An Analysis of Online Courses in Research Ethics in the Fogarty-Sponsored Bioethics Training Programs

Henry Silverman
University of Maryland School of Medicine

Martin Strosberg
Union Graduate College

Florencia Luna
Facultad Latinoamericana de Ciencias Sociales (FLACSO)

Sean Philpott
Union Graduate College

Cheryl A. Hemmerle
United Methodist Communications

ABSTRACT: several training programs sponsored by the NIH/Fogarty International Center's International Research Ethics Education and Curriculum Development Program offer online graduate-level courses in research ethics to participants in low- and middle-income countries. This paper describes the evaluation of four of these online courses and recommendations for improvements to achieve the highest-quality design and delivery. We used an evaluation matrix consisting of 95 criteria based on recommended best practices in eLearning. Our results showed that these courses are developing or meeting nearly 73% of the criteria, while they are not meeting approximately 21% of the criteria. Together, one or more of the courses are developing or meeting 89 of the 95 criteria. These results suggest that the necessary skills and expertise exist in these programs to bring all of the eLearning courses close to 100% proficiency by sharing a common set of best practices. This paper is part of a collection of articles analyzing the Fogarty International Center's International Research Ethics Education and Curriculum Development Program.

KEY WORDS: online courses, education, low- and middle-income countries, research ethics, best practices

DURING THE PAST TWENTY YEARS, SPONSORS from high-income countries (HICs) have shifted many of their research activities to sites in low- and middle-income countries (LMICs) (Glickman et al., 2009). Such research raises several ethical issues, including the adequacy of ethics review by research ethics committees (RECs) in both HICs and LMICs, the validity of informed consent in different cultural settings, and protection of vulnerable subjects against potential exploitation (Benatar, 2001; Bhutta, 2002; Hyder et al., 2004). Governmental agencies have recommended various strategies, including enhancing training capacity in research and research ethics, to address these shortcomings in human subject protections in order to address this increasingly complex research landscape (National Bioethics Advisory Commission [NBAC], 2001a, 2001b). For example, the NBAC report stated that "educational programs aimed at the responsibilities of all parties" is "the foundation of the oversight system and is essential to protecting research participants" (NBAC, 2001b).

There are several international educational programs in research ethics that have employed face-to-face delivery formats for courses and workshops (Program on Ethical Issues in International Health Research at the Harvard School of Public Health, 2002; Public Responsibility in Medicine & Research, 2002; University of South Florida, 2001; University of Washington, 2002). There are, however, limitations to traditional face-to-face courses and workshops for international trainees from LMICs, whether they are offered in their home institutions or in Western universities. First, they fail to reach a large audience, as the busy schedules of professionals make it difficult for them to attend. Second, face-to-face courses are expensive for individuals from LMICs to attend when offered on campuses in high-income countries (HICs) and frequently pose logistical problems, such as visa acquisition.

Recently, online training opportunities in research ethics have been developed for worldwide audiences that can supplement traditional learning by addressing limitations

inherent in face-to-face educational programs (McAlpine, 2000; Pombo, Loureiro, & Moreira, 2010; University of Miami, 2012). Such offerings can reach a much larger number of individuals from diverse geographic locations, as they can be accessed "anytime, anywhere." Issues with reliable Internet availability and limited bandwidth remain in LMICs, but have improved in recent years. Preparation of online training materials initially may require a considerable time and financial investment, but the recurring costs of such training are generally lower, because faculty and student travel costs are eliminated and faculty time required for delivering didactic course material is reduced in the long run. The predominant distance-learning courses in research ethics involve the use of self-paced, self-learning online tutorials (Fogarty International Center, 2013; TRREE, 2013; University of Miami, 2012). But such offerings provide only learner-content interactivity, i.e., acquisition of knowledge, which only addresses the first-order cognitive learning objectives of Bloom's taxonomy scale (Anderson & Krathwohl, 2001).

Alternatively, online courses may adopt a pedagogy that aims to reach higher levels of learning cognitive objectives, for example, to apply knowledge and solve problems (Precel, Eshet-Alkalai, & Alberton, 2009). Appropriate learning activities to achieve these objectives must engage the learners through student-instructor and student-student interactions that encourage the learners to "do something," such as discovering, processing, or applying concepts and information in conjunction with instructor as well as peer feedback. Such learning activities include case study, problem analysis, group debates, discussion forums, self-assessment exercises, and reflective journaling. This type of facilitated-led online learning is associated with favorable outcomes across a wide variety of learners, learning contexts, clinical topics, and learning outcomes (Power, 2008). Recently, Curran and associates compared the effects of a facilitator-led course with a self-paced course in Continuing Medical Education and demonstrated that participants in the facilitator-led course showed significantly higher outcomes on a post-assessment test compared with those in the self-paced course (Curran & Fleet, 2005).

Several research ethics training programs sponsored by the Fogarty International Center/NIH offer facilitator-led distance-learning opportunities to individuals in Argentina, Eastern Europe, and the Middle East (Fogarty International Center, 2012). The objective of this paper is to evaluate the extent to which the online courses in the Fogarty research ethics programs meet best practices in online instruction and make recommendations for adjustments and improvements in order to enhance quality design and delivery.

Methods

Study design: a cross-sectional evaluation of four online courses in the Fogarty Bioethics Program.

BRIEF DESCRIPTIONS OF COURSES

FLASCO Argentina: "Problems of Research Ethics." FLASCO offers this advanced course in research ethics given in Spanish. Trainees take this distance-learning course after meeting in Buenos Aires for introductory research ethics courses. Completion of four face-to-face courses and online courses result in a Diploma in Bioethics; seven courses result in a Specialization degree in Bioethics. The five-month distance-learning course consists of six classes developed by six professors on the following topics with activities and a discussion forum led by each faculty: (1) research ethics regarding children and adolescents, (2) research with subjects who suffer from advanced disease, (3) ethics and social research in health, (4) research ethics in psychiatry, (5) research in the field of human genetics, and (6) research ethics with native communities. Each faculty is responsible for posting online materials, such as didactic background presentations, case study discussions, and assessment questions, and facilitates an interactive discussion forum. Students can obtain "tutoring" help from the faculty by e-mail communications. Two additional discussion forum sessions are led by the directors of the program after the third class and at the end of the course to integrate the knowledge and contents offered in the previous classes.

