Staged Diabetes Management

THIRD EDITION

Mazze • Strock • Bergenstal • Criego • Cuddihy • Langer • Simonson • Powers

INTERNATIONAL DIABETES CENTER

WILEY-BLACKWELL

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Dedication

In 2004 we dedicated the second edition of *Staged Diabetes Management* to the memory of Donnell D. Etzwiler, founder and first president of the International Diabetes Center. A person of ideas and vision, he was steadfast in his mission to improve the lives of people with diabetes throughout the world. Don welcomed the challenges of scientific enquiry and the inevitability of criticism. He was tireless in his willingness to share his ideas through training programs that reached tens of thousands of health professionals; yet, he always had time for the child with diabetes. As we enter our 45th year as simply the IDC, his wisdom seems even more germane to the tasks at hand. His travels reinforced a tradition that opened a worldwide dialogue among scientists, educators, clinicians, and people with diabetes. He taught us that it would be selfish to accumulate but not share knowledge; that successful treatment and education strategies should be disseminated; and that the true importance of scientific discoveries was how successfully they were translated into practice. Most important, he taught us that the true hero in this endeavor is the individual with diabetes.

We dedicate our third edition to Don's fellow travelers, the men and women who work to improve the lives of those with diabetes through research, education and care; and especially to those individuals with diabetes who as advocates for others emulate Don's generosity of spirit.

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About the authors

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Richard M. Bergenstal MD is an endocrinologist and Executive Director of the International Diabetes Center at Park Nicollet. He is Clinical Professor in the Department of Medicine at the University of Minnesota and served as President, Science & Medicine of the American Diabetes Association. In 2007, Dr. Bergenstal was named the American Diabetes Association's Outstanding Physician Clinician of the Year. His clinical research has focused on glucose control and diabetes complications as a Principal Investigator of two National Institutes of Health trials: the Diabetes Control and Complications Trial in type 1 diabetes and the Action to Control Cardiovascular Risks in Diabetes study in type 2 diabetes. Dr. Bergenstal's clinical efforts have been directed toward improving systems of care for patients with diabetes by translating new research findings into practice. He teaches nationally and internationally on the importance of patient-centered team care, and has been listed in Best Doctors in America on numerous occasions. Dr. Bergenstal's contributions focused on assuring continuity between sections and a future perspective.

Amy Criego MD MS attended undergraduate and medical school at the University of North Dakota. She underwent residency training in pediatrics at DeVos Children's Hospital in Grand Rapids, MI, and completed her fellowship training in pediatric endocrinology at the University of Minnesota. She joined the Pediatric Endocrinology group at Park Nicollet Clinic/International Diabetes Center in 2005 and became the Department Chair for Pediatric Endocrinology in 2009. She continues to care clinically for children with diabetes and other endocrine disorders while actively participating in research and medical education. Dr. Criego has been involved with the collaboration between the diabetes and eating disorder teams at the International Diabetes Center and Melrose Institute since joining Park Nicollet in 2005. Her contributions to the text focused on children with type 1 and type 2 diabetes.

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reviewed each chapter, adding both common sense and scientific rigor.

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Margaret A. Powers PhD RD CDE is a registered dietitian and certified diabetes educator. She is a Research Scientist at the International Diabetes Center, where her research focuses on performance improvement with organizations and individuals to improve diabetes outcomes. She recently completed research with 12 health organizations around the county that focused on improving blood pressure measures in people with diabetes. Additionally, she is pioneering work with continuous glucose monitoring to study the glycemic response to food. Dr. Powers has been instrumental in designing programs that help health organizations improve diabetes care and education and in developing additional programs and products designed to improve healthcare outcomes. Throughout the text she assured that nutrition was addressed, balancing the scientific evidence with a behavioral approach.

Acknowledgments

It is generally a daunting task to identify and thank those individuals whose extraordinary efforts made this work possible. In this case it is quite simple. Jeanne Mettner worked almost 1 year to guide the authors through the creation of this third edition of *Staged Diabetes Management*. She acted as research, content, copy, and production editor. Without her, seven authors could not possibly have completed their work. As principal author I relied on Jeanne to help capture the unique contributions of each of the authors and then to organize them into a coherent single work. Each chapter was ultimately my responsibility to form into a single voice. Without Jeanne's assistance it would have been impossible. Helping Jeanne and me find all of the figures, produce new drawings and organize them to fit the text was Bryan Akkerman. His work was somewhat monumental as more than 100 figures had to be produced and properly placed in the text. We are very grateful that the production stages of this book were so ably undertaken by Lindsey Williams, on behalf of Wiley-Blackwell. Lindsey's patience and support have been integral in making sure this book turned out so well. The authors are also grateful to the International Diabetes Center staff, most especially my program coordinator, Dina Melnik, and our editors at Wiley-Blackwell for their devotion to this project.

Introduction

Staged Diabetes Management (SDM) is a systematic approach to preventing, detecting, and treating diabetes, metabolic syndrome, and associated disorders. It uses practice guidelines and clinical pathways, or algorithms, which reflect the responsibilities of the diabetes care clinician, especially the primary care provider and the primary care team.

The purpose of SDM is as follows:

- to provide an organized, evidence-based approach for clinical decision-making
- to provide a consistent set of scientifically based practice guidelines that can be adapted by a community according to its resources
- to identify appropriate criteria for initiating and altering therapies during three treatment phases: start, adjust, and maintain
- to provide a common, customized Master DecisionPath for the metabolic syndrome and each type of diabetes that both patients and providers can use to understand treatment options, to enhance communication, and to optimize therapies
- to facilitate the detection and treatment of diabetes, insulin resistance, and their complications by primary care providers, in consultation with specialists
- to foster a patient-centered team approach to the management of diabetes and associated complications.

SDM does not occur in a vacuum. It requires careful preparation in order to assure successful implementation. This preparation requires addressing four key areas that affect change: organization, innovation, measurement, and incentives. The following section explains the theoretical framework at the foundation of SDM as it is translated into practice.

From theory to practice: an integrated approach to diabetes care

Research worldwide has indicated that the quality of diabetes care in both developed and developing countries, whether at major medical centers or in small clinics, is suboptimal.[1–4] Despite numerous attempts to raise the level of care, studies show that the sentinel events that characterize diabetes care—the level of hemoglobin A_{1c} (HbA_{1c}), retinal and neurological examinations, screening for renal disease, blood pressure management, smoking cessation, and patient education—have had little effect on markedly improving diabetes care outcomes. Because of this stagnation, researchers have initiated studies to determine precisely which factors have stalled the trend towards improved care.

The case for an integrated model of organizational change in healthcare delivery

The most accepted method of encouraging change continues to be a combination of (1) improving the competency of clinicians through ongoing professional education and (2) the development of mechanisms for rapid translation of research findings and care innovations into practice. In part because of the failure of this approach, there has recently been a reemphasis on government-issued care guidelines, direct patient involvement in treatment decisions, and public awareness campaigns.[5] The purpose of this redirection is to ensure better compliance with treatment recommendations and to enhance the ability for disease self-management. Such strategies have in common multiple goals: improve care, lower cost, reduce error, and satisfy both the patient and payer. Not surprisingly, single strategies are likely to fail, and successful strategies are characterized by a multifaceted approach.[6]

Theoretical principles for an integrated approach to diabetes care

Consistent with this new strategic direction in chronic disease management, the International Diabetes Center's approach to innovations in diabetes care is multifaceted and based on an integrated model (Figure 0.1). Within this model, the initial stimulant of change can come from any component of the healthcare delivery system. However, in order for the change to be successful, several key early ingredients are required, including alignment, specificity, application of evidence-based data, and customization.

