Complete Summary

GUIDELINE TITLE

Clinical guideline for adults with diabetes.

BIBLIOGRAPHIC SOURCE(S)

Joslin Diabetes Center. Clinical guideline for adults with diabetes. Boston (MA): Joslin Diabetes Center; 2006 Oct 20. 9 p. [238 references]

GUIDELINE STATUS

This is the current release of the guideline.

This Guideline will be reviewed periodically and modified as clinical practice evolves and medical evidence suggests.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- October 16, 2007, Byetta (exenatide): Amylin Pharmaceuticals, Inc. has agreed to include information about acute pancreatitis in the PRECAUTIONS section of the product label.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Diabetes mellitus

GUIDELINE CATEGORY

Diagnosis
Management
Prevention
Treatment

CLINICAL SPECIALTY

Endocrinology
Family Practice
Internal Medicine
Nutrition
Optometry
Podiatry

INTENDED USERS

Advanced Practice Nurses
Dietitians
Nurses
Physicians
Podiatrists

GUIDELINE OBJECTIVE(S)

To support clinical practice and to influence clinical behaviors in order to improve clinical outcomes and assure that patient expectations are reasonable and informed

TARGET POPULATION

Non-pregnant adults with diabetes mellitus

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Screening

1. Hemoglobin A1C
2. Renal disease
    - Serum creatinine, glomerular filtration rate
    - Micro/macro albuminuria: urine albumin/creatinine ratio
    - Proteinuria
    - Anemia

    - Hyperphosphatemia
3. Lipids
4. Blood pressure
5. Smoking
6. Foot evaluation
7. Eye exam for retinopathy
8. Risk factors for heart disease

Treatment/Prevention/Management

1. Individualized therapy based on patient goals and target lab values
2. Self-monitoring of blood glucose
3. Diabetes self-management education
4. Hypoglycemia (oral carbohydrates, glucagon and/or intravenous glucose)
5. Drug therapy (enteric-coated aspirin, beta-blocker, angiotensin receptor blocker, angiotensin converting enzyme inhibitor, statin)
6. Foot care
7. Referral to specialist
8. Nutrition
9. Lifestyle modification
10. Smoking cessation
11. Immunizations
12. Women's health
13. Men's health
14. Dental care
15. Follow-up

MAJOR OUTCOMES CONSIDERED

- Glycemic control
    - Blood glucose targets
    - A1C targets
- Mortality and morbidity associated with diabetes

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Review of all new papers on selected topics in PubMed, MEDLINE, OUID, Cochrane databases

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Grade of Recommendation	Clarity of Risk/Benefit	Quality of Supporting Evidence
1A Strong recommendation High quality of evidence	Benefits clearly outweigh risk and vice versa.	Consistent evidence from well performed randomized, controlled trials or overwhelming evidence of some other form. Further research is unlikely to change our confidence in the estimate of benefit and risk.
1B Strong recommendation Moderate quality of evidence	Benefits clearly outweigh risk and burdens, or vice versa.	Evidence from randomized, controlled trials with important limitations (inconsistent results, methodological flaws, indirect or imprecise), or very strong evidence of some other research design. Further research is likely to have an impact on our confidence in the estimate of the benefit and risk and may change the estimate.
1C Strong recommendation Low quality of evidence	Benefits outweigh risk and burdens, or vice versa.	Evidence from observational studies, unsystematic clinical experience, or from randomized controlled trials with serious flaws. Any estimate of effect is uncertain.
2A Weak recommendation High quality of evidence	Benefits closely balanced with risks and burdens.	Consistent evidence from well performed randomized, controlled trials or overwhelming evidence of some other form. Further research is unlikely to change our confidence in the estimate of benefit and risk.

Grade of Recommendation	Clarity of Risk/Benefit	Quality of Supporting Evidence
2B Weak recommendation Moderate quality of evidence	Benefits closely balanced with risks and burdens; some uncertainty in the estimates of benefits, risks, and burdens.	Evidence from randomized, controlled trials with important limitations (inconsistent results, methodological flaws, indirect or imprecise), or very strong evidence of some other research design. Further research is unlikely to have an impact on our confidence in the estimate of the benefit and risk and may change the estimate.
2C Weak recommendation Low quality of evidence	Uncertainty in the estimates of benefits, risks, and burdens; benefits may be closely balanced with risks and burdens.	Evidence from observational studies, unsystematic clinical experience, or from randomized controlled trials with serious flaws. Any estimate of effect is uncertain.

