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Vaccines, Immunisation and Health
Supply Chain Management
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**ASSESSMENT OF DIABETES HEALTH COMMODITIES STOCK OUT AND ITS
EFFECT ON DIABETES MANAGEMENT AT CENTRE HOSPITALIER
UNIVERSITAIRE DE KIGALI**

A dissertation submitted to the College of Medicine and Health Sciences at the University of Rwanda, in partial fulfillment of the requirements for the award of a Master's degree in Health Supply Chain Management

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Declaration

I declare that this dissertation contains my own work, except where specifically acknowledged, and has been checked for plagiarism and found to be compliant, and this is the final approved Master's dissertation.

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Abstract

Access to safe, effective and quality medicines is key to achieve sustainable sustainable development goals, but a recurring shortage of health commodities hinders health systems' success, especially for non-communicable diseases. According to the World Health Organization report 2018, accessibility to non-communicable disease medicines is a challenging in low- and middle-income countries. Life-threatening complications associated with diabetes could be prevented or delayed if there is an uninterrupted supply of medicines and other medical devices for early diagnosis and treatment. Self-monitoring blood glucose has been expensive once patients pay them out-of-pocket. Access to affordable treatment is essential to reduce preventable diabetes deaths and improve outcomes. The objective of this study was to assess diabetes health commodities stock out and its effect on the management of diabetes at Centre Hospitalier Universitaire de Kigali. A descriptive mixed method study design was used to gather relevant information that answers research objectives and questions. Analysis was done using MS EXCEL, SPSS 2023, and thematic analysis for qualitative data. Stock out of diabetes health commodities has been observed at Centre Hospitalier Universitaire de Kigali. Apart from few diabetes health commodities that did not run into stock out, many of them have been subjects to stock out at the rate ranging from 4% to 100%. Many respondents perceive an untrained, demotivated, and insufficient workforce as causes of stock out of diabetes health commodities. The inadequate budget allocated to health commodities and stringent procurement process hinder the availability in due time. Only 26.8% always get all the prescribed diabetes health commodities within the hospital, and the hardship to get them brings a financial burden where 51.3% spend 5 to 10% of their monthly earnings. Stock out should be avoided to provide adequate control of diabetes conditions, and fewer or delayed complications associated with poor adherence to medication and uncontrolled blood glucose. Training the workforce in the health supply chain to curb the stock out of health commodities, increasing the budget allocated to purchase health commodities, and incorporating blood glucose test strips among diabetes health commodities that are dispensed to outpatients for better home-based blood sugar monitoring and control, are recommended for better diabetes management.

Keywords: CHUK, Diabetes health commodities, Stock out and diabetes management

Abbreviations and acronyms

CBHI: Community Health Insurance Scheme

CDV: Cardiovascular diseases

CHUK: Centre Hospitalier Universitaire de Kigali

ENT: Ear, Nose and Throat (ENT)

KN: Kigali Nyarugenge

LMICs: Low and Middle –Income Countries

NCDs: Non- Communicable Diseases

OOP: Out –Of -Pocket

SMBG: Self - Monitoring of Blood Glucose

SPSS: Statistical Package of Social Science

UR-IRB: University of Rwanda Internal Review Board

WHO: World Health Organization

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Chapter I: Introduction

I.1. Background

Non communicable diseases are a significant and growing threat in diseases that enhance morbidity and mortality in low- and middle-income countries. Tackling these conditions requires steady availability of appropriate medicines that may out turn in a remarkable reduction of complications and boosted health outcomes in non-communicable diseases patients (1).

Access to safe, effective, and quality medicines is key to achieve sustainable development goals, but the recurring shortages of health commodities, especially non-communicable diseases, hinder the health system's success (2). Low and middle -income countries health systems are limited to treating NCDs like diabetes, which arouses excess mortality (3). Notwithstanding; the importance of medicines in lowering the global health burden of morbidity and mortality, the persistence of access to quality medicines remained unsatisfactory, specifically in Low and Middle -Income countries (LMICs) (4).

Globally in 2017, there were 425 million adult patients with diabetes; the number is expected to rise to 629 million in 2045, where 79% of the increase is projected to occur in low and middle income countries (5).

Diabetes is the 6th leading cause of mortality globally (6), the associated complications like blindness, lower limb amputation, and renal failure are life- threatening conditions to the patients and increase the burden and vulnerability of the poor population (7) . Effective diabetes care necessitates steady access to recommended diagnosis, treatment, and monitoring for hyperglycemia (8) .

International Diabetes Federation report published in 2015 revealed that 415 million of adults have Diabetes Mellitus type 2 of which 75% lived in low-and middle-income countries. Antidiabetes drugs are not prescribed for curative purposes. Still, keep blood glucose under control, which prevents or alleviates diabetes complications, including retinopathy and neuropathy (9). Diabetes, like many diseases in LMICs, can be prevented, treated, or alleviated if there is sustainable access and affordable health commodities at the service delivery points. Availability and affordability of health commodities lessen life-threatening diseases and foster the health sector's success (10).

Suitable pharmacotherapy is highly effective in reducing morbidity and mortality from chronic diseases; until now, the necessary medicines are not readily available in sufficient quantity to

provide adequate healthcare to our patients. The insufficient availability of medicines in the public sector is a general problem (11). Low and middle-Income countries are still struggling to access cardiovascular and diabetes medicines. This increases the burden to pay for health commodities out of their pocket (12,13). A study conducted in rural Rwandan districts for some NCDs drugs on essential medicines list showed the availability of medicines differ from one facility to another(14)

I.2. Problem statement

The global increase in diabetes among adults was estimated at 8.5% of the world's population and is still increasing (15). Life-threatening complications associated with diabetes could be prevented or delayed if there is an uninterrupted supply of medicines and other medical devices for early diagnosis and treatment. Self-monitoring blood glucose (SMBG) has been revealed to be expensive once patients pay them out- of- pocket (OOP)(16). Access to affordable treatment is essential to reduce preventable diabetes deaths and improve outcomes (17).

Recent studies showed that the availability of insulin in low- and middle-income countries was scarce and that 63% of families in low-income countries could not afford insulin as a life-saving medicine(18). The study conducted in China revealed a low rate of antidiabetes availability at the secondary and primary levels of care compared to the same drugs at the tertiary level of care (19). In Rwanda, diabetes prevalence reported in 2013 was 3.2% of the overall non-communicable diseases (20). In 2016, 45% of reported deaths in Rwanda were attributed to NCDs (14). According to the International Diabetes Federation 2021 report , diabetes prevalence in Rwanda raises to 4.5% for adults aging between 20 and 79 years (21) . This shows how diabetes is an emerging disease that needs to be cared for adequately.

Quality and cost-effective health commodities are crucial components of a successful health system. The availability and affordability of health commodities used by diabetes patients can refine their quality of life by ensuring adherence to medication to keep blood sugar levels under control (22).

According to the national guideline for the management of NCDs, treatment adherence is one among many parameters to maintain blood glucose within a limited range for patients taking oral hypoglycemia medications. Patients on insulin treatment should monitor their blood glucose twice a day (23). With the introduction of the Community based health insurance scheme (CBHI)

commonly known as "Mutuelle de Santé", patients would have to pay for 10% of the total medication expenditure which lessens the financial burden for both patients and society.

Well-structured health supply chain management striving to improve access to essential medicines, can polish up patient care efficiency and effectiveness by reducing the financial burden of patients with life-long diseases through co-payment.

