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Pharmaceutical care interventions, their outcomes and patients' satisfaction in antiretroviral drug therapy

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Abstract

Pharmacist's interventions (also known as pharmaceutical care plans) are means of solving the drug therapy problems identified in pharmaceutical care. Outcomes are the results of pharmacists' intervention activities. Patients' satisfaction refers to patients' feeling of fulfillment, pleasure or happiness with the services they have received. This study was designed to determine the types of pharmacist interventions applied in the pharmaceutical care of HIV patients receiving treatment at a tertiary hospital in southeast Nigeria, the types of outcomes of such interventions and level of patients' satisfaction with their drug therapy. The components of the American society of health-system pharmacists (ASHP) guidelines on 'standardized method for pharmaceutical care was used as a data collection instrument to evaluate, document and intervene in the antiretroviral therapy of about one thousand four hundred and seventy three (1,473) patients. The results showed significant reductions in the frequency of the various interventions and parameters measured after the interventions. The study concluded that pharmaceutical interventions influences patients' adherence, optimizes their drug therapy and improves rational prescribing and care resulting in significant improvements in the outcomes of their treatment and levels of satisfaction.

Keywords: Pharmacist Interventions, Outcomes, Pharmaceutical care, HIV/AIDS, Patient satisfaction

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1. Introduction

In 1987, pharmaceutical care was philosophically defined as a covenantal relationship between a pharmacist and a patient in which the pharmacist performs drug use control functions (with appropriate knowledge and skill) governed by the awareness of and commitment of the patient's interest (Hepler, 1987).

Implementation of pharmaceutical care involves six (6) basic steps which includes establishment of a professional/therapeutic relationship, collection of patient-specific data, evaluation of data to identify health and drug related problems, development and implementation of pharmaceutical care plan (pharmacist's intervention which could be patient - focused intervention or drug - focused intervention), evaluation of intervention and follow – up and documentation.

To effectively implement PC, a collaborative working relationship between the pharmacist and the physician must be developed. As such common obstacles such as boundary or turf concerns, communication breakdown, power issues, and lack of trust in another practitioners' competence should be addressed (MacDonough and Doncette, 2001). Pharmacists must accept a responsibility to educate prescribers, patients, and payers about the extent and value of PC services. Precisely, pharmacists must build the demand for PC services at the same time they create the supply (MacDonough et at, 1998).

Pharmacist's interventions (also known as pharmaceutical care plans) are means of solving the drug therapy problems identified in pharmaceutical care. Outcomes are the results of pharmacists' intervention activities. Patients' satisfaction refers to patients' feeling of fulfillment, pleasure or happiness with the services they have received. Patient satisfaction with healthcare reflects the quality of services from the patients' perspective. Its measurement can help evaluate the performance of health service delivery, identify patients who need additional attentions or targeted interventions and predict treatment adherence and outcomes (Goode et al, 2011).

In developed countries, measuring patient-reported outcomes and satisfaction is central to designing and evaluating modern healthcare services and delivery systems (Goode et al, 2011). Studies in these countries have also identified correlates and predictors of patient satisfaction with drug therapy, combined drug therapy and behavioral training in some disease conditions and these have been used to tailor treatments to improve patient satisfaction (Goode et al, 2011).

In the developing countries however, lots of research is being conducted on patient satisfaction with HIV/AIDS treatment (Goode et al, 2011). The levels of satisfaction and the associated factors varied across measures, sub-groups of patients, clinical stages, clinics, regions and healthcare systems making it essential to characterize these attributes in each setting (Goode et al, 2011).

The present study seek to determine the types of pharmacist interventions applied in the pharmaceutical care of HIV patients receiving treatment at a tertiary hospital in southeast Nigeria, the outcomes of such interventions and level of patients' satisfaction with their drug therapy.

2. Method

This is part 4 of 4 from a study carried out using the method described below. Before the study, an application for ethical approval of the study was sent to the management of the medical centre used for the study and the approval was granted.

The components of the American society of health-system pharmacists (ASHP) guidelines on 'standardized method for pharmaceutical care' were designed into a data collection instrument which was used to evaluate, document and intervene in the antiretroviral therapy of about one thousand four hundred and seventy three (1,473) patients.

