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doi: <https://doi.org/10.57709/6074305>

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DIABETES IN AMERICAN INDIAN AND ALASKA NATIVE POPULATIONS

by

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B.S., UNIVERSITY OF GEORGIA

A Capstone Submitted to the Graduate Faculty
of Georgia State University in Partial Fulfillment
of the
Requirements for the Degree

MASTER OF PUBLIC HEALTH

ATLANTA, GEORGIA
2014

TABLE OF CONTENTS

INTRODUCTION

1.1 Background	3
1.2 Purpose of study	5

REVIEW OF THE LITERATURE

2.1 Diabetes	7
2.2 Disparities – with focus on AI/AN population	8
2.3 History of the AI/AN population	12
i. Impact of European colonization	12
ii. Economic hardship and poverty	13
iii. History of health care and the Indian Health Service (IHS)	14
2.4 Evidence of successful diabetes prevention	15

NATIONAL EFFORTS TO ADVANCE AI/AN HEALTH

3.1 Special Diabetes Program for Indians (SDPI)	30
3.2 Notah Begay III Foundation	31
3.3 National Diabetes Education Program (NDEP)	34
3.4 Native Diabetes Wellness Program	35
3.5 Awakening the Spirit: Pathways to Diabetes Prevention & Control	36
3.6 Cherokee Choices	37

DISCUSSION AND RECOMMENDATIONS

4.1 Gaps in Knowledge	39
4.2 Promising findings from the literature	42
4.3 Challenges	44
4.4 Recommendations	45
4.5 Conclusion	46

CHAPTER 1

INTRODUCTION

1.1 Background

Diabetes is the cause of a major health burden in the American Indian and Alaska Native (AI/AN) population in the United States. While rates have been rising throughout the United States over the last two decades (Selvin, Parrinello, Sacks, & Coresh, 2014), the incidence of diabetes among AI/AN individuals remains higher than for any other racial or ethnic group (Barnes, Adams, & Powell-Griner, 2010). In fact, AI/ANs are now over two times as likely to be diagnosed with diabetes than non-hispanic whites in the U.S. Despite improvements in healthcare delivery and access (Bergman, Grossman, Erdrich, Todd, & Forquera, 1999) diabetes continues to be a major cause of morbidity and mortality among AI/AN people across the country.

In order to begin to fully understand the magnitude of the burden of diabetes in the AI/AN population, it is important to first begin with proper context. Within the United States in total, rates of diabetes have risen dramatically in the past twenty years, across nearly every gender, age group and demographic, climbing from 3.7% to 8.3% (U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2011). The current rate represents the now 18.8 million people who are diagnosed as well as the 7 million who remain undiagnosed. Additionally, an estimate based on both fasting glucose and hemoglobin A1c levels shows that 35% of U.S. adults over 20 years of age have prediabetes (National Center for Health Statistics, Centers for Disease Control and Prevention). When applied to the U.S. population, this percentage translates to an estimated 79 million American adults who are

prediabetic (U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2011). As will be discussed later, prediabetes is the leading risk factor for type 2 diabetes, making such an estimation one of great significance.

More troublesome still are the projected diabetes rates for the U.S. over the next several decades. A recent study, using data from the US Census Bureau and the Centers for Disease Control and Prevention, projected that the annual incidence rate for diagnosed diabetes will increase from the current 8 cases per 1,000 to about 15 per 1,000 by the year 2050 (Boyle, Thompson, Gregg, Barker, & Williamson, 2010) (Institute for Alternative Futures, 2010). Considering this projected incidence rate and the current rates of diabetes-related mortality (Murphy, Xu, & Kochanek, 2013) the total prevalence rate – including both diagnosed and undiagnosed cases – would consequently be expected to rise to around 25% to 28% by the year 2050 (Institute for Alternative Futures, 2010). Such projections are largely attributable to the aging of the population in the U.S (Howden & Meyer, 2011) and also to the improvements in diabetes care and management, leading to those with diabetes living longer.