Patients transferred from different district hospitals expect to receive higher management of their conditions. Patients' expectations would be interfered with by recurrent shortages of health commodities, which can worsen their clinical conditions if they cannot afford to pay for the prescribed medicines out of their pockets leading to diabetes complications and increased premature mortality. The availability, cost, and stock out of NCDs including diabetes, have been assessed in three rural districts in Rwanda. yet no study has been conducted at Centre Hospitalier Universitaire de Kigali (CHUK), which is biggest urban public hospital at the same time receiving patients from rural districts in its catchment area.

The current research will help to pinpoint the availability of diabetes health commodities at CHUK and its effect on diabetes management, thereby drawing recommendations based on findings for the effective health supply chain. This will decrease the financial burden that may be incurred by patients resulting from out-of-pocket payments for this life-long disease.

I.3. Study objectives

I.3.1. General Objective

The general objective of this study is to examine the status of stock out for diabetes health commodities and its effect on the diabetes management at CHUK.

I.3.2. Specific objectives

The specific objectives of this study are:

1. To assess the stock out status for diabetes health commodities at CHUK.
2. To determine perceived causes of stock out of diabetes health commodities at CHUK.
3. To identify challenges associated with getting health commodities out of CHUK.
4. To analyze the effect of health commodities stock out on management of diabetes at CHUK.

I.4. Research questions

In this research, we assessed the status of the health commodities stock out for diabetic patients and determined its effect on diabetes management at CHUK.

The questions below were answered by the present study

- What is the status of diabetes health commodities stock out at CHUK?
- What are the perceived causes of stock out of diabetes health commodities at CHUK?
- What challenges do patients face to get their health commodities out of CHUK?
- How do health commodities shortages affect diabetes management at CHUK?

I.5. Significance of the study

This study makes three main contributions. First, this study contributes to redesigning the supply chain of diabetes health commodities to cater for customer demand, thus enhancing their proper management.

Secondly, this study contributes to the well-being of diabetes patients through improved availability of adequate health commodities that meet their clinical conditions and lessen the financial burden resulting from paying their treatment out of pocket, hence enhancing adherence to their treatment

Thirdly, the findings of this study contribute to the existing literature on the availability of diabetes health products. They may also raise other areas of research that would contribute to the effective and efficient management of diabetes conditions at CHUK.

Chapter II. Literature review

II.1. Definitions

Diabetes is a health condition caused by insufficient insulin production by beta –cells, the hormone that allows glucose (sugar) to be transformed into energy, or by impotent use of insulin within the body (24) .

Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes (25).

Stock out is a situation in which the company is unable to meet customer demand due to shortage of stock in the warehouse within a given period of time (26).

II.2. Types of diabetes

There are three main types of diabetes which are type 1, type 2, and gestational

Diabetes type 1 : is caused by an autoimmune reaction, in which the body’s defense system inappropriately attacks the insulin-producing beta cells in the pancreas (27).

Diabetes type 2: is a combination of inadequate production of insulin, and an inability of the body to respond fully to insulin (insulin resistance) (27).

Gestational diabetes: is defined as glucose intolerance resulting in hyperglycemia of varying severity with onset during pregnancy (28).

Hyperglycemia that is first detected at any time during pregnancy is classified as either:

- Gestational diabetes mellitus, or
- Diabetes mellitus in pregnancy

Pregnant women with slightly elevated blood glucose levels are classified as having Gestational diabetes, whilst women with substantially elevated blood glucose levels are classified as having diabetes mellitus in pregnancy (27)

II.3. Availability of diabetes health commodities

Access to medicines is a global public health challenge, and many low and middle-income countries ((LMICs) have broadly experienced a stock out of critical medicines, which alters the treatment outcome (29). Worldwide, many people die or encounter disabilities attributable to diseases that treatments have been proven to cure or alleviate complications resulting from poor or

lack of access to appropriate medicines (30). World Health Organization (WHO) has set to reach 80% of availability and affordability of NCDs Medicines by 2025 in both public and private (31). In 2016, 45% of reported deaths in Rwanda were attributed to NCDs (14). Accessibility to non-communicable diseases treatment is still scarce compared to medicines used to treat acute conditions (11). According to (4) around 2 billion people fail to access essential medicines resulting in increased morbidity and preventable mortality. In Rwanda, the availability of three drugs for NCDs were assessed among them, metformin was assessed as oral hypoglycemic drugs and this study showed that rural health centers experienced more stock out than district hospitals (32). A study conducted in Kenya about access to diabetes medicines at the household level has shown that 35.7% of the participants reported that diabetes medicines are very expensive, 21.4% run out of stock while 14.3% reported that they were managing their diabetes with diet and lifestyle changes. This study showed that the availability of diabetes medicines in households was poor where 26.1% did not have their medicines at home (6). Quality and cost-effective health commodities are of great importance to the success of health systems. Availability and affordability of health commodities used by diabetes patients can improve their quality of life by ensuring adherence to medication that maintain blood sugar under control and adequate access to (SMBG), thus allowing dose adjustment and alleviate diabetes complications (22). Unavailability of diabetes health commodities can lead to nonadherence despite the goodwill of patients as a result of frequent stock out of medicines in public health facilities where patients get their medication at a cheaper prices even subsidized (6).

II.4. Effective health supply chain and availability of medicines

An effective supply chain is vital for any health system to tackle the trend of new diseases. The success of any health system relies on the proactive health supply chain that responds to supply chain dynamics considering new disease trends that meet the healthcare and end-user demands level (32,33). Stock out of essential medicines in countries with limited resources is accentuated compared to developed countries, and this becomes a great constraint to meet patients' needs (17,29). Good health outcomes cannot be achieved without a well-functioning health supply chain that ensures consistent availability of quality health commodities in an appropriate amount resulting from enough financing, qualified workforce, on time information sharing among stock

holders that come up with a good contingent supply plan and on time stock level tracking to replenish stocks in due time (35).

Poor health success can result from scarcity of supply chain performance to avail appropriate health commodities whenever the demands arise and incapacity of the health supply chain to incorporate new diseases trends into the existing supply chain. Ineffective health supply chain greatly impacts healthcare delivery and deadly have repercussions on patients life and can exacerbate diseases management thus increasing financial burden to both individual and health system as a whole (33). In 2020, a study conducted in Kenya has shown that the availability of medicines for non-communicable diseases is more than two fold less to those used to treat communicable diseases and availability is increasing as moves from lower to a higher levels of care (36). Adherence to appropriate diabetes medication is one among other diabetes management practices that have proven to reduce diabetes-related complications by 53-63% and decrease mortality by 46% (37). The weak links among various health system building blocks contributes to the unsuccessful health supply chain, which in return increase the frequency of stock out of health commodities at the point of healthcare service delivery as well as lack of trust by healthcare seekers (38).

II.5. Pharmaceuticals stock out and Quality of Care

Quality of care is frightened by health product inadequacy which becomes an obstacle to reach optimal care by the public (39).

The continued availability of essential drugs in health facilities plays an important role in increasing access to and use of health services. On the other hand, frequent drug shortages have been shown to affect health care use (40).

Drug availability positively enhances patient confidence in the healthcare providers. At the same, the lack of health commodities in the facilities creates distrust of health care providers and contributes to the underutilization of the formal health system. System trust in health care providers is important; it shapes the use of home health services; influences therapy adherence (40).

