

**PHARMACO-ECONOMIC EVALUATION
OF ANTI-DIABETIC THERAPY IN
NORTH-EASTERN NIGERIA**

BY

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OF ANTI-DIABETIC THERAPY IN
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BY

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CERTIFICATION

This is to certify that the Thesis:

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THERAPY IN NORTH – EASTERN NIGERIA”**

**Submitted to the
School of Postgraduate Studies
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is a record of original research carried out**

By:

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In the Department of Clinical Pharmacy and Biopharmacy

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DECLARATION

This work titled “Pharmaco-economic evaluation of anti-diabetic therapy in North-Eastern Nigeria” submitted to the School of Postgraduate Studies, University of Lagos, Nigeria, for the award of the degree of Doctor of Philosophy in Clinical Pharmacy is an original research carried out by **GIWA Abdulganiyu** in the Department of Clinical Pharmacy and Biopharmacy, Faculty of Pharmacy, University of Lagos, under the supervision of Prof. ‘Fola Tayo and Dr. B.A. Aina. This work has not been submitted previously, in whole or in part, to qualify for any other academic award.

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DEDICATION

Affectionately dedicated to God, The Almighty who inculcated in me the spirit of hard work and discipline through my parents and lecturers.

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ACRONYMS

ADA – American Diabetes Association

API – Active Pharmaceutical Ingredient

BCS – Biopharmaceutics Classification System

BMI – Body Mass Index

BNF – British National Formulary

B.P. – British Pharmacopoeia

CE – Cost Effective

CEA – Cost Effectiveness Analysis

CM – Cost Minimization

CMA – Cost Minimization Analysis

CI – Cost of Illness

CIA - Cost of Illness Analysis

DDD – Defined Daily Dose

DM – Diabetes Mellitus

FBS – Fasting Blood Sugar

FDA – Food and Drug Administration

HbA1c – Glycosylated Haemoglobin

NAFDAC – National Agency for Food and Drug Administration and Control

UMTH – University of Maiduguri Teaching Hospital

WHO/HAI – World Health Organization/Health Action International

ABSTRACT

Use of anti-diabetic drugs in the management of Type II DM is for lifetime of the patients from the time of diagnosis. This translates into a substantial cost in drug therapy, especially with increasing prevalence of DM. This group of drugs is also faced with problem of availability, affordability and non-use of generic names. Efforts designed to reduce expenditure on this class of drugs as well as use them more efficiently would be advantageous.

Pharmaco-Economic evaluation of anti-diabetic therapy in North-Eastern Nigeria was conducted.

Relationship between socio-economic status, affordability and glycemic control was determined by assessing and analyzing World Bank socio-economic indicators of poverty for each subject in a cross-sectional study using questionnaire and information obtained from prescriptions (prospective) and case-notes (retrospective) about affordability and glycemic control respectively. CIA, CMA and CEA were conducted using standardized data collection forms and WHO DDD method of assessing drug use. Relationships between degrees of knowledge/practice of lifestyle/dietary modification were determined using questionnaire. Comparative assessment of quality control parameters of branded and generic equivalent anti-diabetic drugs was conducted using B.P. (Standard) methods based on BCS for biowaiver. Results showed that 60% of subjects could not afford their drugs. Poor and non-poor subjects significantly differ in affordability of anti-diabetic drugs and glycemic control. Annual average cost of illness of DM was N47, 924.36. Almost 1242 (78.6%) out of 1580 anti-diabetic drugs prescriptions were in branded names while 338 (21.4%) were in generic names. There was a statistically significant difference in these proportions. Patients were able to afford more generics than branded despite the fact that the latter were prescribed more often. Generic products are lower cost options to branded equivalents for all anti-diabetic drugs analyzed. Glibenclamide (N1.76/unit of effectiveness) was more cost-effective than chlpropamide (N2.97/unit of effectiveness) in the management of moderate hyperglycemia in non-obese Type II DM. Biphasic Isophane Insulin (N12.65/unit of effectiveness) was more cost-effective than soluble insulin + insulin zinc (N30.37/unit of effectiveness) in the management of severe hyperglycemia in non-obese Type II DM. Biphasic Isophane Insulin + Metformin (N15.91/unit of effectiveness) was more

cost-effective than soluble insulin + insulin zinc + metformin (N34.45/ unit of effectiveness) in the management of severe hyperglycemia in obese Type II DM patients. There was an association between degrees of knowledge/practice of lifestyle/dietary modification and glycemic control. All branded and generic equivalent anti-diabetic drugs analyzed, passed B.P. tests for quality control parameters.

The findings forms a basis for pharmacist-physician feedback system to be institutionalized in our public and private pharmacies, especially about patients that could not afford prescribed drugs which could lead to therapeutic failure (e.g. poor glycemic control) and waste of limited health care resources. Spending 88% of per *capita* income on diabetes management alone is a great burden. There was no rational for the observed frequent prescription of more expensive branded anti-diabetic drugs over cheaper generic equivalents, when available and there is guarantee of their effectiveness, using quality control parameters. Therefore, any measure taken to promote rational drug selection such as CMA and CEA will be invaluable in promoting efficient use of limited resources. When diabetes patients acquire knowledge about benefits and practice of lifestyle/dietary modification through a comprehensive educational programme, they would most likely adopt positive behavioral changes that would show clinically significant improvement in glycemic control.

Poverty is a hindrance to good glycemic control (good health) in terms of drug purchase (non-affordability). Irrational prescription of branded over generics can be changed by educational interventions. The process indicators that could rationalize efficiency of anti-diabetic therapy to ensure optimum economic, clinical and humanistic outcomes, from this study are: Drug Selection based on cost-effectiveness (value for money), drug prescription based on cost-minimization (use of generic name), drug supply and quality, patient counseling, patient education, exercise, dietary modifications, lifestyle modifications, complications associated with diabetes mellitus, treatment /compliance, evidence from medication record/case-notes of treatment compliance monitoring by pharmacist, physician, patient relations and self monitoring. Pharmaco-Economic principles should be adopted in our National Health Policy, hence its application at all levels of our healthcare delivery system in taking therapeutic and other healthcare intervention decisions.