EDITORIAL
MEDICAL AND RESEARCH ETHICS IN ETHIOPIA

Since the time of Hippocrates, medical ethics has been a priority topic on medical care and research. In the past few years medical care service and research in Ethiopia are increasing both in volume and type, accompanied with expansion of private health care services and expansion of higher education and research institutions. Like many other developing countries, however, bioethics is a young and new topic in Ethiopia and is mainly focused on medical research ethics, with some components of medical care. With this, medical malpractices and ethical errors on research involving human participants are believed not to be addressed. Recently, many ethical committees and IRBS are established in Ethiopia at the federal, regional health bureaus, universities and research institutions. However, health care practitioners, complaints/patients and researchers believe that Ethical committees and/or IRBs in Ethiopia have no clear guidelines, and the regulatory and ethical review by these bodies introduce delays. This special issue therefore attempts to describe activities of the national ethics committee, experiences from IRBs from one university and one research institution and findings of a study conducted to on the feasibility of rapid ethical assessment (REA) for the Ethiopian research setting.

Historically, Western medical ethics may be traced to guidelines on the duty of physicians in antiquity, such as the Hippocratic Oath. A common framework used in the analysis of medical ethics is the "four principles" approach postulated by Tom Beauchamp and James Childress in their textbook Principles of biomedical ethics. It recognizes four basic moral principles, which are to be judged and weighed against each other, with attention given to the scope of their application. The four principles are:

- Respect for autonomy - the patient has the right to refuse or choose their treatment.
- Beneficence- a practitioner should act in the best interest of the patient.
- Non-maleficence - "first, do no harm"
- Justice - concerns the distribution of scarce health resources, and the decision of who gets what treatment (fairness and equality).

Other values that are sometimes discussed include:

- Respect for persons - the patient (and the person treating the patient) have the right to be treated with dignity.
- Truthfulness and honesty - the concept of informed consent has increased in importance since the historical events of the Doctors’ Trial of the Nuremberg trials and Tuskegee syphilis experiment.

Values such as these do not give answers as to how to handle a particular situation, but provide a useful framework for understanding conflicts.

The Declaration Helsinki published originally in 1964 by World Medical Association (WMA) has set international ethical principles for research involving human participants. The establishment of African-owned ethical bodies capable of running their own ethical concerns has been identified as a priority area in recent years. Recently, many ethical committees and IRBS are established in Ethiopia at the federal, regional health bureaus, universities and research institutions. The Ethiopian Bioethics Initiative helps research sites to form Institutional Review Boards (IRBs) and train the committee members on basic principles of ethical clearance. Under this grant they have established and trained 11 IRBs. However, many health care practitioners, complaints/patients and researchers believed that Ethical Committees and/or IRBs in Ethiopia have no clear guidelines so it is problematic getting approvals. They are also not experienced enough and so are overcautious and they cannot decide on interpretations.

Researchers in Ethiopia reported that one of the difficulties to conduct research is regulatory and ethical review which introduces delays. Some mentioned that it was not uncommon for grants to expire before all approvals were
in place due to the slow systems in the IRBs. In fact, ethics committee members admitted that limited resources, knowledge gaps and membership shortages slowed review times, but also pointed out that lack of awareness of ethical concerns among practitioners and poor quality research applications might introduce poor planning which results on slow and delayed approval.

Therefore, it is timely and important to give clarifications on regulations and development of ethical committees and IRBs functioning in Ethiopia. In this special issue four original papers that dealt with ethical issues in medical practice and research are published.

A three years (2011-2013) review of adverse medical events, claims and decisions taken by the Ethiopian Health Professionals Ethics Committee at the Federal level by Dr Biruk L Wamisho and colleagues showed that the committee verified that 14 of the 60 claims had ethical breach and/or negligence (incompetence) and responded to the concerned authorities. The authors recommended that hospitals should lead in preventing patient injury. Creation of more awareness among Obstetrics and Gynecology specialists, General and Orthopedic Surgeons about medical errors is needed and special training should be given to those joining these specialities.

A review report by Prof Yeyewenhareg Feleke and colleagues showed that the IRB at College of Health Sciences, Addis Ababa University has been pivotal in providing review and follow-up for important clinical studies in Ethiopia. It has been one of the first IRBs to get international accreditations. The paper concluded that important factors in the successes of the IRB among others included leadership commitment, its placement in institutional structure and continued capacity building. However, financial challenges and sustainability issues need to be addressed for the sustained gains registered so far. The authors recommended that similar factors may also be considered for the new and younger IRBs within the emergent Universities and research centers in the country.

The experiences of the Armauer Hansen Research Institute/All Africa Leprosy and Tuberculosis Rehabilitation and Training Center Ethics Review Committee are summarized by Dr Liya Wassie and colleagues. The report concluded that the committee requires general attention in terms of its composition, routine work activities, learning practices and pitfalls. The authors recommended that an independent assessment of the Committee’s activity in general is warranted to evaluate its performance and further (the red labeled sentence ***advisable to delete it from editorial note as well from the manuscript by (Dr. Liya), because evaluation of the committee is more than 83% by international standard) assess the level of awareness or oversights among researchers about the roles of Ethics Review Committees.

Dr Adamu Adissie and colleagues conducted a study on the feasibility of rapid ethical assessment (REA) for the Ethiopian research setting during the period of 2012-2013 and concluded that it is appropriate, relevant, feasible and acceptable by the Ethiopian research community. The authors recommended that REA can be integrated as part of the ethics review and governance system in Ethiopia.

Although, not exhaustive the experiences reported by the four articles have highlighted important frameworks that can be used in the analysis of medical ethics in Ethiopia. In conclusion, while a general lack of materials, infrastructure and facilities were thought to reduce the number and scope of activities by the ethics committees and/or IRBs, human resources were the critical factor. This lack of expertise and research skills was blamed on minimal research focus in clinical education, few opportunities to gain experience and few local experts who could share their knowledge.

Fikre Enquselassie, PhD
Associate Editor in-Chief

**ORIGINAL ARTICLE**

**ANALYSIS OF MEDICAL MALPRACTICE CLAIMS AND MEASURES PROPOSED BY THE HEALTH PROFESSIONALS ETHICS FEDERAL COMMITTEE OF ETHIOPIA: REVIEW OF THE THREE YEARS PROCEEDINGS**

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**ABSTRACT**

**Background:** Medical malpractice is professional negligence by a healthcare provider in which the treatment provided falls below the standard and causes injury or death to the patient.

**Objective:** To describe the adverse medical events, claims and decisions taken by the Ethiopian Health Professionals Ethics Committee at the Federal level.

**Methods:** A three-year report of the Ethics Committee and relevant documents of proclamations and regulations were reviewed.

**Results:** Between January 2011 and December 2013, the committee reviewed 60 complaints against health professionals. About one third of the complaints were filed by the patients and/or their families, about 32% by the police or court and the rest were filed by Addis Ababa health bureau, health professionals and other unrelated observers. Thirty-nine complaints were related to death of the patient and 15 complaints were about disability. Twenty-five of the claims were against Obstetric and Gynecology specialists and 9 were against general surgeons. The committee verified that 14 of the 60 claims had ethical breach and/or negligence (incompetence). The committee took reasonable time to review complaints and respond the concerned authorities.

**Conclusion:** The study showed that of the total claims lower than a quarter (23.3%) were proven beyond the benefit of doubt. More than 3/4 (76.7) of the complaints were wrong. Hospitals should lead in preventing patient injury. Creation of more awareness among Obstetrics and Gynecology specialists, General and Orthopaedic Surgeons about medical errors is needed and special training should be given to those joining these specialities.

**Keywords:** Ethics, Medical ethics, malpractice, negligence, incompetence, health professionals, complaints

**INTRODUCTION**

Medical malpractice is professional negligence by act or omission by a healthcare provider in which the treatment provided falls below the accepted standard of practice in the medical community and causes injury or death to the patient, with most cases involving medical error (1). The definition of medical errors is subject to a lot of debate. Some give due emphasis to outcome based definition; others to process based definition. Taking the process and outcome definition together, medical error is an act of omission or commission in planning or execution that contributes or could contribute to an unintended result (2). This definition captures the major categories of error causation: omission and commission, planning and execution, wrong processes that can lead to errors, whether real or potential (2). Negligence is a care which is below the standard expected of the community of health professionals, and medical adverse event is defined as an injury that was caused by medical management (rather than the underlying disease) and that prolonged the hospitalization, produced a disability at the time of discharge, or both (3).

Death due to medical error is very common; the report of the Institute of Medicine in 1999 showed that around 44,000 to 98,000 hospitalized patients die each year due to preventable error; the 5th common cause of death in USA, more than deaths due to motor vehicle accidents, breast cancer and AIDS (4). Some studies reported an increase on the number of death ranging between 210,000 to 440,000 per year (5). Data is scarcely available on deaths due to medical errors in developing countries; even though, ret-

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Respective chart review done on eight developing countries covering 25 hospitals reported that mortality due to medical errors is very high (6). In fact, WHO estimates that 1 in 300 admitted patients die of preventable medical errors (7). The prevalence of adverse medical events in developed countries for example in USA and Australia were 3.7% and 16.6% respectively (3, 8), and in developing countries, the prevalence ranges from 2.5% to 18.4% (6). Medical errors are more common on patients undergoing surgery, while about half of the cases of medical errors reported by the studies in Harvard and Australian were related to complications from drug treatment, therapeutic mishaps, and diagnostic errors are the commonest non operative events.

There are three major categories of preventable adverse medical events in the primary care: diagnosis, treatment and preventive services; and process errors were classified into four categories, namely, clinician, communication, administration, and blunt end (9). Studies have reported that among adverse events, a significant number of cases, ranging from 23 to 27.6% are due to negligence (3, 10). Medical malpractice claim is very low compared to occurrences of adverse medical events due to negligence: one among eight patient fills medical malpractice claims (11).

The Health Professionals Ethics committee, which was established at National level under Regulation number 76/1994, has been examining complaints related to medical errors due to negligence. Although any Ethiopian can go to courts and fill law suits against any health worker who sustained medical errors on the patient. The court uses information generated by the Ethics Committee, among other sources of information, to decide whether there were any sustained medical errors due to negligence. This is currently substituted by Regulation number 99/2006. A new Health Professionals Ethics Committee was established under the recent regulation.

So far no report has been found in the country on the issue; thus, this study attempts to describe adverse medical events, claims and actions taken by the Ethics Committee based on the three years’ data.

