ICSI Institute for Clinical Systems Improvement

Health Care Guideline

Diagnosis and Management of Type 2 Diabetes Mellitus in Adults

How to Cite this Document

Redmon B, Caccamo D, Flavin P, Michels R, O'Connor P, Roberts J, Smith S, Sperl-Hillen J. Institute for Clinical Systems Improvement. Diagnosis and Management of Type 2 Diabetes Mellitus in Adults. Updated July 2014.

ICSI Members, Sponsors and organizations delivering care within Minnesota borders, may use ICSI documents in the following ways:

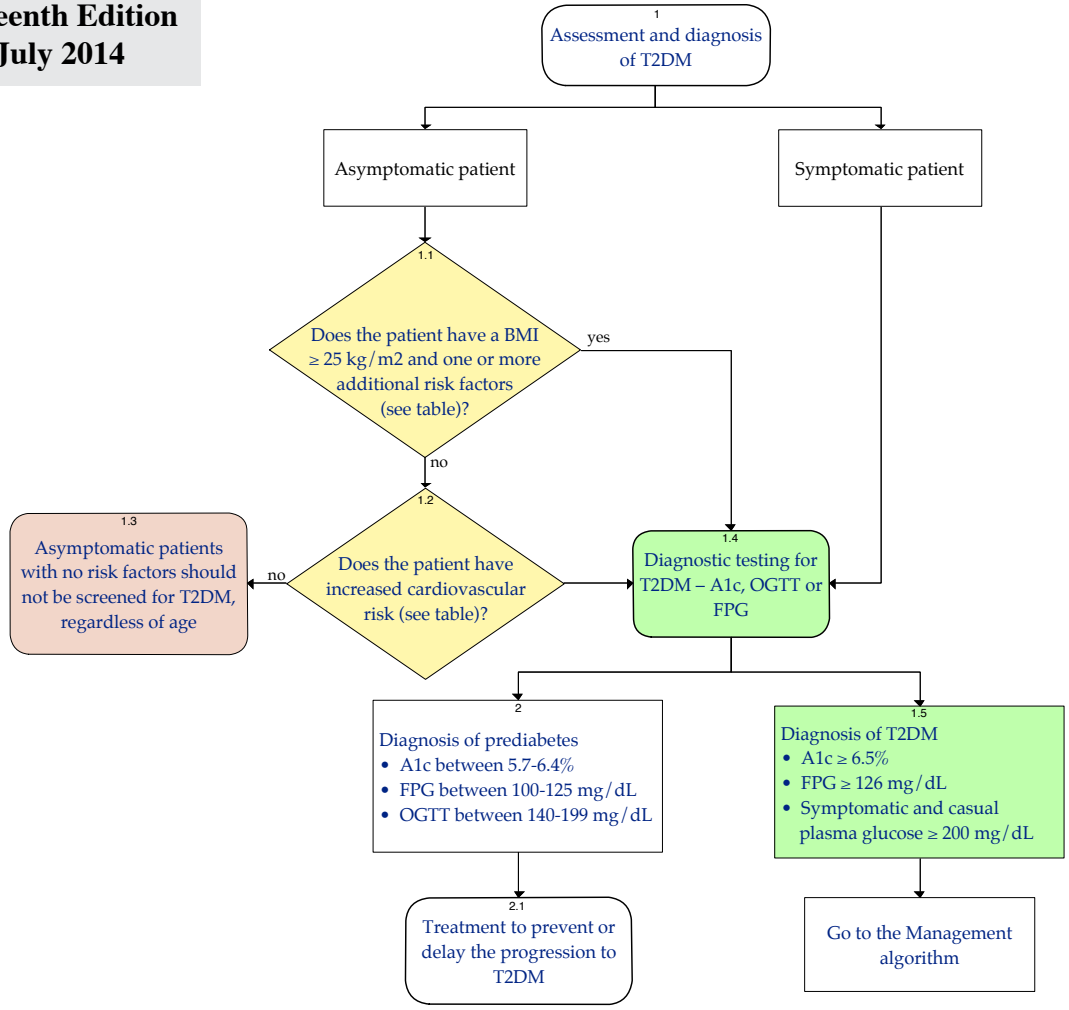
- ICSI Health Care Guidelines and related products (hereinafter "Guidelines") may be used and distributed by **ICSI Member and Sponsor** organizations as well as organizations **delivering care within Minnesota borders**. The guidelines can be used and distributed **within** the organization, to employees and anyone involved in the organization's process for developing and implementing clinical guidelines.
- ICSI Sponsor organizations can distribute the Guidelines to their enrollees and those care delivery organizations a sponsor holds insurance contracts with.
- Guidelines may not be distributed outside of the organization, for any other purpose, without prior written consent from ICSI.
- The Guidelines may be used only for the purpose of improving the health and health care of Member's or Sponsor's own enrollees and/or patients.
- Only ICSI Members and Sponsors may adopt or adapt the Guidelines for use within their organizations.
- Consent must be obtained from ICSI to prepare derivative works based on the Guidelines.
- Appropriate attribution must be given to ICSI on any and all print or electronic documents that reference the Guidelines.

ICSI Institute for Clinical Systems Improvement

Sixteenth Edition
July 2014

Diagnosis Algorithm

Text in blue in this algorithm indicates a linked corresponding annotation.



Risk Factors Table

1.1 BMI ≥ 25 kg/m2 and one or more of the following risk factors:

- High-risk race/ethnicity (e.g., African American, Latino, Native American, Asian American, Pacific Islander)
- Women who have delivered a baby weighing > 9 lb or were diagnosed with GDM
- Women with polycystic ovarian syndrome
- "Prediabetes" as defined by IFG, IGT or A1c on previous testing
- Other clinical conditions associated with insulin resistance (e.g., severe obesity, acanthosis nigricans)
- History of first degree relative with T2DM

1.2 Cardiovascular Risk Factors

- Established ASCVD
- Hypertension (blood pressure ≥ 140/90 mmHg or on hypertension therapy)
- HDL cholesterol < 35 mg/dL
- Triglyceride level > 250 mg/dL
- LDL cholesterol > 70 and calculated 10 year cardiovascular event risk > 7.5 or on lipid lowering therapy

Shared decision-making — Shared decision-making with a full discussion of the risks and benefits of treatment and consideration of patient values and preferences.

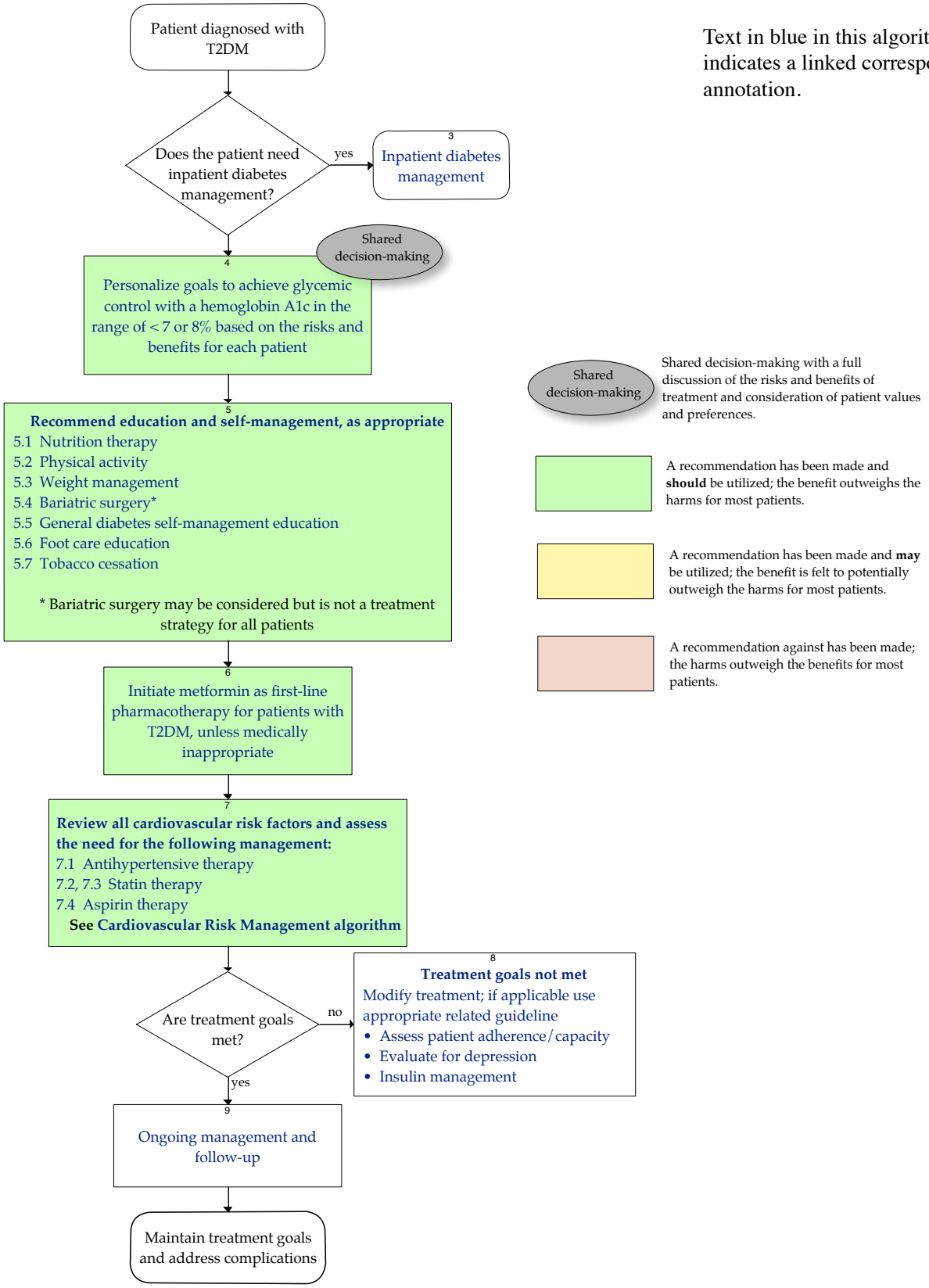
A recommendation has been made and **should** be utilized; the benefit outweighs the harms for most patients.

A recommendation has been made and **may** be utilized; the benefit is felt to potentially outweigh the harms for most patients.

A recommendation against has been made; the harms outweigh the benefits for most patients.

Return to Table of Contents

Management Algorithm

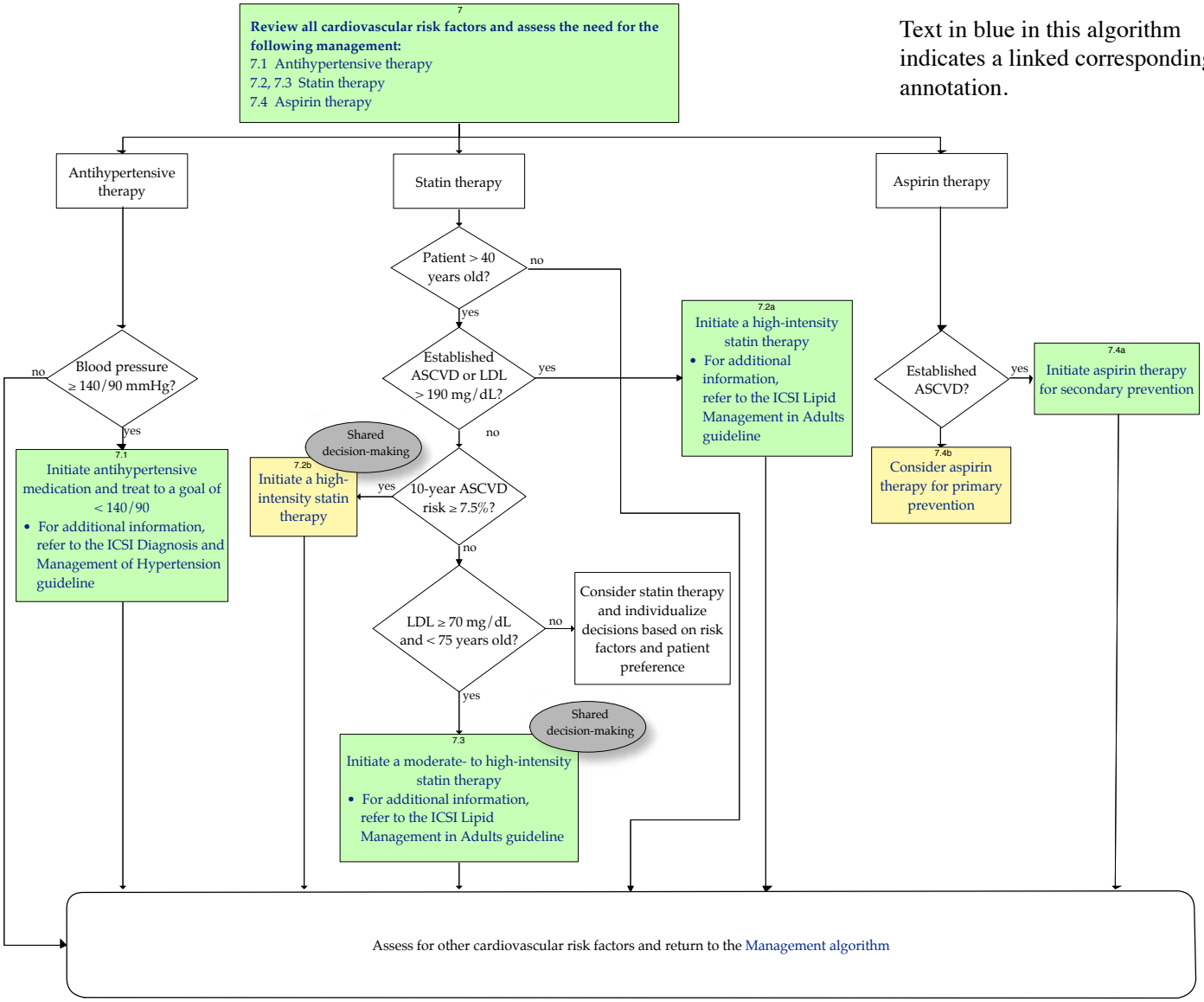


Text in blue in this algorithm indicates a linked corresponding annotation.

Return to Table of Contents

Cardiovascular Risk Management Algorithm

Text in blue in this algorithm indicates a linked corresponding annotation.



Shared decision-making — Shared decision-making with a full discussion of the risks and benefits of treatment and consideration of patient values and preferences.

A recommendation has been made and **should** be utilized; the benefit outweighs the harms for most patients.

A recommendation has been made and **may** be utilized; the benefit is felt to potentially outweigh the harms for most patients.

A recommendation against has been made; the harms outweigh the benefits for most patients.

Return to Table of Contents

Table of Contents

Work Group Members

HealthPartners Medical Group and Regions Hospital
David Caccamo, MD
Family Medicine
Ryan Michels, PharmD, BCPS
Pharmacy
Patrick O'Connor, MD
Family Medicine
Julie Roberts, MS, RD, CDE
Health Education
JoAnn Sperl-Hillen, MD
Internal Medicine

Mayo Clinic
Steve Smith, MD
Endocrinology

Olmsted Medical Center
Penny Louise Flavin, DNP, RN, CNP
Family Practice

University of Minnesota
Bruce Redmon, MD
Endocrinology

ICSI Staff
Cassie Myers
Project Manager
Linda Setterlund, MA, CPHQ
Clinical Systems Improvement Facilitator

Algorithms and Annotations 1-41
- Algorithm (Diagnosis) 1
- Algorithm (Management) 2
- Algorithm (Cardiovascular Risk Management) 3
- Evidence Grading 5
- Foreword
  - Introduction 6
  - Scope and Target Population 6
  - Aims 7
  - Clinical Highlights 7
  - Implementation Recommendation Highlights 8-9
  - Related ICSI Scientific Documents 9
  - Definition/Abbreviations 9
- Annotations 10-41
  - Annotations (Diagnosis) 10-12
  - Annotations (Management) 13-33
  - Annotations (Cardiovascular Risk Management) 33-41

Quality Improvement Support 42-58
- Aims and Measures 43-44
  - Measurement Specifications 45-55
- Implementation Tools and Resources 56
- Implementation Tools and Resources Table 57-58

Supporting Evidence 59-78
- References 60-71
- Appendices 72-78
  - Appendix A – Order Set: Subcutaneous Insulin Management 72-74
  - Appendix B – Treatment of Diabetic Nephropathy 75
  - Appendix C – Using a Semmes-Weinstein Monofilament to Screen the Diabetic Foot for Peripheral Sensory Neuropathy 76
  - Appendix D – Using a Tuning Fork to Screen the Diabetic Foot for Peripheral Neuropathy 77
  - Appendix E – Sample of Hypoglycemia Protocol 78

Disclosure of Potential Conflicts of Interest 79-81
Acknowledgements 82-83

Document History and Development 84-85
- Document History 84
- ICSI Document Development and Revision Process 85

Evidence Grading

Literature Search

This guideline is based on a systematic evidence review evaluating literature published on type 2 diabetes mellitus (T2DM). The literature search was divided into two stages to identify systematic reviews, (stage I) and randomized controlled trials, meta-analysis and other literature (stage II). Literature search terms used for this revision are below and include literature from January 1, 2004, through May 31, 2014. Hand searching of identified articles and work group submission was also undertaken.

The databases searched included PubMed and Cochrane. The search was limited to only studies in the English language. The following searches were performed and utilized in this document in regards to T2DM: screening, diagnosis, diagnostic testing, risk factors, bariatric surgery, blood pressure, lipid management, insulin, nutrition therapy, glycemic control, weight loss, metformin, self-management and education.

GRADE Methodology

Following a review of several evidence rating and recommendation writing systems, ICSI has made a decision to adopt to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology.

GRADE has advantages over other systems including the previous system used by ICSI. Advantages include:

- Developed by a widely representative group of international guideline developers
- Explicit and comprehensive criteria for downgrading and upgrading quality of evidence ratings
- Clear separation between quality of evidence and strength of recommendations that includes a transparent process of moving from evidence evaluation to recommendations
- Clear, pragmatic interpretations of strong versus weak recommendations for clinicians, patients and policy-makers
- Explicit acknowledgement of values and preferences and
- Explicit evaluation of the importance of outcomes of alternative management strategies

Return to Table of Contents

Foreword

Introduction

Diabetes is a chronic disease, that afflicts approximately 26.9% of U.S. residents aged 65 years and older. 1.9 million are diagnosed with diabetes every year, and an additional 7.0 million go undiagnosed and untreated *(Centers for Disease Control, 2011)*. More than 1 in 5 health care dollars in the U.S. goes to the care of people with diagnosed diabetes, costing $245 billion dollars annually *(American Diabetes Association, 2012)*.

Appropriate medication management targeting glycemic control, hypertension, and lipid management is important for reducing morbidity and mortality, and improving long-term quality of life for patients diagnosed with type 2 diabetes mellitus (T2DM). Lifestyle changes such as nutrition therapy, weight loss, increased exercise, and appropriate education and self-management strategies are pivotal to improved outcomes. Inadequate access to care for chronic disease management as well as the cost of medication can contribute to poor control of T2DM and associated cardiovascular risk factors.

In the current iteration of this guideline, we have focused on the importance of appropriate identification and diagnosis, followed by effective approaches to lifestyle management and pharmacologic therapy. Due to the high percentage of the U.S. population that is diagnosed with diabetes and the effect diabetes has on other comorbidities, appropriate management will improve the patient's experience of care and the health of the population, reducing office visits, emergency department visits, cardiovascular complications. Other related conditions will in turn reduce the total cost of care.

Return to Table of Contents

Scope and Target Population

This guideline provides a comprehensive approach to the diagnosis and management of T2DM in adults ages 18 and older. Management recommendations will include nutrition therapy, physical activity, self-management approaches and pharmacologic therapy, as well as the prevention and diagnosis of diabetes-associated complications and risk factors.

The management of gestational diabetes and T2DM in patients who are pregnant is excluded from the scope of this guideline. Oral agents do not have Food and Drug Administration approval for use in pregnancy. Additionally, the glycemia goals used are different in pregnancy and require more aggressive treatment. Please refer to the ICSI Routine Prenatal Care guideline for information relating to gestational diabetes and T2DM in patients who are pregnant.

The diagnosis and management of type 1 diabetes is not included in this guideline.

Return to Table of Contents

Aims

Note: a multifactorial intervention targeting hyperglycemia and cardiovascular risk factors in individuals with diabetes is most effective. Both individual measures of diabetes care, as well as comprehensive measures of performance on broader sets of measures, are recommended. A randomized controlled trial has shown a 50% reduction in major cardiovascular events through a multifactorial intervention targeting hyperglycemia, hypertension, dyslipidemia, microalbuminuria, aspirin and ACE inhibitor use in individuals with microalbuminuria *(Gaede, 2003)*.

Goals for A1c, low-density lipoprotein and other diabetes measures should be personalized, and lower goals for A1c and low-density lipoprotein than those included here in the priority aims and measures may be clinically justified in some adults with T2DM. However, efforts to achieve A1c below 7% may increase risk of mortality, weight gain, hypoglycemia and other adverse effects in many patients with T2DM. Therefore, the aims and measures listed here are selected carefully in the interests of patient safety.

Outcome Measures

1. **Diabetes Optimal Care:** Increase the percentage of patients ages 18-75 years with T2DM mellitus who are optimally managed
2. Management of T2DM in high-risk patients (Trial measure): Decrease the percentage of adult patients ages 18-75 with T2DM mellitus with poorly controlled glucose and cardiovascular risk factors.
3. Lifestyle modification and nutrition therapy – increase the percentage of patients ages 18-75 years newly diagnosed with T2DM who are advised about lifestyle modification and nutrition therapy.
4. Medication Management – increase the percentage of patients with T2DM who are on appropriate medication management.

Return to Table of Contents

Clinical Highlights

- Education and self-management support is necessary for people with prediabetes and T2DM to manage his/her disease.
- Focus on cardiovascular risk reduction (blood pressure control, low-density lipoprotein cholesterol lipid control primarily with statin use, aspirin use and tobacco cessation).
- A1c levels should be individualized to the patient.
- Aggressive blood pressure control is just as important as glycemic control. Systolic blood pressure level should be the major factor for detection, evaluation and treatment of hypertension. The use of two or more blood pressure-lowering agents is often required to meet blood pressure goal.
- Prevent microvascular complications through annual or biannual eye exams, foot risk assessments and foot care counseling, and annual screening for proteinuria.
- Initial therapy with lifestyle treatment and metformin is advised, unless contraindicated.

Return to Table of Contents

Implementation Recommendation Highlights

The following system changes were identified by the guideline work group as key strategies for health care systems to incorporate in support of the implementation of this guideline.

The implementation of T2DM clinical guidelines at medical groups and clinics is a complex and challenging task. However, a number of key processes have been shown to accelerate effective clinical guideline implementation and care improvement *(Sperl-Hillen, 2005)*. These overlapping care elements can be categorized at the medical group and clinician levels:

- Essential elements at the medical group level:
  - **Leadership**. Medical group leaders must communicate the need for change in clinical practice patterns and consistently identify improvement priorities.
  - **Resources**. Resources adequate to the task at hand will be needed to assure the success of a change effort. Resources may include staff time, money and provision of tools (such as electronic medical records) to support care improvement.
  - **Select specific improvement goals and measures**. For most chronic diseases, including diabetes, the most efficient improvement strategy is to focus on a limited number of specific improvement goals. These may be based on observed gaps in care, potential clinical impact, cost considerations or other criteria *(O'Connor, 2005a)*. In T2DM, focusing on glycemic control, lipid control and blood pressure control is a strategy that has been shown to be effective in preventing up to 53% of heart attacks and strokes, the leading drivers of excess mortality and costs in adults with diabetes *(Gaede, 2003)*.
  - **Accountability**. Accountability within the medical group is a management responsibility, but external accountability may also play an important enhancing role to motivate sustained efforts to implement guidelines and improve care. Examples of external accountability include participation in shared learning activities or public reporting of results (such as in pay-for-performance or the Minnesota Community Measures Project).
  - **Prepared practice teams**. The medical group may need to foster the development of prepared practice teams that are designed to meet the many challenges of delivering high-quality chronic disease care.
- Essential elements at the clinic level:
  - **Develop "smart" patient registries**. These are registries that are designed to identify, automatically monitor, and prioritize patients with diabetes based on their risk, current level of control, and possibly patient readiness-to-change.
  - **Assure "value-added" visits**. These are office visits or other patient encounters (by phone, e-mail, etc.) that include intensification of treatment if the patient has not yet reached his/her evidence-based clinical goals. Failure of clinicians and patients to intensify treatment when indicated (referred to as "clinical inertia") is a key obstacle to better diabetes care *(O'Connor, 2005a; O'Connor, 2005b; O'Connor, 2003)*. Previsit planning and best practice prompts may help to increase the efficiency of patient visits and remind clinicians of needed tests and care.
  - **Develop "active outreach."** These are strategies to reach patients with chronic disease who have not returned for follow-up or for other selected elements of care. Outreach strategies that enhance the likeliness of a future provider encounter that addresses one of the barriers to patient activation (discussed below) may be more effective. Simple reporting of lab test results or care suggestions through the mail may be ineffective at addressing these barriers.

Return to Table of Contents

- **Emphasize "patient activation" strategies**. These may include diabetes education and other actions designed to sustain engagement of patients with his/her diabetes care. Many patients with diabetes either (a) do not really believe they have diabetes, or (b) do not really believe that diabetes is a serious disease, or (c) lack motivation for behavioral change, or (d) do not believe that recommended treatments will make a difference to their own outcomes. For care to be effective, these issues must be addressed for many patients *(O'Connor, 1997)*.

Return to Table of Contents

Related ICSI Scientific Documents

Guidelines

- Healthy Lifestyles
- Diagnosis and Treatment of Hypertension
- Lipid Management in Adults
- Major Depression in Adults in Primary Care
- Preventive Services for Adults
- Obesity for Adults, Prevention and Management of

Return to Table of Contents

Definition/Abbreviations

Clinician – All health care professionals whose practice is based on interaction with and/or treatment of a patient.

