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ABSTRACT

Inadequate training in matters of ethics renders health care providers unprepared for dilemmas faced in public health, research, and clinical practice. Certificate course training offer opportunities to gain more knowledge and skills on all matter ethics. Over the past decade, the increase in research activities in Kenya has not been proportionate to training in ethics. The Centre of Biomedical Ethics and Culture (CBEC), Kenya Medical Research Institute (KEMRI) Bioethics training Initiative (CK-BTI) is a Forgyat funded program for building capacity in research ethics for Kenya and Pakistan. This paper evaluates the characteristics of participants that attended the CK-BTI certificate level courses in Kenya between 2017 to 2021. This data was analysed for this paper and utilized information from the training application process. Between November 2017 and July 2021, a total of 1,359 applications were received and 457 (33.6%) trained. The target countries were Kenya and Pakistan but interest was drawn from Tanzania, Uganda, Nigeria, and Zambia. The continued interest in the certificate level ethics courses may imply a need to increase the number of ethics training offered within the East African region.

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INTRODUCTION

Global debates on ethical conduct include practices during the conduct of research, delivery of healthcare services, and work in the public health space. As Kenya has expanded and devolved clinical care, there has also been an increase in research activities (Kenya Demographic & Health Survey, 2014). This suggests that there may be a need for increased awareness and discourse in bioethics, with an enhanced emphasis on training for research regulatory processes personnel can be held accountable and responsible for upholding good research practices once they are trained. Bioethics in healthcare brings understanding and knowledge among healthcare professionals about medical practice. According to Taj & Khan, (2018) stressing the ethical aspects of bioethics, medical professionals are capable of tagging along with ethical codes while practicing especially while dealing with issues. As ethical tribulations are linked with issues in medical care, so by application of bioethics, the healthcare system of our country can be better radically (Taj & Khan, 2018). Bioethics is a blend of scientific and humanistic constituents and does not have to need the recognition of certain long-established standards that are basic to medical ethics. Bioethics contributes to the rights and responsibilities of patients as persons. Its significance replicates in various divisions e.g., medical care, researches, and overall community (Taj & Khan, 2018).

The importance of bioethics education is recognized and integrated among Western countries, especially from the United States of America and other Western developed countries in the past 2 decades (Silverberg, 2000). An acquaintance of knowledge in bioethics is essential, as health care providers possess a duty to maintain professional competence and deliver a standard of care to patients (Stirrat, 2015). A global trend in medical education is the inclusion of bioethics teaching in the required curriculum of medical schools (Joong, Olivia, & Ho, 1999). Kenya is among the top 5 countries conducting clinical trials in Sub-Saharan Africa—particularly in HIV (Puppalwar, Mourya, Kadhe, & Mane, 2015). This notwithstanding, only 2 out of approximately 65 institutions of higher learning in Kenya offer master's level training in ethics. Strathmore University offers a Master of Applied Philosophy and Ethics (MAPE). This is a two-year part-time program providing a base for the development of any human activity (Strathmore University, 2015). The focus is to improve technical efficiency, effectiveness and also impact the community by changing the outlook of the course participants. Moi University offers a Master of Science degree in International Health Research Ethics (Moi University Website, 2019). This program requires a minimum of two years of four consecutive in-person semesters of full-time engagement (Research and Development for Health in Kenya, 2015).

These currently available programs have not seemed adequate to provide the bioethics training to support those interested in short-term, distance-learning or unable to undertake full-time master’s level training. It has therefore been impractical to expect members of the 30 accredited (IERCs) as well as other middle-level employees to undertake this level of training. The IERC members are professionals who have daily work duties and may not be motivated to give a year or two of their time to such programs. Given the number of health care providers Kenya graduates annually, and because there is no evidence of faculty at training institutions being specifically trained in bioethics, the need for training was a clear gap. The 9 medical schools in Kenya train an average of 600 medical doctors annually (Kenya Medical Practitioners and Dentist Board, 2019). In addition, there are 2,166 nurses, 129 dentists, 117 pharmacists (National Commission for Science, Technology, and Innovation, 2018), and over 65 institutions of higher
learning (Commission for University Education, 2017). These graduates would benefit from training in bioethics.

One of the existing barriers to bioethics education in Kenya is lack of qualified staff; a limited number of people have extensive training in bioethics that can then train others (Joong, Olivia, & Ho, 2019). There is no set curriculum in place for which qualified personnel can use to train. Limited financial resources to not only hire qualified staff but also to develop courses and a curriculum (Joong, Olivia, & Ho, 2019).

