

Review of Research and Research Ethics in Cameroon

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Abstract: *Research comprises 'creative work undertaken on a systematic basis in order to increase the stock of knowledge of humans, culture and society, and the use of this stock of knowledge to devise new applications'. Research Ethics involves the analysis of ethical issues that are raised when people are involved as participants in research. The Cameroonian health system was developed through the colonial and post-colonial eras, which then expanded from the provision of limited services in colonial settlements to the training of Cameroonian health workers and the extension of the health network to the more rural areas. In more recent years, health policy was guided by the recommendations of the Alma Ata conference and the adoption of the primary health care model. The research priorities in Cameroon stem from the national priority programmes related to public health problems in Cameroon. These programmes were: HIV/AIDS, malaria, schistosomiasis and helminthiasis, tuberculosis, onchocerciasis, lymphatic filariasis, eradication of the Guinea worm, leprosy, trypanosomiasis, cancer, diabetes and hypertension, blindness, drugs and toxicomania. Effective review of the ethics of scientific and medical research is essential to ensure that unethical research is not permitted. Notwithstanding that, the integrity of the researcher is of critical importance. The accepted method of ensuring that unethical research is prevented is through the establishment of a system in which research ethics committees undertake independent review of scientific protocols. And so, an effective system of review of the ethical propriety of research is a crucial safeguard for participants in research. To improve on the ethical conduct of research, especially health research in Cameroon to the benefit of individuals and the Public, there is a need to identify the gaps for developing bioethics/research ethics educational programme in Cameroon in both Public and Private Institutions. Making bioethics a university requirement for all postgraduate students will be a stepping stone into knowledge and practice of Research/Bioethics in Cameroon*

Key words - Bioethics, research, Health, ethics, IRB, Cameroon.

1. INTRODUCTION:

Research is the systematic investigation into and study of materials and sources in order to establish facts and reach new conclusions. Research comprises 'creative work undertaken on a systematic basis in order to increase the stock of knowledge of humans, culture and society, and the use of this stock of knowledge to devise new applications'.

Research Ethics involves the analysis of ethical issues that are raised when people are involved as participants in research. On the other hand, Bioethics is the study of the typically controversial ethical issues emerging from new situations and possibilities brought about by advances in Biology and Medicine. It can also be viewed as the systematic study of value questions that arise in health care delivery and in biomedicine. Specific bioethical issues that have recently received national and international attention include euthanasia, assisted suicide, new reproductive technologies, cloning, human experimentation, genetic engineering, the neurosciences, abortion, informed consent, acquired immunodeficiency syndrome (AIDS), organ donation and transplantation, and managed care and other concerns in the allocation of health care resources.

In the developing world, research to find new or improved medicines and vaccines is often given high priority. In many circumstances this is appropriate, but research to find better ways of delivering existing products and services to those in need is often equally or more important. Furthermore, 'non-medical' research such as that into provision of improved sanitation, clean water, better nutrition and personal preventive measures may impact on many diseases. The control of HIV infection requires not only research on treatments and potential vaccines, but also studies of behaviour. Thus a spectrum of research may benefit developing countries, ranging from research into genetic determinants of health and disease at one end to pragmatic means of implementing effective treatments at the other (Angell, 1997; Nuffield Council on Bioethics, 1995).

The Cameroonian health system was developed through the colonial and post-colonial eras, which then expanded from the provision of limited services in colonial settlements to the training of Cameroonian health workers and the extension of the health network to the more rural areas. In more recent years, health policy was guided by the recommendations of the Alma Ata conference and the adoption of the primary health care model. These efforts to

expand the provision of health services were not matched with similar ameliorations with regards to health research, as funding for health research dropped dramatically in 1986 following a number of structural adjustments.

The National Health Research system in Cameroon is being coordinated by the government through three ministries: The Ministry for Scientific Research and Innovation (MINRESI), Ministry of Public Health (MINSANTE) and the Ministry of Higher Education (MINESUP). Among these, MINESUP is in charge of academic research, while MINSANTE and MINRESI are in charge of operational research. The Division for Health Operations Research (DROS) of the MINSANTE (established in 2003) coordinates health research in Cameroon. They are the one who define priorities, conduct clinical research, promote a wide range of research activities and participate in the dissemination of results. The DROS also overseeing administrative clearance to conduct health research in Cameroon, apart from institutional review boards (COHRED, 2008).

