

EVALUATING INTERNATIONAL RESEARCH ETHICS CAPACITY DEVELOPMENT: AN EMPIRICAL APPROACH

JOSEPH ALI

Johns Hopkins Berman Institute of Bioethics (USA)

NANCY E. KASS

*Johns Hopkins Berman Institute of Bioethics and
Bloomberg School of Public Health (USA)*

NELSON K. SEWANKAMBO

*Makerere University, College of Health Sciences
(Uganda)*

TARA D. WHITE

Johns Hopkins Berman Institute of Bioethics (USA)

ADNAN A. HYDER

*Johns Hopkins Berman Institute of Bioethics and
Bloomberg School of Public Health (USA)*

ABSTRACT: THE US NATIONAL INSTITUTES OF health, Fogarty International Center (NIH-FIC) has, for the past 13 years, been a leading funder of international research ethics education for resource-limited settings. Nearly half of the NIH-FIC funding in this area has gone to training programs that train individuals from sub-Saharan Africa. Identifying the impact of training investments, as well as the potential predictors of post-training success, can support curricular decision-making, help establish funding priorities, and recognize the ultimate outcomes of trainees and training programs. Comprehensive evaluation frameworks and targeted evaluation tools for bioethics training programs generally, and for international research ethics programs in particular, are largely absent from published literature. This paper shares an original conceptual framework, data collection tool, and detailed methods for evaluating the inputs, processes, outputs, and outcomes of research ethics training programs serving individuals in resource-limited settings. This paper is part of a collection of papers analyzing the Fogarty International Center's International Research Ethics Education and Curriculum Development program.

KEY WORDS: research ethics, bioethics, capacity development, training, program evaluation, Africa

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INTEREST IN INTERNATIONAL RESEARCH ETHICS has increased dramatically over the past 15 years. Major controversies surrounding global HIV/AIDS research in the late 1990s drew researchers, ethicists, and the media into debates concerning placebos, standards of care, informed consent, and global justice (CIOMS & WHO, 2002; de Zoysa, Elias, & Bentley, 1998; Lurie & Wolfe, 1997; Varmus & Satcher, 1997). A notable aspect of these discussions was that with a few exceptions, they occurred among first world commentators about the lives, needs, and cultural expectations of those from poorer countries (Bhutta, 2002; Mbidde, 1997). As the amount of health research being conducted in low- and middle-income country (LMIC) settings increased, in part due to global publicity around identified needs (Global Forum for Health Research, 2000; Gwatkin, 2000), so too did the desire of local LMIC researchers and research institutions to become active participants in bioethics discussions, and relevant critical decisions and processes to help secure local interests, build health systems, and protect human subjects (Benatar, 2002; Bhutta, 2002; CIOMS & WHO, 2002; Macfarlane, Racelis, & Muli-Muslime, 2000; WHO, 2000).

With the turn of the twenty-first century it became clear that significant training investments were needed to support local engagement with both the theoretical and operational aspects of human research ethics (Bhutta, 2002; WHO, 2001). Prior to 2000, most LMIC-based research ethics training occurred through self-paced learning or short workshops, often utilizing materials developed with high-income contexts in mind. After hearing clear calls from the international community for more in-depth and locally relevant training, the US National Institutes of Health, Fogarty International Center (NIH-FIC) established a funding mechanism in 2000 to support the development of bioethics training programs that serve LMIC (US National Institutes of Health, Fogarty International Center, 2000). This first-of-its-kind NIH investment, which continues to fund US and LMIC-based programs to this day, was an important early statement about the link between national commitments to global health research and the corresponding need to promote host-country research oversight capacity.

The NIH-FIC competitive training grant mechanism focuses primarily on supporting programs that provide long-term, master's-level training (three months or greater in length) in bioethics and research ethics, with several funded programs providing one-year degree and nondegree opportunities. The investment allows not only for training of technical personnel, but also of individuals who seek to devote a significant amount of their professional time to building research ethics systems and advancing teaching and scholarship on issues that are of importance to LMIC researchers and communities (Hyder et al., 2009).

