Systematic Implementation of Customized Guidelines: The Staged Diabetes Management Approach

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Diabetes mellitus is a significant public health problem whose worldwide prevalence has been increasing in recent years [1]. Approximately 15 million people in the United States have the disease, one third of whom remain undiagnosed [2]. The disease exacts an enormous economic toll: in 1997, direct and indirect costs of diabetes totaled $98 billion [3]. There is a great imperative to improve diabetes management, as numerous studies reveal that many patients with diabetes receive inadequate care [4–7]. Evidence-based practice guidelines for diabetes have been widely disseminated; however, the literature shows that physicians often fail to utilize guidelines [8–11].

In 1988, a system of care was developed by the International Diabetes Center (IDC), a nonprofit diabetes research and education center located in Minneapolis, MN. Called Staged Diabetes Management™ (SDM) [12], the program provides an evidence-based and systematic approach to diabetes management for the primary care physician that can be customized to the needs of the local community. This article will describe the SDM program and discuss its role in improving the quality of care of patients with diabetes.

The Program

The core of the SDM program consists of practice guidelines, a series of decision paths (algorithms for clinical decision making), and reference materials [13]. The SDM practice guidelines used in the United States are shown in Figure 1. The guidelines, which incorporate all of the American Diabetes Association standards of care, contain recommendations for screening, target blood glucose and other laboratory values, recommended follow-up, and other best practice standards. The SDM Master DecisionPath, which shows the different stages of therapy and when to initiate them, is presented in Figure 2. There are supplementary DecisionPaths for the individual therapy stages and individual drug classes. Clinician quick reference guides for detection and treatment of diabetes and management of complications are also provided with the program.

The SDM implementation process begins with a local site self-assessment that includes a review of all systems that impact on diabetes care. The assessment includes a description of the population served, number of individuals diagnosed with diabetes, therapies used by providers, referral patterns to specialists, availability of diabetes and nutritional education and other resources, current screening activities, clinic staffing, and community awareness programs. A local diabetes team is formed, including a site champion or co-champions to provide leadership and to help ensure ongoing improvement. Following the self-assessment, the diabetes team presents the SDM program to administrative decision makers and other stakeholders with financial interest in improving diabetes care within the organization.

Once the decision is made by the site to move forward with the program, a baseline review of diabetes care is performed. The site may elect to use their own audit instrument or choose to have IDC assist them in collecting clinical diabetes outcomes and measures. Data typically collected include frequency and results of HbA1c, blood pressure, and lipid measurement; frequency of blood glucose self-monitoring, foot exams, retinal eye exams, and screening for microalbuminuria; documentation of diabetes education, nutritional counseling, and smoking cessation counseling; and patient satisfaction data. Some clinics also measure rates of aspirin use and pneumococcal and influenza immunization.

Following this review, IDC staff spend a full day onsite to provide training and to facilitate the customization process. In addition to primary care physicians, representatives from a host of other disciplines (eg, nursing, pharmacy, dietetics, home health, mental health) as well as from the lay community, including patients with diabetes, are invited to attend the training. Following a review of the audit and an update on current diabetes practice and treatment, the group closely
Screening

Screen all patients every 3 years starting at age 45; if risk factors present, start earlier and screen annually.

Risk factors
- BMI > 25 kg/m² (especially waist-to-hip ratio > 1)
- Family history of type 2 diabetes (especially first-degree relatives)
- Age (risk increases with age)
- Hypertension (≥ 140/90 mm Hg)
- Dyslipidemia (HDL ≤ 35 mm/dL and/or triglyceride ≥ 250 mg/dL)
- Previous impaired fasting glucose (IFG) with fasting plasma glucose 110–125 mg/dL
- Previous impaired glucose tolerance (IGT) with oral glucose tolerance test (OGTT) 2-hr glucose value 140–199 mg/dL
- Previous gestational diabetes: macrosomic or large-for-gestational age infant
- Acanthosis nigricans
- American Indian or Alaska Native, African American, Hispanic, Asian, Pacific Islander

Diagnosis

Plasma glucose
- Casual > 200 mg/dL plus symptoms, fasting ≥ 126 mg/dL, or 75 g OGTT 2-hr glucose value ≥ 200 mg/dL; if positive, confirm diagnosis with casual or fasting plasma glucose on subsequent day within 1 week
Symptoms
- Often none
- Common: blurred vision; urinary tract infection; yeast infection; dry/itchy skin; numbness or tingling in extremities; fatigue
- Occasional: increased urination, thirst, and appetite; nocturia; weight loss
Urine ketones
- Usually negative

