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Journal of Public Health and Epidemiology

Full Length Research Paper

A longitudinal data analysis on risk factors for developing type-2 diabetes mellitus at the University of Gondar Comprehensive Specialized Hospital, Gondar, Ethiopia

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Diabetes mellitus is a group of metabolic chronic diseases characterized by high blood sugar levels with multi-system complications. The objective of this study was to assess the risk factors for developing type-2 diabetes mellitus over time in their random blood sugar and to obtain better predictive model for type 2 diabetes patients' random blood sugar (RBS) level in the University of Gondar Comprehensive Specialized Hospital. A retrospective cohort study with a total of 330 diabetic patients who have been active in the follow-up treatment for at least 3 times in three month interval in the hospital from February 2014 to February 2016 was conducted. Linear mixed effects model for longitudinal data were employed to measure the changes in RBS level. The results revealed that the linear distribution trend in the mean RBS level accounted for 79% of the variability in the data and the mean RBS level decreased over time. Age, residence, family history, alcohol intake, dietary type, BMI, treatment, exercise and education status were the significant factors for the change in mean RBS level of the diabetes patients over time. The study also confirmed that among the factors of RBS level included in the study, meat dietary type, patients who do not perform exercise, and body mass index (BMI) were positively correlated with the RBS level while the rest were negatively correlated. It was significant for the patients to do daily self-care activities to prevent long term complications. The government should also contribute to the education of communities to spread awareness creation and enhance prevention mechanisms of diabetes.

Key words: Diabetes mellitus, blood sugar, linear mixed effect, longitudinal data analysis, random blood sugar (RBS).

INTRODUCTION

Diabetes mellitus is a group of metabolic diseases characterized by high blood sugar levels that result from

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defects in either insulin secretion or its action (WHO, 2017). Diabetes mellitus is one of a number of chronic illnesses with multi-system complications. Diabetes is a chronic disease for which control of the condition demands patient self-management (MacPherson et al., 2004). Self-management of diabetes requires time and monitoring of blood-glucose levels. Taking control of diabetes to improve quality of life has put the spotlight on the need for additional support and education for patients with diabetes. Although new treatments and technology have aided in controlling the disease, diabetes can still influence every day social interactions in many ways.

The patient must be aware the types and amounts of food they ingest, they would have to monitor their blood glucose levels at specific times during the day, and medication would be necessary at times when the individual is engaging in social activities (Thorne et al., 2003). The current classification of diabetes is based upon the pathophysiology of each form of the disease. Type-1 diabetes results from cellular mediated autoimmune destruction of pancreatic *β*-cells, usually leading to loss of insulin secretion (Thorne et al., 2003).

Type-2 diabetes results from insulin resistance, which alters the use of endogenously produced insulin at the target cells. Type 2 patients have altered insulin production as well. However, autoimmune destruction of *β*-cells does not occur as it does in type-1, and patients retain the capacity for some insulin production. Because the type-2 patient still produces insulin, the incidence of ketoacidosis is very low compared to type 1, however, ketoacidosis can occur in association with the stress of another illness such as infection (Klinke, 2008). Type-2 patients can go undiagnosed for many years because the hyperglycemia appears gradually and often without symptoms. It is often accompanied by various chronic complications that may affect the productivity and quality of life (Hennekens, 1998). Nowadays, diabetes mellitus is becoming the leading cause of blindness, non-traumatic amputation, and chronic renal failure in the western world (Laing et al., 1999). Globally, the population of people affected by type 2 diabetes was 15.1 million in 2000 (IDF, 2013). The number of people with diabetes worldwide was projected to increase to 36.6 million by 2030 (CDC, 2007b). In 2007, it was indicated that 23.6 million people or 7.8% of the United States population had type 2 diabetes. People with diabetes have an increased risk of developing a number of serious health problems. Consequently, the economic and medical consequences of complications arising from diabetes is high blood glucose levels that can lead to serious diseases affecting the heart and blood vessels, eyes, kidneys, nerves and teeth. In addition, people with diabetes also have a higher risk of developing infections. In almost all high income countries, diabetes is a leading cause of cardiovascular disease and kidney failure (Kahn et al., 2006).

Like the rest of the world, sub-Saharan African countries are experiencing an increasing prevalence of diabetes along with other non-communicable diseases (WHO, 2008). In 2010, it was indicated that 12.1 million people were estimated to be living with diabetes in Africa, and projected to increase to 23.9 million by 2030 (Shaw et al., 2010).

In addition, the International Diabetes Federation (IDF) estimated that 19.8 million people have diabetes in Africa and approximately 75% are still undiagnosed (IDF, 2013). Countries with the highest estimated numbers of persons with diabetes include Nigeria (3.9 million), South Africa (2.6 million), Ethiopia (1.9 million), and Tanzania (1.7 million) (IDF, 2013). Type 2 diabetes contributes up to 90% of the cases (Feleke and Enquselassie, 2007). This spike is due to an aging population and lifestyle changes associated with rapid urbanization and westernization. Because of the high urban growth rate, unhealthy dietary changes, reduction in physical activity and increased obesity it is estimated that the prevalence of diabetes is going to triple within the next 25 years (IDF, 2013). Diabetes is common in Ethiopia but the incidence and prevalence of the disease is not well known ii the society. In recent studies, accesses to blood glucose monitoring and diabetes health education were found to be very low but overall burden of the disease in the country. These studies have a lack of comprehensiveness due to small sample sizes because most of them were limited to the capital city, Addis Ababa. The cost of inpatient diabetes management in the country is a high amount being significantly higher than the cost of other inpatient management categories (Feleke and Enquselassie, 2007). However, diabetes in Ethiopia has never been given the attention it deserves. Glycemic control and management of co-morbid conditions along with diabetes complications are alarmingly sub-optimal and perhaps one of the worst in the world (Abera, 2000).

According to the IDF report, in Ethiopia, about 1.9 million adults aged between 20 and 79 years were estimated to have diabetes in 2013. In addition to this, 2.9 million people living with impaired glucose tolerance are at higher risk of developing diabetes. With national diabetes prevalence of 4.36%, there was around 34,262 estimated diabetes related deaths in the same year.Presently, the incidence and prevalence of the disease has increasing in society. It is evident that, few studies have shown a significant increase in its prevalence over the last four decades. However, diabetes in Ethiopia has never been given the attention it deserves, despite the fact that the rate of incidence and prevalence has been increasing over time. The overall disease burden in the country is unknown because of the limited studies in the country (Abera, 2000). The burden of diabetes also presents a crisis in terms of health care costs, both direct and indirect, ranging from individual to

national economy. According to International Diabetes Federation, an estimated average cost in USD was 1,437 per person with diabetes was spent globally on treating and managing the disease in 2013. Even though health professionals try to control random blood sugar levels, there are many questions which can be raised by individuals. For example, how is the change of RBS level over time? or does the change of RBS level have different patterns on different factors? what are the factors for controlling blood sugar levels of diabetes patients? In Ethiopia, there has not been known and well-developed longitudinal research conducted to know the mean evolution of random blood sugar. In addition, research has been conducted to assess whether blood sugar levels changed over time or whether change in blood sugar control varied by covariates. The empirical risk of having type 2 diabetes increases from 2 up to 6 fold, if a parents or siblings have the disease. Consequently, a positive family history is a practical, albeit a crude way, of figuring out if an individual is likely to have inherited susceptibility to the disease. On the other hand, familial aggregation may occur for non-genetic reasons. Family members often share a similar environment, particularly as children and in adulthood, thus familial aggregation alone is not definitive evidence of genetic determinants. Furthermore, with a disease as frequent as type 2 diabetes two or more family members may well have the disease by chance alone (Helgeson and Gottlieb, 2000).

A longitudinal mixed model project on a nurse-based diabetes management system from San Diego, California showed that multiple variables are associated with glycemic control. The project that collected information from July 18, 2000 to October 7, 2002 focused on a database containing demographics, health status, treatment, laboratory, and behavioral factors for each patient. Age, race, disease duration, medication, number of visits, total cholesterol, BMI, alcohol intake, dietary and insurance status were all significant. However, after controlling baseline A1C, time, other demographic implications, and disease severity factors; only age, insurance status, disease duration, pharmacotherapy, and total cholesterol were significant in the final model contributing significant effects (Philis-Tsimikas and Walker, 2001). The prevalence and incidence of type 2 diabetes vary to some extent between the sexes from one population to another. A longitudinal study of type-2-diabetes with the linear mixed effect model conducted in Ghana reported that, the change in RBS value for males and females were not the same (Timothy et al., 2015). However, a study conducted in Japan states that both sexes have equal chance of being affected by diabetes. Therefore, being male or female may not have effects in the prevalence of type 2 diabetes (Baltazar et al., 2004). Another longitudinal study on type 2 DM reported that significant difference in hyperglycemia between insulin plus Oral Hyperglycemia Agents (OHA) and insulin (p= 0.0321) combinations contributes to better results (Yki-Jarvinen, 2001). The available literature provides little data on the quality of life of patients with type 2 diabetes depending on place of residence. Rural diabetics experience significant impairments or damages in their health or quality of life in relation to urban diabetics. A higher proportion of obesity was found among rural residents compared to urban residents. Since higher obesity is closely linked and the main cause of developing type 2 diabetes, rural patients have a higherrisk of developing the disease. In a study conducted among patients living in the Lublin Province, people with diabetes living in rural areas were more likely to perceive the use of insulin as being burdensome and believe that diabetes has hostile impact on their family life because of the stress than residents of urban areas (Graham et al., 1999). A report that compared the type 2 diabetes in adults and young adults in Europeans opposed to Native American tribes, Mexican Americans, African Americans, Chinese, Polynesians, Asian Indians and Arabs of the Gulf States showed that Europeans who are adults have a higher risk of developing type 2 diabetes than younger citizens. It was clear that young adults are better at controlling their blood sugar levels (Taylor and Lobel, 1989).

The nurses' health study suggests that the risk of type 2 diabetes among Europeans increases even within the normal BMI range. It also states that a BMI of 21 kg/m^2 might be an optimum level and that patients with type 2 diabetes had a higher prevalence with a large BMI because an overweight population has a greatest risk of developing diabetes (Tyler and Blader, 2001). A study has been carried out in the United States of America in 2001 when Miller et al. (2002) evaluated the impact of education intervention on blood glucose levels for 92 type 2 diabetic patients who were older than 45 years of old. Patients were put into literate and illiterate groups and introduced to a ten week follow up in life style changes, physical exercise, and proper dietary use. When the patients were evaluated, the literate group showed a greater improvement in fasting plasma glucose (p=0.05) and glycosylated hemoglobin (p< 0.01) than the illiterate group. So it is clear that the illiterate diabetic patients needed additional education to achieve metabolic control to reduce fasting (random) blood sugar levels and avoid mortality associated with diabetes (Miller et al., 2002).

The main objective of this study was to assess the risk factor for developing type-2 diabetes mellitus over time using the random blood sugar in a follow up study at University of Gondar comprehensive specialized hospital during treatment period of 2 years and to determine their relationship.

MATERIALS AND METHODS

Data description and study design

This study was a retrospective cohort study based on data from diabetic patients. The data used in this study were obtained from University of Gondar Comprehensive Specialized Hospital,

Table 1. Covariates used in the Linear mixed effect Model Analysis for DM Data.

S/N	Variable	Description
1	Gender	1=Female, 0= Male
2	Age	Year
3	Marital status	0 = Divorced, 1 =Married, 2 = Widowed, 3= Single
4	Family history	0 = no family history, 1= has family history
5	Place of residence	0 = rural, 1 = urban
6	Educational status	0 =illiterate, 1 =literate
7	Treatment	0 = insulin, 1 =OHA, 2= combination of both
8	Dietary type	0 =fruit, 1= vegetable, 2 = meat, 3 = others
9	Body mass index	Kilogram per meter square
10	Exercise activity	1 = do not perform exercise, 0= perform exercise
11	Alcohol intake	1 = drinks alcohol drinker, 0= does not drink alcohol

Ethiopia. The data comprised longitudinal measurements of diabetes mellitus type 2 (DMT2) risk factors. The most commonly used test of diabetes is random fasting blood glucose. The test is conducted before eating at least for 8 h, usually overnight. The target populations of this study were all diabetic patients who attended the Hospital and had been active in follow-up treatment for their diabetes for at least 3 times in three month interval in the hospital from February, 2014 to February, 2016. The patients also had a minimum of three and a maximum of eight repeated measurement values. The number of measurements in the data may not be equal for all patients due to the difference in the duration of the follow-up. All the patients of this study were those whose age was greater than 20 but less than 70 years. The patients under 20 and over 70 were not included in the study. Since the life expectancy in Ethiopia is low, those patients over 70 are difficult to include due to their scarcity. Since, there are very few individuals in that age range their contribution would have been minimal.

In this study, 1,456 observations were considered to collect the random blood sugar which was evaluated at fixed time interval of 3 months. Measurements of all the patients were taken at 3, 6, 9, 12, 15, 18, 21, and 24 months which had an equal time interval with 3 months between all measurments. The random blood sugars (RBS) of the patients ranged from 78 to 600 mg/dl, with their mean, median and standard deviation values of 216.8 and 191.5 mg/dl respectively with a standard deviation of 83.35198 mg/dl. Individuals are not only said to be diabetic patients with large levels of RBS, but also for small levels. RBS level higher or lower than the standard value was considered as diabetic. Several potential explanatory variables were also considered in this study. The descriptions of these covariates are presented in Table 1.

Out of the total 1456 patients included in the study, 735 (50.5 %) were females. More than half of the patients (882, 60.6%) live in rural areas. Regarding education status, 688 (47.3%) were illiterate while 768 (52.7%) were literates. Regarding family history, 606 (41.6%) patients' family had a DM while 850 (58.4) had not. The treatment of patients who used both insulin and OHA were 134 (9.2%), OHA users were 538 (37.0%) and the rest used insulin. There were also 740 (50.8%) patients who did not perform an exercise to control their glucose levels but 716 (49.2%) patients were performed some sort of exercise to control their glucose. Regarding dietary type, among all the participants, 115 (7.9%) were fruit eaters, 85 (5.8 %) were meat eaters, 369 (25.3%) were vegetable eaters and 887 (60.9%) were people of other types of diets.

Similarly, 826 (56.7%) of the DM patients were married, 344 (23.6%) were single and the rest 186 (19.7%) of the patients were divorced and widowed. Regarding the continuous covariates, the mean of the baseline for age and body mass index were 46.7 years of age and 24.0886 kg/m^2 with the standard deviation of 14.737 years and 4.33084 kg/m^2 respectively. These variables were standardized to have a mean of 0 and variance of 1 so that their coefficients in the regression model represent the effect per a unit standard deviation change.

Data analysis

Data exploration

As a first step of the analysis, the data was explored in different ways in order to get details that may help to make decisions in the subsequent steps of the analysis. To determine the evolution and balances of the data, the individual and mean profiles with respect to time were plotted. The mean, the variance and the correlation structures were also explored through graphical techniques. In parallel to defining the fixed effects model, a random effects model was chosen to define a covariance model. After deciding the fixed effects, the study selected a set of random effects to be included in the model.

Longitudinal data modeling

The linear mixed effect model is the most widely used method for analyzing longitudinal data which could handle the complications of incomplete measurements in a very natural way. In this study, a linear mixed model was used with the assumption that the vector of repeated measurements in the original scale on each patient follows a linear regression model where some of the regression parameters are the same for all patients (that is population-specific), while others are different across patients (that is patient-specific). Thus, patient-specific parameters represent patients' variability which is random effects. The idea of randomly varying regression coefficients was also a common thread in the so-called two-stage approach to analyzing longitudinal data. In the two-stage formulation, the repeated measurements on each individual were assumed to follow a regression model with distinct regression parameters. The distribution of these individual-specific regression parameters, or random effects, is modeled in the second stage (Verbeke, 2000). Hence, simple explanatory tools using the two-

stage approach were first employed in order to approximate each observed longitudinal profile (that is individual profiles based on the data) by an appropriate linear regression function. Other models are also fitted and compared via information criterion such as BIC and AIC to cross-check the model suggested by the two-stage approach. Often, subject-specific longitudinal profiles can be well approximated by linear regression functions and this leads to a 2-stage model formulation as shown below:

Stage 1: Linear regression model for each subject separately

Response Y_{ij} for i^{th} subject measured at time t_{ij}, $i = 1,2,...,n$, and $j = 1,2,...,n_i$.

Response vector Y_i for i[th] subject: $Y_i = \begin{bmatrix} Y_{i1} \\ Y_{i2} \\ . \\ Y_{ini} \end{bmatrix}$

The model of this stage was given as:

$$Y_i = z_i\beta_i + \varepsilon_i \quad (1)$$

Where, Z_i is a (ni × q) matrix of known covariates; β_i is a q dimensional vector of subject-specific regression coefficients; $\epsilon i \sim N(0, R)$, where R is the variance-covariance matrix of the error term.

Stage 2: In this stage, the interest is to study the between-subject variability and it can now be studied from relating the β_i to known covariates. Stage 2 model is also given as follows:

$$\boldsymbol{\beta_i} = \boldsymbol{k_i\beta + b_i} \quad (2)$$

Where, K_i is a (q × p) matrix of known covariates; β is a p−dimensional vector of unknown regression parameters, $b_i \sim N(0,G)$.

