

Enhancing the Efficiency and Quality of African Research Ethics Review Processes – Through an Automated Review Platform

Boitumelo Mokgatla*, Prince Bahati and Carel I Jsselmuiden

International AIDS Vaccine Initiative (IAVI), Botswana

Abstract

Background: The sheer amount of research being conducted in Africa, the under-resourced research ethics committees (RECs), and the lack of modern review technologies have resulted in unprecedented ethics review timelines.

Method: The Research for Health Innovation Organiser (RHInNO Ethics), an automated review platform, facilitates and manages the entire ethics review process. In 2015, RHInNO Ethics was used by 25 RECs in 8 African countries. We evaluated its impact on efficiency, data security and cost using an online questionnaire administered to REC administrators in user countries.

Results: The RECs interviewed were diverse with membership of 9-46 members; reviewing between 50–2000 protocols annually including observational, investigational new drugs and diagnostics. Reported areas of high impact (81%-100% of respondents) included improved: protocol submission and distribution process, quality of communication between RECs and researchers, standardized review process and data security. Reported areas of medium impact (60%-80% of respondents) included reduced; REC administrator's workload and RECs' administrative costs. Improved reviews of multicenter trials were reported by <60% of respondents. 20% of respondents who used RHInNO Ethics for >2 years reported 57% reduction in review time while those who used RHInNO Ethics for \pm 1 year, (80%) reported it is too early to tell.

Conclusion: RHInNO Ethics has achieved high-impact on data security, submission process, communication, standardization and cost reduction. However, a long-term evaluation approach is needed to determine impact on review timelines. Integration of new M&E indicators on efficiency into the platform would improve RECs capacity to conduct long-term impact.

Keywords: Ethics; Health; Research

Background

Health research initiatives worldwide are growing in scope and complexity, particularly as they move into the developing world [1]. This changing cascade of biomedical research poses new challenges for research ethics committees (RECs) review efficiency and quality. The sheer amount of research now being conducted in Africa has resulted in an unprecedented increase in RECs' workload [2] and the growing trend of multi-centre trials complicate the traditional, institution-oriented oversight system.

This places a severe burden on RECs, which have always operated under significant resource constraints [3]. Majority (93% of the mapped 169 RECs in 37 African countries) use complex paper based review systems [4], which have proven to be problematic in terms of providing comprehensive oversight and tracking of submitted research protocols, monitoring and evaluation, effective communication, data storage and poor continuity of work due to the high turnover of REC membership [5].

The Challenge

The etiology of REC inefficiency is complex. REC members spend a great deal of time preparing REC applications, amendments, renewals, and reports. Poorly functioning review systems can lead to inefficiencies or long review timelines which ultimately lengthens the time to licensure for new medicines, vaccines and medical technologies [6].

169 RECs are reported to be operational in 37 African countries, with great variability in skills, membership, capacity and resources [4]. Most of these RECs are facing substantial challenges, including limited financial and human resources, insufficient training and inadequate standard operational procedures (SOPs), and lack of modernised

information management technologies [3]. One of the major bottlenecks for ethical clearance is the complex paper based review systems widely used by African RECs, which are unable to absorb significantly increased submission volumes [4]. To address the latter, the Council on Health Research for Development (COHRED), working with partners in Africa, designed an intervention to address the need to provide much faster ethical review of research: the RHInNO Ethics, a cloud-based management information system for RECs (<http://www.rhinno.net>) [1]. Since its first rollout in 2012, no study has been conducted to evaluate the platform's impact, nor has any study been conducted to evaluate the technological needs of RECs in Africa, hence the motivation for this survey.

Methodology

An online questionnaire was used to collect both qualitative and quantitative data from the 8 African countries currently using RHInNO Ethics.

***Corresponding author:** Boitumelo Mokgatla, Associate Director for the Policy, Advocacy, Research Preparedness and Regulatory Affairs, International AIDS Vaccine Initiative (IAVI), Botswana, Tel: +2677272626; E-mail: BMokgatla@iavi.org

Received November 22, 2016; **Accepted** January 20, 2017; **Published** January 27, 2017

Citation: Mokgatla B, Bahati P, Jsselmuiden CI (2017) Enhancing the Efficiency and Quality of African Research Ethics Review Processes – Through an Automated Review Platform. J AIDS Clin Res 8: 658. doi: [10.4172/2155-6113.1000658](https://doi.org/10.4172/2155-6113.1000658)

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Results

Basic REC information

Responses were received from all the 8 African countries (Nigeria, Swaziland, Mozambique, Malawi, Tanzania, Kenya, Senegal and South Africa). The user RECs were distributed across Southern, East and West Africa, and operated in English, Portuguese and French languages. Most (80%) of the RECs started using RHInnO Ethics in 2014 (Table 1).

