Evidence Table

Standards of Medical Care in Diabetes--2013

2012 **Recommendations**	**2013** **Recommendations**	**Reason for Change**	**New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper**	
Introduction				
Current criteria for the diagnosis of diabetes				
A1C ≥6.5%. The test should be performed in a laboratory using a method that is National Glycohemoglobin Standardization Program (NGSP)-certified and standardized to the Diabetes Control and Complications Trial (DCCT) assay	No change		Reference 12 in 2013 Standards of Care: Picon MJ, Murri M, Munoz A, Fernandez-Garcia JC, Gomez-Huelgas R, Tinahones FJ: Hemoglobin a1c versus oral glucose tolerance test in postpartum diabetes screening. *Diabetes Care* 35:1648-1653, 2012 Reason for inclusion: Provides evidence to suggest that A1C +/- FPG may not be sensitive to diagnose type 2 DM in women with recent GDM. ABSTRACT Determine usefulness of measuring A1C, alone or with the fasting glucose, compared with OGTT for reassessment of the carbohydrate metabolism status in postpartum women with history of GDM. RESEARCH DESIGN AND METHODS	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			We evaluated the status of carbohydrate metabolism by performing OGTT and fasting glucose and A1C tests in 231 postpartum women with prior GDM 1 year after delivery. RESULTS The prevalence of abnormal carbohydrate metabolism was 45.89% by OGTT criterion, 19.05% by the A1C test criterion, 38.10% by the fasting glucose test criterion, and 46.75% by the A1C-fasting glucose criteria. Using OGTT as gold standard, abnormal carbohydrate metabolism according to the A1C test criterion had 22.64% sensitivity and 54.55% positive predictive value; abnormal carbohydrate metabolism by the fasting glucose criterion had 83.02% sensitivity and 100% positive predictive value. The A1C-fasting glucose test criteria classified 18 women with normal carbohydrate metabolism as having abnormal carbohydrate metabolism. Abnormal carbohydrate metabolism by the A1C-fasting glucose test criteria had 83.02% sensitivity and 81.48% positive predictive value. CONCLUSIONS Results indicate that A1C criterion alone or combined with fasting glucose criterion does not provide sensitive and specific diagnosis of abnormal carbohydrate metabolism in women who have had GDM.	
OR fasting plasma glucose (FPG) ≥126 mg/dl (7.0 mmol/l). Fasting is defined as no caloric intake for at least 8 h, or	No Change			

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
OR 2-h plasma glucose ≥200 mg/dl (11.1 mmol/l) during an oral glucose tolerance test (OGTT). The test should be performed as described by the World Health Organization, using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water	No Change			
OR in a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose ≥200 mg/dl (11.1 mmol/l)	No Change			
In the absence of unequivocal hyperglycemia, result should be confirmed by repeat testing.	No Change			
Testing for diabetes in asymptomatic patients				
Testing to detect type 2 diabetes and assess risk for future diabetes in asymptomatic people should be considered in adults of	No change		Reference 20 in 2013 Standards of Care: Erickson SC, Le L, Zakharyan A, Stockl KM, Harada AS, Borson S, Ramsey SD, Curtis B: New-onset treatment-dependent diabetes mellitus and hyperlipidemia	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
any age who are overweight or obese (BMI ≥25 kg/m2) and who have one or more additional risk factors for diabetes (Table 4). In those without these risk factors, testing should begin at age 45 years. (B)			associated with atypical antipsychotic use in older adults without schizophrenia or bipolar disorder. *J Am Geriatr Soc* 60:474-479, 2012 Reason for inclusion: provides evidence for association between atypical antipsychotic use and incident diabetes. ABSTRACT: OBJECTIVES: To examine the association between atypical antipsychotic medications and incident treatment for diabetes mellitus or hyperlipidemia in elderly adults without diagnoses of schizophrenia or bipolar disorder. DESIGN: Two case-control studies using medical and pharmacy claims data. SETTING: United States managed care population from multiple insurance plans. PARTICIPANTS: Individuals aged 65 and older enrolled in a Medicare Advantage or commercial (health maintenance organization) managed care health plan in the western United States with no claims indicating diagnosis of schizophrenia or bipolar disorder in the 1 year pre-index period. Cases were defined as persons newly initiated on an antidiabetic (n = 13,075) or antihyperlipidemic (n = 63,829) medication on the index date. For the new diabetes mellitus analysis, 65,375 controls were matched to cases based on age, sex, health-plan	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			type, and index date year. In the new hyperlipidemia analysis, 63,829 controls were matched to cases based on the same variables. MEASUREMENTS: Conditional logistic regressions were performed to determine the odds of initiated antidiabetic or antihyperlipidemic medication for participants exposed to atypical antipsychotics compared with those with no exposure. The models included comorbidities possibly associated with the outcome. RESULTS: Exposure to atypical antipsychotics was associated with significantly greater adjusted odds of starting an antidiabetic medication (1.32, 95% confidence interval (CI) = 1.10-1.59) but significantly lower odds of starting an antihyperlipidemic medication (0.76, 95% CI = 0.67-0.87). CONCLUSION: Use of atypical antipsychotics in older adults for conditions other than schizophrenia and bipolar disorder was associated with incident treatment of diabetes mellitus but not of hyperlipidemia, suggesting that older adults may be susceptible to the adverse metabolic consequences of these agents.	
If tests are normal, repeat testing carried out at least at 3-year intervals is reasonable. (E)	No Change			

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
To test for diabetes or to assess risk of future diabetes, the A1C, FPG, or 2-h 75-g OGTT are appropriate. (B)	To test for diabetes or prediabetes, the A1C, FPG, or 2-h 75-g OGTT are appropriate. (B)	Clarification of categories that can be found by testing (as opposed to a risk engine)	Reference 17 in 2013 Standards of Care: 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* 40:11-17, 2011 Reason for inclusion: Provides evidence for validity of A1C to identify prediabetes and those with high CV risk. ABSTRACT: BACKGROUND: The American Diabetes Association (ADA) recently proposed the use of hemoglobin A1c as a practical and valid strategy to identify high-risk people for whom delivery of an intensive lifestyle intervention to prevent type 2 diabetes is likely to be cost effective. PURPOSE: To estimate composite risks of developing diabetes and cardiovascular disease (CVD) for adults with different hemoglobin A1c test results and to compare those risks with those of adults who met the 2003 ADA definition for prediabetes. METHODS: Cross-sectional data from the 2005-2006 National Health and Nutrition Examination Survey were analyzed in 2009. The method of Stern and colleagues was used to estimate the 7.5-year probability of type 2 diabetes,	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			and the Framingham General CVD Risk Engine was used to estimate the 10-year probability of CVD for adults with different A1c results. Sample weights were used to account for sampling probability and to adjust for noncoverage and nonresponse. RESULTS: Among adults meeting the 2003 ADA definition for prediabetes, the probabilities for incident type 2 diabetes (over 7.5 years) and CVD (over 10 years) were 33.5% and 10.7%, respectively. Use of A1c alone, in the range of 5.5% to <6.5%, would identify a population with comparable risks for diabetes (32.4% [SE=1.2%]) and CVD (11.4% [SE=0.6%]). A slightly higher cutoff (≥5.7%) would identify adults with risks of 41.3% (SE=1.5%) for diabetes and 13.3% (SE=0.8%) for CVD-risks that are comparable to people enrolled in the Diabetes Prevention Program. CONCLUSIONS: A1c-based testing in clinical settings should be considered as a means to identify greater numbers of adults at high risk of developing type 2 diabetes and CVD.	
In those identified with increased risk for future diabetes, identify and, if appropriate, treat other cardiovascular disease (CVD) risk factors. (B)	In those identified with prediabetes, identify and, if appropriate, treat other CVD risk factors. (B)	To clarify that increased CV risk is in those with hyperglycemia, not just anyone with increased risk for		

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
		future diabetes		
Screening for type 2 diabetes in children				
	Testing to detect type 2 diabetes and prediabetes should be considered in children and adolescents who are overweight and who have two or more additional risk factors for diabetes (see Table 5 of the "Standards of Medical Care in Diabetes - 2013). (E)	To make a specific recommendation vs. what was previously only in the text.		
Screening for Type 1 diabetes				
	Consider referring relatives of those with type 1 diabetes for antibody testing for risk assessment in the setting of a clinical research study. (E)	To make a specific recommendation vs. what was previously only in the text.	Reference 34 in 2013 ADA Standards of Care: Pescovitz MD, Greenbaum CJ, Krause-Steinrauf H, Becker DJ, Gitelman SE, Goland R, Gottlieb PA, Marks JB, McGee PF, Moran AM, Raskin P, Rodriguez H, Schatz DA, Wherrett D, Wilson DM, Lachin JM, Skyler JS: Rituximab, B-lymphocyte depletion, and preservation of beta-cell function. *N Engl J Med*	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			361:2143-2152, 2009 Reason for inclusion: Provides evidence for some efficacy of early interdiction for type 1 diabetes. ABSTRACT: BACKGROUND: The immunopathogenesis of type 1 diabetes mellitus is associated with T-lymphocyte autoimmunity. However, there is growing evidence that B lymphocytes play a role in many T-lymphocyte-mediated diseases. It is possible to achieve selective depletion of B lymphocytes with rituximab, an anti-CD20 monoclonal antibody. This phase 2 study evaluated the role of B-lymphocyte depletion in patients with type 1 diabetes. METHODS: We conducted a randomized, double-blind study in which 87 patients between 8 and 40 years of age who had newly diagnosed type 1 diabetes were assigned to receive infusions of rituximab or placebo on days 1, 8, 15, and 22 of the study. The primary outcome, assessed 1 year after the first infusion, was the geometric mean area under the curve (AUC) for the serum C-peptide level during the first 2 hours of a mixed-meal tolerance test. Secondary outcomes included safety and changes in the glycated hemoglobin level and insulin dose. RESULTS: At 1 year, the mean AUC for the level	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			of C peptide was significantly higher in the rituximab group than in the placebo group. The rituximab group also had significantly lower levels of glycated hemoglobin and required less insulin. Between 3 months and 12 months, the rate of decline in C-peptide levels in the rituximab group was significantly less than that in the placebo group. CD19+ B lymphocytes were depleted in patients in the rituximab group, but levels increased to 69% of baseline values at 12 months. More patients in the rituximab group than in the placebo group had adverse events, mostly grade 1 or grade 2, after the first infusion. The reactions appeared to be minimal with subsequent infusions. There was no increase in infections or neutropenia with rituximab. CONCLUSIONS: A four-dose course of rituximab partially preserved beta-cell function over a period of 1 year in patients with type 1 diabetes. The finding that B lymphocytes contribute to the pathogenesis of type 1 diabetes may open a new pathway for exploration in the treatment of patients with this condition. Reference 35 in 2013 ADA Standards of Care: Orban T, Bundy B, Becker DJ, DiMeglio LA, Gitelman SE, Goland R, Gottlieb PA, Greenbaum CJ, Marks JB,	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			Monzavi R, Moran A, Raskin P, Rodriguez H, Russell WE, Schatz D, Wherrett D, Wilson DM, Krischer JP, Skyler JS: Co-stimulation modulation with abatacept in patients with recent-onset type 1 diabetes: a randomised, double-blind, placebo-controlled trial. *Lancet* 378:412-419, 2011 Reason for inclusion: Provides evidence for some efficacy of early interdiction for type 1 diabetes. ABSTRACT: BACKGROUND: The immunopathogenesis of type 1 diabetes mellitus is associated with T-cell autoimmunity. To be fully active, immune T cells need a co-stimulatory signal in addition to the main antigen-driven signal. Abatacept modulates co-stimulation and prevents full T-cell activation. We evaluated the effect of abatacept in recent-onset type 1 diabetes. METHODS: In this multicentre, double-blind, randomised controlled trial, patients aged 6-45 years recently diagnosed with type 1 diabetes were randomly assigned (2:1) to receive abatacept (10 mg/kg, maximum 1000 mg per dose) or placebo infusions intravenously on days 1, 14, 28, and monthly for a total of 27 infusions over 2 years. Computer-generated permuted block randomisation was used, with a block size of 3 and stratified by	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			participating site. Neither patients nor research personnel were aware of treatment assignments. The primary outcome was baseline-adjusted geometric mean 2-h area-under-the-curve (AUC) serum C-peptide concentration after a mixed-meal tolerance test at 2 years' follow-up. Analysis was by intention to treat for all patients for whom data were available. This trial is registered at ClinicalTrials.gov, NCT00505375. FINDINGS: 112 patients were assigned to treatment groups (77 abatacept, 35 placebo). Adjusted C-peptide AUC was 59% (95% CI 6·1-112) higher at 2 years with abatacept (n=73, 0·378 nmol/L) than with placebo (n=30, 0·238 nmol/L; p=0·0029). The difference between groups was present throughout the trial, with an estimated 9·6 months' delay (95% CI 3·47-15·6) in C-peptide reduction with abatacept. There were few infusion-related adverse events (36 reactions occurred in 17 [22%] patients on abatacept and 11 reactions in six [17%] on placebo). There was no increase in infections (32 [42%] patients on abatacept vs 15 [43%] on placebo) or neutropenia (seven [9%] vs five [14%]). INTERPRETATION: Co-stimulation modulation with abatacept slowed reduction in β-cell function over 2 years. The beneficial effect suggests that T-cell activation still occurs around the time of clinical	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			diagnosis of type 1 diabetes. Yet, despite continued administration of abatacept over 24 months, the decrease in β-cell function with abatacept was parallel to that with placebo after 6 months of treatment, causing us to speculate that T-cell activation lessens with time. Further observation will establish whether the beneficial effect continues after cessation of abatacept infusions.	
Detection and diagnosis of gestational diabetes mellitus (GDM)				
Screen for undiagnosed type 2 diabetes at the first prenatal visit in those with risk factors, using standard diagnostic criteria. (B)	No change			
In pregnant women not known to have diabetes, screen for GDM at 24–28 weeks' gestation, using a 75-g 2-h OGTT and the diagnostic cut points in Table 6. (B)	No change			
Screen women with GDM for persistent diabetes at 6-12 weeks postpartum, using a test	Screen women with GDM for persistent diabetes at 6-12 weeks postpartum, using the	Clarification		

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
other than A1C (E)	OGTT and non-pregnancy diagnostic criteria. (E)			
Women with a history of GDM should have lifelong screening for the development of diabetes or prediabetes at least every 3 years. (B)	No change			
Women with a history of GDM found to have prediabetes should receive lifestyle interventions or metformin to prevent diabetes (A)	No change			
Prevention/delay of type 2 diabetes				
Patients with IGT (A), IFG (E), or an A1C of 5.7–6.4% (E) 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 min/week of moderate activity such as	No change			

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
walking.				
Follow-up counseling appears to be important for success. (B)	No change			
Based on the cost-effectiveness of diabetes prevention, such programs should be covered by third-party payers. (B)	No change		Reference 51 in 2013 ADA Standards of Care: Diabetes Prevention Program Research Group: The 10-year cost-effectiveness of lifestyle intervention or metformin for diabetes prevention: an intent-to-treat analysis of the DPP/DPPOS. *Diabetes Care* 35:723-730, 2012 Reason for inclusion: Provides evidence for cost-effectiveness of lifestyle intervention and metformin for prediabetes (replaces abstract in prior year's Standards) ABSTRACT: OBJECTIVE: The Diabetes Prevention Program (DPP) and its Outcomes Study (DPPOS) demonstrated that either intensive lifestyle intervention or metformin could prevent type 2 diabetes in high-risk adults for at least 10 years after randomization. We report the 10-year within-trial cost-effectiveness of the interventions. RESEARCH DESIGN AND METHODS: Data on resource utilization, cost, and quality of life were collected prospectively. Economic analyses were performed from health system and societal perspectives. RESULTS: Over 10	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			years, the cumulative, undiscounted per capita direct medical costs of the interventions, as implemented during the DPP, were greater for lifestyle ($4,601) than metformin ($2,300) or placebo ($769). The cumulative direct medical costs of care outside the DPP/DPPOS were least for lifestyle ($24,563 lifestyle vs. $25,616 metformin vs. $27,468 placebo). The cumulative, combined total direct medical costs were greatest for lifestyle and least for metformin ($29,164 lifestyle vs. $27,915 metformin vs. $28,236 placebo). The cumulative quality-adjusted life-years (QALYs) accrued over 10 years were greater for lifestyle (6.81) than metformin (6.69) or placebo (6.67). When costs and outcomes were discounted at 3%, lifestyle cost $10,037 per QALY, and metformin had slightly lower costs and nearly the same QALYs as placebo. CONCLUSIONS: Over 10 years, from a payer perspective, lifestyle was cost-effective and metformin was marginally cost-saving compared with placebo. Investment in lifestyle and metformin interventions for diabetes prevention in high-risk adults provides good value for the money spent.	
At least annual monitoring for the development of diabetes in those with prediabetes is	No Change			

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
suggested. (E)				
	Screening for and treatment of modifiable risk factors for CVD is suggested. (B)	Observational evidence of clustering of CV risk factors with hyperglycemia; new evidence from the DPPOS of improvements in CV risk factors.	Reference 56 of 2013 ADA Standards of Care: Orchard TJ, Temprosa M, Barrett-Connor E, Fowler S, Goldberg R, Mather K, Marcovina S, Montez M, Ratner R, Saudek C, Sherif H, Watson K: Long-term effects of the Diabetes Prevention Program interventions on cardiovascular risk factors: a report from the DPP Outcomes Study. *Diabet Med* 2012 Reason for inclusion: New evidence for improvement of CV risk factors with identification and treatment of people with prediabetes. ABSTRACT: Aims Whether long-term cardiovascular risk is reduced by the Diabetes Prevention Program interventions is unknown. The aim of this study was to determine the long-term differences in cardiovascular disease risk factors and the use of lipid and blood pressure medications by the original Diabetes Prevention Program intervention group. Methods This long-term follow-up (median 10 years, interquartile range 9.0-10.5) of the three-arm Diabetes Prevention Program randomized controlled clinical trial (metformin, intensive lifestyle and placebo), performed on 2766 (88%) of the Diabetes Prevention Program participants (who originally had impaired glucose tolerance), comprised a mean of 3.2 years of randomized treatment, approximately	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			1-year transition (during which all participants were offered intensive lifestyle intervention) and 5 years follow-up (Diabetes Prevention Program Outcomes Study). During the study, participants were followed in their original groups with their clinical care being provided by practitioners outside the research setting. The study determined lipoprotein profiles and blood pressure and medication use annually. Results After 10 years' follow-up from Diabetes Prevention Program baseline, major reductions were seen for systolic (2-3 mmHg) and diastolic (5-6 mmHg) blood pressure, and for LDL cholesterol (0.47-0.54 mmol/l) and triglycerides (0.18-0.32 mmol/l) in all groups, with no between-group differences. HDL cholesterol also rose significantly (0.13-0.16 mmol/l) in all groups. Lipid (P < 0.012) and blood pressure (P < 0.09) medication use, however, were lower for the lifestyle group during the Diabetes Prevention Program Outcomes Study. Conclusion Overall, intensive lifestyle intervention achieved, with less medication, a comparable long-term effect on cardiovascular disease risk factors, to that seen in the metformin and placebo groups.	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
Glycemic control in adults				
Glucose monitoring				
Self-monitoring of blood glucose (SMBG) should be carried out three or more times daily for patients using multiple insulin injections or insulin pump therapy. (B)	Patients on MDI or insulin pump therapy should do SMBG at least prior to meals and snacks, occasionally post-prandially, at bedtime, prior to exercise, when they suspect low blood glucose, after treating low blood glucose until they are normoglycemic, and prior to critical tasks such as driving. (B)	To better delineate the recommendations for type 1 or insulin-deficient patients		
For patients using less-frequent insulin injections, non-insulin therapies, or medical nutrition therapy (MNT) alone, SMBG may be useful as a guide to management. (E)	Deleted			

