المجلس الصحي السعودي
Saudi Health Council

SNDC Diabetes Screening Program

مبادرة الكشف المبكر لداء السكري

November 2020

Saudi National Diabetes Center (SNDC)

المركز الوطني للسكري

SNDC Screening of T2DM diabetes in Saudi population:

National Diabetes screening program is an initiative proposed by Saudi National Diabetes Centre (SNDC) to early detect and treat diabetes and prediabetes in people living in the kingdom of Saudi Arabia. The program involves multiple stakeholders including physicians, health educators/health coach and nutritionists and coordinator. The screening program is intended to be applied by governmental and non-governmental health organizations represented in SNDC. Included in this file, the screening program, proposed implementation plan and training document that should present a roadmap for all stakeholders of the program.

National Diabetes Screening program includes three main documents:

1. **Saudi National Diabetes Screening program:**

- Provides the scientific content of the Saudi national diabetes screening program.
- Involves SNDC for T2DM screening in asymptomatic subjects age 35 and above as well as the criteria for screening Adolescents and children.
- Includes the manpower and resources needed to establish the program.
- Outlines the screening tests and the criteria for diagnosis.
- Provides an overview of the treatment pathways for both DM and pre-DM.

2. **A suggested implementation plan and KPIs**

   Provides a roadmap for the participating health organization to assist a successful implementation.

3. **Training program and materials:**

   - This document provides the training plan and scientific content of the program.
   - Includes job description and roles for each discipline including physicians, health educators/coaches, nutritionists and coordinators.

SNDC

Screening of T2DM diabetes in Saudi population

Definitions

DPP-4i	Dipeptidyl Peptidase 4 Inhibitor
FPG	Fasting Plasma Glucose
GDM	Gestational Diabetes Mellitus
GLP-1	Glucagon-Like Peptide-1
GLP-1 RA	GLP-1 Receptor Agonist
HbA1c	Glycosylated Hemoglobin A1c
HDL	High Density Lipoprotein Cholesterol
HDL-C	High Density Lipoprotein Cholesterol
HF	Heart Failure
HIV	Human Immunodeficiency Virus
IDF	International Diabetes Federation
IFG	Impaired Fasting Glucose
IGT	Impaired Glucose Tolerance
isCGM	Interstitial Continuous Blood Glucose Monitoring
LDL	Low-Density Lipoprotein
MENA	Middle East and North Africa Region
mg/dL	milligrams per deciliter
mmol/L	millimoles per liter
mmol/mol	millimoles per mole
MODY	Maturity-Onset Diabetes of the Young
NAFLD	Non-Alcoholic Fatty Liver Disease
NASH	Non-Alcoholic Steatohepatitis
OGTT	Oral Glucose Tolerance Test
OSA	Obstructive Sleep Apnea
PAD	Peripheral Artery Disease

Introduction:

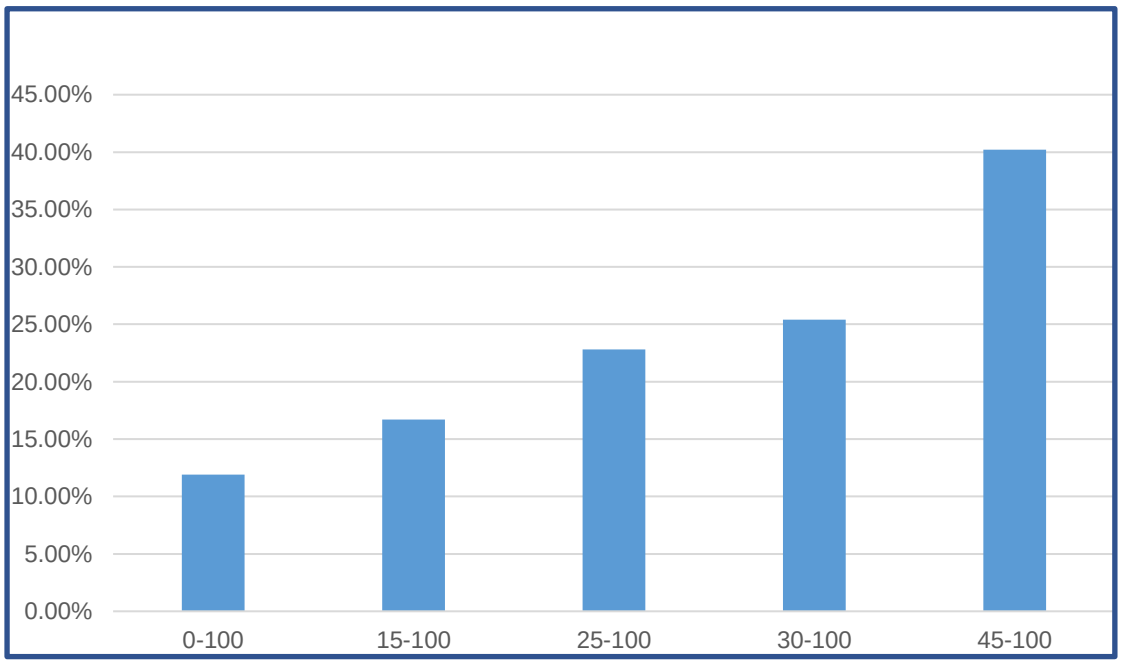
Type 2 Diabetes mellitus (T2DM) is a common disease in Saudi Arabia In 2013, MOH national survey showed DM affects 13.4% (1.75 millions) of the Saudi population aged 15 years and above (El Bcheraoui et al. 2014). Among those identified as diabetics from blood tests, 43.6% were undiagnosed. Also in the same study the number of those with prediabetes was 15.2% of the total population (El Bcheraoui et al. 2014). The other work published by Alrubean in 2014 revealed a prevalence of 11.9% in the whole population (Al-Rubeaan et al. 2014). Earlier in 2004, Al-Nuzha and colleagues revealed a prevalence of 23.7% in those older than 23 years (Al-Nozha et al. 2004).The kingdom is at a higher rank for the diabetes prevalence around the world that is mainly contributed to the lifestyle as well as other factors like genetic predisposition (Cho et al. 2018).

