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Multi country training to strengthen leadership among administrative staff of research ethics committees and national regulatory bodies in the East African Community

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Abstract

Background Clinical research in the East African Community (EAC) has expanded significantly in response to epidemics, increasing the complexity and workload. Research ethics committee (REC) and National research regulatory (NRA) members involved in leadership and administrative work play a vital role in managing daily operations, yet often lack adequate training and support in this area. Earlier capacity building efforts have largely overlooked these unique responsibilities. The training program aimed to strengthen the participant's personal effectiveness and leadership skills (PELS). This study evaluated the early effectiveness of PELS by assessing changes in participants' knowledge scores and exploring participants' perceptions of applying the acquired skills in their work.

Methods A four-month blended training program was implemented from March 2024 to March 2025 in six EAC partner states, namely, the Republics of Burundi, Kenya, Rwanda, South Sudan, Tanzania, and Uganda. We engaged stakeholders to inform curriculum development. Forty stakeholders from the six EAC partner states informed curriculum revision, and an eight-member Training Advisory Committee (TAC) reviewed and approved the revised curriculum. Participants were evaluated using pre- and post -training assessments. Data from the training assessments were downloaded as a Comma Separated Value (CSV) file, cleaned in Microsoft Excel, and exported to STATA 15 for analysis. We performed descriptive analyses and presented findings using percentages and frequencies. Paired t-tests were conducted to assess the significance of pre-test and post-test differences in knowledge scores, with $p<0.05$ considered statistically significant. Participant feedback was collected during and after the training and analysed qualitatively using conventional content analysis identify recurring themes.

Results One hundred twenty-nine (129) participants from six partner states participated in the training. Of these, 50.4% were females. Uganda had the highest participation (31.8%), while Tanzania had the lowest (10.1%). The

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overall mean score for foundational knowledge rose from 63.7% at pre-test to 84.4% at post-test, representing a 20.7% point improvement. In addition, participant qualitative feedback revealed three key themes: ethical leadership and conflict management, teamwork and client service, and self-management and initiative.

Conclusions The multi-country PELS training programme was associated with substantial improvement in participants' foundational knowledge scores, with participant feedback also indicating perceived application of leadership, communication, conflict management, customer service, and self-management skills in the workplace. These findings suggest that a stakeholder-informed blended training approach can provide useful early capacity strengthening for personnel supporting research ethics and regulatory administration in the EAC. Continued institutional support, refresher training, and longer-term evaluation will be important to determine whether these early gains are sustained and translate into improvements in routine research administration.

Keywords Research ethics committees · Capacity building · Personal effectiveness and leadership skills

Background

The gradual rise in clinical and health-related research globally, including the EAC, has been fuelled by the need for evidence-based decision-making in clinical practice as well as health and prevention care [1, 2]. Such an increase in clinical research has resulted in an increase in the volume and complexity of research [3, 4]. It should be noted that during outbreaks and epidemics, urgent research is always required, and this always necessitates expedited approvals, thus increasing the workload of research ethics committees (RECs), affecting the quality of protocol review in the long run [1].

Administrative and leadership personnel within Research Ethics Committees (RECs) and National Regulatory Authorities (NRAs) are key contributors to the effective functioning of research oversight systems. Within RECs, these personnel support the day-to-day administration of the committee by coordinating research submissions, meetings and review processes, maintaining records and guidance documents, facilitating communication with researchers and committee members, supporting compliance and quality improvement, and managing correspondence and complaints. Similarly, administrative personnel within NRAs support the operational processes that facilitate regulatory review, communication, documentation and decision-making [5–7].

Previous studies have shown that many members involved in leadership and administration often lack adequate training and clearly defined roles to effectively manage the growing complexity and volume of work [7, 8]. As research initiatives continue to increase in number and complexity, the capacity of Research Ethics Committees (RECs) to conduct rigorous, timely, and high-quality reviews risks being overstretched unless REC and NRA members are adequately equipped with the essential administrative and leadership knowledge, systems, and institutional support required to enhance operational efficiency and effectiveness.

