



Clinical research studies have led to important, evidence-based strategies for prevention and treatment of diabetes and its complications. Finding ways to disseminate this information effectively to diverse populations in the United States who are living with or at high risk for diabetes remains a critical goal for research. *(Photo credits: Top row (left to right): ©iStockphoto.com/endopack; ©Monkey Business Images | Dreamstime.com; ©iStockphoto.com/YinYang. Bottom row (left to right): ©iStockphoto.com/STEVECOLEccs; Indian Health Service, Division of Diabetes Treatment and Prevention; ©iStockphoto.com/mediaphotos; Rolf Bruderer/Blend Images/Getty Images.)*

CLINICAL RESEARCH TO PRACTICE: TRANSLATIONAL RESEARCH

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INTRODUCTION

Two landmark clinical trials, the Diabetes Control and Complications Trial and the United Kingdom Prospective Diabetes Study, demonstrated that glycemic control and cardiovascular risk factor modification can reduce the risk of diabetes complications. The Diabetes Prevention Program (DPP) and the DPP follow-up study, the DPP Outcomes Study (DPPOS), showed that an intensive lifestyle intervention involving physical activity and a healthy diet or use of the diabetes drug metformin can prevent or delay diabetes for as long as 10 years. However, a huge gap exists between the level of risk factor control for diabetes or its complications that can be achieved through intervention in clinical trials and outcomes that result from actual medical practice. Closing the gap between the ideal and current real-world practice is the essence of “Clinical Research to Practice: Translational Research.” This chapter highlights key advances, questions, and future directions for diabetes translational research with a focus on diabetes prevention, diabetes clinical care (including cardiovascular risk factor modification), patient-centered care, health disparities, and systems of care.

Individuals with diabetes differ in age, overall health status, cognitive functioning, social support, socioeconomic circumstances, and other important factors that influence disease management and health outcomes. Thus, optimal diabetes prevention or treatment that can be implemented in clinical care will vary depending on the needs of the individual, as well as the health care setting or context in which the care is delivered. Research to understand the characteristics of people with diabetes and health care delivery systems that influence diabetes prevention, treatment,

and outcomes should help pave the way to innovative methods for optimal clinical care. Similarly, diabetes self-management and patient education are essential components of patient-centered care for diabetes, but more needs to be known on how best to extend the benefits of self-management skills and education to all people with diabetes.

Diabetes affects persons of all ages, races, ethnicities, and socioeconomic circumstances. Nonetheless, in the United States, people belonging to minority racial and ethnic groups and individuals with low socioeconomic circumstances suffer a disproportionate burden of disease. They have higher rates of type 2 diabetes and certain complications than non-Hispanic whites and tend to develop diabetes at a younger age (1). The challenges inherent in diabetes clinical care are often exacerbated in members of racial or ethnic minority groups, or those who are economically disadvantaged. Significant health disparities have been documented in terms of both processes and outcomes of diabetes care. Translational research efforts are under way to identify the causes of health disparities and to develop innovative strategies for eliminating disparities and improving the health of people with diabetes who belong to minority groups. Cultural tailoring of diabetes interventions, such as the development of culturally appropriate health promotion materials in multiple languages, is an important component of successful translation. Preliminary evidence suggests that culturally tailored interventions are more effective than generic quality improvement interventions for reducing racial and ethnic disparities in intermediate outcomes, such as hemoglobin A1c (HbA1c) values, a measure of blood glucose control. In fact, some

generic interventions and reimbursement schemes could worsen disparities if they favor well-resourced settings caring for advantaged populations.

The costs of diabetes care are increasing beyond inflation in the medical care sector due in part to the rapidly increasing prevalence of type 2 diabetes. Higher costs of care for more people with all types of diabetes may cripple the ability of the health care system to attain optimal health outcomes. The current health care system in the United States is clearly not designed to optimize management of chronic conditions and implement lifestyle and self-management behaviors in an efficient, sustainable, and affordable fashion. Attempts to improve management of diabetes through changes to the health care system over the past 10 years have focused largely on behavioral interventions targeting individuals with diabetes and providers that apply only modest or piecemeal changes in delivery system design. When offered alone, many behavioral interventions show fairly small, often temporary effects. These same interventions may have a more profound impact on care processes and outcomes if combined with substantive changes in the health care delivery system and payment incentives for achieving desired outcomes. Translational research is urgently needed to design, test, and validate

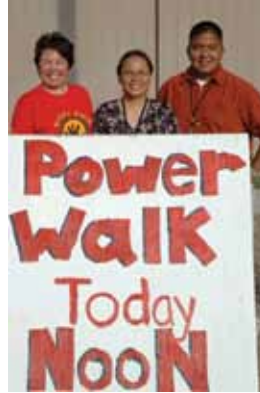
changes to the health care delivery system that can improve the processes and outcomes of diabetes care in the context of ongoing efforts to enhance provider performance, improve diabetes self-management, and implement health information tools.

