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Public Views on Donation and Use of Human Biological Samples for Biomedical Research

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Abstract: ***Background**: Recent advances in biomedical field have increased the value of research on stored biological samples in bio banks to aid in the development of bio medical research in many developing countries. Such research should help in the advancement of healthcare and the tackling of the high burden of disease in those countries. Biological specimens such as Blood, Urine, Tissue samples are usually collected for diagnosis and patient care. The left over samples in the laboratory could make a difference if used for medical advances and improve people's lives. Any research involving human participants should be guided by fundamental ethical principles in order to ensure the protection of their rights. Hence the aim of this study is to assess the perception of the general public towards donation and use of human biological samples for biomedical research. **Methods**: A Cross sectional study was conducted among the general population. A questionnaire was developed which was checked for validity and reliability. The questionnaire consisted of two parts. In the first part participants were asked to enter basic demographic details and second part is the participant's views on donation and use of human biological samples for biomedical research. Online survey was conducted to collect the data. **Results**: A total of 227 people participated in the survey.93.4% of them agreed to donate biological sample for research. Among them 86.8% were willing to participate in a research related to heredity and genes. 97.8% suggested that consent should be taken before conducting research. About 59.9% thought donors should receive financial compensations, while 82.8% thought they should have the right to withdraw consent whenever they want. 83.7% suggested that Samples donated for scientific research should not use for purposes against the wish of the donors, and 98.2% suggested that the Researchers must maintain the privacy and confidentiality of donor information during the course of scientific research. 57.7 % believed that the ethics committee can decide on the use of stored sample for research if it is difficult to reach concerned donors, but 94.7 % of them want a regulatory body to monitor research done on biological samples. **Conclusion**: There was an overall positive attitude towards sample donation for biomedical researches. But concerns regarding privacy and confidentiality remained. These concerns lead to an increased demand for a regulatory body to monitor the bio medical researches done on human biological samples. The public participation in bio medical research is possible, taking into consideration the participants rights.***

Keywords: Biomedical research, Bio bank, Human biological sample, Tissue donors, Delivery of health care

1. Introduction

Research is a broad term for a set of actions aimed at advancing or expanding generalizable knowledge. Theories, correlations, or principles, as well as the facts on which they are founded, are examples of generalizable knowledge that may be validated using established scientific reasoning and observation procedures. In current context, "research" refers to both behavioral and medical studies pertaining to human health.

Understanding epidemiological results, as well as pathological and physiological processes, is essential for progress in disease prevention and medical care. Therefore, at some point, a human-based research is necessary. The collection, assessment, and interpretation of data gained from human research make a substantial contribution to the improvement of human health.

Biomedical research, in general, is a field of science concerned with the prevention and treatment of conditions that cause death and illness in animals and humans. Biomedical researchers investigate biological processes and illnesses using biotechnology techniques in the hopes of discovering viable therapies and cures. The development of novel treatments and medications requires meticulous scientific testing, assessment, and development.

The advancement of biology as a science has been directly related to biological collections. Collections of biomaterials date back to the 17th century. The Carl Linnaeus Botanical Collection, which was developed not only to answer scientific issues of plant categorization but also for practical activities done in botanical gardens, is one of the most well-known instances of biological collections. Biological storage, biological repository, biological collection and bio bank are all terms that are used interchangeably nowadays. A bio bank is a type of bio repository that collects, processes, stores, and distributes specimens and data for research and clinical trials. Bio banking has evolved from simple biological sample storage to complex and dynamic entities that are part of broader infrastructure networks during the last three decades[1].

Recent advances in biomedical field have increased the value of research on stored biological samples in bio banks to aid in the development of bio medical research in many developing countries. Such research should help in the advancement of healthcare and the tackling of the high burden of disease in those countries[2]. Biological specimens such as Blood, Urine, Tissue samples are usually collected for diagnosis and patient care. The left over samples in the laboratory could make a difference if used for medical advances and improve people's lives. Any research involving human participants should be guided by fundamental ethical principles in order to ensure the protection of their rights.

Hence the aim of this study is to assess the perception of the general public towards donation and use of human biological samples for biomedical research.

