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Strengthening research regulatory capacity in the East African community: a multi-country training program on emerging and complex study designs

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Abstract

Background The East African Community (EAC) has experienced a significant increase in volume and complexity of clinical research driven by the epidemics of emerging and re-emerging infectious diseases such as HIV, Ebola, COVID-19, and mpox. This demands for robust research, scientific, and ethical oversight. We aimed to strengthen the capacity of national research regulatory authorities (NRRA), research ethics committees (RECs), and researchers for review and oversight of studies with complex and emerging designs.

Methods We implemented a blended training program from February 2024 to February 2025 in six EAC partner states, including; republic of Burundi, republic of Kenya, republic of Rwanda, republic of South Sudan, republic of Tanzania, and republic of Uganda. Trainees were evaluated using pre and post-training assessments, and also provided qualitative responses.

Results A total of 186 participants completed the training, of which 59.0% (110/186) were males**.** Participants demonstrated a marked improvement in knowledge, with mean scores increasing from 52.9% at pre-test to 84.0% at post-test, and the proportion of participants that passed increased from 18.1% (34/186) at pre-test to 84.2% (157/186) at post-test. Three main themes emerged from the open-ended response evaluations: (1) enhanced understanding of emerging and complex study designs, (2) relevance to professional roles and practice, and (3) demand for advanced methodological training.

Conclusions There was a substantial shift in knowledge on emerging and complex research study designs. We recommend regular training of NRRA and REC members to improve the quality of review of research protocols with complex and emerging study designs.

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Keywords Research ethics committees, Capacity building, Emerging and complex study designs, National research regulatory authority, Researchers

Background

Globally, clinical research plays a fundamental role in improving public health by generating new knowledge and developing interventions, thereby advancing healthcare practice [1]. Over the past two decades, there has been an exponential rise in health-related research worldwide. This growth has been driven by the need for evidence-based decision-making in clinical care, public health, and preventive services. Africa, including the East African Community (EAC), has witnessed a substantial rise in clinical research activity [2, 3]. This increase has been fuelled by shifts in the HIV epidemic, the emergence and re-emergence of infectious diseases such as viral haemorrhagic fevers, coronavirus disease 2019 (COVID-19), and mpox as well as the growing burden of non-communicable diseases and injuries [2, 4–8]. Across sub-Saharan Africa, there is an increasing focus on novel HIV prevention research, next generation HIV therapies, research toward an HIV cure, and the management of HIV-related co-morbidities [4]. In addition to growing research capacity, there are urgent calls for sustainable research funding in Africa to reduce dependence on diminishing international grants and donor aid [9, 10]. With the growing capacity of researchers, both the volume and complexity of research studies and designs have expanded significantly to address these evolving health challenges [11, 12]. This expansion has created multiple challenges, including an increase in the number, scope, and complexity of research protocols requiring review by Research Ethics Committees (RECs) and National Research Regulatory Authorities (NRRAs). These challenges had resulted in an increasing workload and a heightened demand for specialized technical expertise during protocol review and approval processes. Consequently, both researchers and research regulators must continuously update their knowledge and skills to address emerging and complex study designs, as demonstrated during the COVID-19 pandemic [2].

The RECs and NRRAs oversee and regulate the conduct of clinical research with the aim of minimizing risks to human participants while ensuring respect for their rights, values, and interests, and simultaneously advancing scientific knowledge [13]. RECs not only serve as the primary gatekeepers of ethical research review and regulation, but also ensure the scientific rigour of research protocols; therefore must be adequately resourced, capacitated, and positioned to conduct thorough, timely, and efficient reviews [2, 13, 14].

Available evidence indicates that, despite the pressing need to expand health research in low and middle-income countries (LMICs), significant limitations persist in research protocol review and oversight, often resulting in prolonged turnaround time for research approval [15]. A survey by the East African Health Research Commission (EAHRC) across the EAC revealed that a substantial proportion of REC members had never received formal training in research ethics review or the protection of research participants. Given that the effectiveness of the RECs is heavily dependent on the competence, skills, and ethical judgement of their members, this gap represents a serious weakness in the regulatory system and warrants urgent attention [15, 16].

