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RESEARCH ARTICLE

# The impact of Covid-19 pandemic on the research portfolio and approval turnaround time at the Kenya Medical Research Institute

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## Abstract

***Background:*** *The Covid-19 pandemic led to unprecedented impact on many sectors globally including research. We assessed the impact of the Covid-19 pandemic on the research portfolio, and on the approval turnaround time for research protocols submitted to the Scientific and Ethics Review Unit (SERU), at the Kenya Medical Research Institute (KEMRI).*

***Methods:*** *We compared research protocols submitted between October 01, 2019 and March 31, 2020 (Period 1), to those submitted between April 1 and September 30, 2020 (Period 2). A document review tool was used to extract data from the 198 research protocols reviewed and approved over the two periods.*

***Results*****:** *In the two periods under review, the single largest percentage of protocols (89/198, 45.4%) involved infectious and parasitic diseases, and the single largest percentage of study designs was cross-sectional (75/198, 38%). Before the pandemic, the median time taken to review KEMRI-linked protocols was 87 days and for non-KEMRI linked protocols it was 121 days. During the pandemic, approval turnaround time dropped for both KEMRI and non-KEMRI protocols to 66 days and 92 days, respectively, due to the streamlined processes at the KEMRI SERU.*

***Conclusion:*** *The research portfolio was minimally affected by the pandemic. The adoption of email submission, and faster-than-usual processing and review protocols during the pandemic reduced the approval turnaround time.*


***Keywords:*** *Kenya, Africa, developing countries, LMICs, turnaround time, research portfolio, Covid-19, research protocols*

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## Introduction

Studies in 2020 have highlighted the global impact of the Covid-19 pandemic on research [1]. Some publications have focused on Covid-19 related research. For instance, Palmero et al [2] conducted a descriptive and exploratory study to determine if countries in Latin America formulated specific policies to guide ethics review processes during the pandemic. Hinga et al[3] focused on the scientific and ethics review of Covid-19 research in Kenya. Researchers investigated the perceptions of ethics reviewers of Covid-19 research protocols in Pakistan[4]. In 2020-21 when this research was conducted, there was limited data on the impact of the pandemic on the review of research *not* concerning to Covid-19 [4] .

The Scientific and Ethics Review Unit (SERU) of the Kenya Medical Research Institute (KEMRI) is accredited for research ethics review in Kenya, with a mandate to approve protocols on research for human health. Other functions of the KEMRI SERU include monitoring of approved research, conducting research in bioethics, and providing bioethics training. KEMRI SERU functions via three committees.

As of December 31, 2022, KEMRI SERU had reviewed and approved 105 research protocols relating to Covid-19 including 33 clinical trials, 44 epidemiological studies, 11 diagnostic studies, three on bioethics, 10 social science studies, two immunological studies, and two genomic studies [5].

The rise in Covid-19 related research may have increased the workload for SERU. Of the 248 protocols reviewed and approved by the KEMRI SERU from April 2020 to April 2021, 62 (25%) were new research protocols related to Covid-19.

The nature of the pandemic and the need to find quick solutions necessitated a quicker than usual turnaround for review of Covid-19 related research protocols. The KEMRI SERU had standard operating procedures (SOPs) for reviewing research protocols that require a faster-than-

usual review. The SOP applies to quick turnaround reviews in for research in public health emergencies. The same SOPs are also applied for more than minimal-risk research protocols that require a shorter time to review and approve.

Before the Covid-19 pandemic, the three committees of the KEMRI SERU met in person to review hard copies of research protocols. Following the Government of Kenya's restrictions on in-person meetings and physical contact [6], KEMRI SERU introduced e-mail submission of documents for review, virtual committee meetings, and email correspondence to the Principal Investigators (PIs). It also implemented SOPs for quick turnaround review of Covid-19-related protocols, reviewing them on a rolling basis. The KEMRI SERU also developed guidelines for research during the pandemic [7]. We evaluated the impact of these changes on research portfolio and protocol approval turnaround time submitted before and during Covid-19 pandemic.

To the best of our knowledge, there are no published papers documenting the impact of the Covid-19 pandemic on the research portfolio and approval turnaround time by ethics committees in Africa.

### *Definitions*

*Expedited review:* Review of research proposals that pose no more than minimal risk, or a modification of a no more than minimal risk study, or a minor modification of a greater than minimal risk approved protocol.

*Quick turnaround reviews:* Review of a proposal that requires a quicker time because the subject is of major public health concern.

*Approval turnaround time:* The time taken in days from protocol submission to the final approval.

## Methods

### *Study design*

This was a cross-sectional retrospective document review study. Data was extracted from archived records at KEMRI SERU.