Critical to any significant global investment in capacity development is periodic evaluation to measure programmatic impact, support accountability, and facilitate refinement of funding priorities. Programmatic impact can be measured at multiple levels, including the individual, institutional, national, regional, and global levels. Formal and informal methods may be employed, and assessments can be performed by internal and external evaluators (Posavac & Carey, 1997). While some have assessed the short-term impact of research and research ethics training on the acquisition of knowledge and relevant skills (Aggarwal et al., 2011; Ajuwon & Kass, 2008), very few models exist to assess the longer-term professional and regional impact of international research ethics training (Ali, Hyder, & Kass, 2012; Hyder et al., 2007). The scholarly void may, in part, be attributable to challenges in defining relevant measures and predictors of impact in research ethics.

In 2011, the NIH-FIC solicited proposals to perform regional evaluations to assess the impact of a decade of NIH-funded international research ethics training (Millum et al., 2013). Five proposals were funded as supplements to existing training grants. Building upon our previous work in research ethics program and systems evaluation (Ali et al., 2012; Hyder et al., 2007; Hyder et al., 2013), the Johns Hopkins–Fogarty African Bioethics Training Program (FABTP) received supplemental funding to conduct an empirical evaluation of the sub-Saharan regional impact of 10 NIH-FIC research ethics training programs that operated between 2001 and 2011. The specific aims of the assessment were first to measure the degree to which individuals trained under Fogarty African research ethics training programs have demonstrated evidence of individual professional accomplishment, and second, to determine whether any individual, programmatic, or institutional factors were associated with post-training success in research ethics. In this paper we share, in detail, a framework, method, and tool developed for evaluating the inputs, processes, outputs, and outcomes of research ethics training programs serving individuals in LMICs; results are reported elsewhere. Given how little literature on strategies for assessing long-term training in

bioethics for low resource settings was available when we started this project, we hope that the approach described in this paper can be of use to others who seek to measure the impact of capacity development in research ethics, and possibly in other areas of health research.

Empirical Approach

FRAMEWORK

A first objective of the evaluation was to identify an empirical framework or model for evaluating research ethics capacity development. Related published models have largely focused more narrowly on evaluating health research training. Seemingly relevant models seek to capture individual characteristics and training processes that influence trainee engagement with research, as well as the interactions between individuals' research accomplishments and "external drivers" such as institutional, political, social, economic, and cultural factors (Webster et al., 2011; Whitworth, Haining, & Stringer, 2012). For example, Whitworth et al. propose an evaluation model that uses two frameworks to assess (1) the "individual participant's engagement in the research process" (their level of research activity), and (2) the "practice-academic partnership" (the institutional and value-based environment that influences the development and application of research knowledge and skills) (Whitworth et al., 2012). The principal strength of this model is its consideration of the overlapping terrains of individual, program, and external level factors that influence capacity development. It does not, however, provide detailed methods for implementation, nor is it designed to be sensitive to research ethics or the LMIC context.

Another example of a somewhat similar model is offered by the Rural Research Capacity Building Program (RRCBP), which provides training through workshops and research project mentorship to advance research capacity among health workers in a rural part of Australia. In its evaluation model, the program assesses participants' self-reported changes in knowledge and skills during training. A subset of trainees, their managers, and mentors are also sampled for semi-structured qualitative interviews to assess the impact of teaching, mentoring, and networking (Webster et al., 2011). While this approach potentially allows for greater specificity in determining personal influences on the professional development of individual trainees, when a larger study sample is required, individual interviewing becomes more challenging.

Our approach incorporates many of the strengths of the above-described models, using a modified health systems evaluation framework and applying it to research ethics capacity development programs. We first described our

approach in 2007 and have since revisited its application with our own training program (Ali et al., 2012; Hyder et al., 2007). We know of no other framework designed specifically to evaluate LMIC research ethics capacity development programs. A PubMed search conducted in January 2013 using MeSH terms that included “Low-Income, Middle-Income, Africa, African, Research, Ethics, Training, Evaluation, Capacity, and Development” yielded no other published models for international research ethics program evaluation. The framework (hereinafter referred to as the FABTP framework) provides a structure for measuring the career impact of teaching, project- and practice-based learning, mentoring, and networking in research ethics. The FABTP framework has been further extended with this multiprogram evaluation to support the identification of potential predictors of successful training, measured primarily through comparison of individual, program, and institutional factors with pre- and post-training research ethics productivity levels.

