Developing an evidence-based ethics education program for surgical residents in Guatemala

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Abstract

Background: Training in responsible conduct of research and human subjects protections (RCR/HSP) is seldom included in postgraduate medical education in low-and middle-income (LMIC) countries despite requirements that residents undertake research projects. Investigators introduced a Spanish-language training program in RCR/HSP for surgical residents in Guatemala using “off-the-shelf” on-line materials, developed a new in-person curriculum specific to the local context, and compared the two teaching modalities with the aim of generating recommendations to improve resident training. **Methods:** In 2018, surgical residents in three large urban hospitals in Guatemala City completed two on-line programs in RCR/HSP as well as pre- and post-training assessments. Residents in the intervention arm also completed seven weeks of in-person training. Assessments tested awareness of key concepts in the on-line courses with particular attention to international and Guatemalan research regulations. Group differences in matched (pre- and post-) mean scores were analyzed using t-tests to determine gains by study arm assignment. **Results:** Of the 160 surgical residents, 140 completed pre- and post-training assessments and were included in the analytic sample. Overall mean scores improved from 52.7 to 58.7 points out of 100. The differences in gains between the two arms were very small and there was insufficient statistical power to detect significance. Trainees completing in-person training reported greater confidence in recognizing ethical issues, understanding the legal and ethical requirements for research, and identifying, reporting and avoiding scientific misconduct than trainees who completed on-line training only. **Conclusion:** Differences in gains in RCR/HSP knowledge and self-efficacy between trainees completing on-line training only and those completing in-person as well as on-line training are too modest to preference one mode of instruction over another in this setting. Given the limited availability of RCR/HSP faculty, financial resources, and time in the surgical training schedule, however, the investigators recommend that academic authorities in Guatemala consider on-line training programs in RCR/HSP in all surgical residency programs as an affordable and scalable strategy to build ethical research skills in its surgical workforce.

Background

While RCR/HSP/research ethics training programs can vary significantly in content, they share the common goal of building competency in subject protections, understanding of scientific misconduct and conflict of interest, and appreciation of the attributes and conditions necessary for ethical collaboration, data handling and sharing, authorship, and mentorship. Some programs focus on formal guidelines, general ethical principles and historically noteworthy cases of research abuse. These programs provide researchers with information needed to comply with regulatory and institutional guidelines but may not necessarily prepare them to apply ethical reasoning skills to the design and conduct of research [1]. Studies have suggested that researchers are more likely to formulate their concepts of scientific integrity and responsibilities towards others from climate, institutional contexts, and ethical norms than from formal guidelines [2,3].

Training programs in RCR/HSP/research ethics generally take the form of face-to-face short courses, workshops, on-line standardized certificate programs, and hybrid versions that combine one or more of these techniques. Although on-line programs require fewer in-house resources and offer maximum flexibility, particularly when publicly available programs exist such as those available through the Collaborative Institutional Training Program (<https://about.citiprogram.org/en/homepage/>), other important factors need to be considered. A 2009 quantitative meta-analysis of ethics program evaluation efforts, for example, found that ethics courses that emphasize student engagement through highly interactive learning and practice activities promoted instructional effectiveness more than those that relied on self-directed learning [4]. A 2011 randomized-controlled study in Botswana suggested that there was little difference in rule-based knowledge acquisition by trainees completing interactive learning activities compared to on-line, self-paced programs; trainees who participated in context-relevant case discussions with feedback, however, appeared to be more likely to identify ethical issues correctly [5].

Although training in responsible conduct of research and human subjects protections (RCR/HSP) has become a standard part of graduate education in academic medical centers in high-income countries, training in RCR/HSP is still seldom required as part of postgraduate medical education in many low-and middle-income (LMIC) countries. Resource-constrained countries with wide socioeconomic disparity pose added ethical difficulties to medical practice. Standards of care vary depending on access to care, and bioethics training for medical practitioners is seldom sufficiently context-specific to help them resolve practical medical challenges they may encounter in every day practice. With an increasing number of researchers and health professionals from LMIC countries participating in international multi-center research projects, there is a growing need for training programs in these settings to include RCR/HSP in their curricula. This is particularly true in countries like Guatemala where the number of internationally sponsored clinical trials taking place is growing without comparable expansion or evaluation of education and training programs to ensure that research by local research collaborators is conducted ethically.

