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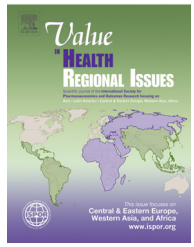

Cost-Utility Analysis of Pharmaceutical Care Intervention Versus Usual Care in Management of Nigerian Patients with Type 2 Diabetes

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ABSTRACT

Objective: To assess the cost-effectiveness of pharmaceutical care (PC) intervention versus usual care (UC) in the management of type 2 diabetes. **Methods:** This study was a randomized, controlled study with a 12-month patient follow-up in two Nigerian tertiary hospitals. One hundred and ten patients were randomly assigned to each of the "intervention" (PC) and the "control" (UC) groups. Patients in the UC group received the usual/conventional care offered by the hospitals. Patients in the PC group received UC and PC in the form of structural self-care education and training for 12 months. The economic evaluation was based on patients' perspective. Costs of management of individual complications were calculated from activities involved in their management by using activity-based costing. The impact of the interventions on quality of life was estimated by using the HUI23-S4EN.40Q (Mark index 3) questionnaire. The primary outcomes were incremental cost-utility ratio and net monetary benefit. An intention-to-treat approach was used. Two-sample comparisons were made by using Student's *t* tests for normally distributed variables data at baseline, 6 months, and 12 months. Comparisons of proportions were done by using the chi-square test. **Results:** The PC intervention led to incremental cost and effect of Nigerian naira (NGN) 10,623 ($69) and 0.12 quality-adjusted life-year (QALY) gained, respectively, with an associated incremental cost-utility ratio of NGN 88,525 ($571) per QALY gained. In the cost-effectiveness acceptability curve, the probability that PC was more cost-effective than UC was 95% at the NGN 250,000 ($1613) per QALY gained threshold and 52% at the NGN 88,600 ($572) per QALY gained threshold. **Conclusions:** The PC intervention was very cost-effective among patients with type 2 diabetes at the NGN 88,525 ($571.13) per QALY gained threshold, although considerable uncertainty surrounds these estimates.

Keywords: cost-effectiveness analysis, cost-utility analysis, Nigeria, patients with type 2 diabetes, pharmaceutical care, usual care.

Introduction

Analytic techniques used for economic evaluation in health care, for example, cost-benefit analysis, cost-effectiveness analysis, and cost-consequences analysis, are designed to compare alternative courses of action in terms of costs and outcomes. The choice of the technique depends on the decision the health economists intend to influence. Quality-adjusted life-years (QALYs) measure health as a combination of the duration of life and the health-related quality of life [1]. The primary outcome of a cost-utility analysis is the cost per QALY, or incremental cost-utility ratio (ICUR), which is calculated as the difference in the expected cost of two interventions divided by the difference in the expected QALYs produced by the two interventions. The results of a cost-utility analysis are compared with a threshold incremental cost-effectiveness ratio (ICER); interventions with an ICER below this threshold are funded, whereas those with an ICER above the threshold tend not to be. Economic evaluations using QALYs as the principal measure of outcome, often termed cost-utility studies, have become increasingly popular in the literature and have also been adopted by a number of health technology assessment agencies as the methodology of choice [1].

Cost-utility analysis was developed to help decision makers compare the value of alternative interventions that have very different health benefits, and it facilitates these comparisons without recourse to placing monetary values on different health states. Cost-utility analysis specifies what value is attached to specific health states, and thus increasingly facilitates the transparency of resource allocation processes [2].

Cost-utility analysis was developed to address the problem of conventional cost-effectiveness analysis, which did not allow decision makers to compare the value of interventions for different health problems. The utilities can now be obtained from standardized and validated health status instruments, making the evidence required to inform cost-utility analysis relatively

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straightforward and cheap to acquire—certainly when compared with the cost of acquiring evidence on clinical effectiveness, and indeed the cost of many of the treatments being reviewed [3].

Diabetes mellitus (DM) is associated with considerable morbidity and mortality [4]. It is also a major risk factor for cardiovascular disease, stroke, and kidney failure [5]. In Africa, DM probably has the highest morbidity and mortality rates of all chronic noninfective diseases [6].

DM was once regarded as a disease of the affluent, but it is now vastly visible as a growing health problem in developing economics because almost 80% of diabetes deaths occur in low- and middle-income countries [7,8]. The national standardized prevalence rate of DM in Nigeria is 2.2%, while the crude prevalence rate is 7.4% in those aged 45 years and above who live in urban areas [9]. Global estimates of the prevalence of diabetes showed that the prevalence of diabetes in Nigeria in 2010 was 4.7% (vs. 3.9% for world population) and that it would be 5.5% (vs. 4.3% for world population) in 2030 [10].