As previously described, the FABTP framework provides a matrix that can be populated with indicators of training program inputs, processes, outputs, and outcomes at the pre-training, intra-training, and post-training levels (Ali et al., 2012; Hyder et al., 2007). With the addition of a third dimension, the framework also differentiates individual, programmatic, and institutional contributing factors (Figure 1). Once the framework's cells are populated with specific indicators and corresponding survey items—a process described in greater detail below—a multidimensional assessment of training program impact is possible, allowing for pre/post training comparisons, as well as the identification of potential predictors of post-training outputs and outcomes.

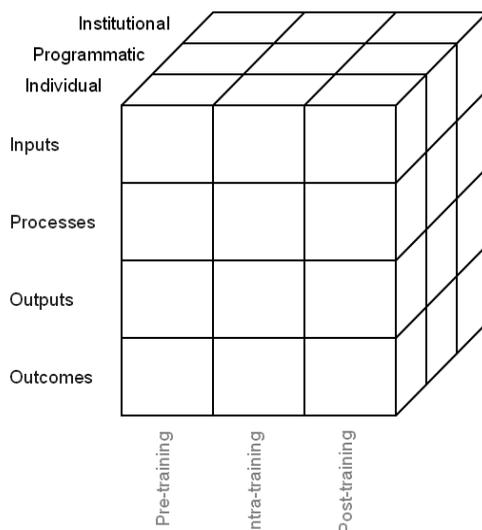


FIG. 1. FABTP Evaluation Framework.

Having refined the FABTP framework to go beyond use for a single program and now to be used in this regional evaluation, we then proceeded with: (1) identifying potential data sources and respondents; (2) populating the evaluation framework with indicators and items, and pairing items with methods for data collection; (3) developing data collection instruments; and (4) implementing data collection processes. While these stages are described separately below, the developmental process was significantly iterative.

DATA SOURCES FOR EVALUATION

The 10 independent training programs included in the evaluation were identified through a query of the NIH Research Portfolio Online Reporting Tools (NIH RePORT) database (US National Institutes of Health, Department of Health & Human Services, 2013) using the following inclusion criteria: NIH Fogarty-funded bioethics training programs that, between 2001 and 2011, offered long-term training (training of three months or greater duration) to individuals who resided in sub-Saharan Africa. Program selections were then confirmed with NIH-FIC. Table 1 lists all 10 programs meeting the eligibility criteria, their geographic focus for trainee selection, as well as their period of operation as documented in NIH RePORT as of 2012.

Two secondary data sources (NIH CareerTrac database and annual program progress reports) and one primary source (individual trainees) were identified to support data collection efforts. The first secondary data source queried was the NIH CareerTrac database (US National Institutes of Health, Division of Extramural Research & Training). CareerTrac is an NIH-managed database established to support the tracking of NIH-funded trainees, their training status, and professional accomplishments. Access beyond NIH is limited primarily to program directors and administrators charged with reporting annually the status and career achievements of trainees from their respective programs. The study team queried NIH for reports on trainees listed in CareerTrac who trained under programs meeting the above eligibility criteria. This led to the initial identification of 222 individual trainees. CareerTrac data available for eligible trainees were sparse and highly dependent on individual programs having provided required and optional trainee data to the NIH. Our February 2012 review of data made available for this evaluation revealed that out of the 10 programs, only one program had entered information in every prompted field in CareerTrac for more than 10% of its trainees (US National Institutes of Health, Division of Extramural Research & Training). As a result, while initially expected to be a source of information to help

TABLE 1. Fogarty-Funded African Research Ethics Training Programs (2000-2012).