The current study has three aims:

1. To implement a training program in human subjects protections and responsible conduct of research for surgical residents in Guatemala
2. To develop a new face-to-face curricula in Spanish that is context-relevant and engaged trainees in active learning of the materials
3. To evaluate the effectiveness of the new training program in comparison to on-line training materials in Spanish

Methods

Study setting

Undergraduate medical education in Guatemala consists of three years of pre-clinical and three years of clinical training. Graduates receive a medical license from the Colegio de Médicos y Cirujanos (College of Physicians); those who wish to pursue careers in surgery must complete a five-year residency, one year of which is a field placement in a hospital providing care for underserved segments of the population. Residency graduates receive a diploma from the national university, Universidad de San Carlos de Guatemala (USAC), which allows them to perform general surgical procedures. Surgeons who complete a fellowship in a surgical subspecialty can register as surgeons with subspecialty training.

Although there are currently efforts to create a 'national' medical education curriculum, including a board examination, medical school and residency curricula may currently vary in content and mode of instruction provided that they meet the curricular requirements of the Office of Registration and Academic Control of the Faculty of Medical Sciences, an administrative unit within USAC. Under these requirements, all undergraduate medical students must complete at least two courses in bioethics and a research project in order to receive a medical degree. In theory, all residency programs in Guatemala are required to include a course in research methods (of which research ethics is a component) and complete an independent research project. While all residents do complete research projects, research methods courses tend to emphasize timely completion of projects rather than the research process itself. It is rare in practice that a residency offers a true methods course, relying instead on mentorship by faculty and trial-and-error research experience to fulfill this curricular requirement. Often residents receive little to no training in research methods, human subjects protections, or responsible conduct of research; few faculty responsible for overseeing resident research activities have experience as researchers themselves and often have limited knowledge of the ethical principles that guide clinical research.

Study sample

This 2018 study took place in the surgical residency programs of three large urban hospitals in Guatemala City with well-established residency training programs- Hospital General San Juan de Dios (HOSPIGEN), Instituto Guatemalteco de Seguridad Social (IGSS) and Hospital Roosevelt. As part of the residency curricula, all surgical residents at the three hospitals ($N = 160$) were required to complete training activities in RCR/HSP. Trainees were advised that the results of pre- and post-training assessments would be used for evaluating individual student performance as well as to advance research on research ethics education in Guatemala. Although all residents were given the opportunity to 'opt out' of having their assessment data used for research purposes, there were no refusals. Residents at IGSS ($n = 48$) and Hospital Roosevelt ($n = 50$) served as the control arm for the purposes of the research activities; residents at HOSPIGEN ($n = 42$) were assigned to the research intervention arm.

Measures

All training programs and assessments were administered in Spanish. Surgical residents at each of the three hospitals were required to complete a pre-training assessment followed by two on-line training programs: a self-paced certificate program in responsible conduct of research, *Conducta Responsable en Investigación* (<http://cri.andeanquipu.org/>), which has been developed for Latin American researchers by

faculty at Universidad Peruana Cayetano Heredia in Peru as part of a NIH Fogarty program; and the National Institutes of Health Office of Extramural Research (NIH) – Protecting Human Research Participants on-line training program (<https://phrp.nihtraining.com/#/>), and to complete post-training assessments. In addition, the residents in the intervention arm (HOSPIGEN), were required to complete seven weeks of face-to-face training in responsible conduct of RCR/HSP) that was embedded in a research methods course taught by a member of the study team.

The intervention RCR/HSP curriculum, developed by members of the study team and taught by one of its Guatemalan team members included 14 hours of content delivered using a combination of didactic lectures and interactive case-based discussions. The curriculum was modeled after one developed by one of the authors and her colleagues as part of a five-year research ethics training and curriculum development program funded by the NIH Fogarty International Center and the Human Genome Research Institute (Grant No. R25-TW009738).

Topics included ethical issues associated with study design; collection and use of data; human research subjects; authorship, and publication. To address the reality that trainees' schedules at HOSPIGEN would inevitably resulted in schedule conflicts and to accommodate those trainees who missed a module, module intensives -with module repetition- were designed and taught during weekends. Every module was also live-recorded, and the video was available to HOSPIGEN trainees to be watched at their own pace as desired. Upon completion of the assigned training requirements for the three hospital residencies, all trainees completed a post-training assessment to assess gains in RCR/HSP knowledge and ethical reasoning skills.

