Assessment of Affordability and Associated Factors of Medicines to Treat Diabetes Mellitus in Public Hospitals Outpatients of Bale Zone, South-Eastern Oromia National Regional State, Ethiopia 2018

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Abstract

Background: As Diabetes Mellitus is one of the leading cause of morbidity and mortality in the world today and specially in sub Saharan Africa including Ethiopia, there is no data available that shows the affordability of diabetic medicines and associated factors to the best of investigator's knowledge. So the aim of this study was to assess the affordability and associated factors of medicines prescribed for diabetes mellitus for patients treated in public hospitals outpatients of Bale zone.

Methods: Facility based cross-sectional study was conducted by using interviewer administered structured questionnaire to patients for affordability study in four public hospitals: namely Ginnir, Robe, Delo Mena general hospitals and Goba referral hospital in Bale zone from August 13 – September 02, 2018. 404 diabetic Patients attending hospitals outpatients were determined by single population proportion formula and consecutive sampling procedure was employed. The data was collected on type of medicines, sociodemographic characteristics of the patients and price of medicine on local language and entered to Epi data version 3.1 for clearance of the error and then exported to SPSS version 20.1 for analysis. Descriptive statistics, bi-variable and multi-variable logistics regression analysis was employed. Ethical clearance was obtained from Institutional review board of Jimma University Institute of Health

Result: The affordability of patients who use injection type medication decreased by the odds of 77% relative to those who use oral medication [AOR=0.23, 95%CI=0.14-0.39]. The affordability of the patients with educational level primary school is affected(reduced) by the odds of 57% with [AOR=0.43,95% CI=0.23,0.79], while the affordability of patients with no formal education is more affected by the odds of 0.72[AOR=0.28, 95%CI=0.15-0.52].

Conclusions: The study revealed that majority of patients do not afford the medicine and the affordability of diabetic patients to buy their medicine is affected by the type of medicine and level of education. Therefore, this required intensive efforts by government and partners as well as hospital managements to achieve the affordability of diabetes medicine

Key words: - Affordability, diabetes mellitus, Bale zone

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Abbreviations

CVD	Cardiovascular disease
DDD	Defined daily dose
ETB	Ethiopian Birr
DM	Diabetes Mellitus
HAI	Health action international
LMIC	Low and middle income countries
NCD	Non-communicable disease
NHA	National health accoount
OOP	out of pocket
PURE	Prospective Urban Rural Epidemiological
SPSS	Statistical package for social science
SSA	Sub Saharan Africa
STG	Standard treatment Guideline
WHO	World Health Orgnization
LPGW	Lowest paid government worker
DALY	disability adjusted life year
OPD	Outpatient department

CHPTER 1. INTRODUCTION

1.1 Background

Medicines are used for prophylaxis, treatment and diagnoses of disease and access to medicine is therefore central in health service delivery. Among the Global Action Plan and Monitoring Framework developed by WHO medicines target for non-communicable diseases is 80% availability of affordable basic technologies and essential medicines including generics required to treat major non-communicable diseases (NCDs) (which the DM is the major one and even risk factor for some of other diseases) in both public and private facilities(1).

The rapidly increasing urbanization and life expectancy have been associated with rapid economic development, ageing populations, reduced physical activity and unhealthy diets which increases the burden of chronic diseases such as diabetes. It is estimated that globally diabetes will affect approximately 642 million people by 2040, mostly among adults of age 20 years and above(2). The most important segment of the population who are in productive age are also in this risk group and pharmacological treatment is mandatory that not only to treat and control high blood glucose level but also to reduce the development of other cardiovascular diseases for which DM is risk factor(3).

Among chronic non communicable disease particularly diabetes is the leading cause of morbidity and mortality around the world(3) and particularly in Sub Saharan Africa(SSA). The burden of these diseases in Sub-Saharan Africa threatens the gains made in health by the major international effort to combat infectious diseases(4).

Access to healthcare is a fundamental human right that has been enshrined in international treaties and recognized by governments around the world(5). Universal access to health depends on access to affordable essential medicines and health technologies. It is known that quality-assured essential medicines should be available at all times in adequate quantities, and at a price that both individuals and the community can afford(1)(6).

Affordability have been expressed by previous studies by comparing the cost of the medicine with the number of day's wages the lowest-paid unskilled government worker needs to purchase one month's supply of medicines according to a standard treatment regimen(1,7,8) but, the study by Attaei and others on availability and affordability of blood pressure-lowering medicines and the effect on blood pressure control in high-income, middle-income, and low-income countries differently considered the affordability as the ratio of total monthly cost of the lowest cost

medicines to the households' monthly capacity to pay (by subtracting basic subsistence needs of household expenditure on food, from monthly household income) and less than 20% was considered affordable (9).

The Studies have repeatedly documented high prices and poor affordability of key essential medicines for non-communicable diseases in many low and middle-income countries (LMICs) both in the public and private sectors(1).

Due to the overall dynamics of time, global region wealth difference and the policy difference between countries, the affordability of medicines to treat DM differs though they didn't quantify recent studies indicate there is huge disparities regarding affordability of medicine to treat diabetes among countries and affordability is far lower in the lower income countries(9).

1.1.1. The concept of affordability measurement.

There are different approaches to measure affordability and each of the approaches have their own limitation and can be measured at macro(country) level and micro(household) level. Considering the micro level estimation of affordability, there are two basic approaches generally used to estimate affordability of a good/service. The "catastrophic" approach and the "impoverishment" approach. The impoverishment approach focuses on the residual income after an expenditure. Under the "catastrophic" approach, the payment for a commodity is deemed unaffordable when it exceeds a certain proportion of a household's resources. The idea is that if a household spends a large fraction of its available budget on a specific item, it will have to reduce its consumption of other goods and services. It relies on the ratio of expenditures for a good under consideration to the total household resources. The limitation of this approach is, what is that ratio which separates the affordability and unaffordability of a good is subjective(10).

The "impoverishment" approach considers the poverty line and the absolute quantity of available resources before and after payment for a commodity. If the household is initially above the poverty line but drops below it after paying for the commodity, it can be said to have been impoverished by the payment. The method is clearly more specifically focused on the poor within society, as the closer the household to the poverty line, the more likely it is that certain expenditures will push the household below it. The limitation of this approach is where to fix the poverty line(10,11).

Overall both approaches can be used by changing the threshold that can help to study the sensitivity of outcome(affordability) to different scales of thresholds and finally in order to incorporate the

equity issues and income distribution in measure of affordability that "the wage of the lowest paid unskilled government worker (LPGW)" developed by World Health Organization(WHO) & Health Action International(HAI) in 2008 is to calculate the affordability of medicines(2,5,8,10,11).

1.2 Statement of the problem

In Ethiopia in 2015 diabetes with other NCDs (cardiovascular diseases, cancer, and mental and substance use disorders) accounted for 30% of the total disease burden in the country that measured in age-standardized DALY rates. Among this, diabetes was the ninth leading cause of premature death and disability and caused 1106 disability adjusted life year lost (DALYs) per 100,000(12).

The study by Chipo Mutyambiz on cost of diabetes mellitus in Africa reveals that annual national direct costs of diabetes differed between African countries and ranged from $3.5 billion to $4.5 billion annually with the most common expenditure were drug costs in which the highest burden due to the costs associated with diabetes was reported in individuals within the low income group(13).

