

Protocol Title: Prevention of Type 2 Diabetes in Adults

Effective Date: TBD	Version: 1.0 (Revised: 07/27/2015)
Approval By: CCC Clinical Steering Group	Planned Review Date: 08/26/16

1 Purpose & Objective

This protocol provides evidence-based care recommendations for prevention of Type 2 Diabetes Mellitus in the primary care setting.

2 Scope of Protocol

2.1 Target Population

This protocol was derived from clinical guidelines for individuals in the CCC population at risk for or diagnosed with Pre-Diabetes Mellitus, **18 years of age or older**.

2.2 Target Users

This protocol is developed for use in primary care settings.

2.3 Excluded Topics

This protocol does not address the clinical management of patients with Type 2 Diabetes, Type I Diabetes, Gestational Diabetes, or Pediatric patients.

2.4 Related Guidelines

Prevention or Delay of Type 2 Diabetes. *Diabetes Care* 2015; 38(Suppl. 1): S31-S32; doi: 10.2337/dc15-S008

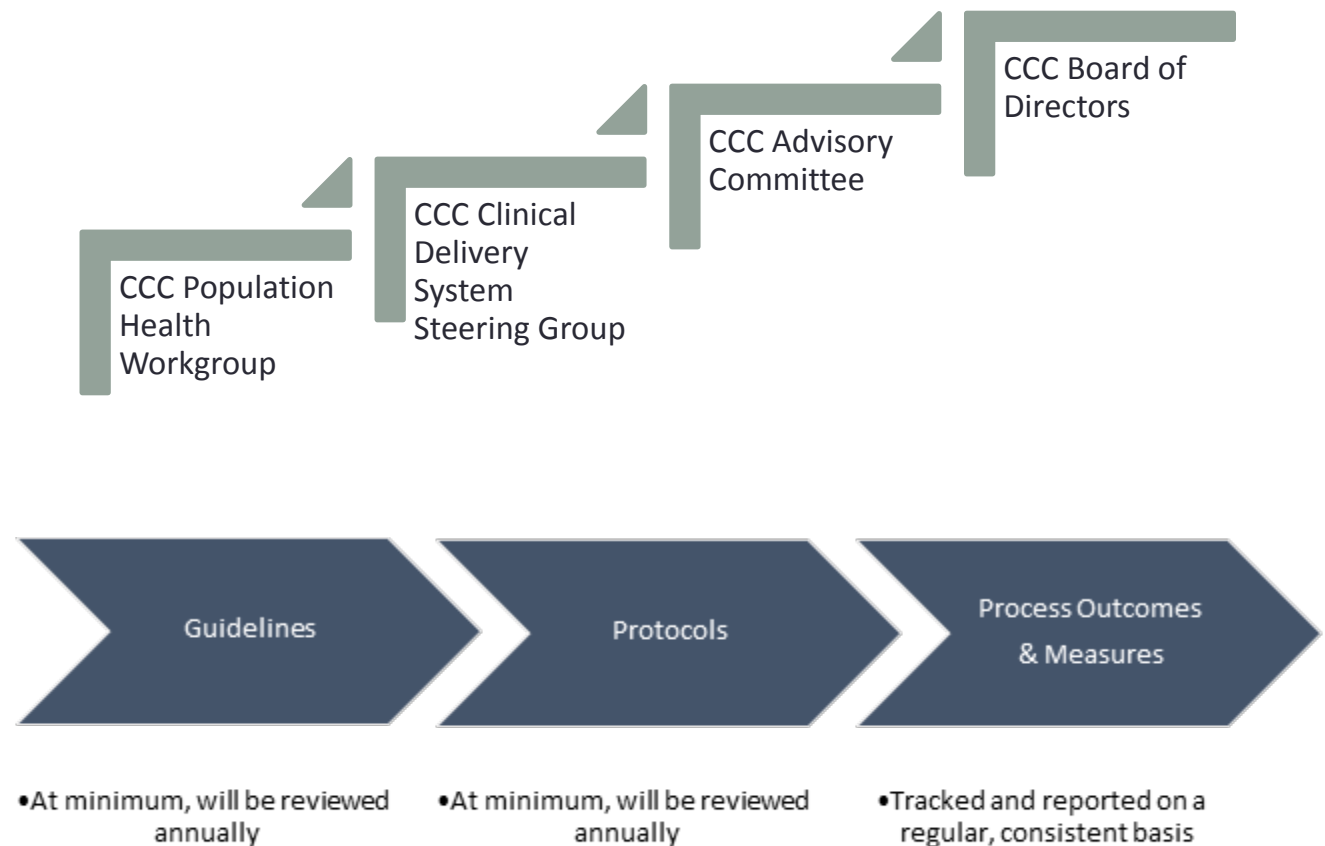
Prevention of type 2 diabetes evidence-based nutrition practice guideline. Agency for Healthcare Research and Quality; Guideline Summary NGC -10573

