

Assessment of knowledge and attitude about bio banking amongst the general public and their willingness to donate bio specimens from a hospital in India

Arathi K¹, Vina Vaswani², Vijaya Hegde³, Arvind Karikal⁴.

ABSTRACT

This study aims to know the attitude and perceptions of biobanks among the general public and their willingness to donate bio specimens from a hospital in India. Biobanks collect, store bio specimens for diagnosis, treatment and research purpose. According to modern bio banking, bio specimens needs to have standard operating procedures to do so. The bio specimen should be kept confidential and anonymous. Do they have an awareness of the role of biobanks? Do they know the concept of consent and implications of retaining specimens in biobanks? This paper evaluates these areas. A cross sectional study was conducted among general public above 18 years of age using convenience sampling. The data was obtained through a questionnaire which was distributed via online using Google forms and assessed the ethical perception of the general public regarding their willingness to donate own biological samples for teaching and research purposes and their awareness and attitude on biobanks. A total of 200 participants were included in the study. 71.4% participants did not have any prior knowledge about biobanks. 59.6% of the participants were willing to donate the biospecimens for advancement in medical research, benefit the society and future generation. 43.8% of respondents emphasised the main discouraging factor in participation in biobank research is that they have fear of sample exploitation. 37.9 percent participants responded that they would like to specify the scope for use when granting permission to use their sample for research. Biobank will advance in medical research only when medical institutes and government bodies' install privacy, consent laws and initiate lot of awareness programmes to improve public perspectives and knowledge about biobanking.

Keywords

Biobanking, Consent, Biospecimens, Ethics, Perception.

INTRODUCTION

Patients submit blood, tissue, biological material to hospitals or institutes during surgical procedures or as a part of the diagnostic work up. Only a small part of the collected sample is usually processed for the diagnostic purpose, the remaining portion of such biological material can be either disposed or be retained for academic or research studies. Commercial entities which store such biological materials for a fee are known as biobanks. These biobanks collect and store different types of biological material, ranging from specimens for therapy such as biopsies to those left over from surgery¹.

All over the world a huge quantity of biological material has been retained under

1. Reader, Department of Oral and Maxillofacial Pathology, A.J. Institute of Dental Sciences.
2. Director, Centre for Ethics, Professor, Department of Forensic Medicine & Toxicology, Yenepoya (Deemed to be University)
3. Professor & Head Department of Public Health Dentistry, A.J. Institute of Dental Sciences.
4. Professor, Department of Oral & Maxillofacial Surgery, AB Shetty Memorial institute of Dental Sciences NITTE (Deemed to be University).

Correspondence:

Arvind Karikal Professor, Department of Oral & Maxillofacial Surgery, AB Shetty Memorial institute of Dental Sciences NITTE (Deemed to be University). Mangalore, India.

Email: drarvindkarikal@nitte.edu.in

Orcid ID: 0000-0002-3444-9063

Cell Phone: +919008964130

various circumstances, such as in archives, museums, archaeological digs, this material mostly was acquired under known and unknown circumstances. Such anonymised archival material could be used for teaching, research, remain in storage or be disposed in a safe manner². Biological samples for research purpose have a long history being used in healthcare and education. The twenty first century has brought new challenges, with new methods of preservation of biological samples and an increase in the number, size, and importance of biobanks has drawn attention to the changing nature of biomedical research. The relationship of the investigator, participant and funding organizations funding biobanks have changed³. Biobanking for medical research depends on the availability of biological material along with associated clinical data, genetic information and lifestyle information. Thus its success depends heavily on trust and good will between the participants the researchers and academicians as they not only provide the biological material but also personal details about their health and living habits⁴.

Pamela Tozzo et al, in 2017³ noted a huge increase in scientific literature concerning novel applications both in public and private research bodies and thus emphasized the importance of biobanks. Internationally the awareness of biobanks has increased due to the growing trend of research towards personalized medicine, especially in the field of oncology. Still a vast majority of people around the world are new to biobanks and are hesitant to be involved in biobanks related research as participants or as donors in cohort studies³. In India public knowledge and awareness is still nascent, hence we would like to assess a sample of Indian adults on their knowledge, perception towards participation in a biobanks and willingness to donate their own biological samples for research.

