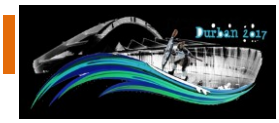
Ethics in Clinical Laboratory Practice



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IFCC Committee on Clinical Laboratory Management - http://www.ifcc.org/ifcc-education-division/emd-committees/c-clm/

Satellite Educational Workshop on Intelligent Clinical Laboratory Management: Impacts on Quality System Improvement

Hilton Durban - October 22, 2017

Presentation Outline

- Evolution of Bioethics
- Ethical guidelines in Belmont report
- Ethical issues in laboratory
  - Ethical issues in pre-analytical phase
  - Ethical issues in analytical phase
  - Ethical issues in post-analytical phase
- Ethical issues in ISO 15189

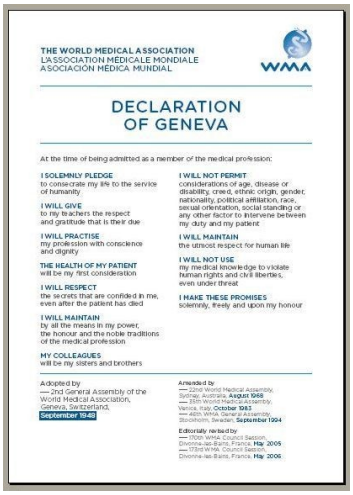
Question

What's your opinion about Ethics in Clinical Laboratory Practice ?

"Even the most rational approach to ethics is defenseless if there isn't the will to do what is right."
Alexander Solzhenitsyn"

Evolution of Bioethics

Nuremberg code (1947)



THE WORLD MEDICAL ASSOCIATION
LA ASSOCIATION MÉDICALE MONDIALE
ASOCIACIÓN MÉDICA MUNDIAL

WMA

DECLARATION OF GENEVA

At the time of being admitted as a member of the medical profession:

I SOLEMNLY PLEDGE to consecrate my life to the service of humanity.

I WILL GIVE to my teachers the respect and gratitude that is their due.

I WILL PRACTISE my profession with conscience and dignity.

THE HEALTH OF MY PATIENT will be my first consideration.

I WILL RESPECT the secrets that are confided in me, even after the patient has died.

I WILL MAINTAIN by all the means in my power, the honour and the noble traditions of the medical profession.

MY COLLEAGUES will be my sisters and brothers.

I WILL NOT PERMIT considerations of age, disease or disability, creed, ethnic origin, gender, nationality, political affiliation, race, sexual orientation, social standing or any other factor to intervene between my duty and my patient.

I WILL MAINTAIN the utmost respect for human life.

I WILL NOT USE my medical knowledge to violate human rights and civil liberties, even under threat.

I MAKE THESE PROMISES solemnly, freely and upon my honour.

Adopted by
— 2nd General Assembly of the World Medical Association, Geneva, Switzerland, **September 1948**

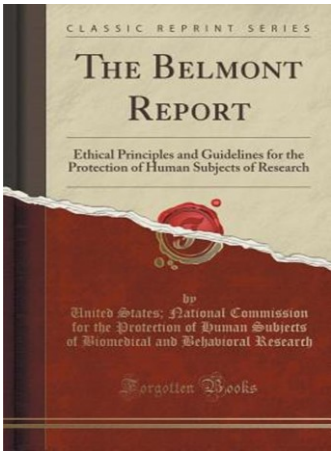
Amended by
— 22nd World Medical Assembly, Sydney, Australia, **August 1968**
— 35th World Medical Assembly, Venice, Italy, **October 1983**
— 46th WMA General Assembly, Stockholm, Sweden, **September 1994**

Editorially revised by
— 170th WMA Council Session, Divonne-les-Bains, France, **May 2005**
— 173rd WMA Council Session, Divonne-les-Bains, France, **May 2006**

Declaration of Geneva (1948)

Evolution of Bioethics

Declaration of Helsinki (1964)



Belmont Report (1978)

Evolution of Bioethics

Declaration of Geneva and the Belmont report are also applicable to the practice of clinical medicine.

