



PHARMACOECONOMIC ANALYSIS OF ANTIDIABETIC TREATMENT: A REVIEW

Cornelius Nwozor*¹, Peter Ughachukwu², Henry Enwelum³, Kosiosochukwu Ifemenam³, Chiemelia Anisiobi⁴, Evarista Chiamaka Chima-iwuoha⁵

¹Department of Physiology, Faculty of Basic Medical Sciences, Chukwuemeka Odumegwu Ojukwu University, Uli Campus, Anambra State, Nigeria.

²Department of Pharmacology and Therapeutics, Faculty of Clinical Medicine, Chukwuemeka Odumegwu Ojukwu University, Awka Campus, Anambra State, Nigeria.

³Department of Obstetrics and Gynecology, Faculty of Clinical Sciences, Chukwuemeka Odumegwu Ojukwu University Teaching Hospital, Amaku, Awka, Anambra State, Nigeria.

⁴Department of Emergency Medicine, Faculty of Clinical Medicine, Royal Devon University Healthcare NHS Foundation Trust (Royal Devon and Exeter Hospital) Exeter, England, EX25DW United Kingdom.

⁵Department of Pediatrics, Ragahid Children Hospital and Maternity, 9/11 Ndikelionwu Street, off Port-Harcourt –Aba Expressway, River State, Nigeria.



*Corresponding Author: Dr. Cornelius Nwozor

Department of Physiology, Faculty of Basic Medical Sciences, Chukwuemeka Odumegwu Ojukwu University, Uli Campus, Anambra State, Nigeria.

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SUMMARY

Diabetes mellitus (DM) is a chronic metabolic disorder characterized by hyperglycemia. In 2010 about 285 million people worldwide had DM. By 2030 438 million adults will have DM. In Nigeria, about 4 million people are living with DM. There are two types of DM: type 1 and 2. Type 2 DM is the commonest DM in an adult population. Treatment is based on the use of oral hypoglycemic drugs when diet fails. Pharmacoeconomics refers to the scientific discipline that compares the value of one pharmaceutical drug or drug therapy to another. This branch of healthcare economics offers important guidance for the management of limited healthcare resources and medical practice. Cost of drug is the total resources consumed in producing the drug or drug formulation. Cost can be divided into: direct, indirect, and intangible cost. Types of pharmacoeconomic evaluation include: cost effectiveness analysis (CEA), cost minimization analysis (CMA), cost benefit analysis (CBA), cost utility analysis (CUA). Pharmacoeconomic evaluation showed that biguanide had the lowest cost per unit. However, sulfonylureas provided superior incremental cost-effectiveness ratio (ICER).

KEYWORDS: Biguanides, cost, diabetes mellitus, pharmacoeconomics, sulfonylureas.

INTRODUCTION

Pharmacoeconomics is defined as the branch of health economics that uses cost-benefit, cost-effectiveness, cost-minimization, cost-of-illness, and cost-utility analyses to compare pharmaceutical products and treatment strategies.^[1] It is the description and analysis of the cost of drug therapy to healthcare systems and society. Pharmacoeconomic research deals with the process of identifying, measuring, and comparing the costs, risks, and benefits of programs, services, or therapies and ascertaining which alternative therapy that gives the best health outcome for the expenditure made.^[2]

Pharmacoeconomics identifies, measures, and compares the costs and consequences of drug therapy to healthcare systems and society. This branch of healthcare economics offers important guidance for the

management of limited healthcare resources and medical practice. Economic evaluations help to alleviate the burden of scarce resources by improving efficient allocation of healthcare financing.^[3]

COSTS

Cost of drug is the total resources consumed in producing the drug. It is the amount paid to the suppliers.^[4] Costs involved in pharmacoeconomics evaluation can be divided into financial cost (mandatory cost) and economic (resource for which no mandatory payment is made).

Opportunity cost is the benefit foregone when selecting one therapy alternative over the next best alternative.^[5] It is the value of the alternative that was foregone. To evaluate the economics of drug therapy, cost is divided into: direct cost, indirect cost, intangible cost.