Though some capacity building initiatives have been implemented in Africa since 2005, to strengthen RECs' and NRAs' capacity, substantial gaps persist, highlighting the need for continued and more targeted investment in ethics systems strengthening [6]. Efforts to strengthen ethics review capacity in Africa have largely focused on training REC chairs and members in ethical principles, theory, and research methods, and less attention has been given to those who manage the day-to-day administrative operations. Leadership and administration strengthening has often been overlooked in capacity building initiatives, receiving limited support such as clarification of roles or access to training tailored to specific responsibilities and potential [6–8]. As a result, REC and NRA members supporting leadership and administration remain under-supported in leadership development and role-specific training. For instance, in Uganda, training for REC administrators was carried out among RECs in central Uganda to support REC administrators on personal effectiveness and leadership skills (PELS) in 2020. This training indicated attainment of knowledge for members on PELS, observed by an increase in average score from 38% in the pre-test to 53% in the post - test assessment [3]. Despite these improvements, the limited gains highlight the need for more comprehensive, sustained, and regionally coordinated capacity building efforts.

We therefore sought to strengthen the personal effectiveness and leadership skills of REC and NRA members across the six EAC partner states, namely the Republic of Burundi, the Republic of Kenya, the Republic of Rwanda, the Republic of South Sudan, the Republic of Tanzania, and the Republic of Uganda. We implemented a multi-country PELS training programme targeting administrative personnel supporting RECs and NRA bodies across six EAC partner states. The programme aimed to strengthen participants' personal effectiveness and leadership skills to support effective stakeholder engagement and efficient research ethics and regulatory administration. This study evaluated the early effectiveness of the training programme by assessing changes in participants' pre- and post-training knowledge scores and explored participants' perceptions of how the acquired skills were applied in their work.

Methods

We conducted a before-and-after training intervention study to evaluate the effectiveness of a multi-country training program targeting training REC administrators, REC and NRA members from March 2024 to March 2025.

Curriculum design

We conducted a stakeholders' meeting where we discussed issues affecting research administration and leadership and reviewed the training curriculum on PELS. The purpose of this review was to identify the areas of greatest need. The team comprised of 40 stakeholders, with representatives from the six EAC partner states were nominated by focal persons in the partner states. The stakeholders were REC and NRA members in the different EAC countries, hence had knowledge of the subject matter. Outcomes of the meeting were shared with the team of content experts, who reviewed and updated the PELS curriculum and the online and physical materials. To update the curriculum, hired content experts from Imprint Uganda [9] conducted a comprehensive review of relevant online publications, policy documents, and textbooks. The updated curriculum was subsequently reviewed and approved by a team of 8 nominated Training Advisory Committee (TAC) prior to implementation. The TAC were selected from each of the 6 EAC partner states with a minimum qualification of a master's degree. In addition, Terms of Reference were developed for each of the nominated TAC members to guide their roles. Following approval, of the curriculum by the TAC, the Infectious Diseases Institute (IDI) virtual learning team developed and packaged the training content into interactive online learning materials for delivery. A team of expert trainers from Imprint Uganda [9] with a minimum of master's degree and more than 10 years of experience in leadership capacity building who contributed to designing the curriculum also delivered the training in all the 6 EAC countries.

Participants and training program

We trained 129 regulatory and ethics professionals that support administrative work from the six EAC partner states; Republic of Burundi, Republic of Kenya, Republic of Rwanda, Republic of South Sudan, Republic of Tanzania and Republic of Uganda. Participants were purposively selected by country focal persons based on their roles. The process included advertising and selection of specific trainees using a checklist with approved considerations by the TAC and training team. The number of trainees to be trained was already determined in the grant application agreement as per funder requirements.

The four- month program was undertaken in six distinct country cohorts between March 2024 to March 2025.

Prior to commencement, an orientation session was conducted for trainers to guide them on the course structure, learning objectives, and delivery approach. Before the commencement of each cohort's training, a virtual orientation for trainees was conducted to familiarize participants with the virtual learning platform. This session

guided trainees on how to navigate the platform, through which they completed all self-paced learning modules, assignments, and assessments, including pre- and post-training tests.

The training was organized in a modular format, starting with an overview of the REC processes to ensure that individuals understood the processes of protocol submissions, research operations, REC stakeholders, and other key players in the research space. Other modules covered key areas such as leadership, customer care, and personal productivity, as shown in Fig. 1 and Table 1 below. The training content was further contextualized in the face-to-face sessions to align with country-specific regulatory environments, thereby facilitating relevance and effective delivery.

