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RESEARCH ARTICLE

Boosting ethics review capacity in public health emergency situations: Co-creation of a training model for French-speaking research ethics committees

Vivi Maketa[1] | Flory Luzolo[1] | Hypolite Muhindo Mavoko[1] | Yves Claeys[2] | Felicien Munday[3] | Robert Yemesi Benge[3] | Willy Bongo Pasi[4] | Darius Mankindu[4] | Samuel Mampunza[5] | Philippe Lukanu[5] | Muteho Kasongo[6] | Edmond Ntabe Namegabe[6] | Leopold Kambale Karafuli[6] | Delphin Phanzu Mavinga[7] | Emmanuel Milandu Massamba[7] | César-Augustin Muaka Khoso[7] | Raffaella Ravinetto[2]

[1]University of Kinshasa, Kinshasa, Democratic Republic of Congo

[2]Institute of Tropical Medicine, Antwerp, Belgium

[3]Comité National d'Ethique de la Santé, Kinshasa, Democratic Republic of Congo

[4]Comité d'Ethique de l'Ecole de Santé Publique de Kinshasa, Kinshasa, Democratic Republic of Congo

[5]Comité d'Ethique de l'Université Protestante au Congo, Kinshasa, Democratic Republic of Congo

[6]Comité d'Ethique de l'Université Libre des Pays des Grands Lacs, Goma, Democratic Republic of Congo

[7]Comité d'Ethique du Centre de Recherche en Santé de Kimpese, Kimpese, Democratic Republic of Congo

Correspondence
Raffaella Ravinetto, Institute of Tropical Medicine, Nationalestraat 155, 2000 Antwerp, Belgium.
Email: rravinetto@itg.be

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Abstract

Background: Ethics review preparedness is a major foundation for national effective response to public health emergencies, because it promotes pertinent research and enhances the protection of research participants and communities. In low-income countries, it can also promote equitable research partnership. However, most relevant literature is in English and not easily accessible for the members of research ethics committees in French-speaking African countries.

Methods: A training module in French, addressing the issue of research ethics review during outbreaks and other public health emergencies, was designed based on a non-systematic literature review, and in order to be complementary to the Democratic Republic of Congo (DRC) national guidelines for ethics review. The module was administered to 42 members of the five ethics committees in DRC that expressed their interest for the training.

Result: This training, co-designed with local stakeholders, in the local working language and taking into account local circumstances and regulation, provided participants with up-to-date insights of research ethics (and research ethics preparedness) in public health emergencies. It resulted in rich reflection and knowledge-sharing on good practices across the ethics committees.

Conclusion: As most participating ethics committees do not have yet explicit standard operating procedures for expedited review of protocols submitted in emergency situations, this would be a next important step to facilitate emergency reviews in the most efficient way.

KEYWORDS
co-creation, Democratic Republic of Congo, developing countries, ethics, research, Sub-Saharan Africa, training

INTRODUCTION

Adequate skills, resources and infrastructures for epidemiological, clinical and behavioural research are

Sustainable Development Goals: Good Health and Well-being; Quality Education.

essential components of an effective national response to outbreaks and other public health emergencies, such as natural and man-made disasters. Furthermore, ethics review preparedness constitutes an important foundation for an effective and comprehensive response [1–3].

The need to uphold internationally-agreed ethics principles and values [4, 5] during public health emergencies is widely recognised [6]. This is particularly important—and challenging—in resource-limited settings, where even in routine situations individual research participants and their communities may be at increased risk of being exploited or harmed [7, 8], for instance because of double-standard ethical practices in the so-called 'ethics dumping [9], or due to 'humanitarian misconception', that is the perception of research participation as a condition to receive humanitarian aid [10]. Furthermore, local researchers and research institutions from LRSs may be denied the due scientific credit and recognition, due to the lack of meaningful and equitable research partnerships [11–14].