Our group previously conducted training in emerging and complex study designs for six RECs at Makerere University and Mulago hospital complex, which resulted in a documented improvement in knowledge, with mean scores increasing from 53.9% (pre-test) to 70.1% (post-test) [11]. In response to the growing volume of multicounty research within the EAC and the need to strengthen protocol review processes, both to enhance quality and reduce turnaround times, the training program was subsequently expanded. This scale-up broadened participation to include RECs, NRRAs, researchers, and clinician scientists in the EAC. The expansion was made possible through funding from the European & Developing Countries Clinical Trials Partnership (EDCTP3), under the SCALE-IT Project (Grant Agreement ID: 101,103,332). The initiative was implemented through a multi-institutional partnership involving the Infectious Diseases Institute (IDI), in collaboration with Epicentre, Kenya Medical Research Institute (KEMRI), East African Health Research Commission (EAHRC), National Institute for Medical Research (NIMR), Ministry of Health Rwanda, the University of Burundi, Uganda National Council for Science and Technology (UNCST), Uganda National Drug Authority (NDA), and the University of Bahr El Ghazal.

The overall objective of the training program was to strengthen scientific and ethical capacity within the EAC to support high-quality research review, conduct, and oversight, in line with international standards. This was achieved by training NRRA personnel, REC members, researchers, and clinician scientists in scientific and ethical review and conduct of research involving emerging and complex study designs, including adaptive platform trials.

Methods

Study design

We conducted a before-and-after intervention study to evaluate the effectiveness of a multi-country training program targeting RECs, NRRA members, researchers, and clinician scientists. To inform the development and refinement of the training curriculum, we held an online stakeholders' engagement to assess existing competencies and identify priority training needs related to the ethical and scientific review of research.

A total of 40 stakeholders, purposively selected by NRRAs from each EAC partner state, participated in the engagement. Feedback from stakeholders was synthesized and shared with a team of carefully selected content experts, who reviewed and updated the curriculum and training materials accordingly. These content experts, experienced researchers with subject-matter expertise, conducted comprehensive reviews of relevant online publications, policy documents, and textbooks to ensure the curriculum reflected current best practices and emerging research methodologies.

The revised curriculum was subsequently reviewed and approved by an eight-member Training Advisory Committee (TAC) comprising representatives from the different EAC partner states. The IDI Virtual Learning Team supported the development of the online training materials and facilitated the enrollment of participants onto the virtual learning platform used for program delivery.

Participants

The training program comprised members of RECs, NRRAs, researchers, and clinician scientists 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.

Members from the other two EAC partner states; Democratic Republic of the Congo (DRC) and the Republic of Somalia, were not included in the training program. This is because these countries hadn't joined the EAC at the time of the grant application. The Democratic Republic of the Congo (DRC) joined the EAC on Tuesday, 29th March, 2022 [17], while the Republic of Somalia joined the EAC on 4th March 2024 [18].

Description of the intervention

The training program was implemented between February 2024 and February 2025. Participant selection involved the official dissemination of training invitations to RECs, NRRAs, and research institutions, followed by the receipt of applications from interested candidates. Interested candidates submitted applications through their institutions. Eligibility was limited to REC members, NRRA staff, researchers, and clinicians actively involved in research review, oversight, and research implementation. Final selection was carried out by the focal persons in each country. Priority was given to applicants whose professional roles were directly relevant to the training content, ensuring that participants who had responsibilities in protocol review, regulatory oversight, and research implementation were considered. Efforts were made to include a diverse representation across countries and professional backgrounds. While selection was guided by professional relevance, the reliance on institutional nominations may have introduced selection bias.

Prior to the commencement of training, an orientation session was conducted for both trainers and trainees to ensure a clear understanding of the training methodology and familiarity with the virtual learning platform. Country-specific trainers were engaged to deliver training in relevant national languages, where appropriate. Trainees completed both pre- and post-training assessments and participated in online self-paced learning activities.

The program comprised three days of face-to-face training, during which all modules presented in Fig. 1 were delivered, followed by two weeks of online self-paced learning via the IDI Virtual Learning Environment (VLE), after which trainees completed the post-training assessment. Upon completion of the course, trainees retained continued access to the training materials to support ongoing learning and capacity development.

Evaluation of the intervention

A 23-item pre-training and post-training assessment (Additional File 1) was administered to participants to evaluate changes in knowledge following the training. A pass mark of 60% was considered based on a previous similar training program [11]. In addition, participants were invited to provide qualitative feedback through open-ended questions administered during post-training evaluation sessions to capture their experiences and perspectives. They explored participants' views on training delivery methods, facilitation approaches, relevance of the content, and preferred formats for future learning.