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
	When prescribed as part of a broader educational context, SMBG results may be helpful to guide treatment decisions and/or patient self-management for patients using less frequent insulin injections or non insulin therapies. (E)	More consistent with the evidence; underscores the self-management value and also to address the problem of SMBG being prescribed but not used properly.	Reference 61 in 2013 ADA Standards of Care: Farmer AJ, Perera R, Ward A, et al. Meta-analysis of individual patient data in randomised trials of self monitoring of blood glucose in people with non-insulin treated type 2 diabetes. BMJ. 012;344:e486 Reason for inclusion: meta-analysis demonstrating the limited efficacy of SMBG in non-insulin-treated patients. ABSTRACT: OBJECTIVE: To assess the effectiveness of self monitoring blood glucose levels in people with non-insulin treated type 2 diabetes compared with clinical management without self monitoring, and to explore the effects in specific patient groups. DESIGN: Meta-analysis based on individual participant data. DATA SOURCES: Medline, Embase, and a recent systematic review of trials on self monitoring of blood glucose. Chief investigators of trials published since 2000 were approached for additional information and individual patient data. INCLUSION CRITERIA: Randomised controlled trials in patients with non-insulin treated type 2 diabetes comparing an intervention using self monitoring of blood glucose with clinical management not using	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			self monitoring. Trials published from 2000 with at least 80 participants were included. DATA COLLECTION : Individual patient data were collected from electronic files and checked for integrity. ANALYSIS: All randomised participants were analysed using the intention to treat principle. A random effects model of complete cases was used to assess efficacy, a sensitivity analysis comprised imputed data, and prespecified subgroup analyses were carried out for age, sex, previous use of self monitoring, duration of diabetes, and levels of glycated haemoglobin (HbA(1c)) at baseline. RESULTS: 2552 patients were randomised in the six included trials. A mean reduction in HbA(1c) level of -2.7 mmol/mol (95% confidence interval -3.9 to -1.6; 0.25%) was observed for those using self monitoring of blood glucose levels compared with no self monitoring at six months. The mean reduction in HbA(1c) level between groups was 2.0 mmol/mol (3.2 to 0.8; 0.25%) at three months (five trials) and 2.5 mmol/mol (4.1 to 0.9; 0.35%) at 12 months (three trials). These estimates were unchanged after imputing missing data, and estimates of effect in trials with higher loss to follow-up or a possibility of co-intervention compared with those with lower loss to follow-up and no co-intervention did not differ	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			significantly (P=0.21). The difference in HbA(1c) levels between groups was consistent across age, baseline HbA(1c) level, sex, and duration of diabetes, although the numbers of older and younger people and those with HbA(1c) levels >86 mmol/mol (10%) were insufficient for interpretation. No changes occurred in systolic blood pressure (-0.2 mm Hg, 95% confidence interval -1.4 to 1.0), diastolic blood pressure (-0.1 mm Hg, -0.9 to 0.6), or total cholesterol level (-0.1 mol/L, 95% confidence interval -0.2 to 0.1). CONCLUSIONS: Evidence from this meta-analysis of individual patient data was not convincing for a clinically meaningful effect of clinical management of non-insulin treated type 2 diabetes by self monitoring of blood glucose levels compared with management without self monitoring, although the difference in HbA(1c) level between groups was statistically significant. The difference in levels was consistent across subgroups defined by personal and clinical characteristics. Reference 62 in 2013 ADA Standards of Care: Malanda UL, Welschen LMC Riphagen II Dekker JM Nijpels G Bot SDM. Self-monitoring of blood glucose in patients with type 2 diabetes mellitus who are not using insulin. Cochrane Database of Systematic	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			Reviews 2012, Issue 1.Art.No.: CD005060. 2012 Reason for inclusion: systematic review supporting the limited evidence for efficacy of SMBG as usually prescribed for non-insulin-using patients. ABSTRACT: BACKGROUND: Self-monitoring of blood glucose (SMBG) has been found to be effective for patients with type 1 diabetes and for patients with type 2 diabetes using insulin. There is much debate on the effectiveness of SMBG as a tool in the self-management for patients with type 2 diabetes who are not using insulin. OBJECTIVES: To assess the effects of SMBG in patients with type 2 diabetes mellitus who are not using insulin. SEARCH METHODS: Multiple electronic bibliographic and ongoing trial databases were searched supplemented with handsearches of references of retrieved articles (date of last search: 07 July 2011). SELECTION CRITERIA: Randomised controlled trials investigating the effects of SMBG compared with usual care, self-monitoring of urine glucose (SMUG) or both in patients with type 2 diabetes who where not using insulin. Studies that used glycosylated haemoglobin A(1c) (HbA(1c)) as primary outcome were eligible for inclusion. DATA COLLECTION AND ANALYSIS: Two authors independently extracted data from included studies and evaluated the studies' risk of bias. Data from the studies were compared to decide whether they were sufficiently homogeneous to pool in a	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			meta-analysis. Primary outcomes were HbA(1c), health-related quality of life, well-being and patient satisfaction. Secondary outcomes were fasting plasma glucose level, hypoglycaemic episodes, morbidity, adverse effects and costs. MAIN RESULTS: Twelve randomised controlled trials were included and evaluated outcomes in 3259 randomised patients. Intervention duration ranged from 6 months (26 weeks) to 12 months (52 weeks). Nine trials compared SMBG with usual care without monitoring, one study compared SMBG with SMUG, one study was a three-armed trial comparing SMBG and SMUG with usual care and one study was a three-armed trial comparing less intensive SMBG and more intensive SMBG with a control group. Seven out of 11 studies had a low risk of bias for most indicators. Meta-analysis of studies including patients with a diabetes duration of one year or more showed a statistically significant SMBG induced decrease in HbA(1c) at up to six months follow-up (-0.3; 95% confidence interval (CI) -0.4 to -0.1; 2324 participants, nine trials), yet an overall statistically non-significant SMBG induced decrease was seen at 12 month follow-up (-0.1; 95% CI -0.3 to 0.04; 493 participants, two trials). Qualitative analysis of the effect of SMBG on well-being and quality of life showed no effect on patient satisfaction, general well-being or general health-related quality of life. Two trials reported costs of self-monitoring: One trial compared the costs of self-monitoring of blood	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			glucose with self-monitoring of urine glucose based on nine measurements per week and with the prices in US dollars for self-monitoring in 1990. Authors concluded that total costs in the first year of self-monitoring of blood glucose, with the purchase of a reflectance meter were 12 times more expensive than self-monitoring of urine glucose ($481 or 361 EURO [11/2011 conversion] versus $40 or 30 EURO [11/2011 conversion]). Another trial reported a full economical evaluation of the costs and effects of self-monitoring. At the end of the trial, costs for the intervention were £89 (104 EURO [11/2011 conversion]) for standardized usual care (control group), £181 (212 EURO [11/2011 conversion]) for the less intensive self-monitoring group and £173 (203 EURO [11/2011 conversion]) for the more intensive self-monitoring group. Higher losses to follow-up in the more intensive self-monitoring group were responsible for the difference in costs, compared to the less intensive self-monitoring group.There were few data on the effects on other outcomes and these effects were not statistically significant. None of the studies reported data on morbidity. AUTHORS' CONCLUSIONS: From this review, we conclude that when diabetes duration is over one year, the overall effect of self-monitoring of blood glucose on glycaemic control in patients with type 2 diabetes who are not using insulin is small up to six months after initiation and subsides after 12 months. Furthermore, based on a best-evidence	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			synthesis, there is no evidence that SMBG affects patient satisfaction, general well-being or general health-related quality of life. More research is needed to explore the psychological impact of SMBG and its impact on diabetes specific quality of life and well-being, as well as the impact of SMBG on hypoglycaemia and diabetic complications. Reference 64, 2013 ADA Standards of Care: Wang J, Zgibor J, Matthews JT, Charron-Prochownik D, Sereika SM, Siminerio L: Self-monitoring of blood glucose is associated with problem-solving skills in hyperglycemia and hypoglycemia. *Diabetes Educ* 38:207-218, 2012 Reason for inclusion: Evidence that many patients do not understand what to do with SMBG data. ABSTRACT: PURPOSE: The purpose of this study was to examine the association between self-monitoring of blood glucose (SMBG) and problem-solving skills in response to detected hyperglycemia and hypoglycemia among patients with type 2 diabetes. METHODS: Data were obtained from the American Association of Diabetes Educators Outcome System, implemented in 8 diabetes self-management education programs in western Pennsylvania. SMBG was	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			measured by asking patients how often they checked, missed checking, or checked blood glucose later than planned. Problem-solving skill was measured by asking how often they modified their behaviors after detecting high or low blood glucose. RESULTS: Most patients checked their blood glucose at least once per day. However, when blood glucose was high or low, many of them reported doing nothing, and only some of them resolved the problem. There were significant associations between self-monitoring of blood glucose and problem-solving skills for hyperglycemia and hypoglycemia, after controlling for age, gender, ethnicity, education, and time since diagnosis. CONCLUSIONS: Patients reported poor problem-solving skills when detecting hyperglycemia and hypoglycemia via SMBG. Patients need to learn problem-solving skills along with SMBG training to achieve glycemic control. Reference 65 in 2013 ADA Standards of Care: Polonsky WH, Fisher L, Schikman CH, Hinnen DA, Parkin CG, Jelsovsky Z, Petersen B, Schweitzer M, Wagner RS: Structured self-monitoring of blood glucose significantly reduces A1C levels in poorly controlled, noninsulin-treated type 2 diabetes: results from the Structured Testing Program study.	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			Diabetes Care 34:262-267, 2011 <u>Reason for inclusion</u>: Makes the point for a more systematic approach to using SMBG, with intensive teaching and active review (as opposed to reflexively prescribing SMBG without really using the data) ABSTRACT: OBJECTIVE: To assess the effectiveness of structured blood glucose testing in poorly controlled, noninsulin-treated type 2 diabetes. RESEARCH DESIGN AND METHODS: This 12-month, prospective, cluster-randomized, multicenter study recruited 483 poorly controlled (A1C ≥ 7.5%), insulin-naïve type 2 diabetic subjects from 34 primary care practices in the U.S. Practices were randomized to an active control group (ACG) with enhanced usual care or a structured testing group (STG) with enhanced usual care and at least quarterly use of structured self-monitoring of blood glucose (SMBG). STG patients and physicians were trained to use a paper tool to collect/interpret 7-point glucose profiles over 3 consecutive days. The primary end point was A1C level measured at 12 months. RESULTS: The 12-month intent-to-treat analysis (ACG, n = 227; STG, n = 256) showed significantly greater reductions in mean (SE) A1C in the STG compared with the ACG: -1.2% (0.09) vs. -0.9%	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			(0.10); Δ = -0.3%; P = 0.04. Per protocol analysis (ACG, n = 161; STG, n = 130) showed even greater mean (SE) A1C reductions in the STG compared with the ACG: -1.3% (0.11) vs. -0.8% (0.11); Δ = -0.5%; P < 0.003. Significantly more STG patients received a treatment change recommendation at the month 1 visit compared with ACG patients, regardless of the patient's initial baseline A1C level: 179 (75.5%) vs. 61 (28.0%); <0.0001. Both STG and ACG patients displayed significant (P < 0.0001) improvements in general well-being (GWB). CONCLUSIONS: Appropriate use of structured SMBG significantly improves glycemic control and facilitates more timely/aggressive treatment changes in noninsulin-treated type 2 diabetes without decreasing GWB.	
To achieve postprandial glucose targets, postprandial SMBG may be appropriate. (E)	Deleted	Lack of evidence		
When prescribing SMBG, ensure that patients receive initial instruction in, and routine follow-up evaluation of, SMBG technique and their ability to use	When prescribing SMBG, ensure that patients receive ongoing instruction and regular evaluation of SMBG technique and SMBG results, as well as their ability to use	Clarification	See above (Reference 65)	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
data to adjust therapy. (E)	SMBG data to adjust therapy. (E)			
Continuous glucose monitoring (CGM) in conjunction with intensive insulin regimens can be a useful tool to lower A1C in selected adults (age ≥25 years) with type 1 diabetes. (A)	No change		Reference 70 in 2013 ADA Standards of Care: Yeh HC, Brown TT, Maruthur N, Ranasinghe P, Berger Z, Suh YD, Wilson LM, Haberl EB, Brick J, Bass EB, Golden SH: Comparative Effectiveness and Safety of Methods of Insulin Delivery and Glucose Monitoring for Diabetes Mellitus: A Systematic Review and Meta-analysis. *Ann Intern Med*E-508, 2012 Reason for inclusion: Systematic review and meta-analysis confirming evidence for CGM in adults with type 1 diabetes. ABSTRACT: BACKGROUND: Patients with diabetes mellitus need information about the effectiveness of innovations in insulin delivery and glucose monitoring. PURPOSE: To review how intensive insulin therapy (multiple daily injections [MDI] vs. rapid-acting analogue -based continuous subcutaneous insulin infusion [CSII]) or method of monitoring (self-monitoring of blood glucose [SMBG] vs. real-time continuous glucose monitoring [rt-CGM]) affects outcomes in type 1 and 2 diabetes mellitus. DATA SOURCES: MEDLINE, EMBASE, and the	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			Cochrane Central Register of Controlled Trials through February 2012 without language restrictions. STUDY SELECTION: 33 randomized, controlled trials in children or adults that compared CSII with MDI (n = 19), rt-CGM with SMBG (n = 10), or sensor-augmented insulin pump use with MDI and SMBG (n = 4). DATA EXTRACTION: 2 reviewers independently evaluated studies for eligibility and quality and serially abstracted data. DATA SYNTHESIS: In randomized, controlled trials, MDI and CSII showed similar effects on hemoglobin A1c (HbA1c) levels and severe hypoglycemia in children or adults with type 1 diabetes mellitus and adults with type 2 diabetes mellitus. In adults with type 1 diabetes mellitus, HbA1c levels decreased more with CSII than with MDI, but 1 study heavily influenced these results. Compared with SMBG, rt-CGM achieved a lower HbA1c level (between-group difference of change, -0.26% [95% CI, -0.33% to -0.19%]) without any difference in severe hypoglycemia. Sensor-augmented insulin pump use decreased HbA1c levels more than MDI and SMBG did in persons with type 1 diabetes mellitus (between-group difference of change, -0.68% [CI, -0.81% to -0.54%]). Little evidence was available on other outcomes. LIMITATION: Many studies were	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			small, of short duration, and limited to white persons with type 1 diabetes mellitus. CONCLUSION: Continuous subcutaneous insulin infusion and MDI have similar effects on glycemic control and hypoglycemia, except CSII has a favorable effect on glycemic control in adults with type 1 diabetes mellitus. For glycemic control, rt-CGM is superior to SMBG and sensor-augmented insulin pumps are superior to MDI and SMBG without increasing the risk for hypoglycemia.	
Although the evidence for A1C-lowering is less strong in children, teens, and younger adults, CGM may be helpful in these groups. Success correlates with adherence to ongoing use of the device. (C)	No change			
CGM may be a supplemental tool to SMBG in those with hypoglycemia unawareness and/or frequent hypoglycemic episodes. (E)	No Change			

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
A1C				
Perform the A1C test at least two times a year in patients who are meeting treatment goals (and who have stable glycemic control). (E)	No change			
Perform the A1C test quarterly in patients whose therapy has changed or who are not meeting glycemic goals. (E)	No change			
Use of point-of-care testing for A1C provides the opportunity for more timely treatment changes. (E)	No change			
Glycemic goals in adults				
Lowering A1C to below or around 7% has been shown to reduce microvascular complications of diabetes and, if implemented soon after the	No change			

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
diagnosis of diabetes, is associated with long-term reduction in macrovascular disease. Therefore, a reasonable A1C goal for many nonpregnant adults is <7%. (B)				
Providers might reasonably suggest more stringent A1C goals (such as <6.5%) for selected individual patients, if this can be achieved without significant hypoglycemia or other adverse effects of treatment. Appropriate patients might include those with short duration of diabetes, long life expectancy, and no significant cardiovascular disease. (C)	No change		Reference 99 in 2013 ADA Standards of Care: Duckworth WC, Abraira C, Moritz TE, Davis SN, Emanuele N, Goldman S, Hayward R, Huang GD, Marks JB, Reaven PD, Reda DJ, Warren SR, Zieve FJ: The duration of diabetes affects the response to intensive glucose control in type 2 subjects: the VA Diabetes Trial. *J Diabetes Complications* 25:355-361, 2011 Reason for inclusion: Post hoc analysis of VADT provides support for duration of diabetes mediating expectation of benefit vs. no benefit or harm of intensive glycemic goals. ABSTRACT: BACKGROUND: The goal of the VA Diabetes Trial (VADT) was to determine the effect of intensive glucose control on macrovascular events in subjects with difficult-to-control diabetes. No significant benefit was found. This report examines predictors of the effect of intensive therapy on the primary outcome in this	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			population. METHODS: This trial included 1791 subjects. Baseline cardiovascular risk factors were collected by interview and the VA record. The analyses were done by intention to treat. FINDINGS: Univariate analysis at baseline of predictors of a primary cardiovascular (CV) event included a prior CV event, age, insulin use at baseline, and duration of diagnosed diabetes (all P < .0001). Multivariable modeling revealed a U-shaped relationship between duration of diabetes and treatment. Modeled estimates for the hazard ratios (HRs) for treatment show that subjects with a short duration (3 years or less) of diagnosed diabetes have a nonsignificant increase in risk (HR > 1.0) after which the HR is below 1.0. From 7 to 15 years' duration at entry, subjects have HRs favoring intensive treatment. Thereafter the HR approaches 1.0 and over-21-years' duration approaches 2.0. Duration over 21 years resulted in a HR of 1.977 (CI 1.77-3.320, P < .01). Baseline c-peptide levels progressively declined up to 15 years and were stable subsequently. INTERPRETATION: In difficult-to-control older subjects with type 2 DM, duration of diabetes altered the response to intensive glucose control. Intensive therapy may reduce CV events in subjects with a duration of 15 years or less and	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			may increase risks in those with longer duration. See below (reference 101)	
Less stringent A1C goals (such as <8%) may be appropriate for patients with a history of severe hypoglycemia, limited life expectancy, advanced microvascular or macrovascular complications, extensive comorbid conditions, and those with longstanding diabetes in whom the general goal is difficult to attain despite diabetes self-management education, appropriate glucose monitoring, and effective doses of multiple glucose-lowering agents including insulin. (B)	No change		See above (reference 99) Reference 101 in 2013 ADA Standards of Care: Ismail-Beigi F, Moghissi E, Tiktin M, Hirsch IB, Inzucchi SE, Genuth S: Individualizing glycemic targets in type 2 diabetes mellitus: implications of recent clinical trials. *Ann Intern Med* 154:554-559, 2011 Reason for inclusion: summary of evidence from multiple clinical trials used as a framework for individualizing glycemic goals. ABSTRACT: One of the first steps in the management of patients with type 2 diabetes mellitus is setting glycemic goals. Professional organizations advise setting specific hemoglobin A(1c) (HbA(1c)) targets for patients, and individualization of these goals has more recently been emphasized. However, the operational meaning of glycemic goals, and specific methods for individualizing them, have not been well-described. Choosing a specific HbA(1c) target range for a given patient requires taking several factors into consideration, including an assessment of the patient's risk for hyperglycemia-related complications versus the risks of therapy, all in the context of the overall clinical setting. Comorbid	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			conditions, psychological status, capacity for self-care, economic considerations, and family and social support systems also play a key role in the intensity of therapy. The individualization of HbA(1c) targets has gained more traction after recent clinical trials in older patients with established type 2 diabetes mellitus failed to show a benefit from intensive glucose-lowering therapy on cardiovascular disease (CVD) outcomes. The limited available evidence suggests that near-normal glycemic targets should be the standard for younger patients with relatively recent onset of type 2 diabetes mellitus and little or no micro- or macrovascular complications, with the aim of preventing complications over the many years of life. However, somewhat higher targets should be considered for older patients with long-standing type 2 diabetes mellitus and evidence of CVD (or multiple CVD risk factors). This review explores these issues further and proposes a framework for considering an appropriate and safe HbA(1c) target range for each patient.	
Insulin Therapy for Type 1 Diabetes				
	Most people with type 1 diabetes should be treated	To provide more specific	See above (reference 70)	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
	with multiple-dose insulin injections (three to four injections per day of basal and prandial insulin) or CSII. (A)	recommendations vs. what was previously only in text		
	Most people with type 1 diabetes should be educated in how to match prandial insulin dose to carbohydrate intake, premeal blood glucose, and anticipated activity. (E)	To provide more specific recommendations vs. what was previously only in text		
	Most people with type 1 diabetes should use insulin analogs to reduce hypoglycemia risk. (A)	To provide more specific recommendations vs. what was previously only in text		
	Consider screening those with type 1 diabetes for other auto-immune diseases (thyroid, vitamin B12, celiac) as appropriate. (B)	To provide more specific recommendations vs. what was previously only in text		

