Informed Consent among Hansen's Disease Patients – A Nigerian Perspective

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Summary

BACKGROUND

Informed consent entails providing potential participants with adequate information needed to decide whether or not to participate in research. In Nigeria, Hansen's disease has remained a disease of public health importance. The associated stigmatization often renders patients vulnerable and prone to exploitation. The act of obtaining informed consent from these patients remain an issue of ethical importance. The study aimed to determine the willingness of Hansen's disease patients to give consent to use their data in the form of pictures, videos and/or oral interviews by a third party.

MATERIALS AND METHOD

This descriptive cross-sectional study was carried out in three states in Nigeria; Ebonyi, Ogun and Cross River States. Data was collected from consenting participants using researcher-administered semi-structured questionnaires.

RESULTS

The study included 93 respondents with a mean (SD) age of 44.9 (20.1) years. The majority 57 (61.29%) of the respondents were farmers while the majority 67 (72.04%) attained primary education. A total of 26 (27.96%) respondents had suffered discrimination in the course of their disease. In their responses, 83 (89.2%) would allow the use of their pictures, 80 (86.0%) their videos and 86 (92.5%) their recorded oral interviews. Among those who would not give consent, the commonest reasons adduced were an intrusion into privacy and lack of trust.

CONCLUSION

Though a majority of the patients would give consent for use of their data intrusion into privacy and lack of trust were major constraints for those not willing to give consent. Caregivers and stakeholders should put more effort into trying to win patients' trust before seeking informed consent.

Keywords: *Informed Consent, Hansen's, Video, Picture, Oral Interview*

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Introduction

Informed Consent is the process of providing sufficient information to a potential participant (client, patient or research subject) in a language that is easily understood by the subject, of the purpose, risks, benefits, expected outcome of a research project, medication, medical procedure, or therapeutic approach in which they have agreed to take part so that the subject can make a voluntary decision regarding the therapeutic intervention or participation in the research study.[1-4]

The principle of informed consent is aimed at the lawfulness of health assistance and tends to reflect the concept of autonomy, respect of persons and of decisional auto-determination of the person requiring and requesting interventions to decide on such interventions or consider alternative interventions.[4, 5] Informed consent therefore captures and conveys the terms of an appropriate relationship between researcher and research participant, the care provider and the patient.[6] The care provider is therefore expected to make a reasonable disclosure to his patient of the nature and probable consequences of the suggested or recommended treatment and to make a knowledgeable disclosure of the dangers within his knowledge which are incident or possible in the treatment he proposes to administer.[7, 8]

Comprehension of informed consent varies with the location of the study and the nature or complexity of the study. In most cases, there is no uniform definition and assessment of comprehension of the key concepts of informed consent among study participants across Africa.[9]

Human infection with Hansen’s disease originally known as leprosy dates back to ancient times. It is a chronic infection caused by *mycobacterium leprae* and a member of the group of diseases classified as neglected tropical diseases (NTDs). Despite the neglect, it can be treated completely with medicines when diagnosed early. The disease mainly affects the nerves and skin. While nerve damage occurs in the form of peripheral nerve enlargement, damage to the skin manifests as anaesthetic skin patches. These patches depict the areas supplied by the affected peripheral nerves. If the disease is not detected early and treated accordingly, the patients may end up with complications such as indolent hand and foot ulcers as well as other physical deformities like auto-amputation of fingers and toes as well as distorted facies. These disfiguring attributes coupled with the primordial concept of leprosy as a disease for the cursed which is highly infectious often results in social isolation and stigmatization of the affected persons. The associated stigma, social isolation and exclusion make this group of people a vulnerable population.

In Nigeria (and some other parts of the world), it has continued to exist as a disease of public health importance with profound psychosocial effects on its victims.[10]. Hofstraat and Brakel[11] documented in their review that people affected by neglected tropical diseases (of which Hansen's is a part) are often a target of stigmatization. In a publication by Ebenso *et al*,[12] their findings showed that connotations of Hansen’s among the Yoruba people of Nigeria depicted the disease as ‘the most shameful and detested condition.

Fear of contracting the disease and social exclusion is closely associated with the disease. People equally believe that the disease might be hereditary, hence family members of patients also suffer discrimination and social exclusion. All these tend to strip this group of people of their dignity.