FPG – fasting plasma glucose

OGTT – Oral glucose tolerance test

T2DM – type 2 diabetes mellitus

Return to Table of Contents

Algorithm Annotations

Diagnosis Algorithm Annotations

1. Assessment and Diagnosis of T2DM

1.1 BMI and Associated Risk Factors of T2DM

Recommendation	Quality of Evidence and Strength of Recommendation
A clinician may test asymptomatic patients for T2DM when the patient has a BMI ≥ to 25 kg/m2) and has one or more additional risk factors (see below), regardless of age. • High-risk race/ethnicity (e.g., African American, Latino, Native American, Asian American, Pacific Islander) • Women who have delivered a baby weighing > 9 lb. or were diagnosed with GDM • Women with polycystic ovarian syndrome • "Prediabetes" as defined by IFG, IGT or A1c on previous testing • Other clinical conditions associated with insulin resistance (e.g., severe obesity, acanthosis nigricans) • History of first-degree relative with T2DM	Quality of Evidence: Low Strength of Recommendation: Weak
Benefits: Patients can develop T2DM without symptoms, and early detection of diabetes allows for earlier implementation of lifestyle modifications and glucose control, and has a legacy effect that can reduce or prevent complications including retinopathy, neuropathy, nephropathy, peripheral vascular disease, and microvascular and cardiovascular disease. Targeted testing for patients of any age who are overweight or obese and have additional risk factors has shown to be cost effective. **Harms:** It is unclear for patients with prediabetes that there is a full understanding of which patients will progress to T2DM. Some patients may have increased testing and treatment without benefit, and having the diagnosis of diabetes could potentially have negative psychosocial and economic ramifications for individuals. **Benefits-Harms Assessment:** Diabetes screening is potentially costly and has not been proven to result in improved patient outcomes. However, the condition is common, serious, and a cause of serious microvascular and macrovascular health complications. Selective testing of high-risk individuals can reduce the costs compared to universal testing. There are no significant harms to the health of individuals who undergo testing.	
Relevant Resources: *Casagrande, 2013; Colosia, 2013; Waugh, 2013; Ackermann, 2011; Li, 2008; Gregg, 2004*	

Return to Algorithm *Return to Table of Contents*

1.2 Cardiovascular Risk

Recommendation	Quality of Evidence and Strength of Recommendation
A clinician may screen asymptomatic patients for T2DM who have increased cardiovascular risk (see below), regardless of age. • Established ASCVD • Hypertension (blood pressure ≥ 140/90 mmHg or on hypertension therapy) • HDL cholesterol < 35 mg/dL • Triglyceride level > 250 mg/dL • LDL cholesterol > 70 and calculated 10-year cardiovascular event risk > 7.5% or on lipid-lowering therapy	Quality of Evidence: Low Strength of Recommendation: Weak
Benefits: Patients can develop T2DM without symptoms, and early detection of diabetes allows for earlier implementation of lifestyle modifications and glucose control, and has a legacy effect that can reduce or prevent complications including retinopathy, neuropathy, nephropathy, peripheral vascular disease, and other microvascular and macrovascular health complications, and reduce the risk of coronary events. Targeted testing for patients with hypertension has shown to be cost effective. **Harms:** It is unclear for patients with prediabetes that there is a full understanding of which patients will progress to T2DM. Some patients may have increased testing and treatment without benefit, and having the diagnosis of diabetes could potentially have negative psychosocial and economic ramifications for individuals. **Benefits-Harms Assessment:** Appropriate management of cardiovascular disease and diabetes is supportive of improved mortality and reduction in CVD events with no significant harms to the health of individuals who undergo screening.	
Relevant Resources: *Casagrande, 2013; Colosia, 2013; Waugh, 2013; Rahman, 2012; Ackermann, 2011; American Diabetes Association, 2010; Li, 2008; U.S. Preventive Services Task Force, 2008*	

Return to Algorithm *Return to Table of Contents*

1.3 Screening

Recommendation	Quality of Evidence and Strength of Recommendation
A clinician should not screen for T2DM in asymptomatic patients without additional risk factors.	Quality of Evidence: Low Strength of Recommendation: Strong
Benefits: Universal screening incurs substantial costs for initial screening procedures, and many individuals would need to undergo additional testing procedures to confirm or refute the initial screening test, leading to both testing costs and economic costs, such as time away from work or other productive activities. Two randomized trials failed to show a benefit of screening for diabetes on overall mortality. One of these trials found little evidence of benefits from screening on clinical measures of diabetic complications, cardiovascular health, medication use or functional status. In this trial, screening for diabetes appeared to shorten the time to diagnosis of diabetes by only about three years. **Harms:** Universal screening would be expected to maximize the number of people diagnosed with diabetes early in their disease process. This would allow for early implementation of therapeutic measures to control hyperglycemia, resulting in a hopefully cost-effective intervention to reduce the incidence of later diabetes-related complications. A randomized trial of screening for diabetes found no evidence of adverse effects of screening on physical or emotional health of screened compared to unscreened individuals. **Benefits-Harms Assessment:** The absence of clinical benefit as shown in data from randomized trials and increase in costs would argue against a recommendation for universal screening in unselected populations or populations judged to be at low risk for diabetes.	
Relevant Resources: *Waugh, 2013; Rahman, 2012; Simmons, 2012; U.S. Preventive Services Task Force, 2008*	

Return to Algorithm *Return to Table of Contents*

1.4 Diagnostic Testing for T2DM and 1.5 Diagnosis of T2DM

Recommendation	Quality of Evidence and Strength of Recommendation
A clinician should diagnose a patient with T2DM through the use of an A1c test with a threshold ≥ 6.5%, FPG ≥ 126 mg/dL or a two-hour plasma glucose ≥ 200 mg/dL on a 75g OGTT. Additionally, if a patient has symptoms of hyperglycemia and casual plasma glucose ≥ 200 mg/dL, diabetes may be diagnosed.	Quality of Evidence: Low Strength of Recommendation: Strong
Benefits: **A1c** testing does not require fasting like other methods of testing, which may increase the likelihood that a patient will undergo testing for T2DM and have appropriate diagnosis and treatment. **A1c** testing also measures chronic glucose exposure over a two- to three-month period and is less influenced by internal factors including stress and/or illness than **FPG** or **OGTT**. Both **OGTT** and **FPG** are not influenced by abnormal red cell turnover conditions, and both allow for clear guidelines of diagnosis, especially for those who have normal fasting blood sugars. **Harms:** **A1c** testing may miss a portion of the population that would be diagnosed with T2DM using **FPG** or **OGTT** criteria, including those that have an abnormal hemoglobins or conditions that affect red blood cell turnover. There may also be racial or ethnic differences in the relationship between glycemia and A1c levels, and these could result in false-negatives or false-positives. **FPG and OGTT** both require fasting, which may reduce screening rates, and decrease appropriate diagnosis and management due to convenience. The two-hour **OGTT** is time consuming in both patient fasting and administration. **Benefits-Harms Assessment:** The general acceptance of all three testing methods and the specific thresholds are well established. Providing a choice of testing methods is likely to increase the likelihood that appropriate patients are tested for diabetes, minimize cost and inconvenience, and allow clinicians to individualize test selection based on individual patient characteristics.	
Relevant Resources: *Waugh, 2013; American Diabetes Association, 2010; Cowie, 2010; Kumar, 2010; Olson, 2010; International Expert Committee, The, 2009; Droumaguet, 2006*	

Supplemental Information

In the absence of unequivocal hyperglycemia, an abnormal A1c, fasting glucose or oral glucose tolerance test result that meets criteria for diabetes should be confirmed by repeat testing before assigning a diagnosis of T2DM.

- It is preferable that the same test be repeated for confirmation of diabetes. There may be cases in which two different tests are available (e.g., A1c and fasting glucose). If both tests meet diagnostic criteria for diabetes, a diagnosis of diabetes can be made.

Return to Algorithm *Return to Table of Contents*

- If two different tests are available and are discordant (e.g., A1c > 6.5%, fasting glucose < 126 mg/dL), then the test whose result is above the diagnostic threshold should be repeated. If it is again above the diagnostic threshold on repeat testing, a diagnosis of diabetes can be assigned.

Return to Algorithm *Return to Table of Contents*

2. Diagnosis of Prediabetes

Prediabetes. Prediabetes is defined as hyperglycemia that is not sufficient to meet the diagnostic criteria for diabetes, but that is associated with an increased risk of progression to T2DM. Diagnosis of prediabetes is made when an individual meets one or more of the following criteria:

- A1c 5.7-6.4%
- Fasting plasma glucose of 100 mg/dL to 125 mg/dL
- Oral glucose tolerance test two-hour plasma glucose: 140 mg/dL to 199 mg/dL

Return to Algorithm *Return to Table of Contents*

2.1 Treatment to Prevent or Delay Progression to T2DM

Patients who are identified with prediabetes should be referred for education and life-style interventions to a qualified health professional (which may include clinician, dietitian, nursing staff and pharmacist).

Intensive lifestyle change or programs have been proven effective in delaying or preventing the onset of diabetes by about 50-58%. Effective lifestyle changes include setting achievable goals, obtaining weight loss when needed (between 5-10% of total body weight is recommended), and increasing physical activity to a minimum of 150 minutes per week *(Tuomilehto, 2001)*.

- Patients with IGT, IFG or an A1c should be referred to an effective ongoing support program targeting weight loss of 7% of body weight and increasing physical activity to at least 150 minutes per week of moderate activity such as walking.
- Metformin therapy for prevention of T2DM may be considered in those patients meeting criteria for prediabetes.
- At least annual monitoring for the development of diabetes in those with prediabetes may be utilized.
- Screening for and treatment of modifiable risk factors for CVD are suggested.

Patients who respond to lifestyle interventions:

- Annual follow-up and reassessment of risks for developing diabetes *(American Diabetes Association, 2014; Chiasson, 2002; Heart Outcomes Prevention Evaluation Study Investigators, The, 2002; Kelley, 2002; Eriksson, 1999)*

Patients who are high risk and not responding to lifestyle interventions:

- Intensify education and counseling on lifestyle interventions. Lifestyle change remains the preferred method to prevent diabetes.

Health care clinicians should follow patients diagnosed with prediabetes on an annual basis to monitor his/her progress and review treatment goals *(American Diabetes Association, 2014)*.

Return to Algorithm *Return to Table of Contents*

Management Algorithm Annotations

3. Inpatient Diabetes Management

Inpatient care may be appropriate in the following situations *(American Diabetes Association, 2004a)*:

- Elderly patients with infection or illness, weight loss, dehydration, polyuria or polydipsia
- Life-threatening acute metabolic complications of diabetes:
  - Hyperglycemic hyperosmolar state with impaired mental status, elevated plasma osmolaity that includes plasma glucose greater than 600 mg/dL
  - Diabetic ketoacidosis with a plasma glucose greater than 250 mg/dL, arterial pH less than 7.30 and serum bicarbonate level less than 15 mEq/L and the presence of moderate ketonuria and/or ketonemia
  - Hypoglycemia with neuroglycopenia that includes blood glucose less than 50 mg
- Uncontrolled insulin-requiring diabetes during pregnancy
- Surgery, infection, steroids – if these conditions cause significant hyperglycemia and rapid initiation of rigorous insulin is needed

Hospitalized patients with diabetes suffer increased morbidity, mortality, length of stay and other related hospital costs compared to non-hyperglycemic inpatients. These negative outcomes are observed more frequently in hospitalized patients with newly discovered hyperglycemia. Hyperglycemia is an independent marker of inpatient mortality in patients with undiagnosed diabetes *(Umpierrez, 2002)*.

Hyperglycemia has been associated with increased infection rates and poorer short-term and long-term outcomes in critically ill patients in the intensive care unit, post-myocardial infarction and post-surgical settings. Earlier studies supported that aggressive glucose management in medical and surgical patients improves outcomes *(Van den Berghe, 2001)*. More recently, intensive management has been linked to increased hypoglycemia and increased mortality in a subset of patients including those with a long history of diabetes and cardiovascular disease *(NICE-SUGAR Study Investigators, The, 2009)*.

The following are suggestions for the inpatient setting *(American Diabetes Association, 2014; Clement, 2004)*:

- Insulin therapy with intravenous insulin in critically ill patients *(Van den Berghe, 2001)*
- Oral glycemic agents may need to be held or the dose adjusted if the patient is hospitalized
- Use of scheduled insulin, with basal coverage (improves glucose control compared to sliding scale coverage alone)
- For insulin-deficient patients, despite reductions or the absence of caloric intake, basal insulin must be provided to prevent diabetic ketoacidosis
- Target preprandial plasma glucose levels to 90-140 mg/dL *(American Diabetes Association, 2014; NICE-SUGAR Study Investigators, The, 2009; American Diabetes Association, 2004a; Clement, 2004; Garber, 2004)*
- Target random plasma glucose to less than 180 mg/dL *(American Diabetes Association, 2014; Holman, 2009; NICE-SUGAR Study Investigators, The, 2009; American Diabetes Association, 2004a; Clement, 2004; Garber, 2004)*
- A protocol should be utilized for patients with hypoglycemia < 70 mg/dL *(American Diabetes Association, 2014; Cryer, 2003)*

Return to Algorithm *Return to Table of Contents*

- Establishing a multidisciplinary team that sets and implements institutional guidelines, protocols and standardized order sets for the hospital results in reduced hypoglycemic and hyperglycemic events

Other considerations include *(Clement, 2004)*:

- For patients who are alert and demonstrate accurate insulin self-administration and glucose monitoring, insulin self-management should be allowed as an adjunct to standard nurse-delivered diabetes management.
- Patients with no prior history of diabetes who are found to have hyperglycemia (random fasting blood glucose greater than 125 mg/dL or random glucose of 200 mg/dL or more) during hospitalization should have follow-up testing for diabetes within one month of hospital discharge *(Umpierrez, 2002)*.

Types of Insulin

Based on outpatient studies, consider insulin Glargine or Detemir as the basal insulin (there are limited inpatient studies to date). In studies comparing Glargine to NPH, the risk of nocturnal hypoglycemia was reduced *(Wang, 2003; Yki-Järvinen, 2000)*. Treatment with insulin Detemir resulted in more predictable glycemic control than NPH insulin *(Vague, 2003)*.

Consider using rapid-acting insulin analogs (e.g., lispro, aspart, glulisine instead of regular insulin) unless the patient is to have nothing by mouth or is on continuous feedings. Initial studies comparing rapid-acting insulin with human regular insulin show rapid-acting insulins to be more effective at reducing the peak postprandial glucose concentration *(Reynolds, 2004)*. They may also lower the demand for endogenous insulin, provide superior postprandial glycemic control, and cause fewer hypoglycemic episodes requiring medical intervention *(Rave, 2006; Pettitt, 2003; Gerich, 2002)*.

Insulin lispro, glulisine and aspart have similar pharmacokinetics; they have an earlier onset and peak of action than regular insulin. Peak action usually occurs at one hour with a duration of three to four hours, while regular insulin has a peak action of two to four hours and a duration of six to eight hours. Lispro, glulisine and aspart may then reduce the occurrence of late postprandial hypoglycemia compared to regular insulin *(Guerci, 2005; John, 2004)*.

Insulin Dosing Schedule

Insulin dosing schedules must be individualized based on a variety of factors, including the severity of diabetes, oral intake, severity of illness and other concurrent diabetic medication. It is not feasible to design a single algorithm for determining an insulin regimen in every patient. The following information provides general guidance in determining initial insulin doses.

Healthy, non-diabetic people are estimated to secrete approximately 0.4-1.0 units of insulin/kg body weight per day *(Polonsky, 1988a; Davidson, 1986)*. Approximately 50% of this insulin is secreted as basal insulin and 50% as postprandial boluses following meals *(Polonsky, 1988b)*. Typical daily insulin doses for people with diabetes range from 0.5 to 0.7 units/kg per day. In the United Kingdom Prospective Diabetes Study of people with T2DM, the median daily insulin dose for people in the intensive insulin treatment arm of the study after a diabetes duration of approximately 12 years was 36 units/day *(UK Prospective Diabetes Study Group, 1998a)*.

Fifty percent of subjects were receiving between 23 and 53 units of insulin per day. The average weight of subjects was 75 kg, so the "average" daily insulin requirement was about 0.5 units/kg *(UK Prospective Diabetes Study Group, 1998a)*. Therefore, in initiating subcutaneous insulin in a hospitalized patient who is eating meals, a total daily insulin dose of 0.6 units/kg is probably reasonable *(Clement, 2004)*. Modification

Return to Algorithm *Return to Table of Contents*

can be made based on clinical judgment for factors such as severity of illness, fragility, renal function, body weight, expected nutritional intake and medication effects (e.g., glucocorticoid medications).

Based on the normal physiology of insulin release and experience with outpatient regimens for managing diabetes with subcutaneous insulin, it has been recommended that inpatient subcutaneous insulin regimens comprise three components *(Clement, 2004)*:

- A basal insulin component
- A prandial insulin component (for patients eating meals)
- A correction, sometimes referred to as "supplemental," insulin component used to treat hyperglycemia before or between meals *(Clement, 2004)*

In a small, randomized trial comparing a basal/prandial insulin regimen to a traditional sliding scale insulin regimen in hospitalized patients with T2DM, the basal/prandial insulin regimen resulted in improved glycemic control during the hospitalization. Hospital length-of-stay or incidences of hypoglycemia did not differ between the basal/prandial insulin regimen or the sliding scale insulin regimen *(Umpierrez, 2007)*.

Basal insulin

Typical approach is to give 40-50% of the estimated total daily insulin dose as the basal insulin component. Common basal regimens include one injection per day of Glargine insulin, usually given at bedtime or twice daily; Detemir insulin given once daily in the evening or given twice daily; twice-a-day injections of NPH insulin, given at breakfast and either at supper or bedtime; or once-a-day NPH insulin given at bedtime *(Vague, 2003)*. Basal insulin would generally be appropriate for any patient being managed with subcutaneous insulin, whether eating meals, nothing by mouth or receiving nutrition as continuous enteral feeding or total parenteral nutrition (TPN) *(Clement, 2004)*.

Prandial insulin

For patients eating meals, several approaches have been suggested to initiate a prandial insulin regimen:

- Divide 50% of the estimated daily insulin requirement into three equal insulin doses given before the three meals.
- Estimate the prandial insulin dose before each meal as 10-20% of the estimated daily insulin requirement.
- Count the carbohydrate content of the meal (one carbohydrate unit = 15 gm of meal carbohydrate), and determine the prandial insulin dose as a set number of units of insulin per meal carbohydrate unit.
- Insulin doses based on grams of carbohydrates consumed.

Typical insulin requirements using this last approach are one to two units of insulin per carbohydrate unit *(Clement, 2004)*.

It is recommended that prandial insulin be given as a rapid-acting insulin analog within 0-15 minutes of the meal *(Clement, 2004)*. Prandial insulin replacement has its main effect on peripheral glucose disposal into muscle. Also referred to as "bolus" or "mealtime" insulin, prandial insulin is usually administered before eating. There are occasional situations when this insulin may be injected immediately after eating, such as when it is unclear how much food will be eaten. In such situations, the quantity of carbohydrates taken can be counted and an appropriate amount of rapid-acting analog can be injected *(Clement, 2004)*.

Patients who are not eating meals will not typically require a prandial insulin component, although they may need periodic correction insulin.

Return to Algorithm *Return to Table of Contents*

Correction (supplemental) insulin

Correction dose insulin is given in addition to the scheduled basal and prandial insulin in order to correct hyperglycemia. For patients eating meals, it is typically given with meals by simply increasing the rapid-acting insulin dose by an additional amount based on the correction schedule. For patients not eating meals (e.g., nothing by mouth, on continuous enteral feeding, total parenteral nutrition), it is reasonable to give periodic short-acting insulin, either as regular insulin or a rapid-acting analog, based on the correction schedule at four- to six-hour intervals *(Guerci, 2005; John, 2004)*. If rapid-acting insulin is used in this situation, an every-four-hour schedule may be optimal. For regular insulin, a four- to six-hour schedule is reasonable *(Clement, 2004)*.

The correction dose insulin schedule must be individualized for the patient. A typical assumption is that one unit of insulin will lower the blood glucose 50 mg/dL *(Hirsch, 2002)*. An empiric "Rule of 1,700" has been proposed as one way of estimating the insulin correction requirement. This rule estimates that the decrease in glucose in response to one unit of insulin = (1,700/patient's total daily insulin dose) *(Davidson, 2003)*. The "Low," "Medium" and "High" correction schedules included on the order set assume that one unit of insulin will lower the blood glucose by approximately 50, 25 and 15 mg/dL, respectively.

There does not appear to be a consensus whether correction insulin should be given at bedtime. Some experts argue against bedtime correction insulin due to a fear of nocturnal hypoglycemia with short- or rapid-acting insulin given at bedtime *(Hirsch, 1995)*. If correction insulin is given at bedtime, the recommendation is that the correction dose should be reduced *(Clement, 2004)*.

Hyperglycemia induced by corticosteroid therapy is often characterized by predominant postprandial hyperglycemia with lesser effects on fasting glucose levels. For patients with corticosteroid-induced hyperglycemia, caution is suggested in prescribing correction dose insulin at bedtime due to the increased risk of nocturnal hypoglycemia *(Clement, 2004)*.

Example:

The following is an example of one possible initial subcutaneous insulin regimen for a hospitalized patient weighing 100 kg with hyperglycemia who is eating meals.

Estimated total daily insulin dose = 100 kg x 0.6 units insulin/kg = 60 units of insulin daily.

Basal: 50% of total daily insulin dose = 30 units given as Glargine or Detemir insulin at bedtime.

Prandial: 50% of total daily insulin dose/3 = 30 units/3 = 10 units of insulin at each meal given as Lispro, Glulisine or Aspart insulin.

Correction schedule: Assuming 1 unit of insulin will drop the blood glucose 50 mg/dL, the "Low" correction schedule on the order set could be used. Using the Rule of 1,700, one would estimate that one unit of insulin = drop in blood glucose of (1,700/60) = 28 mg/dL. In this case, the "Medium" correction schedule might be chosen.

Whatever insulin regimen is initially implemented, it will likely need to be modified over the course of a patient's hospitalization. If a patient is frequently requiring use of the correction schedule, common sense would dictate that either the basal component, prandial component or both need to be modified.

Transition from Intravenous to Subcutaneous Insulin

When transitioning from intravenous to subcutaneous insulin, it is generally recommended that an initial subcutaneous basal insulin dose of long- or intermediate-acting insulin be given prior to discontinuation of the intravenous insulin *(Furnary, 2006)*. Based on the absorption profiles of longer-acting insulins, administering the first subcutaneous insulin dose two hours prior to stopping the insulin infusion would appear to

Return to Algorithm *Return to Table of Contents*

allow sufficient overlap to avoid excessive rebound hyperglycemia when the insulin infusion is discontinued *(Furnary, 2006; Clement, 2004)*.

Determination of the initial basal insulin dose can be made using the guidelines above (e.g., estimating the basal insulin dose as 40-50% of the estimated total daily insulin dose). An alternative method that has been suggested is to estimate the initial basal dose based on the intravenous insulin requirements over a six- to eight-hour period leading up to the transition time. Ideally, this six- to eight-hour period would be a time when the patient was not eating and was not receiving intravenous glucose. The initial basal insulin dose could be calculated as 80% of the estimated 24-hour insulin requirement to provide a margin of safety *(Furnary, 2006)*.

Example:

A patient managed on an intravenous insulin drip is to be transitioned to subcutaneous insulin. Over a recent six-hour period when the patient was not eating and was not receiving intravenous glucose, the patient received a total of 15 units of insulin via the infusion. The estimated 24-hour basal insulin requirement would be 15 x 4 = 60 units. The initial basal insulin dose could be estimated as 80% x 60 units = 48 units.

Often the clinician may want to use a bedtime long-acting insulin (e.g., Glargine insulin) as the subcutaneous basal insulin, but the transition from intravenous to subcutaneous insulin is planned to occur during the day. In these cases, one option would be to give a one-time dose of NPH insulin by subcutaneous injection to act as a bridge until the regularly scheduled long-acting insulin is given *(Clement, 2004)*. A typical NPH insulin dose might be 40% of the planned long-acting insulin dose.

Example:

Using the example above, the clinician plans to give 48 units of Glargine insulin at bedtime as the basal insulin dose on the transition to subcutaneous insulin. However, the clinician would like to transition the patient to subcutaneous insulin during the day rather than waiting until later in the evening when fewer staff are present. A one-time order for NPH insulin 20 units (40% x 48 units = 19.2 units, round to 20 units) could be written to be given two hours before the insulin infusion is stopped. This intermediate-acting insulin would provide temporary basal insulin coverage until bedtime, when the 48 units of Glargine insulin could be given.

Prandial and correction insulin orders should also be written as appropriate for the patient's situation (eating, on tube feeding, etc.) on transition to subcutaneous insulin. This insulin would then be given in addition to the basal insulin in accordance with the order set.

Medication adherence

Non-adherence with medications can limit the success of therapy and help to explain why a patient is not achieving treatment goals. To screen for non-adherence, clinicians can ask patients open-ended, non-threatening questions at each office visit. The assessment should include probes for factors that can contribute to non-adherence (fear of adverse reactions, misunderstanding of chronic disease treatment, depression, cognitive impairment, complex dosing regimens or financial constraints).

- Assess the patient's knowledge of his/her condition and his/her expectations for treatment
- Assess the patient's medication administration process
- Assess the patient's barriers to adherence

Interventions to enhance medication adherence should be directed at risk factors or causes of non-adherence. Interventions may include simplifying the medication regimen, using reminder systems, involving family or caregivers in care, involving multiple disciplines in team care, providing written and verbal medication

Return to Algorithm *Return to Table of Contents*

instructions, setting collaborative goals with patients, and providing education about medications (including potential adverse effects) and about diabetes in general *(Nichols-English, 2000)*.

Depression evaluation

There is a substantial increase in the prevalence of depression among people with diabetes as compared to the general adult population *(Anderson, 2001)*. Depression impacts the ability of a person with diabetes to achieve blood glucose control, which in turn impacts the rate of development of diabetes complications *(de Groot, 2001; Lustman, 2001)*.