A 2-stage approach can be performed explicitly in the analysis for which Yi is summarized by the estimated value of β and the summary statistic of β is analyzed in the second stage. Therefore, the associated drawbacks can be avoided by combining the two stages into one model.

$$\begin{cases} Yi = Zi\beta i + \varepsilon i \\ \beta i = Ki\beta + bi \end{cases} \Rightarrow Yi = ZiKi\beta + Zibi + \varepsilon i \quad (3)$$

Say, $ZiKi = Xi$, from (3), then the linear mixed effect model is given by:

$$Y_i = X_i\beta + Z_ib_i + \varepsilon_i \quad (4)$$

Where, Y_i is the (n_i x 1)-dimensional vector of random blood glucoses of the patient i (i = 1,2,…N), N is the number of subjects, X_i and Z_i are (n_i x p) and (n_i x q) dimensional matrices of known covariates, β is a p-dimensional vector containing the fixed effects, $b_i \sim N(0,G)$ is a q-dimensional vector containing the random effects, and $\varepsilon_i \sim N(0,R)$ is an (n_i x 1) dimensional vector of residual components. A key assumption for this model in the foregoing analysis is that ε and *b* are normally distributed with:

$$E\begin{bmatrix} b \\ E \end{bmatrix} = \begin{bmatrix} 0 \\ 0 \end{bmatrix} \quad \text{and} \quad \text{var}\begin{bmatrix} b \\ E \end{bmatrix} = \begin{bmatrix} G & 0 \\ 0 & R \end{bmatrix}$$

This indicates the random effect and the residual component are independent. The mean and the variance of Y is $X\beta$ and $ZGZ'+R$, respectively while the conditional mean and variance of Y/b is also $X\beta + Zb$, ZGZ' +R respectively. According to the Henderson (1984), the standard mixed model equations is obtained from the value $\hat{G}$, $\hat{R}$ and the known covariates X and Z. The estimate of the covariance matrices are determined based on the maximum likelihood and restricted maximum likelihood.

The maximum likelihood estimation includes both regression coefficients and the variance components, that is, both fixed-effects and random-effects terms in the likelihood function. It treats β as fixed but unknown quantities when the variance components are estimated, but does not take into account the degrees of freedom lost by estimating the fixed effects. This causes ML estimates to be biased with smaller variances. On the other hand, the restricted maximum likelihood estimation includes only the variance components, that is, the parameters that parameterize the random-effects terms in the linear mixed-effects model that accounts for the degrees of freedom lost by estimating the fixed effects. This made a less biased estimation of random effects variances. The estimates of *R* and G are invariant to the value of *β* and less sensitive to outliers in the data compared to ML estimates. However, if REML was used to estimate the parameters, only two models were compared that have the identical fixed-effects design matrices and are nested in their random-effects terms.

The log likelihood function of the covariance matrix of R and G is in the case of ML, and REML were given as follows:

$$\begin{cases} ML: l(G,R) = \frac{-1}{2}\log|V| - \frac{1}{2}rV^{-1} - \frac{n}{2}\log(2\pi) \\ REML: l(G,R) = \frac{-1}{2}\log V - \frac{1}{2}\log\left|X'V^{-1}X\right| - \frac{1}{2}r'V^{-1}r \end{cases} \quad (5)$$

Where, $r = y - x(x'v^{-1}x)^{-1}x'v^{-1}y$

When minimize equation (5) two times by using a ridge-stabilized Newton-Raphson algorithm, one can estimate the value of *V*.

After estimating V, the parameters of the model can be obtained from the normal equation given below:

$$\begin{bmatrix} X'\hat{R}^{-1}X & X'\hat{R}^{-1}Z \\ Z'\hat{R}^{-1}X & Z'\hat{R}^{-1}Z + G^{-1} \end{bmatrix} \begin{bmatrix} \hat{\beta} \\ \hat{b} \end{bmatrix} = \begin{bmatrix} X'\hat{R}^{-1}Y \\ Z'\hat{R}^{-1}Y \end{bmatrix} \quad (6)$$

By simplifying Equation 6, one can get the estimate of,

$$\hat{\beta} = (X'\hat{V}^{-1}X)^{-1}X'\hat{V}^{-1}Y \quad \text{and} \quad \hat{b} = \hat{G}Z'\hat{V}^{-1}(Y - X\hat{\beta})$$

Where, V=Var(Y).

The Akaike information criterion (AIC) and Bayesian information criterion (BIC) were used for selecting the better model. The criteria select the model that minimizes:

AIC = -2(maximized log likelihood - number of parameters in the model)

Thus, a model with the smallest AIC value would be taken as a best among the candidate models. AIC penalizes a model for having many parameters. The Likelihood-Ratio test is employed to assess the appropriateness, adequacy and usefulness of the model. Moreover, the Wald test were also used to test whether the

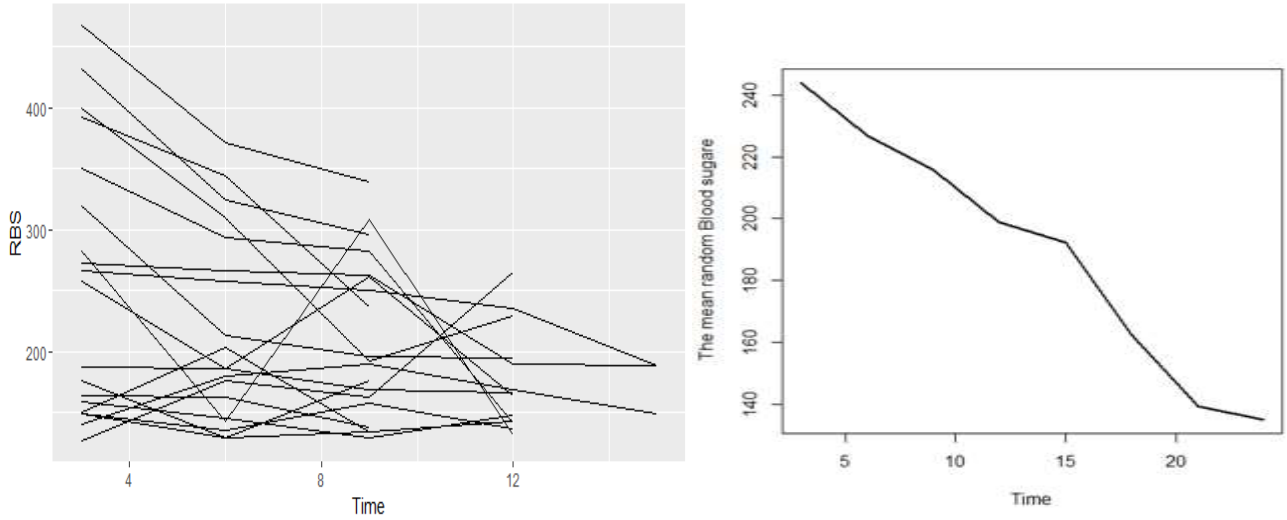

Figure 1a. Over all individual profile of RBS; **b** Over all mean profiles of DM patients.

parameter associated with the fixed effect explanatory variable is zero or not and would be assessed by carrying out statistical tests of the significance of the coefficients (Agresti, 1996, 2008). Some graphical techniques were used to assess peculiarities or the distinctive feature of the model with regard to the data. For detecting outliers, histograms and scatter plot of Empirical Bayes (EB) estimates were used. The EB residuals are defined as the conditional mean of the vector of random effects given the data and the estimated parameter values. A procedure to obtain the empirical Bayes estimates is presented in (Verbeke, 2000). Deletion diagnostics are statistics is used to measure the change in a parameter estimate when some subsets of the data are deleted. Cook's distance is the commonly used statistic for measuring changes in fixed effects. It measures the distance between the fixed effects estimates obtained from the full data and those obtained from the reduced data. To evaluate the effect of measurements of RBS on the variance components, the relative variance change (RVC), which measures the change in variance components with and without deleting a RBS, was employed.

RESULTS AND DISCUSSION

In this study, 1456 observations were considered to collect the random blood sugar levels which was evaluated at fixed time points and measurements. All the patients were taken at 3, 6, 9, 12, 15, 18, 21, and 24 months, which had equal time intervals of 3 months between all measurements. The individual and the mean profile of the patients for their sugar levels starting their follow up and treatment are presented in Figure 1.

The subject profile plots of Figure 1a, was obtained from a randomly selected 20 DM patients. Figure 1a shows that there was a decrease in RBS over time. It is also observed from this plot that there was much variability between patients but less variability within patients over time. From the mean profiles analysis in Figure 1b, the variability of the DM patients was observedand the mean RBS of the individual patients at its initial time was high. After they start the treatment, the RBS level decreased over the time. This is due, to in many cases, the correlation between two repeated measurements decreasing as the time span between those measurements increases. This was very important to determine the type of progression rate for DMT2 disease in terms of RBS over the linear effect of time. In assessing the adequacy of the first-stage linear model to the observed longitudinal profiles, subject-specific coefficients of multiple determinations R^2i (i = 1, 2… N) was used, where, a scatter plot of the subject-specific coefficients of multiple determinations versus the numbers n_i of repeated measurements was conducted. Two such plots based on the first-stage models for linear and quadratic were presented in Figure 2.

Figure 2a and b showed that the values for both linear and quadratic first-stage models were 0.79 and 0.61 respectively. These results revealed that 79 and 61% of the variability in RBS value in the DM patients was explained by the variables included in the model respectively while the remaining variability was described by other factors which are not included in the model. To identify whether the linear or the quadratic time effect model is better, fit the linear mixed model with the same covariance structure but additional quadratic time effect and its interaction with factors in the fixed and the random part was fitted with the value of (AIC, BIC) = (1631.6, 1644) for the linear time effect and (AIC, BIC) = (1836.5, 1761.3) for the quadratic time effect.

A plot of the OLS residual profiles over time, based on the mean structure suggested by the two-stage approach, was employed to check the adequacy of the model.

The plot OLS residual versus time in Figure 3, gave

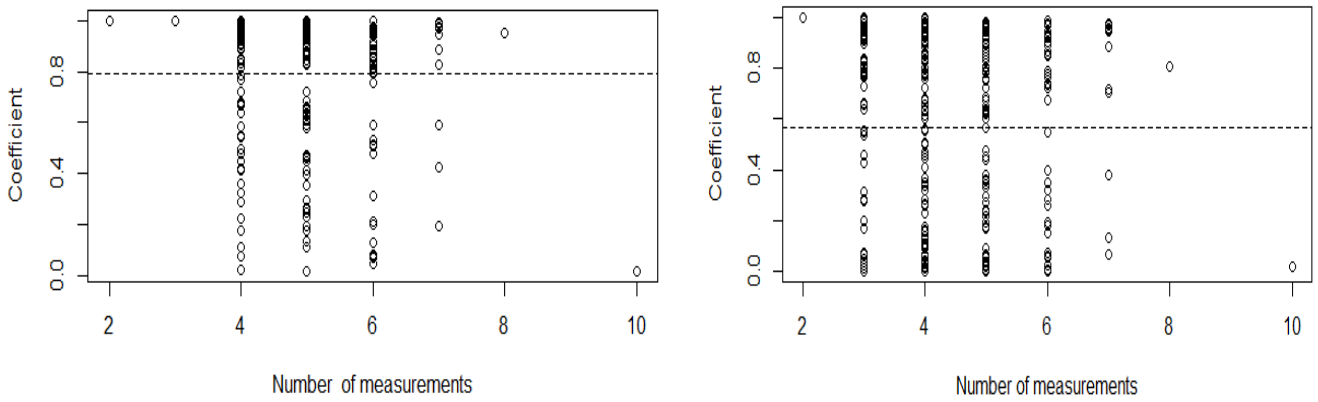

Figure 2. Subject-specific coefficients R^2_i of multiple determinations and the overall coefficient R^2_{meta} of multiple determinations which are shown by dashed line. 2a Linear subject specific profiles; b. Quadratic subject specific profiles.

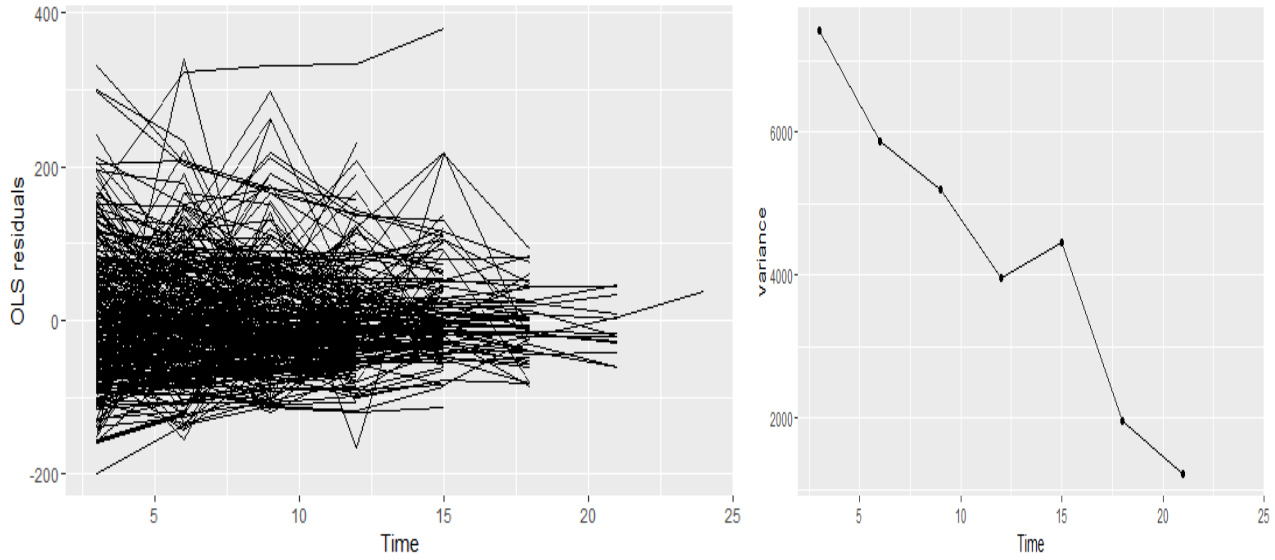

Figure 3. OLS residual profile (a) and variance function of OLS residuals (b).

visual proof that the linear regression trend model provides a good fit to the data. The variance function is shown in Figure 4 which was clearly suggested as non-stationary since the variability varies over time. This also implies the existence of some remaining systematic structure in the residual profiles. By considering Figure 3, it was assumed that the remaining structure in the OLS residual profile might be described by a higher order function over time. Depending on the variance function graph both random intercept and slope were included in the model as a preliminary random effect structure.

By combining all the above explorations, a mixed effect random intercept and random slope with linear time effect was considered for this study.

The significant variables in this study were selected by using backward elimination techniques. The marital status and sex with p value of 0.3315 and 0.4422 respectively were removed from the full model. Also, interactions of main effects over time were insignificant except for the exercise, alcohol, dietary type and BMI. Since these covariates have no other importance in the model improvement, it has to be excluded from the final reduced linear mixed model. The p values above were taken from the model compassion but not from the estimate of the full model. Hence, the final was reduced to a more parsimonious model and was fitted on the data.

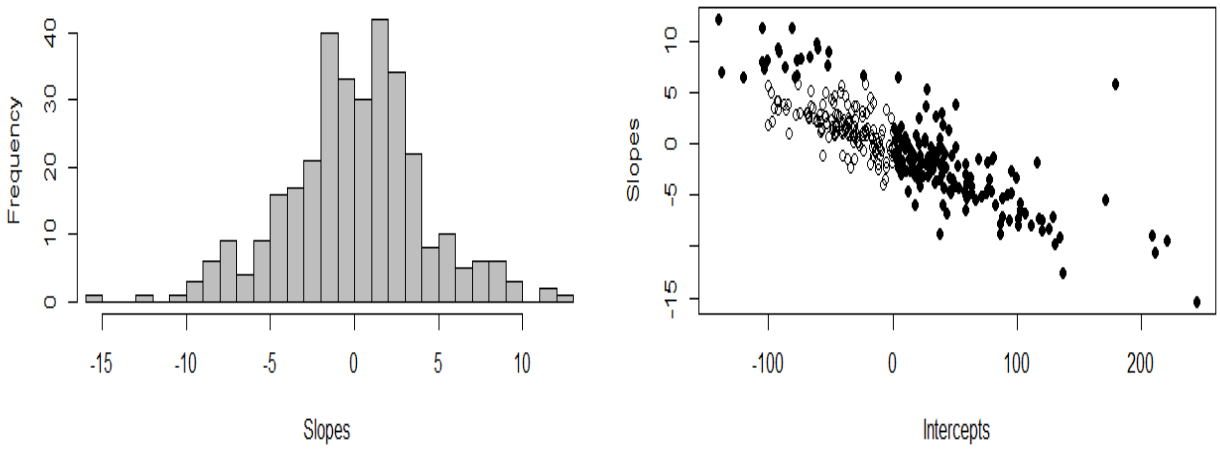

Figure 4. Histograms (a) and scatter plot (b) of empirical Bayes estimates.

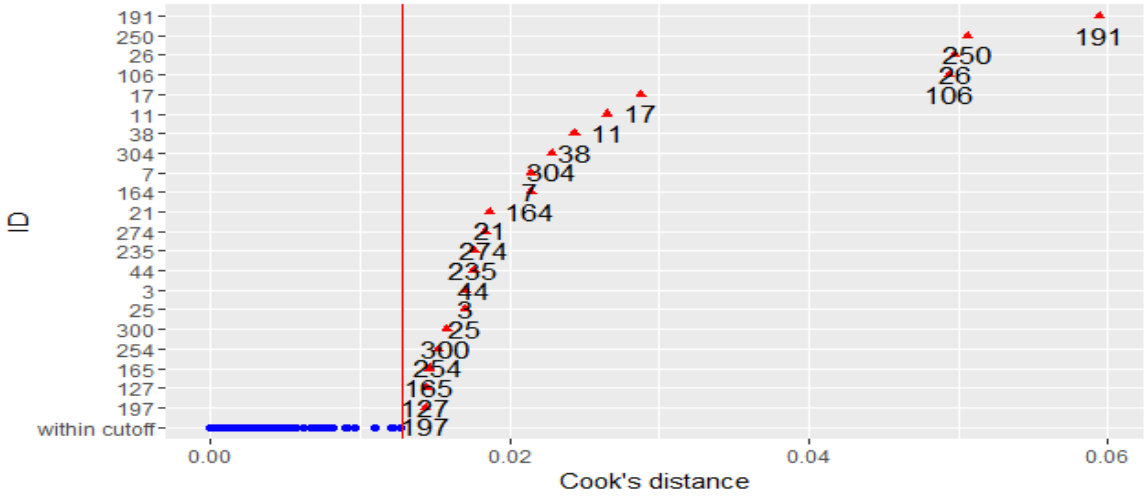

Figure 5. Dot plots of Cook's distance.

