



WORKERS WILLINGNESS TO DONATE HUMAN BIOLOGICAL SAMPLE FOR FUTURE RESEARCH IN A SOUTH WESTERN NIGERIAN TERTIARY HEALTH CENTER

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ABSTRACT

Introduction: Human biological material is recognized as an important tool in research, and the demand for collections that combine samples and data is increasing. The aim of this study was to assess health workers knowledge of bio-banks, willingness to donate human biological samples, as well as their willingness to give consent for future use of their donated biological samples in research.

Methodology: This is a cross-sectional descriptive study. The minimum sample size for this study was determined using the Fisher's Formula. A sample size of 201 was derived and surveyed. . Proportional allocation of the sample sizes was done to the ten groups of staffs based on their population. Simple random sampling technique by balloting was used to select respondents in each group. The questionnaires were self-administered and the data generated were edited and validated manually for errors and entered into the computer for analysis using Epi-Info version 3.4.1.

Results: Of all the respondents, 59.2%, 36% and 33.8% of respondents correctly identified Bio-banks' capacity to store blood, semen and human tissues respectively. More than half of the respondents, 169 (54.3%), would give their consent for future use of their donated samples. 63.4% wanted the option of being able to withdraw their samples at any time while 59.2% stated that they would require a separate consent for each future use of donated samples.

Conclusion: Health workers knowledge of bio-banks and willingness to donate human biologic sample was considerable despite its being a relatively new concept. However most respondents expressed skepticism as regards willingness to give consent for future use of their donated biological samples in research. This study shows that this region is ready for research using Human Biological Samples provided more public enlightenment strategies are put in place.

Keywords: Consent, Bio-banks, Biologic sample, Ethics, Future use, Research.

INTRODUCTION

Recent advances in genetics, molecular biology and biomedical technology have increased the scientific value of research on stored biological samples and have spurred the development of genetic databases and bio-banks. (Abou-Zeid *et al.*, 2010) Human biological material is recognized as an important tool in research, and the demand for collections that combine samples and data is increasing. (Anderlik, 2003) Storage of human tissue after clinical procedures is important for two major reasons. First, the tissue can be used for future diagnosis and treatment of the patient and second, it is a valuable resource for medical research. (Vermeulen *et al.*, 2009)

It has been noted that genetic analysis of human tissue samples may result in highly useful information about genetic explanation of human disease. (Kapp, 2006) The collection, storage, and use of biological samples in future research raise unique ethical and policy issues that have restricted consensus among several national and international documents. (Abou-Zeid *et al.*, 2010) Willingness to contribute biological samples for research is relatively high according to several American and European studies. Such attitudes might not be generalizable to other cultures and countries, as the perception and familiarity of health research might be different in developing countries compared with developed countries. (Abou-Zeid *et al.*, 2010) There is also growing concern about the reuse and exploitation of human biological samples for use in research worldwide. (Langat, 2005) Studies on the public's willingness to donate blood specimens are few and are conducted mainly among western countries. (Wong *et al.*, 2004)

Currently, there is limited empirical research involving the perspectives of individuals from developing countries like Nigeria to the associated ethical challenges in the use of stored human biological samples for research. (Abou-Zeid *et al.*, 2010; Onochie and Akintola, 2011), Even though there is very little discussion in developing countries, collaborative research with institutions from developed countries is on the increase. (Langat, 2005) The growing awareness

of the importance of human biological samples in research has been accompanied by a growing awareness of the deficiencies of existing archives of tissue. (Anderlik, 2003) While some researchers propose that consent should be given for each new study at the time the study is proposed, others support prospective consent with the tissues preserved in bio-banks. (Wendler, 2006) Bio-banks are collections of human biological tissue specimen and related health data. Bio-banks have sparked debate due to the ethical, legal and social implications surrounding utilization of population samples and data. (Hawkins, 2010)

A study carried out in Newcastle, United Kingdom found that 65% of respondents would give consent for their tissue to be used for research into genetic disorders, 59% would give consent for research on general knowledge of body tissues, 59% would give consent for testing medicines, 42% would want to be informed if their tissues were going to be stored after donation and 35% stated that they would want to be consulted if their tissues were to be used for further research. (Goodson and Vemon, 2004).

