CURRICULAR ASPECTS OF THE FOGARTY BIOETHICS INTERNATIONAL Training Programs

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ABSTRACT: THE CURRICULUM DESIGN, FACULTY characteristics, and experience of implementing masters' level international research ethics training programs supported by the Fogarty International Center was investigated. Multiple pedagogical approaches were employed to adapt to the learning needs of the trainees. While no generally agreed set of core competencies exists for advanced research ethics training, more than 75% of the curricula examined included international issues in research ethics, responsible conduct of research, human rights, philosophical foundations of research ethics, and research regulation and ethical review process. Common skills taught included critical thinking, research methodology and statistics, writing, and presentation proficiency. Curricula also addressed the cultural, social, and religious context of the trainees related to research ethics. Programs surveyed noted trainee interest in Western concepts of research ethics and the value of the transnational exchange of ideas. Similar faculty expertise profiles existed in all programs. Approximately 40% of faculty were female. Collaboration between faculty from low- and middleincome countries (LMICs) and high-income countries (HICs) occurred in most programs and at least 50% of HIC faculty had previous LMIC experience. This paper is part of a collection of papers analyzing the Fogarty International Research Ethics Education and Curriculum Development program.

KEY WORDS: curriculum, research ethics, National Institutes of Health, low- and middle-income countries

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THE FOGARTY INTERNATIONAL CENTER'S International Research Ethics Education and Curriculum Development program has provided grants for the development of master's level curricula and educational opportunities in research ethics for professionals from low- and middle-income countries (LMICs) since 2000 (Fogarty International Center, 2012). The overall goal of these grants has been the development of comprehensive ethics education programs, including practicum opportunities in human research ethics in trainee home countries, which would build sustainable research ethics capacity at LMIC institutions. A core set of graduate-level courses was developed by each training program that focused on the internationally relevant ethical, legal, and social considerations relating to research involving human subjects. Innovative curriculum imbued with culturally or scientifically relevant topics to address LMIC participant needs and interests was strongly encouraged. Grants supported education in the skills necessary for participants to provide research ethics leadership, teaching of bioethics, institutional capacity development for ethics conduct, review of research, and scholarship in bioethics. Curricula could be delivered by interactive distance learning technology, if appropriate and sustainable for the LMIC participants and institutions involved. Since 2000, twenty funded programs enrolled approximately 600 long-term trainees from 74 countries, as well as many short-term trainees (Millum et al., 2013).

Though bioethics—including medical ethics, research ethics, and the responsible conduct of research—has been taught in many high-income country universities for decades, opportunities for training in these subjects in LMICs before 2000 were very limited. Consequently, the principal investigators who designed the Fogarty training program curricula had to start de nova in developing curricula that responded to the particular needs of the countries from which trainees were drawn. Moreover, there was-and remains-no generally agreed set of global core competencies for long-term research ethics training. Thus, there are no clear benchmarks regarding curriculum design and delivery against which to evaluate curricula for long-term research ethics training.

A first step in developing such benchmarks would be a description of existing educational programs and the self-assessment of those who have developed and implemented this training. For this report we were interested in how the curricula of the Fogarty research ethics training programs responded to the needs of the trainees and their home countries. We therefore investigated the design of the curricula, characteristics of the faculty involved, experiences and challenges of the program directors in implementing curricula, and whether and how they amended their programs in light of these challenges and feedback from trainees. Given our goals, we interpreted curriculum broadly to include all of the learning experiences and educational activities that are planned to impart knowledge and skills in a specific field of study to a targeted group of individuals.

Methods

Study Design. The cross-sectional survey consisted of closed- and open-ended questions and the collection of data from a publicly available database.

Participants. Currently funded Fogarty programs conducted at least one year of training prior to 2012.

Survey. The program directors of the individual training programs met to discuss the elements to be included in the survey. After this meeting, the authors developed the final draft of the survey and obtained additional feedback from the program directors via e-mail correspondence. The survey included the following domains: (1) trainee demographics; (2) topics and skills taught; (3) teaching methods; (4) strongest components of the training program; (5) feedback mechanisms; (6) challenges encountered in planning and managing the programs; (7) challenges in teaching aspects of the curricula; and (8) perspectives regarding the teaching of Western concepts of bioethics to international trainees.

Data Collection. We collected data regarding faculty from the 26 applications (including renewal applications) funded by FIC/NIH whose grantees responded to the survey. These applications included biography forms from which we collected the following information for the principal investigators and faculty named in each application: gender, advanced degrees (post-baccalaureate) and field, resident country, and for those from HICs, evidence of LMIC experience defined as participation in international organizations or collaboration with LMIC faculty in publications or grants. We queried the FIC-supported trainee database (Career-Trac) to determine whether LMIC faculty members

were previous trainees from International Research Ethics training programs.

