Effective Management of Diabetic Patients in Primary Care

A Toolkit

A Best Practices Project of the Oklahoma Physicians Resource/Research Network and the Oklahoma Foundation for Medical Quality

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Introduction

Management of patients with chronic illnesses like diabetes requires a combination of person-centered, need-based care and systematic, standardized care. Primary care practices tend to do a better job of the former than of the latter. This toolkit provides a synopsis of the methods used successfully by primary care clinicians in Oklahoma to accomplish the systematic aspects of care recommended for diabetic patients.

We have tried to be sensitive to time, cost, and personnel constraints. We have also considered the impact of these recommendations on the care of patients with other or multiple chronic problems. It should be reassuring that these methods are already being used successfully in private practice settings.

Method

In 2000-2001, the Oklahoma Physicians Resource/Research Network (OKPRN) and the Oklahoma Foundation for Medical Quality (OFMQ) conducted a study to identify reasons for physician non-adherence to diabetes care guidelines. While it was clear that all aspects of the guidelines didn't apply to all patients, the largest single reason for non-adherence to the guidelines appeared to be inadequate office systems.

In early 2002, the OFMQ re-reviewed the results of the chart audits conducted during this study to identify clinicians with adherence rates of 90% or better on any of the quality indicators ("exemplars"). In-depth interviews were conducted with each exemplar to determine their methods. Methods reported for individual quality indicators were compared and synthesized by a committee of physicians and nurses to create the recommendations contained in this toolkit. We recognize that each clinician and practice is different and that the recommendations will need to be adapted to fit individual circumstances. The committee identified six key principles, which will be explained in the next section of this notebook.

Note:
Strategies shown to be effective in other settings are included in the Other Management Strategies section. We have also included a sample protocol for staff, several diabetes flowsheets, a list of certified diabetes educators in your area, sources of patient education materials, instructions on the use of the Semmes-Weinstein monofilament for testing sensation, home blood glucose monitoring information, information on a rapid Hgb A1c test device, a list of pharmaceutical representatives with diabetes medications and other products, and information on subsidized medication programs for diabetics.

Quality Indicators and Guidelines

Diabetes Quality Improvement Project (DQIP)
Quality Indicators

1. Hgb A1c tested within the last year;
2. Last Hgb A1c $\leq$ 9.5%;
3. Retinal examination within the last year, or within the last two years in low-risk patients;
4. Fasting lipid profile within the last two years;
5. Most recent LDL cholesterol < 130 mg/dl;
6. Monitoring for diabetic nephropathy;
    a. Last UA positive for proteinuria,
    b. Last urine microalbumin $\geq$ 30 mcg/mg Cr, or last urine microalbumin within the last year.
7. Last systolic BP <140 and last diastolic BP < 90;
8. Foot examination for pulses and sensation within the last year.

Note: These indicators should be considered minimum standards of quality. They don't necessarily apply to every patient, but when examined over a number of different patients, they provide a reliable measure of quality of care.

Note:
In the OKPRN physician adherence study, we also evaluated the following:

1. Pneumococcal; vaccination ever and
2. Influenza vaccination within the last year.

American Diabetes Association
Evidence-Based Guidelines
Adults

Levels of Evidence

A-Level Evidence
Clear evidence derived from well-conducted, generalizable, randomized controlled trials that are adequately powered

B-Level Evidence
Supportive evidence from well-conducted cohort (epidemiologic) studies

C-Level Evidence
Supportive evidence from poorly controlled or uncontrolled studies

Expert Consensus
Consensus of diabetic experts

Glycemic Control

A-Level evidence

- Lowering Hgb A1C has been associated with a reduction of microvascular and neuropathic complications of diabetes.

B-Level evidence

- Develop or adjust the management plan to achieve normal or near-normal glycemia with an A1C test goal of < 7%.
- Lowering A1C may lower the risk of myocardial infarction and cardiovascular death.
- Aggressive glycemic management with insulin may reduce morbidity in patients with severe acute illness, perioperatively and following myocardial infarction.