Trainees underwent two days of highly interactive face -to-face learning in their countries of residence, six weeks of online self-paced learning via the IDI virtual learning environment (VLE) platform, and completed the course with a final virtual day and post-test. Trainees continued to have access to the course materials to ensure continuous learning.

Evaluation of the intervention

A pre-training and post-training assessment test (Supplementary file 1) was administered to assess trainees' foundational knowledge before and after the training (Kirkpatrick Evaluation Level 2) in PELS. The pre and post training assessment were comprised of the same questions, and were composed of multiple-choice questions. Data checks were put in place to avoid skipping questions. The filled assessment forms were completed electronically under the IDI virtual-learning platform with marks awarded automatically by the system. Participants scoring≥60% were classified as having passed [3]. We also collected feedback from the participants during the course of the training and at the end of the training using a survey questionnaire to understand how the training influenced their day-to-day work skills, attitudes, and practices.



Fig. 1 PELS training modules

Table 1 PELS modules and sessions description

Module	Brief Description of Content
Session 0: Welcome and Introduction to the PELS Programme	Introduces participants to the PELS programme, learning objectives, blended learning approach, Moodle platform, assessment process, and expectations for successful participation.
Session 1: Overview of the REC Ecosystem and Processes	Provides an overview of the research ethics ecosystem, REC roles and functions, regulatory environment, stakeholder landscape, research workflow, and common process bottlenecks.
Session 2: Stakeholder Analysis	Covers identification, mapping, prioritisation, and management of internal and external stakeholders using stakeholder analysis tools and communication strategies to strengthen engagement.
Session 3: My Role as a REC Administrator	Defines the responsibilities and core competencies of REC administrators, explores competency gaps, and develops individual professional growth plans to improve REC performance.
Session 4: Personal Productivity	Focuses on goal setting, prioritisation, time management, delegation, agility, records management, and productivity tools to improve efficiency and work quality.
Session 5: WOW! Customer Service I – Timely Problem Solving and Response to Inquiries	Develops skills in responsive customer service, timely communication, problem-solving, handling inquiries, confidentiality, and continuous quality improvement in stakeholder interactions.
Session 6: My Role as a Leader	Introduces leadership principles, leadership versus management, emotional intelligence, leadership styles, and applying leadership skills to improve REC and team performance.
Session 7: Influence Without Authority (IWA)	Builds participants' ability to influence, negotiate, persuade, build alliances, and achieve organisational objectives through collaboration rather than formal authority.
Session 8: Effective Communication	Strengthens oral, written, digital, and interpersonal communication skills, including clear writing, active listening, stakeholder communication, and professional correspondence.
Session 9: Effective Working Relationships	Develops self-awareness, emotional intelligence, networking, collaboration, trust-building, diversity appreciation, and strategies for maintaining productive workplace relationships.
Session 10: Effective Feedback	Equips participants with skills to provide and receive constructive feedback using evidence-based models, coaching techniques, and behaviour change approaches.
Session 11: Conflict Management	Covers conflict prevention, conflict styles, difficult conversations, negotiation, empathy, and practical approaches to resolving interpersonal and workplace conflicts.
Session 12: WOW! Customer Service II – Handling Difficult Stakeholders	Focuses on managing challenging stakeholder interactions, de-escalating conflict, responding to complaints professionally, restoring trust, and coaching others in customer service excellence.

Data management and analysis

The marks were automatically awarded online via the IDI e-learning platform after the participants completed the test. Data from the training assessments were downloaded as a Comma Separated Value (CSV) file, cleaned in Microsoft Excel, and exported to STATA 15 for analysis.

Descriptive analyses were performed using Excel and STATA 15.0, and data were presented using frequencies, percentages, means, ranges, and graphs and figures. Paired t-tests were conducted to assess the significance of pre-test and post-test differences in knowledge scores, with $p<0.05$ considered statistically significant.