Middle East Research Ethics Training Initiative (MERETI): "Advanced Course in Research Ethics." This 15-week online graduate-level course (equivalent to three credit hours) expands on issues presented to trainees during a previous four-week summer face-to-face instruction at the University of Maryland Baltimore campus. In addition to providing traditional educational experiences, the summer program promotes a sense of social community among the trainees that will enhance the subsequent online experience by facilitating a community of inquiry and prevent a sense of isolation that commonly occurs in online courses where there is no face-to-face component (Cox & Cox, 2008; Dickey, 2004; Garrison & Kanuka, 2004; Ibrahim, Rwegasira, & Taher, 2007). The subsequent online experience consists of both synchronous activities (live webinars) and asynchronous activities that include interactive discussion forums, videos, audio PowerPoints,

hyperlinks to materials, polling, and a "lesson activity," which presents a series of interactive content pages in which progression through the lesson is contingent on the learner answering correctly a series of questions that are interspersed within the content pages. Finally, trainees have the ability to communicate with the faculty via e-mails, a message board, and a chat box.

Union Graduate College—Vilnius University. This program consists of seven graduate courses; two are taught face-to-face at an Eastern European institution followed by online courses originating from Union Graduate College. In addition to providing an introductory learning experience, the face-to-face component promotes social interaction that will enhance the online learning experience and provides instruction on how to use the distance-learning platform and the Internet-based resources. For this evaluation, we assessed the following two of their online courses:

- International Bioethics: A 10-week course covering: the history and development of key international institutions, pivotal policies, and theoretical frameworks informing international bioethics and research ethics. The course utilizes readings and videos, interactive discussion forums, short papers, group projects, and case studies of specific areas in international bioethics.
- International Research Ethics: A 10-week course covering the nature, design, and conduct of biomedical research; the history, structure, and practices of RECs in different countries; and the ethical, social, and legal issues involved with basic topics in international research ethics. The course utilizes readings and videos, interactive discussion forums, short papers, and group projects.

Study Tool

Several sources recommend best practices in eLearning (Las Positas College, 2012; MarylandOnline, 2011). These sets of best practices are intended to help faculty and designers create online courses and assess their readiness and instructional and pedagogical soundness. From these sources, we developed an online course evaluation matrix to evaluate four courses in the Fogarty Program. The matrix includes five sections incorporating a total of 95 criteria. These sections are described briefly below and are presented with each of the individual criteria as online supplementary material (Appendix I).

Section 1: Course Overview, Introduction to Students, Goals, and Objectives (21 criteria). This section of the online course evaluation matrix assesses the listed course information (e.g., syllabus, goals, objectives, learning outcomes); pre-course requisites and assessments; academic policies and procedures; instructor information; copyright compliance; and technical requirements and support. These components are essential to providing a solid foundation for the instructional design of the course and the online learning environment.

Section 2: Layout and Design (12 criteria). The layout and design section assesses course navigation, structure, and organization; the use of color schemes, fonts, and typefaces; and other layout and design elements that contribute to an optimum online learning environment.

Section 3: Content and Activities (25 criteria). This section assesses how course content is delivered to meet a variety of learning styles, strategies, and preferences; aligns with course goals, objectives, and outcomes; and utilizes the learning management system's various learning activities and tools.

Section 4: Communication, Interaction, and Collaboration (17 criteria). The communication, interaction, and collaboration section assesses how course design, assignments, and technology effectively encourage exchanges among the instructor, learners, and content.

Section 5: Assessment and Evaluation (20 criteria). This section assesses the process of determining learner achievement and work quality through formative and summative evaluation and assessment, including assigning grades and processes to elicit feedback from learners regarding course improvement and instructor performance.

The following rating scale was used to evaluate the online courses:

- **N** = Non-Existent, meaning either not present but should be included based on course design and content, or present but not appropriate for this course.
- **D** = Developing, meaning some evidence of this criterion but it needs to be presented more clearly or better developed.
- **M** = Meets, meaning evidence of this criterion is clear and is appropriate for this course but more could possibly be added.
- **NA** = Not Applicable, meaning this criterion does not apply based on course design and content.

Data Analysis

One of the authors (CH), an instructional designer not associated with the NIH and who was not involved with the design of any of the Fogarty online courses, individually assessed how well each of the courses was

meeting each of the criteria (at the N, D, M, and NA levels). The following metrics were used to analyze the extent to which courses meet the best practice criteria in the matrix:

1. For each section, the frequencies at which all four courses were satisfying the criteria of each section were assessed at the N (non-existent), D (developing), M (meeting), or NA (not applicable) level. For example, Section I has 21 criteria and, hence, if each of the four courses was assessed as satisfying 8, 6, 7, and 8 of the 21 criteria at the M (meeting) level, respectively, then as a group, it was determined that the courses were "meeting" (M) the criteria of Section I at 34.5% (summing up the individual Ms for each course [29] divided by 84 [21x4]).
2. A "proficiency" rating was calculated based on the percentage of all of the criteria in each of the five sections that were assessed as "meeting" (M) in at least three of the four online courses. A "deficiency" rating was also calculated based on the percentage of all of the criteria in each of the five sections that were assessed as being "non-existent" (N) in at least three of the four online courses. By analyzing which of the best practices criteria are being "meeting" for the whole program, it will be more evident which gaps in best practices need to be addressed.

Results

Figure 1 shows that as a group, all four courses were assessed as satisfying approximately 73% of the 95 criteria of the evaluation matrix at the developing (D) or meeting (M) levels, while just over 21% of the criteria
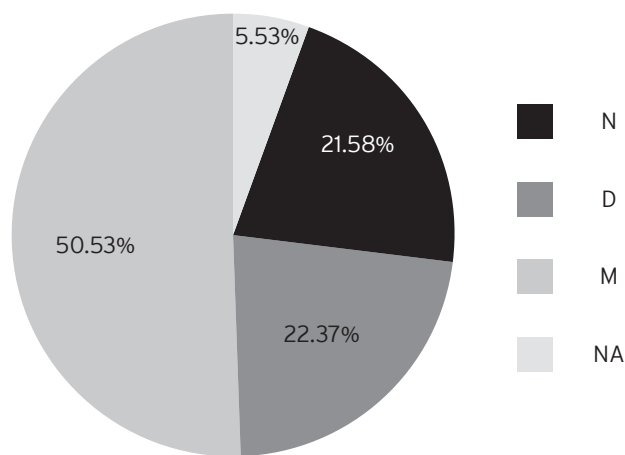
FIG. 1. Percentage of criteria receiving a score of non-existent (N), developing (D), meeting (M), or not applicable (NA) from all of the online courses.

were at non-existent (N) level across all four courses. The overall "proficiency" rating was 43.16%, i.e., 41 of the 95 criteria were assessed at the meeting (M) level by at least three out of the four courses in the program. The overall "deficiency" rating was 16.84%, i.e., 16 of the 95 criteria were assessed at the non-existent (N) level by at least three out of the four courses in the program. Finally, 89 out of 95 criteria were assessed at the developing (D) or meeting (M) levels in at least one of the four courses.

Figure 2 indicates the percentage of the 95 criteria that was assessed at the non-existent (N), developing (D), and meeting (M) levels for each of the four courses. This figure provides a thumbnail view of how well each course in the program is performing with respect to the criteria used to evaluate them for this study. More detail of each course's performance may be viewed in Appendix I of the supplementary online materials.

