OPPORTUNISTIC SCREENING FOR ASYMPTOMATIC TYPE 2 DIABETES

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ABSTRACT

RESEARCH PAPER: Opportunistic Screening for Asymptomatic Type 2 Diabetes

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Many individuals who are at risk for type 2 diabetes do not experience symptoms of diabetes, and therefore are not aware of this condition. Screening for type 2 diabetes and impaired glucose tolerance (IGT) can identify individuals at risk for type 2 diabetes, and prevent or delay complications. The purpose of this study is to evaluate a three step screening strategy for asymptomatic individuals with one or more cardiac risk factors for type 2 diabetes and provide validity for the Diabetes Risk Score. The organizing framework is criteria for opportunistic screening for Diabetes Risk factors. Lindstrom and Tuomilehto (2003) assert that screening can identify individuals for type 2 diabetes or (IGT), and as a result treatment can begin to prevent complications. A sample of 200 patients from three primary care offices in the Fort Wayne, Indiana area will be recruited over 3 months to be screened with the Diabetes Risk Score tool. Patients who are identified as at risk for type 2 diabetes will receive follow-up screening. The validation and use of the opportunistic screening tool for type 2 diabetes or IGT will allow primary health care providers to identify at risk individuals and recommend early intervention and follow-up care.
Chapter I

Introduction

Fifty-seven million Americans have pre-diabetes, a condition that will likely progress to overt type 2 diabetes unless life-style changes are made. Factors contributing to type 2 diabetes include higher prevalence of obesity, decreased mortality among aging persons, and growth in minority populations, who have a higher incidence of diabetes. Pre-diabetic screening is a good option for identifying pre-diabetics because of the high prevalence of diabetes, the morbidity associated with diabetes, and the long asymptomatic phase of the illness. Many factors contribute to potential chronic complications prior to actual diagnosis that are costly and preventable (Centers for Disease Control and Prevention, 2010).

The increase in the number of persons with diabetes results in increased health dollars spent. Specifically, $116 billion dollars total were spent in 2007 for direct care and indirect care to treat diabetes. Fifty-eight billion dollars were spent to treat diabetes related complications and $31 billion dollars spent in general medical costs over a year (American Diabetes Association, 2008). The Centers for Disease Control and Prevention, (2010) estimated that persons with diabetes have medical expenditures 2.3 times higher than undiagnosed cohorts. Over $58.3 billion was spent on hospitalizations of
diabetic related admissions and $9.9 billion was associated with physician office visits. Controlling costs for diabetes will control overall health costs.

The Centers for Disease and Prevention (2010) estimated that indirect costs of diabetes result from absenteeism and decreased productivity. In 2007 diabetes related complications accounted for 15 million absent work days and 6 million reduced productivity days. An additional 107 million lost days were due to unemployment related to diabetes disability. The total indirect cost in 2007 was $58 billion dollars (Centers for Disease and Prevention).

Other factors attributing to indirect costs are pain, suffering, and provision of care by family members, and reduced quality of life. Screening is a low-cost way to address the problems through health teaching to begin interventions to prevent complications. Early interventions will reduce costs and the economic burden of type 2 diabetes (Franciosi et al., 2005). Further study is needed to establish the benefits of a pre-diabetes screening program.

Background and Significance

Undiagnosed diabetes, or pre-diabetes, is an umbrella term for impaired fasting glucose (IFG), impaired glucose tolerance (IGT), or possibly metabolic syndrome. IFG is a fasting glucose between 100 mg/dl - 125/mg/dl. IGT is a glucose value of greater than 140 mg/dl 2 hours after a 75 gram glucose challenge. All individuals with test results over Benchmarks make up the 57 million Americans who have pre-diabetes (Centers for Disease and Prevention, 2010).

In response to the escalating numbers of diabetes incidence in 2001, the ADA revised screening recommendations for diabetes to include all people older than 45 years
of age, and recommended screening every 3 years (Simmons, Thompson, & Engelgau, 2004). In 2004, the American Diabetes Association recommended general screening in asymptomatic persons when at least seven criteria were met. The criteria were: (Missouri Department of Health and Senior Services, 2006, p. 1):

1. The disease impacts health and imposes a significant burden on the population.
2. The natural progression and history of the disease is understood.
3. There is a pre-clinical stage in which the disease can be diagnosed.
4. Tests are available for diagnosis and are accepted as reliable.
5. Treatment yields early benefits as opposed to delayed treatment.
6. The costs are relative to diagnosis, treatment, and available resources in relation to total health expenditures.
7. Screening will be systematic and not an isolated event.

In 2005 the Center for Disease Control and Prevention, the National Institute of Health and the American Diabetes Association (ADA) estimated that 40% of Americans between the ages of 40-74 have pre-diabetes. Pre-diabetes puts this population at risk for macrovascular and microvascular complications. The ADA developed enhanced screening strategies adopted by many state authorities. Under a consensus panel, experts recommended that screening for pre-diabetes be aimed at detecting persons exhibiting a high risk for diabetes (Missouri Department of Health And Senior Services, 2006).

Screening criteria were age, being overweight or a BMI > 25kg/m2. In addition two of the following risk factors were included: a family history (1st or 2nd degree), race ethnicity, signs of insulin resistance including acanthosis nigricans, hypertension, dyslipidemia or polycystic ovary disease. Additional risk factors include: physical
inactivity, delivered a baby weighing > 9 pounds or have been diagnosed with gestational diabetes or a history of vascular disease (Missouri Department of Health and Senior Services).

The consensus panel recommended further testing for initial abnormal laboratory values of individuals who were screened. Lifestyle interventions and possible medicinal therapy were recommended for evidence of pre-diabetes, diabetes, and impaired glucose tolerance. The Consensus panel concluded that to effectively utilize resources, efforts for screening pre-diabetes and diabetes in a medicinal setting should be focused on at risk individuals rather than the population at large (Missouri Department of Health and Senior Services, 2006).

The Current recommendation regarding the screening for pre-diabetes and diabetes by the American Diabetes Association and the National Institute of Health (Islets of Hope, 2009) is to screen individuals older than the age of 45. Other risk factors should be considered and addressed in individuals less than 45 years of age (Islets of Hope).

There are different strategies used to diagnose pre-diabetes. The fasting plasma glucose is the first typical “screen” for diabetes. While fasting glucose is very specific for hyperglycemia, it is not as sensitive for pre-diabetes (Danish & West, 2005). An additional test is the oral glucose tolerance test (OGTT) that is more specific for pre-diabetes. It has been proposed to use the HbA1C test for screening of pre-diabetes. This approach has not been standardized.

Opportunistic screening of high risk individuals has gained attention in the past several years given the physiological understanding of the natural progression of diabetes. Danish and West (2005) identified three specific physiological sequences in the
development of pre-diabetes leading to overt diabetes. Initially there is the onset of insulin resistance, or impaired insulin sensitivity that leads to decreased production of insulin. Impaired resistance can be diagnosed by impaired glucose tolerance testing. Eventually further declination of the B-cell insulin secretion results in overt diabetes. Danish and West argued that at a minimum, persons at high risk for diabetes should be given a risk assessment, random screening, by having patient’ perform self-blood glucose monitoring at home. A strong educational program should be implemented regarding signs and symptoms of diabetes and life-style modification if necessary.

Despite all recommendations from authorities, diabetes screening remains controversial among health care providers. Consensus has yet to be achieved regarding the criteria as to when, how, and at what level hyperglycemia screening should be addressed. General views of practitioners regarding the screening of asymptomatic individuals for the diagnosis of diabetes, or IGT, is not well studied. Conflicts remain despite recommendations from the American Diabetes Association and the National Institute of Health (Whitford, Lamont & Crosland, 2003).

In January (2009) the Mayo Clinic recommended that only individuals should be screened for diabetes if they present with a blood pressure higher than 135/80 Hg. Other recommendations made by authors Aldasouqi, Gossain, Sheehy, and Coursin (2009) reported that the debate regarding screening is ironic because diabetes is reaching epidemic proportions. Furthermore, the US Preventative Services Task Force (USPSTF) recently reported that the risk of “macrovascular complications is incrementally increased with each additional component of metabolic syndrome” (Aldasouqi et al., 2009, p. 384).
Opportunistic screening is cost-effective and under utilized. Identification of individuals who are undiagnosed for diabetes or pre-diabetes is more effective than population screenings. Screening typically works best in generalist practices. Opportunistic screening, based on the Diabetes Risk Score, could prove to be a simple, efficient, valid and inexpensive identification of unknown persons with asymptomatic diabetes, especially in general practices. Identification of at risk individuals could be of particular importance because chronic complications are often diagnosed coincidently with the diagnosis of type 2 diabetes. Using The Diabetes Risk Score to identify patients quickly and efficiently would provide a way for health care providers to identify individuals at risk for diabetes. Franciosi et al. (2005) have validated the Diabetes Risk Score tool. This study builds on the works of Franciosi et al. (2005).

