ABSTRACT
Background: The significance of achieving good glycaemic control cannot be over-emphasized as this goes a long way in the reduction of disease burden arising from diabetes mellitus. In Nigeria, insulin injections are still widely unacceptable thus posing a problem towards achieving optimal glycaemic control in insulin requiring diabetes patients.

Aim: This study aimed to provide information on insulin usage in Nigeria.

Patients and Methods: The study was carried out in the Lagos State University Teaching Hospital (LASUTH) and the Lagos University Teaching Hospital (LUTH), Lagos, Nigeria. Participants were recruited from patients receiving care at the Diabetes Clinic of the above mentioned hospitals. It is a descriptive study in which 100 insulin-requiring diabetes patients were studied via the use of interviewer-administered questionnaire.

Results: Essentially, insulin techniques, glycaemic control and complications of insulin usage were documented.

Conclusions: The main form of insulin used is the human insulin. High cost of insulin is one of the major factors responsible for poor glycaemic control. For proper delivery of diabetes care, insulin, insulin pens and syringes must be available, accessible and at affordable cost.

Keywords: Diabetes mellitus, Insulin injections, Glycaemic control.

INTRODUCTION
Diabetes mellitus (DM) is a metabolic disorder that is seen in 2.2% of Nigerians (1). In Africa, DM is one of the prominent causes of mortality of all non-infective, chronic diseases (2). There are still a lot of erroneous beliefs concerning DM and its treatment amongst Nigerians with the disorder. Insulin usage which is a must for those with Type 1 DM and for some people with Type 2 DM is often seen as burdensome and even a source of stigma for the user. In Nigeria where there is no viable health insurance scheme, payment for medical purposes is often “out of pocket”. As a result of this, people with DM who require insulin for survival may find it difficult to procure the much needed drug thus resulting in epileptic self-administration of insulin. There is a dearth of literature on insulin usage in Nigerians with diabetes. This study aims to bridge this gap.

PATIENTS AND METHODS
This study, a descriptive one, was carried out at the Diabetes Clinics of the Lagos State University Teaching Hospital (LASUTH), Ikeja, and Lagos University Teaching Hospital Lagos (LUTH) from January 2003 to December 2004. These are the biggest government owned hospitals in the South West of Nigeria. These clinics are run once a week and are designed to render care to patients with diabetes-referrals and old patients inclusive. The total number of patients receiving diabetes care each week in these clinics is estimated to be one hundred and twenty.

Data collection was done through the use of questionnaires which were interviewer-administered, clinical examination and laboratory methods. These questionnaires were administered to insulin-requiring patients with DM. Information obtained from the questionnaires include the documented demographic characteristics, type and duration of DM, type of insulin delivery system/devices used insulin injections sites and complications of insulin viz, hypoglycaemia and skin changes. The skin changes sought out for include lipo-atrophy, lipo-hypertrophy, urticaria/rash, hyper-pigmentation and any other skin changes noticed at the site of insulin administration.

Metabolic assessment or glycaemic control was determined using the fasting plasma glucose (FPG) values.

OPERATIONAL DEFINITIONS
1. Good glycaemic control refers to a weighted means of fasting plasma glucose (FPG) ≤120mg%.
2. Poor glycaemic control refers to a weighted means of fasting plasma glucose (FPG) >121mg%.
3. Obesity is said to be present if the Body Mass Index is>25kg/m².
4. Type 1 DM refers to people in whom the diagnosis of DM was made before the age of 30 years and are on insulin for control of DM.
5. Insulin requiring Type 2 DM: These refers to people in whom the diagnosis of DM was made after the age of 30 years and were initially on diet or diet/oral hypoglycaemic agents for glycaemic control but later placed on insulin therapy on an outpatient basis for glycaemic control.

The test statistics used included unpaired Student’s “t” test and Chi squared test. The student’s “t” test was used to test for differences between quantitative variables. The Chi squared test was used to test for associations and comparison of proportions. The level of statistical significance was set at p<0.05.
RESULTS

A total of 100 insulin-requiring DM patients were seen at the outpatient diabetes clinic of LASUTH and LUTH during the period of January – December, 2003. The male: female ratio was 1:1. The mean age standard deviation of the subjects was 45.8(14) years, mean standard deviation of the body mass index was 24.3(4.9) kg/m². The mean age (SD) of males was 47.1±13.4 years while that of females was 44.5±14.8 years. The age range of the male subjects was 15-70 years while that of the female subjects was 18-73 years. With a p value of >0.05, these differences were not statistically significant.

