MEDICAL ETHICS

Principle of ethics

- Doing good and not doing harm- essence of every code of medical ethics
- To exercise the professional skills in an ethical manner and to observe the laws of community-duty of all medical professionals.

History of medical ethics

- Generally considered to be derived from the teaching of Greek Physician Hippocrates (father of Medicine)- known today as Hippocratic oath.
- Modern version of medical ethics is Declaration of Geneva, adopted by World Medical Association in 1948, subsequently amended in 1968, 1983, 1994.
- Essential principle remains the same-the patient interests are paramount.

Fundamental principles of medical ethics

- **Autonomy**- the right of patients to make decisions on their own behalf
- **Beneficence**-the duty or obligation to act in the best interest of patient
- **Non-malificence**- the duty or obligation to avoid harm to the patient
- **Justice**-fairness and giving what is rightfully due
- **Privacy**-according to some may be regarded as fifth principle

General application of ethical principles in MLT

Medical laboratories have responsibilities towards three main groups of people:

- Patients- they are responsible for the quality and integrity of services they provide
- Colleagues and the profession- they should strive to uphold the dignity and respect of their professions and maintain a reputation for honesty, integrity, and reliability.
- Society-responsible for general well being of society

- **Collection of information**-
- sufficient information to identify adequately patient and specimen should be collected , but unnecessary information should not be collected
- These information include clinical information and information relevant to safety of other patients and staff as well as information required for billing purposes and resource management.
- The patient should be aware of the information collected and the purpose for which it is collected.

- **Collection of specimens**-
- All procedures carried out on competent patient requires informed consent.
- If the patient is incompetant because of age or mental status, consent may be given by a parent or properly authorized persion. Forcing someone to undergo medical testing of any kind is an invasion of privacy and a violation of human rights.
- For most laboratory procedures, consent can be inferred when the patient presents him or herself at a laboratory with a request form and willingly submits to the usual collecting procedures, for example, venipuncture.
- Patient in a hospital bed should normally be given the opportunity to refuse.

- Special procedures, including the more invasive procedures, will require a more detailed explanation and, in some cases, written consent.
- This is desirable when there is likelihood of complications following the procedure.
- Laboratories performing human immunodeficiency virus (HIV) testing shall follow National AIDS Control Organization (NACO) guidelines, which include pre-test and post-test counselling.
- The laboratory shall not perform HIV test unless the individual has been given pre-test counselling and post-test counselling is ensured.
- Informed consent of the patient will be taken before the blood is collected.
- The result of HIV test shall be kept strictly confidential.

- In emergency situations, consent might not be possible and under these circumstances it is acceptable to carry out necessary procedures provided they are in patient's best interest

- **Performance of tests**-
- All the tests must be carried out to an appropriate standard which should be determined by professional organization or regulatory authorities.
- Laboratory may refuse to attempt a test rather than produce unreliable result which may cause harm to the patient.
- All laboratory work must be carried out with high level of skill and competence expected for medical, scientific and allied health professions

- **Reporting of results**-
- Test results are confidential unless disclosure is authorized.
- They will normally reported to the clinician who request the test and may be reported to other parties authorized by the patient any by law.
- The laboratory is also responsible for timely reporting and there should be facility to report urgent results as soon as they are available.
- Care must be given to the construction and format test report so as to facilitate correct interpretation and diagnosis.

- **Storage and retention of medical records**-
- The laboratory must ensure that the information is stored so that there are reasonable safeguards against loss, unauthorized acess, tampering or other misuse.
- The test results must never be altered or corrected except by properly authorized persons in accordance with established procedure.
- Laboratories should develop their own protocol or follow standardized protocols indicating how long different results, specimens and slides will be kept for.

- **Financial arrangements**-
- Medical laboratories should not enter into financial arrangements with referring practitioners where those arrangements act as an inducement for the referral of patients.
- Rooms used for primary sample collection should be completely independent and separate from referring practitioners' rooms.
- Laboratories should try to avoid situations that give rise to a conflict of interest.

Some special applications-

- **Autopsies**-
- there are 2 types of autopsies- hospital autopsy and forensic or medicolegal autopsy.
- Hospital autopsy is carried out usually to know the cause of death at the request of hospital authority and forensic autopsy is performed for legal purpose at the request or direction of legal authority.
- The hospital and forensic pathology institutions should have adequate facilities to advise, counsel and support bereaved relatives.
- The body of the deceased person must be handled with respect.