Direct cost

- a) **Direct medical cost.** This is what is paid for specialized health resources and services. It includes the physician's salaries, the acquisition cost of medicine, consumables associated with drug administration, staff time in preparation and administration of medicine, laboratory costs of monitoring for effectiveness and adverse drug reactions.^[4] Direct medical costs can be subdivided into fixed and variable costs. Fixed costs are essentially overhead costs (e.g heat, rent, electricity) that are not readily influenced at the treatment level and thus remain relatively constant. For this reason, they are often not included in most pharmacoeconomic analysis. Variable costs change as a function of volume, and include medications, fees for professional services, and supplies.^[2]
- b) **Direct non-medical cost.** This includes cost necessary to enable an individual receive medical care such as lodging, special diet and transportation, lost work time (important to employers) such as acute otitis media in pediatric patients with professional parents who lost work time during the treatment of their kid.^[4]

Indirect cost

It is cost from the perspective of society as a whole: for example, these might include loss of earnings, loss of productivity, loss of leisure time due to illness, and cost of travel to hospital.^[6] This includes not just the patients themselves but also their family and society as a whole. Indirect costs are difficult to measure, but should be of concern to society. It is the cost incurred by the patient, family, friends or society.^[7]

Intangible cost

It involves the pain, worry or other distress which a patient or their family might suffer. These may be impossible to measure in monetary terms, but are sometimes captured in measures of quality of life. Quality adjusted life year (QALY) is one method by which intangible costs can be effectively integrated in pharmacoeconomic analysis.^[7]

The preferred treatment alternative is that with the lowest cost per QALY (or other health-status utility). QALYs represent the number of full years at full health that are valued equivalently to the number of years as experienced. For example, a full year of health in a disease free patient would equal 1.0 QALY, whereas a year spent with a specific disease might be valued significantly lower, perhaps as 0.5 QALY, depending on the disease.^[8,1]

Outcomes

Another fundamental component of a pharmacoeconomic study is outcomes or benefits. A cost-benefit analysis compares the costs and outcomes of alternative therapies and the outcome is then expressed in monetary terms.^[9]

Utility units

Utility is an economist's word for satisfaction, or sense of well-being. Utility unit measures changes in a patient's satisfaction or sense of well-being in an attempt to evaluate the satisfaction derived from moving from one state of health to another as consequences of the application of drug therapy.^[4]

Quality of life

Quality of life includes physical as well as psychosocial dimension of life. Physical dimension includes presence or absence of pain, immobility, while psychosocial includes level of anxiety, depression experienced and hence the reduced ability of the patient to cope with problems.^[7]

Quality adjusted life years (QALY)

This is a summary of quality and quantity of life. It is measured on a scale of 0-1 like a visual analog scale, from poor to excellent health.

For example, a patient with a rare cancer will live for only 2 years without treatment. A new treatment increases life expectancy by 2 years. However, it is associated with adverse effects which decrease the quality of life by 25%. The QALY is calculated thus:

Life expectancy = 2 (survival without treatment) + 2 (gain in life years) = 4 years.

Adverse drug reactions due to treatment = 0.25%

Hence decrease in quality of life = $2 \times 0.25 = 0.5$ years.

Thus net gain is $2 - 0.5 = 1.5$ or 1.5 QALYs.

Thus the net gain with the new treatment is 1.5 QALYs rather than 2 years.^[4]

PERSPECTIVE

Assessing costs and consequences depends heavily on the perspective of the evaluation. Common perspectives include those of the patient, provider, payer, and society. A pharmacoeconomic evaluation can assess the value of a product or service from single or multiple perspectives. However, clarification of the perspective is critical because the results of a pharmacoeconomic evaluation depend heavily on the perspective taken.^[7]

Patient's perspective

Patient's perspective is paramount because patients are the ultimate consumers of healthcare services. Costs from the perspective of patients are essentially what patients pay for a product or services — the portion not covered by insurance. From a patient's perspective are the clinical effects, both positive and negative of a program or treatment alternative. For example, various costs from a patient's perspective might include insurance copayments and out-of-pocket drug costs, as well as indirect costs, such as lost wages. This perspective should be considered when assessing the impact of drug therapy on quality of life or if a patient will pay out-of-pocket expenses for a healthcare service.^[2]

Provider's perspective

Costs from the provider's perspective are the actual expenses of providing a product or services regardless of what the provider charges. Providers can be hospital, managed-care organizations (MCOs) or private practice physicians. From this perspective, direct costs such as drugs, hospitalization, laboratory tests, supplies, and salaries of healthcare professionals can be identified, measured, and compared. However, indirect costs can be of less importance to the provider. When making formulary management or drug-use policy decisions, the viewpoint of the healthcare organization should dominate.^[2]