The cost of non-adherence to the medication has been proved to be higher than the cost of adherence to both individuals and the health system. Non- adherence can induce unnecessary hospitalization and preventable disabilities (41). A study carried out in Kenya, on availability of medicines at household found that some patients fail to buy their medicines in private pharmacy

outlet because they could not afford them, they have run out of stock leading to non-adherence (6). The study conducted in Ghana, Kenya, and Uganda has revealed that despite the efforts to avail essential medicines to public health facilities continuously, there is still a persistent stock out over 30% of medicines that were looked forward being convenient patients care that leads to delayed; or even omitted to due shortage of health commodities within the institution, this exacerbates the diseases' conditions and complicate their management (30). According to (39), the scarcity of medicines leads to medication errors and inefficiency in health outcomes resulting from the substituting of the appropriate medication for specific clinical conditions. It has been shown that out of pocket payment for essential medicines is above 90% of all the population in countries with low and middle income (42), and this would be extremely a huge burden to people with poor resources especially those with life-long diseases and complications can be fatal due to inaccessibility to appropriate health commodities in due time (4). WHO's a comprehensive approach for clinical care of type 2 diabetes mellitus comprises pharmacological and nonpharmacological treatment intending glycemic control and key cardiovascular disease (CDV) risk factors such as hypertension, elevated cholesterol, and obesity. Pharmacological treatments demonstrated to be more effective in improving diabetes outcomes encompass glucose-lowering drugs, antihypertensive drugs, and cholesterol-lowering drugs(3).

II.6. Conceptual Framework

The conceptual framework provides a link between the independent variables, and dependent variables that underpins the research objectives. The independent variables that may influence stock out under this study include (budget, procurement process, late deliveries, weak stock monitoring, order fill rate, product quality, trained and qualified workforce). The independent variables of this study helped to detect the causality of diabetes health commodities stock out and the impact of the latter on diabetes management was studied.

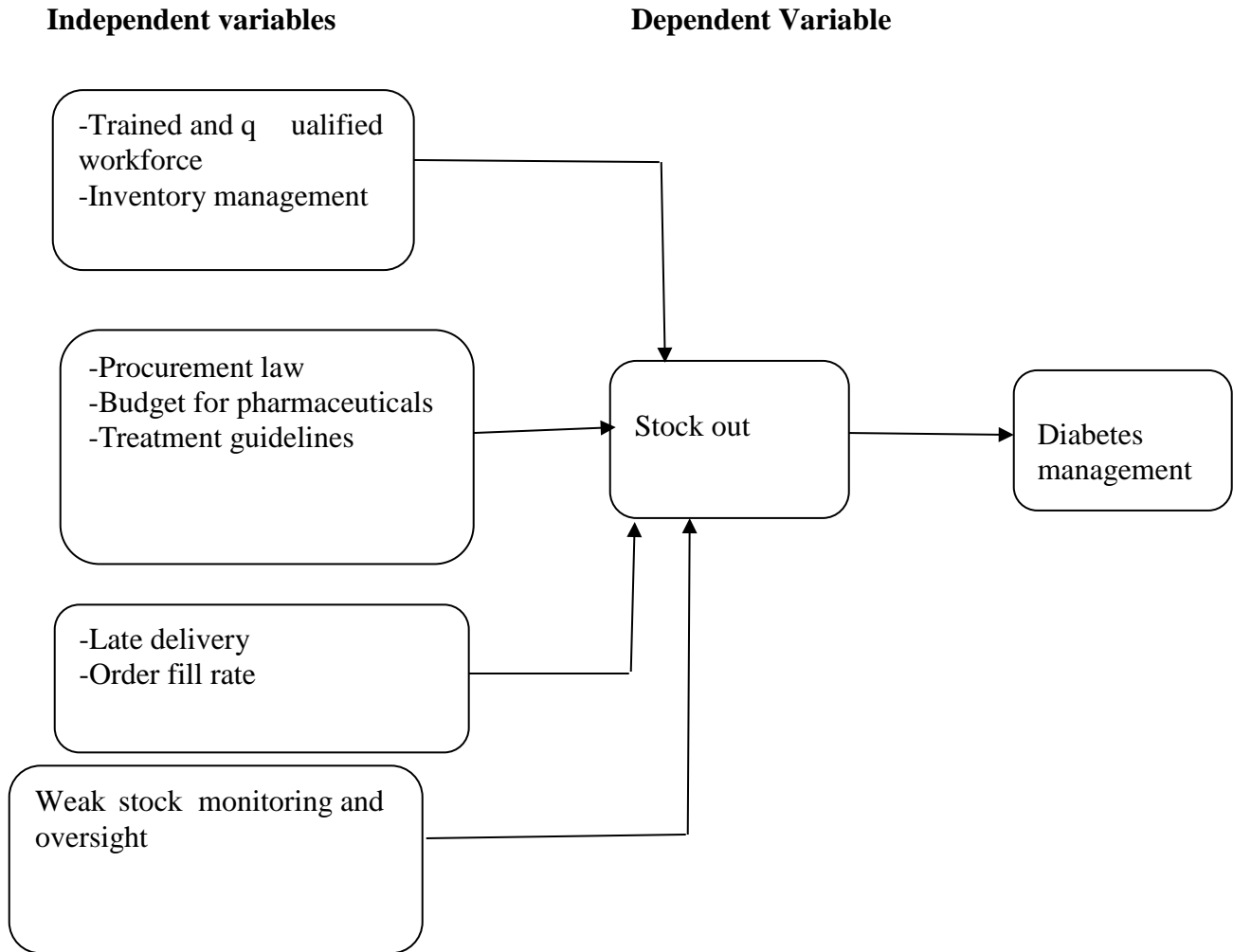


Figure 1. Adapted conceptual framework (43)

Chapter III. Research methodology

III.1. Research design

This is a mixed method study design. The quantitative aspect included a checklist of diabetes health commodities where historical data from January 2019 to December 2020 were collected. This was needed to evaluate what and when diabetes health commodities stock out occurred. The qualitative aspect involved an interview with key health professionals that had knowledge and experience in the management of diabetes at CHUK. By interviewing key personnel, we could be able to better understand how diabetes health commodities stock out affects its management and the challenges

encountered for proper management of diabetes. This helped us to come up with recommendations for diabetes management improvement.

III.2. Location of study

The study was conducted at CHUK, the largest public hospital in Rwanda. CHUK is located at Kigali Nyarugenge (KN) Avenue 4, Kigali. CHUK has the following clinical services and specialties: Allied Health Sciences, surgery, Accident and Emergency, Internal Medicine, Mental, Anesthesiology and critical care, Gynecology and Obstetrics, Pediatrics, Maternal and Neonatology, Ear, Nose and Throat (ENT), Ophthalmology, Neurosurgery, Pediatric Surgery, Urology, Nephrology, Dialysis, Oncology and Dermatology. It provides tertiary level of care and is the biggest referral hospital with capacity of 519 beds. CHUK clients mainly are those transferred from district hospitals providing secondary level of care for better management of their clinical conditions that were not satisfactory being met at low level. CHUK being at top of public Rwandan health system, where most patients with limited resources seek healthcare, thus it should provide best services delivery among others access to appropriate health commodities that cater patients' conditions and expectations.

III.3. Target and study population

Apart from historical data obtained from stock records, this study included internal medicine health professionals, pharmacy staff, procurements officials, and diabetes patients. Only a representative sample was determined to administer the questionnaire because reaching all of them would not be feasible. Two hundred seventy-three (273) new diabetes patients received in a whole year constituted the study population.

III.4. Inclusion and Exclusion Criteria

III.4.1. Inclusion criteria

All health commodities that tackle diabetes management from January 2019-December 2020 Diabetes patients, internal medicine health professionals, procurement officials and pharmacy staff who voluntarily gave informed consent and signed the consent declaration form were included.