- Consent for autopsies- should be taken according to law.
- Non forensic hospital based autopsy requires informed consent from the next of kin. This includes prper explanation of nature and outcome of autopsy, any need to retain tissues to be used for research or teaching purpose.

- **Transfusion medicine**-
- Blood donation should be voluntary and without expectation of payment.
- No pressure should be exerted on potential donors, who should be provided with adequate information about the process to properly consent to donation.
- Blood should be collected under supervision of a physician.
- Confidentiality concerning all personal donor details, including lab results should be ensured.
- The recipient, whenever possible, should be provided with reliable information regarding risks and benefits of blood transfusion.
- Quality assurance is paramount throughout all the stages of blood transfusion. Misuse of blood and blood product should be avoided

- **Research**-
- Ethics plays a vital role in biomedical research to prevent potential harm to patients or research subjects.
- The involvement of medical laboratories in research will centre on analysis of tissue or fluids.
- Proper consent, authorization to use tissue, maintenance of privacy and confidentiality- are the issues usually taken care of by ethics committees established.

- **HIV/AIDS**- testing for HIV needs special consideration.
- s/b performed only on persons who are fully informed of implications of a positive result.
- Confidentiality is specially important.
- Laboratories performing human immunodeficiency virus (HIV) testing shall follow National AIDS Control Organization (NACO) guidelines, which include pre-test and post-test counselling.
- The laboratory shall not perform HIV test unless the individual has been given pre-test counselling and post-test counselling is ensured.

CONSENT

- In simple terms, it can be defined as an instrument of mutual communication between doctor and patient with an expression of authorization/permission/choice by the latter for the doctor to act in a particular way.

Types of consent

- **IMPLIED/IMPLICIT CONSENT**
- The very act of a patient entering a doctor's chamber and expressing his problem is taken as an implied (or implicit) consent for general physical examination and routine investigations.
- For most laboratory procedures, consent can be inferred when the patient presents him or herself at a laboratory with a request form and willingly submits to the usual collecting procedures,
- But, intimate examination, especially in a female, invasive tests and risky procedures require specific expressed consent

- **EXPRESSED/EXPLICIT CONSENT**
- can be oral or written.
- Special procedures, including the more invasive procedures, will require a more detailed explanation and, in some cases, written consent.
- This is desirable when there is likelihood of complications following the procedure.
- Laboratories performing human immunodeficiency virus (HIV) testing shall follow National AIDS Control Organization (NACO) guidelines, which include pre-test and post-test counselling.
- The laboratory shall not perform HIV test unless the individual has been given pre-test counselling and post-test counselling is ensured.
- Informed consent of the patient will be taken before the blood is collected

- Consent is necessary for photographing a patient for scientific/educational/research purpose or for follow up. Specific consent must be taken if the identity of the patient is likely to be revealed while publishing.
- Consent is a must for participation in clinical trials and research projects.

- **INFORMED CONSENT**
- Informed consent must be preceded by disclosure of sufficient information.
- Consent can be challenged on the ground that adequate information has not been revealed to enable the patient to take a proper and knowledgeable decision.
- Therefore, accurate, adequate and relevant information must be provided truthfully in a form (using non-scientific terms) and language that the patient can understand.
- It cannot be a patient's signature on a dotted line obtained routinely by a staff member.

- **PRE-REQUISITES**
- Patient should be competent to give consent; must be an adult and of sound mind.
- In case of children, consent must be obtained from a parent.
- In case of incapacitated persons, close family members or legal guardians can give consent.
- If a patient knowingly prefers not to get full information that attitude also needs to be respected as a part of patient's right to autonomy.

- In emergency situations, consent might not be possible and under these circumstances it is acceptable to carry out necessary procedures provided they are in patient's best interest.
- The laboratory should endeavour to see that results with serious implications are not communicated directly to the patient without the opportunity for adequate counselling.

- **DOCUMENTATION**
- It is important to document the process of consent taking.
- It should be prepared in duplicate and a copy handed over to the patient.
- It should be dated and signed by the patient or guardian, the doctor and an independent witness.
- Assisting nurse preferably should not be a witness.
- Like all other medical records, it should be preserved for at least 3 years.

Confidentiality

- **Confidentiality** is commonly applied to conversations between doctors and patients. This concept is commonly known as patient-physician privilege.
- Legal protections prevent physicians from revealing their discussions with patients, even under oath in court.