
Shaukat Khanum Memorial Cancer Hospital and Research Centre
Fast Facts:

- Double burden of disease
- Population Growth
- Underinvestment in health
- Mixed health care system
- Key health indicators
Health Research Output in Pakistan

Documents by year

Year

Documents
2k 3k 4k 5k 6k 7k 8k

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Pakistan biggest rise in research output in 2018

COUNTRIES WITH BIGGEST RISES IN RESEARCH OUTPUT

Emerging economies top the list for percentage increase in publications from 2017 to 2018.

- Pakistan
- Egypt
- Mainland China
- Hong Kong
- India
- Brazil
- Mexico
- Iran
- Poland
- South Africa

Data: Web of Science
Analysis: Institute for Scientific Information, Clarivate Analytics
Quality of publications as well as the impact these publications are making at local, regional and international level pose an important question.
Research Ethics review In Pakistan

- During normal times
  - Institutional Review Board
  - Research Ethics Committee, National Bioethics Committee, Pakistan
  - Drug Regulatory Authority of Pakistan

- During PHEs

**Ethical Review by REC-NBC**

**Rapid Turnover Review (RTR) for COVID Response**

- Submission of completely filled application package@ NBC secretariat
  - nbcpakist@nih.org.pk
- Submission to REC for Online review (within 24 hours)
- Response of REC communicated to PI via email (within 24-48 hours)
  - Tele conference with PI for immediate response (within 48 hours)

- No response: Project abandoned (after 10 days)
- Unsatisfactory response: Revisions requested within 24 hours; Reconsideration of revisions if appropriate approval is granted
- Satisfactory Response: Approval granted (Within 72 hours of submission)
Pakistan Ethics Framework


Objectives

A depth inquiry of the local context and current structures and practices and the way the NBC-REC and local IRBs responded to the pressures of COVID-19 was done. Evidence was analyzed to identify key insights, and evidence-based recommendations to develop policy and guidance were made. Action on these recommendations can be used to create an operational framework for a national and local approach to ethics review during a public health emergency, aiming to strengthen the preparedness and response to any future PHE.
International workshop


The current pandemic has posed direct ethical challenges setting the need for ethics preparedness to deal with a broad spectrum of issues. A surge in research activities focusing on Novel COVID-19 has left the ethics review bodies overwhelmed, working in difficult situations and facing the challenge of reviewing the studies with limited evidence of the safety and efficacy of interventions proposed.

The review process, conducted by diverse ethics review bodies across different regions, remained variable. In countries with decentralized and underdeveloped ethical review system, this review process remained inconsistent, resulting in inefficiency and duplication of efforts.

The Ethics review workshop held virtually on the 10th and 13th November, 2020 aimed to examine the ethics review process, identifying the variations and challenges that were present across LMICS. It provided an opportunity to voice and discuss the problems and solutions learned so far directed towards a more coordinated and efficient review system.

The workshop was chaired by Farah Asif from Shaukat Khanum Memorial Cancer Hospital and Research Centre in Pakistan and was also organised in partnership with

- Jackeline Alver from the Parasitology Service, Clinical Laboratory Department, at the Tegucigalpa University Hospital, from the Facultad de Ciencias Médicas, Universidad Nacional Autónoma de Honduras (UNAH), in Honduras
- Roxana Lescano who is the past Coordinator of the Peruvian IRB Network and current member of the Peru National COVID-19 IRB
- Julio Canario the Managing Director of Ethikos and the President and Executive Director of the Institute of Mental health and Telepsicology, in Dominican Republic and last but not least.
More than 400 people registered for the workshop on zoom. On the day of the workshop 171 participants joined from 46 countries (as shown on the map below).
Ethics Review in Pakistan During COVID-19

~ A National Workshop ~

offered by
Shaukat Khanum Memorial Cancer Hospital and Research Centre

in cooperation with
The Global Health Network (TGHN)
Good Clinical Practice Alliance – Europe (GCPA)
Strategic Initiative for Developing Capacity in Ethical Review (SIDCER)
MSc Programme in Bioethics, Centre for Ethics, Yenepoya University, India
TOBB University of Economics and Technology, Turkey

Tuesday, February 23, 2021
17:00 to 19:00 Pakistan Time (12:00 – 14:00 UTC)
Scoping review of Literature

This review examined the existing national literature in order to gain insight into the development of ethics review in Pakistan.