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
Pharmacological Therapy for hyperglycemia in Type 2 Diabetes				
At the time of type 2 diabetes diagnosis, initiate metformin therapy along with lifestyle interventions, unless metformin is contraindicated. (A)	Metformin, if not contraindicated and if tolerated, is the preferred initial pharmacologic agent for type 2 diabetes. (A)	To be more consistent with the evidence	Reference 111 of 2013 ADA Standards of Care: Inzucchi SE, Bergenstal RM, Buse JB, Diamant M, Ferrannini E, Nauck M, Peters AL, Tsapas A, Wender R, Matthews DR: Management of hyperglycemia in type 2 diabetes: a patient-centered approach: position statement of the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). *Diabetes Care* 35:1364-1379, 2012 Reason for inclusion: systematic review evidence suggests that after metformin as initial therapy, there are no clear advantages in terms of A1C lowering among additional agents. This guideline suggests consideration of other outcomes that may be important to patients in a shared decision-making approach. No abstract available Reference 112 of 2013 ADA Standards of Care: Bennett WL, Maruthur NM, Singh S, Segal JB, Wilson LM, Chatterjee R, Marinopoulos SS, Puhan MA, Ranasinghe P, Block L, Nicholson WK, Hutfless S, Bass EB, Bolen S: Comparative effectiveness and safety of	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			medications for type 2 diabetes: an update including new drugs and 2-drug combinations. *Ann Intern Med* 154:602-613, 2011 Reason for inclusion: systematic review suggesting that metformin has distinct advantages for initial therapy, but that there are no significant differences in A1C-lowering among classes to be added to metformin. ABSTRACT: BACKGROUND: Given the increase in medications for type 2 diabetes mellitus, clinicians and patients need information about their effectiveness and safety to make informed choices. PURPOSE: To summarize the benefits and harms of metformin, second-generation sulfonylureas, thiazolidinediones, meglitinides, dipeptidyl peptidase-4 (DPP-4) inhibitors, and glucagon-like peptide-1 receptor agonists, as monotherapy and in combination, to treat adults with type 2 diabetes. DATA SOURCES: MEDLINE, EMBASE, and the Cochrane Central Register of Controlled Trials were searched from inception through April 2010 for English-language observational studies and trials. The MEDLINE search was updated to December 2010 for long-term clinical outcomes. STUDY SELECTION: Two reviewers independently screened reports and	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			identified 140 trials and 26 observational studies of head-to-head comparisons of monotherapy or combination therapy that reported intermediate or long-term clinical outcomes or harms. DATA EXTRACTION: Two reviewers following standardized protocols serially extracted data, assessed applicability, and independently evaluated study quality. DATA SYNTHESIS: Evidence on long-term clinical outcomes (all-cause mortality, cardiovascular disease, nephropathy, and neuropathy) was of low strength or insufficient. Most medications decreased the hemoglobin A(1c) level by about 1 percentage point and most 2-drug combinations produced similar reductions. Metformin was more efficacious than the DPP-4 inhibitors, and compared with thiazolidinediones or sulfonylureas, the mean differences in body weight were about -2.5 kg. Metformin decreased low-density lipoprotein cholesterol levels compared with pioglitazone, sulfonylureas, and DPP-4 inhibitors. Sulfonylureas had a 4-fold higher risk for mild or moderate hypoglycemia than metformin alone and, in combination with metformin, had more than a 5-fold increased risk compared with metformin plus thiazolidinediones. Thiazolidinediones increased risk for congestive heart failure compared with	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			sulfonylureas and increased risk for bone fractures compared with metformin. Diarrhea occurred more often with metformin than with thiazolidinediones. LIMITATIONS: Only English-language publications were reviewed. Some studies may have selectively reported outcomes. Many studies were small, were of short duration, and had limited ability to assess clinically important harms and benefits. CONCLUSION: Evidence supports metformin as a first-line agent to treat type 2 diabetes. Most 2-drug combinations similarly reduce hemoglobin A(1c) levels, but some increased risk for hypoglycemia and other adverse events.	
In newly diagnosed type 2 diabetes patients with markedly symptomatic and/or elevated blood glucose levels or A1C, consider insulin therapy, with or without additional agents, from the outset. (E)	No change			
If non-insulin monotherapy at maximal tolerated dose does not achieve or maintain the A1C target over 3-6 months, add a	If non-insulin monotherapy at maximal tolerated dose does not achieve or maintain the A1C target over 3-6 months,	Evidence level changed based on systematic review (ref. 112)	See above (references 111, 112)	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
second oral agent, a GLP-1 receptor agonist, or insulin. (E)	add a second oral agent, a GLP-1 receptor agonist, or insulin. (A)			
	A patient-centered approach should be used to guide choice of pharmacologic agents. Considerations include efficacy, cost, potential side effects, effects on weight, comorbidities, hypoglycemia risk, and patient preferences. (E)	To be more consistent with systematic review evidence that there is no single best choice of agents beyond metformin	See above (reference 111)	
	Due to the progressive nature of type 2 diabetes, insulin therapy is eventually indicated for many patients with type 2 diabetes. (B)	Clarification	See above (reference 111)	
Medical nutrition therapy (MNT) (Pattie and Stephanie)				

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
General recommendations				
Individuals who have prediabetes or diabetes should receive individualized MNT as needed to achieve treatment goals, preferably provided by a registered dietitian familiar with the components of diabetes MNT. (A)	No change			
Because MNT can result in cost-savings and improved outcomes (B), MNT should be adequately covered by insurance and other payers. (E)	No change			
Energy balance, overweight, and obesity				
Weight loss is recommended for all overweight or obese individuals who have or are at risk for diabetes. (A)	No change			

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
For weight loss, either low-carbohydrate, low-fat calorie-restricted, or Mediterranean diets may be effective in the short term (up to 2 years). (A)	No change			
For patients on low-carbohydrate diets, monitor lipid profiles, renal function, and protein intake (in those with nephropathy) and adjust hypoglycemic therapy as needed. (E)	No change			
Physical activity and behavior modification are important components of weight loss programs and are most helpful in maintenance of weight loss. (B)	No change			
Recommendations for primary prevention of diabetes				
Among individuals at high risk for developing type 2 diabetes, structured programs that emphasize lifestyle changes that include moderate weight loss	No change			

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
(7% of body weight) and regular physical activity (150 min/week), with dietary strategies including reduced calories and reduced intake of dietary fat, can reduce the risk for developing diabetes and are therefore recommended. (A)				
Individuals at high risk for type 2 diabetes should be encouraged to achieve the U.S. Department of Agriculture (USDA) recommendation for dietary fiber (14 g fiber/1,000 kcal) and foods containing whole grains (one-half of grain intake). (B)	No change			
Individuals at risk for diabetes should limit intake of sugar sweetened beverages (B)	No change			
Recommendations for management of diabetes: macronutrients in diabetes management				
The mix of carbohydrate, protein, and fat may be adjusted to meet the metabolic goals and	No change		Reference 140 of 2013 ADA Standards of Care: Wheeler ML, Dunbar SA, Jaacks LM, Karmally W, Mayer-Davis EJ, Wylie-Rosett J, Yancy WS, Jr.:	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
individual preferences of the person with diabetes. (C)			Macronutrients, food groups, and eating patterns in the management of diabetes: a systematic review of the literature, 2010. *Diabetes Care* 35:434-445, 2012 Reason for inclusion: New systematic review supporting the paucity of strong evidence for any one proportion of macronutrients for all patients with diabetes in terms of A1C lowering or CV risk factor reduction. No abstract available	
Monitoring carbohydrate, whether by carbohydrate counting, choices, or experience-based estimation, remains a key strategy in achieving glycemic control. (B)	No change			
Saturated fat intake should be <7% of total calories. (B)	No change			
Reducing intake of trans fat lowers LDL cholesterol and increases HDL cholesterol (A); therefore, intake of trans fat should be minimized. (E)	No change			

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
Other nutrition recommendations				
If adults with diabetes choose to use alcohol, they should limit intake to a moderate amount (one drink per day or less for adult women and two drinks per day or less for adult men) and should take extra precautions to prevent hypoglycemia. (E)	No change			
Routine supplementation with antioxidants, such as vitamins E and C and carotene, is not advised because of lack of evidence of efficacy and concern related to long-term safety. (A)	No change			
It is reasonable for individualized meal planning to include optimization of food choices to meet recommended daily allowance (RDA)/dietary reference intake (DRI) for all	No change			

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
micronutrients. (E)				
Diabetes self-management education and support (DSME and DSMS)				
People with diabetes should receive DSME according to national standards and diabetes self-management support when their diabetes is diagnosed and as needed thereafter. (B)	People with diabetes and should receive DSME and DSMS according to national standards for Diabetes Self-Management Education and Support when their diabetes is diagnosed and as needed thereafter. (B)	To be consistent with the revised National Standards for DSME and Support	Reference 152 of 2013 ADA Standards of Care: Haas L, Maryniuk M, Beck J, Cox CE, Duker P, Edwards L, Fisher EB, Hanson L, Kent D, Kolb L, McLaughlin S, Orzeck E, Piette JD, Rhinehart AS, Rothman R, Sklaroff S, Tomky D, Youssef G: National Standards for Diabetes Self-Management Education and Support. *Diabetes Care* 2012 Reason for inclusion: Standards are updated every five years; updated national standards have been expanded to include a greater focus on DSMS and on prediabetes. No abstract available. Reference 157 of 2013 ADA Standards of Care: Frosch DL, Uy V, Ochoa S, Mangione CM: Evaluation of a behavior support intervention for patients with poorly controlled diabetes. *Arch Intern Med* 171:2011-2017, 2011 Reason for inclusion: Evidence suggesting that self-management support interventions likely need to be strong for disadvantaged patients.	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			ABSTRACT; BACKGROUND: Disease management programs that include ongoing telephone support for patients with diabetes have shown promise, but published studies have enrolled few socially and economically disadvantaged patients. METHODS: We conducted a randomized controlled trial with 201 patients with poorly controlled type 2 diabetes mellitus (72% African American or Latino; 74% with incomes of ≤$15,000). Participants were randomized to an intervention package consisting of a 24-minute video behavior support intervention with a workbook and 5 sessions of telephone coaching by a trained diabetes nurse or a 20-page brochure developed by the National Diabetes Education Program. Study measures were completed at baseline, 1 month, and 6 months. Participants' review of the intervention materials was assessed at 1 month. The primary trial end point was hemoglobin A(1c) value. Secondary end points included lipid levels, blood pressure, diabetes knowledge, and self-care behaviors. Data were analyzed with repeated measures analysis of variance. RESULTS: Most participants in both groups (94%) reviewed the intervention provided, and 73% of participants assigned to the experimental group completed 5 sessions of telephone coaching. There	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			was a significant overall reduction in mean (SD) hemoglobin A(1c) value from baseline (9.6% [2.0%]) to 6 months (9.1% [1.9%]) (P < .001), but differences between groups were nonsignificant. Differences on other clinical measures (lipid levels and blood pressure) and measures of diabetes knowledge and self-care behaviors were also nonsignificant. CONCLUSIONS: There was no significant effect of the experimental intervention compared with the control condition. The dose of intervention provided was less than in previously published studies. More intensive interventions may be necessary for the most disadvantaged patients. Reference 158 of 2013 ADA Standards of Care: McGowan P: The efficacy of diabetes patient education and self-management education in type 2 diabetes. *Can J Diabetes* 35:46-53, 2011 Reason for inclusion: RCT showing that outcomes were better with a community DSMS component added to patient education. ABSTRACT: Objective: The goal of this randomized, controlled trial was to compare the 6-month efficacy of didactic diabetes patient education to a model that augmented this education with a self-management program.	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			METHODS: Adults with type 2 diabetes were randomly assigned to a group that received diabetes patient education or to a group that received this education augmented by a community self-management program. Outcome measures were taken at baseline and 6 months. Analysis included pre- and 6-month-post–program paired comparison for each group; a comparison of change between groups; and an intent-to-treat comparison of change between groups. RESULTS: At baseline, there were no between-condition differences with respect to behavioural or biological outcomes or healthcare utilization. The pre- and 6-month-post–program comparison found statistically significant improvements in both groups in terms of glycated hemoglobin (A1C) and weight, and the experimental group had statistically significant improvements in 4 additional outcomes. A 12-month analysis found that baseline scores were statistically lower for both A1C and weight in the experimental group and statistically higher than baseline A1C in the control group. CONCLUSION: Augmenting diabetes patient education with a low-cost community self-management education program brought about additional improvements. Study limitations included self-selection of participants, short-term study duration and lack of comparison studies.	
Effective self-management and quality of life are the key	Effective self-management and quality of life are the key	To be consistent with the revised	See above (reference 152)	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
outcomes of DSME and should be measured and monitored as part of care. (C)	outcomes of DSME and DSMS and should be measured and monitored as part of care. (C)	National Standards for DSME and Support, and to be consistent with evidence for peer support	Reference 176 of 2013 ADA Standards of Care: Long JA, Jahnle EC, Richardson DM, Loewenstein G, Volpp KG: Peer mentoring and financial incentives to improve glucose control in African American veterans: a randomized trial. *Ann Intern Med* 156:416-424, 2012 Reason for inclusion: RCT demonstrating improved A1C with peer support compared to usual care or financial incentives. ABSTRACT: BACKGROUND: Compared with white persons, African Americans have a greater incidence of diabetes, decreased control, and higher rates of microvascular complications. A peer mentorship model could be a scalable approach to improving control in this population and reducing disparities in diabetic outcomes. OBJECTIVE: To determine whether peer mentors or financial incentives are superior to usual care in helping African American veterans decrease their hemoglobin A(1c) (HbA(1c)) levels. DESIGN: A 6-month randomized, controlled trial. (ClinicalTrials.gov registration number: NCT01125956) SETTING: Philadelphia Veterans Affairs Medical Center. PATIENTS: African American veterans aged 50 to 70 years with persistently poor diabetes control. INTERVENTION: 118 patients were randomly assigned to 1 of 3 groups: usual care, a peer mentoring group, and a financial incentives group. Usual care patients were notified of their	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			starting HbA(1c) level and recommended goals for HbA(1c). Those in the peer mentoring group were assigned a mentor who formerly had poor glycemic control but now had good control (HbA(1c) level ≤7.5%). The mentor was asked to talk with the patient at least once per week. Peer mentors were matched by race, sex, and age. Patients in the financial incentive group could earn $100 by decreasing their HbA(1c) level by 1% and $200 by decreasing it by 2% or to an HbA(1c) level of 6.5%. MEASUREMENTS: Change in HbA(1c) level at 6 months. RESULTS: Mentors and mentees talked the most in the first month (mean calls, 4; range, 0 to 30), but calls decreased to a mean of 2 calls (range, 0 to 10) by the sixth month. Levels of HbA(1c) decreased from 9.9% to 9.8% in the control group, from 9.8% to 8.7% in the peer mentor group, and from 9.5% to 9.1% in the financial incentive group. Mean change in HbA(1c) level from baseline to 6 months relative to control was -1.07% (95% CI, -1.84% to -0.31%) in the peer mentor group and -0.45% (CI, -1.23% to 0.32%) in the financial incentive group. LIMITATION: The study included only veterans and lasted only 6 months. CONCLUSION: Peer mentorship improved glucose control in a cohort of African American veterans with diabetes. Reference 177 of 2013 ADA Standards of Care: Tang TS, Funnell MM, Gillard M, Nwankwo R, Heisler M: The development of a pilot training program for peer	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			leaders in diabetes: process and content. *Diabetes Educ* 37:67-77, 2011 Reason for inclusion: Describes process for developing a training program for peers to facilitate DSMS. ABSTRACT: PURPOSE: The goal of this study is to describe the process of developing a program that trains peers to facilitate an empowerment-based diabetes self-management support intervention. METHODS: To guide and advise the development process, the authors formed a peer leader training action committee. The committee was an interdisciplinary group (principal investigator, nurse-certified diabetes educators, dietitian-certified diabetes educators, nutritionist, physician, and 3 community members) that met every 3 months over a 1-year period for continuous quality improvement meetings. During meetings, the committee reviewed and supervised the curriculum development, provided feedback, and informed modifications and improvements. RESULTS: The resulting peer leader training program is a 46-hour program with 2 training sessions conducted per week over a 12-week period. The competency-based training program is based on the theory of experiential learning, and it consists of	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			3 major components--namely, building a diabetes-related knowledge base, developing skills (communication, facilitation, and behavior change), and applying skills in experiential settings. All components are integrated within each training session using a range of instructional methods, including group brainstorming, group sharing, role-play, peer leader simulations, and group facilitation simulations. CONCLUSION: Through the process described above, the authors developed a training program that equips peer leaders with the knowledge and skills to facilitate empowerment-based diabetes self-management support interventions. Future directions include conducting and evaluating the peer training program. Reference 178 of 2013 ADA Standards of Care: Tang T, Ayala GX, Cherrington A, Rana G: A review of volunteer-based peer support interventions in diabetes. *Diabetes Spectrum* 24:85-98, 2011 Reason for inclusion: Systematic review of different forms of peer support interventions in diabetes. No abstract available. Conclusion: Although the peer support model offers greater flexibility and customization compared to the professional-led model, these characteristics also make the empirical	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			examination of peer support challenging. In addition to quantitative investigations, more qualitiative research is needed to understand how incentives of any form affect peer supporters' initial and continued motivation to participate in interventions. In addition, greater transparency is required regarding the peer training process and the assessment methods used to evaluate peer supporters' skills and competency. Without more extensive examination, we cannot replicate, nor can we understand, the underlying mechnisms of the peer support model. Reference 179 of 2013 ADA Standards of Care: Tang TS, Nwankwo R'Whiten Y, Oney C: Training peers to deliver a church-based diabetes prevention program. *Diabetes Educ* 38:519-525, 2012 Reason for inclusionReason for inclusion: Before-after study of the feasibility of training peers to deliver church-based lifestyle modification program. ABSTRACT: PURPOSE: The purpose of this study was to examine the feasibility and acceptability of training peers to function as lifestyle coaches and to deliver a church-based lifestyle modification program. METHODS: We recruited 6 African-American adults to participate in an 8-hour peer	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			lifestyle coach (PLC) training program followed by a subsequent 2-hour booster session. The PLC training program addressed several key areas, including: (1) developing empowerment-based facilitation, active listening, and behavior change skills; (2) learning self-management strategies (eg, reading food labels, counting calories); (3) practicing session delivery; and (4) interpreting clinical lab results. Training evaluation was conducted retrospectively (immediately following the delivery of the diabetes prevention intervention rather than after the 8-hour training session) and measured program satisfaction and efficacy from the perspective of participants. RESULTS: Peer lifestyle coaches' confidence levels for performing core skills (eg, asking open-ended questions, 5-step behavioral goal-setting process) and advanced skills (eg, addressing resistance, discussing sensitive topics) were uniformly high. Similarly, PLCs were very satisfied with the length of training, balance between content and skills development, and preparation for leading group- and individual-based support activities. CONCLUSIONS: Findings suggest that it is feasible to customize a PLC training program that is acceptable to participants and that equips participants with the knowledge and skills to facilitate a church-based diabetes prevention	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			intervention. Reference 180 of 2013 ADA Standards of Care: Dale JR, Williams SM, Bowyer V: What is the effect of peer support on diabetes outcomes in adults? A systematic review. *Diabet Med* epub July 18: 2012 Reason for inclusion: systematic review of peer support in diabetes. ABSTRACT: Aim There is increasing interest in the role that peers may play to support positive health behaviours in diabetes, but there is limited evidence to inform policy and practice. The aim of this study was to systematically review evidence of the impact and effectiveness of peer support in adults living with diabetes. Methods We searched the Cochrane Library, MEDLINE, PubMed, EMBASE and CINHAL for the period 1966-2011, together with reference lists of articles for eligible studies. Data were synthesized in a narrative review. Results Twenty-five studies, including fourteen randomized, controlled or comparative trials, met the inclusion criteria. There was considerable heterogeneity in the design, setting, outcomes and measurement tools. Peer support was associated with statistically significant	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			improvements in glycaemic control (three out of 14 trials), blood pressure (one out of four trials), cholesterol (one out of six trials), BMI/weight (two out of seven trials), physical activity (two out of five trials), self-efficacy (two out of three trials), depression (four out of six trials) and perceived social support (two out of two trials). No consistent pattern of effect related to any model of peer support emerged. Conclusions Peer support appears to benefit some adults living with diabetes, but the evidence is too limited and inconsistent to support firm recommendations. There remains a need for further well-designed evaluations of its effectiveness and impact. Key questions remain over its suitability to the needs of particular individuals, populations and settings, how best to implement its specific components and the sustainability of its effects.	
DSME should address psychosocial issues, since emotional well-being is associated with positive diabetes outcomes. (C)	DSME and DSMS should address psychosocial issues, since emotional well-being is associated with positive diabetes outcomes. (C)	To be consistent with the revised National Standards for DSME and Support	See above (reference 152)	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
	DSME and DSMS programs are appropriate venues for people with prediabetes to receive education and support to develop and maintain behaviors that can prevent or delay the onset of diabetes. (C)	To be consistent with the revised National Standards for DSME and Support and emerging evidence for the role of diabetes educators to facilitate diabetes prevention behaviors	See above (reference 152) Reference 186 of 2013 ADA Standards of Care: Kramer MK, McWilliams JR, Chen HY, Siminerio LM: A community-based diabetes prevention program: evaluation of the group lifestyle balance program delivered by diabetes educators. *Diabetes Educ* 37:659-668, 2011 Reason for inclusion: Non-randomized trial demonstrating the effect of diabetes educators as deliverers of diabetes prevention lifestyle intervention ABSTRACT: PURPOSE: With growing numbers of people at risk for diabetes and cardiovascular disease, diabetes educators report increasing referrals for intervention in prevention of these conditions. Diabetes educators have expertise in diabetes self-management education; however, they are generally not prepared for delivery of chronic disease primary prevention. The purpose of this project was to determine if individuals at risk for diabetes who participate in an intervention delivered by trained diabetes educators in existing diabetes self-management education community-based programs can reduce risk factors for diabetes and	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			cardiovascular disease. METHODS: Diabetes educators in 3 outpatient-hospital programs (urban, suburban, and rural) received training and support for implementation of the Group Lifestyle Balance program, an adaptation of the Diabetes Prevention Program lifestyle intervention, from the Diabetes Prevention Support Center of the University of Pittsburgh. Adults with prediabetes and/or the metabolic syndrome were eligible to enroll in the program with physician referral. With use of existing diabetes educator networks, recruitment was completed via on-site physician in-services, informative letters, and e-mail contact as well as participant-directed newspaper advertisement. RESULTS: Eighty-one participants enrolled in the study (71 women, 10 men). Mean overall weight loss was 11.3 lb (5.1%, P < .001); in addition, significant decreases were noted in fasting plasma glucose, low-density lipoprotein cholesterol, triglycerides, and blood pressure. CONCLUSIONS: These results suggest that the Group Lifestyle Balance program delivered by diabetes educators was successful in reducing risk for diabetes and cardiovascular disease in high-risk individuals. Furthermore, diabetes educators, already integrated within the existing health care system, provide yet another resource for delivery of primary	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			prevention programs in the community.	
Because DSME can result in cost-savings and improved outcomes (B), DSME should be adequately reimbursed by third-party payers. (E)	Because diabetes self-management education and support can result in cost-savings and improved outcomes (B), DSME and DSMS should be adequately reimbursed by third-party payers. (E)	To be consistent with the revised National Standards for DSME and Support	See above (reference 152)	
Physical activity				
People with diabetes should be advised to perform at least 150 min/week of moderate-intensity aerobic physical activity (50–70% of maximum heart rate), spread over at least 3 days per week with no more than two consecutive days without exercise. (A)	Adults with diabetes should be advised to perform at least 150 min/week of moderate-intensity aerobic physical activity (50–70% of maximum heart rate), spread over at least 3 days per week with no more than two consecutive days without exercise. (A)	Clarification that children have different exercise goals		

