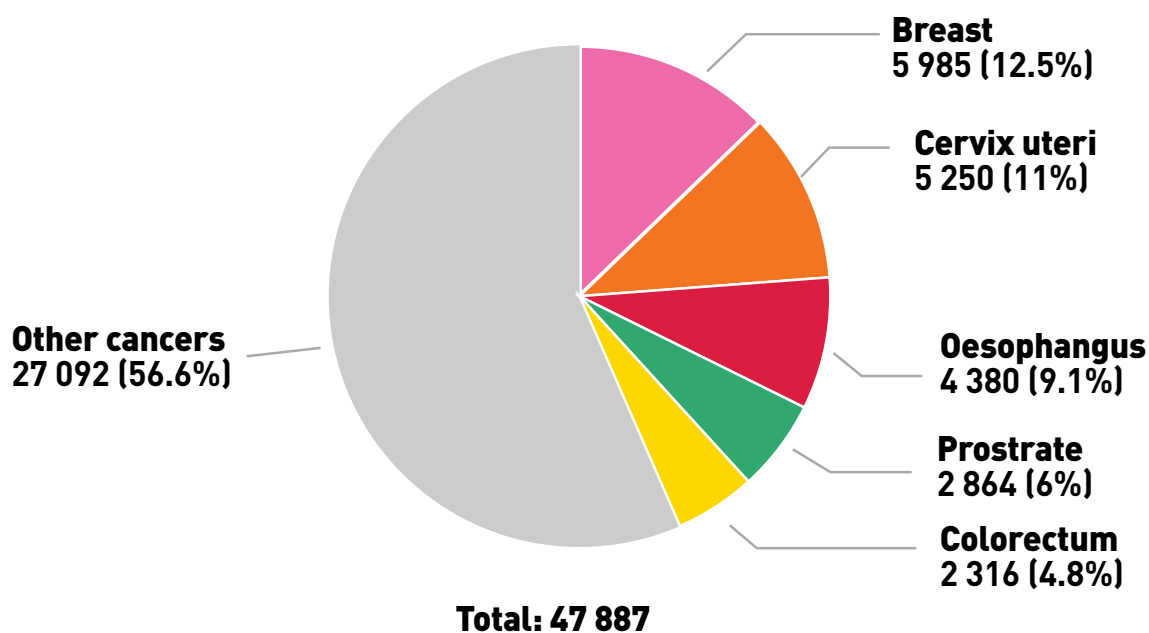
Cancer management has a high economic burden to the individual, community and the public health care system.

Kenya Cancer burden

Kenya

Source: Globocan 2018

Number of new cases in 2018, both sexes, all ages

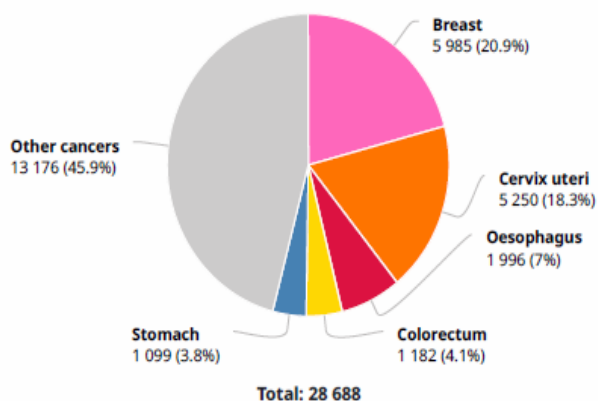


Number of new cases in 2018, males, all ages

Gender Distribution

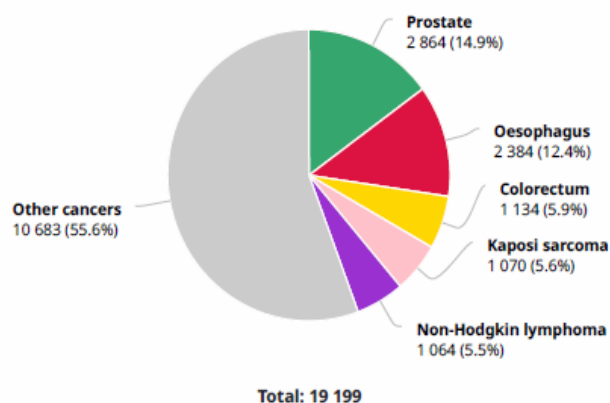
Females

Number of new cases in 2018, females, all ages



Males

Number of new cases in 2018, males, all ages



Kenya

Source: Globocan 2018



Incidence, Mortality and Prevalence by cancer site

Cancer	New cases				Deaths				5-year prevalence (all ages)	
	Number	Rank	(%)	Cum.risk	Number	Rank	(%)	Cum.risk	Number	Prop.
Breast	5 985	1	14.71	4.54	2 553	3	9.20	2.01	13 246	51.68
Cervix uteri	5 250	2	12.91	3.73	3 286	2	11.84	2.64	10 963	42.78
Oesophagus	4 380	3	10.77	2.23	4 351	1	15.68	2.23	4 184	8.21
Prostate	2 864	4	7.04	3.69	1 663	5	5.99	1.73	4 750	18.76
Stomach	2 127	5	5.23	1.15	2 068	4	7.45	1.13	2 713	5.32
Non-Hodgkin lymphoma	1 952	6	4.80	0.57	1 209	8	4.36	0.42	4 119	8.08
Kaposi sarcoma	1 782	7	4.38	0.38	930	10	3.35	0.20	3 803	7.46
Leukaemia	1 699	8	4.18	0.45	1 311	7	4.73	0.41	3 845	7.55
Colon	1 354	9	3.33	0.66	937	9	3.38	0.46	2 350	4.61
Liver	1 346	10	3.31	0.65	1 331	6	4.80	0.65	1 190	2.34

Given ten minutes...

List risk factors associated with various cancer (FOOTNOTE)

ONCOGENESIS**Risk factors**

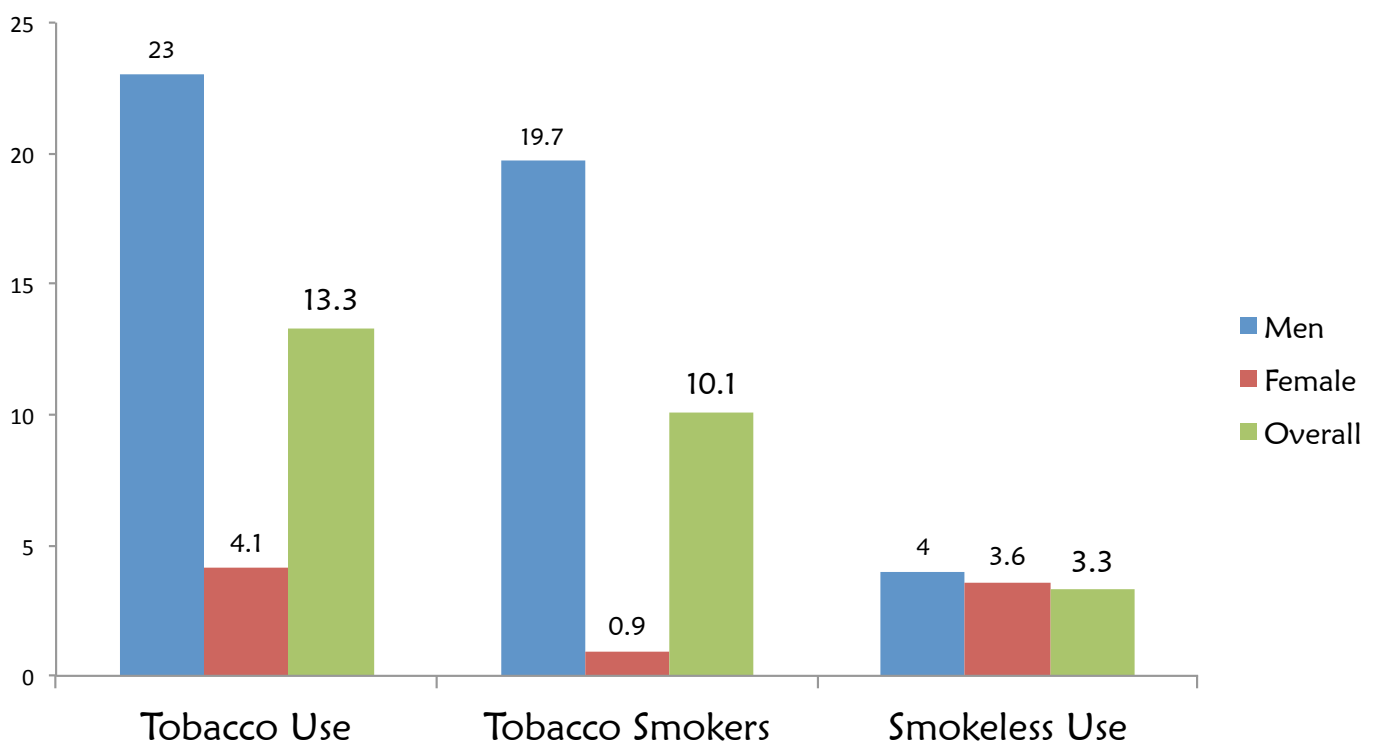
Globally, 5-10% of all cancers are attributed to genetic defects and 90-95% to environmental and lifestyle factors (tobacco, diet, alcohol and physical inactivity)

25-30% are directly tobacco,
 30-35% are linked to diet,
 15-20% are due to infections (eg HPV,HBV) and
 remaining 15-30% - are due to other factors
 (Anand et al 2008).

Some Risk factors and associated cancers

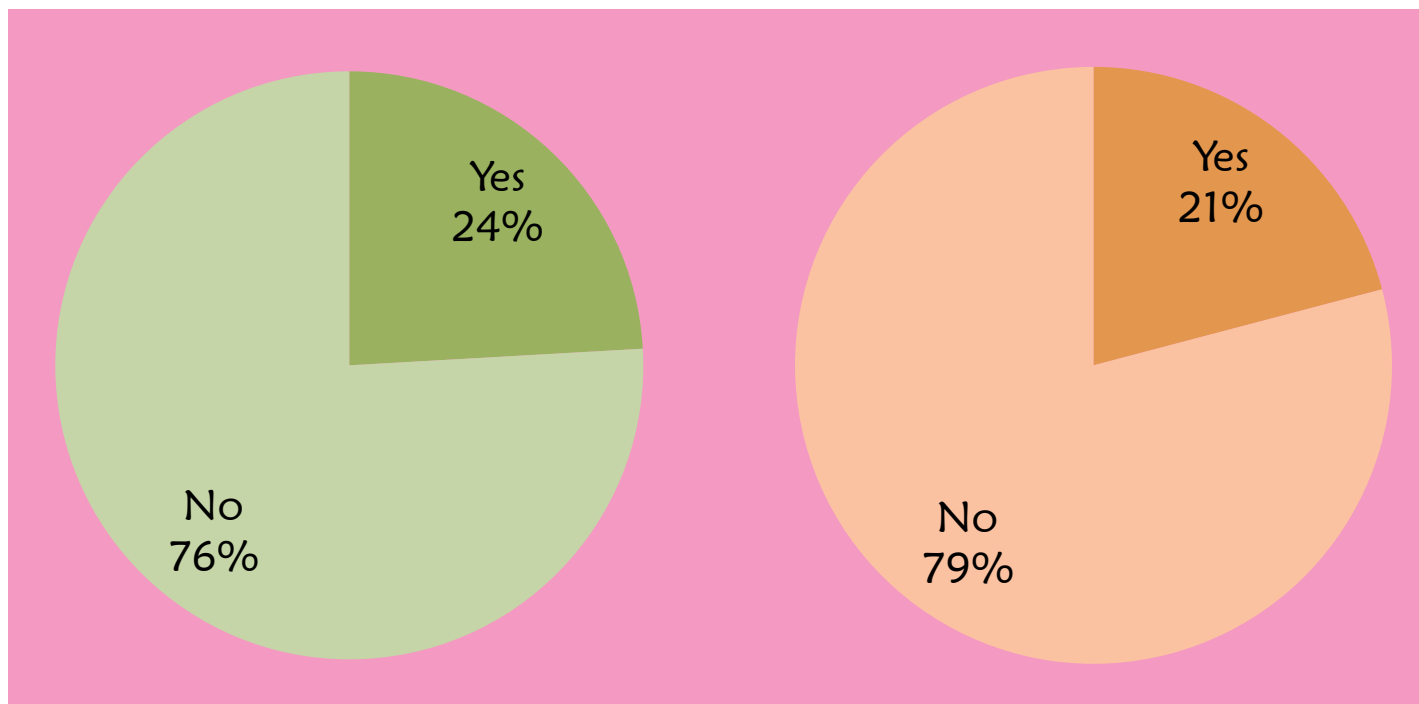
Risk factors	Examples of Associated cancers
Tobacco	Lung and most cancer
Infectious agents	Cervix(HPV) Liver (HBV, HCV) Bladder (Schistosomiasis), Kaposi (HHV8) Stomach (<i>H.Pylori</i>) HIV (<i>Lymphomas</i>)
Ionizing radiation	Leukemias
Food Contaminants	Liver
UV Radiation	Skin
Cytotoxic drugs	Second cancers
Harmful use of alcohol	Causal association with many cancers

Current Tobacco Use

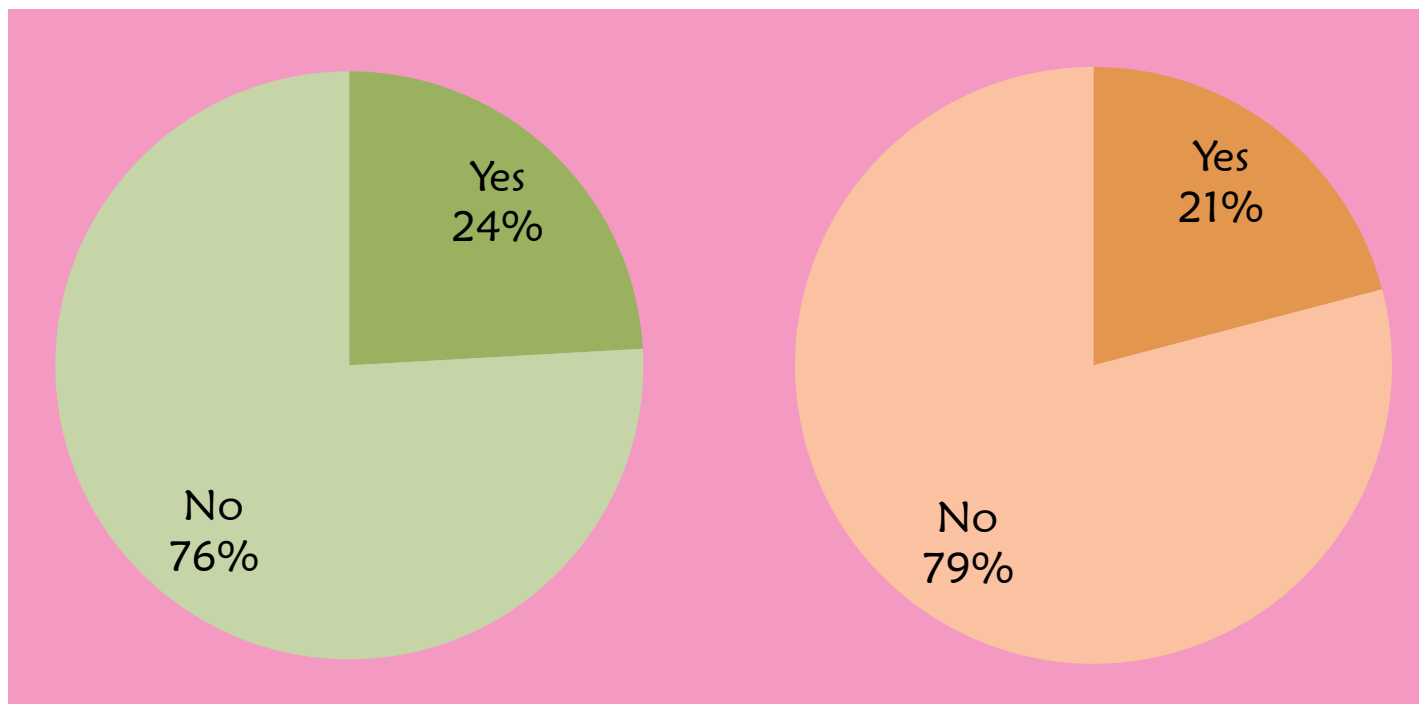


Kenya STEPS Survey 2015

Exposure to SHS at Home

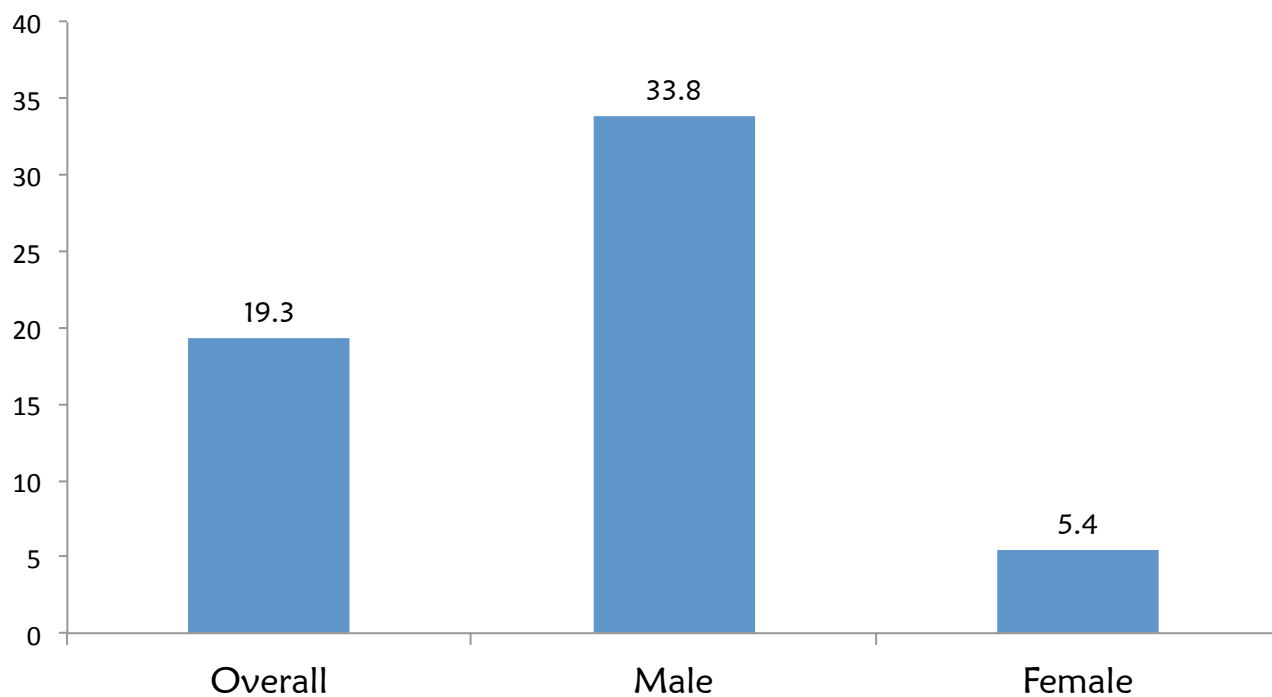


Exposure to SHS at Work



Kenya STEPS Survey 2015

Current Alcohol Drinkers

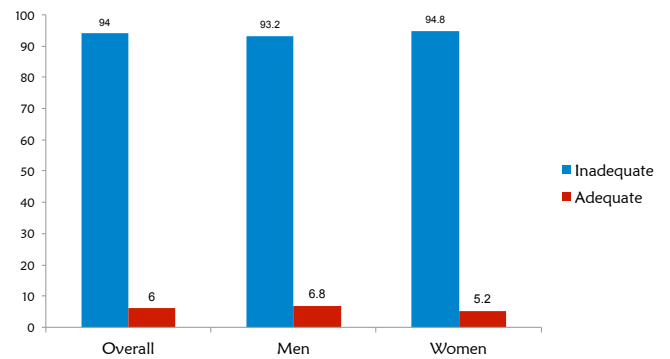


Kenya STEPS Survey 2015

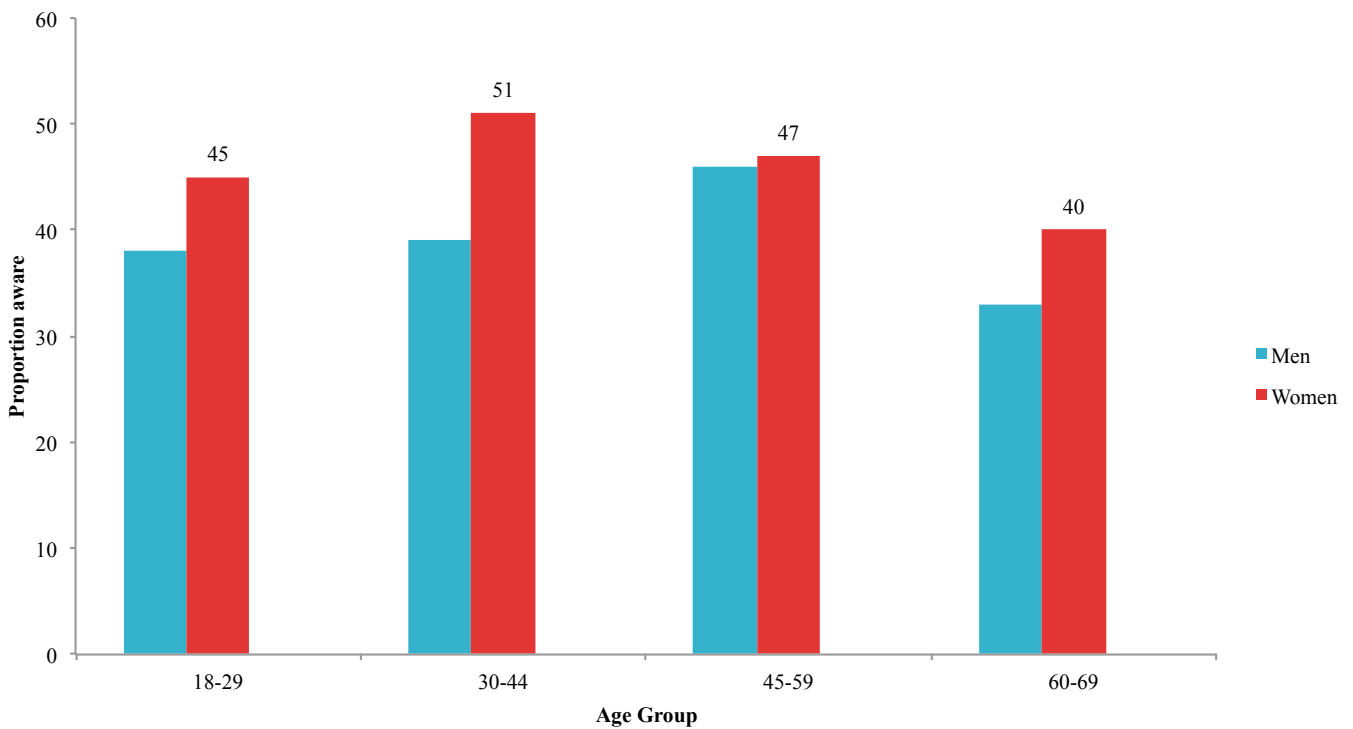
Harmful Use of Alcohol

	Percentage
Heavy episodic drinking	12.7
Drinking of unrecorded alcohol	35.5
Stopped drinking in the past 12 months	17.2

Low consumption of fruits and vegetables



Awareness of screening methods for cervical cancer



Given 10 minutes..