Payer's perspective

Payers include insurance companies, employers, or the government. From this perspective, costs represent the charges for healthcare products and services allowed or reimbursed by the payer. The primary cost for a payer is of a direct nature. However, indirect costs, such as lost workdays, being at work but not feeling well and therefore having lower productivity also can contribute to the total cost of healthcare to the payer. When insurance companies and employers are contracting with MCOs or selecting healthcare benefits for their employees, the payer's perspective should be employed.^[2]

Societal perspective

The perspective of society is the broadest of all perspectives because it is the only one that considers the benefit to society as a whole. Theoretically all direct and indirect costs are included in an economic evaluation performed from a societal perspective. Costs from this perspective include patient morbidity and mortality and the overall costs of giving and receiving medical care. An evaluation from this perspective also would include all the important consequences an individual could experience. In countries with nationalized medicine, society is the predominant perspective.^[2]

Types of pharmacoeconomic evaluation

Cost-effectiveness analysis (CEA)

This is a type of economic analysis that compares the relative costs and outcomes of different courses of action.^[10] CEA evaluates multiple drug treatments for the same condition. The cost of the drug treatments are weighed against the effectiveness of the drug.^[11] The costs of drug treatments include acquisition costs, physician involvement, and nursing costs for administration of the drug. Several parameters are used to measure the effectiveness of drug treatment. Such parameters are: length of hospital stay, duration of treatment required, and mortality rate. The results of a CEA are expressed as outcome for both therapies. CEA is the most commonly applied form of economic analysis. It does not allow comparisons to be made between two totally different areas of medicine with different outcomes.^[12]

The best example of cost-effectiveness analysis is the use of oral rehydration solution for the treatment of acute diarrheal illness in developing countries. Even though this is a symptomatic treatment, the fact that proper oral rehydration therapy can prevent deaths in children can be proved scientifically and cost-effectiveness analysis can further prove that the minimal cost of oral rehydration therapy is something which can be promoted as a public health policy. CEA helps policy makers to judiciously allocate healthcare resources so that more number of life years can be saved.^[10]

Cost-minimization analysis (CMA)

This involves the determination of the least costly alternative when comparing two or more treatment alternatives with equal efficacy and tolerability. CMA is done when the outcomes are the same for the two interventions. Cost is the only input considered. The treatment option with the least cost is selected.^[13]

CMA is relatively straightforward and simple method for comparing competing programs or treatment alternatives as long as the therapeutic equivalence of the alternative being compared has been established. Employing CMA is appropriate when comparing two or more therapeutically equivalent agents or alternative dosing regimens of the same agent.^[14]

Cost-benefit analysis (CBA)

CBA is the most comprehensive and the most difficult of all economic evaluation methods. It is a method that allows for the identification, measurement, and comparison of the benefits and costs of a program or treatment alternative. The benefits realized from a program or treatment alternative are compared with the costs of producing it (both the costs and the benefits are measured and converted into equivalent dollars in the year in which they will occur).^[2]

CBA should be employed when comparing treatment alternatives in which the costs and benefits do not occur simultaneously. CBA also can be used when comparing programs with different objectives because all benefits are converted into dollars and to evaluate a single program or compare multiple programs.^[12] These costs and benefits are expressed as ratio (a benefit-to-cost ratio), a net benefit, or a net cost. A clinical decision maker would choose the program or treatment alternative with the highest net benefit or the greatest benefit-to-cost (B: C) ratio.

- ❖ If the B: C ratio is >1 , the program or treatment is of value. The benefits realized by the program or treatment alternative outweigh the cost of providing it.
- ❖ If the B: C ratio = 1, the benefits equal the cost. The benefits realized by the program or treatment alternative are equivalent to the cost of providing it.
- ❖ If the B: C ratio is <1 , the program or treatment is not economically beneficial. The cost of providing

the program or treatment alternative outweighs the benefits realized by it.^[2]

CBA is not a popular method. Of all pharmacoeconomic methods CBA is probably used the least. The most difficult and challenging part of CBA lies in calculating the benefits in economic terms. Some benefits are easy to convert, others need subjective judgment. CBA may ignore intangible benefits (pain, anxiety, and stress) that are difficult to express in monetary terms.^[15]

Cost-utility analysis (CUA)

This is one of the most useful methods of evaluation in the context of healthcare setup. This analysis compares the costs of different interventions with their outcomes measured in 'utility-based' units. This unit can be level of wellbeing of the patient or level of possible activity of a patient. Quality adjusted life year (QALY) is one of the most common units used for such an analysis.^[16] CUA can compare cost, quality, and the quantity of patient-years. Cost is measured in national currency, e.g naira, euro, or dollar, and therapeutic outcome is measured in patient-weighted utilities rather than in physical units. CUA is the most appropriate method to use when comparing programs and treatment alternatives that are life extending with serious side effects (e.g. cancer chemotherapy), those which produce reductions in morbidity rather than mortality (e.g. medical treatment of arthritis), and when health related quality of life (HRQoL) is the most important health outcome being examined.^[17]

