# **Original Research Article**

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# Pattern and predictors of lepra reactions among patients treated for leprosy in southeast Nigeria: a mixed methods study

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#### **ABSTRACT**

**Background:** Lepra reactions occur among patients treated for leprosy. This study aimed to assess the pattern and predictors of lepra reactions in southeast Nigeria.

**Methods:** This is a convergent parallel mixed-methods study that determined the pattern and explored the experiences of leprosy patients. Participants were recruited by cluster sampling technique. Chi-square test and binary logistic regression analysis were done. In addition, in-depth and key informant interviews were conducted.

**Results:** There were 71 participants in total, comprising 35 males (49.3%) and 36 females (50.7%) with a mean age of 60.39±16.327. The prevalence of type 1 and type 2 lepra reactions were 59.2% (95% CI 47.14-70.17) and 35.2% (95% CI 27.30-50.07) respectively. Type 1 lepra reaction (LR) was significantly associated with gender (p<0.023) and farming (p<0.044). Furthermore, Paucibacillary leprosy (PB) was significantly associated with both types 1 (p<0.022) and 2 (p<0.011) lepra reactions. Type of diagnosis (PB) was a significant predictor of type 1 LR 5.89 (95% CI 1.58 - 21.99) and type 2 LR 8.76 (95% CI 1.67-46.15). Worsening and new lesions led to discrimination and stigmatization for leprosy survivors.

**Conclusions:** Lepra reactions are common among leprosy patients in southeast Nigeria. Male gender, farming and PB leprosy were found to be predictors of leprosy reactions.

**Keywords:** Lepra reactions, Lepra type 1, Lepra type 2, Leprosy, Pattern, Predictors

#### INTRODUCTION

Leprosy is a chronic disease classified as a neglected tropical disease (NTDs) by the World Health Organization (WHO). 1,2 Due to the stigma, shame and fear, it is often under-reported. Paralysis is common in leprosy, resulting from nerve damage caused by Mycobacterium leprae and immune responses during treatment, known as lepra reactions (LR). 3,4 Lepra

reactions are classified into type 1 (reversal reaction), which worsens existing skin lesions and type 2 (Erythema Nodusum Leprosum), which involves new lesions and systemic symptoms.<sup>5–8</sup>

Studies done in Southeast Asia and America show that factors like age, delayed diagnosis, treatment duration and comorbidities influence leprosy reactions.<sup>4,9,10</sup> However, data from Southeast Nigeria remains limited. This study

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aimed to assess the pattern and predictors of LR among leprosy patients treated with WHO multidrug therapy (MDT) in selected treatment facilities in Southeast Nigeria.

#### **METHODS**

#### Study design

This study employed a cross-sectional descriptive design with a convergent parallel mixed-methods approach, collecting both quantitative and qualitative data simultaneously.

#### Study place

This study is part of a larger research conducted in the Southeast geopolitical region of Nigeria between 12th July 2022 to 9th September 2022, in Anambra and Enugu states.

In Anambra, research sites included Nnamdi Azikiwe University Teaching Hospital (NAUTH) and the Okija leprosy settlement. In Enugu, the study was conducted at the largest of the state's four facilities -the Oji River Leprosy settlement, which receives international support.

#### Study population

The target population included patients who completed 5-month treatment for paucibacillary (PB) leprosy, 10-month treatment for multibacillary (MB) leprosy, naïve patients, defaulters, those discharged from facilities, those who had relapsed after treatment and those still residing in settlements post-treatment.

#### Inclusion criteria

This study included participants aged 18 or above who consented, those treated and discharged within the past 5 years and patients actively receiving care in the facilities, including relapse cases.

#### Exclusion criteria

Terminally or mentally ill patients and those who demanded financial compensation for participation were excluded.

#### Sample size determination

The sample size was calculated using the "single proportion formula for sample size determination"11 with a prevalence of 0.014, the last available prevalence of leprosy from a 2008 cross-sectional study in Kaduna state, Nigeria.12 The estimated sample size was 2,981. However, due to dwindling diagnosis and enrollment for treatment and financial constraints, this study recruited only 71 patients over the study period.

#### Sampling technique

A cluster sampling technique was used in this study. The five states in southeast Nigeria namely Enugu, Ebonyi, Abia, Imo and Anambra were initially selected. Enugu and Anambra were ultimately selected. Of the eight identified treatment facilities in these states, four were randomly chosen. Due to logistical and financial limitations, the study was conducted in three out of the four. All eligible patients present during the study period were included.