Alignment of policy, values, and resources

Alignment of policy, organizational values, and resource allocation, however, are recognized as early requirements if change is to be successful. For this alignment to occur, the following must be in place:

- organizational buy-in to the theoretical principles, which may require *organizational alignment* and/or *organizational change*
- identification/recognition of the change champion—a clinical or administrative leader who directs all efforts that support the required changes

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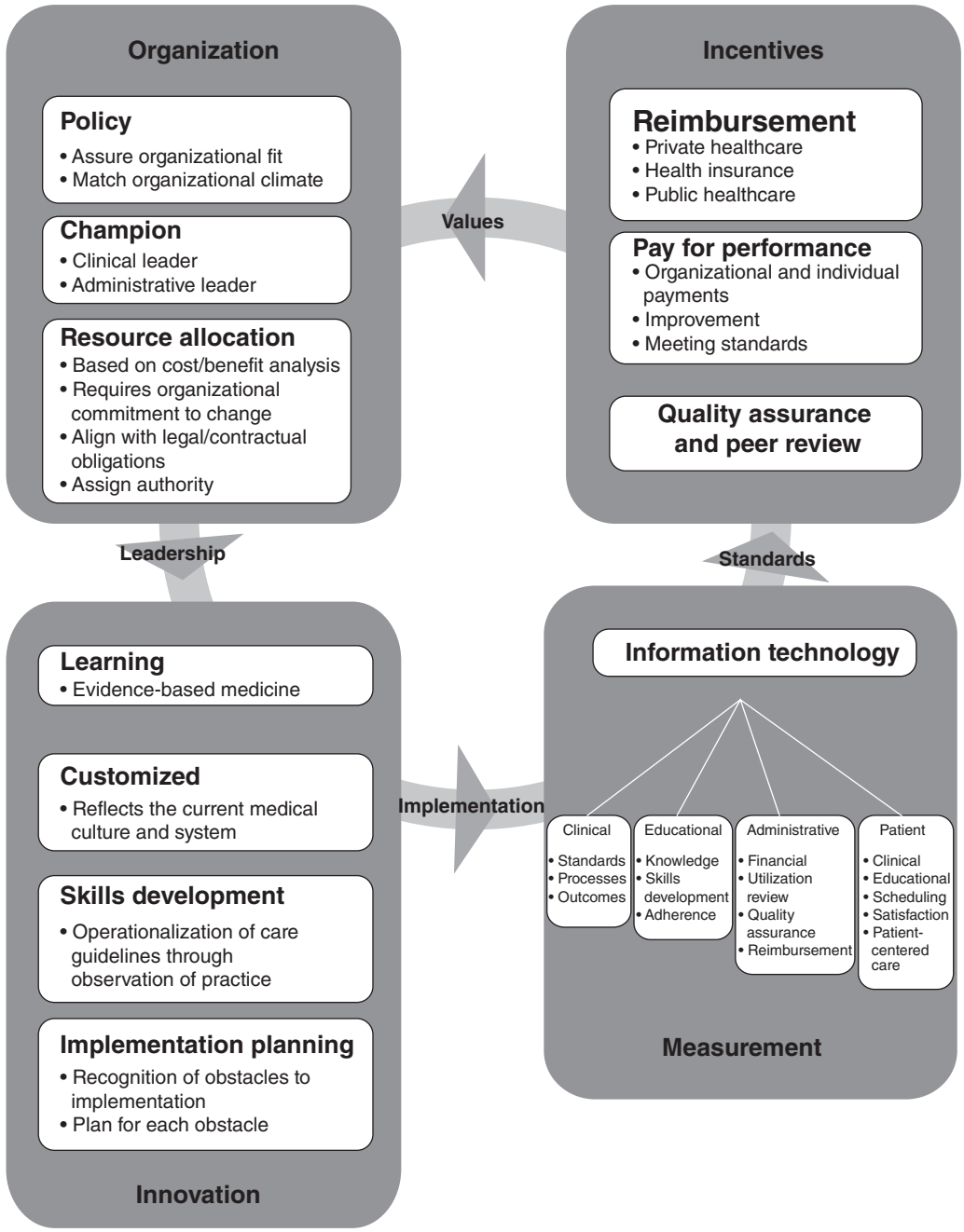

Figure 0.1 Model for organizational change in healthcare.

- identification of the clinical issues that have made change necessary—recognition of a problem that can be quantified establishes the criteria by which the intervention will be measured.

Process specificity and care specificity

By quantifying the clinical problem, healthcare administrators and clinicians can *specify* precisely how the clinical problem will be addressed—then use outcomes data to gauge how well these interventions are working. Specificity requires sufficient details, such as clinical pathways that provide the criteria for initiating and adjusting each therapeutic intervention. Specificity also permits the development of an implementation plan. The implementation plan is based on a healthcare system's unique needs and will facilitate the efficient use of the clinical pathways. (Chronic conditions, such as diabetes, are especially suited to this approach.)

Use of evidence-based data

Establishing standards of care in the absence of an evidence-based, targeted approach to changing care has often been cited as the key factor explaining poor care practices. Most approaches

to change do not adequately address the translation of standards into practice, nor do they consider the unique and often limited resources of organizations implementing change.

Most models accept a priori the willingness of healthcare professionals, especially physicians, to adopt "scientific findings." However, for adoption of standards to lead to successful implementation, a fundamental understanding of the science behind the standards is required. Most models omit this step. The integrated model employs an adoption process based on a thorough understanding of the scientific principles at the foundation of diabetes care. These principles include the pathophysiology and natural history of disease, current therapies, the defects they address, and a dynamic approach to the measurement of clinical outcomes; the last targets the translation of research into clinical practice.

Customization

Once a consensus concerning the scientific basis of the standards has been reached, adoption of common clinical pathways can proceed. The most successful approaches to change allow customization of clinical pathways to reflect the unique resources and clinical environment of the organization. The process of building a consensus by focusing on the science of medicine reinforces two key elements of successful practice changes—"learning" and "values fit." "Learning organizations" are those institutions that put at their highest priority the continued education and skills development of their health professionals. This is reflected in both policies and practices that tangibly support through the allocation of resources their ongoing training and peer review. "Values fit" is an alignment between the organization's values and those of its health professionals.

Alignment lies at the foundation of quality in healthcare delivery. The organization that values peer review cannot expect change from the professional who does not find value in this approach to quality assurance. The physician who places outcomes ahead of income cannot work successfully within an environment in which financial performance has precedence over clinical outcomes. Here again, alignment comes into play; successful change requires the alignment between values and policies, policies and resources, resources and innovation, innovation and measurement, and measurement and incentives.

Measuring change

Process and care specificity serve yet another function: measuring change. The quantification of care outcomes lays a foundation for a common database, which enables ongoing surveillance of clinical and nonclinical processes and outcomes as well as a means of providing feedback to each of the key participants. The role of information technology is pivotal. Although most chronic disease models acknowledge the importance of information technology, few identify the myriad roles information technology assumes. Beyond the traditional feedback to physicians ("report card"), the availability of reports to patients, nonphysician providers (such as diabetes educators), and administrators represents a constellation of data that can (1) reinforce patient-centered care; (2) provide information about utilization, access, cost, and quality assurance; and (3) ensure shared information among care team members.

Measurement also serves as a basis for reimbursement. The traditional incentives for improved care (continuous quality improvement, report cards, education, and peer review) are changing. As this integrated model illustrates, the ongoing collection of clinical data is multipurposed. Among the newest functions of clinical data retrieval are those related to providing physicians and other healthcare workers with incentives for quality performance. Pay-for-performance is a consequence of the linkage between clinical outcomes and incentives. Essentially, pay-for-performance links the quality of care provided by individuals and clinics to the amount of reimbursement for care. At its foundation is the identification of a set of measurable standards. At baseline, all care providers (and consequently their organizations) are graded as to how closely they meet each standard. Improvement in practice is tracked by data review following a specified intervention. Financial rewards in the form of a *bonus* are given to the physicians or clinics (or both) that improve. As the program matures, the standards become more rigorous and the financial rewards become more competitive and may be distributed only to those that meet the newer and higher standards. In diabetes, for example, the standard at initiation of pay-for-performance may be the requirement that 90% of the patients have an annual or biennial HbA_{1c} test carried out. As the program progresses, the measure may change to specify that the incentive requires more than 50% of the patients to achieve an HbA_{1c} level of less than 7%. At this point, those that are improving but have not yet met the standards will receive no incentive payment. This approach may include insurance companies and government agencies establishing the criteria for the incentives independent of the current standards of care promulgated by physician organizations. For example, while an insurance company may require renal screening once every 2 years, the American Diabetes Association may recommend annual evaluation.

Relating payment to performance presents substantial risk. It can result in focusing on only those medical procedures and outcomes that are rewarded. It can also become an unending cycle of behavior change contingent on ever-increasing rewards in which ever-larger payments are required to induce change. Consequently, pay-for-performance can result in a financial burden that is unpredictable because it is contingent upon the number of physicians and clinics willing to participate.