Unfortunately, despite the high prevalence rates of T2DM, there has not been a well-structured program to screen the Saudi population for dysglycemia conditions. Early diagnosis and interventions might delay or prevent T2DM related complications. The burden of the screening program on the health care system is difficult to estimate without proper studies. However, we believe the Saudi health care system can accommodate the screening process and consequently managing patients thereafter. Different screening guidelines have been published with different age limits and clinical criteria. For example, the American Diabetes Association (ADA) recommends screening for T2DM every year in patients aged 45 years or older, or in patients younger than 45 years with other risk factors (American Diabetes 2020). It is expected that diabetes screening program is going to identify more cases of pre diabetes which is the gateway for T2DM. In fact, this is a crucial step as an intervention at this period will help to reduce the prevalence.

The members of the scientific committee at the Saudi national diabetes centre (SNDC) have a consensus agreement to lower the age of screening in the Saudi population to the age of 35 for different reasons. First, the incidence of T2DM in the KSA is one of the highest worldwide as discussed earlier. Second, screening at earlier age will identify more cases of Prediabetes which should be a target for intensive prevention program. Third, after the age 30 years, about 25% of Saudi population were found to have T2DM (Al-Rubeaan et al. 2014). Fourth, previous screening studies have shown that only half of the screened subjects are aware of the T2DM

diagnosis. Therefore, targeting asymptomatic patients will identify more cases. Finally, the major T2DM organisations did not select the screening age limit on the basis of controlled studies. Instead, it was chosen based on the local epidemiological studies and experts consensus.

Having said that, SNDC encourages the participating members to study the effect of applying T2DM screening programs in the population under their care and report to SNDC with the outcomes. This will help to identify the pros and cons of the screening program, to estimate the budget and cost-effectiveness of such program. The National Diabetes screening program is intended to be applied by all organizations represented in SNDC as well as the private sector medical insurance policies.



Prevalence of diabetes in Saudi population by age group

Objectives:

- Primary objective:
  - Identify undiagnosed cases of T2DM and pre diabetes in Saudi population.

- Secondary objectives:
  - Formulate a diabetes screening program in KSA
  - Familiarize physicians with the importance of early diagnosis of T2DM
  - Formulate a clear pathway for the management of newly diagnosed prediabetes and type 2 diabetes

Benefits of the program:

- Identifying undiagnosed subjects with diabetes will help in providing early intervention to treat and mitigate the future complications
- Finding those with prediabetes will help in enrolling them in a diabetes prevention programs which has been shown to be beneficial in halting the risk of future T2DM in 58% (diabetes prevention program).
- Economic benefits are expected as early interventions will reduce the expense of health care in the long run by reducing Diabetes complications.

SNDC criteria for T2DM screening in asymptomatic subjects

1. Age 35 and above
2. Overweight Adults with (BMI ≥25 kg/m2), or with abdominal obesity (≥102 for men and ≥88 for women) who have, in addition, at least one of the following risk factors:

- Family history of T2DM: first-degree relative with T2DM
- Ladies with history of gestational diabetes
- History of CVD
- Hypertension (≥140/90 mmHg or on therapy for hypertension)
- HDL cholesterol level <35 mg/dL (0.90 mmol/L)
- Triglyceride level >250 mg/dL (2.82 mmol/L)
- Smoking
- History of pancreatitis
- Hyperuricemia/gout
- Non-alcoholic steatohepatitis
- Psychiatric disorders (bipolar disorder, depression, schizophrenia)
- HlV infection
- Obstructive sleep apnea
- Cystic fibrosis
- Use of drugs associated with diabetes: glucocorticoids, atypical antipsychotics, statins, highly active antiretroviral therapy or anti-rejection drugs
- Women with polycystic ovary syndrome
- Women with a history of delivery of a macrosomic infant or multiparity
- Physical inactivity
- Other conditions known to be associated with insulin resistance: acanthosis nigricans ... etc.