In the aftermath of the Ebola outbreak in West Africa, WHO developed new guidance for managing ethical issues in public health surveillance and in infectious disease outbreaks [15, 16]; and the Nuffield Council published a report on ethical issues in research in global health emergencies, based on a 2-year enquiry among relevant stakeholders, and with an explicit call to ensure that research is undertaken ethically during global health emergencies [17, 18]. But despite the significant growth of ethics guidance and of ethics review activities [19, 20], many research ethics committees in resource-limited settings are still under-resourced, and they struggle to keep up with adequate standards and procedures [21–23]. These difficulties have multiple causes, including the fact that members have limited or no access to formal training in research ethics, or that they have received training modules that are not up-to-date with the most recent developments in this discipline. This is even more evident when research ethics committees face the challenge to ensure rapid and thoughtful review of research projects submitted during a public health emergency. Under these circumstances, a slow review can delay or hamper the outbreak response, while the review's rapidity can result in losing its depth and breadth. For instance, a research ethics committees that is reviewing many different protocols in emergency mode might end up focusing on traditional ethics issues such as the adequacy of the informed consent and process only, while losing of sight other essential aspects, for example, the engagement with the researched communities, the measures taken for data sharing and biobanking (particularly when data and samples are exported to a third country), the safety and well-being of front-line researchers, the use of mobile phones and social media for data collection in outbreak research, the risk-benefit assessment of repurposed drugs etc. Failure to resolve the tension between rapidity and quality may lead either to the approval of poor-quality, redundant or non-pertinent research, or to delaying urgent relevant research. Innovative mechanisms to facilitate rapid review, such as the pre-review of generic protocols and the pre-adoption of standard procedures for expedited ethics review, have been suggested but, to the best of our knowledge, not (yet) extensively adopted [1].

Difficulties tend to be greater for research ethics committees in French-speaking African countries, many of which are frequently affected by public health emergencies, given the dearth of training initiatives in French (with some notable exception such as the TRREE online modules [24]). These research ethics committees would highly benefit from (re)training on (expedited) ethics review of research conducted during public health emergencies. To do so, research ethics committees need availability of and access to training modules that are developed based the local needs rather than on others (e.g., donors') priorities, and that can be administered locally, with budget requirements limited to the support of organisational aspects locally.

CREATION AND DELIVERY OF AN ETHICS REVIEW TRAINING

In 2020, the Democratic Republic of Congo (DRC) was hit concomitantly by measles, Ebola and COVID-19 outbreaks,

TABLE 1 The training modules

Module	Title		Time allocated
	English	*Official (French)*	
1	Overview of ethical review in epidemics and public health emergencies	*La revue éthique dans des situations d'épidémie et urgences de santé publique*	30′
2	Principles of research ethics in public health emergency situations	*Les principes de l'éthique de la recherche dans l'urgence*	2 h
3	Application of the principles of research ethics in public health emergency situations	*L'application des principes de l'éthique de la recherche dans des situations d'urgence*	3 h
4	Procedural aspects of ethical review of research in epidemics, public health emergencies and disaster situations	*Les aspects procédurales de la revue éthique dans des situations d'épidémie, urgences et désastre*	3 h
5	Simulation of ethical review process in a public health emergency situation: a mock protocol	*Simulation du processus de la revue éthique dans des situations d'urgence*	3 h