The burden of diabetes in the U.S. is both physical and financial. People with diabetes are at an extremely high risk for a wide range of diabetes-related complications and comorbidities, including renal failure, stroke and cardiovascular disease (Gregg & Brown, 2003) (Deshpande, Harris-Hayes, & Schootman, 2008), that are extremely costly not only to one's individual health, but to the health care system as a whole. Considering the cost of treating diabetes-related complications, routine medical care, and the fact that diabetes increases the cost of even treating very general, non-related conditions, people with diabetes have medical expenditures that are over two times as great as they would be in absence of the disease – the average health care cost for a person with diabetes in the US is about \$13,700 per year, as

compared to about \$5,800 for a person without the disease (American Diabetes Association, 2013). From a national health care expenditures standpoint, diabetes cost the United States more than \$245 billion per year in 2012 (American Diabetes Association, 2013) – a 41% increase since 2007 (American Diabetes Association, 2008) – reflecting both direct medical costs and reduced productivity. This number is expected to continue to rise in the coming years, with the total societal cost of diabetes projected to be over \$500 billion by the year 2050 (Institute for Alternative Futures, 2010).

As costly and worrisome as the current trends and projections in diabetes are for the United States population, the situation is much more severe for the AI/AN population. Other racial/ethnic minorities in the United States are known to be disproportionately affected by the disease as well (Engelgau, et al., 2004), including African American, Asian and Hispanic populations, but the extent to which this worsening epidemic has impacted AI/AN communities is significantly greater (National Center for Health Statistics, 2014). Nearly 18% of AI/AN adults are currently diagnosed with diabetes – a rate over two times that of the adults in the general US population – with rates varying by region from 5.5% among Alaska Natives to as high as 50% among American Indians in Arizona (U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2011). Furthermore, diabetes is the 4th leading cause of death in the AI/AN population and the mortality attributable to diabetes is nearly 3 times higher in AI/AN individuals than in any other racial/ethnic group in the US.

1.2 Purpose of Study

With such a vast disparity in evident effect, it emphasizes the need for a more focused attention on the AI/AN population in order to better understand how this has occurred and how it

can be addressed. What can the history and literature tell us about this population and their unique struggle with diabetes? Why is the disparity so great and what can be done to overcome it? The purpose of this study is to explore the depth of the diabetes burden in the AI/AN population in a way that will inform and support future efforts in prevention in AI/AN communities. Key questions for the literature review will surround diabetes and its risk factors, the extent of the disparity found in the AI/AN population, the history of the AI/AN people as it has influenced this disparity, and finally whether or not there exists evidence of successful prevention and intervention in the AI/AN population. Following the literature review, this paper will also identify the national organizations at the forefront of the fight to improve the health and diabetes-related health outcomes of the AI/AN population, elaborating upon their efforts and programs. Final areas of discussion will include existing gaps in knowledge, promising findings from the literature review, challenges, and recommendations for future efforts.

CHAPTER 2

REVIEW OF THE LITERATURE

2.1 Diabetes

Type 2 diabetes is the most common form of diabetes mellitus and accounts for between 90-95% of all diagnosed cases in the United States (Engelgau, et al., 2004). A chronic disease characterized by high glucose levels in the blood, this type of diabetes occurs when the body is unable to use the hormone insulin properly, a dysfunction known as insulin resistance. Insulin resistance eventually results in a pre-diabetic state, in which the pancreas can no longer secrete enough insulin to counteract the dysfunction, and the levels of glucose in the blood will begin to rise. Once a person is pre-diabetic, the chance of developing type 2 diabetes increases significantly and, in fact, most will develop diabetes within 10 years of becoming pre-diabetic (Grundy, 2012). Once developed, diabetes is a life-long, slow moving, systemic disease that comes with an array of complications as it manifests. Such complications are classified as either microvascular or macrovascular events and often lead to problems like vision loss, renal failure, foot ulcers, foot amputation, myocardial infarction, stroke and cardiovascular disease (Gregg & Brown, 2003) (Deshpande, Harris-Hayes, & Schootman, 2008). In fact, a person with diabetes is 2-4 times more likely to die from heart disease has 2-4 times greater risk of stroke than those without diabetes (U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2011). Diabetes has also been associated with a greater risk for cognitive decline and physical frailty leading to falls and fractures in older age groups (Gregg & Brown, 2003). The primary risk factors for type 2 diabetes are well researched and can be categorized into uncontrollable and controllable factors. Uncontrollable risk factors include race/ethnicity,

familial history of diabetes and history of gestational diabetes. Controllable risk factors, meaning they can be either prevented or even reversed, include pre-diabetes, obesity, lack of physical activity, unhealthy eating habits, high cholesterol and high blood pressure.