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
In the absence of contraindications, people with type 2 diabetes should be encouraged to perform resistance training at least twice per week. (A)	In the absence of contraindications, adults with type 2 diabetes should be encouraged to perform resistance training at least twice per week. (A)	Clarification that children have different exercise goals		
Psychosocial assessment and care				
It is reasonable to include assessment of the patient's psychological and social situation as an ongoing part of the medical management of diabetes. (E)	No change		Reference 219 of 2013 ADA Standards of Care: Beverly EA, Hultgren BA, Brooks KM, Ritholz MD, Abrahamson MJ, Weinger K: Understanding physicians' challenges when treating type 2 diabetic patients' social and emotional difficulties: a qualitative study. *Diabetes Care* 34:1086-1088, 2011 Reason for inclusion: Qualitative research suggesting that physicians are aware of the impact on social and emotional difficulties on self-management, but do not feel able to address these issues. ABSTRACT: OBJECTIVE: To explore physicians' awareness of and responses to type 2 diabetic patients' social and emotional difficulties. RESEARCH DESIGN AND METHODS: We conducted semistructured interviews with 19 physicians.	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			Interviews were transcribed, coded, and analyzed using thematic analysis. RESULTS: Three themes emerged: 1) physicians' awareness of patients' social and emotional difficulties: physicians recognized the frequency and seriousness of patients' social and emotional difficulties; 2) physicians' responses to patients' social and emotional difficulties: many reported that intervening with these difficulties was challenging with few treatment options beyond making referrals, individualizing care, and recommending more frequent follow-up visits; and 3) the impact of patients' social and emotional difficulties on physicians: few available patient treatment options, time constraints, and a perceived lack of psychological expertise contributed to physicians' feeling frustrated, inadequate, and overwhelmed. CONCLUSIONS: Recognition and understanding of physicians' challenges when treating diabetes patients' social and emotional difficulties are important for developing programmatic interventions. Reference 221 of 2013 ADA Standards of Care: Ciechanowski P: An integrated model for understanding the experience of individuals with co-occuring diabetes and depression. *Clinical Diabetes*	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			29:43-50, 2011 <u>Reason for inclusion</u>: description of an integrated approach to treating diabetes and depression ABSTRACT: One in eight individuals with diabetes has major depression, and another one-fifth may have less severe but clinically significant depressive symptoms. Diabetes patients with comorbid depression can have worse self-care and treatment adherence, glycemic control, and increased morbidity and mortality. The symptoms of diabetes and depression often intertwine in what can be termed "diapression." Approaching diapression in an integrated manner may be a novel approach to improve patient care.	
Psychosocial screening and follow-up may include, but is not limited to, attitudes about the illness, expectations for medical management and outcomes, affect/mood, general and diabetes-related quality of life, resources (financial, social, and emotional), and psychiatric history. (E)	No change			

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
Consider screening for psychosocial problems such as depression and diabetes-related distress, anxiety, eating disorders, and cognitive impairment when self-management is poor. (C)	Screen for psychosocial problems such as depression and diabetes-related distress, anxiety, eating disorders, and cognitive impairment when self-management is poor. (B)	Higher level recommendation consistent with stronger emerging evidence base	References 209 in 2013 ADA Standards of Care: Scherrer JF, Garfield LD, Chrusciel T, Hauptman PJ, Carney RM, Freedland KE, Owen R, True WR, Lustman PJ: Increased risk of myocardial infarction in depressed patients with type 2 diabetes. *Diabetes Care* 34:1729-1734, 2011 Reason for inclusion: retrospective cohort study showing that those with combination of diabetes and depression are at significantly higher risk of MI. ABSTRACT: OBJECTIVE: To investigate major depressive disorder (MDD), which complicates the course of type 2 diabetes and is associated with an increased risk of cardiovascular disease and death. This risk may be due to a greater susceptibility for myocardial infarction (MI) in depressed patients with type 2 diabetes compared with nondepressed patients with type 2 diabetes. RESEARCH DESIGN AND METHODS: Veterans Administration electronic medical records were analyzed to identify a cohort free of cardiovascular disease in fiscal years 1999 and 2000, aged 25 to 80 years. ICD-9-CM codes were used to create a four-level risk group indicating 1) neither diabetes nor MDD (n = 214,749), 2) MDD alone (n = 77,568), 3) type 2 diabetes alone (n = 40,953), and 4) comorbid MDD and type 2 diabetes	(RM2356-beverly) (2357-katon

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			(n = 12,679). Age-adjusted Cox proportional hazards models were computed before and after adjusting for baseline sociodemographic and time-dependent covariates. RESULTS: After adjusting for covariates, patients with type 2 diabetes alone and patients with MDD alone were at ~30% increased risk for MI, and patients with type 2 diabetes and MDD were at 82% increased risk for MI (hazard ratio 1.82 [95% CI 1.69-1.97]) compared with patients without either condition. CONCLUSIONS: Compared with patients with only diabetes or only MDD, individuals with type 2 diabetes and MDD are at increased risk for new-onset MI. Monitoring cardiovascular health in depressed patients with type 2 diabetes may reduce the risk of MI in this especially high-risk group. <u>References 210</u> in 2013 ADA Standards of Care: Bot M, Pouwer F, Zuidersma M, van Melle JP, de JP: Association of coexisting diabetes and depression with mortality after myocardial infarction. *Diabetes Care* 35:503-509, 2012 <u>Reason for inclusion</u>: retrospective cohort study showing that those with combination of diabetes and depression are at significantly higher risk of mortality after MI.	) (2 3 5 9 - S h e e r)

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			ABSTRACT: OBJECTIVE: Diabetes and depression are both linked to an increased mortality risk after myocardial infarction (MI). Population-based studies suggest that having both diabetes and depression results in an increased mortality risk, beyond that of having diabetes or depression alone. The purpose of this study was to examine the joint association of diabetes and depression with mortality in MI patients. RESEARCH DESIGN AND METHODS: Data were derived from two multicenter cohort studies in the Netherlands, comprising 2,704 patients who were hospitalized for MI. Depression, defined as a Beck Depression Inventory score ≥10, and diabetes were assessed during hospitalization. Mortality data were retrieved for 2,525 patients (93%). RESULTS: During an average follow-up of 6.2 years, 439 patients died. The mortality rate was 14% (226 of 1,673) in patients without diabetes and depression, 23% (49 of 210) in patients with diabetes only, 22% (118 of 544) in patients with depression only, and 47% (46 of 98) in patients with both diabetes and depression. After adjustment for age, sex, smoking, hypertension, left ventricular ejection fraction, prior MI, and Killip class, hazard ratios for all-cause mortality	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			were 1.38 (95% CI 1.00-1.90) for patients with diabetes only, 1.39 (1.10-1.76) for patients with depression only, and as much as 2.90 (2.07-4.07) for patients with both diabetes and depression. CONCLUSIONS: We observed an increased mortality risk in post-MI patients with both diabetes and depression, beyond the association with mortality of diabetes and depression alone. Reference 211 in 2013 ADA Standards of Care: Sullivan MD, O'Connor P, Feeney P, Hire D, Simmons DL, Raisch DW, Fine LJ, Narayan KM, Ali MK, Katon WJ: Depression Predicts All-Cause Mortality: Epidemiological evaluation from the ACCORD HRQL substudy. *Diabetes Care* 35:1708-1715, 2012 Reason for inclusion: Post-hoc analysis of ACCORD study showing that depression associated with all-cause mortality. ABSTRACT: OBJECTIVE: Depression affects up to 20-25% of adults with type 2 diabetes and may increase all-cause mortality, but few well-designed studies have examined the effects of depression on the full range of cardiovascular disease outcomes in type 2 diabetes. RESEARCH DESIGN AND METHODS: A total of 2,053 participants in the ACCORD (Action to	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			Control Cardiovascular Risk in Diabetes) Health-Related Quality of Life substudy completed the Patient Health Questionnaire (PHQ)-9 measure of depression symptoms at baseline and 12, 36, and 48 months. Cox proportional hazards regression models were used to estimate hazard ratios (HRs) (95% CI) for the time-varying impact of depression on protocol-defined clinical outcomes with and without adjustment for demographic, trial-related, clinical, and behavioral variables. RESULTS: In fully adjusted models, depression was not significantly related to the ACCORD primary composite outcome (cardiovascular death, nonfatal heart attack, or stroke) (HR 1.53 [95% CI 0.85-2.73]) or to the ACCORD microvascular composite outcome (0.93 [0.53-1.62]), but all-cause mortality was significantly increased both in those with PHQ-assessed probable major depression (2.24 [1.24-4.06]) and PHQ score of ≥ 10 (1.84 [1.17-2.89]). The effect of depression on all-cause mortality was not related to previous cardiovascular events or to assignment to intensive or standard glycemia control. Probable major depression (by PHQ-9) had a borderline impact on the ACCORD macrovascular end point (1.42 [0.99-2.04]). CONCLUSIONS: Depression increases the risk of all-cause mortality and may increase the risk of	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			macrovascular events among adults with type 2 diabetes at high risk for cardiovascular events.	
Hypoglycemia				
	Individuals at risk for hypoglycemia should be asked about symptomatic and asymptomatic hypoglycemia at each encounter. (C)	New evidence, more specific provider advice	Reference 228 of 2013 ADA Standards of Care: McCoy RG, Van Houten HK, Ziegenfuss JY, Shah ND, Wermers RA, Smith SA: Increased mortality of patients with diabetes reporting severe hypoglycemia. *Diabetes Care* 35:1897-1901, 2012 Reason for inclusion: Prospective cohort study showing that self-reported severe hypoglycemia was significantly associated with mortality ABSTRACT: OBJECTIVE: Hypoglycemia is a cause of significant morbidity among patients with diabetes and may be associated with greater risk of death. We conducted a retrospective study to determine whether patient self-report of severe hypoglycemia is associated with increased mortality. RESEARCH DESIGN AND METHODS: Adult patients (N = 1,020) seen in a specialty diabetes clinic between August 2005 and July 2006 were questioned about frequency of hypoglycemia during a pre-encounter interview; 7 were lost to follow-up and excluded from analysis. Mild	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			hypoglycemia was defined as symptoms managed without assistance, and severe hypoglycemia was defined as symptoms requiring external assistance. Mortality data, demographics, clinical characteristics, and Charlson comorbidity index (CCI) were obtained from the electronic medical record after 5 years. Patients were stratified by self-report of hypoglycemia at baseline, demographics were compared using the two-sample t test, and risk of death was expressed as odds ratio (95% CI). Associations were controlled for age, sex, diabetes type and duration, CCI, HbA(1c), and report of severe hypoglycemia. RESULTS: In total, 1,013 patients with type 1 (21.3%) and type 2 (78.7%) diabetes were questioned about hypoglycemia. Among these, 625 (61.7%) reported any hypoglycemia, and 76 (7.5%) reported severe hypoglycemia. After 5 years, patients who reported severe hypoglycemia had 3.4-fold higher mortality (95% CI 1.5-7.4; P = 0.005) compared with those who reported mild/no hypoglycemia. CONCLUSIONS: Self-report of severe hypoglycemia is associated with 3.4-fold increased risk of death. Patient-reported outcomes, including patient-reported hypoglycemia, may therefore augment risk stratification and disease management of patients	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			with diabetes.	
Glucose (15–20 g) is the preferred treatment for the conscious individual with hypoglycemia, although any form of carbohydrate that contains glucose may be used. If SMBG 15 min after treatment shows continued hypoglycemia, the treatment should be repeated. Once SMBG glucose returns to normal, the individual should consume a meal or snack to prevent recurrence of hypoglycemia. (E)	No change			
Glucagon should be prescribed for all individuals at significant risk of severe hypoglycemia, and caregivers or family members of these individuals should be instructed in its administration. Glucagon administration is not limited to health care	No change			

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
professionals. (E)				
Individuals with hypoglycemia unawareness or one or more episodes of severe hypoglycemia should be advised to raise their glycemic targets to strictly avoid further hypoglycemia for at least several weeks, to partially reverse hypoglycemia unawareness and reduce the risk of future episodes. (B)	Hypoglycemia unawareness or one or more episodes of severe hypoglycemia should trigger re-evaluation of the treatment regimen. (E)	To provide more specific advice, and reflect the evidence that in type 2 patients, hypoglycemia may be more a function of regimen used than glycemic targets		
	Insulin-treated patients with hypoglycemia unawareness or an episode of severe hypoglycemia should be advised to raise their glycemic targets to strictly avoid further hypoglycemia for at least several weeks, to partially reverse hypoglycemia unawareness and reduce risk of future episodes. (A)	Recommendation level changed to reflect the evidence base.		