List common Screening/diagnostic methods

Prevention

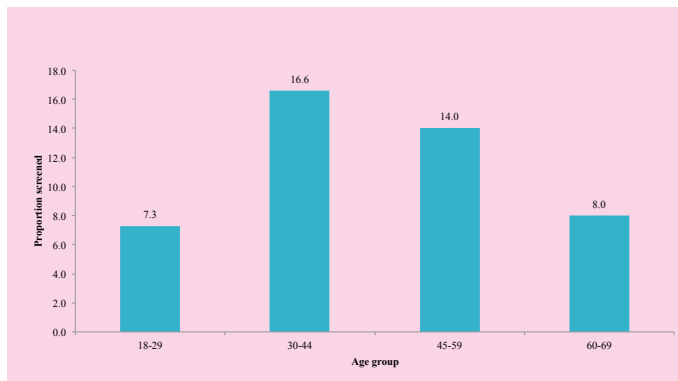
Primary

- Healthy lifestyle
- Stop Smoking
- Vaccination e.g HPV, HBV
- Alcohol control
- Control ionizing radiation

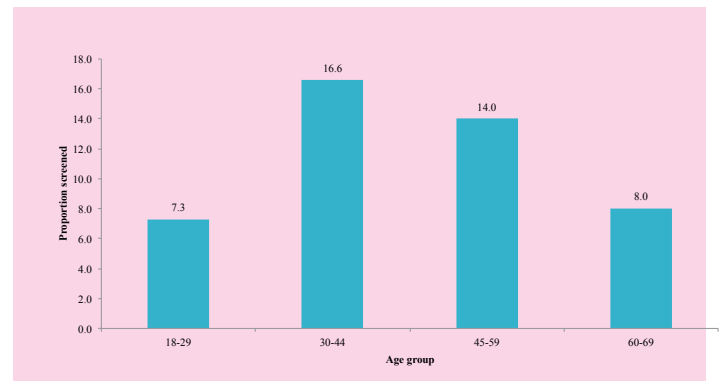
Secondary

- Healthy lifestyle
- Stop Smoking
- Vaccination e.g HPV, HBV
- Alcohol control
- Control ionizing radiation

Awareness of screening methods and ever screened

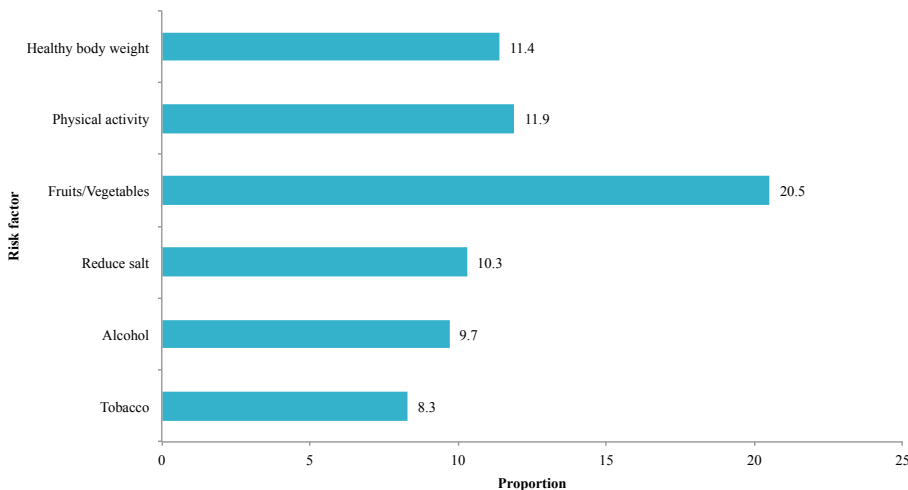


Women ever screened for cervical cancer



Overall screening- 11.3%

Healthy Lifestyle Advice



Social economic impact of cancer

Cancer's toll on population health is linked to the economic burden on families and caregivers. Cumulative economic losses to low- and middle-income countries (LMICs) are estimated at US\$ 107 billion per year. If cancer programmes are fully implemented, it would cost an additional \$20 billion per year (5 % in lower-middle-income).

Social economic impact of cancer...

In terms of annual expenditure per capita, this amounts to \$1.70 annually in lower-middle-income. (Gelband et al 2015). Social impact include: Social burden to care givers, poverty, family disruption, physiological trauma, immature death, loss of employment, dependency etc.

Prevention, screening and Early detection-Challenges

- Low cancer awareness and screening uptake
- Inadequate trained personnel
- Inadequate diagnostic and treatment infrastructure
- Poor patient record and documentation
- low registration rates
- Inadequate funding to cancer prevention and control
- Inadequate coordination of cancer control activities

UNIT 2

Cancer intervention measures

INTRODUCTION TO CANCER INTERVENTIONS

These are measures aimed at implementing a coordinated and responsive cancer control framework that leads to reduction in incidence morbidity and mortality.

Priority Interventions in Kenya

Policy and Guidelines development

Cancer Prevention, Screening, diagnosis, treatment ,surveillance, registration and palliative care activities

Legislation

Human resource and infrastructure capacity building

Advocacy

Priority Interventions...

Coordination, partnership and financing

Monitoring, evaluation and research

Given five minutes to brainstorm

What are the policies and guidelines in Kenya on cancer intervention measures?

Given five minutes to brainstorm

What are the policies and guidelines in Kenya on cancer intervention measures?

Policy environment in Kenya

Legislation

Tobacco Control Act 2007

Alcoholic Beverages Control Act 2010

Cancer Control Act 2012

Policy

National Cancer Control Strategy (2017-2022)

National Cervical Cancer Program Strategic Plan (2012-2015)

National Cancer Management Guidelines 2013

National Cancer Screening Guidelines 2018

Kenya National Strategy for the Prevention and Control of NCDs 2015-2020

Kenya National Cancer Treatment Protocol 2019

National Cancer Protocols and Appropriate Referral 2019

National Cancer Control Strategy 2017-2022

Strategic objectives

- Primary prevention
- Early detection
- Diagnosis and treatment
- Pain relief and palliative care
- Cancer surveillance and research
- Coordination of cancer prevention and control- establishment of NCI
- Monitoring and Evaluation

National Cancer Institute of Kenya

Corporate body under the Cancer Control Act (No. 15) of 2012

Managed by a Board of Trustees

Multi-sectoral membership:

- Government agencies- MOH, National Treasury, AG's office
- Registered cancer associations
- Media owners association
- Philanthropist
- Teaching institution
- Research organizations- NACOSTI, KEMRI

NCI Kenya Mandate cont'd

- Coordination ,documentation and sharing of cancer research, prevention, treatment and registration information
- Establish mechanisms for access to safe treatment and affordable cancer commodities
- Address environmental causes and risk factors
- Human resource capacity building
- Coordination ,documentation and sharing of cancer research, prevention, treatment and registration information
- Establish mechanisms for access to safe treatment and affordable cancer commodities
- Address environmental causes and risk factors
- Human resource capacity building
- Advise the Cabinet Secretary on matters related to cancer treatment
- Oversee establishment of cancer management centers in the country
- Ensure coordination of treatment services, psycho-social and community support of cancer patients

References

National Cancer Control Strategy 2017-2022

STEPS Survey 2015

Globocan Report 2018



MODULE 2

OVERVIEW OF CANCER SCREENING AND DIAGNOSIS

OBJECTIVES

By the end of this module participants should be able to:

Describe cancer screening and diagnostic standards

Explain cancer screening situation

Discuss various cancer screening, diagnostic and monitoring methods

UNIT 1

Cancer Screening, Diagnostic Standards and Monitoring

INTRODUCTION

Cancer Screening are techniques employed for early detection of cancer in asymptomatic individuals.

Goals of Screening:

To detect asymptomatic individuals who could be having abnormalities that indicate a pre-cancerous condition

To improve early detection and link identified individuals to early treatment and care.

Cancer diagnosis involves confirming symptomatic disease.

Early diagnosis improves treatment outcome and reduced disease burden.

Screening and diagnosis standards are defined by /derived from international and national guidelines (WHO, ICCN, NCCP etc).

Given ten minutes...

List cancer screening methods for Breast, cervical and prostate cancers (footnote).

Screening for Breast Cancer

Mammography is the recommended method for women above 40 years

Complementary methods:

Breast examination and awareness,

Ultrasounds.

MRI - in selected high-risk populations.

Note:

Clinical Breast Examination (CBE), Self Breast Examination (SBE), and Ultrasound are not breast cancer screening methods.

(Ref: Kenya National Cancer Screening Guidelines 2018 pgs 27-29)

Summary of breast screening recommendations (KENYA 2018)

Age Group	Recommendation	Interval
25 - 34 years	CBE every 3 years mammogram is not recommended	1 to 3 years
35 - 39 years	CBE and Ultrasound OR mammography*	1 to 3 years
40 - 55 years	CBE + mammography	Annual
56 - 74 years	CBE + mammography	Every 2 years
75 years and older	Consider individual health factors and woman's preference to continue screening	Discuss with patient

Notes:

* The balance of benefits and risks is not great enough to recommend routine screening. Clinical judgement may be used to adjust the frequency of screening considering individual differences

Diagnosing Breast cancer

Clinical: History and Clinical breast examination.

Imaging: Ultrasound, Mammography, MRI.

Tissue Diagnosis: FNA, Exfoliative and fluid cytology, Frozen sections, fixed histology sections, Immunohistochemistry.

Note: Tissue diagnosis is the gold standard

Other important techniques

Immunohistochemistry- technique that helps identify the phenotypic characteristic of each breast cancer (Hormone and other receptors).

It is performed on fixed tissue specimen.

This is important in **individualised** therapy.

Staging breast cancer

Assesses extent of the disease

Determines Prognosis and treatment options.

Only Complete after breast surgery

Staging follows the TNM system (Tumor, Node, Metastasis)

Ranges from Stage 0-IV where stage IV represents the most advanced and worst prognosis

Investigations for staging breast cancer

Pathology examination of breast specimen (Gross and Microscopy)

Blood tests, such as a complete blood count, LFTS, kidney function tests etc)

Imaging (ultrasound, Xray, Breast MRI, PET Scan etc)

Investigations for staging breast cancer

Pathology examination of breast specimen (Gross and Microscopy)

Blood tests, such as a complete blood count, LFTS, kidney function tests etc)

Imaging (ultrasound, Xray, Breast MRI, PET Scan etc)

Given ten minutes...

What are the Screening and diagnostic tests for cervical cancer?

Screening for Cervical Cancer

Methods in use are:

HPV DNA testing

Visual inspection methods (VIA/VILLI)

Cytology-based screening methods (PAP)

WHO SHOULD BE SCREENED AND WHEN?

Any woman who has ever had sex

Mass screening targets: ages 25 to 49 years Screening interval: 5 years for HIV Negative

Individual screening: ages 50-65 every 5 years

For HIV positive clients and other special groups refer to special group section of the Kenya guidelines

Kenya Recommendations

HPV testing is the primary screening method for women above 30 years.

VIA/Villi continues to be the recommended methods where HPV test is not available

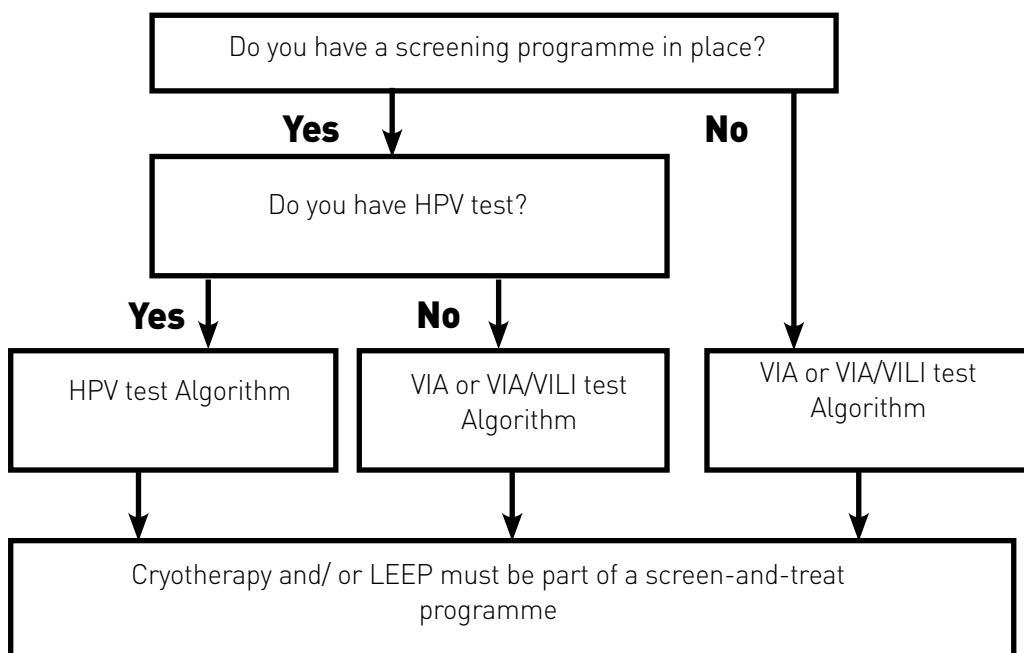
Pap smear is recommended as a primary screening method in the following situations:

- Squamo-columnar junction (SCJ) is not visible, and HPV screening not accessible

- As a primary test in women under 30 years of age

- As a co-test with HPV in HIV positive women

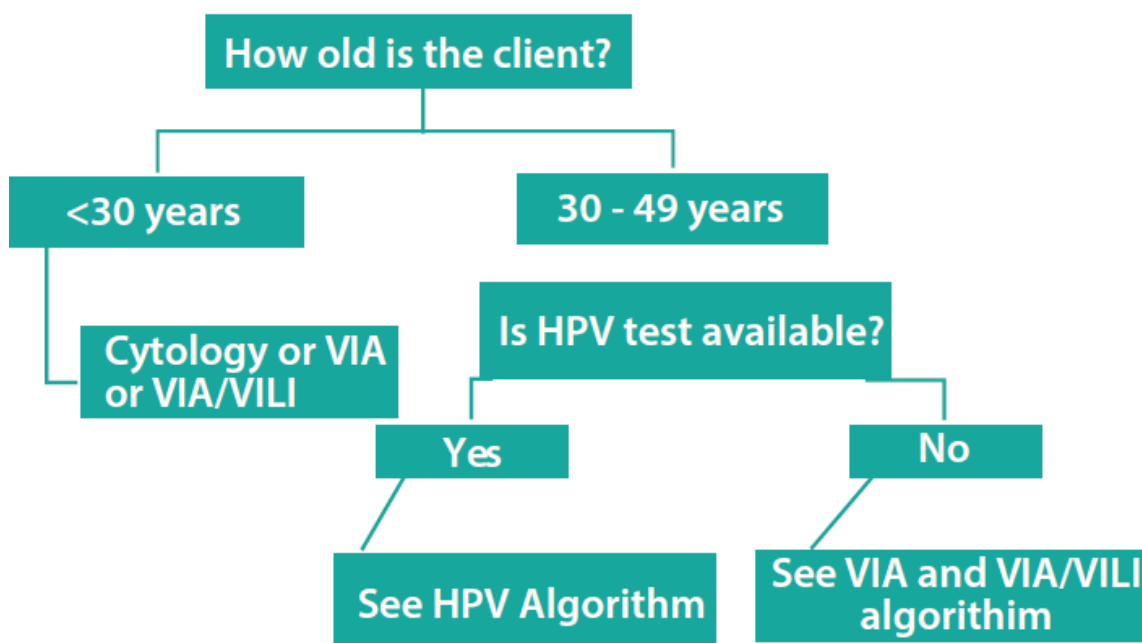
PLANNING FOR CERVICAL CANCER SCREENING



This decision-making flowchart has been developed to assist administrators/managers at County and facility level to choose an appropriate screening strategy

SOURCE: Adopted from WHO Guideline for Screening and Treatment of Precancerous for Cervical Cancer Prevention 2013

CLINICIAN ALGORITHM FOR CHOICE OF SCREENING TEST



Refer to the Kenya National Cancer Screening Guidelines 2018, for the HPV/VIA/VILLI algorithms, pg 43-47

Follow-up for screening results

HVP

High-risk HPV (HR-HPV) negative, re-test after 5 years (after 2 years if HIV positive).
HR-HPV positive- colposcopy, VIA or VIA/VILI and further management is advised (See HPV algorithm in guidelines)

VIA?VILLI

VIA negative, re-test after 5 years. If HIV positive, test yearly
VIA positive, treat as appropriate (LEEP, Cryotherapy, colposcopy and biopsy-See algorithm)

Recommendations for special populations

These are:

- HIV positive
- Pregnant
- Post partum
- Post Hysterectomy
- Those vaccinated against HPV
- 50-64 years
- 65 years and above

Refer to the Kenya National Cancer Screening Guidelines 2018, for the HPV/VIA/VILLI algorithms pg 50.

Diagnosis of cervical Cancer

- Colposcopy
- Biopsy / Punch biopsy
- Endocervical curettage
- Tissue diagnosis: Histologic typing and grading and special tests (p16 immunohistochemistry)

Diagnosis of cervical Cancer

- Colposcopy
- Biopsy / Punch biopsy
- Endocervical curettage
- Tissue diagnosis: Histologic typing and grading and special tests (p16 immunohistochemistry)

Staging cervical cancer

- Assesses extent of the disease
- Determines Prognosis and treatment options.
- Staging follows the FIGO system
- See Staging

Screening for Prostate cancer

- There is no role for MASS screening for prostate cancer.
- Screening for prostate cancer is a highly individualized decision between a client and his caregiver.
- A well-informed patient understands the ratio of benefit to harm of prostate cancer screening.

Screening methods

The standard method of early detection for prostate cancer relies on these 3 tests:

- Serum PSA test
- Digital rectal examination (DRE)
- Transrectal ultrasonography (TRUS) guided biopsy

Patient information before Screening PSA screening

There is no perfect screening test
 Screening may have associated harms
 Prostate biopsy & treatment of prostate cancer have associated risks
 Benefits and harms of screening

WHO SHOULD BE SCREENED

Men to be screened include:

- 40 years, of African descent
- 55-69 years, of Caucasian or Asian origin
- 40-55 years, with a family history of prostate cancer

Routine Screening not recommended

Men aged ≤ 40 years
 Men aged 40 - 54 years at average risk - Caucasians and Asians
 Men age 70 years and above because of other comorbidities
 Any man with life expectancy less than 10-15 years

Frequency of screening by age

Symptoms & Age	PSA level	Frequency of testing
<ul style="list-style-type: none"> • Asymptomatic & 55-69 years • 40-54 years with a family history of prostate cancer • Age ≥ 40 years with a family history of prostate cancer 	<1ng/ml	Every two years*
	1-4ng/ml	Every year
>60 years	2ng/ml	Every 2 years

Interpretation of PSA results

PSA > 10ng/mL - generally should lead to a biopsy.

PSA 4 - 10ng/mL – requires further interrogation with further tests and imaging.

There is no PSA level below which a man can be informed that he does not have prostate cancer.

Rather, the risk of prostate cancer, is continuous as PSA increases.

Other factors to take into context are prostate volume, age, inflammation, ratio of total to free PSA, rate of increase, PSA derivatives and family history rather than using an absolute level to determine the need for a prostate biopsy.

Diagnosing prostate cancer history

History:

Lower urinary tract symptoms (retention, urgency, frequency, dysuria, dribbling);

Haematuria

Bone pain and neurological deficit

Examination: DRE (size, texture, shape)

Biopsy- TRUCUT biopsies for histological confirmation and Gleason Grading

Additional diagnostic and staging tests

Ultrasound

Abdominal-pelvic

Trans-rectal ultrasound

Bone scan

Computerized tomography (CT) scan

Magnetic resonance imaging (MRI)

Positron emission tomography (PET) scan

These tests are usually done to determine extent and spread of the disease and are case dependent

Prostate Cancer Stages

TNM staging

Stage 1-IV

Patient Monitoring

Follow-up processes to assess patient progress, recurrence and response to treatment.

Informs need for change in management.

Include:

Clinical monitoring- history and clinical exam

Imaging techniques

Clinical laboratory techniques- to assess parameters in haematology, Biochemistry, Immunology, tumor markers etc.

Reference

Kenya National Cancer Screening Guidelines 2018

Mayo Foundation for Medical Education and Research, 1998-2016

UNIT 2

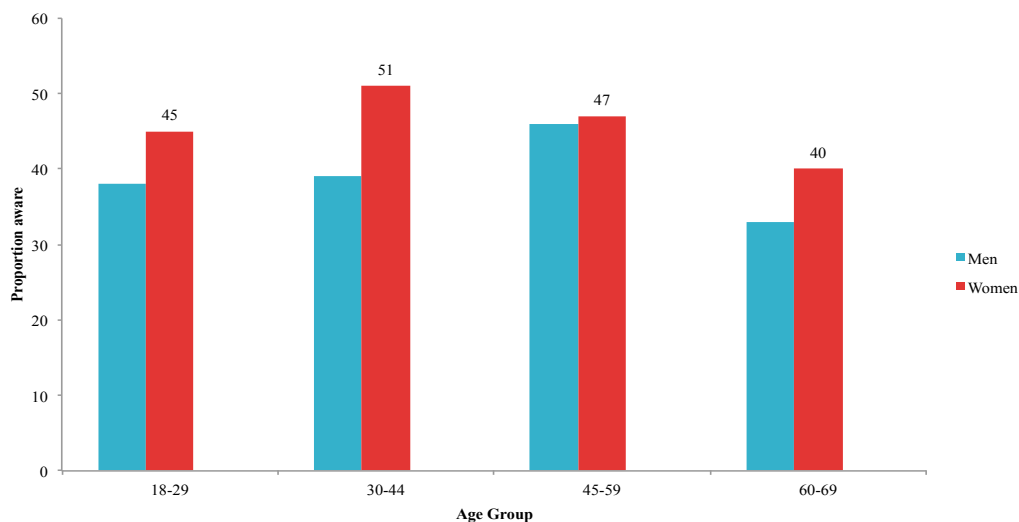
CANCER SCREENING SITUATION IN KENYA

Introduction

Cancer screening activities have ongoing in Kenya, in public and private setups. However, apart from cervical cancer, there paucity of data on other cancers. Before 2017 screening activities have been hampered by several challenges:

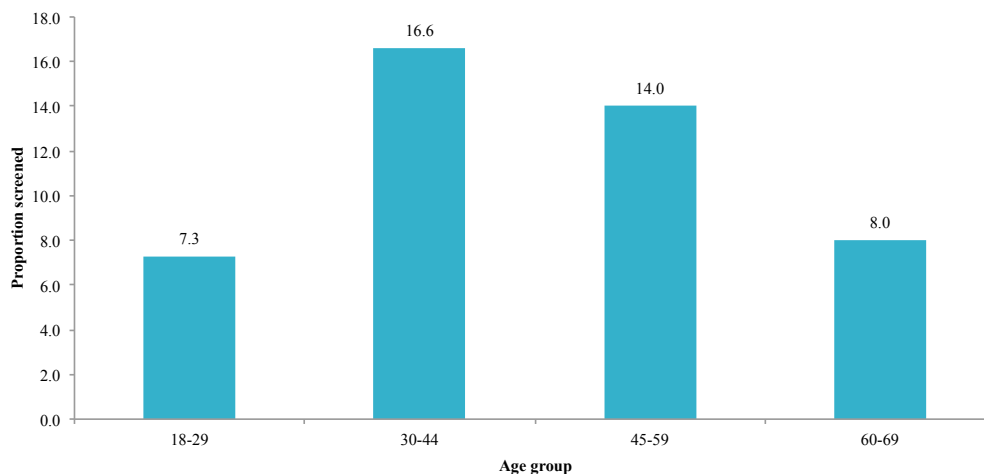
- Lack of coordination, guidelines and data
- Lack of public awareness
- Inadequate resources

