Research Article

Evaluation of The Health Research Ethics Management Information System using The RE-AIM Framework in Indonesia

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Abstract

Increased global awareness of research ethics has encouraged many countries to develop an accountable review process. A recent development in Indonesia is the implementation of the Health Research Ethics Management Information System (SIM-EPK), which digitizes the ethics review by an Institutional Review Board (IRB) that can be monitored nationally. This study aimed to evaluate SIM-EPK using the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework. A total of 30 informants including applicants, reviewers, and the IRB secretariat were involved. Data were collected using the Zoom meeting platform on 26 August 2022 and analyzed using NVivo software version 12. The respondents reported that the SIM-EPK is easily accessible and helpful. However, challenges were identified, including applicants' lack of thoroughness when filling out the submission forms, unfamiliarity with the application, and technical problems such as lengthy CAPTCHA requirements for login and non-automated reminders. Concerns regarding data security, the complexity of submission forms, and institutional support were raised by several respondents. In conclusion, the SIM-EPK is well-received and considered as an effective and efficient digital tool that facilitates the ethical review. For the sustainability of this application, enhanced institutional support and improved data security measures are recommended.
***Keywords**: ethical review, SIM-EPK, RE-AIM, institutional review board, research ethics committee.*

Evaluasi Sistem Informasi Manajemen Etik Penelitian Kesehatan Menggunakan RE-AIM *Framework* di Indonesia

Abstrak

Meningkatnya kesadaran global terhadap etik penelitian mendorong banyak negara untuk mengembangkan proses peninjauan yang akuntabel. Perkembangan terkini di Indonesia adalah penerapan Sistem Informasi Manajemen Etika Penelitian Kesehatan (SIM-EPK) yang mendigitalisasi tinjauan etik oleh Institutional Review Board (IRB) dan dapat dipantau secara nasional. Penelitian bertujuan mengevaluasi SIM-EPK menggunakan kerangka Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM). Sebanyak 30 informan terdiri atas pengusul, peninjau, dan sekretariat IRB. Data dikumpulkan melalui Zoom meeting pada tanggal 26 Agustus 2022 dan dianalisis dengan software NVivo versi 12. Para responden melaporkan SIM-EPK mudah diakses dan bermanfaat. Tantangannya adalah kurangnya ketelitian pelamar saat mengisi formulir pengajuan, ketidakpahaman terhadap aplikasi, CAPTCHA yang panjang untuk login, dan pengingat yang tidak otomatis. Kekhawatiran mengenai keamanan data, kompleksitas formulir pengajuan, dan dukungan kelembagaan juga disampaikan oleh beberapa responden. Disimpulkan bahwa SIM-EPK diterima dengan baik serta dianggap sebagai aplikasi digital efektif dan efisien yang memfasilitasi proses tinjauan etik. Untuk keberlanjutan aplikasi ini, diperlukan dukungan kelembagaan dan peningkatan keamanan data.
***Kata kunci:** tinjauan etik, SIM-EPK, RE-AIM, institutional review board, komite etik penelitian.*

Introduction

Research involving humans must adhere to ethical principles such as respecting the subject's autonomy rights, nonmaleficence, beneficence, and justice, which serve as the foundation of research ethics.[1] However, many violations of ethical principles occurred in the past. One of the most notorious examples was the coercion of prisoners to participate in inhumane medical experiments conducted by Nazi doctors during World War II. These doctors, under the regime of Adolf Hitler, conducted unethical experiments on prisoners in concentration camps. These experiments were often aimed at supporting the Nazi ideology or advancing military objectives, rather than genuine scientific inquiry. They included exposing prisoners to extreme temperatures, testing the effects of chemical agents, and conducting non-consensual surgeries that often resulting in severe suffering or death. This violation of basic human rights was pivotal in developing the Nuremberg Code, which later became one of the cornerstones of ethical research.[2] Another example of ethical violation occurred in the Tuskegee Syphilis Experiment to study the pathophysiological effects of untreated syphilis on a group of black men in America.[3] Following the uncovering of The Tuskegee Syphilis Experiment case, the committee in charge of the investigation proposed three basic principles of research ethics, known as the Belmont Report's Principles.[4] These principles are (i) respect for the dignity of the subject, including the existence of informed consent and protection for vulnerable groups; (ii) beneficence which means not harming others and seeking the maximum possible benefit of action and the minimal impact of harm on both the individual and the community; and (iii) fairness for each research participant to obtain a balanced burden of risks and benefits.[4]