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
	Ongoing assessment of cognitive function is suggested with increased vigilance for hypoglycemia by the clinician, patient and caregivers if low cognition and/or declining cognition is found. (B)	New evidence	Reference 225 of 2013 ADA Standards of Care: Punthakee Z, Miller ME, Launer LJ, Williamson JD, Lazar RM, Cukierman-Yaffee T, Seaquist ER, Ismail-Beigi F, Sullivan MD, Lovato LC, Bergenstal RM, Gerstein HC: Poor cognitive function and risk of severe hypoglycemia in type 2 diabetes: post hoc epidemiologic analysis of the ACCORD trial. *Diabetes Care* 35:787-793, 2012 Reason for inclusion: Post-hoc analysis of ACCORD trial showing that poor baseline cognitive function and decline in function were associated with risk of severe hypoglycemia during the trial. ABSTRACT: OBJECTIVE: Self-management of type 2 diabetes including avoidance of hypoglycemia is complex, but the impact of cognition on safe self-management is not well understood. This study aimed to assess the effect of baseline cognitive function and cognitive decline on subsequent risk of severe hypoglycemia and to assess the effect of different glycemic strategies on these relationships. RESEARCH DESIGN AND METHODS: Prospective cohort analysis of data from the ACCORD trial included 2,956 adults aged ≥55 years with type 2 diabetes and additional cardiovascular risk factors. Cognitive tests (Digit Symbol Substitution Test	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			[DSST], Rey Auditory Verbal Learning Test, Stroop Test, and Mini Mental Status Examination) were conducted at baseline and 20 months. Study outcomes were incident confirmed severe hypoglycemia requiring medical assistance (HMA) and hypoglycemia requiring any assistance (HAA). RESULTS: After a median 3.25-year follow-up, a 5-point-poorer baseline score on the DSST was predictive of a first episode of HMA (hazard ratio 1.13 [95% CI 1.08-1.18]). Analyses of the other cognitive tests and of HAA were consistent with the DSST results. Cognitive decline over 20 months increased the risk of subsequent hypoglycemia to a greater extent in those with lower baseline cognitive function (P(interaction) = 0.037). Randomization to an intensive versus standard glycemic strategy had no impact on the relationship between cognitive function and the risk of severe hypoglycemia. CONCLUSIONS: Poor cognitive function increases the risk of severe hypoglycemia in patients with type 2 diabetes. Clinicians should consider cognitive function in assessing and guiding their patients regarding safe diabetes self-management regardless of their glycemic targets.	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
Bariatric surgery				
Bariatric surgery may be considered for adults with BMI >35 kg/m2 and type 2 diabetes, especially if the diabetes or associated comorbidities are difficult to control with lifestyle and pharmacologic therapy. (B)	No change		Reference 230 of 2013 ADA Standards of Care: Schauer PR, Kashyap SR, Wolski K, Brethauer SA, Kirwan JP, Pothier CE, Thomas S, Abood B, Nissen SE, Bhatt DL: Bariatric surgery versus intensive medical therapy in obese patients with diabetes. *N Engl J Med* 366:1567-1576, 2012 Reason for inclusion: RCT showing significantly higher rates of diabetes remission at 12 months in those undergoing bariatric surgery plus medical therapy vs. medical therapy alone. ABSTRACT: BACKGROUND: Observational studies have shown improvement in patients with type 2 diabetes mellitus after bariatric surgery. METHODS: In this randomized, nonblinded, single-center trial, we evaluated the efficacy of intensive medical therapy alone versus medical therapy plus Roux-en-Y gastric bypass or sleeve gastrectomy in 150 obese patients with uncontrolled type 2 diabetes. The mean (±SD) age of the patients was 49±8 years, and 66% were women. The average glycated hemoglobin	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			level was 9.2±1.5%. The primary end point was the proportion of patients with a glycated hemoglobin level of 6.0% or less 12 months after treatment. RESULTS: Of the 150 patients, 93% completed 12 months of follow-up. The proportion of patients with the primary end point was 12% (5 of 41 patients) in the medical-therapy group versus 42% (21 of 50 patients) in the gastric-bypass group (P=0.002) and 37% (18 of 49 patients) in the sleeve-gastrectomy group (P=0.008). Glycemic control improved in all three groups, with a mean glycated hemoglobin level of 7.5±1.8% in the medical-therapy group, 6.4±0.9% in the gastric-bypass group (P<0.001), and 6.6±1.0% in the sleeve-gastrectomy group (P=0.003). Weight loss was greater in the gastric-bypass group and sleeve-gastrectomy group (-29.4±9.0 kg and -25.1±8.5 kg, respectively) than in the medical-therapy group (-5.4±8.0 kg) (P<0.001 for both comparisons). The use of drugs to lower glucose, lipid, and blood-pressure levels decreased significantly after both surgical procedures but increased in patients receiving medical therapy only. The index for homeostasis model assessment of insulin resistance (HOMA-IR) improved significantly after bariatric surgery. Four patients underwent reoperation. There were no deaths or life-	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			threatening complications. CONCLUSIONS: In obese patients with uncontrolled type 2 diabetes, 12 months of medical therapy plus bariatric surgery achieved glycemic control in significantly more patients than medical therapy alone. Further study will be necessary to assess the durability of these results. Reference 231 of 2013 ADA Standards of Care: Mingrone G, Panunzi S, De GA, Guidone C, Iaconelli A, Leccesi L, Nanni G, Pomp A, Castagneto M, Ghirlanda G, Rubino F: Bariatric surgery versus conventional medical therapy for type 2 diabetes. *N Engl J Med* 366:1577-1585, 2012 Reason for inclusion: RCT showing significantly higher rates of diabetes remission at 2 years with two different forms of bariatric surgery than medical therapy alone. ABSTRACT: BACKGROUND: Roux-en-Y gastric bypass and biliopancreatic diversion can markedly ameliorate diabetes in morbidly obese patients, often resulting in disease remission. Prospective, randomized trials comparing these procedures with medical therapy for the treatment of diabetes are	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			needed. METHODS: In this single-center, nonblinded, randomized, controlled trial, 60 patients between the ages of 30 and 60 years with a body-mass index (BMI, the weight in kilograms divided by the square of the height in meters) of 35 or more, a history of at least 5 years of diabetes, and a glycated hemoglobin level of 7.0% or more were randomly assigned to receive conventional medical therapy or undergo either gastric bypass or biliopancreatic diversion. The primary end point was the rate of diabetes remission at 2 years (defined as a fasting glucose level of <100 mg per deciliter [5.6 mmol per liter] and a glycated hemoglobin level of <6.5% in the absence of pharmacologic therapy). RESULTS: At 2 years, diabetes remission had occurred in no patients in the medical-therapy group versus 75% in the gastric-bypass group and 95% in the biliopancreatic-diversion group (P<0.001 for both comparisons). Age, sex, baseline BMI, duration of diabetes, and weight changes were not significant predictors of diabetes remission at 2 years or of improvement in glycemia at 1 and 3 months. At 2 years, the average baseline glycated hemoglobin level (8.65±1.45%) had decreased in all groups, but patients in the two surgical groups had the greatest degree of improvement (average glycated hemoglobin levels,	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			7.69±0.57% in the medical-therapy group, 6.35±1.42% in the gastric-bypass group, and 4.95±0.49% in the biliopancreatic-diversion group). CONCLUSIONS: In severely obese patients with type 2 diabetes, bariatric surgery resulted in better glucose control than did medical therapy. Preoperative BMI and weight loss did not predict the improvement in hyperglycemia after these procedures. Reference 232 of 2013 ADA Standards of Care: Dorman RB, Serrot FJ, Miller CJ, Slusarek BM, Sampson BK, Buchwald H, Leslie DB, Bantle JP, Ikramuddin S: Case-matched outcomes in bariatric surgery for treatment of type 2 diabetes in the morbidly obese patient. *Ann Surg* 255:287-293, 2012 Reason for inclusion; Retrospective case-matched study of three forms of bariatric surgery vs. medical therapy, showing significantly more weight loss and diabetes remission with surgery and describing differences among procedures. ABSTRACT: OBJECTIVE: To compare the relative efficacy of medical management, the duodenal switch (DS), and the laparoscopic adjustable gastric band (LAGB) to the Roux-en-Y gastric bypass (RYGB)	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			for treatment of type 2 diabetes mellitus (T2DM). BACKGROUND: The RYGB resolves T2DM in a high proportion of patients and is considered the standard operation for T2DM resolution in morbidly obese patients. However, no data exist comparing the efficacy of medical management and other bariatric operations to the RYGB for treatment of T2DM in comparable patient populations. METHODS: We performed a retrospective case-matched study of morbidly obese patients with T2DM who had undergone medical management (nonsurgical controls [NSC]; N = 29), LAGB (N = 30), or DS (N = 27) and were compared with matched T2DM patients who had undergone RYGB. Matching was performed with respect to age, sex, body mass index, and hemoglobin A1C (HbA1C). Outcomes assessed were changes in body mass index, HbA1C, and diabetes medication scores at 1 year. RESULTS: The Roux-en-Y gastric bypass produced greater weight loss, HbA1C normalization, and medication score reduction compared to both NSC and LAGB-matched cohorts. Duodenal switch produced greater reductions in HbA1C and medication score than RYGB, despite no greater weight loss at 1 year. Surgical complications were rarely life threatening. CONCLUSIONS: This study provides an important perspective about the	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			comparative efficacy of LAGB, DS, and NSC to the RYGB for treatment of T2DM among obese patients. After 1 year of follow-up, RYGB is superior to NSC and LAGB with respect to weight loss and improvement in diabetes whereas DS is superior to RYGB in reducing HbA1C and medication score.	
Patients with type 2 diabetes who have undergone bariatric surgery need life-long lifestyle support and medical monitoring. (B)	No changes			
Although small trials have shown glycemic benefit of bariatric surgery in patients with type 2 diabetes and BMI of 30–35 kg/m2, there is currently insufficient evidence to generally recommend surgery in patients with BMI <35 kg/m2 outside of a research protocol. (E)	No change		Reference 235 of 2013 ADA Standards of Care: Cohen RV, Pinheiro JC, Schiavon CA, Salles JE, Wajchenberg BL, Cummings DE: Effects of gastric bypass surgery in patients with type 2 diabetes and only mild obesity. *Diabetes Care* 35:1420-1428, 2012 Reason for inclusion: Cohort study of patients with type 2 diabetes and BMI of 30-35 kg/m2 undergoing Roux-en-Y gastric bypass, showing high rates of diabetes remission at median of 5 years. ABSTRACT: OBJECTIVE: Roux-en-Y gastric bypass (RYGB) ameliorates type 2 diabetes in severely obese patients through mechanisms beyond just weight	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			loss, and it may benefit less obese diabetic patients. We determined the long-term impact of RYGB on patients with diabetes and only class I obesity. RESEARCH DESIGN AND METHODS: Sixty-six consecutively selected diabetic patients with BMI 30-35 kg/m(2) underwent RYGB in a tertiary-care hospital and were prospectively studied for up to 6 years (median 5 years [range 1-6]), with 100% follow-up. Main outcome measures were safety and the percentage of patients experiencing diabetes remission (HbA(1c) <6.5% without diabetes medication). RESULTS: Participants had severe, longstanding diabetes, with disease duration 12.5 ± 7.4 years and HbA(1c) 9.7 ± 1.5%, despite insulin and/or oral diabetes medication usage in everyone. For up to 6 years following RYGB, durable diabetes remission occurred in 88% of cases, with glycemic improvement in 11%. Mean HbA(1c) fell from 9.7 ± 1.5 to 5.9 ± 0.1% (P < 0.001), despite diabetes medication cessation in the majority. Weight loss failed to correlate with several measures of improved glucose homeostasis, consistent with weight-independent antidiabetes mechanisms of RYGB. C-peptide responses to glucose increased substantially, suggesting improved β-cell function. There was no mortality, major surgical morbidity, or excessive	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			weight loss. Hypertension and dyslipidemia also improved, yielding 50-84% reductions in predicted 10-year cardiovascular disease risks of fatal and nonfatal coronary heart disease and stroke. CONCLUSIONS: This is the largest, longest-term study examining RYGB for diabetic patients without severe obesity. RYGB safely and effectively ameliorated diabetes and associated comorbidities, reducing cardiovascular risk, in patients with a BMI of only 30-35 kg/m(2).	
The long-term benefits, cost-effectiveness, and risks of bariatric surgery in individuals with type 2 diabetes should be studied in well-designed controlled trials with optimal medical and lifestyle therapy as the comparator. (E)	No change			
Immunization				
Annually provide an influenza vaccine to all diabetic patients ≥6 months of age. (C)	No change			

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
Administer pneumococcal polysaccharide vaccine to all diabetic patients ≥2 years of age. A one-time revaccination is recommended for individuals >64 years of age previously immunized when they were <65 years of age if the vaccine was administered >5 years ago. Other indications for repeat vaccination include nephrotic syndrome, chronic renal disease, and other immunocompromised states, such as after transplantation. (C)	No change			
Administer hepatitis B vaccination to adults with diabetes as per Centers for Disease Control and Prevention (CDC) recommendations. (C)	Administer hepatitis B vaccination to unvaccinated adults with diabetes mellitus who are aged 19 through 59 years (C).	To update to published CDC recommendation (In press when last year's Standards of Care came out)	Reference 246 of 2013 ADA Standards of Care: Centers for Disease Control and Prevention. Use of hepatitis B vaccination for adults with diabetes mellitus: recommendaitons of the Advisory Committe on Immunization Practices (ACIP). MMWR 60, 1709-1711. 2012 Reason for inclusion: Provides the rationale for new CDC recommendations, inclusing increased hazard ratio for hepatitis B infection among people with diabetes, description of HBV outbreaks with assisted blood glucose monitoring, cost-effectiveness analyses of vaccinating younger vs. older adults.	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			No abstract available.	
	Consider administering hepatitis B vaccination to unvaccinated adults with diabetes mellitus who are aged ≥60 years (C)	To update to published CDC recommendation (In press when last year's Standards of Care came out)	See above (Reference 246)	
Hypertension/blood pressure control				
Screening				
Blood pressure should be measured at every routine diabetes visit. Patients found to have systolic blood pressure ≥130 mmHg or diastolic blood pressure ≥80 mmHg should have blood pressure confirmed on a separate day. Repeat systolic blood pressure ≥130 mmHg or diastolic blood pressure ≥80 mmHg confirms a diagnosis of hypertension. (C)	Blood pressure should be measured at every routine diabetes visit. Patients found to have elevated blood pressure should have blood pressure confirmed on a separate day.(B)	To reflect change in BP target in following recommendation		

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
Goals				
A goal systolic blood pressure <130 mmHg is appropriate for most patients with diabetes. (C)	People with diabetes and hypertension should be treated to a systolic blood pressure goal of less than 140 mm Hg. (B)	To reflect the preponderance of evidence	Reference 262 in 2013 ADA Standards of Care: McBrien K, Rabi DM, Campbell N, Barnieh L, Clement F, Hemmelgarn BR, Tonelli M, Leiter LA, Klarenbach SW, Manns BJ: Intensive and Standard Blood Pressure Targets in Patients With Type 2 Diabetes Mellitus: Systematic Review and Meta-analysis. *Arch Intern Med*1-8, 2012 Reason for inclusion: SR and meta-analysis of trials of intensive vs. standard BP targets in patients with type 2 diabetes, showing no reduction in MI or mortality but small reduction in stroke with more intensive targets. ABSTRACT: BACKGROUND Treatment of hypertension in patients with diabetes mellitus (DM) has been shown to improve cardiovascular outcomes; however, the value of intensive blood pressure (BP) targets remains uncertain. We sought to determine the effectiveness and safety of treating BP to intensive targets (upper limit of 130 mm Hg systolic and 80 mm Hg diastolic) compared with standard targets (upper limit of 140-160 mm Hg systolic and 85-100 mm Hg diastolic) in patients with type 2 DM. METHODS Using electronic databases,	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			bibliographies, and clinical trial registries, we conducted a systematic review and meta-analysis to identify randomized trials enrolling adults diagnosed as having type 2 DM and comparing prespecified BP targets. Data on study characteristics, risk for bias, and outcomes were collected. Random-effects models were used to pool relative risks and risk differences for mortality, myocardial infarction, and stroke. RESULTS The use of intensive BP targets was not associated with a significant decrease in the risk for mortality (relative risk difference, 0.76; 95% CI, 0.55-1.05) or myocardial infarction (relative risk difference, 0.93; 95% CI, 0.80-1.08) but was associated with a decrease in the risk for stroke (relative risk, 0.65; 95% CI, 0.48-0.86). The pooled analysis of risk differences associated with the use of intensive BP targets demonstrated a small absolute decrease in the risk for stroke (absolute risk difference, -0.01; 95% CI, -0.02 to -0.00) but no statistically significant difference in the risk for mortality or myocardial infarction. CONCLUSION Although the use of intensive compared with standard BP targets in patients with type 2 DM is associated with a small reduction in the risk for stroke, evidence does not show that intensive targets reduce the risk for mortality or myocardial infarction. Reference 263 in 2013 ADA Standards of Care: Bangalore S, Kumar S, Lobach I, Messerli FH: Blood pressure targets in subjects with type 2 diabetes	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			mellitus/impaired fasting glucose: observations from traditional and bayesian random-effects meta-analyses of randomized trials. *Circulation* 123:2799-810, 9, 2011 Reason for inclusion: Traditional and bayesian meta-analysis of trials of intensive vs. standard BP targets in patients with type 2 diabetes, showing no reduction in MI or mortality but small reduction in stroke with more intensive targets. ABSTRACT: BACKGROUND: Most guidelines for treatment of hypertension recommend a blood pressure (BP) goal of <140/90 mm Hg, and a more aggressive goal of <130/80 mm Hg for patients with diabetes mellitus. However, in the recent Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial, a lower BP was not beneficial. The optimal BP target in subjects with diabetes mellitus or those with impaired fasting glucose/glucose tolerance is therefore not well defined. METHODS AND RESULTS: We performed PUBMED, EMBASE, and CENTRAL searches for randomized clinical trials from 1965 through October 2010 of antihypertensive therapy in patients with type 2 diabetes mellitus or impaired fasting glucose/impaired glucose tolerance that enrolled at least 100 patients with achieved systolic	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			BP of ≤ 135 mm Hg in the intensive BP control group and ≤ 140 mm Hg in the standard BP control group, had a follow-up of at least 1 year, and evaluated macrovascular or microvascular events. We identified 13 randomized clinical trials enrolling 37 736 participants. Intensive BP control was associated with a 10% reduction in all-cause mortality (odds ratio, 0.90; 95% confidence interval, 0.83 to 0.98), a 17% reduction in stroke, and a 20% increase in serious adverse effects, but with similar outcomes for other macrovascular and microvascular (cardiac, renal, and retinal) events compared with standard BP control. The results were similar in a sensitivity analysis using a bayesian random-effects model. More intensive BP control (≤ 130 mm Hg) was associated with a greater reduction in stroke, but did not reduce other events. Meta-regression analysis showed continued risk reduction for stroke to a systolic BP of <120 mm Hg. However, at levels <130 mm Hg, there was a 40% increase in serious adverse events with no benefit for other outcomes. CONCLUSIONS: The present body of evidence suggests that in patients with type 2 diabetes mellitus/impaired fasting glucose/impaired glucose tolerance, a systolic BP treatment goal of 130 to 135 mm Hg is acceptable. However, with more aggressive	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			goals (<130 mm Hg), we observed target organ heterogeneity in that the risk of stroke continued to fall, but there was no benefit regarding the risk of other macrovascular or microvascular (cardiac, renal and retinal) events, and the risk of serious adverse events even increased.	
Based on patient characteristics and response to therapy, higher or lower systolic blood pressure targets may be appropriate. (B)	Lower systolic targets, such as <130 mm Hg, may be appropriate for certain individuals, such as younger patients, if it can be achieved without undue treatment burden. (C)	To reflect the preponderance of evidence (secondary outcomes such as stroke and microvascular outcomes)	See above (References 262 and 263)	
Patients with diabetes should be treated to a diastolic blood pressure <80 mmHg. (B)	No change			
Treatment				
Patients with a systolic blood pressure of 130–139 mmHg or a diastolic blood pressure of 80–89 mmHg may be given lifestyle therapy alone for a maximum of 3 months and then, if targets are	Patients with a blood pressure greater than 120/80 mmHg should be advised on lifestyle changes to reduce blood pressure. (B)	To reflect changes in systolic BP targets and to be consistent with recommendations for all adults with		