The Centre of Biomedical Ethics and Culture (CBEC) at the Sindh Institute of Urology and Transplantation (SIUT) in Karachi Pakistan (Centre for Biomedical Ethics and Culture, Siut, 2004), in collaboration with the Kenya Medical Research Institute (KEMRI) in Nairobi Kenya developed a bioethics training program named the CBEC-KEMRI Bioethics Training Initiative (CK-BTI). This Fogarty International Centre-funded program sought to build bioethics capacity by offering a variety of training, in both Kenya and Pakistan. The training has targeted research ethics committee members, researchers, public health workers, medical school faculty, clinicians, and other interested stakeholders from health care and research. The program is designed to help participants develop critical thinking skills to resolve matters of ethical challenges arising in research, public health, and clinical practice (CBEC-KEMRI Bioethics Training Initiative, 2017).

The purpose of this paper is to give an overview of the demographics of individuals that are interested in bioethics certificate course training. The paper also highlights the need for more ethics training around East Africa and the diversity of the participants in all areas including country, county, age, sex, institution, and education level.

COURSES AND CURRICULUM

Certificate courses aim to build capacity for many individuals who need support that will enable them to be more proficient in their duties or need capacity in certain aspects of training. The objective of these one-week courses is to rapidly build the capacity of a large number of stakeholders and equip them with a basic understanding of ethics (CBEC-KEMRI Bioethics Training Initiative, 2017). CK-BTI offers 4 certificate course trainings each year which includes: Clinical Ethics, Research Methods, Fundamentals of Bioethics and Research and Public Health ethics. These courses are conducted once every year and involve a variety of teaching methods such as presentations, group discussions, videos, and role-plays. Each certificate course focuses on a different area, Research and Public Health ethics certificate course focus on the ethical issues involving human subject research and public health research as well as contemporary issues. The trainees learn about public health challenges and the ethics of research in disaster situations like epidemics. Participants are introduced to international guidelines for ethical research and specific challenges of conducting ethical research within resource-limited settings like in developing countries. In clinical ethics, participants are introduced to emerging clinical ethics issues especially in situations of resource constraints. The research methodology course includes details of study designs, critical appraisal of research, a basic understanding of biostatistics, and issues of policy in bioethics and research regulation (CBEC-KEMRI Bioethics Training Initiative, 2017).

METHODS

Participant Recruitment

A call for applications for each course is sent out on email and via WhatsApp messages to the CK-BTI networks. The networks developed over the years consist of research and institutions of tertiary learning and all former applicants to CK-BTI courses. As part of the application process, individuals are requested to provide an updated Curriculum Vitae, and a one-page letter of intent describing why they are interested in the course, and what practical benefit might emerge to them and their institution as a result of the training. They also provided 2 letters of reference, with one from a direct or line supervisor which confirms facilitation of the time needed for training. In this study, only descriptive statistics are presented and discussed.

For the Clinical Ethics Course, preference was given to candidates actively involved in healthcare
provision including medical doctors, clinical officers, nurses, administrators, Hospital Ethics Committee members, and those for whom the training will have particular relevance because of their involvement in the care of patients or training or educational activities.

For the Research and Public Health Ethics Course and Practicum preference was given to applicants involved in human subject research, public health practitioners, and those interested in expanding their knowledge in bioethics. Preference was also given to research regulators, policymakers, and members of ethics review committees. The practicum training was scheduled to take place after the research / public health certificate course. Institutional Ethics Review Committees (IERC) members were prioritized for the practicum at the KEMRI-SERU. During the practicum, participants were involved in the review of proposals, attending an ongoing IERC meeting, and using the KEMRI SERU/ ERC office Standard Operating Procedures (SOP) as a framework for how to develop efficient and workable systems for their ERC processes.

The Research Methods course targeted individuals who are involved in the conduct of research, the teaching of research, and those involved in the review of research proposals like members of IERCs.

The Foundations of Bioethics course which provided the foundation and basis of moral reasoning targeted those who showed interest in learning the basics of bioethics, its significance in different aspects of life, and those involved in academic educational activities.

The participants provided demographic data including their workplace, position held, their physical addresses (town and country), research interests, and memberships of any relevant committees. Since the various courses target specific individuals, the selection. The panel made decisions based on the suitability of the individual for that particular course as well as the strength of their application.