Exclusion criteria:

- Children under 18 years
- Pregnant ladies
- Type 1 diabetes mellites.
- Testing for diabetes should be done in an accredited lab.
- Point of care testing and capillary blood glucose should not be used for T2DM diagnosis

Screening and Diagnosis tests:

- Fasting plasma glucose
- HbA1c test (The test should be performed in a laboratory using a method that is NGSP certified and standardized to the DCCT assay)
- Random plasma glucose
- 75-g two-hour oral glucose tolerance test

Fasting plasma glucose:

Methods:

- The test should be performed while the patient is fasting at least for 8 hours.

FPG is inappropriate in:

- Acutely ill patients

- Pregnant ladies
- Patients taking medications that can raise blood glucose

Interpretation of FPG:

Result	FPG
Normal	Less than 100 mg/dl (5.6 mmol/l)
Prediabetes	100 mg/dl to 125 mg/dl (5.6 – 6.9 mmol/l)
Diabetes	126 mg/dl or higher (7 mmol/l)

Random plasma glucose:

Methods:

- The test is usually performed randomly

RPG is inappropriate in:

- Acutely ill patients
- Pregnant ladies
- Patients taking medications that can raise blood glucose
- After extensive exercise immediately

Interpretation of RPG:

Result	RPG
Normal	Not applicable
Prediabetes	Not applicable
Diabetes	200 mg/dl or higher (11.1 mmol/l)

HbA1c testing:

HbA1c methods:

- HbA1c should be done with an assay aligned with diabetes control and complication trial (DCCT) which indicates reporting HbA1c as percentage.
- Some non glycemic conditions can affect HbA1c results listed below

HbA1c is not appropriate to diagnose T2DM in the following conditions

- Patients suspected of having type 1 diabetes.
- Pregnancy.
- Patients with symptoms of diabetes for less than two months.
- Patients at high diabetes risk who are acutely ill.
- Patients taking medication that may cause rapid glucose rise e.g. steroids, antipsychotics.

- Patients with acute pancreatic damage, including pancreatic surgery.
-

Nonglycemic Factors That May Interfere with A1C Measurement

Falsely lower A1C

- Acute blood loss
- Chronic liver disease
- Hemolytic anemias
- Patients receiving antiretroviral treatment for human immunodeficiency virus
- Pregnancy
- Vitamins E and C

Lower or elevate A1C

- Hemoglobinopathies or hemoglobin variants
- Malnutrition

Falsely elevate A1C

- Aplastic anemias
- Hyperbilirubinemia
- Hypertriglyceridemia
- Iron deficiency anemias
- Renal failure
- Splenectomy

Interpretation of HbA1c:

Result	HbA1c
Normal	Less than 5.7 %
Prediabetes	5.7 to 6.4%
Diabetes	6.5% or higher

Oral glucose tolerance testing (OGTT):

Methods:

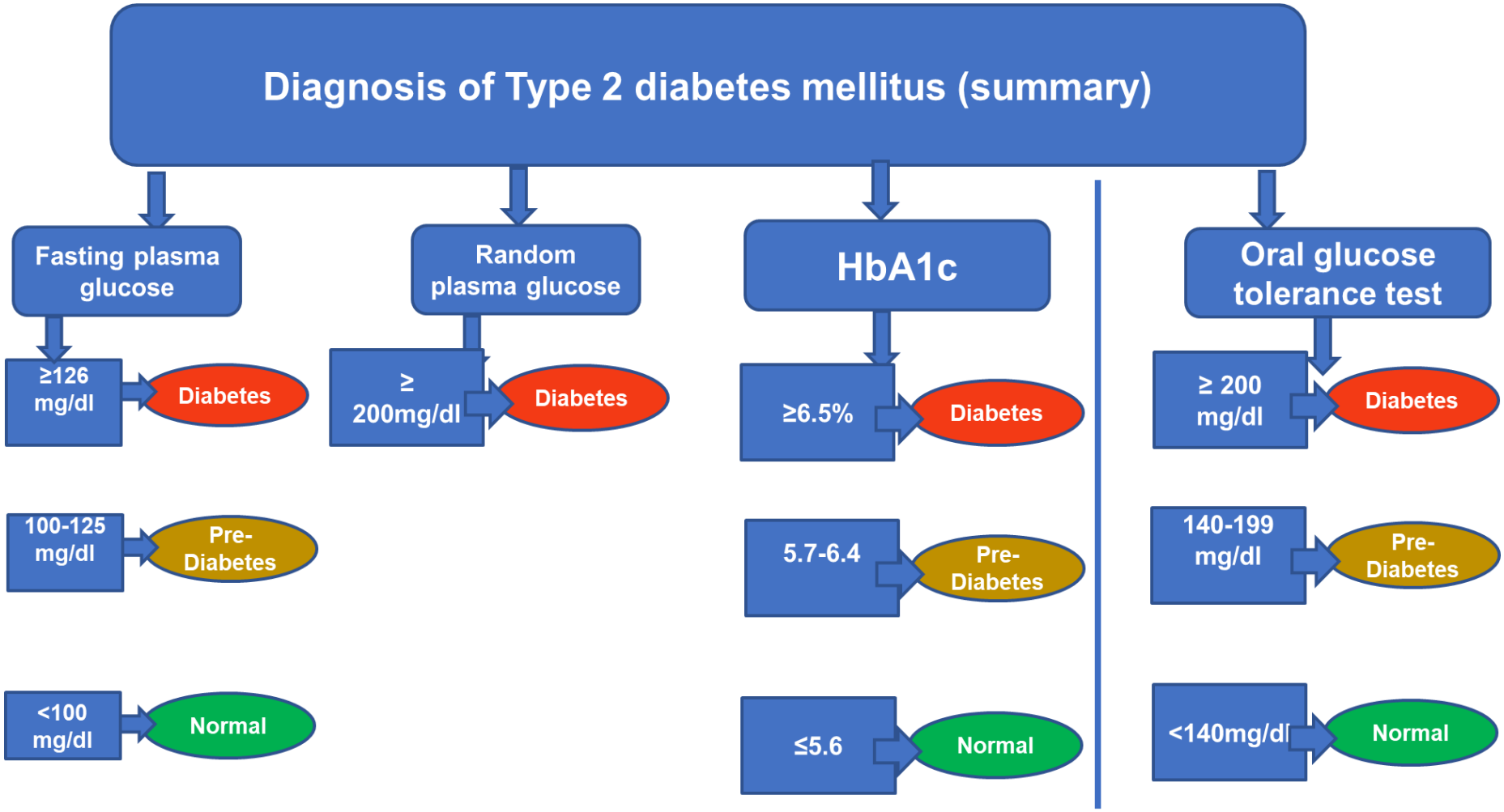
- OGTT is a diagnostic tool to detect T2DM in men and non-pregnant ladies
- Should be done while the patient is fasting at least 8 hours
- Check plasma glucose at 0 time, then give 75 grams of glucose solution then check plasma glucose after 2 hours

OGTT is inappropriate in the following conditions:

- Acutely ill patients
- People with body weight less than 42.6 kg

Interpretation of OGTT:

Result	OGTT
Normal	Less than 140 mg/dl (7.8 mmol/l)
Prediabetes	140 mg/dl to 199 mg/dl (7.8 – 11 mmol/l)
Diabetes	200 mg/dl or higher (11.1 mmol/l)



