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Abstract

Background: Mapping of ethical governance structures is very useful in identifying strengths and weaknesses in order to uphold integrity and ensure standardization. However, reliable countrywide data about ethical review committees (ERCs) is unavailable in Pakistan.

Aims: To evaluate the research ethics governance mechanisms at national level and at key healthcare institutions in Pakistan.

Methods: This pilot mapping exercise used a mixed-methods approach, involving a cross-sectional survey of 19 key healthcare research institutions, and structured in-depth interviews with the chairs of the National Bioethics Committee and the Drug Regulatory Authority of Pakistan.

Results: Eighteen institutions responded to the ethics mapping survey. Twelve public sector ERCs had a permanent structure and 17 had formal terms of reference. Seven ERCs claimed accreditation, although no central accreditation agency exists in Pakistan. Eight ERCs were chaired by the heads of the institutions. There was no fixed tenure for the heads in 13 committees, and 14 committees allowed multiple terms. Six ERCs had follow-up mechanisms for ethical approvals, and 6 took punitive actions in response to any deviation from an approved protocol, or to a scientific misconduct. Two respondents recalled situations where applicants pressured committee members for favourable approvals. Survey respondents mentioned the

lack of central research ethics guidelines as a weakness of the national governance system. Structured interviews revealed the need for formal training of committee members and capacity strengthening, particularly for administrative staff.

Conclusion: There is a need to develop guidelines for local ethics governance in Pakistan, and ensure accreditation of ERCs through the National Bioethics Committee to uphold the integrity of the ethics governance structure.

Keywords: bioethics, research ethics, guidelines, review committee, research protocols, accreditation, Pakistan

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Introduction

Low- and middle-income countries often have compromised health systems and therefore require effective research ethics governance to ensure robust and ethically sound research (1,2). Pakistan is a lower-middle-income country within the Eastern Mediterranean Region and has a developing health sector with limited research output (3). Pakistan operates a 2-tier ethics review mechanism at institutional and national levels. However, the quality of institutional review may vary significantly. Over the years, the number of institutional ethical review committees (ERCs) has increased to meet requirements for funding, collaboration, and publications (4). There are no verifiable data from Pakistan indicating the exact number, nature, and capacity of ERCs, and there is no accreditation process to ensure standardization. At the national level, 2 organizations are involved in ethical scrutiny of some categories of health research: the National Bioethics Committee Research Ethics Committee (NBC-REC), operational since 2004, and the Drug Regulatory Authority of Pakistan Clinical Studies Committee (DRAP-CSC), established in

November 2019. The latter reviews only clinical trials, but the former provides ethical review for a wider spectrum of human research. ERC mapping exercises are useful to identify strengths and weaknesses of ethics governance systems (5–7). In Pakistan, such attempts have been sporadic and restricted to particular institutions or provinces, providing limited information (8,9).

This study used a mixed-methods design to conduct a systematic investigation of research governance mechanisms at key public and private research institutions in Pakistan. It provides the first insight into national level mechanisms, examining NBC-REC and DRAP-CSC processes for their strengths, weaknesses, and overlaps. To the best of our knowledge, such an exercise has not been performed in Pakistan. This study is intended to serve as a pilot towards a nationwide mapping exercise.

Methods

Study design

This mapping exercise used a mixed-methods approach, involving a cross-sectional survey of key healthcare research institutions in Pakistan, and structured in-depth interviews with the chairs of two national regulatory institutions.

Mapping survey

A survey was developed specifically for the purpose of key institutional mapping, with 62 closed-ended questions, in 5 broad areas: (1) general information; (2) membership; (3) training for members; (4) procedure for review of proposals; and (5) challenges to review systems. Open-ended questions exploring the challenges to research ethics governance were also included. The tool was piloted on ERC members (not included in the current survey) to ensure face validity, which resulted in refinement of some questions.