Questions used in the pre- and post-training assessments were designed to test awareness of key concepts covered in the on-line courses with particular attention to international and Guatemalan regulations regarding research. Of particular interest to the study team was the extent to which either mode of delivery contributed to trainees' ability to identify areas of ethical concern when presented with various scenarios and to utilize ethical reasoning to decide upon an ethically appropriate solution from among several choices of action. All questions were classified according to the cognitive skills hierarchy defined in Bloom's taxonomy (Fig. 1) [6] For the purposes of analysis, each question was labeled as requiring either higher- or lower-order thinking, with lower-order questions being those that only measured 'knowledge' and/or 'comprehension' and higher-order questions including those that measured 'application', 'analysis', 'synthesis', and/or 'evaluation' (Figs. 2 and 3). Both the pre- and post-assessments were administered using REDCap, a widely used on-line web application for building and managing online surveys and databases (<https://www.project-redcap.org/>).

Analysis plan

Pre- and post-training assessment data were analyzed in de-identified form and stored separately from academic records. Only those records for which both pre-and post-training assessment data were available and, in the case of the intervention arm, only data from residents who had completed the requisite face-to-face training, were included in the analytic sample (Fig. 4). Results were analyzed using

STATA12 [7]. Descriptive statistics were run for all demographic data, and Pearson's chi-square tests of significance (Fisher exact tests in instances where the cell size was too small) computed to identify where the variability in responses by the two arms was statistically significant. Gains in knowledge irrespective of group assignment were analyzed using matched (pre and post) mean scores. Group differences in mean scores were analyzed using difference-in-differences analysis to determine gains by study arm assignment and account for baseline differences. The small study population (180 surgical residents in all three programs combined) provided insufficient power to determine whether the differences between control and intervention arm gains were statistically significant.

Results

All of the 160 surgical residents enrolled in the 2018 RCR/HSP/human subjects protections training programs at the three hospitals agreed to have their assessment data included in the study. Of these, only 140 surgical residents met the criteria for inclusion in the analytic sample: 42 (100%) from the intervention arm (HOSPIGEN) and 98 (83%) from the control arm, including 48 (76%) trainees from IGSS and 50 (91%) trainees from Hospital Roosevelt. (Fig. 4)

Descriptive statistics appear in Table 1. Most residents were male, with the largest number of trainees in the sample being in their first year of residency training. More than half of the residents reported that they had previously received training in research ethics. Overall only 16% of residents reported no prior experience in conducting research in a study involving patients or information about patients; residency site, i.e. HOSPIGEN (the study intervention arm) or IGSS and Hospital Roosevelt (the study control arm) was significantly associated with whether or not a trainee had had previous research experience involving human subjects or human subjects data ($\chi^2=5.4340$, $p=0.02$) or had been involved in a study requiring ethics committee approval ($\chi^2=17.67$, $p=0.00$). Before the study, more students in the control arm, compared to students in the intervention arm, reported they had never participated in a research study involving human subjects, used secondary data sets as the source of data for their undergraduate research study, or been involved in a study requiring ethics review.

Pre- and post-training assessment scores are reported in Table 2. Overall, mean scores improved in all groups (from 52.7 to 58.7 points out of 100), with a slightly larger, but not statistically significant, gain in the intervention arms. Mean scores in lower-order questions improved by approximately 10 points, with a larger gain (11 points) in the control arm than in the intervention arm (8.5 points). The differences between the arms in both pre- and post-assessments scores for higher-order questions were statistically significant although the overall difference in mean scores for both arms combined was less than four points. The difference between differences in gains between the two arms was very small and, although p-values are reported, the study had insufficient statistical power due to the small sample size to detect significance.

Table 3 reports study findings on measures of trainee familiarity and self-efficacy with respect to RCR/HSP. At the start of the program only 12% of trainees reported being familiar or very familiar with

RCR/HSP, and only 19% reported that they knew enough about RCR/HSP to handle ethical issues that they might encounter in the course of conducting research studies in the future. Following the training, both groups reported having high levels of confidence that they could recognize most of the ethical issues that they encounter in research design and implementation; they knew the ethical principles and legal requirements for research in Guatemala; and they would be able to design and implement a research study that conformed to them. Over 95% of all trainees reported that they were very confident/confident that they understood and could avoid scientific misconduct through fabrication, falsification, and plagiarism in research and that they could recognize any such transgressions by their colleagues. Over 95% of the trainees reported that the training had given them confidence/high confidence to speak up if they observed scientific misconduct by a colleague. Trainees in the face-to-face training reported being higher levels of confidence that they could recognize ethical issues, knew legal requirements, could design ethical research, and could identify, report and avoid scientific misconduct than the trainees in the control arm; the observed differences were statistically significant at the $p < .01$ level.

