

Capacity building in health research ethics in Central Africa: key players, current situation and recommendations

Odile Ouwe-Missi-Oukem-Boyer^{a,g}, Nchangwi Syntia Munung^{b,g}, Francine Ntoumi^{c,d}, Aceme Nyika^{e,h} and Godfrey B. Tangwa^{f,g}

a Centre International de Référence Chantal Biya (CIRCB), Yaoundé, Cameroon

b University of Buea, Buea, Cameroon

c Fondation Congolaise pour la Recherche Médicale (FCRM), Faculty of Health Sciences Marien Ngouabi University, Brazzaville, Republic of Congo

d Institute for Tropical Medicine/University of Tübingen, Germany

e African Malaria Network Trust (AMANET), Dar Es Salaam, Tanzania

f Department of Philosophy, University of Yaoundé I, Cameroon

g Cameroon Bioethics Initiative (CAMBIN), Yaoundé, Cameroon

h Public Health Projects in Africa, Harare, Zimbabwe

Abstract

In the last decade, awareness of the importance of ethics in health research has dramatically increased worldwide. Central Africa, dominated by French-speaking countries, has also witnessed increasing efforts in strengthening Health Research Ethics (HRE), typically in the form of workshops, seminars, conferences, and online courses. These training activities have targeted different persons/groups implicated in health research. Also, a number of initiatives and organisations like the African Malaria Network Trust, Central African Network for Tuberculosis, AIDS and Malaria, Cameroon Bioethics Initiative, Pan African Bioethics Initiative, Réseau d'Éthique Droit et Santé and Training and Resources in Research Ethics Evaluation for Africa have spearheaded HRE capacity building efforts in the subregion.

In this paper, we report on and highlight some major initiatives aimed at building capacity in HRE in Central Africa. We discuss the current state of affairs as regards HRE in the subregion and the way forward for capacity building.

Key words: Health research ethics, Capacity building, Central Africa

Introduction

Health research is definitely important for the enhancement of public health, as it is instrumental to salutary and acceptable advances in science and medicine for diseases that highly burden a population. In Africa, a continent inundated with diseases like HIV, malaria, tuberculosis and a myriad of other neglected tropical diseases, health research is undoubtedly of rather critical importance. And, as stated in the Declaration of Helsinki, (2000, #4) [1], medical progress is based on research which ultimately must rest in part on experimentation involving human subjects. Consequently, the safety, rights and welfare of health research participants need to be adequately protected.

In the wake of research controversies/scandals, such as those connected with the highly publicised Tenofovir

trial in Cameroon [2] or the Trovan case in Nigeria [3] and other research-related mishaps, a few initiatives have been put in place to ensure the protection of research participants and the integrity of data generated from health research conducted in the Central African subregion. The Tenofovir trial in Cameroon left a blemish particularly on the history of ethical review of clinical trials in Central Africa, thereby suggesting the urgent need to build capacity in health research ethics (HRE) in the subregion.

The Central African subregion is dominated by French-speaking countries, including Cameroon, the Central African Republic, Chad, Congo Republic, Equatorial Guinea, and Gabon. However, Cameroon is officially bilingual (English and French) while Equatorial Guinea has Spanish as the first official language and French as the second. The disease profile in this region is typical of that found in most other sub-Saharan African countries and health-related research is principally in the areas of HIV/AIDS, malaria and tuberculosis. Health research is scaling up in the region as evidenced by the number of publications on health research emanating from countries in the region and the number of clinical trials currently registered by the U.S. National Institutes of Health (<http://www.clinicaltrials.gov> accessed 18 October, 2011). However, when compared to other regions in Africa, like Southern and East Africa, Central Africa is still lagging far behind in terms of investment for capacity in Research and Development [4]. Despite this lag in investment, the ever-increasing research activity in Central Africa strongly argues for an urgent need to build capacity in HRE.

Today, the exact number of research ethics committees (RECs)/institutional review boards (IRBs) in Central Africa remains essentially unknown. Based on statistics from the Mapping of African Research ethics review Capacity (MARC) project, an initiative supported by the European and Developing Countries Clinical Trials Partnership (EDCTP) and directed by the Council on Health Research for Development (COHRED) [5], it

clearly appears that, while some Central African countries have a host of RECs/IRBs, others may perhaps have just one or none at all (http://www.healthresearch-web.org/en/regulation_and_ethics_review_of_research, accessed 13 May 2012). Moreover, some of the RECs/IRBs that do exist, at least by name on paper, have remained nonoperational/nonfunctional, and this could be attributed, at least in part, to lack of adequate capacity (both human and financial) for the running of such committees.