**MATERIALS AND METHODS**

Review of the three-year report of the National Ethics Committee was done on December 2014 in Addis Ababa. The document contains summary reports of all complaints that were filed to the National Ethics Committee from January 2011 and December 2013. The document also contains complaint handling process and decisions made by the committee. Relevant proclamation, regulations and guidelines were reviewed during the study period. The Committee has reviewed each complaint thoroughly and requested professional opinions on 17 of the complaints reviewed. Moreover, the committee requested additional professional opinions from Universities on six of the complaints it reviewed. Descriptive data analysis was applied and results are presented in tables and figures.

**RESULTS**

A total of 60 complaints were filed to the Ethics Committee during the three years period. One third (20) of the complaints were filed by patients and/or their family. Nineteen (one third) complaints were filed by the police or court and the rest were filed by Addis Ababa Health Bureau, health professionals and other unrelated observers (Table 1).

<table>
<thead>
<tr>
<th>Complaint filled by</th>
<th>Number</th>
<th>Percent</th>
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<tr>
<td>Patient/family</td>
<td>20</td>
<td>33.33</td>
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<tr>
<td>Police/court</td>
<td>19</td>
<td>31.67</td>
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<tr>
<td>Addis Ababa Health Bureau</td>
<td>11</td>
<td>18.33</td>
</tr>
<tr>
<td>Ministry of Health -Unrelated Observers</td>
<td>3</td>
<td>5.00</td>
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<tr>
<td>Other Health Professionals</td>
<td>2</td>
<td>3.34</td>
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As shown in Figure 2, the nature of medical circumstances for which complaints were filed to the committee are divided into three main categories. Thirty-nine complaints (65%) were due to death of the patient, 15 (25%) were due to physical disability and 6 (10%) complaints were due to issues that are related to fee and administration.
Ownership of health institutions against which complaints were filed:

As shown on Table 2, the number of complaints against private health facilities is slightly higher 32 (53.3%) complaints against privately owned health facilities versus 28 (46.7%) against publicly owned health facilities. Forty three of the complaints (71.7%) were on cases which were seen in the hospitals, while 15 (25%) of the complaints were on patients seen at clinics. Each of the remaining two complaints was from patients seen in a health center and a laboratory.

Table 2: Distribution of sector and type of facility where medical error complaints came from; Ethiopia, January 2011–December 2013

<table>
<thead>
<tr>
<th>Sector/Facility</th>
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<tr>
<td>Sector</td>
<td></td>
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<tr>
<td>Private</td>
<td>32</td>
<td>53.3</td>
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<tr>
<td>Public</td>
<td>28</td>
<td>46.7</td>
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<tr>
<td>Facility</td>
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<tr>
<td>Hospitals</td>
<td>43</td>
<td>71.7</td>
</tr>
<tr>
<td>Clinics</td>
<td>15</td>
<td>25</td>
</tr>
<tr>
<td>Health Center</td>
<td>1</td>
<td>1.7</td>
</tr>
<tr>
<td>Laboratory</td>
<td>1</td>
<td>1.7</td>
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Type of health professionals against whom the complaints were filed: A total of 51 complaints (83%), were filed against Medical Doctors. Among all health professionals whose cases were reviewed by the National Ethics Committee, 25 (38.5%) were Obstetricians/Gynaecologists. General practitioners and Nurses accounted for 6 (9.23%) complaints each. Forty-eight (80%) of the complaints involved some form of surgery or operation room. When specialists are compared, the highest number of complaints were filed against Obstetricians/Gynaecologists (56.8%), General Surgeon (20.45%) and Orthopaedic Surgeon (11.36%). No complaint was filed against internists (Fig. 2).
Outcome of the Review of Complaints and Decisions Passed by the National Ethics Committee:

The committee has verified that 14 of the complaints reviewed were related to ethical breach and/or negligence (the committee calls it incompetence). Out of these, 10 were on patients treated in private health facilities and 4 were on patients seen at public health facilities. On further verification related to medical error or breach of ethical practices by the type of facility, it was found that 8 cases were seen in hospitals and 6 were seen in clinics. The Ethics Committee has also verified that six cases had additional administrative problems besides professional negligence and/or breach of medical ethics. These administrative issues include practicing without licence, not renewing professional licence, and issues related to service fees. The time taken by the committee to review complaints and to respond to the concerned bodies ranged from a minimum of less than a month to a maximum of more than one year, the average being 6.5 months.

The actions made by the committee include revocation of licence, suspension of licence for a limited period and practice under supervision. Licences of four professionals were revoked. The professionals were all Medical Doctors and two of them were foreigners.

The licences of nine professionals were suspended for a limited period prescribed. They are professionals of various disciplines. The committee has also made two physicians and one nurse practice under supervision to improve their competence on managing specific health conditions.

DISCUSSION

A total of 60 complaints were filed to Ethics Committee over the last three years. The experience from other developing countries and from countries with advanced healthcare setup like USA showed the rate of adverse events due to medical errors are higher than our study (5, 7, 9, 13). This may be due to low awareness of patients about adverse events from medical errors. Besides, healthcare workers are one of trusted professionals in that not many patients would think of accusing them of making medical errors. A study carried out in Jimma Hospital which
assessed health workers’ attitude around the current patient's safety measure showed that over 6 out of 10 health professionals believe that there is satisfactory patient safety measures in place (14). This may indicate that majority of health workers are not well informed about the occurrences of medical errors.

Our review showed that about 65% of complaints were due to death and only 25% due to disability; but other evidences suggest that death due to medical adverse events is low compared to disability (3,9). The proportion of medical adverse events resulting in death was as high as 30% in other developing countries (7).

Slightly more complaints were filed from private medical facilities than public/government facilities and in a higher number of complaints of malpractice was encountered on files from private practice than public; but this is not statistically significant. This may also be due to the fact that the number of people seeking care in the private facilities, especially in cities such as Addis Ababa, is increasing. Another factor could be that the awareness and capacity to sue of patients treated at Private practices might be higher/better than those treated in public facilities. In this review it was found that majority of complaints (71.7%) emerged from Hospitals than smaller health care units. This could be due to that medical adverse events are more common during complex care, urgent care, and a prolonged hospital stay as reported by the Study from Institute of Medicine in USA (13).

The results of this study showed that majority complaints (60%) were filed against gynecologists/obstetricians and surgeons, which is slightly higher than the figure reported from the United States where half of medical adverse events were due to surgical procedures (5). From the current study it is difficult to conclude that the number of surgical related malpractice is more than what is reported in other countries, for the total number of cases reviewed is small. The study indicated that more gynecologists/obstetricians were filed than practitioners in other disciplines and this finding is consistent with a study done in the United States which showed more claims were filed against gynecologists/obstetricians. (15). The number of claims in the US study is over 1,400. This could be due to regulated reporting and attention recently given to per-natal mortality.

The decision from the Federal Health Professionals Ethics Committee showed that no medical error took place in the majority (76.7%) of the complaints, malpractice or insufficiency was established beyond the benefit of doubt in only 14 (23.3%) of the accusations. This almost 1:4 ratio is somehow consistent with the study from USA where 40% of claimants had no verifiable medical injuries or medical errors (15).

The average time taken to review and give response to the claimants was 6.5 months; this is by far shorter than the time it took for cases taken to courts from the study done in China, which reported that it took three years from the occurrence of the injury to the closure of claims (16).

The study has some limitations; first, the number of cases reviewed is small to give a complete picture of medical errors in the country, and there were claims whose cases had been arbitrated in courts, in which it is impossible to disclose all the information/data available. Second, the data is not exhaustive on claimants’ socio demographic characteristics, specific departments where they occurred (in-patient or out-patient) and the severity of the adverse effect or the degree of disability etc.

Conclusion and Recommendation:

- The Ethics Committee appears to review complaints and provide response for claimants in shorter period than the courts. Therefore it would be in the interest of the public to forward complaints to the committee. Even establishing such committees at regional and university-Medical School levels may further shorten the time to investigate and reach a sound decision.

- Gynecologists/obstetricians and surgeons are the most frequently sued professionals. There is a need to create awareness among these professionals about medical errors; those joining these fields should be counseled to make informed decisions.

- Hospitals need to be in the forefront in preventing, monitoring and creating awareness on medical errors. Safety measures must be in place in each hospital in the country.

- Further comprehensive study on medical malpractice in the country involving patients and healthcare workers is warranted to assess the magnitude of the problem.

- Moreover, Since more than 3/4 (76.7) of the complaints on health professionals were proved wrong, hospital health institutions should established and use local/institutional discipline committees and forums that resolve conflicts between patients and health professionals. This avoids unnecessary referrals of minor issues to the Federal ethics committee.
REFERENCES

ORIGINAL ARTICLE

REVIEW PAPER ON RESEARCH ETHICS IN ETHIOPIA: EXPERIENCES AND LESSONS LEARNT FROM ADDIS ABABA UNIVERSITY COLLEGE OF HEALTH SCIENCES 2007-2012

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ABSTRACT

Health research in Ethiopia is increasing both in volume and type, accompanied with expansion of higher education and research since the past few years. This calls for a proportional competence in the governance of medical research ethics in Ethiopia in the respective research and higher learning institutes.

The paper highlights the evolution and progress of the ethics review at Addis Ababa University- College of Health Sciences (AAU-CHS) in the given context of health research review system in Ethiopia. Reflections are made on the key lessons to be drawn from the formative experiences of the Institutional Review Board (IRB) and their implications to the Ethiopian health research review system. This article is a review paper based on review of published and unpublished documents on research ethics in Ethiopia and the AAU-CHS (2007-2012). Thematic summaries of review findings are presented in thematic areas - formation of ethics review and key factors in the evolution of ethics review and implications.

The IRB at AAU-CHS has been pivotal in providing review and follow-up for important clinical studies in Ethiopia. It has been one of the first IRBs to get WHO/SIDCER recognition from Africa and Ethiopia. Important factors in the successes of the IRB among others included leadership commitment, its placement in institutional structure, and continued capacity building. Financial challenges and sustainability issues need to be addressed for the sustained gains registered so far. Similar factors are considered important for the new and younger IRBs within the emergent Universities and research centers in the country.