Expert consensus

- Less stringent treatment goals may be appropriate for patients with limited life expectancies, in the very young or older adults, and in individuals with co-morbid conditions.

Self-monitoring of Blood Glucose (SMBG)

B-Level Evidence

- SMBG is an integral component of diabetes therapy.

Expert consensus

- Include SMBG in the management plan.
- Instruct the patient in SMBG and routinely evaluate the patient's technique and ability to use data to adjust therapy.

Hgb A1C Measurement
Expert consensus

- Perform the A1C test at least two times a year in patients who are meeting treatment goals (and who have stable glycemic control) and quarterly in patients whose therapy has changed or who are not meeting glycemic goals.

Medical Nutrition Therapy (MNT)
B-Level evidence

- People with diabetes should receive individualized MNT as needed to achieve treatment goals, preferably provided by a registered dietitian familiar with the components of diabetes MNT.

Physical activity
B-Level evidence

- A regular physical activity program, adapted to the presence of complications, is recommended for all patients with diabetes who are capable of participating.

Blood pressure control
A-Level evidence

- Patients with hypertension (systolic blood pressure $\geq$ 140 or diastolic blood pressure $\geq$ 90 mmHg) should receive drug therapy in addition to lifestyle/behavioral therapy.
- Initial drug therapy may be with any drug class currently indicated for the treatment of hypertension. However, some drug classes (ACE inhibitors, β-blockers, and diuretics) have been repeatedly shown to be particularly beneficial in reducing CVD events during the treatment of uncomplicated hypertension and are therefore preferred agents for initial therapy. If ACE inhibitors are not tolerated, ARBs may be used. Additional drugs may be chosen from these classes or another drug class.
- If one class is not tolerated, the other should be substituted.
- In patients with type 1 diabetes, with or without hypertension, with any degree of albuminuria, ACE inhibitors have been shown to delay the progression of nephropathy.
- In patients with type 2 diabetes, hypertension and microalbuminuria, ACE inhibitors and ARBs have been shown to delay the progression to macroalbuminuria.
- In those with type 2 diabetes, hypertension, macroalbuminuria (>300 mg/day), nephropathy, or renal insufficiency, an ARB should be strongly considered.
- In patients >55 years of age, with hypertension or without hypertension but with another cardiovascular risk factor (history of CVD, dyslipidemia, microalbuminuria, smoking), an ACE inhibitor (if

not contraindicated) should be considered to reduce the risk of cardiovascular events.

C-Level evidence

- In patients with microalbuminuria or overt nephropathy, in whom ACE inhibitors or ARBs are not well tolerated, a non-dihydropyridine CCB (e.g. verapamil or diltiazem; not amlodipine or nifedipine) should be considered.

Expert consensus

- Patients with diabetes should be treated to a diastolic blood pressure <80 mmHg.
- Patients with a systolic blood pressure of 130-139 mmHg or a diastolic blood pressure of 80-89 mmHg should be given lifestyle/behavioral therapy alone for maximum of 3 months and then, if targets are not achieved, in addition, should be treated pharamacologically.
- If ACE inhibitors or ARBs are used, monitor renal function and serum potassium levels.
- In elderly hypertensive patients, blood pressure should be lowered gradually to avoid complications.
- Patients not achieving target blood pressure on three drugs including a diuretic and patients with severe renal disease, should be referred to a specialist experienced in the care of patients with hypertension.

Lipid management

A-Level evidence

- Lowering LDL cholesterol is associated with a reduction in cardiovascular events.
- Medical Nutrition Therapy (MNT) focusing on the reduction of saturated fat and cholesterol intake, weight loss, and increased physical activity has been shown to improve the lipid profile in patients with diabetes.
- Patients who do not achieve lipid goals with lifestyle modifications require pharmacological therapy.
- Statins should be used as first-line pharmacologic therapy for LDL lowering
- Therapy with fibrates in patients with low HDL has been shown to reduce CVD rates and progression of carotid intimal medial progression. When prescribing fibrates, in combination therapy with a statin, care is needed to minimize the risk of myositis.