This associated stigmatization often renders Hansen’s disease patients vulnerable and prone to possible exploitation. The act of obtaining informed consent from this group of vulnerable patients remains an issue of ethical importance that ought to be properly addressed and respected. This is because there is a possibility that the criteria and value judgments employed by vulnerable individuals while weighing the potential risks and benefits of research may differ from those employed by individuals who are not vulnerable. For instance, a Hansen's disease patient may place more emphasis on issues with the potential of worsening stigmatization and social isolation more than any other issue.

Hence, it is often advocated that additional protection, which includes obtaining informed consent, be always provided when carrying out research with vulnerable groups to avoid exploitation of the individuals.

The use of patients' data either in the form of pictures, videos among others have remained relevant and have been documented as effective means of teaching and passing relevant information. The use of these data could be for Health Information, Education and Communication (IEC) purposes; for healthcare workers' training; for research, for policymaking and design among other purposes.

It has been documented that pictures, markedly increase attention to and recall of health education information. Pictures can also improve comprehension when they show relationships among ideas or when they show spatial relationships, and can equally change adherence to health instructions.[13] In addition, they can be very helpful in exposing trainees to rare and complex medical conditions.

Audiovisuals have also become a very effective tool in contemporary medical education. The use of multimedia methods in teaching and learning, including the use of audiovisuals enhances the presentation of medical science concepts to students. Multimedia are equally incorporated into most e-learning platforms which are fast gaining grounds in contemporary education worldwide. Videos simultaneously fuse both auditory and visual information and equally engage various areas of the trainee's cognition during lectures. [14]

Apart from the roles in medical education, medical videos are an effective means of keeping physicians abreast with the latest developments in their field of discipline. And these videos can be easily accessible outside the confines of the hospital facility. The benefits of the use of patients' data either in the form of pictures, videos or oral interviews can be enormous, but these benefits ought to be harnessed without sacrificing the autonomy of the patients, and respect for their dignity. Hence the authors sought to determine the willingness of Hansen's disease patients to give consent for the use of their data in the form of pictures, video and/or oral interview formats by a third party.

Materials and Methods

This study was carried out in three Hansen's disease-endemic states in Nigeria namely, Ebonyi, Ogun and Cross River states. The study was a community-based cross-sectional comparative survey. Participants were recruited from Hansen's disease patients; newly diagnosed Hansen's disease patients on treatment and individuals relieved from treatment.

Consenting newly diagnosed Hansen's disease patients, patients on treatment and individuals relieved from treatment located in the aforementioned states, were included in the study. Non-Hansen's disease patients, Hansen's disease patients not located in the aforementioned states, individuals declining consent.

Ethical considerations

Research approval and Ethical clearance were obtained from the University of Nigeria, College of Medicine Research Ethics Committee.

Informed consent, and assent from minors was obtained from participants after the purpose of the study was explained to them.

Data collection tool

This was done using a pretested semi-structured researcher administered questionnaire. The questionnaire was designed by the researchers and included two sections. The first section assessed participants' demographic information while the second section assessed the experience of stigmatization, willingness to give consent and reasons for declining consent.

Statistical analyses

Collected data were double-entered into an excel spreadsheet and statistical analysis was done using SPSS version 20. Continuous variables were summarized as mean (standard deviation SD) while categorical analyses were expressed as percentages. Chi-square test and univariate logistic regression were used to determine the relationship of age and sex with the willingness to give consent. The strength of association was expressed using Relative Risk Ratio (RRR). For all analyses, a P-value of less than 0.05 was considered significant.

Results

The study included 93 respondents with a mean (SD) age of 44.9 (20.1) years, range 8 – 84 years and male: female ratio of 1.2:1. The majority 57 (61.29%) of the respondents were farmers while the highest level of education for the majority 67 (72.04%) was primary education. The socio-demographic characteristics of respondents are as described in Table 1.