Discussion

This study is a first-ever attempt to understand empirically the extent to which surgical residents are familiar with and can apply ethical principles and regulations in determining right actions in clinical research. It provided an opportunity to consider the relative benefits of on-line and face-to-face training in RCR/HSP in a resource-constrained environment where human and physical resources to teach these topics are limited.

Despite the very high numbers of residents in both arms who reported prior research ethics training and experience with research involving human subjects and/or human subjects data, overall pre-assessment scores were poor. Although it was beyond the scope of this study to examine in any systematic way the reasons for low pre-test scores, a number of underlying factors may be involved. Although most undergraduate medical curricula in Guatemala include courses in ethics, many such courses focus on normative ethics that reinforce predominant social norms in Guatemala rather than introduce students to the country's regulatory environment or internationally accepted ethical principles in research. Most course instruction in Guatemala takes the form of didactic lectures; opportunities for students to engage actively in their own learning is limited. [8] This is a particular shortcoming in research ethics education given the substantial body of literature that supports the use of active learning pedagogy to encourage students to engage with the material through small group work, case discussions, and role play.

In pre- assessments there was no statistical significance between study arms in total scores and scores for lower-order questions; however, residents in the intervention arm had significantly higher scores for questions involving higher-order thinking in comparison to residents in the control arm. HOSPIGEN introduced a year-long, in-person research methods course in 2017 as part of an effort by the hospital

and university authorities to improve training for post graduate surgical trainees. Although HOSPIGEN residents were not explicitly trained in RCR/HSP, they were encouraged to apply concepts, analyze scenarios, apply rules, and evaluate approaches in their research methods coursework– all of which involve higher-order thinking. Residents who had taken or were taking the HOSPIGEN methods course may have drawn more easily on such skills when confronted with a higher-order question in ethics than residents at the other hospitals where similar skills had not been reinforced through coursework.

Intervention arm residents also had significantly higher scores on questions involving higher-order thinking in the post-assessment than control arm residents. This finding would suggest that in-person training sessions may help build critical reasoning skills, a finding that echoes previous work evaluating teaching modalities in Botswana [5]. As with this earlier study, however, the lack of statistical power to determine significance limits the extent to which one can draw definitive conclusions about the value of face-to-face as compared to on-line training. It would be impossible to achieve a sufficiently large sample from among surgical residents in Guatemala to achieve sufficient statistical power; were the Guatemalan authorities to mandate further research on RCR/HSP training programs in ALL residencies in the country, more definitive findings might have been possible, but such a study exceeded the scope of this current effort.

This study's findings of a statistically significant association between gains in self-confidence in a number of domains and arm assignment make a promising case for active-learning approaches in working with these topics. Prior research suggests that greater gains are achieved in learning environments that involve social interaction and active engagement with the subject material. [4, 9-15] Trainees in the intervention arm had 14-hours of peer-to-peer interaction in analyzing and reacting to ethical issues in research and research conduct; such 'practice' is likely to have built trainee confidence in ways that are less easily achieved in more static learning environments. Still, such improvements in self-efficacy must be viewed with some skepticism in light of the very modest gains overall in knowledge and ethical reasoning skills.

This study reveals several uncomfortable truths: first, that, despite, an extensive curricular load in ethics in undergraduate medical school, surgical residents in Guatemala lack basic knowledge in this domain as measured in pre-assessments, and second, that residents received failing scores in post-assessments irrespective of how ethics content was delivered. This latter finding suggests that the challenges in teaching RCR/HSP in busy surgical residencies in this setting may be as much practical ones as pedagogical ones. Surgical residents work long hours as part of their surgical training, often beginning in the early hours of the morning and not finishing their last surgeries until mid-afternoon. In-person class activities begin immediately afterwards and frequently take place in cramped and ill-equipped facilities with inadequate ventilation, poor lighting, and few technology aids - hardly ideal conditions for 'active' engagement with the course content. On-line content is likely to be glossed over in the evenings when residents finally leave the hospital. Certificates of completion from the on-line courses serve merely as evidence that trainees completed the modules and cannot be considered accurate measures of the extent

to which information will be retained or that trainees will be able to apply that information appropriately when faced with an ethical issue in research.