Problem Statement

Individuals who are undiagnosed for pre-diabetes or diabetes are at significant risk for cardiovascular events, often occurring subsequent to the diagnosis of IGT, or type 2 diabetes. IGT is a pre-cursor to type 2 diabetes and has serious consequences related to mortality, morbidity and overall quality of life (Franciosi et al., 2005). Identification of individuals screened by the Diabetes Risk Score could potentiate interventions. This study is a replication of the original Franciosi et al.’s. (2005) study that investigated the use of the Diabetes Risk Score as a screening tool.

Purpose Statement

The purpose of this study is to evaluate the three step evaluation screening process using the Diabetes Risk Score Tool as an opportunistic screening process for persons with pre-diabetes in a primary care setting.
Research Questions

1. Is the three step opportunistic screening strategy effective in identification of pre-diabetes?

2. Is the Diabetes Risk Score a valid tool for identification of pre-diabetes and diabetes?

Conceptual Framework

The framework for this study is opportunistic screening (Lindstrom & Tuomilehto, 2003). Opportunistic screening is a screening strategy used to identify undiagnosed persons who visit a health care clinic for a scheduled visit for pre-diabetes. Opportunistic screening identifies individuals at risk during an outpatient visit (Lindstrom & Tuomilehto). A primary objective for utilization of this framework is to estimate the prevalence and severity of unrecognized pre-diabetes in an outpatient setting.

Definition of Terms

Diabetes Risk Score.

Conceptual: The Diabetes Risk Score (DRS) is based on the concept of opportunistic screening. It is built upon well known risk factors associated with common signs and symptoms associated with diabetes (Franciosi et al., 2005).

Operational: The DRS is a self-administered questionnaire eliciting information such as age, body mass index, and waist circumference, use of blood pressure medication or history of use of blood pressure medication, history of elevated glucose, physical activity and consumption of vegetables, fruits or berries is questioned (Franciosi et al., 2005).
**Three Step Opportunistic Screening Strategy.**

*Conceptual:* The DRS is the initial opportunistic screening strategy used to detect persons with undiagnosed IGT or type 2 diabetes. Following, a FPG and then a 2-hour OGTT will be done to patients.

*Operational:* A person who scores a 9 or higher out of a possible 20 will receive a FBG. A level of 100 mg/dl to 124 mg/dl will indicate IFG, a result greater than 125 mg/dl detects diabetes. A need to perform a 2-hour OGTT is the third step process. A result between 140 mg/dl and 200 mg/dl indicates IGT, a result greater than 200 mg/dl detects diabetes.

**Screening Techniques.**

*Conceptual:* Body mass index (BMI) is a number calculated from a person's height and weight. This index is useful for indicating potential health problems in the present but also in the future (Franciosi et al., 2005).

*Operational:* A BMI > 24kg/m2 was considered overweight (Franciosi et al., 2005).

*Operational:* Waist circumference is measurement at the level midway between the lowest rib and the iliac crest to the nearest 5 mm (Franciosi et al., 2005).

*Operational:* Impaired fasting glucose is a fasting glucose level between the ranges of 100mg/dl and 125 mg/dl (Franciosi et al., 2005).

*Operational:* Impaired glucose tolerance is a 2 hour post glucose challenge range of between 140mg/dl and 200 mg/dl (Franciosi et al., 2005).

*Operational:* Oral glucose tolerance (OGTT) is a fasting glucose level followed by a 75 gram carbohydrate load and a 1 hour and then 2 hour glucose level. Results
greater than 200mg/dl at one hour and greater than 140 mg/dl at two are indicative of diabetes on two separate occasions (Franciosi et al., 2005).

*Operational:* Physical activity of 30 minutes of activity 3-5 days a week (Franciosi et al., 2005).

*Limitations*

Limitations of this study include the size of the sample and location of the study.

*Assumptions*

1. The sample chosen will represent persons at risk for type 2 diabetes and impaired glucose tolerance.
2. The DRS is a valid tool for identification of individuals at risk for type 2 diabetes and impaired glucose tolerance.
3. The DRS is a predictive tool for screening individuals at risk for type 2 diabetes and impaired glucose tolerance when a fasting glucose or an oral glucose tolerance test is not readily available.

*Summary*

Identification of persons with diabetes, or persons at risk for diabetes, not only influences health care costs, but reduces the burden of the diagnosis of diabetes after chronic complications have erupted. Diabetes leads to microvascular and macrovascular changes and impedes homeostasis within the body. Early identification, treatment and evaluation begin with assessment and utilization of screening for at risk individuals. The use of the DRS can simplify the screening process and be used indiscriminately in the primary care setting. The purpose of this study is to evaluate a three step screening
program using the DRS tool with persons at risk for the development of type 2 diabetes, and to validate the DRS tool.
Chapter II

Review of Literature

Introduction

It was estimated that one out of every three persons born in the year 2000 would develop diabetes (National Center for Chronic Disease Prevention and Health Promotion, 2008). In the next 50 years, it has been estimated that diabetes will increase by 198% (National Center for Chronic Disease Prevention and Health Promotion) leading to an insidious effect on population health and economics of healthcare. Early Identification of individuals could minimize the physical, emotional, and financial impact of diabetes. The purpose of this study is to examine whether a three step screening process using the Diabetes Risk Score (DRS) can identify persons with impaired glucose tolerance and diabetes during prescheduled outpatient visits, and provide validity for the DRS.

Organization of the Literature

The four following categories will be explored through review of selected research and literature studies: the framework, the prevalence and severity of diabetes screening, practitioner’s views of screenings, screening methods available for diagnosing diabetes and tools available to screen for diabetes.
**Organizing Framework**

The organizing framework for this study is opportunistic screening. Lindstrom and Tuomilehto (2003) noted there is a lack of consistency in identifying individuals with impaired glucose tolerance (IGT) and type 2 diabetes. The purpose of the Diabetes Risk Score (DRS) tool is to identify pre-diabetes based on questions modeled from risk factors recommended by the American Diabetes Association. A score is provided for each question in that the patient answers. Categorical variables are: age, body mass index, waist circumference, history of antihypertensive medicine, high blood glucose, physical activity, daily consumption of fruits, berries or vegetables.

The DRS is a unique model or tool to utilize and identify persons with diabetes or IGT. It was concluded that the risk factors were practical and that “true primary prevention would be to identify high-risk subjects when they are still in a normoglycemic state and to treat them by interventions that prevent their transition from normoglycemia to impaired glucose tolerance and to overt diabetes” (Lindstrom & Tuomilehto, 2003).

**Prevalence and Severity of Diabetes Screening**

Screening for diabetes traditionally has been done during either by population based screenings, or during opportunistic screenings. Opportunistic screenings offer the advantage of being seen in a medical office, or in an outpatient setting for diagnosis, and appropriate follow-up care. However, the yield from opportunistic screenings may be skewed as a result of other diagnostic labs, including a glucose level, which may exhibit
post-prandial glucose excursions. Undiagnosed diabetes, when diagnosed in a population based setting is often prevalent and severe. Edelman et al. (2002) examined the prevalence and severity of undiagnosed diabetes in an opportunistic outpatient setting.

The authors utilized the hemoglobin A1c (HbA1c), along with the use of a fasting plasma glucose, and examined contributing factors to diabetes including presence of hypertension, obesity (>120% of ideal body weight) and self-reported history of a parent or a sibling with diabetes (Edelman et al., 2002). A total of 1,253 persons were enrolled in the study. Edelman et al. considered a HbA1c of greater than 7.0%, and a fasting glucose of greater than 126mg/dl to be an indication of diabetes and a diagnostic for diabetes, respectively. Traditionally, an A1C is not considered diagnostic; however, the sensitivity, along with a fasting glucose can be reliable 75% to 93% of the time.

Of the 1,253 persons, 258 (21%) had an elevated A1C greater than 6.0%. Of 258 persons, 32 had an elevated A1C greater than 7.0%, and a fasting glucose level greater than 126 mg/dl. Two patients had an elevated A1C yet remained under the 126 mg/dl diagnostic criteria. Of the 1,253 participants, 4.5% had unrecognized diabetes. Of the 7% of identified individuals, 25 persons had an elevated blood pressure, 18 persons had an elevated LDL and 41 persons were obese. The findings correlated with the co-incidence of hypertension, elevated LDL and obesity as three associated risk factors for type 2 diabetes (Edelman et al., 2002).

