Biomedical Research and Ethics in Ethiopia
A Keynote Address

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I. Biomedical Research- An overview

Broadly defined, biomedical research is a multidisciplinary scientific undertaking that involves critical observing, describing measuring and manipulating of natural system to understand basic principles that might possibly lead to finding practical solutions to health problems. Its aim may be to increase fundamental knowledge and understanding of the physical, chemical and functional mechanisms of life processes and disease. Or, it might be an effort to adopt discovery of basic principles or methods of analyses, which were not necessarily focused on any specific disease or disorder, to health problems. Both basic and highly advanced methods and technologies are used in the investigation. E.G

1. In study of top 10 developments in cardiovascular and pulmonary medicine, over 40% of the research needed to realize a particular advancement was conducted by scientists whose initial goal was unrelated to the medical advancement.
2. Revolution in Molecular Biology in particular, knowledge from Genomic and proteomics has led to better understanding of disease processes and made available therapeutic procedures to many recalcitrant diseases.
3. Advances in Immunobiology have revolutionized diagnostic specificity and sensitivity for disease agents and processes; and has enhanced prospects for vaccine development to many infectious agents.
4. Advances in drug discovery has immensely benefited from progress in biomedical research.
5. Radiological, fluorescence and Enzymological phenomena and Nucleic acid replication principles, adapted for diagnosis of infectious agents, are adaptations from fundamental research. E.g., the radioimmunoassay (RIA), Immuno-fluorescence Assay (IFA), Enzyme linked immunosorbent Assay (ELISA), the polymerase Chain Reaction (PCR), etc. are good examples.

6. The adaptation of the laser beam technology for use to sort out and enumerate cells of the immune system is the most powerful technology used in HIV/AIDS and other disease research and diagnosis.
7. Advances in computer technology, progress in mathematical and statistical modeling have broadened the horizon of biomedical research and enabled to decipher complicated biological phenomena related to disease processes.

II Biomedical Research in Ethiopia

1. The present situation

The present state of biomedical research in Ethiopia, in the sense I just defined, can safely be characterized as very poorly developed, considering the relatively long history of higher education/research in the country and the multitude number of health problems the highly populous nation is faced with.

Except for the few institution that are engaged in 'research programs' on some limited diseases (EHNRI/ENARP- HIV.AIDS; AHRI/ALERT- leprosy, TB; IPB-Schistosomiasis, Leishmaniasis), the rest are 'hit-and-run' type undertakings mostly done through the Graduate programs in Addis Ababa University. There is no system of coordination of research activities in the country allowing for redundancy and overlaps in the activities of these institutions.

The source of funding of almost all the biomedical research activities is external, and the projects largely tend to be donor driven, with very limited local input. Hence, suffer from lack of sustainability. E.g. ENARP; ENDOD-based Schisto. Control Project, etc

2. Should Ethiopia support biomedical research?

It is a common knowledge nowadays that Ethiopia and all Sub Saharan African countries suffer from the "diseases of the poor'; and these diseases have seized to attract the priority concern of the rich/industrial countries and the multinationals that fund research projects. This has led to the 90:10 distortions in funding biomedical research in particular, and health research in general. That is, infectious diseases that afflict the underdeveloped world (with 90% of world population) receive only 10% of

the global funding of research while the chronic diseases and the like that are the major problems of the developed countries receive 90% or more.

A pertinent example that would shed light on the magnitude of the neglect the health problems of the poor nations are receiving can be sighted from the area on new drug discovery: Out of the 1233 new medicines patented between 1975 and 1997, barely 1% was for "Tropical Diseases", which are the "Disease of the poor".

This aptly illustrates the need for the underdeveloped countries, including Ethiopia, to develop indigenous capacity in biomedical research and initiate sustainable programs. Although efforts at manpower development in biomedical sciences have been there for over the past 25 or so years (TDR/WHO,SAREC/SIDA, etch) by and large, facilitated by the ESTC, lack of facilities/funds, the poor working atmosphere/conditions and poor remuneration, etc have been driving the trainees to the much more greener pastures in the West!