TABLE 2 Participating research ethics committees

	Comité Ethique National de la Santé (CENS)	Comité d'Ethique de l'Ecole de Santé Publique de Kinshasa (ESPK)	Comité d'Ethique de l' Université Protestante au Congo (UPC)	Comité d'Ethique de Recherche de l'Université Libre des Pays des Grands Lacs (CER-ULPGL)	Comité d'Ethique du Centre de Recherche en Santé de Kimpese (CRSK)
Affiliation	Ministry of Health (MoH)	ESPK, Université de Kinshasa	UPC	ULPGL	CRSK
Town	Kinshasa	Kinshasa	Kinshasa	Goma	Kimpese
Role	National	Institutional	Institutional	Institutional	Institutional
Number of members	12	15	8	7	17
Year established	2013	2006	2014	2005	2020
Mandate	Mandated by the MoH to examine project protocols involving humans. Its approval is mandatory for the use of an investigational drug in clinical trials. It is mandated to supervise other RECs.	It reviews research carried out at/by the ESPK, which aims to be a centre of excellence in public health training, research and community services. It contributes to the improvement of the health and well-being of Congolese people by carrying out research to identify and to resolve public health problems; engaging in community activities designed to promote community participation and to strengthen the capacity to build partnerships, self-sufficiency, and self-determination.	It reviews research carried out at/by the UPC, the biggest private university in Kinshasa, and a centre of excellence and a motor of research in the country. The REC mission is to supervise researchers in the field of research ethics by ensuring that all research carried out within the framework of the UPC complies with standards and directives research on humans being. It also plays a training role for young researchers through the feedback given on the submitted protocols.	It reviews research carried out at/by the ULPGL. The main university and its Faculties of Theology, Community Health and Development, and Medicine are actively involved in research. Noteworthy, Goma has been the place of several catastrophes and outbreaks over the last decades.	It reviews research carried out at/by the CRSK, a rapidly developing research centre, and the only one in DRC and Central Africa with a demographic health surveillance system. The REC is a young committee with vocation to become the starting point for the creation of a provincial REC. It aims to: • protect rights and welfare of human beings participating as subjects in a research study; • provide ethical guidance to local and international researchers in the conduct and implementation of research studies, and to the public; • ensure respect for the fundamental principles of research ethics, namely respect for the individual, beneficence and justice; • review proposed research methods to ensure that they are ethical; • monitor and review biomedical and behavioural research involving humans; • safeguard ethical conduct of research in relation to national and international standards, regulations or codes.
General Standard Operating Procedure (SOP) in place?	No	Yes	Yes	Yes	Yes
SOP for expedited review in emergency?	No	Yes	No	No	Yes

and it has a history of over two decades of natural disasters and of armed conflicts, in particular in the East. Researchers from the University of Kinshasa (UNIKIN), DRC and the Institute of Tropical Medicine (ITM) in Antwerp, Belgium, who previously collaborated in ethics reflection on informed consent and on ancillary care in clinical research in the DRC [25, 26], partnered in 2021 with the DRC National Ethics Committee to co-create and deliver a short training course for ethics reviewers. Based on the priority needs expressed by the partners in DRC, the training focused on ethics review of research conducted during outbreaks and other public health emergencies.

The training modules were conceived and developed based on a non-systematic literature review, that is, an extensive purposive compilation of relevant publications, reports and policy documents, categorised according to the sub-headings of the International CIOMS guidelines [5]. We aimed to make the modules complementary to the national guidelines for ethics review, which were last updated in 2010 and do not include a specific section for expedited review [27]. Special attention was given to emerging issues in research ethics during outbreaks, such as community engagement, collaborative partnership, benefit sharing, data sharing, biobanking, etc.; and to procedural ways to optimise expedited ethics review. The modules were developed in French, which is the working language of the target audience, to be delivered over 2 days—which was seen as a reasonable compromise between the number of topics to be covered, and the available time of the ethical review board members. The training materials were drafted by the two project coordinators at UNIKIN and at ITM, reviewed for accuracy, consistency and completeness by the three other members of the core-team (two from UNIKIN and one from ITM), and revised and approved by the chairperson of the National Ethics Committee. They consist of four PowerPoint modules, each one accompanied by a list of essential literature references and by a list of facultative readings, and of a case-exercise in the form of simulated ethics review of a mock protocol. An overview of the modules is presented in Table 1, and the modules in French are presented as supplemental materials, in order to be publicly available.

TABLE 3 Profile of the trainees

Profession	Gender		Total
	Female	Male	
Medical doctors and nurses	3	14	17
Theologians, philosophers and ethicists	1	6	7
Anthropologists and community experts	3	3	6
Scientists (biomedical sciences, epidemiology, environmental sciences)	2	4	6
Law experts and administrators	2	4	6
Total	11	31	42