Many patients with diabetes do not adhere to their medication regimens, taking the medicine less frequently than prescribed or discontinuing it entirely that out-of-pocket costs are an important barrier to adherence to diabetes medications (14). In line with this the qualitative study conducted on "Assessment of health system challenges and opportunities for possible integration of diabetes mellitus and tuberculosis services" in South-Eastern part of Amhara region also reveals that almost all respondents stated that DM drugs are unaffordable to them. As a result, patients do not take the full course of medication as prescribed by the doctor. They usually take under dose so that they can use the drug for longer time which affects adherence and consequently the blood glucose control which leads them to diabetic complication(15)

Most of the drugs used to treat diabetes in Ethiopia, especially innovator brands are imported from foreign countries and this by itself can affect the affordability(16). On the other hand adherence to diabetes medications is associated with poor prognosis and cost-related non adherence is a major contributor that is directly related to affordability of medications(17).

People with chronic diseases pay for treatment out of pocket because insurance coverage of the country is very low. This exposes the patients to catastrophic expenditure and impoverishment or

discontinue the treatment due to gap in access of the drug whether the drugs are unavailable or unaffordable to them(18) and in line with this 5th Ethiopian national health account(NHA,2015/16) -Household Health Service Utilization and Expenditure Survey revealed that the total coverage of Community Based Health Insurance is only 7.4% which shows us majority of the population pays out of their pocket for treatment that can affect the affordability of medicine and indicates the magnitude of affordability of those patients paying out of pocket left to be assessed (19)

Though public health facilities provide the lower average cost than private drug outlets, lack of availability in the public sector may force patients to purchase their medicines in the more highly priced private sector or forgo treatment altogether(1,20).

As study done by Stephan and others in 2016 indicates impoverishment due to OOP direct medical costs by diabetes mellitus among top 20 leading causes of death including infectious diseases and maternal and neonatal condition in Ethiopia ranks 12th and resulted in 3500 poverty cases(21)

The study conducted by Fisseha and Senthil on the outpatients of Bale Robe hospital(one of the facilities in this study) on retrospective assessment depending on OPD registration log book starting from 2015-2017 reveals that among all cases treated in the outpatient department of the hospital diabetes mellitus reaches the prevalence of 1.43% and considered as a burden in the locality(22).

Despite the prevalence of the diseases another community based study by Chanyalew and Alemayehu in Bale Zone administrative towns (Robe, Goba and Ginner) all of towns which the hospitals in this study are found in, recommended that great emphasis should be given on health education regarding symptoms and risk factors modification for diabetes are necessary due to considerable limited knowledge, attitude and practices were seen that can aggravates the burden of the disease in general and finally leads to the demand of diabetic medicines hence affordability(23).

Up to the best search of the investigator there is no any costing studies and overall the affordability of medicine for DM in public hospitals of Bale zone is not known. Thus, this study will be the base line for studies regarding the access to medicine for this chronic disease. On the other hand, there is no public community pharmacy to support the needy people when the public health facilities run

out of stock of medication to treat diabetes mellitus and only one red cross pharmacy in Goba town; and thus intensified the problem of affordability of medicines to treat diabetes mellitus.

1.3 Significance of the study

This study provides insight for the affordability level of the medicine to treat diabetes mellitus in selected hospitals and also reflects the supply status on the spot of study period. The finding from this study may inform the health facility management to come up with prioritization care for diabetes for affordability of medicines which otherwise leads to discontinuation of treatment or catastrophic expenditure and have impact on subsequent improvement of adherence to medicine for better and that life-long pharmacologic (medicine) therapy. This will also contribute to the reduction of unacceptably stock out associated with low availability of medicines in the public hospitals which leads patients to purchase their medication from private drug outlets that may end up with poor affordability of the medicine.

Besides this fact, there were inadequate availability of data that shows the affordability of those medicines in the study area. So this study proposed to assess the affordability of essential medicines to treat diabetic patients in the Bale zone public hospitals so as the consecutive studies will build up their findings as baseline on.

This study can also provide important information for the promotion of financial risk protection (health insurance) which is on the level of low coverage as shown by 5th National Health Account (NHA) (2015/16) only 7.4% of total population covered, and subsequent design of health policies toward universal health coverage, reduction of direct OOP payments, and finally contributes to affordable medication and diabetic care in general(19).

Studies repeatedly show that the largest share of direct cost of diabetes mellitus treatment and care is the cost of medicine(13), but didn't address the issue of affordability by comparing the cost with their income. Therefore, this study aims to show the level of affordability of the diabetic patients relative to their income per-capita to reveal the relative ability to pay despite the level of the cost.

CHAPTER 2: LITERATURE REVIEW

Among the NCDs diabetes with consequential cardiovascular diseases, have reached epidemic proportions worldwide, and disproportionately affect low and middle-income countries where the disease burden is high and conversely the affordability of medication to treat these diseases is low when compared to high income countries(1,20,24–26). Due to these reason nearly 80% of deaths from chronic diseases in which diabetes mellitus is among the leading diseases, occur in low and middle income countries(25).

Ethiopia is one of the low income countries and especially among the Sub Saharan African countries where the disease burden lies while the affordability of medication for this diseases is low and overly relying on out-of-pocket (OOP) payments to finance the health system that pose a huge financial burden on households, forcing them to receive healthcare at the expense of other essential needs such as food and education (7).

Out of pocket payments at the point of service delivery may force households to delay or abandon some or all health services that people need and at times, household members may be forced to adjust work schedule, downgrade living conditions disrupt children's schooling and also divert them to visit unrecognized health professionals or traditional healers(6).

2.1 Affordability of Medicines for Diabetes

A number of studies which assessed the affordability of medicines to treat NCDs measured the measured the affordability in similar way of measurement which was used by WHO and HAI in their methodology to measure medicine affordability as number of days' wages needed by the lowest-paid unskilled government worker to purchase standard treatments (since chronic disease the amount of medicines to be used for one month)(1,7,24,27,28).

The Prospective Urban Rural Epidemiological (PURE) Studied by Attaei and others between January, 2003 and December, 2009 on Availability and affordability of blood pressure-lowering medicines and the effect on blood pressure control in high-income, middle-income, and low-income countries measured the affordability as deemed affordable if the total monthly cost of the lowest cost medicines was less than 20% of households' monthly capacity to pay. There is part of population which could not have constant monthly income and earn less than that of the lowest-paid unskilled government worker. Therefore, the study by Attaei and others allows the estimation

of affordability as comprehensive study for every segment of the population and for inter-household difference comparisons(9).

Though the similar method (by lowest paid government method) studies show that affordability of medicines to treat chronic diseases like diabetes is low in lower income countries when compared with middle income and high income countries for larger segment of population which rely on the out of pocket payment (the type of major health financing system in low income countries like Ethiopia) apart from those who have insurance (1,9,25).

2.2. Conceptual framework of diabetes mellitus medicine affordability

The conceptual framework for affordability was adopted from housing affordability conceptual framework which put the factors affecting housing as production, exchange and consumption. Therefore, the affordability of medicine is similarly needs the dynamic interplay of those three dimensions, the way of health product provision, payment mechanisms and the purchasing power of patients/households that can be determined by socioeconomic and sociodemographic factors of the patients(29).