In Indonesia, the guidance and supervision of health research ethics is carried out by the National Commission for Health Research Ethics (*Komisi Nasional Etik Penelitian Kesehatan*/ KNEPK), established by the Minister of Health of the Republic of Indonesia in 2002. The commission has successfully published national guidelines for health research ethics. Later on, the Indonesian Minister of Health established the National Health Research and Development Ethics Commission (*Komisi Etik Penelitian dan Pengembangan Kesehatan Nasional*/ KEPPKN) in 2016, and its main role is to supervise the Institutional Research Boards (IRBs).

The dilemma in ethical review continues over time as new ethical issues emerge in research. For this reason, the research ethics committee (REC) must create a standard operating procedure for conducting an ethics review.[5] Another effort to further empower the REC is to digitize the ethics review process. Some issues frequently arise in using management information systems, including overall system performance, ease of use, security, data recapitulation ease, internet connectivity, and cost.[6] In Indonesia, the process for submitting an ethics review is improving. Since 2019, the submission of ethics protocol has been carried out through the application of the Health Research Ethics Management Information System (*Sistem Informasi Manajemen Etik Penelitian Kesehatan*/ SIM-EPK), which was initiated by the KEPPKN via the following website: https://sim-epk-keppkn.kemkes.go.id/. The new version of SIM-EPK was launched in 2021 and becomes the framework for optimizing communication, capacity, monitoring, and evaluating research ethics based on digitalization in the ethics review (ER) process at the REC or IRB.

Evaluation of the use of SIM-EPK based on scientific studies has not been carried out in Indonesia. This study aimed to evaluate SIM-EPK using the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework. The RE-AIM framework was developed to assist researchers and public health practitioners in understanding the factors that affect the impact of a health program or intervention.[7] This study aimed to evaluate SIM-EPK using RE-AIM framework.

Methods

This qualitative study employed Focus Group Discussions (FGDs) to obtain comprehensive insights into the utilization of the SIM-EPK application by Institutional Review Boards (IRBs) across Indonesia. The RE-AIM framework structured the study, directing the examination across five core dimensions. Each dimension served as a distinct analytical lens through which the application's impact and usability were evaluated. The RE-AIM framework is a widely recognized approach for evaluating programs and their impact. This framework aids in assessing not only the outcomes of a program but also its broader implications in terms of feasibility, sustainability, and reach within various population segments, such as program users, implementers, and program organizers.

Invitation letters to participate in this study were sent to the 19 IRBs, which had been registered in the SIM-EPK application. Each IRB was asked to dispatch three participants representing applicants, reviewers, and secretariats. A focused group

discussion (FGD) was conducted on 26 August 2022 via zoom meeting to evaluate the use of the SIM-EPK. A total of 30 subjects attended the FGD, and based on their role in using the SIM-EPK, they were divided into three groups: five applicants, 13 reviewers, and 12 IRB secretariats. The number of study participants was a result of accidental sampling based on their convenient availability to participate in the FGD. The framework terminology used in this study is summarized in Table 1.

Table 1. Terminology of RE-AIM Framework

Domain	Definition
Reach	The mechanism by which the applicant accepts the SIM-EPK and the efforts of the reviewer and the IRB secretariat to encourage the applicant to use the SIM-EPK.
Effectiveness	The benefits received by the applicant, reviewer, and secretariat from using the SIM-EPK.
Adoption	Supporting factors and constraints in using the SIM-EPK.
Implementation	An overview of the successful implementation of the SIM-EPK.
Maintenance	The sustainability of SIM-EPK and improvements required.

Before commencing the FGD, study participants had been informed that their responses would be recorded and the results of the study would be published. Since this study employed a qualitative approach, statistical analysis was not applied; instead, a thematic analysis was conducted to capture in-depth insights and perspectives from the participants. The data were systematically coded and categorized by using NVivo software version 12 to identify patterns, themes, and insights from participants' responses. By applying NVivo, researchers could organize thematic analysis and perform in-depth exploration of participants' perspectives. The study protocol was approved by the Research Ethics Committee of the Faculty of Medicine of Universitas Sebelas Maret (No. 43/ UN27.06.11/KEP/EC/2022).

