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Diabetes Testing Design Proposal

A. Objective

Diabetes is a chronic illness involving the inability of the body to properly produce or respond to insulin, creating irregularities in blood sugar levels which can have dangerous health effects. The goal of this project is to create a means to test blood sugar that is reasonable for the people with diabetes of Kampala, Uganda to use regularly. The low average income of a person in Kampala is not enough to support common methods of testing blood glucose, such as using glucometers and test strips multiple times daily, so the final product must be cheaper to manufacture than current methods. To help reduce costs and improve sustainability, the product must be able to be produced locally. Because blood sugar levels can fluctuate widely in the span of a few hours, it must be convenient and affordable for people to test their blood sugar using this method multiple times a day. The device must be accurate enough to detect high and low levels of glucose, but accuracy to modern standards of glucose testing are not the primary objective of this project— it is more important to create reasonably-accurate, affordable devices than high-accuracy, budget-breaking existing solutions. Safety of the user is, as always, a top concern, and care to limit the risk of infection or excessive blood loss is important.

The goal of this project are not to improve existing educational media or treatment methods, but only to create a device to test blood glucose using the criteria above.

B. Background

Diabetes (diabetes mellitus) is a disease which affects the body's ability to create or use insulin, a hormone created in the pancreas that regulates blood sugar. Type I diabetes is an autoimmune disease, in which the insulin-producing cells in the pancreas are attacked by the immune system, so the body is unable to produce insulin. Type II diabetes occurs when cells become resistant to insulin. The body may still produce insulin, and usually overproduces insulin in an attempt to keep blood sugar levels normal (Higuera). There is no known cure for diabetes, so close monitoring and constant treatment are necessary to keep a diabetic patient healthy. Patients with Type I diabetes may need as many as ten blood sugar level tests a day; patients with Type II diabetes not on oral medication may also need a few tests a day

Diabetes is an increasing global health concern. The World Health Organization (WHO) states that the number of people with diabetes globally has risen from 108 million in 1980 to 422 million by 2014, a 300% increase ("Diabetes Key Facts"). They also note that the prevalence of the disease is increasing quicker in middle- and low-income nations.

This project focuses on the capital city of Uganda, Kampala. The WHO reports that the prevalence of diabetes is 2.8% ("Uganda Country Profile"), causing 1% of the deaths in Uganda in 2016. A study published in *Tropical Medicine & International Health* in January 2016 analyzed the rates of impaired fasting glycaemia (IFG) and diabetes in Uganda, and reported the prevalence of diabetes to be 2.7% in urban regions and 1.0% in rural areas. According to a 2014 census by the Uganda Bureau of Statistics (UBOS), Kampala is the largest city in Uganda, with a population of 1,507,080, roughly four times as populous as the next largest city ("UBOS National Population and Housing Census"). Because of the increased prevalence of diabetes in cities and the increasing prevalence of diabetes in third-world countries, Kampala is a point of interest.

Uganda is a low-income nation: according to the UBOS Key Economic Indicators Q2 2017-2018 edition, the GDP per capita at current prices is 2,475,413 shillings, which is USD $681 at a selling rate of 3,633 shillings per USD ("UBOS Key Economic Indicators"). Other estimates of the national average are even lower: the United States Agency of International Development (USAID) and the Frederick S. Pardee Center for International Futures published a report in November 2017 stating that the GDP per capita is $580 (Rafa et al.). According to this report report, Kampala has the second-highest district GDP per capita of $2,655, exceeded only by Wakiso ($3,250). The study also reports that "Kampala is roughly 5% of Uganda's population, but it generates 22.5% of [Uganda's] GDP." Therefore, the focus is not on the poorer rural areas of Uganda, but actually one of the wealthier ones, but cheaper means of blood glucose testing can be beneficial to a poorer region of Uganda as well. The difference is that Kampala has the resources of a large city, and manufacturing will most likely be concentrated in cities of comparable size.

Using this estimate of GDP per capita in Kampala creates the estimate of a monthly income of $221, and a daily income of roughly $7. (For the $580 estimate for GDP per capita in Uganda, the values are $48 and $1.59, respectively.)

The most common method of blood sugar testing currently is by using glucometers with test strips. A person pricks a finger with a needle to obtain a small volume of blood, which is placed on the test strip, which is then analyzed by the glucometer. The test strips have on them the glucose oxidase enzyme, which reacts with glucose and oxygen to form glucono delta-lactone (which hydrolyzes to form gluconic acid) and hydrogen peroxide. The glucometer has two electrodes which send a current through the test strip, and the amount of gluconic acid on the strip determines how much current flows. The glucometer is calibrated to determine the glucose level from the amount of current detected.

Most current glucose strips cost between $0.40 and $2.00, although diabetes business expert David Kliff claims that mass-producing strips cost large diabetes strip manufacturers only $0.15, with a large profit (Gebel). The cost of a glucometer typically ranges between $20 and $80, but some with more advanced features may cost hundreds of dollars; the cost of lancets to pierce the skin, which may need to be replaced periodically, often cost between $0.05 and $0.22 ("Cost of a Glucose Meter").