#### Study instrument and data collection

An interviewer-administered questionnaire was developed and a biostatistician reviewed it for clarity and alignment with the research questions. Data on patients' biodata, outcome variables and treatment experiences were collected. WHO operational definitions of 1LR, 2LR, PB and MB leprosy were used in this study.

For the qualitative component, two interview guides were developed: one for patients/completed treatment participants and another for health workers. Both tools were validated by NAUTH health workers and pretested.

#### **Analysis**

#### Quantitative analysis

Quantitative data collected through Google form were downloaded into Microsoft Excel and later, exported to the Statistical Package for Social Sciences (SPSS) version 25 for analysis. Categorical data were expressed as percentages. Chi-square test was used to assess associations between outcome variables (lepra types 1 and 2 reactions) and exposure variables. Associations with p-value  $\leq 0.05$  were considered significant. Significant exposure variables were included in binary logistic regression analyses.

### $Qualitative \ analysis$

Grounded theory approach was used in this study. Qualitative data from audio-recorded interviews were transcribed and coded with Nvivo software using Braum and Clarke's thematic analysis. This involved familiarization, followed by code development, then identifying themes and sub-themes. Only themes related to leprosy reactions were reported from the larger study.

#### Ethical considerations

Ethical approval for this study (reference number: NAUTH/CS/66/VER.3/127/2023/063) was obtained from the Research and Ethics Committee of Nnamdi Azikiwe University Teaching Hospital (NAUTHHREC). Informed consent was obtained verbally before enrollment and questionnaire administration.

#### **RESULTS**

#### Sociodemographic characteristics of respondents

A total of 71 participants were recruited, with a mean age of  $60.39 \pm 16$  years. Most respondents (30/71; 42.3%) were between 41 and 60 years old. There was nearly equal representation of male (35/71; 49.3%) and female (36/71; 50.7%) genders. Most participants were unemployed (36/71; 50.7) and majority of those working were farmers (22/71; 31%). About 45% (32/71) had no formal education, while the majority with an education had only primary education (22/71; 31.0%). Table 1 provides these details.

Furthermore, most of the participants were naïve leprosy patients (61/71; 85.9%), followed by relapse cases (8/71; 11.3%) and treatment after default (2/71; 2.8%). Patients who received MDT for more than 12 months constituted majority of participants (47/71; 66.2%) while the least was represented by those who had treatment for 6 months. (5/71; 7.0%)

#### Occurrence of lepra reactions

In this study, both types of lepra reactions were reported, with type 1 occurring more frequently than type 2 reaction. Figure 1 shows the proportion of patients with type 1 reaction at 59.2%, (42/71), type 2 reaction at 35.2% (25/71) and those without reactions at 5.6% (4/71).

# Comorbidities and side effects associated with leprosy reactions

Some respondents had comorbidities while undergoing leprosy treatment. Table 2 shows that most patients did not have comorbidities (60/71; 84.4%), but among those with comorbidities, hypertension was the most common (6/71; 8.4%).

Table 3 lists the side effects and adverse reactions associated with MDT: anaemia (4/71; 5.6%), darkened skin (21/71; 33.8%), fever (3/71; 4.2%), jaundice (3/71; 4.2%), reddish urine (39/71; 54.9%), vomiting (2/71; 2.8%), diarrhoea (1/71; 1.4%) and nausea (1/71; 1.4%).

Figure 2 shows that majority of the participants did not have any residual impairments (39/77;55%). Among participants with impairment after discharge from treatment, the majority had worsening of old lesions (13/77; 18%), followed by those with muscle weakness (10/77; 14%), then those with social problems, especially discrimination and anxiety (5/77; 7%) and lastly those with unusual sensations (4/71; 6%).

#### Factors that influence lepra 1 reaction

The Chi-square test revealed a significant association between type 1 lepra reaction and female gender (p<

0.023), occupation (p<0.044), slit examination (p< 0.005) and PB (p< 0.022), as shown in Table 4.

As shown in Table 5, binary logistic regression indicated that male gender (aOR 0.23 95% CI 0.07–0.76) and farming (aOR 0.19 95% CI 0.04 –0.81) influence type 1 LR slightly. Additionally, patients with PB leprosy had a higher risk of developing lepra type 1 LR compared to those with MB leprosy (aOR 5.89 95% CI 1.58–21.99).