Keywords: Institution Review Board, ethics committee, Research ethics, Addis Ababa University, CHS

INTRODUCTION

As is stipulated in international research governance guidelines, competency in ethics review for medical research is an important factor for the growth and quality of medical research in any given setting. In Ethiopia the past decade has documented unprecedented number and type of medical research conducted by different cadre of medical professionals inside and outside the country [1]. This has been further augmented by the unprecedented expansion of tertiary education and postgraduate programs in all science disciplines including medical science and public health [2]. The growth in number and type of conducted researches need to have equality growing, competent and up to the standard ethics review system. This calls for consideration of equally and in parallel growing ethics review system capable of handling ethics reviews and follow-ups of the volume of research conducted.

With the current trend of expansion of higher institution greater academic freedom and openness for external and international research partnerships one can easily imagine that there will be a greater need in the years to come for a competent national system and institutional capacity. In this whole effort academic institutions play a pivotal role of teaching and leading in medical research including the ethics aspect of it. In Ethiopia, even though the history of modern medical research is not so old, the role played by institutes such as the Addis Ababa University College of Health Sciences in setting exemplary standards for ethics review are to be underlined with key lessons having continual implications for other similar institutions in Ethiopia.

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The objective of this paper is to map out trajectories in the development and reflect on the evolution of health research ethics at AAU-CHS; to provide analysis of key lessons learnt from AAU-CHS's Institutional Review Board (IRB); and to argue for a model of institutional capacity building in order to meet the increasing need for research ethics review in Ethiopia and the way forward.

MATERIALS AND METHODS

We reviewed published and unpublished documents on research ethics in Ethiopia and the evolution and development of research ethics review at AAU-CHS from 2007 to 2012. Key terms used for both online and manual search were; research ethics, medical ethics, IRB, ethics review, Ethiopia, Addis Ababa University. Synonyms and Boolean combination were used as required. Thematic summaries of review findings are presented in the areas of the formation of ethics review and key factors in the evolution of ethics review and their implications. In 2012 the authors were involved in an assessment conducted to evaluate IRBs at AAU/CHS and other seven universities in Ethiopia which are under the Medical Education Partnership Initiative (MEPI) consortium. The same findings were used to illustrate the status of the IRB in 2012.

The paper first introduces the development of bioethics and research ethics in Ethiopia including historical landmarks. This is followed by presentation of the evolution of AAU-CHS IRB with critical reflections on key lessons, challenges and implications.

RESULTS

Evolution of Institutional Research Ethics Board (IRB) at Addis Ababa University CHS: Established in 1950, Addis Ababa University is the oldest and largest higher education institution in Ethiopia, which has made a remarkable contribution to the country through provision of trained manpower, research and community services [3]. The university has contributed as spear-head in higher education and research in Ethiopia and beyond. One of the main campuses of AAU is the College of Health Sciences, which for many years used to be the Medical Faculty having the country's oldest and biggest specialized teaching hospital Tikur Anbessa Specialized Hospital. The College is a merger of School of Medicine, School of Public Health, School of Allied Sciences and School of Pharmacy. It aspires to be a regional center of excellence in health sciences teaching, research and services enhancing the health and productivity of human and animal populations [4].

The College has recently celebrated its Golden Jubilee, in its historical journey of half a century, AAU-CHS has been considered an important national actor and leader in the area of medical care provision, heath workforce training, medical and public health training and research and health system strengthening. This encompassed in addition a role to lead in the area of medical research development, governance and ethics review. Research has been an integral part of the medical education at AAU. It also helped in the establishment of national system for biomedical research ethical review under the Ministry of Science and Technology. Most of the national steering and standing committee members were and are from the Medical Faculty of Addis Ababa University. The then Faculty of Medicine and current College of Health Sciences run an IRB, which is one of the first African IRBs to receive Strategic Initiative for Developing Capacity in Ethical Review recognition from WHO [5]. The IRB also serves in capacity building for the national research ethics review in collaboration with partners i.e. professional associations and donors.

Even before the formation of a Research Ethics Committee (REC) and subsequently an IRB, for many years the College, under the then faculty of medicine had a faculty research and publication committee (FRPC) which was mandated to review and approve research projects and other academic documents and publish guidelines and modules as were required. The FRPC later on evolved to FRPC-1 (for academic staff) and FRPC-2 (for postgraduate research including Masters and PhD projects). Later on the faculty AC decided to rearrange FRPC into Faculty Institutional Review Board (FIRB). The current IRB evolved out of this earlier structure. In 2007 the current IRB was established under the faculty of medicine [6].

Over the years the IRB functioned as independent structure within the Faculty of Medicine and later the College of Health Sciences. During its establishment a document with Terms of Reference (TOR) was developed which clearly stipulated the mandates and operational and structural provisions for its independent function and entity. In addition Standard Operating Procedures (SOPs) were developed and
approved for implementation (2007 later revised in 2009) [6]. The composition of members for the first IRB was representation from different units and departments in the faculty with balanced professional mix and experience in research taken into due consideration.

As mentioned earlier, the IRB is one of the first IRBs to have received an international accreditation. The IRB got recognition through FERCAP/SIDCER [20]. It also had certification from US Federal Wide Assurance and the Ethiopian Science and Technology Ministry. Apart from reviewing research proposals from academic staff and post graduate research students, the IRB provided basic and advanced trainings in research ethics for its members and other academic staff. To mention few, two rounds of training as part of the Medical Education Partnership Initiative (MEPI) in collaboration with CDC, E-based training on research Ethics in collaboration with University of Oslo, An International course on Surveying and Evaluating Ethical Review Practices in collaboration with SIDCER and AHRI were given in various occasions.

From 2008 until 2012, the IRB reported to have revised about 548 proposals. Most research projects are related to higher degrees including Masters and PhD degrees and Clinical Trials. Based on the IRB assessment conducted in 2012, we discuss some of the key observations which were determinant for the success of the IRB compared to IRBs in other universities under the MEPI consortium. The factors include (i) Human Capacity (members, composition and training), (ii) Availability and adherence to Guidelines and SOPs, (iii) Documentation and Archiving, and (iv) Infrastructure (Office-space, Office-equipments, communication facilities and budget).

**Human Capacity (Professional and Administrative):** The number and composition of members of the IRB were governed by its SOP with numbers ranging between 11 and 13, composed from various mixes of professionals with reasonably adequate overall composition in terms of professional mix. The IRB in addition to its regular members, had independent consultants in different areas of expertise [6]. While one of the main problems for most IRBs was unavailability of community representatives and lack of motivations and incentives for the community representatives and also for the other IRB members, AAU CHS always had a community representative in its membership. The IRB in addition had permanent office staff; a secretary and an office assistant. The secretary plays administrative roles without any professional involvement, on top of routine secretarial activities and archiving.

Regarding conducting trainings for IRB members, except for AAU-CHS no other institution was providing research ethics trainings for its members and other staff. The trainings given included basics on research ethics and practical sessions on proposal review. Training is an important pillar for quality and standards of IRB activities. This is one of the areas that require investment and strategic plan to build capacities of available staff and in thinking through the next generation of members.

**Standardized Review Guidelines and Accreditation:** While other institutions had overall guidelines at their best, AAU-CHS was one of the few having detailed operational Standard Operating Procedures Manual (SOPs), Guidelines for Research Applicants and Research Review Procedures manual. These helped in guiding the review and application process in a structured manner with significant degree of consistency. Most do follow the guidelines set by the national research ethics guideline of the Ethiopian Science and Technology Commission [7]. According to local and international guidelines, every REC and IRB is required to have its own guidelines on application procedures and standard operation procedures or TORs [7,8].

Existence of SOPs clarifies and facilitates the decision making procedures and processes in ethical review. Among other things, SOPs shall address points on how reviews are conducted, meetings are held and decisions are passed and communicated. Written policies and procedures specify the membership, committee governance; review procedures, decision-making, communications, follow-up, monitoring, documentation and archiving, training, quality assurance, and procedures for coordination with other RECs. AAU-CHS developed SOP as per requirements of FERCAP/SIDCER for accreditation [5,6]. Subsequently the IRB had international accreditations from WHO/SIDCER (November 22-26, 2009) (Figure 1) at FERCAP Conference in Philippines. IRB of College of Health Sciences, Addis Ababa University registered in USA, and obtained Renewal of IORG-IRBs and Renewal Registration of Federal Wide Assurance (FWA), USA.

The professional mix of reviewers allowed for proper review of not only the ethics and consent forms of the research projects but also the science. When needed consultants were contact to do reviews in their areas of expertise. Apart from the ethical con-
siderations and the consent documents and procedures, thorough reviews were done on the technical rigor and the methodological plausibility of submitted research projects. The IRB followed the principle "Bad science is bad ethics" and that there is a need for relevant review of scientific methods as part of ethical appraisal [9].

AAU-CHS also had mechanisms in place for the follow-up of approved proposals. However, the follow-ups were not satisfactory due to lack of budget and poor compliance from researchers. Follow-up of approved proposals is one of the core functions of IRBs. Approval of an ethically sound research proposal is just the first stage in ensuring ‘protection human subjects’ in research undertakings. Lack of follow-up is due to lack of capacity to do it as there are no provisions in place to make proper follow-up on studies.

*Documentation and Archiving:* In 2012 the IRB was one of the only few institutional boards that provided a well-structured application format for ethics review process. This was accompanied by both hard-copy and electronic archiving system. Archiving and documentation is very important attribute in proving and assuring that standards for IRB requirements are met. This holds true for most international accreditations including WHO/SIDCER and others [5].

The IRB secretariat especially the administrator and secretary had the prime responsibility for this. As discussed earlier, having a dedicated office and office staff was very important for proper documentation and archiving.

*Infrastructure:* Since its establishment, the IRB had a dedicated office space. Presence of an adequate office space was important for running board meetings, to keep the archives and documents related to ethical review and for secretarial functions. Some committees meet in the offices of their chair person or one of its members. This could create sense of insecurity and absence of a focal point where the institutional records and memories are properly stored. Having a dedicated office space is one of the important administrative provisions required for ensuring long term sustained functions.

The IRB did not have a dedicated budget of its own, however, it was reported that it can request for materials like stationary whenever needed from institutional supplies. While there is no any payment scheme in the AAU IRB, few other IRBs try to compensate their members for transportation costs by providing them nominal amount of money from their institutional budget. Most IRB members are already over loaded and busy professionals who are executing their IRB duties on top of all this.