Section 1: Information, Goals, and Objectives. Table 1 shows the overall and individual course analysis of the criteria of Section 1. As a group, all four courses are either developing (D) or meeting (M) the criteria of this section at more than 78%, while the non-existent (N) rate is at 20.24%. The overall proficiency rating in this section (the percentage at which the criteria was assessed at the meeting (M) level by at least three of the four courses) is just over 52%, whereas the overall deficiency rating (non-existent (N) rating by at least three of the four courses) was just over 14%.

Section 2: Layout and Design. Table 2 shows the results for Section 2. All four courses are either developing (D) or meeting (M) the criteria at almost 73%, while the non-existent (N) rate is at 25%. The overall proficiency rating in this section (frequency of M rating of the criteria by at least three of the four courses) is at 68% and the overall deficiency rating (non-existent (N) rating by at least three of the four courses) is at 33%.

Section 3: Content and Activities. Table 3 shows the results for Section 3. All four courses are either developing (D) or meeting (M) the criteria at 86%, while the non-existent (N) rate is at 10%. The proficiency in this section is 36% and the deficiency rate is at 8%.

Section 4: Communication, Interaction, and Collaboration. Table 4 shows the results for Section 4. All four courses are either developing (D) or meeting (M) the criteria at nearly 59%, while the non-existent (N) rate is just over 30% rating. Section 4's proficiency rating is at 35% and deficiency rating is at 24%.
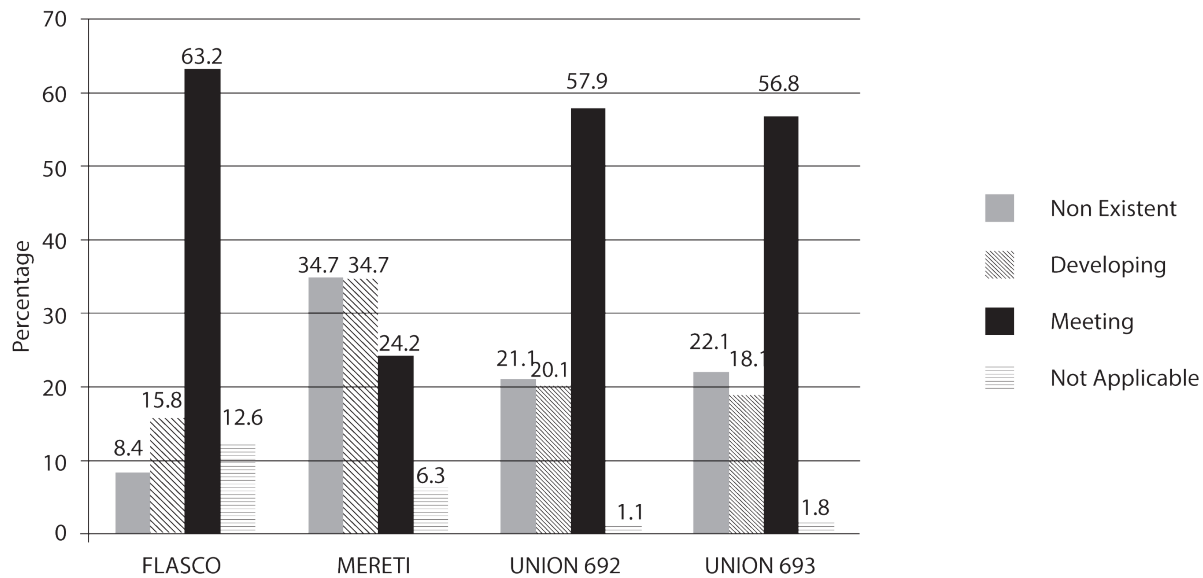
FIG. 2. Percentage of criteria receiving a score of non-existent (N), developing (D), meeting (M), and not applicable (NA) for each online course.

Section 5: Assessment and Evaluation. Table 5 shows the results for Section 5. All four courses are either developing (D) or meeting (M) the criteria at 62.5%, while the non-existent (N) rate is at 27.5%. Section 5's proficiency rating is at 35% and its deficiency rating is at 15%.

Section 6: Results. Table 6 shows the results (non-existent (N), developing (D), and meeting (M)) of the 30 criteria considered to be the most important from the scoring matrix of all five sections. The overall "proficiency" rating for these 30 criteria was 53.3%; 16

of the 30 criteria were assessed as meeting (M) the criteria by at least three out of the four courses in the program. The overall "deficiency" rating was 10.0%; three of the 30 criteria were assessed as being non-existent (N) by at least three out of the four courses in the program.

Discussion

The analysis of the four online courses offered in the Fogarty International Center International Research Ethics Training programs are developing (D) or meeting

TABLE 1. Overall Scoring Totals by Course for Section 1: Information, Goals, and Objectives.

Course	N	D	M	NA	TOTAL
FLACSO					
Number of criteria	0	6	14	1	21
Percentage	0.00%	28.57%	66.67%	4.76%	100.00%
MERETI					
Number of criteria	11	7	3	0	21
Percentage	52.38%	33.33%	14.29%	0.00%	100.00%
Union 692					
Number of criteria	3	3	15	0	21
Percentage	14.29%	14.29%	71.43%	0.00%	100.00%
Union 693					
Number of criteria	3	3	15	0	21
Percentage	14.29%	14.29%	71.43%	0.00%	100.00%
Section Total					
Number of criteria	**17**	**19**	**47**	**1**	**84**
Percentage	20.24%	22.62%	55.95%	1.19%	100.00%

TABLE 2. Overall Scoring Totals by Course for Section 2: Layout and Design.

Course	N	D	M	NA	TOTAL
FLACSO					
Number of criteria	0	2	9	1	12
Percentage	0.00%	16.67%	75.00%	8.33%	100.00%
MERETI					
Number of criteria	4	5	3	0	12
Percentage	33.33%	41.67%	25.00%	0.00%	100.00%
Union 692					
Number of criteria	4	0	8	0	12
Percentage	33.33%	0.00%	66.67%	0.00%	100.00%
Union 693					
Number of criteria	4	0	8	0	12
Percentage	33.33%	0.00%	66.67%	0.00%	100.00%
Total	12	7	28	1	48
Percentage	25.00%	14.58%	58.33%	2.08%	100.00%

(M) nearly three-quarters of the criteria considered best practices in eLearning. Also, 89 of the 95 criteria are being met in one or more of the online courses. This suggests that the necessary skills and expertise exists within the Fogarty programs to bring all of the courses to meet most of the criteria by sharing their best practices.