In another study, Kettis-Lindblad et al found that 86% of respondents would donate a linked blood sample for research purposes and 3% would donate an anonymous sample in a study carried out among the general public in Sweden. (Kettis *et al.*, 2006) It has been found that refusal to consent to bio-bank research is rare with 1 in 690 cases refusing to consent to either storage or use of samples in Sweden. (Johnsson *et al.*, 2008)

Proposals for pediatric bio-banks have prompted questions of whether parental permission is sufficient to continue the use of their biological samples and data after children become adults. An American study found that 46% of respondents believed their consent should be obtained to continue using the use of their samples/data for research. (Goldenberg *et al.*, 2009)

A Finish study among randomly selected members of the public found that 83% of the sample population had little or no knowledge of what bio-banks were, 77% regarded setting up a National bio-bank with a positive light and 30% wanted consent to be regained for every new research project. (Tupasela *et al.*, 2010) A study carried out in Tennessee U.S.A on the donation and storage of left over blood samples from routine clinical tests in general practice found that 61% of respondents were unequivocally positive about storing blood left over from routine tests. (Treweek *et al.*, 2009)

During the past decade the use of stored tissue has become an object of increased ethical concern. A Swedish study found that about 31% of respondents believed they could withdraw their consent to use donated samples and about 4% considered informing donors about research objectives as the most important ethical issue in relation to bio-banks. (Hoeyer *et al.*, 2005) There is widespread disagreement about the type of consent needed for research with stored human biological samples, many believe consent for each future use is required to respect

individuals while others feel using this approach may block important research. Chen et al found that 85% of their research participants permitted unlimited future research with their stored biological samples regardless of their sex or age and about 7% refused all future research. (Chen *et al.*, 2005) In a Spanish study, 50% of consent forms that were reviewed were found not to have mentioned aspects related to ownership of the sample, the free donation of the sample or the place of sample storage. (Saenz *et al.*, 2010)

A study in Ohio U.S.A found that 61% of respondents indicated that potential benefits to their ethnic groups would be a big or moderate part of their decision to donate a sample for genetic research. (Goldenberg *et al.*, 2011) A Brazillian study found that consent from patients by phone and mail for a retrospective clinical study is feasible as 74% of sample patients gave consent to use of stored biological samples for research. (Duque *et al.*, 2010)

The aim of this study is to assess health workers knowledge of bio-banks, willingness to donate human biological samples, as well as their willingness to give consent for future use of their donated biological samples in research.

METHODOLOGY

The study was carried out among the staff of a tertiary healthcare facility in Ido Ekiti, South West Nigeria. There is a total of 1,390 health staffers including 305 doctors, 348 nurses, 37 community health extension workers, 40 laboratory scientists/technicians, 28 pharmacists, 15 radiographers, 7 physiotherapists, 340 health attendants, 3 optometrists and 267 others (including speech therapists, medical psychologists, dieticians, nutritionists and health record officers).

This was a cross-sectional descriptive study to assess the workers' willingness to donate human biological sample for future research in a south western Nigerian tertiary health Centre. The study population included all staff of the hospital. The minimum sample size for this study was determined using the Fisher's Formula. A sample size of 201 was derived and surveyed. Proportional allocation of the sample sizes was done to the ten groups of staffs based on their population. Simple Random sampling technique by balloting was used to select respondents in each group.

Pre-tested, semi-structured, self-administered questionnaire was used to generate quantitative data. The questionnaire was pre-tested at University Teaching Hospital, Ado-Ekiti, Ekiti State. They were self-administered and the data generated were edited and validated manually for errors and entered into the computer for analysis using Epi-Info version 3.4.1. Chi-square test was used to determine statistical significance of observed differences in cross tabulated variables. Level of significance was predetermined at a p-value of less than 0.05.

Clients' consent was obtained before interview. The nature of study, participation status, benefits of the study and confidentiality issues were made clear to the respondents before obtaining their consent. Ethical clearance for the study was obtained from the ethical committee of the Federal Medical Centre, Ido-Ekiti.

RESULTS

A total of 311 questionnaires were completed. More than half of the respondents were women (54.7%) while men accounted for the remaining 45.3%. Those that were aged less than 30 years were 37.9% while 43.4%, 13.5%, and 5.1% of respondents fell into 30-39years, 40-49years, and above 50 years age bracket respectively. Respondents were predominantly Yorubas (85.2%). Christians accounted for 87.8% of all subjects. More than three-quarters of subjects (83.9%) were from the clinical departments and-97.8% of subjects had at least secondary-level education.