The graph of histograms and scatter plots of the Empirical Bayes estimates of the random effects were used to detect model deviations or subject's evolutions over the study time (Verbeke, 2000). Therefore, histograms and scatter plots of the Empirical Bayes estimates for the random effects were employed (Figure 4).

From the plot in Figure 4, both scatter plots and the histogram suggested the presence of some outliers. But still the histogram and the scatter plot did not help to determine which observations are outliers. Cook's distance was used to identify outlier observations with any value which was greater than the cutoff value. This is presented in Figure 5.

The plot in Figure 5 shows that the patient with ID number indicated on the graph had Cook's distance value greater than unit, since the cutoff value is one. Thus, the final linear mixed effect model was fitted by excluding these individual outlier observations.

After we chose the appropriate model, the linear mixed model of the data with estimated value of significant covariates was fitted. The restricted maximum likelihood estimates of covariates and the standard error with its corresponding significance value (p value) is found in the Table 2. Based on the estimated values of the parameters (Table 2) and the corresponding significance values, the following linear mixed effect model was modeled as:

$$Y = 373.29 - 12.43*Time - 37.3x_1 - 26.55x_2 - 19.01x_3 + 41.71x_4 + 84.45x_5 - 17.97x_6 - 27.27x_7 - 0.44x_8 + 2.59x_9 + 3.44x_{10} - 2.39x_{11} - 4.35x_{12} + 0.24x_{13}$$

Table 2. Restricted maximum likelihood parameters estimates of the linear mixed effect model for reduced model.

Effect	Estimate	Std. error	t-value	p-value
Intercept	373.2917	40.83663	9.141098	0.0000
Time	-12.4279	3.81744	-3.255568	0.0012
Non Alcoholic	-37.2972	11.89526	-3.135468	0.0018
No Family History	-26.5524	10.79766	-2.459088	0.0141
Urban	-19.0089	11.58260	-1.641161	0.0101
No Exercise	41.7051	11.46286	3.638277	0.0003
Meat	84.4490	29.60675	2.852358	0.0046
Insulin + OHA	-17.9721	6.69143	-2.685836	0.0073
Literate	-27.2744	11.31629	-2.410190	0.0161
Age	-0.4438	0.21408	-2.073115	0.0384
BMI	2.5992	1.26768	2.050347	0.0406
Time*No Exercise	-2.3923	1.10298	-2.168983	0.0303
Time*Non-Alcoholic	3.4371	1.15745	2.969550	0.0030
Time*Meat	-4.3528	2.83009	-1.538028	0.01243
Time*BMI	0.2361	0.12027	1.963035	0.0499
Likelihood ratio test	**43.93224**			**< 0.0001**

Where, Y is the Random Blood Sugar (RBS) of DM patients and X_1=Non- alcoholic patient; X_2=No-family history patent; X_3= Urban residence; X_4= patients do not perform exercise; X_5= Mostly Meat dietary eater patients; X_6=Treatment of both insulin and OHA; X_7 = Literate patients; X_8 = Age of patients at diagnosis; X_9 = Body mass index (BMI); X_{10}= Interaction of alcohol with time; X_{11}= Interaction of exercise with time; X_{12} = Interaction of meat with time and X_{13}=Interaction of BMI with time.

The statistical analysis results of the linear mixed model were discussed depending on the model fitted above. The average mean value random sugar level of patients was 373.29 keeping the effect of other factors at zero. As one unit increased, the average rate of change in RBS levels was 12.43 mg/dl per unit increased over time. This implied that the rate of change in the mean RBS level decreased by 12.43 mg/dl, keeping constant the other explanatory variables. There was a significant interaction between DM status and time (p=0.0012) such that RBS levels of the patients decreased over time. The other estimated value of covariates were also interpreted and discussed by keeping constant the effect of the remaining factors or taking the constant over time. For a one year increase of age of a patient, the expected value of RBS level reduced by 0.44 mg/dl when the effect of the other factors were kept constant. This supported the findings of (Taylor and Lobel, 1989) that the RBS levels tended to correlate negatively with age. In this study most of the samples had an age range greater than 40. Hence, this result was in line with those of Taylor and Lobel, (1989). In addition, a unit increase in BMI of a patient increases the RBS level by 2.59 mg/dl; this also supported the finding of Tyler and Blader (2001) that a population that had more weight were said to be more obese. This obesity highly correlated with BMI. BMI were calculated based on the value of weight. Since obesity is a main factor for diabetes, and hence the more the obesity of a person is also the greater the BMI. This ultimately shows that with the increase of weight of patients, they are more exposed to greatest risks of having diabetes. The average rate of change of RBS for literate patients decreased by the amount of 27.3 as compared to the illiterate patients keeping the effect of other variables constant. This result clearly showed that literate patients managed the condition of diabetes better, because they were able to understand the basic disease management and treatment plans. This result is in line with the finding of Miller et al. (2002).

Patients who would predominantly eat meat dietary type have been shown to have a significantly higher increase in the mean change value of RBS levels than patients who eat other types of dietary meals. More simply, the mean rate of change of RBS for meat eating patients increased by the value of 84.45 as compared to that of the fruit eaters. The influence on RBS level when people consume more meat may be due to the lack of mineral contents for disease protection. Hence, naturally the RBS level increased by unexpected means. Therefore, people who mostly eat meat were exposed to DM disease and could not with ease control the RBS to attain a normal condition. To reduce the blood sugar, patients would have to abide by a strict diet. Foods associated with cereals, vegetables, and fruits are advised while other dietary methods associated with

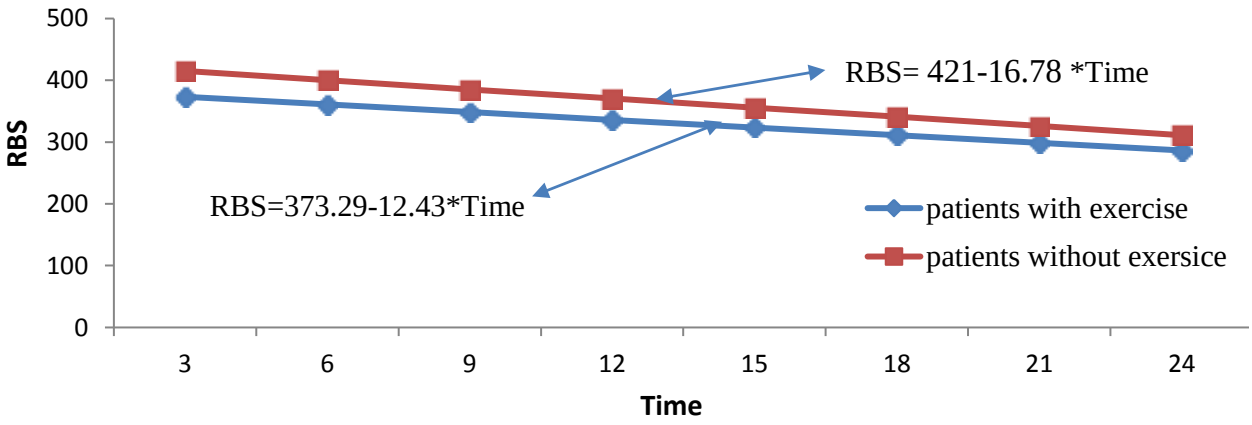

Figure 6. Interaction of activity with time.

eggs, meat, proteins, and starch need to be lessened or even avoided.

Patients use the treatment of insulin, OHA or the combination of them. Among these three treatments, the estimated value for combined treatment was 17.97 which showed that the mean change of RBS level of the patient who uses the combination of the treatment insulin and OHA decreased by 17.97 as compared to the patient who used the insulin treatment. That means that the combination of the two treatments has a greater contribution to the reduction of the random blood sugar of the diabetes mellitus patient opposed to the patient who uses the treatment of insulin. Patients who perform an exercise frequently, no-alcoholic and had no family aggregation (family history) can monitor their RBS well. This indicated that the rate of change in the random blood sugar in their body was higher than that of the alcoholic, had family history and who did not perform regular exercise. An individual with inherited susceptibility to the disease and who did not exercise was negatively correlated with the change in the RBS. These results were also consistent with finding of the study on Diabetes mellitus in the literature of this paper.

The interaction effect of time with exercise, alcohol use, meat as a dietary type and with BMI shows the rate of change in the random blood sugar of the DM patients over time.

The line equations of exercise activity with time given was as follows:

$$Y=\begin{cases}373.29-12.43*Time, & patient\ who\ perform\ exercise\\ 415\text{-}14.82*\mathrm{Time}, & \text{patient who not perform exercise}\end{cases}$$

From the mentioned two line equations, the rate of change can be determined based on the difference of the slopes. This showed that as the visiting time increased by one unit, the average rate of RBS for patients who perform exercise was decreased by the amount of 2.4 as compared to that of patients who did not perform exercise. And hence performing exercise was important for controlling the random blood glucose level in the body. The line graph was presented in Figure 6.

A line equation of alcohol user having interaction over time was given as follows:

$$Y=\begin{cases}373.29\text{-}12.43*\mathrm{Time}, & \text{for alcolic patients}\\ 335.99\text{-}8.99*\mathrm{Time}, & \text{for non-alcolic patients}\end{cases}$$

According to Figure 6, for a one unit increment of time, the average rate of change in the RBS level for DM patients who did not use alcohol, decreased by the rate of 3.44 as compared to patients who use alcohol. Therefore, this revealed that using alcohol increased the patients RBS level in higher rates compared to the non- alcoholic patients.

The line graph of the interaction effect of time with the factor of alcoholic patients was also given in the Figure 7.

A line graph equation of the interaction of dietary type with time is given below:

$$Y=\begin{cases}421-16.78*Time, & \text{patients who abid by a meat diet}\\ 373.29-12.43*Time, & \text{patients who abid by a fruit diet}\end{cases}$$

Similarly, as can be seen from Figure 7, for a one unit increment of the visiting time of the patient, the expected or average rate of RBS level of patients who mostly eat meat increased by 4.35 as compared to the patient who abides by a fruit diet.

Therefore, as can be seen from Figure 8, the patient must restrict the types and amounts of food they consume. They might also have to monitor their blood glucose levels at specific times during the day, and medication might be necessary at times when the individual is engaged in

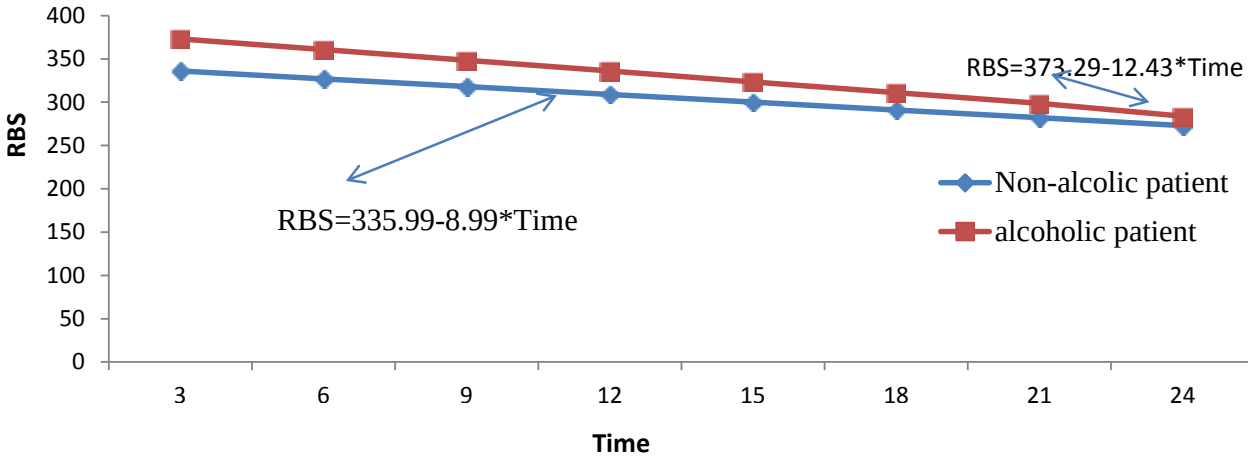

Figure 7. Interaction of alcohol use with time.

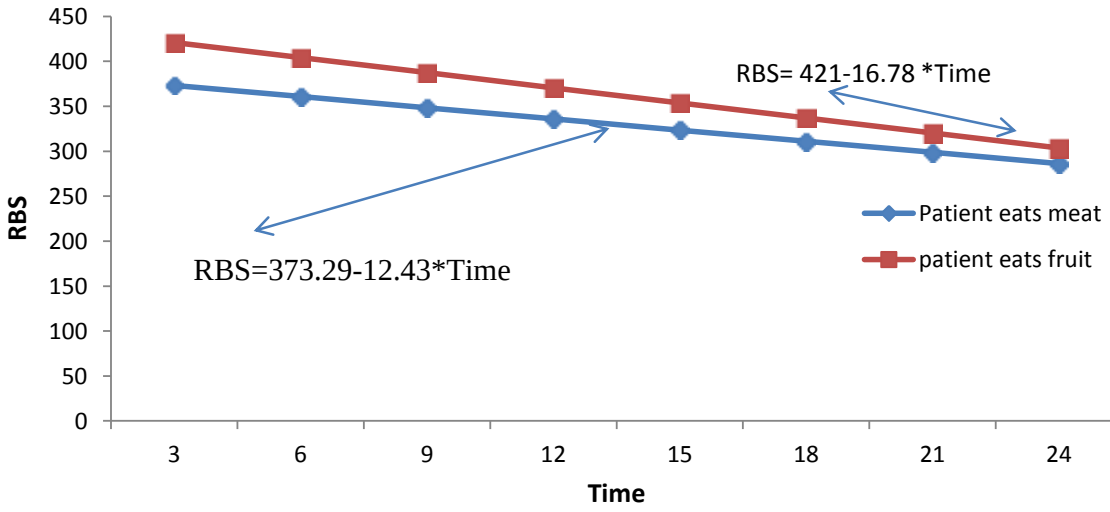

Figure 8. Interaction of dietary type with time.

social activities.

Conclusion

The mixed effects model developed was confirmed to be adequate for the prediction of RBS levels based on the available variable of health determinants. The pattern of mean change in RBS levels revealed a linear distribution that decreased over time. The coefficient of determination explained about 79% of variability in RBS level accounted by the predictor variables. From the individual profile of RBS, there was high variability between subjects and less variability within subjects. And also from the mean profile, the RBS level of the patients decreased over time which was also confirmed with the model that the estimate of time was negative. Among the indicator factors of RBS level, meat as a dietary type, patients who do not perform exercise and body mass index (BMI) correlated positively to the RBS level while the rest are negatively correlated. Hence, more attention was given to control the RBS level of the patients in relation to these factors. The linear mixed-effects model showed that time (duration of follow up), BMI, alcohol use, diet, exercise, education status, residence, age, family history and treatment type have significant influence on the RBS level ($p<0.05$). From the result of the study, patients who live in urban areas, has lower BMI levels, who had no family history, who were educated, did not drink alcohol and who used a combination of insulin and OHA treatment were better suited to control and reduce their RBS in their body over time. But the determinant factors of marital status and sex

were an insignificant variable which showed that there was no significance reduction between males and females over time but it does not mean that RBS was not decreased over time by sex. Similarly, the mean RBS reduction over time was not different among the category of marital status.

CONFLICT OF INTERESTS

The authors have not declared any conflict of interests.

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Full Length Research Paper

Investigation on the effect of a one-day pharmacovigilance training of healthcare professionals

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A key objective of the decentralized pharmacovigilance program is to increase the knowledge of in-service healthcare professionals in pharmacovigilance to enable them develop a culture and practice of adverse drug reactions reporting. It is imperative to evaluate the impact of the training offered, as it is a key component of the national decentralized pharmacovigilance program. Thus the aim of this study was to evaluate the impact of a one-day decentralized pharmacovigilance program training of healthcare professionals on pharmacovigilance in South Africa. Self-administered structured, pre- and post-training questionnaires were retrospectively reviewed. The healthcare professionals' knowledge regarding pharmacovigilance in South Africa significantly increased after the one-day training intervention ($P < 0.002$). There was an increase in the number of correct answers to every question, although to varying degrees. However, despite this increase, it is clear that various aspects of the overall training need to be re-emphasized to have an even greater impact, and there is a strong indication of a positive shift in pharmacovigilance knowledge gained, though to varying degrees.

Key words: Pharmacovigilance, training, health care professionals, impact.

INTRODUCTION

Pharmacovigilance (PV) is the science and activities related to the detection, assessment, understanding, and prevention of adverse drug reactions (ADRs) or any other drug-related problem (WHO Policy Perspectives on Medicines) (Anon, 2004). Pharmacovigilance ensures the safe use of medicines. The National Department of Health's Pharmacovigilance Centre for Public Health Program (NPC) in South Africa (SA), established in 2004, embarked on a program to decentralized PV since 2010. Currently, the focus of this programme is on the management of ADRs in public health program such as Human Immuno-deficiency Virus (HIV)/Acquired Immune Deficiency Syndrome (AIDS) and tuberculosis (TB). To date, 2919 healthcare professionals (HCPs) have been trained in seven of South Africa's nine provinces (NDoH, 2015). These include 169 physicians, 618 pharmacists, 1317 nurses and 798 allied healthcare professionals.

Spontaneous reporting by HCPs has been shown to play an important role in identifying drug safety issues. (Begum et al., 2013). However, under-reporting of ADRs

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has been a real and persistent problem for PV program. In order to improve the reporting rate, it is important to educate the HCPs about PV approaches, its tools and its impact on both the cost and quality of patient care. Ideally, the most appropriate time to train HCPs would be during the undergraduate training. However, in the South African context, PV has not been a very strong component of undergraduate training, or if it exists, it remains largely undocumented (Malangu, 2014). Given the background of insufficient PV training of undergraduates in South Africa, with very large numbers of patient on HIV treatment, the in-service training of HCPs as part of the decentralized PV program in the public health arena is an important route to remedy the existing situation. A key objective of the decentralized PV program is to increase the knowledge of in-service HCPs on PV and ADRs and to enable them to develop a culture and practice of reporting spontaneously. As this in-service training is a key component of the South African National Department of Health decentralized PV program, it is imperative that the impact of the training is evaluated. The aim of this investigation was therefore to assess the impact of the one-day PV training provided during the roll-out of the PV program and advice the decentralized PV program accordingly.