The "Belmont Report" is one of the key works concerning ethics and healthcare research

- Created in 1978 by the U.S. "National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research".
- Outlines ethical principles and guidelines for the protection of human subjects.

Ethical guidelines in Belmont Report

Respect for persons

- Acknowledgement of autonomy and protection of those with diminished autonomy.

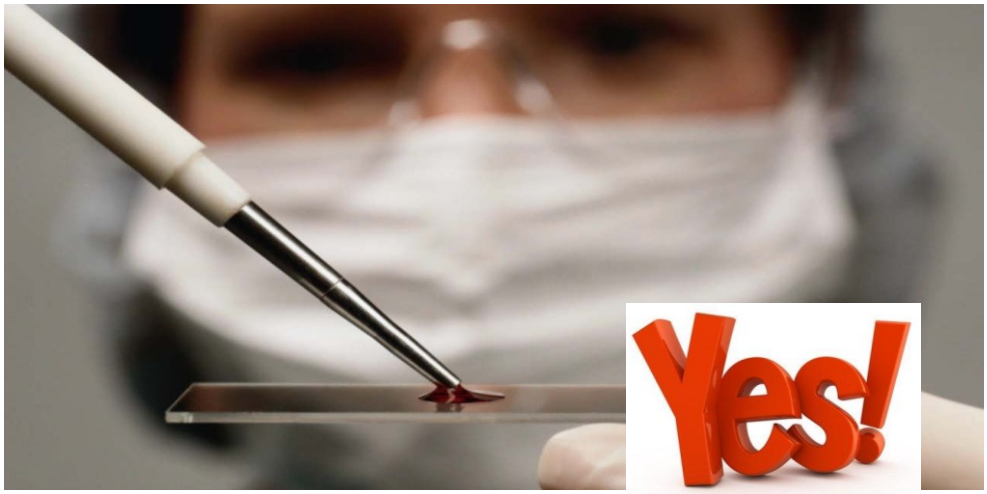
Beneficence

- The duty to act in the best interests of patients or research subjects. The goal of maximizing benefits and minimizing harm.
- Also called non-maleficence.

Justice

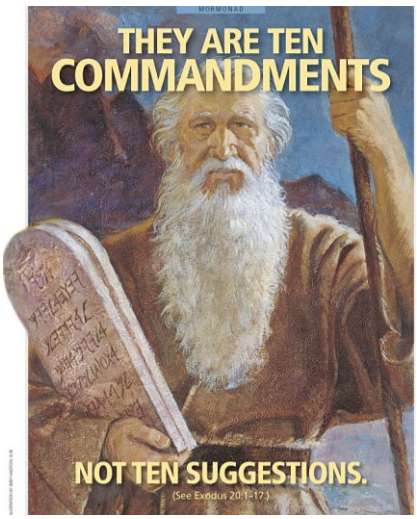
- The duty or obligation to treat patients equally and to distribute, by allocating fairly, what is rightly due in terms of benefits, risks and cost.

Does Laboratory need Ethics ?



Ethical Considerations in AACC

AACC
Improving healthcare through laboratory medicine



Ethical Considerations in AACC

1. **Uphold standards of professionalism**, be **honest** in all professional endeavours, and maintain a high level of **personal integrity**.

2. **Avoid scientific and professional misconduct** including, but not limited to fraud, fabrication, plagiarism, concealment, inappropriate omission of information, and making false or deceptive statements.

3. **Report** any health care professional who engages in fraud or deception or whose deficiency in character or competence jeopardizes patient care or other personnel.

Ethical Considerations in AACC

4. Maintain a **high level of quality** in the product(s) of professional endeavours, including validity and reliability of test results, interpretive opinions, publications, and scientific research.

5. **Respect the privacy and confidentiality** of protected health information encountered during the course of my professional activities in accordance with legal and ethical obligations.

6. **Continuously strive to augment** the professional qualifications, knowledge, and skills, and present them accurately.

Ethical Considerations in AACC

7. **Promote the safety and welfare** of patients, employees, co-workers, colleagues, the public, and the environment.

