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Impact of pharmaceutical care interventions on the occurrence and resolution of drug therapy problems in antiretroviral drug therapy

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Abstract

Pharmaceutical care (PC) has been shown to improve the outcome of drug therapy in many disease conditions. HIV/AIDS is one of the disease conditions that are fraught with many problems that can benefit from this new emphasis of pharmacy practice also known as 'pharmacists care'. This study is designed to determine the number and types of drug therapy problems occurring in the drug therapy of HIV patients receiving treatment at a tertiary hospital in southeast Nigeria and to evaluate the impact of pharmaceutical care activities on the occurrence of these drug therapy problems (DTPs). 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 study showed significant reduction in the incidence of drug therapy problems following the Pharmacist's intervention activities. The study found out that eighty-nine percent (89%) of the prescriptions had potential drug therapy problems before the interventions which were reduced by 12% to seventy-seven percent (77%) after the intervention. The study also identified seventeen (17) different potential drug therapy problems prior to the interventions. A re - evaluation of these potential drug therapy problems after the interventions showed the very significant percentage reductions in the occurrence of each DTP. The study showed that pharmacists' interventions in antiretroviral drug therapy through Pharmaceutical care can significantly reduce the occurrence of drug therapy problems associated with antiretroviral drug therapy

Keywords: Pharmaceutical care, HIV/AIDS, Drug therapy problems, Pharmacist interventions, Hospital pharmacy

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1. Introduction

Drug therapy problems are negative patient outcomes. They can worsen patient health conditions, cause death, prolong patients' length of hospital stay, increase direct cost of medical care and reduce quality of life and patient satisfaction. Identifying them requires a systematic approach where critical thinking and problem solving skills are needed (Oparah, 2010). The existence of DTPs created the need for pharmaceutical care to which it poses considerable and diverse challenges. For instance, as at 2002, about 45,000 pharmaceutical encounters had been documented in the USA [by Strand and co] with over 19,000 DTPs identified, prevented and resolved with considerable financial impacts (Oparah, 2010).

The concept of pharmaceutical and the challenges of HIV/AIDS has been discussed in part one of these presentations where we presented and discussed the results of this study as it relates pharmaceutical care and adverse drug reactions in patients receiving antiretroviral drugs. This part of the study presents and discusses the result of the study as it relates the occurrence and resolution of DTPs through systematically planned and implemented pharmaceutical care activities.

Drug therapy problems has been classified into indication, effectiveness, safety, compliance (adherence) and untreated indication DTPs. Helper and Strand in 1990 however classified them into 7 classes; unnecessary drug therapy, wrong drug, dose too low, dose too high, adverse drug reaction, inappropriate adherence, needs additional drug therapy. Pharmaceutical care concept requires the pharmacist to identify these problems and needs and solve or meet them. This new role requires the pharmacist to apply a higher level of drug knowledge, clinical skill and independent judgment to his work and to accept the burden of responsibility.

2. Method

This is part 3 of 4 from a study carried out using the method described below. The other parts will also be subsequently published in this journal. 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' 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. Data was collected from the patients' prescription sheets, laboratory report forms, care/ART cards, and other relevant forms in their treatment folders. Other relevant information was 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 was implemented where necessary and this 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 will be 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

Drug therapy problems occurring before and after pharmacists' intervention were identified and categorized. Frequencies and descriptive statistics were then calculated for these measures. The study showed significant reduction in the incidence of drug therapy problems following the Pharmacist's intervention activities.