DROS' mission includes:

- ✓ The coordination of health research actors and activities;
- ✓ The definition of priorities according to a consultative process with all actors;
- ✓ The conduct of clinical research studies;
- ✓ The promotion of research within the hospitals, and operations research in the domains of disease control, reproductive health, and food and nutrition;
- ✓ The dissemination of research results.

In addition to an ethical clearance, all health research projects must obtain administrative approval from the DROS. Given its recent implementation just a few years ago, DROS is still in the process of organizing and coordinating health research. Therefore, the exact division of responsibilities between the MINRESI and the MINSANTE is not yet clearly defined (COHRED, 2008).

In the past, the MINSANTE worked with the Strategic Commission for Health Research (Commission Stratégique pour la Recherche en Santé) to act as a multidisciplinary consultative body. Due to financial constraints the Commission could not meet in 2007. Health research is carried out by State Universities and private universities that fall under the auspices of the MINESUP as follows:

- ✓ University of Yaoundé 1.
- ✓ University of Yaoundé 2.
- ✓ University of Douala.
- ✓ University of Buea.
- ✓ University of Dschang.
- ✓ University of Ngaoundéré.
- ✓ Catholic University of Central Africa

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2. HEALTH RESEARCH FINANCING IN CAMEROON:

Due to scarce resources, the Government of Cameroon allocates little funding to health research. For the most part, research in Cameroon is supported by bilateral and multilateral organizations (Ali *et al.*, 2006). The national budget dedicated to health research is about 0.7% of the health budget representing 0.1% of the total budget. This falls far short of the Commission on Health Research for Development's 1990 recommendation that 2% of national health expenditures be spent on health research (Commission on Health Research for Development, 1990).

In 2006 the MINSANTE directed 200,000,000 FCFA (400,000 USD) towards health research through subventions to research institutes and the Faculty of Medicine. The running budget of the DROS is approximately 90,000,000 FCFA (180,000 USD). In 2006, the overall health budget was 71,432,518,218 FCFA (154,500,600 USD). In 2006, the overall budget for the MINRESI was 5,826,069,414 FCFA, from which approximately 300,000,000 FCFA (600,000 USD) were dedicated to health research. External funds constitute the main source of funds for health research in Cameroon. In 1998/1999 they represented 82% of total health research financing in Cameroon (Mbanga G. N. and Sama M. T, 2002).

3. RESEARCH ETHICS IN CAMEROON:

Effective review of the ethics of scientific and medical research is essential to ensure that unethical research is not permitted. Notwithstanding that, the integrity of the researcher is of critical importance. The accepted method of ensuring that unethical research is prevented is through the establishment of a system in which research ethics committees undertake independent review of scientific protocols (Nuffield Council on Bioethics, 1995).

Not all research projects will have results that can be translated directly into practice: research into the natural history of a disease, or the progression of an illness, may not have any immediate practical application. Trials of a medicine may reveal that it is not as effective as expected, or is unsafe, and therefore unsuitable for general use. However, research related to healthcare is usually designed to obtain results that will lead to an improvement in the prevention, diagnosis, treatment, or cure of a disease. One issue that arises when considering whether it is appropriate to conduct a specific research study within a developing country is whether the intervention being studied is likely to be affordable in that country if it is shown to be effective (Van de Perre, 2000).

Cameroon is still in the process of embracing modern concepts and practice of bioethics, and the rate of progress is rather modest. Despite the multidisciplinary nature of bioethics, very few academic institutions in Cameroon have embraced it as a permanent subject on the curriculum and there are very few initiatives with an interest solely in bioethics. The increased incidence of health-related research, progress in molecular biology, research on genetically modified organisms (GMOs), particularly in the agricultural sector, the presence of fertility clinics, etc., have so far failed to generate or stimulate in Cameroon the sort of lively discourse, controversies, and debates that could lead to appropriate regulation and legislation as have been witnessed in other countries.