Identification and management of depression are important aspects of diabetes care. Self-administered or professionally administered instruments, such as PHQ-9, are useful adjuncts to the clinical interview in the identification of depression. The ICSI Major Depression in Adults in Primary Care guideline provides more suggestions for the identification and management of depression. Intervention studies have demonstrated that when depression is treated, both quality of life and glycemic control improve. Counseling may be effective, especially among those who are having difficulty adjusting to the diagnosis of diabetes or are having difficulty living with diabetes. Pharmacotherapy for depression is also effective.

Obstructive sleep apnea

Sleep apnea is a prevalent condition in obese patients with T2DM and is associated with significant comorbidities including hypertension, cardiovascular disease and insulin resistance. Consider referral of symptomatic patients for sleep evaluation. Clinicians should be cognizant of potential obstructive sleep apnea, especially among obese patients *(Foster, 2009a; Foster, 2009b)*.

Referral to an Extended Care Team

Diabetes educator

Consultation with a diabetes educator is suggested if the patient is having difficulty adhering to a nutrition, exercise and medication regimen, and the patient is having difficulty adhering to or accurately completing blood glucose monitoring or may need answers to his/her questions.

Primary care clinician should develop a relationship with a diabetes education program to provide other options for management. The American Diabetes Association publishes a list of recognized educational programs in each state. These programs may be staffed with endocrinologists or primary care clinicians plus diabetes educators including dietitians, nurses and other health care clinicians who are Certified Diabetes Educators or have didactic and experiential expertise in diabetes care and education.

Endocrinologist/nephrologist

Most T2DM management can be managed by a primary care clinician with periodic consultation as needed by an endocrinologist. Consultation with a specialist is suggested if persistent proteinuria, worsening microalbuminuria and elevation in serum creatinine or blood urea nitrogen, or hypertension unresponsive to treatment is seen.

Endocrinologist/neurologist

Consultation with a specialist is suggested if neuropathy progresses and becomes disabling.

Endocrinologist/cardiologist/hypertension specialist

Consultation with a specialist is suggested if blood pressure is refractory to treatment, or the patient has marked associated postural hypotension or symptoms of coronary artery disease.

Return to Algorithm *Return to Table of Contents*

Foot care specialist

A consultation with a specialist is suggested if the patient is unable to care properly for his/her own feet, needs prescriptive footwear and/or more serious problems such as foot deformities (e.g., Charcot deformity), infected lesions, and ulcers, deformed nails or thick calluses are present.

Opthalmology/optometry

Retinopathy is estimated to take at least five years to develop after the onset of hyperglycemia begins. Patients with T2DM who generally have had years of undiagnosed diabetes and who have a significant risk of prevalent diabetic retinopathy at time of diabetes diagnosis should have an initial dilated and comprehensive eye examination soon after diagnosis. Examinations should be performed by an ophthalmologist or optometrist who is knowledgeable and experienced in diagnosing the presence of diabetic retinopathy and is aware of its management. Subsequent examinations are generally repeated annually. Less frequent exams (every two to three years) may be cost effective after one or more normal eye exams, while examinations will be required more frequently if retinopathy is progressing *(American Diabetes Association, 2014)*.

Vascular specialist/surgeon

Consider referral if patient has symptoms of peripheral vascular disease such as loss of pulses and/or claudication.

Return to Algorithm *Return to Table of Contents*

4. Glycemic Control and A1c Goals

Recommendation	Quality of Evidence and Strength of Recommendation
A clinician should personalize goals with patients diagnosed with T2DM to achieve glycemic control with a hemoglobin A1c < 7% to < 8% depending on individual patient factors.	Quality of Evidence: High Strength of Recommendation: Strong
Benefits: Achieving near-normal glycemic control lowers risk of diabetes microvascular complications such as retinopathy, nephropathy and amputations. Achieving A1c of 6.9 to 7.9% may also significantly reduce macrovascular complications based on Steno-2 and UKPDS data. **Harms:** Near-normal glycemic control (A1c around 6.4 to 6.5%) achieved through intensive pharmacotherapy appears to have less benefit for major CV events (ACCORD ADVANCE VADT) and in one large trial significantly increased mortality 20% (ACCORD). In some patients, aggressive pharmacotherapy with insulin, sulfonylureas or certain other agents may lead to weight gain and severe hypoglycemia. The long-term cardiovascular safety of agents other than metformin and human insulins has yet to be established. **Benefits-Harms Assessment:** Therefore, to optimize the balance between benefits and harms for a given patient, personalization of glycated hemoglobin (A1c) goals in the range of < 7% to < 8% is recommended.	
Relevant Resources: *Hemmingsen, 2013; Callaghan, 2012; Anderson, 2011; Ismail-Beigi, 2010; Abraira, 2009; Duckworth, 2009; NICE-SUGAR Study Investigators, The, 2009; Ray, 2009; Turnbull, 2009; ACCORD Study Group, The, 2008; ADVANCE Collaborative Group, The, 2008; Gaede, 2008; Holman, 2008b*	

Supplemental Information

For patients with T2DM, an A1c goal of less than 8% may be more appropriate than an A1c goal of less than 7%, when including the following factors:

- Known cardiovascular disease or high cardiovascular risk, and may be determined by the Framingham or ACC/AHA Cardiovascular Risk Calculator, or alternatively as having two or more cardiovascular risks (BMI > 30, hypertension, dyslipidemia, smoking and microalbuminuria)
- Inability to recognize and treat hypoglycemia, including a history of severe hypoglycemia requiring assistance
- Inability to comply with standard goals, such as polypharmacy issues

Return to Algorithm *Return to Table of Contents*

- Limited life expectancy or estimated survival of less than 10 years.
- Cognitive impairment.
- Extensive comorbid conditions such as renal failure, liver failure and end-stage disease complications.

A multifactorial approach to diabetes care that includes emphasis on blood pressure, lipids, glucose, aspirin use and non-use of tobacco will maximize health outcomes far more than a strategy that is limited to just one or two of these clinical domains *(American Diabetes Association, 2014; Duckworth, 2009; Gaede, 2008; Holman, 2008a)*.

Multifactorial approach

The benefits of a multifactorial approach to diabetes care are supported by the results of the Steno-2 Study of 160 patients with T2DM and microalbuminuria. Multifactorial interventions achieved a 50% reduction in mortality and significant reduction in microvascular complications five years after ending a 7.8-year multifactorial intervention that achieved A1c of 7.8%, low-density lipoprotein 83 mg/dL, blood pressure 131/73, compared to a conventional group that achieved A1c 9%, low-density lipoprotein 126 mg/ dL and blood pressure 146/78 *(Gaede, 2008)*. Results of this study are consistent with the need for reasonable blood glucose control with emphasis on blood pressure and lipid management.

Microvascular/macrovascular complications

Follow-up data from the United Kingdom Prospective Diabetes Study of newly diagnosed patients with T2DM confirm major macrovascular and microvascular benefits of achieving A1c in the 7.1 to 7.3% range, versus A1c of about 8% in the comparison groups *(Holman, 2008a)*. The United Kingdom Prospective Diabetes Study main trial included 3,867 newly diagnosed T2DM patients and showed over a 10-year period a 25% decrease in microvascular outcomes with a policy using insulin and sulfonylureas that achieved a median A1c of 7.1%, compared to 7.9%. A subgroup of obese patients (n=1,704) treated with metformin and achieving a median A1c of 7.3% showed greater advantages over conventional treatment: a 32% reduction of diabetes-related end points (P=0.002), a 42% reduction of diabetes-related deaths (P=0.017), and a 36% reduction of all-cause mortality (P=0.011) *(UK Prospective Diabetes Study Group, 1998b)*.

Several reported clinical trials have evaluated the impact of A1c less than 7% on macrovascular and microvascular complications of T2DM. These studies – the Action to Control Cardiovascular Risk in Diabetes (ACCORD), the Action in Diabetes and Vascular Disease: Preferax and Diamcron Modified Release Controlled Evaluation (ADVANCE), and VADT Trials – are the first that have ever achieved and maintained A1c less than 7% in his/her intensive treatment patients.

Cardiovascular risk

In the ACCORD Trial, excess mortality in the intensive group (A1c mean 6.4% vs. standard group A1c 7.5%) forced the safety board to discontinue the intensive treatment arm earlier than planned *(ACCORD Study Group, The, 2008)*. There was one excess death for every 90 patients in the intensive group over a 3.5-year period of time. In the ADVANCE trial, intensive group patients achieved A1c 6.5% (vs. 7.5% in standard group) but had no reduction in cardiovascular complications or events. In the VADT trial, intensive group patients achieved A1c of 6.9% but had no significant reduction in cardiovascular events or microvascular complications compared to standard group patients who achieved A1c of 8.4%. However, the VADT Trial was underpowered for its main hypothesis tests *(Duckworth, 2009)*. In the ADVANCE trial, intensive group patients had less progression to proteinuria (one less patient advancing to proteinuria for every 100 people in the intensive group over a five-year period of time), but no fewer eye complications in the intensive group than in the standard group. ACCORD analysis showed lower rates of early stage microvascular complications in the intensively treated group. Some patients, especially those with little comorbidity and long life

Return to Algorithm *Return to Table of Contents*

expectancy, may benefit from more intensive glycemic goals as long as hypoglycemia does not become a barrier. However, the risk of lower glycemic targets may outweigh the potential benefits on microvascular complications for many patients *(Ismail-Beigi, 2010; ACCORD Study Group, The, 2008)*.

A meta-analysis analyzed five randomized controlled trials (UKPDS, PROactive, ADVANCE, VADT and ACCORD) for the effect of intensive glucose control on cardiovascular outcomes. Overall, this meta-analysis concluded that more intensive glucose control significantly reduced non-fatal myocardial infarct events and coronary heart disease events (non-fatal myocardial infarct and all-cardiac mortality) with no evidence of either a benefit or adverse effect on all-cause mortality. Heterogeneity among studies was noted with regard to all-cause mortality, suggesting that the impact of glycemic reduction on all-cause mortality may differ among different populations *(Ray, 2009)*. A subset analysis from ACCORD, ADVANCE and VADT suggested that intensive glucose lowering has a modest (9%) but statistically significant reduction in major CVD outcomes, primarily non-fatal MI, with no significant effect on mortality. However, a pre-specified subgroup analysis suggested that major cardiovascular disease outcome reduction occurred in patients without known cardiovascular disease at baseline *(Turnbull, 2009)*.

Glycosylated hemoglobin assays

Glycosylated hemoglobin assays provide an accurate indication of long-term glycemic control. Glycated hemoglobin is formed by the continuous non-enzymatic glycosylation of hemoglobin throughout the lifespan of an erythrocyte. The A1c assay yields an accurate measure of time-averaged blood glucose during the previous six to eight weeks. Clinically, it can assist in determining duration and severity of hyperglycemia and can help guide treatment.

Eating, physical activity or acute metabolic stress does not influence the A1c test. The test can be done at any time of day and does not require fasting.

Self-monitoring blood glucose (SMBG)

Self-monitoring blood glucose (SMBG) allows patients to evaluate his/her individual response to therapy and assess whether glucose targets are being achieved. Results of SMBG can be useful in preventing hypoglycemia and adjusting medications, medical nutrition therapy and physical activity *(American Diabetes Association, 1994)*.

Major clinical trials assessing the impact of glycemic control on diabetes complications have included self-monitoring blood glucose testing (SMBG) as part of multifactorial interventions, suggesting that self-monitoring blood glucose is a component of effective therapy *(American Diabetes Association, 2014)*. Several diabetes management strategies reliant on SMBG testing have demonstrated improved glucose control in patients *(Polonsky, 2011; Weinger, 2011)*.

Table 1 gives ranges of self-monitored glucose readings that would be expected as goals for patients with the corresponding A1c level goals.

Return to Algorithm *Return to Table of Contents*

Table 1. Ranges of self-monitored blood glucose values for various A1c goals

A1c Target	Average Mean Fasting Blood Glucose*	Average Mean Post-Prandial Blood Glucose	Estimated Average Blood Glucose**
< 6%	< 100	< 140	126
7%	90-130	< 180	154
8%	120-160	< 210	182
9%	160-190	< 240	211

* It is not recommended to achieve target fasting glucose values below 70 mg/dL.

** This average uses both fasting and post-prandial blood glucose readings from continuous glucose monitors or from 7-point daily testing.

Table 1 was developed by the diabetes work group based on data currently available from studies of frequently monitored glucose values and will be modified if necessary as further studies become available.

The frequency and timing of SMBG should be dictated by the particular needs and goals of the individual patient. Bedtime glucose goals vary dependent on the patient's treatment program, risks for hypoglycemia and time after last meal. Patients with T2DM on insulin typically need to perform self-monitoring blood glucose more frequently than those not using insulin, particularly if using glucose readings to guide mealtime insulin dosing. It is recommended that patients using multiple insulin injections perform SMBG prior to meals, snack or exercise or when low blood glucose is questioned *(American Diabetes Association, 2014)*. The optimal frequency and timing of SMBG for patients with T2DM on oral or non-insulin injectable therapy are not known but should be sufficient to facilitate reaching glucose goals. SMBG should be performed more frequently when adding or modifying therapy; two-hour post-prandial glucose testing is useful in some patients. The role of SMBG in stable diet-treated patients with T2DM is not known.

Because the accuracy of SMBG is instrumental and user dependent, it is important for health care clinicians to evaluate each patient's monitoring technique and accuracy of equipment. In addition, optimal use of SMBG requires proper interpretation of the data. When appropriate, patients can be taught how to use the data to adjust food intake, exercise or pharmacological therapy to achieve specific glycemic goals.

Return to Algorithm *Return to Table of Contents*

5. Education and Self-Management

5.1 Nutrition Therapy

Recommendation	Quality of Evidence and Strength of Recommendation
A qualified health professional (which may include a clinician, dietitian, nursing staff and pharmacist) should provide nutrition therapy to a patient diagnosed with T2DM as part of a global treatment plan.	Quality of Evidence: Moderate Strength of Recommendation: Strong
Benefits: Nutrition therapy specifically activates patients by more intensively assessing eating and physical activity behaviors and nutrient intake, and provides counseling that results in improved health and may reduce complication of T2DM. Diabetes nutrition therapy can result in cost savings and improved outcomes such as reduction in A1c. Nutrition therapy can be personalized based upon the patient's needs, comorbidities, existing chronic conditions and other key factors. **Harms:** Professionals who do not utilize evidence-based standards/protocols can promote expensive short-term strategies that limit food choices – without scientific evidence – that are not ultimately effective in improving long-term health. Patient activation can be difficult and may not be sustainable for the patient long term, and the increased cost for healthy foods may be a burden for some. **Benefits-Harms Assessment:** The benefit of having a patient activated and counseled based upon his/her needs and the increase of risk reduction outweighs the difficulty in achieving nutrition modification.	
Relevant Resources: *Ajala, 2013; Estruch, 2013; Andrews, 2011; Azadbakht, 2011; Elhayany, 2010; Brehm, 2009; Esposito, 2009; Robbins, 2008; Brunerova, 2007; Nield, 2007; Ash, 2003*	

Recommendation	Quality of Evidence and Strength of Recommendation
A qualified health care professional (which may include a clinician, nursing staff, pharmacist, and registered dietitian) should counsel a patient diagnosed with T2DM to modify his/her diet to reduce sodium intake to < 2,300 mg/day (Strong). Clinicians may counsel patients diagnosed with T2DM and hypertension to further reduce their sodium intake (Weak).	Quality of Evidence: High Strength of Recommendation: Strong/Weak
Benefits: Incrementally lower sodium intakes have shown beneficial effects on blood pressure and mitigation of cardiovascular risk factors with such meal plans as the DASH diet. **Harms:** There is difficulty in achieving both low-sodium recommendations and a nutritionally adequate diet, given such concerns as cost, palatability and availability of lower sodium food products. **Benefits-Harms Assessment:** The beneficial effects on blood pressure and mitigation of cardiovascular risk factors outweigh the inconvenience and cost of finding a diet with a reduced sodium intake. Sodium intake < 1,500 mg/day has shown to be associated with a small increase in mortality, and counseling a patient to reduce sodium intake to < 2,300 mg/day should be considered only on an individual basis with consideration.	
Relevant Resources: *He, 2013; Suckling, 2010*	

Return to Algorithm *Return to Table of Contents*

Recommendation	Quality of Evidence and Strength of Recommendation
A qualified health care professional (which may include a clinician, dietitian, nursing staff and pharmacist) may give a patient diagnosed with T2DM a meal plan that incorporates monitoring carbohydrates.	Quality of Evidence: Moderate Strength of Recommendation: Weak
Benefits: A customized diabetes meal plan that includes the amount of carbohydrate in meals and snacks to improve postprandial glycemia is effective in achieving glycemic control. Carbohydrate intake has a direct effect on postprandial glucose levels and is the macronutrient most of concern in glycemic management. Simplified plate methods that including portion-controlled carbohydrate food sources may be better suited for patients with numeracy and literacy concerns. Carbohydrate intake from vegetables, fruits, whole grains, legumes and dairy products should be advised over intake from other carbohydrate sources, especially those that contain added fats, sugars or sodium. **Harms:** Meal plans that do not adjust for total amount of carbohydrates can result in higher than desired target ranges for postprandial blood glucoses and HgbA1c. If the patient is not given a meal plan at the appropriate literacy level, the ability for the patient to effectively monitor carbohydrates may be difficult and produce less than ideal outcomes. **Benefits-Harms Assessment:** Monitoring carbohydrate intake, whether by carbohydrate counting or experience-based estimation, remains a key strategy in achieving glycemic control and outweighs the difficulty in achieving nutrition modification.	
Relevant Resources: *Ajala, 2013; Estruch, 2013; Azadbakht, 2011; Wiebe, 2011; Elhayany, 2010; Brehm, 2009; Esposito, 2009; Thomas, 2009; Brunerova, 2007; Nield, 2007*	

Supplemental Information

Nutrition assessment

Clinicians providing nutrition therapy should complete a nutrition assessment, and provide tailored education and counseling based on the individual needs of the person with diabetes. While many standardized meal plans and menus are available in print or Web-based, it is through the collaborative development of individualized nutrition interventions with ongoing support for behavior change that best facilitates achievement of patients' health goals *(Evert, 2014)*. Nutrition education should be delivered by health professionals with appropriate training, knowledge and skills, and of sufficient duration and quality to meet patients' needs effectively *(Miller, 2002)*.

Goals and eating patterns

Goals of nutrition therapy for diabetes promote healthful eating patterns designed to lower glucose, blood pressure, and alter lipid profiles to lower cardiovascular risk factors, emphasizing a variety of nutrient-dense foods in appropriate portion sizes to improve overall health *(Evert, 2014)*. Eating patterns or dietary patterns are combinations of different foods or food groups that characterize relationships between nutrition and healthy promotion or disease prevention. Eating patterns include Mediterranean-style, DASH, vegetarian or vegan, low carbohydrate and low fat. Eating plans should take into account individual personal and cultural preferences, health literacy and numeracy, willingness to change behaviors and metabolic goals. Major metabolic goals are to attain individualized glycemic, blood pressure and lipid goals, and achieve and maintain body weight goals to delay and prevent complications of diabetes *(Evert, 2014)*.

Macronutrients

A recent systematic review provides evidence that modifying the amount of macronutrients can improve glycemic control, weight and lipids in people with diabetes. Low-carbohydrate, low-glycemic index (GI), Mediterranean and high-protein diets reduced hemoglobin A1c by 0.12-0.5% compared to comparison or control diets. These hemoglobin A1c reductions were significant, with a reduction of 0.5% that was similar to that achieved by using medication and associated with lower risk of microvascular complications *(Ajala, 2013)*. However, while other various meta-analysis and systematic reviews have been conducted, there is no conclusive evidence regarding an ideal macronutrient distribution for all people with diabetes *(Evert, 2014)*. Another recent systematic review found there is no ideal mix of macronutrients that can be applied and that macronutrient proportions should be individualized *(Wheeler, 2012)*.

Return to Algorithm *Return to Table of Contents* **www.icsi.org**

Meal planning approaches

There are multiple meal planning approaches that can be used as effective nutrition interventions. Examples include carbohydrate counting, simplified healthful food choices (i.e., the Plate Method), and individualized meal plans based on percentages of macronutrients, exchange lists or glycemic index. For individuals using fixed daily insulin doses, consistent carbohydrate intake with respect to time and amount can reduce risk of hypoglycemia and improve glycemic control *(Evert, 2014)*.

Carbohydrate intake

There is insufficient evidence to recommend a specific amount of carbohydrate intake for all people with diabetes. Despite the conflicting evidence evaluating the effect of differing percentages of carbohydrates, monitoring carbohydrates remains a useful strategy. The quantity and the type of carbohydrate in a food influence blood glucose level, and the total amount of carbohydrate is the primary predictor of glycemic response. Therefore, the effect of the amount of carbohydrates and available insulin on postprandial blood glucose should be considered in developing a meal plan. Monitoring carbohydrate intake, either by carbohydrate counting or experience-based estimation, remains a key strategy in achieving glycemic control *(Evert, 2014)*.

Sucrose

It has been demonstrated that the substitution of sucrose for starch for up to 35% of calories may not affect glycemia or lipid levels. Since foods high in sucrose are high in calories, substitution should be made to ensure nutrient density of overall eating pattern. There is evidence from studies of individuals without diabetes that because of rapidly absorbable carbohydrates (such as sucrose or high-fructose corn syrup) large quantities of sugar-sweetened beverages (SSBs) should be avoided to lower risk of weight gain and worsening of cardiometabolic risk factors *(Evert, 2014)*.

Fiber

People with diabetes should consume at least the amount of fiber and whole grain recommended for the general population. Encourage consuming a wide variety of fiber-containing foods such as legumes, fiber-rich cereals, fruits, vegetables and whole grain products to achieve fiber intake goals of 14 g/1,000 calories or about 25 g/day for adult women and 38 g/day for adult men, and meet recommendations to consume at least half of all grains as whole grains *(Evert, 2014)*.

Glycemic index

A recent systematic review on low-glycemic index diets concluded a low-GI diet can decrease HgbA1c by 0.5%, which was statistically significant *(Thomas, 2009)*. Substituting low-glycemic load foods for higher-glycemic load foods may modestly improve glycemia. The ADA nutrition guideline states the evidence evaluating the effect of glycemic index or glycemic load is complex and often difficult to discern the independent effect of fiber compared to that of glycemic index on glycemic control or other outcomes *(Evert, 2014)*. With a lack of a standard definition of a low-glycemic food and different responses in individuals, it is difficult to teach this method to patients. Consideration of glycemic effects of a mixed meal makes it even more difficult to include this in meal planning, especially for those patients with numeracy concerns. Patients who already are competent carbohydrate gram counters perhaps best utilize use of glycemic index or load food lists.

Non-Nutritive sweeteners

There is little evidence that use of non-nutritive sweeteners (NNSs) leads to reduction in body weight. If NNSs are used to replace caloric sweeteners without caloric compensation, then NSSs may be useful in reducing caloric and carbohydrate intake *(Wiebe, 2011)*.

Return to Algorithm *Return to Table of Contents*

Protein

For people with diabetes and no evidence of diabetic kidney disease, evidence is inconclusive to recommend an ideal amount of protein intake for optimizing glycemic control or improving one or more CVD risk measure. While some randomized control trials have compared the effect of higher protein diets to usual intake on diabetes outcomes, they have been small and of short duration. For people with diabetic kidney disease, reducing the amount of protein below usual intake is not recommended because it does not alter glycemic measures, cardiovascular risk measures or the course of glomular filtration rate (GFR) decline. Protein appears to increase insulin response without increasing plasma concentrations, therefore carbohydrate sources high in protein should not be used to treat hypoglycemia *(Evert, 2014)*.

Fat intake

Evidence is inconclusive for an ideal amount of total fat intake, so fat goals should be individualized to be consistent with goals to either maintain or lose weight. The Institute of Medicine recommendations define acceptable macronutrient distribution for total fat as 20-35% of calories. The type of fatty acids consumed is more important than the total dietary fat in supporting metabolic goals and influencing risk of cardiovascular disease *(Evert, 2014)*. The 2013 AHA/ACC Lifestyle Management to Reduce Cardiovascular Risk guideline recommends reduce percent of calories from saturated fat to 5-6% *(Stone, 2014)*.

Monounsaturated fatty acids (MUFA)

The Mediterranean-style mono-unsaturated fatty acid-rich eating pattern is associated with improved glycemic control and reduction in cardiovascular risk factors, and can be utilized as an effective alternative to lower-fat, higher-carbohydrate eating patterns. Studies demonstrated improvements when MUFA (monounsaturated fatty acids) was substituted for carbohydrates and/or saturated fats, but some of the studies included a caloric restriction, which may have contributed to positive outcomes *(Evert, 2014)*. A recent randomized trial, the PREDIMED trial, enrolled subjects with either T2DM or at least three CVD risk factors. The authors concluded an energy-unrestricted Mediterranean diet, supplemented by either extra-virgin olive oil or nuts, resulted in a substantial reduction in the risk of major cardiovascular events among high-risk persons and supported the benefits of the Mediterranean diet for the primary prevention of cardiovascular disease *(Estruch, 2013)*.

Omega-3

An increase in foods containing Omega-3 fatty acids (EPA and DHA from fatty fish) and ALA is recommended because of beneficial effects on lipoproteins, and prevention of heart disease and associations with positive outcomes in observational studies. Evidence does not support recommending omega-3 supplements for the prevention or treatment of cardiovascular events *(Evert, 2014)*.

Sodium

A systematic review of randomized control trials showed that decreasing sodium intake reduces blood pressure in people with diabetes *(Suckling, 2010)*. The Institute of Medicine report suggested there is no evidence on health outcomes to treat certain population subgroups – including people with diabetes – differently than the U.S. population in regards to the amount of salt reduction *(Institute of Medicine, 2013)*.

Alcohol

If one chooses to drink alcohol and has not been cautioned against it, limit intake to one drink per day for women and two drinks per day for men, according to USDA guidelines. A drink is defined as 12 oz. of regular beer, 5 oz. of wine, or 1.5 oz. of 80-proof distilled spirits. To reduce the risk of hypoglycemia, alcohol should be consumed with food, especially if taking insulin or insulin secretagogues.