METHODS

Design and study setting

This is a short prospective, descriptive, before and after intervention study. The setting for this study was in South African public health facilities, specifically in Pixley ka Seme and Namaqualand districts of Northern Cape Province, where PV training was conducted between February and March 2015. All health care professionals in the two districts were invited to attend the training through a memorandum from the provincial head of department. In particular, the training was aimed at HCPs without previous pharmacovigilance training. The training contributes to professional development and participants were expected to have better knowledge, awareness and practice afterwards.

Training intervention

One-day didactic training sessions, delivered by NPC staff were held to introduce the theory and practice of PV, together with the various systems and processes involved in PV practice in South Africa. Four hours of theory, interspersed with four hours of discussion and ADR reporting practice was given to groups of between 30 and 50 participants, a heterogeneous assortment of doctors, nurses and pharmacists but also included a few social workers and laboratory technicians.

Sample size determination and sampling technique

Although, all health care professionals in the two districts were invited, on account of staffing challenges only a limited number of HCPs were allowed to attend the training. The study population was small and consequently, all the 129 participants that came for training were surveyed.

Data collection instrument

To compare the knowledge levels before and after training, a peer-reviewed, structured, self-administered anonymous multiple-choice questionnaire was used as a pre-test/post-test tool. The questionnaire is a standard department tool that has been used over the last few years by National Department of Health (NDoH). The tool was validated when it was initially implemented, hence the researchers could not conduct the traditional validation. The finding from this study may suggest amendments to the data collection tool. The researchers were informed prior to the administration, the tool was pretested and piloted with three staff members at the NDoH in order to identify questions that don't make sense to participants, or problems with the tool. Although, developed and used by NDoH, the tool has not been previously used to analyze the effectiveness of its training intervention. The tool had sixteen items and used both open and closed questions. This study used twelve relevant quantitative questions (questions 2 to 13) that related directly to the aims of this study. Questions 1, 14, 15 and 16 did not form part of this quantitative analysis as they are part of another qualitative sub-study. In order to facilitate interpretation and discussion, the remaining questions were grouped into pharmacovigilance concepts and theory (Questions 2, 5, 7, 9, 10, 12 and 13) and systems and processes in pharmacovigilance (Questions 3, 4, 6, 8 and 11).

Data analysis

All collected data were captured in Microsoft Excel (Microsoft Corp, Redmont, WA, USA) and exported to STATA 13 (StataCorp. 2013). Stata Statistical Software: Released 13 College Station, TX: StataCorp LP) for the statistical analysis. The number of correct answers for each question before and after the training was the variables of interest. Descriptive analyses were run to determine proportions of correct and wrong answers per question and overall. One sample test of proportions was employed to determine differences between the results for each question of the questionnaire as well as the overall results. A p value less than 0.05 was considered statistically significant.

Ethical considerations

Full ethical approval for the study was obtained from the Humanities and Social Sciences Research Ethics Committee of the University of KwaZulu-Natal (HSS/1328/016D), and permission to use the data was obtained from the South African National Department of Health.

RESULTS

Gender

All the HCPs in the district were invited to participate, but only 137 HCPs were trained and 129 were included in the analysis (Table 1). Eight HCPs that came in late for training and only completed a post-test questionnaire were excluded from the analysis. Proportionally, 32.6% (42) were male whereas 67.4% (87) were female.

Professional categories

The majority of the HCPs trained were nurses (87 of

Table 1. Gender and professional categories trained.

Gender	Total N=129	Professional category	Number (%)
Male	42 (32.6)	Physicians	3(2.3)
		Nurses	22(17.1)
		Pharmacists	8(6.2)
		Other	9(6.97)
Female	87 (67.4)	Physicians	1(0.78)
		Nurses	65(50.4)
		Pharmacists	6(4.65)
		Other	15(11.63)

which 65 were female and 22 were male). Others were 4 physicians (1 female, 3 male), 14 pharmacists (6 female, 8 male) and 24 “other” health care workers (15 female, 9 male). The “other” healthcare workers constituted pharmacy assistants, counsellors, laboratory personnel and data capturers.

Responses to questions pre- and post-training

The statistics of the responses to the questions in the tool are presented in Table 2.

DISCUSSION

Gender and professional characteristics

Majority of HCPs who attended the training and responded to the pre and post-test were nurses followed by “other” health care workers, pharmacists and physicians, respectively. This information is of considerable interest when seeking to request permission for the proportions of HCPs to attend training. The proportions trained were found to be representative of the proportions of HCPs in the districts.

Responses to the pre and post-training questionnaires

A heterogeneous mixture of questions on PV, the systems and processes involved in PV practice were asked in the pre and post-test. The result of these tests did not show any specific trends that favored either an increase in the knowledge of the concept of PV or an increase in the knowledge of systems and processes. However, there was an overall positive shift in improved knowledge for each of the questions asked, though to varying amounts. In some areas where there were only small increases in the knowledge gained (Questions 2,9,11 and 12) were flagged for consideration. This may be due to contamination of the testing instrument, where there may be some ambiguity or misunderstanding with the question/s, and/or areas of weakness in the training. The latter may result from a gap between materials delivered versus specific questions asked. This discussion is grouped into two areas:

1. Pharmacovigilance concepts and theory (Questions 2, 5, 7, 9, 10, 12, 13)
2. Systems and processes in pharmacovigilance and its decentralization (Questions 3, 4, 6, 8, 11)

Questions 1, 14, 15 and 16 did not form part of this quantitative analysis as they are part of another qualitative sub-study.

Pharmacovigilance concepts and theory

Which objective of pharmacovigilance do you think is most important? (Question 2 in Questionnaire)

The participants were tested for their knowledge and awareness of the primary aim of pharmacovigilance which is patient safety before (n = 80, 62%) and after the training (n = 98, 76%). The results showed a statistically significant improvement (p = <0.01). Healthcare providers need to understand that with every medicinal product comes its own benefit-harm scale, and that they should always ensure it is more beneficial.

All of the following are threats to national ADR reporting in South Africa except? (Question 5 in Questionnaire)

The participants were taught the importance of reporting ADRs to understand that medicines safety data has to be collated, aggregated and analyzed in order to pick up signals. That there was no significant improvement in the before (n = 31, 24%) and after responses (n = 41, 31.8%)

Table 2. Responses to questions in the pre- and post-test (n = 129).

		Pre-Test	Post-Test	
Question number	**Questions**	**Correct answers (%)**	**Correct answers (%)**	**Test of proportion *p* value**
	Pharmacovigilance concepts and theory			
2	Which objective of pharmacovigilance do you think is most important	80(62)	98(76)	<0.01
5	All of the following are threats to national ADR reporting in South Africa except...	31(24)	41(31.8)	0.05
7	Which of the following persons should not attend meetings of the PV committee	72(55.8)	109(84.5)	<0.01
9	Which of the following is a requirement for proper reporting of an ADR to a PV centre	66(51.2)	104(80.6)	<0.01
10	Which of the following is/are true about spontaneous reporting of ADRs	63(48.8)	70(54.3)	0.25
12	Which of the following does not determine the increased concern about drug safety	32(24.8)	33(25.6)	0.8
13	Which of the following does not support ethical PV	37(28.7)	39(30.2)	0.8
	Systems and processes in pharmacovigilance and its decentralization			
3	Which of the following is/are responsible for monitoring ADRs in South Africa	9(7)	11(8.5)	<0.01
4	What do you think would be the main advantage of decentralised PV in South Africa	76(58.9)	78(60.5)	0.64
6	Within a decentralised PV programme, where would assessments of ADRs interventions be discussed	12(9.3)	96(74.4)	<0.01
8	Which of the following should not be a goal of the decentralised system of PV in South Africa	23(17.8)	31(24.0)	0.11
11	Which represents a logical flow of information about ADRs in a decentralised PV system	65(50.4)	80(62)	0.01
	Total percentage	36.6	51	0.002
	Total number	566	790	

(p = 0.05) is an indication that the training needs more emphasis on the adverse consequences of underreporting on PV. The question is also difficult to evaluate and revision is suggested.

Which of the following persons should not attend meetings of the PV committee? (Question 7 in questionnaire)

The participants were tested for their awareness about who should be present in the cluster and/or pharmacovigilance committee meetings. Based on the programmatic recommendations, the patient should not form part of the committee. Before the training, only 72 participants (55.8%) answered correctly to this question. After the training, the number of correct answers increased significantly (n = 109, 84.5%, p < 0.01).

Which of the following is a requirement for proper reporting of an ADR to a PV centre? (Question 9 in questionnaire)

The correct answer to this question provided information on the awareness of trainees to the importance of a properly and fully completed ADR form. Sixty six (51.4%) of the trainees gave correct answers before the training which increased significantly to 104 (80.6) (p < 0.01) just after the PV training.

Which of the following is/are true about spontaneous reporting of ADRs? (Question 10 in questionnaire)

The spontaneous reporting system is the easiest and cheapest to establish and presently, it is the bedrock of the current decentralized PV program in South Africa (Dheda, 2013). Before the training, 63 participants (48.8%) gave the correct answer which slightly increased to 70 participants (54.3%) after the training, an increase that was not statistically significant (p = 0.25). These results suggest that more training and information on the methods and the differences in the methods in pharmacovigilance be given.

Which of the following does not determine the increased concern about drug safety? (Question 12 in questionnaire)

Pharmacovigilance and drug safety concerns have recently come into the spotlight on account of the rapid scale up of ART (pre-exposure prophylaxis [PrEP], revised guidelines to include

universal test and treats among others) as well as multidrug resistant tuberculosis (MDR-TB), concerns around co-morbidities, prevalence of traditional medicines use (Clayden et al., 2013). HCPs are required to understand the reasons for the increased concerns. That there was no significant increase (p = 0.8) between before (n = 32, 24.8%) and after the training (n =33, 25.6%) is of great concern. This training going forward should be revised to include materials that will put more emphasis on these growing concerns in large treatment program.

Which of the following does not support ethical PV? (Question 13 in questionnaire)

The training gives information on confidentiality, patient education and handling of patient personal identifier information when reporting. Unfortunately, there was no significant difference (p = 0.8) in the correct responses given before (n = 37, 28.7%) and after (n =39, 30.2%) the training. This is an indication that more emphasis needs to be placed on ethical consideration in training going forward.

Systems and processes in pharmacovigilance and its decentralization

Which of the following is/are responsible for monitoring ADRs in South Africa? (Question 3 on questionnaire)

Since 1987, the Medicines Control Council (MCC) of South Africa has been the regulatory body responsible for monitoring the safety of all medicinal products used in South Africa. In 2004, the South Africa NDoH formed the NPC (Dheda, 2016). The participants were tested for their awareness of the existence of the latter and the former bodies. Before the training, only nine participants (7%) were aware of either of the two bodies responsible for monitoring ADRs in South Africa. After the training, although a statistically significant result (p = <0.01) was found, the number only increased to 11 (8.5%). The results obtained, with a mere increase of two, suggest that the component of understanding the PV systems and processes in South Africa is still poorly understood. It is proposed therefore that this component of the training be reinforced in the future and that more information, education and communication material be distributed in public health.

What do you think would be the main advantage of decentralized PV in South Africa? (Question 4 in questionnaire)

The decentralized pharmacovigilance program was established in June 2011 and is currently been rolled-out into Mpumalanga, Northwest, Eastern Cape, Northern Cape, Limpopo, parts of KwaZulu Natal and the Free State provinces. This question tested the awareness of the participants on the program with regard to the purpose of a decentralized pharmacovigilance program. The results, 76 correct answers before (58.9%) and 78 (60.5%) after did not increase significantly (p = 0.64). What was interesting however was the fact that a large number of participants (>59%) clearly understood the main advantage of a decentralized pharmacovigilance process. During the training, information relating to the advantages of decentralizing PV in public health, especially in the era of HIV/AIDS and MDR-TB, and the benefits of the resulting rapid decision-making in rational medication use in patient treatment and management were emphasized.

Within a decentralized PV program, where would assessments of ADR interventions be discussed? (Question 6 in questionnaire)

The decentralized PV program is constituted of pharmacovigilance clusters and or mini pharmacovigilance centers (Dheda et al., 2013). The latter and the former are formed between facilities that have existing referral lines and/or proximity. The clusters themselves are multidisciplinary platforms that include doctors, pharmacists, nurses and other para-medical staff such as laboratory personnel and counsellors. It is within these structures that pharmacovigilance activities are expected to take place. These clusters form the backbone of the decentralized program and trainees are expected to clearly understand their role in the overall programme. Comparatively, before (n = 12, 9.3%) and after the training (n = 96, 74.4%) the awareness by HCPs increased significantly (p < 0.01). This gives an indication that participants really understood their enhanced role in the decentralized PV program post training.

Which of the following should not be a goal of the decentralized system of PV in South Africa? (Question 8 in questionnaire)

The question about the goals of pharmacovigilance was answered correctly by 23 (17.8%) of the trainees before and 31 (24%) after the training. The score did not increase significantly after the training (p = 0.11).

Which represents a logical flow of information about ADRs in a decentralized PV system? (Question 11 in questionnaire)

The correct answer to this question provided information on the awareness of trainees around PV systems and

flow of data/information. 65 (50.4%) of the trainees gave correct answers before the training which increased significantly to 80 (62) ($p < 0.01$) just after the PV training. This together with the increase in knowledge of their enhanced role in the decentralized PV program is positive signs for both the training and the program.

General comments

The HCPs overall knowledge about PV significantly increased after the training ($p < 0.002$). The increase was for every question, though to varying degrees. However, despite this increment, it is clear that various aspects of the overall training need to be re-emphasized to have an even greater impact. It is also suggested that some questions (4, 5, 8, 10, 12, and 13) be reworded to improve clarity. The lack of correct answers in the post evaluation may also be due to the training focused on the positive (increased concern) meanwhile, these questions focused on the negative (does not determine the increased concern). It has been previously shown that healthcare professionals knowledge about PV was inadequate in some countries and it was reported that ADR reporting's increased after the training (Naritoku and Faingold, 2009; Shankar et al., 2006; Rehan et al., 2002; Hema et al., 2012). Therefore, healthcare professionals training are very important to increase ADR reporting. The knowledge of HCPs in pharmacovigilance has been conducted before, however, this is the first study of the impact of the training currently provided to HCPs in the South Africa public health system. Overall, the knowledge of HCPs increased soon after the training. However, a further study needs to be conducted to establish whether this increase remains steady in the long term. Studies have shown that HCPs have some knowledge about the PV program and their spontaneous ADR reporting rate was low and one of the reasons for this was inadequate awareness of reporting ADRs (Oshikoya et al., 2009; Hardeep and Bajaj, 2013; Pedrós et al., 2009). This therefore indicates the importance of appropriate PV training.

Limitations

The first and foremost limitation was imposed by the questionnaire that could not be changed, as it was a standard tool that was used in the PV department. This limited the depth and coverage of the subject matter; however it served the purpose of this study in that it was still capable of giving the researchers an idea of the effectiveness of the intervention. The mode of assessing impact depended on the respondent's ability to recall prior knowledge of PV, may have been subjected to recall bias. A truly representative sample may not have been achieved since HCPs were not selected from each of the five districts in the Northern Cape Province or other provinces of South Africa. Selection bias may have occurred as respondents who are more interested in PV may have been the only ones who attended the workshop, as it was not compulsory. The long term knowledge retention and PV knowledge improvement needs to be conducted. Pre- and post-training data collection tools were not coded to link individual and HCP's gain in knowledge. Finally, a before-after design is sometimes considered not to be the best design when evaluating effects of interventions.

Conclusion

This study investigated the impact of the one-day PV training provided during the roll-out of the PV programme. There is a strong indication of a positive shift in knowledge gained though to varying degrees. It has also highlighted areas of this training that may need further strengthening. As this was a training whose impact was evaluated shortly before and after the intervention, it is suggested that long term knowledge retention and PV knowledge be investigated as well as its translation into increased quality and quantities of reports.

CONFLICT OF INTERESTS

The authors have not declared any conflict of interests.

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Caregiver feeding practices in Sierra Leone

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Sierra Leone is a basis for developing a community based Early Childhood Development (ECD) programme. Using a set of questions in a household survey, it was found that 92% of children are given breast milk as their first food. However, for 39% of children, breastfeeding stops after 40 days. 46% of the children were not breastfed exclusively until six months. 28% of the children did not get three meals per day, and 13% of the mothers reported that the child had insufficient food. Only 86% of mothers had a positive assessment of the quality of food they give to their child. Low degree of diversity in the diet was observed for 38% of children who consume less than 3 types of food. Children whose diet is undiversified represent the majority of those who do not eat fruits and vegetables or protein. Sierra Leone needs to implement a parental feeding counselling programme to improve quality of feeding practices for children. This would reduce stunting and other poor nutritional outcomes.

Key words: Parent, child, feeding, practices, early childhood development (ECD).

INTRODUCTION

Good parenting skills, which can be reinforced through early child development (ECD) leads to school readiness and other good health, education and child protection practices (Heckman, 2013). The philosophy of ECD programmes is to support the parents in child rearing, reinforce good practices and provide new knowledge so that they can improve other practices (Horton, 2013). Helping parents promote their children's development should also improve their self-esteem and general competence as parents. Kuchenbecker et al. (2017) showed that caregiver education improved dietary diversity even in food insecure situations in rural Malawi.

In order to design effective ECD programmes, it is therefore essential that good child rearing practices in the local communities are identified and included in the curriculum and built upon. It is also necessary to understand parents' knowledge and attitudes concerning child development. Karla et al. (2017), in a thematic analysis of caregiver narratives, concluded that in African settings, there are different cultural factors that affect feeding practices. In Sierra Leone, there is limited data and information on cultural and traditional child rearing practices. The objective of this study was to document current parental practices of child feeding in Sierra

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Leone. The results were to be used as an evidence base on which to develop an Early Childhood Development (ECD) policy and strategies going into the future to reduce poor nutritional outcomes in children between 6 months and 6 years.