The survey was administered to selected public and private sector institutes using purposive sampling. Twelve public sector institutes managed by the autonomous Pakistan Health Research Council (now known as Health Research Institute) were identified (9). One focal person from each centre was invited to participate. Three additional key public sector institutions other than the Pakistan Health Research Council were also included. Nonprobability purposive sampling was used to select 4 private sector institutions from 3 major cities because, based on our knowledge (10), these institutions produced a high volume of research papers, and were more suitable to provide the relevant information. Data collection took place in December 2020 and January 2021.

Structured interviews

Structured telephone interviews were conducted with the heads of NBC-REC and CSC-DRAP to better understand how these organizations operate (11). After obtaining verbal informed consent, the interviews were audio-recorded and transcribed verbatim.

Data analysis

Data obtained from the survey were collated through surveymonkey.com. Results generated included descriptive statistics such as frequencies and percentages. Questions were grouped under themes and subthemes. Data from the survey and interviews were merged to provide an overall picture of ethical governance. Ethical approval was obtained from NBC-REC.

Results

Mapping survey

Nineteen institutions received and completed the survey, giving a 100% response. One institution reported a nonfunctioning ERC; therefore, the data from 18 institutions with functioning ERCs were used: 14 from the public sector and 4 from the private sector (Table 1).

Characteristics of committees

All but 2 committees in the public sector were permanent, and 17 had formal terms of reference (publicly accessible in 10 cases). Fifteen committees conducted only ethical reviews, whereas 2 also provided scientific reviews. All committees reviewed research by staff and faculties, and 16 also reviewed student research. Nine committees accepted projects from other institutions.

Information regarding ERC procedures was available on institutional websites for 9 committees, although 17 respondents believed that this information was widely known across their institutions.

Seven respondents (5 public and 2 private) declared that their committees were accredited, although none identified an actual accreditation agency. Twelve ERCs reported following published research ethical guidelines (Table 1). Nine committees (7 public and 2 private) had designated budgets and 16 had secretarial support; of which, 13 had designated secretaries and 3 had no designated staff or budget.

Leadership of ERCs

Eight ERCs (all public) were chaired by the heads of the institutions, 4 were headed by

individuals from outside the institution, and 4 had institutional members as heads. The chairs of 17 committees were appointed by the institutions, and had no fixed tenure in 13 committees (10 public and 3 private). The chairs of 14 committees could serve multiple terms, with 8 serving their second term, and 2 their third and fourth terms. The other respondents either did not respond or were unaware of the term limits for their committees.

Membership composition

On average, committees had 11 members (range 3–21); 13 had 6–15 members, 3 had > 16 members, and 2 had 2–5 members. Committee membership comprised medical doctors (n = 18); researchers or members from outside the institution (n = 15 each); social scientists (n = 8); lay persons (n = 6); ethicists (n = 5); and nurses, religious scholars, or lawyers (n = 4 each). All committee members were nominated by institutions. In 11 committees (9 public and 2 private), there was no fixed tenure, 4 had up to 3 years, and 3 had > 3 years. Fourteen committees had provision for multiple tenures, whereas 2 reported limiting membership to only 1 term. All committees had mechanisms to co-opt additional reviewers.

Training of members

Fourteen committees had no training prerequisite for members; 9 provided training opportunities, and in 7, prior training was not mandatory. Only 2 committees (private) that required mandatory training also funded it. Training was equally likely to be provided at the institution itself, at another institution, or online.

Process of review

The review process in different ERCs is presented in Table 2 . Respondents were asked about deviation from the usual review process. Four respondents (3 public and 1 private) believed that 2–20% of research projects from their institutions bypassed their ERC. Four believed it was because of lack of awareness of ethical requirements; 1 believed researchers wanted to cut corners, and another said researchers considered their projects free of ethical concerns. One also said researchers bypassed the ERC because they were submitting to a journal that did not require ethical clearance. Provision for exemption from review was available for 12 committees. Fifteen ERCs had rejected proposals in the past, 1 had never rejected any proposal, and 2 respondents did not know if they rejected a proposal. Fourteen respondents could not recall external pressure on their committees to obtain approval for a research proposal. Two recalled such pressure, with 1 mentioning that the institutional head pushed for approval for a pharma-funded project.

