



Developing Policy Recommendations for
Pakistan's Ethics Review Framework and IRBs in
Support of Public Health Emergency
Preparedness and Response

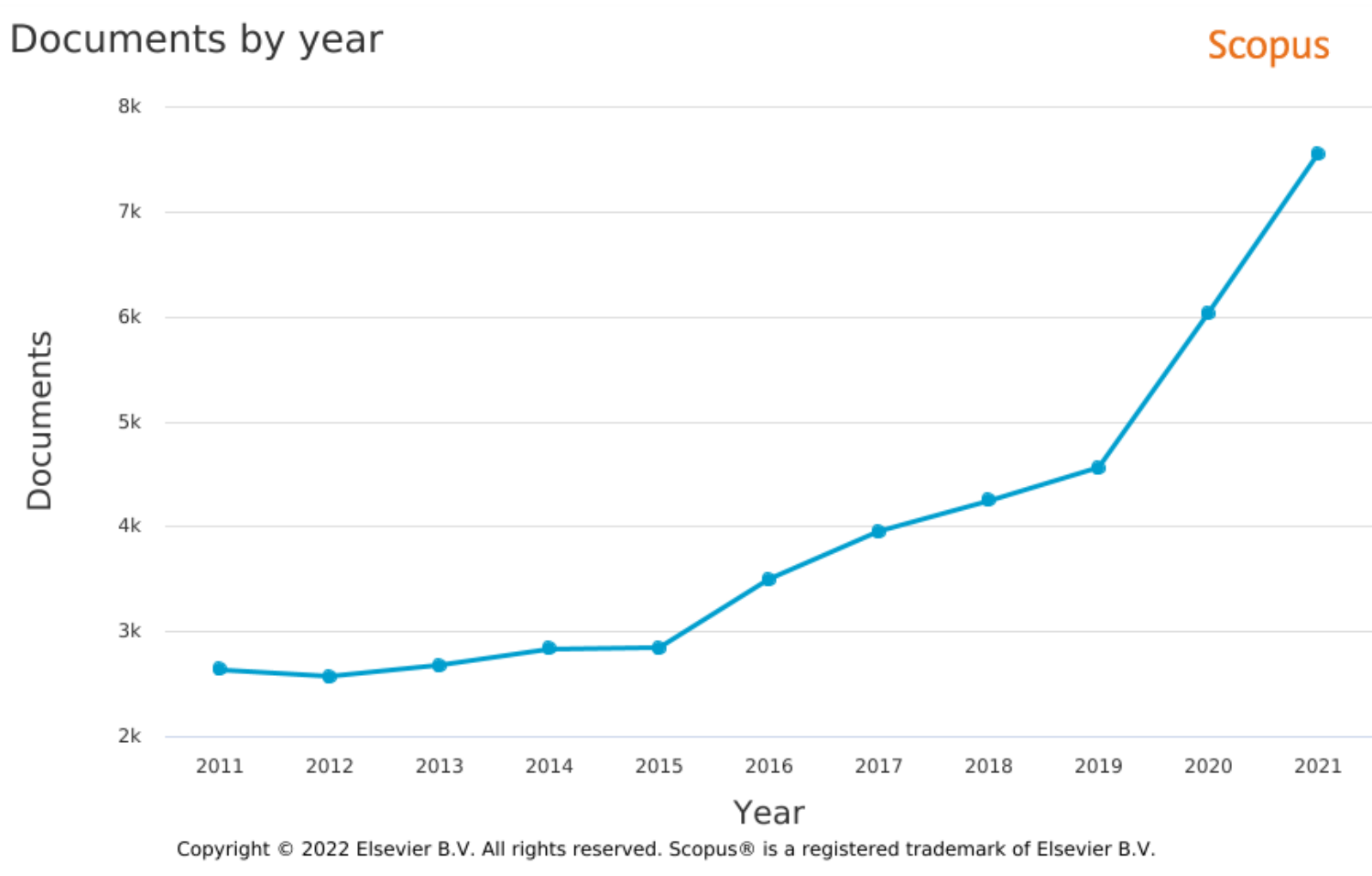
Shaukat Khanum Memorial Cancer Hospital and Research Centre

Fast Facts:

- ❑ Double burden of disease
- ❑ Population Growth
- ❑ Underinvestment in health
- ❑ Mixed health care system
- ❑ Key health indicators