Another practical challenge is one of resources. Despite efforts in the past decade to build capacity in research ethics in Guatemala, there remains only a handful of medical professionals with the content and teaching skills necessary to teach in-person courses in RCR/HSP. While this challenge might be overcome by using a train-the-trainer model to build capacity within each surgical residency program in the country, it is unlikely, given the low remuneration for teaching faculty and limited interest on the part of the surgical staff, that a sufficient number of faculty trainers with expertise in RCR/HSP, active-learning pedagogy, and surgery could be marshalled in the near future for this purpose. Given the very modest difference in gains between the two arms of this study, the adoption of on-line modules for teaching RCR/HSP in this setting seems the more scalable option.

A more tenacious challenge may be one of attitude on the part of medical professionals towards the teaching of ethics in general, particularly in surgery residency programs focused on honing surgical skills in their trainees. Despite recent well-publicized instances of unethical behavior by physicians and residents in Guatemala's public hospitals, doctors (particularly surgeons) are held in high esteem and their decisional authority in matters medical tend to go unchallenged. Course content that may prioritize the rights and concerns of patients over the prerogatives of doctors may not be well received. Doctors are presumed to be ethical professionals and teach by example rather than coursework. Changing these attitudes will take time, although efforts by the Office of Registration and Academic Control of the Faculty of Medical Sciences to improve resident education and the move toward board certification are positive steps in that direction.

It must be noted that one of the on-line training programs utilized in this study, the NIH Office of Extramural Research Protecting Human Research Participants program has been archived due to revisions in the United States Common Rule and is no longer maintained or updated. While this will make replication of this study difficult, the authors' intention, which was to identify best practices in teaching RCR/HSP, can still be served through high-quality replacement programs such as the Research Ethics Online Training program developed by the World Health Organization and soon to be available in Spanish through the Global Health Training Centre (<https://globalhealthtrainingcentre.tghn.org/elearning/research-ethics/>).

Conclusion

Differences in gains in RCR/HSP knowledge and self-efficacy between trainees completing on-line training only and those completing in-person as well as on-line training are too modest to preference one mode of instruction over another in this setting. Given the limited availability of RCR/HSP faculty, financial resources, and time in the surgical training schedule, academic authorities in Guatemala should consider on-line training programs in RCR/HSP in the future in all surgical residency programs as an affordable and scalable strategy to build ethical research skills in its surgical workforce. In addition,

greater attention should be given to the content and quality of research ethics instruction in undergraduate medical schools in Guatemala to ensure that research projects are conducted in an ethical manner and to improve students' familiarity and knowledge of RCR/HSP as they matriculate into the country's residency programs and health care system.

List Of Abbreviations

RCR Responsible conduct of research

HSP Human subjects protections

LMIC Low- and Middle-Income Countries

USAC Universidad de San Carlos de Guatemala

HOSPIGEN Hospital General San Juan de Dios

IGSS Instituto Guatemalteco de Seguridad Social

NIH National Institutes of Health

Declarations

Ethics approval and consent to participate

The study was approved by the Institutional Review Board at Rutgers University and the hospital ethics committees at HOSPIGEN and IGSS. Surgical residents at the three hospitals were given the opportunity to 'opt out' of their assessments being used for the research portion of this project. All trainees gave their consent to have their assessment data included in the analytical sample for this study.

Consent for publication

Not applicable.

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Acknowledgements

Not applicable

Availability of data and materials

The datasets used and/or analyzed during the current study are available in de-identified form from the corresponding author on reasonable request.

Author contributions

MLA, SNM, and FB were responsible for study design, selection of on-line course materials, and development of the in-person curricula. MLA, EMR, MAS, FS and FT were responsible for implementation of the training programs at HOSPIGEN, IGSS, and Hospital Roosevelt, respectively. All authors read and contributed to multiple versions of the manuscript in draft and read and approved the final version.

Competing interests

The authors declare that they have no competing interests.