Respondents had diverse understanding of the mandate of NBC-REC (Table 3).

Follow-up of research proposals

All the committees had record-keeping and archiving mechanisms, but only 6 (4 public and 2 private) had post-approval follow-up systems. Six respondents (3 public and 3 private) recalled punitive actions taken in response to deviation from protocols, or for ethical misconduct, with 8 reporting no actions. In 1 case, the penalty was retraction of the published work by the journal concerned.

Structured interviews with heads of national regulatory institutions

NBC-REC and DRAP-CSC are permanent institutions with secretarial structures. The NBC-REC secretariat was housed at the Pakistan Health Research Council, and DRAP-CSC at the Division of Pharmacy Services. The main role of the NBC secretariat was to receive proposals, forward complete proposals to the REC chair, receive the decisions from the chair, and forward them to the applicants. The secretariat also maintained the NBC website. Except for a short period during the peak of the COVID-19 pandemic, members of the secretariat were not involved in the actual review discussions. Another role played by the secretariat was coordinating with the Ministry of National Health Services Regulations and Coordination and government officials.

Membership of both committees was mostly restricted to those with a medical background, primarily physicians, although NBC-REC had elected members; all but 1 with formal qualifications in bioethics. All members of DRAP-CSC were nominated and had experience mostly in biomedical research. NBC-REC had a mechanism for providing training to its members, but there was no such provision at DRAP-CSC.

Approved proposals required a more stringent follow-up by DRAP-CSC because it was within their mandate to halt ongoing clinical trials or disallow research at a particular site if there are ethical concerns. That committee received its legal regulatory powers through laws governing DRAP. NBC-REC required researchers to submit progress reports during predetermined interviews, primarily for archiving purposes. Prior to the COVID-19 pandemic, NBC-REC reviewed proposals asynchronously via email. The rapid turnaround review for COVID-19-related proposals that required a 72-hour turnaround was implemented in April 2020. Meetings were moved online and scheduled as and when proposals arrived, which necessitated several meetings a month during the first wave of the pandemic. The system worked efficiently and therefore a decision was made to review non-COVID-19, regular proposals during virtual meetings. DRAP-CSC had monthly physical meetings but within 3 months of the onset of the pandemic, they also transitioned to online meetings, being held as and when required.

Challenges to research ethics governance

At the institutional level, most respondents identified deficiency of member training as a challenge to research ethics governance. Two respondents considered lack of resources for post-approval monitoring, and 1 respondent each identified conflict of interest, pressures for approval from within the institution, and negative perception of researchers about the review process. One respondent stated that the added responsibility of reviews was burdensome on the committee members and the chair.

Survey respondents were asked to share perspectives regarding challenges to research ethics governance at the national level. Overall apathy towards research ethics and absence of local guidelines contributed to weak governance structures. One respondent believed that the two national level review steps were an unnecessary duplication of effort, and the required fee payments added a financial burden. Another respondent mentioned that there was a lack of coordination between institutional ERCs and national regulatory institutions. Lack of national ERC accreditation was also highlighted.

During the structured interviews, the NBC-REC chair reported that limited secretariat support was a significant challenge to the functioning of the committee. NBC-REC relied primarily on a single-person secretariat and adequate follow-up of proposals was a particular challenge. In contrast, the DRAP-CSC chair identified no such issues.

Discussion

This study provided a systematic, albeit limited, mapping of research ethics governance systems in Pakistan. Previous mapping attempts conducted in Pakistan have cited poor response rates (12). The 100% response rate in this survey can be attributed to the smaller sample size and the use of personal contacts to engage respondents. This was the first formal account of the review role of DRAP-CSC. A previous study exploring national ethics committees in the Eastern Mediterranean Region included NBC-REC (13), while another study provided an in-depth analysis of NBC-REC during the COVID-19 pandemic (14).