B-Level evidence

- Lowering triglycerides and increasing HDL cholesterol are associated with a reduction in cardiovascular events.
- Lower LDL cholesterol to <100 mg/dl as the primary goal of therapy for adults.

C-Level evidence

- Lower triglyerides to <150 mg/dl (1.7 mmol/l) and raise HDL cholesterol to > 45 mg/dl (1.15 mmol/l) in men and >55 mg/dl (1.40 mmol/l) in women.

Expert consensus

- In adult patients, test for lipid disorders at least annually and more often if needed to achieve goals. In adults with low-risk lipid values, repeat lipid assessments every 2 years.
- When prescribing fibrates or niacin, in combination therapy with a statin, care is needed to minimize the risk of adverse effects.

Aspirin

A-Level evidence

- Use aspirin therapy (75-325 mg/day) in all adult patients with diabetes and macrovascular disease.
- Consider beginning aspirin therapy (75-325 mg/day) for primary prevention in patients $\geq$ 40 years of age with diabetes and one or more other cardiovascular risk factors.

B-level evidence

- Consider aspirin therapy for patients between 30 and 40 years of age with other cardiovascular risk factors.

Smoking Cessation

A-Level evidence

- Advise all patients not to smoke.

B-Level evidence

- Include smoking cessation counseling and other forms of treatment as a routine component of diabetes care.

Coronary Heart Disease Screening and Treatment

Expert consensus

- Perform exercise stress testing in asymptomatic diabetic patients based on the criteria outlined above. Consider a risk factor-based strategy for the diagnosis of CAD that might include stress ECG and/or stress ECHO and/or perfusion imaging.
- Refer patients with signs and symptoms of CVD or with positive noninvasive test for CAD to a cardiologist for further evaluation.
- In patients with treated congestive heart failure, metformin use in contraindicated. The thiazolidinediones are associated with fluid retention, and their use can be complicated by the development of congestive heart failure. Caution in prescribing thiazolidinediones in the settings of known congestive heart failure or other heart diseases as well as in patients with preexisting edema or concurrent insulin therapy is required.

Nephropathy screening and treatment

A-Level evidence

- To reduce the risk and/or slow the progression of nephropathy, optimize glucose control.
- To reduce the risk and/or slow the progression of nephropathy, optimize blood pressure control.
- In the treatment of albuminuria/nephropathy both ACE inhibitors and ARBs should be used:
    - In patients with type 1 diabetes, with or without hypertension, with any degree of albuminuria, ACE inhibitors have been shown to delay the progression of nephropathy.
    - In patients with type 2 diabetes, hypertension and microalbuminuria, ACE inhibitors and ARBs have been shown to delay the progression to macroalbuminuria.
    - In patients with type 2 diabetes, hypertension, macroalbuminuria, and renal insufficiency (serum creatinine >1.5 mg/dl), ARBs have been shown to delay the progression of nephropathy.

B-Level evidence

- With presence of nephropathy, initiate protein restriction to $\leq$0.8 g. kg^{-1} body wt. Day^{-1} (~10% of daily calories), the current adult recommended dietary allowance for protein. Further restriction may be useful in slowing the decline of GFR in selected patients.
- Use of DCCBs are less effective in slowing nephropathy progression compared with ARB therapy in those with diabetes with nephropathy and macroalbuminuria.
- If ACE inhibitors or ARBs are used, monitor serum potassium levels for the development of hyperkalemia.
- Consider referral to a physician experienced in the care of diabetic renal disease when the eGFR has fallen to <60 ml . min^{-1}. 1.73 m^{-2} or if difficulties occur in the management of hypertension or hyperkalemia.