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Tables

Table 1. Descriptive statistics

Variable	All Groups			Control Arm			Intervention Arm		
	N = 140			n = 98			n = 42		
	Num	%	Cum %	Num	%	Cum %	Num	%	Cum %
<i>Gender</i>									
Male	112	81	81	81	83	83	31	76	76
Female	28	19	100	17	17	17	11	24	100
<i>Age</i>	28			28			28		
(Std. Dev.)	(2.23)			(2.30)			(2.07)		
<i>Residency site</i>									
HOSPIGEN	42	30	30				42	100	100
IGSS	48	34	64	48	49	49			
Roosevelt	50	36	100	50	51	100			
<i>Year of residency</i>									
Year 1	47	34	34	30	31	31	17	40	40
Year 2	33	24	58	22	22	53	11	26	66
Year 3	32	23	81	25	26	79	7	17	83
Year 4	28	19	100	21	21	100	7	17	100
<i>Prior training in research ethics</i>									
Yes	78	56	56	55	56	56	23	54	54
No	62	44	100	43	44	100	19	46	100
<i>Type of training</i>									
Semester-normative ethics/philosophy	31	22		24	25		7	17	
≤ 1 semester professionalism/bioethics in medical school*	36	26		20	20		16	38	
Workshop in research ethics/RCR	60	43		44	45		16	38	
Training program in ethical aspects of a specific study/trial	24	17		17	17		7	17	
<i>Prior participation in study with human subjects or subject data±</i>									
As a research subject	34	24		25	26		9	21	
As part of medical school requirements*	87	62		54	55		33	79	
As a trainee/employee of someone else's study	15	11		12	12		3	6	
Never*	22	16		20	20		02	5	
<i>Source of data for undergraduate research study±</i>									
Patient medical records	69	49		49	50		20	48	
Secondary data set containing patient health information*	33	24		28	29		5	12	
In-depth interviews conducted by self	72	51		47	48		25	60	
Focus groups conducted by self	14	10		12	12		02	5	
Clinical trial of investigational drug or device	05	4		4	4		1	2	
On-line survey designed by self	10	7		6	6		9	10	
<i>Involvement in a study requiring IRB review*</i>									
Yes	79	56		44	45		35	83	
No	61	44		54	55		7	17	

*Associations with p-values < 0.05 using Pearson's Chi-square or Fisher exact tests of significance

Table 2. Pre- and post- assessment scores

Variable	All Groups		Control Arm		Intervention Arm		Difference	p-value
	N = 140		n = 98		n = 42			
	Mean	Std. Dev.	Mean	Std. Dev.	Mean	Std. Dev.		
<i>Pre-training assessment¹</i>								
Total score	52.74	8.87	52.22	9.52	53.97	7.12	1.75	0.25
Total score lower-order questions	36.46	11.47	36.1	11.99	37.1	10.26	1.0	0.67
Total score higher-order questions	59.19	9.08	58.3	9.72	61.3	7.09	3.0	0.054
<i>Post-training assessment¹</i>								
Total score	58.71	7.57	58.13	7.85	60.19	6.67	2.05	0.18
Total score lower-order questions	46.83	12.75	47.4	13.98	45.6	9.29	-1.7	0.44
Total score higher-order questions	63.87	7.66	62.7	7.33	66.7	7.72	4.0	0.009
<i>Total Gain²</i>								
Total Score	5.97 ³		5.91		6.22		0.30	0.89
Total score lower-order questions	10.37 ³		11.3		8.5		-2.7	0.39
Total score higher-order questions	3.97 ³		4.4		5.4		1.0	0.63

¹p-value by t-test ²p-value by Difference in differences ³pre and post scores p-value: 0.00 by matched t-test

Table 3. Familiarity and self-efficacy in responsible conduct of research and human subject protections.