III.4.2. Exclusion Criteria

Our study did not include any health commodities that are not primarily intended to diagnose, treat, and monitor blood sugar. Refusal to sign the consent form was another exclusion criteria

III.5. Sample size

The study sample is a subset of the population elements. A sample size is the number of participants selected from the study population. The sample was estimated using the Yamane formula (44), assuming that the confident level is 95% and acceptable margin error is 0.05.

$$n = \frac{N}{1 + N(e)^2}$$

n= sample size, e= margin error.
N= population

The sample was drawn from 273 new cases of diabetes patients received from January 2020 to December that constitute our study population, determined representative sample was 162 patients. Due to the small number of pharmacy staff, the census method was used to answer the questionnaire. Those are procurement officials, pharmacist in charge, storekeepers, and nurses working in different sub-pharmacies where patients got their health commodities

Table 1: Workforce recruited to answer questionnaire

Cadre	Total number
Head of pharmacy department	1
Pharmacist in Charge	2
Nurses in charge of stocks	3
Nurses working in outpatients' sub -pharmacy	5
Nurses working in Emergency sub- pharmacy	4
Nurses working in Internal Medicine sub- pharmacy	2
A Nurse working in Surgery sub pharmacy	1
Director of procurement	1

Procurement officer	4
TOTAL	23

To tackle qualitative aspect of this study, internal medicine health professionals were contacted to participate. Interview guide questions were used to gather information on how diabetes management has been affected by diabetes health commodities stock out. Internal medicine health professionals recruited in this study were dependent on data saturation.

III.6. Data collection instrument and data collection procedures

After getting the approval from CHUK/ Ethics committee. The data were collected using a chest list containing diabetes health commodities that were supposed to be available at the hospital. A structure questionnaire was administered to participants after getting their consent signed.

The checklist was used to tackle objective one related to diabetes health commodities stock out status. Objective two was answered through a structured questionnaire administered to pharmacy and procurement staff. The objective three was answered through questionnaires that were distributed to diabetes patients

The fourth objective was tackled using an interview guide to gather answers from health professionals working in internal medicine.

III.7. Limitation of the study

The study setting was limited to Centre Hospitalier Universitaire de Kigali and may not represent of the entire public health facilities in Rwanda. Therefore, the results may not be generalizable to other public health facilities. However, we remain confident that the situation may not vary significantly. It would be interesting to conduct a larger country-wide study with a larger target of public health facilities. Moreover, the descriptive mixed method of the study relied on data for limited period (January 2019 to December 2020). It would be interesting to determine if the situation was different nationwide or track changes in the future if a prospective or longitudinal study is to be conducted. The study only quantified the stock out of diabetes health commodities and their effect on diabetes management, other factors that may affect proper management of diabetes conditions were not concluded.

III.8. Validity

The validity of a research tool refers to the extent to which a tool really measures what it intends to measure. Content validity refers to the extent to which an instrument is made of appropriate items for the concept to be measured (45). First, the researcher's classmates reviewed the data collection tools to see if the instructions were clear, the language was easily understood, and the tools were easy to use. Second, the researcher's supervisor reviewed the content of the tools to ensure that the data collection tools captured sufficient content to meet the study objectives and were not biased.

III.9. Reliability

According to Taherdoost reliability is defined as the degree of consistency or accuracy with which an instrument measures an attribute (45). Data collection tool was tested prior to main data collection where twenty diabetes patients answered the questionnaire to know if the asked questions are well understood by respondents. Two nurses working in sub-pharmacies as well answered the questionnaire prior to data collection and unclear questions were modified.

III.10. Ethical Consideration

The data collection was carried out after getting ethical clearance from the University of Rwanda, the Institution Review Board (UR-IRB/Ref: CMHS/IRB/300/2021) and CHUK ethics committee (Ref: EC/CHUK/141/2021). The participants got sufficient explanation about the purpose of the study and the risk-benefit to participate in this study; Then they sign written consent voluntarily to participate in the study. The participants were informed that they had the full right to withdraw from the study without any penalty at any time point. Confidentiality was assured to the participants as the provided information was only used anonymously for the study for the study. Participants got time to ask for any information about research, and their questions were answered immediately.

III.10.Data analysis and presentation

The collected data were captured, processed and analyzed using different software such as MS EXCEL; and SPSS, and the results were presented in tables. Descriptive statistics were used to define features of respondents and the risk of inadequate diabetes management. The qualitative

data gathered from the interview were thematically analyzed where data on the audio recorder were transcribed. Participants in transcripts were de-identified and assigned a unique identifier number. After that, the transcripts were analyzed following grounded theory.

Chapter IV. Results and discussions

4.1. Results

This chapter summarizes the key findings of the research based on primary data collected using questionnaires. In addition, interviews with internal medicine clinicians and secondary data extracted from the hospital pharmaceuticals management system are also included. The results are presented in tables.

4.2. Status of stock out

Out of 15 health commodities commonly used in diabetes management for both inpatients and outpatients, the stock out status was assessed by reviewing historical records from January 2019 to December 2020. Gliclazide 30mg had a stock out of 100% for the two years reviewed whereas glimepiride 4mg and blood glucose test strips had a stock out of 25% in 2019 and glimepiride 4mg had a stock out rate of 100% in 2020. Short, intermediate, long-acting insulin, insulin syringes, metformin 850mg, and glycated hemoglobin reagent had a stock out rate ranging from 0- 11%. Vildagliptin 50mg had a stock out rate of 24% and 46% in 2019, 2020 respectively. Glimepiride 3mg, 4mg and gliclazide 60mg had a stock out of above 50% in one of studied years. Lancet, Metformin 500mg, and Glucose meter never run into stock out in the period under this study. The stock out rate was determined using 360 days per year and the number of days the items were not available in the hospital. Even if blood sugar monitoring health commodities stock out rate is not high, those items are not accessible to diabetes outpatients, as shown in tables 16 and 17.

Table 2: Stock out status

No	Diabetes health commodities	Days of stock out 2019	Days of stock out 2020	Stock out rate in 2019(%)	Stock out rate 2020 (%)
1	Long-acting Insulin	19	0	5	0
2	Short acting Insulin	0	24	0	7
3	Intermediate Insulin	40	30	11	8
4	Insulin syringes	10	0	3	0
5	Vildagliptin 50mg	86	164	24	46
6	Glimepiride 3mg	300	92	83	26
7	Glimepiride 4mg	90	360	25	100
8	Gliclazide 60mg	186	30	52	8
9	Gliclazide 30mg	360	360	100	100
10	Metformin 850mg	0	13	0	4
11	Metformin 500mg	0	0	0	0
12	Glucose meter	0	0	0	0
13	Strips	90	0	25	0
14	Lancet	0	0	0	0
15	Glycated hemoglobin reagent	90	30	25	8
	Average stock out/ year			24	20

4.3. Perceived causes of diabetes health commodities stock out

4.3.1. Health commodities procurement process

According to table 3 below, 34.8% of respondents strongly agree and agree that the procurement law does not smoothly facilitate the availability of health commodities. 30.4% and 34.8% of respondent strongly agree and agree respectively that procurement process contributes to the stock out of diabetes health commodities. Also 47.8% of respondents perceive the allocated budget to acquire diabetes health commodities being insufficient, which in returns contributes to stock out.