Analysis. We used descriptive statistics to present the quantitative data. For the open-ended questions, we coded the responses and identified common themes across the training programs. Subsequently, we circulated these results linked with themes to the individual program directors for them to affirm accuracy of interpretations and to submit clarifying comments.

Ethics Approval. The study was submitted to the institutional review board at the University of Maryland and it was classified as nonhuman subjects research.

Results

Thirteen of the 18 FIC-NIH Bioethics grantees that fit our inclusion criteria completed the survey, representing a response rate of 72%. The responding programs drew trainees from a wide geographical area that included countries from Eastern Europe, Central Asia, Africa, the Middle East, and Latin America, as well as India and Pakistan.

Demographics. Table 1 shows the demographic data on trainees who participated in the Fogarty training programs. In most programs (9/13), 50% or more of the trainees were between the ages of 30 and 49. Women represented the majority of the trainees in seven programs, men constituted the majority in five programs, and gender was equally distributed in one program (IU-MOI). In most programs, the majority of the trainees had training in the health professions (e.g., physicians, nurses, dentists, pharmacists), the exception being four programs in which half or more of the trainees had training in the social sciences, humanities, law, or philosophy (IU-MOI, CEE, JH-FABTP, and SARETI). There was a wide diversity regarding the career stages of the trainees. In five programs the majority of trainees were junior (AGA-K, IU-MOI, CWR, DPRET, and CEE), and in five programs the majority were mid-career (MERETI, FLASCO, UNC, SARETI, and MIAMI). Most programs included few senior trainees; in three programs approximately a third of the trainees were at the senior level (WAB, MERETI, and ICMR).

CHARACTERISTICS OF THE TRAINING PROGRAMS

Components. All programs incorporated face-to-face instruction and many (7/13) included distance learning components. The program directors rated different components of their programs: Nearly all respondents (12/13) graded the face-to-face component as the

 $\ensuremath{\mathrm{TABLE}}\xspace$ 1. Demographics of the Training Program.

		University of Iban- dan, Nigeria West African Bioethics (WAB)	AGA Khan University Pakistan (AGA-K)	Case Western Reserve University Romania, Russia, Tajikistan (CWR)	University of Maryland Middle East Research Ethics Training Initiative (MERETI)	Indian Council of Medical Research (ICMR)	Indiana University Kenya (IU-MOI)	Union College Eastern and Central Europe	Latin America (FLASCO)	University of North Carolina at Chapel Hill Fran- cophile Africa (UNC)	Dartmouth College/ Penn Tanzania (DPRET)	Pan- American Bioethics Initiative (MIAMI)	Johns Hopkins Fogarty African Bioethics Training Program (JH-	South Africa Research Ethics Training Initiative Sub- Saharan (SARETI)
Age Groups (%)	18-29 30-49 >50	0 68	36 54	51 43 6	2 72 26	3 81 16	50 25 25	50 50	0 30-50% 30-40%	30 45 25	20 80 0	20 70 10	20 70 10	10 85 5
Gender (%)	Male (%) Female (%)	64 36	44 56	46 54	44 56	57 43	50	40	39	55 45	20	10	34	60 40
Aca- demic Train- ing (%)	Medicine Nursing Other Health Profession	7 0	9 H 01	6 5 3	70 2 11	3 10	0 0	0 0	56	35	20 40 0	00 0	30 <10	0 0
	Philosophy Religious Studies Law Social and Behavioral Life Sciences	0 4 7 12 0	00 00 0 0	m0 0 = 0 0	00 00 = 0	00 -= 1 4	20 10 50 00 00	20 15 15 00 00 00 00 00 00 00 00 00 00 00 00 00	00 58 = 0	01 01 C C C C C C C C C C C C C C C C C	0 0 0 0 0 0 0		000000000000000000000000000000000000000	0 0 24 0 0
Profession (%)	Physician Nurse Other Health Worker University Professor Clergy Lawyer Non-Faculty Researcher	.,	- 625	0	0 0 0 0 55 0	1 4 6 7 6 0 1 F 6 0 0 1 F 6 0 0 1 F 6 0 0 1 F 6 0 0 1 F 6 0 1	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	5 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	2,70 6 047 0	£ £ 6 0 0 0 0 0 0	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0 8 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	20 0 20 0
Stage of Career (%)	Junior Mid-Career Late-Career Other	18 43 39 0	63 35 2 0	88 = 80	16 54 30 0	28 44 26 2	30 0	30	40 95 0	40 60 0 0	0 0 0	40 0 0	30 50 20 0	0 0 0