The longest serving REC has been in existence for 34 years, while the youngest REC has been operational for 3 years. The REC membership ranged from 46 (highest) to 9 (minimum). The REC with the highest number of members, reviewed the highest number of protocols annually, a recorded 2040, while the REC with the lowest number of members reviewed the lowest number of protocols annually, reported as 50 protocols. All the RECs reviewed a mix of research, ranging from phase I, II, III clinical trials to epidemiological and socio-behavioral research.

Impact of the online platform

Respondents were requested to identify areas of impact, which have improved the most and the least since implementation of RHInnO Ethics. Reported areas of impact were classified as high (81%-100%), medium (60%-80%) and low-concurrence (<60%) of respondents, as reflected at below [4] (Figure 1).

The vast majority of REC's reported that RHInnO Ethics had a positive influence on work stream efficiency, even after a relatively short period of use. More than 80% of users reported that both protocol submission and protocol distribution were made easier as a result of the elimination of multiple paper copies. Other high impact areas included;

Country	Implementation Year	Operational Language	Region (Africa)
Kenya	2014	English	East
Malawi	2014	English	Southern
Mozambique	2013	Portuguese	Southern
Nigeria	2014	English	West
Senegal	2013	French	West
South Africa	2012	English	Southern
Swaziland	2014	English	Southern
Tanzania	2014	English	East

Table 1: REC information by country/region/language.

improved communication between REC administrators, reviewers and researchers, increased data confidentiality and security. 60-80% of REC's reported a reduction in both administrative workloads and administrative costs. The platform accessibility and usability, for both reviewers and submitters, helped contribute to these findings. One respondent commented that these work-stream efficiencies would be bolstered with expanded usage, "it will be a plus if more committees in other African countries are to see the benefit of this platform...and the added value with simultaneous submission and review of multicenter trials."

Standardization

There was high-level of reporting that RHInnO Ethics was positively impacting adherence to international ethics review standards and had a potential contribution towards standardization and harmonisation of the ethics review process. One respondent commented: "Our country has multiple national and institutional REC's and each of these committees have different operating procedures and submission requirements. By using RHInnO Ethics, we can move toward harmonization of the ethics review process."

Review timelines

One of the areas where we anticipated RHInnO Ethics would have a significant short-term impact was with review timelines. However, given that 80% of REC's interviewed had used the platform for a year or less, most (64%) reported that it was too early to see any impact on review timelines. Nevertheless, 5 REC's who had used the platform for >2 years, indicated a reduction in review timelines of approximately 56% of all studies, both low and high risk (Figure 2).

Discussion

Emerging and innovative review technologies offer potential to cushion some of the RECs challenges and facilitate efficient reviews and the required oversight. This survey, to the best of our knowledge, is the first to evaluate the effectiveness of modern review technology use by RECs in Africa. It is evident from the survey results that in the wake of increased workload, RECs in Africa are in need of innovative solutions to enhance their efficiency and the quality of reviews. With over 80% of the surveyed RECs reviewing up to 500 protocols annually, an average of 42 protocols monthly, and with most RECs reported to not have full