Table 1: Socio-Demographic Characteristics of Respondents N = 93

Socio-demographic characteristics	Frequency (%)
Sex	
Male	50 (53.76)
Female	43 (46.24)
Marital Status	
Married	53 (56.99)
Single	27 (29.03)
Widowed	12 (12.90)
Divorced	1 (1.08)
Occupation	
Artisan	13 (13.98)
Farmer	57 (61.29)
Pupil/Student	17 (18.28)
Teacher	1 (1.08)
Trader	2 (2.15)
Unemployed	3 (3.23)
Educational level	
Primary education	67 (72.04)
Secondary education	22 (23.66)
Tertiary education	4 (4.30)

Table 2: Respondents' Willingness to Give Consent, N = 93

S/N	Variables	Yes (%)	No (%)	P-value
1	Picture	83 (89.25)	10 (10.75)	0.3648
2	Videos	80 (86.02)	13 (13.98)	
3	Oral interview	86 (92.47)	7 (7.53)	

A total of 26 (27.96%) respondents had suffered some form of discrimination in the course of their disease. The majority 48 (51.6%) of the respondents were from Ebonyi State while the rest of the respondents were distributed as shown in Figure 1. In their responses, 83 (89.2%) indicated a willingness to give consent for their pictures, 80 (86.0%) their videos and 86 (92.5%) their recorded oral interviews to be used (Table 2). Among those who would not give consent, the commonest reasons adduced were an intrusion into privacy and lack of trust, (Table 3).

It was observed that the majority of respondents in the age range 26 - 45 years would give consent for the use of their pictures and those in the age range 46 – 65 for their videos and oral interviews, though this was not statistically significant, (Table 4). Females were 1.03 times more likely than males to give consent for their pictures to be used, but 0.92 times less likely to give consent for their oral interviews to be used. The willingness to give consent for use of videos was identical for both females and males, (Table 5).

Among respondents not willing to give consent, majority 10 (52.63%) cited ‘being sure that the use of the data will benefit others’ as a measure that will facilitate their willingness to give consent, (Table 6).

Discussion

Human infection with Hansen’ disease dates back to ancient times with its associated stigmatization.[15,16] Globally, Hansen's disease is the second most common mycobacterium infection after Tuberculosis. In Nigeria, it has been noted to continue to exist as a disease of public health importance with an annual detection rate of 4000 people and a grade 2 disability rate of 12%[17] Despite achieving the WHO elimination target in some West African countries, the burden of Leprosy remains high in certain localities in those countries.[18] There is indeed perception of Hansen's disease as the most shameful and detested human condition.[16]

Table 3: Reasons for Declining Consent

S/N	Reasons for declining consent	Frequency (%)
1	Lack of trust	8 (50)
2	No financial reward	3 (19)
3	Intrusion into privacy	9 (56)
4	Other reasons like stigma	1 (6.3)
5	Total	21 (131.3)
NB: Total more than 100% due to respondents choosing more than one option		

Table 4: Relationship of Age with Willingness to Give Consent to Use of Data

S/N	Age Ranges (years)	Type of Data			P-value
		Picture (N, %)	Video (N, %)	Oral interview (N, %)	
1	< 18	11 (13.25)	11(13.75)	11 (12.79)	0.999
2	18 – 25	8 (9.64)	6 (7.50)	8 (9.30)	
3	26 - 45	25 (30.12)	23 (28.75)	25 (29.07)	
4	46 – 65	24 (28.92)	26 (32.50)	26 (30.23)	
5	>65	15 (18.07)	14 (17.50)	16 (18.61)	
6	Total	83 (100.00)	80 (100.00)	86 (100.00)	

Of the 93 respondents in this study, 26 (27.96%) had suffered some degree of stigmatization in the course of their illness. Considerable work has been carried out on the stigmatization of Hansen's disease patients, and results from these studies have noted some causes and consequences of stigmatization. Peters *et al*[19] reported Sadness, frustration, loss of confidence, devaluation of their capacity, stress, and hopelessness as some of the feelings encountered among Hansen's disease patients. Sermrittirong *et al*[20] equally reported manifestations of the disease on the body, sociocultural and religious beliefs, and fear of being infected as some of the causes of stigmatization.

In this study, more than half of the study population was comprised of males, and over 70% were low-income earners. Fifty-nine per cent (59%) were aged between 26 to 65 years which form the active and productive age group in any society.