Treatment Options

Medical nutrition therapy: oral agent (α-glucosidase inhibitor, metformin, repaglinide, nateglinide, sulfonylurea, thiazolidinedione); combination therapy (oral agents, oral agent-insulin); insulin stages 2, 3A, 4A

Targets

SMBG
- Self-monitored blood glucose (SMBG)
  - More than 50% of SMBG values within target range
  - Pre-meal: 80–120 mg/dL
  - Post-meal (2 hr after start of meal): < 160 mg/dL
  - Bedtime: 100–160 mg/dL
  - No severe (assisted) or nocturnal hypoglycemia
- Blood pressure < 130/80 mm Hg
- Lipids
  - Cholesterol < 200 mg/dL, HDL > 40 mg/dL, LDL < 100 mg/dL, triglycerides < 150 mg/dL
- Hemoglobin A₁c (HbA₁c)
  - Within 1.0% points of upper limit of normal (eg, normal 6.0%, target < 7.0%)
  - Frequency: every 3–4 months
  - Use HbA₁c, to verify SMBG data

Monitoring

SMBG
- 2–4 times per day (eg, before meals, 2 hr after start of meal, bedtime); may be modified due to cost, technical ability, availability of meters; if on insulin, check 3 AM SMBG as needed
Method
- Meter with memory and log book

Follow-up

Monthly
- Office visit during adjust phase (weekly phone contact may be necessary)

Every 3 months
- Hypoglycemia, medications, weight or BMI, BP, SMBG data (download and check meter), HbA₁c, eye and foot screen, medical nutrition therapy, preconception planning for women of childbearing age, smoking cessation counseling, aspirin therapy

Yearly
- In addition to the 3-month follow-up, complete the following: history and physical, fasting lipid profile; albuminuria screen, dilated eye examination, dental examination, neurologic assessment, complete foot examination (pulses, sensation, and inspection), patient satisfaction evaluation, referral for diabetes and nutrition education, adult immunizations

Complications surveillance
Cardiovascular, renal, retinal, neurologic, foot, oral, and dermatologic

At diagnosis

- **HbA1c < 8% and/or**
  - Fasting plasma glucose < 200 mg/dL
  - Casual plasma glucose < 250 mg/dL

- **HbA1c 8%-11% and/or**
  - Fasting plasma glucose 200-300 mg/dL
  - Casual plasma glucose 250-350 mg/dL

  Consider combination therapy if HbA1c > 9%

**Medical nutrition therapy stage**

If target goals not reached or no significant improvement in glycemic control within 3 months, start **oral agent stage**

Potential cumulative benefit: ~1 percentage point reduction in HbA1c

**Oral agent stage**

- Insulin resistance*: metformin, thiazolidinedione
- Insulin deficiency†: sulfonylurea, repaglinide, nateglinide, or α-glucosidase inhibitor

If target goals not reached after clinically effective dose for 4-8 weeks, start combination oral agent stage, combination oral agent-insulin stage or insulin

Potential cumulative benefit: ~2 percentage point reduction in HbA1c

**Combination oral agent stage**

- Insulin resistance*: add metformin or thiazolidinedione
- Insulin deficiency†: sulfonylurea, repaglinide, nateglinide, or α-glucosidase inhibitor

OR

**Combination oral agent and insulin stage**

Morning FPG > 300 mg/dL: add bedtime NPH

See Combination therapy selection. If target goals not reached after clinically effective dose for 4-8 weeks, start combination oral agent-insulin stage or consider stopping oral agents and start insulin therapy

Potential cumulative benefit: ~2-4 percentage point reduction in HbA1c

**Insulin stage 2**

- R/N = 0 – R/N = 0
- RA/N = 0 – RA/N = 0

If persistent AM hyperglycemia or nocturnal hypoglycemia, start insulin stage 3A; if need more flexibility or intensified insulin regimen, start insulin stage 4A

Potential cumulative benefit: > 4 percentage point reduction in HbA1c

**Insulin stage 3A**

- R/N = 0 – R – N
- RA/N = 0 – RA – N

If persistent midafternoon hyperglycemia, need for more flexibility and/or intensified insulin regimen, start insulin stage 4A

Potential cumulative benefit: > 4 percentage point reduction in HbA1c

**Insulin stage 4A**

- RA – RA – RA – N(G)
- RA(N) – RA – RA – N

Potential cumulative benefit: > 4 percentage point reduction in HbA1c

**Insulin stage 2**

RA = rapid-acting (Lispro, Aspart); N = NPH; G = glargine; 0 = none.