Human and infrastructural capacity in HRE in African countries varies tremendously from country to country in spite of the fact that most of these countries have witnessed a number of initiatives aimed at building capacity in HRE. Some of these initiatives have training as their primary objective while others are involved in networking and research. Such efforts have continued to expand and a rising trend is being experienced in Central Africa. Increasingly, funding agencies seem to be taking more interest in proposals on capacity building in HRE in Africa, though it can be argued that very much still needs to be done [6]. Some of the initiatives (extinct and extant) aimed at building capacity in HRE in Africa include: the Networking for Ethics on Biomedical Research in Africa (NEBRA), the African Malaria Network Trust (AMANET), the EDCTP through funded projects like the Central Africa Network for Tuberculosis AIDS and Malaria (CANTAM) and the Training and Resources in Research Ethics Evaluation (TRREE), the Cameroon Bioethics Initiative (CAMBIN), the Pan African Bioethics Initiative (PABIN), amongst others. In this paper, we discuss some of the key actors (initiatives) of capacity building in HRE in Central Africa, and the impact of some of these initiatives. Furthermore, we look at the current state of HRE to identify some of the causative factors for the sluggishness of the subregion by comparison with other regions in Africa and, finally, we attempt to make some recommendations that could improve the situation and move things forward.

Complementary capacity building activities by various players

Pan-African Bioethics Initiative

One of the earliest initiatives on capacity building in HRE that included Central African countries is that of the Pan-African Bioethics Initiative (PABIN). PABIN (www.pabin.org), a Pan-African organisation created in 2001, has the fundamental aim to strengthen research ethics awareness and discussion across the African continent, through the development of strong national ethical review systems as well as providing regional Good Clinical Practice (GCP) standards and training. In its third meeting (28–30 April, 2003), which was attended by several participants from Central Africa (mainly from Cameroon), the need to strengthen capacity in HRE was appreciated and emphasised. In

2006, the PABIN secretariat, through funding from the WHO/TDR, launched the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER) recognition programme in Africa. The objective of the SIDCER programme is to contribute to human subject protection globally by developing capacity in ethical review and the ethics of health research. This is achieved through certificate-based recognition of ethics committees based on: structure and composition of the ethics committee, adherence to specific policies, completeness of its review process, postreview process and documentation, and archiving [7]. SIDCER operates in Asia and the Western Pacific (FERCAP), Latin America (FLA-CEIS), the former Russian States (FECCIS), North America (FOCUS) and in Africa (PABIN). Through the SIDCER programme, ethics committees have undergone assessment and recognition in Ethiopia, Zanzibar, Madagascar, Uganda, Liberia and the Democratic Republic of the Congo, and plans are underway to extend the programme to the Central African subregion.

Networking for Biomedical Research in Africa

A second initiative, the Networking for Biomedical Research in Africa (NEBRA) project (2005–2006), funded by the European Commission, included 14 African countries amongst which were Cameroon, the Central African Republic, Congo Republic and Gabon. In its 2006 report, NEBRA indicated that HRE in Central African countries is lagging behind. The report for Cameroon showed a highly centralised ethics review system. In the Central African Republic, as of 2006, a ministerial approval for a national ethics committee was pending and in the absence of a functional Research Ethics Committee (REC), ethics approval for research in the country could only be obtained from the Ministry of Health and a relevant expert committee. Similarly there was no legislation regulating human subjects research. The Congo Republic had neither an ethics review structure in place nor specific legislation on research involving humans. The report for Gabon indicated that there was a national ethics committee in addition to other institutional committees, though the NEBRA survey revealed that the national committee had never been operational. Based on the results of the survey, NEBRA then recommended that participating countries elaborate a national strategic plan for the strengthening of ethical review of research.

African Malaria Network Trust

The African Malaria Network Trust, AMANET, (www.amanet-trust.org) through funding from, amongst others, the Bill and Melinda Gates Foundation and the EDCTP, embarked on strengthening HRE in Africa. In order to address effectively the needs of ethics committees on the ground, AMANET conducted a needs assessment survey, which identified existing gaps in terms of ethical review processes in Africa [8]. The AMANET survey included three Ethics Committees in Cen-

tral Africa (two in Cameroon and one in Gabon). Based on the findings of the survey, AMANET implemented interventional capacity building activities tailor-made to address identified gaps.