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
not achieved, be treated with the addition of pharmacological agents. (E)		prehypertension		
Patients with more severe hypertension (systolic blood pressure ≥140 or diastolic blood pressure ≥90 mmHg) at diagnosis or follow-up should receive pharmacologic therapy in addition to lifestyle therapy. (A)	Patients with confirmed blood pressure higher than 140/80 mm Hg should, in addition to lifestyle therapy, have prompt initiation and timely subsequent titration of pharmacologic therapy to achieve blood pressure goals. (B	To reflect changes in systolic BP targets		
Lifestyle therapy for hypertension consists of: weight loss, if overweight; DASH (Dietary Approaches to Stop Hypertension)-style dietary pattern, including reducing sodium and increasing potassium intake; moderation of alcohol intake; and increased physical activity. (B)	Lifestyle therapy for elevated blood pressure consists of: weight loss, if overweight; DASH (Dietary Approaches to Stop Hypertension)-style dietary pattern, including reducing sodium and increasing potassium intake; moderation of alcohol intake; and increased physical activity. (B)	Clarification		
Pharmacologic therapy for patients with diabetes and	No change			

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
hypertension should be with a regimen that includes either an ACE inhibitor or an ARB. If one class is not tolerated, the other should be substituted. (C)				
Multiple drug therapy (two or more agents at maximal doses) is generally required to achieve blood pressure targets. (B)	No change			
Administer one or more anti-hypertensive medications at bedtime. (A)	No change			
If ACE inhibitors, ARBs, or diuretics are used, kidney function and serum potassium levels should be monitored. (E)	If ACE inhibitors, ARBs, or diuretics are used, serum creatinine/eGFR and serum potassium levels should be monitored. (E)	Clarification		

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
In pregnant patients with diabetes and chronic hypertension, blood pressure target goals of 110–129/65–79 mmHg are suggested in the interest of long-term maternal health and minimizing impaired fetal growth. ACE inhibitors and ARBs are contraindicated during pregnancy. (E)	No change			
Dyslipidemia/lipid management				
Screening				
In most adult patients, measure fasting lipid profile at least annually. In adults with low-risk lipid values (LDL cholesterol <100 mg/dl, HDL cholesterol >50 mg/dl, and triglycerides <150 mg/dl), lipid assessments may be repeated every 2 years. (E)	In most adult patients with diabetes, measure fasting lipid profile at least annually (B).	To better reflect the evidence		

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
	In adults with low-risk lipid values (LDL cholesterol <100 mg/dl, HDL cholesterol >50 mg/dl, and triglycerides <150 mg/dl), lipid assessments may be repeated every 2 years. (E)	To better reflect the evidence		
Treatment recommendations and goals				
Lifestyle modification focusing on the reduction of saturated fat, trans fat, and cholesterol intake; the increase of omega-3 fatty acids, viscous fiber, and plant stanols/sterols; weight loss (if indicated); and increased physical activity should be recommended to improve the lipid profile in patients with diabetes. (A)	No changes			
Statin therapy should be added to lifestyle therapy, regardless of baseline lipid levels, for diabetic patients:	No change			

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
• with overt CVD (A) • without CVD who are over the age of 40 years and have one or more other CVD risk factors (A)				
For lower-risk patients than those above (e.g., those without overt CVD and under the age of 40 years), statin therapy should be considered in addition to lifestyle therapy if LDL cholesterol remains >100 mg/dL or in those with multiple CVD risk factors. (E)	For lower risk patients than the above (e.g. without overt CVD and under the age of 40), statin therapy should be considered in addition to lifestyle therapy if LDL-C remains above 100 mg/dl or in those with multiple CVD risk factors (C)	Change in level to reflect the limited (but more than expert opinion) evidence for statin benefits in lower risk patients	Reference 280 of 2013 ADA Standards of Care: Mihaylova B, Emberson J, Blackwell L, Keech A, Simes J, Barnes EH, Voysey M, Gray A, Collins R, Baigent C: The effects of lowering LDL cholesterol with statin therapy in people at low risk of vascular disease: meta-analysis of individual data from 27 randomised trials. *Lancet* 380:581-590, 2012 Reason for inclusion: meta-analysis showing significant benefits of statin therapy even in low-risk individuals. ABSTRACT: BACKGROUND: Statins reduce LDL cholesterol and prevent vascular events, but their net effects in people at low risk of vascular events remain uncertain. METHODS: This meta-analysis included	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			individual participant data from 22 trials of statin versus control (n=134,537; mean LDL cholesterol difference 1·08 mmol/L; median follow-up 4·8 years) and five trials of more versus less statin (n=39,612; difference 0·51 mmol/L; 5·1 years). Major vascular events were major coronary events (ie, non-fatal myocardial infarction or coronary death), strokes, or coronary revascularisations. Participants were separated into five categories of baseline 5-year major vascular event risk on control therapy (no statin or low-intensity statin) (<5%, ≥5% to <10%, ≥10% to <20%, ≥20% to <30%, ≥30%); in each, the rate ratio (RR) per 1·0 mmol/L LDL cholesterol reduction was estimated. FINDINGS: Reduction of LDL cholesterol with a statin reduced the risk of major vascular events (RR 0·79, 95% CI 0·77-0·81, per 1·0 mmol/L reduction), largely irrespective of age, sex, baseline LDL cholesterol or	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			previous vascular disease, and of vascular and all-cause mortality. The proportional reduction in major vascular events was at least as big in the two lowest risk categories as in the higher risk categories (RR per 1·0 mmol/L reduction from lowest to highest risk: 0·62 [99% CI 0·47-0·81], 0·69 [99% CI 0·60-0·79], 0·79 [99% CI 0·74-0·85], 0·81 [99% CI 0·77-0·86], and 0·79 [99% CI 0·74-0·84]; trend p=0·04), which reflected significant reductions in these two lowest risk categories in major coronary events (RR 0·57, 99% CI 0·36-0·89, p=0·0012, and 0·61, 99% CI 0·50-0·74, p<0·0001) and in coronary revascularisations (RR 0·52, 99% CI 0·35-0·75, and 0·63, 99% CI 0·51-0·79; both p<0·0001). For stroke, the reduction in risk in participants with 5-year risk of major vascular events lower than 10% (RR per 1·0 mmol/L LDL cholesterol reduction 0·76, 99% CI 0·61-0·95, p=0·0012) was also similar to that seen in higher risk	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			categories (trend p=0·3). In participants without a history of vascular disease, statins reduced the risks of vascular (RR per 1·0 mmol/L LDL cholesterol reduction 0·85, 95% CI 0·77-0·95) and all-cause mortality (RR 0·91, 95% CI 0·85-0·97), and the proportional reductions were similar by baseline risk. There was no evidence that reduction of LDL cholesterol with a statin increased cancer incidence (RR per 1·0 mmol/L LDL cholesterol reduction 1·00, 95% CI 0·96-1·04), cancer mortality (RR 0·99, 95% CI 0·93-1·06), or other non-vascular mortality. INTERPRETATION: In individuals with 5-year risk of major vascular events lower than 10%, each 1 mmol/L reduction in LDL cholesterol produced an absolute reduction in major vascular events of about 11 per 1000 over 5 years. This benefit greatly exceeds any known hazards of statin therapy. Under present guidelines, such individuals would	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			not typically be regarded as suitable for LDL-lowering statin therapy. The present report suggests, therefore, that these guidelines might need to be reconsidered. Reference 291 of 2013 ADA Standards of Care: Ridker PM, Pradhan A, MacFadyen JG, Libby P, Glynn RJ: Cardiovascular benefits and diabetes risks of statin therapy in primary prevention: an analysis from the JUPITER trial. *Lancet* 380:565-571, 2012 Reason for inclusion: Post-hoc analysis of Jupiter trial, suggesting the CVD benefits of statins outweigh the risks of incident DM. ABSTRACT: BACKGROUND: In view of evidence that statin therapy increases risk of diabetes, the balance of benefit and risk of these drugs in primary prevention has become controversial. We undertook an analysis of participants from the	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			JUPITER trial to address the balance of vascular benefits and diabetes hazard of statin use. METHODS: In the randomised, double-blind JUPITER trial, 17,603 men and women without previous cardiovascular disease or diabetes were randomly assigned to rosuvastatin 20 mg or placebo and followed up for up to 5 years for the primary endpoint (myocardial infarction, stroke, admission to hospital for unstable angina, arterial revascularisation, or cardiovascular death) and the protocol-prespecified secondary endpoints of venous thromboembolism, all-cause mortality, and incident physician-reported diabetes. In this analysis, participants were stratified on the basis of having none or at least one of four major risk factors for developing diabetes: metabolic syndrome, impaired fasting glucose, body-mass index 30 kg/m(2) or higher, or glycated haemoglobin	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			A(1c) greater than 6%. The trial is registered at ClinicalTrials.gov, NCT00239681. FINDINGS: Trial participants with one or more major diabetes risk factor (n=11,508) were at higher risk of developing diabetes than were those without a major risk factor (n=6095). In individuals with one or more risk factors, statin allocation was associated with a 39% reduction in the primary endpoint (hazard ratio [HR] 0·61, 95% CI 0·47-0·79, p=0·0001), a 36% reduction in venous thromboembolism (0·64, 0·39-1·06, p=0·08), a 17% reduction in total mortality (0·83, 0·64-1·07, p=0·15), and a 28% increase in diabetes (1·28, 1·07-1·54, p=0·01). Thus, for those with diabetes risk factors, a total of 134 vascular events or deaths were avoided for every 54 new cases of diabetes diagnosed. For trial participants with no major diabetes risk factors, statin allocation was associated with a 52% reduction in the primary endpoint (HR 0·48,	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			95% CI 0·33-0·68, p=0·0001), a 53% reduction in venous thromboembolism (0·47, 0·21-1·03, p=0·05), a 22% reduction in total mortality (0·78, 0·59-1·03, p=0·08), and no increase in diabetes (0·99, 0·45-2·21, p=0·99). For such individuals, a total of 86 vascular events or deaths were avoided with no new cases of diabetes diagnosed. In analysis limited to the 486 participants who developed diabetes during follow-up (270 on rosuvastatin vs 216 on placebo; HR 1·25, 95% CI 1·05-1·49, p=0·01), the point estimate of cardiovascular risk reduction associated with statin therapy (HR 0·63, 95% CI 0·25-1·60) was consistent with that for the trial as a whole (0·56, 0·46-0·69). By comparison with placebo, statins accelerated the average time to diagnosis of diabetes by 5·4 weeks (84·3 [SD 47·8] weeks on rosuvastatin vs 89·7 [50·4] weeks on placebo). INTERPRETATION: In the	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			JUPITER primary prevention trial, the cardiovascular and mortality benefits of statin therapy exceed the diabetes hazard, including in participants at high risk of developing diabetes.	
In individuals without overt CVD, the primary goal is an LDL cholesterol <100 mg/dl (2.6 mmol/l). (A)	In individuals without overt CVD, the goal is an LDL-C <100 mg/dl (2.6 mmol/l). (B)	Clarification that the primary goal is to prescribe statin		
In individuals with overt CVD, a lower LDL cholesterol goal of <70 mg/dl (1.8 mmol/l), using a high dose of a statin, is an option. (B)	No change			
If drug-treated patients do not reach the above targets on maximal tolerated statin therapy, a reduction in LDL cholesterol of ~30–40% from baseline is an alternative therapeutic goal. (A)	No change		Reference 308 of 2013 ADA Standards of Care: Meek C, Wierzbicki AS, Jewkes C, Twomey PJ, Crook MA, Jones A, Viljoen A: Daily and intermittent rosuvastatin 5 mg therapy in statin intolerant patients: an observational study. *Curr Med Res Opin* 28:371-378, 2012 Reason for inclusion: observational study suggesting that even very low	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			doses of stain have metabolic benefits. ABSTRACT: OBJECTIVE: To examine the efficacy and tolerability of rosuvastatin 5 mg at daily and non-daily dosing regimens. RESEARCH DESIGN AND METHODS: A retrospective survey was conducted at nine primary, secondary and tertiary healthcare centres in the United Kingdom. MAIN OUTCOME MEASURES: Changes in lipid fractions from baseline values after more than 3 months' treatment. RESULTS: A total of 325 patients were identified. These patients were aged 63 ± 10 years, 50% male and prescription was mostly for primary prevention of cardiovascular disease (CVD) (59%). Co-morbidities included: established CVD present in 41%, type 2 diabetes mellitus (15%), hypertension (74%) and smoking (9%). Adverse effects had been documented to simvastatin (75%) or atorvastatin (63%). A total	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			of 289 patients (89%) tolerated rosuvastatin well and were still adherent after a median follow-up of 14.9 (3-79) months. The remainder (n = 36; 11%) discontinued the medication after median 5 months' treatment due to adverse effects. Efficacy was assessed in 224 patients who had adequate data. Baseline lipids were total cholesterol (TC) 7.41 ± 1.50 mmol/L, triglycerides (TG) 2.26 (range 0.36-18.4) mmol/L; high density lipoprotein cholesterol (HDL-C) 1.43 ± 0.47 mmol/L and low density lipoprotein cholesterol (LDL-C) 4.76 ± 1.38 mmol/L. Daily rosuvastatin (n = 134) reduced mean TC by 31%, TG 15% and LDL-C 43% (p < 0.001). Rosuvastatin 5 mg 2-3 times weekly (n = 79) reduced TC 26%, TG 16% and LDL-C 32% (p < 0.001). Weekly rosuvastatin (n = 11) reduced TC 17%, LDL-C by 23% (p < 0.001) but had no effect on TGs. Targets were attained in 17% of CHD-risk equivalent patients and	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			41% of primary prevention patients by National Cholesterol Education Program criteria and 27% and 68% using UK targets. No myositis or rhabdomyolysis was observed and alanine aminotransferase (ALT) and creatine kinase (CK) were similar to baseline. CONCLUSIONS: In this retrospective observational multicentre study, rosuvastatin 5 mg was found to be safe and biochemically effective either as daily or intermittent therapy in patients intolerant to other conventional statin regimens	
Triglyceride levels <150 mg/dl (1.7 mmol/l) and HDL cholesterol >40 mg/dl (1.0 mmol/l) in men and >50 mg/dl (1.3 mmol/l) in women are desirable. However, LDL cholesterol–targeted statin therapy remains the preferred strategy. (C)	Triglycerides levels <150 mg/dl (1.7 mmol/l) and HDL-C >40 mg/dl (1.0 mmol/l) in men and > 50 mg/dl (1.3 mmol/l) in women, are desirable (C). However, LDL-C-targeted statin therapy remains the preferred strategy. (A)	To better reflect the A level evidence for statins.		

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
If targets are not reached on maximally tolerated doses of statins, combination therapy using statins and other lipid-lowering agents may be considered to achieve lipid targets but has not been evaluated in outcome studies for either CVD outcomes or safety. (E)	Combination therapy has been shown not to provide additional cardiovascular benefit above statin therapy alone and is not generally recommended. (A)	To better reflect that there is randomized controlled trial evidence that there is no benefit (ACCORD-Lipid, AIM-HIGH, both cited already)		
Statin therapy is contraindicated in pregnancy. (B)	No change			
Antiplatelet agents				
Consider aspirin therapy (75–162 mg/day) as a primary prevention strategy in those with type 1 or type 2 diabetes at increased cardiovascular risk (10-year risk >10%). This includes most men >50 years of age or women >60 years of age who have at least one additional major risk factor (family history of CVD,	No change			

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
hypertension, smoking, dyslipidemia, or albuminuria). (C)				
Aspirin should not be recommended for CVD prevention for adults with diabetes at low CVD risk (10-year CVD risk <5%, such as in men <50 years of age and women <60 years of age with no major additional CVD risk factors), since the potential adverse effects from bleeding likely offset the potential benefits. (C)	No change			
In patients in these age-groups with multiple other risk factors (e.g. 10-year risk 5–10%), clinical judgment is required. (E)	No change			
Use aspirin therapy (75–162 mg/day) as a secondary prevention strategy in those with diabetes with a history of CVD. (A)	No change			

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
For patients with CVD and documented aspirin allergy, clopidogrel (75 mg/day) should be used. (B)	No change			
Combination therapy with ASA (75–162 mg/day) and clopidogrel (75 mg/day) is reasonable for up to a year after an acute coronary syndrome. (B)	No change			
Smoking cessation (Sue K)				
Advise all patients not to smoke. (A)	Advise all patients not to smoke or use tobacco products. (A)	Added specificity	Reference 319 of 2013 ADA Standards of Care: Voulgari C, Katsilambros N, Tentolouris N: Smoking cessation predicts amelioration of microalbuminuria in newly diagnosed type 2 diabetes mellitus: a 1-year prospective study. *Metabolism* 60:1456-1464, 2011 Reason for inclusion: Provides further benefits for the benefits of smoking cessation in people with diabetes	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			ABSTRACT: The objective of the study was to assess the effect of smoking cessation on microalbuminuria in subjects with newly diagnosed type 2 diabetes mellitus (DM). From 500 smokers newly diagnosed with type 2 DM and microalbuminuria, only 193 (96 men/97 women; age, 56.4 ± 7.8 years) agreed to participate and were educated on smoking cessation, diet, and exercise. Pharmacological interventions were not different among the studied groups. All subjects were contacted by phone monthly with emphasis on smoking cessation. Anthropometric, biochemical parameters and urine specimens were obtained at baseline and at 12-month follow-up. Microalbuminuria was defined as an albumin to creatinine ratio of 30 to 299.9 µg/mg creatinine. Ankle brachial pressure index was determined by ultrasound. A total of	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			120 (62.2%) subjects quit smoking. Prevalence of microalbuminuria was reduced at 1 year to 72.6% in the subjects who quit smoking and to 22.5% in those who continued smoking (P = .015). Multivariate logistic regression analysis demonstrated that independently associated with the reduction in albumin to creatinine ratio (84.8 vs 28.7 µg/mg creatinine) were amelioration of glycemic control (P < .001), blood pressure (P = .02), dyslipidemia (P = .02), and insulin resistance (P = .05). Smoking cessation also reduced the prevalence of peripheral vascular disease (P = .03) and neuropathy (P = .04). From the pharmacological and lifestyle interventions, smoking cessation had the highest and an independent contribution to the reduction of microalbuminuria (P < .001). Smoking cessation in newly diagnosed type 2 DM patients is associated with amelioration of	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			metabolic parameters, blood pressure, and the reduction of microalbuminuria. Stricter counseling about the importance of quitting smoking upon type 2 DM diagnosis is necessary to protect against the development of diabetic nephropathy and vascular complications.	
Include smoking cessation counseling and other forms of treatment as a routine component of diabetes care. (B)	No change			
Coronary heart disease (CHD) screening and treatment				
Screening				
In asymptomatic patients, routine screening for CAD is not recommended, as it does not improve outcomes as long as CVD risk factors are treated. (A)	No change			