![Picture 1](image_url), Recognition Plaque/Shield by WHO/SIDCER– First IRB from Africa and Ethiopia. FERCAP conference on November 22-26, 2009, Philippines
DISCUSSION

Like many other developing countries, bioethics is a young and new topic in Ethiopia and is mainly focused on medical research ethics, with some components of medical professional ethics. In Ethiopia, the agenda of health research ethics was initiated by the then health department of the Ethiopian Science and Technology Commission (ESTC) when in 1994, the commission officially launched a national health science and technology policy and established a broad based body at a level of a council with a function to advise the federal government on health science research and development. The first national health research ethics guideline was developed by the commission in 1995 and has been revised twice, in 1997 and 2004 respectively [10]. All regional and institutional committees need to be registered at the secretariat of National Research Ethics Committee, to be renewed every two years. It has been emphasized that there is a need to further strengthen the local capacity of ethical review of health related research in the country and various efforts have taken place in different points in time since then [11,12].

Important factors of bioethics and research ethics in Ethiopia include sectors in the government such as the Ministry of Science and Technology; Federal Ministry of Health, Ethiopian Food, Medicines and Health Care Administration and Control Authority (EFMHACA); prominent research centers such as Ethiopian Public Health Institute (EPHI) [13] and Armauer Hansen Research Institute (AHRI) [14]; professional associations such as Ethiopian Medical Association (EMA) and Ethiopian Public Health Association (EPHA), Nurses, Midwives and Medical Laboratory technologist associations; and Universities hosting training programs in the fields of Medicine and other health sciences.

Health Research in Ethiopia is dated to more than a century old. The first medical publication from Ethiopia was on “Abyssinia and its Sanitary and Medical Aspects” in The Lancet (1868) [15]. However output in terms of quality and quantity remains low as the total number of publications are still fewer in number. Despite development of medical research in Ethiopia over the past decades it lacks detailed laws and regulations [1]. With the rapid expansion of post-graduate programs in the major public universities and the increased the availability of findings, the number of research projects with human subjects is progressively increasing. These have put increasing demand on the current research governance system to be more effective and efficient [2]. There are various challenges in the research governance systems and capacity at various levels [16]. Community’s awareness about research and research ethics elements in Ethiopia, are not well developed compared to communities in developed countries. A study on consent form standards, suggested that the standards of ethical review and informed consent need to be improved [17]. So far, there are not independent academic courses in research ethics. This is rather addressed under research methods trainings for post-graduate students. Professional associations such as EMA, ETBIN and other partners provide various trainings on ‘research ethics’. But not very structured as such [18].

Some contextual challenges for bioethics and research ethics in Ethiopia include decision-making in medical care and health research at an individual level is determined by ethno-cultural factors existent in the country. Health professionals and researchers therefore need to take time to understand and pay attention to such paradigms which could take different shape across ethnic differences in this multicultural country [19]. In addition, consent and decision-making mechanism are influenced by a number of cultural and social issues such as stigma and discrimination [20-22]. Vulnerability of study subjects therefore need to take time to understand and pay attention to such paradigms which could take different shape across ethnic differences in this multicultural country [19]. In addition, consent and decision-making mechanism are influenced by a number of cultural and social issues such as stigma and discrimination [20-22]. Vulnerability of study subjects is considered a challenge especially during decision making in the informed consent processes [23-24].

For the proper functions of an IRB, well established ethical review system in place with the required standards for application, review and approval procedures is vital. This further needs to be standardized and possibly accredited for the same purpose. Review system encompasses of an established system for proper review of research proposals with involvement of relevant authorities to ensure that ethics review of health-related research is supported by an adequate legal framework that is consistent with the standards; that research ethics committees capable of providing independent review of all health-related research exist at each level; and that an appropriate and sustainable system is in place to monitor the quality and effectiveness of research ethics review.

The core of an IRB and its functions lies in the composition and expertise of its members. Composition has to be multidisciplinary and should be able to reflect the social and cultural diversity of the communities from which the research participants are likely to be drawn. This includes lay people and other
members whose primary background is not in health research and they should be available in reasonably adequate number [8]. Having a community representative is a very key international requirement in establishing IRBs. No full board IRB meeting should be conducted if the community representative is not in attendance of the meeting.

Even though the core of ethics committee and its functions lie on its members, it needs adequate support staff with adequate training for properly executing its technical and administrative responsibilities [8]. To this effect IRBs do need IRB administrators or at least full time secretaries to run the office and secretarial works as well as deal with routine administrative issues [25]. An IRB administrator or its equivalent is responsible for the oversight, administration, implementation, and management of all IRB business, including policies and procedures related to the protection of the rights and welfare of human subjects and the institution’s compliance with all the continually updated regulations, local laws and institutional policies that are applicable [26].

Ethics is a dynamic subject – refresher trainings also needed on regular interval for all IRB members on service. There are various ways of providing trainings such as short courses, long-term courses, on-line courses and refresher seminars. Members need to have trainings on the ethical aspects of health-related research with human participants, how ethical considerations apply to different types of research, and how the REC conducts its review of research, is provided to REC members when they join the committee and periodically during their committee service [8]. Tracking records of IRB members is another important attribute to determine whether an IRB meets required standards. This also helps to regularly audit the capacities of IRBs which needs to be provided for internal auditors and surveyors as this is one criterion for IRB recognition.

As per the existing standards, the archiving and record keeping should always be very confidential and this needs to be insured by keeping the records in safe location and follow standard procedures. There should also be clear procedures on who should access documents, and how [8]. Even if this is claimed by some of the IRBs, it is difficult to verify without SOPs. One advantage of using information technologies (IT) for ethical review and documentations is an electronic data base [25].

According to the current international guidelines, research ethics committees do need adequate resources for their members and staff to fulfill the assigned functions. These resources include, but not limited to, office space and equipments such as computers, stationary, telephone, copy machines etc [8]. An adequate office space is needed not just for holding committee meetings. It is required for all the other important activities beyond the meetings such as routine administrative activities, keeping store of committee files and for keeping records related to review in a secure and confidential manner. [8] An office space is vital for an IRB to create a stable environment for its functions, for proper documentation and archiving and for sustainability of IRB roles.

Most IRB members are already over loaded and busy professionals who are executing their IRB duties on top of all this. Whether IRBs generate their own income or no, it is important to compensate the members for their time and extra efforts on IRBs. Adequate financial resources need to be there to permit the committee to produce high-quality work [8]. If IRBs are not adequately funded, they will be unable to run their mandates successfully. One option for financing IRBs could be charging for ethical review services. There are no uniform practices regarding IRB fees. Some institutes ask for payments for proposal review services and accordingly researchers make budget plan for the IRB services [25].

Depending on ‘IRB costs’ and how expensive it is to run IRBs, there is argument that the IRB services should be charged. The Ethiopian National Guideline also has stated of review fees for projects at national level [7]. However, one potential problem associated with IRB fees could be potential conflict of interest that could results. However, different IRBs follow their own mechanism in ensuring that potential conflict of interest is avoided when implementing IRB fee policy. The bottom line is availing budget for smoothly running the IRB activities. Charging an IRB review fee for commercially sponsored research is a common way for an IRB to supplement the operating budget provided by institutions. Most sponsors would not object to paying reasonable fee. Adequately resourced IRBs benefit both the sponsor as well as the institution, and, most importantly, subjects who participate in research [25].

*Limitations:* This review process in focused only on the period from 2007 to 2012, and is mainly based on documents reviews and formative reflections of establishing members of the IRB with possibility of subjective reflexivity. In addition, the current assessment was limited to assessing IRB/REC systems based on the reports from focal persons without triangulation.
Conclusions and Recommendations: The AAU CHS IRB has made a remarkable progress in the years which followed its establishment in 2007. These formative years can be considered learning experiences for other IRBs in Ethiopia and other countries in similar settings. Important factors in its successfully evolving to this included leadership commitment, its placement in institutional structure, and continued capacity building of its members. Some of the gaps observed on the formative years were questions of sustainability and staff motivation. The lesson learnt and the achievements registered needed to be maintained through continuous monitoring and evaluation in place accompanied with supportive supervision and reaccreditation. There needed to focus on institutional capacity building on ethics review beyond engaging in routines in review processes.

It is important that IRBs provide continuous training for current members on research ethics and training of trainers in certain intervals and encourage the respective IRBs/RECs to run their own local trainings. Motivation of IRB member is a key determinant. There needs to be a mechanism to motivate IRB members and to compensate for the extra services they render. The incentives need to be proportionately adequate and regular.

Further assessment is required on how best to network the existing IRBs with each other and with others in the country and beyond. This includes confidential exchange of electronic information and resources as well as web based links. Also conduct further assessment on how best to address the identified gaps in the future and based on this a strategic plan on how building the capacities of IRBs in the assessed institutions and beyond incorporating the key functions and expectations should be worked out. There should be proper monitoring and evaluation of IRB activities-follow-up studies of similar status on yearly or two yearly bases.

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RESEARCH ETHICS REVIEW PRACTICES: EXPERIENCES OF THE ARMAUER HANSEN RESEARCH INSTITUTE/ALL AFRICA LEPROSY AND TUBERCULOSIS REHABILITATION AND TRAINING CENTER ETHICS REVIEW COMMITTEE, ETHIOPIA

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ABSTRACT

The need for ethics review committees (ERCs) is imperative in the conduct of research to ensure the protection of the rights, safety and well-being of research participants. However, the capacities of most ERCs in Africa are limited in terms of trained experts, competence, resources as well as standard operating procedures. The aim of this report is to share experiences of one of the local institutional ERCs, the Armauer Hansen Research Institute (AHRI)/All Africa Leprosy and Tuberculosis Rehabilitation and Training Center (ALERT) Ethics Review Committee (AAERC), to other ERCs found in academic and research institutions in the Country. In this report, we used an empirical approach to review archived documents of the AAERC Secretariat to assess the Committee’s strengths and weaknesses.

The experiences of the AAERC in terms of its composition, routine work activities, learning practices and pitfalls that require general attention are summarized. In spite of this summary, the Committee strongly acknowledges the functions and roles of other ERCs in the Country. In addition, an independent assessment of the Committee’s activity in general is warranted to evaluate its performance and further assess the level of awareness or oversights among researchers about the roles of ERCs.

Key words: ………

INTRODUCTION

Ethiopia, with an average gross domestic product (GDP) growth rate of 11% (1), aspires to be a middle income country by 2025. It is currently striving to achieve improved educational standards and enhance its science and technology base through expansion of new universities in different administrative regions. Currently there are over 33 government run universities in Ethiopia, which gives the country enormous potential to increase its research activities, contribute to new knowledge, further its economic development, and improve health standards, thus contributing to informed decision making (2). However, there are several obstacles which need to be overcome including inadequate research facilities and absence of appropriate procedures and capacities to undertake ethical reviews (3, 4). These hinder the consistent dissemination of research-outputs to provide research-driven evidence for informed decision-making, as most outputs remain shelved. The inefficient use of resources is a key issue. The primary role of research ethics review committees (ERCs) is mainly to ensure the protection of the rights, safety and well-being of research participants (5, 6). However, the capacities of most ERCs in Africa lack resources, competence and standard operating procedures (SOPs) to function optimally and in an efficient manner (3, 4).