Training Program	Primary Institutional Grantee	Geographic Focus	Period of Operation
1. Indiana University-Moi University Academic Research Ethics Partnership	Indiana University-Purdue University at Indianapolis	Kenya	2008-2012
2. International Research Ethics Networks for Southern Africa (IRENSA)	University of Cape Town	sub-Saharan Africa	2000-2010
3. International Research Ethics Training Program	Case Western Reserve University	Uganda & Nigeria	2000-2012
4. Johns Hopkins-Fogarty African Bioethics Training Program (FABTP)	Johns Hopkins University	AFRO Region of WHO	2000-2012
5. Middle East Research Ethics Training Initiative (MERETI)	University of Maryland Baltimore	Middle East + Sudan	2004-2012
6. South African Research Ethics Training Initiative (SARETI)	University of Kwazulu-Natal	sub-Saharan Africa	2000-2012
7. Strengthening Bioethics Capacity and Justice in Health	University of North Carolina Chapel Hill	Congo + Francophone Africa	2004-2012
8. Training for Scholarships in Research Ethics	Michigan State University	Malawi	2004-2008
9. University of Toronto MHSc in Bioethics, International Stream	University of Toronto	LMICs	2000-2011
10. West African Bioethics Training Program (WABTP)	University of Ibadan	West Africa	2004-2012

validate data obtained from primary sources, CareerTrac was most useful in verifying eligible training programs, developing an initial list of potential trainee respondents, identifying those few trainees who participated in more than one training program, and exploring possible indicators with which to populate the FABTP framework.

The other secondary data source was the annual non-competing progress reports. Program progress reports are required to be submitted annually to the NIH by each program's Principal Investigator (PI) and include descriptions of activities undertaken by long-term trainees supported in the previous year, programmatic activities such as workshops, long-term program accomplishments, changes to program design, administrative challenges encountered, and future plans. For purposes of this evaluation, review of progress reports facilitated limited data verification, for example, by confirming the availability of practicum-based training experiences across programs, and informed the development of indicators and survey questions designed to capture primary data from trainees. While somewhat useful for confirming program and institution-level data, progress reports had little utility for direct collection of trainee-level data as the reports mainly included information about trainees who were in training during the reporting year; moreover, once a program was no longer funded, trainee activities ceased to be formally reported.

The third and primary data source was the individual trainees themselves. After identifying a preliminary CareerTrac count of 222 eligible trainees, we asked all 10

program directors to confirm and supplement the list of trainees meeting eligibility criteria, based on their own records. As a result, 35 additional trainees were identified, of whom three were confirmed as deceased and one as not having any known contact information, resulting in a total of 253 eligible trainees in the target population. As described further below, data were collected from trainees using an online (SurveyMonkey[®]) survey to obtain primary self-reported data on trainee demographics, activities, accomplishments, and experiences before, during, and after their research ethics training. Approval for this project was obtained from the Johns Hopkins Bloomberg School of Public Health Institutional Review Board. The study was explained and voluntary participation was sought from potential trainee respondents through a survey consent cover page.

INSTRUMENT DEVELOPMENT AND DATA COLLECTION

Our approach focused on the development of indicators capable of addressing the study objectives, mostly through the use of a survey to be administered to individual trainees. Both *a priori* and emergent indicators were used to populate the FABTP framework. *A priori* indicators were drawn from previously published applications of the FABTP framework, CareerTrac data fields, and 12 years of experience with internal program evaluation and reporting. Emergent indicators came from discussions among the study team and with program directors about key aspects of the training programs. Table 2 lists sample indicators representing three

overlapping dimensions of the evaluation framework. Training inputs, processes, outputs, and outcomes (first dimension) are assessed at the pre-training, intra-training, and post training levels (second dimension) and further categorized into individual, programmatic, and institutional domains (third dimension). Each cell of the framework is populated with indicators that represent the intersection of all three dimensions, for example, the number of publications a trainee authored or co-authored immediately prior to his/her enrollment in a training program is a *pre-training individual input*; the method of delivery used by a program for its coursework is an *intra-training program process*; and the establishment of an alumni network by a training institution is a *post-training institutional output* (Table 2).

Several indicators were also divided into sub-indicators; for example, the indicator “publications authored/co-authored” was subdivided into bioethics and nonbioethics publications. The populated FABTP framework was then presented to program directors for input focusing on potential missing indicators.

Data for most indicators and sub-indicators were gathered through the trainee survey established for this evaluation project. Data for other indicators were gathered through document review, for example, the age of a program was identified by reviewing data found in program progress reports and confirmed in the NIH RePORT database. Through biweekly team meetings, both open- and closed-ended survey items were drafted. We created a Microsoft Excel® database to match survey

TABLE 2. FABTP Framework: Sample Global and Specific Indicators.