Participant feedback was analysed using conventional content analysis. Owing to the brevity of participants' responses, the analysis focused on identifying recurrent patterns and key ideas rather than conducting an in-depth thematic analysis. All responses were read multiple times to achieve familiarisation with the data. Codes were developed inductively from meaningful text segments, after which similar codes were grouped into categories based on shared concepts. These categories were then synthesized into broader descriptive themes that reflected participants' experiences and perceptions. Representative quotations were selected to illustrate each theme and ensure that the findings remained grounded in participants' own words. To enhance the trustworthiness of the analysis, the coding framework and emerging themes were independently reviewed by members of the research team, with any differences in interpretation resolved through discussion and consensus.

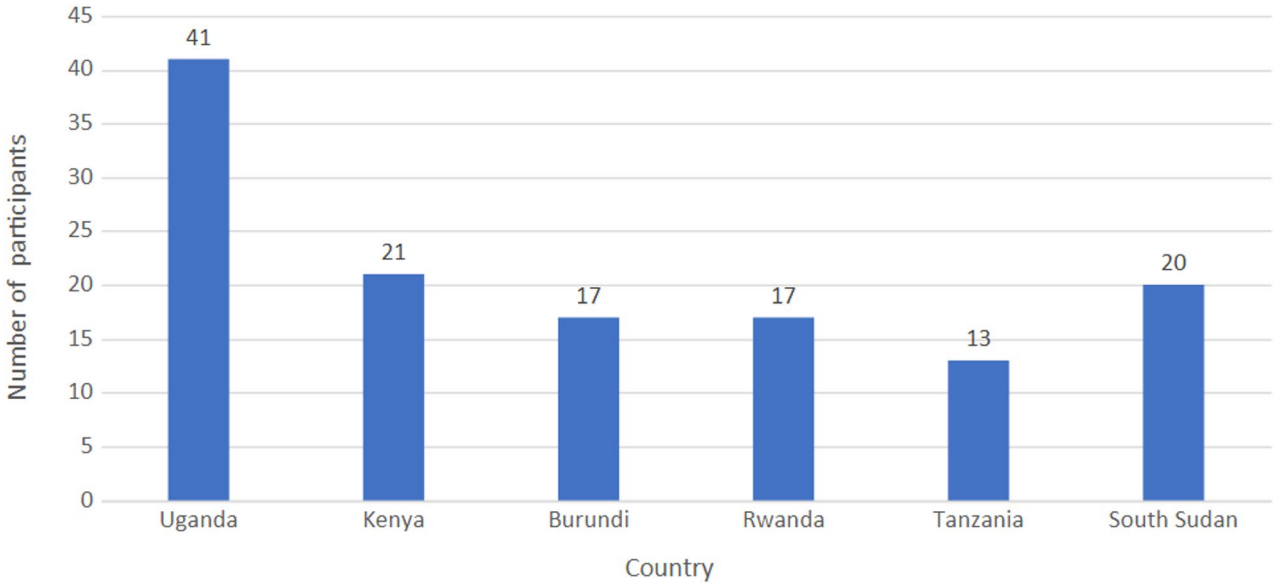


Fig. 2 Number of trainees who attended the training per country

Table 2 Pre-test and post -test training knowledge scores

Assessment	Mean score (%)	SD	95% CI for mean	Score range (%)	Participants achieving, pass rate≥60%, *n* (%)
Pre-test	63.7	17	60.43–67.00	27.3–92.2	26 (20.2)
Post-test	84.4	14.7	81.55–87.26	38.2–100.0	103 (79.8)

Mean difference = 20.7 percentage points (95% CI: 17.24–24.13; paired t-test, $p<0.001$). The proportion achieving ≥60% increased by 59.6 percentage points

Results

One hundred and twenty-nine (129) trainees attended the sessions. The highest participation was from the Republic of Uganda, accounting for 31.8% (41/129), while the lowest number of participants, 10.1% (13/129), was noted from the Republic of Tanzania (Fig. 2). Half of the trainees were females, 50.4% (65/129).

Knowledge improvement following training

Across all the partner states, the proportion of participants achieving the pass threshold (≥60%) increased from 20.2% (26/129) at pre-test to 79.8% (103/129) at post-test, representing a 59.6% percentage point improvement. The minimum score increased from 27.3% at pre-test to 38.2% at post-test, while the maximum score increased from 92.2% at pre-test to 100% at post-test. Overall, there was a statistically significant increase in mean knowledge scores from 63.7% (SD ± 17) at pre-test to 84.4% (SD ± 14.7) at post-test, representing a 20.7% point improvement, 95% CI: 17.2–24.1, $p<0.001$) (Table 2).