The analysis of the results for the individual sections reveals that Section 3 (Content and Activities) was associated with the highest "developing" or "meeting" the criteria and the lowest non-existent (N) rating. As reflected by the individual criteria of this section (Appendix I), these results show that the courses have paid particular attention to the selection of educational content needed to meet the stated goals and learning objectives of the courses and that the selected specific learning activities in these courses will engage learners and impart to them the knowledge and skills needed to respond to real-life situations.

Section 1 (Information, Goals, and Objectives) and Section 2 (Layout and Design) ranked second and third, in terms of either "developing" or "meeting" the criteria. These results point to significant attention to consistent trainee orientation and support of learning in the online environment. The provision of standardized operational procedures and design features ensures that the learner will focus less on the logistics of online course navigation, layout, and design, and more on course content, activities, and interaction, which enhances the online experience. Similar to the comfort

TABLE 3. Overall Scoring Totals by Course for Section 3: Content and Activities.

Course	N	D	M	NA	TOTAL
FLACSO					
Number of criteria	1	1	19	4	25
Percentage	4.00%	4.00%	76.00%	16.00%	100.00%
MERETI					
Number of criteria	3	7	15	0	25
Percentage	12.00%	28.00%	60.00%	0.00%	100.00%
UNION 692					
Number of criteria	3	12	10	0	25
Percentage	12.00%	48.00%	40.00%	0.00%	100.00%
UNION 693					
Number of criteria	3	12	10	0	25
Percentage	12.00%	48.00%	40.00%	0.00%	100.00%
Total	10	32	54	4	100
Percentage	10.00%	32.00%	54.00%	4.00%	100.00%

TABLE 4.   Overall Scoring Totals by Course for Section 4: Communication, Interaction, and Collaboration.

Course	N	D	M	NA	TOTAL
FLACSO					
Number of criteria	2	3	9	3	17
Percentage	11.76%	17.65%	52.94%	17.65%	100.00%
MERETI					
Number of criteria	7	5	1	4	17
Percentage	41.18%	29.41%	5.88%	23.53%	100.00%
UNION 692					
Number of criteria	6	1	10	0	17
Percentage	35.29%	5.88%	58.82%	0.00%	100.00%
UNION 693					
Number of criteria	6	1	10	0	17
Percentage	35.29%	5.88%	58.82%	0.00%	100.00%
Total	**21**	**10**	**30**	**7**	**68**
Percentage	30.88%	14.71%	44.12%	10.29%	100.00%

of the face-to-face classroom environment, the online learning environment must be conducive for optimal learning and is essential for a positive learning experience, particularly because verbal and physical cues for interaction are absent in the online classroom.

Section 5 (Evaluation and Assessment) was ranked fourth overall in terms of either "developing" or "meeting" the criteria. The deficiencies in this section indicate the need to include additional learner assessments to enhance the likelihood of achieving overall course goals and objectives, as well as to provide informed feedback for course and program improvements in assessment and evaluation. Assessment is key for identifying systemic needs for the development and implementation of successful learning strategies. Meaningful assessment should be multidimensional (e.g., assessment of content and tools to deliver the content) and encompass data from direct and indirect measures of learning, with information gathered from students and faculty (Calderon, Patraka, & Ciabocchi, 2012). Ozkan and Koseler developed a self-report instrument to measure student satisfaction that focused on six dimensions that may be used in the pedagogical design and use of learning management systems (Okzan & Koseler, 2009). These included: students' attitudes about e-learning overall; students' perceptions of the respective quality of the instructor; interface system used in e-learning; course content; services provided by administrators and staff

TABLE 5.   Overall Scoring Totals by Course for Section 5: Evaluation and Assessment.

Course	N	D	M	NA	TOTAL
FLACSO					
Number of criteria	5	3	9	3	20
Percentage	25.00%	15.00%	45.00%	15.00%	100.00%
MERETI					
Number of criteria	8	9	1	2	20
Percentage	40.00%	45.00%	5.00%	10.00%	100.00%
Union 692					
Number of criteria	4	3	12	1	20
Percentage	20.00%	15.00%	60.00%	5.00%	100.00%
Union 693					
Number of criteria	5	2	11	2	20
Percentage	25.00%	10.00%	55.00%	10.00%	100.00%
Total	**22**	**17**	**33**	**8**	**80**
Percentage	27.50%	21.25%	41.25%	10.00%	100.00%

TABLE 6. Overall Scores of the Most Important Criteria from All Five Sections.

Criterion	N	D	M	NA
Combined scoring totals by criteria for Section 1: Information, Goals, and Objectives.				
1.1 A course description is provided.	0	1	3	0
1.2 Course goals are clearly defined and aligned to learning objectives and outcomes.	1	0	3	0
1.3 Objectives are clear, measurable, and appropriate to course goals and outcomes.	0	1	3	0
1.4 Objectives specify learning outcomes related to the acquisition and demonstration of knowledge, skills, competencies, behaviors, and/or attitudes.	0	3	1	0
1.8 The course overview and syllabus are present and clearly outline the scope of the course and expectations of the learner.	0	1	3	0
Combined scoring totals by criteria for Section 2: Layout and Design.				
2.1 The course is well-organized into sections, modules, or units that correspond to the course structure and syllabus.	0	1	3	0
2.3 Navigation cues are present; clearly identifiable; offered in text and graphic formats; and are obvious links based upon visual cues such as color, underlining, and text directions (e.g., Start here).	0	1	3	0
2.7 The format is uncluttered and includes white space.	0	0	4	0
2.8 The typeface (font) is easy to read and consistent.	0	1	3	0
2.9 Color is used effectively and consistently.	0	1	3	0
2.10 Images (photographs, etc.) are clear and optimized for efficient loading.	3	1	0	0
2.11 Graphic elements (pictures, animated images, etc.) illustrate information presented in the text to enhance rather than detract.	3	1	0	0
Combined scoring totals by criteria for Section 3: Content and Activities				
3.4 The content is broken into small, incremental learning steps and organized in a logical, consistent sequence.	0	3	1	0
3.5 The content is "chunked" or divided into subunits or subtopics that relate to the main topics.	0	2	2	0
3.10 Course content is delivered using multiple visual, textual, kinesthetic, and/or auditory methods to enhance learning and address different learning styles or preferences.	0	1	3	0
3.11 Audio files meet minimum standards for clarity, file length and size, written transcription, and player requirements and compatibility.	0	2	1	1
3.12 Video files meet minimum standards for clarity, file length and size, written transcription or closed-captioning, and player requirements and compatibility.	0	2	1	1
3.14 The course provides multiple activities that help learners develop critical thinking, creativity, and problem-solving skills.	0	2	2	0
3.15 The course provides a variety of ways for learners to demonstrate knowledge and experiences related to the course content.	0	2	2	0
3.21 The learning activities are realistic, appropriate to the content, goals, objectives, and outcomes, and can be performed with the resources and time available to the learner.	0	0	4	0
3.22 Real-world applications (e.g., case studies, problem-solving scenarios, etc.) are part of the course content and activities.	0	0	4	0
Combined scoring totals by criteria for Section 4: Communication, Interaction, and Collaboration.				
4.3 Learners post personal introductions at the beginning of the course to "break the ice" and set the stage for a community of learning.	3	1	0	0
4.4 Opportunities are provided that foster learner-to-learner communication and interaction throughout the course using a variety of methods (e.g., discussion boards, chat, blog, journal, wiki, email, phone, Skype, etc.).	0	1	3	0
4.5 Opportunities are provided that foster learner-to-instructor communication, and interaction throughout the course using a variety of methods (e.g., discussion boards, chat, blog, journal, wiki, email, phone, Skype, etc.).	1	0	3	0
4.6 Opportunities are provided that foster learner-to-content interaction throughout the course using a variety of methods such as discussion boards, chat, blog, journal, wiki, glossaries, etc.	0	3	1	0
Combined scoring totals by criteria for Section 5: Evaluation and Assessment.				
5.3 Assessments and evaluations use multiple methods, (e.g., quizzes, tests, discussions, essays, projects, assignments, surveys, polls, etc.) appropriately to measure stated outcomes.	0	4	0	0
5.4 Formative assessment and evaluation is used throughout the course to gauge learning and to make adjustments within the course as needed.	2	2	0	0
5.5 Summative assessment and evaluation is used at the end of the course to gauge achievement of course goals, objectives, and outcomes.	1	1	2	0
5.18 Learners have the opportunity to communicate feedback regarding the course structure and content.	0	1	3	0
5.19 Learners have the opportunity to provide feedback regarding the instructor and instructional strategies of the course.	0	1	3	0