AMANET capacity building activities included a series of training workshops on Basic HRE, Advanced HRE and GCP, which were held in various African countries. Although some members of RECs and researchers from Cameroon, Gabon and Republic of Congo benefited from these workshops, no participants were drawn from the other countries in the Central African subregion. Some of the workshops were organised in the Central African countries of Cameroon and the Republic of Congo. Having realised that the demand for training in HRE was overwhelming and could not be tackled through face-to-face workshops alone, AMANET developed four freely available web-based courses, namely, Basic HRE in English, Basic HRE in French, Advanced HRE in English and GCP in English (<http://webcourses.amanet-trust.org/> accessed 13 May 2012). Table 1 shows that 3 countries from the Central African region, namely Cameroon, Gabon and Republic of Congo, responded to the web-based courses.

As revealed by the needs assessment survey, most Ethics Committees lacked basic needs such as offices, dedicated staff, computers, chairs, telephones, fax machines, Internet, secure filing cabinets and other sundries that are generally taken for granted in developed countries. Consequently, AMANET awarded competitive capacity building subgrants of US\$ 50,000 each to twenty Ethics Committees in Africa. Out of the 20 subgrantees, three committees were in Central Africa (two in Cameroon and one in Gabon). In an effort

to promote debate and sharing of ideas, AMANET also developed a bilingual (English and French) online HRE discussion forum, which enabled interactive discussion of real-life ethical challenges encountered in the field. With the Hub of AMANET in Tanzania, a Sub-Hub was established at the Cameroon Bioethics Initiative (CAMBIN) to provide an effective interface between Anglophone and Francophone African countries.

Training and Resources in Research Ethics Evaluation

Training and Resources in Research Ethics Evaluation (TRREE) is another initiative involved in capacity building in HRE in Africa. The aim of TRREE is to provide basic training, while building capacities in the ethics of health research involving humans (<http://elearning.trree.org/mod/resource/view.php?id=70>, accessed 21 October, 2011). Like AMANET, TRREE also has free online courses in HRE in English, Portuguese, and French. This certainly should be of interest to Central African countries since the region is dominated by French-speaking countries. It is therefore likely that researchers and individuals in the subregion, interested in HRE have taken at least one of the TRREE modules on HRE (Table 2). Again, there is an unbalanced situation between Cameroon, Gabon and Republic of Congo, and the other Central Africa countries. Also, the module 3 of the TRREE e-resource has a collection of country legislations, regulations and guidelines, on health research. Cameroon greatly benefited from this specific module, as can clearly be seen from the fact that the country championed the number of TRREE registrations in the region.

Central African Network for Tuberculosis, HIV/AIDS and Malaria

The Central African Network for Tuberculosis, AIDS and Malaria (CANTAM) is the first EDCTP-funded Regional Network of Excellence initiative. The main objective of CANTAM is to strengthen capacities for the conduct of high quality clinical trials on tuberculosis, HIV/AIDS and malaria in Central Africa. Amongst other objectives, CANTAM strives to build capacity of ethics review committees and health regulatory authorities in the subregion. CANTAM involves partners in three (Cameroon, Gabon, Republic of Congo) of the six countries in the region, while one of its partners, Organisation de Coordination pour la lutte contre les Endémies en Afrique Centrale (OCEAC; <http://www.OCEAC.org>) is an organisation involved in the coordination of health research in the Central African subregion. In the Republic of Congo and until 2011, there was only one institutional ethics committee dealing with health research projects. In 2010, CANTAM organised a five-day capacity building workshop for members of RECs/IRBs and National Regulatory Authorities in Central Africa

Table 1: Numbers of candidates who successfully completed AMANET web-based courses as of December 2011

Country	English Basic HRE	French Basic HRE	Advanced HRE	GCP
Cameroon	57	20	45	56
Central African Republic	0	0	0	0
Chad	0	0	0	0
Equatorial Guinea	0	0	0	0
Gabon	5	5	3	47
Republic of Congo	0	2	3	2

Table 2: Numbers of candidates who registered for the TRREE web-based courses as of May 2012

Country	TRREE
Cameroon	268
Central African Republic	2
Chad	3
Equatorial Guinea	NA
Gabon	5
Republic of Congo	39

(in collaboration with AMANET and the CAMBIN) and two others on GCP (in Brazzaville in collaboration with AMANET) and Good Clinical and Laboratory Practices (in Yaoundé in collaboration with the Chantal Biya International Reference Centre for Research on HIV/AIDS Prevention and Management of HIV (CIRCB) and AMANET). Against this background, the Congolese Foundation for Medical Research (FCRM) then established an institutional committee, which is now the second in the country. In view of developing the culture of research, the FCRM strongly recommends that its entire staff be trained using AMANET and TRREE free web-based courses (<http://www.cantam.org/content/networking> accessed 13 May 2012). Moreover, it set up a platform for the exchange of knowledge on HRE at the Faculty of Health Sciences in Brazzaville, in which ethicists from Cameroon were invited to present their experience and challenges in building HRE.