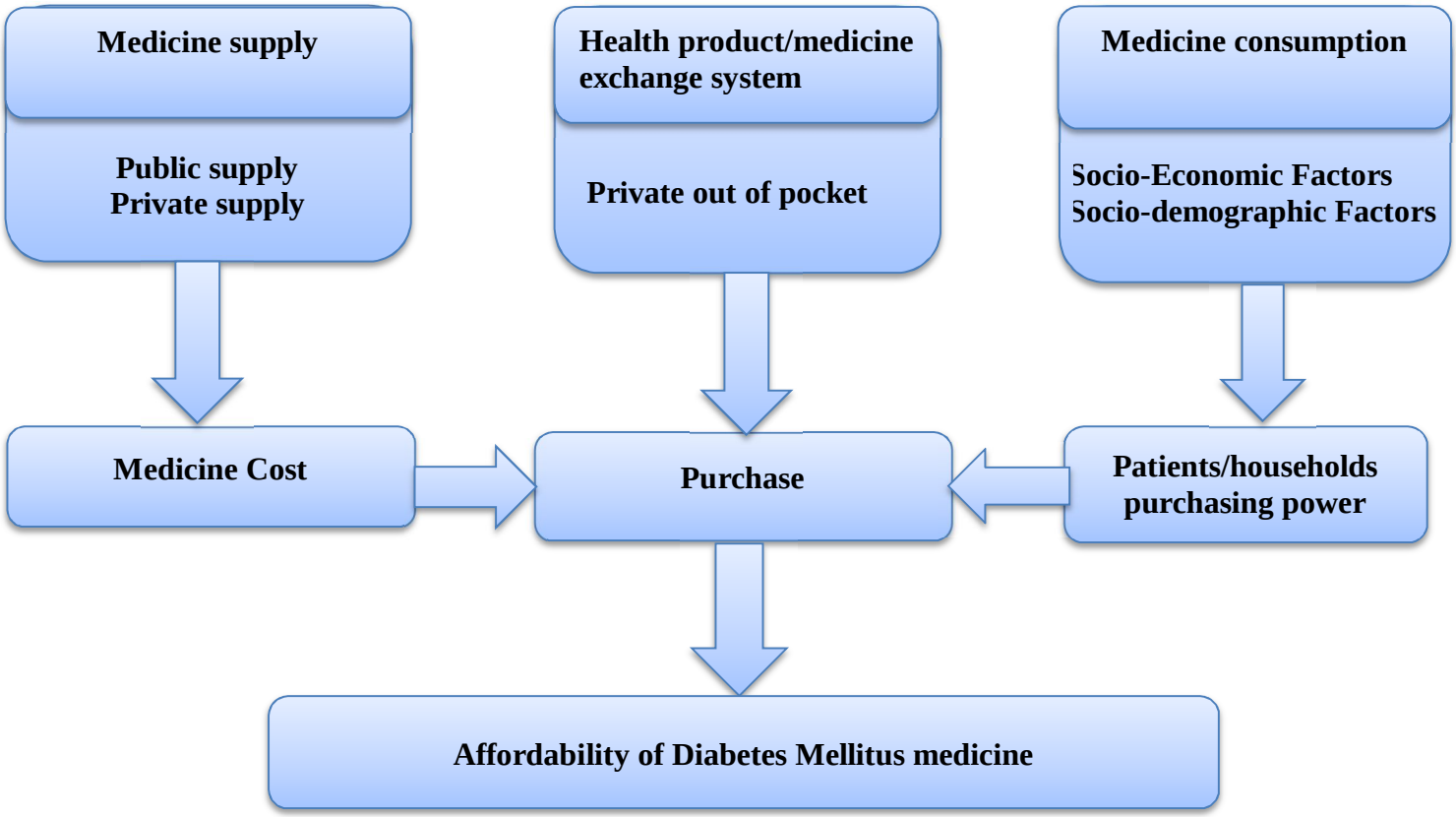

Figure 1 Conceptual framework of Affordability of medicine to treat DM (adopted from(30))

CHAPTER 3: OBJECTIVES AND HYPOTHESIS

3.1 General Objective:

To assess the affordability and associated factors of medicines to treat diabetes mellitus in public hospitals out patients of Bale zone in August 2018

3.2 specific objectives:

- To assess the affordability of medicines for patients to treat diabetes mellitus in public hospitals outpatients of Bale zone
- To assess factors associated to affordability of diabetic medicine for patents attending those hospitals.

CHAPTER 4: METHODS AND MATERIAL

4.1. Study area and period

The study was conducted in Bale Zone, Oromia national regional state, south east Ethiopia from August13-September 2, 2018. There are 20 rural woredas (districts) in the zone and 1 city administration (Robe town) is being the capital city of the zone which is located 430km away from Addis Ababa. The zone has the area of 43, 690.56 sq.km. and share border on the south by Ganale river which separate from Guji zone, on the west by the West Arsi Zone, on the north by East Arsi, on the northeast by Wabe Shebelle river which separate from West Hararghe and East Hararghe Zones, and on the East by the Somali region. The total population of Bale zone is approximately two million and the major economic activities of the zone is agriculture, which is farming, mixed farming and raring of domestic animals and to less extent trade.

There are 4 hospitals and 84 health centers in zone (Bale zone health department 2010 E.C. Plan). The study was conducted in Bale Robe, Dello Menna, Ginnir general hospitals and Goba referral Hospital.

4.2. Study design

Facility based Cross-sectional study design was conducted.

4.3. Population:

4.3.1 Source population

- All diabetic patients treated in four hospitals in Bale zone.

4.3.2 Study population

- All diabetic patients who have been attending the chronic care in public hospitals of Bale Zone during study period.

4.3.3 Inclusion and Exclusion criteria

4.3.3.1 Inclusion criteria

- All diabetic patients who have been attending the chronic care in four hospitals out-patients of Bale Zone.

4.3.3.2 Exclusion criteria

- Pregnant women (gestational diabetes), admitted patients, newly diagnosed patients and patients whose costs covered by insurance.

4.3.3.3 Selection of drug outlets

Public hospitals found in Bale zone. The private drug stores/pharmacies were also included due to patients referred to and visit nearby private drug stores to purchase the medicines when there are medication stock outs from public facility and intended to consider the cost for determining the affordability of those patients using the private drug outlets.

Table 1: The list of private pharmacies

S.N	**Location**	**No.of pharmacies**	**No. of drug stores**	**No. of Rural drug vender**	**Total in the town**
1	Robe Town	1	22	1	24
2	Goba Town	2	7	0	9
3	Ginnir Town	1	7	3	11
4	Delo Mena	0	3	1	4
Total		**4**	**39**	**5**	**48**

4.3.3.4 Selection of Medicines

Selection of medicine was based on perspective of potential impact on the burden of the disease that depends on the standard treatment guideline(STG) of Ethiopia and WHO/HAI methods which was based on the WHO core list of essential medicine for chronic disease.

Table 2: list of medicines for diabetes.

	Diabetes medication	
S.N	**Drug**	**Dose**
1	Insulin human (intermediate acting)	100unit/ml in 10 ml
2	Insulin soluble (regular)	100unit/ml in 10 ml
3	Glibenclamide	5 mg tablet
4	Metformin	500 mg tablet

4.4 Sample Size and Sampling Procedure

4.4.1 Sample size.

There were no previous data available on affordability of medicines to treat DM. Therefore, using the assumption that 50 % of the patients can afford the price of medicine and single population proportion formula with confidence level of 95% and 5% margin of error was employed to determine sample size.

$n= (Z \alpha/2)^2 p (1-p)/d^2$

- n is the maximum possible sample size
- $Z_{\alpha/2}$ is standard score value for 95 % confidence level for two sides normal distribution
- P = (50%) is the assumption of proportion of diabetic population who afford the price of medicine.
- d = is margin of error which is 5%

$$\frac{(1.96)^2(0.5(1-0.5))}{(0.05)^2} = 384$$

By adding 5% non-response rate the final sample size was 404

4.4.2 Sampling technique

The number of DM patients attending diabetic care in those selected hospitals in one month was obtained from each hospital prior to study. The proportional allocation method was made for each hospital. Total DM patients who attend the respective facility was considered as sampling frame for each hospital. But due to time constraint, sequential sampling and interviewing of patients as their arrival at point of care which is exit interview was used up to the final sample size reached.