(e.g., technical support); and supportive issues (e.g., ethical and legal issues, privacy, plagiarism, intellectual property). Finally, faculty input and experience in teaching e-learning courses is also important to the success of e-learning.

The lowest rating was attained in Section 4 (Communication, Interaction, and Collaboration). The pedagogy examined in Section 4 covers all three levels of interactivity involved in online learning: learner-content, learner-to-learner, and learner-instructor. Learner-content interaction is where the students work with a web-based instructional program with the system adapting to their inputs. Learner-instructor interaction occurs via print, electronic dialog, e-mail, computer conferencing, or electronic online classroom discussions. Learner-learner interaction occurs when learners engage in discussions moderated by the instructor, during group projects, or within other forms of group-led activities. While it may be challenging to achieve excellence in communication, interaction, and collaboration through the online medium, these types of interactions in web-based environments support collaborative construction of knowledge through social negotiation that is a key feature of constructivist learning environments, which views learning to be an active rather than passive endeavor. This theory proposes that learning is a dialogic process in which communities of individuals engage socially in talk and activity about shared problems or tasks (Jonassen, Myers, & McKillop, 1996; Merriam, Caffarella, & Baumgartner, 2007). The ultimate goal of such learning is "making meaning," which results from learners engaging, incorporating, and critically exploring the views of others, while new possibilities of interpretations are opened through the interaction (Reeves & Oakley, 1996). Activities that promote a collaborative process of building and reshaping understanding with and among their peers might be especially important in courses that involve ethical reflection (Jonassen et al., 1996; McAlpine, 2000). In one study that evaluated both the content of the module and the tools used to deliver it, students' feedback highlighted the importance of incorporating assignments that encouraged learning and critical reflection via peer assessment and interaction (Pombo et al., 2010). While none of the online Fogarty courses included peer reviews, peer critiques, and peer evaluations, they did rely heavily on activities that foster communications via the use of interactive discussion boards.

There remains the question as to whether online learning achieves learning outcomes equivalent to those achieved with traditional face-to-face learning.

Recently, the U.S. Department of Education performed a meta-analysis of 50 independent studies that compared online to face-to-face courses taught in the U.S and found that, on average, students in online learning conditions performed modestly better than those receiving face-to-face instruction (U.S. Department of Education, 2008).

The acceptance and the effectiveness of online learning in individuals from LMICs are limited. A recent randomized study that compared online with on-site face-to-face delivery of training in biostatistics and research ethics to Indian scientists demonstrated marked and similar improvements of knowledge in these subject areas (Aggarwal et al., 2011). The online training program in the Aggarwal study employed synchronous sessions, in which the participants and instructors logged on at scheduled times to discuss the course material. This contrasts with the Fogarty online courses, which relied predominantly on asynchronous activities sessions. While studies have generally yielded no significant differences between synchronous and asynchronous e-learning (Gunawardena & McIsaac, 2004), learners and instructors see synchronous activities as being more social, make participants feel less isolated, and enhance opportunities to ask and answer questions in real time (Hrastlinski, 2008).

Finally, we would like to point out that all of the Fogarty courses employed a blended pedagogy that consisted of an online experience preceded by a face-to-face component, which helps learners build a sense of community that facilitates a community of inquiry. When there is no face-to-face component, students may report some isolation, and if instructors fail at achieving a certain level of interactivity, students may also report a disconnect with the class, their classmates, and the instructor (Dickey, 2004; Garrison & Kanuka, 2004). The subsequent outcomes may include lower attendance rate, lack of accountability, and attrition. These results are observed in Massive Online Open Courses (MOOC), which may also be due to the lack of community that occurs with these courses (Hill, 2013). A blended learning model may be the preferred model for online course design, as studies have demonstrated the superior effectiveness of blended compared with online only (Power, 2008; Precel, Eshet-Alkalai, & Alberton, 2009) and with face-to-face only learning (Twigg, 2003).

There are several limitations to our study. First, only one of the authors was involved in assessing the extent to which the four Fogarty courses met the eLearning criteria in the matrix used in this study. Accordingly,

our results may be overly subjective. However, this author was independent from the Fogarty program and was not involved with the design of any of the assessed Fogarty courses. Another limitation involves the use of best practices criteria that might not be relevant to the learning styles of individuals from other cultures. Specifically, individuals who have been exposed to only passive learning experiences might vary in their preparedness towards online collaborative communication activities that are prevalent in the Fogarty courses. Future studies should capture feedback from international trainees on their satisfaction with online collaborative activities.

Best Practices

With regard to best practices, the criteria used in the online course evaluation matrix developed for this study provide the framework and guidance necessary to develop courses that meet best practices in online learning. These criteria are based upon academic standard instructional design methodologies and are considered best practices in the field of online course development (Las Positas College, 2012; MarylandOnline, 2011). While it may seem unwieldy to design online courses with attention to all 95 criteria, these criteria demonstrate the highest standards of course design and delivery for optimum learning outcomes and learner experience. As mentioned previously, at least one or more of the four courses were developing (D) or meeting (M) 89 of the 95 criteria. This suggests that the necessary skills and expertise exist in these programs to ensure that future courses come close to meeting almost 100% of the criteria. Accordingly, a model online course could be developed to showcase the instructional design criteria and serve as an ongoing process of implementing best practices for online course development and delivery. Appendix II in the supplementary online materials shows an outline of one way to incorporate the best practices criteria used in this study into an online course instructional design.