strongest feature of their program; six programs rated the distance learning programs as either the first (MIAMI) or the second best aspect of their training program (WAB, MERETI, CEE, ICMR, and FLASCO). Six of the 13 programs offered master's degrees (WAB, AGA-K, CEE, MERETI, IU-MOI, SARETI) and five offered certificate or diploma degrees (MERETI, CEE, SARETI, ICMR, and WAB). Of the programs that incorporated distance learning, four programs offered graduate-level courses that were taught predominantly by distance learning (MERETI, CEE, FLASCO, and ICMR). The language of instruction was English in most of the programs (8/13); French was utilized in the UNC program, Urdu in the AGA-K program, and primarily Spanish in the FLASCO and MIAMI programs.

Topics and Skills. Table 2 lists aspects of the content of the various curricula offered by the training programs. Regarding topics, all programs (13/13) offered courses or multiple hours of instruction in research ethics. International issues in research ethics were taught in 13/13 programs and clinical ethics was taught in 9/13 programs, of which two programs offered an hour or less. All 13 programs gave instruction of varying lengths on human rights, responsible conduct of research, regulatory aspects of RECs, and ethical theory/philosophy. Topics offered as complete courses or taught multiple hours by at least 75% (9/13) of the programs included research ethics, international issues in research ethics, responsible conduct in research, human rights, ethical theory/philosophy, and regulatory aspects of research ethics committees (RECs).

The training programs focused on developing trainees' skills in the following areas: presentation skills (11/13), critical thinking (10/13), research methodology and statistics (9/13), writing/grant writing (8/13), leadership (8/13), and advocacy skills (5/10). Many of the programs (8/13) dedicated part of their coursework to the training of trainers (e.g., teaching pedagogical skills, design of bioethical curricula and training courses) so that trainees could subsequently disseminate the knowledge/skills acquired to colleagues in their home countries. Most of the programs (11/13) made their training materials available to trainees, including syllabi, course notes, PowerPoint slides, question guides, and sample tests.

Teaching Methods. The training programs employed a variety of pedagogical methods. All programs employed lectures, case studies, and small group discussions, seven utilized role-play, and four showed films and videos that addressed bioethical issues. Some programs utilized innovative pedagogical methods, such as the

"collaborative creation of online learning materials"; "House of Commons Debates ... where resolutions are debated and Members of the House participate through a question period and voting"; and the use of drama to demonstrate ethical issues in research. Most programs reported the use of practical experiences, such as mock protocol review (9/13), observation of REC sessions (9/13), and one program each offered an apprenticeship with RECs, visits to US federal agencies (e.g., Office for Human Research Protections), and actual protocol review by the trainees.

Program directors rated the success of these various teaching methods. Six identified interactive forms of learning as particularly successful, including discussions, interviews, and group work. For example, one respondent wrote: "we had the most success in very concentrated small group workshops among key stakeholders that permitted focus over days on specific themes, with plenty of interaction." Another noted that they employed methods appropriate for different purposes. For example: "lectures work well when information is to be didactically conveyed or when highly trained experts are asked to share experiences; in contrast, small group work is best suited to discussing specific cases from an interdisciplinary perspective." Lecturing, particularly without an interactive component, was deemed the least successful method of training among several respondents (5/13). One respondent stated that self-study techniques were less successful. Another stated that a final paper requirement was difficult for trainees because of time pressures when they returned to their home institutions.

Several (4/13) respondents reported additional characteristics that contributed to the success of their programs. For example, one noted the importance of "engaging a large number of local scholars and research ethics regulators in developing curricular content for their own organizations/countries." Another mentioned a requirement that trainees complete a "mentored paper" to complete the program. A third respondent identified a student exchange program and "practicum experiences." One pointed out the "provision of in-country seminars" and the importance of maintaining contact with alumni after training.

Feedback Mechanisms. Programs adopted several mechanisms to obtain trainees' feedback. All programs obtained feedback at the end of a course/workshop, while most programs (12/13) obtained feedback at the end of each teaching session. Ten programs obtained trainees' feedback at the completion of the overall program and six conducted exit interviews, either formally

TABLE 2. Topics and Skills.