Edelman et al. (2002) concluded that screenings are useful in identifying individuals for prevalence, for risk stratification, as well as severity at the time of
diagnosis in opportunistic screenings in medical outpatient environments. The authors conceded that longitudinal studies are necessary to confirm the effectiveness of screening strategies.

**Practitioner’s Views of Screening**

Screening is the responsibility of primary care providers. Practitioners’ attitudes regarding screening for type 2 diabetes have yet to demonstrate effectiveness in outcome studies. As more and more diabetic patients are diagnosed, estimates predict that by 2010, the United Kingdom will have just under 3 million new cases of diabetes (Wylie, Hungin, & Neely, 2002). Attitudes regarding lack of resources, lack of time and pessimism may influence practices when dealing with the presence of impaired glucose tolerance.

Impaired glucose tolerance is demonstrated by hyperglycemia, and insulin resistance, and is considered a stage in the development of type 2 diabetes. Half of all individuals with impaired glucose tolerance will develop diabetes within 10 years. Individuals with impaired glucose tolerance often present to the primary practitioner with cardiovascular problems, complicating the course of treatment. Wylie et al. (2002) proposed that some practitioners believe that impaired glucose tolerance is a social problem related to life-style. The purpose of this study was to evaluate general practitioners attitudes and awareness of the clinical significance of impaired glucose tolerance testing.

The sample originally consisted of 56 participants. Twenty-six practitioners (18 men, 8 women) participated in four focus groups. The mean age was 44, with a range of
30-58 years of age. The average years involved with diabetes care was 11 years, with a range of 1-27 years. Eight participants (six men and two women) were purposively selected for semi-structured interviews. The mean age was 41, with a range of 31-46 years of age. The years of experience on average were 12 years, with a range of 4-24 years. Of the 56 participants 30 declined to be involved in the study. Demographic characteristics of the “drop-outs” were similar to the sample population (Wylie et al., 2002).

A questionnaire was designed to evaluate clinicians’ knowledge of impaired glucose tolerance. A lead investigator carried out the interviews in the focus groups. The lead investigator gave a short presentation regarding the prevalence of impaired glucose tolerance, rise in prevalence, and the clinical significance and management of impaired glucose tolerance. Further discussion centered on attitudes regarding impaired glucose tolerance and the knowledge presented by the lead investigator. A similar approach was used in the semi-structured interview process. The questionnaire was administered verbally. Open-ended questions addressed knowledge of impaired glucose tolerance. A short presentation followed with additional open-ended questions related to the clinician’s attitudes regarding IGT (Wylie et al., 2002).

A qualitative approach based on grounded theory was used to analyze data. Categories and themes were identified. An iterative approach was used to analyze data, beginning with the initial focus group to allow emerging categories and themes to be identified until saturation occurred. To increase the validity of the findings, the researchers shared all outcomes of the study with participants. Twenty-eight of the 34
strongly agreed (10 respondents) or agreed (18 respondents) with the findings (Wylie et al., 2002).

Results from the questionnaires revealed that all participants were aware of impaired glucose tolerance; however 16 were unaware of the risks of impaired glucose tolerance. Twenty-one were unaware of the cardiovascular component, and 17 had no idea how many impaired glucose tolerance patients were seen in practice. Results from the focus groups and interviews demonstrated three themes prior to the presentation and eight themes after the presentation. The three themes prior to the presentation were: “low awareness of the significance and prevalence of impaired glucose tolerance,” “uncertainty of the management of impaired glucose tolerance,” and “the needed support for guidelines for managing impaired glucose tolerance patients” (Wylie et al., 2002, p. 1192).

The eight themes following the presentation were (Wylie et al., 2002, p. 1192):

1. Overwhelming workload related to impaired glucose tolerance (IGT).

2. Screening and management of impaired glucose tolerance were impossible without additional resources.

3. Diversion of clinical staff away from other clinical areas.


5. Positive attitudes about pharmacological interventions.

6. Uncertainty of role in screening and management of IGT.
7. Concerns related to IGT are a social problem, not a medical problem.

8. Health educational model important in interventions.

Wylie et al. (2002) concluded that general practitioners were aware of IGT, yet were unaware of the significance and prevalence of IGT. General practitioners were uncertain of the management of IGT patient’s and requested guidelines for IGT. The findings demonstrated a need for education and training for general practitioners (Wylie et al.). The authors concluded that practitioners were not aware of the clinical significance of the prevalence of neither IGT nor the guidelines.

Whitford, Lamont, and Crosland (2003) believed that reluctance of practitioners to screen asymptomatic individuals for impaired glucose tolerance, or type 2 diabetes, may be due to a lack of knowledge, skills, time and finances. Whitford et al. noted that a general consensus among practitioners was that diabetes screening produces no reimbursement. If an incentive was available more practitioners would perform screenings. However, screening for diabetes creates more work (Whitford et al.). The authors conducted a research study examining potential barriers related to screening for diabetes. The purpose of this grounded theory and study was to evaluate views held by general practitioners and practicing nurses towards screening for type 2 diabetes.

The authors used purposive sampling to select the participants, both experienced and inexperienced in the care of diabetes. As the study evolved, differing views evolved. In all, 10 GP’s and 9 nurses from eight different practices, all of whom lived in North-East England, made up the sample (Whitford et al., 2003). The informants were
interviewed by the researchers using a semi-structured process. Each interview lasted approximately 30-40 minutes. Areas of inquiry included questions examining the benefits of screening for diabetes, the impact of screening to primary care providers, barriers to screening and consequences for patients with a potential diagnosis. The interview process ended when no further themes emerged (Whitford et al., 2003).

An iterative approach was used for data analysis. Questions were of open format; emerging themes became apparent for subsequent interviews. To assess reliability, seven participants with divergent views met to discuss the results of the study. The authors used audiotapes, and further analysis of the audiotapes to validate the findings (Whitford et al., 2003).

Whitford et al. (2003) found five recurring themes. The first identified perceptions regarding “scientific vigor versus faith in screening.” Practitioners who were knowledgeable regarding diabetes were most skeptical towards screening. It was believed that intensive treatment can decrease complications. However, it is unknown if screening for diabetes would decrease complications. Opposing views were that knowledge would benefit patients as early diagnosis leads to early treatment and fewer complications.

The second theme was “screening and the patients.” Practitioners who supported screening believed that patients would want to know about health status. Practitioners who did not support screening thought that screening would lead to anxiety in patients. It was noted among all practitioners that there was little concern regarding the patient’s understanding of the implications of screening. The third theme was “effectiveness of
lifestyle intervention.” All practitioners believed that modifiable factors can improve the outcome of diabetes, yet, did not believe that patient’s would make lifestyle changes (Whitford et al., 2003).

“Lack of resources” was the fourth theme that emerged. Knowledge, skills, time, and costs were concerns for the practitioners. Time was a barrier not related to the screening, but the ongoing management of possible diagnoses. A lack of resources was the last theme, “attitudinal barriers.” Barriers such as ageism, poly-pharmacy and reluctance to screen in deprived areas were noted. There was clear evidence of avoidance of screening, due to the likelihood that attendance would be favorable in areas where it was least needed (Whitford et al., 2003).

The conclusion was that increasing financial resources would promote screening for diabetes. Whitford et al. (2003) confirmed that practitioners believed that screening for type 2 diabetes is worthwhile. Yet, the views were not related to the premise that screening was effective. The authors proposed that additional research should be done to establish evidence-based practice regarding the effectiveness of screening and the management of diabetes.

*Screening Methods for Diabetes*

The Diabetes Prevention Program Group (DPP, 2005) has worked with physicians and others to promote diabetic screening. This study was a large, multi-centered clinical trial evaluating the effectiveness of diagnosing impaired fasting glucose or impaired glucose tolerance, along with interventions which prevent or delay the onset of overt type
2 diabetes. The goal of the screening process was to identify people at high risk for the development of type 2 diabetes so that the individual could be enrolled in a primary prevention study. The purpose of the primary prevention study was to evaluate the effectiveness of identification through screening and the effectiveness of four interventions among the participants (DPP, 2005).