Of all the respondents, 184 (59.2%), 112 (36%) and 105 (33.8%) correctly identified Bio-banks' capacity to store blood, semen and human tissues respectively. Bio-banks were also rightly identified as serving research, commercial and human biological samples storage functions by 33.4%, 36.3% and 58.5% of subjects respectively. In all, 54.3% of all respondents had heard about bio-banks prior to this study and the predominant sources of this knowledge were the internet (13.8%) and the print/electronic media (13.8%).

More than half of the respondents, 169 (54.3%), would give their consent for future use of their donated samples, 63.4% wanted the option of being able to withdraw their samples at any time while 59.2% stated that they would require a separate consent for each future use of donated samples.

Further analysis showed that a significantly greater proportion of men were more willing to give their consent for future use of donated samples compared to women (70.2% vs. 40.6%; $X^2 = 27.23$, $df = 1$, $p = 0.000$). Also a greater proportion of respondents in their thirties (62.2%) were more willing to give consent for future use compared to 54.2%, 42.9% and 12.5% in the less than 30 year, 40 – 49 years and the 50 years & above age groups respectively ($X^2 = 16.87$, $df = 3$, $p = 0.001$). There were no significant associations of willingness to give consent with either educational status or religion.

Subjects that were willing to donate their blood for future use were 156 (50.2%) while 114 (36.7%) and only 92 (29.6%) were willing to donate tissues and semen/vaginal samples respectively. Major reasons for unwillingness to donate samples for future use included fear of pain or discomfort in 155 subjects, fear of loss of future control over donated samples in 139 subjects, and fear of manipulation of donated samples in 130 respondents.

DISCUSSION

Despite limited empirical research involving the perspectives of individuals from developing countries like Nigeria to the associated ethical challenges in the use of stored human biological samples for research, (Abou-Zeid *et al.*, 2010; Onochie and Akintola, 2011) 184 (59.2%), 112 (36%) and 105 (33.8%) of all respondents, correctly identified Bio-banks' capacity to store blood, semen and human tissues respectively. Awareness about bio-banks was seen in 54.3% of respondents and this finding is higher compared to a Finish study among randomly selected members of the public which found, that 83% of the sample population had little or no knowledge of what bio-banks were. (Tupasela *et al.*, 2010) This may be due to the fact that our study was carried out among healthcare workers who by training or association have some background knowledge about the research topic.

It was discovered that the internet and print media were the main sources of information as regards bio-banks in this study. The implication of this finding is that planned interventions that will be carried out on bio-banks should incorporate the mass media and the internet for public enlightenment. With this level of awareness regarding a relatively new practice in this environment, varying degrees of willingness were found among the respondents as 169 (54.3%) stated that they would give their consent for future use of their donated samples in research. This was similar to an American study which found that 46% of respondents believed their consent should be obtained to continue using their samples/data for research. (Goldenberg *et al.*, 2009) The inference that can be drawn from this is that in proposing researches that have to do with bio-banks, the contact addresses including phone numbers, e-mail, house addresses, should be taken from those that donated biologic samples.

These findings were similar despite the difference of the perception and familiarity of health research in developing countries compared with developed countries. (Abou-Zeid *et al.*, 2010) The fact that most (65.6%) of the respondents had tertiary education, and all of the respondents are health workers with most of them (83.9%) working in clinical departments, hence having a good knowledge of healthcare practices could explain this finding.

The control of donated samples is an issue that still sparks debate worldwide, during the past decade the use of stored tissue has become an object of increased ethical concern. (Hoeyer *et al.*, 2005) In this study, 63.4% of all respondents wanted the option of being able to withdraw their samples at any time while 59.2% stated that they would require a separate consent for each future use of donated samples, this finding differed from that of a Swedish study where about 31% of respondents believed they could withdraw their consent to use donated samples, (Hoeyer *et al.*, 2005) as well as the finding by Chen *et al.* that 85% of their research participants permitted unlimited future research with their stored biological samples regardless of their sex or age. (Chen *et al.*, 2005) This study however showed that men were more willing to give their consent for future

use of donated samples compared to women (70.2% vs. 40.6%). These findings show that despite a relatively high level of awareness regarding bio-banks and its uses, people from this region are still skeptical about the future use of donated tissue samples.

Major reasons for unwillingness to donate samples for future use included fear of pain or discomfort in 155 subjects, fear of loss of future control over donated samples in 139 subjects, and fear of manipulation of donated samples in 130 respondents. It is clear that more information is needed for improved level of awareness to increase the proportion of those willing to give consent.