Return to Algorithm *Return to Table of Contents*

5.2 Physical Activity

Recommendation	Quality of Evidence and Strength of Recommendation
A clinician should advise patients diagnosed with T2DM to complete at least 150 minutes a week of aerobic physical activity and resistance training at least twice per week.	Quality of Evidence: High Strength of Recommendation: Strong
Benefits: Exercise is a low-cost, non-pharmacological intervention that has been shown to have a beneficial effect on decreasing metabolic risk factors for the development of complications and cardiovascular disease. Lowering glucose may reduce medication needs via muscle mass development, HGBA1c levels, improve insulin sensitivity, bone density and balance; and it is well tolerated, feasible and safe. **Harms:** Behavior modification may be difficult and challenging to maintain. Concern is that acute rises in blood pressure associated with higher intensity resistance exercise might be harmful, possibly provoking stroke, myocardial ischemia or retinal hemorrhage. Also muscle soreness, fatigue and injury potential are additional harms that may be associated with physical activity. **Benefits-Harms Assessment:** The benefit that exercise has shown to provide in lowering the effects of T2DM and its cost saving outweigh the difficulty in achieving behavior modification and the low risk of cardiovascular events due to acute rises in blood pressure.	
Relevant Resources: *Gibbs, 2014; Look AHEAD Research Group, The, 2013; Church, 2010; Li, 2010; Diabetes Prevention Program Research Group, 2009; Orozco, 2008; Thomas, 2006; Cauza, 2005; Sigal, 2004; Castaneda, 2002; Dunstan, 2002; Boulé, 2001*	

Supplemental Information

The positive benefits of physical activity include improved glycemic control, blood pressure values, lipid profile, depression management and cardiac status, as well as increased insulin sensitivity and effective weight management.

Hypoglycemia is a risk in individuals who participate in physical activity and are taking insulin and/or insulin secretagogues. Depending on the level of physical activity, the medication dosage or the amount of carbohydrate ingested, hypoglycemia can occur. For patients on these drug classes and pre-exercise glucose monitor results are less than 100 mg/dL, additional carbohydrate should be ingested for prevention of hypoglycemia.

Strategies for initiation of increased physical activity

- Start by incorporating 10 minutes of increased activity into each day
  - Use stairs instead of elevator
  - Park car away from building entrance and walk
  - Walk to do errands
- Overcome barriers
  - Self-monitor activity performed using pedometer, time record and/or journal
  - Be consistent
  - Have alternative activities for inclement weather
  - Find enjoyable activities
  - Be active at the time of day that is best for the individual
  - Doing a physical activity with a partner and/or being accountable to someone regarding your progress greatly improves the ability to be successful
- Reinforce the ongoing need and benefits of physical activity at each visit

Return to Algorithm *Return to Table of Contents*

Medical evaluation to assess safety of exercise program

Clinicians should use clinical judgment and assess for conditions that might contraindicate certain types of exercises or be predisposed to injury (e.g., uncontrolled hypertension, severe autonomic neuropathy, severe peripheral autonomic neuropathy or history of foot lesions). High-risk patients should be encouraged to start with short periods of low-intensity exercise, and increase intensity and duration slowly *(American Diabetes Association, 2014)*.

- Assess physical condition and limitations of the patient
- Cardiac stress testing should be considered for the previously sedentary individual at moderate to high risk for cardiovascular disease or other patients who are clinically indicated who want to undertake vigorous aerobic exercise that exceeds the demands of everyday living *(American Diabetes Association, 2014)*. Cardiac stress testing is not routinely necessary in asymptomatic patients before beginning a moderate-intensity exercise program such as walking.
- Assess glucose control
- Assess knowledge of physical activity in relation to glucose control
- When making a referral, make other health care clinicians aware of limitations for exercise

Return to Algorithm *Return to Table of Contents*

5.3 Weight Management

Recommendation	Quality of Evidence and Strength of Recommendation
A qualified health professional (which may include a clinician, dietitian, nursing staff and pharmacist) should counsel an overweight patient diagnosed with T2DM about the need to reduce energy intake while maintaining a healthful eating pattern to promote weight loss.	Quality of Evidence: Moderate Strength of Recommendation: Strong
Benefits: Various energy-restricted eating patterns have been utilized to reduce excess body weight with no specific optimal macronutrient intake to support weight reduction established. A variety of eating patterns has resulted in reduction of energy with weight loss and subsequent improvement in diabetes control and other cardiovascular risk factors. **Harms:** Maintaining a nutritional therapy change maybe difficult for a patient long term and may not be sustained. Unqualified health advisors may recommend overly restrictive diet regimens that result in nutritional deficiencies and/or rapid extreme weight loss, which may contribute to medical conditions such as gallstones. **Benefits-Harms Assessment:** The benefits of a healthier lifestyle outweigh the harms associated with sustainability and the potential for nutritional deficiencies or rapid extreme weight loss. Weight loss and a healthier lifestyle are difficult to sustain, but even small amounts of weight loss and reduction in energy intake can improve outcomes.	
Relevant Resources: *Look Ahead Research Group, The, 2013; Buchwald, 2009; Diabetes Prevention Program Research Group, 2009; Norris, 2005; Ash, 2003*	

Supplemental Information

Because many individuals with T2DM are insulin resistant and overweight or obese, nutrition therapy often begins with strategies that reduce energy intake and increase energy expenditure through physical activity. The optimal macronutrient distribution of weight loss diets has not been established. Studies designed to reduce excess body weight have used a variety of energy-restricted eating patterns with various macronutrient intake, and some included physical activity and ongoing follow-up support. Clinicians should collaborate with overweight or obese individuals with diabetes to develop healthful eating plans that reduce energy to promote weight loss. An eating plan should include appropriate food choices, and portion size needs to reflect energy requirements to ensure appropriate energy balance *(Evert, 2014)*.

Maintenance of weight loss requires an intensive program with long-term support *(Evert, 2014)*. One study concluded the failure of initial weight loss of 6% after 12 weeks of intensive weekly contact with improvement in glycemic control to be sustained at an 18-month follow-up was likely due to a lack of continued

Return to Algorithm *Return to Table of Contents*

contact with a health professional *(Ash, 2003)*. A study comparing a high-monounsaturated fat diet to a high-carbohydrate diet concluded only the high-monounsaturated fat diet group was able to maintain weight loss at 18 months compared to the high-carbohydrate diet group (60% carbohydrate). The authors note the intense, year long behavioral intervention delivered by registered dietitians influenced the dietary compliance and positive outcomes achieved in the study *(Diabetes Prevention Program Research Group, 2009)*.

See the ICSI Prevention and Management of Obesity for Adults guideline for recommended lifestyle strategies.

Return to Algorithm *Return to Table of Contents*

5.4 Bariatric Surgery

Recommendation	Quality of Evidence and Strength of Recommendation
A clinician may recommend a patient diagnosed with T2DM and a BMI > 35 kg/m2 consider bariatric surgery if diabetes or comorbidities are difficult to control with lifestyle and pharmacologic therapy.	Quality of Evidence: Moderate Strength of Recommendation: Weak
Benefits: Large amounts of weight loss – which can be achieved with bariatric surgery, at least in the short term – in resolution of diabetes or improved diabetes control and elimination or reduction in diabetes medications compared to intensive medical management. **Harms:** Bariatric surgery carries a risk of perioperative mortality and perioperative, and long-term complications from surgery. Whether bariatric surgery results in long-term reduced mortality or risk of cardiovascular events compared to intensive medical management is unknown. **Benefits-Harms Assessment:** The potential for resolution or substantial improvement in diabetes with bariatric surgery could outweigh the potential harms from surgery for appropriate patients who wish to consider this option.	
Relevant Resources: *Ikramuddin, 2013; Cohen, 2012; Dorman, 2012; Mingrone, 2012; Schauer, 2012; Maciejewski, 2011; Hoerger, 2010; Makary, 2010; Buchwald, 2009*	

See the ICSI Prevention and Management of Obesity for Adults guideline for discussion of bariatric surgery.

Return to Algorithm *Return to Table of Contents*

5.5 General Diabetes Self-Management and Education

Recommendation	Quality of Evidence and Strength of Recommendation
Diabetes self-management or education by a qualified health care professional (which may include a clinician, dietitian, nursing staff and pharmacist) should be offered to patients diagnosed with T2DM.	Quality of Evidence: High Strength of Recommendation: Strong
Benefits: Diabetes self-management education and support improves patient understanding of the disease, empowers patients to manage their care, and reduces distress. It is cost effective and has been shown to improve knowledge, self-efficacy and self-care behavior skills, and modestly improves glycemic control. **Harms**: Patients may find it difficult to continue education due to the ongoing time commitment and expense. **Benefits-harms Assessment:** Benefit of providing education and support strongly outweighs any potential harms.	
Relevant Resources: *Guicciardi, 2014; Lakerveld, 2013; Pal, 2013; Thorpe, 2013; Steinsbekk, 2012; Tricco, 2012; Tshiananga, 2012; Radhakrishnan, 2011; Gillett, 2010; Deakin, 2009; Duke, 2009; Robbins, 2008; Siminerio, 2006a; Siminerio, 2006b; Siminerio, 2005; Gary 2003*	

Diabetes self-management education includes the ongoing processes of facilitating the knowledge, skill and ability necessary for diabetes self-care. It incorporates the needs, goals and life experiences of the person with diabetes. Education helps people with diabetes initiate effective self-management and cope with diabetes when they are first diagnosed. Ongoing diabetes education helps people with diabetes maintain effective self-management throughout a lifetime of diabetes *(American Diabetes Association, 2014)*.

In the U.S., one option for self-management education is the Outpatient Diabetes Self-management and Training Program. This is a service that educates patients on self-management of diabetes and includes

Return to Algorithm *Return to Table of Contents*

education about self-monitoring of blood glucose, diet, exercise and sometimes medication (oral agents and/or insulin). The treatment plan is developed specifically for the patient, which helps engage and motivate patients to use the knowledge and skills in effective self-management. It follows the national standards for diabetes self-management education programs and American Diabetes Association (ADA) review criteria or the American Association of Diabetes Educators (AADE). Other countries have developed national standards that include many of the same components.

The evidence of the benefits of diabetes self-management education is substantial. Diabetes education is associated with improved diabetes knowledge and improved self-care behavior *(Norris, 2005)* and improved clinical outcomes such as lower HgbA1c, lower self-reported weight, improved quality of life, healthy coping and lower costs *(American Diabetes Association, 2014)*. A recent meta-analysis suggested that educational and behavioral interventions in T2DM produced a moderate decline in HgbA1c of .43%, which was statistically significant. Larger sample size studies and those with better study quality scores had larger HgbA1c declines *(Gary, 2003)*.

Better outcomes are reported when interventions are longer and include follow-up support; are culturally and age appropriate, and tailored to individual needs, address psychosocial issues and incorporate behavioral strategies. Those interventions that promote behavior change in turn improve clinical outcomes *(Steinsbekk, 2012; Radhakrishnan, 2011)*.

Interventions that have psychosocial content (e.g., discuss quality of life with participants, and include empowerment or motivational interviewing) had a positive rate difference of 80% compared to diet outcomes. The relationship between diet and psychosocial issues is particularly relevant for women from high-risk ethnic groups living with T2DM. Interventions that focus on psychosocial support and self-management have proved successful in some studies among Hispanic and African American populations because they address emotions and beliefs about T2DM, deal with the question of how adjusting one's lifestyle may conflict with cultural norms, and demonstrate that incorporating psychosocial coping strategies may be effective in improving dietary behaviors.

The recent literature provides support for a variety of healthy coping interventions in diverse populations, including diabetes self-management education, support groups, problem-solving approaches, and coping skills interventions for improving a range of outcomes. Coping with an emphasis on problem-solving may benefit psychosocial outcomes in addition to self-care behavior and glycemic control, although more studies evaluating a common set of healthy coping outcomes are needed. There has been substantial interest in cognitive behavioral therapy (CBT), including several studies suggesting effectiveness of CBT-based interventions on depressive symptoms and diabetes-related stress, when delivered via novel formats, such as the Internet and/or telephone. However, evidence from recent trials is mixed *(Thorpe, 2013)*.

A Cochrane review *(Deakin, 2009)* concluded group-based training for self-management strategies in people with T2DM is effective by improving fasting blood glucose levels, glycated hemoglobin and diabetes knowledge, and reducing systolic blood pressure levels, body weight and the requirement for diabetes medication. An anticipated benefit of diabetes education for patients is improved glycemic control as a consequence of better patient motivation, adherence to treatment and understanding of the disease. A number of recent systematic reviews and a meta-analysis highlight the effectiveness of nurses and dietitians in multiple studies in delivering effective diabetes education *(Guicciardi, 2014; Steinsbekk, 2012; Tshiananga, 2012)*.

While the Diabetes Education and Self-management for Ongoing and Newly Diagnosed (DESMOND) randomized control trial demonstrated the HgbA1c level was not improved in the trial, this may have been because the major improvements in HgbA1c level achieved in the period after diagnosis of diabetes, as seen in both study arms, may have masked any effect of the intervention *(Gillett, 2010)*. A Cochrane review *(Duke, 2009)* found that individual diabetes education and self-management, compared to usual care, did not significantly improve glycemic control, although there was benefit for those with an A1c greater than 8.0%. Differences in patient characteristics and in education and self-management content and implementation

may have contributed to the variability in outcomes. The review notes the impact may have been diluted by including a high number of participants who had a near normal HgbA1c at baseline. In a subgroup analysis focused on studies where participants had an average baseline HgbA1c of greater than 8%, there was a significant impact of individual education on glycemic control. The authors concluded the systematic review highlighted the benefits of individual education in lowering HgbA1c in a subgroup of patients with poorer control and a mean baseline HgbA1c greater than 8% *(Duke, 2009)*.

The integrated chronic care model (CCM) is increasingly recommended as the preferred model of diabetes care in many countries. While focusing on organization of treatment so that care services are better integrated and more efficiently utilized, an integral component of CCM is support of patient management of patients' own care via diabetes self-management education *(Siminero, 2006b)*.

Although a recent U.S. study based on commercial and Medicare claims databases revealed that patients using diabetes education have lower average medical costs than patients who do not *(Duncan, 2011)*, due to a lack of large-scale population-based trials, the evidence documenting the clinical and economic impact of the CCM approach remains uncertain *(Tshiananga, 2012)*.

A systematic review concluded computer-based diabetes self-management interventions currently have limited effectiveness *(Pal, 2013)*. They appear to have small benefits on glycemic control. The effect size on HgbA1c was larger in the mobile phone subgroup. Current interventions do not show adequate evidence for improving depression, health-related quality of life or weight, but they do appear to be safe *(Pal, 2013)*. Effective nutrition therapy interventions may be part of a comprehensive group education session or an individualized session. Interventions should also include recommendations for physical activity and utilize behavior change counseling to help sustained improved lifestyle modifications *(Evert, 2014)*.

Return to Algorithm *Return to Table of Contents*

5.6 Foot Care Education

Foot Care Education

Education should be tailored to patient's current knowledge, individual needs and risk factors. Patients should be aware of their risk factors and appropriate measures to avoid complications *(American Diabetes Association, 2004d; Mayfield, 1998)*. See "Comprehensive foot exam with risk assessment" in the "Ongoing Management" section.

Education should include:

- Self-inspect feet daily for cuts, bruises, bleeding, redness and nail problems.
- Wash feet daily and dry thoroughly, including between the toes.
- Do not soak feet unless specified by a health care clinician.
- Be careful of hot water.
- Use of lotions, creams or moisturizer is acceptable, but do not use between the toes.
- Do not walk barefoot.
- Check shoes each day for objects that may have fallen inside, excessive wear or areas that may cause irritation.
- Avoid injuries from cutting toenails; avoid self-cutting calluses or corns.
- When to seek care.

Return to Algorithm *Return to Table of Contents*

5.7 Tobacco Cessation

Tobacco smoking increases risk of macrovascular complications 4-400% in adults with T2DM and also increases risk of microvascular complications. Over time, tobacco and nicotine products have expanded (including e-cigarettes, water pipes and dissolvable products) and care teams should be advised about these developments in order to screen and counsel appropriately. Tobacco cessation is very likely to be the single most beneficial intervention that is available, and it should be emphasized by clinicians as described below.

- Identify and document tobacco use status.
- Treat every tobacco user. If the patient is unwilling, the clinician should implement motivational treatments.
- Individual, group and telephone counseling are effective, and their effectiveness increases with treatment intensity.
- Practical counseling (problem-solving/skills training and social support delivered as part of the treatment) is an especially effective counseling strategy and should be implemented by clinicians.
- Numerous effective pharmacotherapies for smoking cessation now exist. Except in the presence of contraindications, these may be used with all patients attempting to quit smoking. Please see the ICSI Healthy Lifestyles guideline for additional information.
- The combination of counseling and medication is more effective than either alone. Therefore, clinicians should encourage all individuals making a quit attempt to use both.
- Telephone quitline counseling is effective. Therefore, clinicians and health care delivery systems should ensure patient access to quitlines and promote their use. HHS National Quitline (1-800-QUITNOW) or 1-800-784-8669 connects you to counseling and information about quitting smoking in your state.
- Tobacco dependence treatments are both clinically effective and cost effective. Effective interventions require coordinated interventions. Just as the clinician must intervene with the patient, so must the health care administrator, insurer and purchaser foster and support tobacco intervention as an integral element of health care delivery.

Return to Algorithm *Return to Table of Contents*

6. Metformin

Recommendation	Quality of Evidence and Strength of Recommendation
A clinician should initiate metformin as first-line pharmacotherapy for patients with T2DM, unless medically contraindicated.	Quality of Evidence: High Strength of Recommendation: Strong
Benefits: Metformin may reduce A1c by 1-1.5%, rarely causes hypoglycemia when used as monotherapy and does not cause weight gain. It is a low-cost, oral medication with a long track record of accumulated patient experience and safety, and it has a beneficial lipid effect. Metformin can also be used in combination with all other glucose-lowering agents. Improved microvascular and macrovascular outcomes have been demonstrated in large clinical trials. In UKPDS, obese patients treated with metformin had reduced complications and overall mortality. **Harms:** The most common side effects are diarrhea, gas and nausea. These side effects can be attenuated by initiating metformin at a low dose and increasing gradually over several weeks or months up to the maximum effective dose. The risk of lactic acidosis, a rare but potentially life-threatening condition, may be increased due to metformin but data are controversial. Conditions that predispose patients to hypoxemia, such as symptomatic CHF or COPD can increase the risk of lactic acidosis. The kidneys clear metformin, and the product label contraindications relate to specific creatinine thresholds. However, other data indicate that metformin seems safe and can be initiated in labeled doses if the GFR is above 45 ml/min, with close monitoring of renal function and continued treatment unless the GFR falls to < 30 ml/min. Metformin should be stopped before surgery or contrast studies with radiographic dye injection for at least 48 hours and until adequate post-event renal function is documented. Long-term metformin use has been associated with vitamin B12 deficiency. **Benefits-Harms Assessment:** The benefits of metformin outweigh the harms for most patients. Monitoring of renal function and conditions that may predispose to lactic acidosis reduce the potential risk. Metformin alone may not be sufficient to achieve recommended blood glucose goals in patients presenting with severe hypoglycemia.	
Relevant Resources: *Al-Shareef, 2012; Lipska, 2011; Salpeter, 2010; Selvin, 2008; Saenz, 2005; UK Prospective Diabetes Study Group, 1998a*	

Return to Algorithm *Return to Table of Contents*

Cardiovascular Risk Management Algorithm Annotations

7. Cardiovascular Risk Factors

7.1 Antihypertensive Therapy

Recommendation	Quality of Evidence and Strength of Recommendation
A clinician should initiate antihypertensive treatment for patients with T2DM with a blood pressure ≥ 140/90 mmHG and treat to a goal of < 140/90.	Quality of Evidence: High Strength of Recommendation: Strong
Benefits: Uncontrolled hypertension is a major risk factor for ASVCD events. Multiple large studies (UKPDS, HOT, ADVANCE) have shown improved cardiovascular outcomes with treatment of blood pressure to this range in patients with diabetes. **Harms:** In many patients with diabetes, two or three or more medications are required to achieve this level of blood pressure control. Medications may be costly, and there are risks of adverse reactions, medication interactions and overtreatment causing hypotension. **Benefits-Harms Assessment:** Considering the high level of ASCVD risk and the significant benefits for primary and secondary prevention of cardiovascular events in treating hypertension, along with the low cost generic status of the vast majority of antihypertensive medications, it is believed that the benefits of treating hypertension to this goal outweigh the risks. Careful attention should be given to monitoring for side effects, medication interactions and avoiding overtreatment.	
Relevant Resources: *Arguedas, 2013; Bangalore, 2011; Nilsson, 2011; ACCORD Study Group, The, 2010b; ADVANCE Collaborative Group, The, 2008; Howard, 2008; Estacio, 2006; Wing, 2003; ALLHAT, 2002; Hansson, 1998; UK Prospective Diabetes Study Group, 1998b*	

Supplemental Information

Uncontrolled hypertension is a major cardiovascular risk factor that also accelerates the progression of diabetic nephropathy *(Morrish, 1991)*. When hypertension is identified, it should be aggressively treated to achieve a target blood pressure of less than 140/90 mmHg. In many patients with diabetes, two or three or more antihypertensive agents may be needed to achieve this goal. The use of generic combination tablets (such as ACE plus calcium-channel blocker or beta-blocker plus diuretic) can reduce the complexity of the regimen and out-of-pocket costs.

Return to Algorithm *Return to Table of Contents*

The UKPDS, HOT, ADVANCE and ACCORD trials are all large randomized clinical trials that allow comparison of more stringent to less stringent blood pressure levels on major cardiovascular outcomes *(ACCORD Study Group, The, 2010b; Zoungas, 2009; Hansson, 1998; UK Prospective Diabetes Study Group [UKPDS], 1998b)*. The UKPDS, HOT and ADVANCE trials all found reduced cardiovascular outcomes with lower achieved blood pressure levels. However, none of these trials achieved average systolic blood pressure levels below 130 mmHg (Table 2). The ACCORD trial found no difference in major cardiovascular outcomes between a more intensive blood pressure intervention targeting systolic blood pressure < 120 mmHg compared to a more standard intervention targeting systolic blood pressure between 130 and 139 mmHg (Table 2). The more intensive blood pressure regimen was associated with a small reduction in the rate of stroke, greater medication use and more serious adverse events *(ACCORD Study Group, The, 2010b)*.

The above studies support a systolic blood pressure goal < 140 mmHg for people with T2DM. We would estimate that targeting a systolic blood pressure < 140 mmHg would result in an achieved blood pressure around 135 mmHg for most people.

Only the HOT trial specifically targeted diastolic blood pressure. In the HOT trial, targeting a lower diastolic blood pressure was associated with fewer cardiovascular events in subjects with T2DM. The average achieved diastolic blood pressure values in the three HOT intervention arms ranged from 81-85 mmHg (Table 2). Based on results from the ADVANCE and ACCORD trials, it appears likely that achieved systolic blood pressure values in the mid-130 range will be associated with diastolic blood pressure values well below 80 mmHg.

The general recommendation from The 2014 Evidence-Based Guideline for the Management of High Blood Pressure in Adults: Report From the Panel Members Appointed to the Eighth Joint National Committee (JNC 8) to treat to a goal of a blood pressure < 140/90 mmHg does not preclude setting individual patient goals lower than that based on patient characteristics, comorbidities, risks or the preference of an informed patient *(James, 2014)*.

Table 2. Comparison of Goal to Mean Achieved Blood Pressure Levels in Randomized Trials of Blood Pressure Control in People with Type 2 Diabetes

	UKPDS		**HOT**			**ADVANCE**		**ACCORD**	
	Intensive	Control	DBP			Treat	Placebo	Intensive	Standard
Goal	< 150/85	< 180/105	≤ 80	≤ 85	≤ 90	----	----	SBP ≤ 120	SBP 130-139
Achieved	144/82	154/87	140/81	141/83	144/85	134/75	144/77	119/69	133/70

While ACE inhibitors and ARBs are preferred first-line therapy, two or more agents (to include thiazide diuretics) may be required. For patients with T2DM, thiazide diuretics in the treatment of hypertension may reduce cardiovascular events, particularly heart failure *(James, 2014; Wing, 2003; ALLHAT Officers and Coordinators for the ALLHAT Collaborative Research Group, 2002; Heart Outcomes Prevention Evaluation Study Investigators, The, 2000; Alkharouf, 1993; Lewis, 1993)*.