The clinical trial that began in 1996 involved 27 clinical centers in the United States. There were three steps in finding participants. The initial goal of sampling was to identify adults at risk for type 2 diabetes who would adhere to the trial, and had no contraindications to the trial. Initial contact was made by a telephone call to assess age, medical history, and medication use (DPP, 2005).

Glucose measurements were evaluated based on capillary blood values and the American Diabetes Association standards for diagnosis. Identification of elevated fasting plasma glucoses promoted additional screening using an OGTT. Delineation of participants was based on low risk, high risk, or diagnosis of diabetes. Following risk stratification, additional screening was done based on gender, age, body mass index (BMI), family history and ethnicity (DPP, 2005).

The risk stratification characteristics which produced the most yields in identifying at risk individuals were age, BMI, and step 1 glucose (FPG). A total number of 3,819 (24%) participants out of 158,183 were identified as high risk for developing type 2 diabetes and were included in the clinical trial. Results were that 40.8% of eligible subjects for the primary prevention study were diagnosed with IGT and IPG.
An important strength of the study was the screening process and assessment of characteristics of age, BMI and step 1 glucose. The strength was due to the scope of the study, the large sample, ethnic diversity, and a standardized screening process. The researchers concluded that a desirable goal for public health policy is the use of efficient screening strategies because early treatment of clinically diagnosed type 2 diabetes has been shown to reduce complications associated with overt diabetes (DPP, 2005).

Opportunistic screening is recommended by the American Diabetes Association (ADA) for impaired glucose tolerance (IGT) and type 2 diabetes. Yet, screening remains controversial. The ADA defined IGT as a 2 hour postprandial blood glucose level of 140-199 mg/dl or impaired fasting glucose of (IFG) as 100-125 mg/dl. The World Health Organization (WHO) defined diabetes as a fasting glucose >126 mg/dl. However, if the range is questionable, OGTT is recommended for diagnosis. Postprandial levels are the same for ADA and WHO. Zhang, Engelgau, Valdz, Caldwell, Benjamin and Narayan (2005) acknowledged variations in standards and sought to determine efficient cut off points for undiagnosed diabetes and pre-diabetes and undiagnosed diabetes.

The sample consisted of individuals 45-74 years of age who had visited a primary care physician at least once in the past year claiming no symptoms or diagnosis of diabetes. The number of participants was not provided (Zhang et al., 2005). Eight cut off values were established regarding the screening of undiagnosed diabetes and pre-diabetes with undiagnosed diabetes. FBG’s, A1C levels and random capillary blood glucoses (RCBG) were drawn on sample patients (Zhang et al., 2005).
Analysis of cut off values for undiagnosed diabetes revealed that 110 mg/dl was the most efficient for FBG, 5.7% was the most efficient for A1C levels, and 120 mg/dl was the most efficient for RCBG. Analysis of cut off values for pre-diabetes and undiagnosed diabetes revealed 100 mg/dl, 5.0%, and 100 mg/dl, respectively (Zhang et al., 2005).

Zhang et al. (2005) concluded that the use of three separate screening tests depends on the goal of the screening. The cut off values for screening pre-diabetes and undiagnosed diabetes should be lower than cut off values for the diagnosis of unknown diabetes. Using the desired cut off values, it is unknown if the same values would demonstrate the same results in long term benefits. The authors (2005) concluded that as physicians and health care providers are from different regional areas, differing views regarding implementing screening tools and at what cut off value to implement will continue to occur.

Johnson, Tabaei, and Herman (2005) recognized that there was debate as to how often screenings should be administered. The authors examined alternative strategies for systematic screening for type 2 diabetes. The American Diabetes Association recommends screening in asymptomatic persons for diabetes if older than 45 years of age. Fasting plasma glucoses have been the standard for screening and diagnosing for diabetes, yet random plasma glucoses has recently gained attention. Johnson et al. (2005) cited that 95% of individuals are screened using a random plasma glucose. Yet debate continues as to what cut-off score is defined as an abnormal value indicative of type 2 diabetes. In this study, the authors aimed to evaluate a screening strategy that provides
adequate yield. The focus was on the method of screening, and the frequency of screening which would protect against false-negatives and false positives at a reasonable cost.

The simulated study sample consisted of a closed cohort of United States (U.S.) citizens 45-74 years of age, with no history of diabetes. In 2000, the U.S. census claimed that 80.3 billion people were in the 45-74 age range. Of these, 7.7 million had diabetes. There were 72.6 million eligible participants for the screening. Exact number of persons screened was not known. Four systematic approaches and strategies were examined based on American Diabetes Standards:

1. Random plasma glucose (RPG) with a cut off point of 100 mg/dl

2. RPG with a cut off point of 160 mg/dl

3. RPG with a cut off point of 130 mg/dl

4. Screening with a multivariate equation including age, sex, BMI, RPG and postprandial glucoses (Johnson et al., 2005, p. 309).

Evaluating the sensitivity and the specificity of the screening strategies was done to provide validity for the findings. Risk factors for diabetes were included.

The strategies were assessed at three different screening intervals over a 15 year time frame. The timed intervals were as follows: baseline and every 5 years, baseline and every 3 years, and baseline and every year. Each strategy was examined for efficacy by calculating the number of false-negatives, true-positives and false-positives at each
screening throughout the 15 year study. By doing so the sample became smaller because diagnosed patients were removed from the sample (Johnson et al., 2005).

Results of the study demonstrated that although both the multivariate equation and the RPG > 130 mg/dl had the same sensitivity, the multivariate equation had more specificity regarding diagnoses of true positives. Timed intervals were evaluated and the conclusion was that the complications resulting from type 2 diabetes were unknown because duration and onset were unknown. In type 1 diabetes, proliferative retinopathy developed 3-5 years after onset, and nephropathy developed 6-10 years after onset. Therefore, the authors reported that screening every 3 years was found to be optimal to avoid complications that may develop while undiagnosed. However, findings from the data for screening for undiagnosed type 2 diabetes were that the multivariate equation and the RPG > 130 mg/dl provided the highest true positives (18.1%) and the least false positives (14.3%) (Johnson et al., 2005).

The authors concluded that screening strategies that utilize both sensitivity and specificity, such as the results of the use of a multivariate equation and random plasma glucose cut off of 130 mg/dl, provided adequate yield and minimized false positives. A 3 year interval was found to be ideal because it minimizes potential false positives, yet is frequent enough to avoid potential chronic complications related to undiagnosed diabetes. The authors also concluded that opportunistic screening is superior to population screening through the use of risk factors and early treatment has been shown to delay and prevent chronic complications (Johnson et al., 2005).
The Diabetes Detection Initiative (Lanza, Albright, Zucker, & Martin, 2007) is a screening tactic used to identify adults who have undiagnosed type 2 diabetes. The researchers hypothesized that screening, based on population only, was too broad and nonspecific. Opportunistic screening was too routine and random. Selective screening was based on identifying risk factors where populations were at a higher risk for developing type 2 diabetes. The researchers chose selective screening initiatives that targeted high risk ethnicity groups, including African Americans, Hispanics, American Indians, Asians, and Pacific Islanders to screen reasoning that the populations were 1.4 times at greater risk for type 2 diabetes than white cohorts.

Participants (n= 364,000) were seen at 42 pilot community clinics that provided sliding scale fee services to persons who were uninsured or within a recognized primary care giver's office with third party reimbursement payers. The 42 pilot clinics were chosen based on epidemiology of the geographical region identifying a high risk of individuals within the chosen communities and a health infrastructure large enough to implement the screening, the follow-up and continuity of care (Lanza et al., 2007).

A distinguishing characteristic of this initiative was the use of social and commercial marketing to influence voluntary behavior so as to improve personal and societal welfare. The researchers utilized geo-demographical segmentation, media channels and promotions. Geo-graphical segmentation was utilized after site selection, and had been used as a marketing tool for communities prior to review. Unique characteristics of a community, promotion of healthy interventions, and understanding community behavior were distinctive characteristics of site-selection. Media channels
and promotional efforts included: local media, community fairs, outreach workers, local businesses, pharmacies, community and senior centers as well as retail outlets. Over 574,000 instruments, which were adapted from the American Diabetes Association risk test, were distributed (Lanza et al., 2007).

The design was both quantitative and qualitative. Quantitative aspects of the study addressed the question: “Did the DDI improve the ability to detect cases of diabetes?” (Lanza et al., 2007, p. 634). Qualitative data was evaluated following discussion groups moderated by trained facilitators. Facilities addressed the group’s understanding of, reaction to, and validation of the findings of the study. Qualitative findings were described. Community members perceived the diagnosis of diabetes as a slow death spiral combined with poor access to health care or disenfranchisement with health care in general. Continuity of care and personal relationships with providers were also a common thread in qualitative results.