Published literature suggests increased age, poor sanitary and socioeconomic conditions, lower level of education, and food insecurity as risk markers for leprosy. Leprosy was associated with male gender, low-income workers, history of food shortage, contact of a leprosy patient, and dwelling in densely populated areas and over-crowded households [18,20,21]. These same socio-economic factors are responsible for the confinement of these lepers to peculiar geographical locations and communities

Table 5: Relationship of Sex with Willingness to Give Consent

Type of Data	**Willingness to give consent**		**Chi sq (χ2)**	**P-value**	**RRR (95% CI)**
	Yes (N, %)	**No (N, %)**			
Picture			0.18	0.6754	
Female	39 (46.99)	4 (40.00)			1.03 (0.8959 to 1.1857)
Male	44 (53.01)	6 (60.00)			
Video			0.00	0.9949	
Female	37 (46.25)	6 (46.15)			1.00 (0.8489 to 1.1792)
Male	43 (53.75)	7 (53.85)			
Oral Interview			1.93	0.1645	
Female	38 (44.19)	5 (71.43)			0.92 (0.8146 to 1.0403)
Male	48 (55.81)	2 (28.57)			

Table 6: Measures that Can Facilitate Willingness to Give Consent

S/N	**Measures**	**Yes Number (%)**	**No Number (%)**	**Total Number (%)**
1	A signed agreement that the picture/video/interview will be used solely for the stated purposes	7 (36.84)	12 (63.16)	19 (100)
2	Financial reward	5 (26.32)	14 (73.68)	19 (100)
3	Being sure it will benefit others	10 (52.63)	9 (47.37)	19 (100)
4	Casting a shadow over the eyes	7 (36.84)	12 (63.16)	19 (100)
5	Picture/video/interview being taken by someone trusted	4 (21.05)	15 (78.95)	19 (100)

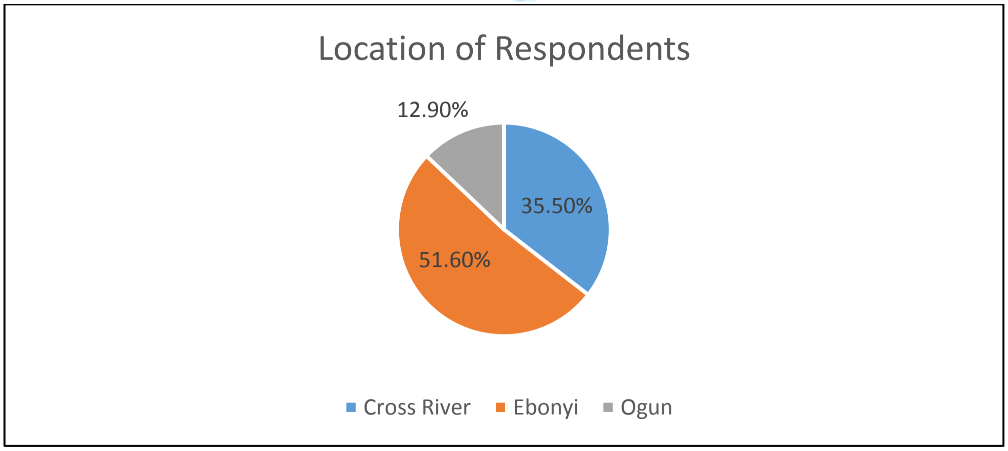

Figure 1: Location of Respondents

The majority of the participants were willing to give consent to the use of their data by a third party. This is interesting in a group of individuals considered to belong to a vulnerable group and required to have additional protection before being enrolled in research. This finding may help in guiding stakeholders in research against the overprotection of this group of individuals. Females were more likely to give consent for their pictures than for their oral interviews. This may be attributed to the fact that considering a stigmatized medical condition, females are likely to be more conscious of being identified than males. Pictures are normally made unidentifiable by covering the eyes/face of the individual before use, but voices in oral interviews may not be easily altered. This may be the reason why females shy away from allowing the use of their oral interviews for fear of identification.

Majority of respondents not willing to give consent cited beneficence as a measure to encourage them to give consent. Beneficence is a prima facie ethical principle that places moral obligations on individuals to act for the benefit of others. This principle is quite valuable in biomedical research as the outcome of research may not always be of direct benefit to the research participants. The use of these patients' pictures, videos or oral interviews is likely to be of great benefit to medical educators and students, training of other healthcare workers, policy advocacy and formation amongst other uses.

Conclusion

The findings in the current study suggest that though stigmatization of the disease still exists, the majority of the patients would give consent for use of their data. However, intrusion into privacy and lack of trust were major constraints for those not willing to give consent.