The above-mentioned initiatives highlight some of the efforts made in building capacity in HRE in Central Africa. While these initiatives have been a strong force in a region that, by comparison with other regions of Africa, is clearly lagging behind in terms of HRE, it may be worthwhile to look at the situation of HRE in each Central African country.

Current ethical review processes in Central Africa

Cameroon

Cameroon is probably one of the very first African countries to have established an ethics review committee. It is also perhaps the only country in the Central African subregion that has some minimal information on existing RECs/IRBs. The very first ethics committee in Cameroon was created as far back as 1987. However, 20 years after, the country has experienced relatively little advancement in the area of HRE [9] when compared to some other African countries that established ethics committees later than Cameroon. In 2006, it was reported that Cameroon's ethics review system was highly centralised with its national ethics committee playing both an advisory role and being involved in protocol review (NEBRA, 2006). Today, the country plays host to approximately 19 different structures for research ethics review, most of which have reviewed at least one protocol, to go by information based on published research articles [10]. The situation reported by NEBRA remains essentially the same and it has been recommended that the national ethics committee in Cameroon should rather play an advisory and supervisory role and not get involved in protocol review [9].

Very recently, a new governmental text has been adopted «On the creation, organisation and functioning of Ethics Committees for research on human health within institutions related to the Ministry of Public Health» (Ministerial Decree No.0977/A/MINSANTE/

SESP/SG/DROS of April 18, 2012), thereby abrogating the 1987 Ministerial Decision «On the Creation and Organisation of an Ethics Committee Regulating All Research Involving Human Beings» (Ministerial Decree No. 079/A/MPH/DS of October 22, 1987). In the near future, the landscape of RECs in Cameroon is probably going to evolve somewhat, as the Ministry of Public Health will now host a new «National Ethics Committee», and several regional and institutional ethics committees for structures and institutions that fall under the Ministry of Public Health. These structures include hospitals, medical schools/faculties and some research institutions. However, in the nearest future, a problem is likely to arise with this new ministerial decision, as institutions under other ministries actively involved in health research (e.g. the Ministries of Scientific Research and Technological Innovation, Higher Education, Environment and Nature Protection) may also feel the need to come out with texts governing research ethics review in their respective institutions. This may lead to a scenario whereby several «National» Ethics Committees exist in the country. The fundamental problem of HRE in Cameroon therefore clearly seems to remain that of the absence of an overarching country-wide framework [9] that takes into consideration the diversity of ethics review structures necessitated by the complex and diverse nature of the country itself.

Since 2003, workshops on HRE have been organised in Cameroon by different bodies, mostly AMANET (in partnership with CAMBIN), the Cameroon Bioethics Society, CIRCB, CAMBIN, the Ministry of Scientific Research and Innovation, the Ministry of Public Health, the former National Ethics Committee and the Réseau d'Éthique Droit et Santé (REDS). Members of ethics committees in Cameroon have also attended workshops across the globe on capacity building in HRE. However, workshops for ethics committee members held in Cameroon have principally been attended by members of just a few ethics committees, indicating that members of a majority of other committees might still need training. Interestingly, capacity building workshops on HRE in Cameroon have also targeted investigators, lawmakers and the civil society. One of such conferences was organised by PABIN and held at the Cameroon National Assembly, where lawmakers were exposed to HRE and the need for regulations governing research involving humans. There is likewise the emergence of non-governmental organisations with a focus on HRE in particular and Bioethics in general. From this, it is clear that many stakeholders are taking an interest in promoting HRE in the country. Principally, there are three legislations/regulations governing health research in Cameroon and the code of ethics, which the NEBRA reported in 2006 to be in progress, is not yet in the public domain.

So, though efforts have been made in Cameroon, much still needs to be done. In particular, vigorous efforts need to be targeted towards the training and continu-

ous education of members of ethics committees, the development of adequate legislation governing research and the training and sensitisation of researchers on research ethics. As argued by Chima, it is irrational to have many local RECs if there are no effective national or regional policies to guide them [11]. Recently, two Cameroon-based institutions (the former «National Ethics Committee» and CAMBIN) received funding from the EDCTP to build capacity in HRE. The former «National Ethics Committee», through the EDCTP-funded project will upgrade the infrastructure of the committee, train members of ethics committees and investigators in Cameroon, update the standard operating procedures of the Ethics Committee, improve upon the process of protocol review and monitor the implementation of approved protocols ([http://www.edctp.org/Project_Profiles.245.0.html?&no_cache=1&tx_viprojects_pi1\[action\]=show_project&tx_viprojects_pi1\[id\]=158&no_cache=1](http://www.edctp.org/Project_Profiles.245.0.html?&no_cache=1&tx_viprojects_pi1[action]=show_project&tx_viprojects_pi1[id]=158&no_cache=1), accessed June 01 2012). On the other hand, CAMBIN will assess the needs of RECs/IRBs in the Central African subregion and design a training package suitable for the training needs of the committees in the subregion. It will also build the capacity of the CAMBIN ethics review and consultancy committee.