Using social marketing between January of 2003 to February of 2004, the risk score tool diagnoses were up to 34.5 cases a month from the baseline of 23 cases per month. A total of 364,000 adults were provided the opportunity to participate in the DDI. Persons who scored a 10 or higher on the risk score were instructed to follow-up with a physician. Individuals who were not recommended to follow up with a physician were lost and not equated into the final results (Lanza et al., 2007).

Lanza et al. (2007) concluded that using marketing to increase community awareness along with risk score stratification is a useful technique for diagnosing
diabetes. However, more research is necessary to explore why so many cases of diabetes remains undiagnosed. Additional research would validate how cost implications before and after screening allow for early intervention. Further research is necessary to address adequate access to healthcare providers, consistent follow-up appointments and the establishment of relationships among persons with diabetes and healthcare providers.

Many physicians regard a glucose level of greater than 200 mg/dl with symptoms of hyperglycemia as informative results. Ziemer et al. (2008) questioned whether a lower random glucose level could be used as an opportunistic screening, to identify not only diabetes patients, but also persons at risk for diabetes. An alternative screening tool was assessed by Ziemer et al. (2008). This screening strategy incorporated the screening tool into routine care, which limits the need for fasting plasma gluceses. The goal of the study was to evaluate whether a random glucose level could detect undiagnosed IGT or type 2 diabetes. Primary care physicians (70%) performed some measurement of glucose over a 3 year period with 95% with a random glucose.

The study took place in Atlanta at Emory University Hospital and Grady Memorial Hospital between January of 2005 and December of 2006. Patients (n=989), between 18-75 years took part in the screening for impaired glucose tolerance. Participants did not include individuals with a prior diagnosis of diabetes or pregnant/nursing women. The participants did include individuals not taking glucocorticoids, and with no recent illness. Trained staff performed a random glucose level on subjects during the first visit. A second visit was scheduled within 3 weeks to do a fasting 75 gram oral glucose challenge
prior to 11 am. Participants had an average age of 48 years. Fifty percent were black and 66% were women (Ziemer et al., 2008).

The average random plasma glucose was 99 mg/dl. Persons with normal plasma glucose were younger and less overweight, with an average glucose level of 93 mg/dl. Persons with abnormal glucose tolerance levels were older and heavier, with fewer incidences of race or gender variants. Persons with only impaired glucose tolerance were more likely to be women. Findings indicated that 619 participants had a normal glucose level, 162 impaired fasting glucose, 78 impaired glucose tolerance, 1 impaired fasting glucose, 81 impaired glucose tolerance, and 50 had diabetes (Ziemer et al., 2008). The authors concluded that as more programs are developed, plasma glucose values drawn randomly with a result greater than 125 mg/dl with appropriate follow-up by a glucose tolerance test might identify many people previously undiagnosed.

Tools to Screen for Diabetes

Lindstrom and Tuomilehto (2003) reported that despite ongoing debates, there was mounting evidence that health care providers should identify patients prior to the existence of altered glucose metabolism. Patients should be screened so that life-style modifications can be implemented to overt implications resulting from hyperglycemia. Lindstrom and Tuomilehto (2003) researched a proposed simple, effective model to identify the risk of altered glucose metabolism. The authors hoped to validate the model the Diabetes Risk Score (DRS).
The sample included 6.6% of the population from North Karelia, Kuopio, South-Western Finland, and the Helsinki-Vantaa region. The age range was 25-64 years old. The participants were stratified to have at least 250 participants of each gender grouped in a 10-year age group. This was done in the original 1987 survey. The participation rate in 1987 was 82% and 765 in 1992 (Lindstrom & Tuomilehto, 2003).

Subjects were mailed questionnaires, and were clinically examined. Age, BMI, waist circumference, history of hypertension and hyperglycemia, physical activity, and daily consumption of fruits, berries and vegetables were recorded. To identify prevalent diabetes in the 1987 study, 4,746 subjects were asked to fast for blood glucose levels and a 75 gram glucose test was administered. In the follow-up study (1992), 4,615 participants between 45-64 years of age were asked to do the same (Lindstrom & Tuomilehto).

The questionnaire assessed the use of blood pressure medication, history of high blood pressure, assessment of physical activity, and daily consumption of vegetables, fruits and berries. Use of blood pressure medication was chosen as an unequivocal marker for hypertension. Evident markers for possible diagnosis of pre-diabetes and diabetes included the physical assessment of age, BMI, waist circumference and the use of antihypertensive drug therapy (Lindstrom & Tuomilehto, 2003).

Logistic regression was used to predict findings. Findings from the 1987 survey resulted in 196 incidents of diabetes. In the 1992 study, 182 incidents of diabetes were recorded. The DRS score was 0-20. A score of > 9 indicated probable risk of diabetes.
The score of 9 had a sensitivity of 0.78% in 1987, 0.81% in 1992, a specificity of 0.77% in 1987, 0.76% in 1992 with a positive predictor value of 0.13 in 1987, and 0.05 in 1992 (Lindstrom & Tuomilehto, 2003).

To assess validity, the authors analyzed the DRS cross-sectionally by identifying subjects who exceeded thresholds for fasting glucose and for postprandial levels. The ROC curves demonstrated the DRS as a valid tool. Lindstrom and Tuomilehto (2003) concluded that the DRS is a valid, sensitive, and specific tool for screening for potential hyperglycemia. Individuals who score high will benefit from modifiable factors regarding potential health outcome. The model has been adopted in Finland nationwide for prevention of type 2 diabetes (Lindstrom & Tuomilehto).

Experimental evidence has shown to decrease the incidence of type 2 diabetes by screening for impaired glucose tolerance. Franciosi et al. (2005) conducted research to validate the Diabetes Risk Score is needed. The purpose of this study was to evaluate the Diabetes Risk Score as a valid screening tool to identify potential people with impaired glucose tolerance or type 2 diabetes. Another purpose was to test the effectiveness of a three-step process to screen undiagnosed people with impaired glucose tolerance and type 2 diabetes.

The sample (n=1,840) consisted of men and women between the ages of 55-75 years. Patients did not have a history of cardiovascular events, yet did exhibit one or more cardiovascular risk factors. All patients gave written consent prior to the study, and a local ethics committee approved the protocol. First, the Diabetes Risk Score was used
as an initial screening tool, followed by a fasting blood glucose and then the
administration of the oral glucose tolerance test in selected groups (Franciosi et al.,
2005).

Patients entering the primary care physician’s office were invited to fill out the
DRS questionnaire. Patients were then referred to an outpatient diabetes clinic for an
OGTT, with FBG and 2 hour postprandial glucose following 75 grams of glucose. All
samples were centrifuged and transferred on dry ice to the laboratory. Plasma glucose
was analyzed using the enzymatic colorimetric method on a Modular Analyzer (Roche
Diagnostics). “Coefficients of variation were 2.3 and 1.9% for fasting and post load
glucose tests, respectively” (Franciosi et al., 2005, p. 1189).

The DRS questionnaire is a tool originally developed to screen patients for diabetes
with diabetes specific risk factors. Scores range from 0-20. Scores higher than 9 indicate
a high risk of developing diabetes, the sensitivity of the tool is 0.78-0.81 and a specificity
of 0.76-0.77. For the detection of overt diabetes, the sensitivity is 0.76-0.77 with a
specificity of 0.66-0.67 (Franciosi et al., 2005).

Of the 1,840 participants, 1,377 (75%) were evaluated. The researchers noted that
the patients who dropped out of the study were no different than the patients who
continued. However men were more likely to drop out of the study, and were more likely
to have left ventricular hypertrophy. Patient characteristics related to impaired glucose
tolerance versus impaired fasting glucose. Diabetes percentages are as follows: 54.9%
had some form of glucose metabolism alteration, 15.4% had IFG, 11.1% had IGT, 11.0% had IGT, and IFG and 17.4% had diabetes (Franciosi et al., 2005).

Based on the findings, different screening strategies should be applied to different individuals. Initially, the diabetes risk score was favorable as an initial screening instrument, with the fasting blood glucose performed for individuals scoring greater than a 9. An oral glucose tolerance test was performed for individuals with fasting plasma glucose between 102 mg/dl-126 mg/dl. This led to notification of 83% of cases of unknown diabetes, and 57% of cases with impaired glucose tolerance (Franciosi et al., 2005).