### *Study procedures*

We developed and utilised a document collection tool recording the protocol unique number, protocol category (KEMRI or NON-KEMRI), study design (randomised controlled trial, laboratory, systematic reviews, cross-sectional and cohort), review category (expedited, quick turnaround, and full committee review), research program area (based on the seven KEMRI programmatic areas [8], and approval turnaround time (from date of first submission to date of approval). Data were abstracted and entered in a Microsoft Excel sheet with column titles indicating the variables of interest.

The reference point was March 2020 when the first case of Covid-19 was diagnosed in Kenya. The period chosen before the pandemic was October 01, 2019 to March 31, 2020, henceforth referred to as Period 1. The period during the pandemic was April 01, 2020 to September 30, 2020, referred to as Period 2. We extracted data from all 198 research protocols reviewed and approved by the KEMRI SERU during these two periods and compared the turnaround time for their approval.

### *Data management and analysis*

The data were stored in a password protected computer and backed up on cloud storage. Data entered in Microsoft Excel were imported into SPSS Version 23 for cleaning and creating the required dummy variables — "time taken for approval", and "research portfolio". We tested for normality of data distribution using nonparametric test (Mann-Whitney U test), using median (interquartile range [IQR]) and Mann-Whitney U test to compare medians between groups because the outcome data of approval turnaround time did not meet normality threshold (Shapiro-Wilk test: $p<0.01$). Data were analysed and compared to obtain information on the research protocol approval turnaround time and the research portfolio (the seven programmatic areas in the KEMRI strategic plan).

### *Ethical considerations*

The research protocol was reviewed and approved by the KEMRI SERU (SERU # 4142) and the World Health Organization (WHO) Ethics Review Committee (CERC.0036). The data were collected and stored in password-protected computers and securely backed up.

## Results

### *Characteristics of protocols submitted to KEMRI SERU*

Out of the 198 research protocols reviewed and approved by KEMRI SERU during both the periods, 169(85%) were KEMRI research protocols (submitted by KEMRI-affiliated investigators) and 29(15%) were submitted by investigators not affiliated to KEMRI. Of the 169 KEMRI research protocols, 102(60%) were submitted during Period 2 and 67 (40%) were submitted during Period 1. Of the 29 non-KEMRI research protocols, 15(52%) were submitted during Period 2 while 14(48%) were submitted during Period 1.

Of the 198 research protocols, 138(70%) went through full board review, 36(18%) were expedited, and 24(12%) were reviewed under quick turnaround review (Supplementary file, available online only)

### *Study designs*

Of the 198 research protocols, 75(38%) were of cross-sectional studies, 35(18%) were laboratory studies, 31(16%) were clinical trials, 23(12%) each were case control and cohort, and 9(10%) desktop-based reviews.

### *Research portfolio*

Of the 198 research protocols, 89 (45%) were on infectious and parasitic diseases. Of these 89, 35(44%) were submitted

during Period 1, while 54(46%) were submitted during Period 2, as described in Supplementary file (available online only).

***Approval turnaround time***

The median turnaround time from submission to final approval of the research protocol in the 12-month period was 79 days (IQR 61-106.7). The median turnaround time was 67 days (IQR 54.2-98) during Period 2 compared to a median of 89 days (IQR 74.5-123.2) in Period 1. Half of all submissions during this entire period required at least one revision before approval as described in Supplementary file (available online only).

The median time taken to review KEMRI research protocols in Period 1 was 87 days (IQR 75.2-107.2) whereas for non-KEMRI research protocols in the same period was 121 days (IQR 73.7-137.2). During Period 2, the time taken to review both KEMRI and non-KEMRI research protocols reduced. Time for expedited review during Period 1 was 93 days (IQR 29.2-142.5) compared to a median of 59 days (IQR 43.7-85.2) during Period 2. There was a similar reduction in approval turnaround time for research protocols earmarked for full board review, from 90 days (IQR 76-117.7) before the pandemic to 84 days (IQR 63.2-113.2) during the pandemic. While the median turnaround time was the same for different review categories before Covid-19 (p=0.64) there were significant differences between review categories during Covid-19 (p<0.01), as described in Table 1.

Using Mann-Whitney U non-parametric test, we tested whether there was a significant difference in the median time taken to review expedited and full board research protocols before and during the pandemic. (There were no data in the quick turnaround category before the pandemic to run a test.) We found no significant difference in the time taken for expedited review before and during the pandemic (p=0.58). However, there was a significant difference in the median time taken to review full board research protocols before and during Covid-19 (p=0.05).