Pre-Training			
	Individual	Program	Institution
Inputs	Age, Gender, Occupation, Location, Degrees, Funding, Research, IRB Service, Publications, Teaching, Network	Age, Funding, Applicants, Applications, Pre-Existing Faculty, Staff, Courses	Age, Funding, Structure, IRB, Location, Network, Resources, Facilities
Process	Application Completed	Applicant Review, Logistics	Admissions Review
Outputs	Selected as Trainee	Selection of Trainee	Admittance
Outcomes	Successful Arrival of Trainee	Successful Arrival of Trainee	Successful Arrival of Trainee
Intra-Training			
	Individual	Program	Institution
Inputs	Goals, Expectations	Location, Courses, Faculty, Staff, Resources, Goals	Location, Network, Resources, Facilities
Process	Course Participation, IRB Experience, Practicum Experience	Orienting, Teaching, Mentoring, Evaluating	Enrollment, Technical Support, Outreach, Resource Sharing
Outputs	Enhanced Knowledge, New Skills, Practicum Product	Training Completed	Degree/Certificate Granted
Outcomes	Trained Individual	Trained Individual	Trained Individual
Post-Training			
	Individual	Program	Institution
Inputs	Opportunities, Resources	Feedback	Structure, IRB, Location, Network, Resources, Facilities
Process	Networking, Professional Development, Education, Collaboration	Mentoring, Continuing Education, Reporting	Technical Support, Outreach, Resource Sharing
Outputs	Occupation, Degrees, Funding, Research, IRB Service, Publications, Teaching, Networking	Alumni Network, Program Growth	Alumni Network, Institutional Growth
Outcomes	Local Capacity Enhanced	Local Capacity Enhanced	Local Capacity Enhanced

items with their corresponding evaluation indicators, and link indicators and items with response options (e.g., yes/no/don't know), question types (e.g., closed-ended), framework levels (e.g., intra-training program input), data sources (e.g., trainees), and survey sections (e.g., during training). The initial database included 20 global indicators and 118 distinct items at the individual, programmatic, and institutional levels. Survey items were then filtered, and those that required trainee responses comprised a survey instrument, first drafted in Microsoft Word[®] and then transferred to the web-based survey platform SurveyMonkey[®]. The complete trainee survey was reviewed by the program director group as well as two unaffiliated colleagues from the Johns Hopkins Bloomberg School of Public Health (JHSPH). Slight modifications were made to incorporate feedback prior to piloting the survey with selected JHSPH master's and PhD students for additional input on language, skip logic, and response burden.

The final trainee survey had two tracks: one for the majority of trainees who had participated in a single Fogarty-funded bioethics training program, and one for the few who had participated in two or more programs. The single-program instrument had 68 items, and the multiple-program instrument had 98 items. Both versions included survey sections for demographics, pre-training information, during-training information, post-training information, and personal reflections. The pre- and post-training sections contained identical items, allowing us to compare outputs, for example, by measuring the number of publications a trainee had before or after training, or the number of classes he or she had taught before or after training. Sample trainee survey questions are provided in Table 3; the full survey is available on request.

The final SurveyMonkey[®] trainee survey was rolled out via e-mail invitation to 253 eligible trainees and remained open for 12 weeks (February–May 2013). Immediately prior to survey rollout, all participating program direc-

TABLE 3. Trainee Survey: Sample Items.*

Questions	Response Options
Demographics (samples)	
In what year were you born? (enter 4-digit birth year; for example, 1976)	Open-ended numerical
In what country were you born?	Open-ended
Pre-Training and Post-Training (samples)	
(Before/After) your Fogarty bioethics training, did you have a leadership role at your institution?	Yes No I don't know
What type of leadership role did you have?	Program Director Department Chair IRB/REC Chair Dean/Vice Dean Other _____
(Before/After) your Fogarty bioethics training, did you serve as an Investigator on a research grant?	Yes No I don't know
On approximately how many research grants were you an Investigator, before your Fogarty bioethics training?	1 grant 2-5 grants 6-10 grants 11+ grants
How many of these research grants were primarily related to bioethics?	0 grants 1 grant 2-5 grants 6-10 grants 11+ grants
On how many research grants (bioethics or non-bioethics) were you the "principal" or main investigator?	0 grants 1 grant 2-5 grants 6-10 grants 11+ grants