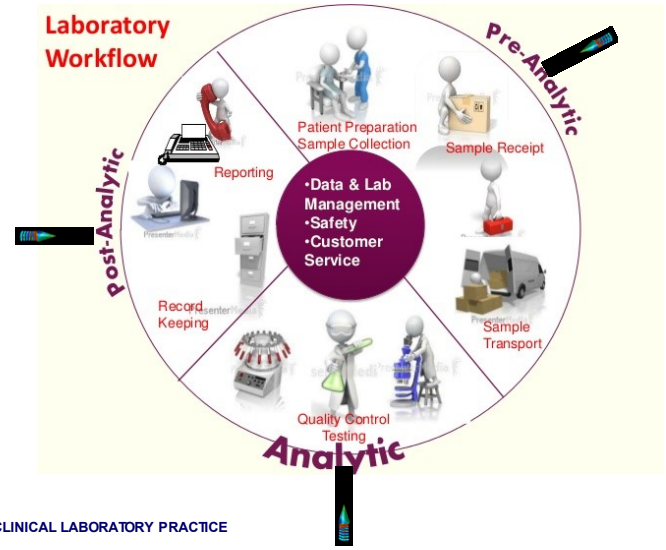
8. Avoid, or promptly disclose and work to resolve, actual or potential **conflicts of interest**.

9. **Encourage open and honest discussion among physicians**, other healthcare providers and/or facility managers regarding disclosure to patients of information about medical errors.

Ethical Considerations in AACC

10. **Comply with relevant laws** and seek to change them when they are contrary to the best interests of the patient."

Ethical Issues in Laboratory



Ethical Issues in Pre-analytical Phase

Ethical Issues in Pre-analytical Phase

The maintenance of ethical standards in the pre-analytical phase is the collaborative responsibility of the laboratory, the health care provider, researcher, phlebotomist, nurse, or whoever collects the specimen.

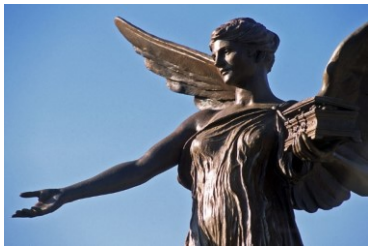
Ethical Issues in Pre-analytical Phase

Their roles include :

- Proper identification of the patient or subject.
- Collection of the appropriate sample using the appropriate technique.
- Appropriate identification and labelling of the sample so that the right tests are performed.
- Appropriate handling of the specimen until testing is performed.

Ethical Issues in Pre-analytical Phase

Applying the three principles



Ethical Issues in Pre-analytical Phase

Consent

- Consent should be informed and may be either expressed or implied.
- Expressed - Subject is asked for written or verbal agreement.
- Implied - When a patient provides a requisition and willingly sits in a collection chair and allows a sample to be taken
- Informed consent may pose an ethical problem if the patient is incompetent to make a decision due to age, mental status, or critical illness.

Ethical Issues in Pre-analytical Phase

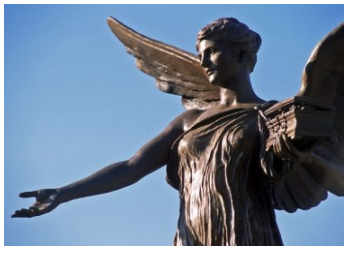
The patient's right to refuse to be tested should be respected.

- In special cases, healthcare professionals have an obligation to consult the guidelines provided by the institution in which they practice, and they must weigh the risks of loss of a patient's autonomy versus the benefits of the testing

Confidential information about patient demographics, and other test details should be given only to appropriate personnel.

- Confidentiality must be maintained at every step of the process including specimen transportation and data entry

Ethical Issues in Pre-analytical Phase



All tests should benefit the patient based on the best medical evidence.

Standard operating procedures and trained personnel should be in place to prevent any adverse events in the collection procedure.

The collection procedure should be carried out using universal precautions to protect the patient and the healthcare worker, and should be performed by properly trained personnel.