Recommendations

The present study has made findings that ought to raise the consciousness of healthcare givers and every other stakeholder on the importance of putting more efforts geared towards winning the patients' trust before attempting to seek informed consent.

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References

1. **Nijhawan LP, Janodia MD, Muddukrishna BS, Bhat KM, Bairy KL, Udupa N, *et al*.** Informed consent: Issues and challenges. *J Adv Pharm Technol Res* 2013;4(3):134-40.
2. **Kadam RA**. Informed consent process: A step further towards making it meaningful! *Perspect Clin Re*s 2017;8(3):107-12.
3. **Hall DE, Prochazka AV, Fink AS**. Informed consent for clinical treatment. *CMAJ* 2012;184(5):533-40.
4. **Mallardi V.** [The origin of informed consent]. Acta Otorhinolaryngol Ital 2005;25(5):312-27.
5. **del Carmen MG, Joffe S**. Informed consent for medical treatment and research: a review. *Oncologist* 2005;10(8):636-41.
6. **Miller T, Boulton M.** Changing constructions of informed consent: qualitative research and complex social worlds. *Soc Sci Med* 2007;65(11):2199-211.
7. **Kirby R, Challacombe B, Dasgupta P, Fitzpatrick JM.** The importance of obtaining truly consensual informed consent. BJU Int 2012;109(12):1743-4.
8. **Kirby R, Challacombe B, Hughes S, Chowdhury S, Dasgupta P.** Increasing importance of truly informed consent: the role of written patient information. *BJU Int* 2013;112(6):715-6.
9. **Afolabi MO, Okebe JU, McGrath N, Larson HJ, Bojang K, Chandramohan D.** Informed consent comprehension in African research settings. *Trop Med Int Health* 2014;19(6):625-42.
10. **Olivier HR.** Psychiatric aspects of Hansen's disease (leprosy). *J Clin Psychiatry* 1987;48(12):477-9.
11. **Hofstraat K, van Brakel WH.** Social stigma towards neglected tropical diseases: a systematic review. *Int Health.* 2016;8 (1):i53-70.
12. **Ebenso B, Newell J, Emmel N, Adeyemi G, Ola B**.Changing stigmatisation of leprosy: an exploratory, qualitative life course study in Western Nigeria. *BMJ Global Health* 2019;4**:**e001250.
13. **Houts PS, Doak CC, Doak LG, Loscalzo MJ.** The role of pictures in improving health communication: A review of research on attention, comprehension, recall, and adherence. *Patient Education and Counseling* 2006; 61: 173–190
14. **Dong C, Goh P.** Twelve tips for the effective use of videos in medical education. *Med Teach*. 2015;37:140–5.
15. **Nations MK, Lira GV, Catrib AM.** Stigma, deforming metaphors and patients' moral experience of multibacillary leprosy in Sobral, Ceara State, Brazil. *Cad Saude Publica* 2009;25(6):1215-24.
16. **Ebenso B, Newell J, Emmel N, Adeyemi G, Ola B.** Changing stigmatisation of leprosy: an exploratory, qualitative life course study in Western Nigeria. B*MJ Glob Health* 2019;4(2):e001250.
17. **Udo S, Chukwu J, Obasanya J.** Leprosy situation in Nigeria. *Lepr Rev* 2013;84(3):229-37.
18. **Tabah EN, Nsagha DS, Bissek AZ, Bratschi MW, Njamnshi TN, Plushke G, *et al*.** The Burden of Leprosy in Cameroon: Fifteen Years into the Post-elimination Era. *PLoS Negl Trop Dis* 2016;10(10):e0005012.
19. **Peters RM, Dadun, Lusli M, Miranda-Galarza B, van Brakel WH, Zweekhorst MB, *et al*.** The meaning of leprosy and everyday experiences: an exploration in cirebon, indonesia. *J Trop Med* 2013;2013:507034.
20. **Sermrittirong S, Van Brakel WH.** Stigma in leprosy: concepts, causes and determinants. *Lepr Rev* 2014;85(1):36-47.
21. **Pescarini JM, Strina A, Nery JS, Skalinski LM, Andrade KVF, Penna MLF, *et al*.** Socioeconomic risk markers of leprosy in high-burden countries: A systematic review and meta-analysis. *PLoS Negl Trop Dis* 2018;12(7):e0006622.