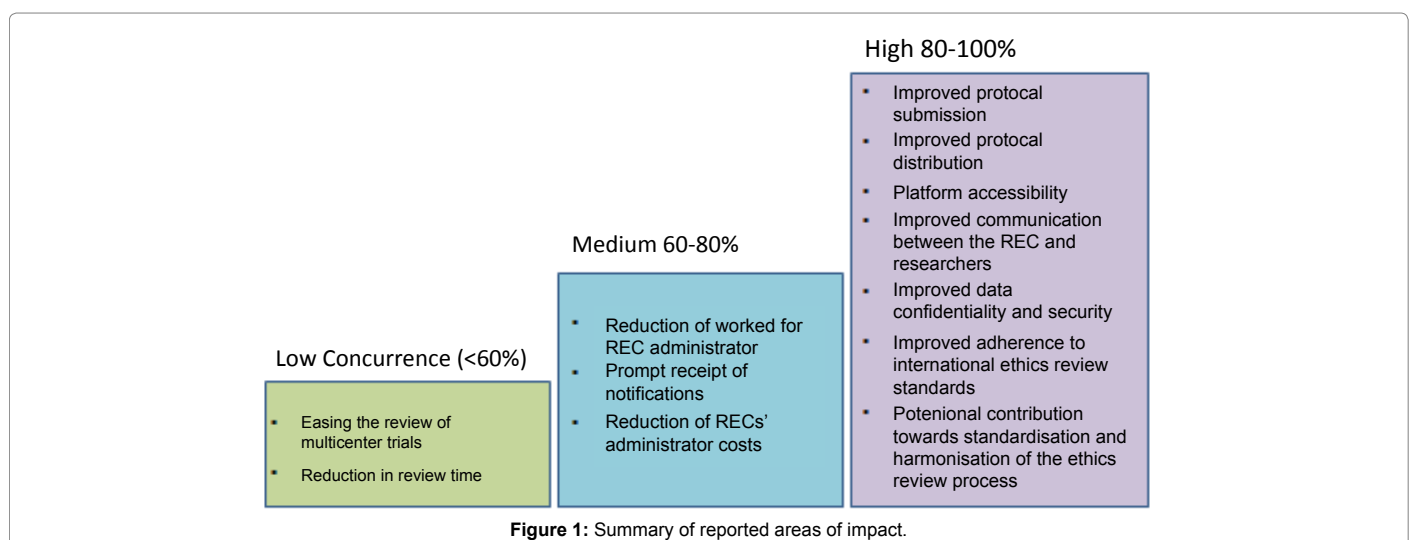


Figure 1: Summary of reported areas of impact.

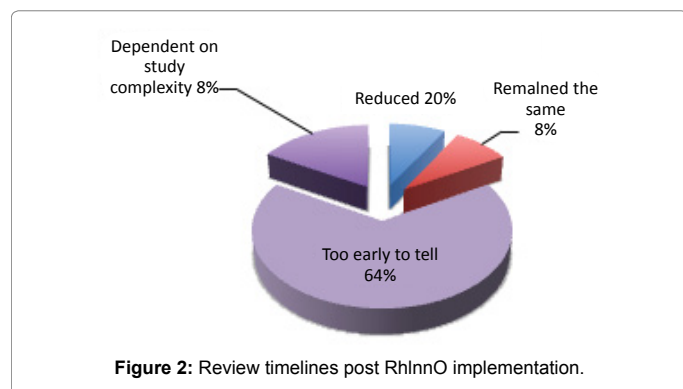


Figure 2: Review timelines post RHInno implementation.

time administrators [4], the need for solutions to lessen the workload of REC administrators cannot be over emphasized.

Most RECs in Africa are reported to be relying on complex paper based systems for reviews [3,4], which could potentially compromise their ability to effectively ensure comprehensive oversight of approved studies, as well as, lead to unprecedented long delays in reviews. The limited ability of RECs to provide oversight of approved studies refutes the whole objective of protection of research participants. It has been correctly argued that 'ethical approval alone does not necessarily ensure protection of the safety and welfare of research participants throughout the research' [5]. Monitoring of research post approvals is crucial for the optimization of the research process, and paragraph 15 of the Declaration of Helsinki (WMA, 2008) places an obligation on the researchers to provide monitoring information to the research ethics committees, especially information about any serious adverse events. Such monitoring requires adequate resources and trained RECs, but these are still limited in most African committees [5,6].

Several previous studies revealed that majority of RECs in Africa are faced with lack of dedicated office spaces [3,4] implying that, quite often protocols are stored in various offices which are not specifically set aside for the RECs, potentially compromising the privacy and confidentiality of their work. Budgetary constraints, lack of training, expertise and lack of full time administrators have also been highlighted as major challenges to African RECs [7-13]. The findings of this survey revealed that the use of modern review technologies, can positively address the communication, storage, security and confidentiality issues as well as, cushion the RECs limited budgets by reducing their operational costs such as telephone, photocopying and protocol distribution costs. These findings are also consistent with some of the recommendations from empirical studies which found the need to harmonize ethical review processes in Africa to be urgent [3,4].

Recommendations

Users of RHInno Ethics have indicated that it is making a positive contribution towards improved efficiency in regulatory review, including workload and cost reduction along with standardization. Review timelines are one such measure of efficiency, and while it is too soon to tell what the overall impact will be, there are positive trends seen from early adopters. These trends reinforce recommendations for increased domestic investment to strengthen the capacity of RECs. Further, it highlights the potential of new technologies to enhance efficiencies and quality – and avenues for improving ethics review infrastructure in Africa.

Limitations of the Survey

The fact that most RECs (92%) only started using RHInno Ethics in

2014, made it difficult to evaluate the long-term impact of the platform on the review timelines. There is a need for a longitudinal evaluation of RHInno Ethics as well as integration of new M&E indicators on efficiency and cost effectiveness into the RHInno Ethics platform to improve REC capacity to conduct long-term impact. Motivations for adoption of RHInno Ethics by regions and the limited adoption by private IRBs would require further research.

Conclusion

The RHInno Ethics has achieved high-impact on data security, submission and distribution process, communication, standardization and cost reduction. However, a long-term evaluation approach is needed to determine impact on review timelines. Integration of new monitoring and evaluation indicators on efficiency into the platform would improve RECs capacity to conduct long-term impact.

Acknowledgement

This work was funded in part by IAVI and made possible by the partnership with the Council on health Research for Development (COHRED) [7].

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