2. Materials and Methods

This Cross sectional study was conducted among the general population. The data were collected using structured, self-administered questionnaires in the English language. The questionnaire was developed by reviewing previous studies. The tool was checked for reliability and face validity. The Cronbach's alpha score was >0.8 which showed good agreement. Face validity was done by giving the questionnaire to subject experts. The questionnaire consisted of 19 questions. Ethical clearance was obtained from the institutional ethics committee before its wider use. Questionnaire send as online forms to participants and data was collected for two months. The questionnaire consisted of two parts. In the first part participants were asked to enter basic demographic details and second part is the participant's views on donation and use of human biological samples for biomedical research. The study participants were selected based on convenience sampling. Study participants above the age of 18 years and those who could read and write English were only included for the study. The collected data was fed into Excel Spreadsheets and analyzed using SPSS Software (Version 23). Descriptive analysis of the data was performed.

3. Results

A total of 227 participants agreed to participate in the study. The sex ratio in the survey was almost equal.50.2% males and 49.8% females participated in the survey. Majority of the participants belonged to the age group of 25 to 35 years.

93.4% of those interviewed indicated that they would donate samples for biomedical research. Among those who are willing to donate samples for biomedical research 86.8% were willing to participate in a research project to heredity and genes. The next few questions were designed to evaluate participant's views on informed consent. Although people are willing to provide samples for research, almost everyone (97.8%) insisted on an informed consent before conducting a biomedical research and 77.5% of the participants felt the need for an impartial witness when they provide consent for the research.

When we asked participants what they believed the potential rights of donors of biological samples to be, about 59.9% thought the donors should receive financial compensation in exchange for donating samples to research, while 82.8% thought that a participant is able to ask to withdraw his samples after participation. About 74.4% believed that the donor would no longer own the sample anymore after donating it and 54.6% opined that the donor has the right to claim his own biological sample after donation to the bio bank.

Concerning the return of research results, 65.2% thought that the results of research conducted on donated samples should appear in the medical records of the participants. Asking participants about issue of security and use of samples, most of them were concerned about issues of security, 98.2% expressed the view that the researchers must maintain the privacy and confidentiality of donor information during the course of scientific research, and 83.7% suggested that the samples donated should not be used for purposes against the wish of the donors. About 94.3% want their sample to be kept anonymised in the laboratory. While asking participants whether Ethics committee can decide on the use of stored sample for research if it is difficult to reach concerned donors, 57.7% responded positively. Still 94.7 % of them desired for a regulatory body to monitor research done on biological samples.

S. No	Questions	Answer		
		Yes	No	Don't Know
1	If you are asked to donate a biological sample for research, would you agree?	212 (93.4%)	6 (2.6%)	9 (4%)
2	Would you participate in a research project related to heredity and genes?	197 (86.8%)	14 (6.2%)	16 (7%)
3	Samples donated for scientific research could be used for purposes against the wish of the donors?	17 (7.5%)	190 (83%)	20 (8.8%)
4	The donor has the right to receive a financial compensation for the donated sample?	136 (59.9%)	36 (15.9%)	55 (24.2%)
5	The sample donated to the bio bank is no longer the property of the donor after donation?	169 (74.4%)	44 (19.4%)	14 (6.2%)
6	Do you think consent needs to be taken before conducting the biomedical research?	222 (97.8%)	4 (1.8%)	1 (0.4)
7	Do you think there should be an impartial witness when you provide consent for research on your biological sample?	176 (77.5%)	21 (9.3%)	30 (13.2%)
8	Do you think you should have the right to withdraw consent to conduct research on your biological sample whenever you want?	188 (82.8%)	24 (10.6%)	15 (6.6%)
9	Do you think we can obtain consent from any of your family members before your biological sample is used for research?	108 (47.6%)	93 (41%)	26 (11.5%)
10	Do you think your biological sample should be kept anonymised in the laboratory?	214 (94.3%)	3 (1.3%)	10 (4.4%)
11	Do you think the Ethics Committee can decide on the use of the stored biological sample for research if it is difficult to reach all concerned donors?	131 (57.7%)	64 (28.2%)	32 (14.1%)
12	Researchers must maintain the privacy and confidentiality of donor information during the course of scientific research?	223 (98.2%)	1 (0.4%)	3 (1.3%)
13	The donor has the right to claim his own biological sample after donation to the bio bank?	124 (54.5%)	72 (31.7%)	31 (13.7%)
14	The results of the scientific research on the samples should appear in the medical records of the donor?	148 (65.2%)	50 (22%)	29 (12.8%)
15	Do you think there should be a regulatory body to monitor research done on biological samples?	215 (94.7%)	2 (0.9%)	10 (4.4%)

4. Discussion

A cross-sectional study was conducted among 227 participants from the general population through Google forms to assess the perception of the general public towards donation and use of human biological samples for biomedical research.

