**How do Ethics Committee members and Medical Researchers view public engagement in the ethical conduct of biobanking research? Perspectives from India**

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ABSTRACT

Public engagement especially in biobanking and genetic research, allows a shift from ‘expert driven’ ethics to a more inclusive bioethical reasoning that encompasses multiple contexts and multiple perspectives. 21 Ethics Committee (EC) members and 22 medical researchers underwent in-depth interviews with a focus on public engagement in biobanking research, the results of which were juxtaposed with public perceptions from across the world including India. The views of both ECs and MRs appear to be influenced by a conventional medical research framework with defined immediate risks and immediate benefits. The alternative theoretical framework that emerges is a shift from an individualistic and regulatory driven ethical approach to a communitarian focus on collective values, and the common good of society. The ethical value of ‘trustworthiness’ of the researcher and the institution appears central, demonstrated through sustained deliberative engagement with the public. Public engagement allows for greater acceptability, participation, sustainability and ethical conduct in biobanking research. [153 words]

INTRODUCTION

We look at ‘public involvement’ as a philosophy within the ‘participatory paradigm’ (1). This has its normative underpinnings in approaches of Communitarian ethics, reflected by Plato and Aristotle, among others, ( 1, 2, 3) in which public perspectives are central to ethical positions, although moral relativism may be an issue (3). Public involvement is also situated within ‘Feminist’ and ‘Care’ ethics, in that specific experiences and points of view of people in a situation determine ethical behavior in addition to just abstract principles (1). We extend ‘public involvement’ beyond ‘subjects’ in research to the notion of ‘participants’ in every sense; their expectations of the ethical conduct of biomedical research and its governance and their voice in the development or enhancement of ethical guidelines (1, 4,5).

A recurring conclusion of studies on research participants has been that the views of the public or the participant is important in defining or refining research ethics regulations and that they (the public) are an important stakeholder who can inform researchers and regulators on concepts which are often considered beyond their scope and understanding (6,7).

In biobanking, specific reasons for public engagement include the starting premise of public good and societal benefit (8,9), gaining the trust and confidence of the public to contribute to a biobank and multiple ethical issues linked to privacy of information; the possibility of secondary or extended research, issues related to consent; the commercialization of research outcomes and benefit sharing. (10,11,12,13) Public engagement strategies are important means to address the ethical and other challenges surrounding biobanks and to uphold the goal of protecting participants (13, 14,15,16,17). There is a limited understanding of perceptions towards public engagement in medical research especially biobanking research (16). Given that researchers are the interface between the public and the translation of research for public good and that research ethics committees are central to the governance of research and the protection of participants, this paper seeks to understand how medical researchers and ethics committee members in India view public involvement in biobanking research by juxtaposing their views against the perceptions of the public themselves.

METHODS

Sample Selection

Primary data were collected from Ethics Committee (EC) members (N= 21) and Medical Researchers (MRs; N=22) using qualitative methods as the purpose was to explore perceptions in depth. Sampling was purposive, covered the categories of ethics committee members as laid down in the ICMR guidelines, (17) and encompassed different institutional backgrounds as indicated in Table 1.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Basic Scientist (BS) | Clinician (CL) | Legal Expert (LE) | Social Worker / Ethicist (SWE) | Lay Person (LA) | TOTAL |
| Government Medical College (GMC) | 2 | 1 | 1 | -- | 2 | 6 |
| Private Medical College (PMC) | 2 | 2 | 1 | -- | 1 | 6 |
| Charitable Hospital (CH) | -- | 1 | 1 | 1 | -- | 3 |
| Corporate Hospital (CoH) | 1 | 1 | -- | -- | 1 | 3 |
| Independent (Ind) Ethics Committee | 1 | -- | 1 | 1 | -- | 3 |
| TOTAL | 6 | 5 | 4 | 2 | 4 | 21 |

Table 1: Distribution & Profile of EC members selected for this study

A spectrum of medical researchers conducting research using stored human biological samples were purposively selected from government and private medical colleges; basic science research institutes; ‘commercial’ private hospitals, pharmaceutical and biotech companies and contract research organizations. (Table 2)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | Basic Science Specialists (BSS) \* | Clinician Researchers(CRs) \*\* | TOTAL |
| Academic Organisations | Medical Colleges (MC) | 4 | 5 | 9 |
| Pure Science Research Institutes (RI) | 5 | 0 | 5 |
| Commercial Organisations | Private Hospitals (PH) | 1 | 2 | 3 |
| Contract Research Organisations (CRO) | 2 | 0 | 2 |
| Pharma / Biotech Companies (CO) | 2 | 1 | 3 |
| TOTAL | | 14 | 08 | 22 |