Materials and methods

A cross sectional study was conducted amongst the general public. The data was collected using convenience sampling. The study protocol obtained clearance from the Institutional Ethics Committee. The Questionnaire was developed in English, and was pilot tested to ensure that the questions and the language that was used were clear and comprehensible to the participants. The questionnaire was validated by subject experts in Bioethics. The questionnaire was modified based on the pilot testing and expert feedback. It was then distributed online using Google forms. The questionnaire was

collected from participants an informed consent was provided to the participants before the questionnaire. No identifying personal information was obtained from the participants.

The questionnaire consisted of three parts

1. Demographic and socioeconomic characteristics
2. Participants' perspectives toward participation in biobanks and storage of their samples.
3. Participants perspectives on consent in biobanking.

Inclusion Criteria:

1. Participants above the age group of 18 years as they are competent to understand the concept of biobanking and give consent independently.
2. Participants who were fluent in English language and are digitally literate with access to the internet.

Statistical analysis and methods

The obtained data was analysed using SPSS version 17, descriptive analysis was done.

RESULTS

350 Google forms were circulated, out of which 203 participants responded. The data showed that 43.3 % participants were from the age group 18-28 years, 24.1 % were between the age group of 29-38 and 32.5% were between 38 years and above. The data showed that 63.1 % of the participants were females and 36.5% were male. Among the total participants, 53.2% of the participants were graduates, 38.4 % were postgraduates and 8.4% of the participants had completed their Pre-university collage. The questionnaire assessed the participants' perspectives toward biobanks and storage of their samples [Chart 1]. 85.2 % of the participants knew that biobank is a bank used for storing biological samples and related data. 11.8% of the participants were not aware about biobank. 42.4% of the participants knew that there are separate biobanks for research and legal purposes. Whereas 33% of the participants responded that the biobank is only for research and 23.2% responded that there is only one biobank for

research and legal purposes. 57.1% of the participants do not know that there are any biobanks in India, whereas 40.9% knew that there are research biobanks in India. 47.3 % of the participants agreed that the purpose of a biobank is to collect and store biospecimens for diagnosis, treatment and research purposes. 37.4 % of the participants strongly agreed to it. Whereas 14.3 % of them reported that they don't have any idea about biobanking concept. 45.3 % of the participants strongly agreed that modern biobanking biospecimens needs to have standard operating procedures to collect process, store and release biospecimens and 23.2 % of the participants had no idea about biobanking protocols. Regarding confidentiality and anonymity of data 78.8% responded that their data should be kept confidential whereas 15.8% were not aware of confidentiality and anonymity of personal data. 79.8% of the participants did not have any experience in participating in research and 17.2% agreed that they did have experience in dealing with biobanking. The participants were asked if they had prior knowledge about biobanks, 71.4% participants did not have any, whereas 24.6% responded that they did have prior knowledge about biobanks.

Perception on biobanking participation and barriers

The domain focussing on the discouraging factors in participating in biobanking, 43.8% of them said that they have fear of sample exploitation, 37.9% responded that the research procedure was unclear. 24.1% of them had fear of negative impact of research on their privacy and confidentiality. Whereas 19.7% and 19.2% responded that they do not have time to participate in research and they do not feel comfortable conducting experiments on their biospecimens. 70.4%, Among the study participants 59.6% of the participants were willing to donate the biospecimens for advancement in medical research and to benefit the society and future generation. Around 21.7% of the participants responded that Biobanks are already established as the core facility of biomedical research in developed countries.

Perspective on consent in biobanking

The domain focussing on participants' perspectives on consent on biobanking, 64.5 % of them strongly agreed to sign the consent form, whereas 12.8% of the participants had no idea about consent form.

The participants were asked "in collection of biological samples for biobanking, what type of informed consent would you be willing to give? 45.8% responded that

consent must be sought for each new study. 43.3% reported that consent must be sought if the new study uses their data with their social security number and 33% responded that consent must be sought if the new study contains diverging steps from the original. Around 26.65 of the participants responded that they would not place any restrictions. It was enough that an ethics review board has given permission [Chart 2,3].