This chapter on “Clinical Research to Practice: Translational Research” offers forward-looking research questions and directions that build on recent advances and chart a path for progress over the next decade. The research goals focus on the need to understand barriers to diabetes care and to develop and validate new approaches to diabetes prevention and management that benefit individuals with the disease as well as the overall health care system. Although specific policy recommendations are beyond the scope of this report, it is important to note that the results of translational research can inform the development of policies related to the health care system. For example, research to evaluate the relative effectiveness of provider incentives could have implications for efforts to reform payment policies. Thus, the research opportunities described in this chapter have the potential to address the diabetes epidemic in ways that create lasting health benefits for people with diabetes and alleviate the societal burden of this devastating disease.

RECENT RESEARCH ADVANCES

Paving the Way to Affordable Prevention or Delay of Type 2 Diabetes in the Community: The NIH-sponsored DPP demonstrated that type 2 diabetes can be prevented or delayed in high-risk adults with either a lifestyle intervention or medication (metformin). The lifestyle intervention, when compared to the drug treatment, was nearly twice as effective in preventing type 2 diabetes among trial participants and it worked in all groups studied, including U.S. minority populations and the elderly. Both interventions were found to be cost effective and, subsequent to the cost effectiveness analysis, metformin became available as a less costly generic medication. In addition, with longer follow-up, researchers have recently reported that prevention or delay of type 2 diabetes with lifestyle intervention or metformin continued to be observed in DPP participants over a 10 year period. However, delivering the more effective lifestyle intervention tested in the DPP to the 57 million Americans with pre-diabetes would be both costly and challenging in primary health care settings. In recent randomized effectiveness trials, group-based intensive lifestyle interventions modeled after the DPP and delivered by trained community workers demonstrated a 5 to 7 percent weight reduction for at least 12 months. These weight loss results are similar to those that reduced onset of type 2 diabetes by 58 percent in the DPP, but the cost of delivering the intervention by community health workers was reduced more than 10-fold compared to the DPP. This model, coverage for which is already being tested by at least one health insurance group, has the potential to deliver an intervention with efficacy similar to that of the cost effective DPP, but at even lower cost.

Narrowing Gaps in Achieving Treatment Targets for Diabetes: Evidence-based guidelines have been developed for the management of diabetes by multiple organizations based on research documenting the benefits of controlling glucose and cardiovascular risk factors. Research indicates that multi-factorial care, including control of glucose, blood pressure, and cholesterol, along with the use of other preventive strategies, such as smoking cessation and daily aspirin therapy, where appropriate, is important for the prevention of diabetes complications and improved long-term outcomes. One study of the effect of a multi-factorial intervention found a nearly 50 percent reduction in mortality in type 2 diabetes. National data, as well as data from a variety of health care settings, including academic and community health centers in both urban and rural locales, indicate a large gap between what is known to be optimal diabetes care and the care that is delivered as part of routine clinical practice. Moreover, in past decades, about one-quarter of people with diabetes have been undiagnosed and thus have not been effectively managed. However, recent national surveillance data find that the appropriate diagnosis of diabetes is increasing, and control of glucose and cardiovascular risk factors is improving in the general population with diabetes. Further, the Translating Research Into Action for Diabetes (TRIAD) study supported by NIH and CDC demonstrated that health care system and provider changes can be systematically implemented in large health care systems to improve the delivery of important processes of care, such as glucose testing. Translational research efforts have contributed to this narrowing of the gap between



Following any successful clinical trial, such as the DPP, the next challenge becomes the search for effective ways to translate the important research findings to real-world settings and diverse communities. (Photo credits (left to right): ©iStockphoto.com/egdigital; Indian Health Service, Division of Diabetes Treatment and Prevention; ©iStockphoto.com/LeggNet)

optimal standards of care and care that is actually delivered.

Interventions To Improve Diabetes Self-

Management: Diabetes requires considerable effort and attention on the part of those with the disease. Effective diabetes self-management is essential to achieving the treatment targets proven to reduce diabetes complications. Interventions to improve diabetes self-management are varied and have demonstrated improvements in diabetes outcomes, particularly in individuals with poor glucose control. Efficacy studies of self-management support have also shown improvements in patient satisfaction, healthy behaviors, self-efficacy, and, in some cases, utilization and clinical outcomes. Additionally, research demonstrates positive outcomes for a variety of diabetes self-management approaches, including programs led by patients, nurses, primary care providers, or other specialists, and delivered to individuals in groups in both health care and community settings. As a result of the body of research demonstrating the benefits of diabetes self-management training, Medicare now allows reimbursement for this service. Moreover, CMS is currently working with organizations on diabetes self-management training, with a focus on minority

populations, as a part of its overall focus on health disparities in the Medicare population.

Research also suggests that individually tailored interventions based on psychosocial or cultural factors are more effective than standardized health education materials or more generic diabetes interventions. Combined analyses of results from many controlled trials also indicate that culturally-tailored patient interventions achieve better diabetes outcomes than general patient interventions at reducing HbA1c levels among people with diabetes who belong to racial or ethnic minority groups in the U.S. population.