Biomedical research is a field of science concerned with the prevention and treatment of conditions that cause death and illness in animals and humans. Biomedical researchers investigate these conditions using modern technology in the hopes of discovering viable therapies and cures. The development of novel treatments and medications requires meticulous scientific testing, assessment, and development.

Majority of the participant we interviewed indicated that they would donate samples for biomedical research. Our results showed similar attitudes towards donating samples for biomedical research to the attitudes of the general public in a study conducted by Bossert S, Kahrass H, Strech D[3]. But there was a slight reduction in the number of participants who are willing to participate in a genetic related research. This might reflect some concerns our interviewees have with regards to genetic research.

The high levels of support for biomedical medical research and for genetic research confirm the results of earlier studies. For example, in a survey of the public's perceptions of biomedical research in Ireland[4], 96% of the respondents agreed with the statement "medical research is important because it results in new and improved treatments for diseases. " 87% agreed that "medical research helps us live longer". As we also found, in the Irish survey support for genetic research is still high but somewhat lower than for medical research.

Although people are willing to provide samples for research, almost everyone insists on an informed consent before conducting a biomedical research and most of them felt the need for an impartial witness when they provide consent for the research. Regarding the potential rights of the donors of biological samples more than half of the participants thought the donors should receive financial compensation in exchange for donating samples to research. We also received contradicting results regarding the rights were 82.8% thought that a participant is able to ask to withdraw his samples after participation. About 74.4% believed that the donor would no longer own the sample anymore after donating it. This results shows the unawareness of the participants regarding the rights of a donor.

Concerning the return of research results, 65.2% thought that the results of research conducted on donated samples should appear in the medical records of the participants. These results are quite similar to the results of survey conducted by Alahmad G and Dierickx K[5]. In which a clear majority of the participants agreed that donors have a right to receive important research results, and that the biobank was obliged to provide important research results to participants. Providing information when it may benefit participants seems to be acceptable and matches the guidelines, under which many biobanks operate[6]. Some difficulties may be faced by biobanks attempting to provide results because of issues related to confidentiality and coding[7, 8]. Moreover, the return of results has a significant cost[9]. Some bio banks are unable to offer the return of any kinds of results, being deliberately designed not to do so.

Asking participants about issue of security and use of samples, we found that most of them were concerned about issues of security, most of them (98.2%) expressed the view that the researchers must maintain the privacy and confidentiality of donor information during the course of scientific research, and suggested that the samples donated should not be used for purposes against the wish of the donors. Confidentiality in genetic research in stored tissue samples is a vital issue because information may be related to sensitive points, and because genetic information is not only individual but also familial. Breaching confidentiality might lead to negative impacts on a donor and his relatives both in the present and the future. A high percentage of agreement among respondents for considering medical information as confidential can possibly be explained by the fear of stigma both for donors and their families, especially in a society such as India where there are high rates of consanguinity and inherited diseases.

While asking participants whether Ethics committee can decide on the use of stored sample for research if it is difficult to reach concerned donors, 57.7% responded positively. It's an interesting result which contradicts the previous questions regarding the privacy. This shows the upstanding attitude of our interviewees. Still 94.7 % of them desired for a regulatory body to monitor research done on biological samples.

Interestingly, most interviewees in this study believed in the benefits of medical research and participation. The majority of them were not concerned about the specific potential obstacles presented to them. Similar findings of a positive attitude towards donating samples for research were found by Khalil et al[10]. Who reported a great trust in medical research among their study sample.

5. Conclusion

There was an overall positive attitude towards sample donation for biomedical researches. But concerns regarding privacy and confidentiality remained. These concerns lead to an increased demand for a regulatory body to monitor the bio medical researches done on human biological samples. The public participation in bio medical research is possible, taking into consideration the participants rights.

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