An increasing amount of research related to healthcare is being supported in Cameroon by governments, government agencies and voluntary organisations in Cameroon, in addition to international bodies such as the World Health Organization (WHO) and multinational pharmaceutical companies. While some forms of sponsorship have been altruistic, others have been driven by academic interests which may not reflect national priorities for research in Cameroon in which the research is to be conducted or by economic considerations related to the marketing of healthcare products.

As of 2010, research studies on HIV/AIDS in Cameroon had given rise to a total of 2011 scientific publications (which is partly attributable to the fact that there exist a variety of HIV strains in Cameroon (Peeters *et al.*, 2003) which the international research community finds fascinating. However, health-related research in Cameroon is not limited to HIV but includes other communicable and non-communicable diseases, as most of these diseases are endemic in Cameroon. Most of this health-related research is, however, externally funded (Nyasse, 2005).

With the ever increasing research activity going on in Cameroon (Tangwa, 2007), one would expect that research ethics should also be gaining ground in the country. And, compared to the other branches of bioethics, research ethics can indeed be said to be relatively more developed in Cameroon, but still in general terms rather rudimentary, when compared to the state of research ethics in the developed world or in other African countries, such as South Africa,

Ghana, Kenya, or Tanzania. Currently, there are initiatives aimed at building capacity in research ethics for both members of research ethics committees and researchers involved in health-related research (Tangwa, 2014).

Wherever research is conducted, not only should the quality of the research be the same, but the value and respect given to participants in research should be equal. In Cameroon, the social, cultural and economic contexts in which research is conducted often differ from region to region. Although there is broad agreement about the general ethical principles which apply to research related to healthcare, namely the duty to alleviate suffering, respect for persons, sensitivity to cultural differences and the duty not to exploit the vulnerable, there has been wide debate about the application of these principles in different research settings. Although the various international guidelines on research related to healthcare have provided some broadly based guidance, they have proved to be somewhat difficult to reconcile and apply in practice. These difficulties were highlighted by the international controversy about a series of clinical trials into the prevention of mother-to-child transmission of HIV in 1997 (Lurie *et al.*, 1997; Angell, 1997).

4. ETHICS REVIEW BOARDS IN CAMEROON:

An effective system of review of the ethical propriety of research is a crucial safeguard for participants in research. It may, however, be absent or ineffective in some developing countries. The Working Party recommends that all countries should establish an effective system for the ethical review of research, which includes the establishment and maintenance of research ethics committees that are independent of government and sponsors of research. Research

should be subject to ethical review in both the country (ies) hosting and the country (ies) sponsoring the research (Nuffield Council on Bioethics, 1995).

There are very few structures in Cameroon which can be said to be wholly or partly dedicated to bioethics issues. In fact, most of the structures that exist are in the form of research ethics committees, created in response to the needs of various researchers and research institutions but most of which are not officially recognized let alone accredited by the government. Aside from RECs, there exist a few nongovernmental and not-for-profit organizations dedicated to bioethics issues. These organizations usually have very little funding for their activities as a consequence of which their actions and sphere of influence is rather limited. The activities of these organizations vary but are mostly geared toward sensitization through training workshops or seminars and publications in journals, magazines, and newspapers. Some of these Research Ethical Committees (REC)/Institutional Review Boards (IRB) in Cameroon are shown on the table below.

SN	REC/IRB NAME	TYPE OF REC/IRB
1	Alpha Royal Clinic IRB - Alpha Royal Clinic	Institutional
2	CAMBIN Ethics Review and Consultancy Committee (ERCC) - Cameroon Bioethics Initiative (CAMBIN)	National
3	Cameroon Baptist Convention Health Board IRB (CBCHB IRB) - Cameroon Baptist Convention	Institutional
4	Cameroon National Ethics Committee - Ministry of Public Health	National
5	Comité d'Ethique du CIRCB (Centre International De Référence Chantal Biya) - Centre International De Référence Chantal Biya	Institutional
6	Faculty of Health Sciences IRB - Faculty of Health Sciences, University of Buea	Institutional
7	The Biotechnology Centre IRB - The Biotechnology Centre	Institutional
8	Tropical Medicine Research Station IRB - Tropical Medicine Research Station, Kumba, Cameroon	Institutional
9	Cameroon Bioethics Society (CBS)	Institutional
10	Reseau sur l'éthique, le Droit et le SIDA (REDS), Cameroon	National