(Continued)

TABLE 3. (Continued)

(Before/After) your Fogarty bioethics training, had you ever attended any bioethics conferences? E.g. IAB, PRIM&R, AMANET, etc. <i>Note:</i> This DOES NOT include training workshops.	Yes No I don't know
How many bioethics conferences did you attended before your Fogarty bioethics training?	1 conferences 2-5 conferences 6-10 conferences 11+ conferences
At how many of these bioethics conferences did you orally present?	0 conferences 1 conferences 2-5 conferences 6-10 conferences 11+ conferences
Intra-Training (samples)	
During your Fogarty bioethics training, did you interact with the institutional review board (IRB/REC) at your training institution?	Yes No I don't know
Did you observe or attend actual IRB/REC meetings?	Yes No I don't know
Were you required to complete a practicum project as part of your Fogarty bioethics training?	Yes No I don't know
What type of practicum project did you primarily pursue for your Fogarty bioethics training?	Empirical research Conceptual/philosophical IRB/REC development Curriculum development/training Other _____
Reflections (samples)	
Which component of your Fogarty bioethics training had the greatest impact on your understanding of research ethics?	Observational experiences (e.g. IRB observation) Academic coursework Networking opportunities Practicum experience Individual mentorship Peer-interaction (e.g. within cohort) Off site/Out of country training component Other _____
Of all the factors that have made you a success in research ethics, which one has had the single greatest impact?	Personal motivation Fogarty bioethics training Other non-Fogarty training Networking over the years Supportive superiors/leadership/supervisors Public recognition (e.g. awards) My publication record Mentoring/advising
Please indicate the degree to which you agree or disagree with the following statements: "My cultural background was appropriately respected by my Fogarty bioethics training program."	Strongly disagree Disagree Neutral Agree Strongly agree

*Full survey available on request.

tors notified their trainees that they should expect to receive the survey. The survey consent page included information indicating that upon completion of the survey, respondents would be entered into two drawings for

an iPad and an iPod (or equivalent). After the initial survey invitation was e-mailed in February 2013, follow-ups occurred to troubleshoot e-mail bounce-backs, two reminders were sent to respondents who partially

completed the survey, and seven biweekly reminders were emailed to all nonresponders. During the last four weeks of recruitment, we attempted to contact remaining nonresponders via telephone, where telephone numbers were available, to confirm that e-mail invitations were received. Of the telephone numbers attempted, 13 had voicemails where messages were left; no potential respondents were reached directly.

TRAINEE SURVEY RESPONSE

At the end of 12 weeks, 171 complete responses were recorded (68% response rate): 164 respondents completed the single-program instrument and 7 completed the multiple-program instrument. Ninety percent of responses were received within one month of rollout, following four reminder e-mails. The median time for survey completion under the single- and multiple-program tracks was 33.5 and 34 minutes, respectively.

All open- and closed-ended survey responses were aggregated and downloaded as a Microsoft Excel[®] spreadsheet, then imported into STATA[®] 12 for data cleaning and analysis. Summary statistics were generated and univariate, bivariate, and logistic regression analyses were performed. Open-ended questions were coded separately, and grouped into emergent themes for content analysis. Additional details of analyses and results are reported separately.

Discussion

The US National Institutes of Health, Fogarty International Center has made a significant investment in international research ethics education and curriculum development. From 2000 to 2012, NIH-FIC awarded over US\$40 million in research ethics capacity development grants for LMICs. Nearly half of the funding supported programs that trained individuals from Africa (US National Institutes of Health, Department of Health & Human Services, 2013). The purpose of NIH-FIC's investment is to

increase the number of developing country scientists, health professionals and relevant academics with in-depth knowledge of the ethical considerations, concepts and applications in clinical and public health research[, in order to]...enhance the career development of individuals from developing countries, as well as strengthen and sustain the capacity to support ethical clinical and public health research at their home institutions and countries. (US National Institutes of Health, Fogarty International Center, 2014)

NIH-FIC requires annual reports and detailed updates from its grantees, describing short- and long-term

accomplishments of both the program in general and of all individual trainees in order to identify whether and how programs are advancing the goals of the funding mechanism. NIH also encourages program collaborations, resource sharing, and the development of best-practices by, among other things, hosting annual meetings of program directors. With this recent initiative to evaluate the impact of its research ethics training investment, NIH has further demonstrated its commitment to high-quality capacity development. In doing so, it has also taken an important step to begin to fill a significant gap in the literature on strategies to evaluate international research ethics capacity development.

