Lifestyle and/or Pharmacologic Interventions
to Delay Onset of Type 2 Diabetes

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Abstract

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Type 2 diabetes mellitus is a chronic and burdensome disease that is increasing worldwide. Risk factors for developing type 2 diabetes include elevated fasting plasma glucose concentrations, obesity, and a sedentary lifestyle. Pre-diabetes, a phenomenon also known as insulin resistance, is now recognized and accepted as a disease state that is potentially reversible. By modifying risk factors with lifestyle interventions, such as a healthy diet and regular exercise, it has been demonstrated that the risk for developing type 2 diabetes can be reduced. Screening high risk patients allows health care providers to evaluate patients' willingness to modify behaviors that put them at increased risk for developing type 2 diabetes. An evidence-based algorithm for assessment and treatment is presented. By emphasizing the benefits of change and addressing the barriers that inhibit change, health care providers can guide patients toward healthier, longer lives without diabetes.
# Table of Contents

- Signature Page ......................................................................................................................... ii
- Abstract ......................................................................................................................................... iii
- Table of Contents ......................................................................................................................... iv
- List of Tables ................................................................................................................................. v
- List of Figures ................................................................................................................................. vi
- Introduction ....................................................................................................................................... 1
- Statement of Purpose ..................................................................................................................... 2
- Theoretical Framework ................................................................................................................... 3
- Review of the Literature ................................................................................................................ 4
- Implications for research, clinical practice, and theory development ........................................... 14
- Summary ......................................................................................................................................... 20
- References ....................................................................................................................................... 21
- Table 1 ........................................................................................................................................... 25
- Table 2 ........................................................................................................................................... 26
- Table 3 ........................................................................................................................................... 27
- Figure 1 .......................................................................................................................................... 28
- Figure 2 .......................................................................................................................................... 29
List of Tables

Table 1

Table 2
Changes in selected clinical and metabolic variables from base-line to the end of year 1 in the subjects in the intervention and control groups .................................................................26

Table 3
Incidence of diabetes .............................................................................................................27
List of Figures

Figure 1
Algorithm for pre-diabetes assessment and treatment ..................................................28

Figure 2
Changes in body weight, leisure physical activity, and glycosylated hemoglobin values ....29
Lifestyle and/or Pharmacologic Interventions to Delay Onset of Type 2 Diabetes

Diabetes is a chronic and burdensome disease that affects approximately 12% of 40- to 74-year-old people in the United States [U.S.] (American Diabetes Association [ADA], 2002b). The incidence of type 2 diabetes has increased five-fold between 1958 and 1996 (Harris & Eastman, 2000). Prevalence is projected to increase worldwide from 135 million in 1995 to 300 million by 2025. Utilizing the American Diabetes Association (ADA) criteria, the prevalence of undiagnosed diabetes among U. S. adults is estimated at 5.4 million (2.7%) and impaired fasting glucose affects 13.4 million (6.9%) (Harris et al., 1998). Worldwide, diabetes is predicted to become epidemic over the next 25 years, with the U. S. among the top three nations with the greatest number of people with diabetes (King, Aubert, & Herman, 1998). Approximately 800,000 people are diagnosed with diabetes each year (Centers for Disease Control [CDC], 1999) and of these, nearly 50% of patients with a new diagnosis of type 2 diabetes have already suffered organ damage (United Kingdom Prospective Diabetes Study Group 33 [UKPDS 33], 1998). Complications affecting the eyes, kidneys, and nerves increase morbidity and mortality in the U. S. (Harris et al., 1998). African Americans and Mexican Americans are at twice the risk for diabetes than non-Hispanic whites (Harris & Eastman, 2000). Women will be affected more often than men (King et al., 1998). Recent estimates of the direct and indirect costs associated with diabetes care in North America exceed $100 billion per year (ADA, 1998).

Guidelines for screening and recommendations for treatment have recently been revised and are under constant review in an effort to prevent or delay the onset of type
2 diabetes (ADA, 2002c). As revisions are guided by research, there is evidence that lifestyle modifications, with or without pharmacologic therapy, may lower the risk of developing type 2 diabetes. In identifying who may be at the highest risk, the phenomenon of pre-diabetes, referred to as insulin resistance (IR), impaired fasting glucose (IFG), and/or impaired glucose tolerance (IGT), is explored. "Glucose intolerance is part of a clustering of risk factors for cardiovascular disease, which includes central obesity, hypertension, high triglyceride levels, and low HDL cholesterol" (Chiasson et al., 1998, p. 1720). During the latent phase of pre-diabetes, risk factors for micro- and macrovascular disease are increased and diabetic complications are developing (Harris & Eastman, 2000). Diabetes is a lifelong disease that patients, guided by health care providers, must manage. Patients' willingness to adopt changes in their lifestyle is often met with considerable resistance. Health care providers must utilize a variety of methods to engage the patient in the therapeutic process (Buse, 1998). Considering the potential impact of delaying or preventing type 2 diabetes on an overburdened health care system, this opportunity cannot be overlooked.

