

Global Guideline for Type 2 Diabetes

Chapter 1: Screening and diagnosis

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Recommendations

■ Standard care

- SD1 Each health service should decide whether to have a programme to detect people with undiagnosed diabetes.
- This decision should be based on the prevalence of undiagnosed diabetes and on the resources available to conduct the detection programme and treat those who are detected.
 - Universal screening for undiagnosed diabetes is not recommended.
 - Detection programmes should target high-risk people identified by assessment of risk factors.
- SD2 Detection programmes should use measurement of plasma glucose, preferably fasting.
- For diagnosis, an oral glucose tolerance test (OGTT) should be performed in people with a fasting plasma glucose ≥ 5.6 mmol/l (≥ 100 mg/dl) and < 7.0 mmol/l (< 126 mg/dl).
- SD3 Where a random plasma glucose level ≥ 5.6 mmol/l (≥ 100 mg/dl) and < 11.1 mmol/l (< 200 mg/dl) is detected on opportunistic screening, it should be repeated fasting, or an OGTT performed.
- SD4 The WHO 1999 criteria [1] should be used to diagnose diabetes; these include the importance of not diagnosing diabetes on the basis of a single laboratory measurement in the absence of symptoms.
- SD5 People with screen-detected diabetes should be offered treatment and care.

This guideline does not deal with lesser degrees of hyperglycaemia detected on screening.

■ Comprehensive care

SD_c1 Resources should be available for diabetes detection programmes.

SD_c2 Investigations to classify type of diabetes (e.g. islet-cell related antibodies, C-peptide, genotyping) should be available.

■ Minimal care

SD_M1 Detection programmes should be opportunistic and limited to high-risk individuals.

SD_M2 Diagnosis should be based on fasting laboratory plasma glucose (preferred) or capillary plasma glucose.

SD_M3 If blood glucose testing is not available, the presence of glycosuria, especially with classical symptoms, may be used to diagnose diabetes.

Rationale

Screening for Type 2 diabetes has important implications for individual health, day-to-day clinical practice, and public health policy. While the early detection and treatment of diabetes seems logical in terms of minimizing complications, there is currently no direct evidence as to whether or not this is beneficial to individuals. Despite this lack of direct evidence, early detection through screening is taking place and is recommended by a number of organizations throughout the world.

The decision about conducting a detection programme should be based on the following considerations [2]:

- **epidemiological** - prevalence of undiagnosed Type 2 diabetes
- **health systems** - capacity to carry out the screening, provide care for those who screen positive, and implement prevention programmes in those at high risk of future development of diabetes
- **population** - acceptability and likely uptake of the screening programme
- **economic** - cost of early detection to the health system and to the individual, and relative cost-effectiveness of early detection compared with improving care for people with known diabetes.

Evidence-base

Diabetes is associated with a range of serious complications which result in reduced quality of life and premature mortality. Early detection and treatment is one strategy proposed for reducing this burden.

Screening / early detection

Type 2 diabetes has a long asymptomatic pre-clinical phase which frequently goes undetected. At the time of diagnosis, over half have one or more diabetes complications [3]. Retinopathy rates at the time of diagnosis range from 20 % to 40 % [4,5]. Since the development of retinopathy is related to duration of diabetes, it has been estimated that Type 2 diabetes may have its onset up to 12 years before its clinical diagnosis [4].

Of people with Type 2 diabetes, the proportion who are undiagnosed ranges from 30 % to 90 %. Overall, data from countries as diverse as Mongolia [6] and Australia [7] demonstrate that for every person with diagnosed diabetes there is another who has undiagnosed diabetes. Other countries have even higher rates of undiagnosed diabetes – 80 % in Tonga [8] and 60-90 % in Africa [9-11]. However, in the USA only 30 % are undiagnosed [12].

Although there is considerable evidence supporting the benefits of improved blood glucose, blood pressure and blood lipid control in Type 2 diabetes, no randomized controlled studies have assessed the potential benefits of

early diagnosis on outcomes in screen-detected diabetes. Therefore there is only limited indirect evidence suggesting that early detection may be beneficial.

Schneider et al. [13] performed an analysis of a mass-screening programme based on urinary glucose levels, conducted in the former East Germany in the 1960s and 1970s. It suggested that people found to have diabetes by screening had an improved outcome compared with those presenting spontaneously with diabetes.

Fasting plasma glucose (FPG) at diagnosis might serve as a surrogate for the duration of diabetes. A post-hoc analysis of UKPDS showed that the frequency of subsequent complications was related to FPG at study entry [14]. The group with an initial FPG <7.8 mmol/l (<140 mg/dl) had significantly lower rates of all major end-points compared with the ≥ 10.0 mmol/l (≥ 180 mg/dl) group and also had significantly lower diabetes-related death rates and myocardial infarction rates compared with the 7.8 to <10.0 mmol/l (140 to <180 mg/dl) group. These findings suggest a benefit of intervening either at lower FPG levels or earlier in the natural history of diabetes, and may be consistent with a benefit derived from early detection.

Studies in progress which may contribute to the knowledge-base on early detection of diabetes are the 'Inter99' study in Copenhagen county, Denmark [15] and the (Anglo-Danish-Dutch) ADDITION study [16].

Screening for diabetes will also identify individuals with lesser degrees of hyperglycaemia who may benefit from interventions to prevent or delay progression to diabetes, and to prevent cardiovascular disease.

Screening strategies

There are several options for strategies to screen for undiagnosed diabetes. The ultimate choice is based on available resources and a trade-off between sensitivity (the proportion of people with diabetes who test positive on the screening test), specificity (the proportion of people who do not have diabetes who test negative on the screening test), and the proportion of the population with a positive screening test which needs to proceed to diagnostic testing.

Most screening strategies include risk assessment and measurement of plasma glucose, performed either sequentially or simultaneously. Screening tests are followed by diagnostic tests (fasting plasma glucose (FPG) and/or an oral glucose tolerance test (OGTT)) in order to make the diagnosis. References 2 and 17 provide a detailed review of screening options. Combined screening strategies have a

sensitivity and specificity in the order of 75 %, and 25 % of the population require diagnostic testing. People who screen negative will need re-testing after 3-5 years. These people should also be offered lifestyle advice to minimize their risk of developing diabetes.

Although the usefulness of urine glucose as a screening test for undiagnosed diabetes is limited because of low sensitivity (21-64 %) [17], specificity is high (>98 %), so it may have a place in low-resource settings where other procedures are not available.

Diagnosis

Following a positive screening test, diagnostic testing is required. This may either be a confirmatory FPG (≥ 7.0 mmol/l, >125 mg/dl) or an OGTT. The diagnostic criteria for diabetes adopted by the WHO [1] and American Diabetes Association (ADA) [18] are accepted internationally.

Consideration

The place of screening for undiagnosed diabetes as part of an overall strategy to reduce the health burden of diabetes is not established. However, many organizations recommend it. The choice of whether to screen or not, and the screening strategy, must be made locally taking into account local considerations.

Implementation

A clear and transparent decision should be made about whether or not to endorse a screening strategy. If the decision is in favour of screening, this should be supported by local protocols and guidelines, and public and health-care professional education campaigns.

Evaluation

Number of health-care professionals and services performing screening, proportion of the population being screened, and detection rate of undiagnosed diabetes should be ascertained. Percentage of diagnosed people entering and continuing in care should be measured.

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