Expert consensus

- Perform an annual test for the presence of microalbuminia in 1) type 1 diabetic patients who have had diabetes > 5 years and 2) all type 2 diabetic patients starting at diagnosis.
- If ACE inhibitors or ARBs are used, monitor serum potassium levels for the development of hyperkalemia.
- Consider referral to a physician experienced in the care of diabetic renal disease when the GFR has fallen to either <70 ml.min^{-1}.1.73m^{-2}, serum creatinine has increased to > 2.0 mg/dl (>180 μmol/l), or difficulties occur in the management of hypertension or hyperkalemia.
- Consider the use of non-DCCBs in patients unable to tolerate ACE inhibitors or ARBs.

- If one class is not tolerated, the other should be substituted.

Foot care

A-Level evidence

- A multidisciplinary approach is recommended for persons with foot ulcers and high risk feet, especially those with a history of prior ulcer or amputation.

B-level evidence

- The foot examination can be accomplished in a primary care setting and should include the use of a Semmes-Weinstein monofilament, tuning fork, palpation, and a visual examination.
- Educate all patients, especially those with risk factors or prior lower-extremity complications, about the risk and prevention of foot problems, and reinforce self-care behavior.

C-Level evidence

- Refer high-risk patients to foot care specialists for ongoing preventive care and life-long surveillance.
- Refer patients with significant claudication for further vascular assessment and consider exercise and surgical options.

Expert consensus

- Perform a comprehensive foot examination annually on patients with diabetes to identify risk factors predictive of ulcers and amputations. Perform a visual inspection of patients' feet at each routine visit.

Diabetic retinopathy screening and treatment

A-Level evidence

- Optimal glycemic control can substantially reduce the risk and progression of diabetic retinopathy.
- Optimal blood pressure control can reduce the risk and progression of diabetic retinopathy.
- Aspirin therapy does not prevent retinopathy or increase the risks of hemorrhage.
- Laser therapy can reduce the risk of vision loss in patients with high risk characteristics.
- Promptly refer patients with any level of macular edema, severe NPDR, or any PDR to an ophthalmologist who is knowledgeable and experienced in the management and treatment of diabetic retinopathy.

B-Level evidence

- Patients with type 1 diabetes should have an initial dilated and comprehensive eye examination by an ophthalmologist or optometrist with 3-5 years after the onset of diabetes.

- 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 is made.
- Subsequent examinations for type 1 and type 2 diabetic patients should be repeated annually by an ophthalmologist or optometrist who is knowledgeable and experienced in diagnosing the presence of diabetic retinopathy and is aware of its management. Examinations will be required more frequently if retinopathy is progressing.
- When planning pregnancy, women with pre-existing diabetes should have a comprehensive eye examination and should be counseled on the risk of development and/or progression of diabetic retinopathy. Women with diabetes who become pregnant should have a comprehensive eye examination in the first trimester and close follow-up throughout pregnancy and for 1 year postpartum. This guideline does not apply to women who develop GDM because such individuals are not at increased risk for diabetic retinopathy.

Immunizations

C-Level Evidence

- Annually provide an influenza vaccine to all diabetic patients 6 months of age or older.
- Provide at least one lifetime pneumococcal vaccine for adults with diabetes. 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 nephritic syndrome, chronic renal disease, and other immunocompromised states, such as postorgan transplantation.

Strategies

Regular diabetes visits (e.g. Q3mo)
Diabetes chart labels
Standard nurse/receptionist protocols
Diabetic registry
Limit number of eye consultants
Chart documentation method

1. Regular Diabetes Visits

The exemplars interviewed by OFMQ schedule diabetics to come in for diabetes care visits every 3 months. Extremely well controlled patients at low risk for complications are seen every 6 months. During these visits, members of the office staff, complete a specific set of tasks according to a written protocol. Patients are informed that, because they have diabetes, it is important that they be followed more closely, and that, until their disease is under perfect control, and everything is completely stable, they need to be seen every 3 months.

Note: An extension of this principle would be to have specific days of the week for diabetes care visits. A further extension would be to use a "group visit" format. Though none of the participants in this project used group visits, this would be a logical next step. Group visits are described more fully in the Other Management Strategies section.

2. Diabetes Chart Labels

OKPRN exemplars use chart labels to alert their clinic staff to patients with diabetes and the need to follow their standard protocol for diabetes care whenever these patients are seen in the office.