Statement of Purpose

The purpose of this manuscript is threefold. Reviewing pertinent research and theoretical models will provide guidance to practitioners regarding lifestyle and/or pharmacological interventions to delay the onset of type 2 diabetes. Overcoming barriers to improve outcomes will be explored. Implications for additional research to further enhance knowledge regarding delaying the onset of type 2 diabetes will be presented.
Theoretical Framework

The Transtheoretical Model (TTM) of behavior change (Prochaska & DiClemente, 1992), is also known as the Stages of Change Model or the Stages of Adoption Model. The model reflects the belief that changes in behavior occur slowly and move forward in predictable patterns or stages. The TTM has been used to gauge readiness to change in such behaviors as cigarette smoking, exercise, diet, and screening mammography. Essential to the progressive movement through stages is a person's positive intention to effect a behavior change. Psychological factors such as motivation, attitude, and behavior characterize stages of adoption. The five fundamental stages are: (a) precontemplation (not interested or unwilling to change), (b) contemplation (considering a change), (c) preparation (decision to make a specific change), (d) action (making the change over a specific period of time) and (e) maintenance and relapse prevention. The action and maintenance stages prescribe certain time frames, depending on the behavior being modified. Relapse and recycling features are utilized when a person does not complete a stage successfully and begins anew in a previous stage. The theory recognizes that relapse occurs often during behavioral change. Relapse and recycling provide avenues to resume in an appropriate stage. Health practices that depend heavily on personal decision making to bring about the targeted behavioral change are especially well-suited for the transtheoretical model (Rakowski, 1996). "It is clear that assessment of the individual's readiness for learning and behavior change is critical" (Sedlak, Doheny, & Jones, 2000, p. 402).

Integration of the stages with the underlying psychological domains of cognitive/experiential and behavior skills allows for full implementation of the
Transtheoretical Model. These domains are the pros, the cons, the processes of change and self-efficacy. Pros denote positive attributes (benefits) and cons denote negative aspects (barriers). The processes of change consist of strategies people may use to be successful in making changes, as with diabetes self-management. Self-efficacy reflects belief in one's ability to achieve certain behaviors, such as increasing physical activity. Translating these processes into well-defined skills or tasks must be matched to the person's current stage of change (Rakowski, 1996).

Review of the Literature

Pathophysiology of Type 2 Diabetes

Type 2 diabetes develops through a combination of factors, both genetic and nongenetic, including lifestyle and environmental exposures. Genetic predisposition is one of the most important family history determinants. Individuals who carry susceptible genes for type 2 diabetes possess at least a 50% probability of disease development (Eriksson, Lindstrom, & Tuomilehto, 2001). Obesity and decreased physical activity may combine with a genetic predisposition leading to insulin resistance (IR) in the muscle and liver, resulting in hyperinsulinemia. Progression of insulin resistance may lead to the hyperglycemia and hyperinsulinemia associated with impaired fasting glucose (IFG) and impaired glucose tolerance (IGT) (Harris & Eastman, 2000). “Insulin resistance is almost always a genetically determined insensitivity to insulin-mediated glucose disposal in peripheral tissues” (Garber, Gavin, & Goldstein, 1996, p. 198). Cigarette smoking, increasing weight, and a sedentary lifestyle combine to reduce carbohydrate disposal induced by exercise, leaving the body
increasingly dependent on insulin to dispose of glucose. Blood glucose levels >200 mg/dl work to slowly desensitize the pancreas and suppress insulin secretion, allowing abnormally high levels of glucose to have toxic effects. Normal glucose tolerance is maintained, however, when the beta-cells can compensate by increasing insulin secretions (Chiasson et al., 1998). Pancreatic workload increases, leading to beta-cell failure in many cases (Garber et al., 1996).

During the latent phase, people with undiagnosed diabetes with risk factors such as obesity, albuminuria, hypertension, dyslipidemia and cigarette smoking are already experiencing complications from diabetes. Harris, Klein, Welborn, and Knuiman (1992) suggest there is a preclinical phase prior to the diagnosis of diabetes, between four and seven years, when detectable retinopathy is likely to have occurred. Beta-cell impairment of the pancreas may occur as a primary event. Subsequent diminished endogenous insulin secretory ability results in hyperglycemia and symptoms diagnostic of diabetes (Harris & Eastman, 2000). Table 1 shows that those undiagnosed with diabetes have risk factor levels similar to those with diagnosed diabetes. In the United Kingdom Prospective Diabetes Study, 21% of newly diagnosed patients with diabetes had pre-existing retinopathy. Elevated levels of microalbuminuria and proteinuria, increased neuropathies, and coronary heart disease are additional complications from undiagnosed diabetes (Harris & Eastman, 2000).

**Diagnostic Criteria**

In 1997, the diagnostic criteria from the World Health Organization [WHO] was reviewed by an expert ADA committee. The ADA expert committee suggested changes to the WHO diagnostic criteria, which had been established previously in 1985. The
ADA-suggested changes for diagnosing diabetes were (a) symptoms of diabetes, plus casual (any time of day without regard to last meal) plasma glucose concentration ≥ 200 mg/dl, or (b) fasting plasma glucose (FPG) ≥ 126 mg/dl (no caloric intake for at least eight hours) or (c) 2-hour plasma glucose (PG) ≥ 200 mg/dl during an oral glucose tolerance test (OGTT) using the equivalent of 75-gram anhydrous glucose dissolved in water (ADA, 2002b). The WHO recommended changing the FPG level from ≥ 140 mg/dl to ≥ 126 mg/dl in 1999 (Richard, Sultan, Daures, Vannereau, & Parer-Richard, 2002). Harris and Eastman (2000) cite that the major difference in the criteria is related to the use of the OGTT. The OGTT is not recommended for diagnosis in clinical practice by the ADA due to difficulty in performing, cost and inconvenience to the patient.