The mean (SD) duration of DM was 9.2±7.7 years with a range of 1-30 years. The mean (SD) of fasting plasma glucose (FPG) was in the poor glycaemic range and this was 170 (77) mg%. (table 1).

Over half (61%) of these subjects had no formal education and were involved in semi-skilled occupations. About 55% of these subjects belonged to a low socio-economic class.

Figure 1 shows that 30 (30%) of insulin requiring subjects were aged between 48-58 years while those that are aged 70 years and above are in the age bracket that least require insulin for the control of their glycaemia.

Seventy percent (70%) of insulin requiring subjects with DM had type 2 DM and this group had a longer mean duration of DM which was statistically significant.

A vast majority, 86 (86%) of the study subjects used human insulin while 14 (14%) were on porcine insulin. The intermediate forms of insulin especially the combination of regular and NPH insulin was the main form of insulin used. The insulin administering devices commonly used by the subjects were the insulin syringes. These were used by 82 (82%) of the subjects while only 18 (18%) used insulin pens. Eight (44%) of those that used insulin pens achieved good glycaemic control while only 16 (24%) of those that used insulin syringes attained good glycaemic control. This difference was statistically significant p<0.05. Of the patients studied, 57 (57%) were non-literate, and in this group, 8 (14%) used insulin pens while 10(23%) of those that were educated used the pens.

About half (51%) of the study subjects admitted to skipping their insulin injections. Only 16 (31%) of the subjects in this group were able to achieve good glycaemic control.

Rotating insulin injection sites was practiced by 85 (85%) of the study subjects while swabbing of insulin injection sites and pinching up of the skin prior to injection was practiced by 84 (84%) and 77 (77%) of the patients respectively. There was no statistically significant difference documented in glucose control in those that rotated their injection sites, swabbed and pinched up their skin prior to insulin injection. Glucose control was generally poor in these groups of people.

A large percentage (72%) of insulin-requiring patients with DM did not practice self-home glucose monitoring. Self-home glucose monitoring was carried out by 28 (28%) of the subjects and of this group, only 8 (28%) used blood glucose meters. The others used stix strips and their urine to assess glycaemic control.

Figure 2 shows the insulin injection sites used the most frequently used injection site was the thigh while 2 (2%) of the subjects used their calf muscles for insulin administration.

The daily frequency of insulin injections is showed in table 2. The occurrence of hypoglycaemia was documented in 70 (70%) of these insulin-requiring people with diabetes. Hypoglycaemic episodes were documented in 80% of people with type 2 DM.

The skin changes that were noted in this study include hyperpigmentation, lipo-atrophy, lipo-hypertrophy and the presence of rashes. Hyperpigmentation was the commonest-occurring skin lesion and this was present in about 37% of the study subjects. These details are shown in figure 3.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Type 1 DM</th>
<th>Type 2 DM</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No (M:F)</td>
<td>30(16:14)</td>
<td>70(34:36)</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>BMI</td>
<td>24.3±4.9</td>
<td>26.8±3.1</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Age</td>
<td>36.1(6.4)</td>
<td>59.2(7.3)</td>
<td>&lt;0.05</td>
</tr>
</tbody>
</table>

| Duration of DM (years) | Mean (SD) | 10.49 (7.88) | <0.05 |

| Glycaemic control   | Mean (SD) | 177 (8) | >0.05 |

| Range               | 80-160    | 68-185   |

Table 2: Frequency of insulin injections

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Once daily</td>
<td>12</td>
</tr>
<tr>
<td>Twice daily</td>
<td>68</td>
</tr>
<tr>
<td>Thrice daily</td>
<td>12</td>
</tr>
<tr>
<td>Four times daily</td>
<td>1</td>
</tr>
<tr>
<td>Infrequently</td>
<td>7</td>
</tr>
</tbody>
</table>

Figure 1: Age distribution of subjects by age group

Figure 2: Insulin injection sites
DISCUSSION

The majority of the subjects studied were middle aged with a mean age of 46 years. Though the males were older than the females; this difference was not statistically significant. The mean weight and Body Mass Index of the subjects were within normal limits. However, people with type 2 DM were overweight while those with type 1 DM had normal BMI. In all, the percentage of those people in the low socio-economic bracket was higher-55%- than those in the higher economic class. The fact that this study was carried out in government hospitals where patient care is partly subsidized may account for this socio-educational picture. Type 2 DM was the main form of diabetes in the patients’ studied-accounting for 70% of them. The global distribution of diabetes is such that type 2 DM is estimated to account for about 98% of all cases of DM (3). Those with type 2 DM were older than those with Type 1 DM and this difference was statistically significant *p*<0.05. This is in keeping with the diagnostic criteria of both forms of DM (4).