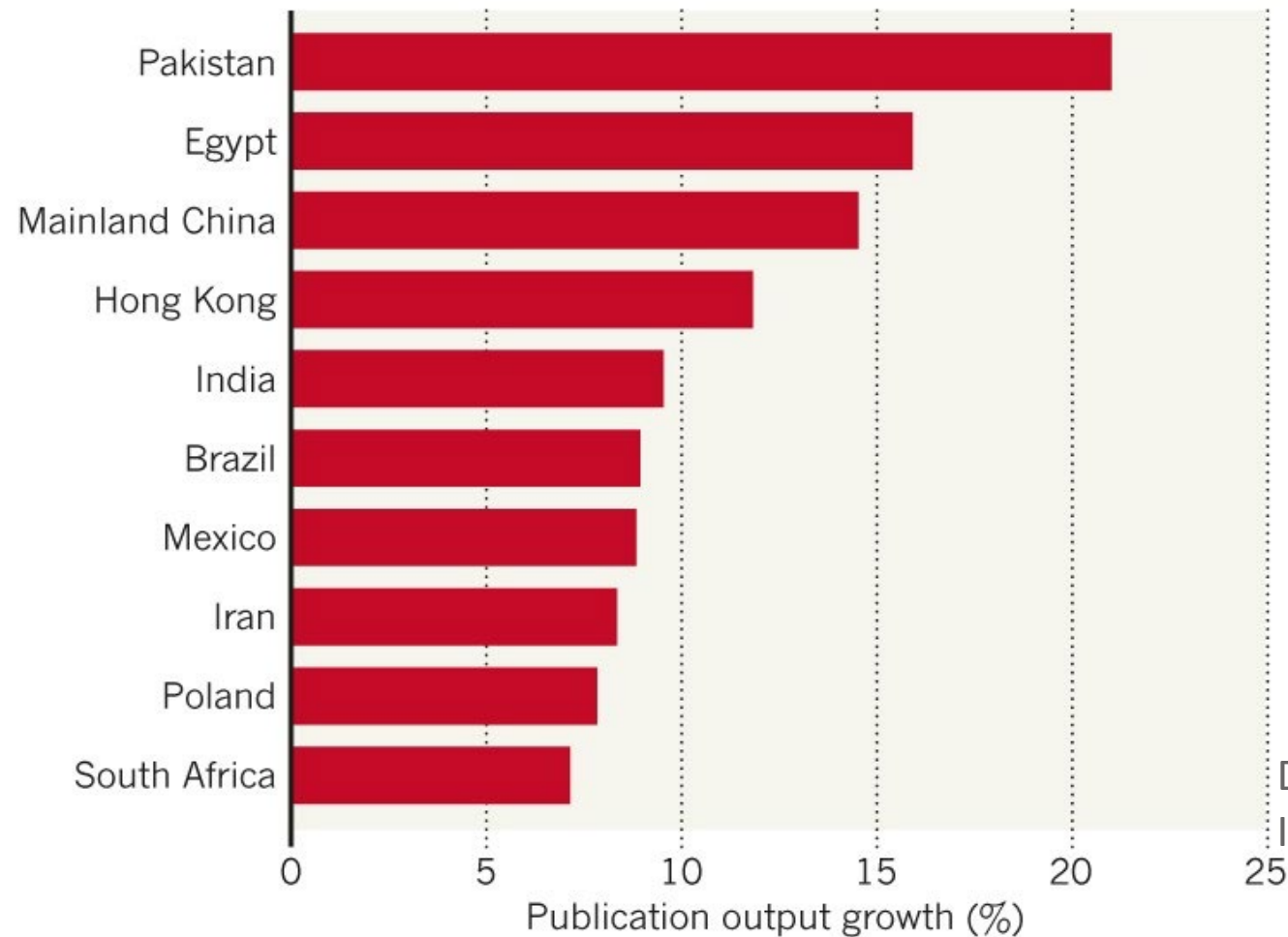
Health Research Output in Pakistan



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.



Data: Web of ScienceAnalysis: Institute for Scientific Information, Clarivate Analytics

What is the quality and impact of Research

- Quality of publications as well as the impact these publications are making at local, regional and international level pose a 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 I



COVID-19

Research Implementation and Knowledge Hub

Supporting Equitable Access to Conducting Research Across the Globe

[Home](#)

[Open Workshops](#)

[Working Groups](#)

[Regional Response](#)

[Research Implementation](#)

[Study Profiles](#)

[Research Resources](#)

[Reports](#)

Pakistan Ethics Framework

Developing a Policy Statement and Recommendations for Pakistan's Ethics Review Framework and IRBs in Support of Public Health Emergency Preparedness and Response

[THE TEAM](#)

[RESULTS](#)

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

Workshop: Ethics review preparedness during COVID-19: challenges and lessons learned.

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 Alger** 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



UNAH
UNIVERSIDAD NACIONAL
AUTÓNOMA DE HONDURAS



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).



National workshop



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:

- ((ethics[Title/Abstract] OR ethical*[Title/Abstract] OR bio-ethic*[Title/Abstract] OR bioethic*[Title/Abstract] OR "institutional review board*" [Title/Abstract] OR IRBs[Title/Abstract]) OR ("Ethics"[Mesh] OR "ethics" [Subheading])) AND ((Lahore[Title/Abstract] OR Faisalabad[Title/Abstract] OR Rawalpindi[Title/Abstract] OR Sargodha[Title/Abstract] OR Gujranwala[Title/Abstract] OR Sialkot[Title/Abstract] OR Gujrat[Title/Abstract] OR Jhelum[Title/Abstract] OR Sheikhupura[Title/Abstract] OR Nowshera[Title/Abstract] OR Mardan[Title/Abstract] OR Peshawar[Title/Abstract]) OR ((pakistan*[Title/Abstract] OR islamabad[Title/Abstract] OR karachi[Title/Abstract]) OR ("Pakistan"[Mesh]))))



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.



Mapping of Existing literature
Scoping review of literature

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
National workshop

A situational analysis of Pakistan's current ethics review system and local IRB practices

Examining the practical challenges and ethical issues faced by Pakistan's ethics review system and IRBs during PHEs

Situational analysis of training and education in Pakistan

Survey of ethics committees
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 PHEs, 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 researchr
- 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 rview during PHE

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



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



UNAH
UNIVERSIDAD NACIONAL
AUTÓNOMA DE HONDURAS