In addition to the cost to one's physical health and wellness, the actual medical expenses related to diabetes can be enormous, impacting the individual, health care systems and the nation as a whole. Due to the vast array of diabetes-related complications along, routine medical care, and the fact that diabetes increases the cost of even treating very general, non-related conditions, people with diabetes have medical expenditures that are over two times as great as they would be in absence of the disease. In fact, the average health care cost for a person with diabetes in the US is about \$13,700 per year and in 2012, the annual cost of diabetes in the United States was \$245 billion – a 41% increase since 2007 – reflecting both direct medical costs and reduced productivity (American Diabetes Association, 2013). Within the IHS, diabetes accounts for a large portion of healthcare costs as well. In regards to treatment expenditures, approximately 1 of every 3 IHS dollars was for services for adults with diabetes with the total IHS diabetes-related treatment costs accounting for 37.0% of all adult treatment costs (O'Connell, Wilson, Manson, & Acton, 2012).

2.2 Disparities – with focus on the AI/AN population

Diabetes has been recognized as a significant public health problem in the AI/AN communities for over 40 years (Bennet, Burch, & Miller, 1971), when it was first researched in the U.S. Pima Indians in Arizona. This findings from that study showed prevalence of diabetes mellitus to be 42% among those 25 years and over, and 50% in those over 35 years of age (Bennett, Burch, & Miller, 1971), which was around ten times greater than the prevalence in the

United States at the time for the same age groups. While the prevalence of diabetes in the Pima Indians of Arizona was and still is quite the outlier as the highest ever recorded worldwide (Baier & Hanson, 2004), the research on this population brought a narrowed focus to AI/ANs as a whole, who continue to show markedly higher rates of diabetes than the rest of the United States.

Today, 17.9% of the adult AI/AN population is currently diagnosed with diabetes, with an additional 30% estimated to be pre-diabetic. In terms of distribution, the burden of diabetes is relatively evenly distributed between genders, although slightly higher in men than in women. Presently, around 18.2% of AI/AN men are diagnosed with diabetes, as compared to 16.2% of AI/AN women (Barnes, Adams, & Powell-Griner, 2010). Across the various age groups, older AI/AN individuals have a disproportionately high prevalence of diabetes (Lee, et al., 2002) with the highest rates seen in those over the age of 65 (National Center for Health Statistics, 2014). Amongst AI/AN youth, however, there is a much more troublesome picture beginning to unfold, with rates much higher than in years past. The prevalence of diabetes in AI/AN youth has been steadily increasing over the past thirty years and at an exponentially faster rate than in their non-AI/AN counterparts in the U.S (Acton, et al., 2002).

This falling age of onset presents very serious public health challenge for the AI/AN population and their affected communities, in that young persons with diabetes will have more years with disease, which greatly increases their risk of developing diabetes-related complications and the likelihood of developing such complications earlier in life. The longer a person – and ultimately, a population – has these kinds of costly and disabling conditions, the more costly and disabling they become (Fagot-Campagna, et al., 2000) (Ghodes D. , 1995). Furthermore, the increase in diabetes in younger age groups means an increase in diabetes among young women of childbearing age, which brings about additional public health concern.

Diabetes is a known and major risk factor for congenital malformation and perinatal mortality (Dunne, Brydon, Smith, & Gee, 2003) (Clausen, et al., 2005), but exposure to diabetes in utero may also contribute to the development of diabetes in childhood, resulting in a vicious cycle of continuously increasing frequencies of diabetic pregnancies, and continuously increasing rates of diabetes in young AI/AN. This cycle appears to be in noticeable effect in the Pima Indians in Arizona (Dabelea, Hanson, Roumain, Knowler, & Pettitt, 1998).