Return to Algorithm *Return to Table of Contents*

7.2 Statin Therapy (High Risk)

Recommendation	Quality of Evidence and Strength of Recommendation
(A) A clinician should recommend high-intensity statin therapy for patients diagnosed with T2DM, between the ages of 40-75 with established ASCVD (strong), and (B) may recommend high-intensity statin therapy for others at a 10-year ASCVD risk ≥ 7.5% (weak).	Quality of Evidence: High Strength of Recommendation: Strong/Weak
Benefits: A high-intensity statin reduces the relative risk of ASCVD events more than moderate-intensity statin in patients with and without diabetes, and in primary and secondary prevention in those with diabetes. **Harms:** Serious adverse events such as myopathy and rhabdomyolysis are rare, but patient characteristics that may influence statin safety and be cause for not recommending high-intensity statin therapy include multiple concomitant comorbidities, impaired renal or hepatic function, a history of previous statin intolerance or muscle disorders, concomitant use of drugs known to affect statin metabolism, a history of hemorrhagic stroke and age > 75. **Benefits-Harms Assessment:** The benefits of high-intensity statin therapy for patients with diabetes and high ASCVD risk usually outweigh potential harm, but side effects and individual patient characteristics that predispose patients to statin toxicity can influence the risk/harm balance. Patient preference should be included in decision-making.	
Relevant Resources: *Taylor, 2013; Cholesterol Treatment Trialists' Colloboration, 2010; Cannon, 2004; Heart Protection Study Collaborative Group, 2003; Heart Protection Study Collaborative Group, 2002*	

Return to Algorithm *Return to Table of Contents*

7.3 Statin Therapy (Moderate Risk)

Recommendation	Quality of Evidence and Strength of Recommendation
A clinician should recommend moderate- or high-intensity statin therapy for all patients diagnosed with T2DM between the ages of 40-75 with a LDL ≥ 70 mg/dL.	Quality of Evidence: High Strength of Recommendation: Strong
Benefits: The use of at least moderate-intensity statin therapy in persons of this age and an elevated LDL level with a diagnosis of diabetes has been shown to be effective. The only trial of high-intensity therapy in primary prevention was performed in a population without diabetes. High-intensity statin therapy reduces the relative risk of ASCVD events more than moderate-intensity statin therapy in patients with ASCVD. Because individuals with diabetes are at substantially increased lifetime risk for ASCVD events and death, similar to those who have had a previous ASCVD event, persons with diabetes with high estimated 10-year ASCVD risk are likely to benefit similarly from high-intensity therapy. **Harms:** Statin therapy appears to cause only a slight increased risk of side effects compared to placebo, and no increased risk of discontinuation of therapy compared to placebo. In clinical practice, the most common side effect observed is muscle symptoms. Some patients who have muscle symptoms can tolerate lower statin doses, changes in statin drugs or alternate-day dosing. Known statin associated serious adverse effects include rare cases of myopathy, hemorrhagic stroke and drug-drug interactions. There are insufficient data to support benefits in individuals with NYHA class II-IV heart failure and individuals undergoing maintenance hemodialysis. Preferences of patients who understand the risks and benefits of statin use should be accounted for, as the potential benefit (especially for primary prevention) may not outweigh the inconvenience and cost of a long-term daily medication with possible side effects for some people. **Benefits-Harms Assessment:** Given the high prevalence of macrovascular disease in those with diabetes and the cardiovascular benefit of statins clearly exceeds the risk of adverse events and modest cost for most patients with T2DM ages 40-75. Intensifying statin therapy should be discussed with the patient in a shared decision-making conversation including the risks and benefits. Patients with characteristics that might be predispose them to statin side effects may be candidates for lower intensity statin dosing.	
Relevant Resources: *Taylor, 2013; Macchia, 2012; AIM-HIGH Investigators, 2011; ACCORD Study Group, The, 2010a; Cholesterol Treatment Trialists' (CTT) Collaboration, 2010; Cholesterol Treatment Trialists' (CTT) Collaborators, 2008; Cannon, 2004; Heart Protection Study Collaborative Group, 2003*	

Supplemental Information

Seventy to seventy-five percent of adult patients with diabetes die of macrovascular disease, specifically coronary, carotid and/or peripheral vascular disease. Diabetes is considered a myocardial infarction risk equivalent to ASCVD risk. Dyslipidemia is a known risk factor for macrovascular disease. Patients with diabetes develop more atherosclerosis than patients without diabetes with the same quantitative lipoprotein profiles. In most patients with diabetes, use of a statin can reduce major vascular events. Beneficial effects of statins on cardiovascular risk reduction may go beyond their quantitative effects on lipid levels.

Return to Algorithm *Return to Table of Contents*

For those with a diagnosis of diabetes who are younger than 40 or older than 75, statin therapy decisions should be individualized based on considerations of ASCVD risk reduction benefits, potential adverse effects and drug interactions, and patient preferences.

For additional information on statin therapy, refer to the ICSI Lipid Management in Adults guideline.

The current evidence does not support the use of combination therapy with statins and other lipid drugs for most patients with T2DM. The National Institutes of Health-sponsored ACCORD lipid study showed no significant reduction in myocardial infarct, stroke or cardiovascular death with a fibrate-statin combination compared to statin monotherapy. However, a subgroup analysis of the primary outcome suggested that there was a gender effect with a possible benefit for men and possible harm for women, as well as a possible benefit for men and women with both low HDL (< 34 mg/dL) and elevated triglycerides (> 204 mg/dL). AIM-HIGH was a study designed to evaluate the cardiovascular outcomes with niacin and statin combination therapy compared to statin monotherapy in patients with coronary heart disease, including a subgroup with diabetes. The study was stopped early in 2011 because of lack of benefit compared to statin therapy alone, including the diabetes subgroup *(AIM-HIGH Investigators, 2011)*.

Return to Algorithm *Return to Table of Contents*

7.4 Aspirin Therapy

Recommendation	Quality of Evidence and Strength of Recommendation
A clinician should recommend aspirin therapy for patients diagnosed with T2DM with established ASCVD and consider aspirin therapy for others where the benefits outweighs the risk in primary prevention.	Quality of Evidence: High Strength of Recommendation: Strong
Benefits: Patients with established ASCVD are at high risk for recurrent events, and aspirin therapy for secondary prevention has been shown to reduce the rate of future events to a clinically meaningful degree. As T2DM is an independent risk factor for ASCVD, patients with T2DM might be expected to benefit from aspirin therapy even before they manifest evidence of ASCVD. **Harms**: Aspirin therapy could increase the risk of clinically significant bleeding and is also associated with medication cost. **Benefits-Harms Assessment:** The substantial reduction in recurrent ASCVD events with aspirin therapy in secondary prevention will outweigh the risk of bleeding for patients with established ASCVD and no contraindications to aspirin use. In patients with T2DM where aspirin is considered for primary prevention, while the risk of clinically significant bleeding is low, it is still likely increased relative to no therapy. At this time, it is unclear whether adding aspirin therapy to other standard therapy for CV risk factors adds net benefit in patients with T2DM who do not have established ASCVD.	
Relevant Resources: *Rosiak, 2013; Macchia, 2012; Soejima, 2012; Valentine, 2012; Antithrombotic Trialists' (ATT) Collaboration, 2009; Belch, 2008; Ogawa, 2008; Campbell, 2007; Pignone, 2006*	

Supplemental Information

Patients with T2DM are at a significantly increased risk for development of heart disease *(American Diabetes Association, 2014)*. Recent trials of aspirin use in diabetes have shown less benefit than older trials for primary prevention, perhaps due to better background A1c, blood pressure, and low-density lipoprotein control and lower smoking rates in recent trials *(Rosiak, 2013; Macchia, 2012; Belch, 2008; Ogawa, 2008)*.

Regular use of ibuprofen may undermine aspirin's antiplatelet effects; patients taking both medications regularly should take immediate-release aspirin at least 30 minutes prior to taking ibuprofen or wait at least eight hours after ingestion of ibuprofen.

Return to Algorithm *Return to Table of Contents*

8. Treatment Goals Not Met

If patients are having difficulty achieving treatment goals, consider the following:

- Modification of treatment goals
- Evaluate for potential contributing issues such as adherence, depression and obstructive sleep apnea

Return to Algorithm *Return to Table of Contents*

- A referral to an extended care team clinician can be helpful; this could be to an endocrinologist or other specialist, diabetes educator, dietitian or pharmacist

Return to Algorithm *Return to Table of Contents*

9. Ongoing Management

Components of ongoing management for successful T2DM care should include the following:

- Regular follow-up with the health care team (via office visit, e-visit, telephone, labs, etc.) should be scheduled yearly. More frequent visits may be necessary if treatment goals are not achieved.
- Patients starting or having a major change in their treatment program (such as initiating insulin therapy) may need to be in contact with their care clinician as often as daily until glucose control is achieved, the risk of hypoglycemia is low, and the patient is competent to conduct the treatment program and should ideally not be delayed greater than one week.
- Perform a targeted history and physical yearly on all patients, with particular attention to the feet, cardiovascular system and blood pressure.

  Targeted annual history and targeted physical exam:

  - Results of self-monitoring blood glucose – validate results at least once a year (e.g., check patient's glucose meter against an office random capillary glucose)
  - Adjustments by the patient of the therapeutic regimen
  - Frequency, causes and severity of both hyperglycemia and hypoglycemia
  - Problems with adherence to therapeutic regimen
  - Symptoms suggesting development or progression of the complications of diabetes
  - Current prescribed medications, over-the-counter medications, dietary supplements and alternative therapies
  - Documentation of eye care specialist exam results
  - Alcohol/drug use patterns
  - Annually screen for microalbuminuria
- Assessment for symptoms of depression
- Weight, body mass index
- Blood pressure – all patients with diabetic nephropathy should be on either an ACE inhibitor or ARB
- Cardiovascular – evaluation of preexisting problems
- Feet (nails, web spaces, calluses, ulcers, structural deformities, protective sensation and shoes)
- At each encounter, ask if the patient has experienced symptoms of hypoglycemia or low blood glucose, review and educate the patient on appropriate recognition, prevention and management. If the patient has a history of severe hypoglycemia (assistance of another person was needed to treat a low glucose) or has developed hypoglycemia unawareness, evaluate the treatment goals for appropriate safety.

Return to Algorithm *Return to Table of Contents*

- All patients with diabetic nephropathy should be on either an ACE inhibitor or ARB unless contra-indicated. Consider early nephrology consultation for patients with macroalbuminuria and/or Cr above 1.5 mg/dL.
- Aggressively control hypertension, dyslipidemia, obesity and protein restriction in all patients with nephropathy.

Specialist dilated eye exam

A dilated eye examination for diabetic eye disease performed by an ophthalmologist or optometrist is recommended annually for patients with T2DM *(American Diabetes Association, 2014)*. Less frequent exams (every two to three years) may be considered in the setting of a normal eye exam. The role of fundus photography is still being considered but doesn't replace a comprehensive exam.

Retinopathy

Prevalence of retinopathy is related to the duration of diabetes mellitus. After 20 years of T2DM, more than 60% of patients have some degree of retinopathy *(Fong, 2004)*. Diabetic retinopathy is estimated to be the most frequent cause of new cases of blindness among adults ages 20 to 74 years.

Up to 21% of patients with T2DM are found to have retinopathy at the time of diagnosis of diabetes mellitus *(Fong, 2004)*. Generally, retinopathy progresses from mild background abnormalities to preproliferative retinopathy to proliferative retinopathy.

Poor glucose control is associated with progression of retinopathy. High blood pressure is a risk factor for the development of macular edema and is associated with the development of proliferative retinopathy *(Fong, 2004)*.

Screening for diabetic retinopathy saves vision at a relatively low cost. In fact, screening costs may be less than the costs of disability payments for those who become blind. Laser photocoagulation surgery is effective in preventing visual loss in diabetic retinopathy. Studies have shown that retinal examinations by clinicians who are not eye care specialists are not reliable in detecting retinopathy *(Fong, 2004; American College of Physicians, 1992; ETDRS Research Group, 1991; Klein, 1987; ETDRS Research Group, 1985; Klein, 1984; Diabetic Retinopathy Study Research Group, The, 1981)*.

Renal assessment and nephrology

Urinary albumin excretion should be tested annually by a microalbuminuria method. There is racial/ethnic variability with regard to the prevalence of end-stage renal disease, with Native Americans, Latinos (especially Mexican Americans) and African Americans having higher rates than non-Hispanic whites with T2DM *(American Diabetes Association, 2004b)*. If albuminuria is above normal, serum creatinine should be measured *(American Diabetes Association, 2004b; Bennett, 1995; Nelson, 1991)*.

Screening to detect microalbuminuria

Measurement of the albumin-to-creatinine ratio in a random, spot collection. Consider early nephrology consultation for patients with macroalbuminuria and/or Cr > 1.5 mg/dL. Aggressive control of hypertension, dyslipidemia, obesity and protein restriction is recommended in all patients with nephropathy.

Several factors can artificially increase the levels of albumin in the urine and should be avoided at the time of the urine collection. These include blood in the urine, prolonged heavy exercise, fever, congestive heart failure, uncontrolled diabetes, severe hypertension, urinary tract infection and vaginal fluid contamination of specimen.

If two out of three screening microalbuminuria tests are positive, the individual has microalbuminuria, and interventions should be considered. A negative finding should be followed annually; a positive finding should

Return to Algorithm *Return to Table of Contents*

be followed periodically, for example annually, to see if the interventions are effective in diminishing the albuminuria *(Hannah, 1999; Mogensen, 1996; Bennett, 1995; National Institutes of Health, 1993)*.

Nephropathy

In T2DM, albuminuria may be present at the time of diagnosis in about 10% of patients, and another 10% later develop it. Progression to renal failure is less certain in type 2 patients than in type 1 patients and appears to be modulated by genetic and other factors.

Patients with clinical nephropathy almost always have retinopathy and coronary artery disease.

Numerous interventions are appropriate at different stages of renal function in order to prevent or slow the progression of renal disease and associated cardiovascular disease, and include *(American Diabetes Association, 2004b)*:

- Glucose control – Improved glucose control at any stage of renal function reduces renal disease progression.
- ACE inhibitor or ARB should be used in all non-pregnant patients with micro or macroalbuminuria. For patients with T2DM, ACE inhibitors or ARBs can reduce progression of macrovascular complications *(Lewis, 2001; Heart Outcomes Prevention Evaluation Study Investigators, The, 2000)*. Within one week of initiation, check for elevations in potassium and creatinine levels.
- Measure serum creatinine at least annually and more often based on stage of chronic kidney disease (CKD).
- Hypertension control – An ACE inhibitor or ARB should be the initial agent of choice. Current JNC and NKF/DOQI recommendations call for treatment of blood pressure to < 130/80 in patients with CKD. However, no single, adequately powered intent-to-treat randomized control trial has shown a benefit of this blood pressure goal in CKD *(Arguedas, 2013; Appel, 2010; Lewis, 2010)*. Hence, the recommendation for lower blood pressure goals in all patients with CKD is based on expert opinion and not fully supported by available prospective clinical trials. Determining whether therapy should specifically be titrated to goals lower than < 140/90 mgHg for specific subgroups of CKD patients (e.g., those with moderate proteinuria) should be considered on an individual patient basis, based on clinical judgment and patient preference.

- Cardiovascular risk factor intervention – Dyslipidemia is often present with microalbuminuria and should be treated aggressively. Dyslipidemia may be an independent risk factor for progression of renal disease. Smoking is associated with the onset and progression of microalbuminuria.
- Restriction of dietary protein has been shown to slow progression of overt nephropathy (macroalbuminuria), and there may be some benefit in dietary protein reduction in microalbuminuric patients. In these circumstances, protein intake should be reduced to the adult recommended daily allowance of 0.8-1.0 g/kg body weight per day with microalbuminuria present, and 0.8 gm/kg body weight per day with macroalbuminuria present *(American Diabetes Association, 2014)*.

Treatment for microalbuminuria includes aggressive blood pressure control with ACE or ARB use as first-line therapy, glycemic control, and aggressive cardiovascular risk factor screening and management.

Strongly consider referral to nephrology any patients with a creatinine greater than 1.5 mg, or nephrotic range proteinuria (greater than 3 gm/24 hour).

Patients with a creatinine clearance of less than 30 mL/min should be referred to nephrology for discussions of future options and to enhance the ability to receive a future transplant. These patients also have significant enough renal impairment that they also benefit from more intensive nutritional interventions and proper management of anemia and bone disease *(American Diabetes Association, 2004b; Karter, 2002; Lewis,*

2001; Heart Outcomes Prevention Evaluation Study Investigators, The, 2000; DeFronzo, 1995; Viberti, 1994; Lewis, 1993; Ravid, 1993).

See Appendix B, "Treatment of Diabetic Nephropathy."

Neuropathy

Peripheral neuropathy is difficult to prevent and treat. Most patients with T2DM and peripheral neuropathy have few symptoms. All patients found to have neuropathy should see a foot care specialist for preventive measures aimed at reducing the incidence of diabetic foot complications.

Good glycemic control should be the first control of symptomatic neuropathy.

Comprehensive foot exam with risk assessment

A foot exam should include assessment for the following risk factor for complications:

- Loss of protective sensation. Protective sensation can be assessed using either a 5.07 Semmes-Weinstein monofilament for light touch or by testing vibration using a 128-Hz tuning fork at the dorsum of the interphalangeal joint of the great toe, or both. Patients with reduced or absent sensation with either of these tests should be educated about their risk and the need for proper foot care to prevent foot complications. See Appendix C, "Using a Semmes-Weinstein Monofilament to Screen the Diabetic Foot for Peripheral Sensory Neuropathy," and Appendix D, "Using a Tuning Fork to Screen the Diabetic Foot for Peripheral Neuropathy."
- Peripheral vascular disease (absent pedal pulse, history of claudication or ischemic skin changes)
- Structural deformities (bunion, hammertoes, Charcot deformity, limited joint mobility or prior amputation)
- Skin disorders (nail deformity, callus, fissure, tinea or ulceration)
- Footwear (excessively worn, ill-fitting or inappropriate shoes)
- Medications can improve quality of life in patients with painful neuropathy

Peripheral Vascular Disease

Peripheral arterial disease is commonly associated with diabetes *(American Diabetes Association, 2003)*. As many as 36% of patients with diabetes have lower-extremity peripheral arterial disease based on lower-extremity blood pressure readings. However, a typical history of intermittent claudication or an absent peripheral pulse is less commonly noted.

Initial screening for peripheral arterial disease should include asking about claudication and assessment of pedal pulses. Consider obtaining ankle-brachial index if clinically indicated.

Peripheral vascular disease in combination with peripheral neuropathy places patients with diabetes at increased risk for non-traumatic amputations of the lower extremity. Peripheral vascular disease may be slowed by smoking cessation and treatment of hypertension and dyslipidemia.

Aggressive daily foot care, inspection of the feet at every office visit for diabetes mellitus, early treatment of foot infections, treatment of callus, use of moisturizing lotion and proper footwear may forestall problems, including amputation. Vascular surgery may also prevent amputation in some patients with established severe peripheral vascular disease *(American Diabetes Association, 2003)*.

Proper high-risk foot management is necessary to prevent ulceration and amputation. Consider referral of patients with claudication and/or absent pedal pulses to vascular surgery.

Return to Algorithm *Return to Table of Contents*

Cardiovascular and Cerebrovascular Complication Assessment

- History of cardiovascular symptoms such as chest pain, vascular claudication, TIA
- Cardiac and carotid exams
- Screening for coronary heart disease
- Evaluate cardiovascular status before advising increased intensity of exercise *(American Diabetes Association, 2004c; Sigal, 2004)*.

Cardiovascular and Cerebrovascular Disease

Treatment includes control of cardiovascular risk factors (hypertension, dyslipidemia and smoking cessation) and aspirin use. Consider referring patients with known coronary artery disease to cardiology and patients with known carotid disease to a specialist.

Heart failure is also common in patients with diabetes. Metformin may be used in stable congestive heart failure if renal function is normal.

Close monitoring of potassium and renal function is necessary especially if patients have concomitant chronic kidney disease as the common use of diuretics, ACE/ARBs and aldsosterone antagonists in these patients may cause hyperkalemia and worsening renal function. Thiazolidinediones should be avoided in patients with congestive heart failure.

For patients with T2DM, thiazide diuretics in the treatment of hypertension can reduce cardiovascular events, particularly heart failure *(Wing, 2003; ALLHAT Officers and Coordinators for the ALLHAT Collaborative Research Group, The, 2002)*.

Special Considerations

- Hepatitis B vaccine should be administered to unvaccinated adults with diabetes who are < 60 years of age. It may be administered to unvaccinated adults with diabetes who are ≥ 60 years of age.
- Influenza vaccine every year
- Pneumococcal vaccine – repeat the vaccination once after age 65 if the initial vaccination was given prior to 65. Consider repeating the immunization for those at risk of losing immunity after five years including nephrotic syndrome, chronic renal disease and other immunocompromised states.

For further information, see the ICSI Immunizations guideline.

Return to Algorithm *Return to Table of Contents*

The Aims and Measures section is intended to provide guideline users with a menu of measures for multiple purposes, which may include the following:

- population health improvement measures,
- quality improvement measures for delivery systems,
- measures from regulatory organizations such as Joint Commission,
- measures that are currently required for public reporting,
- measures that are part of Center for Medicare Services Physician Quality Reporting initiative,
- other measures from local and national organizations aimed at measuring population health and improvement of care delivery.

This section provides resources, strategies and measurement for use in closing the gap between current clinical practice and the recommendations set forth in the guideline.

The subdivisions of this section are:

- Aims and Measures
- Implementation Tools and Resources

Aims and Measures

Note: a multifactorial intervention targeting hyperglycemia and cardiovascular risk factors in individuals with diabetes is most effective. Both individual measures of diabetes care, as well as comprehensive measures of performance on broader sets of measures, are recommended. A randomized controlled trial has shown a 50% reduction in major cardiovascular events through a multifactorial intervention targeting hyperglycemia, hypertension, dyslipidemia, microalbuminuria, aspirin and ACE inhibitor use in individuals with microalbuminuria *(Gaede, 2003)*.

Goals for A1c, low-density lipoprotein and other diabetes measures should be personalized, and lower goals for A1c and low-density lipoprotein than those included here in the priority aims and measures may be clinically justified in some adults with T2DM. However, efforts to achieve A1c below 7% may increase risk of mortality, weight gain, hypoglycemia and other adverse effects in many patients with T2DM. Therefore, the aims and measures listed here are selected carefully in the interests of patient safety.

Outcome Measures

1. **Diabetes Optimal Care:** Increase the percentage of patients ages 18-75 years with T2DM mellitus who are optimally managed *(individual components and composite measure)*:

   Measures for accomplishing this aim:

   Percentage of patients with T2DM mellitus ages 18-75 years old who achieve any or all of the following:

   a. Percentage of patients with HbA1c $\leq$ 8%.

   b. Percentage of patients with blood pressure most recent measurement less than 140/90 mmHg.

   c. Percentage of patients who are tobacco free.

   d. Percentage of patients with established ASCVD and documented daily aspirin use (unless contraindicated).

   e. Percentage of patients ages 40-75 years with T2DM with untreated LDL > 70 mg/dL who are prescribed statin therapy.

   f. Percentage of patients with all of the above.

2. Management of T2DM in high-risk patients (Trial measure): Decrease the percentage of adult patients ages 18-75 with T2DM mellitus with poorly controlled glucose and cardiovascular risk factors *(individual components and composite measure):*

   Measures for accomplishing this aim:

   a. Percentage of patients with T2DM mellitus with HbAlc > 9%.

   b. Percentage of patients with T2DM mellitus with ASCVD and not on statin.

   c. Percentage of patients with T2DM and established ASCVD who do not have documentation of daily aspirin use (exclude patients for whom aspirin is contraindicated).

   d. Percentage of patients with T2DM mellitus with blood pressure measurement greater than 160/100 mmHg.

   e. Percentage of patients who are current smoker.

   f. Percentage of patients with any of the above (a-e).

   Note about trial measure: This measure is intended for internal quality improvement use to measure prevalence of patients with type 2 diabetes whose glucose and cardiovascular factors are poorly controlled.

Return to Table of Contents

3. Lifestyle modification and nutrition therapy – increase the percentage of patients ages 18-75 years newly diagnosed with T2DM who are advised about lifestyle modification and nutrition therapy.

   Measure for accomplishing this aim:

   a. Percentage of newly diagnosed patients who are advised about lifestyle modification and nutrition therapy within one year of diagnosis.

4. Medication Management – increase the percentage of patients with T2DM who are on appropriate medication management.

   Measures for accomplishing this aim:

   a. Percentage of patients ages 40-75 years with untreated LDL > 70 mg/dL who are prescribed statin therapy.

   b. Percentage of patients with established ASCVD with documented aspirin use (unless contraindicated).

Return to Table of Contents

Measurement Specifications

Measurement #1 a, b, c, d, e, f: Diabetes Optimal Care

Measurement Description

Percentage of patients with T2DM ages 18-75 years old who achieve any or all of the following:

a. Percentage of patients with HgbA1c < 8%.
b. Percentage of patients with blood pressure most recent measurement less than 140/90 mmHg.
c. Percentage of patients who are tobacco free.
d. Percentage of patients with established ASCVD with documented daily aspirin use (unless contra-indicated)
e. Percentage of patients ages 40-75 years and T2DM with untreated LDL > 70 mg/dL who are prescribed statin therapy.
f. Percentage of patients with all of the above.

Population Definition

Patients ages 18-75 years old with T2DM.

Data of Interest

$$\frac{\text{\# of patients who achieve any or all of the following control criteria}}{\text{\# of patients ages 18-75 years old with T2DM}}$$

Numerator and Denominator Definitions

Numerator:
a. Number of patients with HgbA1c < 8%.
b. Number patients with most recent blood pressure measurement less than 140/90 mmHg.
c. Number of patients who are tobacco free.
d. Number of patients with established ASCVD with documented daily aspirin use (unless contraindicated).
e. Number of patients ages 40-75 years with type 2 diabetes and untreated LDL > 70 mg/dL who are prescribed statin therapy.
f. Number of patients with all of the above.

Denominator:
a. Number of patients ages 18-75 years old who have T2DM.
b. Number of patients ages 18-75 years old who have T2DM.
c. Number of patients ages 18-75 years old who have T2DM.
d. Number of patients ages 18-75 years old who have T2DM and established ASCVD.
e. Number of patients ages 40-75 years old who have T2DM and untreated LDL > 70 mg/dL.
f. Number of patients ages 18-75 years old who have T2DM.

Return to Table of Contents

Method/Source of Data Collection

Data should be collected from EMR for all patient visits in the past 12 months.

Notes

This is an outcome measure, and improvement is noted as an increase in the rate. This measure should be calculated as both an individual components met and a composite (all components met at the same time) measure.

Goals for A1c, low-density lipoprotein and other diabetes measures should be personalized, and lower goals for A1c and low-density lipoprotein than those included here in the priority aims and measures may be clinically justified in some adults with T2DM. However, efforts to achieve A1c below 7% may increase risk of mortality, weight gain, hypoglycemia and other adverse effects in many patients with T2DM. Therefore, the aims and measures listed here are selected carefully in the interests of patient safety.

Return to Table of Contents

Measurement #2a

Management of T2DM in high-risk patients (Trial Measure)

Measurement Description

Percentage of patients with T2DM with HbAlc > 9%.

Population Definition

Patients ages 18-75 years old with T2DM.

Data of Interest

$$\frac{\text{\# of patients with HbA1c} > 9\%}{\text{\# of patients ages 18-75 years old with T2DM}}$$

Numerator and Denominator Definitions

Numerator: Number of patients with HbA1c > 9%.

Denominator: Number of patients ages 18-75 years old who have T2DM.

Method/Source of Data Collection

Data should be collected from EMR for all patient visits in the past 12 months.

Notes

This is a process measure, and improvement is noted as a decrease in the rate. The purpose of this measure is to decrease the percentage of adult patients ages 18-75 with T2DM with poorly controlled glucose and cardiovascular risk factors (clinical strategies that target high-risk populations may be more viable with limited resources).