Results

Table 2 shows the distribution of study participants from seven provinces in Indonesia. Most respondents were reviewers of research protocols (13/30), followed by the IRB secretariats (12/30) and the applicants of ethics review (5/30). Most respondents reside in Central Java province (13/30), followed by Yogyakarta (5/30), North Sumatera (4/30), South Sulawesi (3/30), Jakarta and East Java (2/30 each). Only one respondent is from West Java.

Reach

The SIM-EPK is an application introduced by the Indonesian Ministry of Health in 2019 to facilitate the application of ER for health researchers involving human subjects. Initially, the SIM-EPK platform was centralized, and as the number of IRBs in Indonesia increased progressively, the application became slow. During the COVID-19 pandemic, the new SIM-EPK version has been developed using local servers. The FGD respondents who had been using the application to submit research protocols agreed that the latest version of SIM-EPK is considered efficient as applying ER through the website is easier than manual submission.

Table 2. Distribution of Study Participants

Residence	Applicant	Reviewer	Secretariat
North Sumatra	0	2	2
Jakarta	0	1	1
Yogyakarta	0	3	2
West Java	0	1	0
Central Java	4	4	5
East Java	0	1	1
South Sulawesi	1	1	1
Total	5	13	12

From the reviewers' perspective, the SIM-EPK system enhances transparency and accountability in the review process by enabling reviewers to monitor key stages such as protocol submission, ER, protocol revision, and final decision-making. To promote mutual understanding between reviewers and applicants, detailed procedures for ER submission via SIM-EPK should be clearly outlined on the IRB website or through a video tutorial. While the SIM-EPK platform manages the submission and review of research protocols, the IRB website serves as an informational resource, providing guidelines on submitting protocols through the system. These guidelines include instructions for file uploads, a list of reviewers, seven universal criteria for protocol assessment, and a sample self-assessment form.

Furthermore, the IRB secretariat should take an active role in familiarizing new researchers and reviewers with the SIM-EPK platform. The SIM-EPK can be demonstrated during a university event or webinar, enabling users to understand how to use this application properly. Thereby facilitating a more efficient protocol submission and review.

Effectiveness

The SIM-EPK system streamlines task completion for applicants, reviewers, and secretariats, enhancing efficiency across the protocol review process. The applicants benefit from the transparency of the ER, which allows them to self-monitor the review process. The ER results can be released promptly, i.e., up to one week for exempted protocols, within two weeks for expedited protocols, and soon after the full-board meeting. The reviewers benefit from the use of a local server, which provides faster access to materials. Additionally, protocols are summarized by the IRB secretary prior to assignment, enabling reviewers to conduct more efficient evaluations. Feedback from respondents indicates that both reviewers and secretariat staff find the SIM-EPK system easy to use and effective in facilitating their respective duties.

Adoption

key factors that support the effective use of the SIM-EPK system include the provision of incentives, financial support, training to enhance reviewer competence, and access to consultation with the SIM-EPK developer when technical difficulties arise. From the secretariat's perspective, supporting factors include the contributions of KEPPKN, which provides ER application forms and offers adequate training for the IRB personnel.

On the other hand, applicants' unfamiliarity with ethics guidelines and research protocols hinders the submission of protocols to the SIM-EPK. Some obstacles reviewers face include the complexity of research protocols, time constraints, incomplete protocols, expensive training costs, low participation in ER, and strict deadlines. The secretariat also faces several obstacles, including limited proficiency in using standard operating procedures (SOPs), expensive training costs, difficulty in the login process due to the six digits CAPTCHA, the lengthy review process, a shortage of reviewers who master the technology, internet connectivity problems, occasional server problems, and difficulties in managing subsequent stages after the installation of the SIM-EPK.

Implementation

The process of submitting research protocols by the applicants via the SIM-EPK system is efficient and seamless without significant problems, and payment transactions are automatically recorded in the cashier system. The ER process through SIM-EPK also runs smoothly and easily compared to the manual ER system. The management of research protocols by the secretariat is easier using SIM-EPK, and there are rarely any problems with the central server. Furthermore, SIM-EPK ensures confidentiality, enables stable connections, and facilitates hassle-free correspondence. The use of a local server additionally offers advantages, such as easier network control and faster resolution of technical issues.