The results of any incentive plan, whether pay-for-performance or peer review, serve as feedback to the organization, which, in turn, uses this information to alter policy and resource allocation. Essentially, the integrated model is a cycle. The organization is linked to the innovation through the *leadership* it selects to guide the change. The *innovation* is connected to *measurement* through the process of implementation. Without translation into practice, therefore, innovation cannot succeed. The measurement is linked to the *incentives* through implementation of practice standards against which change is measured. For example, the implementation of a program designed to assure that each patient has a foot examination requires organizational resources, scientific support for the effectiveness of foot examinations in the prevention of amputations, and quantitative data that measure both the processes and outcomes of foot examinations. This requires careful documentation of each examination as well as measurements of the clinical outcomes of interventions, such as a reduction in the number of amputations. This innovation, however, must also be linked to the standard of practice and associated incentives,

whether reimbursement or successful peer review. The incentive, in turn, reflects the values of the organization. This may result in further resource allocation to diabetes, recognition of the diabetes program and promotion of widespread implementation.

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Part 1

Diabetes care from the perspective of Staged Diabetes Management

1 Introduction to Staged Diabetes Management

Key points

- Integrated models of healthcare delivery address (1) organization and policy, (2) innovation and implementation, (3) measurement and outcomes, and (4) incentives and payment.
- Effective changes in healthcare delivery respond to healthcare needs, the epidemiology of disease, and health policy.
- Healthcare outcomes data often determine which healthcare changes materialize. Such outcomes data include morbidity and mortality measures and cost–benefit analyses.
- Staged Diabetes Management is a systematic approach to clinical decision-making that applies the above principles for effective healthcare delivery. It applies an evidence-based medical model, is customized to reflect the healthcare environment, and is refined through outcomes measurement.

Where does Staged Diabetes Management (SDM) fit in the integrated model of change? At its inception, SDM was singular in purpose: to develop, implement, test, and refine an approach to diabetes care and its comorbidities that improved clinical outcomes. For more than two decades, SDM has remained focused on this purpose. Through ongoing development, translation of its clinical pathways into practice, and measurement of outcomes in medical practices, SDM has expanded its scope to encompass the complete natural history of diabetes, including the period before its inception. Complications management has been integrated as evidence amasses that links overall outcome to management of comorbid states. Associated conditions, such as eating disorders, are now included.

Developing Staged Diabetes Management

At the foundation of SDM is the principle that the approach itself cannot succeed if it is isolated as an innovation without addressing the other elements that constitute the integrated model. Understanding the history of SDM is fundamental to understanding its approach and underlying principles.

SDM was developed during an era of change and discovery. By the late 1980s, it was clear that the changes in diabetes care—focus on tight glycemic control, concern for prevention of complications, intensive education, nutrition management, and patient self-care—required a reevaluation of current care practices. While these issues were initially raised in Europe, the USA and Japan, they soon became universal. Most prominent was a change in the recognition as to who would manage diabetes. Between 1975 and 1985, the care of most people with diabetes in developed countries (e.g., Australia, New Zealand, France, the UK, Austria, Sweden, Norway, Finland, Belgium, Switzerland, Italy, Germany, Japan, the USA, and Canada) was believed to be within the purview of diabetes specialists. In most of these countries, a "diabetes specialist" or "diabetologist" was defined as an individual whose medical and postgraduate training was supplemented by an additional 2–3 years of researching and caring primarily for people with diabetes. In some countries, most notably Japan, the idea that a generalist in medicine would care for a person with diabetes was anathema. There and elsewhere, primary care management of diabetes was to be avoided, even at the cost of providing no medical care.

By the late 1980s, however, it was becoming apparent that the increased incidence and prevalence in type 2 diabetes required a reevaluation of the specialists-only approach to the care of adults with diabetes. During this time, diabetes care was split between those who were considered experts or specialists and those who were generalists. The latter were further segmented into the primary care specialties: family practice, pediatrics, obstetrics, and internal medicine. The specialties in diabetes were subsumed into endocrinology, perinatology and "diabetology" (the last a term used generally in developing countries for a specialist in diabetes). With specialists congregating in large metropolitan areas and the primary care clinicians scattered in rural areas, the two groups rarely met or shared their approaches to diabetes. This complex structure posed a seemingly insurmountable challenge: How would the research findings and related skills that were readily available to specialists find their way to primary care clinicians?

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A second more pressing problem was how individuals with complicated diabetes in rural areas would access high-quality care. Through the late 1980s, this challenge was addressed either by having patients travel to the large medical centers in metropolitan areas or by having them do without these services. The individual with gestational diabetes at risk for cesarean section (C-section) either would move to the large medical center as early as 4 weeks before delivery or would rely on the local family physician, whose C-section experience was very limited. Although epidemiological studies were not geared toward answering the question of how to provide better access to diabetes care in remote areas, many believed that this period was characterized by a disproportionate number of episodes of diabetic ketoacidosis, amputation, neonatal mortality and perinatal morbidity when rural and urban centers were compared.[1]

In the USA, the rising awareness of the need to rely on primary care clinicians to manage diabetes was most apparent in the rural states that constitute the heartland of America. There, reliance on family physicians, many of whom served as internist, pediatrician and obstetrician, obviated the case for diabetes. No other chronic disorder affected each stage of life. The question was simple: Can new research findings and approaches to diabetes be translated into primary care clinical practices? The same question was being asked in the UK public health service, the French and German national health programs, and countless developed and developing countries' ministries of health.

SDM was created as a direct response to the needs of our constituencies at the International Diabetes Center (IDC) in Minneapolis, MN, USA. Because the IDC is recognized by the World Health Organization (WHO) as an expert center in the translation of research findings into clinical practice, the dilemma facing many countries became an IDC mission: to develop a model approach to diabetes that would rapidly translate diabetes research into practices that would allow the primary care clinician to provide exceptional care—equivalent to that of the specialist.

A model approach developed at the IDC would need to be applicable and tested in diverse clinical settings within the USA as well as in developed and developing countries attempting to alter diabetes care. The fundamental challenge was to convert diabetes management from an individualistic-based approach to one that was easily adapted to caring for large numbers of patients in environments with frequently suboptimal resources.

The foundational principles of SDM

From its inception, SDM was based on three underlying principles:

- reproducible scientific evidence would guide clinical decisions
- explicit clinical pathways would be formulated in such a manner as to identify the criteria for selection and advancement of therapy
- all decisions would be tested against clinical outcomes.

Reproducible scientific evidence

Reproducibility of scientific evidence meant that (1) each element of the clinical pathways (DecisionPaths) would have to be tested, (2) the overall approach would need to reflect the natural history of diabetes, (3) the DecisionPaths would be subject to constant review, revision, and retesting, and (4) the reliance on quantitative data would take precedence over qualitative clinical impressions.

Explicit clinical pathways

Explicit clinical pathways resulted in the production of Master and Specific DecisionPaths for each type of diabetes, each treatment modality, and each major step (starting, adjusting, and maintaining) in the treatment pathway (Figure 1.1).

Testing decisions against clinical outcomes

The idea that all decisions would be subjected to verification in clinical outcomes was perhaps the most challenging. SDM would, by design, require incorporation of sentinel process and outcome measures, which by their nature require consensus. Sentinel outcome measures vary by clinic, medical center, national diabetes organization, and government health ministries.

More than a decade ago, the American Diabetes Association (ADA), in collaboration with the National Committee on Quality Assurance (NCQA), identified key or sentinel measures for type 1 and type 2 diabetes. Their selection was based on a consensus from experts and therefore should be considered a guide rather than a standard. Among the measures were both processes (e.g., percentage of patients with at least one measurement of hemoglobin A_{1c} (HbA_{1c})) and outcomes (e.g., HbA_{1c} level). Also included were measures related to macrovascular disease (hypertension and dyslipidemia), microvascular disease (retinal examination and renal status), and education and nutrition. It was believed that these sentinel events reflected the quality of care provided by the institution.

The ADA and NCQA formalized the program of evaluation of sentinel events, officially calling it the Diabetes Physician Recognition Program (DPRP). The IDC uses these sentinel measures to assess SDM effectiveness in its national and international SDM implementation programs.

Thus, SDM is a systematic approach to the prevention, detection, and treatment of diabetes and metabolic syndrome and their complications. At the foundation of SDM lie three principles:

1 identify the underlying physiological defect
2 match the therapy to the underlying defect
3 if one therapy fails, find an alternative; continue advancement of therapy until the outcome is achieved or maintained.