Search strategy:

Survey of IRBs

- Capacity mapping of IRB showed lack of
  - training for reviewing applications during the Covid-19.
  - guidelines in place for reviewing COVID-19 vaccine trials,
  - faced pressure from sponsors, and investigators for possible approval or disapproval of Covid-19 clinical trial.
We mapped literature on research ethics committees and ethics review framework in Pakistan to identify key insights during normal times (non-PHE) and PHEs, as well as “knowledge gaps” related to ethics review system in Pakistan.

**National workshop**
A situational analysis of Pakistan’s current ethics review system and local IRB practices.

**Survey of IRBs**
To analyze the preparedness and response of ethics committees (ethical review framework and process) in Pakistan for conducting ethics review of COVID-19 research (any other PHE research) during PHE.

**Knowledge gaps**
1. Dearth of published literature
2. List of all IRBs in Pakistan is not publicly available, it is not easy/possible to collect this information.
3. No comprehensive empirical data exist to enable to comment on competencies of IRBs in Pakistan.
4. During PHE, no formal mechanism of coordinated ethics review among diverse bodies involved in ethics review in Pakistan.

**Challenges/gaps**
- IRBs started to establish without government directive
- No mechanism to assess, survey, audit, register or inspect IRBs at national level
- NBC REC lacks patronage, Resources and funding
- Most members of IRBs lack formal training to implement their mandate
- No legal penalties for doing research without ethical approval or other violations
- Variable/questionable practices of IRBs
- Human research programs and training of researchers
- IRBs continued to function without any training, guidelines or SOP during COVID-19 and faced challenges.

**Solutions/Way forward**
- Call for action for regulatory measures:
  1. Comprehensive guidance for harmonized ethics review framework in Pakistan based on common standards across provinces
  2. Strong governance structure with patronage, and resources
  3. Synergies between diverse bodies involved in ethics review
- 4. Optimal Training opportunities
- 5. Defined mechanisms of ethics review during PHE.

Shaukat Khanum Memorial Cancer Hospital and Research Centre
Problem statement

- Pakistan’s nascent national ethics review system is barely two decades old and while functional at national (federal) level, does not as yet have strong provincial counterparts as well as local Research Ethics Committees or Institutional Review Boards

- Knowledge gaps

- Challenges
Knowledge gaps

- Dearth of published literature focussed on Research ethics
- List of all IRBs in Pakistan is not publically available, it is not easy/possible to collect this information.
- No comprehensive empirical data exist to enable to comment on competencies of IRBs in Pakistan.
- During PHEs, no formal mechanism of coordinated ethics review among diverse bodies involved in ethics review in Pakistan
Challenges

- NBC REC lacks patronage, Resources and funding
- No mechanism to assess, survey, audit, register or inspect IRBs at national level
- Most members of IRBs lack formal training to implement their mandate
- Variable/questionable practices of IRBs
- Long standing neglect
Framing the options

Develop harmonized ethics review

- Recommendation 1: Develop (co create) comprehensive guidance for ethics review that are adhered to across the ethics review system of Pakistan to enable harmonized ethics review.

- Recommendation No.2: Strengthen Governance structure by provision of sufficient resources.

- Recommendation No.3: Develop synergies and line of communication between IRBs/RECs and NBC-REC and the Drug Regulatory Authority Pakistan (DRAP).
Optimal Training

- Recommendation No.4: Develop plan how to optimize training opportunities as per need.

- Recommendation No.5: Research institutes must (be made accountable to) develop Human Research Programs and commit to provide support and training to its researchers in addition to IRBs.

Ethics review during PHEs

- Recommendation No.6: Develop guidance for ethics review during PHEs: (add reference here)
Contributions:

- The Global health Network
- Good Clinical Practice Alliance – Europe (GCPA) & Strategic Initiative for Developing Capacity in Ethical Review (SIDCER), Leuven, Belgium