Guidelines for pharmacoeconomic evaluation

The guidelines for the practice of economic evaluation of drug treatments that are widely accepted are:

- ❖ Pharmacoeconomic evaluation should be performed and reported from a societal perspective. This entails that all costs and benefits are included irrespective of who actually bears the costs or receives the benefits.^[18]
- ❖ Demographic characteristics of the target population should be identified.
- ❖ Conceptual and practical reasons for choosing the comparator should be set out and justified.
- ❖ Treatment paths of the options being compared should be identified and fully described.
- ❖ The study should use recognized technique of analysis and should be justified.
- ❖ Clinical outcome measure should be identified.
- ❖ All relevant costs should be identified, collected and reported.
- ❖ Discounting should be undertaken considering the time lapse.
- ❖ Sensitivity of analysis should be conducted and reported.
- ❖ Comparisons with results from other studies are handled with care.^[4]

DIABETES MELLITUS

Diabetes mellitus (DM) is a chronic metabolic disorder

characterized by a high glucose concentration — hyperglycemia— caused by insulin deficiency, often combined with insulin resistance.^[19] The medical manifestation of this disorder is hyperglycemia. Very high glucose levels can cause fatigue, dehydration, and even death. Long-standing diabetes is associated with increased incidence of microvascular and macrovascular disease.^[20] Hyperglycemia occurs because of uncontrolled hepatic glucose output and reduced uptake of glucose by skeletal muscle with reduced glycogen synthesis. When the renal threshold for glucose reabsorption is exceeded, glucose spills over into the urine (glycosuria) and causes an osmotic diuresis (polyuria) which, in turn, results in dehydration, thirst and increased drinking (polydipsia). Insulin deficiency causes muscle wasting through increased breakdown and reduced synthesis of proteins. Diabetic ketoacidosis is an acute emergency. It develops in the absence of insulin because of accelerated breakdown of fat to acetylCo-A which, in the absence of aerobic carbohydrate metabolism, is converted to acetoacetate and β -hydroxybutyrate (which causes acidosis) and acetone.^[19]

EPIDEMIOLOGY

In 2010, approximately 285 million people worldwide (6.6%) in 20-79 years age group had diabetes and by 2030 438 million people (7.8%) of adult population is expected to have diabetes.^[21] The total number of individuals with diabetes worldwide is expected to rise from about 170 million (2.8%) in 2000 to about 370 million (4.4%) in 2030.^[22] Type 2 diabetes is the commonest form of diabetes constituting 90% of diabetic population in any country.^[20]

In Nigeria it is estimated that about 4 million people are living with diabetes mellitus. 70-80% (of this number) remains undiagnosed or untreated,^[23] The implication is that many patients present to healthcare centers with advanced disease and attendant high morbidity and mortality.^[24] In the rural areas of Nigeria, diabetes is prevalent in 0-2% of the population, whereas in the urban regions the figures are much higher at 5-10%.^[25] Diabetes has been associated with resurgence of tuberculosis and with the rising prevalence of end-stage kidney disease, erectile dysfunction, stroke, and lower extremity amputation.^[26,27]

Risk factors leading to diabetes mellitus

- ❖ A genetic predisposition
- ❖ Lifestyle factors characterized by high calorie intake and minimal exercise.
- ❖ Central obesity (body mass index [BMI] $\geq 25\text{kg/m}^2$).
- ❖ Habitual physical inactivity.
- ❖ Race or ethnicity.
- ❖ Hypertension ($\geq 140/90$ mmHg in adults)
- ❖ HDL cholesterol $\leq 35\text{mg/dl}$ and/or triglycerides $\geq 250\text{mg/dl}$.
- ❖ History of gestational diabetes or delivery of a baby weighing $>4\text{kg}$.
- ❖ History of vascular disease.