Family-based interventions have demonstrated improved diabetes management in children and adolescents with type 1 diabetes. For example, Behavioral Family Systems Therapy has been used successfully in families experiencing high degrees of family conflict. Future large-scale translational effectiveness trials of family-based approaches are important to validate the use of this type of intervention in the broad pediatric type 1 diabetes population.

Health Care Delivery Changes Improve Diabetes

Outcomes: There is strong evidence that including non-physician health care providers in the delivery of diabetes care can improve diabetes outcomes. Involvement of case managers, including community health workers, to enhance quality of care among members of U.S. racial and ethnic minority groups has resulted in improved disease outcomes, including better diabetes control and the delayed onset of retinopathy. Case management addresses barriers to adherence by educating individuals with diabetes on nutrition, exercise, and self-management; identifying adjunct health services (e.g., home health); providing ancillary services, such as laboratory testing and vaccination; and addressing logistical issues, such as transportation. Research has also shown that nurses or clinical pharmacists using treatment algorithms and providing physician support can improve adherence to standards of care for diabetes, resulting in clinically significant improvements in risk factors for adverse outcomes, including better control of blood glucose, blood pressure, and lipids.

Health Care System Changes that Improve

Diabetes Outcomes: Several studies have demonstrated that comprehensive health care systems-level changes can improve diabetes outcomes. For example, the REACH 2010 project in South Carolina demonstrated that a broad-based coalition of community and health care system partners using multi-factorial interventions could improve care and outcomes for people from U.S. racial and ethnic minority groups

who have diabetes. Sustained, large-scale, regional quality improvement efforts within health centers have also demonstrated improvement in some diabetes care processes, such as obtaining HbA1c measurements and conducting foot exams. Improved processes of care have also demonstrated improved control of HbA1c and lipids. However, improvement in HbA1c only emerged after 4 years, which highlights the importance of measuring longer-term effects of changes to the health care system even when diabetes outcomes are not improved in the short term.

The Chronic Care Model (CCM) has proven to be a useful model to conceptualize the key elements of a health care system that contribute to quality care and improved outcomes in chronic conditions such as diabetes. Elements of the CCM include the community, the health system, self-management support, delivery system design, decision support, and clinical information systems. Reviews have concluded that changes to the various features of the health care system need to be made in concert and reinforce each other to achieve maximum effects. The implementation of the CCM in primary care clinics, including a large group of Federally Qualified Health Centers, has demonstrated improvements in both quality of care and diabetes outcomes over the long term.

Health information technologies also show promise for improving diabetes care in diverse health care settings. For example, researchers have shown that decision support tools within electronic medical records can improve processes of diabetes care. Further, electronic data registries, upon which most system interventions are based, are increasingly derived from electronic medical or health records. However, decision support approaches often fail due to the lack of physician acceptance. These findings highlight the need to understand physician attitudes towards health information technologies and to examine the most effective use of electronic medical records.



Health information technology will play an important role in diabetes prevention and management. *(Photo credit: © iStockphoto.com/YanC)*

KEY QUESTIONS AND FUTURE DIRECTIONS FOR RESEARCH

The growing diabetes epidemic in the United States places tremendous medical and financial burden on individuals with the disease as well as the entire health care system that must cope with escalating costs of treating diabetes and its multiple complications. Translational research approaches are critically important for turning the results of carefully controlled research studies into strategies for diabetes prevention and care that are effective, affordable, safe, and sustainable in diverse “real-world” contexts and populations. The research questions and directions proposed in this “Clinical Research to Practice: Translational Research” chapter are linked by a common theme: the need to understand how interventions can be designed to work in disparate populations and individuals and within discrete systems of care.

Prevention of Type 2 Diabetes

Approximately 79 million Americans have pre-diabetes and are at high risk for developing type 2 diabetes (1). Studies have documented an increase in type 2 diabetes in children, adolescents, and adults, particularly within racial and ethnic minority populations in the United States. Importantly, researchers demonstrated in the landmark DPP that it is possible to prevent or delay the onset of type 2 diabetes in adults with pre-diabetes through intensive lifestyle intervention or medication (i.e., metformin). Successfully translating the results of the DPP and similar studies to the general population could have a profound impact on reducing or slowing the national diabetes epidemic.

Key Questions

- **How can the outcomes of the DPP be translated in diverse settings and populations to prevent type 2 diabetes in youth and adults?**
- **What are the key behavioral and environmental factors that need to be assessed along with genetic markers to better tailor type 2 diabetes prevention approaches?**
- **How can the structures and policies of communities, worksites, and other systems influence behavioral change in individuals to prevent type 2 diabetes?**
- **How can interventions to prevent type 2 diabetes be cost effective at the societal level and financially feasible from the perspective of individual payers and health care organizations?**

Future Directions

- **Determine methods to efficiently identify individuals in the population who are at risk of developing type 2 diabetes and would benefit most from preventive programs.**

Although the major risk factors for development of type 2 diabetes are well known, research is needed to understand how best to use this information to target at-risk individuals for prevention efforts. Risk

prediction models must take into account factors such as the optimal cut-point for a positive test and the risk-benefit ratio of treating individuals who are identified as being susceptible to the future development of diabetes. Robust prediction models are likely to depend on the demographic, socioeconomic, and clinical characteristics of a given population.