Comparing the accuracy of the ADA criteria to the WHO's 1985 criteria was the basis for a study of 1,149 obese participants who had been referred to the Department for Nutritional Diseases and Diabetology in Montpellier, France for obesity management. Participants were given an oral glucose tolerance test according to the WHO standards. Just prior to glucose loading and every 30 minutes thereafter, blood samples were drawn. Their results were classified into one of the three similar categories used by the WHO and the ADA for the purpose of comparing the diagnostic criteria for diabetes mellitus and impaired glucose tolerance. OGTTs were not repeated as recommended for definitive diagnosis (Richard et al., 2002).

Results indicated there was poor agreement between the two criteria, leaving a wide underestimation of glucose intolerance utilizing ADA criteria. "Most (70%) of our obese population with abnormal 2-h plasma glucose displayed a 'non-diabetic'
fasting plasma glucose" (p. 297). There was nearly a four-fold decrease in the prevalence of impaired fasting glucose (ADA criteria) compared to impaired glucose tolerance (WHO criteria). In addition, ADA criteria identified 6% of participants with intermediate glucose abnormalities (latent phase) compared to 22.4%, using the WHO criteria. The authors suggested retaining the WHO criteria using OGTT (Richard et al., 2002).

Screening for Type 2 Diabetes

While the burden of diabetes is well founded, and the benefits of glycemic control are well established, there are no randomized trials to demonstrate the benefits of screening asymptomatic people for early signs of diabetes. For individuals at high risk, however, opportunistic screening within a clinical setting is warranted. Criteria for testing asymptomatic adults include everyone over age 45 or at a younger age if a) overweight, b) have a first-degree relative with diabetes, c) are a member of a high-risk ethnic population, d) have delivered a large baby or had previous gestational diabetes mellitus, e) are hypertensive, f) have high density lipoproteins ≤ 35 mg/dl or triglycerides ≥ 250 mg/dl, g) have previous impaired glucose tolerance or impaired fasting glucose, or h) have associated conditions, such as acanthosis nigricans and polycystic ovarian syndrome (ADA, 2002c).

The benefits from early detection include improved beta-cell function when hyperglycemia is controlled (UKPDS, 1995), reduced diabetic microvascular complications (UKPDS 33, 1998), and provide opportunities to aggressively treat hypertension (ADA, 2002c) and dyslipidemia (ADA, 2002a).

Therapy
Therapy for adult, nonpregnant type 2 diabetes follows well-established protocols and is fundamental for the control of hyperglycemia. Currently, a common therapeutic approach for the treatment of diabetes is referred to as “stepped care.” In step-wise fashion, control of hyperglycemia is usually first attempted by reducing caloric intake and increasing physical activity for two to six months (Buse, 1998). If this step fails to produce the desired decrease in hyperglycemia, an oral hypoglycemic agent is added to assist insulin secretion and/or reduce insulin resistance. Combinations of oral antidiabetes medications may be needed. Exogenous insulin may then be added to the above regimen when combinations of oral medications fail to adequately reduce blood glucose (Harris & Eastman, 2000). Pharmacological treatment utilizing a sulphonylurea or insulin as compared to the conventional treatment of diet to maintain blood glucose levels within the normoglycemic range can reduce the incidence of diabetes complications (UKPDS 33, 1998). Glycemic control for nonpregnant adults with diabetes, as suggested by the ADA, includes a) average preprandial glucose (mg/dl) of <100 as within the normal range, with a goal of 80-120 mg/dl, b) average bedtime glucose (mg/dl) of <110, with a goal of 100-140 as the normal range and c) HgbA1c (%) of <6 as normal, with <7 as the goal to maintain (ADA, 2002c).

Stopping or slowing the progression of type 2 diabetes has been the topic of numerous research trials. In the mid-1970s, the United Kingdom Prospective Diabetes Study (UKPDS) examined whether intensive management to control blood glucose levels utilizing various medications produced better long-term outcomes than the prevailing strategy of diet and lifestyle. In addition, the study also set out to examine whether a specific therapy (sulfonylureas, insulin, or metformin) was efficacious
without increasing other diabetes-related complications, such as cardiovascular disease (Turner, 1998).

After more than 20 years and much controversy, the main conclusion was that intensive therapy (target fasting plasma glucose of <108 mg/dl using increasing doses of pharmaceutical therapy) was beneficial (Nathan, 1998). When metformin was used in the intervention group, there was a reduction in cardiovascular complications in overweight patients. Median A1c reduced from 8.0% to 7.4% (UKPDS 34, 1998). Blood glucose values increased over time, however, indicating the progressive decline of beta-cell secretory function (Turner, 1998).

Diabetes Prevention

The Finnish Diabetes Prevention Study (Tuomilehto et al., 2001) recruited 522 obese men and women with impaired glucose tolerance, as defined by the 1985 World Health Organization. Participants were randomized into a control group (n=257), receiving either brief diet and exercise counseling, or into an intervention group (n=265) where they received more intensive, individualized instructions on weight loss, dietary intake and guided increases in physical activity. The purpose of the study was to determine whether type 2 diabetes can be prevented by lifestyle modifications in people at high risk for developing the disease. Participants were between 40 and 65 (mean 55) years of age with a body mass index (BMI) of 25 or higher (mean 31 kg/m²). Participants in the control group were given general oral and written information (a two-page leaflet) about diet and exercise. Annual visits repeated similar information. No specific individualized programs were offered. Intervention participants were given
individualized education and incentives to facilitate weight loss, healthier eating, and increased exercise. Specifically, intervention participants were to achieve weight loss of 5% or more, reduce total intake of fat to 30%, reduce saturated fat to less than 10% of calories consumed, and increase fiber to at least 15 grams per 1000 kcals. Moderate exercise for at least 30 minutes per day was their physical activity goal.