- ❖ Presence of acanthosis nigricans and polycystic ovary disease.^[28,29]

Classification of diabetes mellitus (DM)

There are two main types of DM

- 1) Type 1 diabetes (previously known as insulin dependent diabetes mellitus – IDDM – or juvenile-onset diabetes)
- 2) Type 2 diabetes (previously known as non-insulin-dependent diabetes mellitus –NIDDM—or maturity-onset diabetes).^[19]

Type 1 DM

This form of the disease has an auto-immune basis of destruction of β -cells of the pancreas in most cases and generally occurs in children and adolescents. There is an absolute deficiency of insulin and the patient requires exogenous insulin therapy for survival. The presence of hypoinsulinemia and associated hyperglucagonemia put such patients at risk of ketosis and ketoacidosis.^[30]

Type 2 DM

It develops in later life. Type 2 diabetes is accompanied both by insulin resistance and by impaired insulin secretion, each of which is important in its pathogenesis. It is associated with obesity, increasing age, hypertension, and family history. Treatment is initially dietary, although oral hypoglycemic drugs usually become necessary.^[19]

Clinical presentation

Type 1 DM patients are prone to developing diabetic ketoacidosis after several days of polyuria, polydipsia, and weight loss. Type 2 DM patients are often diagnosed secondary to unrelated blood testing, as they fail to present with symptoms. Lethargy, polyuria, nocturia, and polydipsia can be seen at diagnosis.^[28]

Diagnosis of diabetes mellitus

Diagnosis of DM is based on any of the three criteria below:

- 1) Classic symptoms of DM (polyuria, polydipsia, unexplained weight loss, blurred vision) and a random plasma glucose concentration of approximately 200mg/dl (11.1 mmol/L).
- 2) Impaired glucose tolerance (IGT). It is a 2-hour post-load plasma glucose value ≥ 140 mg/dl (7.8 mmol/L), but less than 200mg/dl (11.0 mmol/L) during a standard 75g oral glucose tolerance test, OGTT.^[31]

- 3) Impaired fasting glucose (IFG) is plasma glucose of at least 100mg/dl (5.6mmol/L) but less than 126mg/dl (7.0mmol/L) after an overnight (at least 8h) fast.^[28]

Hemoglobin A1c (Glycated hemoglobin) measurement is the gold standard for following long-term glycemic control and risk of microvascular complications in persons with DM for the previous 2 to 3 months.^[28]

Management of diabetes mellitus

- ❖ **Goals of DM management.** The primary goals of DM management are:

- I. To reduce risk of microvascular and macrovascular disease complications
- II. To ameliorate symptoms.
- III. To reduce mortality and improve quality of life.
- IV. To prevent poor wound healing and decreased white blood cell function.
- V. To prevent diabetic ketoacidosis and hyperosmolar hyperglycemic state.
- VI. To maintain blood pressure as near normal as possible.^[32]

- ❖ **Self-monitoring of blood glucose**

- ❖ **Non-pharmacologic therapy.** (a) Medical nutrition therapy is recommended (balanced diet). (b) Exercise. Exercise improves carbohydrate metabolism, insulin sensitivity, cardiovascular function, and improves well-being.^[30]

- ❖ **Pharmacologic therapy.** Currently six classes of oral agents are approved for the treatment of type 2 DM: sulfonylureas, thiazolidinediones, aldose reductase inhibitors, alpha-glucosidase inhibitors, biguanides, dipeptidyl peptidase-4-inhibitors (gliptins).^[19] Oral antidiabetic agents are often grouped according to their glucose-lowering mechanism of action. (a) Insulin sensitizers (that reduce insulin resistance: biguanides and thiazolidinediones (TZDs) or glitazones. (b) Insulin secretagogues (that enhance endogenous insulin release): sulfonylureas.

Pharmacoeconomic analysis of antidiabetic treatment

A study carried out in India in 2012 by^[32] focused on pharmacoeconomic evaluation of antidiabetic drugs from societal perspective. The key aspects of the results are presented in table 1 below. Costs are expressed in naira (₦5.16 Nigerian naira is equivalent to 1 Indian rupee as at December, 2020).

Table 1: Annual treatment cost analysis for single drug therapy.

Therapy	Mean Freq.	Unit cost(₦)	Cost/day(₦)	Annual cost(₦)
BGS	BD	5.93	11.87	4334.40
SUS	BD	8.00	16.00	5841.12
TGZ	BD	7.74	15.48	5650.20
INS	27 units	2.53	68.27	24922.80

BGS= Biguanides, SUS= Sulfonylureas, TGZ= Thio-glitazones, INS= Insulin.
Source:^[32]

Annual treatment cost was calculated for each class of drug prescribed for monotherapy (table 1). The lowest annual cost was found to be spent by patients taking biguanides (₦4334.40) followed by thio-glitazones (₦5650.20), Sulfonylureas (₦ 5841.12), and Insulin (₦24922.80).^[32]

The pharmacoeconomic evaluation done in this study used two main methods: cost-minimization and cost-effectiveness. Results for cost-minimization are shown in the table 2 below.