The methods and tools presented in this paper build on previously published approaches for single-program evaluation in research and research ethics (Ali et al., 2012; Hyder et al., 2007; Webster et al., 2011; Whitworth et al., 2012) and single-institution assessment in research ethics (Hyder et al., 2013). The previously described published models for evaluating *research* capacity development offered by Whitworth et al. and Webster et al. provide good examples of how programs can utilize multidimensional conceptual models for embedded program evaluation. Like many research capacity development programs, *research ethics* programs often seek to impart skills relevant to conducting mixed-methods empirical research. They also, however, focus equally on providing training and resources to develop skills in the interactive teaching of ethics, as well as the analytical capacities needed for research ethics committee service. Moreover, many research ethics trainees also seek training to enhance their capacity to contribute at the research ethics policy and systems levels so they can effectively raise awareness, improve operations, and build support for research ethics within their home institutions and national governments. Evaluating these diverse training functions requires the application of an evaluative framework that accounts for research, teaching, policy, and service-related activities in research ethics.

One of the greatest strengths of the described FABTP framework is its capacity to target trainees, programs, and institutions when determining training impact and predictors of impact. It also incorporates information from the various stages of engagement (pre-, intra-, and post-training) as well as the phases of development (inputs, processes, outputs, and outcomes). The breadth of the FABTP framework also presents some potential methodological challenges. Identifying appropriate indicators and negotiating the multiple dimensions of the framework when developing instruments and collecting data requires a high degree of coordinated effort. Our experience suggests that relevant indicators should be

identified in collaboration with stakeholders, and a phased approach is recommended for data collection. In this multiprogram evaluation, the research team sought the input of the 10 program directors as research methods were developed, tools refined, and data collected. In addition, the evaluation was phased to first collect secondary CareerTrac and progress report data, then primary data from trainees. Following this sequence improved accuracy in identifying potential respondents, informed the development of data collection instruments, and allowed interim analyses to guide our approach to primary data collection.

Another important methodological finding from this evaluation was the relatively high and rapidly achieved response rate (68%). Internet bandwidth and stability is gradually improving across sub-Saharan Africa, yet penetration is still comparatively low (Akue-Kpakpo, 2013). While we initially anticipated the need to implement a fallback strategy of sending downloadable or hardcopy surveys to trainees, it was not necessary to use this approach and all data were collected via the online survey. Factors that may have contributed to a good response rate include the approach used for contacting and re-contacting potential respondents via e-mail and phone, the recruitment support received from program directors, many of whom remain in contact with former trainees, as well as the incentive provided for two randomly selected respondents. Open-ended question responses from trainees also indicated a widespread, sometimes profound, appreciation for the training received, which might suggest that trainees were strongly self-motivated to participate in the survey.

Limitations

A noteworthy potential limitation of the described approach to primary data collection is recall bias, as the time since training completion can be significant for some respondents. In an effort to minimize recall bias, survey questions are not specific to narrowly defined time periods, and response options are provided as ranges rather than specific numbers. Combining data across primary and secondary sources also helps mitigate the potential effects of bias. Additionally, while we were able to secure a satisfactory response rate, 32% of eligible trainees did not respond to our trainee survey. We do not know whether the responses received were fully representative of the entire population. It is possible that those who felt they benefited least from their training were least likely to respond. We did not collect information from nonresponders, so we are unable to confirm whether this assumption is valid. To encourage

responses from trainees who held diverse opinions of their training, our multiple e-mail invitations to potential respondents included the statement that it is valuable “to both the Fogarty International Center, and to individual programs, to hear feedback from trainees about what worked well and what needs improvement in the Fogarty-funded African bioethics programs.”