The training was delivered in French between March and May 2021, by the UniKin researchers, with the online participation of the ITM researchers in two cases only. First, a pilot was conducted with a group of 21 volunteering UNIKIN postgraduate medical students interested or involved in medical research; 15 of them were physically present in Kinshasa and 6 joined online. Second, the short training was delivered to the members of the National Ethics Committee and of four research ethics committees in DRC, including their chairpersons (Table 2). Overall, 42 members from the National Ethics Committee and the four interested research ethics committees agreed to participate, out of 59 who were proposed, and received the training. In order to keep small groups, to respect COVID-19 rules, and to allow adequate interaction and sharing of experiences, the training was separately delivered by National Ethics Committee/Research Ethics Committee. The average attendance rate was of eight participants per training (range: 6–11). Table 3 describes the profile of research ethics committee members, with a majority of health care workers (17), followed by theologists, philosophers and ethicists (7), anthropologists and experts in communication (6), (other) scientists, and law experts and administrators. Trainees feedback was anonymously collected via an online Monkey survey.

DISCUSSION

Ethics review should be a dynamic process, based on reflection and dialogue, so as to allow an explicit justification of the risk assessment of the proposed research, of the choice of adequate mitigation measures, as well as an explicit contextualization of ethics issues [28]. We argue that similarly, training in ethics review should be a dynamic process, preferably based on personal exchange, open dialogue and open discussion between the trainees and the trainers, in order to carefully identify and weigh the different approaches to ethical dilemmas—when possible with the support of theoretical or real-life case studies [9, 29].

The training modules presented here were co-designed by DRC researchers and ethics reviewers, and the chair of a European Institutional Review Board that reviews many collaborative research protocols in global health. They aim to be both informative and interactive, with a lot of time devoted to peer-discussion and exchange of experiences, opinions, and questions across lecturers and participants. The combined inputs and knowledge-sharing seemed to be richer than top-down lecturing and examination, or than online modules—which are of great value for establishing a common baseline understanding of essential principles and procedures in ethics review, but offer limited opportunity for personal exchanges and experience-sharing. Given the relatively small size of participant groups per training—never exceeding 11, it was possible to achieve lively discussions and exchanges even when a trainee or a lecturer was participating online. For instance, in the introductive Module 1, we listed some research carried out in DRC

during outbreaks, natural disasters and armed conflicts in recent years, to trigger reflection on who are the key-research stakeholders under such circumstances, and on the ethical challenges most frequently faced in these concrete in-country situations. After Module 2, where selected essential themes were presented and discussed (i.e., autonomy and informed consent; justice; beneficence and non-maleficence; privacy and confidentiality; and vulnerability), Module 3 centred on the analysis of how these ethics themes are specifically applied in emergency epidemiological [30], clinical, and social science [31] research in DRC. Among the discussed challenges, there were the researcher's access to retrospective data and samples from public health surveillance (and relevant grounds for informed consent waiver); the proper identification of heads of households and—at a different level—of community representatives, as gatekeeper to the research; the justification for oral consent; the identification and mitigation of non-medical risks in research, including therapeutic misconception, stigmatisation, psychological discomfort and legal security; the pertinence of a research for a given population, and the likelihood that they will be benefit from the research findings (i.e., benefit sharing).

It was noted that when an emergency research protocol does not present explicit measures (and related budget) for engaging with the research community, or for providing research capacity building, or for translating the findings of the research into concrete health policies for the research community, it is up to the research ethics committees to raise these issues. The same is applicable for the need to build into protocols equitable provisions for data and samples sharing agreements, and for the valorisation of local research capacities. For instance, in DRC, the INRB [32] has significant research and biobanking capacities, so proposals to export samples to a third country should be duly justified, and accompanied by meaningful provisions not to strip the samples ownership and governance away from the country.

Nonetheless, we cannot ignore that research ethics committees in DRC, as in other countries in the same region, most often act under time pressure, and with limited resources [33,34]. In Module 4, we steered an in-depth discussion about ways to improve the research ethics committee's preparedness to expedited review. The discussions revealed that some research ethics committees lack explicit standard operating procedures for expedited review of protocols submitted in emergency situations. This could greatly enhance the research ethics committee's preparedness for outbreak and other emergencies, which are unfortunately quite frequent in the DRC. It was suggested that locally-adapted standard operating procedures could be (jointly) developed based on the model provided by WHO [35]. It was also noted that the pre-review of generic protocols, still poorly known and used by both researchers and ethics reviewers [1,28], could be useful to accelerate expedited reviews. Furthermore, participants from all the research ethics committees indicated the need to establish a formal or structured network, in order to exchange information across them. This would avoid, for instance, that researchers may submit protocol to another research ethics committee after an initial negative feedback that would not be communicated by the researchers to the next research ethics committee.

