



INDIVIDUALIZATION OF DIABETES CARE: *The Key to Success But Not Without Some Challenges*

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INTRODUCTION

The past 10 years have brought about significant changes in our approach to diabetes management. Predictably, physiologic mechanisms underlying the different types of diabetes continue to be better understood and more medications with novel mechanisms of action have become available. But perhaps the biggest change has been the shift from prescriptive management guidelines to an emphasis on individualization of care.¹ This shift is the culmination of a number of developments; the lack of clinical evidence to support the recommendation of one medication over another;² the recognition that diabetes is only one part of the larger process of multifaceted cardiovascular management; and the mounting evidence that lasting improvement in clinical outcomes requires consideration of patient preferences and values.^{3,4,5}

As we take a journey through this evolution from prescriptive clinical practices to individualization of care, it is clear that the expectation of providing individualized diabetes care presents some significant challenges for current health care systems and practitioners. Unless we make significant changes in how we manage diabetes, successful implementation with subsequent improvements in clinical outcomes will not occur.

THE EVOLUTION TOWARDS INDIVIDUALIZATION OF DISEASE MANAGEMENT

There are more than 50 different types of diabetes which are classified according to etiology.⁶ Specific etiologies and their associated mechanisms of disease pathology are becoming better delineated, and the increase in commercially available diagnostic tools such as genetic testing is allowing us to assign 'type of diabetes' more accurately. However, it is well recognized that while people grouped together under one particular type of diabetes share etiology, they do not necessarily share the same combination of underlying pathologies (e.g. insulin resistance, β -cell failure). Conversely, those labelled with different types of diabetes may share identical pathologies. This discordance between 'type

of diabetes' and 'pathology that contributes to disease expression' has been known and described in the literature for some time,⁷ but it has become more germane with the development of medications that can target differing pathologies. Indeed, these developments have opened the door to challenges of the traditional guideline approach to diabetes management.

Though it is universally accepted and promoted internationally as best practice within clinical settings, the guideline approach is a one-size-fits-all strategy that is geared towards managing 'type of diabetes.' Typically, for a person with type 2 diabetes, the initial recommended treatment is lifestyle modification with or without metformin. This is then followed by an algorithmic list of medications to be introduced in sequential order to achieve target HbA1c.^{8,9} Such prescriptive hierarchies make several incorrect assumptions, the most obvious falsity being that everyone grouped together under one type of diabetes shares the same set of pathophysiologies.⁷ Guideline approaches are also criticized for not being evidence-based, and are dismissed by many as "outdated expert opinion." Except for metformin, there is no evidence to support the recommendation of one medication ahead of another.² Critics also disparagingly describe guidelines as 'treat to failure' approaches, as their stepwise escalation in medical management means that the addition of new medication only occurs when a patient is not meeting their glycemic goal. Thus, since progression of disease is inevitable, a patient will recurrently 'fail' medical management.^{2,10}

To address these inadequacies, a 'pathophysiologic' approach is now advocated. Selection of medication is based on the need to target each pathology contributing to a person's hyperglycemia. Indeed, to ensure enduring glycemic control, the recommendation is to initiate a combination of medications to target all contributing pathologies at disease onset.^{1,2,7,11,12,13}

Proponents of this approach also emphasize the need for diabetes management to shift from our current gluco-centric focus to a broader, more inclusive

consideration of cardiovascular risk. Diabetes is just one part of a much bigger cardiovascular picture and evidence suggests that focusing on glycemic control alone has relatively less impact on reducing a person's cardiovascular risk than does management of other cardiovascular risk parameters such as blood pressure and cholesterol.^{1,10} Thus, selection of an oral hypoglycemic should be based not just on its glucose-lowering efficacy and durability, but also on its ability to target other cardiovascular risk factors such as weight, blood pressure, lipids etc.

Fortunately, the ever increasing array of available therapies is supporting this call for individualization of care. As various mechanisms of disease pathophysiology have become defined, pharmaceutical companies have created drugs to target the pathophysiologies: metformin moderates excess hepatic gluconeogenesis, sulfonylureas and meglitinides enhance endogenous insulin production, thiazolidinediones reduce peripheral insulin resistance, and gliptins and incretin mimetics restore gut endocrine mechanisms. The oldest of these medications were developed with little regard toward management of cardiovascular parameters other than glucose and many have side-effects that negatively affect cardiovascular risk, such as weight gain. However, the newer oral hypoglycemics such as SGLT-2 inhibitors, are being developed with careful consideration of the various cardiovascular risk parameters.