The mean value of the duration of DM was higher in those with Type 2 DM than in those with Type 1 DM. This goes to emphasize the fact that people with Type 2 DM may resort to use of insulin with progressive waning of beta cell function (5).

The main form of insulin used is human insulin: this was used by 86(86%) of the all the subjects studied. For a resource-poor country like ours this figure is impressive. It goes to show that there is an increasing acceptance of the guidelines of the International Diabetes Federation (IDF) which state amongst others that the use of human insulin be embraced by all insulin-requiring DM patients whilst usage of porcine insulin is discontinued (6). The intermediate forms of insulin especially the pre-mixed form of a long-acting and short acting insulin- were commonly prescribed and used. This insulin came in the form of a mixture of 70% of long-acting and 30% of short acting insulin. A small percentage of people mixed insulin themselves. In 68% of the subjects studied, insulin was administered twice daily. However some of these people admitted to under-dosing so as to reduce the cost of insulin replacement. Again the irregular administration of insulin by insulin- requiring DM subjects is brought to the fore by this study in which irregular usage of insulin was documented in 7% of the study subjects. Reasons volunteered by such patients ranged from financial constraints, unavailability inaccessibility to insulin supplies.

The cost of procuring insulin for those using the syringes amounts to about 5,000- 7000 Nigerian Naira monthly while the cost for those on insulin pens range from about 10,000-12,500 Nigerian Naira monthly. This is against the backdrop of a minimum monthly wage of 7,500 Nigerian Naira. In Nigeria, there are three main pharmaceutical companies that have the franchise to distribute insulin and these include Eli-Lilly, Novo Nordisk and an indigenous company that imports insulin from India. This is only a little cheaper than the ones provided by the two “giant” insulin companies and there is no provision of insulin pens yet by this indigenous pharmaceutical company.

For proper delivery of diabetes care, insulin, insulin pens, insulin syringes and needles should be available, accessible and at an affordable cost to all people with diabetes who require them. Continuous accessibility to insulin is still a major problem in many developing countries especially those in sub-Saharan Africa such that there are reports of premature deaths due to the chronic lack of access to insulin in these countries.

Insulin pens and syringes were the insulin administrative devices used by the study subjects. Insulin pumps are yet to be made available to the Nigerian market by the producers. Insulin syringes which come cheaper were commonly used. Only 18 (18%) of them used insulin pens. Though the general trend in this study was that of poor glycaemic control, in those that used the pen devices, a higher percentage of them had good glycaemic control than those that used insulin syringes. There was no relationship noted between the use of either of the administrative devices and socio-economic class. The injection main sites used for insulin administration were the thighs, abdomen, abdomen and the deltoid muscle. All the subjects injected insulin at the recommended sites (8) except for a small percentage of them (2%) who used their calf muscles. The site commonly used was the thigh muscles-this was observed in 62% of the subjects. Only 7% of these people used the abdomen for injections. The technique of insulin administration had no bearing on the glycaemic control as portrayed in this study. More than 50% of people were poorly-compliant with their insulin regimen. The relationship between poor drug compliance and glycaemic control is clearly evident as shown in the results obtained. This is a notable finding in people who require insulin for long-term control of glucose (9).

Self-glucose monitoring, a useful component of patient self care practices is not widely practised amongst our patients with DM. Financial constraints, ignorance and poverty are definite hindrances to this practice. The cost of the glucose measuring meter is 7,500 Nigerian Naira. Reasons for this include high cost of testing supplies, lack of diabetes education, lack of interest by patients and lack of testing supplies.

Hypoglycaemia in diabetes is a reflection of the inadequacies of current medical management of diabetes. This study showed that at some time, 70 (70%) of the insulin requiring subjects had experienced hypoglycaemic episodes. This is not surprising given that the pharmacodynamics of conventional insulin therapies do not reproduce the physiological circulating insulin levels of health, creating risks of severe hypoglycaemia that can be reduced but not avoided by rigidity of lifestyle and prescription of frankly abnormal eating habits (10). The association of skin changes with insulin administration was noted in about 80% of the study subjects and hyperpigmentation was the commonest skin change noted.

High costs and lack of motivation are some of the factors most likely responsible for the poor glycaemic control noted in this study. Educating the diabetes patients, subsidizing insulin costs and accessibility to convenient means of injections such as the use of the insulin pen and blood glucose-monitoring meters will go a long way in motivating the patient toward achieving optimal diabetes control.

REFERENCES