Stages of Staged Diabetes Management therapy

SDM organizes care in terms of stages and phases. Stages refer to type of treatment, with the underlying concept that there should be a consistency in the use of treatment modalities. For example, the notion that medical nutrition and activity therapy (MNT) is composed of both diet planning and activity is a critical element in the management of both blood glucose and blood pressure. Thinking in terms of stages adds a dynamic component; treatment is subject to initiation, adjustment, maintenance, and at times cessation. It places diabetes care in a continuum, beginning with diagnosis and/or initiation of a therapy (starting phase) and moving to the adjusting phase until the targets are reached, at which point the current therapy is maintained.

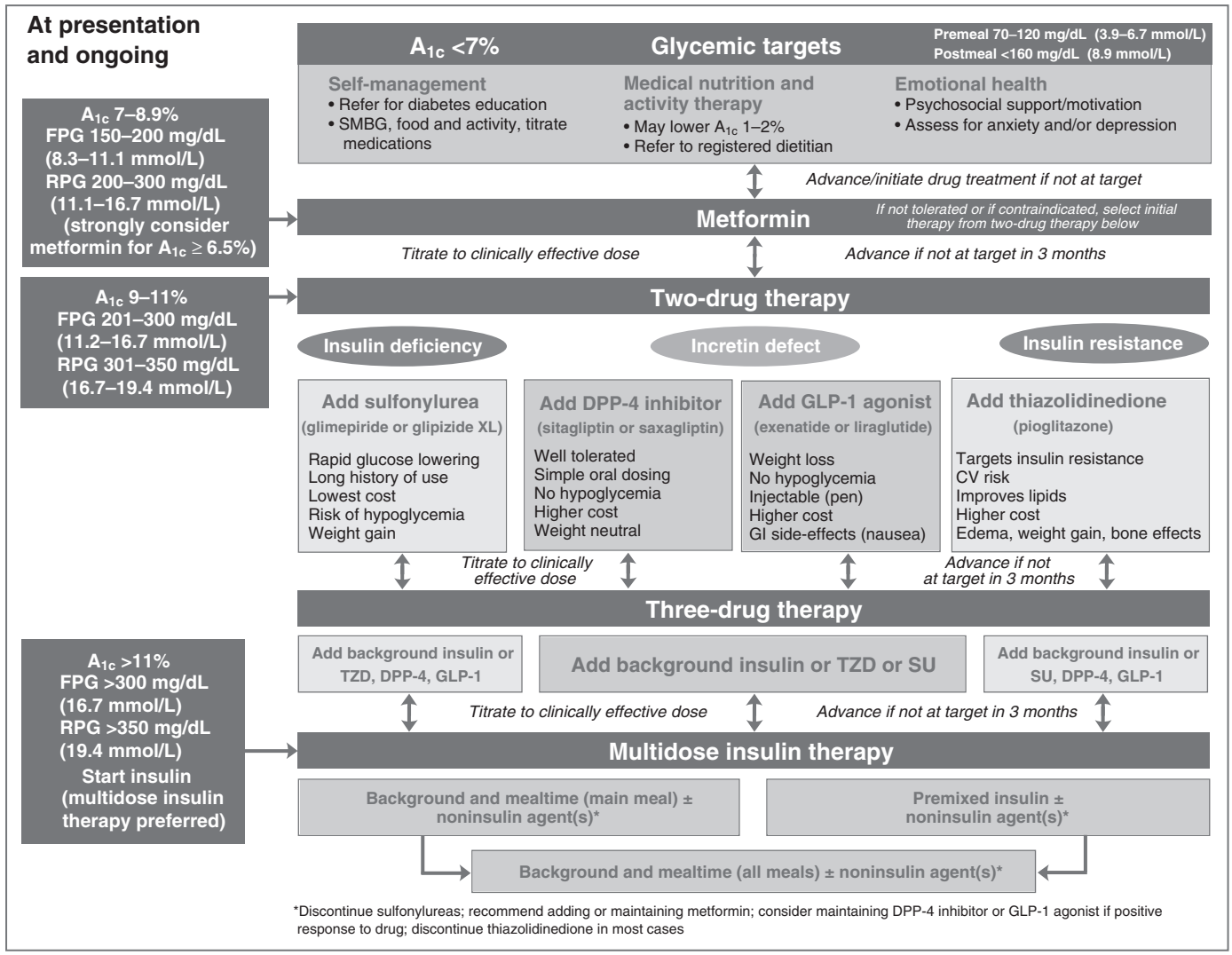


Figure 1.1 Type 2 Master DecisionPath. A_{1c}, hemoglobin A_{1c}; CV, cardiovascular; DPP-4, dipeptidyl peptidase-4; FPG, fasting plasma glucose; GI, gastrointestinal; GLP-1, glucagon-like peptide 1; RPG, random plasma glucose; SMBG, self-monitored blood glucose; SU, sulfonylurea; TZD, thiazolidinedione.

Advances in diabetes therapies, like the disease itself, are dynamic. In the past decade, a new classification of pharmacological agents, incretin-based therapies has been introduced, and older classifications, such as sulfonylureas and insulin, have been reexamined. To promote the dynamic nature of SDM, we chose to call each therapy a stage. The stages include MNT alone or in combination with pharmacological agents, oral hypoglycemic and secretory agents, incretin-based therapies and insulin therapy.

Medical nutrition and activity therapy

In all types of diabetes, MNT combines carbohydrate distribution and caloric intake with activity expenditure. The SDM approach to MNT is to optimize the roles of nutrition and physical activities in lowering blood glucose levels as solo treatment, or to use them in combination with pharmacological agents. *A secondary function of this therapy is to achieve and maintain desirable body weight.*

Insulin sensitizers, secretagogues, and potentiators

These agents are in two general categories based on their action: hypoglycemic or nonhypoglycemic. However, these classifications may be misleading. The oral and noninsulin injectable medications are better understood based on their mode of action:

- Hypoglycemic agents (e.g., sulfonylureas) stimulate insulin production and secretion without regard to the level of glycemic control. Essentially, they are not controlled by ambient glucose.
- Nonhypoglycemic agents are either modulated by the level of glycemic control (e.g., incretin-based therapies) or indirectly affect insulin's effect. For example, they include biguanides as well as glucagon-like peptide 1 receptor agonists and dipeptidyl peptidase-4 inhibitors.

Insulin-based therapies

Generally categorized by their action curve and duration, insulin-based therapies include:

- rapid acting (15 minutes to 3–5 hours)
- regular (30 minutes to 8 hours)
- intermediate acting (14–24 hours)
- long acting (up to 24 hours).

Phases of Staged Diabetes Management therapy

Approaching the treatment of any disease without a structure in mind is akin to driving with a final destination in mind but without a map to follow. To make certain that we have a map and that we know where we are on it, SDM divides the stages into three phases: start, adjust, and maintain. These phases reflect the dynamic nature of treatment. At any time in treatment, the individual is in one of these three phases. Knowing the phase is analogous to knowing one's place on the map. It is possible to understand instantaneously the progress of treatment as well as its goal.

Start phase

The start treatment phase refers to the collection of data upon which to base diagnosis and initiate treatment. Ideally, diabetes care and management of complications begin with baseline data from which the practitioner can assess a patient's clinical status. Each type of diabetes, associated complication, or comorbidity requires different data for diagnosis and clinical decision-making. In type 1 diabetes, for example, clinical symptoms, blood glucose level, antibodies to insulin, insulin level, urine or serum (blood) ketones, serum pH, age, and body weight serve as critical starting points. In type 2 diabetes, blood glucose values, HbA_{1c} level, body mass index, insulin level, comorbidities, age, and sex are critical elements in understanding the nature of this disease. In the latter instance, understanding the underlying metabolic defect—insulin resistance, relative or absolute insulin deficiency, or incretin dysfunction—is vital for therapy selection.