Research Agenda

The approach described in this paper builds, in multiple ways, upon our previously published model for evaluating research ethics capacity development: (1) it adds a new dimension to the FABTP framework that distinguishes individual, programmatic, and institutional factors; (2) it utilizes broader stakeholder input to identify and confirm indicators and items; (3) it introduces an original, web-based trainee survey as a means for collecting primary data; and (4) it extends the approach beyond a single program to demonstrate an application across 10 programs. Additional research is needed to further refine, validate, and test the reliability of the described approach, framework, and tool.

As NIH and other funders of capacity development seek to identify the value of their global investments, having an approach that can be adapted to various settings is important. Perhaps in conjunction with validation efforts, the approach described in this paper can likely be applied beyond sub-Saharan Africa to other programmatic regions within NIH-FIC’s portfolio. Data from such evaluations could establish baselines for future comparative analyses. The FABTP framework can also possibly be adapted and utilized by other funders of international research ethics capacity development. Its utility beyond the domain of research ethics is unknown; however, future exploratory research could identify the scope of its application.

Conclusion

As a locus of change, much rests on the shoulders of individual trainees to share, apply, and expand their newly acquired knowledge and skills. Demands on trainees during and after training, in all areas of their personal and professional lives, can be high. Evaluations, such as the one described in this paper, are critical not only to identify effective program design and management strategies, but also to appreciate the tremendous efforts and accomplishments of individuals who work extremely hard to establish careers and institutionalize research ethics in low-resourced settings. As research ethics training programs around the world develop

further, we hope the approach to evaluation we have described can be further refined and applied locally and across programs to assess the impact of investments.

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Author Note

Please direct correspondence to: Joseph Ali, Johns Hopkins Berman Institute of Bioethics, 1809 Ashland Ave. Room 211, Baltimore, MD 21214 USA. Phone: 1-410-614-5370; E-MAIL: jali@jhu.edu.

Authors' Biographical Sketches

Joseph Ali is Research Scholar at the Johns Hopkins Berman Institute of Bioethics. Mr. Ali's work advances bioethics pedagogy, identifying best methods for bioethics education to support the development of innovative academic programs. His scholarship also seeks to understand and address a range of ethical challenges in domestic and international research ethics—from policy to practice. He serves on a Patient-Centered Outcomes Research Institute (PCORI) National Coordinating Center, Ethics and Regulatory Task Force, and coordinates the Johns Hopkins–Fogarty African Bioethics Training Program.

Nancy Kass is Phoebe R. Berman Professor of Bioethics and Public Health at the Johns Hopkins Berman Institute of Bioethics and the Johns Hopkins Bloomberg School of Public Health, and Deputy Director

for Public Health at the Johns Hopkins Berman Institute of Bioethics. For over 20 years, Dr. Kass has conducted leading empirical research in bioethics, public health, and health policy. Her publications address public health ethics, HIV/AIDS policy, food ethics, informed consent, ethics and learning healthcare, and US and international research ethics. She is Co-Director of the Johns Hopkins–Fogarty African Bioethics Training Program.

Nelson K. Sewankambo is Principal of the Makerere University, College of Health Sciences, Kampala, Uganda. Dr. Sewankambo is co-founder and Co-Principal Investigator of the HIV/AIDS research Rakai Health Sciences Program (RHSP). He has also dedicated his efforts to improving medical and bioethics education both internationally and at Makerere University, and was responsible for innovations such as student-centered education grounded in problem-based learning and community-based education and services. He has also pioneered multidisciplinary student education teams and use of information technologies.

Tara D. White is Executive Director of Warminster Ambulance Corps and Adjunct Professor at Gwynedd Mercy University. She is an alumna of the Department of International Health at the Johns Hopkins Bloomberg School of Public Health and also served as Research Assistant at the Johns Hopkins Berman Institute of Bioethics.

Adnan A. Hyder is Professor in the Department of International Health at the Johns Hopkins Bloomberg School of Public Health, where he is also Director of the Health Systems program and Director of the International Injury Research Unit. He is also Associate Director for Global Programs at the Berman Institute of Bioethics, where he is a Core Faculty Member. His scholarly and pedagogical work focuses on issues related to health systems development, equity, and ethics in low- and middle-income countries of Africa and Asia. Dr. Hyder conducts research to understand the current state of research ethics and health systems development around the world. He is Co-Director of the Johns Hopkins–Fogarty African Bioethics Training Program.

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