Note: This concept could be expanded to patients with other conditions requiring systematic management approaches (e.g. patients with asthma, hypertension, CHF, etc.).

3. Standard Protocol

The exemplars use diabetes care protocols in much the same way that they use lists for the equipment needed for various minor surgical procedures. Some use specific diabetes flowsheets completed by office staff, while others use simple "to do" lists. In some offices, the protocols involve only nurses or medical assistants. In others, they include front office staff and/or others.

4. Diabetic Registry

Some exemplars have created registries of their active diabetic patients including the dates of their visits and selected care parameters (e.g. last Hgb A1C values). These are used for periodic quality checks. For example, these clinicians are able to generate a list of diabetic patients who have not been seen in the last 6 months so that reminder letters can be sent.

A registry can be built prospectively as patients with diabetes come in to see you, or retrospectively from billing information. Registries can contain whatever information you plan to use for quality control or they can include all information relevant to diabetes care.

We have created a PDA-based registry that can be used by your nurse or medical assistant to assist with the visit protocols in addition to periodic quality audits. It is free for your use and we will be glad to teach your nurse or medical assistant to use it.

Again, this method could be expanded to patients with other conditions.

5. Limit the Number of Eye Consultants to Whom You Refer Diabetic Patients

OKPRN exemplars identify one or two ophthalmologists or optometrists willing to recall diabetic patients for yearly exams and to reliably send copies of their notes to the referring clinician. They recommend these consultants to all of their diabetic patients who don't have another preference.

6. Chart Documentation Method

Exemplars develop methods for documenting the standard components of care provided to diabetic patients. This is done in several different ways to suit individual styles and preferences, but most commonly it involves a diabetes flow sheet. We have included several examples in this notebook.

Diabetes Care Protocol

Front Office Staff:

1. Check date of last ophthalmology or optometrist appointment. Schedule if more than 1 year. Request most recent note from ophthalmologist or optometrist if not already in chart.

Nurse:

1. Vital signs including: weight, BP and P lying and standing, and height if last height more than 1 year ago.
2. Obtain urine if last UA or urine microalbumin was more than 1 year ago:
   a. If last UA was negative for protein and last microalbumin $\leq$ 20 order urine microalbumin
   b. If last UA was negative for protein and last microalbumin > 20 order UA.
   c. If last UA was positive for protein, obtain urine and hold for physician order.
3. Order or perform Hgb A1C if last one was more than 3 months ago.
4. Order fasting lipid panel if last one was more than one year ago.
5. Ask patient to remove shoes and socks.

Other Management Strategies

Group visits
Electronic medical records
Bar coding
System-wide registry
Use of diabetic educators

Group Visits

Group visits are of two types, scheduled and "drop in." In both types, patients with the same health problem (e.g. diabetes) arrive at the clinic at the same time and are involved in both individual and group activities. Specific times are set aside and staff are mobilized to provide education and counseling. Patients generally see the physician individually as well. In large practices, diabetic educators, podiatrists, eye care specialists, and nutritionists can be scheduled to be available.

The advantages of group visits are efficiency for the practice and peer support for the patients. Several small clinical trials have shown that many patients like group visits and that average Hgb A1C values are improved by this method.

The biggest challenges are scheduling logistics and billing. Some physicians bundle all services under a physician visit, making sure to see every patient briefly and reviewing the notes of the other providers. Some providers can bill separately (e.g. podiatrists and diabetes educators) In managed care settings, the visits may be included as part of the capitation.

Electronic Medical Records

Electronic medical records (EMR's) can be useful for organizing information and for generating both physician and patient reminders. However, we believe that unless the office staff is included in the process of reacting to the reminders and inputting information, EMR's will not substantially increase practice adherence to systematic care guidelines over a long period of time.

Bar Coding

While there is no published information showing that bar coding improves efficiency or adherence to guidelines, the method is intriguing enough to be included in the Toolkit.