5. ETHICAL CLEARANCE:

To get the required administrative authorization from DROS, each health research project must first obtain an ethical clearance. The clearance can be obtained from either the National Ethics Committee (Implemented in 1987) or from one of four other Research Ethics Committees that have been approved and registered at the DROS. These Research Ethics Committees are linked to the Cameroon Baptist Church (CBC), the International Centre “Chantal Biya” (CIRCB), the Faculty of Medicine of Yaoundé and the University of Buéa. The Cameroon Bioethics Initiative (CAMBIN), a branch of the Pan African Bioethics Initiative (PABIN), is establishing an Ethics Committee, as well as capacity building activities. The MINRESI is currently in the process of creating an Ethics Committee. According to the MINSANTE, many health research projects are still undertaken without any ethical and / or administrative clearance.

Submitting an Application for Ethics Clearance:

General Considerations

Researchers must complete all forms by themselves, as by signing these forms, they take responsibility for all the information.

- i. When submitting documents, the Principal Investigator is the sole responsible contact person.
- ii. No correspondence will be conducted with Pharmaceutical companies.
- iii. Communications will only be received from and directed to the Principal Investigator.
- iv. The protocol and supporting documentation must be submitted by the researcher in person.
- v. All applications must be submitted on the IRB application form

When requested, it is the responsibility of the investigator to attend the meeting of the IRB at which his/her protocol is to be considered. If this is not possible, the PI would nominate a sub-investigator to attend.

Completing the Application Form for Ethics Approval

The Application Form must be TYPED in capital and lower case. All forms to be handed in, must be completed in full and relevant signatures must be provided. Should this not be done, the evaluation process will not commence.

Copies for submission: For each submission 4 sets of the protocol and relevant documents must be submitted, unless otherwise indicated on the IRB application checklist. An electronic version must also be submitted.

Other documents to be submitted

All appendices must be stapled to the IRB Application for Review Form and properly collated in each of the copies to be submitted.

The Checklist of the IRB Application for ethical clearance clearly indicates the documents that need to be submitted. However, it is not only limited to these.

For all research:

- i. Personalised Covering letter from the Investigator
- ii. Completed Application Form for review of research protocol (4 Copies)
- iii. Copies of the research protocol (4 Copies)
- iv. Short summary of protocol (4 Copies)
- v. Participant information and informed consent document(s) (4 Copies)
- vi. Declaration of Storage of Research Data for at least 10 years
- vii. Updated Curriculum Vitae of Principal and Sub-investigator(s)
- viii. Receipt confirming payment of review fees

Where applicable:

- i. LANACOME Approval
- ii. Letter of Clearance from a Biostatistician
- iii. Principal Investigator(s) Declaration for the storage of research data and/or documents
- iv. Written approval or permission from regional public health authorities to conduct the study at a regional institution(s)
- v. Written approval or permission on official letterhead from relevant institutes, managers, principals and/or directors to conduct the study
- vi. Guardian consent form (for participants under the age of 21) (may be incorporated with assent form)
- vii. Minor assent form (for participants between the ages 7 to 20)
- viii. Data capturing sheet(s)
- ix. Questionnaires/interview schedules
- x. Insurance Certificate for research participants (for clinical trials)
- xi. Material Transfer Agreement
- xii. Data Sharing Agreement
- xiii. Any other relevant document(s)

6. CONCLUSION:

To improve on the ethical conduct of research, especially health research in Cameroon to the benefit of individuals and the Public, there is a need to identify the gaps for developing research/bioethics educational programme in Cameroon in both Public and Private Institutions. Despite the multidisciplinary nature of bioethics, very few academic institutions in Cameroon have embraced it as a permanent subject in the curriculum and there are very few initiatives with an interest solely in bioethics. Making bioethics a university requirement for all postgraduate students will be a stepping stone into knowledge and practice of research/Bioethics in Cameroon.

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