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Guidelines are developed and approved through the Clinical Oversight Committee that reports to the Joslin Clinic Medical Director of Joslin Diabetes Center. The Clinical Guidelines are established after careful review of current evidence, medical literature and sound clinical practice.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grade of Recommendation	Clarity of Risk/Benefit	Quality of Supporting Evidence

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COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guideline was approved by the Joslin Clinical Oversight Committee on 10/20/06.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions of the recommendation and evidence level grades (1A to 2C) are provided at the end of the "Major Recommendations" field.

A1C

Screen

Check hemoglobin A1C (A1C) 2 to 4 times a year as part of the scheduled medical visit, with frequency dependent upon revision of treatment program and the need to reinforce behavior changes. Increase frequency when therapy has changed and/or when glycemic goals are not met. Having the A1C result at the time of the visit can be useful in making timely treatment decisions. [**1C**]

A1C target goal should be individualized for each patient; aiming to achieve the lowest possible level may be modified based upon presence or absence of microvascular and/or macrovascular complications and life expectancy. [**1A**]

Goal

The true goal of care is to bring A1C as close to normal as safely possible. [**1C**]

A goal of < 7% is chosen as a practical level for most patients using medications that may cause hypoglycemia to avoid the risk of that complication. Achieving normal blood glucose is recommended if it can be done practically and safely. [**1B**]

Joslin's A1C goal is consistent with that of the American Diabetes Association (ADA). Other expert panels, such as American Association of Clinical Endocrinologists/International Diabetes Federation (AACE/IDF) suggested in August 2001 that the goal of treatment should be ≤ 6.5%.

Treatment

If A1C is > 7% and <8%, or above the individualized goal for 6 or more months:

- Review and clarify the management plan with the patient with attention to:
    - Meal plan [**1B**]
    - Activity program [**1A**]
    - Medication administration schedule, technique and practices [**1A**]
    - Self-monitoring blood glucose (SMBG) schedule and technique [**1A**]
    - Treatment for hypoglycemia and hyperglycemia
    - Sick day management practices
- Reassess goals and adjust medication as needed [**1A**]
- Communicate individualized glycemic goals to patient
- Consider referring patient to diabetes educator (DE) for evaluation, diabetes self-management education (DSME) and ongoing consultation [**2A**]
- Consider referring to registered dietitian (RD) for medical nutrition therapy (MNT) [**2B**]
- Schedule follow-up appointment within 3 to 4 months or more frequently as situation dictates

If A1C is ≥ 8%:

- Review and clarify the plan as previously noted [**1B**]
- Assess for psychosocial stress [**1C**]
- Refer patient to DE for evaluation, DSME and ongoing consultation. Document reason if no referral initiated. [**1A**]
- Intensify therapy
- Refer patient to RD for MNT [**1B**]
- Communicate individualized glycemic goals to patient

If history of severe hypoglycemia or hypoglycemia unawareness (a condition in which the patient is unable to recognize symptoms of hypoglycemia until they become severe):

- Assess for changes in daily routine such as decreased food intake or increased activity [**1C**]
- Refer to diabetes educator for evaluation, DSME and hypoglycemia prevention; encourage family/friend attendance
- Review use of glucagon
- Consider loosening A1C goal [**2C**]
- Communicate goals to patient
- Adjust medications accordingly
- If insulin-treated, consider use of a more physiologic insulin replacement program [**1C**]
- Consider and screen for other medical causes [**1C**]
- Consider referral for blood glucose awareness training, if available [**1B**]
- Schedule follow-up appointment within 1-2 months. If history of recent, severe hypoglycemia or change in pattern of hypoglycemia, recommend increase in frequency of communicating blood glucose levels to physician or diabetes educator. [**1B**]

Glucose Monitoring

Self-monitoring of blood glucose (SMBG) is an important component of the treatment program for all people with diabetes. Its use is to gauge treatment efficacy, help in treatment design, provide feedback on the impact of nutritional intake and activity, provide patterns that assist in medication selection, and for those on insulin, assist in daily dose adjustments. [**1A**]