The study found out that eighty-nine percent (89%) of the prescriptions had potential drug therapy problems before the interventions which were reduced by 12% to seventy-seven percent (77%) after the intervention. The study also identified seventeen (17) different potential drug therapy problems prior to the interventions. A re - evaluation of these potential drug therapy problems after the interventions showed the following percentage reductions;

1. ART - ineligible patient starting ART (57%).
2. Wrong patient name/no name on prescription (100%).
3. Incorrect drug combination/regimen (48%).
4. Incorrect dosage (57%).
5. No drug for another medical problem (77%).
6. Possible drug - drug/drug - disease interaction (63%).
7. Possible aggravation of adverse effects by drug (56%).
8. Inappropriate duration of drug administration by patient (66%).
9. Inappropriate frequency of drug administration by patient (82%).
10. Lack of adherence counseling (70%).
11. Contraindication/drug allergy (64%).
12. Confusing/incomplete prescription (22%).
13. Lack of CD4 count and other laboratory investigations (57%).
14. Abrupt stoppage of drug administration by patient (46%).
15. Refusal to take drugs by patient (100%).
16. Intake of drug overdose by patient (55%).
17. Prescriber's handwriting ineligible/unclear (100%).

This shows that the incidence of each of these potential drug therapy problems was reduced by over 55% (except one case that had 22% reduction) after the interventions.

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)		
2 yrs - 15 yrs	146	146	0	10
15 yrs above	1327	1327	0	90
Total (T)	1473	1473	0	100

Table 1 shows that 90% of patients involved in the study were adults (18years and above) while 10% of the patients were children (2yrs – 15yrs).

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. Distribution of incidence of Drug Therapy Problems (DTPS)

Variable	Frequency of Patients		Difference (A - B)	%difference (A - B)/ A x 100).
	Pre-intervention evaluation (A) (% of total)	Post -intervention evaluation (B) (% of total)		
Number of non - DTP cases.	160 (11%)	341 (23%)	-181	113%
Number of DTP cases.	1313 (89%)	1132 (77%)	181	13%
Total (T)	1473	1473	0	0

Table 4. distribution of the frequency of DTPs

DTPs	Frequency of DTPs		Difference (A - B)	% difference (A - B)/A X 100.
	Pre - intervention evaluation (A)	Post - intervention evaluation (B)		
ART - ineligible patient starting ART.	21	9	12	57
Wrong patient / name or no name on prescription.	13	0	13	100
Incorrect drug combination / regimen.	29	15	14	48
Incorrect dosage regimen.	169	72	97	57
No drug for a medical problem.	145	34	111	77

Possible drug – drug /drug - disease interaction.	19	7	12	63
Possible aggravation of adverse effects by drug.	9	4	5	56
Inappropriate duration of drug intake by patient.	35	12	23	66
Inappropriate frequency of drug intake by patient.	656	116	540	82
No adherence counseling by adherence counselors.	211	63	148	70
Contraindication / drug allergy.	39	14	25	64
Written prescription confusing or complex.	951	747	207	22
No prescriber's name or signature on prescription paper.	201	611	-410	(-204)
CD4 Test / other tests not done as should.	916	394	522	57
Patient stopped taking his/her drugs.	46	25	21	46
Patient refused to take drugs.	5	0	5	100
Patient taking overdose.	11	5	6	55
Prescriber's handwriting ineligible/unclear.	12	0	12	100

Table 3 above shows that the interventions resulted in a 113% increase in the incidence of non – DTP cases as well as a 13% decrease in the incidence of DTP cases.

Table 4. Distribution of the frequency of DTPs

DTPs	Frequency of DTPs		Difference (A – B)	% difference (A – B)/A X 100.
	Pre - intervention evaluation (A)	Post - intervention evaluation (B)		
ART - ineligible patient starting ART.	21	9	12	57
Wrong patient / name or no name on prescription.	13	0	13	100
Incorrect drug combination / regimen.	29	15	14	48
Incorrect dosage regimen.	169	72	97	57
No drug for a medical problem.	145	34	111	77
Possible drug – drug /drug - disease interaction.	19	7	12	63

Possible aggravation of adverse effects by drug.	9	4	5	56
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Patient refused to take drugs.	5	0	5	100
Patient taking overdose.	11	5	6	55
Prescriber's handwriting ineligible/unclear.	12	0	12	100

4. Statistical analysis

Hypothesis

H₀: Pharmaceutical care interventions do not reduce the occurrence of drug therapy problems (DTPs) in patients receiving antiretroviral drug therapy.