Awareness of screening methods for cervical cancer



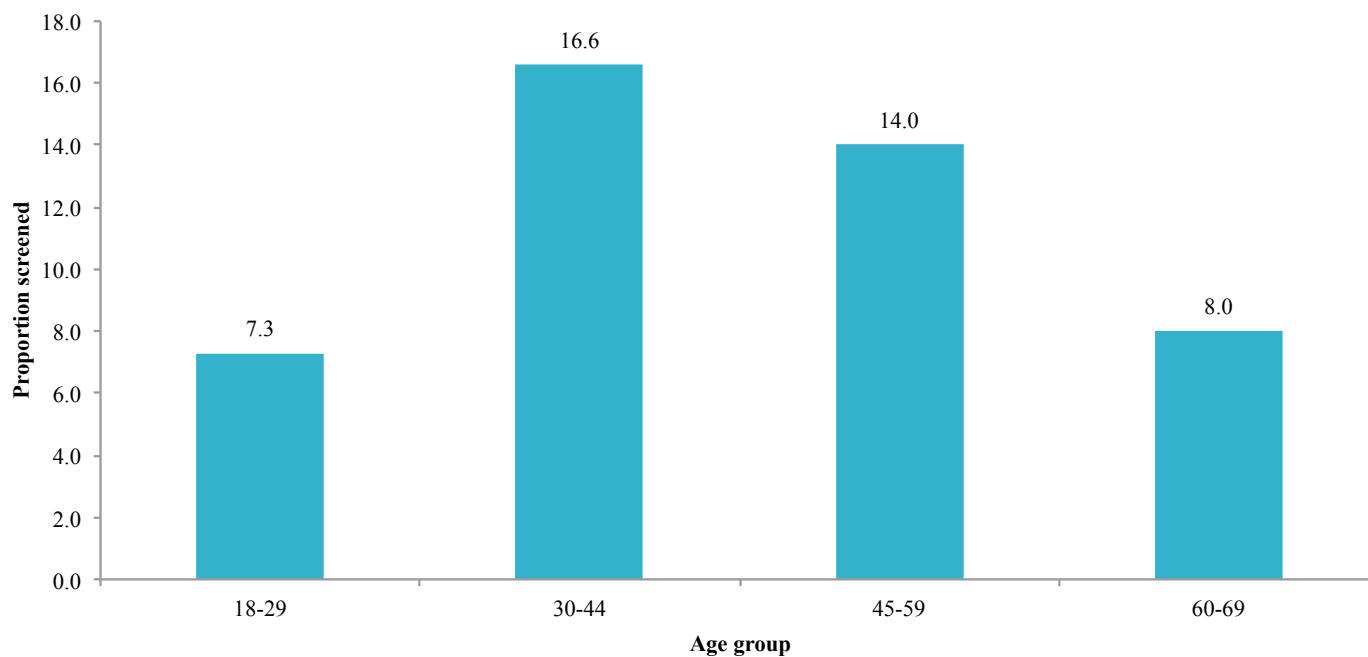
Kenya STEPS Survey 2015

Awareness of screening methods and ever screened



Overall screening- 11.3%

Women ever screened for cervical cancer



Overall screening- 11.3%

MoH Interventions in screening

Establishment of the National Cancer institute (NCI) in 2015

Establishment of National Cancer Control Program (NCCP) in 2016

Launch of the National Cancer Control Strategy (NCCS) 2017-2022 in July 2017

Development of Kenya National Cancer Screening Guidelines, 2018

The Screening guidelines are implementing Pillar 1 of NCCS (Prevention, Early Detection and Cancer Screening)

Purpose of the 2018 guidelines:

- Standardize and coordinate screening,
- Provide operational protocols and
- Improve the outcome

The 2018 screening guidelines are in line with Kenya's cancer burden (Globocan 2018)

They focus on:

- Breast
- Cervical
- Prostate
- Esophagus
- Colorectal
- Childhood cancers
- Oral cancers

Way forward

Implementation of the Kenya National Cancer Screening Guidelines, 2018
Quality data management to inform policy.

References

The STEPS survey 2015
Kenya National Cancer Screening Guidelines 2018

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MODULE 3

BREAST CANCER

INTRODUCTION

This module introduces the participant to epidemiology, pathology and clinical presentation of breast cancer and describes specimen collection, handling process including laboratory diagnosis.

Objectives

- Describe the epidemiology, causes and risk factors of breast cancer
- Explain the anatomy, pathology and clinical presentation of breast cancer
- Describe the processes of specimen collection and handling
- Perform, process and report FNA and biopsy specimens

UNIT 1

Epidemiology, Causes and Risk Factors of Breast Cancer

Given 10 minutes...

What do you know about the epidemiology of breast cancer?

Epidemiology of Breast Cancer

Globally, breast cancer accounts for 11.6% of the overall cancer burden.

In females, breast cancer is the leading type of cancer in incidence and mortality,

Accounts for 25% of all cancer cases in women worldwide

Breast cancer incidence rates are highest in developed countries

In women, it is second to cervical cancer as a cause of death in sub-saharan africa

(Globocan 2018)

Breast cancer in Kenya

It is the 3rd leading cause of cancer deaths after oesophageal and cervical cancers

In 2018, there were 5985 new cases, accounting for 12.5% of all newly diagnosed cancer cases, and 21% among women alone.

The incidence was 14.71%

(Globocan 2018)

Given 10 minutes...

Brainstorm and list the risk factors and causes of breast cancer.

Risk Factors

Family history and heredity
Genetic predisposition- BRCA gene mutation
Reproductive factors:
prolonged endogenous estrogens
early menarche,
late menopause,
late age of first birth, or nulliparity

Hormone replacement therapy
Previous abnormal biopsy
Chest wall radiation
Low breast density
No breastfeeding history
Lifestyle – obesity, physical inactivity,
tobacco & alcohol

UNIT 2

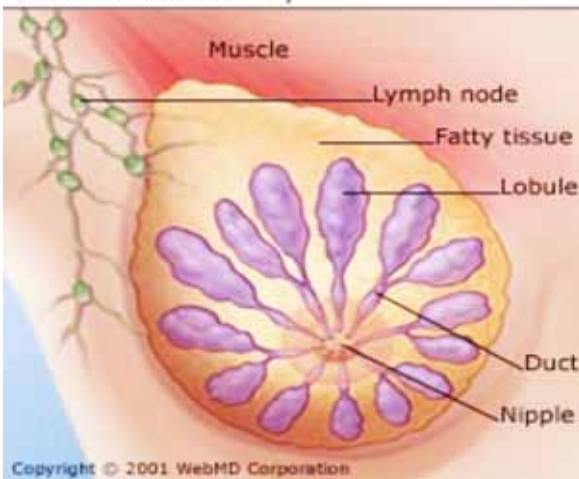
Anatomy, Pathology and Clinical Presentation of Breast Cancer

Anatomy and Physiology of the Breast

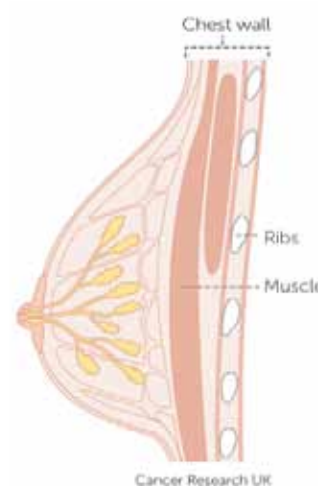
Breast is a secretory gland which produces milk in mammals
Located in the anterior mammary line overlying the pectoral muscles
It's organized into 15-20 lobes, each with several lobules which form milk
Each lobe is drained to the lactiferous ducts which converge to a nipple

Anatomy

Breast Anatomy

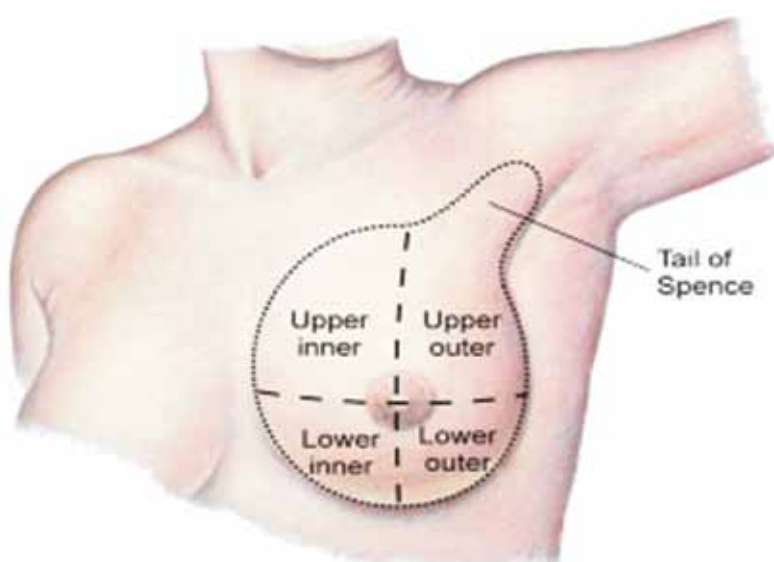


-Each breast has 15 to 20 sections (lobes) arranged like the petals of daisy
-Inside each lobe are many smaller structures called lobules
-At the end of each lobule are tiny sacs (bulbs) that can produce milk.



-Lobes, Lobules and bulbs, are linked by a network ducts
-Ducts carry milk to the nipple

'Quadrants of the breast'

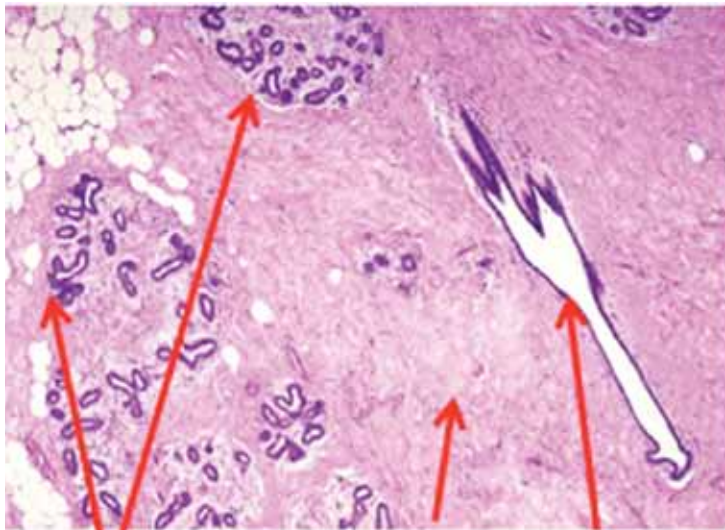


Histology of the Breast

Has complex branching structure of the terminal ductal lobular unit (TDLU) and large duct system.
The Ducts are lined by a single layer of ductal epithelial cells supported by myoepithelial cells.

Micro anatomy

Low power

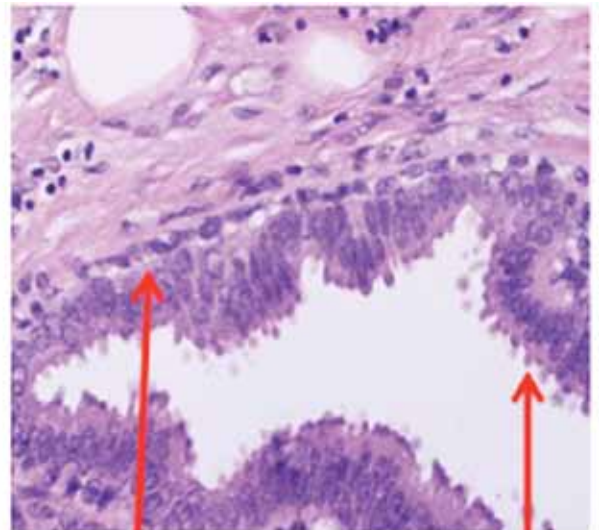


Lobules

Fibrous tissue

Duct

High power



Myoepithelial cells

Ductal cells

Pathophysiology

In most cases, cancer of the breast arises from the ductal epithelium lining the lactiferous ducts. When breast cancer spreads, it commonly occurs locally, invading the breast stroma. Metastasis occurs in the nodes of the axilla and neck. Distant metastases include bone, liver, lungs and brain and are often the cause of death.

Given five minutes...

List the types of breast cancer

Types of Breast Cancer

Early non invasive- DCIS, LCIS,

Invasive:

Carcinomas - invasive ductal carcinoma, invasive lobular carcinoma)

Stromal tumours -phylloides tumour

Lymphomas

Histological classification OF BREAST CARCINOMA

Distribution of Histologic Types of Breast Cancer	
Types	Percentages
Carcinoma In-situ	15- 30%
DCIS	80%
LCIS	20%
Invasive carcinoma	70- 85%
Invasive ductal carcinoma - NOS	79%
Lobular carcinoma	10%
Tubular/cribriform carcinoma	6%
Other carcinoma	6%

For five minutes ...

Deliberate among yourself and list down the signs and symptoms of breast cancer.

Signs and symptoms of Breast Cancer

A non-tender breast lump Skin changes: Ulceration, peau-d'orange, dimpling (tethering)

Nipple retraction

Nipple discharge

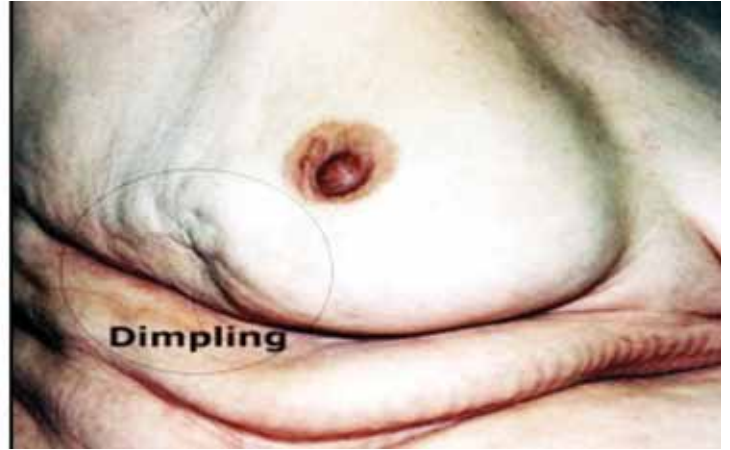
Axillary lymph nodes enlargement

Oedema of the upper limb

Pain (pain is usually also a late symptom)

Uniform breast enlargement

Signs of metastasis e.g. bone pain, fracture, unresolving cough

Peau de orange**Dimpling****Ulceration & fungation**

Grading & Staging of Breast Cancer

Grading takes into account;

- frequency of cell mitosis,
- Tubules formation,
- nuclear pleomorphism

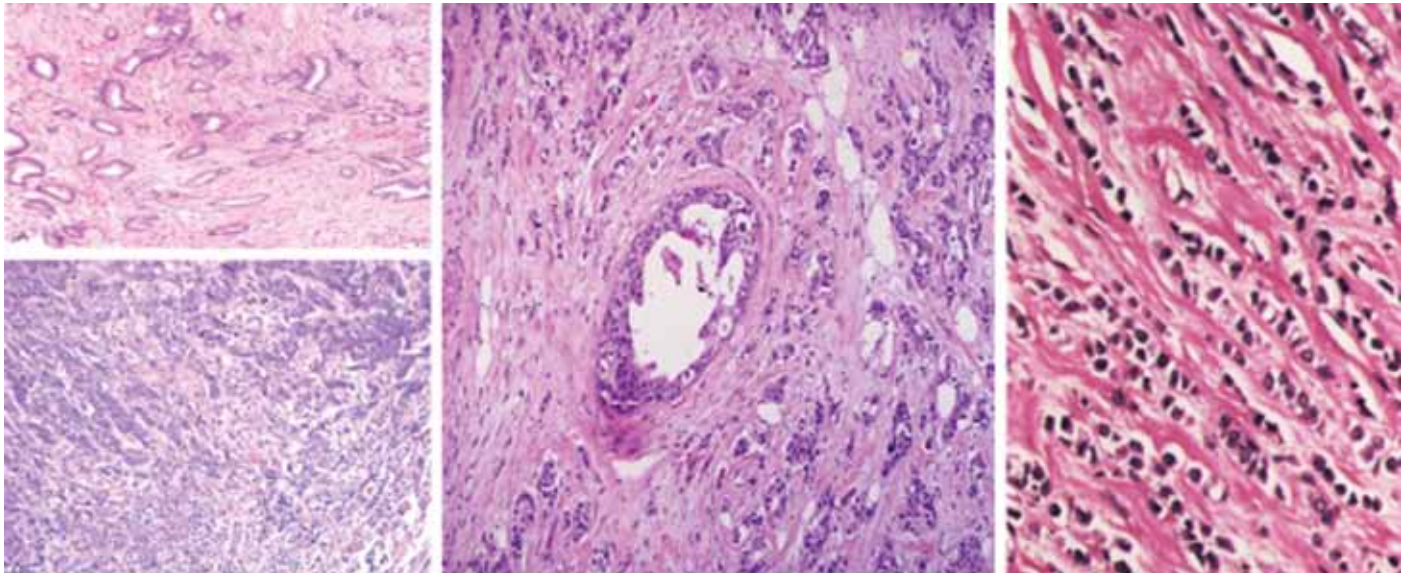
Bloom-Richardson Grade

Low grade = BR score 3-5 = grade 1

Intermediate grade = BR score 6- 7 = grade 2

High grade = BR score 8-9 = grade 3

Invasive ductal carcinoma



Staging of Breast Cancer

Depends on the

- Tumor size
- Lymph node involvement
- Metastasis

TNM staging (see annex)

Overview of Management

Management is multidisciplinary

- Surgeon, radiologist, pathologist, medical oncologist and radiation oncologist oncology nurse etc.

UNIT 3

Sample Collection, Processing and Handling

Specimen Types

FNAs
Nipple discharge/nipple imprint
smear
Biopsies (excision, incisions ,
core biopsy
Mastectomy specimen
Lymph nodes
Imprints done on wedge biopsies
Imprints done on ulcerated
tumor

Specimen Handling and Preparation

There shall be an SOP for each different type of specimen
Each SOP shall follow the approved SOP format of the institution
Mastectomy, incision ,core biopsy, lymph nodes and FNA SOP
shall include :
Container type
Volume and type of fixative
Duration of fixation
Slicing before fixation
Grossing and measurement and margin description
Follow approved protocols e.g. *link CAP Protocol breast 2018*)

Reporting/Interpretation for Breast Cancer Results

The pathology report shall follow approved reporting protocol (*e.g. link CAP Protocol breast 2018*)

The following shall be included:

- Tumour type, size, location, necrosis ,calcification
- Histology grade(differentiation)
- Skin and Nipple status
- Lymph nodes, Neural and Vascular involvement
- Hormone and receptor status
- Pathological staging

Archiving of Reports and Samples

Store the specimen after the reporting is done for 6 months
File slides in filing cabinets for 10 years
Archive tissue blocks for 10 years
Reports should be filed for 10 years
Selection of suitable teaching and museum materials alongside disposal

Turn Around Time

Where there is a cytologist/pathologist

FNA results- 3 days
Histology Results- 7 days
Immunohistochemistry- 14 days

Where no Pathologist/Cytologist

Referred slides 5 days
electronic image sharing 5 days
Physical slide/block/ referred specimen and consultation report-10 days

UNIT 4

Performing an FNA and biopsy (Practical)

Performing an FNA and biopsy Procedure

Will be done in a clinical setting

This procedure is done by trained personnel

Supervised by a pathologist/surgeon

Follow the annexed SOP for performing an FNA and Biopsy

FNA procedure- Video

Perform FNA procedure according to the annex on the same (video/illustration)

<https://www.youtube.com/watch?v=LB8q1mqLuxA>

Laboratory processing of specimens (practical)

This will be for laboratory personnel under supervision by cytologist and histo-technologist.

FNA sample staining (H/E)- Follow SOP in annex.

Histology staining: Demonstrate the tissue processing, embedding, sectioning, mounting and staining (H/E).

References

Ackerman's Surgical pathology Juan Rosai (2011) 10th edition

American Joint committee on Cancer (AJCC) Breast Cancer Staging 7th Edition

Kenya National Cancer Screening Guidelines, 2018

College of American Pathologists (CAP) protocols, 2018



MODULE 4

CERVICAL CANCER

INTRODUCTION

This module introduces the participant to epidemiology, pathology and clinical presentation of cervical cancer and describes screening process including laboratory diagnosis.

Objectives

At the end of this session participants should be able to:

- Describe the epidemiology, causes and risk factors of cervical cancer
- Explain the anatomy, pathology and clinical presentation of cervical cancer
- Describe the processes of specimen collection and handling
- Perform, process and report Pap and histology specimens

UNIT 1

Epidemiology, Causes and Risk Factors of Cervical Cancer

Epidemiology of Cervical Cancer

2nd leading cause of death in women globally

2nd leading cause of cancer deaths in women in Kenya (40 per 100,000 population)

Accounts for about 10% of cancer deaths in women in Kenya

Given Five Minutes...

Mention the risk factors associated with cervical cancer

Risk factors for cervical cancer

Human papillomavirus (HPV DNA is present in over 95% of cervical cancer and its precursor lesions)

HPV infection is main and underlies most of the factors i.e.

- Early initiation of sexual intercourse

- Having multiple sexual partners

- Having a sexual partner with multiple sexual partners

- Co-infection with other sexually transmitted infections

- Multi-parity

- Immunosuppression, including HIV/AIDS infection

- Tobacco use

UNIT 2

Anatomy, Pathology and Clinical Presentation of Cervical Cancer

INTRODUCTION

This unit shall introduce the anatomy of cervix, and pathology and clinical presentation of cancer of cervix.

Given ten Minutes

Brainstorm on the presentation of a patient with cervix cancer

Signs & Symptoms of Cervical Cancer

Pre-invasive cancer of cervix is asymptomatic

Early signs of invasive cancer

Vaginal discharge

Post coital bleeding

Irregular vaginal bleeding and spotting

Post menopausal bleeding

Late signs

Urinary frequency & urgency

Back ache

Lower abdominal pain

Very late signs

Severe back pain

Weight loss

Oliguria (due to ureteric obstruction)

Urinary and fecal incontinence

Edema

Dyspnea

Anatomy of the Cervix

Occupies the lower third of the uterus

It measures 2.5-3cm

Connected to the vaginal vaults

Consists of ectocervix and the endocervix separated by the transformation zone (TZ)

TZ varies with age and is the site of most cervical cancers

Anatomy of the Cervix



Source :WebmMD.com

Histology of the Cervix

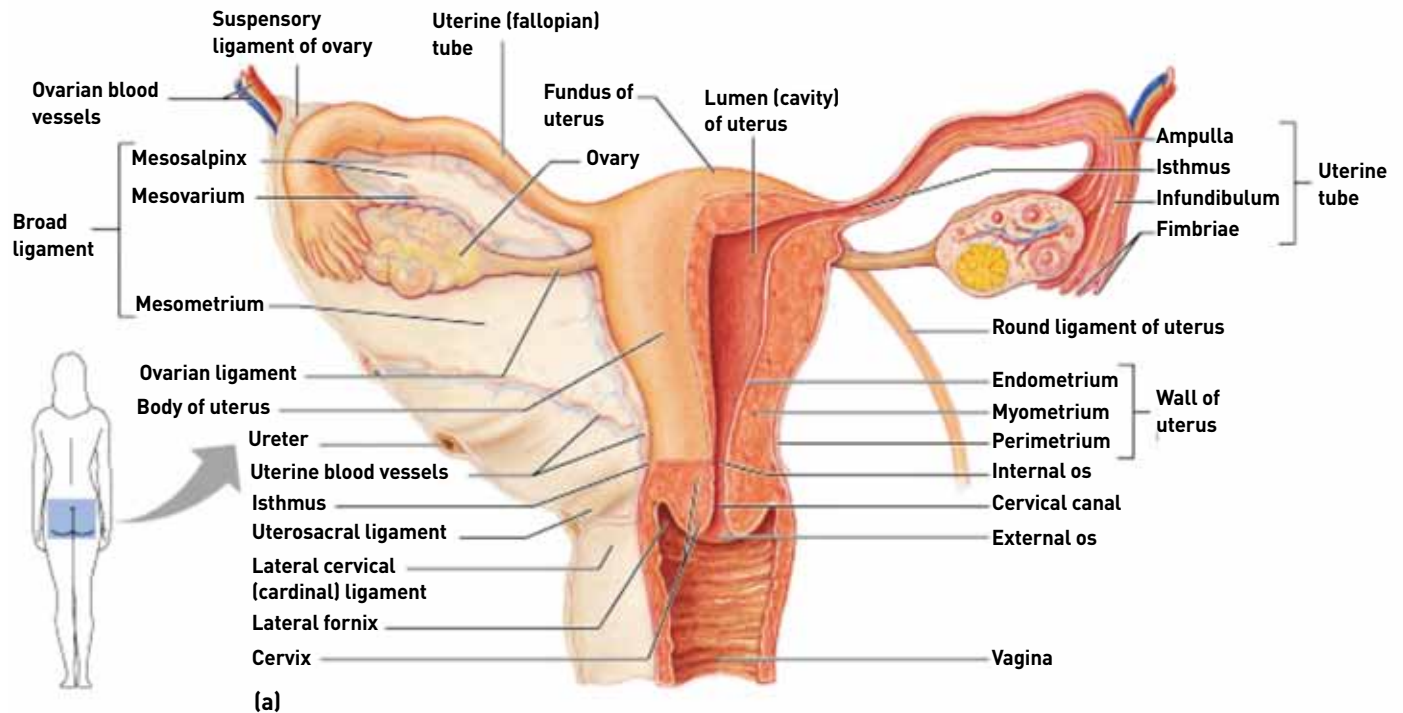
Ectocervix - stratified squamous epithelium

Endocervix - simple columnar epithelium with a ciliated brush border

Endocervical glands (nabothian) lined by cuboidal secretory epithelium

Smooth muscle and connective tissue deep to mucosa

Anatomy of the Female Genital Tract



Copyright © 2001 Benjamin Cummings, an imprint of Addison Wesley Longman, Inc.