Knowledge scores varied across the six EAC partner states (Fig. 3). Kenya had a relatively high mean pre-test score (74%) but showed only a small improvement following the training. In contrast, South Sudan showed a decline in mean knowledge score between the pre- and post-tests. Rwanda recorded the highest mean post-test score (95%), while South Sudan recorded the lowest (62%).

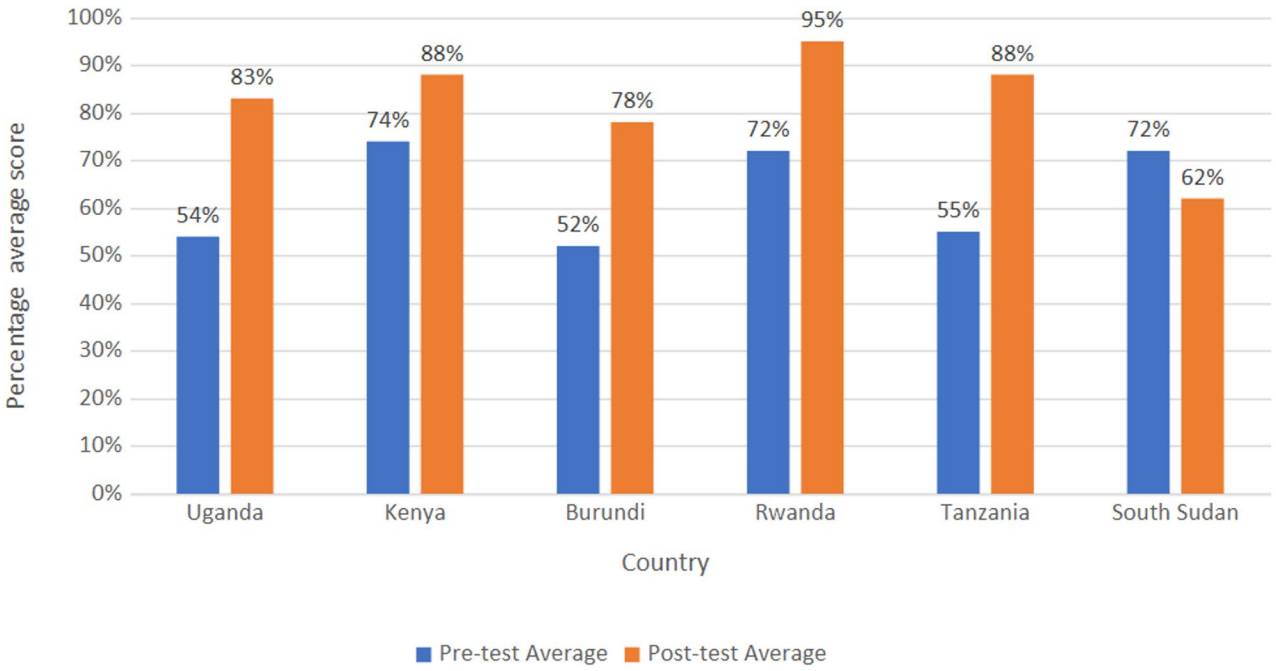


Fig. 3 Knowledge shift per country

Participant feedback

Participant narratives across the different EAC countries revealed three broad themes describing how the intervention influenced professional practice.

Theme 1: ethical leadership and conflict management

Participants reported applying ethical leadership and communication skills to manage conflicts, address power dynamics, and resolve challenging relations with colleagues and stakeholders. Emphasis was placed on listening to multiple perspectives, transparency, and consensus-building to restore professional relationships and resolve disputes.

> "A junior staff member included a senior staff on his study for funding, without his approval, and the senior staff only got to know about it when funding was available. What I did was listen to all sides, and at least everyone agreed to sit at the round table and resolve it." (Participant, Rwanda)

Theme 2: teamwork and client service

Participants described enhanced teamwork and collaboration alongside a stronger client-centred orientation in their professional roles. This included proactive follow-up, empathetic engagement, and deliberate efforts to improve responsiveness and efficiency within institutional processes.