H_a: Pharmaceutical care interventions reduce the occurrence of drug therapy problems (DTPs) in patients receiving antiretroviral drug therapy.

To test this hypothesis, we use the distribution of the outcome of interventions in drug therapy problems as shown in table 8 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,

$$X^2_{\text{cal}} = \frac{[F_o - F_e]^2}{F_e} = \frac{(1078 - 50)^2}{50} + \frac{(395 - 50)^2}{50} = 21,136 + 2380.5 = 23,516$$

$$\text{Also Df} = (R - 1) (C - 1)$$

$$= (2 - 1) (2 - 1)$$

$$= 1$$

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

Thus we have,

$$X^2_{\text{cal}} = 23,516 \text{ and}$$

$$X^2_{\text{tab}} = 3.84$$

Therefore, based on our decision rule, we reject H_0 and accept H_a since $X^2_{\text{cal}} > X^2_{\text{tab}}$ and conclude that pharmaceutical interventions prevent potential drug therapy problems in the management of patients on chronic anti - infective drug therapy.

5. Discussion

Drug therapy problems have negative effects on pharmaceutical care and results in negative drug therapy outcomes. Their identification and resolution is imperative for the success of any drug therapy program.

The most prominent drug therapy problems indentified in the study include inappropriate frequency of drug intake by patients where it was observed that many of the patients were taking their drugs irregularly. Most of the antiretroviral drugs at the time of the study were recommended to be taken every 12 hours (twice daily) with just a few of them recommended for once daily dosing. Many of the patients were not able to adhere to the recommended dosing frequencies of these drugs and in some cases the drugs were taken only when the patients felt like taking them or when they remembered to take them or worse still, when they felt ill. This poor adherence is capable of compromising their treatment, induce drug resistance and cause therapeutic failure and early death. The pharmaceutical care interventions however resulted in a significant reduction in the occurrence frequency of this drug therapy problem. Another drug therapy problem identified was the lack of adherence counseling for the patients and this could have been the cause of many of the patient - related drug therapy problems identified in the study.

The frequency of its occurrence was also reduced significantly after the interventions. Many of the prescriptions were also observed to be confusing / complex and this could result in fatal errors in the dispensing of medications. The improvement in the frequency of occurrence of this problem incidentally, was not as high as in the case of the other drug therapy problems. This is an indicator for training or retraining of

medication prescribers on the need for clarity in prescription writing. Again many of the prescriptions had no prescriber's name or signature on them and in many cases also the dosage regimens were incorrect. In many other cases no drugs were prescribed for certain medical problems of the patients. These could have been because the prescribers were always hurrying over the patient consultations as a result of an overwhelming number of HIV/AIDS patients they need to see during the clinic days. The pressure is understandable however but not enough to be allowed to compromise patients' lives. Another important problem was the observation that too many of the patients were not also adhering to their laboratory investigations schedules. These investigations includes CD4 counts, liver function tests, kidney function tests, hematological tests etc and they are needed for the monitoring of drug therapy efficacy and safety in the patients. The implication of this is that for many of the patients, the investigations for monitoring their treatment was not always available and this falls short of recommended treatment procedures. It predisposes the patients to drug – related complications and can also compromise their treatment outcomes.

Interestingly the frequencies of occurrence of these drug therapy problems as well as those of the other drug therapy problems shown in the results above were greatly reduced after the pharmacists' intervention activities. The only exceptions were the problem of confusing / complex prescriptions which showed a relatively low reduction in the frequency of its occurrence and the problem of lack of prescribers' names/signatures on the prescriptions which rather showed very high increase in the frequency of its occurrence.

Though more studies may be needed in this area, yet the results of this study are very indicative of the imperative of a more widespread adoption of pharmaceutical care and more specifically drug therapy management roles by hospital pharmacists in Nigeria and beyond.

6. Conclusion

The study identified frequent DTPs associated HIV and other health conditions. It also showed that pharmacists' interventions in antiretroviral drug therapy through Pharmaceutical care can significantly reduce the occurrence of drug therapy problems associated with antiretroviral drug therapy.