Data management and analysis

Assessment marks were automatically recorded through the VLE, with built-in data checks to prevent skipped questions. The results were exported as a Microsoft Excel file, cleaned, and prepared for analysis. Descriptive analyses were conducted using Microsoft Excel and STATA 15.0, and the findings were summarized using frequencies, percentages, means, ranges, and graphical representations.

Open-ended responses were analysed using conventional content analysis. Given the brevity of responses, the analysis focused on identifying recurring ideas rather than in-depth thematic interpretation. All responses

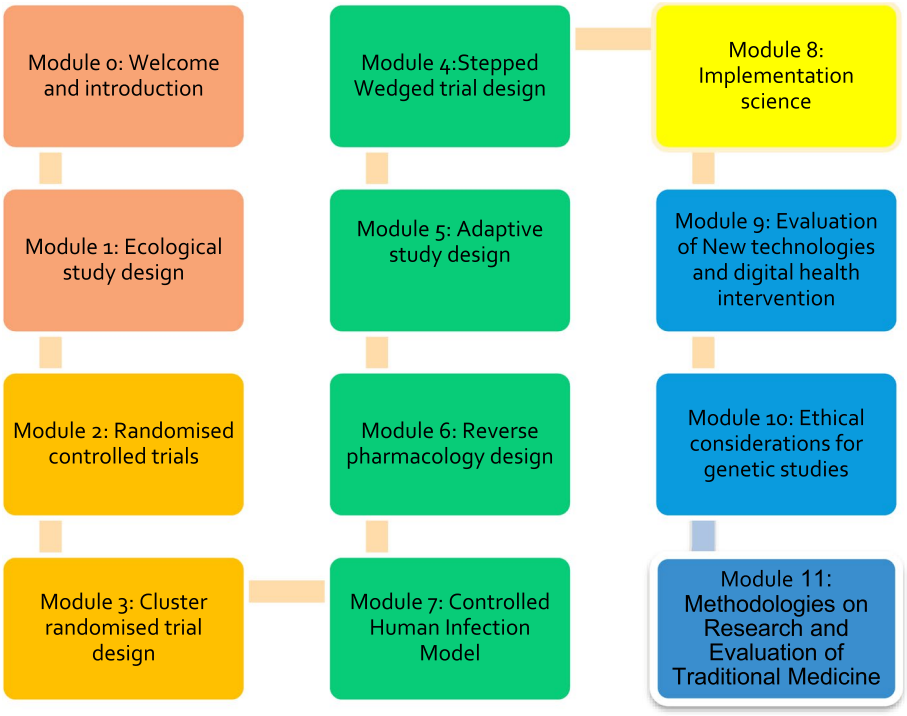


Fig. 1 Training sessions

were read repeatedly to achieve familiarisation. Meaningful texts were identified and assigned descriptive codes that were developed inductively. Similar codes were grouped into categories reflecting shared patterns across responses, and related categories were further synthesised into broader descriptive themes. Representative quotes were selected to illustrate key themes and to ensure that the findings remained grounded in participants' perspectives. To enhance analytical rigour, the coding framework and emerging themes were reviewed and discussed among members of the research team, and discrepancies were resolved through consensus.

Results

A total of 186 participants from the six EAC partner states attended the training, and all completed both the pre- and post-training assessments. The largest proportion of participants was from Uganda, representing 26.9% (50/186) of the total. Overall, 59.0% (110/186) of participants were male, while 41.0% (76/186) were female.

Of the eligible participants, 161 completed the demographic questionnaire, yielding a response rate of 86.6%. Among those respondents, 48.4% (78/161) had completed a bachelor's degree, while the smallest group, 3.1% (5/161), held a diploma. Regarding experience in clinical trials-related work, 46.6% (75/161) had less than one year of experience, followed by 21.1% (34/161) with less than three years of experience.

The majority of participants, 76.4% (123/161), had not previously received training on emerging and complex study designs. In terms of professional roles, 44.1% (71/161) were REC members, 24.8% (40/161) were researchers, and 14.9% (24/161) were NRRA members (Table 1).

Knowledge shift after the training

Across all partner states, the proportion of trainees scoring above the pass mark of 60% increased markedly from 18.1% (34/186) at pre-test to 84.2% (157/186) at post-test. Overall, the mean knowledge score improved from 52.9% at pre-test to 84.0% at post-test, demonstrating a substantial gain in knowledge following the training.

Compared to other partner states, trainees from the Republic of Rwanda got a higher 57% mean mark at pre-test, followed by those from the Republic of Tanzania, 54.0%. At post-test, those from the Republic of Kenya scored a higher mean mark 93.7% while those from the Republic of Uganda scored the least, 60% (Fig. 2).