Each participant in the intervention group met with a nutritionist seven times during the first year of the study and once every three months thereafter. Individual guidance offered exercise program choices of walking, jogging, swimming, aerobic ball games, or skiing. Circuit resistance training, with progressive stations and individual tailoring, were also offered to improve exercise capacity of large muscle groups (Tuomilehto et al., 2001). Free membership to an exercise club was included as an incentive to continue training (ADA and National Institute of Diabetes, Digestive and Kidney Diseases, 2002) [ADA and NIDDKD, 2002].

Study results at the end of the first year indicated that only modest changes in diet and exercise resulted in reduced incidence of developing diabetes. Weight loss exceeding 5% was achieved by 43% of the subjects in the intervention group, compared to 13% in the control group (p=0.001). Weight loss among intervention group participants averaged 9.2 pounds after one year and 7.7 pounds after two years. Participants eating less than 30% of total energy as fat was 47% for the intervention group and 26% for the control group (p=0.001). Intake of saturated fat of less than 10% of energy intake was reflected by 26% of the intervention group and 11% for the control group (p=0.001). Similar results were achieved for fiber intake. Exercise over 4 hours per week was attained by 86% of the intervention group and 71% of the control
During the first year of the 6-year study, the mean body weight decreased more in the intervention group than the control group. Significant decreases in waistline circumference, fasting plasma glucose concentration, plasma glucose concentration following 2-hour oral glucose challenge, and the serum insulin concentration following the 2-hour glucose challenge were also noted in the intervention group (see Table 2). At 2 years, weight loss over 5% remained significantly higher in the intervention group (43% of participants) than in the control group (13% of participants) (p=0.001). After an average 3.2 years at follow-up, the incidence of diabetes in the intervention group was 58% lower than in the control group. Primary prevention of type 2 diabetes utilizing lifestyle modifications was, therefore, strongly suggested in the primary health setting (Tuomilehto et al., 2001).

The Diabetes Prevention Program Research Group enrolled 3,234 men and women into the Diabetes Prevention Program [DPP] study who were at high risk for developing type 2 diabetes, as demonstrated by elevated plasma glucose concentrations, increased glucose concentrations following an oral glucose load, and BMI > 24 kg/m². Participants' mean age was 51 years; average BMI was 34 kg/m². Fifty percent of the participants were minorities (Diabetes Prevention Program Research Group, 2002). Glucose intolerance levels were nearly identical to those in the Finnish study (ADA and NIDDKD, 2002). The purpose of this study was to “compare the efficacy and safety of each of three interventions (an intensive lifestyle intervention or standard lifestyle recommendations combined with metformin or placebo) in preventing or delaying the development of diabetes” ("The Diabetes Prevention Program," 1999, p. 623).
Participants assigned to the standard lifestyle recommendations, plus metformin group (n=1073) received 850 mg of metformin twice a day. Participants assigned to the standard lifestyle recommendations, plus placebo (n=1082) received placebo twice a day. There were 1,079 participants assigned to an intensive program of lifestyle modification (Diabetes Prevention Program Research Group, 2002).

All participants met with a case manager regarding healthy lifestyle choices and to discuss goals of losing 5-10% of their baseline weight, gradually increasing their physical activity to 30 minutes each day, 5 days a week, and avoiding alcohol and tobacco products. Standard lifestyle recommendations were provided to the medication groups in written form and in an annual 20-30 minute individual session. To reduce weight and to increase physical activity, participants were encouraged to follow the Food Guide Pyramid and the equivalent of a National Cholesterol Education Program Step 1 diet (Diabetes Prevention Program Research Group, 2002). Goals for the intensive lifestyle intervention group included losing 7% of baseline body weight, maintaining 150 minutes/week of moderate activity, diet training, exercise, and behavior modification. Case managers met with participants for at least 16 sessions in the first 24 weeks and at least monthly, thereafter. Sessions included education on behavioral change strategies, such as problem solving and relapse prevention. Two supervised group exercise sessions were offered each week. Participants failing to achieve their desired goals were given the “tool box” approach, in which incentives such as aerobic exercise tapes, home exercise equipment, and membership to an exercise facility, were offered. ("The Diabetes Prevention Program," 1999). Diabetes was diagnosed according to the 1997 ADA criteria: fasting plasma glucose of ≥126 mg/dl or
≥ 200 mg/dl two hours after a 75-gram oral glucose load. Participants were monitored by oral glucose tolerance testing if indicated by semiannual fasting plasma glucose tests. Glycosylated hemoglobin (HbA1c) was performed and physical activity was self-reported and assessed annually using the Modified Activity Questionnaire (Diabetes Prevention Program Research Group, 2002).

Results from the DPP lifestyle intervention group included weight loss of approximately 12 pounds for the study duration (ADA and NIDDKD, 2002). Fifty percent had achieved the goal of 7% weight loss by the end of the first 24 weeks. Seventy-four percent maintained 150 minutes/week of exercise for the same time period. The intervention group had significantly lowered their risk for developing diabetes through diet and exercise (see Table 3) (Diabetes Program Prevention Research Group, 2002). Glycosylated hemoglobin (%) were reduced initially, then slowly increased in the lifestyle and metformin groups, while values in the placebo group steadily grew (Figure 2). With an average follow-up of 2.8 years, there was a 58% relative reduction for developing diabetes in the intensive lifestyle group vs. placebo, a 31% relative reduction in the standard lifestyle recommendations plus metformin group than in the placebo group, and a 39% relative reduction in the incidence of diabetes in the intensive lifestyle intervention group than in the metformin group (ADA & NIDDKD, 2002).