\* *Pharmaceutical medicine, cancer biology, neurosciences and mental health, human genetics, molecular medicine, proteomics and epidemiology*

\*\* *Hematology, oral oncology, surgical oncology, pediatric nephrology and psychiatry.*

Table 2: Distribution & Profile of Medical Researchers selected for this study

All participants were from the city of Bangalore, South India. Names and contact details were sought from the internet and from existing contacts and followed a snowball method of sampling. The aim was to get a range of views and not to compare sub- groups. There was no predetermined sample size and data collection continued till data saturation was reached. Codes have been given to denote the category a person belongs to. Gender and age were not criteria for selection or analysis.

Data Collection

In- depth interviews were chosen as the preferred tool for data collection as it allowed for comprehensive probing, and avoided the influence of other respondents and socially desirable responses in a group setting. All interviews were carried out by the first author, in English, the language of choice of all respondents and at a place of convenience, usually their work place. The interview guide had two broad sections; the first addressed specific ethical aspects of biobanking research based on an unfolding case vignette of a hypothetical research study using stored human biological samples. The second focused on the broader aspects of public trust and public engagement. The funneling technique was used in the design of questions; the opening questions were broad, and then narrowed down with specific probes based on personal experiences. Each in-depth interview lasted 60-90 minutes. Data was collected between September 2014 and November 2015.

In order to obtain a range of public perceptions towards biobanking and add to the data collected by the authors in an earlier study with the Indian public which achieved data saturation on a relatively small sample, possibly because of a general lack of awareness of biobanking(16), data was pooled from multiple sources (supplementary file). This allowed for ethical issues to be compared between three constituent groups – the Public, Medical Researchers in the Indian context and EC members in the Indian context. We consider this reasonable as the latter two groups would be expected to be more informed about biobanking, given its emerging importance. Data was tracked using PubMed with the key words ‘biobanking’ AND ‘public’ AND ‘perceptions’. This yielded 26 papers. In addition, the authors also used papers that they had collected manually over a period of 3 years.

Data Analysis

All interviews were audio recorded, transcribed, and rechecked with the audio recording for errors. Coding was an iterative process that started during data collection and followed an inductive approach guided by Grounded Theory (18,19). Open coding was done by the first author on every line of the transcribed data using NVIVO (version 9.0) software whereby a coding framework with themes and sub themes evolved. (The themes identified were reviewed by the other two authors and differences were discussed till consensus was reached. To analyse the gaps in perception between the EC members, MRs and the public, the views of the public on ethical issues in biobanking from earlier studies in India and other countries were summarized along specific themes. The purpose was not to validate specific outcomes but rather to highlight views of the public on the one hand and MRs and EC members on the other. At the next level, themes were unified into meta-themes with an exploration of new theoretical constructs of public engagement as an ethical premise.

ETHICS APPROVAL

Ethics Approval was received from the Institutional Ethics Committee of the St. John’s Medical College, Bangalore. Written consent was obtained from participants. No payment was made to them.

RESULTS

Four broad themes convey the key perceptions of the public towards biobanking. Views of the EC members and the MRs in this study have been presented with regard to these themes, focusing on the synergies and gaps between their views and that of the public. The tag of the organizational category and the membership type has been used to denote a quote of the EC member and the tag of organizational category and researcher type has been used for the MRs.

1. **Expectations of Biobanking Research**

MRs believe that people have a ‘false set of expectations’ (BSS, RI) from biomedical research. In their view, public participation in medical research is primarily for direct health benefit – this may not occur (BSS, CRO). MRs admit that they are unable to effectively communicate with the public, particularly about the possibility of failure in research.

Most EC members admitted that they were not familiar with ‘biobanking research’ but did review ‘retrospective studies using stored samples’. While the ECs seem to view research in terms of long term benefit to society as do the public (8,9, 20,21 ,22,23), ECs believe that the public are unaware of the long term benefit of biobanking research and are unsure of how to convey this message . ECs see their role primarily as reviewers of the ethical issues in research proposals and can only assume and believe in the long term benefit to society of biobanking research (BS,GMC, PMC).

Published literature suggests that people are generally willing to participate in biobanking research or are even optimistic about it but with certain caveats such as the expectation of societal or healthcare benefit.( 8, 9, 16, 20, 21, 22, 23) Even Asian communities had an expectation of positive outcomes on health care while participating in biobanking research (24 , 25,26,27).