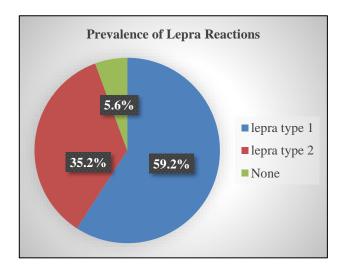


Figure 1: Prevalence of lepra reactions among study participants.

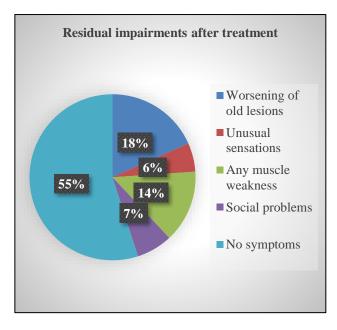


Figure 2: Residual impairments after treatment.

#### Factors that influence lepra 2 reaction.

Table 6 shows a significant association between type 2 reaction and PB leprosy (p<0.011) on Chi-square test. Binary logistic regression analysis, as shown in Table 7, indicates that PB patients are at greater risk of developing type 2 LR compared to MB leprosy patients (aOR 8.77

95% CI 1.67–46.15). Other variables were not significantly associated with type 2 LR.

#### Interview results

Key informant and in-depth interviews were conducted with patients and selected staff involved in the leprosy programme. Participants included three patients, a public health expert, a chief nursing officer, a leprosy focal doctor and a pharmacist technician.

#### Occurrence of lepra reactions

Most participants experienced leprosy reactions erroneously perceived them as adverse reactions. For instance, one participant reported. "When I was taking those drugs, I noticed that my wounds were getting worse and my skin was getting darker. I was encouraged to continue taking my drugs as the wounds will get better over time."

#### Comorbidities and lepra reactions

When asked about his knowledge of lepra reactions, one health worker reported. "I am not sure about what lepra reactions are, but I know that the patients sometimes react to the drugs, especially those that have infections caused by the wounds and this oftentimes makes them to be very sickly; If they keep taking the drugs for some time, they will get better."

Adverse/side effects of medications used in Leprosy treatment

Regarding side effects, one health worker remarked. "They used to have skin discolorations and some of them gain excess weight during treatment".

Another health worker reported "In the course of management, there may be adverse effects like moon face due to prednisolone, weight gain, change in complexion. In one patient, her weight became times two. One had pruritus. One came with joint pains for which he was evaluated for rheumatoid arthritis. This patient is also a sickle cell patient."

#### Impact of leprosy reactions after treatment

According to a 40-year-old leprosy survivor, "Because of the wound, you will have people who will stigmatize you. As long as you have a deformity, when you go home, you are stigmatized and you will die as a result of it. For me now, if I go to the village, I use to experience stigmatization over there.

They still see me as having leprosy. Those who returned home after treatment did not stay up to 1 year before they died as a result of stigmatization. The people who get to survive longer are those who do not have deformities and people do not know that they are deformed". Lepra reactions have devastating impacts on patients and affect their ability to resume daily activities.

Table 1: Socio-demographic characteristics of respondents.

Socio-demographic characteristics	Frequency	%
Age (in years)		
21-40	10	14.1
41-60	30	42.3
61-80	25	35.2
81-100	6	8.5
Gender		
Male	35	49.3
Female	36	50.7
Marital status		
Married	64	90.1
Single	4	5.6
Widowed	3	4.2
Place of origin		
Akwa-Ibom	1	1.4
Anambra	40	56.3
Ebonyi	1	1.4
Enugu	28	39.4
Imo	1	1.4
Occupation		
Artisan	8	11.3
Civil servant	2	2.8
Farming	22	31.0
Private business	3	4.2
Unemployed	36	50.7

Continued.

Socio-demographic characteristics	Frequency	0/0
Level of education		
No formal education	32	45.1
Primary education	22	31.0
Secondary education	14	19.7
Tertiary education	3	4.2
Case categorization		
Naïve patients (New cases)	61	85.9
Relapse	8	11.3
Treatment after default	2	2.8
<b>Duration of treatment</b>		
6 months	5	7.0
6.1 month to 12 months	19	26.8
Greater than 12 months	47	66.2
Follow visits after treatment completion		
Yes	64	90.1
No	7	9.9

Table 2: Comorbidities in patients treated in Southeast Nigeria.