Adjust phase

During the adjust treatment phase, changes in therapy—whether in dose, timing/regimen, food plan, or exercise/activity—are made to optimize metabolic control. Lasting anywhere from days to months, this phase is marked by substantial patient involvement in collecting data upon which clinical decisions depend. The principles and data by which major alterations in treatment are made are mapped out in the Master DecisionPaths and Specific DecisionPaths for each stage. Detailed in the start and adjust DecisionPaths for each stage (therapy) of diabetes management are the selection criteria, initial dose calculations, and contraindications. For the purpose of routine diabetes management, a single standard or guideline for glucose control is highly desirable. Several multicenter clinical trials have concluded that, independent of the type of diabetes, the purpose of treatment is to safely restore near-normal glycemic patterns. The exact nature of "near normal" remains controversial. SDM defines near normal as safely mimicking diurnal glucose patterns of individuals without diabetes. While the results of the Diabetes Control and Complications Trial[2] in type 1 diabetes, the UK Diabetes Prospective Study,[3] and the Action to Control Cardiovascular Risks in Type 2 Diabetes (ACCORD trial)[4] generally demonstrated the desirability of one standard of glucose control, it should be understood that the glycemic goals tend to be in the form of acceptable ranges—for example, 70 and 140 mg/dL (3.9 and 7.8 mmol/L) for nonpregnancy and 60–120 mg/dL (3.3–6.7 mmol/L) in pregnancy. These ranges tend to be based on consensus rather than on randomized controlled trials comparing all potential ranges. Increasingly, studies are relying on glycosylated hemoglobin as their clinical definition of "normal." Such studies target HbA_{1c} below 7%, 6.5%, or 6% (normal is generally considered <5.7% in nonpregnancy).

SDM employs the following principle: if the metabolic goal is not met within a specified period of time, the therapy should be adjusted, supplemented, or replaced. It is this last point that underscores the need for thinking about diabetes in terms of phases. The goal should be to move the patient from adjust to maintain as quickly and as safely as is reasonable. Patients in the adjust phase are at higher risk for complications. It is not until they reach the maintain phase that the risk of complications is substantially lowered.

Maintain phase

This phase begins when the patient has reached and is involved in maintaining the diurnal glucose patterns associated with the long-term prevention of complications. Patients are expected to move in and out of this phase independent of the type of treatment, based on such factors as changes in lifestyle, compliance with regimen, psychological and social adjustment to diabetes, willingness to achieve tighter control, and natural progression of diabetes. Thus, some changes in therapy are expected in this phase, but they are related more to fine-tuning than to major alterations in dose of medication.

Phases in the treatment of insulin resistance and complications

As with the treatment of diabetes, management of insulin resistance-related disorders such as prediabetes, dyslipidemia, and hypertension can be organized into start, adjust, and maintain therapy. Naturally, for each disorder, the object is to restore normal or near-normal status whenever possible. In many cases, because of preexisting comorbidities, the objective is to prevent further progression of the complication.

Principles for practice guidelines

SDM relies on local, national, and international standards to lay the foundation for treatment. SDM consists of a set of practice guidelines for each type of diabetes, for metabolic syndrome, and other complications. Practice guidelines are structured to address prevention, screening, and diagnosis; treatment options; metabolic targets; monitoring; and follow-up. Table 1.1 shows the type 2 diabetes practice guidelines. These guidelines are for adults and may not apply to pediatric patients.

Table 1.1 Type 2 diabetes practice guidelines (based on US practice)

Screening	Screen all patients every 3 years starting at age 45; if risk factors present, start annual screen earlier
Risk factors	• BMI ≥25 kg/m^2 (≥23 kg/m^2 in Asian Americans) • Family history of type 2 diabetes • Physical inactivity • Hypertension (≥140/90 mmHg) • Dyslipidemia (HDL <35 mg/dL (<0.9 mmol/L) and/or triglycerides >250 mg/dL (>2.8 mmol/L)) • A_{1c} ≥5.7%, IFG (FPG 100–125 mg/dL (5.5–6.9 mmol/L)), or IGT (2 h/75 g OGTT 140–199 mg/dL (7.8–11.0 mmol/L)) on previous testing • Previous gestational diabetes: macrosomia or large-for-gestational-age infant (>9 lbs (>4.1 kg)) • History of vascular disease • Acanthosis nigricans • Polycystic ovary syndrome • American Indian or Alaska Native; African American; Asian; Native Hawaiian or other Pacific Islander; Hispanic or Latino
Diagnosis	
Plasma glucose	A_{1c} ≥6.5%; random (casual) plasma glucose ≥200 mg/dL (≥11.1 mmol/L) plus symptoms, fasting ≥126 mg/dL (≥7.0 mmol/L), or 2 h/75 g OGTT ≥200 mg/dL (≥11.1 mmol/L); if positive, confirm diagnosis within 7 days
Symptoms	Often none *Common*: blurred vision; UTI; yeast infection; dry, itchy skin; numbness or tingling in extremities; fatigue *Occasional*: increased urination, thirst, and appetite; nocturia; unexplained weight loss
Urine ketones	Usually negative
Treatment options	MNT; metformin; two-drug therapy; three-drug therapy; insulin therapy
Targets	• >50% of SMBG values within target range
SMBG	• Premeal 70–120 mg/dL (3.9–6.7 mmol/L) • Postmeal <160 mg/dL (<8.9 mmol/L) (2 hours after starting meal) • Premeal to 2 hours postmeal rise within 40 mg/dL • Bedtime 80–120 mg/dL (4.4–6.6 mmol/L) • No severe (assisted) or nocturnal hypoglycemia • Adjust premeal target upwards if decreased life expectancy, frail elderly, cognitive disorders, or other medical concerns (e.g., cardiac disease, stroke, hypoglycemia unawareness, ESRD)
A_{1c}	• Target <7% (less stringent A_{1c} goals are appropriate for some individuals; see above for examples) • Frequency: every 3–4 months • Use A_{1c} to verify SMBG data
Blood pressure	<130/80 mmHg
Lipids	LDL <100 mg/dL (<2.6 mmol/L); HDL >40 mg/dL (>1.0 mmol/L) men, >50 mg/dL (>1.3 mmol/L) women; TRI <150 mg/dL (<3.9 mmol/L) *Note* Consider target LDL <70 mg/dL for those with evidence of CVD
Monitoring	Meter with memory and logbook
SMBG	*For MNT, oral agent, and GLP-1 mimetic therapy*: 3 times/day while adjusting therapy (e.g., fasting, before largest meal, and 2 hours after start of largest meal); reduce to 3 times/day, 2 or 3 days/week once targets achieved *For insulin therapy*: 1–4 times/day (or more); may be modified because of cost, technical ability, level of blood glucose control, or availibility of meters; if on insulin, check 3 AM SMBG as needed
CGM	Consider supplementing with CGM to identify glycemic patterns
Follow-up	
Monthly	Office visit while adjusting therapy (weekly phone contact may be necessary)
Every 3 months	Hypoglycemia; medications; weight/BMI; MNT; BP; SMBG data (download meter); A_{1c}; eye and foot screen; diabetes/nutrition education; smoking cessation counseling; aspirin therapy if appropriate; preconception planning for women of child-bearing age; depression screen
At diagnosis and 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; neurological assessment; comprehensive foot examination (pulses, nerves, and inspection); referral for diabetes and nutrition education
Complications/surveillance	Cardiovascular, renal, retinal, neurological, foot, oral, and dermatological

A_{1c}, hemoglobin A_{1c}; BMI, body mass index; BP, blood pressure; CGM, continuous glucose monitoring; CVD, cardiovascular disease; ESRD, end-stage renal disease; FPG, fasting plasma glucose; GLP-1, glucagon-like peptide 1; HDL, high-density lipoprotein; IFG, impaired fasting glucose; IGT, impaired glucose tolerance; LDL, low-density lipoprotein; MNT, medical nutrition and activity therapy; OGTT, oral glucose tolerance test; SMBG, self-monitored blood glucose; TRI, triglycerides; UTI, urinary tract infection.

For more than a decade, the US Institute of Medicine (IOM) has been evaluating the characteristics of practice guidelines that contribute to successful implementation. Defined by the IOM, practice guidelines are "systematically developed statements to assist practitioner and patient in decisions about appropriate healthcare for specific clinical circumstances."[5] Incorporating science and clinical judgment, practice guidelines are meant to improve the quality of care by ensuring consistency in the delivery of healthcare services. Quality of care has been directly associated with reduced variation in medical practice.[5] A common practice guideline accepted by all healthcare providers removes inconsistencies in the diagnosis and treatment of medical conditions and

results in more effective use of healthcare resources, improved outcomes, cost savings, and reduced risk of legal liability for negligent care.