Lifestyle Modification Barriers

Modifiable risk factors for developing type 2 diabetes include obesity and physical inactivity. Obesity was named the single most important risk factor by the World Health Organization in 1985 (Eriksson et al., 2001). Cross-sectional and
prospective studies also demonstrate a close association with obesity and type 2 diabetes. "Obesity and physical inactivity are the most important potentially modifiable risk factors for type 2 diabetes" (p. 191).

Personal beliefs about the effectiveness of treatment, such as weight loss and exercise, act as important barriers in the self-management of diabetes. Glasgow, Hampson, Strycker, and Ruggiero (1997) investigated general and regimen-specific barriers to predict success in diabetes self-management. The survey sample of 2,056 participants was generally older, female, married, and Caucasian with a diagnosis of diabetes for an average of over ten years. The majority (86%) of the participants were patients with type 2 diabetes.

Personal beliefs related to specific regimens in managing diabetes were evaluated using a five-point scale where 3=fairly, 4=very, and 5=extremely effective. Participants perceived that taking diabetes medication as prescribed (4.52 ± 1.01 SE) and avoiding sweets (4.21 ± 0.08 SE) were the most effective self-management regimes. Participants believed that low-fat or low-calorie diets, exercise, and avoiding tobacco products were less effective in managing diabetes (Glasgow et al., 1997).

Implications for Research, Clinical Practice, and Theory Development

Screening to identify those individuals who are at high risk for developing diabetes needs to become easier, more cost-effective and efficient. Screening should be done in the clinical setting that promotes awareness of pre-diabetes and education to prevent its onset. By utilizing the Transtheoretical Model (TTM) of Change (Stages of Change model) clients may be more accurately evaluated as to their current stage of readiness for learning, and interventions may then be more closely matched during the
Sedlak et al. (2000) recently completed a study using three osteoporosis prevention educational programs to increase knowledge of osteoporosis, increase health beliefs, and increase behaviors aimed at decreasing the risk of developing osteoporosis. Intense intervention groups (n=31) consisted of college-aged women who expressed an interest in osteoporosis education. They met for three sessions over three weeks and were given homework assignments including recording calcium and caffeine intake and exercise activity. Intermediate group participants (n=35) consisted of community members aged 22-83 that received one three-hour educational session with no homework. Brief intervention participants (n=18) were nurses who received one 45-minute educational session and no homework. All participants were evaluated pre-and post-test.

The authors concluded that knowledge is the easiest variable to change, however, increased knowledge did not alter the participants' health beliefs, nor did knowledge increase osteoporosis preventive behaviors. "Participants in all three education programs had significantly higher levels of knowledge at posttest" (Sedlak et al., 2000, p. 400) than at pretest (intense: p<0.001; intermediate: p<0.01; brief: p<0.001). Health beliefs were only altered in the intermediate group, where participants increased their belief that calcium intake was beneficial. The impact on osteoporosis preventive behaviors was significant only for the intense program who reported drinking less caffeine (p<0.05). Utilizing the Transtheoretical Model of Change was suggested to "first assess the readiness for change and plan an intervention that best meets their needs" (p. 402). Further research needs to be directed toward
applying the TTM to people with pre-diabetes.

Behavioral counseling and the stages of change model were utilized in the Change of Heart Study (Steptoe, Kerry, Rink, & Hilton, 2001), a randomized controlled trial that assessed stages of change as related to fat consumption, physical activity and cigarette smoking. Patients were recruited if they were a regular cigarette smoker (>1 cigarette/day), had high cholesterol (6.5-9.0 mmol/L), or had a combination of high BMI (25-35 kg/m²) and low physical activity (<12 exercise-related activities of moderate or higher intensity in the previous 4 weeks lasting at least 20 minutes). Participants attended primary care centers that were randomly assigned as behavioral intervention clinics or control clinics. Nurses in the behavioral intervention groups were trained to assess the participants' readiness to change behavior, and to use attitude adjustment, goal setting, and behavioral advice to encourage behavior change. All participants with high cholesterol were counseled in dietary fat reduction and in increasing physical activity if they were sedentary. Smokers were counseled in cessation and nicotine replacement. Behavioral counseling sessions were offered three times for participants in the behavioral intervention group (n=316) with two risk factors for coronary heart disease and twice for participants with only one risk factor. Participants in the control practices (n=567) received information related to health promotion and positive lifestyle changes (Steptoe et al., 2001).

All participants were evaluated and assigned to one of the five stages of change for each behavior studied (fat consumption, cigarette smoking, and physical activity). Smoking cessation was evaluated by cotinine-verified abstinence and self-report. Dietary fat was evaluated by use of a food frequency questionnaire. Physical activity
was measured by exercising 20 minutes for three or more times per week. Participants in both groups were assessed at 4 months and again at 12 months (Steptoe et al., 2001).