Data were collected from the patients' prescription sheets, laboratory report forms, care/ART cards, and other relevant forms in their treatment folders. Other relevant information were also obtained from the patients through oral interview. The data collected at this stage formed the base-line/ pre - intervention data for the study.

After documentation of these base-line data, pharmaceutical care interventions were implemented where necessary and there included:

1. Patient education using a validated educational material applied uniformly to all the patients in the study.
2. Healthcare personnel education, counseling and discussions.
3. Recommendations for changes of drugs/regimens, change of drug dose interval, duration or dosage form, addition of more drugs, treatment of untreated conditions, implementation of non-drug therapy, patient referral.
4. Ensuring that patients do their laboratory tests.
5. Monitoring the laboratory test results and carrying out interventions where necessary.
6. Giving patients access to pharmacists any time they needed it i.e. maintaining constant communication between the patients and the pharmacists.

Then a repetition of the data collection and documentation above was done nine (9) months after the implementation of the pharmaceutical care interventions mentioned above. This data represents the post - intervention data. The two data sets (baseline / pre-intervention & post-intervention data) were then be collated, analyzed and compared to see if the interventions resulted in any significant differences in the occurrence of drug therapy problems.

Appropriate statistical analysis was also applied to the data using Microsoft Excel and SPSS tools. Inclusion and exclusion criteria used for the study were;

1. New patients were excluded from the study since they will have had no previous encounter with the system and so no existing data on them.
2. Patients selected were those who have received treatment, drugs and counseling from the hospital for at least nine (9) months (i.e. who have visited the hospital for at least three (3) times).
3. Both adults and children as well as males and females were involved in the study.

4. Patients whose medications will last for less than three (3) months were excluded from the study. This is to give the interventions enough time to make impacts and produce the possible results and to ensure uniformity of treatment duration and contact with the pharmacist in all the participating patients.

3. Results

The results of the study are shown in the tables below. Table 1 shows that 90% of patients involved in the study were adults (above 15 years) while 10% of the patients were children (0 – 15 yrs).

Table 1. Age distribution

Age Range	**Number of Patients**		Difference (A – B)	% of total = A or B/T x 100
	Pre - intervention evaluation (A) (% of total)	Post - intervention evaluation (B) (% of total)		
0 yrs – 15 yrs	146	146	0	10
15 yrs above	1327	1327	0	90
Total (T)	**1473**	**1473**	**0**	**100**

Table 2 shows that most of the patients in the study were females (65%) while the male patients accounted for 35% of the study population.

Table 2. Sex (gender) distribution

sex	**Number of Patients**		Difference (A - B)	% of total = A/T or B/T x 100
	Pre - intervention evaluation (A) (% of total)	Post - intervention evaluation (B) (% of total)		
Male	513	513	0	35
Female	960	960	0	65
Total (T)	**1473**	**1473**	**0**	**100**

Table 3 shows that there were interventions in all the cases under study.

Table 3. Distribution of pharmacist interventions

Variable	Number of Interventions		Difference (A - B)	% Difference (A - B)/ A X 100
	Pre - intervention (A) (% of total)	Post - intervention (B) (% of total)		
No Intervention	0	0	0	0
Intervention	1473	1473	0	0
Total (T)	**1473**	**1473**	**0**	**0**

Table 4 shows that the frequency of contacts with prescriber for prescription review/clarification was reduced by 11% after the interventions. Also refusal to dispense medications was reduced by 88%, discussion of event with patient or caregiver (47%), change of drug therapy (88%). However, medication information was provided for all the patients in both pre and post interventions, hence the 0% change.

Table 4. Distribution of types and frequencies of interventions

Interventions	Frequencies of interventions		Difference (A – B)	% Difference (A - B)/ A X 100.
	Pre - intervention (A). (% of total)	Post- intervention (B) (% of total)		
Contacted prescriber / healthcare personnel for prescription review/clarifications.	968 (66%)	875 (59%)	93	11
Provision of medication information	1473 (100%)	1473 (100%)	0	0
Did not dispense medication.	365 (25%)	45 (3%)	320	88
Discussed event with patient or caregiver.	1184 (80%)	626 (42%)	558	47
Drug therapy changed	367 (25%)	44 (3%)	323	88

Table 5 shows that there was 98% decrease in incidence of 'no positive' outcome and a 36% increase in the incidence of positive outcomes.