## Discussion

The Covid-19 pandemic disrupted many activities across the world, including research regulation [9]. Some Research Ethics Committees (RECs) in Africa made quick adjustments

**Table 1: Time taken to review different types and categories of research protocols before (Period 1) and during Covid-19 pandemic (Period 2)**

| Attribute | Period 1 | | | Period 2 | | |
|---|---|---|---|---|---|---|
| | Median No. of days (IQR) | Mean No. of days (SD) | p-value | Median No. of days (IQR) | Mean No. of days (SD) | p-value |
| **All research protocols** | 89.5(74.5-123.2) | 106.9(55.7) | - | 67(54.2-98) | 76.1(33.0) | - |
| **Protocol type** | | | | | | |
| KEMRI | 87.5(75.2-107.2) | 106.2(60.2) | 0.20 | 66(54-89.5) | 72.8(28.8) | 0.07 |
| NON KEMRI | 121.5(73.7-137.2) | 109.7(31.6) | | 92(60-133) | 95.3(48.3) | |
| **Category of review** | | | | | | |
| Expedited | 93(29.2-142.5) | 88.2(61.8) | 0.64 | 59(43.7-85.2) | 63.9(28.5) | <0.01 |
| Quick turnaround | - | - | | 55.5(43-65.2) | 59.9(29.7) | |
| Full board | 89.5(76-117.7) | 107.9(55.6) | | 83.5(63.2-113.2) | 88(31.8) | |
| **Design of study** | | | | | | |
| Case control | 98.5(66.7-128.5) | 98.2(30.5) | 0.04 | 79(43-117) | 77.5(35.5) | 0.21 |
| Cohort | 91.5(84-116) | 105.4(33.4) | | 86.5(56.5-105.7) | 82.4(30.7) | |
| Clinical trial | 80(76-122) | 101.8(45.1) | | 71.5(58.2-105.0) | 82.1(32.0) | |
| Cross-sectional | 84.5(73-104.2) | 95.5(37.4) | | 64.5(54.2-84.7) | 71.1(32.6) | |
| Laboratory studies | 71(54.-178) | 112.4(85.5) | | 64.5(47-91.5) | 69.7(30.2) | |
| Desktop-based reviews | 235(158.7-269.2) | 221(59.9) | | 118(84.5-137.5) | 112.4(35.1) | |

to their operations to respond to the pandemic by rapidly reviewing Covid-19 research protocols for implementation [10]. The KEMRI SERU shifted to electronic processes leading to a reduction of protocol review and approval timelines. These adjustments may be a learning point for possible good practices for other ethics review committees in other low- and middle-income countries (LMIC) settings.

***Approval turnaround time for research protocols***

This retrospective analysis indicates that the review turnaround time for all research protocols reduced significantly after the Covid-19 pandemic set in.

Our findings are consistent with those found by Vindrola-Padros et al [11], which showed that RECs in the UK had established fast-track systems for reviewing emergency studies on Covid-19. At the KEMRI SERU, the activation of the quick turnaround review track as a way of responding to the Covid-19 emergency reduced the review timelines for Covid-19 related studies. Notably, the removal of the paper-based system of submission and review of research proposals reduced the time to approval by doing away with physical transport of review documents to reviewers in the KEMRI centres across Kenya.

We also noted a significant reduction in approval turnaround time for research protocols categorised as expedited reviews during, as compared to before, the pandemic. Similar reductions in approval turnaround time were seen for research protocols earmarked for full committee review. Pwint et al in a study within another resource-constrained setting (Myanmar) [12] found similar reductions in turnaround time for protocols eligible for expedited reviews reviewed online. Our findings are similar to those of Ijkema et al [13] who compared expedited with full committee review in Netherlands between March and August 2020 and March and August 2019. They found that the number of review days were fewer in expedited reviews compared to full committee reviews because RECs in Netherlands established ad-hoc sub-committees to review Covid-19 protocols. The KEMRI SERU did not have a specific sub-committee charged with the expedited review of Covid-19 protocols. A study in Kilifi, Kenya [3] found that the entire regulatory system in Kenya, including peer review, RECs, national regulators (pharmacy and poisons board and the national commissions for science, technology and innovation) prioritised review and approval of Covid-19 protocols. To support investigators submitting protocols during the pandemic, the KEMRI SERU developed guidelines to improve the oversight and conduct research in that period.