System-wide Registries

Some large practices or groups of practices have established system-wide registries of diabetic patients. These function in the same way that individual provider registries do, but they offer the additional advantage of improved continuity and coordination of care among multiple providers.

Use of Diabetic Educators

Certified diabetes educators are trained to provide education to diabetic patients on:

1. Clear patient-friendly explanations of the pathophysiology of Type 1 and Type 2 diabetes.
2. Nutrition education, geared to the patient's lifestyle and personal preferences.
3. Information for insulin-requiring diabetics such as: types of insulin, time actions, "matching" the short-acting insulin dose to the meal content/expected activity, injection technique, proper storage, appropriate syringe disposal.
4. Self-monitoring of blood glucose technique and proper record keeping for use in pattern management.
5. Exercise guidelines and precautions.
6. Proper foot care and footwear guidelines.
7. Facilitating patient confidence in mastering complex self-care skills and understanding the need to see their medical provider frequently.

Medicare will pay for the services of certified diabetes educators within specific guidelines.

Medicare Guidelines for Payment for Diabetes Education

Special Immunization Clinics

In a previous OKPRN study of pneumococcal immunization methods, we determined that exemplary practices included the following components:

1. The physician must believe in the importance of adult immunizations.
2. Responsibility for the immunizations is delegated to the nurse or medical assistant with a specific protocol including a method for identifying eligible patients.
3. Regular oversight of nurse performance.
4. Special immunization clinics in the fall and linkage of pneumococcal vaccination with flu vaccination.

Special immunization clinics may be offered either during the week, after hours, or on weekends. Patients can walk in obtain required immunizations without excessive waiting.

Patient Education Materials

A variety of patient education materials are available. Materials that have been professionally produced and tested with patients are generally proprietary, but if purchased in bulk, relatively inexpensive.

Materials available through the specialty organizations (e.g. AAFP) are often very useful and either free or reasonably priced.

Internet sites with diabetes patient education materials include:

www.dsok.net
www.diabetes.org
www.americanheart.org
http://store.diabetes.org
www.idcpublishing.com
www.staywell.com
www.krames.com
mhinshaw@medimedia.com Michael Hinshaw – Oklahoma Representative - 1-800-333-3032
okpro.menright@sdps.org
Oklahoma Foundation for Medical Quality
(405) 840-2891 or 1-800-522-3414

Home Blood Glucose Monitoring Systems

Home blood glucose monitoring appears to improve patient understanding of their disease and, as a result, blood glucose control. Particularly when patients combine glucose monitoring with a diet diary, they are able to identify food products and eating habits that most affect their blood glucose.

The optimal timing of finger stick blood glucose measurements depends upon the treatment regimen. However, in general, ideal measurement times include fasting in the morning and one hour after meals. The fasting glucose is a measure of basal insulin and the postprandial glucose levels are a measure of response of the blood glucose to meals. Once control has been established, most patients need not measure their glucose levels four times a day. They can simply rotate their measurements through a set of specified times.

Hgb A1C Analyzer Information

Hemoglobin A1C is a measure of average blood glucose over the preceding three months. In the past, most practices have had to send HgbA1C's to an outside laboratory. The result is therefore not available at the time of the visit. This creates additional staff and physician time, paperwork, and phone calls. Now there is at least one Hgb A1C analyzer for physician offices, and while the initial investment is significant, it may pay for itself fairly quickly depending upon the number of diabetic patients the practice cares for.

Based upon the Medicare 2003 fee schedule, Medicare allows $11.95 for a Hgb A1C (CPT code 83036) based upon a diagnosis of diabetes mellitus (ICD-9 codes 250.00-250.93) or abnormal gluscose tolerance (ICD-9 code 790.2).

Pharmaceutical Representatives

This section of the Toolkit can be used to keep the business cards of pharmaceutical representatives who handle diabetic care products.

Subsidized Medication Programs

This section of the Toolkit includes information on subsidized and discounted medication programs related to diabetes.

www.needymeds.com

www.rx-canada.com

www.themedicineprogram.com

www.medcentercanada.com

REFERENCES