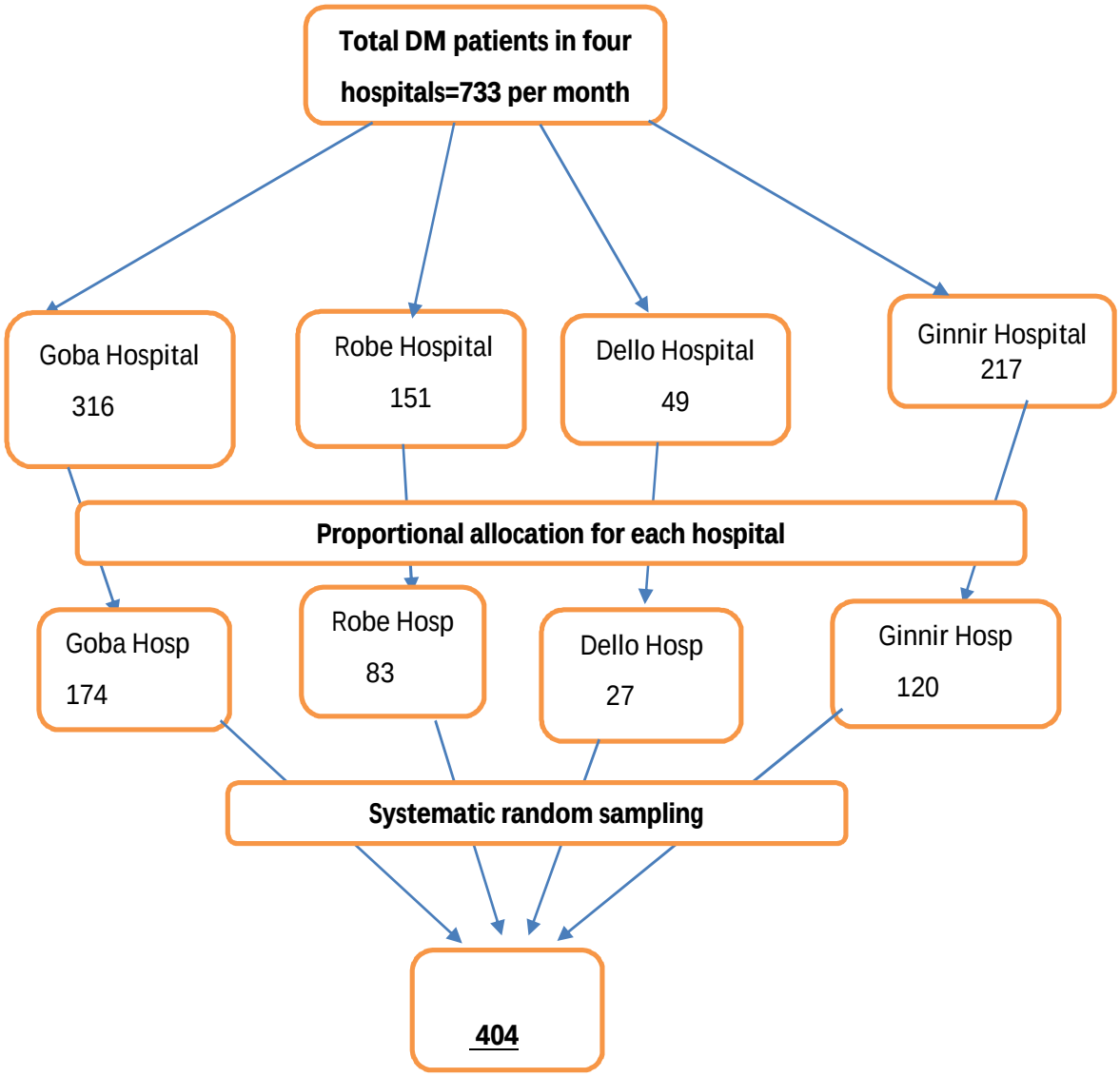

Figure 2: Proportional allocation of sample size to each hospital

4.5. Data collection tools and procedures (Instrument, personnel, data collection technique)

4.5.1 Data collection tool.

The tool was developed by reviewing different literatures on socio economic and demographic characteristics of patients as well as cost of the medicine, standard treatment guideline of Ethiopia and WHO core list of essential medicine to treat chronic disease(DM) for selection of medicine. Major components of the tool include structured questioners regarding socio-economic, socio-demographic and the type of medication they use as well as the quantity of each medicine depending on defined daily dose of each medicine and their cost(31)(23).

4.5.2 personnel

Four data collectors; 2 B.Sc. pharmacy professionals, 2 B.Sc. nurse and three supervisors; 2MPH holders and one pharmacist were trained and assigned to health facility (out of their regular working facility for data collectors) in four towns namely Ginnir, Robe, Goba and Dello Menna where those selected public hospitals are located. Training was given for both data collectors and supervisors regarding objective and the level of effort to be made to maintain quality of the data by supporting with practical demonstrations of data collection in order to get the accurate data.

4.5.3 Data collection technique

Interviewer administered structured questionnaire for Socio-economic and socio-demographic characteristics of the patients and cost of the selected medicines for affordability at four public hospitals was conducted.

4.6 Study variables

4.6.1 Dependent variable

Affordability of medicines to treat diabetes mellitus

4.6.2 Independent Variables

Age, sex, education, residential place, occupation, relationship/roll in the family type of medicine, comorbidity.

4.7 Operational definition

Urban: Is a town where those study facility (hospitals) are found in (Goba town, Robe town, Ginnir town and Delomena town)

Rural: All residence area of the patients in the catchment area of those hospitals different from those four towns (in which study hospitals are located) including all small towns found in the zone

Affordability = Cost of diabetes medicine/income per-capita

Definition of Affordability

Affordability is a normative term and can be viewed differently by different individuals that can be explained by mainly two approaches: Catastrophic method and Impoverishment method, in the case of medicine the third method which is the lowest paid unskilled government worker method developed by WHO. All methods have their own strength and drawbacks which made them to be chosen circumstantially depending on the fit of the method to the title and area of interest. In this study the Catastrophic method is the approach of the study while the lowest paid unskilled government worker is also considered for discussion purpose(10).

By using the catastrophic method approach, the payment for the DM medicine is deemed "catastrophic" (unaffordable) when it exceeds a 20% of a household's resources, in the case of this study monthly household's income per-capita. The idea is that if a household spends a large fraction of its available budget on this medicine, it is forced to reduce its consumption of other goods and services. Though wide applicability it is not without limitation that how different thresholds are being used and

appropriate for a given area or country is lent itself to subjectivity or normativity of the method(9).

The "impoverishment" method takes the absolute quantity of available resources before and after payment for a commodity under the consideration. If the household is initially above the poverty line but drops below it after paying for the commodity, it can be said to have been "impoverished" by the payment. In the case of this study (with short life span) gathering the data on all available resources from households is difficult and moreover, the cost of medicine is being continuously incurred in monthly bases that even for their lifelong they will continuously have exposed to the expenditure which the impoverishment status of the households cannot be determined at a given specific point in time. Therefore, the study of affordability by this method is best fit to assess the

affordability of assets like buying house and car which will happen only at a given point in time that enables as to determine the affordability of households' weather buying that asset pushes down them to below the poverty line(10).