Central African Republic

The Central African Republic, to the best of our knowledge, and at the time of writing, currently has one functional REC, called the Comité Scientifique de Validation des Protocoles et Résultats de la Recherche en Santé (CSVPRS) (http://www.healthresearchweb.org/en/central_african_republic/ethics_2116 accessed 13 May, 2012). The NEBRA project and Effa et al., in a publication on ethics committees in West and Central Africa [12] had reported the possible creation of an ethics committee in 2005, but it appears that it was only recently that one was created. This might explain why there is little or no activity on capacity building in HRE though health research and clinical trials are obviously going on in the country. Previously, ethics approval for clinical trials in this country was obtained from the Ministry of Public Health [12]. Currently, this seems to be the task of the CSVPRS, whose members do not seem to require specific training in ethics review of research nor continuous education in research ethics.

Chad and Equatorial Guinea

In the Central African subregion, Chad and Equatorial Guinea appear not to have any RECs and might still be virgin areas for organisations involved in capacity building in HRE in Africa. To the best of our knowledge, there is little or no literature on research ethics in these two countries and, in 2005, it was stated that there was no national research bioethics committee in Chad [13]. The NEBRA study does not seem to have included either country. Equally, these two countries do not seem to have had any participants in any of the AMANET

workshops nor has anyone from these countries completed any of the AMANET courses on HRE. Marginally, one participant from Chad is indicated as attending the GCP workshop (organised by CANTAM in Brazzaville in collaboration with AMANET in 2009) and three individuals registered on the TRREE web-based course can be identified as based in Chad. Surveys involving RECs in Africa [8, 14, 15] equally say nothing on HRE in these countries. There appear to have been plans to establish an ethics committee in Chad in 2008, when UNESCO together with some stakeholders in Chad had a meeting in N'Djamena to discuss the possibility of establishing a national bioethics committee in Chad (unesdoc.unesco.org/images/0018/001895/189548e.pdf accessed 25, October 2011), but up to this moment, the existence of a committee is nowhere apparent. More recently (2010/2011), CAMBIN has participated in the MARC project, mapping HRE committees in Franco-phone Africa [5], and despite several contacts and attempts, no REC or IRB could be mapped in Chad (<http://www.healthresearchweb.org/en/chad/ethics> accessed 13 May 2012). In the near future, however, the OCEAC plans to set up and host an ethics committee for Central African countries, and help Chad and Equatorial Guinea to establish their own national ethics committees (Hélène Degui, personal communication).

Gabon

The situation of HRE in Gabon would seem better than that in Chad, Equatorial Guinea and even Cameroon, considering that great progress seems to have been made within a very short period. In 2005, it was reported that Gabon had no national structure for ethics review but that there were two research ethics committees in Gabon, both located at the Centre International de Recherche Médicale de Franceville (CIRMF); one for animal research and the other for human subjects research [12]. This would seem to indicate that Gabon is the only country in the Central African subregion that has/had an operational animal ethics committee. However, the institutional ethics committee for animal research called «Comité d'Ethique et de Contrôle de l'Usage des Animaux» seems to have been functional only for a short period of time, in the years before 2000. Later on, the CIRMF instead used an international ethics committee dealing with animal experimentation to get ethics approval for animal research (Pierre Rouquet, personal communication). As far as the ethics committee for human subjects research is concerned, and to the best of our knowledge, this committee has always been virtual. In 2006, NEBRA in its final report indicated the «apparent» existence of a National Ethics Committee in Gabon.

An EDCTP-funded project called TEACRA (Training on Ethical Aspects of Clinical Research for members of African national ethics committees and for African physicians/investigators) also attempted research ethics capacity building for some countries in the subregion.