Adapted from Benjamin Cunningham

Pathogenesis of Cervical Cancer

HPV infection and transformation

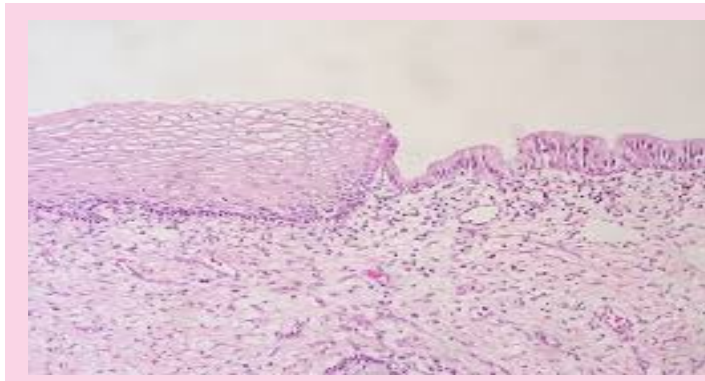
CIN 1, CIN 2, CIN 3 are pre-cancerous lesions

CIS and invasive tumour

CIN 1 & CIN 2 can regress spontaneously

A varied timeline between progression from CIN 1 and invasive tumour (due to e.g. virus type, HIV)

Normal cervix histology



Histology of cervix

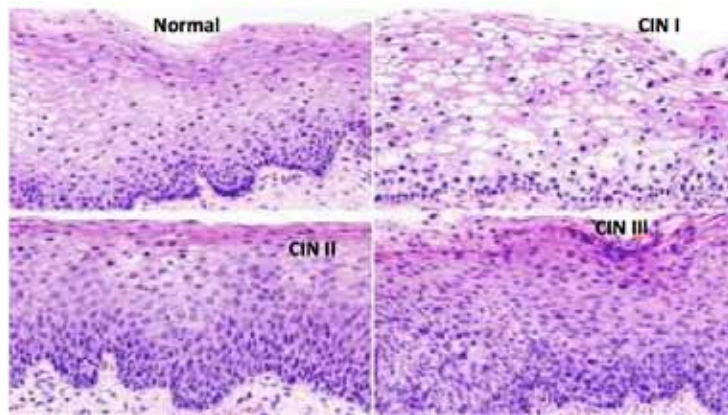


Normal cervix with stratified non-keratinizing squamous epithelium merges at the transformation zone (squamocolumnar junction) to endocervix lined by tall mucinous columnar cells as seen here at low power. The endocervix has underlying endocervical glands that are also lined by tall mucinous columnar cells
 Micrograph courtesy of: library.med. Utah. edu

Cervical Intraepithelial Neoplasia

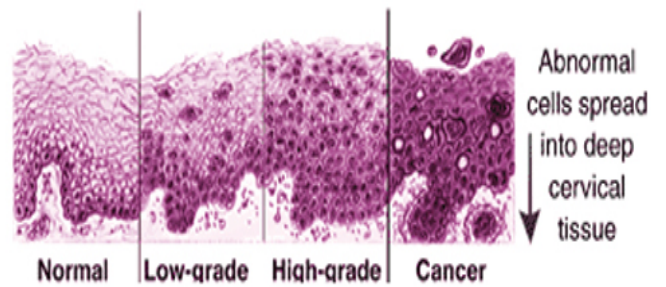
The cells undergo changes that reflect a loss of controlled growth. Ranges from CIN I i.e. mild dysplasia, nuclear angulation and vacuolization. CIN II is more severe and affects more layers of the epithelium. CIN III also called carcinoma in-situ (CIN) involves all layers.

Cervical Intraepithelial Neoplasia

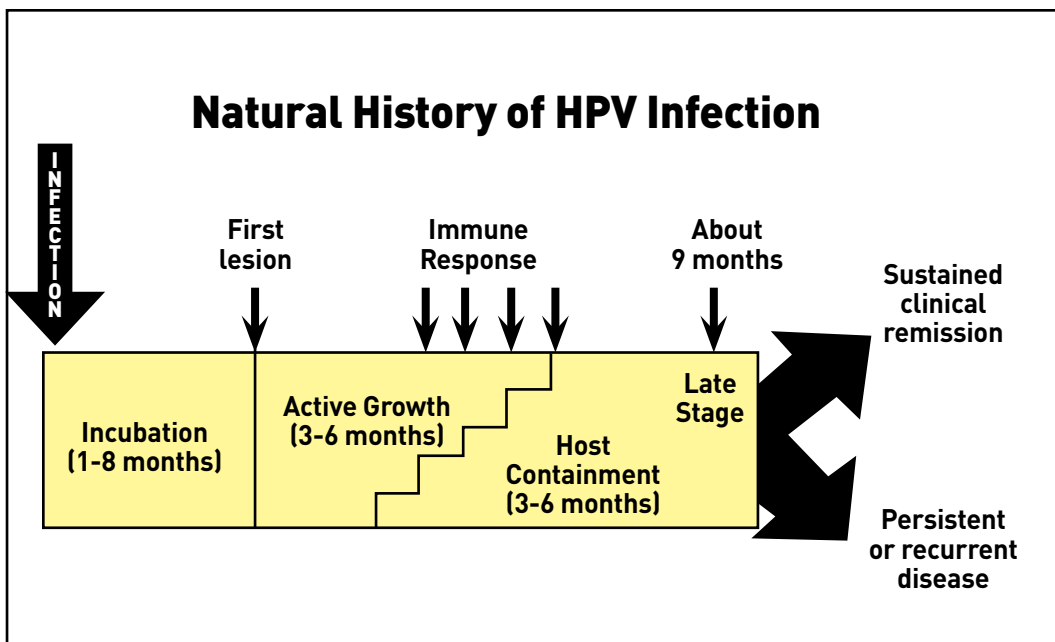


Source: medcell.med.yale.edu

CIN progression



Source : crudem.org



National Guidelines on Prevention & Management of Cervical, Breast, and Prostate Cancers, 2012.

Types of Cervical Cancers

Over 95% of cervical cancers are squamous cell carcinomas

Adenocarcinomas

Aggressiveness is dependent on histology grade, differentiation (well to poorly), and HPV serotypes, and comorbidities as immunosuppression, etc.

Staging of Cervical Cancer

Staging may require EUA and biopsy

Staging – FIGO staging is based on tumor size, extent of pelvic and distance spread

See table in annex for FIGO (guideline prevention & management of the 3 cancers)

UNIT 3

Specimen Collection and Handling

INTRODUCTION

This unit explains the handling of pap smear and cervical incision biopsy samples.

It also covers the handling of hysterectomy and associated tissue and the expectations from a good laboratory report.

Sample Types

PAP smears

HPV testing

Biopsy

Hysterectomy and associated tissue

Uterus, attached or separate Tubes

Ovary, Nodes, omentum tissue, etc.

Sample Handling and Preparation

PAP smear – SOP for this in annex.

Material is placed on a just labeled slide and fixation done immediately after collection to avoid air drying.

In the lab, staining is done and slides dispatched for reporting.

Reports are typed, original copy put in the patient file, duplicate copy is filed in the lab.

The slide specimen is filed / archived.

Hysterectomy and associated tissues

Tissue is presented whole to the laboratory immediately or immersed in 10% buffered formalin in a minimum of 1:5 ratio.

Relevant orienting markings are done and explained by the surgeon.

Separate and labelled containers are used to ease identification.

Laboratory processes and reports presence, type and extent of involvement in sampled.

Sample Handling and Preparation

Colposcopy biopsy trimming, processing, embedding, sectioning, staining, mounting (follow the SOP in the annex).

Reports are typed, original copy put in the patient file, duplicate copy is filed in the laboratory.

The slide specimen is filed for storage and archive.

Material for training and illustration collected alongside.

Reporting/Interpretation of Cervical Cancer Results

PAP smear – Bethesda 2014 (see annex)

For invasive cancer – cancer type (CIS, invasive), differentiation, depth of invasion

Archiving of Reports and Samples

Store the specimen for six months after reporting is done

File slides in filing cabinets for 10 years

Archive tissue blocks for 10 years

Reports should be filed for 10 years

selection of suitable teaching and museum specimen alongside disposal

Turn Around Time

Where there is a cytologist/pathologist

FNA results - 5 days

Histology - 7 days

Immunohistochemistry - 14 days

Where no pathologist/Cytologist

Referred stained slides 5 days

Electronic image sharing 5 days

Physical slide/block/specimen referral and consultation report -10 days

UNIT 4

Performing, processing and reporting PAP smears and histology specimens

Performing a PAP smear Procedure

Will be done in a clinical setting

This procedure is done by a trained personnel

Supervised by a specialist

Follow the annexed SOP for performing Pap smear

Consider the sources of error

Patient preparation

Sample collection, labeling, fixation, processing and reporting

Report dispatch and archiving

References

Ackerman's Surgical pathology Juan Rosai (2011) 10th edition

American Joint committee on Cancer (AJCC) Cervical Cancer Staging 7th Edition

Kenya National Cancer Screening Guidelines, 2018

College of American Pathologists (CAP) protocols, 2018



MODULE 5

PROSTATE CANCER

Objectives

- Describe the epidemiology, causes and risk factors of prostate cancer
- Explain the anatomy, pathology and clinical presentation of prostate cancer
- Describe the processes of specimen collection, handling and laboratory diagnosis
- Perform and report a Digital rectal examination

UNIT 1

Epidemiology, Causes and Risk Factors of Prostate Cancer

Epidemiology of prostate Cancer

Prostate cancer is a disease of the aging male, the majority presenting after 65 years.

Account for 7.1% of all cancer cases globally; more common in blacks.

Second in incidence and mortality, among males after lung cancer globally.

Accounted for 6% (2,864) of all the new cases in Kenya .

Responsible for 5% (1,663)number of cancer deaths in Kenya , ranking fifth.

(GLOBOCAN 2018).

Given 10 minutes...

Describe the causes and risk factors for prostate cancer

Causes and Risk Factors

Cause is unknown

Age: most important factor

Race: is more common in blacks

Family history- genetic defect Chromosome 1, band Q24 in < 10% of cases

Diet: inadequate intake of micronutrients e.g. zinc, selenium, vitamin E

High testosterone levels.

Infections e.g. chronic prostatitis and frequent STIs

UNIT 2

Anatomy, Pathology and Clinical Presentation of Prostate Cancer

Anatomy of the Prostate

Pear shaped, average 20gm in adults.

Bi-lobed; surrounds the base of the bladder and proximal urethra.

Has 4 anatomic zones (peripheral, transitional, central & periurethral).

75% of tumours occur in the peripheral zone

Transitional and periurethral are commonly involved with benign nodular hyperplasia.

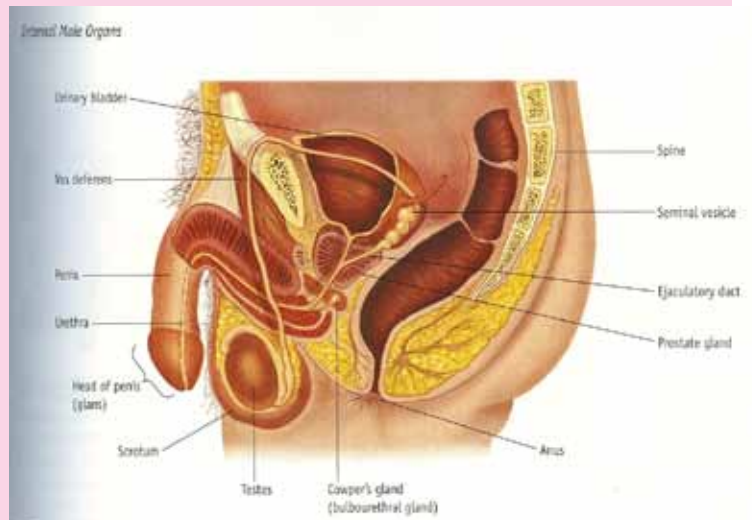
Covered by a prostatic capsule- a fibromuscular layer.

Histology.

Composed of acini and secretory ducts. Both acini and ducts contain, secretory cells, basal cells and scattered neuroendocrine cells.

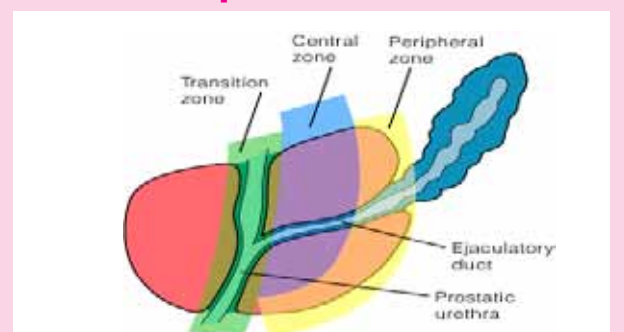
Secretory cells produce prostatic surface antigen(PSA) and prostatic acid phosphatase.

Anatomy

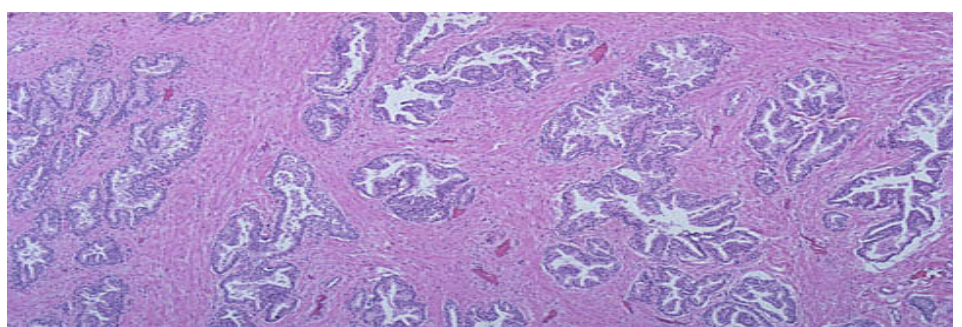
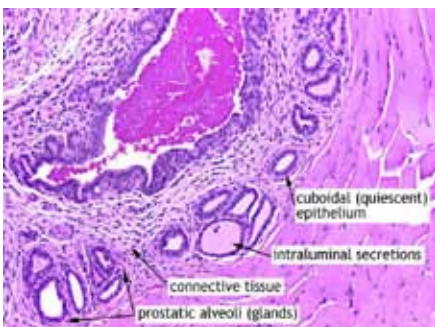


Adapted from w3.brownsteinhealth.com

Zones of the prostate



Normal microscopic anatomy of prostate



Physiology of the Prostate

Prostate secretes prostatic fluid

acidic (pH 6.4)

forms about 20% of semen volume.

It contains prostaglandins, zinc, citric acid, immunoglobulins, phosphatases and proteases.

Pathogenesis of Prostate Cancer

Develops in the acini of prostatic ducts

Peripheral zone (PZ)

70% of cancers

Transitional zone (TZ)

20%

Spread is through lymphatics and blood stream

Local spread to rectum

Given 10 minutes...

List the signs and symptoms of prostatic cancer

Signs & Symptoms of prostate Cancer

Early state (confined to prostate)

Asymptomatic

Lower urinary tract Obstructive symptoms

- Retention

- Hesitancy

- Dribbling

- Weak force of stream

Hematuria

Hemospermia

Advanced (spread to the regional pelvic lymph nodes)

- Edema of the lower extremities

- Pelvic and perineal discomfort

Signs of metastasis

- Bone pain (vertebral column)

- Fractures

- Neurological deficits

Histologic types of prostate cancer

Adenocarcinoma -95% .

Includes intraductal prostatic adenocarcinoma (a recently recognized high grade cancer)

- Nearly always high grade acinar carcinoma Gleason pattern 5

- in some cases it is possible that its a precursor lesion

Rare histopathologic types

Small cell carcinoma

Mucinous carcinoma

Endometrioid cancer (prostatic ductal carcinoma)

Transitional cell cancer

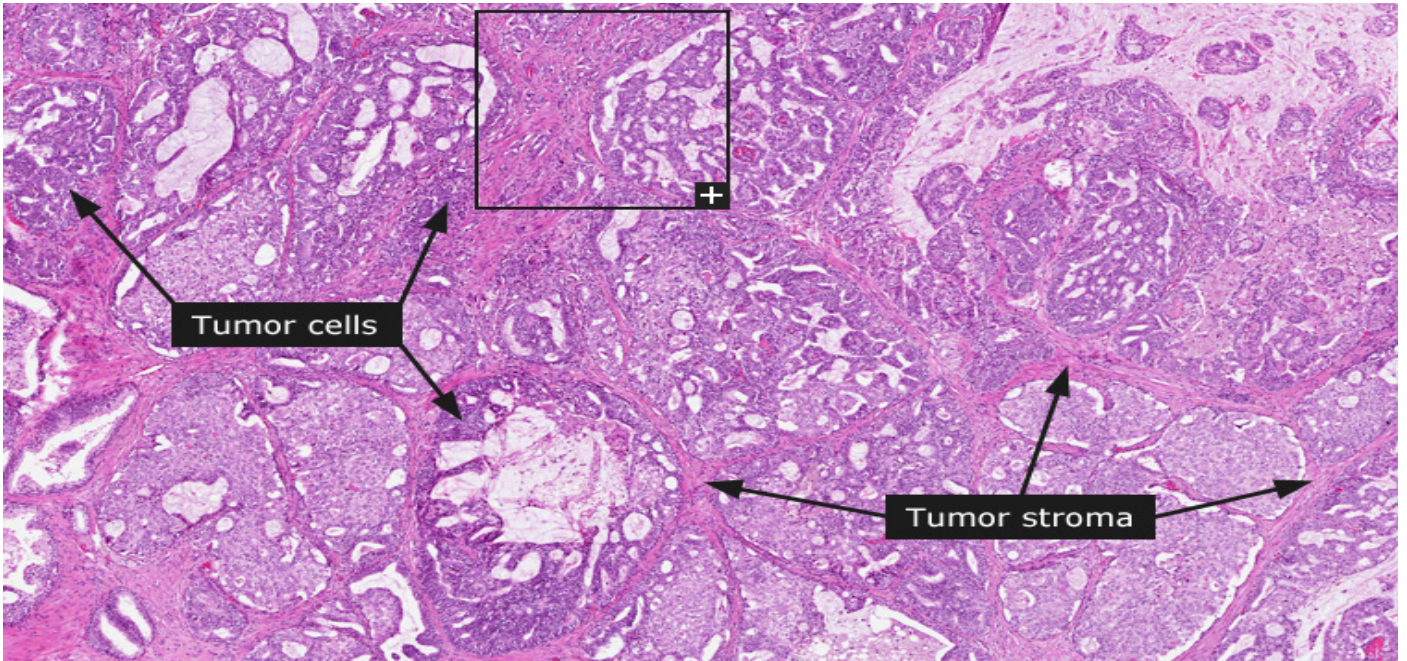
Squamous cell carcinoma

Basal cell carcinoma

Adenoid cystic carcinoma (basaloid)

Signet-ring cell carcinoma

Neuroendocrine cancer



Adopted from imgacarde.com prostate cancer histology

Grading & Staging of prostate Cancer

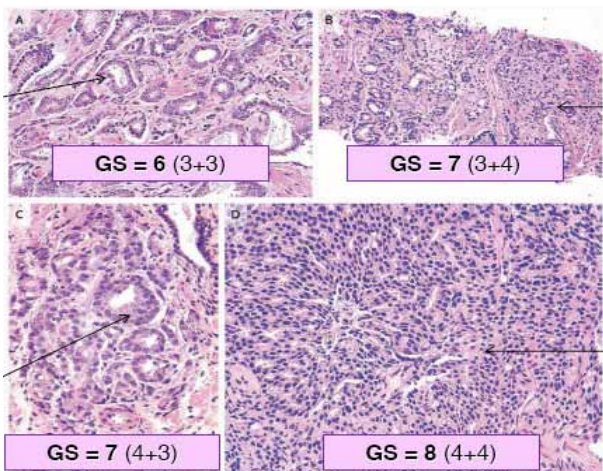
Grading, is histological:

Gleason score; 2-10 score, higher score poor prognosis

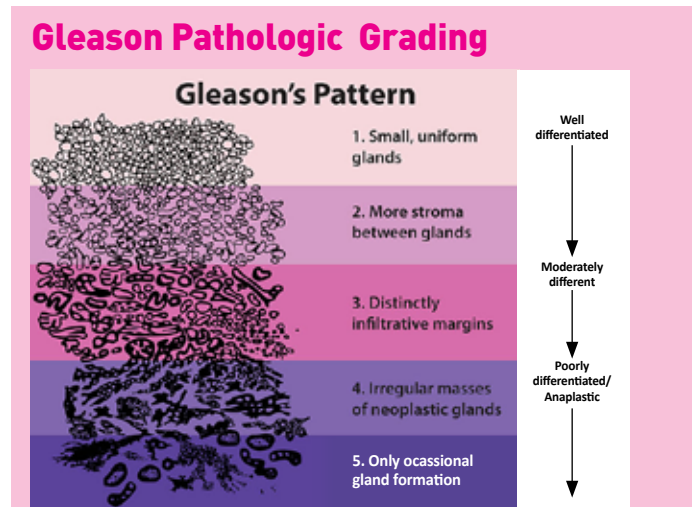
Group grading.

Staging gives the extent and spread of the tumour to other anatomical sites in the body.