In its guidelines for clinical practice, the IOM argues that ". . . scientific evidence and clinical judgment can be systematically combined to produce clinically valid, operational recommendations for appropriate care that can and will be used to persuade clinicians, patients and others to change their practices in ways that lead to better health outcomes and lower healthcare costs."[5] Valid practice guidelines facilitate consistent, effective, and efficient medical care and ultimately lead to improved outcomes for patients. To accomplish this goal, guidelines must contain sufficient detail to have measurable clinical outcomes. For best results, practice guidelines should be specific, comprehensive, and accepted by the community of physicians and other medical team members. Guidelines need to be flexible enough for everyday use in clinical practice and must reflect the available community resources.

The first principle of practice guidelines is that they are based on sound scientific findings. SDM practice guidelines are based on the recommendations of the ADA, the National Diabetes Data Group, the International Diabetes Federation, the WHO, the American Association of Diabetes Educators, the American Association of Clinical Endocrinologists, and other diabetes organizations representing several countries outside the USA. These organizations have reviewed the current scientific data and many have reached consensus on major elements of diabetes care:

- diagnostic criteria and classification
- treatment options
- therapeutic targets for blood glucose, HbA_{1c}, blood pressure, and lipids
- frequency of blood glucose, urine ketones, and HbA_{1c} monitoring
- complication surveillance (eye and foot examinations, screening for microalbuminuria)
- medical follow-up
- need for intensive treatment of complications.

These organizations have also addressed insulin resistance and many have reached a working consensus that does the following:

- relates insulin resistance to hyperglycemia, hypertension, dyslipidemia, central obesity, and renal disease
- recognizes the need to intensively screen, diagnose, and treat each condition
- recognizes the increased risk of developing one condition when another exists
- sets general treat outcome goals.

The second principle of practice guidelines is that they contain sufficient specificity to allow for their implementation. The SDM Master and Specific DecisionPaths (Figures 1.2 and 1.3) aid in implementing the practice guidelines.

The third principle of practice guidelines is that they are adapted to the community, adopted by the healthcare providers, and reflect the specific resources of the community. The key components of this process include the following:

- community needs assessment and engagement
- orientation to SDM
- adaptation and adoption of practice guidelines by healthcare professionals
- implementation plan for SDM
- plan for short-term and long-term outcome assessment.

Master DecisionPath

The SDM Master DecisionPath (Figure 1.2) outlines the therapeutic stages for each type of diabetes and shows the most effective route for attaining glycemic control. The Master DecisionPath also provides a generalized method for initiating and altering treatment. Based principally upon blood glucose levels—measured by fasting and/or casual venous and capillary methods, and HbA_{1c}—the selection of therapies has become more complicated as experts gain greater understanding about additional biomarkers (such as insulin level), symptoms, and physiological conditions. By laying out the therapies according to specific criteria, the selection process can become more consistent. Employing a common DecisionPath enables all team members and the patient to understand the overall treatment plan. It also enables the team to understand the alternative treatments should the initial selection fail. Finally, it establishes a treatment timeline. If a therapy

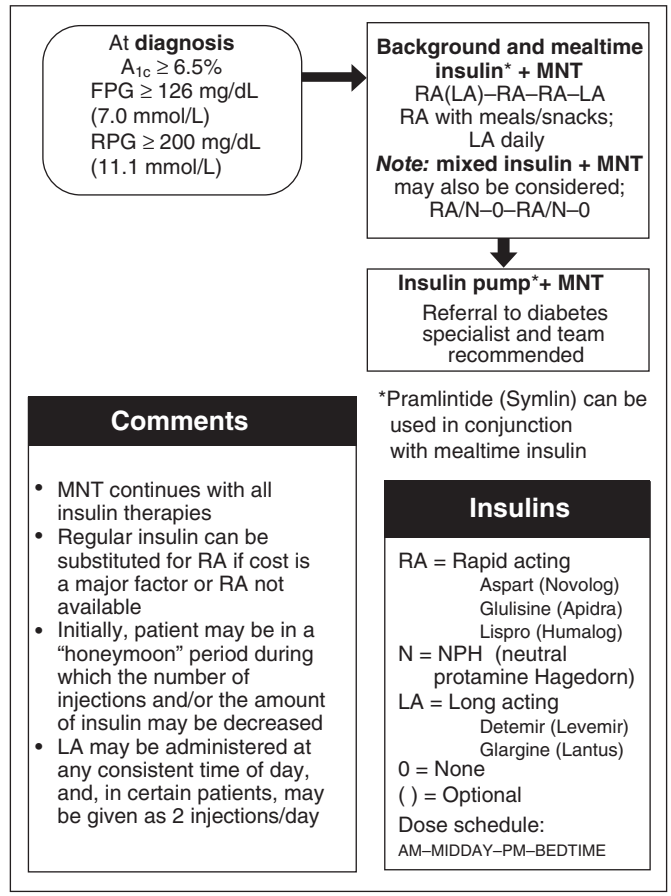


Figure 1.2 Type 1 Master DecisionPath. FPG, fasting plasma glucose; RPG, random plasma glucose; MNT, medical nutrition and activity therapy.

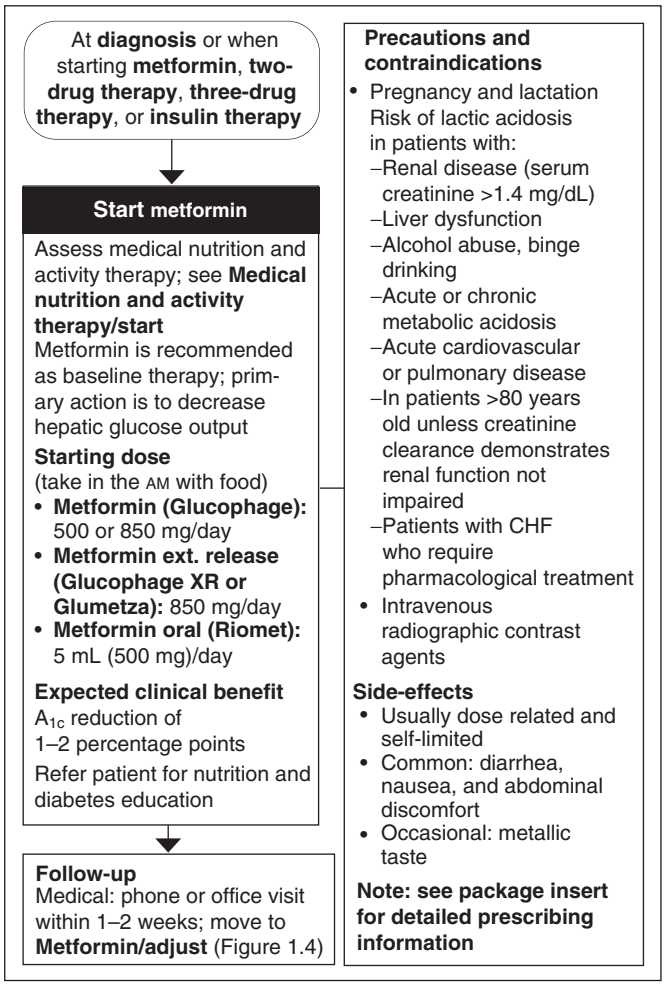
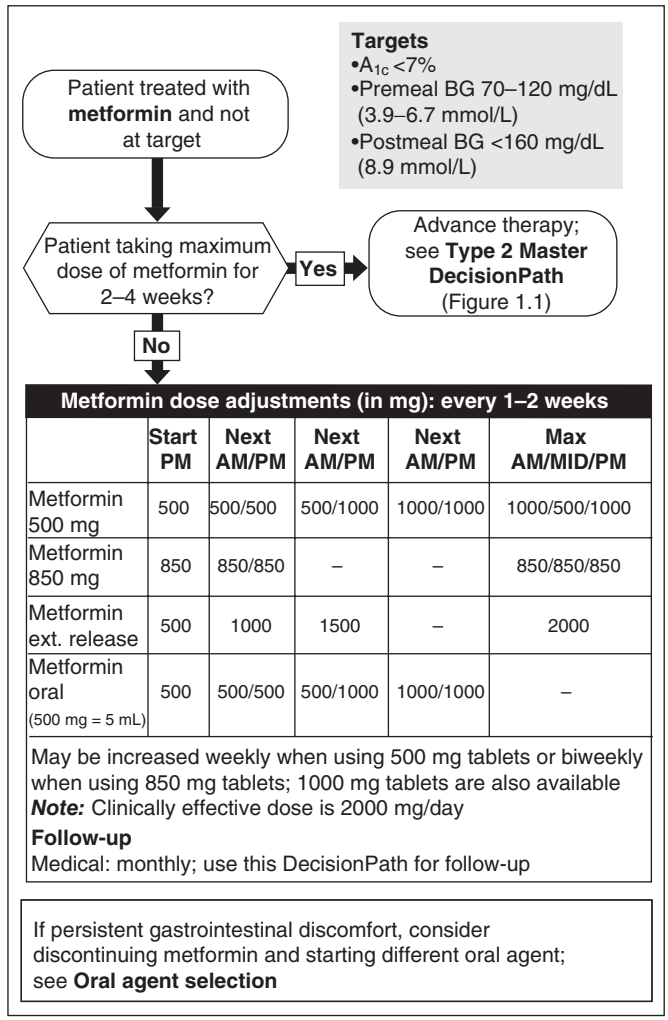


Figure 1.3 Type 2 metformin/start. CHF, congestive heart failure; A_{1c}, hemoglobin A_{1c}.