Maintenance

Several issues need to be addressed to improve the management of research protocols using SIM-EPK. Applicants have expressed the need for government regulations to ensure the proper and consistent use of the system. They also emphasized the importance of presenting protocol form information in a clear manner to prevent difficulties during submission. Additionally, applicants requested sample file formats for system uploads, comprehensive guidelines, and robust security measures to ensure the safety of their submissions.

Reviewers, on the other hand, highlighted the necessity of data security within the SIM-EPK system. They also suggested implementing strategies to encourage daily notification checks by

reviewers. Furthermore, reviewers recommended the introduction of government regulations allowing a single ethics approval to be valid across multiple research sites and the standardization or accreditation of IRBs. In cases of server-related issues, it was suggested that the IRB secretariat be notified immediately. Reviewers also proposed simplifying the CAPTCHA process to three digits to streamline the login process.

Discussion

Ethics review is a crucial step before conducting research, ensuring that research activities meet ethical standards, including respect for persons, beneficence, and justice—principles that differ significantly from routine health services.[8] Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) is an evaluation method used for almost 20 years and is widely developed. It is applied in health behavior research and public health and extends to communities and companies. The RE-AIM framework (Reach, Effectiveness, Adoption, Implementation, and Maintenance), an evaluation method developed over nearly two decades, has been widely applied in health behavior research, public health, and beyond, extending to communities and corporations. This framework focuses on the adaptation process and uses qualitative research methods to explore the "how and why" behind outcomes.[9] In the present study, the RE-AIM framework was employed to evaluate KEPPKN's recent program, the launching of SIM-EPK application.

Evaluation of the Reach dimension shows that the applicants experienced time efficiency and ease of use, and the review process proceeded smoothly. The Effectiveness dimension further demonstrated the SIM-EPK's efficiency, with the average time for ethics approval being two weeks, which is within the ideal ER processing time of 21 working days. The findings emphasize the importance of streamlining and digitalizing ER process, as demonstrated by the SIM-EPK's positive impact on time efficiency and accessibility, so that the use of SIM-EPK can be adopted by other RECs or IRBs to reduce delays. Practical steps such as providing video tutorials and written guidelines on the IRB website could help further reduce submission errors. Regular webinars or university events showcasing the system can familiarize new users, thereby expanding the system's reach effectively.

In terms of the Implementation dimension, it shows that the SIM-EPK provides easy access and time efficiency, reflecting the convenience reported by respondents and highlighting the system's effectiveness in managing ethical reviews. This result aligns with an internal assessment at the IRB of the Faculty of Medicine of Universitas Sebelas Maret. The turnaround time of ER using the old version of the SIM-EPK was longer, with processing times reaching 58 days in 2019 and 46 days in 2020.

The analysis of the adoption dimension revealed several obstacles to adopting the SIM-EPK. These include inaccuracies in the applicant's protocol, which causes errors during protocol submission, reviewers' unfamiliarity with the features in the SIM-EPK, back-and-forth processing, and six-digit CAPTCHA during the login process. A previous study suggested that a real-time revision of research protocols during an IRB meeting has significantly reduced the ER process time by 40%.[10] The identified key barriers to adoption, such as protocol errors and reviewers' unfamiliarity with system features, suggesting that addressing these through training and user-friendly design could improve overall efficiency. Providing a dedicated support team or hotline for technical issues could also help overcome obstacles related to the use of the system. Furthermore, the study stresses the need for broader dissemination of education in research ethics, particularly for undergraduate students and early-career researchers, to mitigate protocol-related issues and reduce submission or revision delays.

The evaluation of the Maintenance dimension emphasizes concerns in SIM-EPK sustainability, so there is a need to improve the system, particularly if it is to be implemented across all RECs or IRBs nationwide. To address the concerns about multiple ER processes from different RECs/IRBs, KEPPKN must propose a standardized toolkit to minimize inconsistencies in ethical decisions. This toolkit, encompassing globally accepted ethical guidelines, would be vital for the comprehensive review of high-risk research protocols.[11] In fact, the implementation of a standardized toolkit for ER across RECs/IRBs is crucial for maintaining research integrity and the objectivity of reviewers.