METHODOLOGY

Sampling

All the districts in Sierra Leone were divided into two strata (urban and rural). Households were selected using a two-stage cluster sampling methodology. The first stage was selecting a predetermined number of Enumeration Areas (EAs) in each strata and the second stage was selecting households in the selected EAs. A sample of 1,500 households was selected based on similar studies conducted in the West Africa region (Seurat, Per. Comm., 2013). Mothers or care givers of over 2,000 children (Table 10) of between 6 months and 72 months were selected to be interviewed from the 1,500 households. If a mother/care giver had two children of 6 to 72 months, one child was selected using a Kishi selection table of random numbers. If a mother/caregiver had more than two children of 6 to 72 months, a maximum of two children were selected on condition that one is less than 36 months and the other of more than 36 months.

Data collection

Data was collected as part of a larger study using a standardized and pre-coded questionnaires. The survey questionnaire had three parts. Relevant to this paper are survey questions on characteristics of the household, the mother and each interviewed child from 6 to 72 months and survey questions related to child feeding practices. Data related to the food eaten by the child during the day preceding the survey was collected. For breakfast, lunch and dinner meals, the survey documents, a list comprising: (i) rice or cereal, (ii) bread, (iii) milk or milk products, (iv) meat, (v) fish or eggs, (vi) tubers, (vii) other vegetables, (viii) fruit, (ix) beverages (other than water), and (x) other foods. For each of the three main meals, mothers had the opportunity to mention four food items. Thus, information was used firstly to describe the food items that have been consumed during meals, secondly to identify the variety of food items in the meal, and thirdly to identify children who did not have proteins during the day or fruits at any of the three meals of the day. The daily diet of young children is considered as diversified if it includes foods from at least four different food groups (WHO, 2002; 2010). In this study, sources of protein are considered to be milk, milk products, fish, and eggs. In the analysis, meat has been separately analysed as it is a major source of protein in the study population.

Data analysis

Quantitative data was analysed using SPSS. Qualitative data from opened ended questions was analysed through categorisation on emerging themes. Tables were generated for all the areas in the three parts of the questionnaire. This paper focused only on practices related to feeding practices.

Limitations

The study questions were translated from English to local languages (such as Krio and others depending on district) and translated back into English. This could lead variations which may affect the results. Parental practices discuss issues which may be culturally embarrassing. This may lead to under reporting of socially unacceptable behaviours and over reporting of socially acceptable behaviours. The results could also be affected by recall bias. Data collection did not include anthropometric measurements. This limits the depth of the conclusions that can be drawn.

Ethical clearance

The study was cleared by a national multi-sectoral Early Childhood Development Committee in Sierra Leone.

RESULTS

Breastfeeding

The majority of the children in the sample received their very first feeding from their mother as breast milk (Figure 1). Only 56.6% of the children were exclusively breastfed up to six months.

Suckling

Among the 2,450 children aged 6 months to 6 years of age who were breastfed for whom information is available, only 31.8% still suckled on the day of the survey. The majority of them are less than 15 months old and suckle one to ten times a day. Among the 68.2% of children who are no longer breastfed, three quarters stopped suckling when they were between 13 and 24 months old (Table 1).

Mother's opinions on bottle feeding

Seventy-four (73.6%) of the mothers had favourable views on bottle feeding (Table 2).

Child feeding

Number of meals eaten by the child during the day preceding the survey

Over half (56.7%) of children had three meals the day before the survey. Slightly over a quarter of the children had at most two meals a day. Only few of the children had at most one meal on the day that preceded the survey (Table 3).

Perception of the mothers on adequacy of food eaten by their children

Nearly three-quarters of mothers think their child has

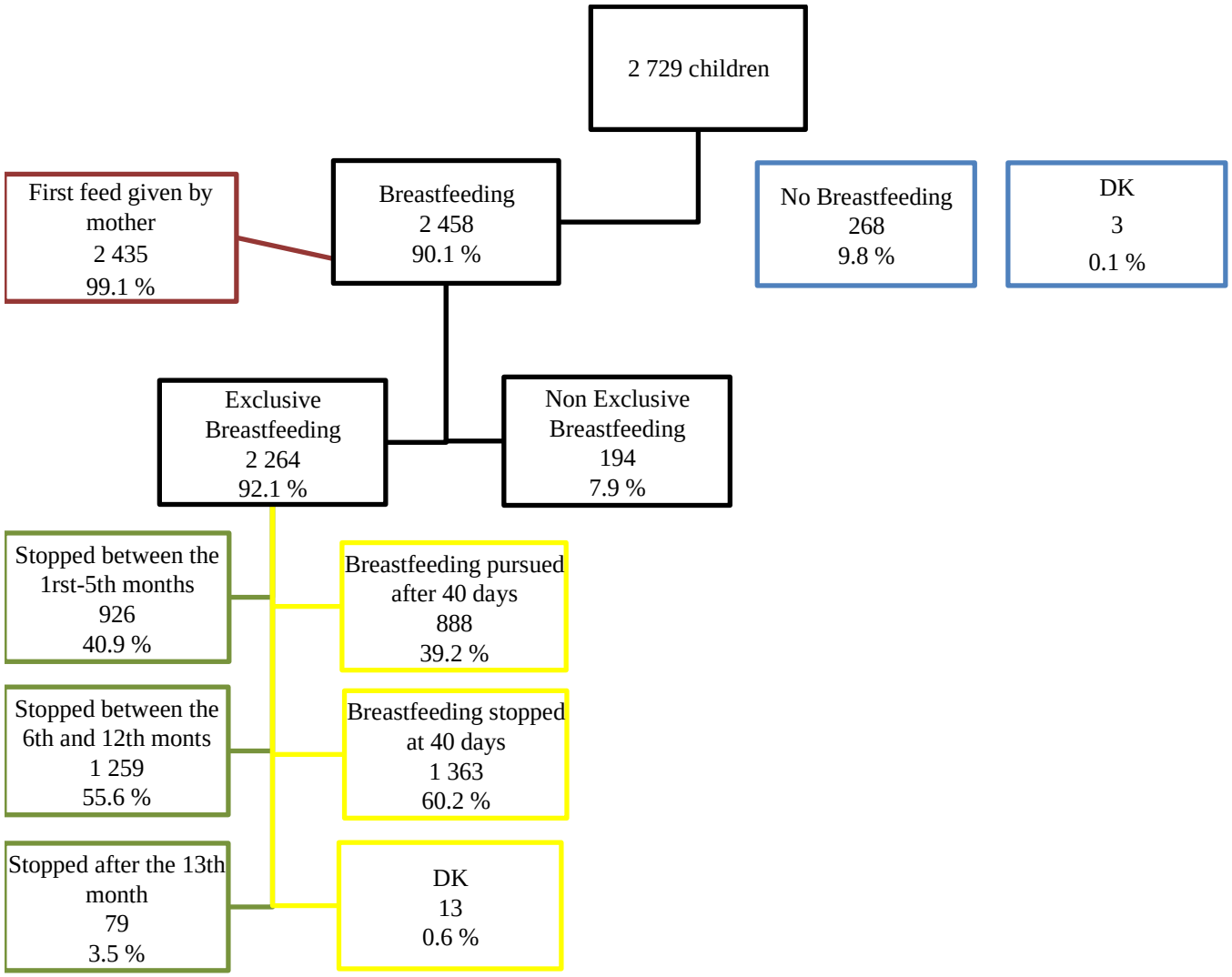

Figure 1. Distribution of children by number of days of exclusive breast feeding (DK= Don't Know).

Table 1. Current status of suckling.

Number of children (122 450)			
Still suckling (%)		**No longer suckling**	
Total	**779 (31.8)**	**Total**	**1,671 (68.2)**
Age group		Age when he/she stopped	
Under 15 months	536 (68.8)	1 - 5 months	43 (2.6)
16 - 35 months	223 (28.6)	6 - 12 months	288 (17.6)
Over 36 months	20 (2.6)	13 - 18 months	742 (45.4)
Total	779 (100.0)	19 - 24 months	488 (29.8)
Number of feeds per day		Over 25 months	75 (4.6)
1 - 10	530 (69.6)	Total	1,636 (100.0)
11 - 20	153 (20.1)		
Over 20	79 (10.4)		
Total	762 (100.0)		

Table 2. Opinions of mothers about the possible use of a feeding bottle.

Opinion on feeding bottle	Numbers	%
Favourable	1,993	73.6
Not favourable	595	22.0
Does not know	119	4.4
Total	2,707	100.0

Table 3. Number of meals taken by children during the previous day.

Number of meals	0	1	2	3	>4	Total
Total number	8	82	657	1,534	424	2,705
%	0.3	3.0	24.3	56.7	15.7	100.0
Cumulative (%)	0.3	3.3	27.6	84.3	100.0	-

Table 4. Sufficiency of food and number of meals eaten the previous day.

Sufficient quantity of food		Yes, certainly		More or less		At times not enough		Often not enough		Total	
		Number	%	Number	%	Number	%	Number	%	Number	%
Number of meals	0	6	0.3	1	0.3	1	0.3	0	0.0	8	0.3
	1	41	2.1	13	3.4	13	4.4	15	27.3	82	3.0
	2	370	18.8	160	41.2	111	37.9	15	27.3	656	24.3
	3	1,213	61.7	160	41.2	139	47.4	20	36.4	1,532	56.7
	>4	336	17.1	54	13.9	29	9.9	5	9.1	424	15.7
	Total	1,966	100.0	388	100.0	293	100.0	55	100.0	2,702	100.0
	%	72.8%	-	14.4%	-	10.8%	-	2.0%	-	100.0%	-

enough to eat (and among them, 21.2% think so even if their child has at best two meals a day). Table 4 shows that few mothers believe that their child has more or less adequate food to eat and also that their child has at times or often not enough to eat.

Mothers (14.7%) in rural areas versus 8.8% in urban areas felt that the food eaten by their children is sometimes or not sufficient enough. This also applies to mothers in the poorest quintile and richest quintile (20.7 and 5.4%, respectively) (Table 10).

Quality of food given children

The vast majority of mothers (85.9%) believe that the quality of food they give to their child is good. In contrast, only a minority of mothers finds that the quality of the food for their child is poor or does not know how to characterize it.

In addition to this, there is the perception, for 43.2% of them, that the amount of food they give to their children is not enough (Table 5).

Parental feeding support

While 31.1% of the children eat at very regular times and 26.9% at relatively regular times, some 42.9% eat at flexible hours. In addition, 64.5% of the children aged 6 months to 6 years eat alone, without the help of an adult (Table 6).

At 9 months, 89.8% of children are assisted to eat. This proportion drops very sharply with age, reaching 66.9% at 18 months, 47.5% at 2 years, 21.8% at 3 years and 13.3% at 4 years.

Diversity of meals fed to children

From Table 7, 63.7% of children had a diversified diet, with foods from at least four different groups. A large number of children (13.0%) consume only one or two types of food in a day.

Children whose diet is already little diversified represent 75.0% who consume no fruits and vegetables, while 69.7% of them do not consume protein and 40.2%

Table 5. Distribution of children in insufficient food situation.

Quality of foods	Food quite sufficient						No/Total (%)
	No		Yes		Total		
	Number	%	Number	%	Number	%	
Good	213	61.6	2,107	89.4	2,320	85.9	9.2
Average	95	27.5	199	8.4	294	10.9	32.3
Poor or DNK	38	11.0	50	2.1	88	3.3	43.2
Overall	346	100.0	2,356	100.0	2,702	100.0	12.8

Table 6. Regularity of the child's meal times and help to eat.

Regularity of meal times?	How does the child eat?				
	He/She eats alone	He/She eats with the help of an adult	He/She eats with the help of another child	Total	
				Number	%
Very regular times	489	318	34	841	31.1
Fairly regular meal times	505	217	7	729	26.9
Flexible hours	753	370	15	1,138	42.0
Total	1,747	905	56	2,708	100.0
%	64.5%	33.4%	2.1%	100.0%	-

Table 7. Diversity of food in the child's meals on the day.

Number of food items	Overall			Protein			Meat			Fruits and vegetables		
	Number	%	Cumul. %	With	Without	Without (%)	With	Without	% Without	With	Without	Without (%)
1	55	2.0	2.0	3	52	4.3	0	55	2.2	0	55	6.5
2	300	11.0	13.0	22	278	22.9	1	299	11.8	64	236	27.8
3	671	24.7	37.7	155	516	42.5	6	665	26.2	326	345	40.7
4	707	26.0	63.7	425	282	23.2	21	686	27.1	553	154	18.2
5	518	19.0	82.7	440	78	6.4	52	466	18.4	472	46	5.4
6	326	12.0	94.7	319	7	0.6	52	274	10.8	315	11	1.3
7	124	4.6	99.2	124	0	0.0	37	87	3.4	123	1	0.1
8	20	0.7	100.0	20	0	0.0	17	3	0.1	20	0	0.0
9	1	0.0	-	1	0	0.0	1	0	0.0	1	0	0.0
Total	2,722	100.0	-	1,509	1,213	100.0	187	2,535	100.0	1,874	848	100.0

Source of proteins are milk, milk products, fish, eggs, meat. Meat has been separately analysed as it is a major source of protein in the study population.

of those do not eat meat. 44.6% (1,213 of the 2,722 children in the sample) did not eat proteins the day before the survey. If meat is removed from the group of protein items, 93.1% of the children will be considered as not having consumed it. Consumption of fruits and vegetables is higher (1,814 children who have eaten it out of the 2,722 in the sample), but it is also observed that nearly a third of them (31.2%) do not consume them (Table 7).

Consumption of fruits and vegetables by age

While protein consumption is almost the same, whether children are six months or six years old, the presence of fruits and vegetables in the child's diet varied by children's age. Figure 2 is a probability model of children that eat fruits and vegetables at least once a day by their age. From the shape of the curve, fruits and vegetables are introduced into the diet of children between the ages

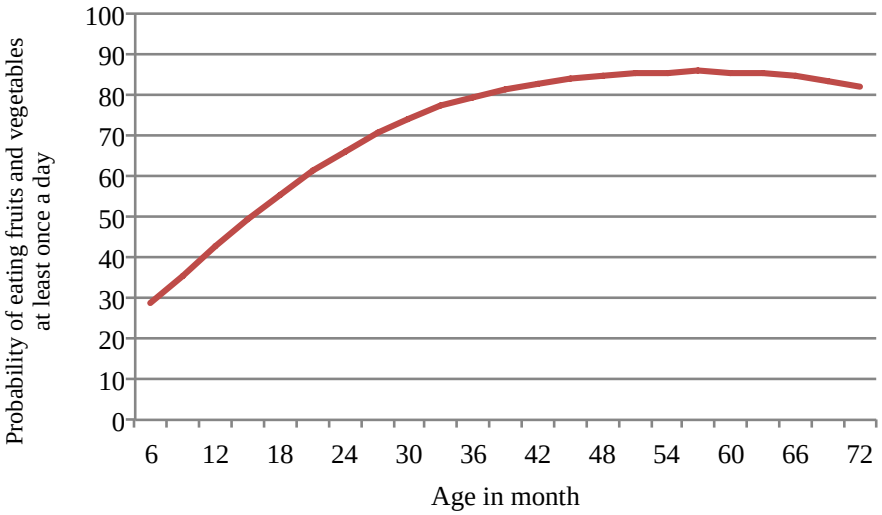

Figure 2. Probability of eating fruits and vegetables at least once a day by age.

Table 8. Distribution by the presence or not of meat and fruit/vegetable.

Meat	Fruits and/or vegetables		Overall
	No (%)	Yes (%)	
No	651 (26.1)	1,661 (66.6)	2,312 (92.7)
Yes	29 (1.2)	153 (6.1)	182 (7.3)
Overall	680 (27.3)	1,814 (72.7)	2,494 (100)

vegetables on the day preceding the visit of the interviewer. Only 6.1% of the children had meals that included meat, fruit and vegetables. Thus, 67.8% (1.2% + 66.6%) of the children consumed only one food group out of the two (Table 8).

Difficulties with accessing food

Over half of mothers (53%) said they scarcely or never have a problem in finding food (45% said they never faced it) (Table 9). However, 53% of families living in rural areas are more often or at times have difficulty in getting food, as against 32% in urban homes.

DISCUSSION

Breast feeding

Exclusive breastfeeding for the first six months of a child's life could save 12 to 20% of child deaths (Government of Sierra Leone, 2014). Hence, awareness must be increased in communities, inclusive of women and men, on the importance of breast feeding. In addition, lower than expected numbers of children suckled the day before the survey. This calls for parental education to increase appropriate feeding practices. Similarly, the large favourability of bottle feeding calls for increased parental education.

Bottle-feeding has been known to increase diarrhoea diseases where it is inappropriately used, leading to poor nutritional outcomes. Appropriate bottle feeding counselling should therefore be targeted to mothers in Sierra Leone.

Child feeding

Children are at least expected to have 3 meals a days. This calls for further analysis to determine why children are given at least 3 meals a day.

Income level of the family but also the geographical location (urban/ rural) affects adequacy of food provided to children of 6 months to 6 years in Sierra Leone. This may be related to poverty levels in the country. Appropriate social protection interventions may need to be designed to address this serious anomaly.

Table 9. Perception of mothers on the frequency of difficulties in obtaining food by area.

Food problems	Geographical area					
	Overall		Urban		Rural	
	N	%	N	%	N	%
Often	231	8.5	65	7.6	166	8.9
At times	1 046	38.5	209	24.4	837	44.9
Scarcely	231	8.5	86	10.0	145	7.8
Never	1 212	44.6	496	57.9	716	38.4
Total	2 720	100.0	856	100.0	1 864	100.0

Table 10. Respondents by region, area of residence and wealth quintile.

