Diabetes Mellitus: Test and Tools

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In 2017, there are 425 million patients living with diabetes in the world. This figure is estimated to increase by 45% or the equivalent of 629 million patients by 2045. Cardiovascular and kidney complications are the leading cause of death for diabetic patients in the world. Indonesia ranked 6th out of ten countries with the highest number of diabetes patients, which is 10.3 million patients in 2017, and expected to increase to 16.7 million patients in 2045.^[1]

Since 2014, a national social security system has been implemented in Indonesia, thus began the tiered referral era. In this condition, most diabetes mellitus patients will be treated at the first level of health facilities. Only when complications arise or things that require being referred to a specialist will be sent to a referral hospital. This causes most of the diagnosis and monitoring of therapy results to be carried out at the first health facility, which generally has limitations in medical facilities and personnel. For that, we need tools that can bridge the boundaries of medical facilities and personnel with the

accuracy of diagnosis and monitoring therapy in diabetes mellitus patients.

What is the guideline say?

According to American Diabetes Association, diabetes may be diagnosed based on plasma glucose criteria, either the fasting plasma glucose (FPG) value or the 2-h plasma glucose (2-h PG) value during a 75-g oral glucose tolerance test (OGTT), or A1C criteria.^[2] Guidelines for the management of diabetes mellitus in Indonesian adults issued by the Indonesian Society of Endocrinology (PERKENI) states that the diagnosis of diabetes mellitus includes examining fasting blood glucose ≥ 126 mg/dl, oral glucose tolerance test ≥ 200 mg/dl, or random blood glucose ≥ 200 mg/dl with classical diabetes symptoms, or HbA1C ≥ 6.5 % with standardized examination.

HbA1C examination has been used as a standard for the diagnosis of diabetes mellitus for years. This examination has begun to be used as a definitive diagnosis of diabetes mellitus since the Diabetes Control and Complications Trial (DCCT) study showed an association between HbA1C levels and the risk

of complications from diabetes mellitus. Subsequent studies from United Kingdom Prospective Diabetes Study (UKPDS) also demonstrated an association between HbA1C levels and risk of complications, such as the level of HbA1c 10 % indicating a three times greater risk of retinopathy than the level of HbA1c 7.5%. [3]

What kind of tools are available?

Many methods have been developed to perform HbA1c assays based on differences in the structure between glycosylated and those that are not. The developed methods include ion-exchange chromatography, electrophoresis, boronated affinity chromatography, and immunoassay methods. The existence of these several methods implies challenges in standardizing HbA1C examinations. This standardization is needed to ensure that HbA1C results can be correlated with studies from DCCT and UKPDS that show an association between HbA1C levels and complications that can occur. For this reason, a standard HbA1C examination was created by the American Association for Clinical Chemistry (AACC), which implemented The National Glycohemoglobin Standardization Program (NGSP) to standardize HbA1C tests since 1996.[4]

(HPLC) High-Performance Liquid Chromatography and electron spray mass spectrometry are some of the methodologies used as references for measuring HbA1c. Still, these two examinations require substantial costs, facilities, and infrastructure. This is, of course, a problem related to the financing that must be issued if this examination is a routine examination for diabetes patients in Indonesia.

What are the options?

In the last few months, HbA1c examination by Point of Care Testing (POCT) is developed in Indonesia. POCT is a method of examination performed outside the central laboratory using instruments. In diabetes mellitus patients, POCT is commonly used for blood glucose control such as glucometer examination. Currently, POCT checks are also being used to monitor HbA1C. The challenge that has been raised is the need for standardization with a tool that has been established as a definitive diagnosis. POCT for HbA1C examination has several advantages such as the use of a practical tool in the sense that it can be used immediately without having much special preparation, results that can be seen in a short time, the use of fingerstick instead of venous blood so that the patient will be more comfortable.[5]

Several studies report improved outcomes from the implementation of POCT to use in the outpatient and inpatient setting, both in the form of medical outcomes such as enhanced disease control, operational outcomes such as decreased length of stay, and financial outcomes (cost control).[6] In his review article, *Schnell* concluded that examining HbA1 utilizing POCT would improve compliance with the implementation of HbA1c examination recommendations as a method of monitoring blood glucose control, improving clinical outcomes, and improving patient education and motivation, improve the quality of life of patients, also saving costs.[7]

Most of the data above were obtained from patients who performed blood glucose control at the referral hospital. With the tiered referral system of the *Sistem Jaminan Sosial Nasional* currently in effect in Indonesia, the largest number of patients will be in primary health care. A diagnostic examination system and monitoring of therapeutic results are simple but high accuracy is needed. A study is

needed to see how the accuracy and efficiency of the POCT examination for Hba1c used in primary health services in Indonesia so that it can be used as the basis for the wider use of POCT-HbA1C.

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