► **Develop sustainable approaches to prevent type 2 diabetes through integration of health care services and community programs.**

The DPP intervention was implemented in the rigorous, controlled setting of a clinical trial in people who met specific criteria for participation in the trial based in part on their level of risk for developing diabetes. Delivery of a group-based adaptation of this intervention in community settings is a highly promising strategy to prevent or delay type 2 diabetes in a sustainable and cost effective manner. Advancing the translation of these approaches will require improved understanding of how community programs can be linked with primary health care systems that identify persons at high risk for type 2 diabetes in order to offer access to evidence-based community programs at a cost that is affordable to them, and to provide follow-up for the possible development of type 2 diabetes and management of other cardiometabolic risk factors. Importantly, existing and new interventions targeting individuals who are at risk of developing diabetes must be evaluated in the context of any major redesign of systems of care and/or payment reform.

► **Identify components of the physical environment or place of care that influence diabetes prevention and control to inform public health efforts.**

Increased density of neighborhood fast food outlets has been associated with unhealthy lifestyles, poorer psychosocial profiles, and increased risk of obesity among older adults. Healthful food resources have been shown to be inversely related to insulin resistance—an association that is partly mediated by diet, physical activity, and body mass index. Poor housing conditions appear to be an independent contributor to the risk of diabetes among urban, middle-aged African Americans. Understanding the interaction of these and other environmental factors with biological susceptibility to diabetes is crucial for the development of tailored interventions to prevent and control diabetes in vulnerable populations.

► **Determine the best approaches for the prevention of type 2 diabetes in youth.**

Youth with or at risk of type 2 diabetes might require specialized strategies for prevention and intervention that differ from the standard approaches to care in adults. Because the DPP included only participants who were 25 and older with an average age of 51 years, it remains an open question whether the DPP interventions would be efficacious in at-risk youth. Understanding the best approaches for children and young adults has been limited by the lack of comparative, large-scale intervention studies and the difficulties in recruiting and retaining youth for long-term clinical studies. Conducting school or community-based research and multi-center trials to compare the effectiveness of prevention and treatment strategies in youth will help determine how best to delay or prevent diabetes and its complications in this vulnerable population.

Diabetes Clinical Care

Diabetes clinical care is a multi-factorial process that goes well beyond the daily control of blood glucose levels. Clinical studies have demonstrated that individuals with diabetes have low frequency of achievement of targets for management of glycemia, blood pressure, and lipids even when they have access to medical care, increasing their risk for incidence and progression of diabetic complications. In addition, research suggests that those diabetes management targets must be tailored to take into account the needs of individuals with the disease. The NIH-supported Action to Control Cardiovascular Risk in Diabetes Study (ACCORD) tested whether aggressive management of blood glucose levels could reduce cardiovascular disease in people with type 2 diabetes who were at high risk of having a heart attack or stroke. One arm of the trial using aggressive therapy to reduce HbA1c to below 6.0 percent (i.e., to non-diabetic levels) had to be stopped early due to a higher rate of death in participants assigned to this treatment. At first glance, this result was at odds with other clinical trials that reached the opposite conclusion: that intensive glucose management could reduce the risk of cardiovascular disease and other complications in people with type 2 diabetes. However, ACCORD participants were significantly older, had a longer duration of diabetes, and often had pre-existing cardiovascular disease, in contrast to participants in other studies. Together, these clinical trials suggest that a more personalized approach to diabetes clinical care will be needed to ensure patient benefit and safety. Future research can inform this effort by examining ways to optimize clinical care of diabetes in people with different profiles and needs (e.g., medical, behavioral, psychological, social, and cultural). Many of these issues are also addressed in the “Special Needs for Special Populations” chapter. This effort will also be advanced by developing and testing measures that predict good

health outcomes in the diverse population of individuals who are living with diabetes.

Key Questions

- **What are the best approaches to optimize cardiometabolic risk reduction in diverse populations with pre-diabetes or type 2 diabetes?**
- **How can diabetes management and outcomes be improved in older persons with diabetes who often have serious comorbidities?**
- **How can diabetes management processes be improved to alleviate the burden of disease in younger people with diabetes?**
- **What is the most appropriate sequence, rate of intensification, and tailoring of therapeutic goals to individual patient characteristics to optimize health outcomes and safety?**

Future Directions

- **Develop individualized care approaches to optimize outcomes.**

One-size-fits-all approaches are not appropriate for people with diabetes. Goals of care and treatment approaches should vary based upon factors such as life expectancy, comorbidities, patient preferences, and social and cultural milieu. Ultimately, improving the quality and length of life of people with diabetes are the most important goals for diabetes care. Tailored behavioral and multi-component health care system approaches are likely to be most effective in achieving these goals. The development of best care practices must take into account the many biological, behavioral, environmental, economic, and social factors that affect diabetes

progression and treatment in an individual with the disease.