The presence of functional national regulatory institutions is promising. NBC-REC, formally notified in 2004, started with sporadic reviews in the initial years, but has since increased its review portfolio several folds. However, it has its challenges, including limited administrative and secretarial support. The secretariat has mostly not been involved in actual meetings, leaving tasks such as minute taking to the chair.

Duplication of ethical review by NBC-REC and DRAP-CSC of proposals already reviewed within institutional committees was identified as a cause of delays. However, given the nascent field of ethics governance in Pakistan, and variability of review capacity at institutional levels, it is important that NBC-REC continues to play a central review role. The current process ensures uniformity and quality control in governance that may not otherwise have been possible in Pakistan because of the lack of accreditation and regulation of ERCs.

The absence of national guidelines governing research ethics was highlighted as a deficiency. Locally adapted guidelines play a vital role in informing context-dependent governance (15). Twelve of our respondents reported following guidelines from various sources, including NBC and the Higher Education Commission. However, these institutions had no actual guidelines, which highlighted the unfamiliarity with the review processes among institutions expected to be more knowledgeable about these matters. Another important challenge identified at the national level was that while ERCs knew about NBC-REC, their responses reflected a lack of clarity regarding its mandate. If study participants occupying prominent roles in research institutions were confused, then a significantly wider lack of awareness can be assumed, which paves the way for systems to be bypassed. There is anecdotal evidence of foreign-funded studies requiring NBC-REC review being published without ever reaching the committee.

CSC-DRAP is a new development in research ethics governance, providing an enforcement arm to the regulatory framework. Its mandate is limited to reviewing and regulating clinical trials, and it has reviewed and permitted 22 mostly COVID-19-related clinical trials between November 2019 and January 2021. Some of the work of DRAP-CSC is a duplication of that of NBC-REC, but it also provides accreditation to clinical sites, contract research organizations, and physical inspections of trial sites. DRAP authorization is a prerequisite for importing and marketing of drugs in Pakistan; therefore, the institution can prevent a clinical trial from starting, or halt it in case of concerns. With barely 1 year of experience, it is too soon to infer the long-term impact of this institution.

The number of ERCs has increased over the years in Pakistan. In our study, all participating institutes except 1 had a functional committee. Nonexistence of an ERC within the Pakistan Health Research Council umbrella is a matter of concern, reflecting a possible lack of research at that institution. The institution is located in an underdeveloped province with poor health indicators and low research output.

The trend towards an increase in the number of institutional ERCs reflected heightened awareness for such a need. However, these committees often only exist on paper, and may not conduct rigorous review of research projects (16, 17). The increasing number of ERCs could be

in response to the request by regulators such as Higher Education Commission, College of Physicians and Surgeons Pakistan, and Pakistan Medical Commission requiring physicians to publish research so they can qualify for fellowships or secure promotions, rather than a desire to observe ethical norms during research (18, 19).

Institutional commitment to ethical review governance is critical for successful functioning of committees, and is reflected in the support provided through budgets, secretarial assistance, and training opportunities. In this survey, while most committees had some secretarial support, only 9 had budgetary allocations. A well-functioning secretariat assists in the organization of meetings and ensures steady communication with applicants and proper post-approval follow-up, and requires funding (20). ERCs now require members to obtain formal certification in research ethics (21, 22). However, only 2 ERCs in this study had any training requirements. This is concerning because most committee members had no such training in their professional education.

Our survey illustrated diversity of membership in most committees. It was unsurprising that most committees primarily had physicians as members because the survey covered only medical institutions; however, it was encouraging to note that most committees also had external representation. This added diversity and led to unrestricted discussions, with external members generally being more forthcoming with critical comments (23). Only 4 committees had nurses, which, while expected because of their marginalized status in the medical hierarchy, was disappointing because their exclusion resulted in the loss of important perspectives (24). Although lay person and community representation on committees is recommended, only 6 committees in our survey had such representation. This can be explained by the exclusionary culture associated with medical practice in Pakistan. An encouraging finding was the inclusion of social sciences representation on 9 committees. This reflected a move of committees beyond their traditional comfort zone of reviewing biomedical research, and an enhanced ability to review public health and social sciences research. It was noteworthy that 5 committees had ethicists as members, implying that few committee members may have received formal bioethics training.