1. **Perceived Risks**

ECs and MRs did not consider ‘risk’ an issue in biobanking studies, mainly because there was no ‘intervention’ for the subject. Hence, the long term benefit to science and society outweighed any ‘risk’. In contrast, the public voiced fears about the confidentiality of their personal information, the commercialization of research, the transfer of samples and, to some extent, the disclosure of results to family members and the implication of results to health care (10,11,14,16, 21, 25, 28).

For the MRs, maintenance of confidentiality was a fulfillment of an EC regulation. They believed that it was “not too big an issue” for people, especially those with minimal education (BSS, CO). ECs on the other hand felt that to a large extent, doctors did not think much about confidentiality and needed to be trained in this matter (LA,CL,GMC). The legal importance of not having a person identified and their privacy protected was emphasized by ECs. A minority of EC members raised issues about the implications of breach of confidentiality in terms of personal damage to the person’s reputation, job prospects, and health insurance coverage. The risk of losing confidentiality of medical information is perceived differently across the world, with privacy and controlling access of medical records a more prominent concern in the Western public than in Eastern communities (14, 29, 30). People feel that loss of confidentiality is a reduced risk if the MR is “trustworthy”, if their sample and data is “handled responsibly” and the “context understood”, and if there is a possibility of a therapeutic outcome (16, 21, 22, 25, 31, 32, 33). This point on ensuring safeguards and enabling trust was not raised by both ECs and MRs in the present study.

The commercialization of research outcomes and its implications were a perceived risk for biobank participants . Basic scientists felt this was not an issue as commercial agencies were not interested in their type of research. Clinician researchers, on the other hand, felt that companies sponsoring the research should ensure that health benefits accrue to the community of patients. ECs did not see themselves as having much of a role in this matter. A minority, mainly the lay voices on the ECs were emphatic that a sample given for diagnostic purposes and fully paid for by the participant could not be exploited for research with a commercial intent. This was in line with the views of the public (16,20,34). In most countries, while profits and monetary gain out of a ‘donation of a sample’ was unacceptable, the reality of the need for commercial investment to translate research into improved diagnostics or clinical interventions of public benefit was acceptable (16, 20, 34). An open discussion and sharing such information with sample contributors is considered desirable (9, 16, 21). In general, people place more trust in individual researchers than commercial organizations and insurance companies (35).

People also fear the risk of being discriminated as a community or a country, if samples are transferred (34), MRs felt this was more a governmental regulatory issue which restricted and impeded their research. Lay persons on ECs were concerned about ‘misuse’ specifically in terms of racial discrimination, eugenics and even bioterrorism. This coincided with the public in certain countries who were concerned about the values, religious beliefs etc. of the place or researcher receiving the samples being different from those of the contributor (34,36). Most of the other EC members in our study did not think people would be concerned about what happened to their sample after donating it and hence did not consider this an important ethical issue apart from legal statutory requirements and inclusion in the consent form. MRs believed that regulations about transfer of samples were outdated with novel research approaches especially involving molecular biology and advancing technologies and did not factor public perceptions in the issue of transfer of samples.

While disclosure of results to the family were not viewed with fear in most studies, two from Australia and Canada emphasized the need for consent of the individual and family counseling as prior requirements to revealing results to the family (21, 37). EC members also emphasised the role of genetic counselors which MRs considered ideal, but impractical in India. The dependence on the doctor to ‘take the call’ was a common view of both MRs and ECs.

1. **Issues of Consent and Personal Autonomy**

The ethical issue of great concern across a number of studies on biobanking research is to do with ‘consent’. For both ECs and MRs, consent was the first and primary ethical concern in stored sample or biobanking research. ECs in general and most MRs stated that this was a mandatory requirement that needed to be fulfilled. Absence of consent could jeopardize secondary research and complicate ‘commercial claims’ in the long term (most MRs, EC-BS, CoH).