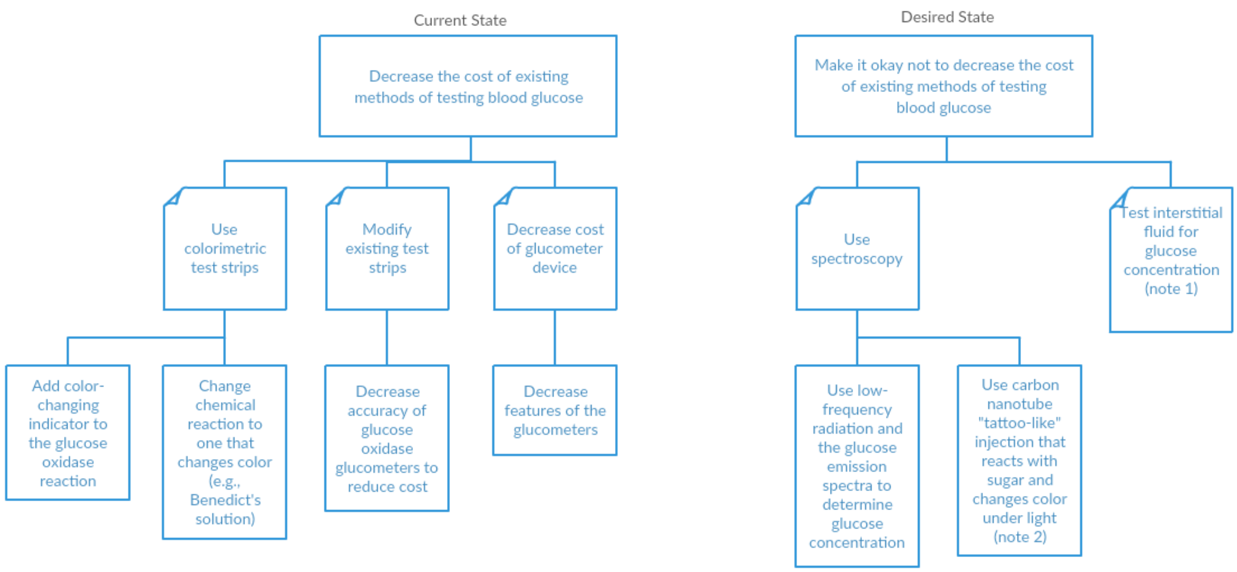
These costs are very high for the average person in Kampala. First of all, a glucometer may cost several days of a person's income. If a person with Type I diabetes has to have ten tests a day, it may cost a few dollars per day, which makes up a large part of a person's daily income.

Another common test is continuous glucose monitoring (CGM), which has a sensor under the skin and takes measurements of blood sugar every few minutes. But the cost of these devices is very high: the machine itself may cost $2,500 (Wan et al.), very impractical for low-income people. There is also the HbA1c screening test to measure long-term average blood glucose concentration, but this is not designed for regular screening.

C. Methodology

(Because the final solution has not been agreed upon, this section, the expected results, and the cost sections will all be generalized for all possible solutions.)

<u>Duncker Diagram</u>



Notes:
1. Source: https://www.sciencedaily.com/releases/2018/04/180409170952.htm
2. Source: https://engineering.mit.edu/engage/ask-an-engineer/how-do-glucometers-work/

There are two main approaches to the problem: to decrease the cost of existing methods of testing blood glucose, or to work on alternative methods of testing blood glucose.

The glucose-oxidase reaction used commonly in glucometer test strips can be used along with a color-changing chemical reaction to test glucose concentration. This doesn't require a glucometer (and electricity), nor does it need the expensive metal electrodes in the test strips. This was experimented with previously by G Cubed Solutions (Ofek et al.)

Another possibility is to use experimental methods of determining blood glucose level. MIT students experimented with the possibility with injecting (similar to tattoos) carbon nanotubes that reacted with glucose, and changed color when infrared light was shone onto them so that glucose level could be shown colorimetrically (Jensen). While injections are expensive and invasive, modifications of this method can be explored. A different method using spectroscopy could involve shining infrared (or lower frequencies) of light at a major blood vessel and testing for glucose's emission spectrum. This is similar to the idea of infrared vein finders ("Vein Visualization Technology"). Because spectrometry machines may be expensive, because it is non-invasive and quick, it may be desirable to have one community-use spectrometer machine in a diabetes center.

<u>Gantt Chart</u> (provisional)

Task	Week														
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Introduction and initial research	X	X	X	X											
Design proposals			X	X	X										
Research and design					X	X	X								
Implementation							X	X	X	X	X	X	X	X	
Testing and analysis													X	X	X

D. Expected Results

The expected result must be a cheap product that uses common chemicals or technology that can be manufactured locally in Kampala. The device will be simple to use and cheap.

If the device is a modification of the existing glucose oxidase reaction commonly used in glucometers, it must be cheap (at most $0.01 or less per strip) to be affordable. This may include colorimetric strips that conduct a chemical reaction and approximates the blood glucose concentration by observing the color of the resulting strip. If the device involves spectroscopy, it will be a non-invasive technique. It may be either a small, personal device or an advanced machine that can be used at a clinic and perform quick tests.

In either case, the final product will be easy to use and either cheap for personal use (an improvement of the glucose testing strip), or very convenient to be used by the community (spectroscopy).

E. Cost

The cost will depend on the choice of final project, but the final design should be cheaper to manufacture than current models, including labor and materials. If glucose oxidase is used with an indicator, glucose oxidase can be bought at $45 to $110 per kilogram ("Glucose Oxidase Price"), which would cost $0.000045 to $0.00011 per milligram, and only a few milligrams of glucose oxidase and acid-base indicator (to detect levels of gluconic acid) will be necessary to create a simple and cheap colorimetric test strip.

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