In conclusion, health workers knowledge of bio-banks was considerable despite its being a relatively new concept. Willingness to donate human biological samples was expressed by a significant number of respondents which bodes well for researchers in this region, however most respondents expressed skepticism as regards willingness to give consent for future use of their donated biological samples in research with a good majority preferring separate consent for each future use. This shows that a lot of information still needs to be shared with prospective donors as regards the inner workings of the bio-banks, and research methods. This will go a long way in allaying any doubts about tissue donation, implications of tissue storage as well as the credibility of bio-banks. This study shows that this region is ready for research using Human Biological Samples provided effort is put in to disseminate more information.

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Table-1. Socio demographic characteristics of respondent

Variable	Frequency	Percent
Age Group		
< 30 yrs	118	(37.9)
30 - 39 yrs	135	(43.4)
40 - 49 yrs	42	(13.5)
≥ 50 yrs	16	(5.1)
Sex		
Male	141	(45.3)
Female	170	(54.7)
Ethnicity		
Hausa	15	(4.8)
Yoruba	265	(85.2)
Igbo	20	(6.4)
Others	11	(3.5)
Religion		
Christianity	273	(87.8)
Islam	30	(9.6)
Traditional	8	(2.6)
Department		
Clinical	261	(83.9)
Non Clinical	50	(16.1)
Educational status		
Primary	7	(2.3)
Secondary	100	(32.2)
Tertiary	204	(65.6)

Table-2. Knowledge about bio-banks

	Yes (%)	No (%)	Don't Know (%)
Bio Banks can store the following			
Urine	139 (44.7)	41 (13.2)	131 (42.1)
Stool	136 (43.7)	45 (14.5)	131 (42.1)
Sputum	143 (46.0)	42 (13.5)	126 (40.5)
Saliva	144 (46.3)	37 (11.9)	130 (41.8)
Blood	184 (59.2)	16 (5.1)	111 (35.7)
Semen	112 (36.0)	60 (19.3)	139 (44.7)
Human tissue	105 (33.8)	68 (21.9)	138 (44.4)
Money	34 (10.9)	139 (44.7)	138 (44.4)
Nail Clipping	86 (27.7)	51 (16.4)	174 (55.9)
Skin Snips	104 (33.4)	43 (13.8)	164 (52.7)
Concerning Bio Banks			
Used for research purpose	104 (33.4)	70 (22.5)	137 (44.1)
Commercial Purpose	113 (36.3)	61 (19.6)	137 (44.1)

Storing samples for future	182 (58.5)	12 (3.9)	117 (37.6)
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Table-3. Willingness to give consent for Future Use of Donated Samples

Variable	Frequency (Percent)
Have you heard of bio banks before	
Yes	169 (54.3)
No	142 (45.7)
Where did you first learnt about bio bank	
Internet	43 (13.8)
Research Articles	27 (8.7)
Newspaper/Media	43 (13.8)
Others	34 (10.9)
No response	164 (52.7)
Consent for Future use of Donated Samples	
Yes	169 (54.3)
No	142 (45.7)
Option of withdrawal of donated samples	
Yes	200 (63.4)
No	111 (35.7)
Separate Consent for each Future Use	
Yes	184 59.2
No	127 40.8

Table-4. Age, sex, education, religion and Willingness to give consent for future use of donated sample

	Willingness to give consent for Future Use of Donated Samples		
	Yes (%)	No (%)	Total (%)
Sex			
Male	99 (70.2)	42 (29.8)	141 (100)
Female	69 (40.6)	101 (59.4)	170 (100)
$\chi^2=27.23$ df=1 P _{value} = 0.00			
Age Group			
< 30	64 (54.2)	54 (45.8)	118 (100)
30 – 39	84 (62.2)	51 (37.8)	135 (100)
40 – 49	18 (42.9)	24 (57.1)	42 (100)
50 and above	2 (12.5)	14 (87.5)	16 (100)
$\chi^2=16.87$ df=3 P _{value} = 0.001			
Education			
Primary	5 (71.4)	2 (28.6)	7 (100)
Secondary	56 (56.0)	44 (44.0)	100 (100)
Tertiary	107 (52.5)	97 (47.5)	204 (100)
$\chi^2=1.214$ df=2 P _{value} = 0.545			
Religion			
Christianity	147 (53.8)	126 (46.2)	273 (100)
Islam	17 (56.7)	13 (43.3)	30 (100)
Traditional	4 (50.0)	4 (50.0)	8 (100)
$\chi^2=0.140$ df=2 P _{value} = 0.932			