Trainees' experience

We identified three main themes from the open-ended responses: (1) enhanced understanding of emerging and complex study designs, (2) relevance to professional roles and practice, and (3) demand for advanced methodological training.

Table 1 Participant characteristics by country

Characteristic	Country						
	Uganda	Kenya	Tanzania	South Sudan	Burundi	Rwanda	Total
	N = 50, N(%)	*N* = 31, N(%)	*N* = 28, N(%)	*N* = 15, N(%)	*N* = 18, N(%)	*N* = 19, N(%)	*N* = 161, N(%)
Gender (*N* = 186)							
Male	30 (60.0)	13 (42.0)	17 (68.0)	11 (73.9)	12 (68.0)	8 (58.0)	91 (56.5)
Female	20 (40.0)	18 (58.0)	8 (32.0)	4 (26.1)	6 (32.0)	11 (42.0)	67 (41.6)
Level of education							
Diploma	2 (4.0)	1 (3.2)	1 (3.6)	0	0	1 (5.3)	5 (3.1)
Bachelors	5 (10.0)	17 (54.8)	11 (39.3)	2 (13.3)	1 (5.6)	11 (57.9)	47 (29.2)
Masters	25 (50.0)	12 (38.7)	14 (50.)	9 (60.0)	12 (66.7)	6 (31.6)	78 (48.4)
PhD	17 (34.0)	0	2 (7.1)	3 (20.0)	4 (22.1)	0	26 (16.1)
Others	1 (2.0)	1 (3.3)	0	1 (6.7)	1 (5.6)	1 (5.2)	5 (3.1)
Years of experience in clinical trials-related work							
< 1 year	18 (36.0)	18 (58.0)	14 (50.0)	10 (66.7)	7 (38.9)	8 (42.1)	75 (46.6)
1—< 3 years	10 (20.0)	4 (12.8)	9 (32.1)	1 (6.7)	5 (27.8)	5 (26.3)	34 (21.1)
3—< 5 years	8 (16.0)	3 (9.7)	3 (10.7)	1 (6.7)	1 (5.6)	3 (15.8)	19 (11.8)
5—< 10 years	6 (12.0)	4 (12.9)	2 (7.2)	1 (6.7)	4 (22.1)	2 (10.5)	19 (11.8)
> 10 years	8 (16.0)	2 (6.6)	0	2 (13.2)	1 (5.6)	1 (5.3)	14 (8.7)
Frequency of refresher trainings							
Annually	6 (12.0)	5 (16.1)	4 (14.3)	1 (6.7)	3 (16.7)	5 (26.3)	24 (14.9)
Every 2 years	2 (4.0)	3 (9.7)	0	0	1 (5.6)	0	6 (3.7)
Every 3 years	2 (4.0)	0	1 (3.6)	2 (13.3)	0	2 (10.5)	7 (4.3)
Every 5 years	1 (2.0)	0	0	0	0	0	1 (0.6)
None	39 (78.0)	23 (74.2)	23 (82.1)	12 (80.0)	14 (77.7)	12 (63.2)	123(76.4)
Composition							
REC member	42 (84.0)	10 (32.3)	10 (35.7)	3 (20.0)	5 (27.8)	1 (5.3)	71 (44.1)
NRA member	6 (12.0)	5 (16.1)	5 (17.9)	3 (20.0)	5 (27.8)	0	24 (14.9)
Researcher	1 (2.0)	10 (32.3)	8 (28.6)	8 (53.3)	6 (33.3)	7 (36.8)	40 (24.8)
Clinician	1 (2.0)	4 (12.9)	3 (10.7)	1 (6.7)	2 (11.1)	6 (31.6)	17 (10.6)
Students (Bsc, masters, PhD)	0	1 (3.2)	1 (3.6)	0	0	4 (21.1)	6 (3.7)
Others	0	1 (3.2)	1 (3.6)	0	0	1 (5.3)	0