Adding to the heightened rates of diabetes in AI/AN population is the fact that AI/ANs are also disproportionately affected by diabetes and diabetes-related complications as compared to every other racial/ethnic group in the U.S. (Barnes, Adams, & Powell-Griner, 2010). Given the current rate of diabetes in the general U.S. population, AI/AN adults are over twice as likely to be diagnosed with diabetes than their non-hispanic white counterparts in the U.S. Of arguably more concern, however, is the widening disparity between rates of diabetes in AI/AN youth and non-hispanic white youth in the U.S. From 1990 to 1998, there was a 58% increase in prevalence of diabetes among AI/AN individuals ages 20-29 as compared with a 9.1% increase in the general population. From 2002 to 2005, among children and adolescents ages 10-19, the incidence per year of type 2 diabetes was 32.0 per 100,000 for AI/AN as compared to an incidence rate of 3.7 per 100,000 for non-Hispanic, white youth of the same age group (U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2011). From 1990 to 2009, the rate of diabetes in AI/AN youth ages 10-19 rose from 3.42 to 6.81 per 1000, a 110% increase in less than 10 years (Indian Health Service, 2012). With such trends taking place, this age group is now 9 times more likely to develop diabetes than non-Hispanic white youth in the US (SEARCH for Diabetes in Youth Study Group, 2006).

AI/AN individuals also face poorer health outcomes from diabetes and diabetes-related conditions than the rest of the United States, especially the non-Hispanic white members of the U.S. population (Heron, 2013). Diabetes ranks as the 4th leading cause of death in the AI/AN population with 5.5% of all deaths being attributed to diabetes. By comparison, the white population in the U.S. ranks diabetes as the 7th leading cause of death, with only 2.6% of all deaths being attributed to diabetes.

In terms of understanding why AI/AN individuals seem to be at inherently higher risk for developing diabetes, theories tend to point to the removal and relocation of the AI/AN population that was discussed earlier. Obesity is a known and prominent risk factor for type 2 diabetes. While a lacking health care system and poverty can be key factors in higher rates of obesity, and ultimately diabetes, in the AI/AN population, researchers suggest there could be a genetic explanation as well. One such explanation is known as the “thrifty genotype theory.” This theory attributes the rise in rates of obesity and diabetes in indigenous populations to the incredibly stark contrast between today’s modern environment and the way of life maintained by the AI/AN people for thousands of years prior to being removed from ancestral lands and consolidated onto reservations. The theory purports that these indigenous people, having lived and thrived for so long in environments where food sources were unpredictable, developed a type of “energy-thrifty” genetic makeup, allowing for the conservation of much needed resources within the body (Bouchard, 2007). However, in the current modern day environments, in which food is plentiful year round, such extreme conservation within the body is no longer warranted, and could instead be having rather damaging effects. In other words, the same thrifty genes that helped the AI/AN people survive could actually be an underlying cause for their heightened risk

for developing type 2 diabetes (Neel, 1962), set in motion by the systematic removal of AI/AN people from their native lands by the US government.

2.3 History of the AI/AN population

i. Impact of European colonization

At the time of first contact with Europeans, the continental United States was fully occupied by an estimated 2.5 million indigenous people, representing over 300 distinct Native American Nations. By the end of the 19th century, however, this population had reduced to 250,000 – a mere 10% of what it once was (Fleming, 1995). This level of demographic collapse was brought about a number of factors as the Europeans arrived and colonized, though the primary reasons were disease, warfare, and geographic removal and relocation of the tribes. The European explorers and colonists brought with them a host of deadly diseases never before seen in the Americas. These included smallpox, bubonic and pneumonic plague, typhus, influenza and measles had catastrophic effects on the AI/AN population (Cook, 1998), most notably of course, smallpox, which in some regions killed at least 50% of the population in a matter of weeks (Carlos & Lewis, 2012). Warfare between American Indian tribes and European settlers was also an unfortunate part of colonization post-European arrival, adding to the immense loss of life already caused by disease. In some terrible cases, the Native Americans actually experienced some of the earliest examples of biological warfare as well, documented by both British and French officers, in which they gave the Native Americans blankets intentionally infected with the smallpox virus (Murphy, Hay, & Rose, 1984) (Poupard, Miller, & Granshaw, 1989). Perhaps the most disruptive and lasting factor, however, was the geographic removal and relocation of the AI/AN people. In reality, this process began relatively early, although the first

official legal justification did not come until the Indian Removal Act (IRA) of 1830. The IRA Act allowed for the required relocation of most American Indians located east of the Mississippi to areas west of the river. Those who chose not to move were forced to give up large portions of the land they had previously occupied and were thereafter slowly concentrated onto increasingly small and isolated areas with few natural resources, far from contact with the developing U.S economy and society. These areas would eventually become the American Indian reservations that exist today.