In this context, our aim is to share practical experiences of one of the institutional ERCs in Ethiopia, namely the AHRI/ALERT Ethics Review Committee (AAERC). The Secretariat of this Committee is hosted by the Armauer Hansen Research Institute (AHRI), a biomedical research facility under the Federal Ministry of Health (FMoH) and part of the

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All Africa Leprosy and Tuberculosis Rehabilitation and Training Center (ALERT). The strength of AHRI lies in its basic immunological and molecular biology research activities. This impacts favorably on capacity building activities through the provision of postgraduate training support. It does this in partnership with different universities and serves as a hub for technology and skill transfer in the country (2). The Institute has contributed immensely towards building capacity for research ethics committees, through provision of short-term skill building trainings on the principles and practices of research ethics and good clinical and laboratory practices. It has also served as the secretariat for the PanAfrican Bioethics Initiative (PABIN). It is however evident that there also exists other ethics committees in the Country that perform and function in a similar or better way. In this paper we summarize the experiences of the AAERC in terms of its composition, routine work activities, learning practices and pitfalls that require general attention.

MATERIALS AND METHODS

In this report, we used an empirical approach to review archived documents of the AAERC Secretariat to assess the Committee’s strengths and weaknesses. We discuss its overall practices in terms of its structure, composition, review activities, learning practices and the way forward. This approach could possibly be used for educational purposes by other Ethiopian academic and research institutions. The Committee further discussed the data compiled from its archived documents, during its internal audit meeting in December 2014 to provide additional insight. We additionally used an already existing and validated evaluation tool (7), developed by the Middle East Research Ethics Training Initiative (MERETI) to evaluate the Committee’s overall performance and identify areas for improvement. This tool measures the quality of a given ERCs in terms of its organization, membership and educational training, minutes recording and documentation practices, internal operating guidelines, method of communicating decisions, its internal resources and provision of continuous review (7). Institutional permission was obtained to compile and publish the data for experience sharing. The data presented in this report include data compiled from documents archived in the AAERC Secretariat since the development of its first SOP in 2007, with a particular and detailed focus on activities compiled over the past three years (2012-2014).

RESULTS

Setting: As the name implies, the scope of AAERC is to review research protocols to be conducted at AHRI and/or ALERT (or elsewhere) in collaboration with AHRI. With recommendations from the FMoH (2), AHRI has expanded its research portfolios into other translational research and clinical trial activities. The Committee has been functioning since 1986, and has gone through extensive transformation since then to attain current acceptable standards in terms of its composition, operational practices and capacity, including expertise and resources. The need to transition to clinical trial activities in 2004 pushed AHRI to upgrade itself to meet the standards of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use and Good Clinical Practice (ICH-GCP). This enabled it to conduct ethically acceptable research and/or trials. The Committee developed its first working SOP in 2007 and revised it in 2009 with technical and advisory assistance from the World Health Organization, Special Program for Research and Training in Tropical Diseases (WHO/TDR). With support from the Institute, the Committee was evaluated by and received recognition from the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER) in 2009 and since then, it continues to strive for improved performance in its organization, review process, report delivery and documentation and archiving.

Structure: Like most research ethics review committees in Ethiopia, the AAERC lacks structural and administrative hierarchical positions within the ALERT Center. However, it functions as an autonomous joint Committee linking clinical (ALERT Hospital) and research services (AHRI) of the Center. Further, it communicates its activities via its host, AHRI.

Overview of the AAERC review practices: The Secretariat, which is composed of the chairperson, the Committee’s secretary and administrative secretaries, receives complete protocols as per the Committee’s protocol submission checklist and assigns unique identification numbers for further execution of review by the Committee. Depending on the level of risk anticipated in a research protocol (8,9), the Secretariat decides whether research protocols can be reviewed by the full board expedited by selected members, or be exempted from review. The whole
Committee meets every month to review at least three research protocols that potentially pose greater than minimal risk to study participants. Apart from its regular meetings, the Committee also holds expedited reviews to review research protocols with minimal risk (10, 11). Reviewers are assigned by the Secretariat based on their areas of expertise, convenience of the reviewer to expedite reviews, and with due consideration given to involving a layperson. Extraordinary meetings are also held to review research protocols that require urgent decisions, such as those affected by seasonality or other pressing factors. Since the beginning of 2014, the Committee developed internal criteria to exempt research protocols as described earlier (11, 12) to ease the workload of the Secretariat and of the Committee as a whole. In addition to providing administrative and logistical support, the Secretariat organizes short-term training on research ethics, and liaises with researchers to provide assistance as required.

**Composition:** Data from the past three years (2012-2014) indicate that the AAERC membership constitutes a fair gender balance (5 females and 8 males in 2012 and 6 males and 6 females in the year 2013 and 2014). Age wise, there has also been a good mix of the older, middle and younger generations. The Committee also consists of experts with different professional background over the past three years: social scientists (psychologists, lawyer and social workers), clinicians (dermatologists, endocrinologist, internists, orthopedic surgeon, public health specialist, ophthalmologist and pediatrician) and biomedical scientists (microbiologists, immunologists and parasitologists) (Figure 1A).

In addition, the Committee membership is well balanced in terms of having a layperson (social worker) and lawyer, both of whom are not based at AHRI/ALERT. In terms of institutional affiliations, the majority (more than 50%) of the AAERC members are from outside the Center (AHRI/ALERT) (Figure 1B) to ensure an independent review. Overall, the composition fulfils the criteria for ERC members set by international guidelines, such as ICH-GCP (13).
Figure 1. Composition the AHRI/ALERT Ethics Review Committee by expertise (A) and institutional affiliation (B) over three years (2012-2014)

Protocol review practices: The number of protocols reviewed by the AAERC shows an increasing trend since 2007 (Table 1), with an average of 34 and median 28 protocols per year (Range: 17-62). Accordingly, the overall proportion of approved protocols by the Committee is relatively fair (Table 1). It was further noted that, the relative proportion of approved protocols correlates with the type of protocols reviewed by the full board compared to expedited protocols. In-depth analysis of the review and approval processes over the past three years (2012-2014) indicated that a relatively larger number of applicants withdrew in recent years (4 in 2012, 15 in 2013 and 8 in 2014), which were also mainly expedited.

The AAERC secretariat often follows pending applications to ensure compliance and our communication reports received from applicants indicated that some applicants changed the study sites and move to other service facilities that may be relatively less stringent. While reviewing these protocols, the AAERC held a total of 15 regular meetings in 2012, 11 in 2013 and 15 in 2014, of which two of the meeting sessions were extraordinary meetings in the years 2012 and 2014. Furthermore, the average time period that the Committee spent to issue approval since the time of application, was about two months; however, it is often less for expedited reviews.
Table 1: Total number of protocols reviewed by the AHRI/ALERT Ethics Review Committee since the development of its first SOP (2007-2014)

<table>
<thead>
<tr>
<th>Year</th>
<th>Protocols reviewed by full board (n)</th>
<th>Expedited review protocols (n)</th>
<th>Total approved protocols (n, (%))</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>12</td>
<td>5</td>
<td>10 (59%)</td>
<td>17</td>
</tr>
<tr>
<td>2008</td>
<td>21</td>
<td>5</td>
<td>18 (69%)</td>
<td>26</td>
</tr>
<tr>
<td>2009</td>
<td>11</td>
<td>10</td>
<td>13 (62%)</td>
<td>21</td>
</tr>
<tr>
<td>2010</td>
<td>13</td>
<td>9</td>
<td>11 (50%)</td>
<td>22</td>
</tr>
<tr>
<td>2011</td>
<td>25</td>
<td>5</td>
<td>18 (60%)</td>
<td>30</td>
</tr>
<tr>
<td>2012</td>
<td>28</td>
<td>8</td>
<td>32 (89%)</td>
<td>36</td>
</tr>
<tr>
<td>2013</td>
<td>29</td>
<td>33</td>
<td>47 (76%)</td>
<td>62</td>
</tr>
<tr>
<td>2014</td>
<td>28</td>
<td>30</td>
<td>42 (69%)</td>
<td>61*</td>
</tr>
</tbody>
</table>

AHRI= Armauer Hansen Research Institute; ALERT= All Africa Leprosy and Tuberculosis Rehabilitation and Training Center; *Three protocols were exempted and the remaining 8 are pending in the year 2014 from review until this report was compiled.

Regarding the diversity of reviewed research protocols, the Committee often reviews protocols within the scope of ALERT's clinical services and AHRI's disease research portfolios. The majority of the research protocols submitted to the AAERC focus on HIV and mycobacterial diseases, particularly tuberculosis, whereas very limited research protocols were proposed on specific research disciplines, such as on research ethics and evaluation of information technology facilities in research institutions that fall under the cross-cutting research category (Figure 2A).

Similarly, most of the categories of the research types were clinical and basic biomedical, which fall under the scope of the hospital and research services within the ALERT Center (Figure 2B). Besides, most of the applications have been submitted as part of post-graduate studies for masters and PhD programs. In terms of data acquisition, the source of data for the majority of the applications were from primary source, i.e., with direct involvement of research participants (33 in 2012, 48 in 2013 and 42 in 2014). Additionally, there have been some studies conducted on stored specimens and review of medical records.
Figure 2. Diversity of research protocols submitted for AHRI/ALERT Ethics Review Committee by disease portfolio (A) and research discipline (B) over three years (2012-2014). The category under 'Others' includes studies on malaria, medicinal plants, podoconiosis, bioequivalence study, blood donation, depression due to chronic illness, generic drug use, hospital acquired infections, influenza, maternal health, meningitis, mental health, typhoid fever, birth defects, breast cancer, cervical cancer, hepatitis, diabetes, feeding practices, migration in female domestic workers, schizophrenia.
Parallel activities and AAERC’s performance evaluation by MERETI:

The AAERC further evaluates the conduct of research protocols through site visit assessments. However, despite a larger number of protocols reviewed with more than minimal risk and clinical trial protocols, the number of site visit assessments made by the Committee was limited (only 1 in the past three years). As part of its routine practices, the Committee also managed to revise parts of its SOP and also developed new SOPs, particularly on reviewing research protocols involving biobanks, biorepository specimens and/or linked archived data, and reviewing research protocols involving social and behavioral studies with human subjects (Submitted for publication). These modifications and new developments were made possible due to observations and reflections made in every meeting as part of informal learning processes. Such reflective practices also enabled the Committee to identify issues that require improvement for better performance within the Committee through provision of informal training. The Committee also actively participates in different national workshops held on research ethics.