Presence of comorbidities	Frequency	0/0
Chronic leg ulcer	1	1.4
Hypertension	6	8.4
Diabetes	2	2.8
HIV	1	1.4
Tuberculosis	1	1.4
None	60	84.4
Total	71	100

Table 3: Adverse effects experienced during treatment.

Side effects/adverse effects reported during treatment	Frequency	%
Anaemia	4	5.6
Darkened skin	24	33.8
Diarrhoea	1	1.4
Fever	3	4.2
Jaundice	2	2.8
Reddish discolouration of urine	39	54.9
Nausea	1	1.4
Vomiting	2	2.8

Table 4: Bivariate analysis of type 1 lepra reaction and some selected variables.

Bivariate analysis	Experienced lepra type 1 reaction yes (%)	No (%)	Total	Pearson chi-square value (X2)	P value
Age (in years)					
Less than 40	6 (60.0)	4 (40.0)	10	0.003	0.950
40 and above	36 (59.0)	25 (41.0)	61		
Gender					
Male	10 (27.8)	26 (72.2)	36	5.610	0.023*
Female	19 (54.3)	16 (45.7)	35		
Occupation					
Artisan	3 (37.5)	5 (62.5)	8	9.802	0.044*
Civil servant	2 (100.0)	0 (0.0)	2		
Farming	4 (18.2)	18 (81.8)	22		

Continued.

Bivariate analysis	Experienced lepra type 1 reaction yes (%)	No (%)	Total	Pearson chi-square value (X2)	P value
Private business	1 (33.3)	2 (66.7)	3		
Unemployed	19 (52.8)	17 (47.2)	36		
<b>Treatment centre</b>					
NAUTH	1 (50.0)	1 (50.0)	2	0.147	0.929
Oji	27 (40.3)	40 (59.7)	67		
Okija	1 (50.0)	1 (50.0)	2		
Slit examination bef	fore treatment				
No	5 (100.0)	0 (0.0)	5	7.790	0.005**
Yes	24 (36.4)	42 (63.6)	66		
Diagnosis of leprosy					
Paucibacillary	11 (64.7)	6 (35.3)	17	5.267	0.022*
Multibacillary	18 (33.3)	34 (66.7)	54		
Comorbidities					
Diabetes Mellitus	2 (100.0)	0 (0.0)	2	6.435	0.376
Hypertension	3 (50.0)	3 (50.0)	6		
HIV	0 (0.0)	1 (100)	1		
Tuberculosis	0 (0.0)	1 (100.0)	1		
Chronic Ulcer	1 (100.0)	0 (0.0)	1		
Nil	36 (60.0)	24 (40.0)	60		
Case categorization					
New case	36 (59.0)	25 (41.0)	61	1.659	0.436
Relapse	4 (50.0)	4 (50.0)			
Treatment after default	2 (100.0)	0 (0.0)			
Follow up visit					
No	4 (57.1)	3 (42.9)	7	0.13	0.912
Yes	38 (59.4)	26 (40.6)	64		
<b>Experienced compli</b>	cations				
Worsening of old lesions	8 (61.5)	5 (38.5)	13	4.520	0.340
Unusual sensations	1 (25.0)	3 (75.0)	4		
Any muscle weakness problem	8 (80.0)	2 (20.0)	10		
Any social problem	2 (40.0)	3 (60.0)	5		
Nil	23 (57.0)	16 (41.0)	39		
<b>Duration of treatme</b>	nt				
Less than 6 months	3 (60.0)	2 (40.0)	5	0.017	0.999
6.1 to 12 months	11 (57.9)	8 (42.1)	19		
Greater than 12 months	28 (59.6)	19 (40.4)	47		

<sup>\*\*</sup>Very significant with p</=0.005; \* Significant with p</=0.05.

Table 5: Binary logistic regression analysis of lepra type 1 reaction and some selected exposure variables.

Variable	Crude odds ratio (95% CI)	P value	Adjusted odds ratio (95% CI)	P value
Age (in years)				
<40	1.07 (0.27 – 4.20)	0.921	0.34 (0.06– 1.95)	0.225
>/= 40	1.00 (Ref)		1.00 (Ref)	
Gender				
Male	0.32 (0.12 - 0.87)	0.025	0.23 (0.07 - 0.76)	0.016*
Female	1.00 (Ref)		1.00 (Ref)	
Occupation				
Farming	0.21 (0.06 - 0.72)	0.013	0.19 (0.04 - 0.81)	0.025*
Others	1.00 (Ref)		1.00 (Ref)	

Continued.