In 2008, agreement around the need for individualization of diabetes care was further strengthened with the advent of the ACCORD14 and ADVANCE 15 trials. Each study took a large population of adults with diabetes and attempted to drive their HbA1c to below 6.5% (47 mmol/mol). For some participants these attempts to tighten HbA1c resulted in increased cardiovascular events and all-cause mortality. Retrospective analysis found these participants to be elderly individuals who had multiple chronic diseases, were taking multiple medications, and had high cardiovascular risk scores. It is still not entirely clear why this group did particularly poorly, but the ensuing consensus has been that it is not appropriate to hold patients to identical targets that conform to some gold standard, but that glycemic goals should be individualized.^{1,16}

In response to increasing criticism of prescriptive guidelines, and to the growing evidence supporting individualization of care, the 2012 American Diabetes Association/European Association for the Study of Diabetes (ADA/EASD) issued consensus recommendations for the management of type 2 diabetes that

shifted away from the familiar algorithmic approach.¹ Proclaiming “individualization of treatment [as] the cornerstone of success,” their guidelines are a veritable reference list of evidence-based management options. They come with the explicit directive that implementation of their guidelines “will require thoughtful clinicians to integrate current evidence with other constraints and imperatives in the context of patient-specific factors,” with the “intent. . . to encourage an appreciation of the variable and progressive nature of type 2 diabetes, the specific role of each drug, the patient and disease factors that drive clinical decision making, and the constraints imposed by age and comorbidity.”¹

THE EVOLUTION TOWARDS INDIVIDUALIZATION OF PATIENT MANAGEMENT

The conventional model of health care evolved around the management of acute episodic illness. During an acute disease event (e.g. heart attack), clinicians are expected to act quickly and decisively. Little time is spent providing patient education about the disease process or treatment options; this is especially true if the presentation is a life-threatening event. The clinician is clearly in charge and the patient surrenders autonomy so the treatment can proceed quickly.

This model of care is ill-suited to the medical and psychosocial complexities of chronic disease. As lifelong illnesses, management is about control, not cure, which means the person has to live with and independently manage their disease on a daily basis. This places key treatment decisions such as lifestyle choices and taking medications entirely under patient control. Furthermore, as each person is a unique and autonomous individual with their own set of beliefs and priorities about life, disease management will not be successful if selected treatments do not suit the patient's unique life-situation and cultural and personal beliefs.¹⁷⁻¹⁹ Thus, models of chronic disease management have had to shift from treatment that is administered to passive recipients by medical experts, to treatment that is planned collaboratively with patients.³ Key influences behind this shift have been the Chronic Care Model²⁰ and the Institute of Medicine report, *Crossing the Quality Chasm*.²¹ Both place patient-centered care at the heart of their models.

PATIENT-CENTERED CARE IN DIABETES

The concept of patient-centered care was introduced over 40 years ago,²² but only with the escalating prevalence of chronic disease has its use

entered mainstream clinical care. To provide patient-centered care is to be “respectful of and responsive to individual patient preferences, needs, and values . . . ensuring that patient values guide all clinical decisions.”²¹ In other words, providers must acknowledge that each individual has a unique set of life commitments, leisure activities, and personal experiences of the disease due to culture, beliefs, and personal values; appreciate that all of these factors impact how a person chooses to manage their own disease, and therefore accept that the patient is the expert when it comes to understanding what medical management plan will best accommodate their personal experiences.²³

This requires a significant shift in the roles of both patient and provider; the patient is now an active contributor to the decision-making process while the provider must relinquish their role as ‘management expert’ and become an educator, a consultant in the true sense of the word. Their responsibility is to ensure that each patient acquires a sufficient understanding of their disease and its management options so they can make sound decisions about their illness management.³ This contrasts with the current approach to patient education which simply provides medical reasons as to why a patient should comply with a recommended management plan.

Since patient-centered care has proven to be cost-effective with a positive impact on health outcomes and healthcare utilization, it is included as a core attribute of the 2012 ADA/EASD recommendations for the management of type 2 diabetes.^{1,24,25} Indeed, the approach is considered “particularly appropriate” given the lack of evidence supporting the selection of one management option over another.¹

THE CLINICAL APPLICATION OF INDIVIDUALIZED DIABETES CARE

While patient-centered care is being held up as the gold standard approach for diabetes management, it is unrealistic to think that clinicians will be able to adhere to its tenets within the confines of our current clinical settings.

The outcome of patients’ decisions about their diabetes management depends on their knowledge and understanding of the subject.⁵ They must be medically well-informed, which means that for care to be patient-centered, patient education must be detailed

and disease-specific so that each patient fully understands not just disease pathology, but their disease pathology; they need to know about all the available treatment options and how they work; and they need to understand the long term health consequences of different management choices.²⁴

Any sound pedagogical endeavour requires regular attention and review to assure full comprehension and understanding of a subject. Unfortunately, whether because of funding arrangements or clinic schedules, diabetes care is provided in isolated brief appointments, which makes it difficult, if not impossible, to deliver comprehensive education. Patients are inevitably left with gaps in their knowledge rendering them poorly informed, incapable of making sound medical decisions. This immediately places the provider back in the role of the ‘expert’ making management recommendations. To successfully empower patients with the knowledge they need for sound decision making will require a series of closely spaced appointments. Until such rearrangements are made, the 2012 ADA/EASD call to individualize care will simply result in providers tailoring medical management to each patient’s underlying pathologies.