Dose schedule: AM-midday-PM-bedtime

**Insulin stage 3A**

RA = rapid-acting (Lispro, Aspart); N = NPH; G = glargine; 0 = none.

Dose schedule: AM-midday-PM-bedtime

**Insulin stage 4A**

RA = rapid-acting (Lispro, Aspart); N = NPH; G = glargine; 0 = none.

Dose schedule: AM-midday-PM-bedtime

**Comments**

1. Monthly reduction in SMBG of 15–30 mg/dL and/or HbA1c of 0.5-1.0 percentage points is considered significant improvement
2. Continue with medical nutrition therapy throughout all stages of therapy
3. The master decision path is bidirectional with movement in either direction between therapies
4. Ultralente may be used in place of NPH
5. Insulin sensitizers may be added when total daily insulin dose > 0.7 U/kg

STAGED DIABETES MANAGEMENT

Table 1. Results of Controlled Trial Evaluating Staged Diabetes Management (SDM)

<table>
<thead>
<tr>
<th>Clinic</th>
<th>n</th>
<th>Mean HbA1c (SEM)</th>
<th>Mean Within Subject Change HbA1c (SEM)</th>
</tr>
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<tbody>
<tr>
<td></td>
<td></td>
<td>Baseline 9 Months 15 Months</td>
<td>9 Months 15 Months</td>
</tr>
<tr>
<td>SDM</td>
<td>54</td>
<td>9.30 (0.32) 8.42 (0.30) 8.68 (0.28)</td>
<td>-0.90 (0.28) -0.62 (0.30)</td>
</tr>
<tr>
<td>Control</td>
<td>52</td>
<td>9.21 (0.32) 9.41 (0.29) 9.15 (0.32)</td>
<td>+0.20 (0.27) +0.06 (0.28)</td>
</tr>
<tr>
<td>P</td>
<td></td>
<td>NS 0.001 0.009</td>
<td>0.001 0.006</td>
</tr>
</tbody>
</table>

SEM = standard error of the mean. (Adapted with permission from Benjamin EM, Schneider MS, Hinchey KT. Implementing practice guidelines for diabetes care using problem-based learning. A prospective controlled trial using firm systems. Diabetes Care 1999;22:1672–8.)

examines the guidelines and DecisionPaths and customizes them to best meet the needs of their community. For example, a community might decide that movement from the medical nutrition therapy stage to the oral agent stage should occur sooner than 3 months or they might adjust the minimum fasting plasma glucose level signaling initiation of the insulin stage. Community risk factors, practice patterns, and available resources are some of the factors that impact customization. Everyone is encouraged to participate and the process ensues until agreement is reached.

The group is asked to apply their customized guidelines to actual patients in a problem-based learning exercise using case studies generated by the site. The training concludes with the group development of an “action plan” that identifies areas needing improvement, priority strategies to implement, individual task assignments, and a timeline for completion. These might include such concrete steps as hanging a poster-sized copy of the Master DecisionPath in the examination room or posting a sign instructing diabetic patients to remove their shoes and socks.

Effectiveness of SDM

There have been a number of studies conducted in diverse settings that have attempted to document the efficacy of SDM. A controlled trial was conducted in 144 patients with type 2 diabetes in 2 university-based internal medicine outpatient clinics. Doctors and staff in one of the clinics went through SDM training. At 15 months, intervention patients demonstrated significant improvement in glycemic control and in physician adherence to standards of care. Results are shown in Table 1 and Figure 3 [14].