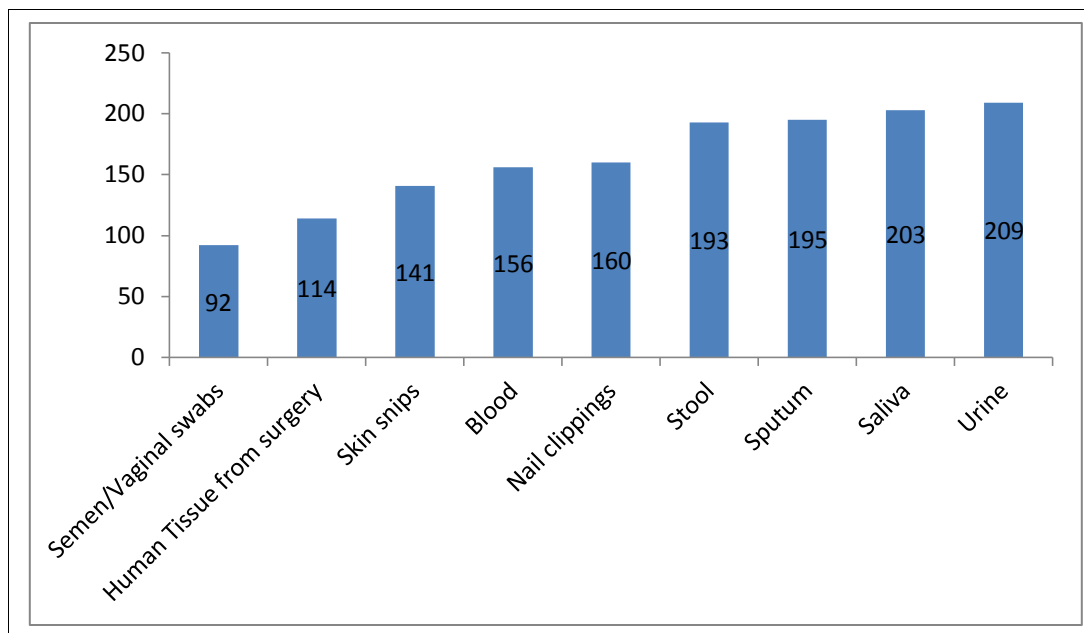


Figure-1. Willingness to Donate Human Biological Samples

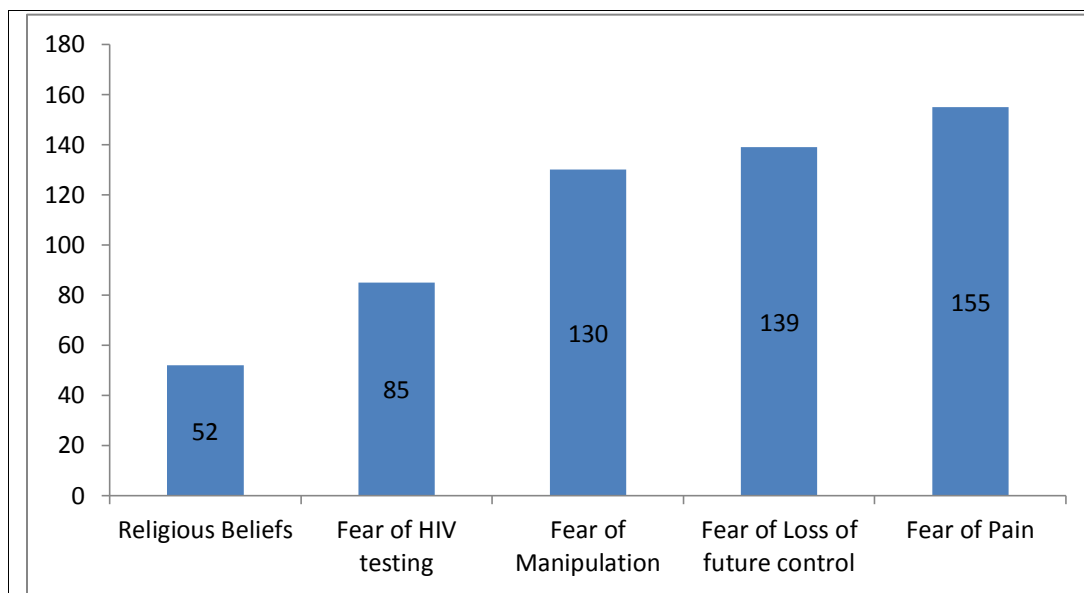


Figure-2. Reasons for Refusal to Donate Human Biological samples