Table 3: Policy, laws governing procurement and stock out health commodities

Statement	Response	Frequency	%
The procurement law smoothly facilitates to availability of health commodities (n=23)	Strongly Disagree	4	17.4
	Disagree	3	13.0
	Neutral	11	47.8
	Agree	4	17.4
	Strongly agree	1	17.4
The procurement process is a big hindrance to timely avail health commodities (n=23)	Strongly Disagree	1	4.3
	Disagree	3	13.0
	Neutral	4	17.4
	Agree	8	34.8
	Strongly agree	7	30.4
The budget to acquire health commodities is sufficient to meet customer demand (n=23)	Strongly Disagree	3	13.0
	Disagree	8	34.8
	Neutral	9	39.1
	Agree	2	8.7
	Strongly agree	1	4.3

4.3.4. Workforce in health supply chain

As detailed in table 4, 34.8% of respondents agreed that trained staff have impact on adequate management of diabetes health commodities. Above 65% of respondent strongly agree and agree that sufficient number of workforces coupled with motivation contributes to the success of supply chain. Furthermore, 73.9% and 26.1% strongly agree and agree respectively that the experienced staff to watch over the flow of diabetes health commodities and consistently ensure that sufficient quantities are available to meet patients' demand.

Table 4: Workforce in health supply chain and availability of health commodities

Statement	Response	Frequency	%
Staff training has an impact on the management of diabetes health commodities (n=23)	Strongly Disagree	4	17.4
	Disagree	3	13.0
	Neutral	11	47.8
	Agree	4	17.4
	Strongly agree	1	17.4
The number of staff contributes to the success of CHUK health supply chain (n=23)	Strongly Disagree	0	0
	Disagree	1	4.3
	Neutral	1	4.3
	Agree	6	26.1
	Strongly agree	15	65.2
Staff motivation contributes to the success of health supply chain (n=22)	Strongly Disagree	0	0
	Disagree	0	0
	Neutral	1	4.5
	Agree	6	27.3
	Strongly agree	15	68.2
The experience of staff in health supply chain impacts the success of health supply chain (n=23)	Strongly Disagree	0	0
	Disagree	0	0
	Neutral	0	0
	Agree	6	26.1
	Strongly agree	17	73.9

4.3.5. Workforce perception of the effect of diabetes health commodities stock out

As shown in the table below, more than 65% of respondents strongly agree and agree that diabetes patients do not always find their prescribed health commodities within the hospital. More than 90% of respondents pointed out that diabetes patients are financially being affected by stock out of diabetes health commodities.

Table 5: Effect of diabetes health commodities stock out

Statement	Response	Frequency	%
Diabetes patients always find their health commodities within CHUK (n=23)	Strongly Disagree	8	34.8
	Disagree	8	34.8
	Neutral	4	17.4
	Agree	2	8.7
	Strongly agree	1	4.3
Stock out of diabetes health commodities affect department reputation, institution, and healthcare of patient (n=23)	Strongly Disagree	1	4.3
	Disagree	1	4.3
	Neutral	0	0
	Agree	3	13.0
	Strongly agree	18	78.3
The satisfaction of healthcare providers depends on the ability to provide relevant treatment meeting patients presented complaints or symptoms (n=23)	Strongly Disagree	1	4.3
	Disagree	0	0
	Neutral	0	0
	Agree	5	21.7
	Strongly agree	17	73.9
Financially, patients are affected by stock out of diabetes health commodities (n=23)	Strongly Disagree	0	0
	Disagree	0	0
	Neutral	1	4.3
	Agree	1	4.3
	Strongly agree	21	91.3

4.3.6. Socio-demographic data and age distribution of diabetes patients

According to projected sample size of 162 patients, 133 questionnaires were filled by diabetes patients representing a response rate of 82%. The respondents comprised 60 (45.1%) males and 73(54.9%). As described in the table below, diabetes is an emerging disease attacking different categories of people. According to the respondents' age 39.1% were aged between 56-65years old, 24.8% were aged between 46 and 55 years, and those with 66 years and above were represented 15.8% of respondents and the least represented age group between 18-25 years aged representing only 0.8% of all respondent.

Table 6: Socio-demographic data and age distribution of diabetes patients

Variables		Frequency	%
Gender (n=133)	Male	60	45.1
	Female	73	54.9
Age (n=133)	18-25 Years	1	0.8
	26-35 years	6	4.5
	36-45 Years	20	15.0
	46-55 Years	33	24.8
	56-65Years	52	39.1
	66 years and above	21	15.8

4.3.7. Duration diagnosis confirmed as diabetes

Among our respondents, 51.1% of respondents had confirmed diabetes for more than five years, followed by 29.3% with confirmed diabetes between 3 and 5 years. In contrast, for 16.5% the diagnosis was confirmed since between 1 and 2 years, and those with diabetes of less than one year were represented 3.1%. This proves that diabetes is a chronic condition, its management that requires pharmacological intervention has to be done adequately to play its role effectively.

Table 7: Duration for confirmed diabetes among the study population

Confirmed diabetes	Frequency	%
Below 1 year	4	3.1
Between 1 and 2	22	16.5
Between 3 and 5	39	29.3
Above 5 years	68	51.1
Total	133	100

4.3.7. Diabetes follow-up at CHUK

Diabetes patients who visit the hospital monthly for clinical follow-up represent 89.7% of all respondents, whereas 9.5% answered that they come once a quarter. Only 1(0.8%) reported visiting the hospital when complication arises. For this variable, 126 out of 133 respondents provided their answers.

Table 8: Diabetes follow-up at CHUK

Frequency of hospital visit	Frequency	%
Once a month	113	89.7
Once a quarter	12	9.5
When complications arise	1	0.8
Total	126	

4.3.8. Patients' treatment type

As shown in the table below, 65.6% of respondents were on oral hypoglycemic treatment whereas 45 (34.4 %) of respondents were using insulin injection to maintain their blood glucose within acceptable limits. Patients on insulin injection may need more home-based blood glucose monitoring than those on oral hypoglycemic treatment. We obtained responses from 131 out of 133 respondents for this specific variable.

Table 9: Patients' treatment type

Hypoglycemic agent	Frequency	%
Oral	86	65.6
Injection	45	34.4
Total	131	100

4.3.9. Patients' response on availability of diabetes health commodities within the hospital

As described in the table below, among the diabetes patients who responded to the questionnaire, only 26.8% always get all the prescribed diabetes health commodities within the hospital, the same number of respondents (26.8%) often get prescribed within the hospital. 28.3% replied that they sometimes get their prescribed diabetes health commodities at the hospital while 5.5 % and 12.6% responded that they rarely and never get their prescribed diabetes health commodities within hospital. This may result in poor management of diabetes for those patients who cannot afford to buy in retail pharmacies. We obtained responses from 127 out of 133 respondents for this specific variable.

Table 10: Frequency of getting diabetes health commodities within the hospital

How often are health commodities gotten from the hospital?	Frequency	%
Always	34	26.8
Often	34	26.8
Sometimes	36	28.3
Rarely	7	5.5
Never	16	12.6
Total	127	100.0

4.3.10. Clinical conditions and lack of prescribed health commodities

As shown in the table below, the clinical conditions of 20.6% of the respondents worsened due to stock out of prescribed health commodities within the hospital. The respondents highlighted that they do not adhere to prescribers' instructions because the out-of-pocket payment in retail pharmacies is costly for those whose insurances do not copay in private. The severity of worsened clinical conditions is detailed in the below table11

Table 11: Clinical conditions and lack of prescribed health commodities

Worsening clinical conditions	Frequency	%
Yes	27	20.6
No	103	78.6
Total	131	100

4.3.11. Lack of prescribed health commodities and worsening of clinical conditions

The severity of clinical conditions that worsened due to lack of diabetes health commodities are as follows: shifting from oral hypoglycemic agent to injection, which corresponds to 3.8% of respondents, hospitalization below five days, which represents 11.5% of respondents, morbidity represents 19.2%, hospitalizations above five days represent 26.9%, coma represents 38.5%. Clinical conditions may be worsened by others factors that were not assessed in this study. Still, because patients did not get their health commodities within the hospital, their worsened clinical conditions are directly linked to the missed doses or monitoring

Table 12: Severity of the situation due to the lack of prescribed health commodities

Severity	Frequency	%
Coma	10	38.5
Hospitalization below five days	3	11.5
Hospitalization above five days	7	26.9
Shifting from oral hypoglycemic agent to injection	1	3.8
Morbidity	5	19.2
Total	26	100.0

4.3.12. Financial impacts of the lack of medications for patients

As shown in the table below, 73 (60.3%) of respondents said they are financially affected by stock out of diabetes health commodities because they cannot easily afford to buy them out of their pockets. The proportion of financial burden incurred by patients who do not get their health

commodities within the hospital are described in the table 14. For this variable, we received responses from 126 out of 133 respondents.