The frequency of SMBG is highly individualized and should be based on such factors as glucose goals, medication changes and patient motivation. Most patients with type 1 diabetes should monitor at least 3 times per day [**1A**]; for patients with type 2 diabetes, the frequency of monitoring is dependent upon such factors as mode of treatment and level of glycemic control. [**1C**]

In order to obtain meaningful data for treatment decisions, it is helpful for the patient to monitor several days (e.g., 2 to 4) in a row. Often, obtaining readings 2 hours postprandially is useful, particularly during these periods of intensive monitoring, as postprandial hyperglycemia has been implicated in increased macrovascular risk. [**1A**]

It is recommended for patients who:

- Have an elevated A1C but fasting glucose is on target.
- Are starting new intensive insulin treatment regimens or who are experiencing problems with glycemic control.
- Are using glucose-lowering agents targeted at postprandial glucose such as repaglinide, nateglinide, exenatide or pramlintide.
- Are making dietary and exercise changes as an evaluation tool.

Encourage the patient to bring SMBG results (written record or meter for downloading) at each visit for review with provider/educator.

Hypoglycemia

Prompt action is recommended for the treatment of hypoglycemia. When possible, the patient should confirm symptoms with SMBG to document hypoglycemia. All patients with type 1 diabetes should ensure that a family member/companion/caregiver knows how to administer a glucagon injection in the event the patient is unable or unwilling to take carbohydrate orally. [**1C**]

Symptoms of hypoglycemia include: sweating, tremor, palpitations, dizziness, confusion, tiredness, inability to concentrate, difficulty speaking.

Treatment

- If patient is symptomatic or unable to confirm hypoglycemia with SMBG, or if blood glucose levels are <70 mg/dl (< 90 mg/dl at bedtime or overnight), treat it as mild-moderate hypoglycemia.
- Caution patient to avoid alternate site testing with blood glucose meter.
- For mild to moderate hypoglycemia (plasma glucose 51 to 70 mg/dl), begin with 15 to 20 grams carbohydrate (1/2 cup juice or regular soft drink, 3 to 4 glucose tabs, or 8 to 10 hard candies). If glucose level is ≤50 mg/dl, consume 20 to 30 grams carbohydrate. [**1C**]
- Recheck blood glucose after 15 minutes. [**1B**]
- Repeat hypoglycemia treatment if blood glucose does not return to normal range after 15 minutes. [**1C**]
- Follow with additional carbohydrate or snack if next meal is more than one hour away. [**1C**]
- If hypoglycemia persists after second treatment, patient or companion should be instructed to contact healthcare provider.
- In event of severe hypoglycemia (altered consciousness, unable to take carbohydrate orally, or requiring the assistance of another person) treat with glucagon and/or intravenous glucose. [**1C**]
- For patients with hypoglycemia unawareness, the threshold for treatment of hypoglycemia needs to be individualized. [**2C**]

Education

- Wear or carry diabetes identification.
- Inform patient of need to check blood glucose before driving, periodically during a long drive, and when operating heavy machinery. [**1B**]
- Instruct patient to carry treatment for hypoglycemia at all times.
- Identify possible causes of hypoglycemia in order to prevent it. [**1C**]
- Be clear in communicating modified treatment goals in individuals with hypoglycemia unawareness (see section in original guideline document on *Hypoglycemia Unawareness*). [**1C**]

Diabetes Self-Management Education (DSME)

Individuals with newly diagnosed diabetes should receive:

- DSME according to National Standards for Diabetes Self-Management Education [**1A**]

- Individualized Medical Nutrition Therapy (MNT) [**1A**]
- Multiple visits to evaluate progress towards goals [**1A**]

Individuals with existing diabetes should receive:

- An annual assessment of DSME and MNT, preferably by a trained Diabetes Educator [**2B**]
- Initial and ongoing assessment of psychosocial issues [**1C**]

Renal Disease and Macro-Micro Albuminuria

Screen

Measure serum creatinine at least annually to estimate glomerular filtration rate (GFR) regardless of degree of urine albumin excretion. (See the *Joslin Diabetes Center & Joslin Clinic Guideline for Specialty Consultation/Referral*). [**1C**]