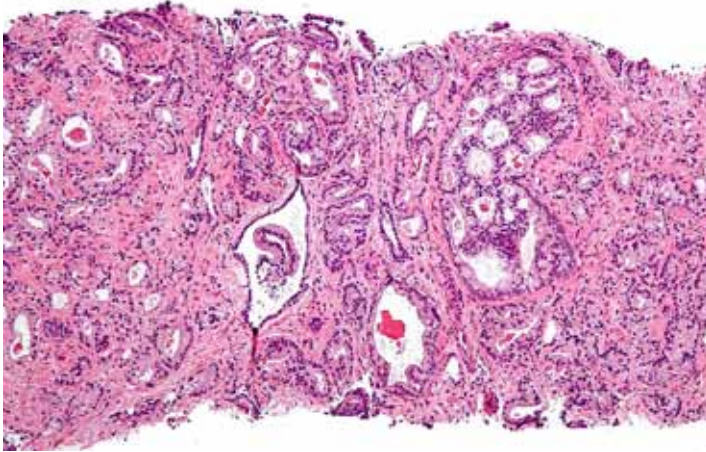
TNM staging (Stage I-IV) *see annex*



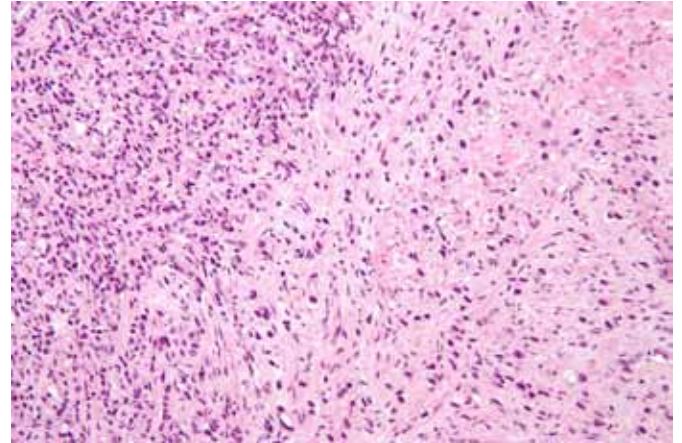
Adopted from imgacarde.com prostate cancer histology



Grade 4



Adopted from imgcarde.com prostate cancer histology



Adopted from imgcarde.com prostate cancer histology

Grading of Prostate cancer

New category	Histological descriptions of new grading categories
Grade 1	• Only individual, discrete well-formed glands
Grade 2	• Predominantly well-formed glands with lesser component of poorly formed, fused, and/or cribriform glands
Grade 3	• Predominantly poorly formed poorly formed, fused, and/or cribriform glands with lesser component of well-formed glands
Grade 4	• Only poorly formed, fused, and/or cribriform glands or • Predominantly well-formed glands with lesser component lacking gland formation or • Predominantly lacking gland formation and lesser component of well-formed glands (but poorly formed, fused, and/or cribriform glands can be a minor component)
Grade 5	• Lacks gland formation – or has glands with necrosis -- with or without poorly formed, fused, and/or cribriform glands

College of American Pathologists Staging

Stage 1	Tumour cannot be detected by DRE: Elevated incidental PSA for another benign condition
Stage 2	Tumour can be felt during DRE but confined to the prostate
Stage 3	Tumour extends outside the prostate and can be in the seminal vesicals but has no distant metastasis.
Stage4	Tumour has spread to other organs

TNM staging

T1 & T2 stages –cancer confined to prostate

T3 & T4 cancer has spread beyond the prostate

Spread beyond the prostate is the most important prognostic parameter

Overview of Management

Multidisciplinary includes:

- Surgery
- Radiotherapy
- Hormonal therapy
- Chemotherapy
- Watchful waiting

UNIT 3

Sample Collection, Processing, Handling and laboratory diagnosis

Sample Types

TRUCUT biopsy – 10–12 cores representing 6 lobes (Most common diagnostic procedure)
TURP (Prostatic chippings) –process all
Prostatectomy specimen- describe, weigh ,and take representative sections

Specimen Handling and Preparation

There shall be a SOP for handling prostate specimen
The SOP shall follow the approved SOP format of the institution
TRUCUT biopsy , prostatic chippings and prostatectomy specimen SOP shall include :
Container type
Volume and type of fixative
Duration of fixation
Slicing before fixation
Grossing and measurement and margin description
Follow approved protocols *e.g. link CAP Protocol breast 2018*

Laboratory processing of specimens (practical)

This will be for laboratory personnel under supervision by Pathologist and histo-technologist.
Histology staining: Demonstrate the tissue processing, embedding, sectioning, mounting and staining (H/E)

Reporting/Interpretation for Prostate Cancer Results

The pathology report shall follow approved reporting protocol
The following shall be included:
Tumour type, size, location, necrosis ,calcification
Histology grade (Gleason score & group grade)
Neural and Vascular involvement
Pathological staging
(link CAP Protocol prostate 2018)

Archiving of Specimens

Store the specimen after the reporting is done for 6 months
File slides in filing cabinets for 10 years
Archive tissue blocks for 10 years
Reports should be filed for 10 years
Selection of suitable teaching and museum materials alongside disposal

Archiving of Reports and Samples

Store specimen for 6 months after the reporting is done
File slides in filing cabinets for 10 years
Archive tissue blocks for 10 years
Reports should be filed for 10 years

Turn Around Time

Where there is a cytologist/pathologist

Histology Results- 7 days

Immunohistochemistry- 14 days

Where no Pathologist/Cytologist

Referred slides 5 days

electronic image sharing 5 days

Physical slide/block/ referred specimen and consultation report-10 days

UNIT 4

Performing and reporting a Digital Rectal Exam

Performing DRE Procedure

To be done in a clinical setting

This procedure is done by trained personnel

Supervised by a surgeon

Follow the annexed SOP for performing DRE

Report- size, texture, nodularity whether fixed to rectum, tender

DRE procedure- Video

DRE procedure in the annex

Perform DRE procedure according to the annex on the same (video/illustration)

References

Ackerman's Surgical pathology Juan Rosai (2011) 10th edition

Ministry of Health, Kenya: National Guidelines for Cancer Management- August 2013

American Joint committee on Cancer (AJCC) Breast Cancer Staging 7th Edition

Kenya National Cancer Screening Guidelines, 2018

College of American Pathologists (CAP) protocols, 2018

A decorative graphic consisting of a horizontal purple bar that spans the width of the page. On the left side, a pink square overlaps the purple bar, extending downwards. The text 'MODULE 6' is centered within the purple bar in a white, sans-serif font.

MODULE 6

OTHER CANCERS

INTRODUCTION

This unit introduces the health worker to screening, diagnosis and laboratory specimen handling methods for common cancers other than breast, cervix and prostate.

Objectives

At the end of this module the participant should be able to: -

- List the top ten adult neoplasms in Kenya
- Outline top five childhood neoplasms
- Explain the screening and laboratory diagnosis of other adult neoplasms
- Explain screening and laboratory diagnosis of the five childhood neoplasms
- Discuss specimen types and handling of these neoplasms

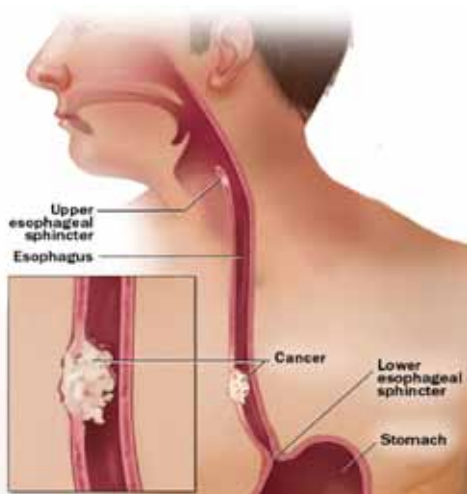
Ten common adult cancers in Kenya

Breast	Non – Hodgkin’s lymphoma
Cervix	Kaposi’s sarcoma
Esophagus	Leukemia
Prostrate	Colon
Stomach	Liver

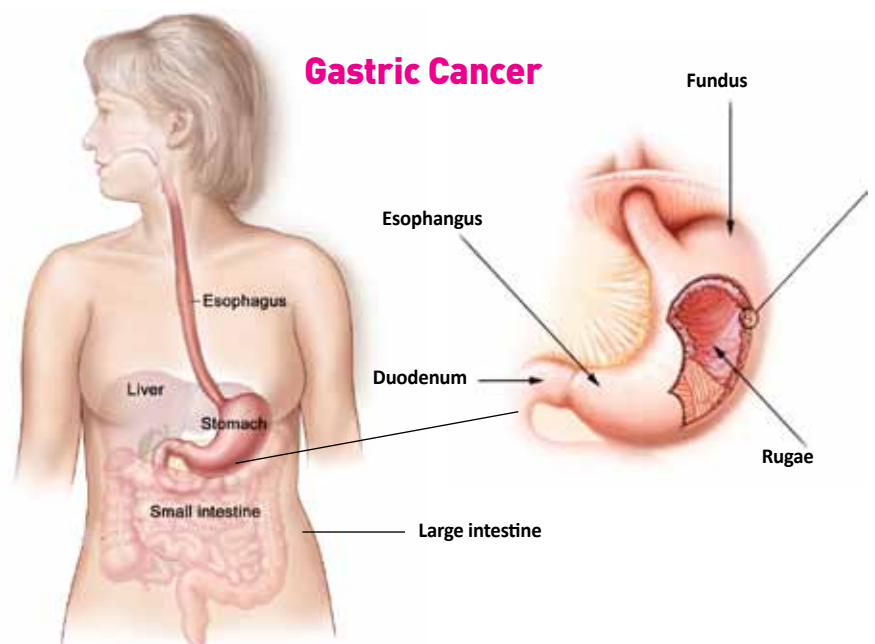
Childhood Cancers

Leukaemias particularly ALL/lymphoma
 Retinoblastoma
 Wilm’s tumors
 Neuroblastoma
 Medulloblastoma

Esophageal cancer



Gastric Cancer



Screening and diagnosis

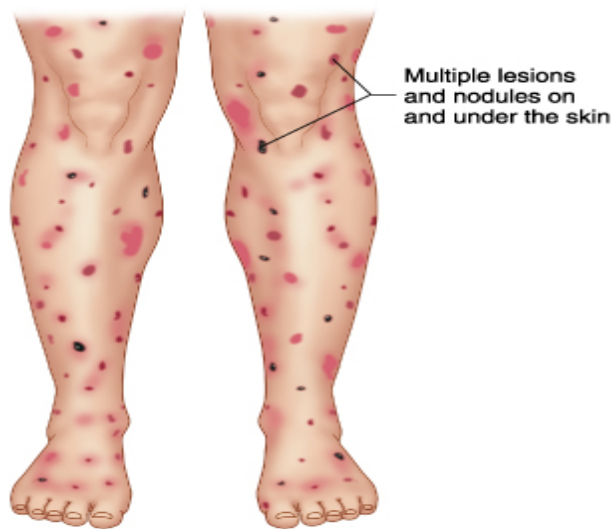
Early stages are asymptomatic

High index of suspicion to enable early endoscopy and biopsy

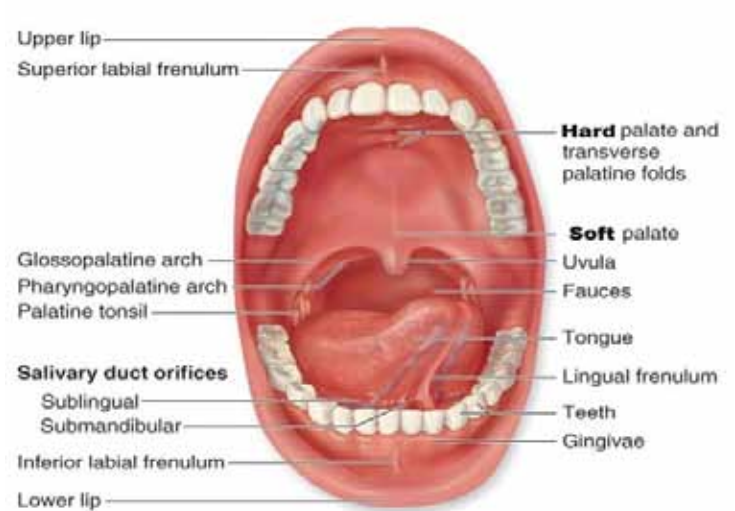
Persistent dyspepsia and PUD should arouse early suspicion

High association with Human Papilloma virus and *Helicobacter pylori*

Kaposi sarcoma



Oral Kaposi Sarcoma



Kaposi sarcoma

Four types described

Classic

Endemic

Immuno-suppression therapy related epidemic

Screening and diagnosis – Kaposi's Sarcoma

Immuno-suppression/HIV infection should arouse suspicion

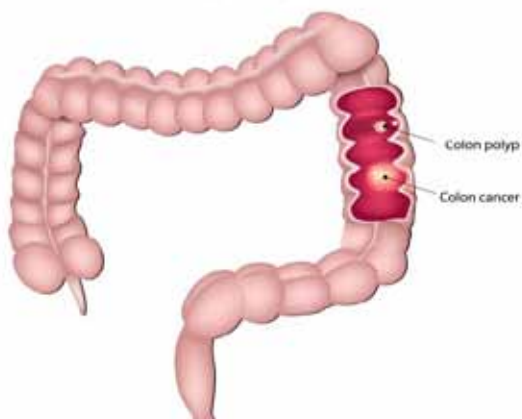
High association with Human herpes 8 and immuno-suppression

It affects multiple organs but mainly cutaneous, mucosa and lymph nodes

The diagnosis is by histology and viral markers

Colon Cancer

COLON CANCER AND POLYP



Colon Cancer

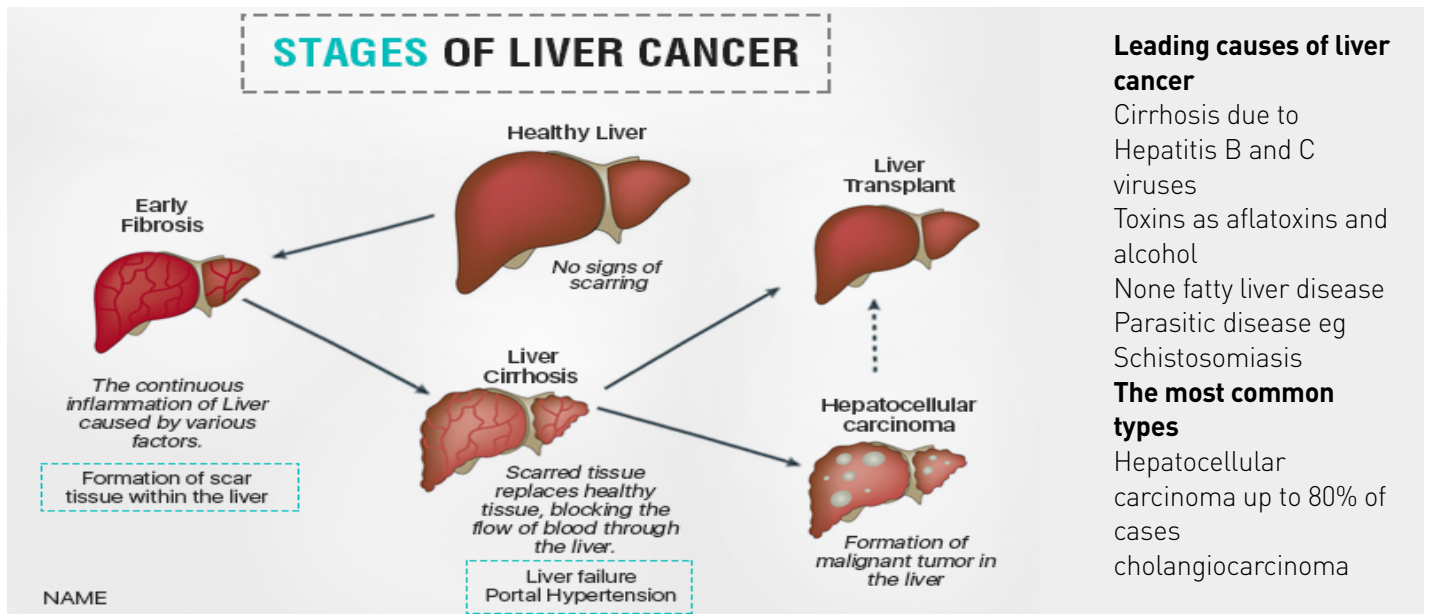
Early stages are asymptomatic

Familial history and polyposis are major risk factors

High index of suspicion required for early colonoscopy and biopsy

Faecal occult blood, irregular bowel movements and other non specific signs

Liver Cancer



Leading causes of liver cancer

Cirrhosis due to Hepatitis B and C viruses
 Toxins as aflatoxins and alcohol
 Non fatty liver disease
 Parasitic disease eg Schistosomiasis

The most common types

Hepatocellular carcinoma up to 80% of cases
 cholangiocarcinoma

Source: <https://www.vinayakgastrohospital.in/liver-cancer.html>

Liver cancer – signs and symptoms

Depend on what type of cancer is present.

Hepatocellular carcinoma is associated with liver enlargement, abdominal mass, abdominal pain, emesis, anaemia, back pain, jaundice, itching, weight loss and fever.

Cholangiocarcinoma is associated with sweating, jaundice, abdominal pain, weight loss.

Diagrams source

Diagrams in unit adopted from Gastric Cancer Treatment (PDQ®)-P, National Cancer Institute.

Childhood cancers

The causes for most are unknown

Few environmental Factors are implicated.

Ionising radiation, Drugs and chemicals.

Infectious agents eg Epstein Barr Virus (EBV), HPV, HIV and Malaria,

Genetic factors, e.g. for hereditary retinoblastoma, Wilms tumour, Leukaemia and lymphoma.

Childhood cancers

The causes for most are unknown

Few environmental Factors are implicated:

Ionising radiation, Drugs and chemicals.

Infectious agents eg Epstein Barr Virus (EBV), HPV, HIV and Malaria,

Genetic factors, e.g. for hereditary retinoblastoma, Wilms tumour, Leukaemia and lymphoma

Early detection and diagnosis leads to better treatment outcomes.

Community level awareness by parents and community health workers important.

Awareness of signs and symptoms of cancer increases clinical suspicion.

Non-specific signs and symptoms occur early.

Danger signs and symptoms

- Persistent unexplained weight loss
- Recurrent or persistent fevers of unknown origin
- Constant tiredness or noticeable paleness
- Development of excessive bruising, bleeding or rash
- Increased swelling or persistent pain in bones, joints, back or legs
- Lump or mass, especially in the abdomen, neck, chest, pelvis or armpits
- Rapidly growing mass on the jaw
- A mass in the abdomen with or without bloody urine
- Headaches, often with early morning vomiting

Given five minutes...

List the types of samples collected to analyze for most of these cancer

Screening and Laboratory Diagnosis

Screening and diagnosis is similar to other breast, cervix and prostate cancers.

They include:

FNA
 Fluid cytology
 Histology biopsy
 Peripheral Blood film (PBF)
 Bone Marrow Aspirate(BMA) and / or trephine biopsy,
 Molecular studies e.g. flow cytometry

Sample Types

Biopsy	Trephines
Surgical biopsies	Blood
Brushings	FNA
Washings	Body fluids
Bone marrow	Scrapings
	Imprints

Specimen handling

Generally specimens for these cancers are handled following broadly similar principles as for breast, cervical and prostate cancers.

SOPs should be customized to fit the specific type of specimen.

Management of Other Cancers

The guidelines for screening these cancers are elaborated in the Kenya National Cancer Screening guidelines 2018. The management of these cancers are detailed in the National Guidelines for Cancer Management, 2013.

References

Ackerman's Surgical pathology Juan Rosai (2011) 10th edition
 American Joint committee on Cancer (AJCC) Breast Cancer Staging 7th Edition
 Kenya National Cancer Screening Guidelines, 2018
 College of American Pathologists (CAP) protocols, 2018
 Globocan 2018



MODULE 7

SPECIMEN REFERRAL AND NETWORKING

Objectives:

At the end of this training, the participant should be able to:

- Develop sample referral pathways,
- Identify documentation associated with sample referrals
- Apply acceptance and rejection criteria for specimens
- Apply code of conduct and ethics in handling laboratory samples

UNIT 1

Introduction, Definition and terms used

INTRODUCTION

This module defines referral systems, discusses their justification and method of formation. It explains specimen handling, concurrent documentation, and referral logistics. Mention is made on contractual obligations required for its effective implementation.

Referral Definition

"A referral system is defined as a mechanism to enable clients' health needs to be comprehensively managed using resources beyond those available where they access care."—KENYA HEALTH SECTOR REFERRAL STRATEGY 2014 – 2018
"For all the health care service delivery levels to provide the much needed health services equitably and cost-effectively, the referral system needs to be strengthened". James Macharia, Cabinet Secretary Ministry of Health.

Discussion points

Given 10 minutes...

List available information that is required to assist referral network establishment.
List possible impediments to referral network establishment.

Available information

Demography data
Number and categories of health facilities
Regional disease burden/patterns
Economic activities of the area

Impediments to the establishment

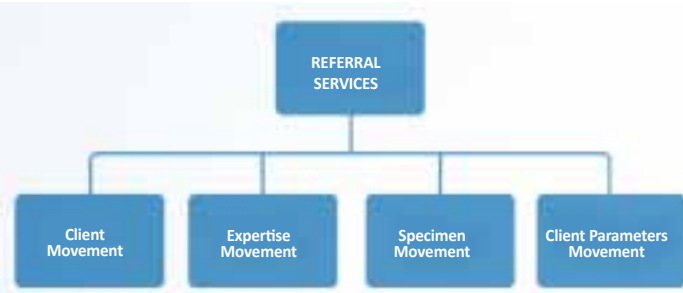
Procurement bottlenecks
Health financing system
Personnel
Rapid technology advancement
Community hurdles and health seeking behavior
Health Information Systems in place
Political climate
Ineffective networking of the different levels
Bypassing of lower level facilities
Lack of awareness on where to get cost-effective health services for different conditions
Inappropriate referrals
Inadequately resourced facilities according to norms and service standards
Lack of effective referral system monitoring
Ineffective networking of the different levels
Bypassing of lower level facilities
Lack of awareness on where to get cost-effective health services for different conditions
Inappropriate referrals
Inadequately resourced facilities according to norms and service standards
Lack of effective referral system monitoring

Considerations in a referral network

- Referral Levels, Sites mapping, selection and development
- Available expertise and equipment in facilities and regions
- Cost Benefit Analysis: of Development versus out-sourcing as strategy
- Logistics of Utilizing referral networks
- Code of conduct and ethics in handling laboratory samples

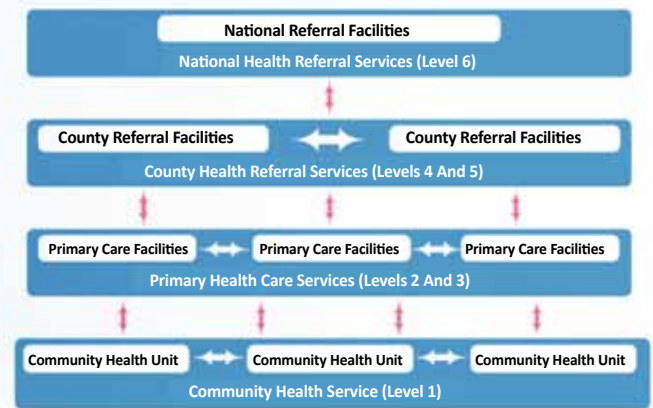
Referral Strategy

Figure 3.1. Framework for health referral services in Kenya



Referral Strategy...1

Figure 3.2. The overall referral chain



Referral Strategy...2

Figure 5.2: Organisational structure of laboratory services in Kenya.



Terms Used in Referral

Client movement: Actual client moving to an appropriate level of care.

Client parameters movement: Client information for supportive diagnosis moved to appropriate levels of the system.

Consultation: A process of seeking specialized services for clients between health providers.

Counter-referral: Re-directing referred client to originating unit post resolution.

Specimen movement: Referral that involves movement of a specimen in the system.

Transfer: A process by which a client is moved from one facility to another.