Perception of participants on the use and re-use of biological sample

The study participants were asked in their opinion, for what purposes can old samples be used without having to ask the patient's permission? 48.8% responded that could be used for the development of medicines and treatments in pharmaceutical and biotech firms. 42.4% responded for the original purpose of diagnosis. 40.4% for Medical research in public institutions (such as universities and public hospitals), 30.5% were for solving crimes and 19.2 and 16.3% were for the development of medicines and treatments in international firms and for determining family relations respectively. The

study participants were asked for what purposes can these research samples be used without having to ask patients permission?" 46.8% of the participants opted only for the original purpose of diagnosis. 46.3% for development of medicines and treatments in pharmaceutical and biotech firms. 34.5 % and 33% were for Medical research in public institutions (such as universities and public hospitals) and for solving crimes respectively. 20.2% and 14.8% for the development of medicines and treatments in international firms and for determining family relations respectively [Chart 4].

Perception on consent type in biobanking

Here the participants were asked if they were to give sample (biological materials) to a biobank, and what type of consent would you be willing to give? 37.9% wanted to define the scope of use where as 26.1% informed that re-consent should be sought if the research setting changes. 18.2 % agreed that they would give open consent and 17.7% reported that they would not give consent to add their sample to a biobank.

DISCUSSION

Research on biological samples is an investigation conducted to discover new facts or to get additional information about a certain disorder, by collecting and

conducting experiments on biospecimens such as blood, urine, hair, nails or body tissue removed after surgery, or by collecting information either from health records or questionnaires.

Biobank is an organised repository in which donated biospecimens are stored. Biospecimens compiled are linked to the donor along with identifiable personal and health information. These repositories of archived material usually support various studies including that on genetics. Hence protocols are mandatory for biobanks to operate under strict privacy and confidentiality to ensure protection of all personal identifying information of the donor. This works by encryption of data using codes to make it impossible to identify the donor. These codes are then kept under supervision and given limited access only. Any research team intending to use these samples in research will not have the code that links samples to identifying personal information⁵.

Trust is an integral part in successful operation of biobanks⁶. This study investigated what a sample of the Indian general public knew and thought about biobanking, taking an approach to examine the general public's willingness to donate biological samples to a biobank for research purposes and the reasons behind their answers, confirming a previous report from Porter et al. (2014) in a survey conducted in a smaller, different sample population⁶.

This study found that members of the public are concerned about the possibility of residual clinical material being used by biobanks without adequate knowledge of participation. While this concern is not likely to translate directly into participant willingness to participate at the time of procurement, the informed consent process is very important to participants and should be a key consideration when implementing either sample collection strategy. Appropriate, easy to understand language on procurement strategies should be included in biobank consent information, wherever it is applicable.

The discouraging factors in participating in biobanking were fear of sample exploitation, research procedure being unclear, fear of negative impact of research on their privacy and confidentiality, not having time to participate in research and not being comfortable conducting experiments on their biospecimens. Similar apprehensions were assessed in a survey conducted by David Wendlerv One-time general consent for research

on biological samples in 2006⁷.

Confidentiality was considered important by the participants. Recent studies and legal cases indicate that the general public do not understand the information presented during the informed consent process for biospecimen and biobank research^{8,9}. The use and disclosure of the details of one's illness and medical history, though without the mention of one's name and personal identifiers, were considered acceptable. These studies emphasise the importance of appropriately informing and obtaining consent from individuals. Consent must be sought for each new study, if the new study uses their data with their social security number and if the new study contains diverging steps from the original. The consent form should define the scope for use and re-consent should be sought if the research setting changes.