Franciosi et al. (2005) concluded that the DRS screening tool is an effective, simple and valid instrument for screening patients for undiagnosed hyperglycemia. Franciosi et al. reported that the tool must be sensitive and specific to avoid false-negatives and true-positives. When the DRS was used in conjunction with a FBG, the tool was an option for opportunistic screening for cardiovascular patients.

Continued efforts are needed to identify diabetes. The Finnish Diabetes Risk Score (FINDRISC) is one screening tool. The goal of the study was to determine whether the FINDRISC questionnaire or a simplified version of the FINDRISC would identify undiagnosed diabetes patients at high risk (Bergmann, Reimann, Bornstein, & Schwarz, 2009).

Individuals (n=921) with a familial history of metabolic syndrome were recruited for a cross-sectional study. Participants (n=771) completed the FINDRISC questionnaire.
Of the 771 participants there were 326 (42.3%) men and 445 (57.7%) women between the ages of 14 and 93. In this sample 67 patients were newly diagnosed with diabetes, with no significant differences noted between men and women. However, shared traits were age, weight, elevated blood pressure, and elevated lipids levels with low HDL-C values (Bergmann et al., 2009). Over three-fourths of the participants, 84% (n=921) completed the FINDRISC questionnaire. In addition a physical examination was done that included anthropometric measurements, fasting lipid evaluation and a fasting overnight 75 gram OGTT (Bergmann et al., 2009).

The questionnaire retained six of the eight questions from the original FINDRISC questionnaire: body mass index (BMI), waist circumference, and use of blood pressure medication, history of high blood glucose and a family history of diabetes (Bergmann et al., 2009). A cutoff value of 14 best predicts the presence of diabetes or no diabetes. The mean score for this group was 9.33 +/- 5.92. The range of scores was 0-23. Based on this calculation, 70.1% of all individuals were positively identified, and 21.4% were falsely identified. Bergman et al. (2009) concluded that the simplified FINDRISC questionnaire is a simple inexpensive, quick tool to use in primary practice to detect undiagnosed persons with diabetes (Bergman et al., 2009).

Evidence strongly suggests that dietary and exercise interventions can reduce and delay complications and the risk of developing diabetes (Kahn, Cheng, Thompson, Imperatore, & Gregg, 2009). However, implementing interventions may become a financial issue in the future. Researchers believed that a simple validated tool to
accurately identify persons at risk for diagnosis would provide patient and society an appropriate intervention with a diabetes prevention program.

Kahn et al. (2009) planned to develop and validate a scoring system without the use of a 2 hour glucose challenge. The authors conducted a 14.9 year longitudinal study with the Artherosclerosis Risk in Communities to establish and validate a diabetes scoring system. The scoring system was dependent on patients’ responses to basic questions and an enhanced questionnaire. The goal was to follow participants with diabetes for 14.9 years. The basic measurements included: waist circumference, maternal diabetes, hypertension, paternal diabetes, short stature, black race, age 55 years and older, increased weight, rapid pulse, and smoking history. Other questions addressed glucose levels, waist circumference, maternal diabetes, triglycerides, black race, paternal diabetes, low high-density lipoprotein, short stature, high uric acid, aged 55 years or older, hypertension, rapid pulse, and nonuse of alcohol.

Participants (n=12,729) were 45-64 years old. Individuals were randomly chosen to be either the derivative sample (n=9,587) or the validation sample (n=3,142). The baseline sample characteristics were: a mean age of 53.9 years; 44% were male; 22.8% were black; 30.7% had hypertension; 15.1% reported a maternal history of diabetes; and 8.8% reported a paternal history of diabetes. Recreational alcohol and tobacco consumption was reported: 29.7% had moderate use of tobacco; 28.5% heavy tobacco use; 23.8% no alcohol use; and 17.3% had alcohol use. Limitations were a lack of questions regarding presence of previous gestational diabetes and potential limited knowledge of parental diabetes (Kahn et al., 2009).
The prediction scores combined multifaceted factors with assigned numeric integers. Diabetes status was completed at year 3, year 6 and year 9 with standardized screening markers. In the derivation group, members (n=1,821) had diabetes and in the validation group (n=586) had diabetes. The researchers concluded that the basic informational questions identified adults at high risk for diabetes. However, the advanced questions, along with fasting blood glucoses better identified persons at extreme risks. Kahn et al. (2009) proposed that the use of scoring systems allow practitioners a simple, inexpensive tool to identify persons who would best be suited for lifestyle prevention programs in order to ward of type 2 diabetes.

Summary

The goal of screening for impaired glucose tolerance and type 2 diabetes is to control hyperglycemia, and prevent acute complications associated with treatment, and long-term complications associated with lack of treatment. In order to assess a patient’s glycemic health, screening strategies have been established, assessed, and evaluated to identify the most valid, cost-effective and practical tool for primary care providers to utilize. Edelman et al., (2002) concluded that the prevalence and severity of diabetes justifies screening in opportunistic settings. The severity of diabetes coincided with the co-morbid conditions of obesity, hypertension and hyperlipidemia. The authors recommended longitudinal studies to confirm the effectiveness of such screenings.

Consensus related to screening for diabetes among health care providers remains controversial. Despite effective screening strategies, practitioners have yet to practice
strategic screenings for diabetes. Wylie et al. (2002) reported that several themes emerged from the study. Perceptions such as pessimism, and management issues, as well as staffing issues, in addition to use of polypharmacy were all barriers found to interfere with positive feelings towards screening for diabetes. The authors concluded that while practitioners are aware of diabetes screenings, practitioners are unaware of the significance and the severity of impaired glucose tolerance.

Whitford et al. (2003) concluded that perceptions about diabetes and screenings among health care providers were identified as: “scientific vigor versus faith in screening,” “screening and the patients,” “effectiveness of lifestyle interventions,” “lack of resources,” and lastly “attitudinal barriers.” While all themes are important, the authors reported that ultimately increasing financial resources to allocate for screening was essential to actually performing the screening.

Screening methods for diabetes has been the focus for many research groups. The Diabetes Prevention Program (DPP, 2005) Group completed an early study with significant identification of persons with diabetes. Common factors among persons diagnosed were age, BMI, and positive step one glucose. The DPP group recommended that health public policy should incorporate screenings into health care.

The Diabetes Detection Initiative (DDI) (Lanza et al., 2007) found that screening asymptomatic individuals benefited the people and the community. The (DDI) group utilized social marketing and community awareness, along with risk stratification as tools for the diagnosis of diabetes. Almost a 25% increase in diagnosis in the community
was found to identify unknown diabetes patients.

In a supportive study of screening, Zhang et al. (2005) contributed to the screening dilemma as to what level of hyperglycemia is considered diabetes, and what level is considered pre-diabetes. The authors concluded that cut off values for pre-diabetes should be lower than cut off values for diabetes. However, longevity studies should examine the long term benefits of such screenings. Ziemer et al. (2008) concluded that a random glucose > 125 mg/dl would trigger an order for a glucose tolerance test for pre-diabetics.

Johnson et al. (2005) examined cut off levels and the frequency of recommended screenings. A random plasma glucose >130 mg/dl was the optimal cut off value for undiagnosed type 2 diabetes. The optimal frequency to screen for diabetes was 3 years, reasoning that some chronic complications typically will develop in 3-5 years after onset.

Lindstrom and Tuomilehto (2003), and Franciosi et al. (2005) identified the DRS as a simple, efficient and valid tool to screen patients for unknown diabetes. Franciosi et al. (2005) reported that the DRS is sensitive and specific enough to avoid false-negatives and true-positives. Individuals who score high on the DRS may benefit from modifiable risk factors regarding health outcomes, especially when done with a fasting glucose level. This tool is used nationwide in Finland.

Practitioners (Bergmann et al., 2009) used a similar tool that was based on the DRS, the Finnish Diabetes Risk Score (FINDRISC). It is a self-administered questionnaire. The researchers concluded that the basic version of the tool identified
persons at high risk for diabetes, yet the more advanced questionnaire, along with a fasting plasma glucose better identified persons with an extreme risk for diabetes. The Diabetes Prevention Program Outcome Study, a follow-up study to the DPP study, examined long-term potential complications. Initial screening strategies will be paramount in the eventual outcome of longitudinal studies.
Chapter III

Method and Procedures

Introduction

Diabetes, despite available screening tools, goes undiagnosed in one quarter of all persons with diabetes, or approximately 5.7 million individuals (Centers for Disease Control and Prevention, 2010). Early detection of individuals with diabetes is important in reducing the risk of complications, reducing the costs, and reducing the morbidity and mortality effects of this chronic disease. There are valid screening tools that are available, yet controversy continues regarding the “best” tool to use, as well as what procedure to use. This chapter will describe methodologies and the procedure of the research study.