Variable	All Groups N = 140			Control Groups n = 98			Intervention Group n = 42			p-value*
PRE-TEST	Num	%	Cum %	Num	%	Cum %	Num	%	Cum %	
<i>Familiarity with research ethics/bioethics</i>										0.08
Very familiar	4	3	3	3	3	3	1	2	2	
Familiar	30	21	24	16	16	19	14	33	35	
Somewhat familiar	81	58	82	58	59	78	23	55	90	
Not familiar at all	25	18	100	21	22	100	4	10	100	
<i>Do you feel you know enough about research ethics and RCR to handle any ethical issue that you may encounter in the course of conducting your research studies?</i>										0.43
Yes	19	14	14	15	15	15	4	10	10	
No	121	86	100	83	85	100	38	90	100	
POST-TEST										
<i>After completing this training, I can recognize most of the ethical issues that I encounter in the course of designing and implementing a research study.</i>										0.01
Not at all confident	0	0	0	0	0	0	0	0	0	
Somewhat confident	11	8	8	8	8	8	3	7	7	
Confident	111	79	87	83	85	93	28	67	74	
Very confident	18	13	100	7	7	100	11	26	100	
<i>After completing this training, I am familiar with the ethical principles and legal requirements that guide the conduct of research in Guatemala.</i>										0.005
Not at all confident	0	0	0	0	0	0	0	0	0	
Somewhat confident	12	9	9	8	8	8	4	10	10	
Confident	105	76	85	80	83	91	25	59	69	
Very confident	22	15	100	9	9	100	13	31	100	
<i>After completing this training, I can design and implement a research study that conforms to the ethical principles and legal requirements that guide the conduct of research in Guatemala.</i>										0.000
Not at all confident	1	1	1	0	0	0	1	2	2	
Somewhat confident	10	7	8	9	9	9	1	2	4	
Confident	102	73	81	80	82	91	22	53	57	
Very confident	27	19	100	9	9	100	18	43	100	
<i>After completing this</i>										0.000

training, I understand what constitutes fabrication, falsification, and plagiarism in research.

Not at all confident	0	0	0	0	0	0	0	0	0
Somewhat confident	5	4	4	5	5	5	0	0	0
Confident	84	60	64	72	73	78	12	29	29
Very confident	51	36	100	21	22	100	30	71	1000

Using what I have learned from this training, I will be able to avoid scientific misconduct through plagiarism or fabrication and falsification of data.

Not at all confident	0	0	0	0	0	0	0	0	0
Somewhat confident	4	3	3	4	4	4	0	0	0
Confident	82	59	62	71	72	76	11	26	26
Very confident	54	38	100	23	24	100	31	74	100

Using what I have learned from this training, I will be able to detect scientific misconduct by others.

Not at all confident	0	0	0	0	0	0	0	0	0
Somewhat confident	4	3	3	3	3	3	1	2	2
Confident	101	72	75	82	84	87	19	45	47
Very confident	35	25	100	13	13	100	22	53	100

This training has given me the confidence to speak up if I observe scientific misconduct by a colleague.

Not at all confident	0	0	0	0	0	0	0	0	0
Somewhat confident	7	5	5	5	5	5	2	5	5
Confident	96	69	74	77	79	84	19	45	50
Very confident	37	26	100	16	16	100	21	50	100

*p-value computed using Fisher exact test

Figures

Figure 1

Bloom's taxonomy of cognitive learning objectives. An illustration of the learning levels in ascending level of difficulty as delineated in Bloom's taxonomy.

If an investigator at a US institution wishes to conduct a research study in Latin America, with which of the following guidelines for ethical research should s/he comply? (Circle ALL that apply.)

- a. Council for International Organizations of Medical Sciences
- b. United States Common Rule
- c. The ethics regulations of the Latin American country
- d. The Health Insurance Portability and Accountability Act

Figure 2

Sample test question requiring lower-order thinking according to Bloom's taxonomy. One of the test questions used in the current study to assess lower-order cognitive learning of course material by participants.

Read the following case and answer the questions that follow:

A group of surgeons in Mexico has been invited to join a multisite study comparing efficacy of two surgical techniques for repairing hip fractures in elderly patients with advanced osteoporosis. One of the techniques is already used by the surgeons in Mexico but the other technique is one that, while common elsewhere, is not standard of care in the country. As co-investigators, the Mexican group are going to alternate using the new technique with the currently prescribed treatment over a period of two years; data would be collected on post-surgical complications, mobility, and mortality at one year.

Which of the following statements are true?

1. The hospital should not consider this project to be research, as the new technique has been proven effective in other settings where they it is now the standard of care.
2. Because one of the techniques is not the standard treatment for the repair of hip fractures in the hospital, it must treat their participation in the project as clinical research.
3. Patients in whom either technique is used during the two-year period must give their informed consent to participate as research subjects in the proposed project.
4. The hospital's surgery department must receive ethics committee approval prior to adopting the project for treatment of hip fractures in its elderly patients.

Figure 3

Sample test question requiring higher order thinking according to Bloom's taxonomy. One of the test questions used in the current study to assess higher-order cognitive learning of course material by participants.

Figure 4

Flowchart of study population. An illustration of how study population was assigned to study arms and analytic sample was determined.