The other method which has been used by WHO and Health Action International (HAI) is the wage of the lowest paid unskilled government worker to calculate the affordability of medicines. Such affordability has been expressed in terms of the number of days the lowest paid government worker has to work to be able to pay for a course of treatment of chronic disease usually one moth curse of treatment which depends on the defined daily dose of specific medicine for specific patient. This method is also subjected to a critique that it may tend to overestimate affordability, as substantial proportion of the population earns less than the lowest paid government worker. Eventually**,** affordability is the cost of treatment in relation to the consumers' income which is not more than 20 % of monthly income of the household after the food(basic) expenditure(9).

This in turn can be related to the definition of catastrophic health care expenditure WHO proposed that health expenditure be viewed as catastrophic whenever it is greater than or equal to 40% of a household's non-subsistence income, i.e. income available after basic needs have been met. In the case of total health care, the expenditure includes other non-chronic illnesses, laboratory investigations and direct non-medical cost. When we see this threshold only for medicine to treat DM is being considered that corresponds to a partial part of the total health care expenditure that catastrophic measurement cutoff point used by WHO. In conclusion this study used the catastrophic method to operationalize the concept of affordability (1) information on household income per-capita; (2) knowledge of the price of the medicines in question, and (3) a definition of "catastrophic expenditure"(32).

4.8. Data analysis procedures

After collection, the data was checked for completeness, edited, cleaned, coded and entered in to Epi-data version 3.1 and then exported to SPSS version 20.1 software. The analysis was done as frequency table and charts to measure the ratio of the price of medicines to the monthly income per-capita after the food expenditure for affordability by using different threshold scale to analyze the sensitivity of affordability to different income level of the patients. Each independent variable was taken in to and run by bi-variable logistic regression to check for their association, those variables

with p-value < 0.25 in bi-variable analysis were taken to multi-variable logistic regression. Then independent predictors determined by using p-value <0.05 and adjusted odds ratio with 95% confidence interval.

4.9. Data quality management

The data collection tool was prepared and translated to local language (Afan Oromo) and translated back to English by different language professionals to check for consistency. Actual data collection was preceded by pre-test of the material on 5% of sample size at Dodola hospital which is different from the actual study facilities and is similar in population and geographical area for assuring the quality of the data collection material. Then the collected data was not included in the analysis but used only for validation of the data collection material. The training was given for data collectors and supervisors and after the data collection procedure and approaches to patients were demonstrated and checked for the compliance of the data collectors to the training they received. Finally, Epi-Data was used for data entry in order to refine the error.

4.10. Ethical consideration

Ethical clearance was obtained from Institutional review board of Jimma University Institute of Health. Letter of cooperation to all concerned bodies was obtained from Bale Zone Health Department. Informed consent was obtained from each Hospital and from each study participants as well as care givers or their family in the case of children by informing the purpose of the study, its procedure and confidentiality of the information.

4.11. Dissemination plan

After approval from Jimma University institute of health, public health college, department of Health Economics, Management and Policy, the finding of this study will be presented to studied hospitals and Bale zone health department, regional health bureau and other concerning stakeholders like partners and nongovernmental organizations and finally the effort will be made to publish in scientific journal.

CHAPTER 5. Result

5.1 Sociodemographic and socioeconomic characteristics of the participant

5.1.1. Sociodemographic characteristics of the participant

A total of 400 Goba specialized, Dello Mena, Ginnir and Robe general hospitals respondents participated in the study with the response rate of 99%, but 4 (1%) of the responses were excluded from the analysis because of their incompleteness. From the total of 400 respondents 232(58%) were male. The age of respondents ranges from 8 to 90 with the mean age of 46.3(SD ±18) and 171(42.8%)were in the age range of 45-65. There were 27(6.8%) respondents from Delomena general hospital,119(29.8%) respondents from Ginnir general hospital,173(43.3%) respondents from Goba referral hospital and 81(20.25%) respondents from Bale Robe General hospital. Generally227(57%)of respondents were attending general hospital. Among the study participants, majority 224(56%) of them were rural resident. Relatively large number of participants is farmer 144(36%), while Daily laborer and others in common comprises only 2% of study participants.

Table 3: Socio-demographic characteristic of diabetic patients attending Bale Zone Hospitals, South east Ethiopia, August13-September 02/ 2018

Variable	**Category**	**Frequency(n=400)**	**Percentage**
Type of hospital	General Hospital	227	56.8
	Referral Hospital	173	43.3
Sex	Male	232	58
	Female	168	42
Age in year	<25	54	13.5
	25-34	49	12.5
	35-44	68	17
	45-65	171	42.8
	>65	58	14.5
Occupation	Farmer	134	36
	Marchant	32	8
	Housework	62	15.5
	Student	49	12.3
	Government work	32	8

Table 3: Socio-demographic characteristic of diabetic patients attending Bale Zone Hospitals, South east Ethiopia, August13-September 02/ 2018(*Continued*)

	NGO/Private(Employed)	12	3
	Retired	61	15.3
	Daily Laborer	6	1.5
	Other	2	0.5
Marital Stats	Single	31	7.8
	Currently married(monogamous)	291	72.8
	Currently married(polygamous)	8	2.0
	Divorced	7	1.8
	Widowed	34	8.5
	Not applicable(child)	29	7.3
Level of Education	No Formal Education	162	40.5
	Primary School	141	35.3
	Secondary and above	97	24.3
Relationship/roll in the house	House wife/Mother	141	35.3
	Husband/Father	188	47
	Son/Daughter	58	14.5
	Relative	10	2.5
	Other	3	0.8
Total number of family members(size)	≤5	207	51.8
	≥6	193	48.3

5.1.2 Socioeconomic characteristics of patients

More than half 248(62%) of patients' households earn less than mean 444.18 ETB. Regarding the cost that they incurred due to medicine, 133(33.3%) of patients paid greater than or equal to mean (132.00 ETB), while the rest pay less than or equal to mean.

Table 4:Socio-economic characteristic of diabetic patients attending Bale Zone Hospitals, South east Ethiopia, August13-September 02/ 2018

Variable	Category by mean	Frequency(n=400)	Percentage
Income per-capita after food	≤444.18	248	62
	>444.18	152	38
Cost of payment for DM medicine	≤132.0075	267	66.8
	>132.0075	133	33.3

5.2. Comorbidity profile of diabetic patients.

As per the report of study participants' majority of them 333(83.3) have only disease of the concern diabetes mellitus, but other non-communicable disease comorbidity than diabetes mellitus were seen on 67(16.8%) of patients. Among these, 61(91%) of patients have hypertension, 5(7.9%)of patients have asthma and 1 patient (1.49%) has cancer (colon cancer).

The distribution of comorbid(concomitant) disease among diabetic patients attending hospitals' outpatients is high among the older age group. For example, 43% of patients with age group greater than 65 years old have concomitant disease, 22% of patients within age group between 45 and 65 have concomitant disease while DM patients within age group less than 24 years have no concomitant disease. This is in line with the etiology of the occurrence of the diabetes which people develops at the older age. Comorbidities due to non-communicable disease is seen more in urban than in rural patients.