Return to Table of Contents

Measurement #2b

Measurement Description

Percentage of patients with T2DM with ASCVD and not on a statin.

Population Definition

Patients ages 18-75 years old with T2DM.

Data of Interest

$$\frac{\text{\# of patients with ASCVD and not on a statin}}{\text{\# of patients ages 18-75 years old with T2DM}}$$

Numerator and Denominator Definitions

Numerator: Number of patients with ASCVD and not on a statin.

Denominator: Number of patients ages 18-75 years old who have T2DM.

Method/Source of Data Collection

Data should be collected from EMR for all patient visits in the past 12 months.

Notes

This is a process measure, and improvement is noted as a decrease in the rate. The purpose of this measure is to decrease the percentage of adult patients ages 18-75 with T2DM with poorly controlled glucose and cardiovascular risk factors (clinical strategies that target high-risk populations may be more viable with limited resources).

Return to Table of Contents

Measurement #2c

Measurement Description

Percentage of patients with T2DM and established ASCVD who do not have documentation of daily aspirin use (exclude patients for whom aspirin is contraindicated).

Population Definition

Patients ages 18-75 years old with T2DM.

Data of Interest

$$\frac{\text{\# of patients with established ASCVD and no documentation of daily aspirin use (unless contraindicated)}}{\text{\# of patients ages 18-75 years old with T2DM}}$$

Numerator and Denominator Definitions

Numerator: Number of patients with established ASCVD who do not have documentation of daily aspirin use (exclude patients for whom aspirin is contraindicated).

Denominator: Number of patients ages 18-75 years old who have T2DM.

Method/Source of Data Collection

Data should be collected from EMR for all patient visits in the past 12 months.

Notes

This is a process measure, and improvement is noted as a decrease in the rate. The purpose of this measure is to decrease the percentage of adult patients ages 18-75 with T2DM with poorly controlled glucose and cardiovascular risk factors (clinical strategies that target high-risk populations may be more viable with limited resources).

Return to Table of Contents

Measurement #2d

Measurement Description

Percentage of patients with T2DM with blood pressure greater than 160/100 mm/Hg.

Population Definition

Patients ages 18-75 years old with T2DM.

Data of Interest

$$\frac{\text{\# of patients with BP} > 160/100 \text{ mmHg}}{\text{\# of patients ages 18-75 years old with T2DM}}$$

Numerator and Denominator Definitions

Numerator: Number of patients with blood pressure measurement greater than 160/100 mmHg.

Denominator: Number of patients ages 18-75 years old who have T2DM.

Method/Source of Data Collection

Data should be collected from EMR for all patient visits in the past 12 months.

Notes

This is a process measure, and improvement is noted as a decrease in the rate. The purpose of this measure is to decrease the percentage of adult patients ages 18-75 with T2DM with poorly controlled glucose and cardiovascular risk factors (clinical strategies that target high-risk populations may be more viable with limited resources).

Return to Table of Contents

Measurement #2e

Measurement Description

Percentage of patients who currently smoke.

Population Definition

Patients ages 18-75 years old with T2DM.

Data of Interest

$$\frac{\text{\# of patients who currently smoke}}{\text{\# of patients ages 18-75 years old with T2DM}}$$

Numerator and Denominator Definitions

Numerator: Number of patients who currently smoke.

Denominator: Number of patients ages 18-75 years old who have T2DM.

Method/Source of Data Collection

Data should be collected from EMR for all patient visits in the past 12 months.

Notes

This is a process measure, and improvement is noted as a decrease in the rate. The purpose of this measure is to decrease the percentage of adult patients ages 18-75 with T2DM with poorly controlled glucose and cardiovascular risk factors (clinical strategies that target high-risk populations may be more viable with limited resources).

Return to Table of Contents

Measurement #2f

Measurement Description

Percentage of patients with T2DM with any of the following (2a-2e) (composite measure).

Population Definition

Patients ages 18-75 years old with T2DM.

Data of Interest

$$\frac{\text{\# of patients with any of the following (2a-2e)}}{\text{\# of patients ages 18-75 years old with T2DM}}$$

Numerator and Denominator Definitions

Numerator: Number of patients with any of the following (2a-2e).

Denominator: Number of patients ages 18-75 years old who have T2DM.

Method/Source of Data Collection

Data should be collected from EMR for all patient visits in the past 12 months.

Notes

This is a process measure, and improvement is noted as a decrease in the rate. The purpose of this measure is to decrease the percentage of adult patients ages 18-75 with T2DM with poorly controlled glucose and cardiovascular risk factors (clinical strategies that target high-risk populations may be more viable with limited resources).

Return to Table of Contents

Measurement #3a

Measurement Description

Percentage of newly diagnosed patients who are advised about lifestyle modification and nutrition therapy within one year of diagnosis.

Population Definition

Patients ages 18-75 years old with T2DM.

Data of Interest

$$\frac{\text{\# of patients who are advised about lifestyle modification and nutrition therapy within one year of diagnosis}}{\text{\# of patients ages 18-75 years old with T2DM}}$$

Numerator and Denominator Definitions

Numerator: Number of patients who are advised about lifestyle modification and nutrition therapy within one year of diagnosis.

Denominator: Number of patients ages 18-75 years old who have T2DM.

Method/Source of Data Collection

Data should be collected from EMR for all patient visits in the past 12 months.

Notes

This is a process measure, and improvement is noted as an increase in the rate.

Return to Table of Contents

Measurement #4a

Measurement Description

Percentage of patients ages 40-75 years with untreated LDL > 70 mg/dL who are prescribed statin therapy.

Population Definition

Patients ages 40-75 years old with T2DM and untreated LDL > 70 mg/dL.

Data of Interest

$$\frac{\text{\# of patients who are prescribed statin therapy}}{\text{\# of patients ages 40-75 years old with T2DM and untreated LDL > 70 mg/dL}}$$

Numerator and Denominator Definitions

Numerator: Number of patients who are prescribed statin therapy.

Denominator: Number of patients ages 40-75 years old who have T2DM and untreated LDL > 70 mg/dL.

Method/Source of Data Collection

Data should be collected from EMR for all patient visits in the past 12 months.

Notes

This is a process measure, and improvement is noted as an increase in the rate.

Return to Table of Contents

Measurement #4b

Measurement Description

Percentage of patients with established ASCVD with documented aspirin use (unless contraindicated).

Population Definition

Patients ages 18-75 years old with T2DM.

Data of Interest

$$\frac{\text{\# of patients with established ASCVD with documented aspirin use (unless contraindicated)}}{\text{\# of patients ages 18-75 years old with T2DM}}$$

Numerator and Denominator Definitions

Numerator: Number of patients with established ASCVD with documented aspirin use (unless contraindicated).

Denominator: Number of patients ages 18-75 years old who have T2DM.

Method/Source of Data Collection

Data should be collected from EMR for all patient visits in the past 12 months.

Notes

This is a process measure, and improvement is noted as an increase in the rate.

Return to Table of Contents

Implementation Tools and Resources

Criteria for Selecting Resources

The following tools and resources specific to the topic of the guideline were selected by the work group. Each item was reviewed thoroughly by at least one work group member. It is expected that users of these tools will establish the proper copyright prior to his/her use. The types of criteria the work group used are:

- The content supports the clinical and the implementation recommendations.
- Where possible, the content is supported by evidence-based research.
- The author, source and revision dates for the content is included where possible.
- The content is clear about potential biases and when appropriate conflicts of interests and/or disclaimers are noted where appropriate.

Return to Table of Contents

Implementation Tools and Resources Table

Author/Organization	Title/Description	Audience	Web Sites/Order Information
American Diabetes Association	**American Diabetes Association:** The mission of the association is to prevent and cure diabetes and to improve the lives of all people affected by diabetes. Wide variety of information on diabetes as well as recent publications; series of journals for both consumers and health professionals; community resources.	Patients and Families; Health Care Professionals	http://www.diabetes.org
Centers for Disease Control and Prevention	**Centers for Disease Control and Prevention:** Educational materials in Spanish as well as English, and low literacy public health and community campaigns for educating about diabetes and diabetes prevention.	Patients and Families	http://www.cdc.gov/diabetes
The Food and Nutrition Information Center	**The Food and Nutrition Information Center:** Sponsored by the United States Department of Agriculture (USDA), this site is user friendly and filled with current information on almost any nutrition topic.	Patients and Families; Health Care Professionals	http://www.nal.usda.gov/fnic/
HealthFinder	**HealthFinder:** A-Z health information organizations and health care topics.	Patients and Families	http://www.healthfinder.gov
International Diabetes Center	**International Diabetes Center:** International Diabetes Center at Park Nicollet has provided world diabetes care, education, publications and research programs that have met the needs of people with diabetes and their families since 1967.	Patients and Families	http://www.idcpublishing.com
Mayo Clinic	**Mayo Clinic: Disease and Condition Centers** Information and tools to help you manage a chronic disease or condition.	Patients and Families	http://www.mayoclinic.org/diseases-conditions/type-2-diabetes/home/ovc-20169860
Minnesota Community Measurement	The D5.org The D5 is a set of five treatment goals that, when achieved together, represent the gold standard for managing diabetes. Reaching all five goals greatly reduces a patient's risk for the cardiovascular problems associated with diabetes.	Patients and Families	http://www.mnhealthscores.org/diabetes-13184

Return to Table of Contents

Author/Organization	Title/Description	Audience	Web Sites/Order Information
National Institutes of Diabetes, Digestive and Kidney Diseases	**National Institute of Diabetes, Digestive and Kidney Diseases:** Data, statistics, information for health professionals, educational materials in Spanish as well as English, and low literacy. This Web site is a division of the National Institutes of Health.	Patients and Families; Health Care Professionals	http://www.niddk.nih.gov Also, links to NDEP, NKDEP, NIDDK
National Institutes of Health	**National Institutes of Health:** This user-friendly site helps you start a search for health information by directing you to some credible databases.	Health Care Professionals	http://www.nih.gov

Return to Table of Contents

The subdivisions of this section are:

- References
- Appendices

References

Links are provided for those new references added to this edition (author name is highlighted in blue).

Abraira C, Duckworth WC, Moritz T. Glycaemic separation and risk factor control in the veterans affairs diabetes trial: an interim report. *Diabetes Obes Metab* 2009;11:150-56. (High Quality Evidence)

ACCORD Study Group, The. Effects of combination lipid therapy in type 2 diabetes mellitus. *N Engl J Med* 2010a;362:1563-74. (High Quality Evidence)

ACCORD Study Group, The. Effects of intensive blood-pressure control in type 2 diabetes mellitus. *N Engl J Med* 2010b;362:1575-85. (High Quality Evidence)

ACCORD Study Group, The. Effects of intensive glucose lowering in type 2 diabetes. *N Engl J Med* 2008;358:2545-59. (High Quality Evidence)

Ackermann RT, Cheng YJ, Williamson DF, Gregg EW. Identifying adults at high risk for diabetes and cardiovascular disease using hemoglobin A1c national health and nutrition examination survey 2005-2006. *Am J Prev Med* 2011;40:11-17. (Low Quality Evidence)

ADVANCE Collaborative Group, The. Intensive blood glucose control and vascular outcomes in patients with type 2 diabetes. *N Engl J Med* 2008;358:2560-72. (High Quality Evidence)

AIM-HIGH Investigators, Boden WE, Probstfield JL, et al. Niacin in patients with low HDL cholesterol levels receiving intensive statin therapy. *N Engl J Med* 2011;365:2255-67. (Moderate Quality Evidence)

Ajala O, English P, Pinkney J. Systematic review and meta-analysis of different dietary approaches to the management of type 2 diabetes. *Am J Clin Nutr* 2013;97:505-16. (Systematic Review)

Al-Shareef MA, Sanneh AF, Aljoudi AS. Clinical effect of metformin in children and adolescents with type 2 diabetes mellitus: a systematic review and meta-analysis. *J Family Community Med* 2012;19:68-73. (Systematic Review)

Alkharouf J, Nalinikumari K, Corry D Tuck M. Long term effects of the angiotensive converting enzyme inhibitor captopril on metabolic control in non-insulin dependent diabetes mellitus. *Am J Hypertension* 1993;6:337-43. (Reference)

ALLHAT Officers and Coordinators for the ALLHAT Collaborative Research Group, The. Major outcomes in high-risk hypertensive patients randomized to angiotensin-converting enzyme inhibitor or calcium channel blocker vs diuretic: the antihypertensive and lipid-lowering treatment to prevent heart attack trial (ALLHAT). *JAMA* 2002;288:2981-97. (High Quality Evidence)

American College of Physicians, American Diabetes Association, and American Academy of Ophthalmology. Screening guidelines for diabetic retinopathy. *Ann Intern Med* 1992;116:683-85. (Guideline)

American Diabetes Association. Diagnosis and classification of diabetes mellitus. *Diabetes Care* 2010;33:S62-S69. (Reference)

American Diabetes Association. Hospital admission guidelines for diabetes. *Diabetes Care* 2004a;27:S103. (Reference)

American Diabetes Association. Nephropathy in diabetes. *Diabetes Care* 2004b;27:S79-S83. (Reference)

American Diabetes Association. Peripheral arterial disease in people with diabetes. *Diabetes Care* 2003;26:3333-41. (Guideline)

American Diabetes Association. Physical activity/exercise and diabetes. *Diabetes Care* 2004c;27:S58-S62. (Guideline)

Return to Table of Contents

American Diabetes Association. Preventive foot care in diabetes. *Diabetes Care* 2004d;27:S63-S64. (Reference)

American Diabetes Association. Self monitoring of blood glucose (consensus statement). *Diabetes Care* 1994;17:81-86. (Reference)

American Diabetes Association. Standards of medical care in diabetes – 2014. *Diabetes Care* 2014;37:S14-80. (Guideline)

American Diabetes Association. Statistics about diabetes. Available at: http://www.diabetes.org/diabetes-basics/statistics/. 2012. (Reference)

Anderson RJ, Freedland KE, Clouse RE, Lustman PJ. The prevalence of comorbid depression in adults with diabetes: a meta-analysis. *Diabetes Care* 2001;24:1069-78. (Meta-analysis)

Anderson RT, Narayan KM, Feeney P, et al. Effect of intensive glycemic lowering on health-related quality of life in type 2 diabetes: ACCORD trial. *Diabetes Care* 2011;34:807-12. (High Quality Evidence)

Andrews RC, Cooper AR, Montgomery AA, et al. Diet or diet plus physical activity versus usual care in patients with newly diagnosed type 2 diabetes: the early ACTID randomised controlled trial. *Lancet* 2011;378:129-39. (High Quality Evidence)

Antithrombotic Trialists' (ATT) Collaboration. Aspirin in the primary and secondary prevention of vascular disease: collaborative meta-analysis of individual participant data from randomised trials. *Lancet* 2009;373:1849-60. (Meta-analysis)

Appel LJ, Wright Jr JT, Greene T, et al. Intensive blood-pressure control in hypertensive chronic kidney disease. *N Engl J Med* 2010;363:918-29. (Reference)

Arguedas JA, Leiva V, Wright JM. Blood pressure targets for hypertension in people with diabetes mellitus. *Cochrane Database Syst Rev* 2013;10:CD008277. (Systematic Review)

Ash S, Reeves MM, Yeo S, et al. Effect of intensive dietetic interventions on weight and glycaemic control in overweight men with type II diabetes: a randomised trial. *Int J Obes Relat Metab Disord* 2003;27:797-802. (Moderate Quality Evidence)

Azadbakht L, Fard NR, Karimi M, et al. Effects of the dietary approaches to stop hypertension (DASH) eating plan on cardiovascular risks among type 2 diabetic patients: a randomized crossover clinical trial. *Diabetes Care* 2011;34:55-57. (High Quality Evidence)

Bangalore S, Kumar S, Lobach I, Messerli FH. Blood pressure targets in subjects with type 2 diabetes mellitus/impaired fasting glucose: observations from traditional and bayesian random-effects meta-analyses of randomized trials. *Circulation* 2011;123:2799-2810. (Meta-analysis)

Belch J, MacCuish A, Campbell I, et al. The prevention of progression of arterial disease and diabetes (POPADAD) trial: factorial randomised placebo controlled trial of aspirin and antioxidants in patients with diabetes and asymptomatic peripheral arterial disease. *BMJ* 2008;337:a1840. (High Quality Evidence)

Bennett PH, Haffner S, Kasiske BL, et al. Diabetic renal disease recommendations: screening and management of microalbuminuria in patients with diabetes mellitus: recommendations to the Scientific Advisory Board of the National Kidney Foundation from an ad hoc committee of the Council on Diabetes Mellitus of the National Kidney Foundation. *Am J Kidney Dis* 1995;25:107-35. (Reference)

Boulé NG, Haddad E, Kenny GP, et al. Effects of exercise on glycemic control and body mass in type 2 diabetes mellitus: a meta-analysis of controlled clinical trials. *JAMA* 2001;286:1218-27. (Meta-analysis)

Brehm BJ, Lattin BL, Summer SS, et al. One-year comparison of a high-monosaturated fat diet with a high-carbohydrate diet in type 2 diabetes. *Diabetes Care* 2009;32:215-20. (High Quality Evidence)

Return to Table of Contents

Brunerova L, Smejkalova V, Potockova J, Andel M. A comparison of the influence of a high-fat diet enriched in monounsaturated fatty acids and conventional diet on weight loss and metabolic parameters in obese non-diabetic and type 2 diabetic patients. *Diabet Med* 2007;24:533-40. (Moderate Quality Evidence)

Buchwald H, Estok R, Fahrbach K, et al. Weight and type 2 diabetes after bariatric surgery: systematic review and meta-analysis. *Am J Med* 2009;122:248-56. (Systematic Review)

Callaghan BC, Little AA, Feldman EL, Hughes RAC. Enhanced glucose control for preventing and treating diabetic neuropathy. *Cochrane Database Syst Rev* 2012;6:CD007543. (Systematic Review)

Campbell CL, Smyth S, Montalescot G, Steinhubl SR. Aspirin dose for the prevention of cardiovascular disease: a systematic review. *JAMA* 2007;297:2018-24. (Systematic Review)

Cannon CP, Braunwald E, McCabe CH, et al. Intensive versus moderate lipid lowering with statins after acute coronary syndromes. *N Engl J Med* 2004;350:1495-504. (High Quality Evidence)

Casagrande SS, Cowie CC, Fradkin JE. Utility of the U.S. preventive services task force criteria for diabetes screening. *Am J Prev Med* 2013;45:167-74. (Low Quality Evidence)

Castaneda C, Layne JE, Munoz-Orians L, et al. A randomized controlled trial of resistance exercise training to improve glycemic control in older adults with type 2 diabetes. *Diabetes Care* 2002;25:2335-41. (High Quality Evidence)

Cauza E, Hanusch-Enserer U, Strasser B, et al. The relative benefits of endurance and strength training on the metabolic factors and muscle function of people with type 2 diabetes mellitus. *Arch Phys Med Rehabil* 2005;86:1527-33. (Low Quality Evidence)

Centers for Disease Control, The. National diabetes fact sheet, 2011: fast facts on diabetes. 2011. (Reference)

Chiasson JL, Josse RG, Gomis R, et al. Acarbose for prevention of type 2 diabetes mellitus: the STOP-NIDDM randomised trial. *Lancet* 2002;359:2072-77. (Reference)

Cholesterol Treatment Trialists' (CTT) Collaboration. Efficacy and safety of more intensive lowering of LDL cholesterol: a meta-analysis of data from 170,000 participants in 26 randomised trials. *Lancet* 2010;376:1670-81. (Meta-analysis)

Cholesterol Treatment Trialists' (CTT) Collaborators. Efficacy of cholesterol-lowering therapy in 18,686 people with diabetes in 14 randomised trials of statins: a meta-analysis. *Lancet* 2008;371:117-25. (Meta-analysis)

Church TS, Blair SN, Cocreham S, et al. Effects of aerobic and resistance training on hemoglobin A1c levels in patients with type 2 diabetes: a randomized controlled trial. *JAMA* 2010;304:2253-62. (High Quality Evidence)

Clement S, Braithwaite SS, Magee MF, et al. Management of diabetes and hyperglycemia in hospitals. *Diabetes Care* 2004;27:553-91. (Reference)

Cohen RV, Pinheiro JC, Schiavon CA, et al. Effects of gastric bypass surgery in patients with type 2 diabetes and only mild obesity. *Diabetes Care* 2012;35:1420-28. (Low Quality Evidence)

Colosia AD, Palencia R, Khan S. Prevalence of hypertension and obesity in patients with type 2 diabetes mellitus in observational studies: a systematic literature review. *Diabetes Metab Syndr Obes* 2013;6:327-38. (Low Quality Evidence)

Cowie CC, Rust KF, Byrd-Holt DD, et al. Prevalence of diabetes and high risk for diabetes using A1c criteria in the U.S. population in 1988-2006. *Diabetes Care* 2010;33:562-68. (Low Quality Evidence)

Return to Table of Contents

Cryer PE, Davis SN, Shamoon H. Hypoglycemia in diabetes. *Diabetes Care* 2003;26:1902-12. (Reference)

Davidson PC, Hebblewhite HR, Bode BW, et al. Statistically based CSII parameters: correction factor (CF) (1700 rule), carbohydrate-insulin ratio (CIR) (2.8 rule), and basal-to-total ratio. *Diabetes Technol Ther* 2003;5:237. (Reference)

Davidson JK. Endogenous insulin, proinsulin, and C-peptide. *In* Clinical Diabetes Mellitus: A Problem Oriented Approach. Thieme Inc., New York. 1986;219-22. (Reference)

DeFronzo RA. Diabetic nephropathy: etiologic and therapeutic considerations. *Diabetes Reviews* 1995;3:510-64. (Reference)

Deakin TA, McShane CE, Cade JE, Williams RD. Group based training for self-management strategies in people with type 2 diabetes mellitus. *Cochrane Database Syst Rev* 2009;(2):CD003417. (Systematic Review)

de Groot M, Anderson R, Freedland KE, et al. Association of depression and diabetes complications: a meta-analysis. *Psychosom Med* 2001;63:619-30. (Reference)

Diabetes Prevention Program Research Group. 10-year follow-up of diabetes incidence and weight loss in the diabetes prevention program outcomes study. *Lancet* 2009;374:1677-86. (High Quality Evidence)

Diabetic Retinopathy Study Research Group, The. Photocoagulation treatment of proliferative diabetic retinopathy: clinical application of diabetic retinopathy, (DRS) findings, DRS report number 8. *Ophthalmology* 1981;88:583-600. (Reference)

Dorman RB, Serrot FJ, Miller CJ, et al. Case-matched outcomes in bariatric surgery for treatment of type 2 diabetes in the morbidly obese patient. *Ann Surg* 2012;255:287-93. (Low Quality Evidence)

Droumaguet C, Balkau B, Simon D, et al. Use of HbA1c in predicting progression to diabetes in French men and women: data from an epidemiological study on the insulin resistance syndrome (DESIR). *Diabetes Care* 2006;29:1619-25. (Low Quality Evidence)

Duckworth W, Abraira C, Moritz T, et al. Glucose control and vascular complications in veterans with type 2 diabetes. *N Engl J Med* 2009;360:129-39. (High Quality Evidence)

Duke SAS, Colagiuri S, Colagiuri R. Individual patient education for people with type 2 diabetes mellitus. *Cochrane Database Syst Rev* 2009;(1):CD005268. (Systematic Review)

Duncan I, Ahmed T, Li Q, et al. Assessing the value of the diabetes educator. *Diabetes Educ* 2011;37:638-57. (Cost-Effectiveness)

Dunstan DW, Daly RM, Owen N, et al. High-intensity resistance training improves glycemic control in older patients with type 2 diabetes. *Diabetes Care* 2002;25:1729-36. (High Quality Evidence)

Elhayany A, Lustman A, Abel R, et al. A low carbohydrate Mediterranean diet improves cardiovascular risk factors and diabetes control among overweight patients with type 2 diabetes mellitus: a 1-year prospective randomized intervention study. *Diabetes Obes Metab* 2010;12:204-09. (High Quality Evidence)

Eriksson J, Lindstrom J, Valle T, et al. Prevention of type II diabetes in subjects with impaired glucose tolerance: the diabetes prevention study (DPS) in Finland. *Diabetologia* 1999;42:793-801. (Reference)

Esposito K, Maiorino MI, Ciotola M, et al. Effects of a Mediterranean-style diet on the need for antihyperglycemic drug therapy in patients with newly diagnosed type 2 diabetes: a randomized trial. *Ann Intern Med* 2009;151:306-14. (Moderate Quality Evidence)

Return to Table of Contents

Estacio RO, Coll JR, Tran ZV, Schrier RW. Effect of intensive blood pressure control with valsartan on urinary albumin excretion in normotensive patients with type 2 diabetes. *Am J Hypertens* 2006;19:1241-48. (High Quality Evidence)

Estruch R, Ros E, Salas-Salvadó J, et al. Primary prevention of cardiovascular disease with a Mediterranean diet. *N Engl J Med* 2013;368:1279-90. (High Quality Evidence)

ETDRS Research Group. Early photocoagulation for diabetic retinopathy: ETDRS report number 9. *Ophthalmology* 1991;98:766-85. (Reference)

ETDRS Research Group. Photocoagulation for diabetic macular edema: ETDRS report number 1. *Arch Ophthalmol* 1985;103:1796-1806. (Reference)

Evert AB, Boucher JL, Cypress M, et al. Nutrition therapy recommendations for the management of adults with diabetes. *Diabetes Care* 2014;37:S120-43. (Guideline)

Fong DS, Aiello L, Gardner TW, et al. Retinopathy in diabetes. *Diabetes Care* 2004;27:S84-S87. (Reference)

Foster GD, Borradaile KE, Sanders MH, et al. A randomized study on the effect of weight loss on obstructive sleep apnea among obese patients with type 2 diabetes: the sleep AHEAD study. *Arch Intern Med* 2009a;169:1619-26. (Reference)

Foster GD, Sanders MH, Millman R, et al. Obstructive sleep apnea among obese patients with type 2 diabetes. *Diabetes Care* 2009b;32:1017-19. (Reference)

