MONITORING THE AVAILABILITY AND PRICE OF INSULIN IN HEALTH FACILITIES AND HOUSEHOLDS IN MALI

Study protocol

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1. INTRODUCTION

More than 16 million people in Africa are living with diabetes and it is estimated that by the year 2045, this number will increase to 41 million (an increase of 156%). Nearly 70% of diabetes cases in African countries are undiagnosed and 77% of people with diabetes die from the condition before the age of 60. The prevalence of diabetes in adults aged 20 to 79 years in Mali stands at 1.8%, with 143,400 cases of diabetes reported in 2017.

Even though diabetes can be managed, access to treatment interventions is limited. For example, the suboptimal availability and the high prices of insulin in health facilities have been documented as two of the barriers to insulin access in many countries. Access to insulin and other diabetes supplies (such test strips and syringes) are particularly limited in African countries. More specifically in Mali, previous studies have shown poor availability of insulin and related medical supplies. The table below shows the availability of insulin and supplies for managing diabetes in public health facilities in Mali. With the exception of urine glucose test strips, the availability of insulin and related supplies were below 50%.

Table 1. Availability of insulin and supplies for managing diabetes in public facilities in Mali

	% of health facilities having product in stock
Insulin	17%
Any form of testing materials	43%
Urine glucose test strips	54%
Ketone strips	13%
Glucometer	43%
Spectrophotometer or blood analysis equipment	23%

The high price of insulin and related medical supplies has also been a concern in Mali. For example, a 2006 report by the International Diabetes Federation showed that the cost of an insulin syringe ranged between US$0.20 and US$0.60, the cost of a urine glucose test was about $0.89, and the cost of a blood glucose test was US$2.38 in the public sector in Mali. A more recent study in 2016 showed that the government procurement price for a 10ml 100IU vial of human insulin was 3,510 CFA ($ 5.90). In the public sector, patients paid 4,520 CFA ($ 7.60) for 10ml 100IU human insulin. This price is equivalent to approximately 4 days wage of the lowest paid unskilled government worker. Median patient prices in private pharmacies for 10ml 100IU human insulin was 4,975 CFA ($ 8.36), while the same volume and strength of

analogue insulins was 29467 CFA ($49.52) – 42500 CFA ($71.43) depending on the analogue type. These prices are respectively equivalent to 4.3 to 36 days' wages of the lowest paid unskilled government worker. The limited availability and high price of insulin and related supplies in both the public and private sectors makes the cost and availability monitoring in health facilities and households very important.

The 2016 Lancet Commission on Essential Medicines recommended the creation and maintenance of information systems for collecting routine data on the availability and affordability of essential medicines in both public and private sectors. In-person interviews, which have been the primary method of data collection, particularly in low- and middle-income countries (LMICs), are expensive and resource intensive. Collecting data on medicines through telephone interviews holds great potential for implementing the recommendation of the Lancet Commission. Phone interviews are less expensive, less time consuming, and offer flexibility for larger sample size studies. The high mobile phone ownership in low- and middle-income countries (LMICs) is an added advantage to this mode of data collection. For example in 2016, there were 96 mobile phone subscriptions per 100 people in LMICs, which is close to the worldwide subscription rate of 100.7 per 100 people.

Health Action International (HAI), and Boston University School of Public Health have developed a phone-based system (which includes a mobile phone application, dashboard and user manual suitable for use in any country) for monitoring the availability and prices of insulin and related supplies in health facilities and households. This monitoring tool, which will be made publicly available for countries and organizations to use at no cost, is expected to be piloted in four countries initially: first in Mali, then in Kyrgyzstan, Peru and Tanzania. This work will be implemented under the Addressing the Challenge and Constraints of Insulin Sources and Supply (ACCISS) Study which HAI coordinates. ACCISS aims to address inequities and inefficiencies in the global insulin market.

Santé Diabète is piloting the monitoring tools in Mali. Santé Diabète is a non-governmental organization (NGO) that works to improve access to diabetes prevention and management services in Mali and other African countries. The patient registry of people living with diabetes in particular makes Mali an ideal country for the piloting of the monitoring tools.