Among the prescribed brands, the lowest cost per unit of drug was biguanides (₦ 5.93) and the highest was for DPP IV inhibitors (₦192.16). The cost difference among the prescribed brand was more prominent among the drug under the class of alpha glucosidase inhibitors (₦47.16). This is presented in table 2 below.^[32]

Table 2: Cost-minimization analysis of prescribed drugs per unit.

Therapy	Average lowest cost(₦)	Average highest cost(₦)	Difference in costs(₦)
AGI	24.30	71.47	47.16
SUS	8.00	31.58	23.58
TGZ	7.74	41.90	34.09
INS	2.53	2.53	0
DPPI	192.16	192.16	0
BGS	5.93	12.80	6.86

AGI= Alpha glucosidase inhibitor, SUS= Sulfonylureas, TGZ= Thioglitazones, INS=Insulin, DPPI= Dipeptidyl

Table 4: Discounted QALY and incremental cost (IC) with standard therapy.

Therapy	Diff.in QALY	Diff.in Annual cost(₦)	Discounted QALY	Discounted IC(₦)
BGS	0.1	1506.72	0.003	45.20
TGZ	0.26	190.92	0.00078	5.73
INS	0.31	-572.30	0.0093	-17.18

IC= Incremental cost. QALY=Quality adjusted life years. BGS=Biguanides, TGZ=Thioglitazones, INS=Insulin. Source:^[32]

Table 5: Incremental cost-effectiveness ratio (ICER) with standard therapy.

Therapy	QALY	Annual cost(₦)	ICER(₦)
BGS	0.38	4334.40	15067.20
TGZ	0.22	5650.20	732.72
INS	0.17	24917.64	-1847.28

BGS=Biguanides, TGZ=Thioglitazones, INS=Insulin. QALY=Quality adjusted life years. ICER=Incremental cost-effective ratio

Source:^[32]

Patients taking biguanides and thio-glitazones monotherapy have to pay an incremental cost of ₦15067.20/QALY and ₦732.72/QALY to gain the increased QALY similar to that of sulfonylureas. In case of Insulin monotherapy the sulfonylureas would dominate in both QALY and less amount paid per year.

peptidase-4-inhibitors, BGS= Biguanides.

Source:^[32]

Table 3: Cost analysis of combination drugs of prescribed brands available in market per unit.

Therapy	Average lowest cost(₦)	Average highest cost(₦)	Difference in costs(₦)
AGI+BGS	35.66	41.85	6.19
SUS+BGS	18.73	24.82	6.09
DPP IV I +BGS	105.01	105.01	0
TGZ+BGS	23.53	30.13	6.60
BGS+SUS+TGZ	25.70	34.21	8.51

AGI= Alpha glucosidase inhibitor, SUS= Sulfonylureas, TGZ= Thioglitazones, BGS=Biguanides, DPPI= Dipeptidyl peptidase-4-inhibitors, BGS= Biguanides.

Source:^[32]

Among the combination drugs available, lowest cost per unit was obtained for sulfonylureas plus biguanides (₦18.73), while the highest was for biguanides plus DPP IV inhibitors (₦105.01). The cost difference was highest among a combination of biguanides plus sulfonylureas plus thio-glitazones (₦8.51).^[32]

Cost-effectiveness analysis revealed the following: incremental cost per quality of life in years gained for single drug therapy with standard sulfonylureas (1.00 QALY; ₦5841.12) therapy.

Finally, single therapy was shown not to be advisable for treatment as it failed to possess the increased QALY. Sulfonylurea has shown to provide a superior ICER than biguanide which was most commonly prescribed for single drug therapy and held the lowest cost.^[32]

CONCLUSION

Pharmacoeconomics is a branch of health economics that seeks to increase efficient allocation in health sector. It is a new field that is gaining recognition. The lowest annual cost was found to be spent by patients taking biguanides (₦4334.40). Among the combination drugs available, lowest cost per unit was obtained for sulfonylureas plus biguanides (₦18.73). Sulfonylurea has shown to provide a superior ICER (incremental cost effectiveness ratio) than biguanide which was most commonly prescribed for single drug therapy and held the lowest cost. Pharmacoeconomics is important because it helps policy makers in the health system to properly evaluate costs of

competing drug therapies so that patients can have optimal healthcare.

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