Table 5: Comorbidity profile by age group, sex and residence of diabetic patients attending Bale Zone Hospitals, South east Ethiopia, August13-September 02/ 2018

Variable	**Category**	**Other disease**	**Total**	
		Yes	Frequency(n=400)	Comorbid disease
Age	≤24	0	54	0
	25-34	1	49	2
	35-44	3	68	4.4
	45-65	38	171	22
	>65	25	58	43
Sex	Male	36	232	15.5
	Female	31	168	18.5
Residence	Rural	22	224	9.8
	Urban	45	176	25.6

5.3. Type of diabetic medicines prescribed and supplied to patients

From among four hundred patients, 120 of them were prescribed intermediate acting insulin, 120 Glibenclamide and Metformin, 57 intermediate and regular Insulin, and 8 patients were prescribed Glibenclamide alone. Regarding the supply of medicines from the hospital (where it was prescribed from) patients those who were prescribed both regular and intermediate acting Insulin were fully supplied from hospitals; among 120 patients who were prescribed intermediate acting insulin only, 118 patients got their medicines from the same prescribing hospitals while 2 of them couldn't find and sent to private pharmacies. Among patients those were prescribed both Metformin and Glibenclamide in combination, only one patient was supplied both drugs, 72 of them were supplied only Metformin while 47 of them were couldn't find both drugs from the prescribing hospitals. Unfortunately, patients who were prescribed only Glibenclamide as a single drug couldn't find the drug from anywhere. Finally, when we see the type of medication, 177(44.3%) of the patients prescribed injection form, while the rest use oral medicine.

Table 6: Medicines prescribed and percent supplied to diabetic patients attending Bale Zone Hospitals, South east Ethiopia, August13-September 02/ 2018

Type of Drug	**Number of patients**	**Drug supplied from hospital(n=400)**	**Percent supplied**
Intermediate acting Insulin	120	118	98
Regular and intermediate acting insulin	57	57	100
Glibenclamide	8	0	0
Metformin	95	62	65
Glibenclamide and Metformin	120	1, (*72only Metformin*)	0.8

5.4 statistical analysis

From the total number of study participants (400) due to the total absence of income after food which is to mean households completely use their monthly income for food consumption only, 10 study unit was treated as missing cases by SPSS, because of the nature of estimation of affordability as a ratio of expenditure(numerator) to the income(denominator). In case of this study the ratio of cost of DM medicine to the income per-capita after food at the 20% cutoff point(9). Therefore, those 10 patients were already considered as they are not affording the cost to buy their DM medicine. At the level of 20% cutoff point of their income including those reported as missing cases by SPSS the majority 278(69.5%) patients do not afford to buy their medicine to treat diabetes mellitus. In this case if the level of affordability threshold even taken to as high as 40% of income per-capita after food only half of the study participants can afford the medicine.

5.5. Association of dependent variable with independent Variables.

Using bi-variable logistic regression associations between affordability of DM medicine and socio-demographic, drug related and hospital related factors were analyzed. Thus in bi-variable logistic regression among socio-demographics: residence and level of education were associated with affordability of DM medicine at p-value <0.25, but marital status, occupation, sex, relationship in the household, family member with chronic disease as well as patient related factors like other concomitant disease, duration(length) of illness and treatment year were not associated with

affordability of DM medicine, while among drug related factors type of drug has association with affordability of DM medicine.

All variables those show significance in bi-variable logistic regression at p-value <0.25 were entered in to multivariable logistic regression. Type of drug, Level of education of patient and residence were left in multivariable logistics regression model. According to this study, the affordability of patients who use injection type medication decreased by the odds of 77% relative to those who uses oral medication [AOR=0.23, 95%CI=0.14-0.39]. The affordability of the patients with educational level primary school is affected(reduce) by the odds of 0.57[AOR=0.43,95% CI=0.23,0.79], while the affordability of patients with no formal education is affected by the odds of 0.72[AOR=0.28, 95%CI=0.15-0.52].

Table 7: Factors associated with affordability of diabetic medicines for patients attending Bale Zone Hospitals outpatients, South east Ethiopia, August13-September 02, 2018

Variable	**Category**	**Affordability**		**COR(95%)**	**AOR[a](95%)**
		Afford	**Not Afford**		
Residence	Rural	56	168	0.56(0.36-0.85)*	0.86(0.52-1.42)
	Urban♦	66	110	1	1
Education	No formal Education	40	122	0.35(0.2-0.59)*	0.28(0.15-0.52)**
	Primary School	35	106	0.35(0.2-0.61)*	0.43(0.23-0.79)**
	Secondary school & above♦	47	48	1	1
Type of DM drug	Injectable	29	148	0.27(0.17-0.44)*	0.23(0.14-0.39)**
	Oral Drug♦	93	130	1	1

*a -Adjusted for residence, *- significant at P value <0.25, **- significant at P value <0.05, ♦ Reference category.*

The statistical model is:

Logit(Y)=0.6-1.47X-0.85K-1.29N Where Y: Affordability of DM medicine

X: Injection type medicine

K: Primary level of education

N: No formal education

Logit (Affordability of DM medicine) =0.6-1.47(injection type medicine)-0.85(primary level of education)-1.29(no formal education)

The final model can be shown as follows:

$$P(Affordability = 1) = \frac{e^{0.6-1.47X-0.85K-1.29N}}{1 + e^{0.6-1.47X-0.85K-1.29N}}$$

Regarding type of medication, when the affordability of patients using injection (with odds ratio 0.23) is compared with those who use oral medicine, which means that a person who uses injection is only 0.23 times (i.e. much less) likely afford than a person who uses oral medicine, having allowed for educational level. When the inverse exp(B) is calculated, i.e. 1/0.23 = 4.35, it can be said that a patient who uses oral medicine affordability is 4.35 times the odds of a patient who uses injection type of medicine, having allowed for educational level. In the same manner when we compare the affordability of patients among educational level, a patient with an educational level of primary school only affords only 0.43 times the odds of a patient with educational level of secondary school and above. The inverse of this 1/0.43 = 2.33, which means a patient with educational level secondary and above affords 2.33 times the odds of the patient with educational level of primary school. Similarly, DM patients who have no formal education only 0.28 times the odds of those patients who have educational level secondary and above. The inverse of this is also show us patients with educational level secondary and above afford to buy their medicine 3.57 more the odds of those who have no formal education.