The public consider it ‘morally correct’ to have their consent sought, explaining that it gave people control, and allowed for ‘active choice’, and ‘voluntary contribution’ (9, 16, 21, 38). The importance of getting the consent was not, in the eyes of the public, a legal or contractual fulfillment, which they felt protected the researcher and the institution (16), but a process of reinforcing their understanding of the purpose of the research. They also expected it to be taken at a time when ‘they were not in pain’ and in a ‘clear state of mind’ (9). The value of consent as a “person-centered” philosophy, with maximal disclosure of information, including, explaining the importance of the individual’s sample, the kind of diseases that would be researched and the possible implications of such research was what was considered ‘informed consent’ even though the exact research might not be known at the time of consent (16, 25, 34). Lay persons and social workers on ECs seem to have a similar outlook. People also wanted to enable research rather than have their consent delay or waste resources of the research (9, 36, 38); this was echoed in the views of most MRs, who were confident that as “patients have a certain amount of faith in the institution or the doctor-researcher, there was no need for re-consent for secondary or extended use of the sample”. However, studies from developing countries suggest that people wanted to be kept informed regarding outcomes of the study and not be forgotten after their initial consent was taken (9, 16, 31, 34).

The nature of ‘broad consent’ expected by most basic scientists on ECs as well as MRs included a clearance for storage and disclaimers regarding benefits from outcomes, commercialization, and patents. Thus, while it seems that the public understood the reasons for broad consent in terms of the greater good of enabling science and research, MRs had a narrower perspective based primarily on their research interests.

For some communities the additional assent from a family or a community through a group assent system would ensure that scientists remain accountable and cultural fears are addressed. (23, 34, 39) There was also the expectation that ECs would monitor research and ensure that the interests of the participants were protected even if the samples were anonymised (22). MRs involved with genetic research spoke about community and family fears of identification even when anonymised in the case of pedigree studies of families with rare diseases. ECs had not thought about these issues.

1. **Expectations of public engagement**

The need for public engagement in biobanking research is a polarized debate. Most studies indicate that public knowledge about biobanks is generally low and some suggest that the public, is thus, not in a position to provide informed views. A contrary view is that this is the very reason why an active engagement with the public is important - so that through discussion and deliberation, people get informed and become active stakeholders (8, 29). Among most of the respondents of this study, the notion of ‘public’ was constrained to ‘research participants’, or ‘potential participants’ from patients visiting the hospital and, by very few, as the ‘general populace’.

Greater awareness about research and reasons for public support: People want research to be demystified and the use of biological sample donations and biobanking research to be explained in an “easy to understand” and “engaging manner” from a “credible source” (25, 40). Public also felt that it was ‘the moral duty of the researcher’ to provide clear communication (40). In contrast, certain MRs felt that this would ‘tie their hands’ and that such communication was a luxury given the constraints of time and resources. Certain clinicians admitted to limitations in the doctor-patient communication which went beyond health care, “...in every sphere in India, we tend to talk down to the general community” (EC, CL, PMC). ECs felt that it was not their role to create awareness and engage with the public. The media was cited as the means to reach the public and educate them about ethics. (EC, BS, GMC)

Actively seeking the views of the public: The idea of listening to the public rather than of educating or instructing them was alien to the MRs and ECs and associated with some nervousness and defensiveness by basic scientists who felt that “if you start asking people about their expectations, it would start pulling you down … they will ask what benefit will I get? Then people will not allow the person to do research. It is an obstructive thing… some people will start nagging you”. However literature indicates that the greater the discussions on the purpose of the research and sharing of information in a consultative, deliberative mode with the public, the less restrictive is the consent (38), and there is greater trust and an alignment of values (33, 39). The outcome of active engagement results in people moving away from being passive objects of research (41) and enables greater accountability and acknowledgement of ‘contribution’ (16). A lone voice of a lay EC member stressed the need for ECs “to build a sense of community and common good among the public” (EC,LA,CoH).

Shared governance of the biobank facility: While multi stakeholder representation including that of different professional groups, researchers and members of the public was suggested as a means of sharing governance of the biobank (9,33); MRs felt that ensuring that the person’s sample was used ‘only for scientifically valid purposes’ was the crucial point of good governance. Having a lay person and the other non- medical persons on the EC was the other way that ensured public participation in decision making with regard to the ethical practice of biomedical and biobanking research. These lay members were considered “trained and who kept abreast with latest know how on medical research while the general public were unaware and hence had misconceptions” (EC, SWE, IND; MR,AC, CR). There seems to be a reluctance on the part of MRs in perceiving the public as ‘stakeholders’ because of their ‘ignorance’ and possible ‘interference’ with the research process, while lay members of ECs were more open to engagement with public. This openness and transparency was suggested by the public as the means to ensure public accountability to inspire trust (9, 16, 39, 40). The concept of Community Advisory Boards (25, 40, 42), to develop communication strategies and sense the sentiments of people (25, 36) was not mentioned by any MR or EC member.