> "For me, it has been about giving everyone who interfaces with my office a wow customer experience. Yesterday I got a fee waiver approval in less than one hour by helping the PI work on the request letter and following it through to approval." (Participant, Uganda)

Theme 3: self-management

Participants reported improved self-management skills, including planning, time management, and active listening, alongside increased self-efficacy. These changes enabled them to recognise their capacity to influence change beyond formal authority and to initiate improvements in workplace practices.

> "Now, as a lab technologist and student, I know my ability to make a difference goes beyond what I once thought. I've started initiating conversations and advocating for small process changes at work, and I've seen my ideas spark real change." (Participant. Kenya)

Discussion

The training was designed to equip participants with foundational in Personal Effectiveness and Leadership Skills (PELS), enabling them to efficiently manage stakeholder relationships and improve the efficiency of research administration and turnaround time for protocol reviews.

Evidence from this capacity-building initiative demonstrated a statistically significant and notable improvement in foundational knowledge in PELS, as reflected in a significant rise in post -test training performance. These gains highlight the effectiveness of the updated training curriculum in addressing existing knowledge gaps in handling complex and demanding tasks. These results slightly differ from those of a similar training conducted in Uganda, where the participants scored a lower average mark at pre-test (38%) and post-test 53% [10]. Notably, the involvement of participants from diverse professional and institutional contexts may have facilitated peer learning and exchange of experiences during the training increasing knowledge gain.

Beyond the improvement in mean knowledge scores, the training also resulted in a substantial increase in the proportion of participants attaining the predefined minimum knowledge threshold. This suggests that the programme not only improved average performance but also enabled a greater proportion of participants to attain the expected level of knowledge in key areas relevant to REC administration and leadership. Similar results following research ethics capacity-building programmes have been reported in Uganda and other low- and middle-income countries, where training significantly enhanced participants' knowledge in research ethics review and administration [11, 12]. These findings highlight the potential value of structured capacity-building programmes in strengthening the knowledge base of REC and NRA involved in administrative and leadership roles, consequently, supporting institutional capacity for ethical oversight and effective research administration.

Although the overall analysis demonstrated a significant improvement in knowledge scores, the magnitude and direction of change varied across countries. Participants from Kenya, who had a relatively high mean pre-test score, showed only a small improvement following training. This may partly reflect competing work demands that limited engagement with the online learning materials after the face-to-face sessions. In contrast, participants from South Sudan demonstrated a decline in mean knowledge scores. This finding may be partly due to challenges encountered during the online learning, particularly poor internet connectivity and power supply constraints reported by participants. Moreover, participants from South Sudan were given an additional month beyond the post-test deadline to complete the course because of these challenges, and less than half attended the final online session. Such constraints may have limited participants' engagement with the online learning materials and post-training assessment. Similar challenges related to access to reliable internet and power supply have been reported as barriers to the delivery and uptake of digital and blended health training in low-resource settings [13, 14].

A critical strength of this program was its foundation in stakeholder-driven curriculum design. Through an online consultation involving 40 nominated stakeholders from the six EAC partner states, priority training needs were identified. Feedback from this meeting was used by a team of content experts to revise the curriculum, drawing upon international best practices, academic literature, and region-specific research ethics guidance. The

curriculum was further reviewed and endorsed by a TAC composed of representatives from all EAC states, ensuring contextual relevance and regional stakeholder ownership. Involving stakeholders in such curriculum reviews is key to ensuring quality feedback that can help to enhance alignment of information to the needs of the participants, as observed in previous training in Uganda [3, 15, 16]. Such a collaborative approach not only strengthens the relevance of the training program but also promotes a sense of ownership among stakeholders, thereby enhancing the sustainability and long-term impact of the training.

The integration of the revised content into the IDI virtual-learning platform also supported flexible access to training materials. This blended approach, combining online modules with face-to-face practice of skills and stakeholder-informed case studies, enhanced participant engagement and understanding. Moreover, it will contribute to the sustainability of training outcomes, as trainees can continue accessing materials through the online platform. We provided an online self-paced training module on PELS, which can be accessed on the IDI e-Learning platform for refresher training; https://elearning.idi.co.ug/index.php/personal-effectiveness-and-leadership-training-for-research-and research-ethics-committees-rec-administrators/.