Table 13: The lack of medication affects the patient financially

Patient's finance affected	Frequency	%
Yes	76	60.3
No	50	39.7
Total	126	100.0

4.3.13. Out of pocket expenses of diabetes health commodities

The below table describes patients' expenses to buy prescribed health commodities out of the hospital to manage their blood sugar levels, where 19.7% of respondents spend less than 5%, 51.3% of respondent's spend between 5-10%, 17.1% of respondents spend between 10-20% whereas 11.8% of respondents spend above 20% of their monthly earnings. As lifelong medical conditions, the financial burden incurred by diabetes patients may decrease adherence to medication, which may result in poor management of diabetes and enhance diabetes complications.

Table 14: Out of pocket expenses of diabetes health commodities

Expenses on medication	Frequency	%
Below 5% of your earning	15	19.7
Between 5 and 10%	39	51.3
Between 10 and 20%	13	17.1
Above 20%	9	11.8
Total	76	100.0

4.3.14. Home based blood glucose monitoring

As shown in the table above, blood glucose was monitored only by 75 (57.3%) of respondents whereas 42.7% of respondents could not able to monitor their blood sugar due to various reasons described in table 16. Diabetes management needs effective collaboration between patients and health care providers, which cannot be accomplished without home-based blood glucose monitoring. Thus, access to diabetes monitoring health commodities is very critical. For this variable, 131 out of 133 respondents provided their answers.

Table 15: Home based blood glucose monitoring

Blood glucose monitoring	Frequency	%
Yes	75	57.3
No	56	42.7
Total	131	100.0

4.3.15. Reasons of none monitoring blood glucose

Diabetes patients do not regularly monitor their blood sugar as instructed by physicians due to lack of health commodities to perform home based sugar monitoring. Inappropriate blood sugar monitoring may result in preventable risks. Among diabetes patients who participated in this study 56 of them representing 42.7% (table 15 home-based blood glucose monitoring) did not monitor their blood sugar for various reasons. There is a lack of blood glucose test strips that correspond to 73.2%, representing a significant number, followed by 16.1%, which do not have any health commodities used to monitor blood glucose at home.

Table 16: The reason of none monitoring blood glucose

Availability of glucose monitoring device at home	Frequency	%
No glucometer	1	1.8
No strips	41	73.2
No glucometer, strips and lancet	9	16.1
No strips and lancet	3	5.4
No glucometer and lancet	2	3.6
Total	56	100.0

4.3.16. Doctors' perspective regarding stock out and diabetes management**a. Doctors' experience with diabetes health commodities stock out**

There is a frequent oral hypoglycemic stock out compared to insulin. This is also confirmed by historical reviewed records shown in table 2. The more hypoglycemic oral treatment is not available, the more prescribers are pushed to keep changing patients' regimen without any clinical

indications. Patients never get blood glucose test strips; this may seem to be contradict the result in table 1 showing stock out status where strips stock out rate is very low. The available strips are only used for hospitalized diabetes patients, and physicians perceive stock out as a serious problem for diabetes management that need comprehensive management.

One respondent said *“No one can be happy with stock out; patients never get blood glucose test strips within the hospital. There is frequent stock out of oral hypoglycemic agents, and this is a serious problem that may result in serious complications”. In my practices, I could not get 40% of what I need to treat my patients, we are not worst but we should improve”*

b. Doctors' perception on diabetes stock out

Stock out is perceived as poor planning that leads to improper forecasting of required health commodities that do not consider confirmed diabetes cases with regimen to be available.

The following are quotes from some respondents:

“I perceive stock out is a result of poor planning and improper forecasting that does not consider diabetes prevalence and regimen. The budget also allocated to purchase health commodities is insufficient which should not be the case”

“It is something dangerous that we should always aim avoid, less than 50% are controlled that is reflected in international scale, we are not the worst but I can do better than the rest of world and I think stock out of medication contributes hugely”.

c. Challenges in diabetes management

Where patients with other insurances rather than CBHI can easily afford their medication due to facilitation through insurance co-payment, diabetes patients with CBHI struggle to afford prescribed health commodities out of the hospital. Some fail to buy out of pocket and come back with high blood sugar resulting from limited resources. Patients are asked to administer insulin at home without knowing their blood sugar for dose adjustment. The interviewed doctors commonly pinpoint that stock out of blood glucose test strips makes diabetes management hard

*“Some patients do not buy prescribed medication when are not available in the hospital, then you meet them after one month and find their blood sugar has been very high with some complications like sight issue”. **One doctor reported***

d. Effect of stock out on diabetes management; doctors' perspective

All interviewed doctors (4/4) highlighted that patients did never get blood glucose test strips within the hospital; this has a significant impact on diabetes management leading to uncontrolled blood glucose or hypoglycemia due to unadjusted insulin resulting from unaffordability of blood glucose test strips for outpatients. Frequent stock out of oral hypoglycemic treatment does not allow dose adjustment due to stock out of some strengths.

4.2. Discussions

Based on key findings highlighted in chapter four, a motivated supply chain workforce coupled with their sufficient number and experience would yield tremendous improvement towards the availability of health commodities that cater patients' demands. Above 60% of respondents agreed that this would result in remarkable success of health supply chain and contribute to the availability of diabetes health commodities. A Competent workforce is among six building blocks of the health system; there is a need to ensure that the available workforce are sufficient, motivated and trained to cater health supply chain demand. Inadequate health supply chain professionals lead to poor performance that enhances stock out of health commodities (46) . The respondents in this study revealed that poor planning coupled with lack of sufficient funds to contribute to the shortage of diabetes health commodities which translate into poor diabetes management. The study conducted by Prinja S et al , has disclosed that low availability of medicines in the public sector and persistent stock-outs are due to factors such as lack of funds, unreliable forecasting, and inadequate procurement/distribution mechanism in the supply chain(42).