	Start PM	Next AM/PM	Next AM/PM	Next AM/PM	Max AM/MID/PM
Metformin 500 mg	500	500/500	500/1000	1000/1000	1000/500/1000
Metformin 850 mg	850	850/850	–	–	850/850/850
Metformin ext. release	500	1000	1500	–	2000
Metformin oral (500 mg = 5 mL)	500	500/500	500/1000	1000/1000	–

Figure 1.4 Type 2 metformin/adjust. A_{1c}, hemoglobin A_{1c}; BG, blood glucose.

fails, the Master DecisionPath guides the progression to other stages.

Specific DecisionPaths

The heart of the DecisionPath approach is the intersection of stage and phase (start, adjust, or maintain). SDM provides a Specific DecisionPath for each such intersection, which describes the action to be taken in terms of the specific therapy and also indicates the general path being followed and the progress being made. There are two types of Specific DecisionPath: start and adjust/maintain.

Using type 2 diabetes metformin/start as an example (Figure 1.3), note that the structure of the start DecisionPath begins with the entry criteria (blood glucose at diagnosis or failure of a previous therapy). It then moves to the medical visit and the blood glucose targets along with notes related to starting the treatment. After the "how to start" comes the follow-up information. The same structure is used for all start DecisionPaths.

A second type of Specific DecisionPath relates to adjusting/maintaining the current therapy. As shown in the metformin/adjust DecisionPath (Figure 1.4) the DecisionPath begins with a brief review of key data and a reminder of the target levels. These data (current medications, diabetes control, adherence, weight change, and hypo/hyperglycemic events) are common for all forms of diabetes. This review is followed by a closer evaluation of current glycemic control.

When glycemic target levels are reached, the patient enters a maintenance phase. The DecisionPaths for adjusting therapy contain guidelines for routine follow-up, which are consistent with the standards of practice recommended by national diabetes organizations. These include the frequency of visits and the period of time between visits. Over the period of 1 month, the average self-monitored blood glucose should drop by 15–30 mg/dL (0.8–1.7 mmol/L), which corresponds to a drop in the HbA_{1c} of 0.5–1 percentage point. If this is occurring, the current treatment is continued without any adjustment. If these criteria are not met, further adjustment is necessary.

If the target blood glucose level has not been reached, the next step is to determine why. Often, the therapy does not match the underlying defect. Sometimes, however, patient nonadherence to the regimen is the cause. When this is the case, the Ancillary

DecisionPaths entitled "Psychological and Social Assessment" and "Diabetes Management Adherence Assessment" are used to address issues related to adherence. However, *an underlying principle of SDM is that therapies, not patients, fail.* Thus, if adherence is not the problem, the next step is to assess whether any improvement has occurred.

Each pharmacological agent has a maximum safe and effective dose. For oral agents, SDM utilizes maximum dose criteria provided in the package insert but also reports the clinically effective dose, which sometimes is well below the maximum recommended dose. For example, the clinically effective dose of sulfonylureas is approximately two-thirds the maximum dose. For insulin, in general, between 1 and 1.5 U/kg (depending on the type of diabetes and the age of the patient) is considered the maximum safe dose. Exceeding this range requires a reevaluation of the therapy.

SDM provides similar criteria for each adjust phase and provides reasons for moving from one stage to the next. For example, the choice of combination or insulin therapy is based on whether the lack of improvement is due primarily to fasting hyperglycemia or postprandial hyperglycemia. For background (basal) insulin, the criteria for moving to background (basal) and mealtime (bolus) insulin are persistent fasting hyperglycemia, nocturnal hypoglycemia, or insufficient improvement in HbA_{1c}.

Criteria for adjusting and changing therapy

The underlying principle in SDM is that there is a rational and consistent set of criteria that can be applied when considering moving a patient from one therapy (stage) to another. Part of the principle is that the decision is founded on (but not limited to) verified self-monitored glucose data and HbA_{1c}. The therapeutic goal is to achieve a lowering of 0.5–1.0% in HbA_{1c} each month with a parallel improvement in blood glucose as measured by an average 15–30 mg/dL (0.8–1.7 mmol/L) reduction in self-monitored blood glucose (SMBG) or continuous glucose monitoring (CGM) *without* an increased risk of hypoglycemia. To achieve this therapeutic goal, current therapy must be reconsidered frequently. Assessing the patient's adherence to the treatment plan includes reviewing his or her blood glucose monitoring technique and records, reviewing his or her food plan and activity record, and assessing the patient's consistency in following the pharmacological regimen.

An important step in assessing the current therapy is to ensure that a sufficient number of self-monitored tests are performed and that the data from these tests are verified. Generally, when episodic testing is employed (SMBG), the optimal frequency is a minimum of four tests each day at randomly selected times. If CGM is employed, it is optimal to have at least 2 weeks of monitoring in order to understand the underlying diurnal pattern and select appropriate therapy. Thereafter, at least the same period (2 weeks) is required for therapy adjustment. The initial CGM can be supplemented by SMBG thereafter until a therapy change is indicated. If patterns of SMBG data confirm blood glucose levels consistently greater than target, CGM can be instituted to corroborate the SMBG and the therapy may be altered until the maximum effective dose is reached. If no improvement occurs, an alternative therapy is selected in accordance with the Master DecisionPath. The change to more complex therapies permits greater flexibility in reaching a particular blood glucose target.

Metabolic syndrome, complications, and hospitalization DecisionPaths

The DecisionPaths for vascular complications, nephropathy, retinopathy, neuropathy, and foot disease generally follow the same format as those for treatment of diabetes. They differ in terms of their subject matter. They address prevention, screening, and diagnosis as well as starting and adjusting therapy (an example is provided in Figure 1.5).

The patient and Staged Diabetes Management

In principle, because patient participation is a fundamental part of SDM, providers should give a modified version of the Master DecisionPath to each patient to familiarize them with available therapeutic options. Along with learning about the Master DecisionPath, the patient should be aware of the tests that are generally performed, such as HbA_{1c}. One approach is to provide patients with booklets or logbooks that provide places to record blood glucose and HbA_{1c} targets and actual values. Electronic recordkeeping is also available, with software for downloading meters, pumps, and applications to follow trends. Additionally, SDM encourages the use of a progress record, a tool that allows patients and providers to track the course of treatment over time. The progress record provides the history of care at a glance, allowing both patient and provider to see where they have been and where they are going. This is a valuable aid in teaching and in maintaining adherence to complex therapies because the patient is kept informed and involved at every step.

The diabetes care team and team development

Although the concept of a diabetes care team is not new, the idea that the patient is a member of the team remains controversial. Because of the reliance on patient-collected data combined with the need for the patient to cooperate, understand the therapies, and follow complex regimens, the patient must be considered at the center of the care team. In primary care management, the team may include the physician, nurse educator, nurse practitioner, physician's assistant, pharmacist, and dietitian with the psychologist/social worker or exercise physiologist included where available. This team approach is especially needed in the absence of a diabetes specialist. If a specialist is available, the team might include both the primary care physician and a diabetes specialist. Under such circumstances, the DecisionPath to be followed would include the conditions for referral and would be shared by all involved in diabetes care.

DecisionPaths specify the role of each professional. The nurse and dietitian have especially unique roles to play, roles that in many instances the physician cannot assume without additional training and time. The DecisionPaths and the narratives include specific information about nutritional interventions and education.