Topics	University of Ibandan, Nigeria West African Bioethics (WAB)	AGA Khan University Pakistan (AGA-K)	Case Western Reserve University (CWR)	University of Maryland Middle East Research Ethics Training Initiative (MERETI)	Indian Council of Medical Research (ICMR)	Indiana University Kenya (IU-MOI)	Union College Eastern and Central Europe (CEE)	Latin American (FLASCO)	University of North Carolina at Chapel	Dart- mouth College/ Penn (DPRET)	University of Miami (MIAMI)	Johns Hopkins Fogarty African Bioethics Training Program (JH-	South Africa Research Ethics Training Initiative
Research ethics	Course	Course	Course	Course	Multiple Hours	Multiple Hours	Course	Course	Course	Course	Multiple Hours	Course	Course
Clinical ethics	Course	Course	Course	≤1hour	Multiple Hours	No	≤1hour	Course	Multiple Hours	Course	9 8	0 N	o Z
International issues in research ethics	Yes	Multiple Hours	Course	Course	Multiple Hours	Course	Multiple Hours	Multiple Hours	Course	Course	Multiple Hours	Course	Course
Responsible conduct of research	Course	≥1hour	Course	Course	≥1hour	Multiple Hours	Multiple Hours	≥ 1 hour	Multiple Hours	Multiple Hours	≥ 1 hour	Multiple Hours	Course
Human rights	Course	Course	Multiple Hours	Multiple Hours	Multiple Hours	≤1hour	Multiple Hours	≤1hour	Multiple Hours	Multiple Hours	≤1hour	Multiple Hours	Multiple Hours
Ethical theory/ philosophy	Course	Course	Course	Course	Multiple Hours	<1hour	Course	Multiple Hours	Multiple Hours	Course	Multiple Hours	Multiple Hours	Multiple Hours
Regulatory aspects of research ethics	Course	Multiple Hours	Course	Course	Multiple Hours	Multiple Hours	Course	Multiple Hours	Multiple Hours	Multiple Hours	≥ 1 hour	Multiple Hours	Course
Health policy	o N	Course	Multiple Hours	≤1hour	≤1hour	No	Multiple Hours	Multiple Hours	Multiple Hours	Course	≤1hour	≤1hour	Multiple Hours
Pediatric research	o N	≤1hour	Multiple Hours	Multiple Hours	Multiple Hours	≤1hour	< 1 hour	≤1hour	Multiple Hours	Multiple Hours	< 1 hour	Multiple Hours	Course
Issues in genetic research	N N	< 1 hour	Multiple Hours	Multiple Hours	Multiple Hours	< 1 hour	Multiple Hours	< 1 hour	o N	Multiple Hours	Multiple Hours	_S	o N
Good clinical practice	Multiple Hours	< 1 hour	Multiple Hours	Multiple Hours	Multiple Hours	o N	Multiple Hours	< 1 hour	Course	Multiple Hours	≥1 hour	≤1hour	<1hour
Skills Critical thinking	>	>	>	×	>	>	>	>	>	>	>	>	×

(Continued)

TABLE 2. (Collulated)	llueu)												
Topics	University of Iban- dan, Nige- ria West African Bioethics (WAB)	AGA Khan University Pakistan (AGA-K)	Case Western Reserve University (CWR)	University of Maryland Middle East Research Ethics Training (MERETI)	Indian Council of Medical Research (ICMR)	Indiana University Kenya (IU- MOI)	Union College East- ern and Central Europe	Latin American (FLASCO)	University of North Carolina at Chapel	Dart- mouth College/ Penn (DPRET)	University of Miami (MIAMI)	Johns Hopkins Fogarty African Bioethics Training Program (JH-	South Africa Research Ethics Training Initiative (SARETI)
Research methodol-	>	>	×	>	>	>	>	×	>	×	×	>	>
Writing skills/ Grant writing skills	>	×	>	>	>	>	>	×	>	×	×	>	×
Presentation skills	>	>	>	>	>	>	>	×	>	>	×	>	>
Advocacy skills	×	>	×	×	>	>	>	×	>	×	×	×	×
Leadership skills	×	>	>	×	>	>	>	×	>	>	×	>	×
Mock protocol review	×	>	>	>	>	>	>	×	>	>	×	>	>
Observation of research ethics committees	×	>	>	>	×	>	>	>	>	>	×	>	>
Teaching skills	×	×	>	×	>	>	>	×	×	>	×	×	×
Conflict resolution	×	×	×	×	×	×	>	×	×	×	×	×	>
Drama skills for public engagement	×	×	×	×	>	×	×	×	×	×	×	×	×

TABLE 2. (Continued)

TABLE 3. Academic Backg	rounds of Faculty from Hi	ah-Income Country (F	HIC) and Low- and Mic	ddle-Income Countr	v (LMIC) Programs.