Purpose

The purpose of this study is to examine a three step screening process using the Diabetes Risk Score (DRS) as an opportunistic screening tool for persons with pre-diabetes in a primary care setting and to validate the tool. This is a replication of a study originally conducted by Franciosi et al. (2005).
Research Questions

1. Is the DRS a valid tool for identification of pre-diabetes and diabetes?
2. Is the three step tool an opportunistic screening strategy effective in identifying pre-diabetes and diabetes?

Population, Sample and Setting

The population for the study will be adults who attend a primary care provider’s office in the Northern Indiana. Generally, two practitioners see a total of 20-30 patients daily. The author will evaluate individuals without a known history of diabetes. The study will run 90 days with a target goal sample of 200 individuals completing the study. The individuals will not have a history of diabetes or hyperglycemia. The sample will be between the ages of 46-65 years old. Exclusion criteria are: use of chemotherapeutic agents, recent birth, hypertriglyceridemia, acute and/or chronic pancreatitis. Individuals will sign informed consents explaining the study.

Protection of Human Rights

The study will be submitted to the Institutional Review Board (IRB) of Ball State University and the medical director of the primary care providers’ office. All individuals will be protected ethically. All names and information about the patients will be anonymous; no individuals will be included involuntarily. All information about the patient’s test results and medical records will be anonymous. All participants will receive a full explanation of the study. The individual can withdraw at any time without penalty.
Risks for the study include potential complications from obtaining small blood samples using venipuncture. Benefits for the study include potential diagnosis of impaired glucose tolerance or pre-diabetes.

**Procedures**

Following approval from the IRB and the medical director at the primary care office, a description of the study will be provided to the general practitioners and staff. The staff will not administer the tool, yet will be informed of the study guidelines and procedures. Participants will be pre-existing patients at the office. Participants will be provided with written information regarding the study, including the risks and benefits. Participants will be greeted at a regularly scheduled appointment by the researcher. The researcher will have a conference with each patient to obtain consent. The researcher will administer the DRS screening tool. Following the completion of the DRS questionnaire, participants will go to a laboratory to undergo a 2 hour glucose tolerance test. A separate appointment may be required to obtain a fasting glucose level; this will be communicated to the participant. The researcher will collect data from the questionnaire, and the laboratory results that will include fasting plasma glucose, a 1 hour test result, and a 2 hour test result following a 75 gram glucose oral load.

Participants will be provided results following confirmed laboratory results. The DRS results will be discussed approximately 30 days following the research study after the study has been completed. If emergent laboratory results emerge, the primary practitioner will be notified immediately.
Design

The design chosen for the research study is descriptive, because it will convey information related to a particular field of study, screening for and diagnosing diabetes. Burns and Grove (2009, p. 237) stated that descriptive designs “vary in levels of complexity.” Whether the design is simple or complex, the goal of a descriptive design is to describe variables in the chosen field of study (Burns & Grove).

Instrumentation, Reliability and Validity

The DRS is self-administered questionnaire to gather information about the diabetic risk factors, originally developed by Lindstrom and Tuomilehto (2003). It was validated from a multivariate logistic regression model based on an independent population survey completed in 1992, with a prospective follow-up 5 years later (Lindstrom & Tuomilehto). The DRS is based on well known diabetes risk factors (Franciosi et al., 2005). The following lists the variables and the scoring systems:

1. Age: <45 = 0; 45-54 = 2; 55-64 = 3; > 64 = 4
2. BMI: < 25 = 0; 25-30 = 1; >30 = 3
3. Waist circumference: < 94 cm (man) =0; < 80 cm (woman) = 0; 94 cm-102 cm (man) = 3; 80 cm- 88 cm (woman) = 0; >102 cm (man) = 4; > 88 cm (woman) = 4
4. History of elevated blood pressure: No = 0; Yes = 2
5. Treatment of hyperglycemia: No = 0; Yes = 5
6. Family history of diabetes: No = 0; Yes, with 1st degree relative = 5; Yes, with 2nd degree relative = 3
7. Physical activity: > 30 minutes = 0; < 30 minutes = 2

8. Consumption of daily vegetable, fruits and berries: Every day = 0; < 1 a day = 1.

The scores are totaled. A score of 0-20 is the range. A score of at least 9 identifies individuals at risk for pre-diabetes and diabetes. A score of 9 or higher has a sensitivity of 0.78-0.81 and a specificity of 0.76-0.77. For the actual detection of diabetes and a score of 9, the sensitivity is 0.76-0.77 and a specificity of 0.66-0.67.

Additional tools utilized were the use of fasting blood glucoses and also a 75 gram oral glucose tolerance test (OGTT). A fasting blood glucose level between 100 mg/dl and 125 mg/dl is considered impaired fasting glucose and a glucose level of between than 140mg/dl-199mg/dl is considered impaired glucose tolerance (Centers for Disease Control and Prevention, 2010); both pre-diabetes states. A fasting glucose greater than 126 mg/dl and a OGTT result > 200 mg/dl is considered overt diabetes (Centers for Disease Control and Prevention).

Data Analysis

Patient’s responses, along with laboratory results from assessing fasting glucose levels, and laboratory results from a 75 gram glucose load will be analyzed. Clinical data will be evaluated using a non-parametric method typically seen in clinical diagnostic levels indicating diabetes. Ordinal data, such as “degree of diabetes,” or levels indicating hyperglycemia, will be address by this statistical technique. Clinical data diagnostics are based on current diagnostic criteria for pre-diabetes and diabetes by the American Diabetes Association (2008). A score of 9, originally determined by Franciosi et al.
was calculated by the receiver-operating characteristics curves identifying the sensitivity of the DRS versus the false-positive rate. The score of 9 was chosen to minimize false-positives while maximizing true-positives. The original DRS study demonstrated the area under the curve quantifies the DRS as a valid tool that accurately identifies individuals with diabetes from individuals who do not.

Summary

This chapter provides the description and methodologies of this study. Methodologies and procedures were defined. The purpose of the study was to evaluate the tool and a three step screening process using the DRS. A descriptive design assessing multiple variables will evaluate approximately 200 individuals as a sample. Data collected using the DRS questionnaire and the use of statistical analysis will be used to determine validity. This study replicates a previous study by Franciosi et al. (2005). Further information gleamed from this study will attempt to validate rationale for opportunistic screening for diabetes and pre-diabetes to improve overall health care concepts related to hyperglycemia.
References