Urgent referrals: Are done for conditions that threaten life, limb or eyesight to prevent serious risk to health.

UNIT 2

Developing specimen referral pathway

Referral Justification

Has basis in

Challenges in accessibility of reliable effective and sustainable Diagnostic service.

A referral network shall Increase access to laboratory support for cancer diagnosis and treatment.

Has precedence

HIV and TB referral models may be adopted

Benefits of a referral system

Improving the quality of tests results and utilization of services.

Increase access to specialized services.

Will reduce the direct costs of accessing and delivering health services due to pooling.

Improved quality of health data collection and management.

Tracking of specimens and documentation.

Preparing for Referral networks

Identify Health facilities and Laboratory Menus/ capacities in a region

Estimate the number of laboratory request or disease burden in the catchment area

Determine what relationships can be established to collect the specimens and have them reported

Determine what cost implications arise and how to address them

Preparing for Referral networks

Identify Health facilities and Laboratory Menus/ capacities in a region

Estimate the number of laboratory request or disease burden in the catchment area

Determine what relationships can be established to collect the specimens and have them reported

Determine what cost implications arise and how to address them

Implementation-level Issues

Ineffective networking of the different levels

Bypassing of lower level facilities

Inadequately resourced facilities according to norms and service standards

Lack of effective referral system monitoring

Inadequate communication and transport systems

Ineffective referral and feedback system

Lack of referral coordinating forums and review meeting

Issues of financing

Lack of integration

Scaling up of Specimen movement

The aim is to provide an effective system to facilitate movement of specimens for diagnosis through the various levels of the health system.

Requires

- Functional integrated laboratory referral networks
- Laboratory referral guidelines, including entailed documentation
- MOUs between laboratories within the networks
- Tools, e.g. SOPs for specimens packaging

Issues at the Policy and Strategic Levels

- Transport policy for the health sector
- Bypass policy ... geographic, affiliation, and political consideration
- *Coordination of referral services
- Quality assurance
- Financial issues

**Clarity required on when to shift to or between Public, Private, University, Research and Teaching facilities and the implications to clients, patients and institutions*

Factors in Specimen Referral

Quality of report per Expertise and specialist overwhelms, others are:

- Administrative structures.
- Distance, Logistics and costs, and Health Financing Systems.
- History of facility.
- Type of facility e.g. private, faith based, Universities, etc.
- Type of Contracts and Service agreements.
- Short and Long term projections.

Given 5 minutes...

List the possible players and their roles in the specimen referral system.

Anticipated Government role in Referral

- Government to Strengthen peripheral Referral Hospitals and Laboratories.
- All users in referral zones to be targeted in capacity building & training for quality specimen and results handling
- Periodic reviews to note areas of restructuring and capacity improvement.

Roles in referral networks

Administration:

Finance and Logistics
Strategic focus

with referral Laboratory,
Receiving results, Interpretation

projections and focus

Clinicians:

Description and Identification of
Specimen, necessary orientation
marking, Requisition Form
Completion, Clinical Consultation

Pathologists and Laboratory technologist:

Specimen handling and
Consultation
Specialist consultations
Scientific strategic plan,

Courier Service

Transport

Laboratory information Network

Data management

Fit with Existing Policies, NPHLS Reference Labs and *Referral Networks

Use and adapt national guidelines e.g.

Kenya National Referral Policy 2018

National Guideline for Laboratory Specimen 2012 Referral network (Kenya)

National Specimen Strategy 2010, revised 2013 (Kenya)

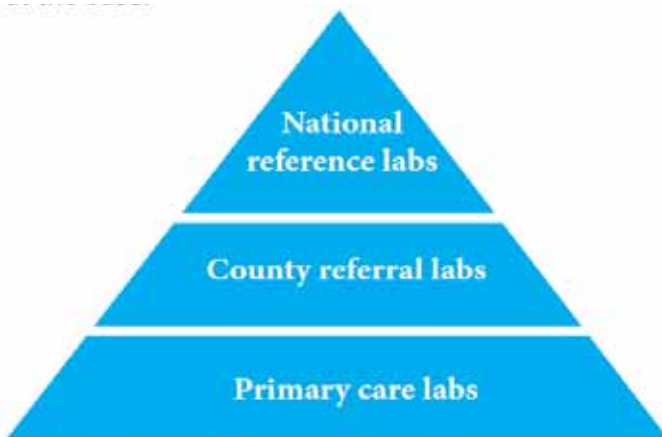
**Use and expansion of National Oncology Reference Laboratory (NORL) and Kenya National Cancer Laboratory at Division of Pathology and Forensic Services*

The Key Components of the Kenya Service Delivery Approach is The Kenya Health Policy 2012–2030

In it are community health services (level 1) to National Level (Level 6).

Laboratory Specimen Referral services should strive to follow this cascade

GOK Structure of Integrated Laboratory Specimen Referral Networks



Annexes, Tools and Documents in Specimen Referral

Number Laboratories and County's involved in referral net works

Test types and institutional availability

Training types (biosafety, specimen packaging, specimen handling, etc.) and personnel trained

Equipment placement, availability and maintenance logs

Referral and specimen tracking Forms and logs

Histology- Cytology Requisition Form

Register of Specimens, their referral Laboratories, and reports Release and collection dates

Laboratory Worksheet

Delivery Books, Packaging Documentation

Equipment, Tests, and Materials Availability

Number of laboratory personnel trained

laboratory referral guidelines

national and county laboratory referral coordinators

Developed ILRN tools

SOPs for specimens packaging

SOPS on quality assurance developed

Laboratory referral request forms

laboratory tests menu for ILRN

Annexes, Tools and Documents in Specimen Referral

Number Laboratories and County's involved in referral net works
Test types and institutional availability
Training types (biosafety, specimen packaging, specimen handling, etc.) and personnel trained
Equipment placement, availability and maintenance logs
Referral and specimen tracking Forms and logs
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Register of Specimens, their referral Laboratories, and reports Release and collection dates
Laboratory Worksheet
Delivery Books, Packaging Documentation
Equipment, Tests, and Materials Availability
Number of laboratory personnel trained
laboratory referral guidelines
national and county laboratory referral coordinators
Developed ILRN tools
 SOPs for specimens packaging
 SOPS on quality assurance developed
 Laboratory referral request forms
laboratory tests menu for ILRN

UNIT 3

Specimen Acceptance and Rejection criteria

Given 10 minutes...

1. List the reasons the laboratory may use to reject a specimen

2. What are the consequences of specimen rejection to,

- Patient
- Clinician
- Hospital
- Relatives
- Community

Specimen Acceptance and rejection criteria

Rejection Criteria:

Laboratory Menu and test availability

Requisition Form entries,

Specimen Suitability adequacy ,

Appropriate container labelling & integrity,

Preservative

Packaging & Transport conditions documentations,

Contamination

Legal documents and declarations

Any sample not meeting the acceptance criteria should be either be rejected / and or returned and corrective action taken.

A rejected specimen logo is to be maintained and discussed with laboratory users periodically and as appropriate

Given 5 minutes...

List the guiding principles for local and international specimen packaging?

Packaging and Shipping Infectious Substances

Safety is the main focus:-

Protecting

persons

Specimen integrity

Environment

Training requirements on regulations for:

Packaging and shipping infectious biological materials

Safety of post analysis specimen remnants packaging, archiving and disposal.

Organizations Responsible for Regulating Transport of Hazardous Materials

International Civil Aviation Organization (ICAO)

A UN agency Regulating safety in air transport of dangerous goods and sets standards

International Air Transport Association (IATA)

A member organization regulating hazardous material movement on member airlines

Regionally- **OSHA- Occupational Safety and health administration**

Packaging and transport

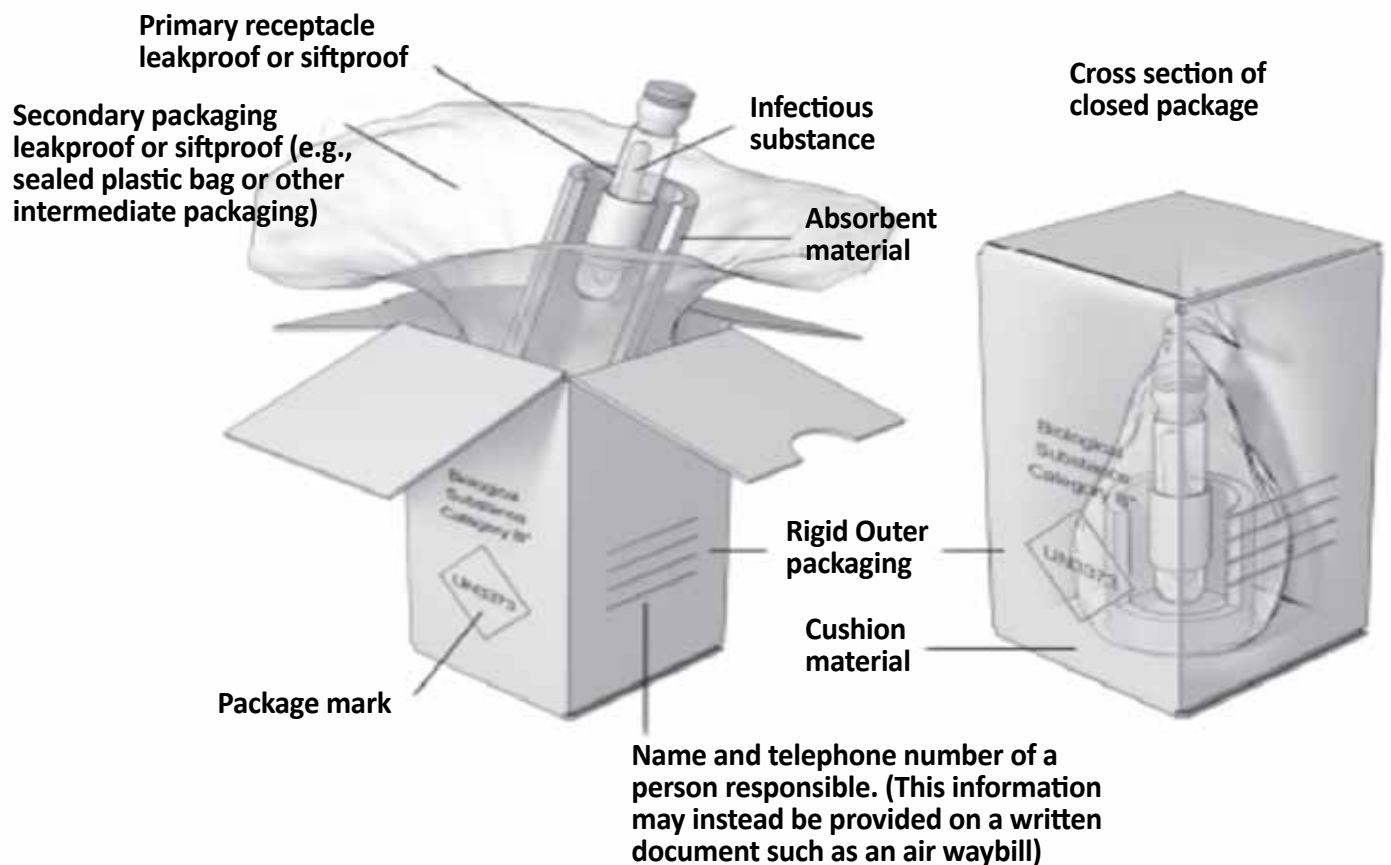
Specimens for referral should be categorized as

- Non infectious
- Potentially infections or
- Infectious

and treated accordingly following the regulations

Model and instructions for triple packaging of specimens

Triple packaging Requirements



Source: WHO 2004 ¹⁰

UNIT 4

Code of ethics in specimen referral

Challenges in Code of conduct and ethics in referral services

Implementation-level Issues

- In-availability of expected test menus and appropriate information
- Ineffective networking of the different levels
- Bypassing of lower level facilities
- Inappropriate referrals
- Inadequately resourced facilities according to norms and service standards

Challenges in Code of conduct and ethics in referral services

Implementation-level Issues

- In-availability of expected test menus and appropriate information
- Ineffective networking of the different levels
- Bypassing of lower level facilities
- Inappropriate referrals
- Inadequately resourced facilities according to norms and service standards
- Lack of effective referral system monitoring
- Inadequate communication and transport systems
- Ineffective referral and feedback system
- Lack of referral coordinating forums and review meetings
- Issues of financing, laboratory share of collected revenue
- Lack of integration



MODULE 8

**QUALITY MANAGEMENT SYSTEM IN CANCER
SCREENING AND DIAGNOSIS**

Objectives

- Describe quality management systems
- Describe quality assurance measures required for cancer screening and diagnosis
- Discuss biosafety and biosecurity measures
- Describe problem solving techniques

INTRODUCTION

By the end of this module participants should be able to:

- Describe quality assurance measures, quality standards,
- Apply problem solving techniques and
- Discuss laboratory safety and biosecurity measures in cancer screening.

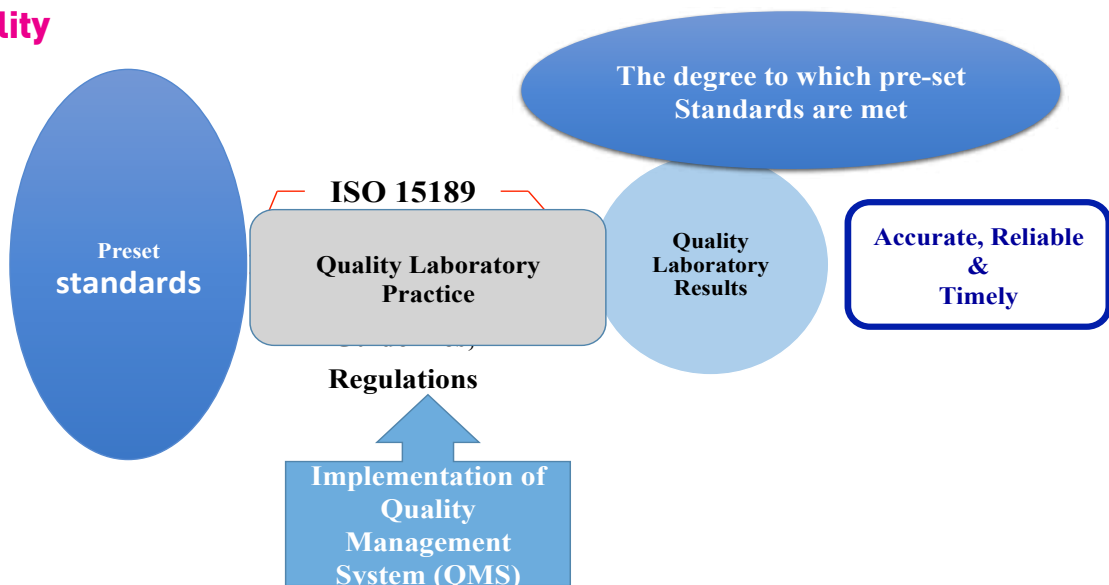
UNIT 1

Quality management systems

Brainstorm

Given five minutes define quality

What is Quality



Quality Assurance (QA)

A systematic and planned approach to monitor, assess and improve quality of services on a continuous basis. Standards are set for a testing.

Managers/supervisors ensure consistent adherence to standards.

QA is a coordinated system designed to detect, control and prevent the occurrence of errors in patient care.

QA and QI need change of attitude and sense of ownership.

Quality Control (QC)

Quality Control is defined as a system for verifying and maintaining a desired level of quality in an individual test or process.

Activities span the testing process from the moment of specimen collection until the time the physician receives the report.

Internal quality control (IQC)

Based on monitoring the test procedures.

Measurements on specially prepared materials

Repeated measurements on routine specimens.

Daily statistical analysis of data obtained

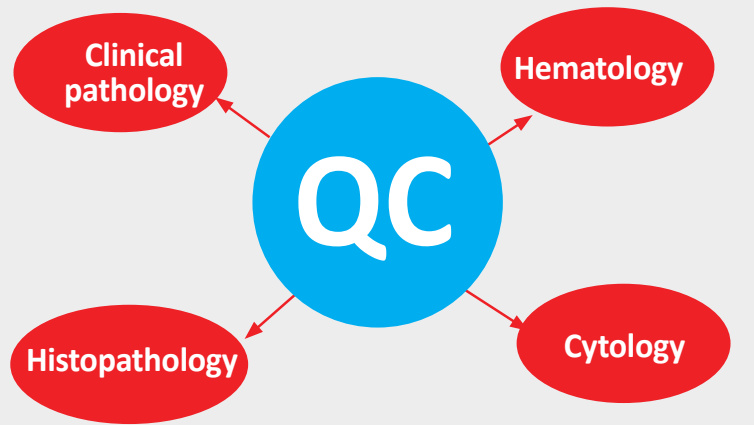
Inter/intra observer variability

Measure of uncertainty

Using known standards specimen

Internal quality control (IQC)

Based on monitoring the test procedures.
 Measurements on specially prepared materials
 Repeated measurements on routine specimens.
 Daily statistical analysis of data obtained
 Inter/intra observer variability
 Measure of uncertainty
 Using known standards specimen



Quality Improvement (QI)

A systematic approach to the processes of work that looks to remove waste, loss, rework, frustration, etc., in order to make the processes of work more effective, efficient, and appropriate.

Implementation Guidelines for the Kenya Quality Model for Health 2011

Anything that enhances an organization's ability to meet quality requirements. *Quality improvement* is one part of quality management.

ISO 9000

External Quality Assessment (EQA)

Ongoing process in which a series of proficiency specimens, the characteristics of which are not known to the participants, are sent to each laboratory on a regular basis.

The laboratory is tested on its accuracy in its usual procedures.

EQA should be provided by an accredited institution

Inter-laboratory comparison schemes

EQA cont'd

The components of EQA include: Validation testing, Proficiency testing and Support Supervisory Visits.

Benefits

- Allows comparison of performance and results among different test sites
- Provides early warning for problems associated with kits or operations
- Provides evidence of testing and staff quality
- Indicates areas that need improvement
- Identifies training needs

Total Quality Management (TQM)

A management approach of an organization, centered on quality, based on the participation of all its members and aiming at long-term success through customer satisfaction and benefits to all members of the organization and to society.

Implementation Guidelines for the Kenya Quality Model for Health • 2011

Standards and Guidelines

Regulations: WHAT to do

Standards: - Define Compliance

Licensure : - Granting of ability to practice

Certification: - assurance that a product, process conforms to specific requirements.

Accreditation:- is recognition for competency



Standards and Guidelines

Guidelines

Provide "how to advice"

Serve as a tool to meet the standards

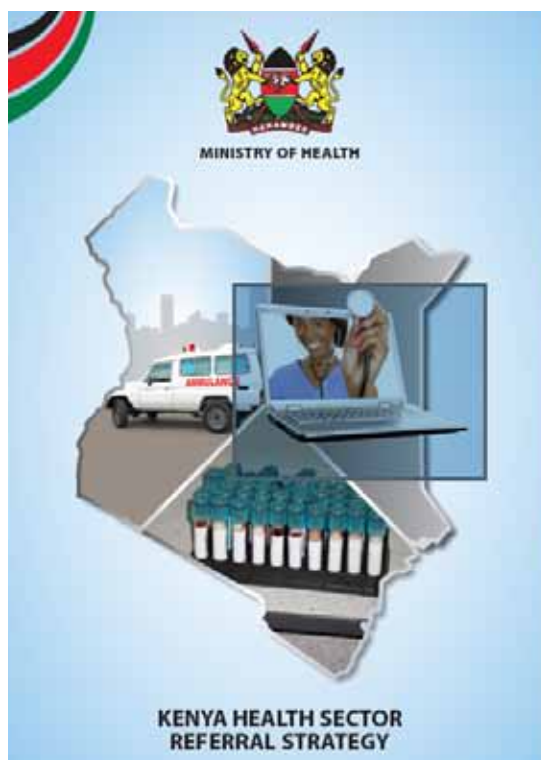
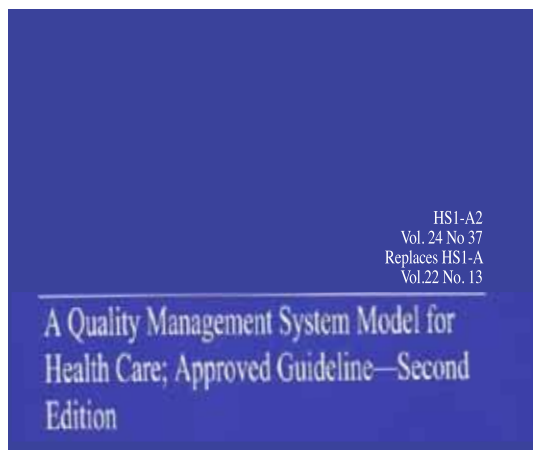
INTERNATIONAL STANDARD

ISO 15189

Third edition 2012-11-01

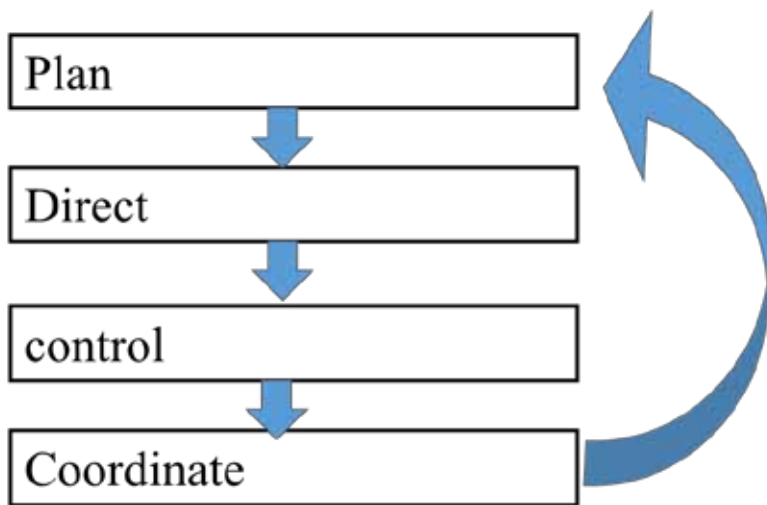
Medical laboratories – Requirements for quality and competence

Laboratoires de biologie médicale – Exigences concernant de la qualit' et la compétence