Screen for micro/macro albuminuria by checking urine albumin/creatinine (A/C) ratio as follows:

- Type 1 patients 5 years after diagnosis and then yearly [**1C**]
- Type 2 patients at diagnosis (after glucose has been stabilized) and then yearly [**1C**]
- Annually in all patients up to age 70 years [**2C**]
- As clinically indicated in patients > 70 years of age

Micro/macro albuminuria is recognized as a major independent risk factor for coronary heart disease in patients with diabetes. Albuminuria may be measured with a spot or timed urine collection. Spot urine is preferred.

Continue use of routine urinalysis as clinically indicated. [**2C**]

Treatment

If A/C ratio < 30 mcg/mg or timed urine 30 mg/24 hr:

- Recheck in 1 year

If A/C ratio 30-300 mcg/mg or timed urine 30-300 mg/24 hr:

- Confirm presence of microalbuminuria with at least 2 of 3 positive collections done within 3 to 6 months. In the process, rule out confounding factors that cause a false-positive such as urinary tract infection (UTI), pregnancy, excessive exercise, menses or severe hypoglycemic event. [**1C**] Consider testing first morning urine.
- Consider consult with nephrology team for blood pressure control, successive increases in microalbumin and other issues (i.e., GFR < 60 ml/min) [**2C**]
- Once confirmed:
    - Evaluate blood pressure (BP) and initiate/modify aggressive blood pressure treatment to achieve a BP of < 130/80 mmHg [**1A**]

- Recommend patient self-monitor BP with portable cuff and maintain a record/log. The monitoring schedule should be determined with physician and is based on patient circumstance
- Strive to improve glycemic control with an optimal goal A1C of < 7% or as otherwise clinically indicated for individual patients [**1A**]
- Refer to diabetes educator for glucose management
- If microalbuminuria persists, initiate/ modify angiotensin converting enzyme (ACE) inhibitor or angiotensin II antagonist treatment. Check K^+ and creatinine 1 to 2 weeks after making changes. [**1A**]
- Repeat A/C ratio at least every 6 months. Consider increase in frequency when changes in medication are made. [**2C**]

If A/C ratio > 300 mcg/mg (> 300 mg/24 hr) or proteinuria (positive dipstick for protein or ≥ 30 mg/dl):

- Follow all guidelines as stated for A/C ratio 30 to 300 mcg/mg
- Consider BP goal of < 125/75 mmHg [**2B**]
- Consult with nephrology if: [**1C**]
    - Rapid rise in serum creatinine, abnormal sediment, or sudden increase in proteinuria
    - Creatinine is elevated (> 1.8 mg/dl in women, > 2.0 mg/dl in men)
    - Refinement of treatment program needed to prevent further deterioration
    - Problems with ACE inhibitors, difficulties in management of high BP, or hyperkalemia
    - If questioning etiology of nephropathy
    - Creatinine clearance < 60 ml/min
    - Difficulties in management of hyperphosphatemia
    - Anemia due to renal disease
- Consider reducing protein in the diet [**1B**]

Cardiovascular Health

(Also see sections on *Lipids, Blood Pressure*, and *Smoking*)

Treatment

A daily enteric-coated aspirin (ASA) (75 to 325 mg) as a primary prevention strategy for everyone > 40 years of age [**1A**]; also for men and women ≥ 30 years of age [**1C**] with any ONE of the following risk factors:

- Family history of premature* coronary artery disease (CAD) or stroke
- Hypertension (HTN)
- Current cigarette smoker
- Micro/macro albuminuria
- Hyperlipidemia

*Premature – 1st degree male relatives younger than 55; 1st degree female relatives younger than 65

Recommend ASA (unless contraindicated) as a secondary prevention for everyone with: [**1A**]

- History of myocardial infarction; angina or documented CAD
- Vascular bypass
- Non-hemorrhagic stroke
- Transient ischemic attack (TIA)
- Peripheral vascular disease (PVD)

(Possible contraindications for ASA therapy may include allergy, bleeding tendency, anticoagulant therapy, recent gastrointestinal bleeding and clinically active hepatic disease). Eye disease is usually not a contraindication for ASA therapy.