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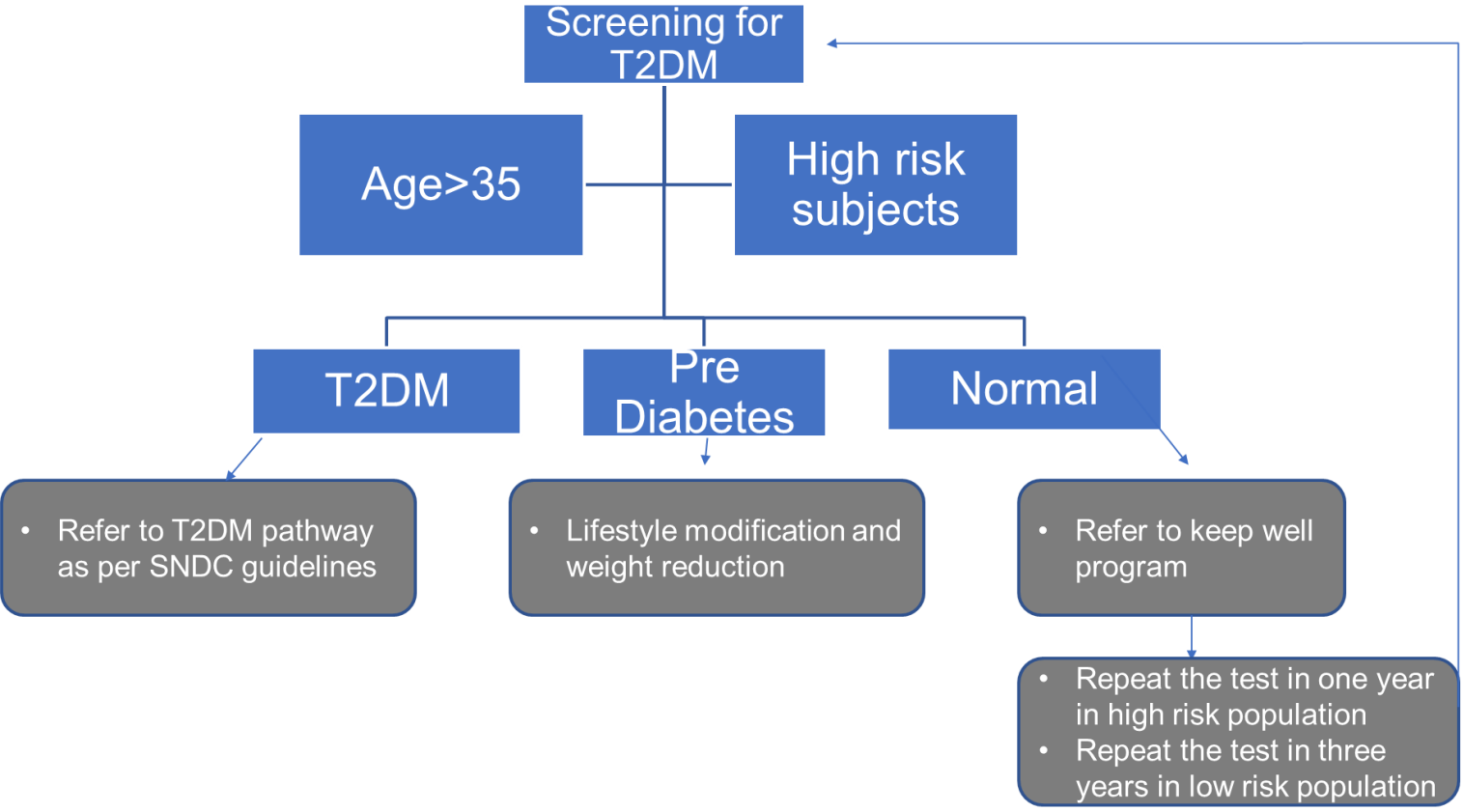
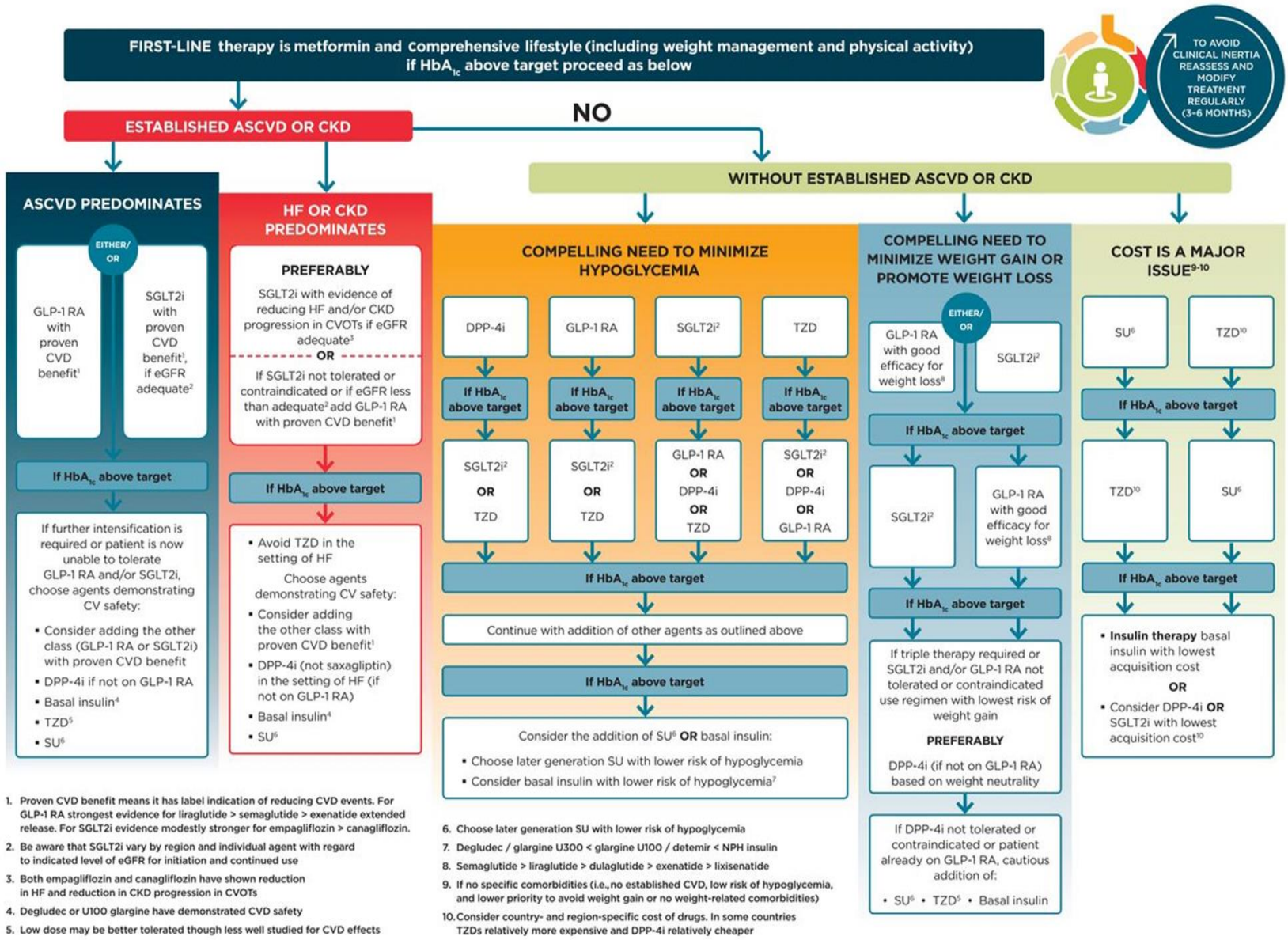
Which test should be used?