Only 26.8 % of respondents reported to always get their prescribed health commodities within the hospital. Diabetes being an emerging disease, there is a need to monitor health supply chain adequately and ensure all diabetes health commodities from diagnosis to home based blood glucose monitoring are available. Even if diabetes management needs a comprehensive approach, pharmacological aspect should contribute its part in full. Stock out of assessed diabetes health commodities can be grouped into three categories: Health commodities with stock out ranging from 0-10%, 30-63%, and above. These figures would be translated into to low adherence to prescribed health commodities leading to micro or macro vascular complications. The availability of essential medicines and supplies in public hospital has been found to be insufficient and triggers catastrophic healthcare expenditure; the study conducted in two health facilities in North India found that the availability of diabetes medicines was 44 and 47% (42). We found that insulin short,

intermediate, and long- acting stock out ranges from 0-11% for two years reviewed; there is a low rate compared to the study conducted in Lusaka Zambia 2016, where stock out for insulin short and long - acting were 83% and 63% respectively (47).The study on adherence to non-communicable diseases was conducted in Ahmedabad (48), where 58.8% of diabetes patients had poor adherence to prescribed medications. Among our respondents 42.7% do not monitor their blood glucose as instructed by clinicians due to unaffordability of prescribed diabetes health commodities outside the hospital. Patients with community-based health insurance cannot easily afford to pay for commodities their prescribed health commodities out of pocket. Considering 34.4% of respondents as shown in table 9 are insulino-dependent, home based glucose monitoring would contribute to better glucose control. Diabetes, like other non-communicable requires long term compliance, sometimes even for lifelong. Diabetes patients bear enormous out-of-pocket payment and incur up to three times higher medical cost compared to those without diabetes (49). Considering the reason underscored by diabetes patients in table 16, reasons for not monitoring blood glucose implies that consistent availability of all diabetes health commodities would contribute, and lower the non-adherence to prescribers' instructions, thus lessen the short- and long-term clinical conditions worsening. Cost due to medicines has been shown to decrease adherence to medication and demand for health care services (49).

Below we quoted just two respondents reflecting on what happens in real clinical practice with regard to the stock out diabetes health commodities in the hospital.

Respondent 1:"Patients never get test strips, you cannot really know if the prescribed antidiabetic regimen is controlling the blood glucose, so you have to wait the entire month to adjust the dose or even change the regimen. Patients end up having complications or unnecessary frequent visit. Sometimes patients with community-based health insurance who cannot afford medicines outside the hospital, you try to prescribe what is available instead of sending them away with nothing".

Respondent 2:"There should not be stock out because you are asking patients to inject insulin without knowing blood glucose, so he/she may die from hypoglycemia or diabetes cannot be controlled resulting from injecting low or overdose. We meet patients after one month and you found the blood sugar has been high, patients started having complications, which affects patient's life expectancy".

CHUK should avoid stock out of diabetes health commodities to help patients to quickly access and afford diabetes health commodities, hence lessening patients' financial burden through copayment.

Chapter V. Conclusion and Recommendations

5.1. Conclusion

Stock out of diabetes health commodities at the CHUK has been shown to contribute to inadequate management of the diabetes condition. Understaffing, unmotivated and inexperienced workforce in the supply chain, and rigid procurement process and laws disrupt the availability of diabetes health commodities, leading to deficiency in the healthcare supply chain. Nonadherence to prescriber instructions has been highlighted among diabetes patients and results from the unaffordability to pay diabetes health commodities out of pocket. Beneficiaries of community-based health insurance do not have access to co-payment in retail pharmacies; this induces poor management of diabetes and non-adherence to treatment that would create a financial burden for both families and the health system thereafter. Further studies on noncommunicable treatment adherence among community health insurances beneficiaries; would be crucial and help advocate for them and find solutions that contribute to a growing global health problem.

5.2. Recommendations

5.2.1 Recommendations for policy and practice

Based on the findings from this study, we are recommending the following:

1. To advocate for budget increment to avail all health commodities that cater for diabetes patients demands
2. To train workforce in health supply chain to curb stock out of health commodities
3. To incorporate blood glucose test strips among diabetes health commodities that are dispensed to outpatients for better blood sugar monitoring and control

5.2.2. Recommendations for further research

Based on areas not exhaustively explored by the study, the researcher recommends to conduct further studies to determine:

1. Financial burden of diabetes management among patients in informal sector
2. Factors that affect adherence to non-communicable diseases treatment

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Appendix 1. Data collection form for availability of Diabetes Health Commodities at CHUK

Diabetes health commodities	Days of Stock out
Insulin lente	
Insulin rapide	
Mixed Insulin	
Insulin syringes	
Vildagliptin 50mg	
Glimeperide 3mg	
Glimeperide 6mg	
Gliclazide 60mg	
Gliclazide 30mg	
Metformin 850mg	
Metformin 500mg	
Glucose meter	
Strips	
Lancet	
Glycated hemoglobin reagent	

Appendix 2. Questionnaire for Patient

Dear Sir/Madam,

This questionnaire intends to gather information regarding your views on diabetes health commodities stock out and its effect on diabetes management at CHUK. Your response will be strictly used for academic purposes only and will be handled confidentially without disclosure of your identity whatsoever.

Section A: Background Information

1. Gender

1) Male

2) Female

2. Age

a. Between 18-25

b. Between 26-35

c. Between 36-45

d. Between 46-55

e. Between 56-65

f. Above 70

3. Highest level of Education

a. None

b. Primary

c. Secondary level

d. Advanced diploma (A1)

e. Bachelor (A0)

f. Masters

Others,

explain.....

Section A. Assessment of stock out on patients' care 1.

For how long have you been diagnosed diabetes?

➤ Below 1 year

➤ Between 1 and 2

➤ Between 3 and 5

➤ Above 5 years

2. Do you visit CHUK for diabetes follow up on which basis?

	Yes	NO
Once a month		
Once a quarter		
When complications arise		

1. Are you on oral hypoglycemic treatment? YES

No

No

2. Do you get all prescribed health commodities at CHUK? Yes

3. If no, do you manage to get your health commodities out of the hospital? Yes

No

4. Did your clinical conditions worsen due to lack of prescribed health commodities?

Yes

No

5. If yes, what was the severity of the situation

	Yes	NO
Coma		
Hospitalization below 5 days		
Hospitalization above 5 days		
Shifting from oral hypoglycemic agent to injection		
Morbidity		

8. Did the lack of health commodities at Hospital affect your compliance to prescription instruction? Yes No

9. Did the lack of medication affect you financially? Yes No

10. If yes, what proportion of your monthly earning does it take?

	Yes	NO
Below 5% of your earning		
Between 5 and 10%		
Between 10 and 20%		
Above 20%		

11. How often did you get all your medication within the hospital?

a. Always

b. Often

c. Sometimes

d. Rarely

e. Never

Do you monitor your Blood Glucose as indicated? Yes No

12. If no, what is the reason among the follow

	Yes	NO
No Glucometer		
No Strips		
Lancet		
Other reason:		

Appendix 3. Questionnaire for pharmacy and procurement staff

Dear Sir/Madam,

This questionnaire intends to gather information regarding your views on diabetes health commodities stock out and its effect on diabetes management at CHUK. Your response will be strictly used for academic purposes only and will be handled confidentially without disclosure of your identity whatsoever.

Section A: Background Information

1. Gender

a) Male

b) Female

2. Highest level of Education

a. Advanced diploma
(A1)

b. Bachelor (A0)

c. Masters

Others, explain.....

In the table below, rate your perception on how you agree with the statements given. Tick in the box according to perception as follow; strongly agree = 5, agree = 4, neutral = 3, disagree = 2, strongly disagree = 1.

N0	Item	5	4	3	2	1
	<u>Section B : Information management system</u>					
1	The facility has integrated the usage of information technology in managing its diabetes health commodities					
2	I am knowledgeable and certified in using computer applications regarding management of diabetes health commodities					
3	I regularly enter data into software when I receive or dispense diabetes health commodities					
4	Did the management system has the alert to reorder on time?					