Region	Area	Quint. 1	Quint. 2	Quint. 3	Quint. 4	Quint. 5	Quint. 1 and 2		Quint. 4 and 5		Overall	
		N	N	N	N	N	N	%	N	%	N	%
East	Rural	210	142	89	47	30	352	68.0	77	14.9	518	100.0
	Urban	14	18	37	64	35	32	19.0	99	58.9	168	100.0
	Overall	224	160	126	111	65	384	56.0	176	25.7	686	100.0
North	Rural	184	226	225	150	54	410	48.9	204	24.3	839	100.0
	Urban	0	7	5	23	54	7	7.9	77	86.5	89	100.0
	Overall	184	233	230	173	108	417	44.9	281	30.3	928	100.0
South	Rural	140	119	106	66	0	259	60.1	66	15.3	431	100.0
	Urban	0	9	14	57	45	9	7.2	102	81.6	125	100.0
	Overall	140	128	120	123	45	268	48.2	168	30.2	556	100.0
West	Rural	2	6	5	32	40	8	9.4	72	84.7	85	100.0
	Urban	1	18	47	124	284	19	4.0	408	86.1	474	100.0
	Overall	3	24	52	156	324	27	4.8	480	85.9	559	100.0
Overall	Rural	536	493	425	295	124	1029	54.9	419	22.4	1873	100.0
	Urban	15	52	103	268	418	67	7.8	686	80.1	856	100.0
	Overall	551	545	528	563	542	1096	40.2	1105	40.5	2729	100.0

Parental feeding support: Support with eating

At 18 months, a large number of children are not being assisted with feeding. This large number needs further examination as it may mean that children that need assistance with feeding are being left alone, leading to inadequate feeding.

Diversity of food/meals

The daily diet of young children is considered as diversified if it includes foods from at least four different food groups (WHO, 1990). Based on this definition, alot of children in the study do not have a diversified diet. Consumption of non-diversified meals and consumption of meals with no meat, fruits and/or vegetables may be a cause for poor nutritional outcomes in children in Sierra Leone. Parents need support to diversify food for children.

Difficulties with accessing food

Only slightly over half of mothers had no difficulties in accessing food. This is quite a low figure if the child related nutritional problems in Sierra Leone are to be addressed. The scenario is worse in rural areas. This calls for appropriate nutritional, social protection or other government interventions to increase access of food for mothers with children between 6 months and 6 years, especially in rural areas where a majority of the population reside.

Conclusion

Poor nutrition outcomes in Sierra Leone may be related to poor parental feed practices. Parental practices related to breast feeding, child support and feeding support have been found to be sub optimal in this study. In particular, there is need for attention to breast feeding practices, child feed, caregiver feeding support, dietary diversity and access to food. Mothers of children 6 months to 6 years have also problems with accessing food in general and diversified foods, such as meat, fruits and vegetables in particular. Nutrition outcomes in Sierra Leone would be improved by developing a comprehensive community based early childhood development programme to improve feeding related parental practices. Mekonnen et al. (2017) have recommended similar interventions for populations with suboptimal feeding practices in Ethiopia. Future studies in this area should collect data on dietary intake, disaggregated by age. In addition, future research of this type should collect anthropometric data to triangulate findings from caregiver practices data. This will enable further assessment of food and dietary intake by age as recommended by WHO. The effects of feeding practices could also be better understood if future studies could collect anthropometric data at the same time that mothers/caregivers practices are being studied.

CONFLICT OF INTERESTS

The authors have not declared any conflict of interests.

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Prevalence of hepatitis B and C among HIV/AIDS patients attending Bingham University Teaching Hospital Jos Plateau State Nigeria: A retrospective study

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The prevalence of hepatitis B and C (HBV and HCV) among HIV infected persons is a major public health problem in Nigeria. The increasing number of people living with HIV in Nigeria has presented the health care system with new co-morbid infections such as HBV and HCV. This study was designed to investigate the prevalence of hepatitis B and C among HIV/AIDS patients attending Bingham University Teaching Hospital Jos Plateau State Nigeria. The study was a retrospective study that reviewed all clinical case records of HIV/AIDS patients seen from 1st January, 2012 to 31st December, 2016. Information such as age, sex, marital status, occupation, educational level, hepatitis B and C status, CD4 T lymphocyte count, signs and symptoms were retrieved using structured questionnaire. Data were analysed and presented in simple percentage while Chi-square test was used to test for associations between variables at P<0.05. According to the results, more than two-third of the patients (1051, 68.10%) were females and 576 (37.30%) were in the age group of 38-47 years with a mean age of 42.60±9.9 years. The prevalence of HBV was 56.70% while HCV was 30.30%. In addition, both HBV and HCV were significantly found among HIV infected females compared to HIV infected males. The mean CD4 cells/µl for HBV positive was 500.48±101.81 while HCV positive was 557.33±121.76. The study showed the prevalence of hepatitis B and C among the HIV infected patients. Therefore routine screening for hepatitis B and C markers among HIV patients should be carried out regularly.

Key words: Prevalence, HIV/AIDS patients, hepatitis B, hepatitis C, CD4 count, Bingham University.

INTRODUCTION

Globally, an estimate of 36.7 million people was living with Human Immuno-Deficiency Virus (HIV) in 2016. Sub-Saharan Africa remains most severely affected with nearly 1 in every 25 adults (4.2%) living with HIV, accounting for nearly two-thirds of the people living with HIV worldwide (World Health Organisation, 2017).

Furthermore, there were about 3.2 million people living with HIV as at 2016, with an estimated 160 000 Acquired

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Immune Deficiency Syndrome (AIDS) related death recorded (UNAIDS, 2017). These AIDS related death can be attributed to the increase in mortalities and morbidities from liver diseases amongst HIV patients which is partly due to co-infection with hepatitis B and C viruses (HBV and HCV) as these viruses promote liver fibrosis by increasing intra-hepatic apoptosis (Greub, 2000; Macias et al., 2005; Iser et al., 2011; Chiekulie Kevin Diwe et al., 2013).

Hepatitis which refers to an inflammation of the liver is becoming a major public health concern in sub-Saharan Africa including Nigeria. For instance, Sub-Saharan Africa has been shown to be endemic for hepatitis B with an estimated >8% prevalence in the population or in some 65 million people (Sonderup and Spearman, 2017). Furthermore, hepatitis C infection is prevalence in about 36 million people and the rates of co-infection with hepatitis B is up to 36% with the highest rate recorded in West and Southern sub-Saharan Africa (Matthews et al., 2014). Similarly, record from Nigeria reveals that over 35 million people have been estimated to live with hepatitis B and C viruses (Modi and Feld, 2007; Tremeau-Bravard et al., 2012; Madhava et al., 2002) while a pooled prevalence of HBV in Nigeria from studies carried out between 2000 and 2013 was 13.6% (Musa et al., 2015).

Thus, the study estimated the prevalence of HBV and HCV among HIV/AIDS patients as it remains the foundation for understanding the interrelationship between these viruses along with designing health promotion programs for the prevention and control of these epidemics. Therefore, the retrospective study investigated the prevalence of hepatitis B and C infection among HIV/AIDS patients seen from 1st January 2012 to 31st December 2016 at the Bingham University Teaching Hospital Jos, Plateau State, Nigeria.

MATERIALS AND METHODS

Study design

This study was a retrospective study that reviewed all clinical case records of HIV/AIDS patients seen from 1st January, 2012 - 31st December, 2016.

Study area

The study was conducted in Bingham University Teaching Hospital in the Jos North Area of Plateau State in North Central Nigeria.

Study population

The study population consists of all HIV/AIDS patients seen at Bingham University Teaching Hospital from 1st January, 2012 to 31st December, 2016. Bingham University Teaching Hospital is the second largest Teaching Hospital in Jos metropolis and offers a range of health care services including diagnosis and treatment of HIV/AIDS patients. The population of HIV/AIDS cases for the stated period were 1,544.

Inclusion criteria

HIV/AIDS positive patients seen only within the period of 5 years (1st January, 2012 to 31st December, 2016) who attended Bingham University Teaching Hospital were included in the study.

Exclusion criteria

Excluded from the study, were HIV/AIDS patients not seen within the period under review.

Instrument and method of data collection

A checklist was designed to collect information on the demographic characteristics of patients, HBV and HCV status, CD4 count, signs and symptoms. The data was abstracted by the researcher and three research assistants from the record of diagnosed HIV/AIDS patients, who were coming to the hospital from 1st January, 2012 to 31st December, 2016. Clinical data were collected from HIV-positive patients coming for CD4 monitoring from 1st January, 2012 to 31st December, 2016. Overall, a total of 1544 entries were retrieved for the retrospective study on the prevalence of HBV and HCV infection among HIV/AIDS patients. Information in the records includes patients' demographic information, HBV and HCV status, CD4 count, signs and symptoms the patients presented at the time of treatment. The data were sorted and extracted after obtaining approval from the ART clinic through the hospital management board. The CD4 count in micro litre (µl) was classified according to the CDC Classification System for HIV-Infected Adults and Adolescents. Thus T-cells ≥500 µl was classified as category 1, T-cells 200-499 µl classified as category 2 and T-cells <200 µl classified as category 3 (CDC, 1993).

Data analysis

The collected data were entered into the computer and analysed using Statistical Package for Social Sciences version 20 (IBM Corp., Chicago, USA). Simple percentage were used to describe the basic features of the retrieved data while inferences between variables of interest were drawn using Chi-Square test at $P<0.05$. The data were collected to ensure confidentiality of patients' information as no identifiers were used and the results were used for research purpose only.

Ethical consideration

Ethical clearance was obtained from the Department of Public and Community Health, Novena University Ogume and from Bingham hospital management board to the ART clinic.

RESULTS

Socio-demographic characteristics of the respondents

According to Table 1, 624 (40.40%) of the respondents were married and more than two third (1051, 68.10%) were females. Most (576, 37.30%) were between the age group of 38-47 years. Furthermore, almost half of the respondents (775,50.30%) were into business and 935(60.30%) attained secondary education.

Table 1. Socio-demographic characteristics of HIV/AIDS patients in Bingham University Teaching Hospital from 1st January, 2012 to 31st December, 2016.

Variable	Frequency (N=1544)	Percentage
Marital Status		
Married	624	40.40
Single	311	20.10
Widow	142	9.20
Widower	64	4.10
Divorce	403	26.10
Sex		
Male	493	31.90
Female	1051	68.10
Age		
18-27	64	4.10
28-37	447	29.0
38-47	576	37.30
48-57	340	22.0
58-67	98	6.30
68-77	19	1.20
Occupation		
Civil servant	529	34.30
Business	775	50.30
Housewife	85	5.50
Retired	22	1.40
Student	133	8.60
Educational Status		
Primary	96	6.20
Secondary	497	32.20
Tertiary	935	60.30
None	16	1.0

Mean Age: 42.60±9.9.

Status of hepatitis B and C

According to Figure 1, 876 (56.70%) of the respondents were positive to hepatitis B virus and 668 (43.30%) were negative to hepatitis B virus. Furthermore, more of the respondents (1076, 69.70%) tested negative to hepatitis C infection while (468, 30.30%) were hepatitis C positive.

From Table 2, HBV were more common in patients aged 38-47 (26.90) and 28-37 (17.70%) years compared to patients in other age groups. Also, patients aged 48-57 years (183, 11.90%) were more positive to HCV than other age groups. Similarly, more females (621, 40.20%) than males (255, 16.50%) were HBV positive.

CD4 count of the patients

As shown in Figure 2, 781 (50.60%) of the patients were in category 2 as they had T-cells of 200-499 µl while 763 (49.40%) were in category 1 as they had T-cells of ≥500 µl and none of the patients recorded T-cells fell into category 3.

Patient current regimen

The regimen of the patients shows that more of them have a combination of lamivudine and Efavirenze (593, 32.0%) followed by a combination of Tenofivir and Lamivudine (528, 28.50%) while 394 (21.30%) had a combination of Efavirenze and Tenofivir (Table 3).

Signs and Symptoms of the patients

As shown in Table 4, more of the patients presented

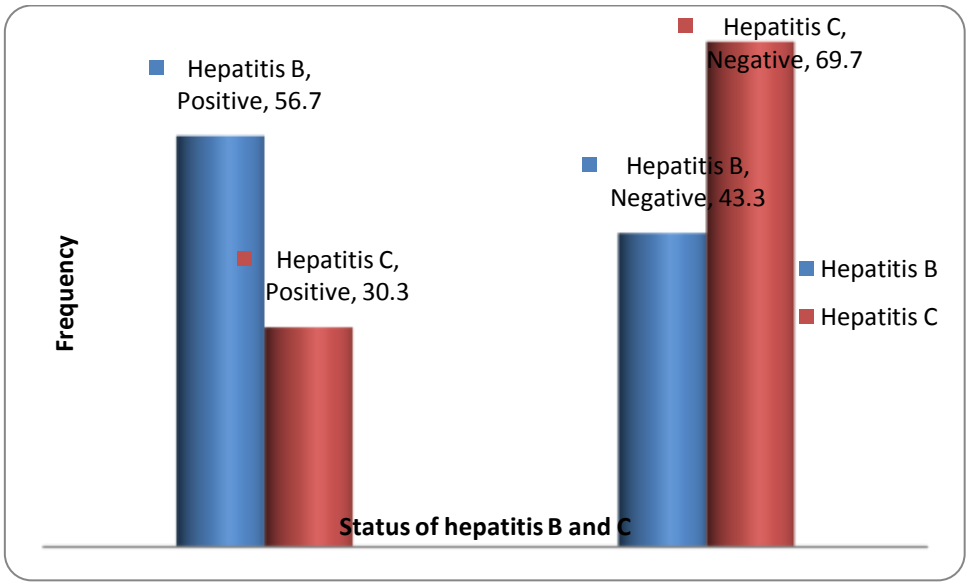

Figure 1. Status of hepatitis B and C among HIV/AIDS patients.

Table 2. Association of demographic variables and HBV and HCV.

Variables	Hepatitis B (N=1554)		Hepatitis C (N=1554)		P-Value
	Positive	Negative	Positive	Negative	
Age (Years)					
18-27	13(0.80%)	51(3.30%)	13(0.80%)	51(3.30%)	
28-37	273(17.70%)	174(11.30%)	86(5.60%)	361(23.40%)	
38-47	416(26.90%)	160(10.40%)	130(8.40%)	446(28.90%)	0.0001
48-57	130(8.40%)	210(13.60%)	183(11.90%)	157(10.20%)	
58-67	29(1.90%)	69(4.50%)	53(3.40%)	45(2.90%)	
68-77	15(1.0%)	4(0.30%)	3(0.20%)	16(1.0%)	
Sex					
Male	255(16.50%)	238(15.40%)	199(12.90%)	294(19.0%)	0.0001
Female	621(40.20%)	430(27.80%)	269(17.40%)	782(50.60%)	
Mean CD4 cells/µl	500.48±101.89	522.46±139.41	557.33±121.76	489.39±113.30	0.0001

abdominal pain (472, 10.20%) at the hospital, followed by heartburn (40, 8.70%), headache (363, 7.80), rashes (361, 7.80), waist pain (343, 7.40) and weakness (335, 7.20%).

DISCUSSION

Viral hepatitis (HBV and HCV) has become a major public health concern worldwide especially among HIV patients (WHO, 2008; WHO, 2011). Furthermore, the relationship in the mode of transmission between the three viruses; HIV, HBV and HCV has made it more pertinent to assess the prevalence of HBV and HCV among HIV patients. The study reported the prevalence of both HBV and HCV among HIV/AIDS subjects. Furthermore, most of the respondents CD4 T lymphocyte were in Category 2 and 1 as their CD4 count was >200 µl above.

The socio-demographic characteristics of the patients show that more of the patients were females representing more than two-third of the total cases of HIV patients reviewed in this study. This finding is similar to other studies which reported more females than males in their studies (Lacombe 2010; Muriuki et al., 2013; Tremeau-Bravard et al., 2012; Opaleye et al., 2014; Obadiah, 2011). The finding confirms previous assertions that women are more sexually vulnerable to HIV and other sexually transmitted infections than male (WHO, 2000). Furthermore, the majority of HIV infected patients were

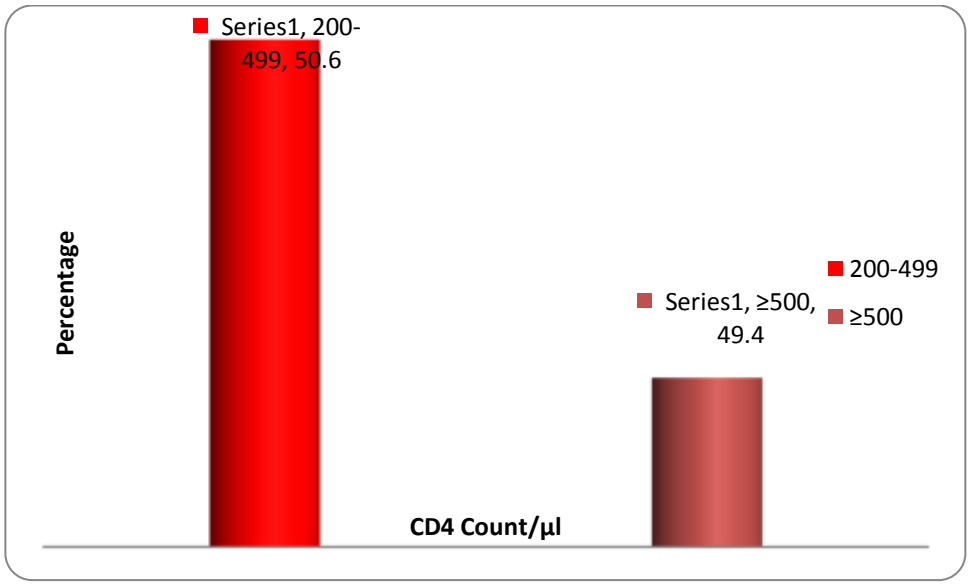

Figure 2. CD4 Count of the HIV/AIDs patients.

Table 3. The regimen of the patients.

Patients current regimen	Frequency*(N=1854)	Percentage
Tenofivir(TDF)/Lamivudine(3TC)	528	28.50
Efavirenze/Tenofivir(EFVTDF)	394	21.30
Lamivudine(3TC)/Efavirenze(EFV)	593	32.0
Combivir(AZT)/Lamivudine(3TC)	135	7.30
Nevirapine(NVP)/Combivir(AZT)	111	6.0
Lamivudine(3TC)/Nevirapine(NVP)	10	0.50
Truvada(FDC)/Tenofivir(TDF)/Lamivudine(3TC)	72	3.90
Combivir (CBV)	2	0.10
Abacavir (ABC)	3	0.20
Emtricitabine (FTC)	3	0.20
Lopinavir/Ritonavir (LPV-r)	3	0.20

*Multiple responses.

between the ages 28-57 years old with a mean age of 42.60±9.9 years. This signifies a higher HIV prevalence among adults and the age distribution is similar to previous studies (Balogun et al., 2012; Opaleye et al., 2014; Tremeau-Bravard et al., 2012).