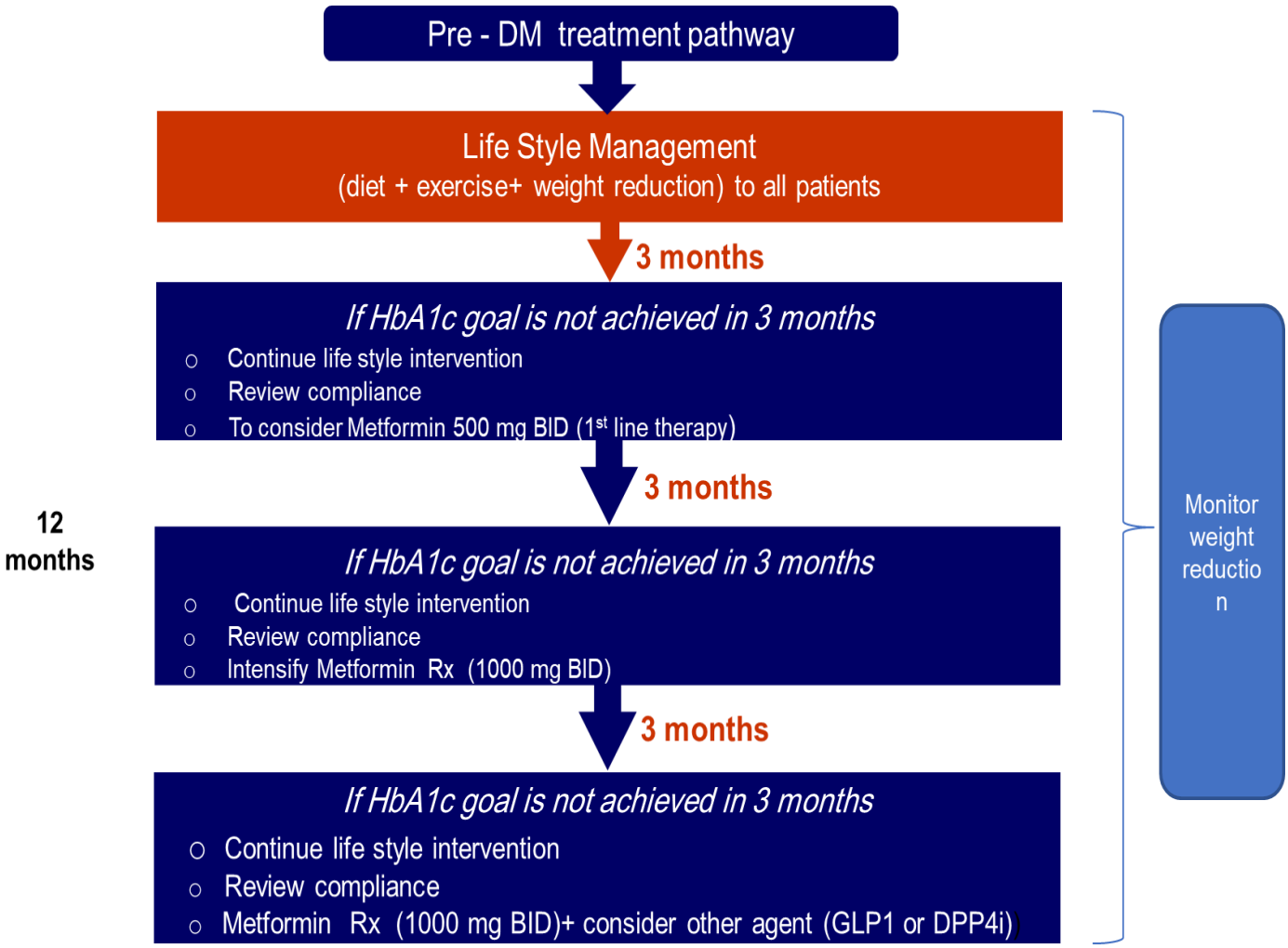
- All listed tests can be used to diagnose T2DM with acceptable sensitivity and specificity.
- Fasting plasma glucose is the preferred test for diabetes screening because it is the most widely available test with acceptable credibility to diagnose T2DM. Also, it's a cheap test, easily performed and results can be quickly obtained.
- Capillary blood testing should not be used to diagnose T2DM.
- Subjects should be encouraged to have a proper eight hours fasting.
- HbA1c testing dose not mandate fasting and should be avoided in subjects with Anaemia, chronic kidney disease and inherited forms of Anaemia.
- OGTT is not commonly used to screen T2DM.