Type and length of tenure for members and chairs emerged as a concern. Membership and chairpersonship were entirely by nomination, which may have limited committee membership to older people, given the hierarchical culture in Pakistan. The lack of fixed tenure indicated potential stagnation. The ERC being chaired by the head of the same institution reflected a potential conflict of interest. While this was an accepted trend noted in an unpublished study in 2010, this survey showed that 8 of the 18 committees were chaired by their institutional heads (25, 26). Our sample was limited, but it was alarming to see that institutions were unaware of or were ignoring this potential conflict of interest.

Our effort to present a realistic snapshot of research ethics governance in Pakistan had some limitations. The survey covered only selected institutions, and the interviews only captured the perceptions of the chairs of the 2 national committees, and not the members, whose views could add valuable insight.

Conclusion

Our survey indicated variation in the type and quality of review at the institutional level, which was a reflection of the operations of the ERCs. Accreditation of all ERCs through the NBC could ensure uniformity, quality control, and stronger cohesion between national and institutional ethics governance systems. This study highlights the need to have a comprehensive, countrywide mapping of research and ethics regulatory capacity in Pakistan, and the need for national research ethics guidelines. A local, relevant guidance document would be important to provide a framework for ethical conduct, especially with the growth of research in Pakistan.

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Competing interests: None declared.

Analyse de la situation de la gouvernance de l'éthique de la recherche au Pakistan

Résumé

Contexte : La cartographie des structures de gouvernance de l'éthique est très utile pour en identifier les points forts et les faiblesses en vue de maintenir leur intégrité et d'assurer leur normalisation. Cependant, il n'existe pas de données fiables à l'échelle nationale sur les comités d'évaluation éthique au Pakistan.

Objectif : Évaluer les mécanismes de gouvernance de l'éthique de la recherche au niveau national et dans les principaux établissements de santé au Pakistan.

Méthodes : Cet exercice pilote de cartographie a utilisé une approche mixte, impliquant une enquête transversale auprès de 19 établissements clés de recherche en santé, et des

entretiens structurés approfondis avec les présidents du Comité national de bioéthique et de l'Autorité de réglementation pharmaceutique du Pakistan.

Résultats : Dix-huit établissements ont répondu à l'enquête de cartographie éthique. Douze comités d'évaluation éthique du secteur public possédaient une structure permanente et 17 avaient un mandat officiel. Sept comités ont demandé une accréditation, bien qu'il n'existe aucun organisme d'accréditation central au Pakistan. Huit comités d'évaluation éthique étaient présidés par les responsables des établissements. Treize comités étaient sans mandat fixe pour les responsables, tandis que 14 autorisaient les mandats multiples. Six comités disposaient de mécanismes de suivi pour les approbations éthiques, et six avaient pris des mesures de sanction en réponse à tout écart par rapport à un protocole approuvé ou à une faute scientifique grave. Deux répondants ont évoqué des situations où les demandeurs avaient fait pression sur les membres du comité pour obtenir des approbations favorables. Les personnes interrogées ont pointé l'absence de lignes directrices centralisées sur l'éthique de la recherche en tant que faiblesse du système national de gouvernance. Des entretiens structurés ont révélé la nécessité de soumettre les membres du comité à une formation officielle et de renforcer les capacités, notamment en ce qui concerne le personnel administratif.

Conclusion : Il est nécessaire d'élaborer des lignes directrices pour la gouvernance locale de l'éthique au Pakistan et d'assurer l'accréditation des comités d'évaluation éthique par l'intermédiaire du Comité national de bioéthique afin de maintenir l'intégrité de la structure de gouvernance de l'éthique.

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