Type of Advanced Degree	Faculty in HIC-based Programs (n=226)	Faculty in LMIC-based Programs (n=176)
Medicine and Public Health	53% (1-22 faculty)	45% (4-10 faculty)
Philosophy and Bioethics	32% (2-10 faculty	33% (2-10 faculty)
Social Science	12% (0-7 faculty)	24% (1-7 faculty)
Law	5% (0-2 faculty)	11% (1-5 faculty)

or informally. Four respondents provided examples of adjustments they made to the programs in light of the feedback. One program instituted a new REC administration course and an REC rotation. One changed the course instructors. Another adjusted the program's content to suit the local culture and trainees' needs, making the curriculum more "secular" and teaching philosophy in "more simple terms." One program "added more sessions for tutoring them, [the trainees] as they requested" and "spoke with research ethics committees about ways of making their [trainees] visits more useful."

ACADEMIC BACKGROUNDS OF THE FACULTY

On average, HIC- and LMIC-based program awards involved similar numbers of faculty (HIC-based programs averaged 15 faculty/program, range of 3-31; LMIC-based programs averaged 16 faculty/program, range of 11-21). HIC- and LMIC-based programs also employed similar numbers of faculty with health professional and philosophy/bioethics advanced degrees (see Table 3). However, twice as many faculty with advanced social science degrees (most commonly anthropology, psychology, or sociology) and law degrees taught in LMIC-based programs. Some faculty had more than one advanced degree. All LMIC-based programs involved faculty with degrees in each of the four categories compared to two-thirds of the HIC-based programs.

Four HIC-based programs included no law expert faculty and one included no law or social science expert faculty.

Overall, 41% (13/32) of program directors were female. Of the LMIC-based programs (n = 11), 50% of the program directors were female compared to 35% PIs for HIC-based programs (n = 15). Five programs designated multiple program directors since NIH allowed this practice in 2008. On average, HIC (38%, range 0–67%) and LMIC (41%, range 21-64%) based programs designated similar numbers of female faculty.

HIC/LMIC FACULTY COLLABORATION

Table 4 shows data regarding faculty collaboration between the HIC and LMIC programs. Substantial collaboration between faculty from HICs and LMICs was found in most programs: 30% of the faculty in HIC-based program awards were from LMICs and 17% of the faculty in LMIC-based program awards were from HICs. Of the 15 HIC-based programs, 13 included LMIC faculty, and of the 11 LMIC-based programs, six included HIC faculty. Of the HIC faculty participating in HIC programs, 51% had LMIC experience. All HIC faculties participating in LMICbased programs had LMIC experience; that is, they previously participated in international organizations or collaborated with LMIC faculty in publications or grants.

TABLE 4. Degree of Faculty Collaboration Between High-Income Countries (HICs) and Low- and Middle-Income Countries (LMICs).

	Faculty in HIC-based Programs (n=226)	Faculty in LMIC-based Programs (n=176)
Residing in HIC	66% (3-19 faculty/program)	17% (0-15 faculty/program)
Residing in LMIC	30% (1-12 faculty/program)	79% (5-20 faculty/program)
Residing in both HIC and LMIC	4% (0-2 faculty/program)	3% (0-1 faculty/program)

Challenges for the Training Programs

ACADEMIC CHALLENGES

Academic challenges were the most frequently cited challenges, mentioned by 8 of the 13 respondents. These included difficulty in designing curricula that (a) incorporated a wide variety of academic disciplines (e.g., ethical theory, research methods, regulatory aspects); (b) suited the trainees' diverse professional/ academic backgrounds; and (c) were relevant to the local needs and culture of trainees. For example, one respondent stated: "Initially, the greatest challenge was understanding what gaps in knowledge and experience were common to the trainees from the various countries and which courses/curriculum components would best address those gaps." Another respondent said: "Determining what would be suitable topics for various levels of learners like medical undergraduates, medical and non-medical post-graduate students, researchers, faculty and ethics committee members was a challenge." Another program director stated: "[It was] challenging when trainees were at different levels of background in comparison to each other, and also sometimes with different levels of background compared to other graduate students with whom they were sometimes in graduate classes."

Several program directors expressed concerns about the educational backgrounds of the trainees. In particular, they mentioned gaps in trainee familiarity with research methodology, grant writing skills, and presentation skills. One respondent stated: "One particular challenge we faced was that some trainees came into the program with less background in empirical research methodology and we felt it was impossible for them to properly engage in research ethics discussions without more knowledge about research methods."