Variable	Crude odds ratio (95% CI)	P value	Adjusted odds ratio (95% CI)	P value
Slit examination before tr	eatment			
Yes	0.00	0.999	0.00	0.999
No	1.00 (Ref)		1.00(Ref)	
Diagnosis of leprosy				
Paucibacillary	3.67 (1.17 – 11.52)	0.026	5.89 (1.58 – 21.99)	0.008**
Multibacillary	1.00 (Ref)		1.00 (Ref)	

<sup>\*\*</sup>Very significant with p</= 0.005; \* Significant with p</= 0.05; CI – confidence interval; cOR=crude odds ratio; aOR= adjusted odds ratio.

Table 6: Bivariate analysis of Type 2 reactions and some selected exposure variables.

Bivariate analysis	Experienced lepra type 2 reaction yes (%)	No (%)	Total	Pearson chi-square value (X²)	P value
Age (in years)	<i>yes</i> (70)				
Less than 40	4 (40.0)	6 (60.0)	10	0.019	0.890
40 and above	23 (37.7)	38 (62.3)			
Gender	/	( )			
Male	25 (71.4)	10 (28.6)	35	2.619	0.106
Female	19 (52.8)	17 (47.2)	36		
Treatment centre	,	,			
NAUTH	2 (100.0)	0 (0.0)	2	2.601	0.272
OJI River	40 (59.7)	27 (40.3)	67		
Ojika	2 (100.0)	0 (0.0)	2		
Diagnosis	,				
Multibacillary	29 (53.7)	25 (46.3)	54	6.542	0.011*
Paucibacillary	15 (88.2)	2 (11.8)	17		
Occupation		,			
Farming	11 (40.7)	11 (25.0)	22	3.756	0.440
Private business	1 (3.7)	2 (4.5)	3		
Civil servant	1 (3.7)	1 (2.3)	2		
Artisan	1 (3.7)	7 (15.9)	8		
Unemployed	13 (48.1)	23 (52.3)	36		
Slit examination done befo	re treatment				
Yes	27 (40.9)	39 (59.1)	66	3.301	0.069
No	0 (0.0)	5 (100.0)	5		
Presence of comorbidities					
Diabetes Mellitus	21 (100.0)	0 (0.0)	2	7.988	0.239
Hypertension	2 (40.0)	3 (60.0)	5		
HIV	0 (0.0)	1 (100.0)	1		
Tuberculosis	0 (0.0)	1 (100.0)	1		
Chronic ulcer	1 (100.0)	0 (0.0)	1		
Nil	21 (35.0)	39 (65.0)	60		
Case categorization		,			
Naïve patients (new case)	22 (36.1)	39 (63.9)	61	0.186	0.245
Relapse	3(37.5)	5 (62.5)	8		
Treatment after defaulter	2(100.0)	0 (0.0)	2		
Follow visits		,			
Yes	24 (37.5)	40 (62.5)	64	0.077	0.782
No	3 (42.9)	4 (57.1)	7		
Complications after treatm					
Worsening of old lesion	7 (53.8)	6 (46.2)	13	7.688	0.104
Unusual sensation	0 (0.0)	4 (100.0)	4		
Any muscle weakness	3 (30.0)	7 (70.0)	10		
Any social problem	0 (0.0)	5 (100.0)	5		
Nil	17 (43.6)	22 (56.4)	39		
<b>Duration of treatment</b>		, ,			
Less than 6 months	2 (40.0)	3 (60.0)	5	1.523	0.467
6.1 to 12 months	5 (26.3)	14 (73.7)	19		
Greater than 12 months	20 (42.6)	27 (57.4)	47		
		( )			

<sup>\*</sup>Significant with p≤0.05.