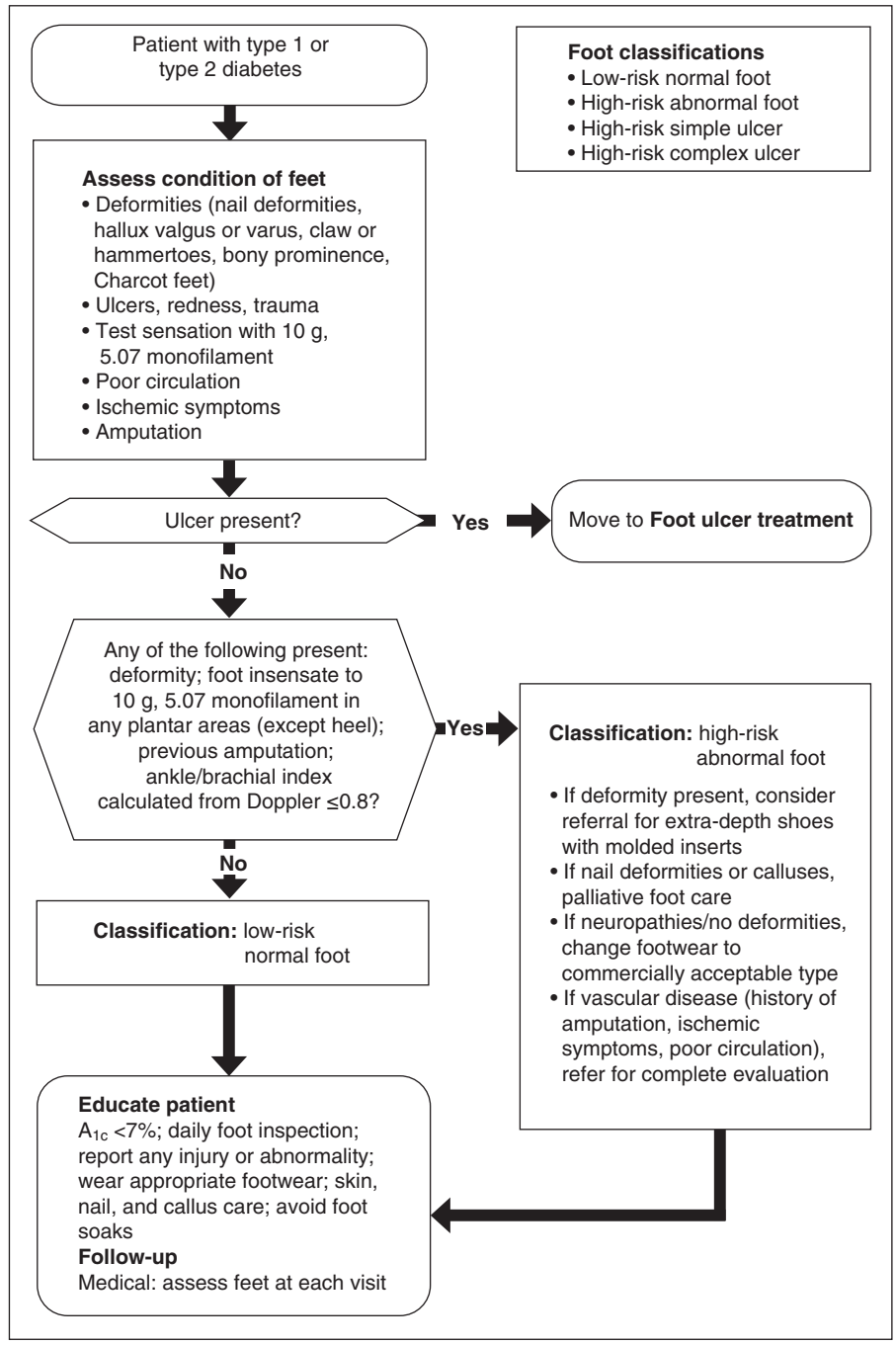


Figure 1.5 Foot assessment and treatment. A_{1c}, hemoglobin A_{1c}.

Primary care provider

The primary care provider is specifically trained for, and skilled in, comprehensive first contact and continuing care for persons with diabetes, particularly adults. Responsibilities include health promotion, disease prevention, health maintenance, counseling, patient education, diagnosis, and treatment. The primary care provider coordinates the care of the individual with diabetes using other health professionals, consultation, and/or referrals as appropriate. The primary care provider serves as an advocate in the healthcare system for the patient so that cost-effective care can be achieved.

Frequently, primary care physicians would be considered the "diabetologist," but this term itself is often misunderstood. In the USA, there is no such degree or board examination for the specialty of diabetology. A diabetologist is often considered any health professional with expertise in diabetes. However, for both legal and ethical considerations, the physician specialist in diabetes is generally referred to as a board-certified endocrinologist. This designation is different from those physicians whose practice concentrates on diabetes. Currently, the NCQA recognizes individual providers or groups of providers as a "Recognized Physician," indicating that the physician (or group of physicians)

has undergone a careful evaluation of clinical practice and met specific criteria for the treatment of diabetes. This focus on assessing expertise by clinical outcomes in place of formal education is in part recognition that extensive clinical experience with beneficial outcomes is an important factor in measuring clinical ability.

Diabetes educator

The team member known as the "diabetes educator" provides initial and ongoing education related to self-management, survival skills, prevention and detection of complications, as well as diabetes skills training. Generally nurses, dietitians, pharmacists, and psychologists are educators who have extensive knowledge of diabetes medical management and ample experience in self-management education. In the USA, the National Certification Board for Diabetes Educators certifies the expertise of educators by making certain that they have provided at least 1000 hours of diabetes patient education and passed a national examination. Upon successful completion of the national examination, the healthcare professional is qualified as a Certified Diabetes Educator (CDE).

Registered dietitian

The registered dietitian is responsible for assessing the nutritional needs of the individual and helping develop a food plan consistent with the nutrient requirements for growth and development in children and sustained good health in adults. Often a CDE as well, the dietitian addresses eating habits, suggests changes in behavior, and designs a course of action to optimize the nutritional component of diabetes care. Dietitians will also work with patients to establish an activity and/or exercise plan.

Psychologist/social worker

The psychologist/social worker assesses the individual's initial and ongoing emotional adjustment to diabetes as well as the family's adjustment. Recently, as patients are more involved in clinical decisions and day-to-day therapy adjustments, the psychologist's role as a force for empowering patients to participate in their own care has received renewed emphasis.

Other care team members

Pharmacists, podiatrists, exercise physiologists, and such specialists as cardiologists, neurologists, and nephrologists can also be members of the diabetes care team. The underlying concept of team care is that all healthcare providers and the patient agree in advance as to the course of treatment. This avoids both misunderstandings and counterproductive treatment. More important, it significantly reduces error.

Developing the team

The idea that the team works closely together and is consequently in the same physical location has been replaced with the notion that the team comprises any group of healthcare professionals representing several disciplines with a common goal of improving care—specifically, restoring glycemic control to prevent microvascular and macrovascular complications. The advent of electronic-based medical records and self-care information has allowed for team development to be geographically and temporally separated. While ideally the team members should be located in the same facility and use electronic media to communicate in a coordinated fashion to assure that information is shared in a time-sensitive manner, proximity and systems compatibility is not always feasible. Large primary care multiclinic practices, for example, may require access to educators and dietitians but may not be in a position to locate these personnel in one center. For the convenience of both the patient and provider, they may have to be mobile. In a 4 year efficacy study of teams in diabetes management, the authors concluded that geographically separated teams require coordination and synchronization.[6] Essentially, they argue that, for such teams to develop, they need to be synchronized and, although in different facilities, they must undergo the same key steps as would be undertaken in face-to-face team development.

Team development, whether in the same location or separated, is a four-step process: (1) forming, (2) storming, (3) norming, and (4) performing.[7]

1 *Forming*. In forming the team, members define the boundaries of their profession and detail their activities.

2 *Storming*. During the second, or storming, stage, conflicts over roles and responsibilities occur.

3 *Norming*. In the third stage, "norming," team members resolve conflicts and establish routine interrelationships.

4 *Performing*. The fourth stage, performing, is measured by the ability of the team members to achieve their goals. This process requires agreement on care guidelines, goals, and clinical pathways, open access to the same data, patient participation, and, most important, ongoing assessment of team activities and clinical outcomes.

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