Fat reduction results for the behavioral intervention patients demonstrated a substantial increase from baseline action/maintenance stage (39.4%) to 67.1% at 4 months and 68.4% at 12 months. Control group participants in the action/maintenance stage at baseline also increased their proportion from 41.5% to 59.2% at 12 months. "Among patients who were at an earlier stage at baseline, the odds (adjusted for age, sex, and general practice) of moving to the action/maintenance stage for the behavioral intervention group vs. the control group were 2.15 (95% confidence interval (CI)=1.30, 3.56) at 4 months and 1.26 (95% CI=0.73, 2.18) at 12 months" (Steptoe et al., 2001, p. 267). For patients in the behavioral intervention group and in precontemplation and contemplation stage at baseline, the results related to fat consumption were particularly effective. Physical activity change differed from fat reduction patterns. For all stages, there was a "marked increase in the proportion of patients in the behavioral intervention group in the action/maintenance stage after 4 months (21.6% increase) and 12 months (20.0% increase). A lesser increase was observed among patients in the control group" (p. 267). However, patients in the preparation stage versus the earlier stages of precontemplation/contemplation were most likely to move into action/maintenance. Cigarette smoking participants showed the least amount of movement between stages from baseline. The stage-based framework for lifestyle change was found to be very suitable for this type of study (Steptoe et al., 2001).

Peterson and Hughes (2002) utilized the Transtheoretical Model with 50 patients referred to a diabetes education center with $A_{1c} >9.0\%$. Each participant was asked to
indicate which of the following statements they agreed with the most (if any): "I am intending to make changes in my diabetes management in the next 6 months" (contemplation stage), "I am intending to make changes in my diabetes management in the next month" (preparation stage), "I have made changes in my diabetes management in the last 6 months" (action stage), or "My diabetes has been in good control for more than 6 months" (maintenance stage) (p. 267). A negative response to all four statements placed the participant in the precontemplation stage. A1c was drawn at 3 months, 12 months, and 24 months. A program designed to improve clinical outcomes in diabetes education was offered to all participants and completed in 3 months. Barriers (cons) were identified for each participant and educational support relating to these barriers was offered.

Although the study size was small and 15 participants did not receive follow-up at 24 months, participants who indicated a readiness to change (preparation or action stage) based on their responses to four simple statements, had significant improvement (average of 2.5%) (p<.001) in their A1c. "The education intervention was more effective among patients willing or eager to change their current self-management" (Peterson & Hughes, 2002, p. 270).

The Transtheoretical Model identifies the patient's position on the continuum of change, and health care practitioners can focus the office visit on helping the patient move toward the next stage. A valid set of stages of change for a specific behavior change is an essential requirement (Rakowski, 1996). Brief and simple advice is a good beginning, as the response will indicate to the provider the next step in the dialog (Zimmerman, Olsen, & Bosworth, 2000). The short-term objective of
intervention is modest, gradually moving from one stage to the next (Rakowski, 1996). Resistance is evidence the provider has moved further ahead in the change process than the patient. Maintaining a positive relationship, relating risk factors as they apply personally to the patient, and posing questions that provoke thought are examples of moving patients into the contemplative stage (Zimmerman et al., 2000).

Application of Research to Practice

A proposed algorithm based on synthesis of the aforementioned research that can be applied to clinical practice for patients at high risk for type 2 diabetes was developed (Figure 1). It should be noted that pharmacologic therapy is not officially recommended by the ADA for pre-diabetes. Based on TTM research, the approach to patients with pre-diabetes in the precontemplative or contemplative stage should not be focused on clinical outcomes initially, but on embracing the benefits (pros) and minimizing the barriers (cons) through educational encounters. Unfortunately, there is no universal approach that encourages behavior modification with meaningful results. Education alone was shown to increase knowledge, but not to change behaviors (Sedlak et al., 2000). Intensive counseling and incentives to motivate physical activity were vital to the success of the Finnish (Tuomilehto et al., 2001) study and the Diabetes Prevention Program study (Diabetes Prevention Program Research Group, 2002). Additional research is needed to determine practical, cost-effective methods to move patients through stages and assist them in maintaining a new lifestyle. Effective techniques to assist patients who would benefit from lifestyle changes need to be developed and practiced. Each patient must be viewed individually for optimal success, and health care providers can effectively match clients with appropriate health care interventions.
Summary

Evidence that type 2 diabetes can be prevented or delayed was demonstrated by the Finnish and DPP studies. Researchers need to continue to assess whether these intervention strategies will be cost-effective in preventing diabetes-related morbidity and mortality. Two randomized lifestyle intervention trials that included dietary modifications and regular exercise (30 minutes per day), and resulted in improved physiologic outcomes (reduced fasting and 2-hour post-load glucose concentration, $A_1c$, and BMI) demonstrated delayed onset of type 2 diabetes. Although the interventions were highly intensive, participants experienced dramatic risk reduction through weight loss and exercise. Assessing readiness to change for at-risk patients may be a key component to matching patient care interventions appropriately and with better outcomes. Maintaining improved outcomes over time (continued weight loss and increased activity) will continue to be the greatest challenge.
References


Diabetes Prevention Program Research Group. (2002). Reduction in the


Table 1. Risk factors for complications in adults aged ≥ 25 years with diagnosed and undiagnosed Type 2 diabetes, US National Health and Nutrition Examination Survey, 1988-1994