Prevention and Delay of Type 2 Diabetes in Children and Adults Algorithm; Revised: 04/24/14 Publication Number: E45-11825 (PDF, 721kb), Texas Diabetes Council

Centers for Disease Control and Prevention Diabetes Prevention Recognition Program: Standards and Operating Procedures; January 1, 2015; www.cdc.gov/diabetes/prevention/recognition

3 Protocol Development & Review Process

Protocol Development & Review Process



This protocol originated in the CCC Clinical Protocol Subcommittee, led by an Endocrinologist specializing in Diabetes. A group of clinical staff met and converged on the items in this document. The above depiction describes the approval and subsequent review process for this protocol.

Group Name	Approval Date
CCC Population Health Work Group	07/27/15
CCC Clinical Protocols Workgroup	n/a
CCC Clinical Delivery System Steering Group	08/26/15
CCC Advisory Committee	TBD
CCC Board of Directors	TBD

4 Screening Criteria & Risk Factors

4.1 Assessing Risk for ages 18 and older:

4.1.1 Body Mass Index of $\geq 25\text{kg/m}^2$ *and one of the following additional risk factors: screen at baseline and yearly

- Physical inactivity
- First degree relative with diabetes
- High risk race/ethnicity (e.g. African American, Latino, Native American, Asian American, Pacific Islander)
- Women delivering a baby weighing greater than 9 lbs or were diagnosed with Gestational Diabetes Mellitus (GDM)
- Hypertension ($>140/90$ mmHg or on therapy for hypertension)
- Low Density Lipoprotein (LDL) $>100\text{mg/dl}$
- Women with polycystic ovarian syndrome
- Other clinical condition associated with insulin resistance (severe obesity, acanthosis nigricans)
- History of Cardiovascular Disease (CVD)
- High risk medication (i.e. anti-psychotics)

* BMI $\geq 23\text{kg/m}^2$ is considered high risk for persons of Asian descent

4.1.2 In the absence of meeting criteria associated with item #1, general testing should:

- Begin at 45 years of age.
(During this period, if life is limited due to other major illness; DO NOT SCREEN)
 - If results are normal, testing should be repeated **at least at 3-year intervals**, with consideration of more frequent testing depending on initial results (e.g. those with pre-diabetes should be tested yearly and risk status re-assessed).

5 Screening Tests

Practically speaking, screening for diabetes occurs in many ways and venues within our community. We suggest using different methods on 2 separate days to confirm a diagnosis of prediabetes. For example, if a patient has an elevated fasting glucose on blood work, ask him to return for an HbA1c or an OGTT. While any combination of the below tests will suffice, consider individual patient characteristics when choosing the method. For example, OGT may be preferred over HbA1c in patients with significant anemia.

5.1 Hemoglobin A1C (A1C)

- This test should be performed in a laboratory using a method that is NGSP certified and standardized to the DCCT assay (i.e. not a Point of Care fingerstick assay).
- If abnormal Point of Care (finger stick) result, confirm with laboratory assay.

5.2 Fasting Plasma Glucose (FPG)

- Fasting is defined as no caloric intake for at least 8 hours.

5.3 2 hour Oral Glucose Tolerance Test (OGTT)

- The test should be performed as described by the World Health Organization (WHO), using a glucose load containing the equivalent of 75g anhydrous glucose dissolved in water.