Consider using beta-blocker in all patients with a history of MI or with documented CAD unless contraindicated. [**1A**]

Consider recommending aerobic exercise if not clinically contraindicated and a weight-loss program if overweight or obese. [**1A**]

Consider using ACE inhibitors (or angiotensin receptor blockers [ARBs] if ACE inhibitors not tolerated) in patients with known CAD or cardiovascular risk factors. [**1A**]

Lipids

Screen

Adults should be screened annually for lipid disorders with measurements of serum cholesterol, triglycerides, and low density lipoprotein (LDL) and high density lipoprotein (HDL) cholesterol, preferably fasting. [**1C**]

Lipid Goals (mg/dl)

LDL-cholesterol (LDL-C):

< 100 if no diagnosed cardiovascular disease (CVD) **[1A]**

< 70 if diagnosed CVD **[1B]**

HDL-cholesterol (HDL-C):

> 40 (men); >50 (women) **[2C]**

Triglycerides: < 150 (fasting) **[2C]**

Treatment

All patients should receive information about a meal plan designed to lower blood glucose and improve lipids, physical activity recommendations, and risk reduction strategies. Consultation with appropriate education discipline is preferred. [**1A**]

Institute therapy after abnormal values are confirmed.

For patients in whom CVD is not yet diagnosed

If LDL-C ≥100 mg/dl:

- Optimize glycemic control [**1A**]
- Refer to registered dietitian for intensive dietary modification; therapeutic lifestyle changes (TLC) [**1A**]
- Consider referral to exercise specialist or DE for exercise prescription
- Recheck lipids within 6 weeks
- If LDL-C remains >100, initiate medication with goal of lowering LDL-C by at least 30% or to < 100, whichever is lower, preferably with a statin [**1A**]

If LDL-C < 100 mg/dl:

Consider statin therapy if age > 40 yrs and one more CVD risk factor is present (hypertension, smoking, albuminuria or family history of premature CVD). [**1A**]

Patients with LDL-C < 100 mg/dl and fasting triglycerides ≥ 150 mg/dl or HDL-C ≤ 40 mg/dl:

- Optimize glycemic control [**1A**]
- Refer to RD for dietary modification; TLC [**1A**]
- Consider referral to exercise specialist for exercise prescription
- Recheck lipids within 6 weeks
- Consider medication if fasting triglycerides >200 mg/dl and/or HDL-C ≤ 40 mg/dl (fibrate preferred if fasting triglycerides > 500 mg/dl) [**2C**]
- In patients with fasting triglyceride levels 200-499 mg/dl, calculate non-HDL-C (total cholesterol minus HDL-C) and consider starting or titrating statin if non-HDL-C >130 [**1C**]
- Consider adding fibrate or niacin if fasting triglycerides > 200 and/or HDL-C ≤ 40 mg/dl, and LDL/non-HDL-C at goal. [**2C**]
- Initiate treatment with very low fat diet and fibrate if triglycerides > 1000 mg/dl for prophylaxis against acute pancreatitis; rule-out other secondary causes; reassess lipid status when triglycerides < 500 mg/dl. [**1A**]

Patients with cardiovascular disease (CVD)

If LDL-C ≥ 70 mg/dl:

- Optimize glycemic control [**1A**]
- Refer to RD for intensive dietary modification; TLC [**1A**]
- Consider referral to exercise specialist or DE for exercise prescription [**1A**]
- Consider starting lipid lowering agent (preferably statin) immediately if LDL-C is > 100. [**1A**]
- Recheck lipids within 6 weeks.
- If LDL-C remains > 70, initiate medication (preferably statin) with goal of lowering LDL-C to < 70. May require combination of statin with another lipid lowering agent to achieve this goal. [**1B**]

Blood Pressure

Screen

Check BP at all routine visits with patient sitting for 5 minutes. Use proper-sized cuff.