► **Identify methods to improve the quality of life and outcomes of older persons with diabetes.**

Professional societies have issued detailed guidelines for the clinical care of older persons with diabetes. Optimal implementation of these guidelines has been hampered by a number of factors, including the traditional belief that one size fits all in diabetes care—in particular, the concept that intensive risk factor control is suitable in all people with diabetes. Moreover, the focus on cardiovascular risk factor modification to the exclusion of quality of life and geriatric symptoms might not be appropriate in the elderly. A lack of data from clinical trials in the elderly diabetic population has made it difficult to determine the best means to care for these individuals. Database studies, clinical trials, and studies of the incorporation of geriatric principles in diabetes care could contribute to improvements in the quality of life and better health outcomes in older persons with diabetes.

► **Identify strategies for attaining optimal health outcomes in youth with type 1 diabetes.**

Management of type 1 diabetes in children and adolescents can be challenging for them, their caregivers, and their health care providers. On a daily basis, diabetes management to avoid the acute complication of hypoglycemia while avoiding long-term complications from hyperglycemia requires careful balancing of food intake, physical activity, and insulin treatment, as well as frequent glucose monitoring. Very young children with diabetes are not capable of complex disease management and might not be able to communicate the warning signs of hypoglycemia. These

children must rely on parents and other caregivers to monitor their condition around the clock. Over time, older children and adolescents can transition to self-management as they develop the cognitive and psychosocial skills needed to assume more responsibility for their own care. Older teenagers also need support to successfully make the transition from pediatric care to adult care. Diabetes management in children and young adults must take into account the potential for long-term complications.

Several randomized trials have demonstrated that family-based strategies are effective approaches to improve diabetes outcomes in children and adolescents. However, these approaches are often time consuming and costly. An important role for future translational research is to evaluate affordable and sustainable adaptations of these efficacious interventions. Research evaluating new and age-appropriate strategies for pediatric diabetes care will also be important in advancing the quality of care for youth with type 1 diabetes. These approaches need to optimize daily glucose control to minimize the development of risk factors for future end-organ complications, while also addressing the psychosocial needs of youth with diabetes and their families.

► **Determine systems of care that optimize processes and improve outcomes for people with diabetes.**

The traditional diabetes care paradigm has relied upon the well-trained provider working with the patient to provide high-quality care and facilitate diabetes self-management. The provider-patient relationship is likely to remain the heart of quality diabetes care, but research advances have indicated the power of embedding these interactions within systems of care

that promote individualized approaches—the right care delivered to the right person at the right time. Comparing various practice and business models of care will also elucidate ways to optimize quality of care and diabetes outcomes. Research to identify the factors that define an optimal system of care for diabetes has the potential to broadly improve outcomes for large numbers of people with the disease.

► **Find ways to make clinical trials more generalizable to diverse populations in different settings.**

Traditionally, clinical trials select relatively narrowly defined populations, often without significant comorbidities, to maximize internal validity. Moreover, study participants are often selected based on demonstrated adherence, and resources that are often not available or practical in the clinical setting may be applied to further maximize adherence. Thus, the applicability of these studies may be limited for diverse populations with comorbidities who receive care in community settings outside of a research trial. Studies that specifically address how to translate important clinical trial results for the general, non-study population should be supported. As a part of this effort, novel ways to increase generalizability of research need to be explored, such as broader inclusion criteria, the use of practice-based research networks, and specific targeting of diverse populations in different settings.

Patient-Centered Care

Diabetes is a complex, heterogeneous disease that affects men and women of all ages, races, ethnicities, and socioeconomic circumstances. People with diabetes vary considerably in terms of comorbidities, cognitive status, and ability to manage their disease. Diabetes health care must take into account the individual and

the context in which that individual is being treated. For example, the appropriate care of an otherwise healthy teenager with type 1 diabetes will differ significantly from that needed by an elderly person with type 2 diabetes and coronary heart disease. Researchers are working to define patient-specific factors that influence diabetes care, including both medical and self-management of the disease.

Key Questions

- **What self-management approaches support clinical care and ensure better outcomes for those whose diabetes is accompanied by multiple comorbidities?**
- **Which factors unique to the individual with diabetes, intervention, health care system, and context outside of the health care setting contribute to the success of self-management approaches?**
- **How can people with diabetes become more effectively engaged in the self-management of their disease in concert with their health care provider's efforts?**
- **How can evidence-based self-management interventions, using cognitive behavioral approaches, be incorporated into clinical and community-based care?**

Future Directions

- **Identify a concise, practical set of behavioral and psychosocial factors, including both process and outcome measures, that can be collected and used on a routine basis to inform patient-centered care.**

Translating the results of clinical research into practical changes in diabetes care is often slowed by variability

in the outcomes measures used by different trials or studies. In trials of diabetes care, routine measurements of particular factors, such as health literacy or numeracy level or other potential factors influencing treatment outcomes, would enable researchers to directly compare the results of independent trials. A common, practical, and time efficient set of participant-centered measures is needed that might include collaboratively set goals, self-management behaviors, and related psychosocial factors, such as self-efficacy and diabetes distress. Identifying a common set of measures would still leave room for investigators to incorporate unique measurements or classification strategies into their own studies. In addition, standardized measures could also be used for quality improvement of diabetes care and for research on the links between processes and outcomes.