The prevalence of hepatitis B virus from the study shows that more of the patients tested positive to HBV. This prevalence of HIV/Hepatitis B co-infection (56.70%) was higher than previous studies from Ikole-Ekiti South-West Nigeria (Opaleye et al., 2014), Niger-Delta South-South Nigeria (Ejele and Ojule , 2004), Lagos South-West Nigeria (Balogun et al., 2012), Ibadan South-West Nigeria (Otegbayo et al., 2008), Jos North-Central Nigeria (Adekeye et al., 2013), Ilorin North-Central Nigeria (Olatunji and Iseniyi, 2008) and Maiduguri North-Eastern Nigeria (Baba et al., 1998). Furthermore, other studies with lower prevalence outside Nigeria include a study in South-Africa (Parboosing et al., 2008), Senegal (Diop-Ndiaye et al., 2008), France (Larsen et al., 2008) and Thailand (Sungkanuparph et al., 2004). This observed difference of prevalence of HBV of the current study as compared with other studies might probably be due to varying sample size and the study design of the current study which reviewed a 5 years clinical records.

In addition, the sex stratification prevalence of HBV shows that more females were HBV positive than males. This finding is similar to a previous study (Opaleye et al., 2014) but was however different from other studies (Mehmet et al., 2005; Muriuki et al., 2013). Furthermore, the statistically observed difference of HIV infection in

Table 4. Signs and symptoms presented by the patients.

Signs and Symptoms	Frequency*(N=4632)	Percentage
Fever	277	6.0
Headache	363	7.80
Abdominal pain	472	10.20
Heartburn	404	8.70
Waist pain	343	7.40
Weakness	335	7.20
Cough	226	4.90
Catarrh	188	4.10
Boil	117	2.50
Loss of Appetite	200	4.30
Backpain	198	4.30
Rashes	361	7.80
Vagina Discharge	261	5.60
Ear problem	207	4.50
Body pain	115	2.50
Painful Mic	61	1.30
Body Itching	41	0.90
Hyperpigmented patches	33	0.70
Swollen Armpit	27	0.60
Dizziness	18	0.40
Vomiting	45	1.0
Dysentary	19	0.40
Macular Rash	125	2.70
Diarrhoea	77	1.70
Jaundice	69	1.50
Dark Urine	27	0.60
Fatique	10	0.20
Joint Pain	13	0.30

*Multiple responses.

both male and female in the current study reveals unequal exposure to HBV infection which is in line with previous studies (Opaleye et al., 2014; Agbede et al., 2007). In the same vein, the prevalence of 30.30% for HCV reported in the current study was higher than that reported in previous studies (Tremeau-Bravard et al., 2012; Muriuki et al., 2013; Forbi et al., 2007). Similarly, more females were positive to HCV than their male counterpart which is in line with result from previous studies (Muriuki et al., 2013; Lesi et al., 200); but at variance with other studies (Forbi et al., 2007; Agwale et al., 2004). Furthermore, there was a significant relationship between the sex of the patients and their HCV status. This was slightly different from a previous study (Muriuki et al., 2013).

Based on the Centre for Disease Control classification system for HIV infection which was used to categorise the severity of the HIV infection of the patients shows that almost all of the patients were in category 1 (T-cells of ≥500 µl) and 2 (T-cells of 200-499 µl). This result shows that the patients were still in the asymptomatic, acute HIV or persistent generalized lymphadenopathy stage of the infection. Although, the patients displayed some signs and symptoms consistent with category B symptomatic conditions and category C which is the AIDS-indicator conditions; it can be probably deduce that the various combination of antiretroviral drug regimen the patients were currently taking might have help to improve their CD4 count and also help in suppressing the manifestation of the full blown AIDS. This finding is slightly different from the study in Ikole-Ekiti South-Western Nigeria where almost one third of the patients from that study were in category 3 (Opaleye et al., 2014). Furthermore, the mean CD4 count was higher in HBV negative patients as compared with HCV patients which were higher in positive patients. The finding was also slightly different from the study in Ikole-Ekiti (Opaleye et al., 2014).

The main limitation of the study is that the study was solely depended on the clinical records of the ART clinic at the Bingham University Teaching Hospital in identifying HIV, HBV and HCV patients without carrying out any

confirmatory clinical laboratory test.

Conclusion

In conclusion, the study shows the prevalence of hepatitis B and C among the HIV infected patients. Therefore, we recommend that HIV patients should be routinely screened for hepatitis B and C markers. Also, intervention should be directed at implementing hepatitis B and C prevention strategies as part of HIV routine education among HIV patients. This will help reduce the severity of morbidity such as exposure to cirrhosis and mortality rate associated with hepatitis B and C infection including antiretroviral drug associated hepatoxicity among these patients.

CONFLICT OF INTERESTS

The authors have not declared any conflict of interests.

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Knowledge, attitude and practice on hand washing and associated factors among public primary schools children in Hosanna town, Southern Ethiopia

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The burden of communicable diseases within developing countries is mainly influenced by poor personal hygiene practices Despite substantial evidence about the effectiveness of hand washing, especially using soap at all critical time, the practice is poor in developing countries including Ethiopia. The problem is not researched well on children who are major risk groups for diarrheal diseases, ARI and other hygiene related problems. To assess knowledge, attitude and practice of hand washing and associated factors among primary school children in Hosanna town, SNNPR, Ethiopia. Institution based cross sectional study was conducted with sample size of 246 students in Girma Bekele primary school in Hosanna town from April 15 -30/2016.Data was collected using interviewer administered pre tasted structured questionnaires by trained data collectors. From students participated in this study over all 167(69.9%) students have good and 72 (30.1%) have poor knowledge. Knowledge of students in this primary school is affected by grade of student and area of residence with (AOR, 95% CI 9.099(.587-.850) and (AOR.384; 95% CI (.114-.299)) respectively. Regarding the attitude of students 142(59.4%) and 97(40.6%) have good and poor attitude respectively. Overall 172(71.97%) of students have good practice and 67 (28.03%) have poor practice toward hand washing. Majority of the study subjects has adequate knowledge and about more than half of them have positive attitude. Overall practice of HW is good but utilization of soap and HW after toilet visit is low. Maternal educational status, area of residence, age, sex and grade of student are factors that affect KAP of school children toward hand washing with soap.

Key words: Primary school children, hand washing, knowledge, attitude and practice, Ethiopia.

INTRODUCTION

Water, sanitation and hygiene are a crucial but all too often underplayed part of the prevention and control of neglected Tropical diseases. Diseases including Trachoma, Soil-Transmitted helminthis and schistosomiasis all

demand practical interventions so that their prevention, treatment and ultimately their elimination can be achieved by the international community as soon as possible (WASH, 2012).

Hand washing is the act of washing hands with plain or antimicrobial soap and water and it is the single most preventive measure for reducing the spread of contagious diseases. In fact skin is the body's first line of defense against bacteria, therefore careful attention to hand care is an essential part of the hand hygiene program. The presence of dermatitis, cracks, cuts or abrasions can trap bacteria and compromise hand hygiene (Core, 2002). According to CDC report estimates each year nearly 2 million patients in the United States get an infection in hospitals, and about 90,000 of these patients die as a result of their infection. More widespread use of hand hygiene products that improve adherence to recommended hand hygiene practices will promote patient safety and prevent infections (Core, 2002).

The two biggest killers of children in the developing world today are diarrheal disease and respiratory tract infections (Jennifer and Param, 2014). The simple act of washing hands with soap can cut diarrhoea risk by almost half, and respiratory tract infection by a third (Jennifer and Param, 2014). There is improvement on morbidity and mortality rates but still diarrheal diseases are responsible for 21% of all deaths and 2.5 million deaths per year which has either direct or indirect relation with poor hand washing. In developing countries, there were 3.2 episodes of diarrhoea per child per year in under five children with mortality rate of 4.9 children per 1000 per year (Kosek et al., 2003).

Lack of knowledge on hand washing has association with prevalence of diarrhoea (Ejemot et al., 2008; Mengistie et al., 2013).

Proper hand washing with soap (HWWS) is important for school children's health improvement and disease prevention which in turn reduces absenteeism due to illness. The practice is significant for schoolchildren, who might suffer a more severe burden of hygiene-related diseases compared to adults (Vivas et al., 2010; Thanh Xuan et al., 2013; WASH, 2012. Promotion of hand washing through education in school children and provision of safe and clean water supply as well demonstration of proper hand washing techniques in schools saves children from such life threatening but easily preventable illness (Ejemot et al., 2008; WASH (2012); Ejere, 2004; Mohammed et al., 2013; Garg et al., 2013). The level of knowledge and practice of students in schools is relatively better in developed countries but it needs more intervention in low income countries including Ethiopia WASH (2012). Rubanprem et al., 2014). The latest available evidences indicate that Ethiopia has made some progress towards access to basic sanitation by reaching 28% of the population in 2014, compared to a 3% baseline in 1990 but considerable number of children and mothers are still dying due to failure to reach them with high impact interventions (Controlling diarrheal disease in Vietnam, 2015).

A study conducted by the United Nations Children's Fund (UNICEF) and the Ethiopian Ministry of Health found that study participants in rural Ethiopia had poor status regarding knowledge, attitudes, and practices (KAP) of hygiene (Kumie and Ali, 2005). Approximately, 60% of children surveyed did not know about the possible transmission of diseases through human waste (Assefa and Kumie, 2014).

Simple hygienic measures such as washing hands with soap were poorly practiced, especially in rural areas (Kumie and Ali, 2005). Another study conducted by the Research-inspired Policy and Practice Learning in Ethiopia (RiPPLE), a program surveying rural households in the southwest region of Ethiopia, found that hand washing practices were also poor (Research-inspired Policy and Practice Learning in Ethiopia (RIPPLE), 2008). New hand washing facilities, in addition to awareness and knowledge about proper hygiene, have led to some changes in behaviour and attitude, yet the prevalence of hand washing remains low in this region Ministry of health (MOH) (2015). Despite substantial evidence about the effectiveness of hand washing, especially using soap at all critical time, the practice is poor in developing countries including Ethiopia. The problem is not researched well on children who are major risk groups for diarrheal diseases, ARI and other hygiene related problems.

Although hand washing after contact with faecal material (for example after defecation), before and after meal, before food preparation and cleaning baby provides important barrier to faeco-oral transmitted disease, cause of point of contamination in schools with poor hygiene and sanitation facilities are much more broader than these points means level of knowledge, attitude and practice as well as other associated factors of students need further studies to intervene in areas with gap of HWWS in primary schools.

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Objectives of the study

The general objective

The general objective was to assess the knowledge, attitude and practice of hand washing and associated factors among primary schools children in Hosanna town, SNNPR, Ethiopia.

Specific objectives

The specific objectives of the study were: 1) to assess knowledge of hand washing among primary schools children in Hosanna town, SNNPR, Ethiopia, in 2016; 2) to assess the attitude towards hand washing among primary school children in Hosanna town, SNNPR, Ethiopia in 2016; 3) to assess the hand washing practice among primary schools children in Hosanna town, SNNPR, Ethiopia in 2016 and 4) to determine associated factors of knowledge, attitude and practice of hand washing among primary schools children in Hosanna town, SNNPR, Ethiopia.

MATERIALS AND METHODS

Study area and period

This study was conducted in Hosanna town which is located in 232 km South West from Addis Ababa, Ethiopia. Hosanna is an administrative centre of Hadiya Zone with a total population of 92,735, according to 2007 census. There are six public educational facilities in the Town Administration, among which three are primary schools, two high schools and one preparatory school. There are four governmental (one general hospital and there health centres) and 12 non-governmental health facilities in the town. The study was conducted from April 15 to 30, 2016.

The study was conducted at Hosanna town Primary School, a government-owned institution which provides free education to children in grades 1-8 who live in Hossana. A school based cross-sectional study involving quantitative method was undertaken among 246 randomly selected students. Eligible students were selected using simple random sampling technique from the existing sampling frame (student's roster). In every step of selection, simple random sampling technique was used.

Data collection process and tools

Data were collected using interviewer administered questionnaires at school and socio demographic and socio economic variables are completed with parents. Eight data collectors from three health centres participated in data collection. Each student was interviewed using a structured questionnaire in a safe room specifically dedicated for this study by the school administration. All data collectors were trained on interviewing skills, content of the questionnaire, data quality and ethical conduct. Two graduate students supervised the overall process, assisted interviewers and collected completed questionnaires on daily basis. All completed questionnaires were checked for consistencies and completeness of the data.

The questionnaire was initially drafted in English, and translated to Amharic, and then pre-tested in 10% of sample size outside of the study area to assess the suitability with regards to duration, language appropriateness, content validity, and question comprehensibility. Based on the feedback from the pilot test, corrections were made.

Data quality assurance

After data collection, each questionnaire was given a unique code by the principal investigator. The principal investigator prepared the template and entered data using Epi Data version 3.1 then exported to SPSS version 20. Five percent of the entered data was re-checked by comparing the entered data with the actual questionnaire. Frequencies are used to check for missed values and outliers. Any errors identified at this time were corrected after revision of the original data using the code numbers.

Data analysis

The data were cleaned for inconsistencies and missing values. Simple frequencies run to see the overall distribution of the study subject with the variables under study. Bivariate and multivariate analysis was used to determine the association between different factors and the outcome variable.

Inclusion and exclusion criteria

All children in the age range between 5-18 years and registered at primary schools of Hosanna town in 2015/2016 academic year were included in the study. Students with hearing and speaking disabilities were excluded from the study.

Study variable

Dependent variable

Dependent variable included: knowledge, attitude and practice towards hand washing.

Independent variables

Independent variables included: Socio- demographic (Age, sex, Religion, area of residence, grade of student, family size, and educational status of parents; Socio economic (Occupation of parents); Health system related at school and home (History of illness; Availability of water and soap and Information on HHWS.

Operational definitions

Hand washing at critical time

It includes washing hand before preparing food, before eating food, after eating, after cleaning baby and after visiting toilet.

Good practice

Those students who scored at least 60% and above in practice questions.

Poor practice

Those students who answer less than 60% of practice questions.

Good Knowledge

Those students who scored at least 60% and above in knowledge questions.

Poor knowledge

Those students who fail to answer 60% of the knowledge questions.

Positive attitude

Those students who could answer/score at least sixty percent and above from the questions that measure attitude.

Negative attitude

Those students who could not answer at least 60% of attitude questions.

Ethical considerations

Prior to data collection, written ethical clearance was obtained from research and ethics committee of AAU College of Allied Health Sciences, Department of Nursing and Midwifery. During data collection, each parent of the child that participates in the study was informed about the purpose, scope and expected outcome of the research, and appropriate informed verbal consent was taken. Consented parents completed the socio -demographic and socio-economic information. During the interview all participating children were informed about the purpose, scope and expected outcome of the research, and appropriate informed verbal asset obtained.

RESULTS

Socio-demographic characteristics

A total of 246 school children were recruited from the school giving a response rate of 97%. From the total students who participated (239) in this study 116 (48.5%) are males and 123 (51.5%) are females with mean age of 11.66 years. Majority of the respondents' families (160, 66.9%) were protestant religion followers whereas 17.2, 12.6 and 3.3% were Orthodox, Muslim and other religion followers respectively (Table 1)

Knowledge about hand washing

The global hand washing day as a movement is a critical initiative; it is a source of information and enhances knowledge of individuals on practice of hand washing.

From the respondent students 158 (66.1%) have information on global hand washing day but only 3 reported the exact month in which global hand washing day is celebrated.

Benefit of washing their hands using clean water and soap was reported by 108 (45.2%), 83 (34.7%), and 39 (16.3%) to promote health, prevent transmission of disease and to be beautiful respectively (Table 2).

Based on the specific responses by the participant students, over all 167(69.8%) and 72 (30.1%) students had good and poor knowledge respectively.

Factors that affect level of knowledge

Primarily, variables that had p-value <0.2 at bivariate analysis were used to develop logistic model in order to identify factors which are more strongly linked with the outcome knowledge. On multivariate logistic regression, educational status of mother and grade of student were found to be significantly associated to knowledge toward hand washing.

The likelihood students in 2nd cycle are 8 times [AOR, 9.099; 95% CI (4.36-.17.36)] more likely to have good knowledge on hand washing than those students in first cycle (Table 3).

Attitude towards hand washing

Among the participant students, 222 (92.9%) and17 (7.1%) said that it is their own and their parents' responsibility to wash their hands respectively. Based on six questions/scale to measure the attitude towards hand washing, 142 (59.4%) and 97 (40.6%) had positive and negative attitude respectively.

There is no statistically significant association with different socio demographic variables and attitude towards hand washing.

Practice of hand washing

Of the total respondents, 237(99.2%) washed their hands in the morning of the interview day and only two students failed to wash their hands because they were aroused from their sleep. From those who have washed their hands in the morning of the interview day, about 204 (85.4%) reported the use of soap and the remaining 33 (13.8%) used water only to wash their hands. Water and soap (188, 78.7%) are more used in the families of students to wash their hands followed by water only (50, 20.9%). The usage of soap is elaborated in the following bar graph before and after some activities.

Overall, 172 (71.97%) of the students had good practice and 67 (28.03%) had poor practice toward hand washing (Table 4).

Table 1. Socio demographic characteristics of the students in Girma Bekele primary school Hosanna Ethiopia, 2016.