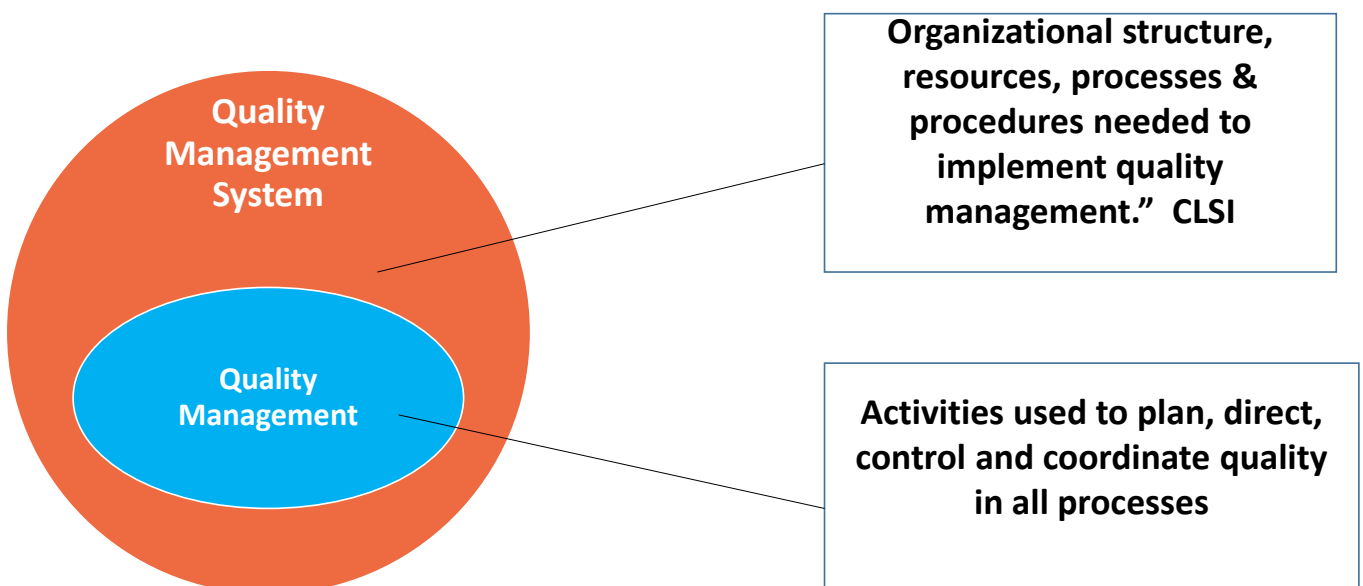


Quality Management

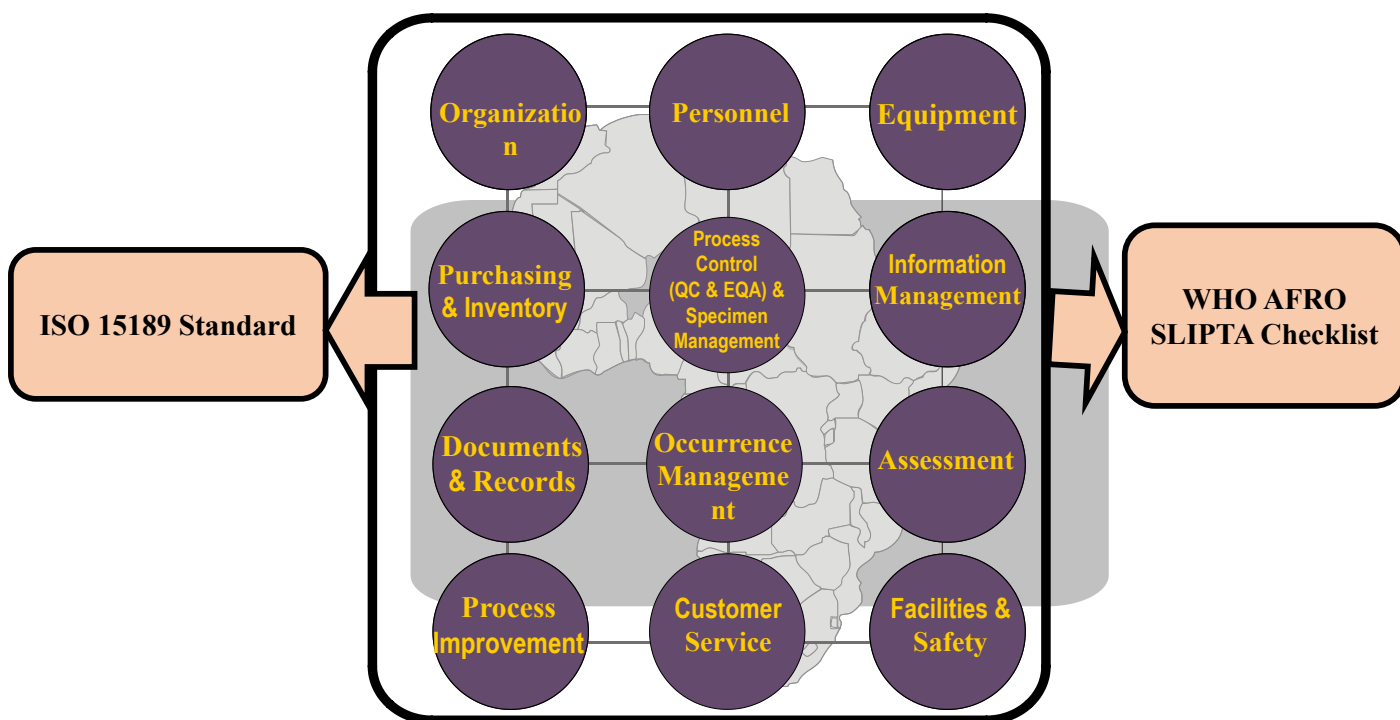
Includes all the activities that organizations use to **plan, direct, control** and **coordinate** quality for all its processes.



Quality Management System



12 Quality System Essentials



Importance of QA systems

- It Sets the standards for level of operation
- Meets/exceeds customer's expectations
- Provides means to prevent, detect and correct problems
- Ensures that clients receive accurate test results within a reasonable time period
- Becomes the core of M&E and improvement of systems
- Reduces cost

QMS Enables Laboratories to:

- Demonstrate the ability to consistently meet customer, stakeholder and regulatory requirements
- Identify opportunities for improvement
- Continually improve

The Six Domains of Health Care Quality

Safe: Avoiding harm to patients from the care that is intended to help them.

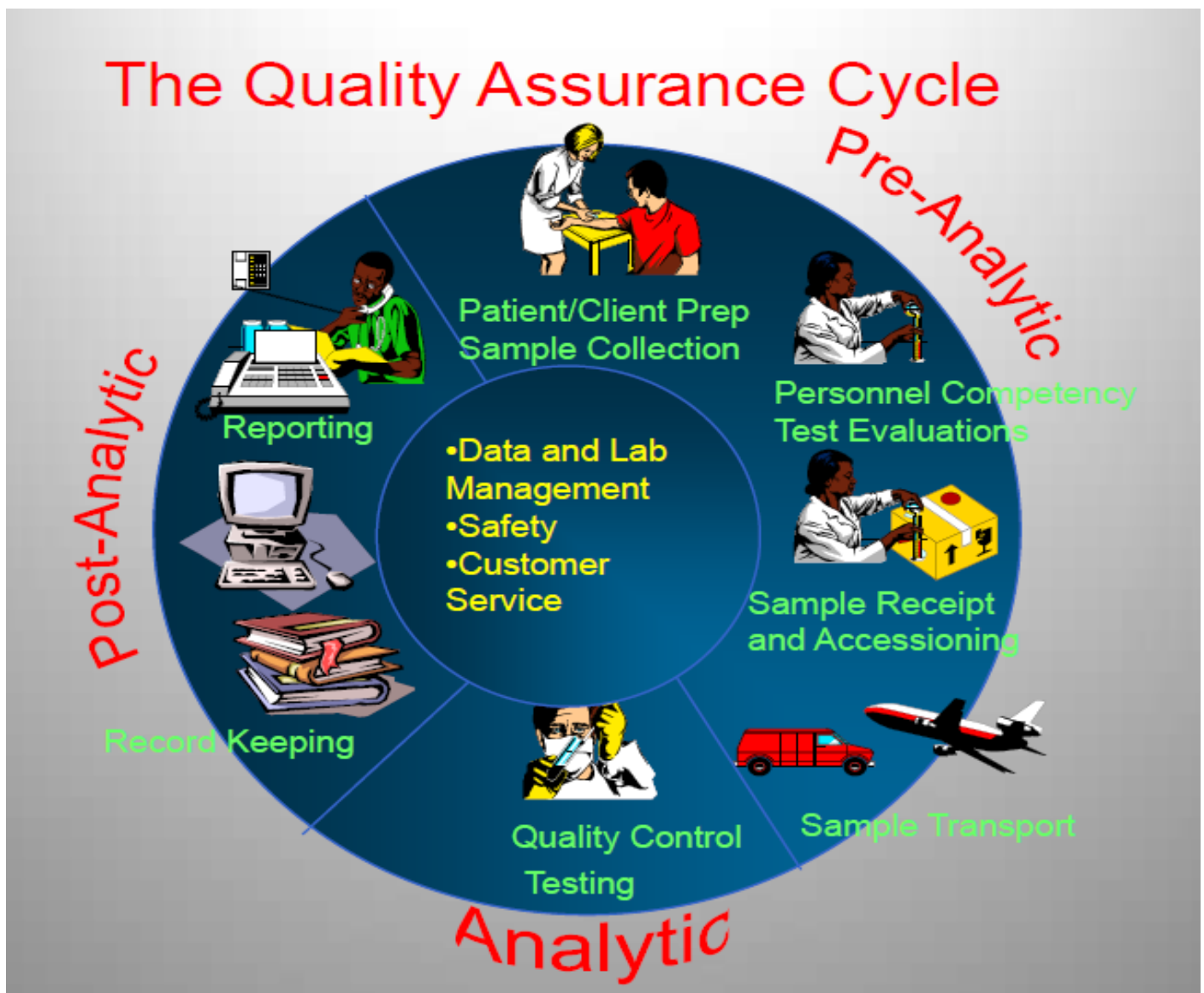
Effective: avoiding underuse and misuse, respectively.

Patient-centered: respectful and responsive care to individual patient needs, in all clinical decisions.

Timely: Reduce harmful delays.

Efficient: avoid waste of resources.

Equitable: avoid biasness in service delivery.



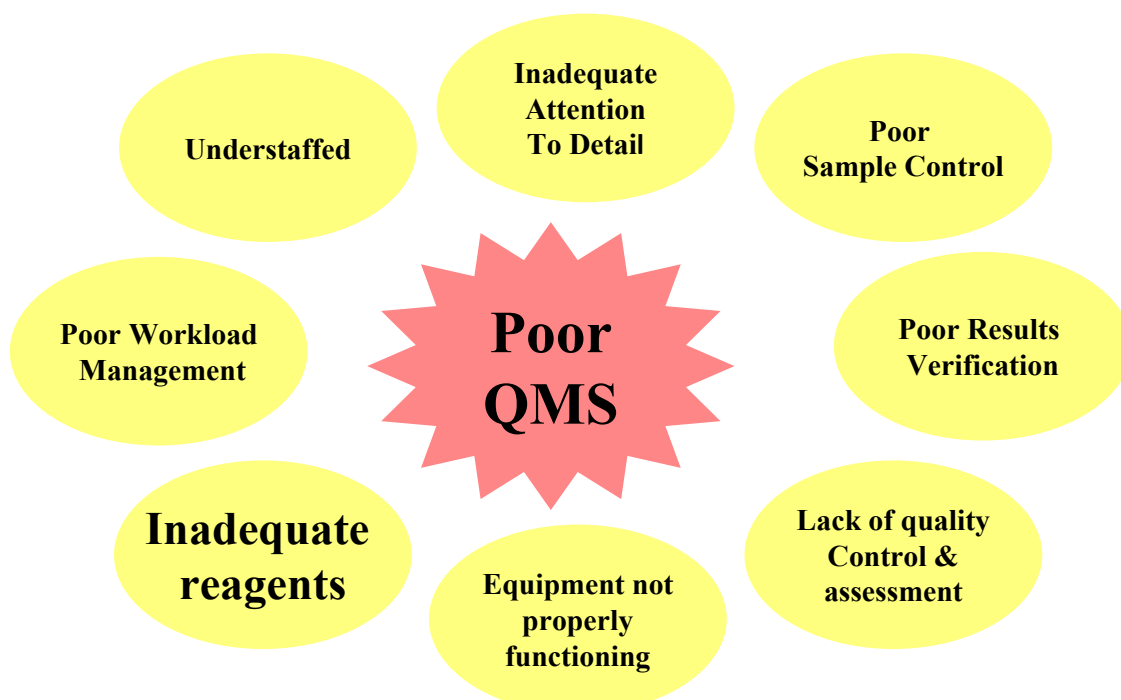
UNIT 2

Quality assurance measures required for cancer screening and diagnosis

Factors influencing quality:

Pre analytical	Analytical	Post analytical
Right Specimen	Laboratory professionals	Recording
Right collection	Reagents	Interpretation
Right labeling	Equipment	Turnaround time
Right quantity	Selection of test - SOP	Report to right user
Right transport	Records	
Right storage	Bio-Safety	

Why Do Laboratory Errors Occur?



Pre-analytical phase factors

Category	Variables
Sample collection	Patient identification and preparation, counselling, requisition labeling Specimen collection technique Collecting wrong specimen Volume Specimen collection items
Sample Handling	Storage of reagents and specimen Agitation, centrifugation, processing Transportation, reagents preparation, equipment preparation
Patient Factors	Physiological variables Pathological states

Analytical phase factors

Category	Variables
Equipment	<ul style="list-style-type: none"> • Validation /verification • Service contract • calibration
Reagent	<ul style="list-style-type: none"> • controls and calibrator expired • Improper measurements of specimen or reagents • Expired reagent
Method	<ul style="list-style-type: none"> • Algorithm/protocol not followed • Failure to adhere to SOPs • Incorrect timing of test • Controls not run or failed • Method not validated/verified
Personnel	<ul style="list-style-type: none"> • Staff qualification and competency • Staff attitude, no clear tasks
Environment	<ul style="list-style-type: none"> • Out of range temperature and humidity • Dusty • Clutter

Post analytical

Category	Variables
Reading and interpretation of results	<ul style="list-style-type: none"> • Not using standard protocol • Incompetence
Reporting and recording of results	<ul style="list-style-type: none"> • Transcription error in reporting • Report illegible • Not use of SI units • Record not maintained
Releasing and archiving of reports	<ul style="list-style-type: none"> • Report sent to the wrong location or lost • Information system not maintained • Poor TAT • Archive not maintained

Preventing and Detecting Errors

Select an appropriate testing workspace
 Check inventory and expiration date
 Review testing procedures
 Record pertinent information, and label test device
 Collect appropriate specimen
 Check equipment validation or calibration is done
 Perform and review Quality Control (QC)
 Follow safety precautions
 Follow equipment and method SOP
 Correctly interpret test results



Specimen rejection

Sample not accompanied with a duly filled request form
 Mislabeled/unlabeled
 Improper transport temperature or container/medium
 Quantity not sufficient (QNS)
 Leaking
 Delay in transport
 Inappropriately received in fixative, or received dried up
 Must communicate with management and care team

Procedure Manuals and SOPs

Standardization purposes in line with policy guidelines

Must be updated annually

SOPs written in a special format as per ISO 15189:2012;5.5.3

Adhere to Manufacturer manuals/instructions

Follow Institutional quality policy guidelines

Analysis of Control Materials

Procure controls materials as per manufactures recommendation

May prepare in house standardize control materials

Need data set of at least 20 points, obtained over a 30 day period

Calculate mean, standard deviation, coefficient of variation; determine target ranges

Develop Levy-Jennings charts, plot results

Observe westguard rule

Analytical errors

Assessment of analytical errors are not an easy task

Maintained by:

Intradepartmental consultation ; review selected cases by colleague

Comparison with other reports (cytology, frozen)

Reviewed by same person – for precision

Reviewed by different person – for accuracy

Slide transferring and examination between two institution

On-site microscopic review

UNIT 3

Safety in cancer screening and diagnosis

What is Safety

Safety is taking necessary precautions to protect yourself, the client and others against infection, accident or injury.

All specimens and materials that you come in contact with should be treated as infectious

Bio-safety

Definition: Prevention of exposures, occupationally acquired infections and release of organisms to the environment by health workers in the biomedical environment.

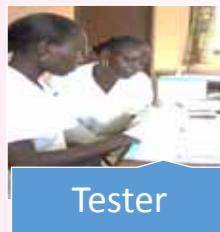
Procedures involved in testing are potentially dangerous.

Universal or standard safety procedures must be followed.

Who Needs to be safe?

We cannot wait until a serious accident occurs before we implement safe practices

Bio-Hazard is an organism or substance capable of causing infection, disease or death



Tester



Client



Others



Safety requires that you

Maintain clean and orderly work spaces

- Keep work places clean, uncluttered
- Disinfect daily and after all spills
- Use appropriate concentrations of hypochlorite or bleach solution for different cleaning jobs
- Restrict /limit access when working
- Lock supplies in safe, secure area
- Dispose of contaminated sharps and wastes in sharps disposal containers

Develop personal safe working habits

- Wear fresh pair of gloves, right way
- Wear lab coat/apron
- Wash hands before and after collecting specimen from each person
- Keep food out of the testing area.



Do's and Don'ts: Sharps and Waste Containers

Do NOT break, bend, re-sheath or reuse lancets, syringes or needles
 Do NOT shake sharps containers to create space
 Never Place Needles or Sharps in regular Waste Containers
 Incineration of Waste appropriately
 Disinfect Work Areas with appropriate disinfectant

Immediate Steps Taken by Exposed Healthcare Worker

Exposure to eyes or nose

Flush exposed mucous membranes with water only

Sharps Injury

If bleeding occurs, allow bleeding for a few seconds before washing
 Flush the area well in clean running water and wash thoroughly with soap
 Do not apply bleach, antiseptics or disinfectants into wound
 Cover with dressing if necessary

Immediately inform supervisor of exposure and action taken

Immediate Steps Taken by Exposed Healthcare Worker

Exposure to eyes or nose

Flush exposed mucous membranes with water only

Sharps Injury

If bleeding occurs, allow bleeding for a few seconds before washing
 Flush the area well in clean running water and wash thoroughly with soap
 Do not apply bleach, antiseptics or disinfectants into wound
 Cover with dressing if necessary

Immediately inform supervisor of exposure and action taken

UNIT 4

Corrective action and problem-solving

General Process for Problem Solving

Define the problem.

Gather data/evidence

Ask why and identify the true root cause associated with the defined problem.

Identify corrective action(s) that will prevent recurrence of the problem.

Implement the corrective action(s)

Observe the corrective actions to ensure effectiveness.

If necessary, reexamine the RCA.

Symptom Approach vs. Root Cause

If we do a poor job of identifying the root causes of our problems, we will waste time and resources putting band aids on the symptoms of the problem

Symptom Approach

"Errors are often a result of worker carelessness."

"We need to train and motivate workers to be more careful."

"We don't have the time or resources to really get to the bottom of this problem."

Root Cause

"Errors are the result of defects in the system. People are only part of the process."

"We need to find out why this is happening, and implement mistake proofs so it won't happen again."

"This is critical. We need to fix it for good, or it will come back and burn us."

Tools and Techniques for RCA

Five Whys

Cause and Effect

Brainstorming

Pareto analysis

Control charts

Many more others

Five Whys Analysis

Helpful in tracing the chain of events (starting with the nonconformance and working backwards)

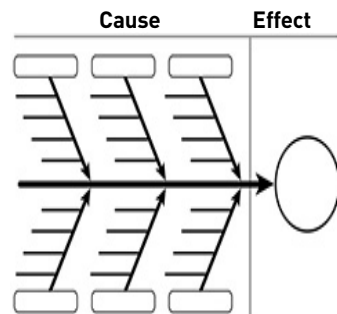
Asking Why five times Nature of the problem becomes clear

Helps get to true cause of problem



Fishbone

A technique to graphically identify and organize possible causes of a problem (effect). Also known as the Cause & Effect Diagram or Ishikawa Diagram. It helps identify the most likely ROOT CAUSES of a problem. Focuses problem solving and reduce subjective decision making.



Brainstorming

Brainstorming is a process in which a group quickly generates as many ideas as it can on a particular problem and/or subject.

Why is it useful?

Brainstorming is useful because it can help a group of people utilize its collective brainpower to generate many ideas in a short period of time. It stimulates creativity and promotes involvement and participation.

Pareto Analysis

Pareto analysis is a formal technique useful where many possible courses of action are competing for attention. It is a prioritization technique that helps separate the major causes (vital few) of a problem from the minor ones (the trivial many). It is also known as the 80/20 rule i.e.. 80% of the problems are due to 20% of the causes.

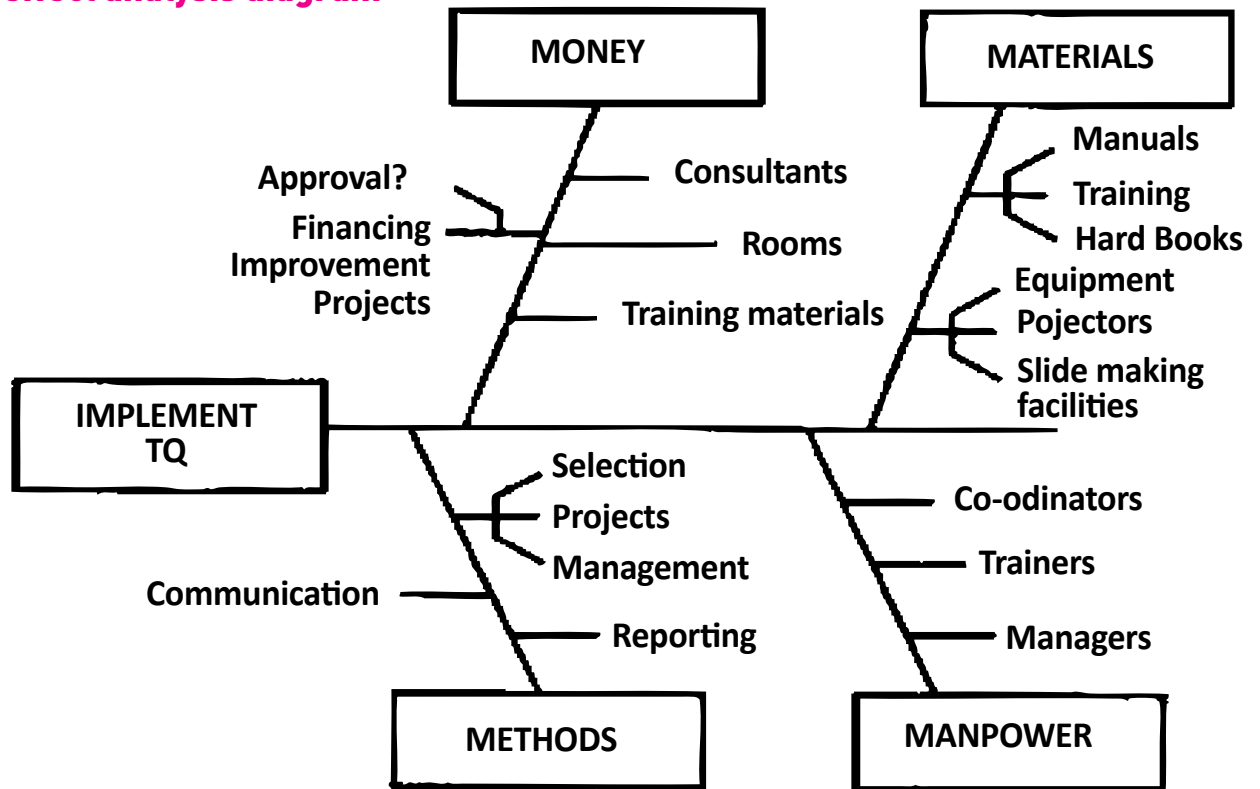
How to select the final root!

Changing too many variables at once may be a problem. Select the one action that is MOST likely to correct the problem. Record the findings and observations after this adjustment is made to see if it fixes the problem. If the problem happens again, select another variable from the list.

Solution Effect Analysis

This is a tool that is used to test potential solutions and to identify all the effects of these solutions. Once a solution has been identified, there is a tendency to implement it straight away. You should check that solution does solve the problem that you identified in the first place and that your solution does not cause other problems by its effect or implementation.

Solution effect analysis diagram



References

ISO 15189:2015
 ISO 9001
 ISO 17025
 ISO15190
 Clinical laboratory standard institute (CLSI) 2014
 Implementation Guidelines for the Kenya Quality Model for Health 2011
www.healthcatalyst.com



MODULE 9

**COMMUNICATION, ADVOCACY, AND
SOCIAL MOBILIZATION**

Objectives

By the end of this module, the participant will be able to;

Discuss communication, advocacy, and social mobilization

Describe steps and principles in advocacy and social mobilization in cancer work

Describe communication channels and components for effective communication in cancer work

Discuss myths, beliefs, stigma associated with cancer and demystification

INTRODUCTION

This module introduces the concepts of communication advocacy and social mobilization to the participant. It explains essentials of good advocacy, mobilization and communication in relation to cancer work.

Communication



<https://www.shutterstock.com/search/communication>

What is communication?