Technological advances, automated sample processor, computerisation have initiated revolutionary changes in the field of medical research. In addition to all these, the International Organisation for Standardization has illustrated the requirements for archives stored in biobanks (ISO 20387:2018)¹⁰⁻¹² Wherein it stresses the concept of biobanks being legal entities driving the process of acquisition, processing, storage, testing, analysing the biological samples and their related information and data^{13,14}. Confidentiality and data protection, are the two main concerns in biobanking, as samples contain extensive genetic information and the stored samples have rich value in research. Hence there is a need for data protection law. A breach of confidentiality is the greatest potential risk to the donors and their families, which may result in public disclosure of donor's identities, their genetic and private health information. In a study conducted by Oliver et al, 34.6% of donors reported that their greatest risk to biobanking participation was revealing their identity¹⁵. The present study also emphasised on the elevated privacy concerns and confidentiality which affects participation consent. The discouraging factors in participating in biobanking were fear of sample exploitation (43.8%), research procedure being unclear (37.9%), fear of negative impact of research on their privacy and confidentiality (15.8%).

Participants in the present study strongly agreed that modern biobanking needs to have standard operating procedures to collect, process, and store and release biospecimens. From the point of view of the public or

prospective participants, there is a clear need for a legal and institutional body that can protect their interest. Therefore, In the ICMR 2017 guidelines, Biobanks should have well-structured standard operating procedures for collection, coding, anonymization, storage, access and sharing of specimens. Similar opinions were voiced by Manjulika Vaz et al 2015, where emphasis was placed on the role of the Institutional Ethical Committee (IEC). IEC should not be restricted only to the concerned Institution, instead it should also consider the benefit of the society at large and also extend its role and responsibilities towards the study participants through regular monitoring and frequent interactions¹⁵. The present study, however, considerably expanded our understanding of people's perceptions towards biobanking in India, and thus can serve as a basis for more focused enquiry into the area. The participants in the current study were from educated groups and hence, were possibly more articulate and able to voice independent views than the average member of the general public. The study stresses on the need to initiate public awareness and educational programs to encourage participation in research and inform participants of their rights and responsibilities.

CONCLUSION

The vast majority of the general public invited to take part in the survey answered the questionnaire, making up a representative sample of the target population. Although the questionnaire was administered to a particular sample of educated young Indians, which cannot represent the Indian population at large, our findings suggest a generally positive attitude to the idea of donating biological samples to a biobank for research purposes, archiving of biological specimens from donors for use in research, has become a vital resource for healthcare research, medical care, and drug discovery. The creation of biobanks depends majorly upon people's willingness to donate their samples for research purposes and to agree to sample storage. Therefore, knowing public's attitudes towards participation in a biobank and biobank management is important and deserves investigation. In India, due to low level of literacy, paternalism and therapeutic misconception, the idea of consent in Biobanking is mere formality, without empowering the concerned patients. Hence multi-tiered consent and re-consent becomes mandatory. The biobanks also need to be accredited

and licensed. Further studies are required considering various other parameters like socioeconomic status, literacy, different cultural and ethnic background as this would give us more insight to assess the perception of the general public towards biobanking.

Consent for Publication: The author reviewed and approved the final version and has agreed to be accountable for all aspects of the work, including any accuracy or integrity issues.

Disclosure: The author declares that they do not have any financial involvement, association, or entity directly or indirectly with the subject matter or materials presented in this editorial. This includes honoraria, expert testimony, employment, ownership of stocks or options, patents, or grants received or pending royalties.

Data Availability: The data is exclusively available from the principal author for research purposes only.

Authorship Contribution: All authors contributed significantly to the work, whether in the conception, design, utilization, collection, analysis, and interpretation of data or all these areas. They also participated in the paper's drafting, revision, or critical review, gave their final approval for the version that would be published, decided on the journal to which the article would be submitted, and made the responsible decision to be held accountable for all aspects of the work.