The overall performance of the AAERC, when evaluated by the MERETI standards (12), was estimated to be 163/200 (82%) (Figure 3). The Committee identified areas that require further improvement including revision of the existing SOP, provision of templates for informed consent forms, an improved follow-up/tracking mechanism to thoroughly follow progress reports from each protocol application, and conducting site visits during its internal audit meeting made in December 2014. The Committee also recommended that a policy be developed on institutional biorepository/biobank for proper management, sharing and utilization of resources.

Figure 3. Evaluation of the AHRI/ALERT Ethics Review Committee by the MERETI standards
DISCUSSION

In view of a number of guidelines on research ethics including the ICH-GCP and CIOMS, which suggest for an independent review of research protocols (6, 13), it has been imperative that all research protocols receive ethical approval before initiation. This implies that in the absence of competent ethical review systems, the conduct of a research will not be publicized and hence findings from the research cannot be applied for informed decision and better utilization of the new knowledge. Such review mechanisms are therefore critical not only to protect the rights and safety of research participants, but also to evaluate the scientific integrity, the design and conduct of a proposed research, to draw valid and acceptable recommendations (11, 14).

In this report, a summary of data collected from one local institutional research ethics review committee over few years, is presented based on archived information available in its Secretariat. The purpose of presenting the data in this report is to share experiences (both strengths and limitations) and learning practices of the AHRI/ALERT Ethics Review Committee with other ERCs found in academic and research institutions in the Country. This report emerged as a result of the Committee’s internal audit report after self evaluation of its routine activities over the years. The Committee also identified its weaknesses and forwarded some recommendations that can be shared with others for educational purposes and for its own improvement.

Absence of structural positioning of ERCs in institutional organization systems could be one factor that limits the capacity of ERCs to optimally function within their institutions, thus impeding their autonomy and independence in decision making. This might have emerged as a result of lack of knowledge or oversight of the role of ERCs in the conduct of any research. On the other hand, the limited scope of review services provided by institutional review boards (IRBs) may limit provision of competent and adequate review activities for researchers coming from abroad with genuine collaboration and partnership. Widening the scopes of IRBs, on the other hand, could be a burden and might be too cumbersome for proper handling of review protocols. In this regard, the Committee recommends widening the scope of review services offered by IRBs in exceptional circumstances and in separate modalities. In this regard, the Committee suggests the involvement of professional associations, private ethics review committees and others such as the Ethiopian bioethics initiatives (ETBIN) in taking part and playing significant roles in provision of independent ethics review services for the needy.

The cohesion among the members of AAERC that resulted from a fair gender balance and age mix, multidisciplinary expertise and institutional affiliations, has greatly helped the Committee to improve its performance. It has contributed to motivating the Committee to share reflective experiences and improve regular attendance by Committee members. It is felt that this can serve as a driving force for an improved and smooth succession plan for recruiting new members to replace the existing ones. As recommended by the WHO guideline, the four basic principles for good ethical review including independence, pluralism, competence and transparency (15) further ensures the quality of discussion and recommendations given to applicants.

The increased trend seen in the number of protocols reviewed over the years could be as a result of an increased number of academic institutions in the Country demanding the conduct of research by students as part of their dissertations. In addition, support provided by AHRI to higher academic institutions, and the use of facilities at AHRI/ALERT by researchers, have increased through time (2). On the other hand, the quality of research protocols particularly submitted for expedited reviews seem to have declined, as noted from the total number of approved protocols over the years. Since such protocols were largely of poor quality in terms of describing the study rationale, research design, and feasibility to conduct the proposed study both in terms of infrastructural facilities as well as level of expertise required to perform the study, applicants often fail to comply with the Committee’s recommendations following review.

The Committee had the impression that such poor quality submission also reflects the inadequate level of supervision and mentorship received by applicants, who are mostly students. For some, this process delayed approval of their research protocols and for others it led them to withdraw and shift to other facilities, where they think they would be treated more leniently. The shift to other facilities strongly implies the need for capacity building of research ethics committees in the Country so as to have uniform standards for submission, review and approval and further the need for networking with different
IRBs to ensure acceptable and similar standards. Such practices can minimize duplication of efforts and ease the workload of different IRBs (16). The Committee's weakness in providing timely reports and review comments to applicants also contributed to a lesser degree, in the withdrawal of research protocol applications.

One of the limitations of the AAERC was limited site visit assessments made over the three years, which requires prior planning and financial resources. Inefficiency in the continuous assessment of approved protocols has been identified as an additional drawback. This can be improved through establishment of a database and full time and skilled personnel for efficient follow-up. In addition to its readiness to undertake independent evaluations, the Committee strongly believes that the practice of self evaluation can be further explored and continuously implemented for improved services. While reporting these analyses, the AAERC is preparing itself for another external audit by the WHO/TDR through the SIDCER program. Further independent assessments are however warranted to evaluate the Committee's function in terms of consumer satisfaction and its quality in general. This also opens ways to further assess the level of awareness or oversights among researchers about the roles of ERCs. In this regard, the Committee strongly believes in the need for provision of continuous training on research ethics at higher academic institutions to enhance awareness as well as maintain the level of competence among members of IRBs.

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REFERENCES


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ABSTRACT

One of the challenges in the process of ethical medical research in developing countries, including Ethiopia, is translating universal principles of medical ethics into appropriate informed consent documents and their implementation. Rapid Ethical Assessment (REA) has been suggested as a feasible approach to meet this application gap. In the past few years REA has been employed in few research project in Ethiopia and have been found to be a useful and practical approach. Feasibility assessment of REA for the Ethiopian research setting was conducted between 2012-2013 in order to inform the subsequent introduction of REA into research ethics review and governance system in the country. REA was found to be an appropriate, relevant and feasible venture. We argue that REA can be integrated as part of the ethics review and governance system in Ethiopia. REA tools and techniques are considered relevant and acceptable to the Ethiopian research community, with few practical challenges anticipated in their implementation. REA are considered feasible for integration in the Ethiopian ethics review system.

Key words: Rapid Ethical Assessment, Feasibility, Research Ethics, Ethiopia

INTRODUCTION

The inflexible use of international ethical guidelines in health research have prompted investigators to seek an approach for adapting these guidelines to local situations. Studies have emphasized the importance of addressing local context, especially in the developing world where there is a disconnection between what is assumed by researchers and the practical reality [1-3]. Rapid assessment techniques have been documented to play important role in improving research consent process in developing countries by understanding and addressing contexts. One of those approaches suggested for further use is named as Rapid Ethical Assessment or Appraisal (REA) [4-7]. Rapid Ethical Assessment (REA) is a brief qualitative intervention designed to map the ethical terrain of the research setting preferably prior to a research team starts recruiting participants with the purpose of connecting ethical principles to contexts and realities on the ground. REA attempts to discover, describe and respond to the ethical issues specific to a particular research setting, and as such should help researchers to address the issues that genuinely matter to proposed study participants and their community. The assessment is conducted among key stakeholders to inform the design of the particular research project. Its findings are utilised to inform and guide the research consent process; ranging from the conception and development of the consent form, to the way consent is obtained. REA as a methodology employs constellation of action research, rapid assessment and ethnography. This makes the approach a multi-mix, multi-disciplinary approach with overlaps between various techniques. REA employs an ethnographic qualitative design with a blend of anthropologic ethnographic enquiry, action research and rapid assessment techniques (4-7). REA were serially piloted in Ethiopia. During these rounds of interventions the feasibility of REA for integration into the current research ethics review and governance system was assessed. In this paper we summarise the key findings from the REA intervention employed so far in Ethiopia and key considerations for integrating REA in to the ethics governance in Ethiopia.

MATERIALS AND METHODS

Feasibility assessment on REA in the Ethiopian context was conducted based on REA piloted in to three different community based studies in to five loca-
tions in Ethiopia, in 2012-2013. The locations were Ayra in Eastern Ethiopia, Soddo and Butajira in Southern Ethiopia, Mekele Zuria from Northern Ethiopia, and Zeway from South Central Ethiopia (Figure 1). During the pilots, observations and documentations of REA implementation processes were done. This was preceded by an acceptability assessment where researchers, ethics review committee members and policy makers from academic institutions such as Addis Ababa University (AAU), Jimma University (JU), Ethiopian Health and Nutrition Institute (EHNRI), University of Gondar (UoG) were interviewed. In addition two REA workshops were conducted among researchers to collect feedback about REA. (Figure 1)

Figure 1. The five REA Pilot locations in Ethiopia, 2012/2013.

Based on data from the different phases of the REA project, feasibility analysis was conducted to determine feasibility in terms of time, cost and skill were assessed to answer the following question; how much does REA cost? what skills are needed? are the skills transferable? who will conduct the REA, the researcher or another expert? Is REA acceptable to researchers? Is it possible to integrate the tool into existing research ethics appraisal systems? Is it user-friendly and cost effective?

We explored how REA might be integrated into the existing research governance and ethical review system based on opinions from researchers and research ethics stakeholders, our observations and documentation of how the REA fitted into the pilot research projects, and the reflections and feedback from REA workshop participants. Thematic analysis of qualitative data based on cycles of coding were conducted. We then triangulated findings from all three phases of the project to identify relevant themes related to the various components of feasibility. Transcripts, memos and summaries of interviews, discussions and observations were coded to identify patterns and emerging themes in line with the variables of interest. Following the coding of responses using themes, we categorized and synthesized the results thematically. Thematic variables used to measure the various components of feasibility included attitude and perception about REA, satisfaction with REA, suitability of REA, perceived demand and expressed intent to use REA, actual use of REA, expertise and resources needed and available for REA (such as time, financial costs, human resources), training and skills needed, efficiency of implementation in terms of adaptability and flexibility; accommodation of the tool into the system and scalability.

RESULTS

REA feasibility results are presented in three categories; its acceptability to intended end-users; practicality in its implementation; and dynamics of its integration into the current system and potentials for further expansion.

