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Laboratory diagnosis and the use of Glucometers in the Management of Diabetes Mellitus

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Diabetes Mellitus (DM) is a global concern. Nigeria has not been spared the burden of this disease. Diabetes accounts for a significant number of hospital admissions and deaths in Nigeria.[1]

Diagnosis of DM is confirmed by laboratory or biochemical investigation. A provisional diagnosis is made first in cases with clear clinical features, such as hyperglycaemic crises or overt complications and substantiated by a biochemical diagnosis. Diagnosis using any of the diagnostic tools is usually by two different tests done on the same specimen or two abnormal results from two different specimens from the same patient. Effective management of diabetes mellitus is multidisciplinary. The chemical pathologists and clinicians must work hand in glove.

Screening is done for adults above 45 and for at-risk individuals. The American Diabetes Association (ADA) recommends screening all asymptomatic adults for DM starting from 45 years and three yearly thereafter.[2] Obese and overweight adolescents and adults below 45 years and any overweight person with an extra risk regardless of age should also be screened at any opportunity. Extra risk factors include hypertension, increased cholesterol, heart disease, etc. Children who are obese (body mass index at the 95th percentile) and have at least one additional risk factor should be screened at 10 years of age or at the onset of puberty, whichever comes first. [3] Risk factors for children include maternal history of GDM or DM and race (Blacks, American Indian, Hispanic). Screening should be repeated every 3 years.

In Nigeria, yearly baseline investigation is encouraged (including plasma glucose) starting from 40 years. This is because the life expectancy in Nigeria is lower than in developed countries.

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It was 55 years in 2019 [4], now 62 years (2024)[5] compared to 78 and 81 in America and the United Kingdom.[4] Individuals with pre-diabetes are screened yearly. Pregnant women without a history of DM should be screened between 24-28 weeks of gestation. Those at high risk should be screened before the 24th week using non-pregnant parameters.

Several tests are used to make a diagnosis of DM.[6] One test is the fasting plasma glucose (FPG); the diagnostic value for diabetes is >/= 7mmol/L, impaired fasting glucose is >= 6.1 (ADA 5.6), while normal is 3.3-5.5mmol/L. Another test is the Oral Glucose Tolerance test. (OGTT) which is a standardised challenge test. This test identifies borderline individuals more effectively. It is more sensitive for making the diagnosis of DM and impaired glucose tolerance. It's indicated when the results from an FPG are equivocal and when the clinical symptoms do not correspond with the result. It is used to screen non-diabetic pregnant women. The OGTT has two types: the 1-hour plasma glucose OGTT, which is a one-step approach. 95% of obstetricians in the United States prefer it as a screening test for pregnant women. 75 grams of anhydrous glucose are used; a baseline and 60-minute specimen are taken. The two-step approach uses 50 grams of oral glucose and fasting is required. Specimens are taken at baseline, 30, 60, 90 and 120 minutes.

A third test is the random plasma glucose test. It is most useful in emergency states, when a patient presents with classic symptoms of hyperglycaemia or is experiencing a hyperglycaemic crisis. In such situations immediate intervention is required. It is not as sensitive as the FPG. A value above 11 mmol/L is diagnostic.

A fourth test is the glycated haemoglobin (Hb A1c). This is very important for assessing glycaemic control over three months. Proteins react spontaneously with glucose in the blood to form glycated derivatives. This reaction is not enzyme-dependent; it is physiologic and occurs slowly over time. The percentage of glycated proteins is a marker of the fluctuations in blood glucose. It has lower sensitivity and higher cost than plasma glucose. Some haemoglobin variants, such as AS, AC and SS, interfere with results, and interpretation should be done with caution. In cases with increased red blood cell turnover, pregnancy, HIV infection and haemodialysis, plasma glucose is preferred. However, it is recommended by the ADA for diagnosis of type 2 DM in paediatric patients. The expected result is <5.7%; 5.7-6.4% is prediabetes and a value of 6.5% is diabetic. The frequency of testing depends on the diagnosis and type of treatment.

Other miscellaneous tests that help qualify the diagnosis, rule out complications, and monitor the efficacy of treatment include blood lipid profile, serum C-peptide, insulin, urine analysis of glucose, ketones, and microalbumin. Approximately a third of children with type 1 DM present with ketoacidosis.

Reliability of laboratory results is crucial to the proper management of the patient. Though FPG is easy to perform, the reliability or trustworthiness of the result is essential. Hence the need for quality control. Tertiary laboratories are involved in internal and external quality control programmes. The aim is to ensure that the results produced are as close to the "true" value as possible and can be compared with the highest standards. Using wrong results or values to manage a patient can be as fatal as having a wrong diagnosis ab initio.

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The management of DM has evolved over the years to include patient participation. Self-monitoring of blood glucose is an essential component of the management of DM. [7] Hence, the use of glucometers is encouraged. There are numerous advantages to this, and the overall outcome is improved.

Calibration of glucometers is indispensable. Calibration means adjusting or marking the glucometer in such a way that it can be used in an accurate and exact way. It could also compare a known measurement (the standard) and the measurement using the glucometer. The aim is to improve the precision and accuracy of the glucometer. There are different calibration points; they include before use, at regular intervals (for example, every six months), after an incident (e.g., a fall or manhandling) and when observations appear questionable. It is the role of the chemical pathologist (laboratory physician) to ensure quality control of all clinical chemistry point-of-care devices used within a hospital. The chemical pathologist also advises on devices to purchase and how to use them. They help interpret results and troubleshoot when there is a crisis. This calibration involves the use of standards and comparison with already known and proven values and methods.

Quality control can be internal or external. Many glucometers come with standards from the manufacturer that can be repurchased. All chemical pathology laboratories should have their glucose standards as well. These could be purchased or constituted locally.

When a glucometer is not giving accurate results. There is a protocol to follow. First, go through the checklist, then eliminate contraindications and take your kept records to a chemical pathologist who would troubleshoot. It is important to ensure that the instructions have been read and followed, the strips are stored in the right conditions, the specimen was taken from the right site and is the right size, contraindications were ruled out, and proper records were kept.

There are some contraindications to the use of glucometers. For example, dialysis with maltose-containing dialysate can interfere with results from a glucometer. In addition, peripheral circulatory failure, which could be caused by severe dehydration, hyperosmolar states, with or without ketosis, hypotension, shock and peripheral vascular disease, severe dehydration, and variations in oxygen tension. High concentrations of non-glucose reducing substances, bilirubin, and increased haematocrit can also alter the results.

Overall, both the laboratory and the use of glucometers are invaluable to the diagnosis and management of diabetes mellitus.

Conflict of interest statement
None to declare

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