Table 5. Distribution of intervention outcomes

Outcomes	Number of		Difference (A – B)	% Difference (A - B)/ A X 100
	Pre -intervention (% of total)	Post -intervention (% of total)		
No outcome.	395 (27%)	9 (1%)	386	98
Positive outcome	1078 (73%)	1464 (99%)	386	36
Total (T)	**1473**	**1473**	**0**	**0**

Table 6 above show that there was a 93% decrease in the number of drug regimen change, a 90% decrease in the number of drug dose change, a 17% decrease in number of anomalies / errors that needed resolution and an 18% decrease in number of potential DTPs that were prevented by the interventions.

Table 6. Distribution of types and frequencies of positive intervention outcomes

Intervention outcomes	No. of Positive Outcomes		Difference (A – B)	% Difference (A–B)/ A x 100
	Pre -intervention (% of total)	Post- intervention (% of total)		
Drug/Regimen changed	370 (25%)	27 (2%)	343	93
Dose changed	394 (27%)	41 (3%)	353	90
Anomaly/Error resolved	1287 (87%)	1073 (73%)	214	17
Intervention prevented potential harmful DTP	1285 (87%)	1057 (72%)	228	18

Table 7 shows that there was a 125% increase in the number of patients that were satisfied with their treatment after the interventions. There was also a 72% decrease in the number of patients that were dissatisfied with their treatment. The number of indeterminate cases also decreased.

Table 7. Distribution of patients' satisfaction with their treatment

Patient satisfaction	No. of Positive Outcomes		Difference (A – B)	% Difference (A–B)/ A x 100
	Pre -intervention (% of total)	Post- intervention (% of total)		
Satisfaction	530 (36%)	1195 (81%)	665	125
Dissatisfaction	738 (50%)	210 (14%)	528	72
Indeterminate	205 (14%)	68 (5%)	137	67
Total.	1473 (100%)	1473 (100%)	0	0

4. Statistical analysis

Hypothesis 1

H_{o1}: Pharmaceutical care interventions do not improve the positive outcomes in the care of patients receiving antiretroviral drug therapy.

H_{a1}: Pharmaceutical care interventions improve the positive outcomes in the care of patients receiving antiretroviral drug therapy.

Decision rule

Accept null hypothesis if the value of the chi - square calculated is less than the chi - square table value and reject the alternative hypothesis, otherwise accept the alternative hypothesis if the value of the chi - square calculated is greater than the chi - square table value and reject the null hypothesis. Mathematically, the above decision rule is stated as follows:

Accept H_o if X^2 (Cal) < X^2 (tab)

Accept H_a if X^2 (Cal) > X^2 (tab)

To test this hypothesis, we use the distribution of the outcome of interventions in drug therapy problems as shown in Table 5 which is adjusted thus,

VARIABLES	POSITIVE OUTCOME	NEGATIVE OUTCOME	TOTAL
Pre - intervention	1078	395	1473
Post- intervention	1464	9	1473

We will use the lower pre - intervention figures. Here again, the expected frequency is 50/50 as the chance probability is also half (1/2).

As such:

$$X^2cal = \frac{(F_o - F_e)^2}{F_e} \qquad X^2cal = \frac{(F_0 - F_e)^2}{F_e} = \frac{(1464-50)^2}{50} = \frac{(1078-50)^2}{50}$$

$$= 39{,}987.92 + 21{,}135.68$$

$$= 18{,}852.24$$

Also Df = (R – 1) (C – 1)

= (2 – 1) (2 – 1)

= 1

Again from chi - square (X^2) table, Df 1 at 95% confidence level = 3.84

Thus we have,

X^2 cal = 18,852.24 and

X^2 tab = 3.84

Therefore, based on our decision rule, we reject H_{o1} and accept H_{a1} since X^2 cal > X^2 tab and conclude that Pharmaceutical care interventions improve the positive outcomes in the care of patients receiving antiretroviral drug therapy.