Ethical Issues in Pre-analytical Phase

- Additional specimens shall not be collected for research procedures without informed consent from the patient and approval from the appropriate ethics board.
- Specimens should be labelled with at least 2 unique identifiers, and all aliquot tubes should be similarly identified.
- Samples should be transported in a manner to preserve the integrity of the sample.

Ethical Issues in Pre-analytical Phase

- Providing access to a wide variety of laboratory tests at reasonable cost.
- Evaluating the need to introduce new tests and the opportunities to discontinue older tests when better tests are available.
- No preference given to individuals to facilitate or expedite the collection process at the expense of other patients.

Ethical Issues in Analytical Phase

Ethical Issues in Analytical Phase

Confidentiality, quality and competence are vital for all laboratories and settings

Ethical Issues in Analytical Phase

Confidentiality during the analytical phase may be almost a by-product of automation in a laboratory

Challenges of maintaining confidentiality during the analytical phase are often greater in small laboratories that perform manual testing

Ethical Issues in Analytical Phase

Applying the three principles

Ethical Issues in Analytical Phase

Patient have the right to decline to have their specimens analyzed even after the specimens have been collected and processed.

Confidentiality should be respected and maintained. In point-of-care testing, special care should be taken to maintain confidentiality as much as possible.

Ethical Issues in Analytical Phase

Good laboratory practice should involve the establishment of a rigorous quality assurance program encompassing quality control testing, proficiency testing and laboratory accreditation.

Ethical Issues in Analytical Phase

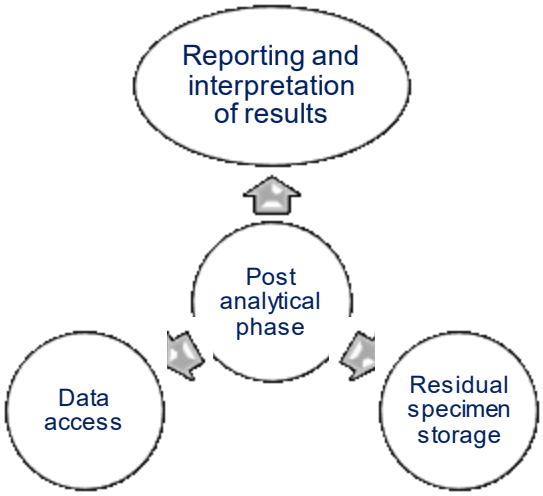
All patient samples are to be treated equally. There should not be any discrimination in the analysis of patient samples based on gender, age or racial origin is an injustice.

Laboratories should develop appropriate operating procedures for STAT/priority testing, and state which tests are included and the expected turnaround times.

It is expected that all specimens are analyzed accurately and in a timely manner.

Ethical Issues in Post-Analytical Phase

Ethical Issues in Post-Analytical Phase



Ethical Issues in Post-Analytical Phase

Laboratories should have a policy for specimen storage that is analyte dependent.

Archiving of results in either electronic or hard copy format is an important aspect of good laboratory practice. Archived documents may include:

- *request forms*
- *raw analytical and quality control data*
- *results*
- *reports.*

Ethical Issues in Post-Analytical Phase

Policies on retention and destruction of medical records and specimen retention and discard should be put in place.

Identification of authorized personnel allowed to access medical records such as doctors, patients, and laboratory staff should be documented in the policy manual.

In addition, the patient should be allowed to give consent for access by others (such as family members) as required.

Ethical Issues in Post-Analytical Phase

Applying the three principles

Ethical Issues in Post-Analytical Phase

Confidentiality of results

Ethical Issues in Post-Analytical Phase

Patients have a reasonable expectation that their samples will be used solely for the laboratory testing requested by the clinician.

Individuals have the right to decide when and if their records or specimens shall be used outside the normal medical care to which they have consented.

Ethical Issues in Post-Analytical Phase

Any further testing of residual samples should be approved by a local ethics committee or board, and patient consent may be required.

Ethical Issues in Post-Analytical Phase

Misinterpretation of results → Patient harm

Qualified personnel should interpret reports.