Acceptability of REA to intended users: The researchers who were interviewed generally had positive perceptions about REA and thought this is a useful approach. Their main concern however was the practicality of the REA approach. As conducting a rapid qualitative study to improve consent process is a new concept, many had to ask more to learn before understanding it.

Researchers who employed REA were happy with the outcomes of the REA process and appreciated the experience. They expressed their appreciation and satisfaction with the feedback they obtained for the consent processes of their studies. REA workshop participants appreciated the relevance of REA and the descriptions and illustrations used. They were very excited to learn about this new technique and expressed interests to know more in due course. Participants also said that the tools appear to suitably address very important aspect of research in low income settings.
Researchers and ethics committee members interviewed appreciated the contribution of REA towards improving the standards of medical research. They appreciated the fact that REA creates a good opportunity for researchers to understand their research community in relation to the research process and particularly the consent process. Respondents expressed general acceptance towards REA and considered the principles governing REA and its application to be similar to the principles behind pre-test studies conducted before the actual studies.

If the participants understood [the community] well, this will simplify the process of research. I think it is a very good idea. ... Especially in Ethiopia and [other] developing countries, [where] there are diverse cultures, lot of surprises will be there waiting for you [in the community], so I think it is a good idea. This can [even] be included in the guideline(s).

[Academician and Researcher, AAU]

REA respondents expressed their concerns that some researchers might resist REA as a mainstream tool. Possible reasons included the additional work burden that it might result, and not being able to understand its benefits fully. This was considered especially important in the early stages of introducing REA. Introducing REA as a pre-requisite for ethical appraisal and as a mandatory requirement without adequate awareness and background work might be very unpopular. Accordingly, training and awareness raising were considered vital along with continued negotiation and demonstration of the benefits of REA.

Putting it (REA) as a [mandatory] requirement might bring resistance among researchers...[just] because it is a new thing. People resist new things because of lack of knowledge. So it should be done slowly, showing it in other studies, showing its benefit. When they see the benefits, if one study is done properly it will be a base for another study, it will be like that. Eventually it will grow slowly as a culture (among researchers). [Academician and researcher, AAU]

During discussions with researchers about REA, there was a lot of confusion regarding the term 'rapid ethical assessment'. Many thought this meant a tool to speedily address the ethical approval process. It took considerable discussion to clarify this. REA workshop participants initially misunderstood the term 'Rapid Ethical Assessment'. As many researchers are frustrated with the current very protracted ethical appraisal process, they thought this tool was intended to speed up the review process and were surprised to learn that REA involves addition of a step or process. When they heard more and got more informed, they were not disappointed, but appreciated the importance of this new tool and considered using it despite the demands it creates on researchers. Overall, researchers approached for this assessment expressed concerns that REA might be an additional burden to researchers in terms of time and budget. Other respondents stressed the need for awareness raising and training on REA. Some were concerned about too much involvement with the community before the actual data collection might bring about contamination of the instrument and measurement bias during the field research.

Practicality of REA in its Implementation Process:
It was mentioned that REA might become an additional burden both to the individual researcher and the research governance system (including ethical review) due to the additional pressure and burden on the researcher by increasing the process and steps of research and increased complexity of the review process.

This (REA) will increase the bureaucracy and make the process long, and it complicates the ethical process .... I don’t think we need another body for this. No need of additional review. It will increase the time [needed for the review]. Then you have to pass [through] all this to start working. It lengthens the steps. As you make it more organizational, it will increase the complexity specially in our environment which is already bureaucratic. It is bureaucratic in [responding]. [As] the capacity level is low, they (the review systems) need to be [first] strengthened. [IRB member and researcher, EHNRI]

Respondents felt that applicability would depend on the type of research under consideration. To introduce REA not in blanket fashion for all research, but only for selected type of research projects based on criteria such as risk level and anticipated ethical issues (e.g. community-based research, invasive procedures, biological specimens involved) appeared more sensible.

It depends up on the research question, ... so if there was a check list ... based on the research question... like clinical trial, ... sensitive issues, like genetic studies, in remote areas, vulnerable population.

[IRB member and researcher, AAU]

Others suggested that it would be difficult to introduce REA based on the research-type, risk and harm levels, as it would be difficult to foresee risks in research. To address this dilemma, an all-inclusive approach of national REA was suggested.
It will be better if it is not like that, it is hard to classify research a priori, which one does harm. It is hard to decide in the beginning. It is hard to predict what research could do to the society, you can't say “let me do formative [REA] for this one and not for this one”.

[IRB member and Researcher, JU]

This refers to doing a ‘one-off’ REA at the national level to map out all possible ethical issues at the national level for subsequent use by researchers. This point is further presented in detail under the section on integration below.

Instead of doing REA for every study separately, it was suggested that REA be done at a national level to map out existing ethical considerations in the various ethnic and cultural groups. Then the issues and recommendations could be included in a national document as a guideline (catalogue) researchers could use this information as a reference for research in a specific setting.

Instead of doing a formative assessment (REA) for all research which is tedious, there should be a guideline (guiding document). You can do a [national] survey (REA), and put it on the guideline, saying this is the Ethiopian community [and], if you want to get a signed consent you should do like this [depending on the site]. Otherwise if you come to [do REA in] all research, one it might be different what each researcher will bring (find), [and] there might be conflicting outcome, the formative [REA findings] that you bring (find) is (could be) different from what another person might bring, there might not be a common ground. [IRB, Researcher and academician, JU]

According to the respondents, important resource considerations included time and cost. It was stressed by participants that the approach is resource-intensive and may not be practical time-wise. Considering time as an important factor, there was a dilemma about how much time is enough to be allocated. The issue of cost and the implication of additional cost needs for REA was mentioned. Most local research projects operate under meagre budgets, and REA will be another competing factor for the budget available. During the REA pilot studies, we documented resource inputs required for REA implementation.

It needs a lot of resource [including] time. When we start a research, there are deadlines and time constraints. To study exhaustively we need time, so it depends on resource and time. If the area is far, it is hard to go there and do it and come. Making it as a requirement is a little hard. [Academician and researcher, AAU]

Costing: In the REA pilot studies, the budget planning took into consideration line items such as personnel costs, transportation and field instrument as well as data management and analysis costs. Average costing per REA amounted to 42,812.5 Ethiopian Birr (ETB) (approximately £1500 or 2250 USD). This excludes the costs of other items which were not directly paid for such as IT equipments and software. Compared to field research budgets of the individual research projects, the REA cost ranged from 1.92% in Adami-Tulu (Zeway) to 4.99 % in both Ayra and Soddo. The overall details of field costs of the four different locations are presented in Table 1.

Table 1 Field site project costing compared to REA costs for the four REA pilot sites, 2012-2013.

<table>
<thead>
<tr>
<th>Site</th>
<th>Parent project research cost estimates</th>
<th>Proportion of cost of REA* against project cost</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ETB</td>
<td>USD</td>
</tr>
<tr>
<td>Butajira</td>
<td>748,850</td>
<td>39,413</td>
</tr>
<tr>
<td>Adami Tulu</td>
<td>2,233,000</td>
<td>117,526</td>
</tr>
<tr>
<td>Ayra</td>
<td>856,662.5</td>
<td>45,087</td>
</tr>
<tr>
<td>Soddo</td>
<td>856,662.5</td>
<td>45,087</td>
</tr>
</tbody>
</table>

* Average cost per REA ~ 42,812.5 ETB
**Time:** This took into account the time needed per project for planning (preparation for field work) and implementation (time in the field). Each of the days spent on the field were longer than normal working days (on average, 12 hours a day spent on field work and analysis. Overall, the average time range for REA was 4 to 6 weeks (including initial analysis); 3-5 weeks for the data collection and field work, and one week to compile the summary findings and communicate back to the researcher (Table 2).

<table>
<thead>
<tr>
<th>Site</th>
<th>Time Period</th>
<th>Total Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Butajira</td>
<td>November/December, 2012</td>
<td>6 weeks</td>
</tr>
<tr>
<td>Adamu Tulu</td>
<td>January/March, 2013</td>
<td>5 weeks</td>
</tr>
<tr>
<td>Wollega</td>
<td>Mid March/April, 2013</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Soddo</td>
<td>Mid April/May, 2013</td>
<td>4 weeks</td>
</tr>
<tr>
<td>Mekele</td>
<td>July/August, 2013</td>
<td>4 weeks</td>
</tr>
</tbody>
</table>

**Manpower:** Manpower needed for REA included the REA team and its technical expertise. The profile of personnel involved in terms of professional expertise and other characteristics for each pilot project and field sites are presented below (Table 3).

<table>
<thead>
<tr>
<th>Project</th>
<th>No of REA team members</th>
<th>Team Composition and Expertise (#)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Butajira</td>
<td>5</td>
<td>Anthropologist (1); Public Health professional (2); Expert insiders (2)</td>
</tr>
<tr>
<td>Adami-Tulu</td>
<td>5</td>
<td>Health professional and PI (1); Public Health Professional (2); Anthropologist (1); Expert Insider (1):</td>
</tr>
<tr>
<td>Ayra</td>
<td>5</td>
<td>Anthropologist (1); Public Health professional (2); Expert Insider (1); PI of the Cervical Cancer Project (1)</td>
</tr>
<tr>
<td>Soddo</td>
<td>5</td>
<td>Anthropologist (1); Public Health professional (2); Expert Insider (1); PI of the Cervical Cancer Project (1)</td>
</tr>
<tr>
<td>Adigdom</td>
<td>5</td>
<td>Anthropologist (1); Public Health professional (2); Expert Insider (1); PI of the Cervical Cancer Project (1)</td>
</tr>
</tbody>
</table>

1 USD ~ 19 ETB ; 1 GBP ~ 28.5 ETB
Refers to the research into which the REA is to be employed.
**Feasibility of Integrating REA to Existing System:**

Study respondents considered the process of REA integration to be a time-taking process. To this effect, integration was thought to happen at two levels: a) integration with the research project to be conducted; and b) integration into the existing ethics system and guidelines.

As part of integrating REA into individual research projects, it was recommended to integrate REA into pre-test phases of research. REA and pre-test studies were thought to share similar principles in improving the implementation of research during field data collection. Integrating REA to the main study would simplify the issue of ethical clearance for REA component of the project as the REA would be approved together.