- **Understand the long-term effects of diabetes interventions with regard to sustained behavioral change (patient and/or provider) and diabetes health outcomes.**

Clinical studies evaluating the effectiveness of diabetes intervention strategies are often limited in duration due to multiple factors, including the difficulty in retaining study participants over long periods of time. Thus, it is often difficult to identify which interventions result in temporary improvements that are not sustained after the end of the study and which lead to lasting changes in behavior and health outcomes. Long-term follow-up research to assess the sustainability of diabetes interventions and identify factors associated with enduring success is warranted.

- **Understand how to increase diabetes self-management.**

Diabetes self-management is an important tool for improving health outcomes. Yet, individuals vary in

their desire to engage in self-management, and different self-management training strategies work better in some people than others. For example, some individuals with diabetes learn self-management best in group education settings, whereas others do better by working with a case manager. Research identifying which people benefit the most from specific diabetes self-management interventions holds promise for improving the quality and efficiency of care.

Approaches to self-management education that can reach a higher percentage of people with diabetes need to be developed and validated. Strategies might include in-office education, the use of community health workers or “health coaches,” Internet-based communication (Web portals or email systems), or telephone management approaches. Research on these strategies should consider what approaches work best for which people and under what circumstances. Researchers must also consider the role of the individual’s family in self-management support, as well as changes in self-management during development and aging. Moreover, the field needs clearer definitions, typologies, and measurement tools of self-management to facilitate comparison of interventions across different studies.

Health Disparities

While overall quality of care for diabetes across the country remains suboptimal, it is particularly worrisome for individuals with diabetes from minority groups, and those who are poor or uninsured. These troubling differences in health care delivery, processes of care, and outcomes have been demonstrated across the United States in a variety of health care settings. Several research studies have evaluated interventions to improve health outcomes among racial and ethnic minority populations in the United States. These studies suggest that improving processes of care

(e.g., frequency of lab testing or referral) do not always translate into improved diabetes outcomes. More information is needed about the causes of disparities and how to reduce the disparities in health care delivery and outcomes in the poor, the uninsured, and in ethnic and racial minority groups, including African Americans, American Indians, Asian Americans, Hispanics, and Native Hawaiians and other Pacific Islanders. Routine collection of race/ethnicity data and stratification of quality of care measures and outcomes will support efforts to identify deficiencies in care and reduce disparities.

Key Questions

- **What health care interventions are effective at reducing disparities in diabetes outcomes?**
- **When are culturally tailored interventions necessary and more effective, as opposed to using more general interventions, in reducing health disparities in diabetes outcomes?**
- **How can health communication science be harnessed for the reduction of health disparities in the prevention and control of diabetes?**

Future Directions

- **Identify effective interventions to reduce racial, ethnic, and socioeconomic disparities in diabetes care and outcomes.**

Reducing disparities between minority populations and non-Hispanic whites will require comparative research designs to evaluate culturally tailored interventions for improving shared decision making, self care, and outcomes. Such studies must take into account multiple

factors at the level of the individual (e.g., sociocultural barriers, limited literacy and health literacy, logistical barriers to care, trust, language barriers, and social support); provider (e.g., communication barriers, implicit bias, and information technology limitations); community (e.g., community assets and challenges, and neighborhood contextual effects); and the health system (e.g., insurance issues, resource and infrastructure inequities, and reimbursement disparities). Effective interventions must also address issues of health care financing, access to care, and the special needs of resource-poor health organizations serving vulnerable populations. The willingness of providers and health care systems to acknowledge disparities and to specifically address these differences as part of overall quality improvement programs is critical to developing and validating successful multi-target interventions.

Some minority groups, including American Indians, Alaska Natives, Native Hawaiians and other Pacific Islanders, and Asian Americans, are understudied with regard to disparities in diabetes outcomes and care. New approaches are needed to study these relatively smaller populations and to discern the underlying causes and potential remedies for health disparities in these groups.

- **Identify effective ways to improve the health of individuals on the fringe of health care systems.**

People most at risk for poor diabetes outcomes are often those who are uninsured or underinsured—i.e., on the fringe of health care systems. These individuals often disproportionately rely on urgent and emergent care facilities for routine care. Finding innovative ways of transitioning these persons to the primary care system will be important to future efforts at reducing

racial/ethnic disparities in chronic disease outcomes such as diabetes. To date, little research has been done in this area.

- ▶ **Advance the study of health communication science and technologies to test strategies for addressing health disparities in diabetes prevention and control.**

The role of culture is a critical factor in enhancing the effectiveness of health communication. Despite general agreement that interventions and materials need to be culturally appropriate for the target population, more research is needed on how best to achieve such appropriateness. An improved understanding and advancement of theoretical models of behavior change could help guide the development and testing of culturally targeted health communication designed to make information about diabetes prevention and control more relevant and effective for specific audiences. Such strategies must factor in rapidly changing information technologies, financial constraints, and the need for ongoing training of quality staff. Collaboration of diverse stakeholders, including academics, health professionals, and lay participants, will help foster research to improve organizational and public health information systems and develop audience-appropriate information for diabetes prevention and control.