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<tr>
<th>Source</th>
<th>Problem</th>
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<th>Framework or Concept</th>
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<th>Results</th>
</tr>
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<tbody>
<tr>
<td>Edelman et al. (2002)</td>
<td>The prevalence of diabetes in clinical settings is unknown.</td>
<td>To identify prevalence and clinical severity of undiagnosed type 2 diabetes or IGT in a major medical center</td>
<td>Community based, population based and opportunistic based screenings</td>
<td>1,253 (11.0%) out of 11,145 outpatients at a major center in Durham Veterans Affairs Medical Center</td>
<td>Cross-sectional observational study</td>
<td>A1c measurements, demographic information, questionnaire using Kaplan-Feinstein comorbidity index; including height, weight, blood pressure, blood lipids, and urine albumin measurements.</td>
<td>Of the 11,145 surveys that were mailed, 1,253 individuals participated. 995 had an A1c &lt; 6.0%; one person had diabetes; 358 individuals had an A1c &gt; 6.0%; 55 persons were diagnosed with diabetes.</td>
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<td>Wylie, Hungin &amp; Neely (2006)</td>
<td>The diagnosis of impaired glucose tolerance is due to a general lack of awareness by healthcare providers; some believe glucose tolerance is a social problem related to lifestyle.</td>
<td>To evaluate general practitioners’ attitudes and awareness regarding the clinical significance of impaired glucose tolerance</td>
<td>Grounded theory</td>
<td>34 general practitioners in primary care in Northeastern England</td>
<td>Mixed methodology; qualitative and quantitative</td>
<td>Questionnaire and open-ended focus groups with semi-structured interviews following a lecture from a lead investigator on impaired glucose tolerance.</td>
<td>Health care providers felt that screening for IGT was a social problem and not a medical one. Educational and lifestyle instructions were essential through community programs; and if medicinal, then guidelines are needed.</td>
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<td>Whitford, Lamont &amp; Crosland (2003)</td>
<td>There is agreement among health provider’s about potential barriers and consequences of screening for type 2 diabetes.</td>
<td>To identify potential health care provider’s beliefs about potential barriers and consequences of screening for type 2 diabetes</td>
<td>Grounded theory</td>
<td>Purposive sampling, 10 general health care providers and 9 nurses from eight separate practices</td>
<td>Grounded theory</td>
<td>Semi-structured questionnaires requesting information from participants on potential barriers in performing screening individuals for type 2 diabetes.</td>
<td>Consensus that screening is worthwhile; uncertainty remains related to lack of long term studies and inadequate office resources.</td>
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<td>Source</td>
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<td>Diabetes Prevention Group (DPP) (2005)</td>
<td>Primary prevention of type 2 diabetes serves as a means of reducing the risk of complications. Prevention among individuals at risk could decrease and decline the number of complications experienced by type 2 diabetes persons.</td>
<td>To identify adults at risk for diabetes and enroll individuals into a primary prevention study to reduce diabetes related morbidity and mortality</td>
<td>Diabetes Prevention Program</td>
<td>30,383 individuals who completed an oral glucose tolerance test, &gt; 25 years of age, no history of diabetes, and a body mass index &gt; 24 kg/m2</td>
<td>Multi-centered randomized clinical trial</td>
<td>The DPP instruments were life-style modifications, intensive diet, physical and behavior modification; use of Metformin and use of Rezulin, which was stopped during the study.</td>
<td>Based on OGTT results, the DPP screening approach identified 27% of OGTT patients, and 13% with un-recognized diabetes needed for primary prevention study.</td>
</tr>
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<td>Zhang, Engelau, Valdez, Caldwell, Benjamin and Venkat (2005)</td>
<td>There are variations in standards in determining efficient cutoff points for undiagnosed and pre-diabetes.</td>
<td>To evaluate RFG, RPG and OGTT with efficient cutoff points for detection of diabetes and pre-diabetes</td>
<td>WHO and the ADA criteria cutoff points for diagnosis</td>
<td>45-75 year old persons without history of diabetes, seen by their care provider in the last year. Sample size unknown</td>
<td>Quasi-experimental design</td>
<td>Eight cutoff values were utilized based on WHO and ADA standards based on IFG, IGT, RCBG and A1c predictive values.</td>
<td>Results depended on the goal of screening. Values for screening for pre-diabetes should be lower than for diabetes.</td>
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<td>Johnson, Tabaei &amp; Herman (2005)</td>
<td>There is continued debate among healthcare providers as to how often to screen for type 2 diabetes.</td>
<td>To categorize the screening strategy with a focus on accuracy, timeliness and efficiency to protect against false negatives and false positives</td>
<td>American Diabetes Association screening protocol</td>
<td>Simulated closed cohort of 72.6 million individuals aged 45-74 years of age with no prior history of diabetes</td>
<td>Longitudinal study</td>
<td>Four screening tests. RPG cutoff of 100 mg/dl, RPG with a cutoff of 160 mg/dl, RPG with a cutoff of 130 mg/dl and screening with a multivariate equation.</td>
<td>RPG &gt;100 mg/dl= 91% sensitivity and 87% specificity, RPG &gt; 130 mg/dl= 64% sensitivity and 87% specificity, &gt; 160 mg/dl 44% sensitivity and 96% specificity; multivariate equation was 63% sensitivity and 96% specificity and estimated to be done every three years.</td>
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<td>Source</td>
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<td>Purpose or Research Question</td>
<td>Framework or Concept</td>
<td>Sample</td>
<td>Design</td>
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<td>Lanza, Albright, Zucker &amp; Martin (2007)</td>
<td>There is substantial evidence to support mobilization of screening standards to identify individuals with undiagnosed diabetes.</td>
<td>To identify through various screening techniques unidentified individuals with type 2 diabetes</td>
<td>The Diabetes Detection Initiative utilizing social marketing, media, channels, promotion and geographical segmentation</td>
<td>364,000 individuals from 42 pilot community clinics</td>
<td>Mixed methodology: qualitative and quantitative</td>
<td>The American Diabetes Association risk test.</td>
<td>The use of the risk test through social marketing increases the number of found patients with diabetes from 23% to 34.5% on a monthly basis.</td>
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<td>Ziemet et al. (2008)</td>
<td>Healthcare providers do not routinely screen for type 2 diabetes or IGT; finding convenient methods to identify type 2 diabetes patients into routine care is necessary.</td>
<td>Determine if random plasma glucose detects undiagnosed type 2 diabetes or IGT</td>
<td>Opportunistic screening for impaired glucose tolerance study (SIGT)</td>
<td>990 participants aged 18-75 years of age with no prior history of diabetes, no pregnancy, no glucocorticoid use, and the ability to work during the previous week</td>
<td>Cross-sectional descriptive study</td>
<td>Random plasma glucose defined by the American Diabetes Association of &gt; 110 mg/dl as IFG and a subsequent OGTT 2 hour &lt; 140 mg/dl.</td>
<td>The AROC was 0.80 for RPG to diagnose diabetes and was 0.72 to identify IGT and were significant (p&lt;0.001). Screening with RPG can be an initial tool with further evaluation for patients at risk.</td>
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<td>Lindstrom &amp; Tuomilehto (2003)</td>
<td>Healthcare professionals should identify patients prior to existence of altered glucose metabolism.</td>
<td>To test the Diabetes Risk Score (DRS) as an inexpensive, efficient tool to detect unidentified individuals for type 2 diabetes</td>
<td>Risk factors based on American Diabetes Association screening process</td>
<td>A random sample of 35-64 year old individuals in 1987 (n=4,746) and in 1992 (4,615) without a history of drug treated diabetes were questioned and followed for 10 years</td>
<td>Correlation predictive</td>
<td>The DRS is an instrument used to evaluate persons at risk for diabetes. Such risks include; age, body mass index, hypertension, and lack of exercise, consumption of berries, fruit and vegetables.</td>
<td>A DRS value of &gt; 9 indicated 0.78% sensitivity and a 0.81% for specificity in 1987. In 1992, the DRS identified diabetes with a sensitivity of 0.81% and a specificity of 0.76%.</td>
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<td>Franciosi et al., (2005)</td>
<td>Healthcare providers do not routinely screen for type 2 diabetes or IGT.</td>
<td>To evaluate the DRS as an initial tool to identify individuals with type 2 diabetes or IGT.</td>
<td>Risk factors based on American Diabetes Association screening criteria</td>
<td>1,377 individuals without a history of diabetes, no cardiovascular events (CV), yet had one or more CV risk factors</td>
<td>Multi-centered prospective cohort study</td>
<td>The DRS is an instrument used to evaluate persons at risk for diabetes such as age, BMI, hypertension, lack of exercise, consumption of berries, fruits and vegetables.</td>
<td>The DRS identified 83% of the subjects with type 2 diabetes and 57% of the subjects with IGT.</td>
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<td>Bergman, Reiman, Bornstein &amp; Schwartz (2009)</td>
<td>There is a need for an effective screening strategy to identify individuals with high risk for developing type 2 diabetes.</td>
<td>To assess whether the Finnish Diabetes Risk Score (FINDRISC) or a simplified version could be used to identify persons at risk for diabetes</td>
<td>FINDRISC model</td>
<td>771 participants between the ages of 14 and 93</td>
<td>Cross-sectional study</td>
<td>The FINDRISC questionnaire addresses 6 attributes; age, BMI, waist circumference, Hx of high blood pressure and a family Hx of diabetes.</td>
<td>The mean FINDRISC score was 9.33 +/-. 5.92. The best cutoff for diagnosis for diabetes was 14 with a sensitivity of 70.1% and a specificity of 78.6%.</td>
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<td>Kahn, Cheng, Thompson, Imperatore &amp; Gregg (2009)</td>
<td>Clinicians need efficient, cost-saving tools rather than taxing diagnostic tests to identify diabetes or patients at risk for diabetes.</td>
<td>Develop a sample scoring system based on gender, history, weight, height, and clinical data without sample of blood to identify patients at risk for diabetes</td>
<td>The Atherosclerosis Risk in Communities (ARIC) study to derive data provides a predictive scoring system</td>
<td>15,792 adults aged 45-64 years old. 3,063 persons were excluded for various reasons; leaving 12,729 available participants</td>
<td>Longitudinal study</td>
<td>Predictive-correlative.</td>
<td>The basic model provided 33% of diagnosis of diabetes at 10 years. The enhanced model provided 46% of diagnosis at 10 years.</td>
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