Several studies have been conducted within the Indian Health Service, one of the early adopters of SDM. In one study using a pre/post design, 506 American Indians in Arizona with type 2 diabetes were followed for 2.5 years. More than 60% had HbA1c values that exceeded 8% at baseline. At the end of the study, mean HbAlc values had decreased from 10.5 ± 1.2% to 8.4 ± 0.9% (P = 0.001) [15]. In an Indian Health Service clinic in Minnesota, SDM was applied and evaluated for effectiveness in improving diabetic foot care outcomes. Four periods were compared: standard care period (1986–89);
the public health period (1990–93), during which patients were screened for foot problems and high-risk individuals received foot care education and protective footwear; the SDM period (1994–96); and the SDM-outreach period (1997–99), during which local outreach clinics were provided in addition to SDM. Patients enrolled in the SDM program showed a 47% to 75% reduction in lower extremity amputations over the 14-year study (Table 2) [16,17].

A large mixed-model HMO that adopted the SDM protocols for their disease management program also saw positive results. In a before and after study, mean baseline HbA1c for all program participants was 8.51%. At 3-month follow-up, the mean HbA1c value for 2794 of 3291 participants had decreased to 7.41% (P < 0.001). At 1-year follow-up, the HbA1c value for 605 of 663 patients remaining in the system had decreased from mean baseline of 8.76% to 7.41% (P < 0.001). Initial cost analysis based on claims data revealed a $35 per member per month cost reduction after implementation of SDM [18].

A large health care system implemented a quality improvement project incorporating SDM in their primary care clinics. Approximately 7000 members were identified with diabetes. During 12 months, the mean HbA1c improved from 7.86% to 7.47% and the proportion of patients with HbA1c > 10% fell from 10.3% to 7.2%. The LDL testing rate rose from 47.4% to 57.4% and mean LDL fell from 120 mg/dL to 101 mg/dL. All changes were statistically significant [19].

SDM has also been employed in programs targeting nurse case managers. In one pre/post study, significant improvements in glycemic control and lipid control were observed when nurse case managers utilized SDM with endocrinologists as consultants [20]. The implications of the nurse case manager model are significant with regard to the potential to reduce the cost of care and improve quality in a variety of settings.

**Costs**

Although SDM will initially increase costs due to more outpatient visits and higher laboratory and medication costs, improvements in glycemic control would be expected to reduce long-term complications and associated costs. In a 2-year pilot study conducted by a large managed care organization, emergency room visits and hospitalizations were tracked for patients randomly assigned to SDM (n = 64) or non-SDM (n = 59). At 2 years, the SDM group had a decrease in both HbA1c (8.2% to 7.7%) and total cholesterol (194 mg/dL to 173 mg/dL, P < 0.0001), while values had increased in the non-SDM group. Costs for emergency room visits were 72% lower and costs for inpatient services were 45% lower for SDM patients compared with non-SDM patients. After subtracting the laboratory, medication, and nursing costs associated with SDM, costs of care were 31% lower for SDM patients compared with non-SDM patients [21]. Other studies have conclusively shown the cost of poorly controlled diabetes to be excessively high, and a program that improves adherence to diabetes guidelines may help to lower overall health care costs [22].

**Summary**

SDM is an evidence-based, systematic program for improving diabetes management in the primary care setting. The program is unique because it is customized according to the needs of the local community, a process that builds consensus and engenders a sense of ownership among program participants. Studies of SDM have documented improved processes and outcomes of care and greater clinician adherence to guidelines [23]. SDM has been implemented in more than 400 sites across the United States and adopted by primary care practices in 22 countries. SDM is an effective process to foster the translation of research into practice for primary care providers caring for patients with diabetes.

**Table 2. Incidence of Lower Extremity Amputation (LEA) in a High-Risk Diabetic Community in Northern Minnesota**

<table>
<thead>
<tr>
<th>Period</th>
<th>Patient-yrs at Risk</th>
<th>LEA Cases, n</th>
<th>LEA/1000 Patient-yrs</th>
<th>Percent Change</th>
<th>P Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard Care</td>
<td>1464</td>
<td>42</td>
<td>29</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Public Health</td>
<td>1544</td>
<td>33</td>
<td>21</td>
<td>−25</td>
<td>0.24</td>
</tr>
<tr>
<td>SDM</td>
<td>1314</td>
<td>20</td>
<td>15</td>
<td>−47</td>
<td>0.016</td>
</tr>
<tr>
<td>SDM-Outreach</td>
<td>1779</td>
<td>13</td>
<td>7</td>
<td>−75</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

*Chi-square (compared with Standard Care period).

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**References**

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