With the increasing demand for better management of type 2 diabetes, attention has focused on the potential benefits of pharmaceutical care (PC) to improve patients' health outcomes. Many PC programs have been established in various countries to enhance clinical outcomes and the health-related quality of life. These programs were implemented by pharmacists, with the cooperation of physicians and other health care professionals. PC and the expanded role of pharmacists are associated with many positive diabetes-related outcomes, including improved clinical measures [11], improved patient and provider satisfaction [12,13], and improved cost of management [12,14]. The pharmacists can, therefore, in collaboration with physicians and other health care professionals, contribute to an improvement in the quality of life of patients with diabetes by informing and educating patients, answering their questions, and, at the same time, monitoring the outcomes of their treatment [15]. In view of the above issues, the objective of this study was to assess the cost-effectiveness of the PC intervention in the management of type 2 diabetes versus usual care (UC).

Methods

Study Design

This study was a randomized, controlled, and longitudinal prospective study with a 12-month patient follow-up. The study followed the Consolidated Health Economic Evaluation Reporting Standards guideline for reporting economic evaluation of interventions [16]. The study protocol was approved by the Research Ethical Committees of the University of Nigeria Teaching Hospital, Ituku Ozalla, and Nnamdi Azikiwe University Teaching Hospital, Nnewi, in which this study was conducted. These hospitals are tertiary hospitals that serve as referral centers to most of the hospitals in the southeastern part of Nigeria.

Inclusion Criteria

Patients with type 2 DM who fulfilled the entrance criteria were identified and included in the study. Inclusion criteria included patients with type 2 diabetes who were on oral hypoglycemic therapy and provided written informed consent in addition to willingness to abide by the rules of the study and being certified fit to take part by the consulting physician.

Exclusion criteria were patients who were diagnosed with type 1 diabetes (to avoid complexity in the scope of the study), patients who were younger than 18 years (they are legally regarded as dependents and consequently they cannot take decisions of their own), patients who were pregnant (they are generally not allowed to participate in a study of this nature by the institutions used for the study), and patients who expressed willingness to withdraw from the study (participation is voluntary). The sample size determination showed that a sample size of at least 104 patients was required in each of the control and intervention groups [17]. Based on these data, to ensure sufficient statistical power and to account for "dropouts" during the study, a target sample size of 220 patients was recruited (110 patients from each of the hospitals). The folders of the 110 selected patients in each hospital were assigned numbers 1 to 110, which represented an individual patient. Patients were randomly assigned to one of two groups (intervention group or control group) on the basis of the number assigned to their folders by using online "random sequence generator" [18] with sequence boundaries of 1 to 110 (boundaries inclusive) set in a two-column format: the first column was a priori designated to the intervention group PC (55 patients) and the second column to the control group UC (55 patients).

Patients in the UC group received the usual/conventional care offered by the hospitals, which included hospital visits on appointment or on a sick day, consultations with physicians, prescription of drugs and routine laboratory tests, review of diagnosis and medications, refilling of prescriptions by patients, and referral. This UC was offered with education/training of the patients in an uncoordinated manner and without structured educational materials. Patients in the PC group received UC and PC for 12 months on monthly schedule. This additional PC included a stepwise approach: setting priorities for patient care, assessing patients' specific educational needs and identification of drug-related problems, development of a comprehensive and achievable PC plan in collaboration with the patient and the physician, implementation of this plan, and monitoring and review of the plan from time to time [19]. The nurses collaborated with the pharmacists in terms of organizing the patients and patients' folders, taking point-of-care testing, counseling the patients, and reinforcing the information given to the patients during training sections. The physicians provided the visitation/appointment schedule for the patients, and prescription of laboratory tests. They were also involved in the implementation of consensus strategies in managing drug-related problems in areas of changing, substitution, and withdrawal of medications. All the members of the health care team were trained before the implementation of the intervention.

The medical and educational contents of the training materials were evaluated by the physicians and nurses in diabetes clinics before the researchers conducted the training for the patients. The physicians and nurses were asked to rate the materials as being excellent, very good, good, fair, poor, and useless.

The monthly educational/training program for the patients consisted of four sections of 90 to 120 minutes. The program covered the following areas: diabetes overview and its complications, self-monitoring blood glucose techniques and interpretation of diabetes-related tests, medications and their side effects, lifestyle modification, counseling, and effective interaction with health providers. PC provided ground for the patients to monitor and react to changes in their blood glucose levels, allowing them to integrate their diabetes into the lifestyle they preferred.

Data Collection

Data were collected on utilization of health care resources for 12 months for control and intervention groups at baseline, 6 months, and 12 months. Information was obtained on the frequency of self-monitoring, number and average duration of visits to a hospital, daily doses of drugs taken regularly, and the variable of "other health care resource use," including primary care (general practitioner and nurse consultations), hospital care (visits to an accident and emergency department, outpatient care, day hospital care, and inpatient care), auxiliary health care (services of a podiatrist, optician, or dietitian), and private health care. These data were collected by means of patients' PC diaries notes