S/N	Variable	Category	Frequency (n=239)	
			Number	%
1	Grade of student (n=239)	1-4	102	42.7
		5-8	137	57.3
2	Area of residence (n=239)	Hosanna town	217	90.8
		Local kebele	22	9.2
3	Educational status of mother (n=239)	Can't read and write	36	15.1
		Grade 1-8	106	44.4
		Grade 9-12	52	21.8
		Diploma and above	45	18.5
4	Occupation of father (n=239)	Government employee	125	52.3
		Private employee	68	28.5
		Daily labourer	10	4.2
		Farmer	34	14.2
		Student	2	.8
5	Occupation of mother (n=239)	Government employee	68	28.5
		Private employee	23	9.6
		House wife	146	61.1
		Student	2	0.8
6	History of illness (n=239)	Yes	66	27.6
		No	173	72.4
7	Illness diagnosed (n=66)	Diarrhea	39	59.09
		RTI	7	10.6
		Intestinal parasite	7	10.6
		Other problems	13	19.71

Table 2. Knowledge and Attitude of students on hand washing among GirmaBekele primary school children Hosanna, Ethiopia, 2016.

S/N	Characteristics	Category	Frequency (n=239)	
			Number	%
1	Have information on HWWS(n=239)	Yes	239	100
		No	0	0
2	Have information on global hand washing month (n=239)	Yes	158	66.1
		No	81	38.7
3	Source of information on global hand washing day	Television	134	56.10
		Teachers	62	26.10
		Family	14	5.7
		Radio	8	3.2
		health worker	21	8.90
4	Human faces contains disease causing microorganisms (n=239)	Yes	167	69.8
		No	6	2.5
5	Unclean hands are way to transmission of disease. (n=239)	Yes	233	97.5
		No	6	2.5
6	Hands become visibly dirty(n=239)	Before meal	68	28.5
		After meal	23	9.6
		After play	73	30.5
		After toilet	2	.8

Table 2. Contd.

7	Risk to contaminate food and water if we do not wash our HWS (n=239)**	After toilet	27	11.3
		After playing	73	30.54
		Before meal	219	91.6
		After meal	223	93.3
		After work	193	80.7
8	Needed to wash hand properly (n=239) **	Soap	98	41.00
		Clean water only	29	12.13
		Soap and clean water	106	44.35
9	If you fail to wash your hands you will be exposed to disease. (n=239)	Strongly agree	112	46.86
		Agree	97	40.5
		Disagree	21	8.7
		Strongly not agree	9	3.7
10	It is order of parents or teachers to wash your hands. (n=239)	Strongly agree	24	10.04
		Agree	31	12.97
		Disagree	124	51.9
		Strongly not agree	60	25.10
11	If you fail to wash your hands you will be exposed to disease. (n=239)	Strongly agree	101	42.25
		Agree	40	16.7
		Disagree	50	20.92
		Strongly not agree	48	20.08

Table 3. Logistic regressions of factors affecting knowledge of hand washing among school children in GrimaBekele primary school, Hosanna Ethiopia April 2016.

Characteristics		Level of knowledge		P	COR (CI 95%)	P	AOR (CI 95%)
		Good (%)	Poor (%)				
Sex of student	Male	27(23.4)	88(76.6)	1	1.77(1.01-.3.13)	0.259	0.355(-1.329)
	Female	43(34.7)	81(65.3)	0.048			
Grade of student	1-4	48(49.02)	54(50.98)	1	(4.37-16.04)	0.000	8.70(4.36-17.36)*
	5-8	119(88.3)	16(11.7)	0.020			
Area of residence	Rural	9(40.9)	13(59.09)	1	4(1.62-.9.83)	0.171	0.461(0.15-1.39)
	Urban	158(73.7)	57(26.3)	0.003			
Educational status of mother	Illiterate	16(44.4)	20(55.6)	1	3(1.51-.7.26)	0.396	1.59(0.544-4.66)
	1-8	77(72.64)	29(27.36)	0.003			
	9 -12	39(78)	11(22)	0.002	4(1.73-11.32)	0.187	1.85(0.74-4.62)
	≥Diploma	35(77.7)	10(23.3)	0.506	4(1.67-11.45)	0.008	6.374(1.49-14.92)*

Factors that affect practice toward hand washing

From those factors that affect practice of elementary school children area of sex and grade of students are among the major ones (Table 5).

DISCUSSION

From those having information on HWWS, television (81, 33.9%) and teachers (77, 32.2%) are main sources of information followed by health extension workers (40, 16.7%) and family (23, 9.6%) in Girma Bekele Primary School. Compared with this study in Indonesia on hand washing practices among elementary school students, parents (91.86%), health workers (50.0%) and teachers (34.9%) are major sources of information (Ministry of Health (MOH), 2015).

This study shows that the main source of information is television followed by teachers. In South Africa, the main sources of information are teachers and television (Setyautami et al., 2012). This variation could be due to access to television and other media's role in the home of students. In Bangladesh, it is indicated that multivariate

Table 4. Practice of students on hand washing among GirmaBekele primary school children Hosanna, Ethiopia, 2016.

S/N	Characteristics	Category	Frequency (n)	
			Number	%
1	Have you washed your hands today?	Yes	237	99.2
		No	2	0.8
2	If yes for above question what material do you have used? (n=237)	Water only	33	13.8
		Soap and water	204	85.4
3	Why you don't wash your hand today?(n=2)	Lack of water	-	-
		Lack of time	2	0.83
		I do not found my hands dirty	-	-
4	Which one is more practiced to wash your hand in your family?(n*)	Towel	2	0.83
		Soap and water	188	78.7
		Water only	50	20.9
5	When do you wash your hands?	Before meal	205	85.7
		After meal	185	78.2
		After work	49	20.70
		After play	30	12.40
		After toilet	15	6.30
6	For how long duration do you wash your hand at a time?	For less than 30 s	47	19.7
		30 s-1min	37	15.4
		I do not know	155	64.9
7	In average for how many times you wash your hands per day?(n=239)	six and above six times	121	50.6
		Blow six times	111	46.5
		I do not know	7	2.9

Table 5. Logistic regressions of factors affecting practice of hand washing among school children in GrimaBekele primary school, Hosanna Ethiopia April 2016.

Characteristics		Level of practice		P	COR (CI 95%)	P	AOR (CI 95%)
		Good (%)	Poor (%)				
Sex of student	Male	81(86.9)	13(13.8)	1	1.87(1.75-4.89)	0.020	1.66(1.453-2.19)*
	Female	138(95.1)	7(4.9)	0.211			
Grade of student	1-4	48(49.02)	54(50.98)	1	3.92(2.36-5.06)	0.000	8.56(4.35-16.83)*
	5-8	119(88.3)	16(11.7)	0.010			
Area of residence	Urban	175(90.2)	42(9.8)	1	1.78(1.511-1.97)	0.044	0.337(0.116-0.973)
	Rural	8(36.36)	14(63.64)	0.012			

analysis of socio-economic factors including education of household head and respondent, water availability and access to media have strong positive association with hand washing with soap (Sibiya and Gumbo, 2013).

From the medical report of the students' families, diarrhoea accounts for about 39 (16.3%) and 59% of all cases. Even this large figure may be due to outbreak of acute watery diarrhoea in the past two months in the area it has direct or indirect relation with hand washing especially with soap. In rural Bangladesh it is stated that promotion of hand washing resulted in reduction of diarrhoeal disease (Ejemot et al., 2008). Study in Ariba Minch also showed that that the prevalence of diarrhoea was significantly associated with poor hand washing practice (AOR= 2.33, 95%CI =1.80, 4.15) (Ejere, 2004).

Knowledge about hand washing

From the study participants 158(66.1%) have information on global hand washing day but only 3 reported the exact month in which global hand washing day is being

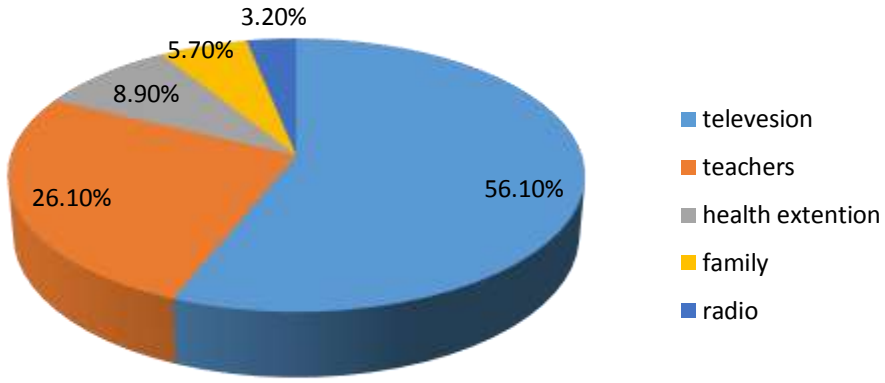

Figure 1. Source of information on global hand washing day among GrimaBekele primary school students, 2016.

celebrated; the main sources of information about global hand washing day are television (89, 56.3%), teachers (41, 25.95%) and health extension workers (14, 5.9%). This finding is better than that of South Africa where almost all the students do not have information on it and lack clue on global hand washing month (Sibiya and Gumbo, 2013). Even if there is time discrepancy between the studies, this study shows better exposure for media.

Of the students who participated in this interview in GrimaBekele primary school, 167 (69.9%) and 72 (30.1%) students had good and poor knowledge about hand washing respectively (Figure 1). When we compared this with knowledge of students report in University of Sri Jayewardenepura (77%), (Provincial Infectious Diseases Advisory Committee, 2014) the level is lower in the school showing slight variation of current study students. But it was better with the case of Northern Shoa of Ethiopia where about 52% of the students were classified as having adequate knowledge of proper hygiene including HWWS (Sibiya and Gumbo, 2013).

Of all the school students in GrimaBekele primary school, 233 (97.5%) know that unclean hands is a way of transmitting germs and 167 (69.9%) know that human faces contains disease causing microorganisms; 70 (29.3%) and 6 (2.5%) students do not know that the presence of disease causing microbes in faecal matter and unclean hands are a way of transmitting disease respectively (Figure 2). When we compare this with Bangladesh where 83% of the total respondents are aware that unhygienic practices facilitate growth and transmission of 'germs' (Akter and Ali, 2014) is lower. In Angolale of Ethiopia the importance of hand washing after defecation was witnessed by 75% of students who participated while the majority of the participants reported that hand washing before and after meals was important (Sibiya and Gumbo, 2013).

The benefit of washing their hands using clean water and soap was reported for promotion of health (108, 45.2%), prevention of disease transmission (83, 34.7%) and to be beautiful (39, 16.3%). Studies also show that there is association between healthy seeking behaviour and sexual attractiveness concern on hand hygiene in Middle School of Delhi (Garg et al., 2013).

Overall, 167 (69.8%) and 72 (30.1%) students had good and poor knowledge respectively. In comparing this with the case of Northern Ethiopia with adequate knowledge of hygiene 52% (Vivas et al., 2010) in this school there was more number of students with adequate knowledge.

Attitude towards hand washing

Of the 239 students in GrimaBekele primary school, 142 (59.4%) and 97 (40.6%) had good and poor attitude respectively. In comparing this with study in South Africa with good attitude (91.40 ± 1.16%) (35), the level of attitude was less in this study. This finding is almost similar with finding from Lake Mereb District of Ethiopia with positive hygiene behaviour of 61.6% (Tadesse, 2000).

Practice of hand washing

Of the total respondent students in GrimaBekele Primary School, 237(99.2%) washed their hands in the morning of the interview day. From those who have washed their hands in the morning of the interview day about 204

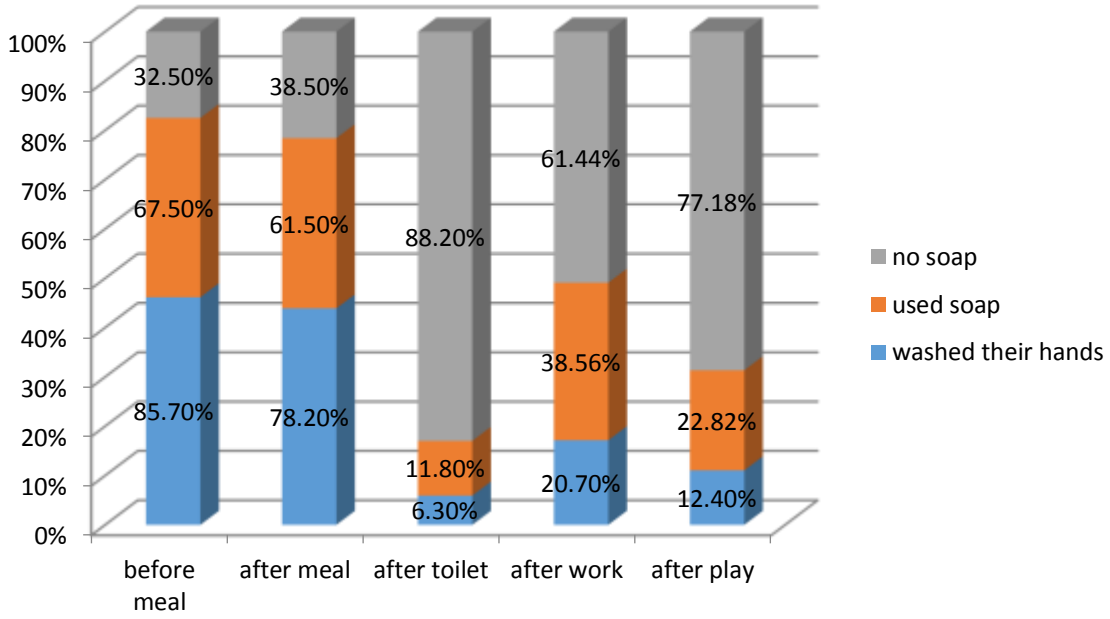

Figure 2. Hand washing times and soap utilization among GrimaBekele Primary school students, 2016.

(85.4%) reported the use of soap and the remaining 33 (13.8%) used water only to wash their hands. The practice is less than that of Ghana after toilet visit hand washing with soap (90.2%) (Tadesse, 2000); but better in comparison with that of Northern rural Vietnam where 319 (66%) students used soap to wash their hands (Thanh Xuan et al., 2013). Studies in northern Ethiopia also showed that nearly all participants reported washing their hands the day before the interview (99.7%), but only 36.2% of children reported usage of soap (Vivas et al., 2010). This good practice in the school may be due to awareness created by wash club in the school and different media but utilization of soap still needs more intervention.

Most students wash their hands before meal (205, 85.7%) and after meal, (185, 78.2%) whereas only 15 (6.3%) after defecation. This finding has similarity with finding from South Africa interims of most frequent practice of hand washing before meal (Sibiya and Gumbo, 2013), but practice after toilet visit in this school is lower than that of South Africa. In Vietnam, the common time for hand washing was before eating (60%) and after defecation (23%) (Thanh Xuan et al., 2013). In Babile town Ethiopia, 98.3% of the children regularly practiced hand washing before meals (Monney et al., 2014). This shows better practice of hand washing in the school but those students fail to wash their hands prior to meal 32 (13.5%), after toilet visit and those that do not use soap are at high risk for food born disease.

On duration of hand washing, 155 (64.9%) do not know how long duration they wash their hands at a time and of the remaining, 84 students 47(19.7%) and 37(15%) said they used <30 s and 30 s-1 minto wash their hands respectively. The finding of inspection in Vietnam reveals that only 10 out of 319 school children who performed in required demonstration protocol (Vivas et al., 2010) strongly agree with this self-reported practice in the school. The percentage of students who report practice of washing their hands at recommended times (30-60 s) was only 15.1%. In comparison of the case with 58% in Vietnam, (Vivas et al., 2010) the duration of hand washing once a time is very low in the school students; this may promote transmission of disease causing microbes from wet hand and increased number of residual micro-organisms on hand.

The frequencies of wash per day show that the hand washing practice is mainly related with meal times. Overall, 172 (71.97%) of students had good practice and 67 (28.03%) had poor practice toward hand washing. From those factors that affect practice of elementary school children are area of residence, availability of hand washing materials and grade and sex of students are among major ones.

Females were 2 times [AOR, 1.66; 95%CI (1.45-2.19)] more likely to have good hand washing practice than that of males. This could be more concern of females toward hygiene and beauty issues (Tadesse, 2000). Students in the second cycle were 8 times more with AOR, 8.56; 95%CI (4.35-16.83) to have good practice than those in the first cycle. This finding has similarity with more common correlates of self-reported HWWS with increasing grade level of students in Vietnam [Grade 4

vs. grade 1: odds ratio (OR) =4.14 (2.00-8.56), grade 7 vs. grade 1: OR=7.76 (3.67-16.4) (Thanh Xuan et al., 2013).

Conclusion

Majority of the study subjects have adequate knowledge about hand washing and about more than half of elementary school children have good attitude. Majority of the students were not using soap even though they report having soap in their home. Hand washing with soap is also under reported practice after defecation. Maternal educational status, area of residence, age and sex of student, grade of student and availability of hand washing materials are among factors that affect KAP of school children toward hand washing with soap.

RECOMMENDATIONS

The school should have to provide basic information to improve knowledge attitude and practice of the students on hand washing. Wash club in the school should have to go further to improve accesses of hand washing facilities at school. Therefore, other associated factors like hand washing habit of food handlers at home like mothers and/servants, conditions in the school including play environment, interpersonal contacts including shaking hands, observation of accessibility and availability of hand washing facility at home and other related factors should have to be investigated to come up with better findings with possible intervention.

CONFLICT OF INTERESTS

The authors declare that they have no conflict of interest.

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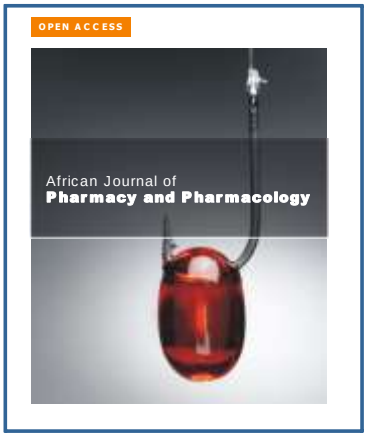

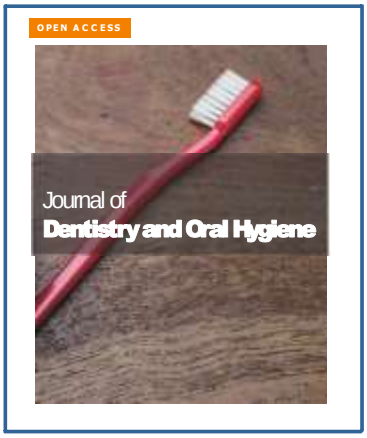

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