Several respondents (7/13) also indicated that philosophical concepts and ethical theory were difficult topics to teach, particularly for trainees with health sciences backgrounds. For example, one respondent stated that "teaching western philosophy to healthcare and allied field students [was difficult]. Usually students enter medical/nursing education without exposure to social science and philosophy. Therefore, getting exposure to 'gray areas' understanding makes them [a] little 'lost' because philosophy especially challenges the mathematical thinking." Another respondent said that "translating training in philosophy and communicating bioethics to actual practice" was difficult. Two programs mentioned difficulties in finding faculty to teach philosophy to trainees. For example, one respondent stated it was difficult to "[find] applied philosophers who could engage

successfully with our health professionals in our introductory foundations modules."

Regarding other topics that were difficult to teach, one respondent stated: "I would say probably the most challenging skill (if not concept) to develop in our trainees was more sophisticated case analysis." Research methodology, particularly quantitative methods, was considered difficult to teach in one program. The concepts of vulnerable populations and the purpose of RECs were noted as challenging to teach in another program (Loue & Loff, 2013). Finally, another respondent stated that "the Program must also prepare its fellows to be 'agents of change,' serving as educators, policy researchers, and advocates," which is "a much more complex and problematic task" (Strosberg, Gefenas, & Famenka, 2014).

Program directors developed several solutions to respond to these challenges. For example, to develop curricula for a diverse group of trainees, one respondent established a trainee feedback system to regularly assess their opinions on the curriculum and revise the course content accordingly. To ensure objectivity, an independent course evaluator gave input biannually. Regarding issues related to the backgrounds of trainees, one program instituted a selection process that included a four-day workshop to assess the skills and work ethic of potential trainees prior to gaining final acceptance into the program. Another respondent designed a 10-week workshop on research methods to overcome trainees' lack of knowledge. Other programs added research methods and grant writing training skills to the curriculum.

INSTITUTIONAL CHALLENGES

Institutional challenges constituted the second most commonly reported difficulty (5/13). For example, one respondent mentioned the following barrier: "Institutional processes for introducing new curriculum; e.g., multidisciplinary curriculum was relatively novel and providing justification for a specific department to host the course among other possible departmental locations." Another program director mentioned: "getting buy-in from the School of Public Health and harmonizing the new curriculum with the existing curriculum offerings. Once this was accomplished, the next hurdle was getting sufficient local human resources to implement/teach the courses offered, given the high local workload, i.e., the already high student/teachers ratio. Overcoming these challenges meant convincing the School of Public Health that a bioethics component of the MPH program would be a winning proposition for them, that could potentially attract those who might not be as interested in the other tracks of the MPH." Other respondents expressed the following concerns regarding

resource-limited settings: "identifying core faculties and providing motivation for sustainability"; "[identifying] curricula and training locations"; "securing continuous support from foreign institutions"; and "provision of adequate human resources."

Regarding solutions to some of these institutional challenges, one respondent applied for a planning grant to help the institutional process of introducing new curricula and "leadership buy-in." In addition, the program director devoted "significant personal and political capital" to implementing a multidisciplinary curriculum and mentoring faculty and students to build an adequate infrastructure for the training program.

CULTURAL, POLITICAL, AND ECONOMIC CHALLENGES

Several programs reported cultural concerns related to trainees' self-study habits, previous exposure to active learning techniques, and language barriers. For example, one respondent stated that "fellows had not experienced active learning in the classroom, where the student is expected to participate/be involved in the learning process, rather than sitting in a classroom while a professor presents a lecture and then leaves the room without taking questions or involving the student in exchanges." To address these issues, faculty emphasized the amount of work expected during the trainee recruitment phase and ensured that most of the work would be accomplished during class time, so less effort was expected of trainees after hours. In another program, active learning was emphasized during an orientation session with "examples on how to be involved and what to expect" during the program, and mentors were assigned to guide trainees in the process.

Several programs noted that it was challenging to get trainees to fulfill program requirements in a timely manner, mainly due to training program requirements competing with the trainees' primary job responsibilities in their home institutions. For example, one program director stated: "After trainees return home and we began the online learning portion, it would be difficult for several to maintain engagement with the program due to busy professional and personal lives."

One program reported cultural challenges in the program that included difficulty in "managing interactions between junior and senior trainees due to rigid hierarchy in academia." To resolve this issue, the program director allowed junior trainees to lead the discussions during group work and required that they have an "equal voice" with senior trainees during class interactions.

Political and economic instability in the home countries of the trainees was reported as a challenge for two

programs (CEE and MERETI). One program director stated: "[they] disrupt the professional and personal lives of the fellows. This disruption occasionally led to diminished course participation and problems of retention." To manage such issues, program directors were more accommodating and flexible with time requirements for trainees coming from countries with frequent political and economic unrest.