Thus, the problem of the critical mass of scientists in the diverse fields of biomedical sciences is still with us. Moreover, the question of Government commitment to support a sustainable program of research in biomedical sciences is yet to come! A crying need for a visionary leadership so that Ethiopia is not left behind in exploiting the revolution in the field of biomedical sciences is yet to find a solution!

A very fresh and pertinent example of total dependence on donor driven funding in research is what happened to the "Ethiopian AIDS Vaccine Initiative", which is now, frustrated following termination of the Netherlands government funding. The Netherlands Government was instrumental in developing the necessary capacity, which unfortunately was not complemented by Ethiopian Government sustainable commitment.

3. Can we Afford Research in Biomedical Sciences?

The question is that of whether or not we are willing to make a quality investment in the future. Thus, it is an intelligent choice to be made!

I will quote President Roosevelt's statement, which he made on inaugurating a cancer research centre at the now, NIH, about building a strong America, nearly 70 years ago:

> "…We cannot be a strong nation unless we are a healthy nation. And so we must recruit not only men and materials, but also knowledge and science in the service of national strength".

III Ethics Vs Bioethics

1. Ethics

- Deals with what is good and bad and with moral duty and obligation (Webster Dictionary). Thus, it had remained a near exclusive domain of moral philosophers and religious thinkers.
- In the profession – I refers to the principles of conduct of governing and individual or the group.

2.Medical Ethics

Focuses on doctor-patient relationship (i.e. the virtues possessed by the 'good' doctor); relationship between doctors- to the extent befitting George Bernard Shaw's remark that "all professions are conspiracies against the laity".

John Gregory (1817) sought to develop a universal moral basis for medical ethics, thus freeing it from narrow religious and parochial concerns to transcend to the "ethics of care" Traditional Medical Ethics.

These days, Medical Ethics is considered as part of Bioethics.

3. Bioethics

- The original meaning- The Science of survival, in the ecological sense; an interdisciplinary study aimed at preserving the biosphere.
- Shift in meaning-Refers to the growing interest in ethical issues arising from health care in relation to recent developments in biomedical sciences- myriads or moral questions made pressing by the emerging biomedical technologies.

- Bioethics considers issues well beyond the scope of traditional Medical Ethics (1960s and 70s- important period of cultural and social changes and activism):

    - Multi- disciplinary actors are involved in medicine, nursing, biomedical sciences, law, philosophy, economics, public policy.
    - Asks deep philosophical questions about the nature of Ethics, the value of life, what it is to be a person, the significance of being human, etc.
    - It embraces issues of public policy and the direction and control of science**.**

IV. Bioethics in Ethiopia

It is a subject of very recent awareness in Ethiopia. And the situation of Bioethics education is very poor as formal education is non existent in Ethiopia. Therefore, there is an urgent need for formal education on the basic understanding of the aims of ethical reviews. Introduction of standard documents on bioethics, such as:

i. Helsinki, CIOMS, ICH,GCP,WHO -GCP, WHO operational Guidelines,
ii. National legislations and local policies,
iii. EC's standard operating procedures must be implemented without delay.

To assist the medical practitioners and biomedical researchers to gain proper awareness about the standard documents on bioethics; to keep them informed about possible revisions and amendments of standard documents and to update them on current developments in research ethics, continuing education must be provided. This can be done by an institution of national ethical review system and voluntary civic movements on bioethics, which must link up with Regional and global partners in bioethics. E.g. Ethiopian Bioethics Initiative (ETBIN) must link up with the pan African Bioethics Initiative (PABIN), the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER), etc.

V. Ethical Review of Biomedical Research Projects

With regard to the purpose of ethical review in biomedical research, WHO in its Operational Guidelines for Ethics Committees has the following to say, "The purpose of EC reviewing biomedical research is to contribute to safeguarding the dignity, rights, safety, and well-being of all actual or potential research participants".