Hypothesis 2

H_{O2}: Pharmaceutical care interventions do not improve the satisfaction patients derive from their chronic anti - infective drug therapy.

H_{a2}: Pharmaceutical care interventions improve the satisfaction patients derive from their chronic anti - infective drug therapy.

Decision rule

Accept null hypothesis if the value of the chi - square calculated is less than the chi - square table value and reject the alternative hypothesis, otherwise accept the alternative hypothesis if the value of the chi - square calculated is greater than the chi - square table value and reject the null hypothesis. Mathematically, the above decision rule is stated as follows:

Accept H_o if X^2 (Cal) < X^2 (tab).

Accept H_a if X^2 (Cal) > X^2 (tab).

To test this hypothesis we use the satisfaction column of table 7 as shown below to compare the level of satisfaction among the patients before and after the interventions.

Distribution of patients' satisfaction with their treatment

Patient satisfaction	**No. of Positive Outcomes**		Difference (A – B)	% Difference (A–B)/A x 100
	Pre -intervention (% of total)	Post- intervention (% of total)		
Satisfaction	530 (36%)	1195 (81%)	665	125
Dissatisfaction	738 (50%)	210 (14%)	528	72
Indeterminate	205 (14%)	68 (5%)	137	67
Total	1473 (100%)	1473 (100%)	0	0

Here the expected frequency (F_e) is also 50/50 because the chance probability is half (1/2).

As such,

$$X^2 cal = \frac{(F_0 - F_e)^2}{F_e} = \frac{(1195 - 50)^2}{50} = \frac{(530 - 50)^2}{50} = 26{,}220.50 + 4608.00 = 21{,}612.50$$

Now, degree of freedom (Df) = R – 1) (C – 1)

= (2 – 1) (2 – 1)

= (1) (1)

= 1

Then from chi - square table,

Df 1 at 95% confidence level = 3.84

Thus we now have,

X^2 cal = 21,612.50 and

X^2 tab = 3.84

Therefore based on our decision rule, we reject H_{o2} and accept H_{a2} since X^2 cal > X^2 tab and conclude that pharmaceutical care interventions improve the satisfaction patients derive from their antiretroviral drug therapy.

5. Discussion

The results of the present study demonstrated the positive influence of pharmaceutical care interventions on the positive outcomes of drug therapy and patient satisfaction. It showed that generally there were needs for one form of intervention or the other in all the 1,473 patients involved in the study. This point to the existence of an overwhelming pool of diverse patients' needs and drug therapy problems (DTPs) that need pharmacists' attention. The concept and philosophy of pharmaceutical care has however enabled the pharmacist to fulfill these patients' needs and solve these drug therapy problems.

The study identified the pharmacists' interventions applied to the pharmaceutical care of the HIV patients in the study to include physician communication and education, other caregivers' communication and education, patient education, refusal to dispense wrong / doubtful prescriptions and change of drug therapy.

The study also identified the outcomes of the interventions to include drug regimen change, drug dose change, resolutions of anomalies / errors and prevention of potential drug therapy problems (DTPs).

The results showed that the need for the different types of interventions reduced greatly after the interventions. This was because the interventions improved adherence on the part of the patients, rational prescribing on the part of the physicians (or prescribers) and rational care from other caregivers involved the treatment of these HIV/AIDS patients, as a result of which the issues that lead to interventions got

reduced. For the same reasons the number of outcomes also reduced after the interventions. Generally the incidence of 'No Outcome' reduced by 98% while that of 'Positive outcomes' increased by 36% both indicating patient care improvement.

These improved outcomes may therefore be the reason for the high level of satisfaction expressed by the patients as the number of patients who expressed satisfaction with their drug therapy increased by 125% after the interventions, another pointer to the great potential of pharmaceutical care for improving the outcomes of drug therapy, medical care and general patient wellbeing.

For these results and reasons we join the global community of pharmaceutical care researchers in making a case for it and advocate for its widespread adoption and application especially in Africa where its implementation seem to be facing numerous challenges and lethargy.

