Staged Diabetes Management

THIRD EDITION

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

INTERNATIONAL DIABETES CENTER

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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.

About the authors

Roger S. Mazze PhD is the Head of the World Health Organization Collaborating Center at the International Diabetes Center (IDC) and Mayo Clinic and Professor as well as Vice President of the Park Nicollet Institute and Chief Academic Officer of the IDC. For the past 24 years he has held the rank of Clinical Professor of Family Medicine and Community Health at the University of Minnesota Medical School, and, previously, Professor of Biostatistics, Epidemiology, and Community Health and Executive Director and Coprincipal Investigator of the Diabetes Research and Training Center at Albert Einstein College of Medicine. He was also Distinguished Visiting Scientist of the United States Centers for Disease Control. Dr. Mazze is a past Cochairperson for the American Diabetes Association Council on Health Care Delivery. Author of more than 100 articles, chapters, comments, and arguments, he served as visiting professor to medical schools throughout Europe, Asia, and Latin America. As principal author of *Staged Diabetes Management*'s three editions, beyond his own contributions, his responsibility was to provide a single "voice" to the text.

Ellie S. Strock APRN-BC FAANP CDE is Director of Technology Development and Translational Research at the International Diabetes Center and Chief Education Director for the World Health Organization Collaborating Center at the International Diabetes Center and Mayo Clinic. She is a board-certified Adult Nurse Practitioner for Park Nicollet Health Services. Mrs. Strock served as co-investigator on numerous clinical trials focusing on advanced technologies and clinical decision-making. She organized and directed Staged Diabetes Management (SDM) training programs throughout the USA, Europe, Asia, and Latin America and

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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

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the Minnesota Department of Health Diabetes Steering Committee. His contributions focused on type 2 diabetes and complications.

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

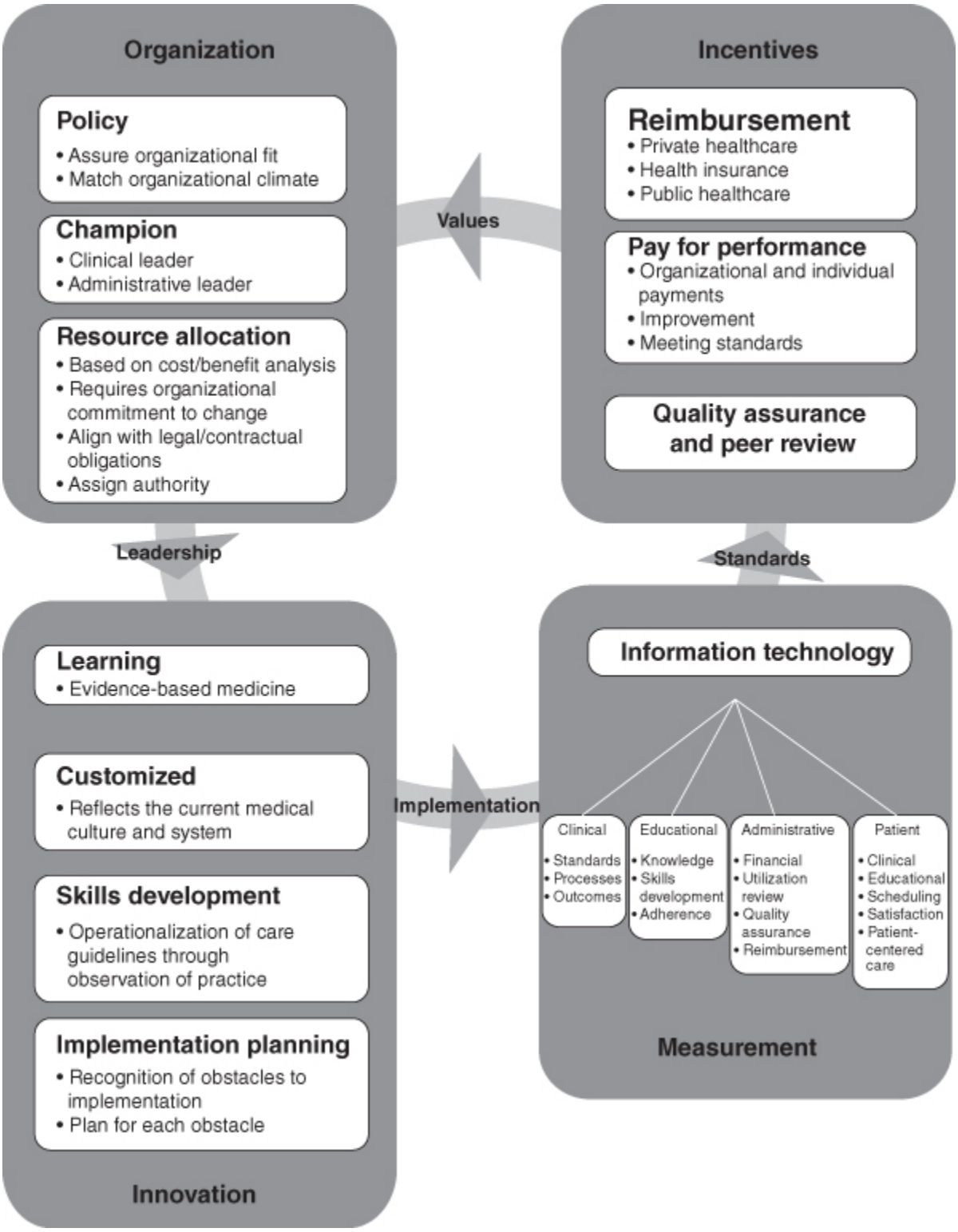
The most accepted method of encouraging change continues to be a combination of (1) improving the competency of clinicians through ongoing professional education and (2) the development of mechanisms for rapid translation of research findings and care innovations into practice. In part because of the 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.

Figure 0.1 Model for organizational change in healthcare.



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
- 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)