The adaptation and digitalization of information systems in health services are lengthy and require repeated evaluations and updates so that these adaptations can be carried out broadly throughout all regions. Several indicators of the adoption of health information/technology systems, according to the World Health Organization (WHO), include

easy access, universality, effectiveness and sustainability, ease of reach, and privacy and security of health information.[12] The existence of perceived constraints can be the basis for improving the health information system, such as the SIM-EPK. Despite improving the ER system, the IRB system also needs to be updated to meet its function of providing ultimate protection to human research participants whilst delivering a timely ethical review.[13] An internal assessment using IRB metrics is a good starting point for reviewing the effectiveness of the IRB and identifying problems that delay ethics approval.[14]

From the applicants' perspective, our study highlights that unfamiliarity with the ethical guidelines and the content of research protocols is the main problem in ER. These findings are consistent with a previous study,[15] for greater dissemination of research ethics within academic environments, particularly among undergraduate students. Earlier research has also identified factors contributing to delayed ethics approval, including issues with protocol writing (such as excessive technical jargon), concerns about data security and participant safety, and unclear compensation for study participants.[16] Thus, while improving the ER process and IRB system is essential, any effort to increase awareness and knowledge of research ethics is much more critical. Delays in protocol submission can significantly prolong the overall ethics review timeline, even when the review duration itself is within acceptable limits.[17]

The study has several strengths that contribute to its overall value. First, it provides significant insights into ER processes in Indonesia. By involving 30 participants from applicants, reviewers, and IRB secretariats across Indonesia, the research provides valuable insights into the challenges and successes of using the application. Second, the implementation of FGD allowed an in-depth exploration of user experiences and perspectives. As the results, the study informs the practical benefits of the SIM-EPK, such as time efficiency and ease of use. The study also identifies critical areas for improvement, such as system sustainability and the need for standardized ER toolkits, providing actionable recommendations for policy and practice. Third, the analysis comprehensively addresses multiple dimensions of the RE-AIM framework, offering a robust evaluation on SIM-EPK performance.

However, there are some limitations to consider. First, the findings are based on a specific institutional context, limiting their generalizability to other settings, particularly those with different technological or organizational infrastructures. Second, the use of accidental sampling could introduce selection bias, as only participants willing to join the FGD were included, which may not represent all SIM-EPK users. Third, the Reach and Sustainability dimensions of RE-AIM were not fully evaluated since the study only involved users who have already interacted with the application, not a broader population. Moreover, the study did not incorporate direct feedback from all stakeholders involved in ER, such as research participants or funding bodies, which could offer a more holistic perspective on the SIM-EPK's performance. Fourth, while Effectiveness and Implementation aspects were analyzed, evaluating Adoption and Maintenance aspects requires further research with a larger sample and long-term follow-up. Lastly, the reliance on qualitative methods, while valuable for exploring underlying processes, may not fully capture the quantitative metrics needed to assess long-term impact of the system.

Future studies could address these limitations by incorporating mixed-method approaches and evaluating the cost-effectiveness of the system to provide a more comprehensive understanding of its impact and feasibility. Further research is needed to explore the scalability of the SIM-EPK system and its adaptability to other regions or contexts. Studies could also examine the impact of system enhancements, such as improved data security features and simplified workflows, on user satisfaction and system adoption rates. Additionally, investigating the integration of artificial intelligence tools for protocol screening and review automation could provide innovative solutions for addressing existing challenges.

Conclusion

The SIM-EPK has proven to be an effective and efficient tool for managing ER. To sustain the use of SIM-EPK, it is recommended that several improvements be made. These include addressing concerns about data security, simplifying the system's workflow, reducing the number of CAPTCHA digits required for login, and providing a more concise protocol submission form through KEPPKN. Furthermore, regular evaluation and feedback mechanisms should be established to continuously improve the system based on user experiences. Incorporating automated notifications for task deadlines and enhancing server reliability

will further ensure seamless operation. By addressing these aspects, the SIM-EPK can not only maintain its effectiveness but also serve as a scalable model for digitalizing ethical review processes across diverse research settings.

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