Changing health care structures to accommodate the provision of patient-centered care will require a change in reimbursement and in scheduling of appointments, but a more difficult challenge may be persuading providers to forfeit their role as management expert. Many clinicians, particularly those based in a hospital setting, will struggle with the idea that a patient is able and in a better position to choose suitable management regimes.²⁶ Indeed, even the 2012 ADA/EASD recommendations falter when it comes to shifting full responsibility to the patient: “. . . it is patients who make the final decisions regarding lifestyle choices and, to some degree, the pharmaceutical interventions they use.” Until clinicians understand that they will need to change their behavior, the provision of patient-centered care will not be realized.⁵

INDIVIDUALIZATION OF DIABETES CARE IMPROVES HBA1C

In 2006, prior to the 2012 ADA/EASD guidelines, a diabetes clinic was set up in New Zealand that provided a truly individualized clinical approach. Situated within a primary care clinical setting, GPSI Diabetes*

* General Practitioner with Special Interest in Diabetes. GPSI is a term introduced by the British National Health Service to identify general practitioners who have completed some further training in a particular discipline of medicine.

was designed with one goal—to produce patients empowered with the knowledge and information necessary to self-manage their own diabetes. Diabetes care was provided within the framework of a patient-centered medical model²² and a physiologic approach to disease management was subscribed to.

A detailed description of this service has been recently published.²⁷ To ensure consistency in the provision of the six interactive components of the patient-centered model used, a set of loosely structured, diabetes-specific, patient-centered approaches was created. This meant that everyone who attended was first informed of the expectation that they would be choosing their own management regime. Subsequent patient education included a review of normal glucose metabolism, and the pathophysiology of diabetes and disease progression. Medications, their mechanisms of action, pharmacokinetics, side effects, and the disadvantages and advantages of each were reviewed. All treatment options were included regardless of whether the provider considered them appropriate for the patient. Each patient was then provided with information about the unique set of pathologies contributing to their diabetes. Nutritional education focused on how various food types affect blood sugar, but the patients were never told that certain foods were ‘good’ or ‘bad.’ Each patient was given an explanation of what is measured by glycosylated haemoglobin (HbA1c), along with information on its prognostic value for disease complications and cardiovascular risk. Patients were not told “you must get your sugars down,” but were simply given the same information as healthcare providers have, which supports tight glycemic control. Finally, all patients were given instruction on how to monitor for disease progression; how pre- and post-prandial blood sugars determine treatment needs and/or dose adjustments; and when to call for help.

Because the service was publicly funded, there were no restrictions on how often a patient could attend, and clinic schedules were arranged according to need. Thus, education was provided during a series of 30 minute appointments held in quick succession following which the patient was discharged back to their primary care provider. The average number of appointments attended was four

although how many each patient actually attended was determined by individual need.

The success of this service is noteworthy. The average decrease in HbA1c was 2% points (20 mmol/mol). This reduction was statistically significant ($p < 0.001$) and sustained for the two year duration of data review, despite patients being discharged from the intervention back to their primary care provider. Equally noteworthy was the closing of the ethnic gap between indigenous Maori and European New Zealanders. New Zealand, like any health care system internationally, struggles with ethnic disparity in health; Maori referred to GPSI Diabetes had an average HbA1c 2% points (20 mmol/mol) higher than that of European New Zealanders. However, after the GPSI Diabetes intervention, they experienced larger improvements in HbA1c leaving no statistical difference in HbA1c between Maori and European New Zealanders.

INDIVIDUALIZATION OF DIABETES CARE IS THE CORNERSTONE OF SUCCESS

Good evidence supports glycemic control, yet achieving long-term glucose control within real world clinical settings has proven difficult.²⁸ With the introduction of the 2012 ADA/EASD guidelines it seems we have finally been provided with a recipe for success; evidence based, and now with some indication that such recommendations provide immediate and long-term improvements in diabetes outcomes, it would seem that individualization of care is indeed the “cornerstone of success”¹

The challenge ahead is how to implement individualization of diabetes care so that it is universally available to all people with diabetes. Rearranging reimbursement policies and appointment schedules to support patient education are just two of the necessary changes that will need to be realized within healthcare organizations. Medical education, which has traditionally focused on teaching diagnostic and management skills,²⁶ will also need to change to include teaching clinicians the skills that support collaborative and respectful partnerships with patients. Of course, none of these ideas are new; the issue is getting them to happen. What is clear is that until we address these changes, health care providers will continue to do poorly when it comes to diabetes care.

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