7. Recommendations

- Regular training and mentoring of medical doctors (especially the ones on training/internship) should be enforced to minimize the incidence of prescription errors and potential DTPs. The same should be applicable to other healthcare providers so as to improve the overall quality of care offered to patients.
- Therapeutic as well as pharmaceutical audit of healthcare services should be carried out more frequently so as to detect DTPs as well as prevent them.
- Patients should also be educated on the need to report side/adverse effect as well as other problems they may encounter in the course of treatment.

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- 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
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Head of Clinical Services
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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

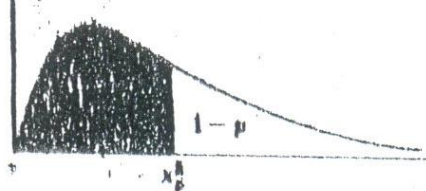
Appendix A. Data collection form

TOTAL	PHARMACY NUMBER (Insert if applicable)	AGE & SEX
	CLIENT'S UNIQUE ID NUMBER	
	M F	REGIMEN
	M F	
	AZT+3TC+NVP	IDENTIFICATION OF DRUG THERAPY PROBLEMS
	D4T+3TC+NVP	
	AZT+3TC+EFZ	
	D4T+3TC+EFZ	
	No potential or actual drug therapy problems identified	PHARMACIST'S INTERVENTION
	ART-ineligible client commencing ART	
	Wrong client / wrong or no client's name	
	Incorrect drug combinations/Regimen	
	Incorrect dosage regimen	
	Incorrect dosage form	
	Wrong drug for the medical problem	
	No drug for the medical problem	
	No valid indication for the drug	
	Possible Drug - Drug or Drug-Disease Interaction	
	Drug may aggravate adverse effects	
	Duration inappropriate	
	Frequency inappropriate	
	Client's adherence counseling not done or completed	
	Contraindication, drug allergy	
	Abbreviations not understood	
	Written order confusing/ incomplete	OUTCOME OF INTERVENTION
	No prescriber's name, signature or date	
	Handwriting illegible or unclear	
	No intervention taken	REPORTED OR DETECTED ADVERSE DRUG REACTIONS
	Contacted the prescriber or other health care personnel to clarify error	
	Recommendation/medication information provided	
	Did not dispense medication	
	Discussed event with patient or caregiver	
	Drug therapy initiated/ changed	
	NONE	
	Drug/Regimen changed	
	Dose changed	
	Dosage form changed	
	Anomaly or Error resolved	
	Anomaly or Error not resolved	
	Action prevented potential drug therapy problem	
	Recommendation to prescriber not accepted	
	No Adverse Drug Reactions Detected	
	Fatigue / weakness	
	Nausea	
	Vomiting	
	Abdominal pain	
	Anorexia (loss of appetite)	
	Sudden weight loss	
	Muscle weakness	
	Jaundice	
	Skin rashes	
	Lipodystrophy (Fat accumulation or Redistribution)	
	Extremity wasting with venous prominence; thin arms and legs	
	Facial thinning	
	Increased urination	
	Excessive thirst or hunger	
	Headache	
	Pain, tingling or numbness in hands or feet	
	Dry Mouth	
	Dizziness	
	Insomnia	
	Nightmares	
	Anaemia	