Postural BP should be checked initially as clinically indicated and if orthostatic, check at each follow-up visit. [**1C**]

- *Orthostatic hypotension*: defined as a fall in systolic BP (SBP) of 20 to 30 mmHg or diastolic BP (DBP) of 10 to 15 mmHg upon change in position
- *Acute hypertension* (>180/110 mmHg) warrants *immediate attention* [**1C**]

Goal

- BP goal for each patient >18 years old is <130/80 mmHg and modified for comorbidities [**1B**]
- BP goals for patients with proteinuria > 1 gm is < 125/75 mmHg [**1C**]
- Initial goal for patients with isolated systolic hypertension (SBP >180 mmHg & DBP < 80 mmHg) is a SBP <160 mmHg
- Initial goal for patients with SBP 160 to 179 mmHg is to lower SBP by 20 mmHg. If well tolerated, lower BP goals may be indicated. [**1B**]
- Strong evidence suggests significant benefits to be gained if BP < 130/80 mmHg [**1B**]

Treatment

If SBP 130-139 mmHg or DBP 80-89 mmHg, a 3-month trial of behavioral therapy is warranted, including: **[1C]**

- Counseling about meal plan, exercise, weight loss, sodium reduction, alcohol and stress reduction
- Consider referral to RD for MNT
- Encourage home BP monitoring
- Instruct patient to have BP checked on 3 separate occasions before next appointment
- Follow-up with healthcare provider within 2 to 4 weeks
- If BP remains above goals, initiate or adjust therapy with antihypertensive agents as clinically indicated
- Studies have shown that aggressive management and control of blood pressure may result in long-term benefits.
- If BP remains > 130/80 mmHg after 3 months of attempted lifestyle modification, or if BP > 140/90 mmHg at initial visit, add a pharmacological agent to behavioral modification.

Drug Therapy

- In choosing an initial anti-hypertensive drug, the most important thing is that it be efficacious. In that sense, any available antihypertensive drug can be an appropriate choice. However, other considerations (cost, presence of

proteinuria, or co-existing CAD) dictate a preference for ACE inhibitors, ARBs, beta-blockers and diuretics. [**1A**]
- ACE inhibitors or ARBs are the drugs of choice for patients with evidence of nephropathy. These drugs require monitoring of serum creatinine and K^+ within 1 week of starting therapy and periodically thereafter. [**1A**]

Smoking

Assess patient's smoking status on a routine basis.

Treatment (If patient smokes)

- Discuss rationale for and strongly recommend smoking cessation [**1A**]
- Review options available to assist in smoking cessation, including medications and cessation programs [**1B**]

Feet

Screen

Screening should include: (1) a foot evaluation for sensorimotor (monofilament), skin and soft tissues integrity, vascular sufficiency (pedal pulses) and biomechanic integrity, and (2) an examination of shoes for wear.

Frequency

- For healthy type 1 patients without complications: conduct foot screen at time of diagnosis and at least annually thereafter [**1C**]
- For type 2 patients without complications, check at baseline and at least annually thereafter [**1C**]
- For the "at-risk patients" check at all routine interval visits [**1C**]

"At-Risk Patients" includes patients who smoke, have vascular insufficiency, neuropathy, retinopathy, nephropathy, history of ulcers or amputations, structural deformities, infections, skin/nail abnormality, are on anticoagulation therapy or who cannot see, feel or reach their feet.

Treatment

For patients with acute problems or who are "at risk":

- Refer to podiatrist for routine care and evaluation [**1B**]
- Refer to diabetes educator for foot care training* [**1C**]

**Foot care training* will include information about:

- Avoidance of foot trauma
- Daily foot inspection
- Proper footwear
- Impact of loss of protective sensation on morbidity
- Need to stop smoking

- Action to take when problems arise

For current ulcer or infection: mild [**1C**]

***Mild Infection or Ulcer*: superficial (no foul odor), no significant ischemia, no bone or joint involvement, no systemic toxicity, minimal or no cellulitis (< 2 cm):

- Instruct non-weight bearing
- Apply local dressings
- Consider baseline x-ray to evaluate for bone integrity and possible osteomyelitis
- Consider systemic antibiotic therapy
- Refer to podiatrist for debridement or further treatment
- Refer for foot care training
- Ensure follow-up appointments are kept

For limb-threatening* ***ulcer or infection***: [**1C**]

***Limb-threatening: deep ulcer, bone or joint involvement, gangrene, lymphangitis, >2 cm cellulitis, systemic toxicity, significant ischemia, no social support system, immunocompromised, foul odor in ulcer, and osteomyelitis presumed to be present if probed to the bone.