Furnary AP, Braithwaite SS. Effects of outcome on in-hospital transition from intravenous insulin infusion to subcutaneous therapy. *Am J Cardiol* 2006;98:557-64. (Reference)

Gaede P, Lund-Andersen H, Parving HH, Pedersen O. Effect of a multifactorial intervention on mortality in type 2 diabetes. *N Engl J Med* 2008;358:580-91. (High Quality Evidence)

Gaede P, Vedel P, Larsen N, et al. Multifactoral intervention and cardiovascular disease in patients with type 2 diabetes. *N Engl J Med* 2003;348:383-93. (High Quality Evidence)

Garber AJ, Moghissi ES, Bransome Jr ED, et al. American college of endocrinology position statement on inpatient diabetes and metabolic control. *Endocr Pract* 2004;10:77-82. (Reference)

Gary TL, Genkinger JM, Guallar E, et al. Meta-analysis of randomized educational and behavioral interventions in type 2 diabetes. *Diabetes Educ* 2003;29:488-501. (Meta-analysis)

Gerich JE. Novel insulins: expanding options in diabetes management. *Am J Med* 2002;113:339-40. (Reference)

Gibbs BB, Brancati FL, Chen H, et al. Effect of improved fitness beyond weight loss on cardiovascular risk factors in individuals with type 2 diabetes in the Look AHEAD study. *Eur J Prev Cardiol* 2014;21:608-17. (High Quality Evidence)

Gillett M, Dallosso HM, Dixon S, et al. Delivering the diabetes education and self management for ongoing and newly diagnosed (DESMOND) programme for people with newly diagnosed type 2 diabetes: cost effectiveness analysis. *BMJ* 2010;341:c4093. (Cost-Effectiveness Analysis)

Gregg EW, Cadwell BL, Cheng YJ, et al. Trends in the prevalence and ratio of diagnosed to undiagnosed diabetes according to obesity levels in the U.S. *Diabetes Care* 2004;27:2806-12. (Low Quality Evidence)

Guerci B, Sauvanet JP. Subcutaneous insulin: pharmacokinetic variability and glycemic variability. *Diabetes Metab* 2005;31:4S7-4S24. (Reference)

Return to Table of Contents

Guicciardi M, Lecis R, Anziani C, et al. Type 2 diabetes mellitus, physical activity, exercise self-efficacy, and body satisfaction: an application of the transtheoretical model in older adults. *Health Psychol and Behav Med* 2014;2:748-58. (Low Quality Evidence)

Hannah R, Levin N, London R, et al, eds. Renal disease in the managed care setting: selection and monitoring of outcome criteria. *Am J Kidney Dis* 1999;33(Suppl 1):S1-S23. (Reference)

Hansson L, Zanchetti A, Carruthers SG, et al. Effects of intensive blood-pressure lowering and low-dose aspirin in patients with hypertension: principal results of the hypertension optimal treatment (HOT) randomised trial. *Lancet* 1998;361:1755-62. (Moderate Quality Evidence)

He FJ, Li J, MacGregor GA. Effect of longer-term modest salt reduction on blood pressure. *Cochrane Database Syst Rev* 2013;4:CD004937. (Systematic Review)

Heart Outcomes Prevention Evaluation Study Investigators, The. Effects of an angiotensin-converting – enzyme inhibitor, ramipril, on cardiovascular events in high-risk patients. *N Engl J Med* 2002;342:145-53. (Reference)

Heart Outcomes Prevention Evaluation (HOPE) Study Investigators. Effects of ramipril on cardiovascular and microvascular outcomes in people with diabetes mellitus: results of the HOPE study and MICRO-HOPE substudy. *Lancet* 2000;355:253-59. (High Quality Evidence)

Heart Protection Study Collaborative Group. MRC/BHF heart protection study of cholesterol lowering with simvastatin in 20,536 high-risk individuals: a randomised placebo-controlled trial. *Lancet* 2002; 360:7-22. (High Quality Evidence)

Heart Protection Study Collaborative Group. MRC/BHF heart protection study of cholesterol-lowering with simvastatin in 5,963 people with diabetes: a randomised placebo-controlled trial. *Lancet* 2003;361:2005-16. (High Quality Evidence)

Hemmingsen B, Lund SS, Gluud C, et al. Targeting intensive glycaemic control versus targeting conventional glycaemic for type 2 diabetes mellitus. *Cochrane Database Syst Rev* 2013;11:CD008143. (Systematic Review)

Hirsch IB. Insulin in the hospital setting. New York, Adelphi, 2002;25. (Reference)

Hirsch IB, Paauw DS, Brunzell J, et al. Inpatient management of adults with diabetes. *Diabetes Care* 1995;18:870. (Reference)

Hoerger TJ, Zhang P, Segel JE, et al. Cost-effectiveness of bariatric surgery for severely obese adults with diabetes. *Diabetes Care* 2010;33:1933-39. (Low Quality Evidence)

Holman RR, Farmer AJ, Davies MJ, et al. Three-year efficacy of complex insulin regimens in type 2 diabetes. *N Engl J Med* 2009;361:1736-47. (Reference)

Holman RR, Paul SK, Bethel MA, et al. Long-term follow-up after tight control of blood pressure in type 2 diabetes. *N Engl J Med* 2008a;359:1565-76. (High Quality Evidence)

Holman RR, Paul SK, Bethel MA, et al. 10-year follow-up of intensive glucose control in type 2 diabetes. *N Engl J Med* 2008b;359:1577-89. (Low Quality Evidence)

Howard BV, Roman MJ, Devereux RB, et al. Effect of lower targets for blood pressure and LDL cholesterol on atherosclerosis in diabetes: the SANDS randomized trial. *JAMA* 2008;299:1678-89. (High Quality Evidence)

Ikramuddin S, Korner J, Lee WJ, et al. Roux-en-Y gastric bypass vs intensive medical management for the control of type 2 diabetes, hypertension, and hyperlipidemia: the diabetes surgery study randomized clinical trial. *JAMA* 2013;309:2240-49. (High Quality Evidence)

Return to Table of Contents

Institute of Medicine. Sodium intake in populations: assessment of evidence. May 2013. (Reference)

International Expert Committee, The. International expert committee report on the role of A1c assay in the diagnosis of diabetes. *Diabetes Care* 2009;32:1327-34. (Low Quality Evidence)

Ismail-Beigi F, Craven T, Banerji MA, et al. Effect of intensive treatment of hyperglycaemia on microvascular outcomes in type 2 diabetes: an analysis of the ACCORD randomised trial. *Lancet* 2010;376:419-30. (High Quality Evidence)

James PA, Oparil S, Carter BL, et al. 2014 evidence-based guideline for the management of high blood pressure in adults: report from the panel members appointed to the eighth joint national committee (JNC 8). *JAMA* 2014;311:507-20. (Reference)

John R, Fogelfeld L. Inpatient management of diabetes and hyperglycemia. *Dis Mon* 2004;50:438-79. (Reference)

Karter AJ, Ferrara A, Liu JY, et al. Ethnic disparities in diabetic complications in an insured population. *JAMA* 2002;287:2519-27. (Low Quality Evidence)

Kelley DE, Bray GA, Pi-Sunyer FX, et al. Clinical efficacy of orlistat therapy in overweight and obese patients with insulin-treated type 2 diabetes. *Diabetes Care* 2002;25:1033-41. (Reference)

Klein R, Klein BEK, Moss SE, et al. The Wisconsin epidemiologic study of diabetic retinopathy. III. Prevalence and risk of diabetic retinopathy when age at diagnosis is 30 or more years. *Arch Ophthalmol* 1984;102:527-32. (Reference)

Klein R, Moss SE, Klein BEK. New management concepts for timely diagnosis of diabetic retinopathy treatable by photocoagulation. *Diabetes Care* 1987;10:633-38. (Reference)

Kumar PR, Bhansali A, Ravikiran M, et al. Utility of glycated hemoglobin in diagnosing type 2 diabetes mellitus: a community-based study. *J Clin Endorcinol Metab* 2010;95:2832-35. (Moderate Quality Evidence)

Lakerveld J, Bot SD, Chinapaw MJ, et al. Motivational interviewing and problem solving treatment to reduce type 2 diabetes and cardiovascular disease risk in real life: a randomized controlled trial. *Int J Behav Nutr Phys Act* 2013;10:47. (Moderate Quality Evidence)

Lewis EJ, Hunsicker LG, Bain RP, et al. The effect of angiotensin-converting-enzyme inhibition on diabetic nephropathy. *N Engl J Med* 1993;329:1456-62. (Reference)

Lewis EJ, Hunsicker LG, Clarke WR, et al. Renoprotective effect of the angiotensin-receptor antagonist irbesartan in patients with nephropathy due to type 2 diabetes. *N Engl J Med* 2001;345:851-60. (Reference)

Lewis JB. Blood pressure control in chronic kidney disease: is less really more? *J Am Soc Nephrol* 2010;21:1086-92. (Reference)

Li C, Lai Y, Tseng C, et al. A population study on the association between leisure time physical activity and self-rated health among diabetics in Taiwan. *BMC Public Health* 2010;10:277. (Moderate Quality Evidence)

Li G, Zhang P, Wang J, et al. The long-term effect of lifestyle interventions to prevent diabetes in the China Da Qing diabetes prevention study: a 20-year follow-up study. *Lancet* 2008;371:1783-89. (Low Quality Evidence)

Lipska KJ, Bailey CJ, Inzucchi SE. Use of metformin in the setting of mild-to-moderate renal insufficiency. *Diabetes Care* 2011;34:1431-37. (Low Quality Evidence)

Return to Table of Contents

Look AHEAD Research Group, The. Cardiovascular effects of intensive lifestyle intervention in type 2 diabetes. *N Engl J Med* 2013;369:145-54. (High Quality Evidence)

Lustman PJ, Gavard JA. Psychosocial aspects of diabetes in adult populations. *In* Diabetes in America, 2nd Ed. 507-18. On-line reference, accessed July, 2001 at http://diabetes-in-america.s-3.com/. (Reference)

Macchia A, Laffaye N, Comignani PD, et al. Statins but not aspirin reduce thrombotic risk assessed by thrombin generation in diabetic patients without cardiovascular events: the RATIONAL trial. *PLoS* 2012;7:e32894. (High Quality Evidence)

Maciejewski ML, Livingston EH, Smith VA, et al. Survival among high-risk patients after bariatric surgery. *JAMA* 2011;305:2419-26. (Low Quality Evidence)

Makary MA, Clarke JM, Shore AD, et al. Medication utilization and annual health care costs in patients with type 2 diabetes mellitus before and after bariatric surgery. *Arch Surg* 2010;145:726-31. (Low Quality Evidence)

Mayfield JA, Reiber GE, Sanders LJ, et al. Preventive foot care in people with diabetes. *Diabetes Care* 1998;21:2161-77. (Reference)

Miller CK, Edwards L, Kissling G, Sanville L. Nutrition education improves metabolic outcomes among older adults with diabetes mellitus: results from a randomized controlled trial. *Prev Med* 2002;34:252-59. (Moderate Quality Evidence)

Mingrone G, Panunzi S, De Gaetano A, et al. Bariatric surgery versus conventional medical therapy for type 2 diabetes. *N Engl J Med* 2012;366:1577-85. (Moderate Quality Evidence)

Mogensen CE, Keane WF, Bennett PH, et al. Prevention of diabetic renal disease with special reference to microalbuminuria. *Lancet* 1996;346:1080-84. (Reference)

Morrish NJ, Stevens LK, Fuller JH, et al. Risk factors for macrovascular disease in diabetes mellitus: the London follow-up to the WHO multinational study of vascular disease in diabetics. *Diabetologia* 1991;34:590-94. (Low Quality Evidence)

National Institutes of Health. Morbidity and mortality of dialysis (consensus statement, online). 1993;11:1-33. (Reference)

Nelson RG, Knowler WC, Pettitt DJ, et al. Assessment of risk of overt nephropathy in diabetic patients from albumin excretion in untimed urine specimens. *Arch Intern Med* 1991;151:1761-65. (Reference)

NICE-SUGAR Study Investigators, The. Intensive versus conventional glucose control in critically ill patients. *N Engl J Med* 2009;360:1283-97. (High Quality Evidence)

Nichols-English G, Poirier S. Optimizing adherence to pharmaceutical care plans. *J Am Pharm Assoc* 2000;40:475-83. (Reference)

Nield L, Moore HJ, Hooper L, et al. Dietary advice for treatment of type 2 diabetes mellitus in adults. *Cochrane Database Syst Rev* 2007;(3):CD004097. (Systematic Review)

Nilsson PM. Target blood pressure in diabetes patients with hypertension – what is the accumulated evidence in 2011? *J Zhejiang Univ Sci B* 2011;12:611-23. (Systematic Review)

Norris SL, Zhang X, Avenell A, et al. Long-term non-pharmacological weight loss interventions for adults with type 2 diabetes mellitus. *Cochrane Database Syst Rev* 2005;(2):CD004095. (Systematic Review)

O'Connor PJ. Commentary – improving diabetes care by combating clinical inertia. *Health Serv Res* 2005a;40:1854-61. (Low Quality Evidence)

O'Connor PJ. Overcome clinical inertia to control systolic blood pressure. *Arch Intern Med* 2003;163:2677-78. (Low Quality Evidence)

Return to Table of Contents

O'Connor PJ, Crabtree BF, Yanoshik MK. Differences between diabetic patients who do and do not respond to a diabetes care intervention: a qualitative analysis. *Fam Med* 1997;29:424-28. (Low Quality Evidence)

O'Connor PJ, Sperl-Hillen JM, Johnson PE, et al. Advances in patient safety: clinical inertia and outpatient medical errors. *AHRQ* 2005b;2:293-308. (Low Quality Evidence)

Ogawa H, Nakayama M, Morimoto T, et al. Low-dose aspirin for primary prevention of atherosclerotic events in patients with type 2 diabetes: a randomized controlled trial. *JAMA* 2008;300:2134-41. (High Quality Evidence)

Olson DE, Rhee MK, Herrick K, et al. Screening for diabetes and pre-diabetes with proposed A1c-based diagnostic criteria. *Diabetes Care* 2010;33:2184-89. (Low Quality Evidence)

Orozco LJ, Buchleitner AM, Gimenez-Perez G, et al. Exercise or exercise and diet for preventing type 2 diabetes mellitus. *Cochrane Database Syst Rev* 2008;(3):CD003054. (Systematic Review)

Pal K, Eastwood SV, Michie S, et al. Computer-based diabetes self-management interventions for adults with type 2 diabetes mellitus. *Cochrane Database Syst Rev* 2013;3:CD008776. (Systematic Review)

Pettitt DJ, Opsina P, Kolaczynski JW, Jovanovic L. Comparison of an insulin analog, insulin aspart, and regular human insulin with no insulin in gestational diabetes mellitus. *Diabetes Care* 2003;26:183-86. (Reference)

Pignone M, Eamshaw S, Tice J, Pletcher MJ. Aspirin, statins, or both drugs for the primary prevention of coronary heart disease events in men: a cost-utility analysis. *Ann Intern Med* 2006;144:326-36 (Low Quality Evidence)

Polonsky WH, Fisher L, Schikman CH, et al. A structured self-monitoring of blood glucose approach in type 2 diabetes encourages more frequent, intensive, and effective physician interventions: results from the STeP study. *Diabetes Technol Ther* 2011;13:797-802. (Reference)

Polonsky KS, Given BD, Hirsch ET, et. al. Quantitative study of insulin secretion and clearance in normal and obese subjects. *J Clin Invest* 1988a;81:435-41. (Reference)

Polonsky KS, Given BD, Van Cauter E. Twenty-four-hour profiles and pulsatile patterns of insulin secretion in normal and obese subjects. *J Clin Invest* 1988b;81:442-48. (Reference)

Radhakrishnan K. The efficacy of tailored interventions for self-management outcomes of type 2 diabetes, hypertension or heart disease: a systematic review. *J Adv Nurs* 2011;68:496-510. (Systematic Review)

Rahman M, Simmons RK, Hennings SH, et al. Effect of screening for type 2 diabetes on population-level self-rated health outcomes and measures of cardiovascular risk: 13-year follow-up of the Ely cohort. *Diabet Med* 2012;29:886-92. (Low Quality Evidence)

Rave K, Klein O, Frick AD, Becker RHA. Advantage of premeal-injected insulin glulisine compared with regular human insulin in subjects with type 1 diabetes. *Diabetes Care* 2006;29:1812-17. (Reference)

Ravid M, Savin H, Jutrin I, et al. Long-term stabilizing effect of angiotensin-converting enzyme inhibition on plasma creatinine and on proteinuria in normotensive type II diabetic patients. *Ann Int Med* 1993;118:577-81. (Moderate Quality Evidence)

Ray KK, Seshasai SR, Wijesuriya S, et al. Effect of intensive control of glucose on cardiovascular outcomes and death in patients with diabetes mellitus: a meta-analysis of randomised controlled trials. *Lancet* 2009;373:1765-72. (Meta-analysis)

Reynolds NA, Wagstaff AJ. Insulin aspart: a review of its use in the management of type 1 or type 2 diabetes mellitus. *Drugs* 2004;64:1957-74. (Reference)

Return to Table of Contents

Robbins JM, Thatcher GE, Webb DA, Valdmanis VG. Nutritionist visits, diabetes classes, and hospitalization rates and charges: the urban diabetes study. *Diabetes Care* 2008;31:655-60. (Low Quality Evidence)

Rosiak M, Postula M, Kaplon-Cieslicka A, et al. The effect of doubling the dose of acetylsalicylic acid (ASA) on platelet function parameters in patients with type 2 diabetes and platelet hyperreactivity during treatment with 75 mg of ASA: a subanalysis of the AVOCADO study. *Kardiol Pol* 2013;71:552-57. (Moderate Quality Evidence) (Moderate Quality Evidence)

Saenz A, Fernandez-Esteban I, Mataix A, et al. Metformin monotherapy for type 2 diabetes mellitus. *Cochrane Database Syst Rev* 2005;(3):CD002966. (Systematic Review)

Salpeter SR, Greyber E, Pasternak GA, Salpeter EE. Risk of fatal and nonfatal lactic acidosis with metformin use in type 2 diabetes mellitus. *Cochrane Database Syst Rev* 2010;(4):CD002967. (Systematic Review)

Schauer PR, Kashyap SR, Wolski K, et al. Bariatric surgery versus intensive medical therapy in obese patients with diabetes. *N Engl J Med* 2012;366:1567-76. (High Quality Evidence)

Selvin E, Bolen S, Yeh HC, et al. Cardiovascular outcomes in trials of oral diabetes medications: a systematic review. *Arch Intern Med* 2008;168:2070-80. (High Quality Evidence)

Sigal RJ, Kenny GP, Wasserman DH, Castaneda-Sceppa C. Physical activity/exercise and type 2 diabetes. *Diabetes Care* 2004;27:2518-39. (Low Quality Evidence)

Siminerio LM. Implementing diabetes self-management training programs: breaking through the barriers in primary care. *Endocr Pract* 2006a;12:124-30. (Low Quality Evidence)

Siminerio LM, Piatt G, Zgibor JC. Implementing the chronic care model for improvements in diabetes care and education in a rural primary care practice. *Diabetes Educ* 2005;31:225-34. (Low Quality Evidence)

Siminerio LM, Piatt GA, Emerson S, et al. Deploying the chronic care model to implement and sustain diabetes self-management training programs. *Diabetes Educ* 2006b;32:253-60. (Low Quality Evidence)

Simmons RK, Echouffo-Tcheugui JB, Sharp SJ, et al. Screening for type 2 diabetes and population mortality over 10 years (ADDITION-Cambridge): a cluster-randomized controlled trial. *Lancet* 2012;380:1741-48. (High Quality Evidence)

Soejima H, Ogawa H, Morimoto T, et al. Aspirin reduces cerebrovascular events in type 2 diabetic patients with poorly controlled blood pressure. *Circ J* 2012;76:1526-32. (Low Quality Evidence)

Sperl-Hillen JM, O'Connor JP. Factors driving diabetes care improvement in a large medical group: ten years of progress. *Am J Manag Care* 2005;11:S177-S185. (Low Quality Evidence)

Steinsbekk A, Rygg LO, Lisulo M, et al. Group based diabetes self-management education compared to routine treatment for people with type 2 diabetes mellitus: a systematic review with meta-analysis. *BMC Health Serv Res* 2012;12:213. (Systematic Review)

Stone NJ, Robinson JG, Lichtenstein AH, et al. 2013 ACC/AHA guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults: a report of the American college of cardiology/American heart association task force on practice guidelines. *Circulation* 2014;129:S1-S45. (Reference)

Suckling RJ, He FJ, MacGregor GA. Altered dietary salt intake for preventing and treating diabetic kidney disease. *Cochrane Database Syst Rev* 2010(12):CD006763. (Systematic Review)

Taylor F, Huffman MD, Macedo AF, et al. Statins for the primary prevention of cardiovascular disease. *Cochrane Database Syst Rev* 2013;1:CD004816. (Systematic Review)

Thomas D, Elliott EJ. Low glycaemic index, or low glycaemic load, diets for diabetes mellitus. *Cochrane Database Syst Rev* 2009;(1):CD006296. (Systematic Review)

Thomas DE, Elliott EJ, Naughton GA. Exercise for type 2 diabetes mellitus. *Cochrane Database Syst Rev* 2006;(3):CD002968. (Systematic Review)

Thorpe CT, Fahey LE, Johnson H, et al. Facilitating healthy coping in patients with diabetes: a systematic review. *Diabetes Educ* 2013;39:33-52. (Systematic Review)

Tricco AC, Ivers NM, Grimshaw JM, et al. Effectiveness of quality improvement strategies on the management of diabetes: a systematic review and meta-analysis. *Lancet* 2012;379:2252-61. (Systematic Review)

Tshiananga JK, Kocher S, Weber C, et al. The effect of nurse-led diabetes self-management education on glycosylated hemoglobin and cardiovascular risk factors: a meta-analysis. *Diabetes Educ* 2012;38:108-23. (Meta-analysis)

Tuomilehto J, Lindström J, Eriksson JG, et al. Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. *N Engl J Med* 2001;344:1343-50. (High Quality Evidence)

Turnbull FM, Abraira C, Anderson RJ, et al. Intensive glucose control and macrovascular outcomes in type 2 diabetes. *Diabetologia* 2009;52:2288-98. (Meta-analysis)

UK Prospective Diabetes Study (UKPDS) Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). *Lancet* 1998a;352:837-53. (High Quality Evidence)

UK Prospective Diabetes Study (UKPDS) Group. Tight blood pressure control and risk of macrovascular and microvascular complications in type 2 diabetes: UKPDS 38. *BMJ* 1998b;317:703-13. (High Quality Evidence)

Umpierrez GE, Isaacs SD, Bazargan N, et al. Hyperglycemia: an independent marker of in-hospital mortality in patients with undiagnosed diabetes. *J Clin Endocrinol Metab* 2002;87:978-82. (Reference)

Umpierrez GE, Smiley D, Zisman A, et al. Randomized study of basal-bolus insulin therapy in the inpatient management of patients with type 2 diabetes (RABBIT 2 trial). *Diabetes Care* 2007;30:2181-86. (Reference)

U.S. Preventive Services Task Force. Screening for type 2 diabetes mellitus. Available at: http://www.uspreventiveservicestaskforce.org/Page/Topic/recommendation-summary/diabetes-mellitus-type-2-in-adults-screening?ds=1&s=. 2008. (Systematic Review)

Vague P, Selam JL, Skeie S, et al. Insulin Detemir is associated with more predictable glycemic control and reduced risk of hypoglycemia than NPH insulin in patients with type 1 diabetes on a basal-bolus regimen with premeal insulin aspart. *Diabetes Care* 2003;26:590-96. (Reference)

Valentine N, Dan de Laar FA, van Driel ML. Adenosine-diphosphate (ADP) receptor antagonists for the prevention of cardiovascular disease in type 2 diabetes mellitus. *Cochrane Database Syst Rev* 2012;11:CD005449. (Systematic Review)

Van den Berghe G, Wouters P, Weekers F, et al. Intensive insulin therapy in critically ill patients. *N Engl J Med* 2001;345:1359-67. (Reference)

Viberti G. Outcome variables in the assessment of progression of diabetic kidney disease. *Kidney Intl* 1994;45:S121-24. (Reference)

Wang F, Carabino JM, Vergara CM. Insulin glargine: a systematic review of a long-acting insulin analogue. *Clin Ther* 2003;25:1541-77. (Reference)

Waugh NR, Shyangdan D, Taylor-Phillips S, et al. Screening for type 2 diabetes: a short report for the national screening committee. *Health Technol Assess* 2013;17:1-90. (Systematic Review)

Return to Table of Contents

Weinger K, Beverly EA, Lee Y, et al. The effect of a structured behavioral intervention on poorly controlled diabetes: a randomized controlled trial. *Arch Intern Med* 2011;171:1990-99. (Moderate Quality Evidence)

Wheeler ML, Dunbar SA, Jaacks LM, et al. Macronutrients, food groups, and eating patterns in the management of diabetes: a systematic review of the literature, 2010. *Diabetes Care* 2012;35:434-45. (Systematic Review)

Wiebe N, Padwal R, Field C, et al. A systematic review on the effect of sweeteners on glycemic response and clinically relevant outcomes. *BMC Medicine* 2011;9:123. (Systematic Review)

Wing LMH, Reid CM, Ryan P, et al. A comparison of outcomes with angiotensin-converting-enzyme inhibitors and diuretics for hypertension in the elderly. *N Engl J Med* 2003;348:583-92. (Moderate Quality Evidence)

Yki-Järvinen H, Dressler A, Ziemen M, The HOE 901/3002 Study Group. Less nocturnal hypoglycemia and better post-dinner glucose control with bedtime insulin Glargine compared with bedtime NPH insulin during insulin combination therapy in type 2 diabetes. *Diabetes Care* 2000;23:1130-36. (Reference)

Zoungas S, de Galan BE, Ninomiya T, et al. Combined effects of routine blood pressure lowering and intensive glucose control on macrovascular and microvascular outcomes in patients with type 2 diabetes: new results from the ADVANCE trial. *Diabetes Care* 2009;32:2068-74. (High Quality Evidence)

Return to Table of Contents

Appendix A – Order Set: Subcutaneous Insulin Management

This order set will cover the orders of subcutaneous insulin management. This order will not include admission orders or other specific orders for the patient's condition outside of insulin management. The target population is hospitalized adults who require subcutaneous insulin for their clinical care and does not include orders for critical care patients.