This project had Gabonese researchers at the forefront of building research ethics capacity in Gabon. The TEACRA project (2006–2008), spearheaded by the Vienna School of Clinical Research, organised a number of training courses in HRE in collaboration with the Medical Research Unit of the Albert Schweitzer Hospital in Lambaréné, Gabon. The first two workshops (Les Aspects Ethiques de la Recherche Clinique, Ethical Aspects of Clinical Research) were organised in 2007 (<http://www.uni-tuebingen.de/delta/daten/training/Lambarene%20report%202007.pdf>- Accessed 27 October 2011) and 2008 («Ethical Aspects of Clinical Research – The role of the Ethics Committee in the light of relevant regulations» (http://www.uni-tuebingen.de/delta/daten/training/agenda_Ethics_2008.pdf accessed 27 October 2011)). The 2007 workshop was organised for future members of the National Ethics Committee, which was eventually created in 2007. Worthy of note is the fact that, though some of the TEACRA workshops included researchers from other African countries, they were all held in Gabon. Gabon has therefore been able to make remarkable progress in research ethics. In March 2009, with support from the ABC project («Assisting Bioethics Committees») from UNESCO (<http://unesdoc.unesco.org/images/0015/001559/155952e.pdf>) and the help of a grant from the EDCTP (<http://www.edctp.org/Announcement.403+M57c9a8e620a.0.html>, accessed 13 May 2012), Gabon was able to establish an operational National Ethics Committee called the «Comité National d’Ethique de la Recherche (CNER)». Surprisingly enough, however, in the same year 2009 and month, the Gabonese Government, through its Minister of Health, proceeded to create a second National Ethics Committee, called the «Comité d’Ethique pour les Sciences de la Vie et de la Santé (CESVS)», with a similar mandate to that of the CNER. Despite a very confusing situation, the CESVS, however, seems never to have been functional, and the CNER is the only operational National Ethics Committee (Pierre-Blaise Matsiegui, personal communication). In 2010, the CNER was awarded a second grant from the EDCTP aimed at strengthening the National Ethics Committee (CNER) in Gabon and creating a Central African Ethics Committee Network. This capacity building grant is still ongoing. (http://www.edctp.org/fileadmin/documents/our_work/EDCTP_project_portfolio.pdf).

Republic of Congo

Following a 2002 ethics workshop in Libreville, Gabon, organised by AMANET and PABIN, the Congolese minister of health mandated a group of individuals to draft recommendations on ethics committees in the Congo [12]. In 2006, NEBRA, reported that there existed no operational REC in the Congo and that the Congo had no existing national legislation pertaining to the conduct of biomedical research. Five years after the Libreville workshop, the Republic of Congo established its

first institutional ethics committee (Comité d’Ethique de la Recherche en Sciences de la Santé, CERSSA) created by the «Délégation Générale de la Recherche», in 2007, though it only became functional in 2009. In 2009, CANTAM initiated an audit of the CERSSA, and came up with a few recommendations, among which the lack of visibility of the committee was raised and the need for a grant to support training of members of the committee was underlined. As a consequence, in 2011, with the support of CANTAM, the CERSSA organised the first «Days of Bioethics» in the Congo, with the objective of promoting good research ethics practice amongst Congolese researchers, research institutions and the public. In early 2012, the Fondation Congolaise pour la Recherche Médicale (FCRM) created its own institutional ethics committee. This committee receives support for training and logistics from the FCRM. Within a few months this new IRB has become operational and has already reviewed several protocols. Congolese researchers and members of institutional ethics committees in the Congo have participated in AMANET and CANTAM workshops and also taken the AMANET and/or TRREE online courses. Equally, the CERSSA was recently awarded a capacity building grant of the EDCTP (http://www.edctp.org/Newly_signed_grants.500.0.html, accessed 11 June 2012), hence addressing most of the recommendations made during the 2009 audit.

Discussion and Recommendations

With the intense health research activity going on in the region and plans to begin sites for clinical trials for HIV, malaria and tuberculosis in many countries in the subregion, capacity building in HRE in Central Africa can no longer be sidelined. The last five years have seen efforts to build capacity in HRE in the subregion but such efforts have so far had little impact. Whilst the fact that the subregion is predominantly French-speaking might be a hindrance to many organisations and institutions wishing to build capacity in HRE in Africa, there are currently a number of organisations aiming to promote HRE in the subregion and in Africa at large. Despite this, funding for capacity building in HRE in Central Africa is clearly rudimentary when compared to funding in other regions like Southern and Eastern Africa. It is therefore not clear whether the funding bodies have received few grant applications from the region or whether these agencies have little interest in building such capacity in the subregion.