<table>
<thead>
<tr>
<th>Risk factors</th>
<th>Diagnosed diabetes (%)</th>
<th>Undiagnosed diabetes (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>1480</td>
<td>273</td>
</tr>
<tr>
<td>HbA1c &gt;7.0</td>
<td>55.4</td>
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<td>Body mass index ≥ 30 kg/m²</td>
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<td>56.2###</td>
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<td>Microalbuminuria</td>
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<td>Hypertension</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Previously undiagnosed, ≥ 140/90 mmHg</td>
<td>6.5</td>
<td>11.6</td>
</tr>
<tr>
<td>Previously diagnosed, ≥ 140/90 mmHg</td>
<td>32.5</td>
<td>30.5</td>
</tr>
<tr>
<td>Previously diagnosed, &lt; 140/90 mmHg</td>
<td>25.8</td>
<td>19.7</td>
</tr>
<tr>
<td>Not hypertensive</td>
<td>35.2</td>
<td>38.3</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Previously undiagnosed, LDL≥130mg/dl</td>
<td>27.6</td>
<td>32.6</td>
</tr>
<tr>
<td>Previously diagnosed, LDL≥130mg/dl</td>
<td>22.7</td>
<td>14.7</td>
</tr>
<tr>
<td>Previously diagnosed, LDL&lt;130mg/dl</td>
<td>13.0</td>
<td>9.2</td>
</tr>
<tr>
<td>Not hyperlipidemic, LDL&lt;130mg/dl</td>
<td>36.7</td>
<td>43.5###</td>
</tr>
<tr>
<td>Serum total cholesterol</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;200 mg/dl</td>
<td>33.2</td>
<td>34.2</td>
</tr>
<tr>
<td>200-239 mg/dl</td>
<td>33.8</td>
<td>38.3</td>
</tr>
<tr>
<td>≥240 mg/dl</td>
<td>33.0</td>
<td>27.5</td>
</tr>
<tr>
<td>HDL cholesterol</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;35 mg/dl</td>
<td>25.7</td>
<td>29.3</td>
</tr>
<tr>
<td>35-45 mg/dl</td>
<td>32.1</td>
<td>36.2</td>
</tr>
<tr>
<td>&gt;45 mg/dl</td>
<td>42.2</td>
<td>34.5###</td>
</tr>
<tr>
<td>Triglyceride</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;200 mg/dl</td>
<td>59.0</td>
<td>50.0</td>
</tr>
<tr>
<td>200-399 mg/dl</td>
<td>36.0</td>
<td>40.1</td>
</tr>
<tr>
<td>≥400 mg/dl</td>
<td>11.0</td>
<td>9.9</td>
</tr>
<tr>
<td>LDL cholesterol</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;100 mg/dl</td>
<td>16.7</td>
<td>23.0</td>
</tr>
<tr>
<td>100-129 mg/dl</td>
<td>32.7</td>
<td>23.7</td>
</tr>
<tr>
<td>130-159 mg/dl</td>
<td>29.2</td>
<td>34.8</td>
</tr>
<tr>
<td>≥160 mg/dl</td>
<td>21.5</td>
<td>18.5</td>
</tr>
<tr>
<td>Cigarette smoker</td>
<td>18.6</td>
<td>23.4</td>
</tr>
</tbody>
</table>

Microalbuminuria defined as urinary albumin/creatinine ratio of 30-300µg/mg. Clinical proteinuria defined as urinary albumin/creatinine ratio of >300µg/mg. Hypertension defined as blood pressure ≥ 140/90 mmHg or taking antihypertensive medication. Hyperlipidemia defined as LDL cholesterol ≥ 130 mg/dl or treated with prescribed diet or medication. LDL cholesterol data excludes subjects with triglyceride ≥ 400 mg/dl, for whom the Friedewald equation is not valid.

*p<0.01, ###p<0.05

Source: Harris & Eastman, 2000
Table 2. Changes in Selected Clinical and Metabolic Variables from Base-line to the End of Year 1 in Subjects in the Intervention and Control Groups*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Intervention Group (N=256)</th>
<th>Control Group (N=250)</th>
<th>P Value###</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>mean ± SD 95% CI</td>
<td>mean ± SD 95% CI</td>
<td></td>
</tr>
<tr>
<td>Change in waist circumference (cm)</td>
<td>-4.4 ± 5.2 -5.1 to -3.9</td>
<td>-1.3 ± 4.8 -1.9 to -0.7</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Change in plasma glucose (mg/dl)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fasting</td>
<td>-4 ± 12 -6 to -2</td>
<td>1 ± 12 0 to 2</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>2 Hr after oral glucose challenge</td>
<td>-15 ± 34 -19 to -11</td>
<td>-5 ± 40 -8 to -2</td>
<td>&lt;0.003</td>
</tr>
<tr>
<td>Change in serum insulin (μg/ml)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 Hr after oral glucose challenge</td>
<td>-29 ± 64 -37 to -21</td>
<td>-11 ± 51 -18 to -4</td>
<td>0.001</td>
</tr>
</tbody>
</table>

*A total of 15 subjects withdrew from the study within the first year; 1 additional subject did not undergo testing at one year, although she remained in the study. CI denotes confidence interval.