> Integrating it (REA) to the pre-test phases is better than doing it alone. It will also save time. Because whatever you do, you test them on the pre-test and it will be an input when you do your main study. I think this will be good. When clinical trial is done, ... they do the background (pilot) study. I think this thing is already there. ... you need to add this in there.... carrying it out at the pre-test or pilot time is good. Because it is( it gets) already approved [together]. [Academician and researcher, AAU]

When it comes to system integration, it was mentioned repeatedly that REA needs to be mainstreamed and should be part of the existing guidelines for research and ethical governance. The country circumstances in terms of ethno-cultural diversity to be taken in to consideration, as a justification for including it in the guideline. While it is possible to include REA in the guidelines, this would need to be accompanied by continuous capacity building and training.

> This (REA) can be included in the guideline, ... adding it (REA) to the guideline allows them [researchers] to think about it ... [and include it in their protocol] ... but ... do they see the guideline? The most important things are ... continuous trainings for investigators. [Academician and researcher, AAU]

However, mainstreaming REA into the current research governance system is not an easy process. Caution in application was advised in order to keep the approach as simple as possible. Participants expressed the need for more workshops as a means for dissemination and expansion of REA to wider audiences.

**DISCUSSION**

Based on the feasibility analysis practical issues and considerations in applying REA for further use in the Ethiopian setting were identified. REA implementation appears feasible, yet some areas require caution and must be addressed in parallel. According to models suggested by researchers who have conducted feasibility assessment in public health interventions, three general categories are considered important [8] [9].

**End-user related feasibility:** Potential end-users of REA are researchers, ethics committee members and REA team members. There are two levels of acceptance by end-users, the first one concerns perceptions and attitudes towards the REA, while the second level is more practical where end-users agree to use it. Researchers and ethics committee members acknowledged the need for REA as an approach which would address these gaps. Acceptability is expressed through user’s perspectives and perceptions; how do researchers, the REA team and the wider research ethics community accept the tool.

Since REA is a very new approach, concerns about potential resistance were expressed. According to Rogers’ theory on "diffusion and adoption of innovation", the rate at which a new approach diffuses for use by its users depends on the nature of the end-users [10]. While only a few will adopt the innovation immediately, the majority take time. A few will never adopt the new technology at any cost. While it is too early to appreciate the whole dynamics of REA acceptance by its end users, the model is worth considering [11]. The other reasons for resistance include practicality, the potential cost and time burdens and researchers’ perceptions about the current ethical approval system. Despite this, the pilots showed that researchers could actually engage with REA and integrate it into their research project. This was chiefly because researchers were convinced in the added value of REA in improving the consent process and increasing the quality of the research process.

**Process-related feasibility:** Implementation of an intervention is a continuous process which starts with planning and making sure what is planned is exe-
cuted [8]. Three important resource considerations in the process of employing REA included cost, time and manpower.

It was possible to conduct REA at a reasonable cost of 42,815.5 Birr per REA. In view of the benefits one gets from the REA, the budget it consumes seems reasonable. Several factors might have contributed in attaining this reasonable cost. We tended to be conservative in expenditure and negotiated minimum possible pricings for items and personnel. Though the REA costs were covered by a separate budget, when we compared the ratio of budget spent for each REA, this ranged between 1.92 % and 5.72 % of the overall budget allocated for the parent research projects. Researchers need to plan well in advance to cater for the budget needs, by considering REA as part of the overall research proposal and accordingly budget for it part of the main research project.

On average it took 4-6 weeks to conduct REA. Rapid assessments are generally considered to be conducted in an average of 6 weeks [2]. Previous researchers have conducted REA in range of 5 to 7 weeks [6] [7]. Despite such short durations, very useful findings were generated. This may convince end-users that REA can generate useful results in a reasonably short period of time. Considering the fact that researchers may spend weeks or months waiting for ethical review [12], planning a 6 week REA does not seem unrealistic.

Regarding manpower, the average number of professionals needed was 5 per REA team. The number was reasonable and manageable as a group for creating a group dynamics. In rapid assessments it is recommended that the team need not be big in number [2]. In rapid ethnography, it is recommended that the rapid process is augmented by involvement of a mix of professionals who have a good team dynamics. It was possible to implement this in our pilot REAs. The REA team was composed of a mix of individuals from different disciplines as well as members from the study area who were considered to be key informants and were in some senses ‘gate-keepers’ to the community during the field work. The social scientist member had the role in making sure that the qualitative designs were properly done, and advised the whole REA process. Health professionals helped the team in exploring the health issues in the research and their public health and clinical implications. The outsiders brought new issues to the community, while insiders helped in balancing views and avoiding assumptions from outside [2]. It was possible to train other experts to do REA and to transfer REA skills and expertise into the pool of identified personnel.

The flexible and adjustable nature of REA helped meeting practical challenges in the process of implementation throughout the phases of pilots. During the field survey, some of the challenges of implementation which required adaptation included timing and duration. During analysis of REA findings, the provision for iterative analysis and daily-debriefings helped a lot in providing usable results for researchers on time. Important considerations regarding communication of feedback were timing (when to disclose information - during, before or after the actual survey) and format (written or verbal). There was room for flexibility in choosing from the stated options.

System-related Feasibility: The integration of REA into the existing system depends on a number of factors. All feasibility considerations discussed earlier such as acceptability and applicability are important considerations for integration, as integration is a process rather than a one-off event. New approaches pass through a number of phases and steps before they fully integrate into routine practice [13]. Suggestions given as to make effective ways of charting the integration of REA included integrating REA into the pre-test phases of studies; including REA in the National Research Ethics guidelines; and conducting a National Survey of ethical issues using REA.

Most research project have a pre-test phase to check the tools and make revisions and adjustments accordingly[14, 15]. REA and pre-test would share the principle of adjusting the tool and the process based on field experiences. However they have two distinct and separate objectives and would be difficult put them together. Though the duration of pre-test studies may vary from project to project, they are mostly completed in a couple of days. Whereas REA needs an average of 4-6 weeks depending on the circumstances in the field. Pre-tests are conducted in a population other than the actual population but with some shared similarity to avoid contamination, while REA studies are conducted in the population to be included in the main study, with focus on the ethnocultural and ethical issues related to the actual target population.

Development of REA to the level of national guidelines is a process that takes time. Issues eligible for inclusion in national guidelines require awareness raising and advocacy, a series of workshops and finally buy-in from a higher governing body at na-
tional level. In this case, the responsible body would be the Ministry of Science and Technology. The three Ethiopian national ethics guidelines had to pass through these stages [16]. During the recent revision of the national research ethics guideline, attempts were made to introduce the concept of REA, however, this may be premature given low levels of awareness and the lack of extensive documentation on REA. Respondents also doubted the practicality of introducing REA to all research projects and suggested a differentiated approach depending on the type of research. In addition they argued that the findings of one research REA might be applied to a similar research project, avoiding the need to repeat REA. Application of ethical checks based on checklist and criteria have been commonly practised even for a consent process. Based on those criteria and level of risk assumed IRBs can prescribe practical approaches (Belmont, ICH) (17,18).

As part of introducing REA for national usage, a ‘national REA’ was suggested as a one-off ethnographic survey in all the ethno-cultural pockets in Ethiopia with the objective of mapping out ethical issues. The results would be collected for reference for future studies. This was thought to be more feasible and cost-effective approach, than prescribing REA for every study. The suggestion was made with the assumption that the ethical issues identified for one piece of research could be reasonably applied to another. Such multi-sited approaches have been suggested and discussed by other researchers [19, 20]. However, contexts and realities are not static and the same is true with ethical issues associated with them, weakening arguments for this approach. In addition, assessing ethical issues in the absence of a planned research project is far from ideal. Ethical issues are a function of settings as well as the research question and study design being proposed. Based on experiences so far, REA discloses ‘unexpected’ ethical issues related to a specific project. Thus, merely studying the context will not be enough. REAs are done in the reality of the setting and the issues and not in general terms. Earlier work has also indicated drawbacks of such approaches [20]. On the other hand conducting national REA would be a hugely expensive exercise and time-consuming, whose findings would be severely limited. Project-specific REAs will definitely be of use to the proposed project, leaving the question of which projects should be preceded by REA.

Limitations: In documenting feasibility outcomes we relied on outcome measurement in the absence of comparison groups. Cost-feasibility and cost-effectiveness studies that employ economic models and cost-effectiveness analysis were beyond the scope of the current project.

Conclusions: Based on the findings, application of the REA tool and its integration into the existing research governance system in Ethiopia appears feasible. However some practical concerns will need to be addressed in parallel. There is a good level of recognition and acceptability of REA by its end users; researchers and ethics community. REA is flexible and adaptable to circumstances, settings and needs. The resources needed for REA are not different from most research and with proper planning and trans-disciplinary collaboration it should be possible to implement REA in research projects conducted in Ethiopia. REA results were conveyed to researchers in a reasonably short period and were feasible.

It was possible to demonstrate the potential to integrate REA into the current research review and governance system at two levels; within individual research project; and into the existing research governance system. Integration within research proposals has the advantages of an integrated review and efficiency in planning and resource management. Acceptability and practical feasibility of the approach, cost-effectiveness and flexibility for easy adoption, all contribute as key factors for successful integration. Integration with pre-tests seems unrealistic as the two have distinct and separate objectives, timings and settings.

However, concerns remain that REA might place additional burdens on researchers and the research governance system. Main issues identified were time and budget constraints, ‘contamination’ related to the data collection instrument, the flexibility in modifying the consent form in the field might affect the quality and standards of the IRB approved consent forms and procedures. Creating understanding about REA is not automatic and many potential stakeholders had misunderstandings and unworkable expectations. Conducting national REA to generate a national ‘catalogue’ of ethical issues also appears unrealistic as it would be very expensive and its findings would not reflect the unique dilemmas related to individual projects.

Recommendations are made in three areas: a) Continuous awareness raising through workshops for researchers, research ethics committees and regulators, with the aim to promote REA and its use. In addition the researchers there is need to design a mechanism to involve data collectors and field work-
ers in the conduct of REA. b) It is advised to follow a differentiated approach to develop criteria for projects requiring REA than a more general one as projects have their own peculiarities. There is a need to guide researchers opting to use REA in relation to the resource and skill needs and the planning considerations so as to have a practical financial and time budgeting. The costing need to be made based on the realistic market for the listed items, with an adequate time and man power allocated. As much as possible the REA plan need to be integrated into the initial research proposal development. As part of wider use the model of implementation where REA is an integral part of the research project is to be further pursued. There is a need to further document resource feasibility of REA with a cost-benefit analysis. c) For wider implementation, documented guidelines in applying REA need to be developed. In preparation for wide scale application continue working on awareness and capacity building of various stakeholders at institutional and policy levels.

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