Screening for T2DM
Age>35
High risk subjects
T2DM
Pre Diabetes
Normal
Refer to T2DM pathway as per SNDC guidelines
Lifestyle modification and weight reduction
Refer to keep well program
Repeat the test in one year in high risk population
Repeat the test in three years in low risk population

Diabetes treatment Pathway (ADA)



1. Proven CVD benefit means it has label indication of reducing CVD events. For GLP-1 RA strongest evidence for liraglutide > semaglutide > exenatide extended release. For SGLT2i evidence modestly stronger for empagliflozin > canagliflozin.
2. Be aware that SGLT2i vary by region and individual agent with regard to indicated level of eGFR for initiation and continued use
3. Both empagliflozin and canagliflozin have shown reduction in HF and reduction in CKD progression in CVOTs
4. Degludec or U100 glargine have demonstrated CVD safety
5. Low dose may be better tolerated though less well studied for CVD effects
6. Choose later generation SU with lower risk of hypoglycemia
7. Degludec / glargine U300 < glargine U100 / detemir < NPH insulin
8. Semaglutide > liraglutide > dulaglutide > exenatide > lixisenatide
9. If no specific comorbidities (i.e.,no established CVD, low risk of hypoglycemia, and lower priority to avoid weight gain or no weight-related comorbidities)
10. Consider country- and region-specific cost of drugs. In some countries TZDs relatively more expensive and DPP-4i relatively cheaper


Pre - DM treatment pathway
Life Style Management
(diet + exercise+ weight reduction) to all patients
3 months
If HbA1c goal is not achieved in 3 months
Continue life style intervention
Review compliance
To consider Metformin 500 mg BID (1st line therapy)
3 months
If HbA1c goal is not achieved in 3 months
Continue life style intervention
Review compliance
Intensify Metformin Rx (1000 mg BID)
3 months
If HbA1c goal is not achieved in 3 months
Continue life style intervention
Review compliance
Metformin Rx (1000 mg BID)+ consider other agent (GLP1 or DPP4i)
12 months
Monitor weight reduction

Screening for prediabetes and/or T2DM in asymptomatic adolescent:

- Screening should be considered after 10 years of age, if they are overweight (BMI ³ 85th percentile) or obese (BMI 95th percentile) in addition to at least one of the following risk factors:

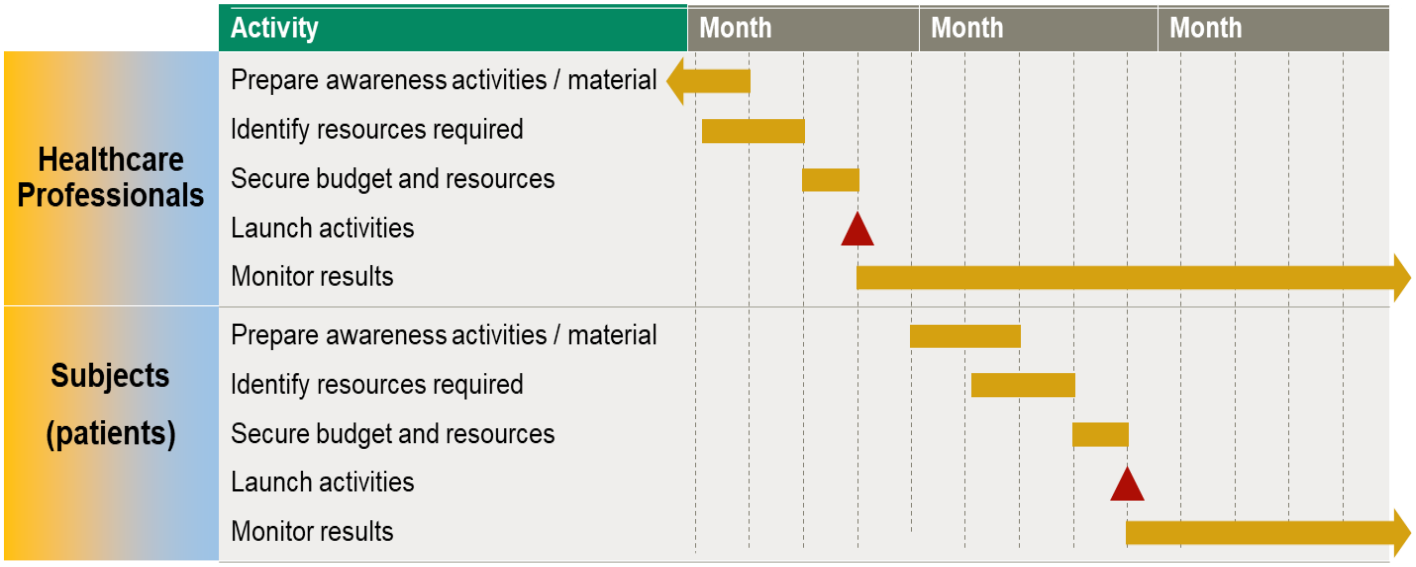
    1. Family history of T2DM: first- or second-degree relative
    2. Maternal history of DM or GDM during pregnancy of the child
    3. Hypertension
    4. Dyslipidemia
    5. Acanthosis nigricans
    6. Polycystic ovary syndrome (PCOS)
    7. Small-for-gestational-age birth weight