- Consider hospitalization and refer to a podiatrist and vascular surgeon for immediate evaluation and treatment
- Ensure appointments are kept and prevention strategies are implemented

Eyes

Exam Schedule

Refer patient for comprehensive dilated eye exam or validated retinal color imaging to determine level of retinopathy.

- Type 1: initial eye exam within 3 years after diagnosis of diabetes once patient is 9 years or older. Exams annually thereafter. [**1B**]
- Type 2: at diagnosis and annually thereafter [**1B**]
- Pregnancy in pre-existing diabetes: prior to conception and during first trimester; follow-up as determined by first trimester exam [**1B**]

For intensive insulin therapy (pump therapy or multiple daily injections) -consult with patient's eye doctor prior to and 2 to 4 months after initiating therapy.

Treatment

Aggressively treat known medical risk factors for retinopathy: [**1A**]

- Strive to improve glycemic control with optimal A1C goal of < 7%
- Monitor eye disease carefully when intensifying glycemic control
- Strive for BP <130/80 mmHg
- Treat micro/macro albuminuria

- Strive to maintain total cholesterol, LDL, HDL and triglyceride levels as per the recommendations outlined in the *Lipids* Section of the original guideline document
- Treat anemia

Revise activity program depending on the level of retinopathy. Consider consultation with exercise physiologist.

Reinforce follow-up with eye care provider for any level of retinopathy including no retinopathy. The frequency of follow-up is dependent upon the level of retinopathy and is determined by the eye care provider.

- For high-risk proliferative diabetic retinopathy, scatter (panretinal) photocoagulation is indicated promptly [**1A**]
- For clinically significant macular edema (CSME) - focal laser is generally indicated regardless of level of retinopathy [**1A**]
- The level of diabetic retinopathy and diabetic macular edema (DME) generally determines follow-up: [**1A**]

If Mild Nonproliferative Diabetic Retinopathy

- Without DME 12 months
- With DME* 3 to 4 months

If Moderate Nonproliferative Diabetic Retinopathy

- Without DME 6 to 9 months
- With DME* 3 to 4 months

If Severe – Very Severe Nonproliferative Diabetic Retinopathy

- Without DME** 3 to 4 months
- With DME* 3 months

If Proliferative Diabetic Retinopathy less than High-Risk

- Without DME** 1 to 4 months
- With DME* 1 to 3 months

If High-Risk Proliferative Diabetic Retinopathy

- With or without DME – scatter laser surgery with follow-up in 3 months

*Focal laser surgery is generally indicated for CSME

**Scatter laser surgery may be indicated, especially for type 2 diabetes or type 1 diabetes of long duration

Intravitreal and periorbital steroid injections are sometimes used in clinical practice to treat macular edema despite no definitive studies on their

effectiveness or safety to date. These modalities are currently under rigorous investigation to further define their role.

Immunizations

Recommend the following vaccines:

- Influenza vaccine - yearly for all adult patients with diabetes [**1B**]
- Pneumococcal vaccine – once for all patients with diabetes. [**1B**]
- People ≥ 65 years of age should receive a second dose of pneumococcal vaccine if:
    - They received the previous dose ≥ 5 years earlier *and*
    - They were < 65 years of age when they received the previous dose

Women's Health

- Women with the potential for conception should receive information about contraception use and relation to blood glucose control and fetal development [**1C**]
- Refer to the *Joslin Diabetes Center & Joslin Clinic Guideline for Detection and Management of Diabetes in Pregnancy* for more details
- Follow appropriate guidelines for pap/pelvic and mammography screening for primary care patients [**1A**]
- Individualize approach to bone health for women with risk factors for osteoporosis, including surgical and natural menopause [**1B**]
- If sexual dysfunction exists, assess for infections or hormonal, psychological, or structural etiologies. Refer to specialist as indicated. [**1C**]

Men's Health

At initial & annual visit, discuss sexual function. If dysfunction exists, assess for hormonal, psychological, or structural etiologies. Refer to specialist as indicated. [**1C**]

Dental Care

At initial visit and annually, discuss need for dental exams at least every six months. If evidence of gingivitis, may need dental evaluation/treatment every 3 to 4 months.