6. Conclusion

The study identified the pharmacists' interventions applied to the pharmaceutical care of the HIV patients in the study to include physician communication and education, other caregivers' communication and education, patient education, refusal to dispense wrong / doubtful prescriptions and change of drug therapy. It also identified the outcomes of the interventions to include drug regimen change, drug dose change, resolutions of anomalies / errors and prevention of potential drug therapy problems (DTPs).

These interventions influenced the patients' adherence, optimized their drug therapy and improved rational prescribing and care resulting in significant improvements in the number positive outcomes and levels of patient satisfaction ($p=0.5$).

7. Recommendations

1. Regular exchange of knowledge, ideas and experiences should be encouraged through the organization and attendance of national and international conferences and workshops.
2. Finally, the role of the pharmacist in patient care can no longer be over emphasized. As such government should make adequate efforts to develop and utilize the abundant skills and potentials of pharmacists and pharmaceutical care.

Acknowledgement

We are very grateful to;

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2. Federal medical centre Owerri, Imo state, Nigeria (my birth and work place) for the permission to carry out this study and many other studies there and for always encouraging us the staff to carry out research studies.
3. My numerous patients who endured many months of questioning, examinations and counseling. We appreciate your patience and sacrifice. It was all for your good and better health.

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Appendix A. Ethical approval for the study

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Head of Administration Services
Mrs. Nnenna Onyegbula
BSc, MPA, AHAN

Head of Clinical Services
Dr. E. C. Osuagwu
M.B;B.S, FWACS
CHIEF CONSULTANT OBST. & GYNAE

23rd November, 2009

FMC/OW/HCS.11/114

Pharm. Nwaozuzu Ezeudo
Pharmacy Department
Federal Medical Centre
Owerri.

RE: PERMISSION TO CARRY OUT RESEARCH ON THE IMPACT OF PHARMACEUTICAL CARE IN THE MANAGEMENT OF PATIENTS ON ANTIBIOTICS (ANTI-INFECTIVE) THERAPY.

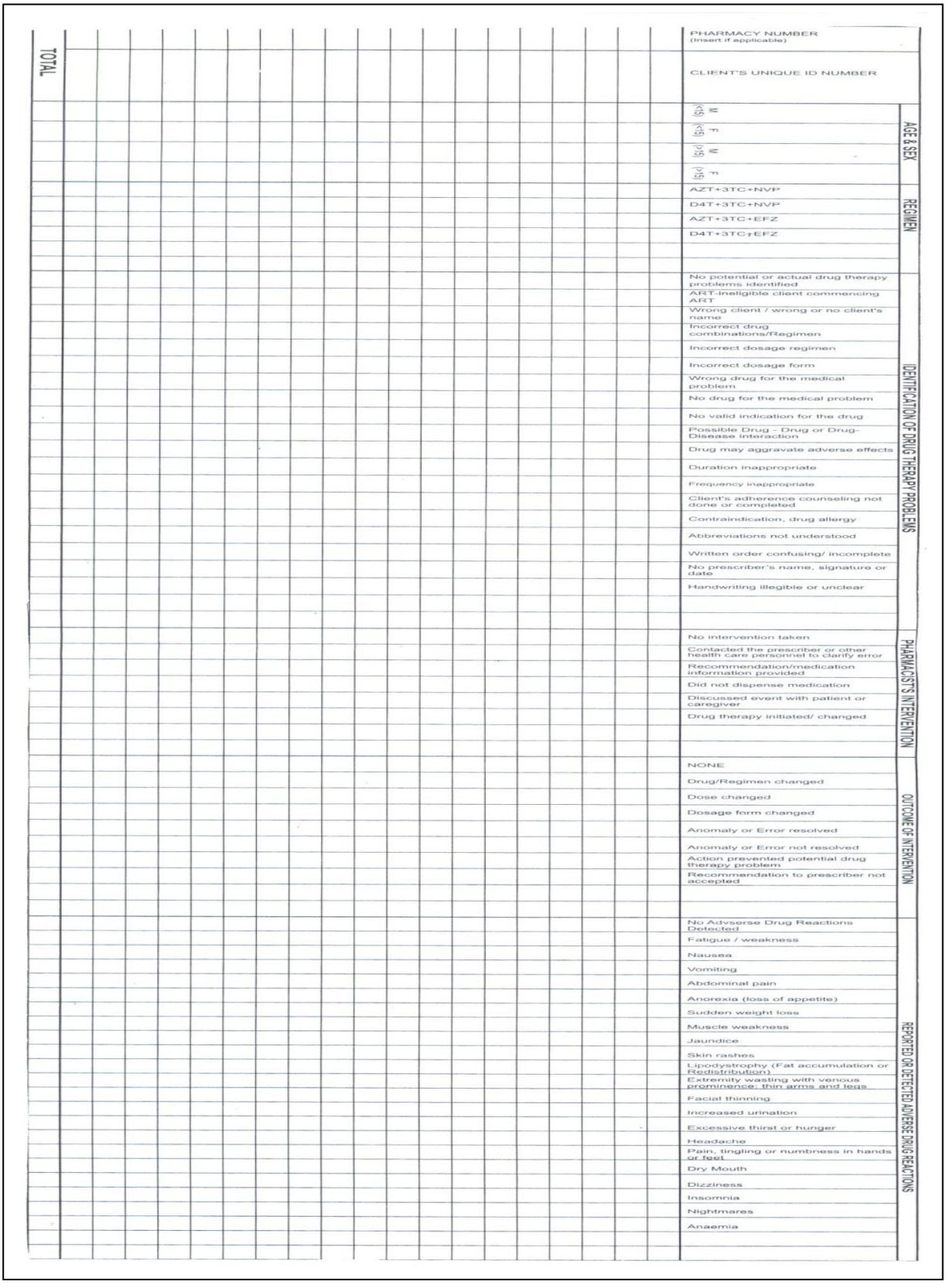
The Ethical committee acknowledges receipt of your research proposal dated 10th July 2009.