Ethical Issues in Post-Analytical Phase

The reporting of results should be performed in a manner such that the patient's clinician receives the right result within an appropriate time with information that allows for the correct interpretation of the results.

Ethical Issues in Post-Analytical Phase

Results should include -

- An appropriate name for the test performed
- An appropriate reference interval, which may be age and gender specific
- The unit of measurement
- A designation that the test is within or above the reference interval (when possible)

Ethical Issues in Post-Analytical Phase

Turnaround time (TAT) should be as short as possible based on laboratory conditions for that test, and achieving this TAT should not compromise validity of the results

Ethical Issues in Post - Analytical Phase

- Timely access to results.
- Provide complete information in a report
- Avoid delays
- Inform clinicians regarding any error and correct results as soon as possible

Ethical Issues in Post - Analytical Phase

- The reporting of results should be consistent for all patients.
- Rapid reporting, whenever required in special cases
- Withholding of laboratory results because the patient has not paid should be avoided.

Ethical Issues in ISO 15189

Ethical Issues in ISO 15189

Section 4.1.1.3 of the document summarizes the ethical conduct expected in laboratories.

The document states that laboratories should have in place means to ensure that:

- There is no involvement in any activities that would diminish confidence in the laboratory's competence, impartiality, judgment or operational integrity
- Management and personnel are free from any undue commercial, financial, or other pressure and influences that may adversely affect the quality of work

Ethical Issues in ISO 15189

- Where potential conflicts in competing interests exist, they shall be openly and appropriately declared
- There are appropriate procedures to ensure that staff treat human samples, tissues or remains according to relevant legal requirements
- Confidentiality of information is maintained

Summary

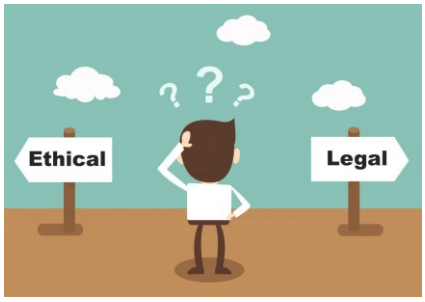
Professional personnel of a medical laboratory are bound by the ethical codes of their respective profession.

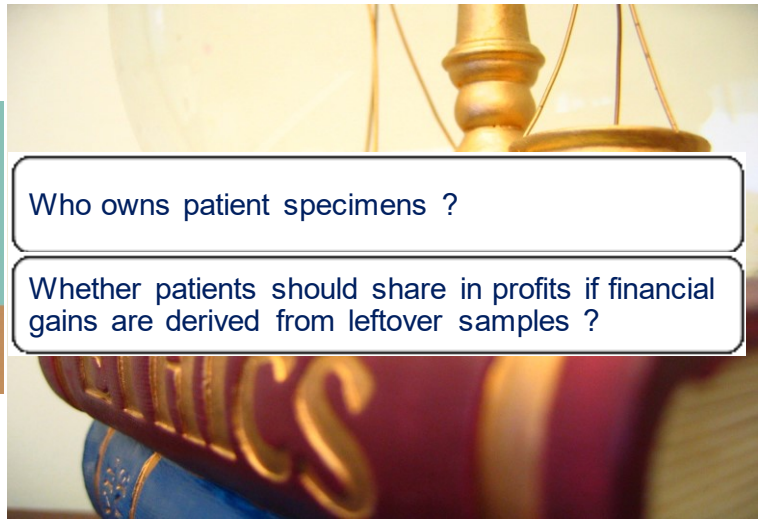
Laboratories shall not engage in practices restricted by law and should uphold the reputation of their profession

Always patient's welfare is paramount

Laboratories should try to avoid situations that give rise to a conflict of interest.

Some unanswered questions





Who owns patient specimens ?

Whether patients should share in profits if financial gains are derived from leftover samples ?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International Federation of Clinical Chemistry and Laboratory Medicine
PRIMUM NON NOCERE
First
Do No Harm
Thank you
PRAVEEN SHARMA/ETHICS IN CLINICAL LABORATORY PRACTICE
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