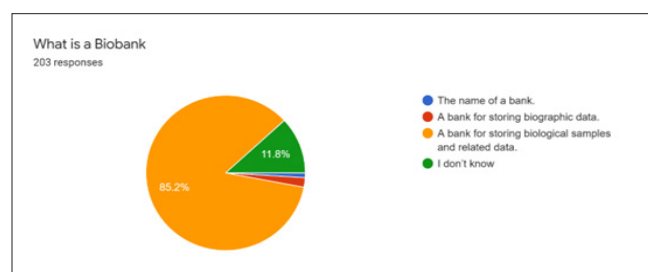


Chart 1:

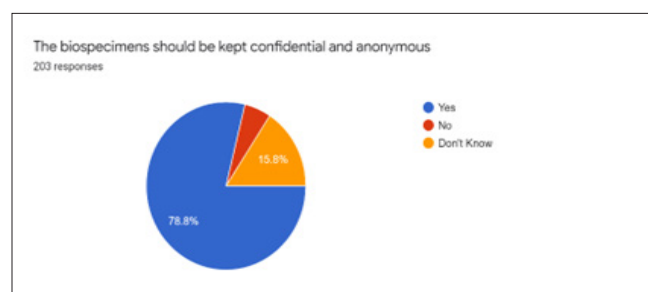


Chart 2:

“If you wanted to be asked whether a sample of yours could be added to a biobank, what type of consent would you be willing to give?”

203 responses

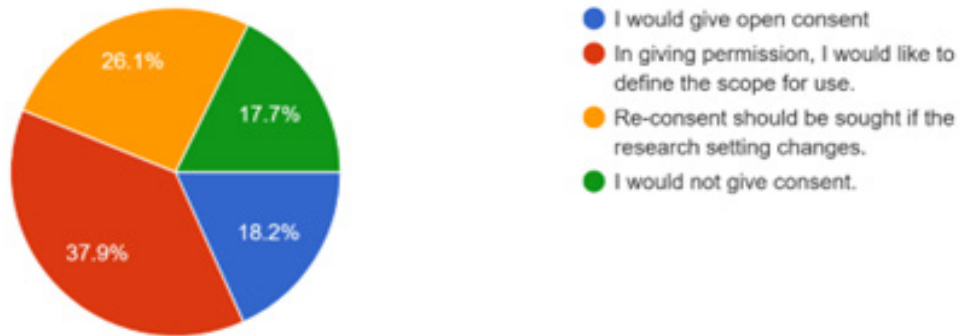


Chart 3:

“Many samples have also been collected in India during the course of scientific research in which participants have participated willingly. In most ...tients permission?” (You may choose more than one)

203 responses

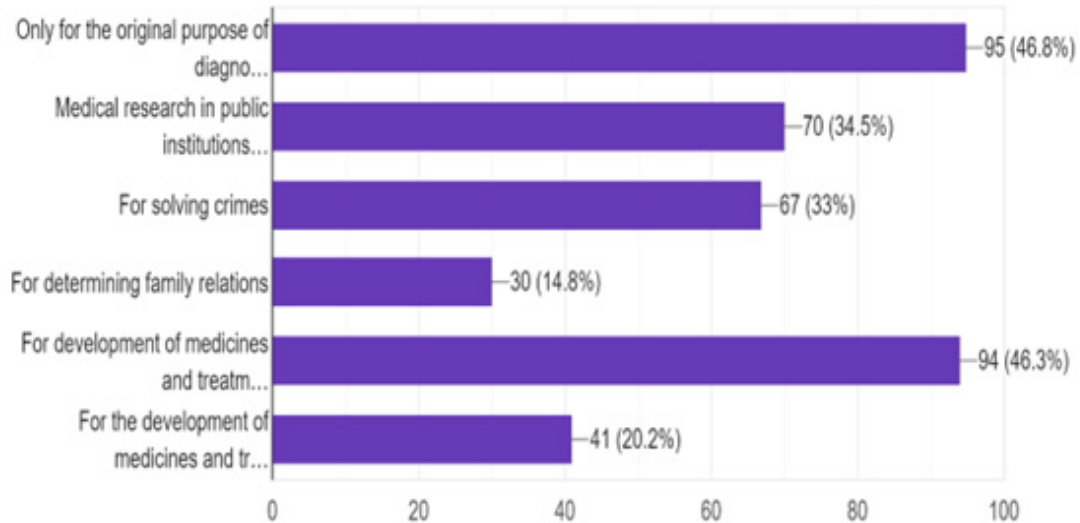


Chart 4:

References

1. Carlo Petrini. Ethical and legal considerations regarding the ownership and commercial use of human biological materials and their derivatives. *Journal of Blood Medicine* 2012;3
2. Jones DG R Gear, K A Galvin J. Stored human tissue: an ethical perspective on the fate of anonymous, archival material. *Journal of Medical Ethics*. 2003 Dec 1;29(6):343–7.
3. Pamela Tozzo, Antonio Fassina and Luciana Caenazzo Tozzi et al. Young people's awareness on biobanking and DNA profiling: results of a questionnaire administered to Italian University students. *Life Sciences, Society and Policy* (2017) 13:9.
4. Kumar S, Dagli N, Haque M. Human-on-Chip Technology: Current State and Future Challenges. *Bangladesh J Med Sci*. 2024 Jan;23(1):7-11.
5. Leena Merdad, Lama Aldakhil, Rawan Gadi, Mourad Assidi, Salina Y. Saddick, Adel Abuzenadah, Jim Vaught, Abdelbaset Buhmeida and Mohammed H. Al-Qahtani. Assessment of knowledge about biobanking among healthcare students and their willingness to donate biospecimens. *BMC Medical Ethics* (2017) 18:32.
6. Hanin Makhlof, Nasr Alrabadi, Omar F Khabour, Karem H Xlzoubi, Wael Al-Delaimy. Population's perspectives toward biobanks in scientific research: a study from Jordan. *Pharmacogenomics and Personalized Medicine* 2019;12 23-32.
7. Porteri C, Pasqualetti P, Togni E, Parker M. Public's attitudes on participation in a biobank for research: An Italian survey. *BMC Medical Ethics*. 2014;15:81.
8. David Wendlerv One-time general consent for research on biological samples *BMJ* vol 332 4 March 2006;332:544–7
9. Allen J, McNamara B. Reconsidering the value of consent in biobank research. *Bioethics* 2011; 25:155–166.
10. Riegman PH, Morente MM, Betsou F, De Blasio P, Geary P, Marble Arch International Working Group on Biobanking for Biomedical Research. Biobanking for better healthcare. *Molecular oncology*. 2008 Oct 1;2(3):213-22.
11. Sarojini S, Goy A, Pecora A, Suh KS. Proactive biobanking to improve research and health care. *J Tissue Sci Eng*. 2012;3(02):116.
12. Hubel A, Spindler R, Skubitz APN. Storage of the human biospecimens: selection of the optimal storage temperature, *Biopresev biobank*, 2014;165-175.
13. Annaratone L, De Palma G, Bonizzi G, Sapino A, Botti G, Berrino E, Mannelli C, Arcella P, Di Martino S, Steffan A, Daidone MG. Basic principles of biobanking: from biological samples to precision medicine for patients. *Virchows Archiv*. 2021 Aug; 479:233-46.
14. Ranju GA, Serice T. Ethical gap to implement utilitarianism in healthcare policy: A hidden Pandemic Ethics Crisis. *Bangladesh J Med Sci*. 2021 Sep;20(5):178-82.
15. De Souza YG, Greenspan JS, Biobanking past present and Future: responsibilities and benefits. *AIDS* 2013 Jan 1;27(3):303.
16. Ahmed N, Abbasi MS, Zuberi F, Qamar W, Halim MSB, Maqsood A, Alam MK. Artificial Intelligence Techniques: Analysis, Application, and Outcome in Dentistry-A Systematic Review. *Biomed Res Int*. 2021 Jun 22;2021:9751564.
17. Oliver JM, Slashinski MJ, Wang T, Kelly PA, Hilsenbeck SG, McGuire AL. Balancing the risks and benefits of genomic data sharing: genome research participants' perspectives. *Public health genomics*. 2012 Dec 30;15(2):106-14.
18. K Khan MB, Khan FA, Vaswani V, Kulkarni U, Mohan PR. The awareness and perception about the Ethical concerns related to the Biobanks among Medical and Dental practitioners- A questionnaire based study. *Annals of Applied Bio-Sciences*. 2017 Apr 10;4(2): A99–103.