Communication is the process of sharing of ideas, information, knowledge, and experience among people to take action.

Communication may take place between one person and another, between an individual and a group or between two groups.

Communication facilitates creation of awareness, acceptance and action at individual, group and inter-group level.

The process always involves a sender and a receiver regardless of the number of people concerned.



Principles of effective communication in cancer work

Simplicity

Brief and concise

Relevant

Attractive

contextual

Why communication in cancer work?

To have dialogue with communities.

Influence decision making

Raise awareness

Enhance public participation

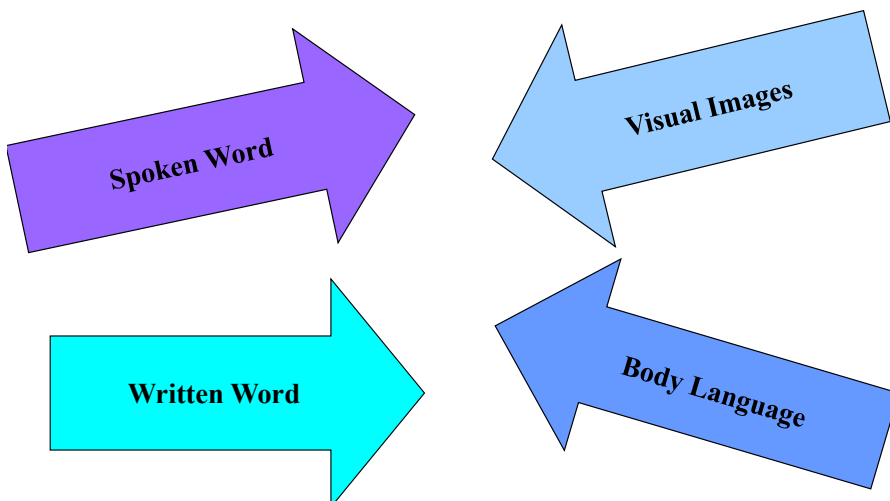
Inform new ideas, laws and policies to the public

Initiate action

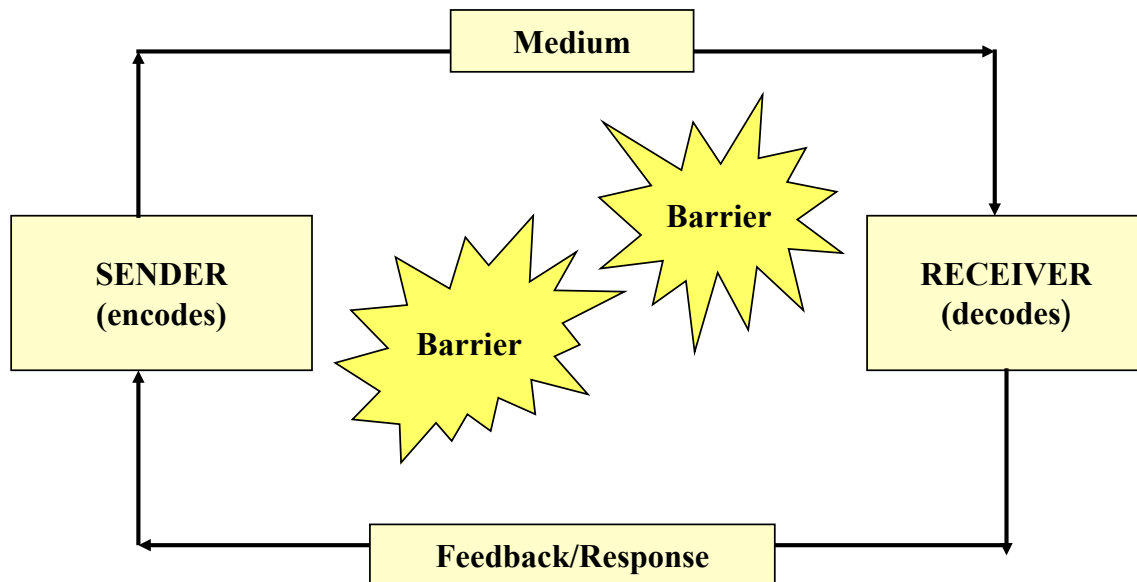
Given five minutes...

List the various types of communication.

What are the most common ways we communicate?



The Communication Process



Types of Communication

One-way communication

Two-way communication

1. One-way communication

Linear communication: information flow from source to receiver.

No input (feed back) from receiver.

Commonly used in advertising; message designed to persuade Receiver to action prescribed by Sender.

Best used by organizations when message is simple and needs to be communicated quickly, e.g. date and time of a meeting.

No opportunity to clear misunderstanding.

Meaning is controlled by the Receiver.

2. Two-way communication

More complex

Information flows from Source to Receiver and back from the receiver to the source.

Feedback occurs- allows the sender to find out how the message is received.

enables monitoring and adaption to better suit its purpose.

Components of communication

- 1) Source (sender)
- 2) Message
- 3) Medium
- 4) Receiver
- 5) Effect and feedback

Communication stages

Purpose of communication promote improvements in health through the modification of the human, social and political factors that influence behaviours.

To achieve these objectives, a successful communication must pass through several stages:

- Reaching the intended audience
- Attracting the audience's attention
- Understanding the message (perception)

Given five minutes...

List down the barriers to communication

Common barriers to effective communication of cancer messages

- Competition for attention (noise)
- Language differences.
- Lengthy message.
- Over-complicated, unfamiliar and/or technical terms.
- Using inaccessible media.
- Emotional barriers and taboos.
- Differences in perception and viewpoint.
- Physical disabilities (hearing and visual disability).
- Inability to recognize non-verbal communication e.g body language, cues, gestures etc.
- Age and cultural differences.
- Attitudes and Beliefs.
- Lack of attention, interest, distractions, or irrelevance to the receiver.
- False assumptions and prejudices (hearing what you want to hear.

Characteristics of effective communication

- All barriers have been removed.
- The proper media has been chosen.
- A good presentation has been made.
- Two – way communication has been established.
- The receiver should:*
- Be aware, interested, and willing to accept the message.
- Listen attentively.
- Understand the value of the message.
- Provide feedback.

Characteristics of effective communicator

An effective verbal communicator:

- C**larifies
- L**istens
- E**ncourages empathically
- A**cknowledges
- R**estates/repeats

An effective nonverbal communicator:

- Relaxes
- Opens up
- Leans toward the other person
- Establishes eye contact
- Shows appropriate facial expressions

Given ten minutes...

What is advocacy and social mobilization?

**Advocacy**

Advocacy is a process of sensitizing, implementing and creating awareness and follow up, in policy makers and other stakeholders to achieve a stated objective.

Advocacy is continuous and adaptive, and gathers organizes and formulates information into argument, which is then communicated to policy-makers.

Should adopt bottom-up approach, vice versa or both.

Should adopt Multi-sectoral approach.

Social mobilization

This is the process of marshaling community support for a particular cause by actively engaging the community resulting in sustainable community ownership and participation.

Important in public health issues such as prevention and screening of diseases.

Social mobilization establishes networks at the grassroots that in turn drive the efforts to achieve the stated goals.

In cancer, the goals may be improving screening uptake and prevention services, access to care, and awareness.

Targets of social mobilization

Community leaders

Interest groups

Grassroot organisations

Advocacy**Cancer targets in advocacy and mobilization**

Prevention, screening and early detection (e.g HPV vaccination)

Legislation e.g taxation and tobacco control

Policy

Resource allocation

Research

others

Principles of Advocacy and social mobilization

Multi-sectoral approach

Inclusivity

Ownership

Evidence based

Equity

Coordination and partnership

Cost effectiveness

Gender equity

Accountability

Rights based approach

Management of conflict of interest

Stakeholders

Identify the policy makers and stakeholders (all Inclusive)

Individuals

Interest groups e.g cancer survivors, support groups

Community level- village elders, church, youth & women groups, local administration

County level- county administration

National level- National Executive, legislature, independent bodies,

Non profit institutions

International state and non state organisations (WHO, USAID, UNICEF etc)

Media(TV, radio, Newspapers, Social media)

Steps in Advocacy at all levels

Identify the problem,

Initial visit and discussion

Suggest solutions

Design implementation

Assign roles and responsibilities e.g committees

Allocate resources

Implement

Analyse, generate and report and disseminate outcomes

Monitor and evaluate

References

CDC Manual

UNICEF

Guidelines for Social Mobilization , Social Mobilization and Training Team Control, Prevention and Eradication Department Programme on Communicable Diseases, World Health Organization.

References

CDC Manual

UNICEF

Guidelines for Social Mobilization , Social Mobilization and Training Team Control, Prevention and Eradication Department Programme on Communicable Diseases, World Health Organization.



MODULE 10

MONITORING AND EVALUATION

Objectives

- Define concepts of monitoring and evaluation in cancer prevention and control
- Outline cancer indicators
- Discuss cancer data collection tools including cancer registry

INTRODUCTION

This module equips the health workers with the necessary Knowledge on monitoring and evaluation in cancer screening and diagnosis.

Module outline

- Concepts of monitoring and evaluation
- Cancer indicators
- Cancer data collection tools and methods

Given ten minutes...

In your own view what is monitoring and evaluation?

What is Monitoring and Evaluation

Collection, storage, analysis and transforming data into information for use in making informed decisions for project/program management and improvement, policy formulation, and advocacy.

Definition of Monitoring

Routine collection and analysis of data on a project/program in progress.

Is a continuous assessment providing stakeholders with information on the progress Of ongoing activities.

Its purpose is to determine if the outputs, deliveries and schedules planned have been reached so that action can be taken to correct the deficiencies as quickly as possible.

Monitoring

Requires collection of data at multiple points throughout the program cycle, including at the beginning to provide a baseline

These data is used to:

- Measure progress
- Track changes over time.
- Measure effectiveness, efficiency
- Inform decision making

Given five minutes...

What is evaluation?

Give examples of evaluation?

Evaluation

It is the periodic, retrospective assessment of a project/program conducted internally or by external independent assessors.

a systematic and objective examination concerning the relevance, effectiveness, efficiency and impact of activities in the light of specified objectives.

It measures the extent to which changes in outcomes can be attributed to the program.

Evaluation focuses on the implementation process and asks key questions:

How well has the program been implemented?

Is implementation uniform and consistent.

Did the program achieve intended objectives?

What was project cost benefit ratio?

Monitoring & Evaluation

Monitoring	Evaluation
Clarifies program objectives	Analyzes why intended results were or were not achieved
Links activities and their resources to objectives	Assesses specific causal contributions of activities to results
Translates objectives into performance indicators and set targets	Examines implementation process
Routinely collects data on these indicators, compares actual results with targets	Explores unintended results
Reports progress to managers and alerts them to problems	Provides lessons, highlights significant accomplishment or program potential, and offers recommendations for improvement

The World bank

Importance of Monitoring and Evaluation

M&E helps program implementers:

Make informed decisions regarding program operations and service delivery.

Ensure the most effective and efficient use of resources

Objectively assess the impact of the project

Meet organizational reporting and other requirements.

Use data for resource mobilization.

INDICATORS

Given five minutes

What are indicators?

Give examples of indicators.

Definition of Indicators

A variable that measures one aspect of a program or project that is directly related to the program's objectives.

Indicators are signs of progress – they are used to determine whether the programme/intervention is on its way to achieving its objectives and goal.

An outcome indicator has two components:

- A baseline

- A target

Indicators must have clearly defined sources of data

Examples of Cancer Indicators

Cancer incidence rate

Proportion of deaths attributed to cancer

Proportion of healthcare workers trained in cancer management

Proportion of laboratories with capacity to diagnose cancer

Number of facilities offering chemotherapy services

Proportion of women screened for cervical cancer

Data Characteristics

Accurate—correct values, valid, and attached to the correct patient record.

Accessible—easily obtainable with controlled access.

Comprehensive— covers entire scope

Consistent—reliable

Timely and current

Importance of data

Data plays a critical role in health care delivery

Supports decision making

Forms basis for Periodic reviews

Aids investigators in addressing relevant research questions

Ensuring quality data

Managing data before starting a program and throughout its life cycle is essential to ensure its current usability, long-run preservation and access.

This entails:-

- Ensuring data quality

- Point of Assessment

- Collection i.e. review form before patient leaves clinic

- Entry i.e. range restrictions, logical checks

- Post entry clean up queries

- Statistical Analysis: data trends (entirely relies on quality in the collection and entry phase)

Application of the data

- Ongoing monitoring
- Periodic evaluation
- Safety/adverse event reporting
- Reporting
- Ongoing analysis
- Research

Given five minutes...

Give examples of data management tools needed in cancer program

Cancer Data Management Tools

- Lab request form
- Laboratory summary data report (MOH 706)
- Outpatient and inpatient Cancer register
- IARC tool for extracting and reporting
- Cancer program monthly summary form
- Cancer Referral Form
- Cancer Screening and Treatment Form
- Cancer Screening Card

M&E and Health Information system

The establishment of well-functioning information systems is vital for a successful M&E.

Ideally, information from facility-based records should be linked to national database to allow aggregation of data on key indicators.

Where available, national cancer registries can be used to monitor cancer incidence and mortality rates.

CANCER REGISTRATION

Given ten minutes...

Define cancer registry and outline its significance in prevention and control of cancer.

Cancer Registry

The cancer registry provides basic measures of the burden of disease;

- numbers of deaths (mortality),
- new diagnoses (incidence),
- people living with the disease (prevalence)
- Probability of surviving the disease
- People living with terminal cancer

Cancer Registry

The cancer registry provides basic measures of the burden of disease;

numbers of deaths (mortality),
new diagnoses (incidence),
people living with the disease (prevalence)
Probability of surviving the disease
People living with terminal cancer

Population based cancer registry at Ministry of Health
Receives data from 47 county registries
Three regional population based cancer registries
Eldoret Cancer Registry-1998
Nairobi cancer registry- 2001
Kisumu cancer registry-2010.

Cancer Registration in Kenya

A fully functional and dedicated cancer registry with appropriate expertise is the cornerstone of cancer control surveillance.

Population-based cancer registries are in Nairobi at Kemri, at Eldoret in MTRH and in Kisumu

Hospital-based cancer registries are under development in Nyeri, Embu, Nakuru, Mombasa and Meru counties among others.

Cancer Registry Definition

Is an information system designed for the collection, storage, management and analysis of data on persons with cancer in a hospital, region or a given population.

Aims to assess and control the impact of cancer on the community.

Types of Cancer Registries

Population-based registries

Hospital-based registries

Others include

- Special cancer registries that are limited to particular cancers
- Pathology-based cancer registries
- Laboratory cancer registries

Given 10 minutes...

Outline the roles of cancer registries

Use of Cancer Registry data

To plan and evaluate health services

Help assess & control impact of malignancies on the communities

To improve patient care through timely follow up and management

To help decision makers in developing cancer policies

To assist physicians to determine efficacy of diagnostics, cancer therapy and interventions

Track cancer patients

Goals of Population-based Cancer Registries

- Cancer prevention
- Early detection
- Determination of cancer rates and trends
- Patterns of care and outcomes
- Research
- Aims at reducing the cancer burden in the community
- Evaluation of control efforts
- Improvement of patient care
- Professional education
- Administrative information
- Clinical research

References

- National cancer control strategy

ANNEX 1. Lab Procedure for FNA stain (H/E)

1. Leave slides in 95% Alcohol for 15min
2. Transfer to 95% alcohol- 10dips
3. Transfer to distilled water -10dips
4. Stain Transfer to Hematoxylin
5. Change to 0.05% HCL acid -10 dips
6. Chang to a second 0.05% HCL- 10 dips
7. Wash in Scotts's tap water for 1 minute
8. Stain in 1% eosin for minute
9. Three changes of 95 % alcohol, 20 dips each
10. Two changes of Absolute alcohol 20 dips each
11. Three changes in Xylene
12. Mount in DPX

ANNEX 2. Lab Procedure for histology staining using Heamatoxylin & Eosin method

1. Deparaffinize the section: flame the slide on burner and place in the xylene. Repeat the treatment.
2. Hydration: Hydrate the tissue section by passing through decreasing concentration of alcohol baths and water. (100%, 90%, 80%, 70%)
3. Stain in hematoxylin for 3-5 minutes
4. Wash in running tap water until sections “blue” for 5 minutes or less.
5. Differentiate in 1% acid alcohol (1% HCl in 70% alcohol) for 5 minutes.
6. Wash in running tap water until the sections are again blue by dipping in an alkaline solution (eg. ammonia water) followed by tap water wash.
7. Stain in 1% Eosin Y for 10 minutes
8. Wash in tap water for 1-5 minutes
9. Dehydrate in increasing concentration of alcohols and clear in xylene
10. Mount in mounting media
11. Observe under microscope

ANNEX 3. Procedure for performing FNA

FNA sample collection procedure

1. Identify yourself to the patient
2. Check the patient's file or doctors notes to establish the site of lesion and confirm patients identity
3. Record the clinical information and describe the lesion after physical examination
4. Label slide with the patients name or hospital number
5. Examine the nature of the lesion (solid, cyst, mobile etc
6. Clean the overlying skin with antiseptic
7. Immobilize the lesion with two fingers to lessen the movement once pricked.
8. Pull the plunger back not more than 1 ml
9. Insert then sterile needle with the attached 10/20 ml needle into the lesion (not directly into the centre of lesion as it is most often necrotic) with the dominant hand with the other immobilizing the lesion.
10. The syringe piston is retracted to approximately 5ml mark to produce and maintain negative pressure
11. Move the needle up and down and around in all angles to loosen the cells
12. The needle is moved in various directions to sample cells from different areas of the mass while maintaining the negative pressure
13. Do not allow the needle to leave the lesion. Allow plunger to its original position when only the hub of the syringe is filled with aspirate material.
14. Withdraw after releasing the plunger and disconnect the syringe
15. Fill syringe with air and connect to the syringe
16. Express aspirate onto the slide NEAR to the frosted label) end while holding the needle to prevent it from disconnecting from the syringe if needle is blocked.
17. Place a second slide on the first, and gently but firmly allow the material to spread to the edges
18. Pull the 2 slides apart keeping them firmly but gently completely opposed
19. Hold the slide horizontally (if the slide is held at an angle, the material may be sprayed off the slide), and then insert the slide in fixative or spray if using a can. Fixation should be immediate. One can be air dried depending on the stain to be used.
20. Clearly mark the slides as to which are to be fixed or air dried.
21. Repeat procedure if necessary. Label all slides
22. If Tuberculosis is suspected clinically, rinse the needle and syringe in TB transport media or sterile saline and send for mycobacteria culture/gene expert
23. Inform the patient where and when to get the results
24. Send the sample and the request form to the laboratory for processing and diagnosis

Annex 4: Learner's Course Evaluation

Course Title

Facilitator:

Date:

Below are a series of statements. Please respond by circling the number you feel most reflects your opinion.

	Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
The course fulfilled the objectives set out in the curriculum	5	4	3	2	1
The course satisfied my needs and expectations	5	4	3	2	1
The content was presented at a level which could readily be understood	5	4	3	2	1
There was opportunity for group work	5	4	3	2	1
There was opportunity for individual participation	5	4	3	2	1
The material presented had practical relevance	5	4	3	2	1
The course content built on trainees prior learning and experience	5	4	3	2	1
I feel I contributed to class discussion	5	4	3	2	1
I was motivated to learn	5	4	3	2	1
Course handouts & texts helped reinforce learning	5	4	3	2	1
There was a variety of teaching methods	5	4	3	2	1
The teaching methods used helped me learn effectively	5	4	3	2	1
The facilitator/s knew their subject thoroughly	5	4	3	2	1
The facilitator/s achieved a good rapport with the group	5	4	3	2	1
There was opportunity for feedback and evaluation	5	4	3	2	1

Additional Comments (Please feel free to continue comments overleaf)

Which aspects of the course worked well? _____

How could the course be improved? _____

Would you recommend this module to others? Please outline your reasons. _____

Any other comments, _____

Signature: (optional) _____

Thank you for taking the time to complete this form. Your input is an integral part of the evaluation and review process.

Annex 5. CAP College of American Pathologists) reporting protocol links

- Breast: DCIS- <https://documents.cap.org/protocols/cp-breast-dcis-18protocol-4100.pdf>
Invasive breast- <https://documents.cap.org/protocols/cp-breast-invasive-18protocol-4100.pdf>
- Cervix: <https://documents.cap.org/protocols/cp-female-reproductive-uterine-cervix-18protocol-4100.pdf>
- Prostate: <https://documents.cap.org/protocols/cp-male-genital-prostate-18protocol-4030.pdf>

Annex 6: Digital Rectal Examination (DRE) procedure

Equipment:

- Disposable non sterile gloves
 - Disposable apron
 - Water soluble lubricating gel
 - Procedure pad
 - Tissues/ wipes
 - Waste bag
 - Hand washing/ decontamination facilities
 - Access to toilet/ commode/ bedpan
1. Introduce yourself as a staff member and any colleagues involved at the contact
 2. Verbally confirm the identity of the patient
 3. Explain procedure to the patient to gain co-operation and verbal consent
 4. Establish that the patient has no known allergies
 5. Ask the patient if they wish to use the toilet prior to undertaking the procedure
 6. Ensure privacy at all times.
 7. Ensure that a bedpan, commode or toilet is readily available DRE can stimulate the need for bowel movement
 8. Decontaminate hands prior to procedure
 9. Where possible, assist the patient to lie in the left lateral position with knees flexed, the upper knee higher than the lower knee, with the buttocks towards the edge of the bed
 10. Place a procedure pad beneath the patient's hips and buttocks
 11. Wash hands with soap and water or decontaminate with alcohol hand rub and put on disposable gloves and fresh apron
 12. Place some lubricating gel on a swab and gloved index finger
 13. Inform patient that the procedure is about to start
 14. Observe anal area prior to the insertion of the finger into the anus for evidence of skin soreness, excoriation, swelling, hemorrhoids, rectal prolapse and infestation
 15. On insertion of finger assess anal sphincter control; resistance should be felt Digital insertion with resistance indicates good internal sphincter tone, poor resistance may indicate the opposite
 16. Complete digital examination, faecal matter may be felt within the rectum; note consistency of any faecal matter
 17. Clean anal area after the procedure
 18. Dispose of equipment in appropriate clinical waste bin and remove gloves.
 19. Assist patient into a comfortable position and offer toilet facilities as appropriate
 20. On completion of procedure remove and dispose of apron
 21. Decontaminate hands following removal of personal protective equipment (PPE)
 22. Document findings and report to medical team

Annex 7. Bethesda system reporting for Cervical cytology

Follow this link: <https://web.archive.org/web/20081223051738/http://nih.techriver.net/>

Annex 8. National Cancer Institute (NCI) reporting for Breast cytology

Cytology reporting categories*.

C1 Inadequate

C2 Benign

C3 Atypia probably benign

C4 Suspicious of malignancy

C5 Malignant

*From Diagnostic Cytopathology of the Breast by Zakhour and Wells

Annex 9 : Procedure for Pap Stain

1. Leave slides in 95% Alcohol for 15min
2. Transfer to 95% alcohol- 10dips
3. Transfer to distilled water -10dips
4. Stain Transfer to Hematoxylin
5. Change to 0.05% HCL acid -10 dips
6. Chang to a second 0.05% HCL- 10 dips
7. Wash in Scotts's tap water for 1 minute
8. One change of 90% alcohol 10 dips each
9. Two changes of 95% alcohol 10 dips each
10. Stain on Orange Green for 15 min
11. Transfer to three changes of 95% alcohol 10 dips each
12. EA 3 minutes
13. Three changes of 95 % alcohol, 20 dips each
14. Two changes of Absolute alcohol 20 dips each
15. Three changes in Xylene
16. Mount in DPX



**INTERGRATED
CANCER SCREENING,
DIAGNOSIS AND
LABORATORY
MANAGEMENT**