Both trainers and trainees had a positive perception of the short training. Via a simple Monkey survey feedback, trainees acknowledged the importance of the topics, the added value of the suggested readings, and the rich peer-exchanges between facilitators and participants. The only common complaint was that they would have appreciated more time to share more with the trainers and better assimilate the concepts taught.

LIMITATIONS AND LESSONS LEARNED

Our experience presents some limitations. First, the favourable outcome is at least partly due to the fact that the project was conceptualised and implemented by a small group of researchers and ethics reviewers with a long story of collaboration. It cannot be assumed that the same results would be achieved with a broader, multi-country collaboration. On the other hand, a positive lesson learned here is that the co-design of a research ethics training with local stakeholders, with in-depth knowledge of local contexts, constraints and regulations, is an essential ingredient to target the trainees' needs.

Second, most trainees and lecturers were physically present, so we cannot assume that an equally good peer-discussion, grounded in trust, could be achieved online; to do so, we recommend to keep small and homogenous groups—in this project, we never exceeded a number of 11 participants, all belonging to the same research ethics committee (REC).

Third, all trainees were members of research ethics committees, already experienced in research ethics, which allowed us to focus on emerging issues in research ethics that are particularly relevant to public health emergency situations; a different approach would be required for unexperienced ethics reviewers.

Last, the positive outcome of this work is reported based on a simple online survey across trainees, and on the perceptions of the trainers and research ethics committees representatives that co-author this manuscript, while no direct comparison was conducted versus alternative teaching methods. A more meaningful assessment would be based on an estimation of the long term impact of the training on the decision making process, for instance how many of the trained research ethics committees will have implemented new or updated standard operating procedures for expedited review (at the moment of the training, only one of the research ethics committees had one in place); how many other research ethics committees in DRC requested the training; whether the timelines of emergency review improve over time etc. This would require additional resources, on the one hand to support one or more workshop(s) for writing up a model SOP for expedited review, and on the other hand to conduct prospective

monitoring and evaluation of the research ethics committees performance in emergency situations.

In terms of financial feasibility, the overall cost of this 5-month project was 25,000 USD, including the modules development, salaries, organisational costs and overheads. Expanding the training to other research ethics committees, either in or outside DRC, would require much smaller budgets, potentially limited to covering the costs for the local workshops, while trainers travel may be not needed—if the trainer(s) join(s) online or is/are locally based. At country level, the latter could be made possible by organising initially a 'training of trainers' event at a central location.

The availability of local trainers would also make it possible to train any new members on an ongoing basis, and to organise regular retraining on a two- or three-year intervals. It would be important that local trainers consider the possibility to regularly adapt the modules based on local experiences, and perhaps to introduce new mock protocols for the simulated review.

CONCLUSION

This training on research ethics review during public health emergencies, co-designed with local stakeholders, in the local working language and taking into account local circumstances and regulation, provided the participants with up-to-date insights of research ethics (and research ethics preparedness) in public health emergencies, and resulted in reflection and knowledge-sharing on good practices across the National Ethics Committee and research ethics committees in DRC. The next step would be to implement at the level of each research ethics committee effective measures that will allow them to deal with expedited reviews in the most efficient way.

This project was designed and conducted in partnership with the National Ethics Committee and some of the main research ethics committees in DRC; therefore, it may represent an opportunity to build a more formal national ethics network and a common/coordinated approach, including common procedures to expedited ethics review during outbreaks and other public health emergencies. In the longer term, these modules could be adapted and expanded to other French speaking countries in the region, particularly those confronted with frequent outbreaks.

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DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no datasets were generated or analysed during the current study. However, we provide as Supplemental Materials the final training modules.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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