Appendix C. Chi - square distribution table

APPENDIX C

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



ν	$\chi^2_{.995}$	$\chi^2_{.99}$	$\chi^2_{.975}$	$\chi^2_{.95}$	$\chi^2_{.90}$	$\chi^2_{.85}$	$\chi^2_{.80}$	$\chi^2_{.75}$	$\chi^2_{.70}$	$\chi^2_{.65}$	$\chi^2_{.60}$	$\chi^2_{.55}$	$\chi^2_{.50}$	$\chi^2_{.45}$	$\chi^2_{.40}$
1	.0001	.0008	.0016	.0039	.0158	.102	.455	1.32	2.71	3.84	5.02	6.63	7.88	10.8	
2	.0100	.0201	.0506	.108	.211	.575	1.89	2.77	4.01	5.09	7.88	9.21	10.6	18.6	
3	.0717	.115	.210	.352	.584	1.21	2.37	3.11	4.26	7.81	9.35	11.3	12.8	18.8	
4	.207	.297	.484	.711	1.00	1.92	3.36	5.80	7.78	9.49	11.1	13.8	14.9	18.5	
5	.412	.564	.891	1.15	1.61	2.37	4.35	6.63	9.24	11.1	12.8	15.1	16.7	20.6	
6	.676	.872	1.24	1.64	2.20	3.45	6.86	7.84	10.6	12.6	14.4	16.8	18.5	22.6	
7	.989	1.24	1.60	2.17	2.89	4.25	6.35	9.04	12.0	14.1	16.0	18.5	20.8	24.8	
8	1.34	1.66	2.18	2.73	3.49	5.07	7.34	10.8	13.4	15.5	17.5	20.1	22.0	26.1	
9	1.73	2.00	2.70	3.34	4.17	5.90	8.34	11.4	14.7	16.9	19.0	21.7	23.9	28.0	
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	25.6	29.6	
11	2.60	3.06	3.82	4.57	5.58	7.66	10.3	13.7	17.3	19.7	21.9	24.7	27.2	31.8	
12	3.07	3.57	4.40	5.28	6.30	8.44	11.8	14.8	18.5	21.0	23.3	26.2	28.8	32.9	
13	3.57	4.11	5.01	5.89	7.04	9.30	12.9	16.0	19.8	22.4	24.7	27.7	30.8	34.6	
14	4.07	4.68	5.63	6.57	7.79	10.2	13.8	17.1	21.1	23.7	26.1	29.1	31.8	36.1	
15	4.60	5.26	6.26	7.20	8.56	11.0	14.8	18.2	22.3	25.0	27.5	30.6	32.8	37.7	
16	5.14	5.81	6.91	7.86	9.31	11.9	15.8	19.4	23.5	26.3	28.8	32.0	34.3	39.8	
17	5.70	6.41	7.56	8.67	10.1	12.8	16.8	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	17.8	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	18.8	22.7	27.2	30.1	32.9	36.2	38.0	43.8	
20	7.43	8.26	9.59	10.9	12.4	15.5	19.9	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	20.9	24.9	29.6	32.7	35.5	38.9	41.3	46.8	
22	8.64	9.54	11.0	12.3	14.0	17.2	21.9	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	22.9	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	23.9	28.2	33.2	36.4	39.4	43.0	45.6	51.2	
25	10.5	11.6	13.1	14.6	16.5	19.9	24.9	29.3	34.4	37.7	40.6	44.8	46.9	52.8	
26	11.2	12.2	13.8	15.4	17.4	20.8	25.9	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	26.9	31.5	36.7	40.1	43.2	47.0	49.6	55.6	
28	12.5	13.6	15.3	17.0	18.9	22.7	27.9	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	28.9	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	29.8	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	45.8	51.8	55.8	59.7	63.7	66.8	73.4	
50	28.0	29.7	32.4	34.8	37.7	42.0	49.9	56.8	63.2	67.5	71.4	76.2	79.5	86.7	
60	36.5	37.6	40.5	43.2	46.5	52.8	59.9	67.0	74.4	79.1	83.8	88.4	92.0	99.6	
70	46.2	45.4	48.8	51.7	55.8	61.7	69.9	77.0	85.5	90.5	95.0	100	104	114	
80	56.2	53.5	57.2	60.4	64.8	71.1	79.9	88.1	98.0	102	107	112	116	125	
90	66.2	61.8	65.6	69.1	74.8	80.8	89.6	98.6	108	113	118	124	128	137	
100	77.9	70.1	74.2	77.9	82.4	90.1	99.9	109	119	124	130	136	140	149	

Source: E. S. Pearson and H. O. Hartley, *Biometrika Tables for Statisticians*, Vol. 1 (1966), Table 8, pages 187 and 188.