5.6 Sensitivity of affordability of patients at varying cutoff points of income

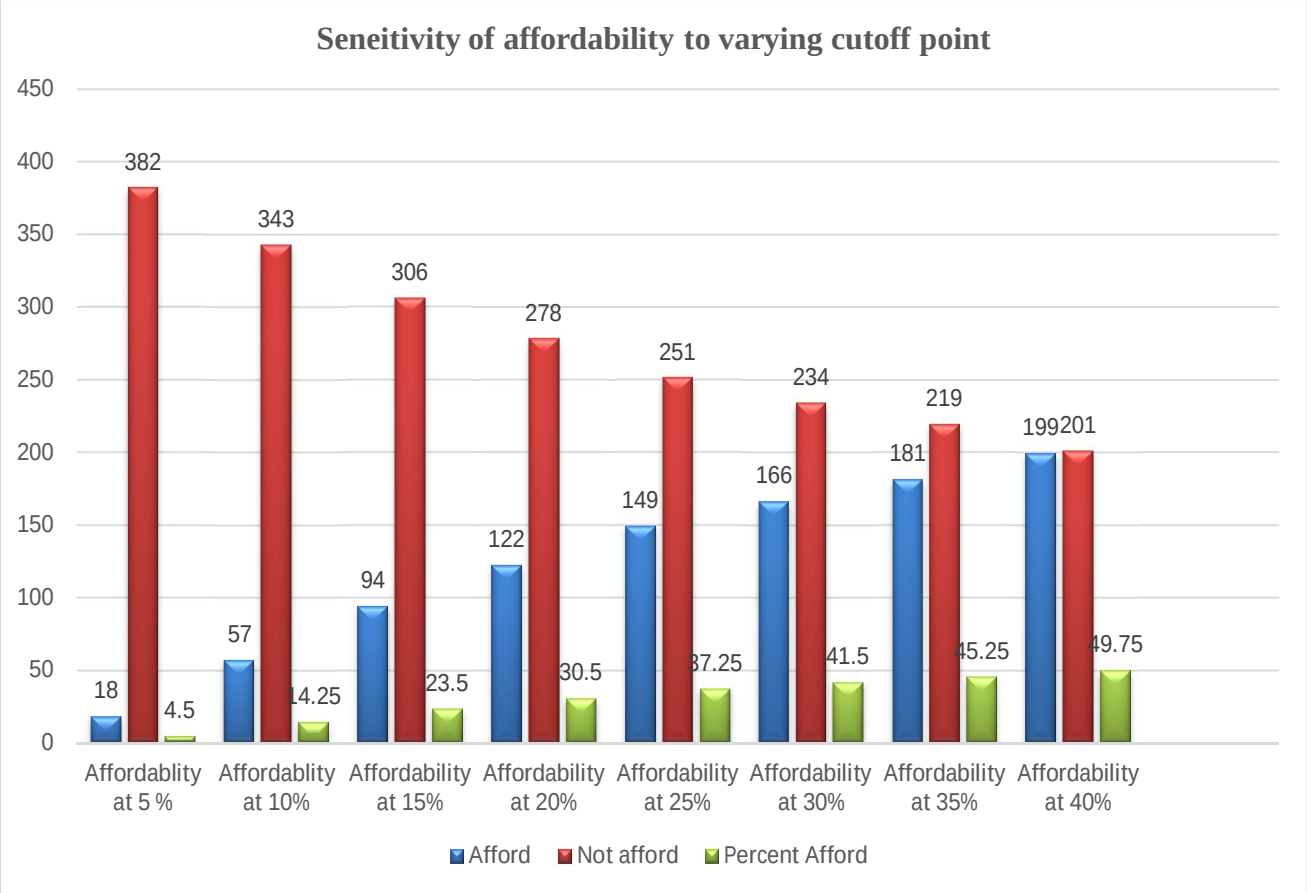

Figure 3: sensitivity of affordability at varying cutoff point of percentage drug expenditure to treat diabetes mellitus for patients attending Bale Zone Hospitals outpatients, South east Ethiopia, August13-September02, 2018

Affordability of the patients at 5 % of the threshold of their income per-capita after food is as less as 4.5% of study population, while more patients 30.5% afford at the threshold of 20% of their income per-capita after food. In such a way, when the level of threshold rises to 40% more patients enter to the affordable region of the cost(expenditure). In general, 69.5 % of study population have been paying for their medication that is catastrophic because they should not discontinue up to the level of their effort and being exposed to catastrophic expenditure.

Chapter 6. Discussion

Taking safe and efficacious medicine with the rational use in to consideration, access to medicines is influenced by many factors such as affordability, availability and sustainable financing and reliable supply systems. One of the elements restricting access to medicines is high medicine prices. This can have a detrimental effect on patients' health as well as the healthcare system in terms of lack of patient compliance with treatment and subsequent hospitalization for serious complications as well as inequitable healthcare. To increase access to medicines, one would thus need to ensure that medicines are affordable in order to counteract the existing barriers that might hinder medicine access.

6.1. Availability of medicine as a factor influencing affordability of medicine.

Affordability of a given commodity solely depends on the existence of the item itself without which we cannot say anything about it. The availability of medicine in public hospitals cannot be hundred percent fulfilled is known, and the government and hospital managements work for the best to avail the medicine for their respective need of the patients. There was availability problem of oral DM medicines (Glibenclamide and Metformin) in all four study hospitals especially Glibenclamide was not in the market of those towns (including private pharmacies) where study hospitals located at all. Metformin was supplied for 65% of patients for whom it was prescribed as a single drug. Therefore, this unavailability leads patients to search the medicine from elsewhere which eventually increases the cost and hence affects the affordability. One study participant of 60 age reported "*I left with the dose of four days and I will order my stock out medicine to bring from Adds. If I can't, I will come back to hospital and consult my doctor to switch the medicine as I did some time*". This indicates that the availability of medicine affects not only the affordability, but also the management of chronic follow up which may in turn exposes the patients to poor prognosis and eventually hospitalization that patients may incur even more unaffordable cost.

6.2 Sensitivity of affordability to different threshold.

When variables, those which are significant in multivariable logistics regression at 20% of household's capacity to pay (the cut off at 20% of the per capita income after food deduction) to different level of percentage of the drug expenditure was used to analyze the sensitivity of affordability at different level of income (5%,10%,15%,20%,25%,30%,35%,40%) shows that 95.5% of study population could not afford at 5% cutoff level of income per-capita after food. This

is to mean that if patients pay 5% of their income per-capita after food deducted (common basic necessity) for medicine those households will be exposed to catastrophic payment. Unexpectedly, when we see the affordability of those patients' households at the 40% cutoff point of their income per-capita payment for the medication 50.3%(more than half of study participants) will be still exposed to catastrophic payment.

The sensitivity of affordability is inherent to the varying threshold of income level that 2.5% of the study participant cannot afford to buy their medicine even above the zero price without affecting their need of food, while taking the threshold to as much as 40% still exposes more than half (50.3%) of study participant to catastrophic expenditure. When the threshold is taken down to 5% only 4.5% of study participants afford the price of medicine. By using this method, the level of the income of different individuals, communities and even countrywide level difference can be used differently in setting the level of threshold (cutoff point) to measure the affordability. This is mainly due to difference in the level of capacity to pay for commodities, for example setting the threshold of affordability at 5 % can take away all the income of a person when cost of the commodity is equal to the income of a Person, while others those who are wealthy can pay only less than 5 % of their income for the same commodity. On the other hand, if the threshold is taken up to 40%, those who's their income consumed by the cost of the commodity greater than 5% up to the maximum of 40% can enter to affordable region of the expenditure due to the same commodity. Therefore, the catastrophic method of measuring affordability of something differs between countries as their economic status differs and level of threshold for developing countries is thought to be less than those of developed countries thus the threshold is subjective.

Previous studies were measured affordability of medicine in different methods that the finding from those different methods differ and even had they applied on the same study unit the finding would have been different due to their difference in measurement. For example, study conducted in Jimma health centers in January 2011 measured the affordability of medicine by the perception of patients that medicines are affordable, fairly affordable and not affordable. In this case the perception of two persons with same economic status (capacity to pay) may differ and in the same way the perception of persons with the different capacity to pay may be the same which can be said the limitation of method as other methods also have their own limitation(18).

The other study conducted in East Wollega zone in January 2015 measured the affordability as many other studies on affordability and availability of medicine by Lowest Paid Government Worker method (WHO methodology) and found medicines were not affordable, since it takes more than one-day wage of Lowest Paid Government Worker(7). In this method also, as discussed in methodology part since there is substantial part of population earn less than the lowest paid government worker and this is confirmed by this study that 8(2%) of the study participants cannot be considered due to their household monthly income is less than that of lowest paid government worker (860 ETB). In the same manner the method concludes the unaffordability of the medicine for those who have relatively higher income that may have capacity to pay. In general, the lowest paid government worker method developed by WHO cannot show the inter-households difference in affordability, but generalizes the affordability by the days of wages needed by the lowest paid unskilled government worker.