Research Agenda

Studies are needed to determine the efficacy of online learning in developing countries, in general, and for online courses in research ethics education, in particular. A recent randomized study compared a synchronous online activity (participants and instructors logged on at scheduled times) with on-site delivery of training in biostatistics and research ethics to Indian

scientists and demonstrated marked and similar improvements of knowledge in these subject areas for both training activities (Aggarwal et al., 2011). It remains unknown whether online courses in ethics that forgo online synchronous (live) components and thus rely exclusively on asynchronous activities could have comparable learning outcomes to an on-site face-to-face experience. Instead, studies should assess a blended pedagogy compared with an on-site instruction only experience.

Educational Implications

Developing an international distance-learning program warrants attention to technological limitations, as well as to cultural considerations regarding pedagogy, learning styles, and acceptance of online learning in LMICs (Mathur & Oliver, 2007). Rather than export their existing programs to LMICs without much adaptation to local needs or sensitivity to local cultures, Western universities should create new ones based on genuine collaboration with their counterparts in LMICs (Larsson et al., 2005). One major consideration would be to embrace blended programs that include a face-to-face component, not only because such programs build a sense of community, but also because LMICs might still be skeptical about the practices of eLearning (Ibrahim et al., 2007). For example, several Arab universities require that distance-learning programs include at least half of its instruction via a face-to-face component (personal communication, Bakr Bin Sadiq, 2013). Regarding other cultural differences, learners from LMICs may not be as familiar with online learning strategies used in Western universities, e.g., frequently participating in a discussion forum that requires an active participatory style, which contrasts with a predominant passive pedagogic style employed in LMIC universities. Thus, to ensure a successful instructional model, collaborators need to discuss educational practices that occur within the educational systems of both countries and incorporate culture as an overarching concern (Mathur & Oliver, 2007).

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responsibility of the authors and do not necessarily represent the official view of the NIH.

Author Note

Please direct correspondence to Henry Silverman, University of Maryland School of Medicine, 110 South Paca Street, Second Floor, Baltimore, MD 21201. Phone (410) 328 4811. E-MAIL: hsilverm@medicine.umaryland.edu.

Authors' Biographical Sketches

Henry Silverman is Professor of Medicine at the University of Maryland School of Medicine. He is program director of the Middle East Research Ethics Training Initiative (MERETI) that is sponsored by the Fogarty International Center/NIH research ethics training program. Dr. Silverman conceived the idea for this study, helped analyze the data, and wrote the first and final drafts of the manuscript.

Florencia Luna is Independent Researcher at CONICET (National Scientific and Technological Research Council), Argentina, and is Director of the Program of Bioethics at FLACSO (Latin American University of Social Sciences) and was President of the International Association of Bioethics (IAB) (2003–2005). She assisted with the analysis of the study and helped edit portions of the manuscript.

Sean Philpott is Associate Professor of Bioethics and Director of the Center for Bioethics and Clinical Leadership of Union Graduate College. Before joining Union Graduate College he was Science and Ethics Officer at the international nonprofit organization PATH, where his work focused on building the capacity of developing country researchers and stakeholders to design, conduct, and monitor clinical trials. He assisted with the analysis of the course materials and edited portions of the manuscript.

Martin Strosberg is Professor of Bioethics in the Program in Bioethics at Union Graduate College. He is currently Principal Investigator and Co-Program Director on a grant from the National Institutes of Health, Fogarty International Center, "E-Education in Research Ethics: Central and Eastern Europe." He assisted with the analysis of the course materials.

Cheryl A. Hemmerle spent five years as a freelance writer, graphic designer, and consultant prior to joining United Methodist Communications in 2007 as Technical Training Specialist. Cheryl developed the scoring matrix for this study and used it to analyze the eLearning programs in this study.

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Appendix I: Tables of Individual Criteria

SECTION 1. Combined scoring totals by criteria for information, goals, and objectives.

Criterion	N	D	M	NA
1.1 A course description is provided.	0	1	3	0
1.2 Course goals are clearly defined and aligned to learning objectives and outcomes.	1	0	3	0
1.3 Objectives are clear, measurable, and appropriate to course goals and outcomes.	0	1	3	0
1.4 Objectives specify learning outcomes related to the acquisition and demonstration of knowledge, skills, competencies, behaviors, and/or attitudes.	0	3	1	0
1.5 Module, section, or unit objectives and outcomes are clearly presented to the learner and are aligned with the larger course goals, objectives, and outcomes.	0	1	3	0
1.6 Course goals and objectives are relevant to the subject matter and to the "real world" in which the content may be applied.	0	0	4	0
1.7 Course prerequisites are listed and pre-course learning assessment tools are utilized to determine learner readiness and level of knowledge, skills, competencies, behaviors, and/or attitudes at the beginning of the course.	0	2	2	0
1.8 The course overview and syllabus are present and clearly outline the scope of the course and expectations of the learner.	0	1	3	0
1.9 Instructor information is available to learners with contact, biographical, availability information and picture.	1	0	3	0
1.10 Learners are provided with a list of supplies such as textbooks and other instructional materials needed for the course.	1	1	2	0
1.11 Information is provided regarding the number of credit hours earned for successful completion.	1	1	2	0
1.12 The grading policy is provided including grading scale and weights.	1	1	2	0
1.13 A calendar of due dates and other events is provided (may be incorporated into the syllabus).	1	0	3	0
1.14 The workload on learners is neither too much nor too little for the scope, timeframe, and level of the course.	0	0	4	0
1.15 A list of technical competencies necessary for course completion is provided.	3	0	1	0
1.16 A list of technical requirements such as connection speed, hardware, and software is provided.	3	0	1	0
1.17 A code of conduct including netiquette standards and academic integrity expectations is provided in compliance with institutional and/or programmatic policies and procedures.	0	1	3	0
1.18 A statement of ADA Compliance and request for special services is provided.	3	0	0	1
1.19 Orientation and tutorials for use of the online learning management system and other technical tools is provided.	1	3	0	0
1.20 Contact information for technical support is provided.	0	1	3	0
1.21 A list of academic and/or programmatic resources with links to the institution's library, tutoring center, counseling services, and other resources is provided.	1	2	1	0

SECTION 2. Combined scoring totals by criteria for layout and design.