Teaching Western Concepts

We asked the program directors about their perspectives regarding the teaching of Western concepts of bioethics. Six programs described their curricula as predominantly Western-based (JH-FABTP, MIAMI, CEE, WAB, DPRET, and UNC); one program was described as being "balanced" between African and Western concepts (IU-MOI); one was not Western-based (ICMR); two described their curricula as "global" (FLASCO and SARETI); two described themselves as balanced between Islamic and Western concepts (CWR and AKA-K); another was initially predominantly Western-based, but incorporated more Islamic concepts with the help of former trainees (MERETI). One respondent mentioned that the program dedicated a module to indigenous value systems.

The program directors were asked about trainee concerns with the teaching of Western concepts to trainees from non-Western countries. Three programs acknowledged possible concerns (WAB, UNC, and JH-FABTP), but 12/13 respondents stated that trainees themselves had not voiced concerns about the issue (the other program did not respond to this question). Three noted that trainees are often interested in Western concepts and would "express appreciation for exposure" to these concepts. Additionally, one respondent stated that they had "received great support from the trainees for our program focus." One respondent cautioned that "scholars themselves did not explicitly express such concerns, but it would be unreasonable to assume that such concerns do not exist." A third noted that "many/most of our trainees regard the issue as overstating Western and African differences." One respondent explained that the Western-based curriculum was not a concern, but was a matter of "relevance in certain aspects." For example, "the concept of autonomy in a hierarchical society has to be modified in culturally suitable language to fit the constitutional requirement of individual freedom." Another stated that "educational systems have also tended to portray local philosophy systems of thought as primitive/animist—pejorative terms that diminish interest in critically evaluating these ethical frameworks."

Discussion

This paper represents the first attempt to describe the experiences with the design and implementation of curricula and the characteristics of faculty in programs providing long-term training (one year or more) in research ethics to individuals from LMICs. The variations in curricula content, pedagogical methods, and faculty expertise reflect the realities of providing training to a diverse group of trainees from different contexts. To respond to the challenges of providing training to learners with different levels of proficiencies, programs included additional remedial instructions in various content areas and skill sets. Furthermore, although most trainees came from backgrounds where passive learning was the educational norm, the various programs used interactive methods and active learning principles that were more appreciated by the trainees. Several studies have showed that multiple teaching methods are important to adapt to the different learning styles of students (Diaz & Cartnal, 1999; Peacock, 2001; Vaughn & Baker, 2001).

Furthermore, to accommodate geographic barriers that exist between faculty and trainees in these international programs, seven of the programs incorporated distance learning methods, of which four offered graduate-level courses within this medium. A review of these four courses showed that they are meeting almost 75% of what are considered best practices in distance learning and that almost 100% of the criteria are being met in one or more of the courses (Silverman et al., 2013). This suggests that the necessary skills and expertise exist within the Fogarty programs to bring all of the courses close to meeting all of the criteria by sharing a common set of best practices.

Considering the diversity of educational gaps and needs among the different trainees, there will not be a single, optimal curriculum design that fits all circumstances. Nonetheless, it is useful to describe some of the common elements that were present in more than 75% of the programs. Frequent topics included: research ethics, international issues in research ethics, responsible conduct of research, human rights, ethical theory/philosophy, and regulatory aspects of RECs. Common skills taught by the programs included: critical thinking, research methodology/statistics, writing skills, and presentation skills. Curricula in both HIC- and LMIC-based programs were delivered by internationally experienced faculty with a mixture of expertise in public health and medicine, philosophy and bioethics, social science, and law.

Several commentators have voiced concerns regarding the application of Western moral philosophical concepts in countries that embrace cultural norms and practices that differ from Western countries, as well as the teaching of Western philosophy in international training programs on research ethics (Benatar, 2004; De Vries & Rott, 2011). Our data show that most programs acknowledge using Western sources for their curricula, and program directors largely do not think this is a problem, as most respondents noted minimal concern among the trainees related to this issue. This might be a product of the self-selecting sample of program directors and trainees, who might be expected to be more open to Western systems of thought since they are self-enrolled in a US-funded education program. Moreover, our data showed that there was a large degree of collaboration between HIC and LMIC faculty in these programs, especially in HIC-based programs. Such diversity in these programs might prevent the dominance of a single conception of bioethics or make the acceptance of Western concepts more likely. Our data indicate that only six programs used predominantly Western concepts. One curriculum was not Western-based and six contained balanced Western and non-Western approaches. These latter programs likely responded to the cultural settings from which trainees were drawn. Respondents who emphasized the global nature of the sources for their curricula or noted the interest of trainees in Western concepts suggest the value of transnational exchange of ideas.