Half of the submissions during both Period 1 and 2 required more than one revision before final approval. This study did not explore the reasons for multiple revisions for research protocols before approval. Ford et al [14], determined that the measures put in place by REC directors at Clinical and Translational Science Award institutions — including dedication of more staff and resources for review of Covid-19 related research — shortened the time for review of this research. The KEMRI SERU did not increase staff or resources to the unit during the pandemic. The reduction of approval timelines at KEMRI SERU could be attributed to the introduction of e-mail submission of documents, virtual meetings, and e-mail correspondence to the PIs. The introduction of virtual meetings increased attendance during monthly meetings, and more members were available to review research protocols including those in the quick turnaround category. Since research protocols were sent on e-mail, there were no cases of misplaced documents compared to hard copy submissions. Additionally, all Covid-19 related research protocols used the quick turnaround review mechanism. The requirement to make one or more revisions before approval remained the same in the two periods under review, indicating that the review remained robust despite the shortened time for review. A 2021 study by Sisa et al [15] in Ecuador found that the requirement for major protocol changes resulted in longer periods of correspondence between researchers and the RECs resulting in an increased time to approval. Another study by Vindrola-Padros et al [11] found that the delay in obtaining ethics clearances was a result of prolonged communication with the REC and the time taken by investigators to respond to the comments or changes requested.

The approval turnaround time for research protocols in the infectious and parasitic diseases program reduced during Period 2. This reduction is attributed to the fast tracking of research protocols related to Covid-19, which is categorised under "infectious and parasitic diseases".

***Research portfolio***

*Research program areas*

Our findings indicate that most research protocols reviewed and approved at KEMRI SERU during Period 2 addressed infectious and parasitic diseases due to the focus on Covid-19 research. Harper et al[16] found out that the multinational funding focused on the support towards Covid-19 research and caring for Covid-19 patients. In our study, we did not compare the funding for Covid-19 research with other types of research in KEMRI.

A significant increase in the number of research protocols in the category of public health and health systems research was also noted from Period 1 to period 2, reflecting the kind of research studies conducted during the pandemic, focusing on the pandemic and its impact on public health and healthcare system in Kenya. The increase in the number of research protocols in two program areas (infectious and parasitic diseases, and health systems) may also be linked to a KEMRI institutional call providing research funding in the area of Covid-19 research at the height of the pandemic. Pwint et al [12]showed that 22% of the Covid-19 research protocols reviewed and approved at the Department of Medical Research, Myanmar, between April and October

2020 were in the category of public health and socio-behavioural research.

The increase from 12 (15.2% of 79 study designs) to 23 (19.7% of 117 study designs) in the proportion of laboratory related research protocols may be related to the many research studies on molecular characterisation and sequencing of the coronavirus that were reviewed and approved by the KEMRI SERU during the Covid-19 period. In contrast, Pwint et al found out that the REC at the Department of Medical Research, Myanmar, reviewed and approved 13(81%) of all research proposals reviewed) Covid-19 related studies on public health and socio-behavioural aspects between April and October 2020 [12]. None of the Covid-19 related studies reviewed at Myanmar in this period had laboratory and genetic aspects.

*Study designs*

There was no significant change in the number of clinical trials reviewed and approved by the KEMRI SERU during the pandemic. The focus of research stakeholders, including sponsors, regulators and researchers, may have shifted to Covid-19 research. Franzen et al indicates that only 20-30% of clinical trials globally are carried out in LMICs with less than 10% in Sub-Saharan Africa [17], the barriers including financial and human constraints, regulatory and ethical delays and competing demands.

During the period of review, the proportion of cross-sectional studies to the overall number of studies increased by 13.2% (i.e. 43.6%-30.4%) from Period 1 to Period 2. This design is appropriate to measure outcome and exposure to Covid-19, prevalence of the disease within clinics, and for population surveys. The cross-sectional study design might have also been preferred because it is faster and relatively inexpensive and useful in a pandemic situation with an urgent need for epidemiological information on Covid-19 [18].

***Recommendations***

Based on our research findings, RECs should be flexible and quickly adapt to the changes that will allow continuity of research. The specific steps include: shifting from paper-based to electronic submission of documents, virtual meetings, e-correspondence with PIs, and adoption of quick turnaround and expedited review mechanisms. The findings of this study reiterate the importance of ethics preparedness during pandemics and epidemics to ensure continuity of research in emergency situations.

## Conclusion

The research portfolio of protocols submitted to KEMRI SERU was minimally affected by the Covid-19 pandemic with infectious and parasitic disease still forming the bulk of the submission both before and during the Covid-19 pandemic.

The approval turnaround time reduced significantly during the Covid-19 pandemic due to the streamlined processes at the KEMRI SERU including the introduction of email submission, virtual REC meetings, quick turnaround review of Covid-19 related protocols, and email correspondence to the principal investigators.

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