DISCUSSION

The following inferences can be drawn about biobanking research and the ‘phantom public’ (8) from this study; that:

* People, think and have opinions. Circumstances make them passive and fearful. Their fears affect their perceptions. They are sensitive to the practical issues of research. It seems that people in general have an intrinsic desire of serving the common good and of going through some inconvenience, or enduring some personal risk for the sake of the ‘greater good’. They expect assurances that their contribution to scientific research results in societal benefit , and expect guarantees of trustworthiness from the researchers and the system using their samples .
* for MRs, it is the research and the science that are the end points, with the hope that humanity will be benefited in the long run. Knoppers and Laberge raised similar questions in the mid -nineties, of whether in sample based research, ‘persons [are seen] as sources’, or ‘samples as persons? (43)’. Most biobanking research requires prospective medical data through follow up with the ‘sample source’ and hence would require a sustained contact. The clinician-researcher who is in direct contact with the ‘sample source’ is compelled to be more engaged with the contributor and also to communicate possible outcomes with clinical significance to the individual or the family.
* ECs see ‘Consent’ as their major concern with biobanking research, otherwise considered ‘low risk’. The mandatory nature of the consent is to enable secondary research, keep the researcher and institution ‘safe’ and avoid any problems with regulators or publishers. The frame of reference for ECs appears to be conventional research and clinical trials. In the single study, clinical trial encounter, the protection against harm to the participant is clear and the role of the EC quite well defined. Since biobanking involves the use of a large number of samples from a population, addressing wider population interests is a challenge.

The ‘active’ participant will likely have a greater ‘stake’ in the research process, demand opportunities to articulate needs and expectations and be discerning, reducing reliance on blind trust and ultimately ensuring sustained involvement in research. Acknowledgement of being a ‘contributor’ (16,29) rather than a ‘source’; a participant rather than a ‘subject’ entitled to ‘two way altruism’ (16, 44) as for instance by ‘giving back’ test results research findings and new knowledge and of being a recipient of ‘benefit sharing’ are suggestions from the public to engage them in biobanking research. Figure 1 summarises the changes in position and outlook demanded of longer term biobanking research in three key stakeholders; the public, the researcher and the ethics committee.



Figure 1: Researcher – Ethics Committee – Public dynamics in ethical research

Thus, as shown in figure 1 there is a need for a dynamic shift in roles and beliefs of MRs and ECs with the changing models of research and its accompanying ethical imperatives. The present ‘principlist’ ethical approach needs to give way to a communitarian focus on collective values, and the common or greater good. (3, 33, 37) This shift would involve a ‘bottom up’ listening to and an understanding of the ‘public’. The Role of the EC as the third axis linking the needs of the public to the needs of the researcher and to ethical scientific advancement is important. This is not difficult in the way the EC is structured because lay / non medical voices exist in the EC and the scientist / medical voices are sufficiently represented. Importantly, this should lead to a better dialogue between the different ‘voices’ on the EC and an arrival at a consensus concerning public engagement and other contentious issues. Felt et al argue that Ethics Committees need to move from being ‘pure expert bodies’ who function as ‘technocrats’ and need to engage in ethical debates with the public as medical research advances so that the underlying values can be discussed (5). The evolving nature of ethical positions with regard to new areas of medical research and medical technology compels us to have an open mind and admit to arriving at best practices only in consultation with those most affected. There will always be a need to understand the discrepancies between institutional and local values; individual and collective values (45). Confidence that this is possible and worth it in the long run, can be drawn from the studies of the San Community in South Africa (46) and the UK Biobank (47).

CONCLUSIONS & WAY FORWARD

The key element of “trustworthiness” has emerged as central to the MR-EC- Public relationship, articulated as two aspects: transparency and accountability.

The former can be achieved by an active communication with the public disclosing and discussing the long term purpose, the benefit, the safeguards towards risks and outcomes of the research and an active listening to the views, feedback, fears and expectations of the public from the research they are expected to participate in.

Accountability can be achieved by governance structures that include the voice (s) of the local communities and ‘affected population’ so that rules and guidelines regarding usage, transfers etc can be determined by a cross section of people who represent the stakeholders.

It is evident from the analysis of the various forms of data used in this study that public engagement is vital for the ethical conduct of biobanking research where the focus moves from the individual to the public. The gap that exists between the views of MRs/ECs concerning public engagement in biobanking research and the views of the public need to be bridged for wider acceptability, greater participation and sustainability of research in the future..

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