This document outlines the design of the pilot study, and the methods of data collection from health facilities and people using insulin at a household level.

2. STUDY OBJECTIVES

Primary objectives

The primary objectives of the availability and price monitoring system are to:

1. Provide regular information on the availability and prices of insulin and related supplies in Mali;
2. Measure changes in availability and prices over time; and
3. Provide information to stakeholders about insulin prices and availability.

The secondary objective is:

1. To harness lessons that can be used to revise the monitoring tools

3. METHODS

3.1 Study design

This study will use a time series study design to collect data on the availability and prices of insulin and related supplies (blood glucose test strips and syringes) from health facilities and households.

3.2 Study sites

The study will be implemented in health facilities and households in six regions of Mali. These regions were selected based on:

3.3 Recruitment of study participants

3.3.1 Health facilities

Data will be collected in the public and private sectors. All public health facilities and private pharmacies/licensed drug stores in the study regions are eligible to participate in the study. The list of these health facilities and their contact telephone numbers will be obtained from the patient registry and Ministry of Health. A total of 30 public and 30 private pharmacies/licensed drug stores (5 facilities from each of the four sectors in each region) will be randomly selected from the study regions to participate in the study. Selected facilities will be called by telephone, the study will be discussed with them, and they will be asked if they are interested in participating in the study. Interested facilities will be administered a verbal consent over the phone.

3.3.2 Households (People using insulin)

Currently the registry of people living with diabetes lists 750 people with Type 1 and 15 000 people with Type 2 diabetes. Using this registry, a random sample of 20 people with Type I

diabetes and 20 people with Type 2 diabetes will be selected from each region. The total number of participants will be 240 i.e. 120 people with Type I and 120 people with Type 2 diabetes.

3.3.4 Exclusion criteria

People with diabetes who do not use insulin will be excluded from this study. Additionally, facilities and households who do not have contact phone numbers will also be excluded.

3.4 Data collection

Data will be collected through quarterly telephone interviews with the facility and household participants in each region. Data collectors will be trained on key concepts of determining the availability and price of insulins, ensuring data quality, ethics of data collection (through both telephone and in-person (validation) interviews) and phone etiquette. Data will be collected using survey instruments programed on a smart phone (or tablet), with the software application CommCare (20). After training, the study instrument will be pilot-tested by the trained data collectors and revised based on the feedback received from the pilot.

3.4.1 Facility level data collection

Data will be collected on the availability and prices of all categories of insulin in stock (human, analogue and animal), insulin types (short-acting, intermediate-acting, long-acting, rapid acting, mixed) and presentations (cartridges, pre-filled pens, vials). For each insulin, data will be collected on the brand name, manufacturer, strength (IU/ml), volume of insulin (ml), pack size, and pack price. Data will also be collected on the availability and prices of the lowest-priced insulin and tuberculin syringes in stock on the day of data collection.

For comparison purposes, data will be collected on the availability and prices of the most common strengths of two oral antidiabetic medicines – metformin 500mg and glibenclamide 5mg tablets. Additionally, data will be collected on the most commonly used oral statin (INN name and strength) and the most commonly used oral antihypertensive medicine (INN name and strength) in the country. For these two groups of comparators, data will be collected on the product with the lowest unit price - brand name, manufacturer, pack size, pack price and unit price.

3.4.2 Household level data collection

Data will be collected on the availability of insulin the patients have at home, and the price and place of their most recent purchase of this. Data will also be collected on the category of insulin (human, analogue or animal), brand name, manufacturer, presentation (cartridges, pre-filled pens, vials), strength (IU/ml), volume of insulin (ml), and the pack size purchased. Furthermore, data will be collected on the availability and price of insulin syringes (or tuberculin syringe if used) and blood glucose test strips when available in the home. Data on how often people test their blood glucose levels will also be collected.

3.4.3 Validation visits

During the first quarter of the telephone monitoring, validation visits will be conducted with a 10% subsample of facility and household participants. This will involve conducting an unannounced in-person interview with them to validate the data collected on the phone within 24 hours of the phone interview. The validation visits will be carried out in Bamako and one other region in the survey.