Patient Information *(Two are required.)*

Last Name: _____

First Name: _____

Date of Birth: ___/___/_____

Patient's Age: _____

ID #: _____

Legend:
- ☐ Open boxes are orders that a clinician will need to order by checking the box.
- ☑ Pre-checked boxes are those orders with strong supporting evidence and/or regulatory requirements that require documentation if not done.

Admitting/Attending Information

Admit unit: _____

Attending physician: _____

How to contact: _____

Diagnosis

Admitting diagnosis: _____

Secondary diagnosis: _____

Nursing

Blood glucose level goals
- ☐ Preprandial = 90-140 mg/dL
- ☐ Postprandial less than 180 mg/dL
- ☐ Other: _____ mg/dL

Blood glucose monitoring frequency (Select all that apply.)
- ☐ _____ minutes before meals
- ☐ Bedtime
- ☐ 0200-0300 (all times listed in 24-hour time)
- ☐ Nothing by mouth, total parenteral nutrition (TPN), or continuous enteral feeding: monitor based on insulin dosing schedule every:
  - ☐ 4 hours
  - ☐ 6 hours

- ☐ Other _____

Return to Table of Contents

Dosing schedule

☐ Basal insulin (check one)

☐ Glargine insulin _____ units subcutaneous at _____ hours (24-hour time)

☐ Glargine insulin twice daily:
Units subcutaneous at hours (24-hour time) AND
Units subcutaneous at hours (24-hour time)

☐ Detemir insulin _____ units subcutaneous daily at _____ hours (24-hour time)

☐ Detemir insulin twice daily:
_____ units subcutaneous at _____ hours (24-hour time) **AND**
_____ units subcutaneous at _____ hours (24-hour time)

☐ NPH insulin _____ units subcutaneous each a.m.
_____ units subcutaneous each evening meal
_____ units subcutaneous at bedtime

☐ Other _____ units subcutaneous every _____ hours (24-hour time)

☐ Prandial insulin (***Do not give if patient is NPO or if preprandial glucose is less than 60 mg/dL.***)

☐ Lispro insulin _____ units subcutaneous at _____ hours (24-hour time)

☐ Aspart insulin _____ units subcutaneous at _____ hours (24-hour time)

☐ Glulisine insulin _____ units subcutaneous at _____ hours (24-hour time)

☐ Other _____

Breakfast	Lunch	Supper
_____ units/meal OR _____ units: CHO unit* OR _____ units per ____ grams of carbohydrates	_____ units/meal OR _____ units: CHO unit* OR _____ units per ____ grams of carbohydrates	_____ units/meal OR _____ units: CHO unit* OR _____ units per ____ grams of carbohydrates

* Note: 1 CHO (carbohydrate) unit equals 15 grams of carbohydrate.

☐ Correction (***in addition to prandial dose above***)

Glucose level	☐Low	☐Med	☐High	☐Individual
Less than 120 mg/dL	0 units	0 units	0 units	0 units
120-149 mg/dL	0 units	1 units	2 units	___ units
150-199 mg/dL	1 units	2 units	3 units	___ units
200-249 mg/dL	2 units	3 units	4 units	___ units
250-299 mg/dL	3 units	5 units	7 units	___ units
300-349 mg/dL	4 units	7 units	10 units	___ units
350 or greater	5 units	8 units	12 units	___ units

☐ Bedtime (If blood glucose is less than 200 mg/dL, do not give correction dose; if greater than 200 mg/dL, give 50% of correction dose. *Patients receiving corticosteroids may be at greater risk for nocturnal hypoglycemia, so caution is required in giving insulin correction dose at bedtime for these patients.)*

Return to Table of Contents

Corrective dose insulin for patients who have nothing by mouth, on total parenteral nutrition or on continuous enteral feeding *(to be given in addition to basal insulin)*

Check one:

☐ Regular insulin – check blood glucose every 6 hours and administer insulin dose based on correction schedule
☐ Lispro insulin – check blood glucose every 4 hours and administer insulin dose based on correction schedule
☐ Aspart insulin – check blood glucose every 4 hours and administer insulin dose based on correction schedule
☐ Glulisine insulin – check blood glucose every 4 hours and administer insulin dose based on correction schedule
☐ Other _____ – check blood glucose every ____ hours and administer insulin dose based on correction schedule
☐ Other diabetic medications: _____
_____

Transition from intravenous insulin to subcutaneous insulin:

☐ Administer initial dose of subcutaneous basal insulin two hours prior to discontinuation of intravenous insulin infusion. Record blood glucose prior to administering basal insulin dose.
☐ Initial dose of subcutaneous basal insulin
  ☐ Glargine insulin _____ units at _____hours (24-hour time)
  ☐ Detemir insulin _____ units at _____hours (24-hour time)
  ☐ NPH insulin _____ units at _____hours (24-hour time)
☐ Discontinue intravenous insulin infusion at _____hours (24-hour time). Record blood glucose at time intravenous insulin infusion is discontinued.
☐ Subsequent basal, prandial and correction insulin doses in accordance with orders above

Diet

☐ Consistent carbohydrate (CHO) meal plan
☐ Bedtime snack
☐ Other _____

Laboratory/Diagnostic Testing

☐ A1c (if A1c from past 2-3 months or unknown)
☐ Electrolytes, blood urea nitrogen (BUN), creatinine
☐ Alanine amino transaminase (ALT)
☐ Asparate transaminase (AST)
☐ Hypoglycemia protocol

Discharge/Transition Planning – Patient Education

☐ Diabetes clinical nurse specialist consult *(reason for consult):*_____
☐ Diabetes education consult inpatient survival skills *(reason for consult):* _____
☐ Diabetes education consult outpatient *(reason for consult):*_____
☐ Nutrition services consult *(reason for consult):*_____

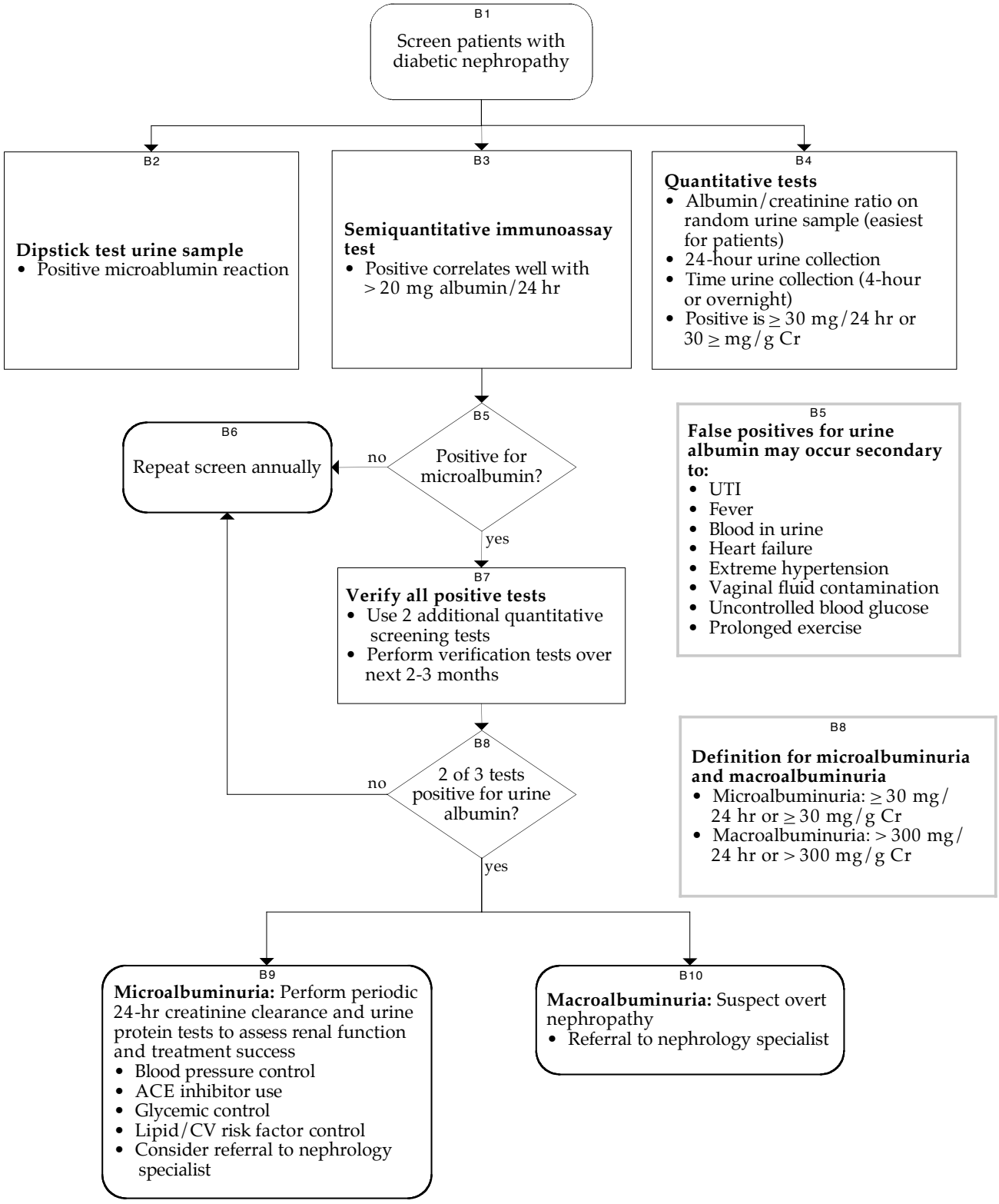
Authorized Prescriber Signature: _____

Printed Name:_____

Date & Time of Orders: ____/____/____ _____:_____ hours

Return to Table of Contents

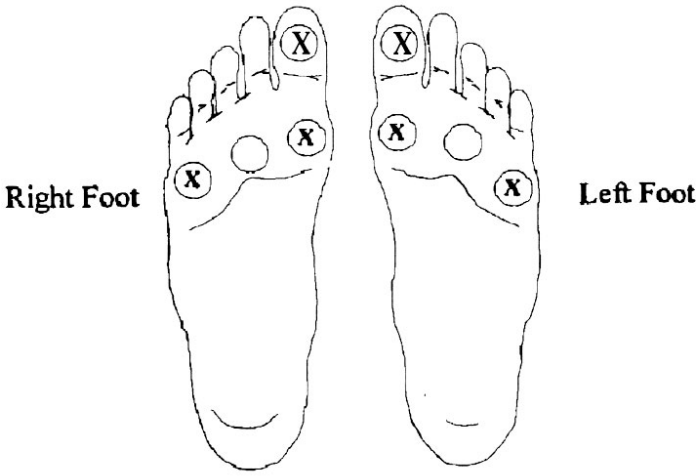
Appendix B – Treatment of Diabetic Nephropathy



Return to Table of Contents
BACK

Appendix C – Using a Semmes-Weinstein Monofilament to Screen the Diabetic Foot for Peripheral Sensory Neuropathy

1) Show the monofilament to the patient and touch it to his/her arm to demonstrate that it does not hurt.
2) Use the Semmes-Weinstein 5.07/10 gram monofilament to test sensation at the indicated sites on each foot*. Avoid applying the monofilament to calluses, ulcers, or scars. A foot exam is not reimbursed my Medicare without monofilament sensation testing in four locations.



3) Hold the monofilament perpendicular to the skin and touch it to the skin using a smooth motion with sufficient force to cause the filament to bend. The test should take about 1-1/2 seconds at each site.

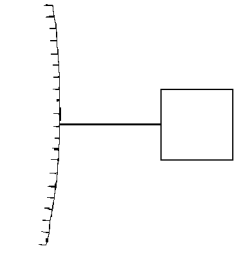


Figure 1

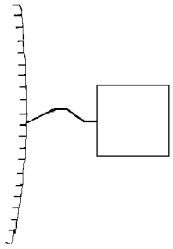


Figure 2

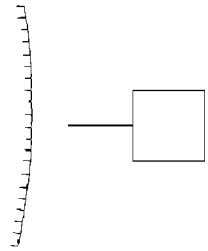


Figure 3

4) Ask the patient to respond "yes" when the filament is felt. If the patient does not respond when you touch a given site on the foot, continue on to another site in a random sequence. When you have completed testing all sites on the foot, retest any site(s) where the patient did not feel the filament.
5) The results of the monofilament testing should be documented in the medical record**. **PATIENTS WHO CANNOT FEEL THE MONOFILAMENT AT ANY SITE SHOULD BE CONSIDERED TO BE INSENSATE AND AT INCREASED RISK FOR ULCERATION AND AMPUTATION.**

*Testing at the first and fifth metatarsal heads is sufficient. This combination of sites has been shown to detect the insensate foot with reasonable sensitivity (80%) and specificity (86%). Testing the great toes may be of added benefit.
**Chart documentation is required for the American Diabetes Association – Clinician Recognition Program. An annual diabetic foot examination is also one of the eight diabetes quality improvement project (DQIP) measures adopted by the National Committee for Quality Assurance (NCQA) and the Health Care Financing Administration.

Return to Table of Contents BACK

Appendix D – Using a Tuning Fork to Screen the Diabetic Foot for Peripheral Neuropathy

Peripheral neuropathy can be assessed by vibration perception threshold using a 128-cps tuning fork. The assessment is abnormal if the patient cannot sense the vibration of the tuning fork when it is pressed against the foot.

1. To initiate tuning fork vibration, tap the fork to the ball of your hand.
2. Apply the tuning fork on the wrist of the patient. This is a preliminary step to ensure the patient knows what sensation they should expect.
3. Next, apply the tuning fork, perpendicularly with constant pressure, on a bony part on the dorsal side of the distal phalanx of the first toe. The patient's eyes should be closed during testing.

4. Ask the patient if he/she feels the vibration. If he/she responds "yes," ask him/her to inform you when the vibration stops. An abnormal result occurs when the patient informs you that the vibration stops before you can feel the vibration end.
5. Perform the test three times.
6. The test is positive if the patient correctly answers at least two out of three applications, and negative ("at risk for ulceration") with two out of three incorrect answers.

Return to Table of Contents BACK

Appendix E – Sample of Hypoglycemia Protocol

Sample Hypoglycemia Protocol

For glucose less than 70 mg/dL, patient is not alert/unresponsive	Give 1 amp of D50 IV If no IV access, administer 1 mg glucagon IM May repeat glucagon x1 Call covering physician
For glucose 60-70 mg/dL, but patient is NOT symptomatic	No treatment; Recheck glucose in 30 min. if more than 30 min. until next meal
For glucose 60-70 mg/dL, patient is symptomatic but alert	Give 15 gm of carbohydrates. Choose one of the following: • 4 oz. of any juice by mouth • 15 gm of glucose gel • 3 glucose tablets
For glucose 45-59 mg/dL, patient is alert	Give 20 gm of carbohydrates. Choose one of the following: • 6 oz. of any juice by mouth • 20 gm of glucose gel • 4 glucose tablets *If nothing by mouth, give 1/2 amp of D50 IV*
For glucose less than 45 mg/dL, patient is alert	Give 30 gm of carbohydrates. Choose one of the following: • 8 oz. of any juice by mouth • 30 gm of glucose gel • 6 glucose tablets *If nothing by mouth, give 1/2 amp of D50 IV*

Adapted from Hennepin County Medical Center, Minneapolis, MN

Recheck blood glucose every 15 minutes and repeat until blood glucose is greater than 60 mg/dL without symptoms, or blood glucose is greater than 70 mg/dL if symptoms persist. Once the patient is stable, recheck glucose after 60 minutes.

Return to Table of Contents

ICSI has long had a policy of transparency in declaring potential conflicting and competing interests of all individuals who participate in the development, revision and approval of ICSI guidelines and protocols.

In 2010, the ICSI Conflict of Interest Review Committee was established by the Board of Directors to review all disclosures and make recommendations to the board when steps should be taken to mitigate potential conflicts of interest, including recommendations regarding removal of work group members. This committee has adopted the Institute of Medicine Conflict of Interest standards as outlined in the report, Clinical Practice Guidelines We Can Trust (2011).

Where there are work group members with identified potential conflicts, these are disclosed and discussed at the initial work group meeting. These members are expected to recuse themselves from related discussions or authorship of related recommendations, as directed by the Conflict of Interest committee or requested by the work group.

The complete ICSI Policy regarding Conflicts of Interest is available at http://bit.ly/ICSICOI.

Funding Source

The Institute for Clinical Systems Improvement provided the funding for this guideline revision. ICSI is a not-for-profit, quality improvement organization based in Bloomington, Minnesota. ICSI's work is funded by the annual dues of the member medical groups and five sponsoring health plans in Minnesota and Wisconsin. Individuals on the work group are not paid by ICSI but are supported by his/her medical group for this work.

ICSI facilitates and coordinates the guideline development and revision process. ICSI, member medical groups and sponsoring health plans review and provide feedback but do not have editorial control over the work group. All recommendations are based on the work group's independent evaluation of the evidence.

Return to Table of Contents

Disclosure of Potential Conflicts of Interest

David Caccamo, MD (Work Group Member)
Family Physician, Family Medicine, HealthPartners Medical Group and Regions Hospital
National, Regional, Local Committee Affiliations: None
Guideline Related Activities: None
Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

Penny Louise Flavin, DNP, RN, CNP (Work Group Member)
Family Practice, Olmsted Medical Center
National, Regional, Local Committee Affiliations: None
Guideline Related Activities: None
Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

Ryan Michels, PharmD, BCPS (Work Group Member)
Clinical Pharmacist, HealthPartners Medical Group and Regions Hospital
National, Regional, Local Committee Affiliations: None
Guideline Related Activities: None
Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

Patrick O'Connor, MD (Work Group Member)
Family Medicine/Geriatrics, Senior Clinical Investigator, HealthPartners Medical Group and Regions Hospital
National, Regional, Local Committee Affiliations: None
Guideline Related Activities: Lipid Management in Adults, Diagnosis and Treatment of Hypertension
Research Grants: Received institutional payment for research grants from NIH (National Institute of Health), AHRQ (Agency for Healthcare Research and Quality, NIMH (National Institute of Mental Health), NHLBI (National Heart, Lung and Blood Institute) and to develop standards of diabetes care for American Diabetes Association
Financial/Non-Financial Conflicts of Interest: None

Bruce Redmon, MD (Work Group Member)
Endocrinology, Professor, University of Minnesota Medical School
National, Regional, Local Committee Affiliations: None
Guideline Related Activities: None
Research Grants: NIH (National Institute of Health) related to ongoing diabetes clinical trial, including the Look Ahead study and GRADE study
Financial/Non-Financial Conflicts of Interest: Consults for the University of Minnesota and Optum Insight and is paid directly to the physician's employer

Julie Roberts, MS, RD, CDE (Work Group Member)
Registered Dietician, HealthPartners Medical Group and Regions Hospital
National, Regional, Local Committee Affiliations: None
Guideline Related Activities: None
Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

Return to Table of Contents

Steve Smith, MD (Work Group Member)
Endocrinology, Consultant, Medical Director of Patient Education, Mayo Clinic
National, Regional, Local Committee Affiliations: None
Guideline Related Activities: None
Research Grants: None
Financial/Non-Financial Conflicts of Interest: None

JoAnn Sperl-Hillen, MD (Work Group Member)
Internal Medicine, Investigator, HealthPartners Medical Group and Regions Hospital
National, Regional, Local Committee Affiliations: None
Guideline Related Activities: Has served on guideline group for BMJ Online T2DM guideline
Research Grants: Receives programmatic support paid to her institution for the following: Stimulated Diabetes Training for Resident Physicians (NIDDK funded), Primary investigator; Personalized Physician Learning for HTN (NHLBI), co-investigator; Priorities (NHLBI), co-investigator; Hyperlink (NHLBI), co-investigator; travel and expenses paid for by an educational grant from Sanofi through the International Diabetes Center
Financial/Non-Financial Conflicts of Interest: None

Return to Table of Contents

The ICSI Patient Advisory Council meets regularly to respond to any scientific document review requests put forth by ICSI facilitators and work groups. Patient advisors who serve on the council consistently share his/her experiences and perspectives in either a comprehensive or partial review of a document, and engaging in discussion and answering questions. In alignment with the Institute of Medicine's triple aims, ICSI and its member groups are committed to improving the patient experience when developing health care recommendations.

All ICSI documents are available for review during the revision process by member medical groups and sponsors. In addition, all members commit to reviewing specific documents each year. This comprehensive review provides information to the work group for such issues as content update, improving clarity of recommendations, implementation suggestions and more. The specific reviewer comments and the work group responses are available to ICSI members at http://www.icsi.org.

Return to Table of Contents

Acknowledgements

ICSI Patient Advisory Council

The work group would like to acknowledge the work done by the ICSI Patient Advisory Council in reviewing the Diagnosis and Management of Type 2 Diabetes Mellitus in Adults and thank them for suggestions to improve the Shared Decision-Making opportunities throughout the document.

We want to thank the following member groups for reviewing and commenting on this document.

Invited Reviewers

During this revision, the following medical groups reviewed this document. The work group would like to thank them for his/her comments and feedback.

HealthPartners Health Plan, Minneapolis, MN
Mayo Clinic, Rochester, MN
Medica, Minneapolis, MN
Metropolitan Health Plan, Minneapolis, MN
River Falls Medical Clinic, River Falls, WI
UCare, Minneapolis, MN

Return to Table of Contents

ICSI
Institute for Clinical Systems Improvement

Document History and Development:

Diagnosis and Management of Type 2 Diabetes Mellitus in Adults

Document Drafted Nov 1994 – Apr 1995
First Edition Mar 1996
Second Edition Apr 1997
Third Edition May 1998
Fourth Edition Apr 1999
Fifth Edition Apr 2000
Sixth Edition Oct 2001
Seventh Edition Oct 2002
Eighth Edition Dec 2003
Ninth Edition Dec 2004
Tenth Edition Dec 2005
Eleventh Edition Dec 2006
Twelfth Edition Apr 2008
Thirteenth Edition June 2009
Fourteenth Edition Aug 2010
Fifteenth Edition May 2012
Sixteenth Edition Begins Aug 2014

Original Work Group Members

Greg Angstman, MD
Family Practice, Work Group Leader
Mayo Clinic

Richard Bergenstal, MD
Endocrinology
International Diabetes Center

Mary Bergene
BHCAG Representative
Honeywell, Inc.

Don Bishop, PhD
Minnesota Department of Health Representatives
Minnesota Dept. of Health

Cindy Clark, MS
Minnesota Department of Health Representatives
Minnesota Dept. of Health

Janet Davidson, RN, CDE
Nurse Clinician
Park Nicollet Clinic

Jinnet Fowles, PhD
Measurement Advisor
Institute for Research and Education HealthSystem Minnesota

Marion Franz, RD, CDE
Dietetics
International Diabetes Center

Patrick O'Connor, MD
Family Practice
HealthPartners

Teresa Pearson, MS, RN, CDE
Health Education
HealthPartners

Peg Sannes, RPh
Pharmacy
HealthPartners

Mary Shelerud, RN
Facilitator
Mayo Clinic

Dace Trence, MD
Endocrinology
HealthPartners

Bruce Zimmerman, MD
Endocrinology
Mayo Clinic

The next revision will be no later than August 2019.

Return to Table of Contents

Contact ICSI at:
8009 34th Avenue South, Suite 1200; Bloomington, MN 55425; (952) 814-7060; (952) 858-9675 (fax)
Online at http://www.ICSI.org

ICSI Document Development and Revision Process

Overview

Since 1993, the Institute for Clinical Systems Improvement (ICSI) has developed more than 60 evidence-based health care documents that support best practices for the prevention, diagnosis, treatment or management of a given symptom, disease or condition for patients.

Audience and Intended Use

The information contained in this ICSI Health Care Guideline is intended primarily for health professionals and other expert audiences.

This ICSI Health Care Guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients and families are urged to consult a health care professional regarding his/her own situation and any specific medical questions they may have. In addition, they should seek assistance from a health care professional in interpreting this ICSI Health Care Guideline and applying it in his/her individual case.

This ICSI Health Care Guideline is designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and is not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition.

Document Development and Revision Process

The development process is based on a number of long-proven approaches and is continually being revised based on changing community standards. The ICSI staff, in consultation with the work group and a medical librarian, conduct a literature search to identify systematic reviews, randomized clinical trials, meta-analysis, other guidelines, regulatory statements and other pertinent literature. This literature is evaluated based on the GRADE methodology by work group members. When needed, an outside methodologist is consulted.

The work group uses this information to develop or revise clinical flows and algorithms, write recommendations, and identify gaps in the literature. The work group gives consideration to the importance of many issues as they develop the guideline. These considerations include the systems of care in our community and how resources vary, the balance between benefits and harms of interventions, patient and community values, the autonomy of clinicians and patients and more. All decisions made by the work group are done using a consensus process.

ICSI's medical group members and sponsors review each guideline as part of the revision process. They provide comment on the scientific content, recommendations, implementation strategies and barriers to implementation. This feedback is used by and responded to by the work group as part of his/her revision work. Final review and approval of the guideline is done by ICSI's Committee on Evidence-Based Practice. This committee is made up of practicing clinicians and nurses, drawn from ICSI member medical groups.

Implementation Recommendations and Measures

These are provided to assist medical groups and others to implement the recommendations in the guidelines. Where possible, implementation strategies are included which have been formally evaluated and tested. Measures are included which may be used for quality improvement as well as for outcome reporting. When available, regulatory or publicly reported measures are included.

Document Revision Cycle

Scientific documents are revised every 12-24 months as indicated by changes in clinical practice and literature. Each ICSI staff monitors major peer-reviewed journals every month for the guidelines for which they are responsible. Work group members are also asked to provide any pertinent literature through check-ins with the work group mid-cycle and annually to determine if there have been changes in the evidence significant enough to warrant document revision earlier than scheduled. This process complements the exhaustive literature search that is done on the subject prior to development of the first version of a guideline.

Return to Table of Contents