- The items from 3-7 are signs of insulin resistance or conditions associated with insulin resistance
- If tests for DM type 2 or prediabetes are normal, they should be repeated every 3 years.
- If BMI in those individuals is increasing, it is recommended to repeat the testing in an interval less than 3 years.

Monitoring of the program and KPIs:

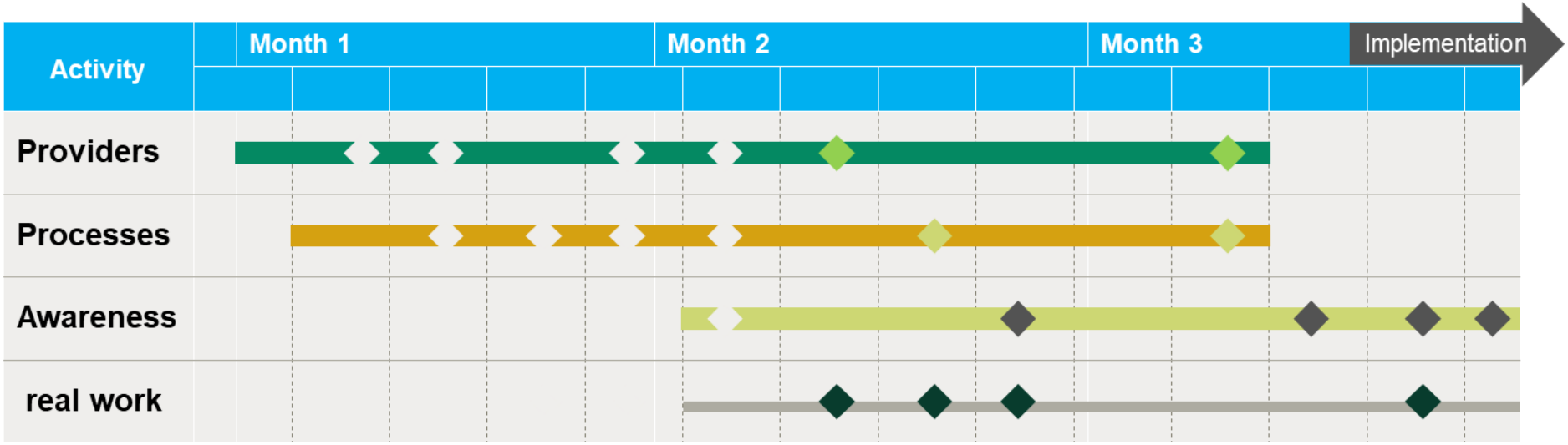
- Data should be reported to SNDC
- KPIs should be reported to SNDC
- Tracking of the screened cases should be taken into consideration to formulate a national database that will help in planning the future actions.

workplan



Suggested implementation plan

Type 2 Diabetes screening implementation plan



Providers

1. Develop selection criteria
2. Select providers
3. Assess facility readiness
4. Nominate leaders
5. Nominate implementation teams
6. Define supply availability approach

Processes

1. Select guidelines
2. Design coordination processes
3. Develop training plan
4. Define KPI measuring approach

Awareness

1. Develop content
2. Select organizations

Field work

1- Launch screening program
2- data collection
3- data analysis
4- revision of criteria

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Providers:

Select Providers

- Physicians
- Nurses
- Lab techs
- Health coach/educators

Facility readiness

- Awareness of the program
- Availability of the needed staff and services

Nominate champions

- Each centre should nominate a champion to lead the process and be responsible for the data collection and reporting

Implementation team

- Can be the same as the providers
- Coordinators could be added if available

Proseccos:

select guidelines

- SNDC guidelines

Coordination process

- To be added by SNDC

Training plan

- full day lectures and workshop (content to follow in separate document)

KPIs

- Defined

Awareness:

Develop content

- Meeting with stakeholders in SNDC
- Letters
- Workshop

select organizations

- To be added by SNDC

Field work:

Launch the program

- A launch date to be selected

Data collection

- Data to be collected using a shared folder

Data Analysis

- Data to be pooled and analysed
- Variables to be defined later

Revision of the criteria

- Screening criteria to be reviewed and changed depending on the numbers

Suggested KPIs:

- 10% of target population are screened in the first year
- 80% of screened subjects are directed to the right channel as in the pathway
- 80% satisfaction of the stakeholder in satisfaction questionnaire (to be formulated later)

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