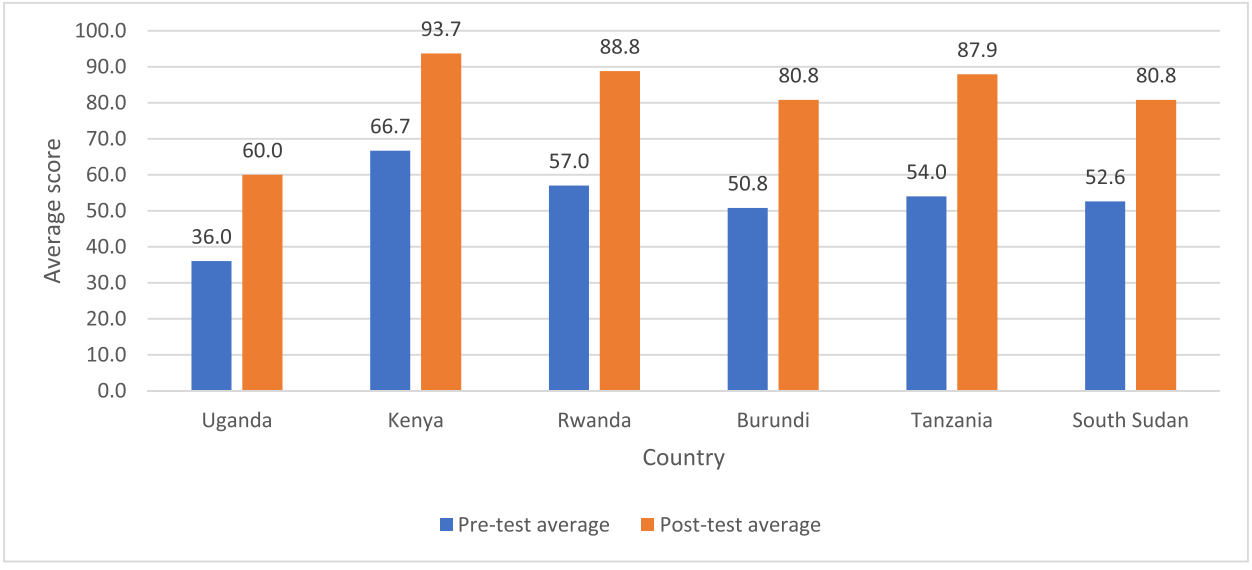


Fig. 2 Knowledge shift per country

Enhanced understanding of emerging and complex study designs

Participants frequently reported improved conceptual understanding of complex and emerging trial methodologies and regulatory processes.

> *"Attending the SCALE-IT training specifically on emerging and complex study designs was incredibly beneficial. The hands-on approach strengthened my understanding of regulatory requirements, trial protocols, and data management." (Participant, Kenya).*

Similarly, a trainee from Rwanda emphasized greater insight into complex research processes:

> *"I now have a much clearer understanding of the step-by-step process of drug discovery. It was eye-opening to learn about the rigorous journey and the time it takes to bring a drug to market." (Participant, Rwanda).*

Relevance to professional responsibilities

Participants emphasized that the training content was directly applicable to their roles within research institutions and regulatory environments, improving their foundational knowledge.

> *"This knowledge not only improved my personal skills but it also made the team more adept at precisely managing clinical trials and producing outstanding research results." (Participant, Kenya).*

Demand for advanced methodological skill development

While participants valued the foundational knowledge gained, they also indicated interest in further advanced training in statistical analysis, big data analytics, and artificial intelligence applications in research.

Discussion

This training demonstrates the effectiveness of a structured, regionally tailored program designed to enhance the capacity of REC and NRRA members, researchers, and clinicians across the East African Community (EAC). The program aimed to equip stakeholders with the knowledge and skills necessary to scientifically and ethically review research protocols involving emerging and complex study designs, in alignment with international standards.

Evidence from the training indicates that the program was highly effective, as demonstrated by marked improvements in participants' knowledge and positive evaluations of the course. Though no hypothesis testing was conducted, this improvement was observed across a wide demographic and professional spectrum, including representation from all six EAC partner states. The results are consistent with previous REC training in Uganda, though the current study achieved a greater magnitude of knowledge gain [11].

The training's success was supported by country-specific trainers, contextualized case scenarios, and a blended learning approach combining face-to-face sessions with online self-paced modules. These strategies enhanced understanding of local ethical challenges and ensured accessibility for participants with diverse professional backgrounds. Participants will continue to access the materials via the IDI Virtual Learning Platform, supporting continuous learning (https://elearning.idi.co.ug/index.php/training-on-emerging-and-complex-study-designs-for-research-ethics-committee-members/).