Whichever the case, bioethics and research-related organisations and institutions in the subregion need to spearhead the development of research ethics in the region and to mobilise funds for such activities. As far as the EDCTP is concerned, however, increasing support towards this region has to be acknowledged, with grants awarded to Ethics Committees in Gabon, Repub-

lic of Congo and Cameroon. Principal investigators and sponsors of clinical trials in countries in the subregion need to have a budget line for building capacity in HRE at the trial sites. Equally, besides universities and government-owned research centers, the subregion plays host to a number of big research institutions, including but not limited to, the Institut Pasteur International Network, l'Institut de Recherche pour le Développement and OCEAC. Considering that these organisations are actively engaged in health-related research, they need to be the vanguards of HRE promotion in the subregion. There is also a need for the governments of Central African countries to take interest in HRE and to promote capacity building in HRE in their respective countries as well as the subregion as a whole.

Legislation governing biomedical research involving humans is absent in almost all the countries in the subregion and the need to develop such legislation is of primary importance. Guidelines for such legislation are readily available in existing guidelines and regulations and can easily be adapted to the situation of the individual countries [11, 16] in the subregion. Such legislation should clearly define how RECs would be created considering that with the current state of affairs of ethics committees in the Central African subregion, a scenario whereby several «National» Ethics Committees exist in the country is likely to arise in the not too distant future.

The ever increasing health-related research in Africa calls for a proportionate rise in the setting up of functional health research oversight/governance structures and mechanisms [16]. One such structure that urgently needs to be put in place in all countries involved in health research is the Ethics Review Committee. In the Central African subregion, while some countries have at least a functional REC, others are yet to set up an ethics committee. Capacity building efforts for research ethics in Central Africa therefore need first and foremost to focus on identifying the needs of already existing RECs in the subregion, the establishment of at least a REC in each country in the region, training of REC members on the development of standard operating procedures (SOPs), assisting them in developing SOPs for their respective committees, training REC administrators on the overall day-to-day running of the activities of ethics committees, organisation of short training workshops on HRE to meet the needs of investigators and, above all, the introduction of research ethics in the curriculum of social science and health science education in universities in the subregion. Once these are achieved, the subregion might then be in a position to promote good practice of research ethics amongst all stakeholders involved in health-related research.

Equally recommendable is the need for networking between institutions charged with promoting HRE in the subregion. Such networking could easily provide a platform for debates on the common needs of research oversight structures, source funding for training in re-

search ethics, act as an interface between the various stakeholders involved in promoting health research and advocate good practice of HRE in the subregion.

Conflict of interest: The authors received support from CANTAM (Central Africa Network on Tuberculosis, HIV/AIDS and Malaria funded by EDCTP).

Acknowledgement: We are grateful to Pr. C. Boundja (Institutional ethics committee for FCRM) for his helpful contribution. We are also thankful to Drs Pierre Rouquet, Hélène Degui and Pierre-Blaise Matsiegui for the shared information. CAMBIN currently holds a grant from the EDCTP. The funders played no role in the writing of this manuscript.

Zusammenfassung

Aufbau und Etablierung einer Ethik der Gesundheitsforschung in Zentralafrika: Hauptpersonen, aktuelle Situation und Empfehlungen

In den letzten zehn Jahren ist die Wahrnehmung für die Dringlichkeit einer Ethik der Gesundheitsforschung weltweit dramatisch gestiegen. Anstrengungen zur Etablierung einer Ethik der Gesundheitsforschung – normalerweise in Form von Workshops, Seminaren, Konferenzen und Online-Kursen – waren auch im von französischsprachigen Ländern dominierten Zentralafrika zu verfolgen. Die Ausbildungsbemühungen richteten sich an unterschiedliche im Bereich der Gesundheitsforschung tätige Personen und Gruppierungen. Aktivitäten zur Etablierung der Forschungsethik in dieser afrikanischen Subregion gingen unter anderem von Initiativen und Organisation aus wie dem «African Malaria Network Trust», dem «Central African Network for Tuberculosis», von «AIDS and Malaria», der «Cameroon Bioethics Initiative» und der «Pan African Bioethics Initiative», dem «Réseau D'Éthique Droit et Santé» und dem Programm «Training and Resources in Research Ethics Evaluation for Africa». In dem vorliegenden Beitrag beleuchten wir einige Initiativen zum Aufbau und der Etablierung einer Ethik der Gesundheitsforschung in Zentralafrika, diskutieren den Status quo und fragen nach zukünftigen Entwicklungsmöglichkeiten.