The qualitative findings provide participants' self-reported accounts of applying aspects of the acquired PELS-related skills in their workplaces. Improvements in ethical leadership, communication, stakeholder engagement, conflict management, customer service, and self-management suggest that the programme influenced professional behaviours in addition to increasing knowledge. Similar findings have been reported in research ethics leadership and professional development programmes, where experiential learning and workplace application strengthened participants' confidence, communication skills, and leadership practices [12]. Translating knowledge into practice is particularly important for REC administrators because improved leadership and interpersonal competencies can enhance stakeholder satisfaction, facilitate efficient protocol processing, and improve the overall quality of research ethics administration.

Strengths, limitations, and conclusion

A key strength of this capacity-building programme was the experiential and blended learning approach, combining face-to-face and virtual skills-based sessions, self-paced online learning, and formative assessments to support participant engagement. The use of pre- and post-training assessments enabled measurable evaluation of knowledge gains among a diverse group of REC and NRA members from the six EAC Partner States. Furthermore, stakeholder engagement and involvement of a Training Advisory Committee (TAC) ensured that the curriculum was contextually relevant, regionally harmonized, and responsive to participant needs. The involvement of expert trainers who developed the curriculum also supported effective delivery across diverse settings.

The before-and-after design without a comparison group limits causal attribution of observed improvements to the intervention. Participants were selected through country focal persons, which may have introduced selection bias. In addition, limited baseline information was collected on participant characteristics, including years of experience, educational background, institutional role, and prior research ethics training; therefore, we could not assess whether differences in participant profiles contributed to variations in outcomes observed across countries. The evaluation focused on immediate knowledge gains and self-reported experiences; thus, long-term knowledge retention, application of skills in routine practice, and effects on institutional outcomes such as review quality and turnaround times were not assessed. Future evaluations should incorporate longitudinal follow-up and objective performance indicators to determine the sustained impact of such interventions. Although assessment tools were expert-reviewed, they were not formally validated, and self-reported feedback may have been influenced by social desirability bias. Finally, findings may have limited generalizability beyond the EAC context.

The capacity-building programme substantially improved participants' foundational knowledge related to PELS. Sustaining these gains will require continuous professional development, institutional support, and regionally harmonized training approaches. Periodic refresher training, mentorship, and follow-up evaluations will be important to assess knowledge retention and determine whether training translates into improved protocol review

quality, more efficient ethical and regulatory processes, and stronger capacity to support innovative research designs.

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Authors' contributions MA Participated in coordinating the training program and drafting project survey tools, collecting data, conducting data analysis, drafted, revised and finalised the manuscript, BT participated in program administration, cross checked analysis and revised final manuscript, BM, HO, SG, SW, HN, JK, VM, RN, LMS, NT, BC, JWA, SO, PA, conceptualised the idea participated in writing the protocol, revised and finalised the manuscript. PBK conceptualised the idea, took the lead in writing the protocol and project implementation and coordination, and revised and finalised the manuscript. All authors read and approved the final manuscript submitted.

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Data availability The datasets used and/or analysed during the training program assessments are available from the corresponding author upon reasonable request. All data generated or analysed during this training program are included in this published article.

Declarations

Ethics approval and consent to participate The concept of the situational analysis that informed this training program was approved by Makerere University School of Medicine Research Ethics Committee (SOMREC), Reference Number (#REC REF 2020–024), and Uganda National Council of Science and Technology (UNCST), Reference Number (HS542ES). SOMREC is under the Makerere University School of Medicine. Administrative approvals to conduct the training were provided by different EAC partner institutions.

The work reported in this manuscript describes training activities and associated assessments which are non-research in nature and were conducted to assess training effectiveness. The assessments were not designed to generate generalizable knowledge and therefore did not meet the definition of research requiring ethics committee review or approval [17, 18]. No additional data were collected for research purposes during the training activities described in this manuscript.

Administrative approval to conduct the trainings was obtained from the respective partner institutions across the six EAC partner states. Co-Investigators and focal persons in each country informed all relevant stakeholders about the training program and associated assessments. Participation was entirely voluntary, and all trainees provided their informed consent to take part in the training and evaluation activities. All methods were performed in accordance with relevant guidelines and regulations, such as the 1964 Declaration of Helsinki.

Consent for publication Not applicable. The manuscript does not include any individual person's data.

Competing interests The authors declare no competing interests.

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