Criterion	N	D	M	NA
2.1 The course is well-organized into sections, modules, or units that correspond to the course structure and syllabus.	0	1	3	0
2.2 Course navigation is clear, functional, and consistent.	0	1	3	0
2.3 Navigation cues are present; clearly identifiable; offered in text and graphic formats; and are obvious links based upon visual cues such as color, underlining, and text directions (e.g., Start here).	0	1	3	0
2.4 Hyperlinks to other parts of the course are accurate, functional, and minimize the use of pop-up windows or new windows.	0	0	4	0
2.5 Hyperlinks to external sources (other websites and webpages outside the course) are accurate, functional, and open in a new window.	3	0	1	0
2.6 The layout is visually and functionally consistent throughout the course.	0	0	4	0
2.7 The format is uncluttered and includes white space.	0	0	4	0
2.8 The typeface (font) is easy to read and consistent.	0	1	3	0
2.9 Color is used effectively and consistently.	0	1	3	0
2.10 Images (photographs, etc.) are clear and optimized for efficient loading.	3	1	0	0
2.11 Graphic elements (pictures, animated images, etc.) illustrate information presented in the text to enhance rather than detract.	3	1	0	0
2.12 Course design indicates a conscious effort to comply with Section 508 of the Rehabilitation Act of 1973 to make electronic and information technology accessible to persons with disabilities.	3	0	0	1

SECTION 3. Combined scoring totals by criteria for content and activities.

Criterion	N	D	M	NA
3.1 The content directly relates to course goals, objectives, and outcomes.	0	0	4	0
3.2 The content is appropriate for the learner's ability and experiences.	0	0	4	0
3.3 The content is accurate, relevant, and current.	0	0	4	0
3.4 The content is broken into small, incremental learning steps and organized in a logical, consistent sequence.	0	3	1	0
3.5 The content is "chunked" or divided into subunits or subtopics that relate to the main topics.	0	2	2	0
3.6 The content is related to other material the learner may have experienced.	0	0	4	0
3.7 Headings and subheadings are used to organize content.	0	4	0	0
3.8 Required course content is clearly delineated from supplementary elements.	0	1	3	0
3.9 A glossary is provided that defines common, unusual, or technical terms used in the course.	3	0	1	0
3.10 Course content is delivered using multiple visual, textual, kinesthetic, and/or auditory methods to enhance learning and address different learning styles or preferences.	0	1	3	0
3.11 Audio files meet minimum standards for clarity, file length and size, written transcription, and player requirements and compatibility.	0	2	1	1
3.12 Video files meet minimum standards for clarity, file length and size, written transcription or closed-captioning, and player requirements and compatibility.	0	2	1	1
3.13 Appropriate copyright permission is obtained and displayed for articles, images, audio, video, and other media used in the course.	2	1	1	0
3.14 The course provides multiple activities that help learners develop critical thinking, creativity, and problem-solving skills.	0	2	2	0
3.15 The course provides a variety of ways for learners to demonstrate knowledge and experiences related to the course content.	0	2	2	0
3.16 The writing style is clear and direct using a conversational tone that employs the second person (you) and in a supportive and encouraging manner.	0	2	1	1
3.17 Clear directions are given for each assignment or activity, including the grading standard and point or percentage value where applicable.	1	1	2	0
3.18 Verbs are in the active, not passive, voice.	0	2	1	1
3.19 Sentences are short and paragraphs are brief.	0	2	2	0
3.20 Numbers are used to identify sequential steps in a task or process, while bullets are used to list items that are not prioritized or sequential.	0	2	2	0
3.21 The learning activities are realistic, appropriate to the content, goals, objectives, and outcomes, and can be performed with the resources and time available to the learner.	0	0	4	0
3.22 Real-world applications (e.g., case studies, problem-solving scenarios, etc.) are part of the course content and activities.	0	0	4	0
3.23 Learners are linked to resources beyond the course material for further exploration and learning.	0	1	3	0
3.24 Summaries are provided throughout the course content, particularly at the end of topics, lessons, units, sections, or modules.	3	0	1	0
3.25 A bibliography or reference list includes a variety of material such as websites, books, journals, and multimedia.	1	2	1	0

SECTION 4. Combined scoring totals by criteria for communication, interaction, and collaboration.

Criterion	N	D	M	NA
4.1 An announcement of welcome by the course instructor appears at the start of the course and directs learners to the course introduction and syllabus, etc.	3	0	1	0
4.2 The introduction to the course takes into account the learners' backgrounds, ability levels, and expectations, including their personal learning goals and objectives.	0	2	2	0
4.3 Learners post personal introductions at the beginning of the course to "break the ice" and set the stage for a community of learning.	3	1	0	0
4.4 Opportunities are provided that foster learner-to-learner communication and interaction throughout the course using a variety of methods (e.g., discussion boards, chat, blog, journal, wiki, email, phone, Skype, etc.).	0	1	3	0
4.5 Opportunities are provided that foster learner-to-instructor communication and interaction throughout the course using a variety of methods (e.g., discussion boards, chat, blog, journal, wiki, email, phone, Skype, etc.).	1	0	3	0

SECTION 4. (Continued)

Criterion		N	D	M	NA
4.6	Opportunities are provided that foster learner-to-content interaction throughout the course using a variety of methods such as discussion boards, chat, blog, journal, wiki, glossaries, etc.	0	3	1	0
4.7	Expected turn-around time in responding to learners' emails (e.g., within 24 hours or between 24 and 48 hours, etc.) is stated.	3	1	0	0
4.8	Methods for communicating with learners about course updates and changes via announcements, email, etc., are stated.	2	1	1	0
4.9	The course provides separate forums for community, course questions and content discussion.	1	0	3	0
4.10	Discussions are organized in clearly defined forums and/or threads.	0	0	4	0
4.11	The instructor's role in discussion activities is clearly defined.	1	0	3	0
4.12	The course provides opportunities for learners to collaborate through group work that directly relates to course goals, objectives, and outcomes.	2	0	2	0
4.13	Guidelines for forming work groups and assigning roles within each are clearly stated.	0	0	2	2
4.14	Benchmarks and expectations of group participation are clearly stated.	2	0	0	2
4.15	Guidelines for how, when, and where the final group work product will be delivered is provided.	0	0	2	2
4.16	Learners engage in peer activities, such as peer reviews, peer critiques, peer evaluations, etc.	3	0	0	1
4.17	Guest speakers (e.g., professionals in the field, community leaders, practitioners, etc.) are included in the course.	0	1	3	0

SECTION 5. **Combined scoring totals by criteria for evaluation and assessment**.