Résumé:

Le renforcement des compétences en matière d'éthique de la recherche en santé en Afrique centrale: acteurs-clés, état des lieux et recommandations

Au cours de la dernière décennie, l'importance des questions d'éthique de la recherche en santé a été largement reconnue au niveau mondial. Des efforts importants visant au renforcement des connaissances dans ce domaine ont aussi été réalisés en Afrique centrale, qui est composée d'une majorité de pays francophones. Ils ont pris la forme classique de séminaires de travail, de conférences et de cours en ligne. Ces activités de formation ont été destinées à différents groupes

et personnes engagés dans la recherche en santé. Dans cette partie de l'Afrique, un certain nombre d'initiatives et d'organisations sont à l'origine de ces activités visant au renforcement des compétences dans le domaine de l'éthique de la recherche en santé. Il s'agit notamment des organisations et initiatives suivantes: African Malaria Network Trust; Central African Network for Tuberculosis, AIDS and Malaria; Cameroon Bioethics Initiative; Pan African Bioethics Initiative; Réseau d'Éthique Droit et Santé; Training and Resources in Research Ethics Evaluation for Africa. Dans cet article sont présentées et détaillées certaines des initiatives principales dont le but est la formation des compétences dans ce domaine. La place de l'éthique de la recherche en santé dans cette partie de l'Afrique est analysée et des recommandations pour le renforcement des capacités sont formulées.

Correspondence

Dr. Odile Ouwe Missi Oukem-Boyer
 Centre de Recherche Médicale et Sanitaire (CERMES)
 PO Box 10887, Niamey
 Niger

E-Mail: oukem[at]cermes.org

Manuscript submitted: 14.8.2012
 Revisions submitted: 23.11.2012
 Accepted: 28.12.2012

References

1. The World Medical Association. Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects. 2008
2. Mills EJ, Singh S, Singh JA, Orbinski JJ, Warren M, Upshur RE. De-

- signing research in vulnerable populations: lessons from HIV prevention trials that stopped early. *BMJ* 2005;331:1403–6.
3. Nigerians sue Pfizer over test deaths. Available at: <http://news.bbc.co.uk/2/hi/business/1517171.stm> (Accessed on 10 December 2012).
4. Nwaka S, Ilunga TB, Da Silva JS, Rial Verde E, Hackley D, De Vre R, et al. Developing ANDI: a novel approach to health product R&D in Africa. *PLoS Med.* 2010;7(6):e1000293.
5. Ijsselmuiden C, Marais D, Wassenaar D, Mokgatla-Moipolai B. Mapping african ethical review committee activity onto capacity needs: the marc initiative and hrweb's interactive database of recs in Africa. *Dev World Bioeth.* 2012;12(2):74–86.
6. Ogundiran TO. Enhancing the African bioethics initiative. *BMC Med Educ.* 2004;4:21–3.
7. Pan African Bioethics Initiative. Strategic Initiative for developing Capacity in Ethical Review (SIDCER). Newsletter of PABIN. 2007; 001(1):5–6.
8. Nyika A, Kilama W, Tangwa GB, Chilengi R, Tindana P. Capacity building of ethics review committees across Africa based on the results of a comprehensive needs assessment survey. *Dev World Bioeth.* 2009;9(3):149–56.
9. Tangwa GB, Munung NS. Sprinting research and spot jogging regulation: the state of bioethics in cameroon. *Camb Q Healthc Ethics.* 2011;20(3):356–66.
10. Munung NS, Che CP, Ouwe-Missi-Oukem-Boyer O, Tangwa GB. How Often are Ethics Approval and Informed Consent Reported in Publications on Health Research in Cameroon? A Five-Year Review. *J Empir Res Hum Res Ethics.* 2011;6(3):93–7.
11. Chima SC. Regulation of biomedical research in Africa. *Bmj.* 2006; 332(7545):848–51.
12. Effa P, Massougbdji A, Ntoumi F, Hirsch F, Debois H, Vicari M, et al. Ethics Committees in Western and Central Africa: Concrete Foundations. *Developing World Bioethics.* 2007;7:136–42.
13. Kirigia JM, Wambebe C, Baba-Moussa A. Status of national research bioethics committees in the WHO African region. *BMC Med Ethics.* 2005;20(6).
14. Ateudjieu J, Williams J, Hirtle M, Baume C, Ikingura J, Niare A, et al. Training needs assessment in research ethics evaluation among research ethics committee members in three African countries: Cameroon, Mali and Tanzania. *Dev World Bioeth.* 2010;10(2):88–98.
15. Nyika A, Kilama W, Chilengi R, Tangwa G, Tindana P, Ndebele P, et al. Composition, training needs and independence of ethics review committees across Africa: are the gate-keepers rising to the emerging challenges? *J Med Ethics.* 2009;35(3):189–93.
16. Noor RA. Health research oversight in Africa. *Acta Trop.* 2009; 112(1):19.