Refer to dental specialist if oral symptoms such as sore, swollen, or bleeding gums, loose teeth or persistent mouth ulcers occur. [**1C**]

Definitions:

Grade of Recommendation	Clarity of Risk/Benefit	Quality of Supporting Evidence
1A Strong recommendation	Benefits clearly outweigh risk and vice versa.	Consistent evidence from well performed randomized, controlled trials or overwhelming

Grade of Recommendation	Clarity of Risk/Benefit	Quality of Supporting Evidence
High quality of evidence		evidence of some other form. Further research is unlikely to change our confidence in the estimate of benefit and risk.
1B Strong recommendation Moderate quality of evidence	Benefits clearly outweigh risk and burdens, or vice versa.	Evidence from randomized, controlled trials with important limitations (inconsistent results, methodological flaws, indirect or imprecise), or very strong evidence of some other research design. Further research is likely to have an impact on our confidence in the estimate of the benefit and risk and may change the estimate.
1C Strong recommendation Low quality of evidence	Benefits outweigh risk and burdens, or vice versa.	Evidence from observational studies, unsystematic clinical experience, or from randomized controlled trials with serious flaws. Any estimate of effect is uncertain.
2A Weak recommendation High quality of evidence	Benefits closely balanced with risks and burdens.	Consistent evidence from well performed randomized, controlled trials or overwhelming evidence of some other form. Further research is unlikely to change our confidence in the estimate of benefit and risk.
2B Weak recommendation Moderate quality of evidence	Benefits closely balanced with risks and burdens; some uncertainty in the estimates of benefits, risks, and burdens.	Evidence from randomized, controlled trials with important limitations (inconsistent results, methodological flaws, indirect or imprecise), or very strong evidence of some other research design. Further research is unlikely to have an

Grade of Recommendation	Clarity of Risk/Benefit	Quality of Supporting Evidence
		impact on our confidence in the estimate of the benefit and risk and may change the estimate.
2C Weak recommendation Low quality of evidence	Uncertainty in the estimates of benefits, risks, and burdens; benefits may be closely balanced with risks and burdens.	Evidence from observational studies, unsystematic clinical experience, or from randomized controlled trials with serious flaws. Any estimate of effect is uncertain.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate management of diabetes in adults

POTENTIAL HARMS

Not stated

CONTRAINDICATIONS

CONTRAINDICATIONS

Possible contraindications for aspirin (ASA) therapy may include allergy, bleeding tendency, anticoagulant therapy, recent gastrointestinal bleeding and clinically active hepatic disease). Eye disease is usually not a contraindication for ASA therapy.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This Guideline focuses on the unique needs of the patient with diabetes. It is not intended to replace sound medical judgment or clinical decision-making and may need to be adapted for certain patient care situations where more or less stringent interventions are necessary.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

If patient fails to keep scheduled appointments, has frequent hospitalizations or missed days of work/school:

Since many factors contribute to patients' ability to manage their care, the provider should:

- Engage patient in identifying and resolving contributing factors or barriers to under-utilization or over-utilization of healthcare services
- Consider referral to diabetes educator (DE), social service or mental health professional to address possible underlying psychosocial problems
- Establish a process for follow-up communication regarding lapsed services

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Joslin Diabetes Center. Clinical guideline for adults with diabetes. Boston (MA): Joslin Diabetes Center; 2006 Oct 20. 9 p. [238 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

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GUIDELINE DEVELOPER(S)

Joslin Diabetes Center - Hospital/Medical Center

SOURCE(S) OF FUNDING

Joslin Diabetes Center

GUIDELINE COMMITTEE

Joslin Clinical Oversight Committee

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This Guideline will be reviewed periodically and modified as clinical practice evolves and medical evidence suggests.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Joslin Diabetes Center.

Print copies: Available from the Joslin Diabetes Center, One Joslin Place, Boston, MA 02215

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on April 18, 2007. The information was verified by the guideline developer on May 10, 2007. This summary was updated by ECRI Institute on November 6, 2007, following the U.S. Food and Drug Administration advisory on Byetta (exenatide).

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