###P values were determined by a two-tailed t-test for the difference between the groups

Adapted from Tuomilehto et al., 2001
Table 3. Incidence of Diabetes

<table>
<thead>
<tr>
<th>Variable</th>
<th>No. of Participants (%)</th>
<th>Reduction in Incidence (95% CI)*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Lifestyle vs. vs. vs. Lifestyle</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Placebo Placebo Metformin Placebo Metformin</td>
</tr>
<tr>
<td></td>
<td></td>
<td>percent percent percent percent</td>
</tr>
<tr>
<td>Overall</td>
<td>3234 (100)</td>
<td>58 (48 to 66) 31 (17 to 43) 39 (24 to 51)</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td>48 (27 to 63) 44 (21 to 60) 8 (-36 to 37)</td>
</tr>
<tr>
<td>25-44 yr</td>
<td>1000 (30.9)</td>
<td>59 (44 to 70) 31 (10 to 46) 41 (18 to 57)</td>
</tr>
<tr>
<td>45-59 yr</td>
<td>1586 (49.0)</td>
<td>71 (51 to 83) 11 (-33 to 41) 69 (47 to 82)</td>
</tr>
<tr>
<td>≥ 60 yr</td>
<td>648 (20.0)</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>1043 (32.3)</td>
<td>65 (49 to 76) 37 (14 to 54) 46 (20 to 63)</td>
</tr>
<tr>
<td>Female</td>
<td>2191 (67.7)</td>
<td>54 (40 to 64) 28 (10 to 43) 36 (16 to 51)</td>
</tr>
<tr>
<td>Race or ethnic group</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>1768 (54.7)</td>
<td>51 (35 to 63) 24 (3 to 41) 36 (14 to 52)</td>
</tr>
<tr>
<td>African American</td>
<td>645 (19.9)</td>
<td>61 (37 to 76) 41 (16 to 63) 29 (-18 to 58)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>508 (15.7)</td>
<td>66 (41 to 80) 31 (-9 to 56) 51 (13 to 72)</td>
</tr>
<tr>
<td>American Indian</td>
<td>171 (5.3)</td>
<td>65 (7 to 87) 25 (-72 to 68) 52 (-35 to 83)</td>
</tr>
<tr>
<td>Asian</td>
<td>142 (4.4)</td>
<td>71 (24 to 89) 38 (-55 to 75) 52 (-46 to 84)</td>
</tr>
<tr>
<td>Body mass index</td>
<td></td>
<td></td>
</tr>
<tr>
<td>22 to &lt;30</td>
<td>1045 (32.3)</td>
<td>65 (46 to 77) 3 (-36 to 30) 63 (44 to 76)</td>
</tr>
<tr>
<td>30 to &lt;35</td>
<td>995 (30.8)</td>
<td>61 (40 to 75) 16 (-19 to 41) 53 (28 to 70)</td>
</tr>
<tr>
<td>≥ 35</td>
<td>1194 (36.9)</td>
<td>51 (34 to 63) 53 (36 to 65) -4 (-47 to 26)</td>
</tr>
<tr>
<td>Plasma glucose</td>
<td></td>
<td></td>
</tr>
<tr>
<td>In the fasting state</td>
<td></td>
<td></td>
</tr>
<tr>
<td>95-109 mg/dl</td>
<td>2174 (67.2)</td>
<td>55 (38 to 68) 15 (-12 to 36) 48 (27 to 63)</td>
</tr>
<tr>
<td>110-125 mg/dl</td>
<td>1060 (32.8)</td>
<td>63 (51 to 72) 48 (33 to 60) 30 (6 to 48)</td>
</tr>
<tr>
<td>Two hours after an oral load</td>
<td></td>
<td></td>
</tr>
<tr>
<td>140-153 mg/dl</td>
<td>1049 (32.4)</td>
<td>76 (58 to 86) 41 (11 to 61) 59 (27 to 77)</td>
</tr>
<tr>
<td>154-172 mg/dl</td>
<td>1103 (34.1)</td>
<td>60 (41 to 72) 38 (13 to 56) 34 (2 to 56)</td>
</tr>
<tr>
<td>173-199 mg/dl</td>
<td>1082 (33.5)</td>
<td>50 (33 to 63) 26 (3 to 43) 33 (9 to 51)</td>
</tr>
</tbody>
</table>

*CI denotes confidence interval
Adapted from the Diabetes Prevention Program Research Group, 2002
Figure 1  Algorithm for Pre-diabetes Assessment and Treatment

Screen high-risk clients for pre-diabetes by fasting plasma glucose (FPG)\(^1\)
\[ \text{If FPG} \geq 110 \text{ mg/dl and } <126 \]
Briefly describe current research directed at lifestyle modification to prevent onset of type 2 diabetes
Identify the client's stage of change and engage the client toward the next stage\(^2\)
Confirm pre-diabetes by repeat FPG on subsequent day\(^1\)

Provide brief and simple advice
Goal is for client to think about making a change (e.g. weight loss, increase activity, dietary changes)
Personalize their risk factors by reviewing their lab results and general health profile
Assess clients barriers for change
Express concern, not scare tactics\(^3\)

Discuss pros and cons of change
Discuss possible solutions to one "con"
Praise client for progress toward next stage
As client begins to make lifestyle changes, reinforce the decision, emphasizing the "pros"
Celebrate even small success
Continue to evaluate strategies for success
Recheck FPG after 3 months\(^3\)

If relapse occurs, reinforce the "pros"
Consider relapse as a lesson learned for the future, not a failure
Remind client that change is a process\(^3\)

\(^1\) ADA (2002c)
\(^3\) Zimmerman, Olsen, & Bosworth (2000).
Figure 2. Changes in body weight (Panel A) and Leisure Physical Activity (Panel B). Each data point represents the mean value for all participants examined at that time. The number of participants decreased over time because of the variable length of time that persons were in the study. Changes in weight and leisure activity over time differed significantly among the treatment groups (p<0.001 for each comparison). Glycosylated Hemoglobin Values (Panel C). The analysis included all participants, whether or not diabetes had been diagnosed. Glycosylated hemoglobin values in the three groups differed significantly from 0.5 to 3 years (p<0.001).

Adapted from Diabetes Prevention Program Research Group, 2002