Following a meeting of the Committee held on 30th October, 2009, you have been given permission to carry out the said research.

You are also to ensure patients' confidentiality in this regard.

DR. E.C. OSUAGWU
HEAD OF CLINICAL SERVICES/CHAIRMAN ETHICAL COMMITTEE

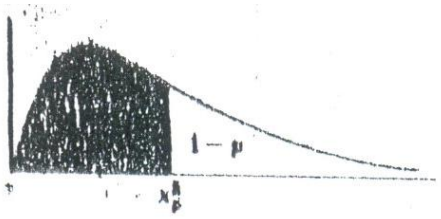
Appendix A. Data collection form



Appendix C. Chi – square distribution table

APPENDIX C

Percentile Values (χ^2_p) for the Chi-Square Distribution with ν Degrees of Freedom



ν	$\chi^2_{.005}$	$\chi^2_{.01}$	$\chi^2_{.025}$	$\chi^2_{.05}$	$\chi^2_{.10}$	$\chi^2_{.25}$	$\chi^2_{.50}$	$\chi^2_{.75}$	$\chi^2_{.90}$	$\chi^2_{.95}$	$\chi^2_{.975}$	$\chi^2_{.99}$	$\chi^2_{.995}$	$\chi^2_{.999}$
1	.0000	.0002	.0010	.0039	.0158	.102	.455	1.32	2.71	3.84	5.02	6.63	7.88	10.8
2	.0100	.0201	.0506	.103	.211	.575	1.39	2.77	4.61	5.99	7.38	9.21	10.6	13.8
3	.0717	.115	.216	.352	.584	1.21	2.37	4.11	6.25	7.81	9.35	11.3	12.8	16.3
4	.207	.297	.484	.711	1.06	1.92	3.36	5.39	7.78	9.49	11.1	13.3	14.9	18.5
5	.412	.554	.831	1.15	1.61	2.67	4.35	6.63	9.24	11.1	12.8	15.1	16.7	20.5
6	.676	.872	1.24	1.64	2.20	3.45	5.35	7.84	10.6	12.6	14.4	16.8	18.5	22.5
7	.989	1.24	1.69	2.17	2.83	4.25	6.35	9.04	12.0	14.1	16.0	18.5	20.3	24.3
8	1.34	1.65	2.18	2.73	3.49	5.07	7.34	10.2	13.4	15.5	17.5	20.1	22.0	26.1
9	1.73	2.09	2.70	3.33	4.17	5.90	8.34	11.4	14.7	16.9	19.0	21.7	23.6	27.9
10	2.16	2.56	3.25	3.94	4.87	6.74	9.34	12.5	16.0	18.3	20.5	23.2	25.2	29.6
11	2.60	3.05	3.82	4.57	5.58	7.58	10.3	13.7	17.3	19.7	21.9	24.7	26.8	31.3
12	3.07	3.57	4.40	5.23	6.30	8.44	11.3	14.8	18.5	21.0	23.3	26.2	28.3	32.9
13	3.57	4.11	5.01	5.89	7.04	9.30	12.3	16.0	19.8	22.4	24.7	27.7	29.8	34.5
14	4.07	4.66	5.63	6.57	7.79	10.2	13.3	17.1	21.1	23.7	26.1	29.1	31.3	36.1