The participants were drawn from various disciplines including medicine, academia, nursing, administration, pastors, armed forces, and both public and private practice. Although the program’s main focus is to build capacity in Kenya, applications have been received from other countries in the region including Uganda, Tanzania, Nigeria, Zambia, and Cameroon. Each year the program sought to train 45 individuals in the Research and Public Health Ethics course and Practicum, 20 individuals in the Clinical Ethics course, 20 in the Foundations of Bioethics course, and 20 in the Research Methods course. This target was surpassed due to the large number of applications that have been received. The program was designed to offer 5 candidates from Pakistani train in the Research and Public Health Ethics course including the Practicum. Scholars from Pakistani have opportunities to attend research ethics courses in Karachi, however, the structured practicum is unique. These trainees each spend a total of 2 weeks in Kenya, the first week attending the research ethics course that is timed to coincide with the practicum period.

**Data Analysis**

Information collected from participants on entry was used to come up with a summary of the variables through the years. Information on their sex, education background, current profession, IERC membership, and physical addresses. This information was collected per training then put together on an excel sheet and finally analysed to compare the different variables.

**RESULTS**

**Complete Applications**

There has been a total of 1,116 complete applications between November 2017, when the program began, and July 2021. A complete application includes all documents requested by the program to be considered for training, these are curriculum vitae, a letter of intent, and 2 reference letters. An additional 243 applications during the same period were not complete hence they were not considered. The following abbreviations are used for the certificate courses offered.

- RPHECC + P = Research and Public Health Ethics Certificate Course and Practicum
- CECC = Clinical Ethics Certificate Course
• RMCC = Research Methods Certificate Course
• FBCC = Fundamentals of Bioethics Certificate Course

Of note, only the RPHECC+P was offered in 2017. The second year in 2018 saw the addition of the CECC. In 2019 all 4 courses were offered and this paper covers demographics until July 2021 which was when the Research Methods Certificate Course training was offered. The total number of both complete and incomplete applications received is in brackets.

Table 1: Total number of complete applications from November 2017- July 2021

<table>
<thead>
<tr>
<th></th>
<th>RPHECC + P</th>
<th>CECC</th>
<th>FBCC</th>
<th>RMCC</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2017</td>
<td>63 (68)</td>
<td></td>
<td></td>
<td></td>
<td>63 (68)</td>
</tr>
<tr>
<td>2018</td>
<td>77 (79)</td>
<td>42 (56)</td>
<td></td>
<td></td>
<td>119 (135)</td>
</tr>
<tr>
<td>2019</td>
<td>82 (100)</td>
<td>58 (83)</td>
<td>38 (59)</td>
<td>138 (139)</td>
<td>316 (381)</td>
</tr>
<tr>
<td>2020</td>
<td>75 (106)</td>
<td>66 (78)</td>
<td>113 (139)</td>
<td>96 (130)</td>
<td>350 (453)</td>
</tr>
<tr>
<td>2021</td>
<td>-</td>
<td>99 (118)</td>
<td>58 (68)</td>
<td>111 (136)</td>
<td>268 (322)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>297 (353)</strong></td>
<td><strong>265 (335)</strong></td>
<td><strong>209 (266)</strong></td>
<td><strong>345 (405)</strong></td>
<td><strong>1,116 (1,359)</strong></td>
</tr>
</tbody>
</table>

A total of 457 participants have been trained from November 2017- July 2021. Out of the 457 participants, 190 (42%) were male and 267 (58%) were female; 410 (89.71%) Kenyans, 14 (3.06%) Pakistanis, 12 (2.63%) Tanzanians, 17 (3.72%) Ugandans and 2 (0.44%) Zambians and 2 (0.44%) Nigerians.

Out of the 47 counties in Kenya, CK-BTI has trained at least one individual from 30 (64%) counties so far. Nairobi County has the highest number of trainees with a total of 124 (43.97%) while the lowest numbers originate from counties in the Northern parts of Kenya such as Lodwar, Kapsowar, and Bomet with only 1 (0.35%) individual attending each of the courses over the years.

Table 2: Institution participation in the courses from 2017- July 2021

<table>
<thead>
<tr>
<th>Institutions</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
<th>2020</th>
<th>2021</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Research Institutions</td>
<td>3</td>
<td>5</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>20</td>
</tr>
<tr>
<td>2 Hospitals</td>
<td>2</td>
<td>4</td>
<td>6</td>
<td>12</td>
<td>7</td>
<td>31</td>
</tr>
<tr>
<td>3 Universities</td>
<td>10</td>
<td>9</td>
<td>11</td>
<td>12</td>
<td>9</td>
<td>51</td>
</tr>
<tr>
<td>4 Government</td>
<td>7</td>
<td>12</td>
<td>5</td>
<td>9</td>
<td>2</td>
<td>35</td>
</tr>
<tr>
<td>5 Non-Governmental (NGO)</td>
<td>3</td>
<td>7</td>
<td>4</td>
<td>5</td>
<td>0</td>
<td>19</td>
</tr>
<tr>
<td>6 Others</td>
<td>4</td>
<td>3</td>
<td>1</td>
<td>5</td>
<td>0</td>
<td>13</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>29</strong></td>
<td><strong>40</strong></td>
<td><strong>31</strong></td>
<td><strong>47</strong></td>
<td><strong>22</strong></td>
<td><strong>121 (169)</strong></td>
</tr>
</tbody>
</table>