5	The usage of health commodities management software improved the availability of diabetes health commodities					
6	I always consider lead time when ordering or informing for ordering diabetes health commodities					
7	I know the estimated quantity of each diabetes health commodities used monthly or yearly					
8	The management system contributes to the availability of diabetes health commodities					
Section C: Policy and Laws						
9	The procurement law smoothly facilitates to availability of health commodities					
10	The procurement process is a big hindrance to timely avail health commodities					
11	The budget to acquire health commodities are sufficient to meet customer demand					
<u>Section C: Workforce</u>						
12	Staff training have impact of management of diabetes health commodities					
13	The number of staff contribute to the success of CHUK health supply chain					
14	Staff motivation contribute to the success of health supply chain					
15	The experience of staff in health supply chain impacts the success of health supply chain					
<u>Section D: Effect of stock out</u>						
16	Diabetes patients always find their health commodities within CHUK					
17	Stock out of diabetes health commodities affect department reputation, institution and healthcare of patient					
18	The satisfaction of healthcare providers depends on the ability to provide relevant treatment meeting patients presented complaint or symptom					
19	Financially, patients are affected by stock out of diabetes health commodities					

Appendix 4. Interview guide

1. During your time at CHUK what has been your experience with diabetes health commodities stock out at CHUK?
2. What is your perception on diabetes health commodities stock out?
3. At which extent do you think diabetes health commodities stock out effect diabetes management at CHUK?
4. What challenges have you experienced during diabetes management resulted from stock out of diabetes health commodities at CHUK?
5. How would you describe the current situation today of diabetes health commodities at CHUK?
6. What would be your suggestion to improve diabetes health commodities at CHUK?
7. Any additional information?

Appendix 5. Informed consent form

Title: Assessment of diabetes health commodities stock out and its effect on diabetes management at Centre Hospitalier Universitaire de Kigali

PART I: Information Sheet Introduction

I am Adeline NZAMUKOSHA Masters student at University of Rwanda, college of medicine and health sciences in Health supply chain management. I am conducting research entitled assessment of diabetes health commodities stock out and its effect on diabetes management at CHUK. I want to share information about this study with you so that you can participate in the study

Purpose of the research

The purpose of this study is to assess diabetes health commodities stock out and its effect on diabetes management at CHUK. This may lead to the decrease stock out of diabetes health commodities and improve diabetes management at CHUK

Type of Research Intervention

This will be observational study

Selection of participants

You have been chosen to take part in this study because you are diabetes patients, you provide care to diabetes patients or you are involved in health supply chain at CHUK. The gathered information that will help us to identify and understand the best way to provide recommendations and solutions to enhance diabetes management through improved availability of diabetes health commodities

Voluntary Participation

Your participation in this study is voluntary. It is your choice whether to participate or not. The choice that you make will have no bearing on your professional standing or your everyday life.

You may change your mind later and stop participating even if you agreed earlier.

Procedures

You will be invited to participate in a survey by filling out a questionnaire. The survey will require 20 minutes to complete. There will be no sensitive question but you may always not answer a question that you may not feel comfortable to respond to. The information that will be provided will be kept confidential. Your name will not be filled on the form, you will be identified by the number and no one will access your information except the researcher

Duration

The group discussions will each take approximately 30 minutes of your time.

Risks and Discomforts

E.g. There is no risk associated with this study that can affect you negatively. During the group discussion, you may decide to share information. But, again, you may decline to answer any questions that you do not wish to answer or stop the interview at any time, without giving any reasons. **Benefits**

There will be no direct benefit to you, but with your participation we hope to improve the diabetes management through enhanced availability of diabetes medicines

Reimbursements/ Incentives

You will not receive any payment or any other benefit to take part in this study, but your participation in this research is essential.

Confidentiality

We will not share your information to anyone beyond the research team. Your information will be kept private. You will not be required to provide your name; your information will be having a number on it that will be only known by research team instead of your name. Your information will be kept in a password protected research computer.

Sharing of Research Findings

The summary of the aggregated results of this study will be shared to hospital authorities before it is made widely available to the public. We will in the future publish on the process and the results, but you and your feedback will remain anonymous.

Right to refuse or withdraw

To reiterate, you do not have to take part in this research if you do not wish to do so, and choosing to participate will not affect your job or job-related evaluations in any way. You may stop participating in the group discussion(s) or interview at any time that you wish without your job or care being affected.

Whom to contact in case you have questions about your rights as a research participant All research on human volunteers is reviewed by CMHS/IRB that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the CMHS/IRB through the:

Chairperson:

Secretary: Prof. Kato Njunwa

.....

Mobile phone: 0788490522

Mobile phone:

If you have any questions about this research, you may address your query to lead investigators:

Local	Lead	Investigator:	NZAMUKOSHA	Adeline	Tel.0788217455
Supervisor:	Dr.	HAHIRWA	Innocent	Tel	0786006010

If you choose to be part of this research study, I will also give you a copy of this consent form to keep for yourself.

Do you have any questions?

PART II: Certificate of Consent

I have been asked to participate in a study entitled assessment of diabetes health commodities stock out and its effect on diabetes management at Centre Hospitalier Universitaire de Kigali

I have read the information provided above. I have asked all the questions; I have at this time. I voluntarily agree to participate in this research study. I may withdraw my consent at any time and stop participation without penalty. By agreeing to be in this research, I have not given up any of my legal rights.

I consent voluntarily to be a participant in this study: Yes / No

I agree to be recorded: Yes / No

Print name of participant:

Signature of participant:

Date (day/month/year):

**Print name of Researcher: NZAMUKOSHA ADELINÉ Date
(day/month/year):**

If illiterate:

A literate witness must sign (if possible, this person should be selected by the participant, not be a parent, and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness:

Signature of witness:

Date (day/month/year):

Thumb print of participant:

I have accurately read or witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

**Print name of Witness:
(day/month/year)**

Signature of Witness:

Date

CMHS INSTITUTIONAL REVIEW BOARD (IRB)

Kigali, 20th /10/2021
Ref: CMHS/IRB/300/2021

NZAMUKOSHA Adeline
Master's in Health Supply Chain Management
CMHS, University of Rwanda

Dear NZAMUKOSHA Adeline

RE: ETHICAL CLEARANCE

Reference is made to your application for ethical clearance for the study entitled "*Assessment of diabetes health commodities stock out and its effect on diabetes management at Centre Hospitalier Universitaire de Kigali*"

Having reviewed your application and been satisfied with your protocol, your study is hereby granted ethical clearance. The ethical clearance is valid for one year starting from the date it is issued and shall be renewed on request. You will be required to submit the progress report and any major changes made in the proposal during the implementation stage. In addition, at the end, the IRB shall need to be given the final report of your study.

We wish you success in this important study.


Dr Stefan JANSEN
Ag Chairperson Institutional Review Board,
College of Medicine and Health Sciences, UR



Cc:

- Principal, College of Medicine and Health Sciences, UR
- University Director of Research and Postgraduate studies, UR

Review Approval Notice

Dear NZAMUKOSHA ADELINE,

Your research project: “Assessment of diabetes health commodities stock out and its effect on diabetes management at Centre Hospitalier Universitaire de Kigali”

During the meeting of the Ethics Committee of University Teaching Hospital of Kigali (CHUK) that was held on 17th Dec,2021 to evaluate your request for ethical approval of the above-mentioned research project, we are pleased to inform you that the Ethics Committee/CHUK has approved your research project.

You are required to present the results of your study to CHUK Ethics Committee before publication by using this link:www.chuk.rw/research/fullreport/?appid=481&&chuk.

PS: Please note that the present approval is valid for 12 months.

Yours sincerely,

Dr Emmanuel Rusingiza Kamanzi
The Chairperson, Ethics Committee,
University Teaching Hospital of Kigali



Scan code to verify.

“University teaching hospital of Kigali Ethics committee operates according to standard operating procedures (Sops) which are updated on an annual basis and in compliance with GCP and Ethics guidelines and regulations “

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