Criterion		N	D	M	NA
5.1	Course assessment and evaluation are aligned with learning goals, objectives, and outcomes.	0	1	3	0
5.2	Assessment and evaluation processes and expectations are clearly communicated.	0	2	1	1
5.3	Assessments and evaluations use multiple methods, (e.g., quizzes, tests, discussions, essays, projects, assignments, surveys, polls, etc.) appropriately to measure stated outcomes.	0	4	0	0
5.4	Formative assessment and evaluation is used throughout the course to gauge learning and to make adjustments within the course as needed.	2	2	0	0
5.5	Summative assessment and evaluation is used at the end of the course to gauge achievement of course goals, objectives, and outcomes.	1	1	2	0
5.6	Learners engage in a pre-course assessment to set the baseline of their initial knowledge, skills, competencies, behaviors, and attitudes related to the course goals, objectives, and outcomes.	4	0	0	0
5.7	Learners have opportunities for self-assessment (e.g., practice quizzes, study questions, etc.).	4	0	0	0
5.8	Assessments and evaluations provide learners with ample opportunities to practice and apply concepts and skills in realistic and relevant ways that enforce learning outcomes.	0	4	0	0
5.9	Explicit rubric, rationale, and/or characteristics are provided for each graded assignment.	2	0	2	0
5.10	Learner participation is defined and a mechanism for measuring quality and quantity is provided.	2	0	2	0
5.11	Defined course procedures for reporting grade information complies with FERPA and institutional/programmatic regulations on reporting grade information to students.	3	0	0	1
5.12	Assessments and evaluations are designed and administered to uphold academic and/or programmatic integrity.	0	0	4	0
5.13	A grading scale that defines letter grades and/or weights, if applicable, is provided.	2	0	2	0
5.14	Penalties assessed to grades, if applicable, are provided.	0	0	2	2
5.15	The opportunity for earning extra credit and/or retaking assessments, if applicable, is provided.	0	0	0	4
5.16	The instructor clearly communicates when, what type, and how feedback will be provided to learners when their performance is being assessed or evaluated.	1	0	3	0
5.17	The instructor clearly communicates the availability, time allotment, and due date of all graded assignments.	1	0	3	0
5.18	Learners have the opportunity to communicate feedback regarding the course structure and content.	0	1	3	0
5.19	Learners have the opportunity to provide feedback regarding the instructor and instructional strategies of the course.	0	1	3	0
5.20	A gradebook is available so learners can check their progress in compliance with FERPA regulations.	0	1	3	0

Appendix II

Sample outline of an online course template using all 95 criteria. Keep in mind that the actual application of this outline may vary slightly based upon the instructional goals, objectives, and outcomes as well as the course content, activities, evaluation, and assessment choices made by the individual instructor or course creator. Nonetheless, the sample outline demonstrates how these 95 criteria can be incorporated to achieve highest proficiency and best practices for online learning in the Fogarty-Sponsored Training Program. It will be up to the directors and faculty of the program to determine what adjustments should be made and applied across the program with regard to criteria, proficiencies, and best practices.

This sample template for an online course assumes the use of the Moodle or Joule learning management system and a three-column theme format. Adjustments can easily be made for a two-column theme format by placing all left and right sidebar items together on one side and the middle section or main content section (Topic Outline, etc.) on the other side.

HTML Block:
Hyperlinks to the following, all opening in new windows (2.2-2.5)
- Technical Requirements (1.16)
- Contact Information for Technical Support (1.20)
- Code of Conduct (1.17)
- ADA Statement (1.18)
- LMS Orientation Tutorials (1.19)
- Academic/Programmatic Resources (1.21)

Note: This block could be a sticky block appearing in all institution courses.

Admin Block:
Access to Grades (5.9, 5.11, 5.13-5.15, 5.20)

Welcome (4.1)
Course Description (1.1, 4.2)
Instructor Information, link to LMS profile for lead instructors (1.9, 4.5)
Course Overview and Syllabus (1.8), recommend using webpage feature in LMS, book activity or PDF to collocate the following:
- Course prerequisites (1.7)
- Course goals (1.2 and 1.6)
  Course and section objectives (1.3, 1.4, 1.5 and 1.6)
- Instructor information (1.9, 4.5) including turn-around time for response to learners' emails, etc. (4.7) and communicating about course updates, etc. (4.8)
- List of supplies, textbooks, and instructional materials (1.10)
- List of technical requirements (1.16)
- Contact information for technical support (1.20)
- Code of conduct (1.17)
- Instructor's role in discussion activities (4.11)
- ADA statement (1.18)
- Number of credit hours (1.11)
- Grading policy, scale, and weights (1.12, 5.9-5.15)
- Assessment and evaluation processes and expectations (5.2, 5.18)
- Instructor's feedback methods and timeframe (5.16)
- Calendar of due dates, etc. (1.13, 5.17)

Pre-Course Learning Assessments (1.7, 4.6), recommend using LMS feedback or quiz activity.
Technical Competencies (1.15).
Forums:
- News Forum to communicate course updates, etc. (4.8, 4.10-4.11)
- Personal introductions, expectations of the course, etc. (4.3, 4.10-4.11)
- Questions related to the course (4.9-4.11)
- Open discussion on/off topic (4.9-4.11)

Module 1:
Topic corresponding to Syllabus/Course Outline (2.1, 3.7)
Section Overview and Objectives (1.5)
Section Content organized in Book or Lesson format (2.2-2.12, 3.1-3.7, 3.10, 3.13, 3.16, 3.18-3.20, 3.22-3.25, 4.17), recommend using the Book activity for strictly content-based materials and the Lesson activity for content and assessment combined such as integrating graded quizzes, choices, etc.
Audio, Video Content Delivery, recommend it be incorporated into book or lesson activity (3.10-3.12)
Required Readings (3.7, 3.23), may be incorporated into content book or lesson including copyright and source notations (3.13)
Supplementary Readings (3.7, 3.23), may be incorporated into content book or lesson including copyright and source notations (3.13)
Assessment, Interaction, and Learning Activities such as quizzes, assignments, forums, etc. (3.14-3.15, 3.17, 3.21-3.22, 4.1-4.16, 5.1-5.10, 5.12, 5.16-5.19)
Module 2, etc.:
Repeat as above for all subsequent sections, units, modules for the entire course.

Block: Participants (4.4-4.5)
Block: Calendar of due dates, etc. (1.13)
Block: Activities
- Assignments (3.14-3.15, 3.17, 3.21, 4.5-4.6, 4.12-4.16, 5.13-5.17)
- Blog (4.4-4.6)
- Book (3.10, 3.21)
- Chat (4.4-4.6)
- Choice (3.14-3.15, 3.17, 3.21)
- Database (3.23, 3.25)
- Feedback (3.14-3.15, 3.17, 3.21, 5.1-5.10, 5.13-5.19)
- Forum (3.14-3.15, 4.4-4.6, 4.9-4.11, 5.13-5.17)
- Glossary (3.9, 3.15, 4.6)
- Lesson (3.10, 3.14-3.15, 3.17, 3.21, 5.13-5.17)
- Quiz (3.14-3.15, 3.17, 3.21, 5.1-5.10, 5.13-5.17)
- Wiki (4.4-4.6, 5.13-5.17)
- Workshop (3.14-3.15, 3.17, 3.21, 4.4, 4.6, 4.12-16, 5.13-5.17)