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
Treatment				
In patients with known CVD, consider ACE inhibitor therapy (C) and use aspirin and statin therapy (A) (if not contraindicated) to reduce the risk of cardiovascular events. In patients with a prior myocardial infarction, B-blockers should be continued for at least 2 years after the event. (B)	No change			
Longer-term use of β-blockers in the absence of hypertension is reasonable if well tolerated, but data are lacking. (E)	Delete	Felt to be unnecessary		
Avoid thiazolidinedione (TZD) treatment in patients with symptomatic heart failure. (C)	No change			
Metformin may be used in patients with stable congestive heart failure (CHF) if renal function is normal. It should be	No change			

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
avoided in unstable or hospitalized patients with CHF. (C)				
Nephropathy screening and treatment				
General recommendations				
To reduce the risk or slow the progression of nephropathy, optimize glucose control. (A)	No Change			
To reduce the risk or slow the progression of nephropathy, optimize blood pressure control. (A)	No Change			
Screening				
Perform an annual test to assess urine albumin excretion in type 1 diabetic patients with diabetes duration of ≥5 years and in all type 2 diabetic patients starting at	No Change			

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
diagnosis. (B)				
Measure serum creatinine at least annually in all adults with diabetes regardless of the degree of urine albumin excretion. The serum creatinine should be used to estimate GFR and stage the level of chronic kidney disease (CKD), if present. (E)	No Change			
Treatment				
In the treatment of the nonpregnant patient with micro- or macroalbuminuria, either ACE inhibitors or ARBs should be used. (A)	In the treatment of the non-pregnant patient with modestly elevated (30-299 mg/d) (C) or higher levels (>300 mg/d) of urinary albumin excretion (A), either ACE inhibitors or ARBs are recommended.			
If one class is not tolerated, the other should be substituted. (E)	Delete	Implied in “either” statement in prior recommendation		
Reduction of protein intake to	Reduction of protein intake to	Recommendation		

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
0.8–1.0 g · kg body wt–1 · day–1 in individuals with diabetes and the earlier stages of CKD and to 0.8 g · kg body wt–1 · day–1 in the later stages of CKD may improve measures of renal function (urine albumin excretion rate, GFR) and is recommended. (B)	0.8–1.0 g · kg body wt–1 · day–1 in individuals with diabetes and the earlier stages of CKD and to 0.8 g · kg body wt–1 · day–1 in the later stages of CKD may improve measures of renal function (urine albumin excretion rate, GFR) and is recommended. (C)	level lowered to reflect the conflicting evidence base		
When ACE inhibitors, ARBs, or diuretics are used, monitor serum creatinine and potassium levels for the development of increased creatinine and hyperkalemia. (E)	When ACE inhibitors, ARBs, or diuretics are used, monitor serum creatinine and potassium levels for the development of increased creatinine or changes in potassium. (E)	Clarification that potassium changes may be in either direction depending on drug class		
Continued monitoring of urine albumin excretion to assess both response to therapy and progression of disease is reasonable. (E)	No Change			
When estimated GFR (eGFR) is <60 ml.min/1.73 m2, evaluate and	No Change			

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
manage potential complications of CKD. (E)				
Consider referral to a physician experienced in the care of kidney disease when there is uncertainty about the etiology of kidney disease (heavy proteinuria, active urine sediment, absence of retinopathy, rapid decline in GFR), difficult management issues, or advanced kidney disease. (B)	Consider referral to a physician experienced in the care of kidney disease for uncertainty about the etiology of kidney disease, difficult management issues, or advanced kidney disease. (B)	Clarification		
Retinopathy screening and treatment --				
General recommendations				
To reduce the risk or slow the progression of retinopathy, optimize glycemic control. (A)	No change			
To reduce the risk or slow the progression of retinopathy, optimize blood pressure control. (A)	No change			

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
Screening				
Adults and children aged 10 years or older with type 1 diabetes should have an initial dilated and comprehensive eye examination by an ophthalmologist or optometrist within 5 years after the onset of diabetes. (B)	No change			
Patients with type 2 diabetes should have an initial dilated and comprehensive eye examination by an ophthalmologist or optometrist shortly after the diagnosis of diabetes. (B)	No change			
Subsequent examinations for type 1 and type 2 diabetic patients should be repeated annually by an ophthalmologist or optometrist. Less-frequent exams (every 2–3 years) may be considered following one or more normal eye exams. Examinations will be required				

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
more frequently if retinopathy is progressing. (B)				
High-quality fundus photographs can detect most clinically significant diabetic retinopathy. Interpretation of the images should be performed by a trained eye care provider. While retinal photography may serve as a screening tool for retinopathy, it is not a substitute for a comprehensive eye exam, which should be performed at least initially and at intervals thereafter as recommended by an eye care professional. (E)	No change			
Women with pre-existing diabetes who are planning a pregnancy or who have become pregnant should have a comprehensive eye examination and be counseled on the risk of development and/or progression of diabetic retinopathy. Eye examination should occur in the first trimester with close follow-	No change			

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
up throughout pregnancy and for 1 year postpartum. (B)				
Treatment				
Promptly refer patients with any level of macular edema, severe nonproliferative diabetic retinopathy (NPDR), or any proliferative diabetic retinopathy (PDR) to an ophthalmologist who is knowledgeable and experienced in the management and treatment of diabetic retinopathy. (A)	No change			
Laser photocoagulation therapy is indicated to reduce the risk of vision loss in patients with high-risk PDR, clinically significant macular edema, and some cases of severe NPDR. (A)	No change			
	Anti-VEGF therapy is indicated for diabetic macular edema. (A)	New evidence and FDA indication	Reference 372 of 2013 ADA Standards of Care: Nguyen QD, Brown DM, Marcus DM, Boyer DS, Patel S, Feiner L, Gibson A, Sy J,	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			Rundle AC, Hopkins JJ, Rubio RG, Ehrlich JS: Ranibizumab for diabetic macular edema: results from 2 phase III randomized trials: RISE and RIDE. *Ophthalmology* 119:789-801, 2012 <u>Reason for inclusion</u>: RCT of anti-VEGF therapy, showing significant improvements in visual outcomes compared to laser therapy. ABSTRACT: PURPOSE: To evaluate the efficacy and safety of intravitreal ranibizumab in diabetic macular edema (DME) patients. DESIGN: Two parallel, methodologically identical, phase III, multicenter, double-masked, sham injection-controlled, randomized studies. PARTICIPANTS: Adults with vision loss from DME (best-corrected visual acuity [BCVA], 20/40-20/320 Snellen equivalent) and central subfield thickness ≥275 μm on time-domain optical coherence tomography (OCT). INTERVENTION: Monthly intravitreal ranibizumab (0.5 or 0.3 mg) or sham	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			injections. Macular laser was available per-protocol-specified criteria. MAIN OUTCOME MEASURES: Proportion of patients gaining ≥15 letters in BCVA from baseline at 24 months. RESULTS: In RISE (NCT00473330), 377 patients were randomized (127 to sham, 125 to 0.3 mg, 125 to 0.5 mg). At 24 months, 18.1% of sham patients gained ≥15 letters versus 44.8% of 0.3-mg (P<0.0001; difference vs sham adjusted for randomization stratification factors, 24.3%; 95% confidence interval [CI], 13.8-34.8) and 39.2% of 0.5-mg ranibizumab patients (P<0.001; adjusted difference, 20.9%; 95% CI, 10.7-31.1). In RIDE (NCT00473382), 382 patients were randomized (130 to sham, 125 to 0.3 mg, 127 to 0.5 mg). Significantly more ranibizumab-treated patients gained ≥15 letters: 12.3% of sham patients versus 33.6% of 0.3-mg patients (P<0.0001; adjusted difference, 20.8%; 95% CI,	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			11.4-30.2) and 45.7% of 0.5-mg ranibizumab patients (P<0.0001; adjusted difference, 33.3%; 95% CI, 23.8-42.8). Significant improvements in macular edema were noted on OCT, and retinopathy was less likely to worsen and more likely to improve in ranibizumab-treated patients. Ranibizumab-treated patients underwent significantly fewer macular laser procedures (mean of 1.8 and 1.6 laser procedures over 24 months in the sham groups vs 0.3-0.8 in ranibizumab groups). Ocular safety was consistent with prior ranibizumab studies; endophthalmitis occurred in 4 ranibizumab patients. The total incidence of deaths from vascular or unknown causes, nonfatal myocardial infarctions, and nonfatal cerebrovascular accidents, which are possible effects from systemic vascular endothelial growth factor inhibition, was 4.9% to 5.5% of sham	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			patients and 2.4% to 8.8% of ranibizumab patients. CONCLUSIONS: Ranibizumab rapidly and sustainably improved vision, reduced the risk of further vision loss, and improved macular edema in patients with DME, with low rates of ocular and nonocular harm. <u>Reference 373</u> of 2013 ADA Standards of Care: earson PA, Comstock TL, Ip M, Callanan D, Morse LS, Ashton P, Levy B, Mann ES, Eliott D: Fluocinolone acetonide intravitreal implant for diabetic macular edema: a 3-year multicenter, randomized, controlled clinical trial. *Ophthalmology* 118:1580-1587, 2011 <u>Reason for inclusion</u>: RCT of intra-vitreal steroids for DME, suggesting significantly better visual outcomes than standard laser therapy	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			ABSTRACT: PURPOSE: We studied the 3-year efficacy and safety results of a 4-year study evaluating fluocinolone acetonide (FA) intravitreal implants in eyes with persistent or recurrent diabetic macular edema (DME). DESIGN: Prospective, evaluator-masked, controlled, multicenter clinical trial. PARTICIPANTS: We included 196 eyes with refractory DME. METHODS: Patients were randomized 2:1 to receive 0.59-mg FA implant (n = 127) or standard of care (SOC additional laser or observation; n = 69). The implant was inserted through a pars plana incision. Visits were scheduled on day 2, weeks 1, 3, 6, 12, and 26, and thereafter every 13 weeks through 3 years postimplantation. MAIN OUTCOME MEASURES: The primary efficacy outcome was ≥15-letter improvement in visual acuity (VA) at 6 months. Secondary outcomes	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			included resolution of macular retinal thickening and Diabetic Retinopathy Severity Score (DRSS). Safety measures included incidence of adverse events (AEs). RESULTS: Overall, VA improved ≥3 lines in 16.8% of implanted eyes at 6 months (P=0.0012; SOC, 1.4%); in 16.4% at 1 year (P=0.1191; SOC, 8.1%); in 31.8% at 2 years (P=0.0016; SOC, 9.3%); and in 31.1% at 3 years (P=0.1566; SOC, 20.0%). The number of implanted eyes with no evidence of retinal thickening at the center of the macula was higher than SOC eyes at 6 months (P<0.0001), 1 year (P<0.0001; 72% vs 22%), 2 years (P=0.016), and 3 years (P=0.861). A higher rate of improvement and lower rate of decline in DRSS occurred in the implanted group versus the SOC group at 6 months (P=0.0006), 1 year (P=0.0016), 2 years (P=0.012), and 3 years (P=0.0207). Intraocular pressure (IOP) ≥30 mmHg was recorded in	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			61.4% of implanted eyes (SOC, 5.8%) at any time and 33.8% required surgery for ocular hypertension by 4 years. Of implanted phakic eyes, 91% (SOC, 20%) had cataract extraction by 4 years. CONCLUSIONS: The FA intravitreal implant met the primary and secondary outcomes, with significantly improved VA and DRSS and reduced DME. The most common AEs included cataract progression and elevated IOP. The 0.59-mg FA intravitreal implant may be an effective treatment for eyes with persistent or recurrent DME.	
The presence of retinopathy is not a contraindication to aspirin therapy for cardioprotection, as this therapy does not increase the risk of retinal hemorrhage. (A)	No change			
Neuropathy screening and treatment				

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
All patients should be screened for distal symmetric polyneuropathy (DPN) at diagnosis of type 2 diabetes and 5 years after the diagnosis of type 1 diabetes and at least annually thereafter, using simple clinical tests. (B)	No change			
Electrophysiological testing is rarely needed, except in situations where the clinical features are atypical. (E)	No change			
Screening for signs and symptoms of cardiovascular autonomic neuropathy should be instituted at diagnosis of type 2 diabetes and 5 years after the diagnosis of type 1 diabetes. Special testing is rarely needed and may not affect management or outcomes. (E)	No change			
Medications for the relief of specific symptoms related to DPN and autonomic neuropathy	No change			

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
are recommended, as they improve the quality of life of the patient. (E)				
Foot care				
For all patients with diabetes, perform an annual comprehensive foot examination to identify risk factors predictive of ulcers and amputations. The foot examination should include inspection, assessment of foot pulses, and testing for loss of protective sensation (10-g monofilament plus testing any one of: vibration using 128-Hz tuning fork, pinprick sensation, ankle reflexes, or vibration perception threshold). (B)	No change			
Provide general foot self-care education to all patients with diabetes. (B)	No change			
A multidisciplinary approach is recommended for individuals	No change		Reference 387 of 2013 ADA Standards of Care: Lipsky BA,	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
with foot ulcers and high-risk feet, especially those with a history of prior ulcer or amputation. (B)			Berendt AR, Cornia PB, Pile JC, Peters EJ, Armstrong DG, Deery HG, Embil JM, Joseph WS, Karchmer AW, Pinzur MS, Senneville E, Infectious Diseases Society of America: 2012 Infectious Diseases Society of America clinical practice guideline for the diagnosis and treatment of diabetic foot infections. *Clin Infect Dis* 54:e132-e173, 2012 <u>Reason for inclusion</u>: New guideline on diagnosis and treatment of diabetic foot infections ABSTRACT: Foot infections are a common and serious problem in persons with diabetes. Diabetic foot infections (DFIs) typically begin in a wound, most often a neuropathic ulceration. While all wounds are colonized with microorganisms, the presence of infection is defined by ≥2 classic findings of inflammation or purulence. Infections are then classified into mild (superficial and limited in size and depth), moderate (deeper or more extensive), or severe (accompanied by systemic	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			signs or metabolic perturbations). This classification system, along with a vascular assessment, helps determine which patients should be hospitalized, which may require special imaging procedures or surgical interventions, and which will require amputation. Most DFIs are polymicrobial, with aerobic gram-positive cocci (GPC), and especially staphylococci, the most common causative organisms. Aerobic gram-negative bacilli are frequently copathogens in infections that are chronic or follow antibiotic treatment, and obligate anaerobes may be copathogens in ischemic or necrotic wounds. Wounds without evidence of soft tissue or bone infection do not require antibiotic therapy. For infected wounds, obtain a post-debridement specimen (preferably of tissue) for aerobic and anaerobic culture. Empiric antibiotic therapy can be narrowly targeted at GPC in many acutely infected patients, but those at risk for infection with antibiotic-resistant organisms or with chronic, previously treated, or severe infections usually	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			require broader spectrum regimens. Imaging is helpful in most DFIs; plain radiographs may be sufficient, but magnetic resonance imaging is far more sensitive and specific. Osteomyelitis occurs in many diabetic patients with a foot wound and can be difficult to diagnose (optimally defined by bone culture and histology) and treat (often requiring surgical debridement or resection, and/or prolonged antibiotic therapy). Most DFIs require some surgical intervention, ranging from minor (debridement) to major (resection, amputation). Wounds must also be properly dressed and off-loaded of pressure, and patients need regular follow-up. An ischemic foot may require revascularization, and some nonresponding patients may benefit from selected adjunctive measures. Employing multidisciplinary foot teams improves outcomes. Clinicians and healthcare organizations should attempt to monitor, and thereby improve, their outcomes and processes in caring for DFIs.	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
Refer patients who smoke, have loss of protective sensation and structural abnormalities, or have history of prior lower-extremity complications to foot care specialists for ongoing preventive care and life-long surveillance. (C)	No change			
Initial screening for peripheral arterial disease (PAD) should include a history for claudication and an assessment of the pedal pulses. Consider obtaining an ankle-brachial index (ABI), as many patients with PAD are asymptomatic. (C)	No change			
Refer patients with significant claudication or a positive ABI for further vascular assessment and consider exercise, medications, and surgical options. (C)	No change			
Assessment of common comorbid conditions				

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
For patients with risk factors, signs or symptoms, consider assessment and treatment for common diabetes-associated conditions (see table 15). (B)	No change			
Children and adolescents				
	As is the case for all children, children with diabetes or prediabetes should be encouraged to engage in at least 60 minutes of physical activity each day (B).	To be consistent with federal guidelines for all children		
Glycemic control				
Consider age when setting glycemic goals in children and adolescents with type 1 diabetes. (E)	No change			

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
Screening and management of chronic complications in children and adolescents with type 1 diabetes				
Nephropathy				
Annual screening for microalbuminuria, with a random spot urine sample for albumin-to-creatinine ratio (ACR), should be considered once the child is 10 years of age and has had diabetes for 5 years. (B)	No change			
Treatment with an ACE inhibitor, titrated to normalization of albumin excretion, should be considered when elevated ACR is subsequently confirmed on two additional specimens from different days. (E)	No change			
Hypertension				

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
	Blood pressure should be measured at each routine visit. Children found to have high-normal blood pressure or hypertension should have blood pressure confirmed on a separate day. (B)	To provide more specific recommendation vs. what was previously only in text		
Initial treatment of high-normal blood pressure (systolic or diastolic blood pressure consistently above the 90th percentile for age, sex, and height) includes dietary intervention and exercise, aimed at weight control and increased physical activity, if appropriate. If target blood pressure is not reached with 3–6 months of lifestyle intervention, pharmacologic treatment should be considered. (E)	No change			
Pharmacologic treatment of hypertension (systolic or diastolic blood pressure	No change			

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
consistently above the 95th percentile for age, sex, and height or consistently >130/80 mmHg, if 95% exceeds that value) should be considered as soon as the diagnosis is confirmed. (E)				
ACE inhibitors should be considered for the initial treatment of hypertension, following appropriate reproductive counseling due to its potential teratogenic effects. (E)	No change			
The goal of treatment is a blood pressure consistently <130/80 or below the 90th percentile for age, sex, and height, whichever is lower. (E)	No change			
Dyslipidemia				
Screening				

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
If there is a family history of hypercholesterolemia or a cardiovascular event before age 55 years, or if family history is unknown, then consider obtaining a fasting lipid profile on children >2 years of age soon after diagnosis (after glucose control has been established). If family history is not of concern, then consider the first lipid screening at puberty (≥10 years). For children diagnosed with diabetes at or after puberty, consider obtaining a fasting lipid profile soon after diagnosis (after glucose control has been established). (E)	No change			
For both age-groups, if lipids are abnormal, annual monitoring is reasonable. If LDL cholesterol values are within the accepted risk levels (<100 mg/dl [2.6 mmol/l]), a lipid profile repeated every 5 years is reasonable. (E)	No change			

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
Treatment				
Initial therapy may consist of optimization of glucose control and MNT using a Therapeutic Lifestyle Changes (Step 2) American Heart Association diet aimed at a decrease in the amount of saturated fat in the diet. (E)	No change			
After the age of 10 years, the addition of a statin in patients who, after MNT and lifestyle changes, have LDL cholesterol >160 mg/dl (4.1 mmol/l), or LDL cholesterol >130 mg/dl (3.4 mmol/l) and one or more CVD risk factors, is reasonable. (E)	No change			
The goal of therapy is an LDL cholesterol value <100 mg/dl (2.6 mmol/l). (E)	No change			