Systems of Care

Diabetes care is delivered in a variety of settings both within the traditional health care system (e.g., hospitals, health centers, physician offices) and outside of it (e.g., community centers, schools, worksites). The successful translation of research findings related to diabetes prevention and control depends on multiple factors within these settings, including payment models, the composition of health care delivery teams, the institution

of community partnerships and, increasingly, the availability and use of population management tools, such as disease registries and electronic medical records. Identifying optimal systems to support the distribution of evidence-based care and the adoption of new behaviors is a major focus of translational diabetes research.

Key Questions

- **How can multi-level interventions, combining policy/marketing, community, organization, delivery system, provider, and patient/family components, be implemented and sustained to improve diabetes care and outcomes?**
- **What are the key principles for adapting evidence-based interventions to real-world settings in ways that make them locally relevant, preserve their effectiveness, and expand their reach to a higher proportion of people with diabetes?**
- **How do novel mechanisms for payment of health care services affect the process and outcomes of diabetes care?**
- **How can interventions to control diabetes be cost effective for society and financially feasible from the perspective of individual payers and health care organizations?**
- **What practical measures of the quality/processes of diabetes care bear the strongest relationship with better downstream outcomes? Can reporting of such measures and novel methods of payment improve these outcomes?**
- **Can decision support tools or other health information technologies be used**

to facilitate breakthroughs in clinical performance related to diabetes care and quality improvement?

Future Directions

- **Understand how changes in the structure of health care delivery systems can lead to improvements in diabetes care and prevention.**

Interest in the patient-centered medical home has increased rapidly over the past few years. The medical home combines the principles of continuous, comprehensive, coordinated primary care with practice innovations such as health information technology, chronic care management, and quality improvement. The patient-centered medical home changes the way care is organized, coordinated, and delivered, and thus may have an impact on diabetes outcomes. Translational research is needed to determine how to best organize care in ways that optimize outcomes. For example, does the patient-centered medical home (or other models of care) improve diabetes outcomes?

- **Develop strategies to implement and sustain organizational efforts to improve diabetes care and outcomes.**

Dissemination and implementation of interventions to improve diabetes prevention, care, and outcomes in the health care setting and community have been limited. Relatively little effort has been devoted to studying the process of implementing health care interventions. Community strategies have been limited by factors such as the time needed to develop working partnerships and the lack of incentives for community involvement. Moreover, the level of buy-in and implementation of interventions after research funding has ended

(institutionalization) depends on organizational climate and individual leadership. Innovative, mixed-method research drawing upon fields such as implementation and dissemination science, organizational readiness, and economics is needed to progress toward these goals. In addition, new paradigms for research planning, such as longer time frames to allow for the development of meaningful community partnerships, will ensure stronger foundations for sustainable programs. Translational research to evaluate programs for diabetes prevention and improved care should consider and measure factors related to adoption, cost, and sustainability.

- **Integrate multi-level interventions (combined policy/marketing, organization, provider, patient/family, community) synergistically to enhance the likelihood of success and sustainability.**

Substantive changes that link the health care delivery system to the community and incorporate multiple levels of interventions might include: co-location of primary care services and community organizational programs that support behavior change, such as primary care clinics at the YMCA; redesign of primary care clinic processes to streamline ongoing health risk assessment, tailoring of educational and counseling resources during the visit, and group meetings; planned and/or group visits that involve community program partners or peer navigators that help to link individuals with other community resources between visits; formal tracking and communication tools that help to strengthen linkages between community resources and primary health care providers; and co-location or integration of diabetes and mental health services. Studies are needed to determine which integrated programs are most effective at delivering diabetes prevention

and care services in ways that benefit individuals and the community in the long term. Such research must take into account that the optimal program for diabetes intervention might differ depending on the composition, current health status, or other contextual elements of particular communities.

► **Identify optimal settings for delivery of diabetes interventions.**

Systems theory has documented that context is critical for determining the success of interventions. These findings, along with advances in “the science of place,” have shown that settings are critically important factors that need to be addressed for translation success. For example, schools might provide an opportunity to implement diabetes prevention efforts for youth, whereas worksites or churches might be ideal venues for delivery of adult or family-based interventions.

► **Evaluate “natural experiments” that occur when policy or care changes are instituted in health care settings that affect large numbers of people with diabetes.**

Estimates that diabetes care costs will almost double in the next 25 years motivate efforts to consider a major redesign of chronic care delivery in order to expand access to and quality of health care. Structural changes in health care can be costly and challenging to evaluate. However, given considerable costs predicted for future diabetes care, it is likely that some changes in care will be implemented without the benefit of controlled trials. In these cases, research that evaluates these “natural experiments” will help clarify what changes in care work, and under what circumstances. Ideally, studies of changes in the structure of the chronic care delivery system should consider changes in the methods for financing and payment. Crucial factors such as

variation in the costs, quality, and outcomes of diabetes and related comorbidities that occur with substantive changes in the structure of the delivery system should also be evaluated. Successful evaluation of “natural experiments” may often require collaboration among multiple stakeholders, including the NIH, CDC, AHRQ, private health care providers and purchasers, and other partners.