15	4.60	5.23	6.26	7.26	8.55	11.0	14.3	18.2	22.3	25.0	27.5	30.6	32.8	37.7
16	5.14	5.81	6.91	7.96	9.31	11.9	15.3	19.4	23.5	26.3	28.8	32.0	34.3	39.3
17	5.70	6.41	7.56	8.67	10.1	12.8	16.3	20.5	24.8	27.6	30.2	33.4	35.7	40.8
18	6.26	7.01	8.23	9.39	10.9	13.7	17.3	21.6	26.0	28.9	31.5	34.8	37.2	42.3
19	6.84	7.63	8.91	10.1	11.7	14.6	18.3	22.7	27.2	30.1	32.9	36.2	38.6	43.8
20	7.43	8.26	9.59	10.9	12.4	15.5	19.3	23.8	28.4	31.4	34.2	37.6	40.0	45.3
21	8.03	8.90	10.3	11.6	13.2	16.3	20.3	24.9	29.6	32.7	35.5	38.9	41.4	46.8
22	8.64	9.54	11.0	12.3	14.0	17.2	21.3	26.0	30.8	33.9	36.8	40.3	42.8	48.3
23	9.26	10.2	11.7	13.1	14.8	18.1	22.3	27.1	32.0	35.2	38.1	41.6	44.2	49.7
24	9.89	10.9	12.4	13.8	15.7	19.0	23.3	28.2	33.2	36.4	39.4	43.0	45.6	51.2
25	10.5	11.5	13.1	14.6	16.5	19.9	24.3	29.3	34.4	37.7	40.6	44.3	46.9	52.6
26	11.2	12.2	13.8	15.4	17.3	20.8	25.3	30.4	35.6	38.9	41.9	45.6	48.3	54.1
27	11.8	12.9	14.6	16.2	18.1	21.7	26.3	31.5	36.7	40.1	43.2	47.0	49.6	55.5
28	12.5	13.6	15.3	16.9	18.9	22.7	27.3	32.6	37.9	41.3	44.5	48.3	51.0	56.9
29	13.1	14.3	16.0	17.7	19.8	23.6	28.3	33.7	39.1	42.6	45.7	49.6	52.3	58.3
30	13.8	15.0	16.8	18.5	20.6	24.5	29.3	34.8	40.3	43.8	47.0	50.9	53.7	59.7
40	20.7	22.2	24.4	26.5	29.1	33.7	39.3	45.6	51.8	55.8	59.3	63.7	66.8	73.4
50	28.0	29.7	32.4	34.8	37.7	42.9	49.3	56.3	63.2	67.5	71.4	76.2	79.5	86.7
60	35.5	37.5	40.5	43.2	46.5	52.3	59.3	67.0	74.4	79.1	83.3	88.4	92.0	99.6
70	43.3	45.4	48.8	51.7	55.3	61.7	69.3	77.6	85.5	90.5	95.0	100	104	112
80	51.2	53.5	57.2	60.4	64.3	71.1	79.3	88.1	96.6	102	107	112	116	125
90	59.2	61.8	65.6	69.1	73.3	80.6	89.3	98.6	108	113	118	124	128	137
100	67.3	70.1	74.2	77.9	82.4	90.1	99.3	109	118	124	130	136	140	149

Source: E. S. Pearson and H. O. Hartley, *Biometrika Tables for Statisticians*, Vol. 1 (1966), Table 8, pages 137 and 138.