5.4 Random Plasma Glucose (RPG)

- Not a finger stick

Other considerations

- Routine measurement of insulin levels is not recommended

6 Criteria for Diagnosis of Pre- Diabetes

- HbA1c $\geq 5.7\%$ and $< 6.5\%$;
- FPG ≥ 100 and < 126 mg/dL or;
- Two-hour Plasma Glucose (PG) ≥ 140 and < 200 mg/dL during an OGTT or
- Random plasma glucose ≥ 140 and < 200 mg/dL in a laboratory (not a fingerstick)
- Repeat tests to rule out laboratory error; if the A1c is elevated in an individual of normal body weight and without other risk factors, we recommend that the diagnosis be confirmed with an OGT

6.1 Patient Self-Monitoring of Blood Glucose (SMBG) for patients with Pre-Diabetes

Self –monitoring of blood glucose in patients with Pre-Diabetes (defined above in Section 6.0) is optional and at the discretion of the provider and patient. SMBG may be considered if deemed that the patient may alter lifestyle choices based on results.

6.2 A1C monitoring in patients with Pre-Diabetes

- Every 12 months:
 - Patients who are meeting treatment goals and have HbA1c in normal range
- Every 6 months (At least two times a year):
 - Patients who are not meeting treatment goals and have HbA1c in Pre-Diabetic range
- Point of Care (POC) testing for HbA1c provides opportunity for more timely treatment changes

7 Lifestyle Algorithm

An Intensive Group Lifestyle Intervention (IGLI) shall be recommended to all patients who are overweight/obese or who have Pre-DM based on above criteria. The IGLI shall contain the key components as outlined in the Diabetes Prevention Program (DPP)¹ and may be administered through a community organization such as the YMCA or through the patient's primary care home.^{2,3}

The goal of the IGLI will be to assist the overweight or obese patient in losing $\geq 7\%$ of their body weight over a 6 month period through healthy well-balanced diet (approximately 500-1000 calories < maintenance as determined by a registered dietician) and increases in moderate intensity aerobic physical activity (180 minutes per week). The diet intervention shall also include recommendations for limiting saturated fat and increasing fiber through vegetables, fruits, and whole grains. For persons of normal body weight, emphasis will be placed on exercise, maintaining a normal body weight, and nutrient quality in the diet.

We understand that all patients will not be able to participate in IGLI; nevertheless, the healthcare team will educate patients that **IGLI are the most effective evidenced-based intervention.**

Austin-based IGLI

YMCA Diabetes Prevention Program

CommUnity Care Group Lifestyle Balance Program (available only to patients with CUC as their medical home).

For patients who cannot participate in IGLI, education and goal setting can be done by various members of the healthcare team including registered dietitians, physicians, mid-level providers, nurse educators, behavioral health counselors, medical assistants, and community health workers using patient-centered techniques such as motivational interviewing, Solutions Focused Brief Therapy, and Cognitive Behavioral Therapy. **All patients should be referred to the registered dietitian** and may be referred to other disease preventative programs as follows:

- Austin/Travis County HHS: Road to Health Program
- Texas A&M AgriLife Extension: Step up and Scale Down Program
- WeViva
- The Sustainable Food Center: The Happy Kitchen/La Cocina Alegre
- Capitol Area Food Bank CHOICES nutrition education classes
- Other Texas programs found in the CDC National Diabetes Prevention Program: Registry of
- Recognized Programs⁴

8 Medication Treatment

8.1 Medication to prevent or delay diabetes

- Patients with pre-diabetes as defined by testing criteria above shall be offered treatment with metformin in absence of known contraindications. *
 - Metformin has been shown to be effective in preventing/delaying diabetes at doses ranging from 500-1700 mg daily.^{5,6}
 - We recommend starting with 1000 mg daily and titrating to 1500 mg as tolerated.
 - Metformin immediate release or extended release (ER) formulations may be used. The ER preparation tends to be better tolerated from the standpoint of GI side effects. Patients using the ER preparations may notice pills/fragments in bowel movements. This is normal.
- Patients should understand that the IGLI is approximately twice as effective at preventing diabetes as metformin.
- Patients with pre-diabetes may participate in IGLI and take metformin if they choose.
- Metformin may be particularly beneficial in patients with BMI > 35, aged < 60 years, and women with prior gestational DM

*Metformin is contraindicated in renal insufficiency (women Cr 1.4, Men Cr 1.5), ESLD, CHF or other conditions resulting in increased risk of lactic acidosis.

8.2 Medications to reduce other risk factors for Atherosclerotic Vascular Disease

- Blood Pressure goal of < 140/90 mmHg
- Treat Hypertension with or without micro albuminuria with ACE/ARB (First line)
- Consider a Thiazide Diuretic and Calcium Channel Blocker as alternative agents
 - *Reference Hypertension Protocol
- Screen for and treat dyslipidemias per national guidelines. Patients with known ASVD or CAD should be treated with moderate to high intensity statin therapy.