A total of 150 IERC members have been trained so far, with 36 in 2017, 19 in 2018, 34 in 2019, 54 in 2020, and 8 as of July 2021. Out of the 30 accredited IERCs, the program had trained members from 23 (77%) committees so far.

In total, the program has trained individuals from 169 institutions spread across the five countries. There have been trainees from 20 (11.8%) research institutions, 31 (18%) hospitals, 51 (30%) Universities, 35 (21%) from government-based institutions, 19 (12.3%) from non-governmental institutions, and 13 (7.7%) from others such as Kenya Legal & Ethical Issues Network on HIV (KELIN), Ethics and Anti-Corruption Commission (EACC) and Population survey of Kenya. The table below provides a summary of the institutions the program has trained;
Table 3: Education level of participants from 2017-July 2021

<table>
<thead>
<tr>
<th>Education Level</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
<th>2020</th>
<th>2021</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 PhD</td>
<td>19</td>
<td>15</td>
<td>29</td>
<td>20</td>
<td>10</td>
<td>93</td>
</tr>
<tr>
<td>2 Master’s Degree</td>
<td>24</td>
<td>32</td>
<td>83</td>
<td>35</td>
<td>25</td>
<td>199</td>
</tr>
<tr>
<td>3 Bachelor’s Degree</td>
<td>10</td>
<td>11</td>
<td>25</td>
<td>9</td>
<td>15</td>
<td>70</td>
</tr>
</tbody>
</table>

DISCUSSION

In the four years of the program, three quarters (77%) of IERCs have had at least one member trained. This is important because one of the goals of the training programs specifically research ethics is to improve human subjects’ protection in research. Because the program targets training members of IERCs this shows good progress towards the achievement of CK-BTI overall goals. These findings are consistent with existing literature that shows the importance of making bioethics programs relevant to the individual’s environment and providing a consistent structure that enables the learners to focus on the content (Silverman, Strosberg, Luna, Philpott, & Hemmerle, 2013).

The majority of participants were drawn from hospitals and institutions of higher learning, it is not surprising that most of them have Masters Degrees and PhDs. This is representative of those likely serving in IERCs who can benefit from new knowledge and implement what they learn from the training. Even with their extensive knowledge, the training participants still managed to engage with the course curriculum as a refresher, proving even participants with experience in conducting and reviewing research can benefit from these courses (Dubois, Dueker, Anderson, & Campbell, 2008).

The courses have drawn interest both locally and regionally getting participants from Uganda, Tanzania, Nigeria, and Zambia, even though the training initially targeted Kenya and Pakistan. Over the years, a total of 45 applications from non-Kenyans have been received, that is; Uganda, Tanzania, Zambia, Nigeria, and Cameroon. The numbers are good considering the training was initially created with a focus on Kenya and Pakistan. This may indicate a lack of certificate-level training in bioethics in their own countries hence the need to seek alternatives.

LIMITATION

The current limitation of the study is that it is difficult for the program to track the impact the training has had on the participants, in terms of career progression or differences in the practice of their roles. In the future, the program plans to measure the long-term impact it has had on its alumni as well as the faculty conducting the training.

CONCLUSION

The CKBTI program was developed to increase bioethics capacity by adequately training members of IERCs in Kenya and other low- and middle-income countries. This program has managed to train individuals from not only Kenya and Pakistan but also around the East African region. This may imply a growing interest in certificate training in bioethics among healthcare professionals, researchers, and other citizens. Efforts in providing more ethics courses may be beneficial to individuals, institutions, and the country in general.

ABBREVIATIONS

KEMRI: Kenya Medical Research Institute
CBEC: Centre of Biomedical Ethics and Culture
CK-BTI: CBEC-KEMRI Bioethics Training Initiative
IERCs: Institutional Ethics Review Committees
CBEC-SIUT: Centre for Bioethics and Culture Sindh Institute of Urology and Transplantation

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Declaration of Conflicting Interests

The author(s) declare no conflicts of interest with respect to the research, authorship, and/or publication of this article.

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