The training also encouraged interdisciplinary dialogue between RECs, NRRAs, clinicians, and researchers, which is critical for effective protocol review in increasingly complex research environments. This aligns with global trends, where health research has evolved from largely observational studies to complex interventional designs requiring advanced methodological and ethical expertise [2]. The training, therefore, contributes to strengthening foundational knowledge of participants related to the review and design of emerging and complex study design protocols. However, further evaluation would be required to determine whether these knowledge gains translate into improved practice in protocol development and review.

Strengths and limitations

Strengths

- Pre- and post-training assessments enabled measurable evaluation of knowledge gains across diverse professional backgrounds.
- Stakeholder engagement and inclusion of a Training Advisory Committee (TAC) ensured the curriculum was contextually relevant and regionally harmonized.
- The blended learning approach accommodated the busy schedules of REC and NRRA members, researchers, and clinicians, while country-specific trainers facilitated comprehension in local languages.

Limitations

- The study used a before-and-after design without a control group, limiting causal inference.
- Participants were selected via convenience sampling by country focal persons, which may have introduced selection bias.
- Knowledge was assessed immediately post-training, so long-term retention and translation into professional practice were not measured.

- The assessment tool, though expert-informed, was not formally validated, which may have affected reliability.
- Self-reported feedback may have been influenced by social desirability bias, potentially overestimating perceived improvements.
- Findings may have limited generalizability beyond the EAC context.
- Non-response to some evaluation components may have been due to some participants not completing the questionnaire via the Virtual Learning Environment (VLE) or from competing professional commitments, potentially introducing response bias.

Conclusion

The capacity-building program substantially improved participants' knowledge of emerging and complex study designs. Sustaining these gains will require continuous professional development, institutional support, and regionally harmonized training efforts. Periodic refresher courses, mentorship programs, and follow-up evaluations are recommended to assess the translation of knowledge into improved protocol review quality, turnaround times, and innovative research design.

Best practices

- Stakeholder engagement: A meeting of 40 members from across the EAC guided curriculum updates and ensured relevance.
- Training Advisory Committee (TAC): Eight members from each EAC partner state reviewed and approved the training curriculum, materials, and guided implementation.
- Focal persons: Country-based focal persons facilitated participant selection and coordination of in-country training sessions.
- Blended learning approach: Combining face-to-face sessions with online modules accommodated participants' schedules and enhanced learning.
- Country-specific trainers: Facilitated translation and contextualization, ensuring comprehension across local languages.
- Continuous access: Trainees retained access to online materials to support ongoing learning.

Research agenda

Future research should evaluate whether the training leads to improved efficiency and quality in protocol review by RECs and NRAs, as well as enhanced design of high-quality, innovative research protocols by researchers and clinicians that can address evolving disease challenges.

Educational implications

This program highlights the value of tailored, regionally relevant training for enhancing the capacity of REC and NRRA members, researchers, and clinicians. Key implications include:

- The need for regular curriculum updates to reflect evolving research methodologies and designs.
- Blended learning with country-specific examples enhances understanding and applicability.
- Rolling out similar programs to all accredited RECs and NRRAs across the EAC will support continuous professional development.
- Refresher courses and peer mentorship are critical for preparing members to review protocols involving emerging and complex study designs effectively.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12910-026-01418-2.

Supplementary Material 1

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Authors' contributions

MA coordinated the project, developed the survey tools, collected and analyzed data, and drafted, revised, and finalized the manuscript. BT contributed to project administration, cross-checked the data analysis, and revised the final manuscript. BM, HO, SG, SW, JK, HN, VM, RN, LSM, NT, BC, JWA, SO, and PA conceptualized the study, participated in protocol development, and contributed to revising and finalizing the manuscript. PBK conceptualized the study, led the protocol development, oversaw project implementation and coordination, and contributed to revising and finalizing the manuscript. All authors read and approved the final manuscript.

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Data availability
The datasets generated and/or analysed during the project are available from the corresponding author upon reasonable request. All data supporting the findings of this study are included within this published article.

Declarations

Ethics approval and consent to participate
The concept was approved by Makerere University, School of Medicine Research Ethics Committee, SOMREC (#REC REF 2020–024), and UNCST (HS542ES). The SOMREC is under Makerere University, School of Medicine, and is accredited under the Uganda National Council of Science and Technology, https://uncst.go.ug/details.php?option=smenu&id=9&Research%20Ethics%20Committee%20Acreditation.html. Administrative approvals to conduct the training were 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 study activities were conducted in compliance with the principles of the Declaration of Helsinki.

Consent for publication
Not applicable. The manuscript does not contain data from any individual person.

Competing interests
The authors declare no competing interests.

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