There are several limitations to our report. First, we did not examine other sources of evidence, such as curriculum documents, and we did not obtain the perspectives of the trainees. Finally, we were unable to extensively follow up with the individual program directors regarding interesting lines of inquiry, which would necessitate a more focused qualitative research methodology; for example, using interviews or focus groups.

Best Practices

These international research ethics training programs are unusual in the diversity of their target audiences both within and across programs. The Fogarty programs are located around the world and draw trainees from different countries with very different social, economic, and cultural environments. Moreover, the trainees varied in educational backgrounds, academic ranks, and levels of experience. As such, best practices would include the use of multiple pedagogical methods in training programs to accommodate the different learning styles of students. Program directors also need to be resilient and willing to make accommodations for various political and cultural effects on trainees' academic performances. Finally, to ensure that no one specific type of trainee predominates

in a program, when selecting trainees, program directors should ensure adequate gender, professional, and academic rank representation. To ensure adequate trainee mentorship, a similar diversity of faculty should be involved in the program.

The Fogarty experience demonstrated that international programs need to be flexible in pedagogical approaches and be ready and able to adapt to the context in which the trainees operate. Feedback mechanisms and continuous evaluation of the courses are important to accommodate the diversity of needs and learning styles. In addition, they ensure the inclusion of culturally sensitive content that makes the curriculum more relevant to trainees. While the diversity of the trainees resists the recommendation of a single, model curriculum, a curriculum consisting of core content and skills areas could be recommended. The topics and skill sets we identified as being taught in at least 75% of the programs would constitute a start for developing such a core.

Research Agenda

As noted previously, our study obtained the perspectives of the directors of the Fogarty programs. A future area of inquiry would be to assess the challenges experienced by trainees, especially those who lack the necessary skill sets and who come from educational backgrounds that employed different teaching methods. Furthermore, it would be useful to document the challenges trainees face incorporating research ethics training in their home institutions and how these challenges and achievements relate to aspects of the research ethics curriculum that trainees were taught. Finally, we identified topics and skills taught by at least threequarters of the programs. An analysis of syllabi would help further identify core topics and skills for long-term training in research ethics. This would be useful in developing a set of core competencies from which programs intending to establish international programs in research ethics can draw.

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References

- Benatar, S. R. (2004). Towards progress in resolving dilemmas in international research ethics. *Journal of Law, Medicine & Ethics*, 32(4), 574–582.
- De Vries, R., & Rott, L. (2011). Bioethics as missionary work: The export of Western ethics to developing countries. In C. Myser (Ed.), *Bioethics around the globe*. Oxford: Oxford University Press.
- DIAZ, D. P., & CARTNAL, R. B. (1999). Students' learning styles in two classes: Online distance learning and equivalent oncampus. *College Teaching*, *47*(4), 130–135.
- Fogarty International Center. (2012). *International Bioethics Education and Career Development Award (Bioethics)*. Retrieved from www.fic.nih.gov/Grants/Search/Pages/Awards-Program-Bioethics.aspx.
- LOUE, S., & LOFF, B. (2013). Is there a universal understanding of vulnerability? Experiences with Russian and Romanian trainees in research ethics. *Journal of Empirical Research on Human Research Ethics*, 8(5), 17–27.

- MILLUM, J., GRADY, C., KEUSCH, G., & SINA, B. (2014). Introduction: The Fogarty International Research Ethics Education and Curriculum Development program in historical context. *Journal of Empirical Research on Human Research Ethics*, 8(5), 3–16.
- Peacock, M. (2001). Match or mismatch? Learning styles and teaching styles in EFL. *International Journal of Applied Linguistics*, 11(1), 1–20.
- SILVERMAN, H. J., STROSBERG, M. A., LUNA, F., PHILPOTT, S., & HEMMERLE, C. A. (2013). An analysis of online courses in research ethics in the Fogarty-sponsored training programs. *Journal of Empirical Research on Human Research Ethics*, 8(5), 59–74.
- Strosberg, M. A., Gefenas, E., & Famenka, A. (2014, this issue). Research ethics review: Identifying policy and program gaps. Journal of Empirical Research on Human Research Ethics, 9(2).
- VAUGHN, L., & BAKER, R. (2001). Teaching in the medical setting: Balancing teaching styles, learning styles and teaching methods. *Medical Teacher*, 23(6), 610–612.