9 Management and Referrals

9.1 Pre-Diabetes Minimum Practice Recommendations

(Adapted from Texas Diabetes Council and Texas Department of State Health Services – Diabetes Minimum Practice Recommendations – Revised 8/9/12)

Complete History & Physical	Initial visit and at clinician's discretion (including risk factors, exercise & diet)
Family History	Annually
Education & Counseling	Intensive Group Lifestyle Intervention is preferred; if patient cannot participate, then alternate recommendation below
Diabetes Prevention Education ¹	Initial visit, annually, and at clinician's discretion
Medical Nutrition Therapy	Initial visit, annually, and at clinician's discretion
Exercise Counseling	Initial visit and at clinician's discretion
Preconception counseling and family planning for women of reproductive age	Initial Visit and at clinician's discretion
Depression Screening²	Initial visit and at clinician's discretion
Lifestyle/Behavior	
Smoking Cessation	Initial visit and at clinician's discretion
Alcohol Reduction	Initial visit and at clinician's discretion
Physical Examination	
Blood Pressure Target: <140/90 mm Hg Target: <125/75 mm Hg if ≥1g proteinuria	Every visit
Weight/Height	Every visit (Height annually)
BMI Adult Overweight = BMI 25-29.9 Adult Obesity = BMI ≥ 30	Every visit
Foot Exam <ul style="list-style-type: none"> • Visual inspection for skin and nail lesions, calluses, infections, deformities • Monofilament & 128 Hz tuning fork • Pedal Pulses 	Every visit Annually or as needed Annually or as needed
Oral/Dental Inspection Refer for dental care every 6 months	Every visit
Laboratory Studies	
A1c	Every 6 -12 months
Kidney <ul style="list-style-type: none"> • BUN/Creatinine 	

<ul style="list-style-type: none"> eGFR Urine MicroAlb:Cr ratio 	<p>Annually or every 6 months if abnormal, or on diuretics, ACEIs/ARBs</p> <p>Annually or every 6 months if abnormal</p>
<p>Liver</p> <ul style="list-style-type: none"> AST (SGOT) / ALT (SGPT) 	<p>Annually or every 3-6 months if abnormal</p>
<p>Lipid Profile</p> <ul style="list-style-type: none"> Triglycerides HDL LDL 	<p>Annually if at goal; otherwise every 6 months</p>
TSH	Annually or as needed
Immunizations⁶	
Influenza vaccine	Annually
Pneumococcal vaccine	Age <65; Repeat ≥ 65 (at least 5 yrs apart)
Tdap	Every 10 yrs
Shingles vaccine	One time at age 60
Hepatitis A	2 doses
Hepatitis B	3 doses

² Patient Health Questionnaire-2 (PHQ2, depression screen) and Patient Health Questionnaire-9 (PHQ9, depression diagnosis)

⁶Refer to CDC guidelines at <http://www.cdc.gov/vaccines/schedules/easy-to-read/index.html> for updates

9.2 Referrals

- Registered dietitian for MNT
- Dentist for comprehensive periodontal examination
- Behavioral Health Professional, if needed

10 Protocol Development Team

Name	Affiliation
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Megan Cermak, MPH	Central Health

11 References

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2. The Healthy Living Partnerships to Prevent Diabetes Study. *Am J Prev Med* 2013; 44(4S4): S324-S332.
3. Diabetes Prevention Program Community Outreach Perspective of Lifestyle Training and Translation. *Am J Prev Med* 2013; 44(4S4): S339--S345.
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5. Knowler WC, Barrett-Connor E, Fowler SE, Hamman RF, Lachin JM, Walker EA, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Engl J Med.* 2002;346(6):393–403.
6. Ramachandran A, Snehalatha C, Mary S, Mukesh B, Bhaskar AD, Vijay V. Indian Diabetes Prevention Programme (IDPP) The Indian Diabetes Prevention Programme shows that lifestyle modification and metformin prevent type 2 diabetes in Asian Indian subjects with impaired glucose tolerance (IDPP-1) *Diabetologia.*2006;48(2):289–97. Epub 2006 Jan 4.