► **Develop new approaches to study the impact of system- and policy-level interventions on diabetes control and prevention.**

Observational epidemiologic studies and randomized controlled trials (RCTs) have provided a large proportion of the current science base for interventions in clinical and public health practice, but neither traditional cohort studies nor RCTs have been adequately flexible or practical to test the continual innovation in health service approaches used in health systems and in communities. This may be because the practical and financial costs of randomization, implementation of intervention, and new data collection for interventions designed to be spread broadly across large populations often make them impractical for inclusion in traditional randomized trials. Surveillance system data have not filled this gap either, as they are often neither flexible nor specific enough to measure the impact of population-targeted interventions. These limitations, along with the increasing need for a stronger evidence base of policy-level interventions for diabetes control and prevention, point to the need for new research platforms that facilitate the study of systems- and policy-level interventions that take advantage of already occurring or imminent interventions and policy initiatives. This need may be achieved through better use of quasi-experimental or adaptive study designs, efficient time-sensitive surveillance approaches, and practical trials

of new interventions occurring as part of ongoing public health practice. These designs will require efficient assembly of diverse datasets and/or augmentation of available data systems and identification of appropriate control groups to permit inferences about causal effects of policies and interventions.

- **Identify promising strategies, such as pay-for-performance and public reporting of performance measures, to bridge the persistent gap in quality of diabetes care and outcomes.**

Payment coverage of diabetes services is likely to affect quality of care and outcomes. Cost sharing with high co-pay/co-insurance levels and, possibly, high deductible arrangements can have a negative impact on self-management behaviors, utilization of preventive services, risk factor control, and longer-term outcomes. Potentially beneficial changes in the delivery system design (e.g., team care, community linkages, and lay health worker and peer interventions) are not supported by fee-for-service reimbursement to physicians, but research suggests that salaried physicians do not provide better care, and individual capitation payments can result in undertreatment. Although performance incentives have been increasingly adopted by public and private insurers, their overall effectiveness at improving health care delivery and health outcomes remains uncertain, and the potential for unintended negative consequences exists. Research into the

effect of such incentives on diabetes care and diabetes outcomes is warranted. This essential question should probe beyond earlier work comparing fee-for-service, patient capitation payments, and physicians who are salaried. New ideas about blended payment systems may have clear advantages over these earlier models. Examples include condition-specific capitation and/or multi-provider, episode-of-care payments coupled with pay-for-performance. Fundamental payment reform strategies that will facilitate team-based care, provide adequate support to change the roles and responsibilities of clinical team members, reward behavior change and lifestyle intervention activities, support linkages with the community, and promote more widespread and efficient use of health information technology should also be studied.

- **Identify new uses of health information technology to improve diabetes care.**

The rapid development of information technology to support health care offers exciting new opportunities for improvements in diabetes care. Technologies, such as personal health records, Web portals, and other means of chronic disease management, are becoming more widely available, although the implementation and effectiveness of these tools can vary across different health care settings. Researchers are studying the best approaches to incorporate new technologies in ways that help people with diabetes become more involved in their care and improve self-management and outcomes.

IMPORTANCE OF RESEARCH GOALS AND STRATEGIES: HOW TRANSLATING RESEARCH OUTCOMES MAY LEAD TO IMPROVEMENTS IN HEALTH

The multidisciplinary diabetes research enterprise supported by the NIH and other public and private agencies has uncovered a wealth of information on effective means to prevent type 2 diabetes and improve long-term outcomes both for people with type 1 and people with type 2 diabetes. These findings often result from controlled, randomized clinical research trials with volunteers who have been carefully selected to meet specific criteria for participation. However, large gaps persist between knowledge generated from the most successful clinical trials and current medical practice for diabetes prevention and control. With its focus on real-world applications, translational research is essential for bridging those gaps to improve the lives and health of all individuals who are at risk of developing diabetes or who live with this disease every day.

Translational research addresses the context of diabetes prevention and care—how can the often generalized results of clinical research be adapted to suit the needs of individuals, diverse population groups, or different health care delivery settings or systems? If pursued, the translational research goals and directions described

in this chapter have the potential to make a substantial impact on the national diabetes epidemic. Effective methods for widespread prevention of type 2 diabetes in high-risk individuals and populations could significantly reduce the number of people who are affected by this devastating and costly disease. Likewise, improved diabetes care and self-management practices that are optimized for the individual can prevent or delay the onset of complications that represent a major source of morbidity and mortality and account for a large proportion of health care spending for diabetes. New, validated approaches for social and cultural tailoring can help underserved populations, including racial and ethnic minorities and the poor, receive the benefits of research to improve diabetes care and outcomes. Such efforts to reduce disparities in diabetes health care must be linked to strategies to improve the overall efficiency of the health care delivery system in managing this complex disease. Collectively, translational research efforts are key to improving the health of the American public and reducing the escalating costs of health care for diabetes in the United States.