Despite this level of unaffordability, in Ethiopia out of pocket-payments account for a significant portion of health care financing, wealth differences may cause differences in health care utilization and access which may in turn lead to (unfair) differences in health. Therefore, this study revealed the level of difference in affordability of medicine to treat diabetes mellitus that, there is a considerable difference in capacity to pay(affordability) of study participants that 10(2.5%) of them cannot afford the medicine even above zero price while others 18(4.5%) of them can afford the price of the medicine even when the threshold is taken to as low as 5% of their income per-capita (this is to mean when affordability is measured from the point of view of small portion of the income per-capita). In line with the qualitative study undertaken in South East Amhara region in 2014 those patients in this study whose especially their income per-capita after food is zero, when they fail to get the money they obliged to miss the medicine(15). In order to avert this problem concerned bodies (ministry of health, partners, diabetic association and patients themselves) should discuss the way to reduce the risk of catastrophic cost of medicine that can possibly leads to non-adherence and the consequences of hospitalization, which further exacerbates the catastrophe due to out of pocket payment at the point of care. As indicated in the systematic review study, cost of diabetes mellitus in Africa in 2017, out of pocket healthcare costs are a hindrance to healthcare access and could lead to catastrophic health expenditure and impoverishment in which the cost of drugs is the largest portion of total direct cost as high as 64% in Ethiopia(13).

Health insurance is a means of pooling risk across different population groups as a means of avoiding the financial burden of unanticipated and catastrophic conditions in health and it is a means by which individuals pay money to insurance companies to avoid the risk or uncertainty associated with ill health. Ethiopia's community based health insurance is already put in action and on progress, but social health insurance is still not implemented while its proclamation was approved by the House of People's Representatives in August 2010, and four months later the Council of Ministers approved the establishment and additionally a strategy document and operating manual were produced by the Federal Ministry of Health. Had it been put in to action social health insurance has the potential over that of the informal sector(voluntary health insurance which may have the adverse selection problem) to support people with low income(in formal sector because of its mandatory nature) and also beyond that contribute to population of the country in reduction of affordability problem and care of diabetes mellitus and hence medicine by the nature of the cross subsidization(33). Ultimately though the coverage of insurance is increasing, it is low as shown by the Ethiopian health accounts household health service utilization and expenditure survey undertaken in 2015/16 G.C. which is only on the level of 7.4% of the country's populations indicates that, despite the effort, there is a lot left to be done(19)

Chapter 7 Conclusion and Recommendation

7.1 Conclusion

This study reveals that there is affordability problem of medicines to treat diabetic mellitus that should be used lifelong. Patients who use injection type medication less afford than those who use oral medication. Patients with educational level below and primary school less afford to buy the medicine than those who have educational level secondary school and above. Unavailability of medicine at health facility also seen that might worsen the affordability of those medicine. In this study the independent predictors of affordability of medicines to treat diabetes mellitus are education level and type of medication.

7.2 Recommendation

Uninterrupted effort should be made to solve affordability problem in such a way that making a focus on both voluntary (community based health insurance) and mandatory (social health insurance) to increase the coverage of the insurance.

Therefore, this required commitments from all concerned bodies working on health care.

Accordingly: -

Ministry of health and Oromia Regional Health Bureau should focus on: -

- Increasing the coverage of community based health insurance
- Commencing the social health insurance as fast as possible.

Hospital management

- Should facilitate the availability of diabetes mellitus medicines through efficient logistics management system

Diabetic association.

- Should lobby for subsidized medication and affordable treatment cost at the point of care for diabetic patients
- Should strive to incorporate all diabetic patients as a member.

7.3. Limitation of the study

The sampling technique used in this study was non probability sampling technique, consecutive sampling method, this may affect the representativeness of selected study units to infer.

The study focuses only on the out patients and not include the complications of diabetes mellitus which involves hospitalization of the patients that may even leads to more catastrophic expenditures and other treatment expenses such as laboratory tests and supplies needed for diabetic care.

Most medicines which were stock-out from hospitals during the study period were couldn't take in to cost because of unavailability from the market, patients may buy at the time the medicine comes in to the market even after week.

Different countries may use different thresholds to assess the affordability depending on their populations' economic status, but I couldn't find the affordability study by the catastrophic method that undertaken in our country to use or compare the finding. Therefore, the threshold used in this study is based on the study undertaken to large study area and may not exactly fit to this specific study area.

The method of capturing the information about income of those households was by asking the patient itself (care giver or family in the case of children) that lacks the robustness of the data's accuracy.

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Annex 1. Data collection tool

S.N	**Variable**	**Response**	**Jump**
1.	Hospital	1.Dello Mena 2. Ginnir 3. Goba 4. Robe	
2.	Hospital type	1. General 2.Referal	
3.	Sex	1 Male 2 Female	
4.	How old are you?		
5.	Where is your current residence?	1. Rural 2.Urban	
6.	What is your current occupation?	1 Farmer 2 Marchant 3 housework	
		4 Student	
		5 Government employee	
		6 NGO/private employee	
		7. Retired 8 .Daily laborer 9.Other	
7.	Marital status	1 Single	
		2 Currently married (monogamous)	
		3 Currently married (polygamous)	
		4 Divorced	
		5 widowed	
		6 Not applicable(child/ under age)	
8.	What is your relationship/roll in the household	1 House wife/Mother	
		2 Husband/father	
		3 Son/daughter	
		4 Relative	
		5 Other	
9.	Level of Education	1 Illiterate .	
		2 Only read and write	
		3 Primary school	
		4 Secondary school	
		5 Diploma	
		6 Degree and above	
10.	What is your total number of family?		

11.	How much do you earn monthly/yearly?	_____ ETB, in kind_____	
12.	How much do your spouse earn monthly?	_____ETB, in kind_____	
13.	How much is your other type of income	_____ ETB in kind_____	
14.	Monthly total family income	_____ETB	
15.	Money spent for food	_____ETB, in kind_____	
16.	Is there family member with chronic disease	Yes, No	If "no" jump to Q. No 19
17.	If yes to question above what are those disease	1 hypertension, 2 Diabetes, 3 Asthma, 4 Cancer, 5 CVD	
18.	What is monthly payment for treatment?	_____ETB	
19.	What type of payment do you use	1.OOP 2. Insurance 3. others	
20.	Do you have other chronic NCD?	Yes, No	If "no" jump to Q. no 23
21.	If yes to ques above	1.Hpn 2. CVD 3. Asthma 4 cancer	
22.	What is monthly payment for treatment?	_____ETB	
23.	Duration of illness in year/month?		
24.	Duration of treatment in year/month?		
25.	For how long you supplied the drugs	1.1month 2. 2month 3. 3 month 4 4 month	
26.	What type of DM drug do you use/prescribed for you?	1.Insulin Intermediate, 2. Insulin soluble(R) 3. Glibenclamide, 4. Metformin,5.insuline syringe 6.Other	
27.	What type of DM drug you supplied from hospital pharmacy	1.Insulin Intermediate, 2. Insulin soluble(R) 3. Glibenclamide, 4. Metformin,5.insuline syringe 6.Other	
28.	Have you got those drugs which are stock-out in hospital from other area	1 Yes, 2No	If "no" jump to Q. no 30
29.	If yes to Ques.No.26 from where did you get the medicine.	1.Private pharmacy/drug store 2. Red cross pharmacy	

30.	Which medicine is not totally in the local market?	1.Insulin Intermediate, 2. Insulin soluble(R) 3. Glibenclamide, 4. Metformin,5.insuline syringe 6.Other	
31.	Cost of available medicines pre month supplied in ETB.	1.Insuline Intermediate_____ 2. Insulin regular_____ 3. Glibenclamide_____ 4. Metformin_____ 5. Insulin syringe_____ Others_____	
32.	**Total cost of medicines per month**	_____ETB	

DECLARATION

I, the undersigned, declare that this thesis is my original work, has not been presented for a degree in this or any other university and that all sources of materials used for the thesis have been fully acknowledged.

Name: _____

Signature: _____

Name of the institution: _____

Date of submission: _____

This thesis has been submitted for examination with my approval as University advisor

Name and Signature of the first advisor _____

_____

Name and Signature of the second advisor _____

_____