The two most important safeguards to achieving ethical review of biomedical research are: judicious constitution of ethical review committees and establishing an effective process the EC would follow in the review.

The critical tasks of constituting ECs and establishing a credible ethical review process can only be achieved if the principles of Independence, Competence, Pluralism and Transparency are adhered to.

- Independence- the ECs must be independent from political, institutional, researcher, funder, etc. influences,
- Competence- including members with relevant scientific expertise,
- Pluralism- committee membership must be multi-disciplinary and multi-sectoral; must "… balance age and gender distribution, and laypersons representing the interests and the concerns of the community must be included", WHO.
- Transparency- in membership recruitment; in the review and decision making process of the ECs, etc

1. The Global Situation

As a result of new challenges brought about by advances in biomedical sciences and the attendant technologies, there is a rekindling of global concern about competence and uniformity in ethical clearance of biomedical research globally. Many global initiatives (SIDCER, the NIH program on Bioethics, the MRC program, etc) organize workshops and symposia in an attempt to create awareness at the global level. The purpose is to emphasis the importance of enforcement of the various ethical codes in biomedical research, now than ever before.

The new challenges that make ethical reviews very complicated are the fact that they touch on highly sensitive issues. E.g., Research in genomics involves molecular genetic testing and screening, gene therapy, reproductive cloning, genetically modified foods and health

- Clinical drug trial and vaccine trial raise the ethical issue whereby participating communities may not be able to afford the products after trials are over.
- Nowadays trials are commercialized and conducted cheaply in low standard of health care countries.
- Commercial companies doing clinical trials and researchers usually look for lax or soft ethical clearance sites. i.e. they shop around.
- Bogus scientific researchers target Environments/countries/communities that lack competence in ethical clearance.

2. The Situation in Ethiopia

i. The conscious move by the ESTC to catch up with new developments in bioethical thinking and practices is notable.

ii. Lack of capacity in ethical clearance of projects and hence lack of confidence within the existing ethical clearance process may have forced some useful collaborative projects to move to locations/countries that are more competent.

iii. The NECC review process of project proposals is perceived as "bureaucratic, politically influenced and is lacking transparency", by some. As a result, efforts are made by researchers to avoid/bypass it in as much as possible. There is a feeling among some that researchers with good access to the NECC/the secretariat do get expedited reviews. The "preliminary screening' in practice, by secretariat, is considered to be a more involved 'filtering 'procedure than simple verification of the completeness of the research proposal document.

iv. Investigators have been heard complaining that the NECC does not provide opportunity for them to clarify issues on a face-to face basis

v. No guidelines on experimental animal use in biomedical research exist for the country.

VI. Recommendations:

1. Biomedical research capacity must be consciously built in Ethiopia ~ Improve health by benefiting from the revolution in molecular biology~ Build the future of the country.
2. Initiate a process to develop a research and researcher-friendly bioethical review system in the country.

a. The current practice of the Department of Health of ESTC serving as a Secretariat must be replaced by the NECC having its own small unit as a Secretariat to maintain its full independence.

b. The NECC through its chair must be the official correspondent with the principal investigator(s) of the proposal being reviewed.

c. NECC must not be involved in routine ethical reviews. NECC's role must be:

i. Policy-making
ii. Guidelines preparation to enforce a uniform process of ethical review in the Country,
iii. Education to the ECs and the general public,
iv. Accreditation of RECCs and IERCs (NB: NECCs can be mandated by the NECC to accredit IECCs),
v. Fund raising for promotion of bioethics,
vi. Professional and financial support to ECs and civic movements on ethics.
vii. Monitoring and evaluation EC review practices in the whole country.
viii. Review proposals that are referred to it by the ECs,
ix. Serve as a national body of appeal.

Thank you!