Variable	Crude odds ratio (95% CI)	P value	Adjusted odds ratio (95% CI)	P value
Age (in years)				
<40	1.15(0.29 - 4.53)	0.840	0.50 (0.08 - 3.27)	0.471
≥40	1.00 (Ref)		1.00 (Ref)	
Gender				
Male	0.45 (0.17 - 1.20)	0.108	0.44 (0.14 - 1.33)	0.150
Female	1.0 (Ref)		1.00 (Ref)	
Occupation				
Farming	0.49(0.17 - 1.35)	0.167	0.61 (0.18 - 2.07)	0.423
others	1.00(Ref)		1.00 (Ref)	
Slit examination	done before treatment			
Yes	0.00	0.999	0.00	0.999
No	1.00 (Ref)		1.00 (Ref)	
Diagnosis				
Paucibacillary	6.45 (1.35 – 31.06)	0.023	8.77 (1.67 – 46.15)	0.01*

1.00 (Ref)

Table 7: Binary logistic regression between type 2 reaction and some selected exposure variables.

#### **DISCUSSION**

Multibacillary

To our knowledge, this is the first study in Nigeria to examine the pattern and predictors of lepra reactions among leprosy patients in the Southeast. The mean age of participants reflects the delayed onset of leprosy and lepra reactions, consistent with the long incubation period of *Mycobacterium leprae*.<sup>13</sup> Unlike previous research reporting a male predominance (1.5:1), our study showed a nearly equal gender distribution.<sup>13,15</sup> About 45 percent of the participants experienced impairments, including worsening of old lesions, suggestive of persistent type 1 LR and psychosocial challenges.

1.00 (Ref)

Other studies carried out in southeastern Nigeria and other parts of the world have reported similar findings. <sup>16-20</sup> Most respondents (74%) were treated for MB leprosy, consistent with findings that untreated PB leprosy can progress to MB leprosy. Compared to studies from Brazil, India, Nepal and Thailand, where type 1LR ranged from 30 percent and type 2 LR from 19-26%, this study reported a higher overall occurrence. <sup>21-25</sup> Type 1 LRs accounts for 59.2 percent of cases, nearly double the 35.2 percent for type 2 LRs, which differs from the findings of Motta et al, who reported more type 2 (34.6%) than type 1 reactions (19.6 percent). <sup>4</sup>

This study identified coinfections and comorbidities but none showed a significant association with either type of lepra reaction. Similarly, a larger Brazilian study found coinfections in 39.1 percent of participants, including oral infections.<sup>4</sup>

The complications reported in our study were worsening symptoms and muscle weakness, likely linked to lepra reactions and paralysis resulting from delayed presentation and treatment. <sup>23,26–28</sup> These complications, which significantly impact quality of life, have been widely documented in other studies. <sup>29–32</sup>

This study found an association between male gender and type 1 reaction but not with type 2 reaction. After adjusting for confounders (age, treatment centres, occupation and diagnosis), binary logistic regression showed that males appeared to be more protected against type 1 reactions. This aligns with earlier studies highlighting the roles of genetics34 and hormones, particularly estrogen, in susceptibility to infections like leprosy and lupus.<sup>35–37</sup>

Most participants were farmers and an initial association was observed between farming and type 1 reaction. While a systematic review has reported higher leprosy rates among manual laborers and farmers, after adjusting for confounders, farmers had a lower risk of developing type 1 reactions compared to other occupations.<sup>38</sup>

Furthermore, PB leprosy was significantly associated with both types 1 and 2 reactions. After adjusting for confounders, patients with PB were found to be 6 times more likely to develop type 1 reaction and 9 times more likely to develop type 2 reaction. This contrasts with a 2015 retrospective study in India, which found no link between reaction type and diagnosis.<sup>39</sup>

Qualitative findings of this study highlight challenges unique to African leprosy patients, including late treatment, poor drug adherence due to side effects, coinfections, comorbidities and persistent stigma.40 Lepra reactions continue to pose significant challenges, especially post-treatment. Their debilitating effects underscore the need for further research in this area.

#### Limitations

This study was conducted in only three facilities across two states in Nigeria. Some centres were excluded due to lack of patients, limited resources and logistical risks.

<sup>\*</sup> Significant with p≤0.05; NA- not available; cOR-crude odds ratio; aOR-adjusted odds ratio; CI-confidence interval.

These factors affected the study's sample size and power and hence, a larger study is highly recommended.

#### **CONCLUSION**

Lepra reactions are common among patients treated for leprosy in Southeast Nigeria. This study found that occupation, gender and a diagnosis of PB leprosy are associated with LR. In addition, leprosy patients with few skin lesions in Southeast Nigeria are more at risk of developing all types of lepra reactions. Men have a lower chance of developing lepra reactions. Further studies need to be done to explore these findings.

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Institutional Ethics Committee

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