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
Retinopathy				
The first ophthalmologic examination should be obtained once the child is ≥10 years of age and has had diabetes for 3–5 years. (B)	No change			
After the initial examination, annual routine follow-up is generally recommended. Less frequent examinations may be acceptable on the advice of an eye care professional. (E)	No change			
Celiac disease				
Consider screening children with type 1 diabetes for celiac disease by measuring tissue transglutaminase or anti-endomysial antibodies, with documentation of normal total serum IgA levels, soon after the diagnosis of diabetes. (E)	No change			

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
Testing should be considered in children with growth failure, failure to gain weight, weight loss, diarrhea, flatulence, abdominal pain, or signs of malabsorption or in children with frequent unexplained hypoglycemia or deterioration in glycemic control. (E)	No change			
Consider referral to a gastroenterologist for evaluation with endoscopy and biopsy for confirmation of celiac disease in asymptomatic children with positive antibodies. (E)	Consider referral to a gastroenterologist for evaluation with possible endoscopy and biopsy for confirmation of celiac disease in asymptomatic children with positive antibodies. (E)	To be consistent with guidelines that some children may not need a biopsy	Reference 434 of 2013 ADA Standards of Care: Husby S, Koletzko S, Korponay-Szabo IR, Mearin ML, Phillips A, Shamir R, Troncone R, Giersiepen K, Branski D, Catassi C, Lelgeman M, Maki M, Ribes-Koninckx C, Ventura A, Zimmer KP: European Society for Pediatric Gastroenterology, Hepatology, and Nutrition guidelines for the diagnosis of coeliac disease. *J Pediatr Gastroenterol Nutr* 54:136-160, 2012 Reason for inclusion: New guidelines that suggest not all children need a small bowel biopsy ABSTRACT: OBJECTIVE: Diagnostic	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			criteria for coeliac disease (CD) from the European Society for Paediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN) were published in 1990. Since then, the autoantigen in CD, tissue transglutaminase, has been identified; the perception of CD has changed from that of a rather uncommon enteropathy to a common multiorgan disease strongly dependent on the haplotypes human leukocyte antigen (HLA)-DQ2 and HLA-DQ8; and CD-specific antibody tests have improved. METHODS: A panel of 17 experts defined CD and developed new diagnostic criteria based on the Delphi process. Two groups of patients were defined with different diagnostic approaches to diagnose CD: children with symptoms suggestive of CD (group 1) and asymptomatic children at increased risk for CD (group 2). The 2004 National Institutes of Health/Agency for Healthcare Research and Quality report and a	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			systematic literature search on antibody tests for CD in paediatric patients covering the years 2004 to 2009 was the basis for the evidence-based recommendations on CD-specific antibody testing. RESULTS: In group 1, the diagnosis of CD is based on symptoms, positive serology, and histology that is consistent with CD. If immunoglobulin A anti-tissue transglutaminase type 2 antibody titers are high (>10 times the upper limit of normal), then the option is to diagnose CD without duodenal biopsies by applying a strict protocol with further laboratory tests. In group 2, the diagnosis of CD is based on positive serology and histology. HLA-DQ2 and HLA-DQ8 testing is valuable because CD is unlikely if both haplotypes are negative. CONCLUSIONS: The aim of the new guidelines was to achieve a high diagnostic accuracy and to reduce the burden for patients and their families. The performance of these	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			guidelines in clinical practice should be evaluated prospectively.	
Children with biopsy-confirmed celiac disease should be placed on a gluten-free diet and have consultation with a dietitian experienced in managing both diabetes and celiac disease. (B)	No change			
Hypothyroidism				
Consider screening children with type 1 diabetes for thyroid disease using thyroid peroxidase and thyroglobulin antibodies soon after diagnosis. (B)	No change			
Measuring TSH concentrations soon after diagnosis of type 1 diabetes, after metabolic control has been established, is reasonable. If normal, consider rechecking every 1–2 years, especially if the patient develops symptoms of thyroid dysfunction, thyromegaly, or an	No change			

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
abnormal growth rate. (E)				
Transition from pediatric to adult care				
As teens transition into emerging adulthood, health care providers and families must recognize their many vulnerabilities (B) and prepare the developing teen, beginning in early to mid adolescence and at least one year prior to the transition. (E)	No change			
Both pediatricians and adult health care providers should assist in providing support and links to resources for the teen and emerging adult. (B)	No change			
Preconception care (Jennifer)				
A1C levels should be as close to normal as possible (<7%) in an individual patient before	No change			

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
conception is attempted. (B)				
Starting at puberty, preconception counseling should be incorporated in the routine diabetes clinic visit for all women of child-bearing potential. (C)	No change			
Women with diabetes who are contemplating pregnancy should be evaluated and, if indicated, treated for diabetic retinopathy, nephropathy, neuropathy, and CVD. (B)	No change			
Medications used by such women should be evaluated prior to conception, since drugs commonly used to treat diabetes and its complications may be contraindicated or not recommended in pregnancy, including statins, ACE inhibitors, ARBs, and most non-insulin therapies. (E)	No change			

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
Since many pregnancies are unplanned, consider the potential risks and benefits of medications that are contraindicated in pregnancy in all women of child-bearing potential, and counsel women using such medications accordingly. (E)	No change			
Older adults				
Older adults who are functional, cognitively intact, and have significant life expectancy should receive diabetes care using goals developed for younger adults. (E)	Older adults who are functional, cognitively intact, and have significant life expectancy should receive diabetes care with goals similar to those developed for younger adults. (E)	Clarification	Reference 452 of 2013 ADA Standards of Care: Kirkman M, Briscoe VJ, Clark N, Florez H, Haas L, Halter JB, Huang E, Korytkowski M, Munshi M, Odegard P, Pratley R, Swift C: Diabetes in Older Adults. *Diabetes Care* 35: 2012 Reason for inclusion: new report of consensus development conference discussing the evidence, gaps, and issues in treating diabetes and its comorbidities in heterogeneous population of older adults with diabetes.	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			No abstract available.	
Glycemic goals for older adults not meeting the above criteria may be relaxed using individual criteria, but hyperglycemia leading to symptoms or risk of acute hyperglycemic complications should be avoided in all patients. (E)	Glycemic goals for some older adults might reasonably be relaxed, using individual criteria, but hyperglycemia leading to symptoms or risk of acute hyperglycemic complications should be avoided in all patients. (E)	Clarification	See above (Reference 452)	
Other cardiovascular risk factors should be treated in older adults with consideration of the time frame of benefit and the individual patient. Treatment of hypertension is indicated in virtually all older adults, and lipid and aspirin therapy may benefit those with life expectancy at least equal to the time frame of primary or secondary prevention trials. (E)	No change		See above (Reference 452)	
Screening for diabetic complications should be individualized in older adults, but particular attention should be	No change		See above (Reference 452)	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
paid to complications that would lead to functional impairment. (E)				
Cystic fibrosis–related diabetes				
Annual screening for CFRD with OGTT should begin by age 10 all patients with CF who do not have CFRD. (B) Use of A1c as a screening test for CFRD is not recommended. (B)	No change			
During a period of stable health the diagnosis of CFRD can be made in CF patients according to usual diagnostic criteria. (E)	During a period of stable health the diagnosis of CFRD can be made in CF patients according to usual glucose criteria. (E)	Clarification, since A1C is not recommended		
Patients with CFRD should be treated with insulin to attain individualized glycemic goals. (A)	No change			
Annual monitoring for complications in patients with CFRD is recommended,	No change			

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
beginning 5 years after the diagnosis of CFRD. (E)				
Diabetes care in the hospital				
All patients with diabetes admitted to the hospital should have their diabetes clearly identified in the medical record. (E)	No change			
All patients with diabetes should have an order for blood glucose monitoring, with results available to all members of the health care team. (E)	No change			
Goals for blood glucose levels				
Critically ill patients: Insulin therapy should be initiated for treatment of persistent hyperglycemia starting at a threshold of no greater than 180 mg/dl (10 mmol/l). Once insulin therapy is started, a glucose	No change		Reference 469 of 2013 ADA Standards of Medical Care: Hsu CW, Sun SF, Lin SL, Huang HH, Wong KF: Moderate glucose control results in less negative nitrogen balances in medical intensive care unit patients: a randomized, controlled study. *Crit*	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
range of 140–180 mg/dl (7.8 to 10 mmol/l) is recommended for the majority of critically ill patients. (A)			*Care* 16:R56, 2012 Reason for inclusion: RCT providing supportive evidence for moderately lower glycemic targets in MICU patients ABSTRACT: INTRODUCTION: Hyperglycemia and protein loss are common in critically ill patients. Insulin can be used to lower blood glucose and inhibit proteolysis. The impact of moderate insulin therapy on protein metabolism in critically ill patients has not been evaluated. We compared urinary nitrogen excretion, nitrogen balance, serum albumin concentrations, prealbumin concentrations, and clinical outcomes between patients receiving moderate insulin therapy (MIT) and conventional insulin therapy (CIT) in a medical ICU. METHODS: Patients were randomly divided into groups and treated with MIT (glucose target 120 to 140 mg/dl) or CIT (glucose target 180 to 200 mg/dl). Calories and protein intake were recorded each day. On days 3, 7 and 14, the 24-hour urinary	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			nitrogen excretion, nitrogen balance, and serum albumin and prealbumin concentrations were measured. Clinical outcomes data were collected. RESULTS: A total of 112 medical ICU patients were included, with 55 patients randomized to the MIT group and 57 patients randomized to the CIT group. Patients treated with MIT showed a trend towards increased nitrogen balance (P = 0.070), significantly lower urinary nitrogen excretion (P = 0.027), and higher serum albumin (P = 0.047) and prealbumin (P = 0.001) concentrations than patients treated with CIT. The differences between the two groups were most significant on day 3, when all factors showed significant differences (P < 0.05). CONCLUSIONS: Moderate glucose control results in less negative nitrogen balances in medical ICU patients. Differences are more significant in the early stages compared with the late stages of critical illness.	
More stringent goals, such as 110–140 mg/dl (6.1–7.8 mmol/l) may be appropriate for selected	No change		See above (Reference 469)	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
patients, as long as this can be achieved without significant hypoglycemia. (C)				
Critically ill patients require an intravenous insulin protocol that has demonstrated efficacy and safety in achieving the desired glucose range without increasing risk for severe hypoglycemia. (C)	No change			
Non–critically ill patients: There is no clear evidence for specific blood glucose goals. If treated with insulin, the pre-meal blood glucose targets generally <140 mg/dl (7.8 mmol/l) with random blood glucose <180 mg/dl (10.0 mmol/l) are reasonable, provided these targets can be safely achieved. More stringent targets may be appropriate in stable patients with previous tight glycemic control. Less stringent targets may be appropriate in those with severe comorbidites. (E)	No change-		Reference 470 of 2013 ADA Standards of Care: Umpierrez GE, Hellman R, Korytkowski MT, Kosiborod M, Maynard GA, Montori VM, Seley JJ, Van den Berghe G: Management of hyperglycemia in hospitalized patients in non-critical care setting: an endocrine society clinical practice guideline. *J Clin Endocrinol Metab* 97:16-38, 2012 Reason for inclusion: New guideline on glycemic targets for hospitalized patients outside the ICU ABSTRACT: OBJECTIVE: The aim was	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			to formulate practice guidelines on the management of hyperglycemia in hospitalized patients in the non-critical care setting. PARTICIPANTS: The Task Force was composed of a chair, selected by the Clinical Guidelines Subcommittee of The Endocrine Society, six additional experts, and a methodologist. EVIDENCE: This evidence-based guideline was developed using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) system to describe both the strength of recommendations and the quality of evidence. CONSENSUS PROCESS: One group meeting, several conference calls, and e-mail communications enabled consensus. Endocrine Society members, American Diabetes Association, American Heart Association, American Association of Diabetes Educators, European Society of Endocrinology, and the Society of Hospital Medicine	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			reviewed and commented on preliminary drafts of this guideline. CONCLUSIONS: Hyperglycemia is a common, serious, and costly health care problem in hospitalized patients. Observational and randomized controlled studies indicate that improvement in glycemic control results in lower rates of hospital complications in general medicine and surgery patients. Implementing a standardized sc insulin order set promoting the use of scheduled basal and nutritional insulin therapy is a key intervention in the inpatient management of diabetes. We provide recommendations for practical, achievable, and safe glycemic targets and describe protocols, procedures, and system improvements required to facilitate the achievement of glycemic goals in patients with hyperglycemia and diabetes admitted in non-critical care settings.	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			Reference 474 of 2013 ADA Standards of Care: Baldwin D, Zander J, Munoz C, Raghu P, Delange-Hudec S, Lee H, Emanuele MA, Glossop V, Smallwood K, Molitch M: A randomized trial of two weight-based doses of insulin glargine and glulisine in hospitalized subjects with type 2 diabetes and renal insufficiency. *Diabetes Care* 35:1970-1974, 2012 Reason for inclusion: RCT suggesting that lower weight-based doses of basal-bolus insulin are equally effective and lead to less hypoglycemia in hospitalized patients with renal insufficiency ABSTRACT: OBJECTIVE Renal insufficiency may increase the risk of hypoglycemia in hospitalized patients with diabetes who are treated with insulin. We randomized inpatients with type 2 diabetes and chronic renal failure to treatment with two different dose levels of	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			insulin glargine and glulisine and studied control of hyperglycemia and the frequency of hypoglycemia. RESEARCH DESIGN AND METHODS. We conducted a multicenter, prospective, randomized trial to compare the efficacy of once-daily glargine and three-times daily glulisine at 0.5 vs. 0.25 units/kg/day. A total of 107 subjects had type 2 diabetes for >1 year, had a glomerular filtration rate <45 mL/min but did not require dialysis, and had an initial blood glucose (BG) >180 mg/dL. Doses were adjusted based on four-times daily BG measurements for 6 days. RESULTS Mean BG on the first day was 196 ± 71 mg/dL in the group receiving 0.5 units/kg (0.5 group) and 197 ± 55 mg/dL in the group receiving 0.25 units/kg (0.25 group; P = 0.94). On days 2 to 6, mean BG was 174 ± 52 mg/dL in the 0.5 group and 174 ± 46 mg/dL in the 0.25 group (P = 0.96). There were no significant differences between groups in the percentage of BG values within the target range of 100 to 180 mg/dL on any of the 6 study days. In the 0.5 group, 30%	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			experienced hypoglycemia (BG <70 mg/dL) compared with 15.8% of the 0.25 group (P = 0.08). CONCLUSIONS Reduction of initial glargine/glulisine insulin weight-based dosing in hospitalized patients with diabetes and renal insufficiency reduced the frequency of hypoglycemia by 50% without compromising the control of hyperglycemia.	
Scheduled subcutaneous insulin with basal, nutritional, and correction components is the preferred method for achieving and maintaining glucose control in non–critically ill patients. (C)	No change			
Glucose monitoring should be initiated in any patient not known to be diabetic who receives therapy associated with high risk for hyperglycemia, including high-dose glucocorticoid therapy, initiation of enteral or parenteral nutrition, or other medications such as octreotide or immunosuppressive	No change			

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
medications. (B) If hyperglycemia is documented and persistent, consider treating such patients to the same glycemic goals as patients with known diabetes. (E)				
A hypoglycemia management protocol should be adopted and implemented by each hospital or hospital system. A plan for preventing and treating hypoglycemia should be established for each patient. Episodes of hypoglycemia in the hospital should be documented in the medial record and tracked. (E)	No change			
Consider obtaining an A1C on patients with diabetes admitted to the hospital if the result of testing in the previous 2–3 months is not available. (E)	No change			
Patients with hyperglycemia in the hospital who do not have a diagnosis of diabetes should	No change			

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
have appropriate plans for follow-up testing and care documented at discharge. (E)				
Strategies for improving care				
Care should be aligned with components of the Chronic Care Model to ensure productive interactions between a prepared proactive practice team and an informed activated patient. (A)	No change		Reference 518 of 2013 ADA Standards of Care: Tricco AC, Ivers NM, Grimshaw JM, Moher D, Turner L, Galipeau J, Halperin I, Vachon B, Ramsay T, Manns B, Tonelli M, Shojania K: Effectiveness of quality improvement strategies on the management of diabetes: a systematic review and meta-analysis. *Lancet* 379:2252-2261, 2012 Reason for inclusion: Systematic review and meta-analysis of different pre-specified types of QI strategies in diabetes, showing that many are effective. Replaces older SR. ABSTRACT: BACKGROUND: The effectiveness of quality improvement (QI) strategies on diabetes care remains unclear. We aimed to assess	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			the effects of QI strategies on glycated haemoglobin (HbA(1c)), vascular risk management, microvascular complication monitoring, and smoking cessation in patients with diabetes. METHODS: We identified studies through Medline, the Cochrane Effective Practice and Organisation of Care database (from inception to July 2010), and references of included randomised clinical trials. We included trials assessing 11 predefined QI strategies or financial incentives targeting health systems, health-care professionals, or patients to improve management of adult outpatients with diabetes. Two reviewers independently abstracted data and appraised risk of bias. FINDINGS: We reviewed 48 cluster randomised controlled trials, including 2538 clusters and 84,865 patients, and 94 patient randomised controlled trials, including 38,664 patients. In random effects meta-	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			analysis, the QI strategies reduced HbA(1c) by a mean difference of 0·37% (95% CI 0·28-0·45; 120 trials), LDL cholesterol by 0·10 mmol/L (0·05-0.14; 47 trials), systolic blood pressure by 3·13 mm Hg (2·19-4·06, 65 trials), and diastolic blood pressure by 1·55 mm Hg (0·95-2·15, 61 trials) versus usual care. We noted larger effects when baseline concentrations were greater than 8·0% for HbA(1c), 2·59 mmol/L for LDL cholesterol, and 80 mm Hg for diastolic and 140 mm Hg for systolic blood pressure. The effectiveness of QI strategies varied depending on baseline HbA(1c) control. QI strategies increased the likelihood that patients received aspirin (11 trials; relative risk [RR] 1·33, 95% CI 1·21-1·45), antihypertensive drugs (ten trials; RR 1·17, 1·01-1·37), and screening for retinopathy (23 trials; RR 1·22, 1·13-1·32), renal function (14 trials; RR 128, 1·13-1·44), and foot abnormalities (22 trials; RR 1·27,	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
			1·16-1·39). However, statin use (ten trials; RR 1·12, 0·99-1·28), hypertension control (18 trials; RR 1·01, 0·96-1·07), and smoking cessation (13 trials; RR 1·13, 0·99-1·29) were not significantly increased. INTERPRETATION: Many trials of QI strategies showed improvements in diabetes care. Interventions targeting the system of chronic disease management along with patient-mediated QI strategies should be an important component of interventions aimed at improving diabetes management. Interventions solely targeting health-care professionals seem to be beneficial only if baseline HbA(1c) control is poor.	
When feasible, care systems should support team-based care, community involvement, patient registries, and embedded decision support tools to meet	No change		See above (Reference 518)	

2012 Recommendations	2013 Recommendations	Reason for Change	New Evidence Citations from Review of 2011-2012, Reason for Inclusion, and Abstract of the paper	
patient needs (B).				
Treatment decisions should be timely and based on evidence-based guidelines that are tailored to individual patient preferences, prognoses, and co-morbidities. (B)	No change		See above (Reference 518)	
A patient-centered communication style should be employed that incorporates patient preferences, assesses literacy and numeracy, and addresses cultural barriers to care (B)	No change		See above (Reference 518)	