ii. Economic hardship and poverty

Within this context, it is easy to understand why one of the greatest struggles inherent to modern day American Indian/Alaska Native reservations is the development of a thriving economy. Economic development has proved to be very difficult for the reservations and the reason can almost solely be attributed to the success of the policy that created them to begin with – the isolation of the AI/AN population away from the major growth and development seen in the rest of the United States. The result has been a deep-rooted, pervasive poverty, both for tribal governments and those AI/AN individuals living on reservations, and a quality of life that is shockingly low. Assimilation into American society was once believed by some to be the answer to this problem, which the federal government tried to accomplish through a variety of tactics, including the Dawes Act of 1887. This Act described an allotment policy that would divide the already small areas of land controlled by American Indian governments amongst the individuals living within each reservation. It did not have its desired effects, however, and most AI/AN groups were worse off than before (Sandefur, 1989). The federal government even attempted to do away with reservations as independent entities entirely through termination

legislation in 1953 (American Indian Relief Council) and tried to put into place incentives for AI/AN individuals to migrate into more urban areas. This too saw little success and was eventually abandoned. The failure of these assimilation efforts by the US government underscore the reality that the American Indian reservations, with all their flaws and hardships, still provide the AI/AN people with a much needed cultural base in which they can retain aspects of their heritage, values and original way of life that would otherwise disappear forever.

iv. History of health care and the Indian Health Service (IHS)

The provision of health services to all members of federally recognized tribes originally stemmed from the relationship formed in 1787 between the federal government and the Indian tribes. Until the mid-19th century, however, these services were the responsibility of the Bureau of Indian Affairs of the Department of the Interior and unfortunately, minimal services were actually provided (Sandefur, 1989), leaving the quality of life in terms of healthcare very low.

Despite these challenges, some efforts to improve the quality of life for the AI/AN people were successful and the biggest of these was the creation of the Indian Health Service (IHS) in 1955. The IHS was established to replace the Bureau of Indian Affairs with the intention of improving the healthcare of AI/AN individuals living on reservations. Since that time it has done just that with significant improvements in AI/AN life expectancy and major reductions both in morbidity and mortality for a number of infectious diseases (Bergman, Grossman, Erdrich, Todd, & Forquera, 1999). However, there are substantial problems with the IHS that have begun to have a negative effect on the once highly successful service. The main issue lies in the fact that the appropriations to the IHS allows for considerably less care expenditures per capita than the average US citizen would receive. In fact, according to the IHS, the yearly personal health

care expenditures for an average person in the US is nearly 3 times that for an AI/AN person under the IHS. Such low expenditures have resulted in a limited range of services available within IHS hospitals, the result of which has been an increasing number of services that must be contracted out to non-IHS facilities. This type of outsourcing costs the IHS exponentially more than if the services had been provided internally, ultimately meaning that as the IHS grows more dependent on non-IHS personnel and facilities to provide necessary services, the already limited funds will have a shorter and shorter reach (Cunningham, 1993). Unfortunately, with the federal government's recent cuts in budget appropriations, this type of trend does not bode well for a program like the IHS. While the IHS saw increases in funding each year from 2009 to 2013, in 2013, the budget was reduced by \$3 million. Delivering an even bigger blow, sequestration and rescission cut another \$228 million from the 2013 funding, representing over 5% of its annual budget (Roubideaux, 2013). Overall, while the quality of health care for AI/AN individuals has improved greatly over the last several decades, as a product of persisting challenges inherent to the IHS and tribal health care systems, the quality of and access to care is still very much lacking. This is likely a major factor in the IHS's inability to curb the worsening rates of diabetes in the AI/AN people (Roubideaux, Statement of the Indian Health Service, 2013).

2.4 Evidence of successful diabetes prevention

It has been demonstrated through the results of several intervention studies in the United States and abroad that diabetes incidence can be reduced by lifestyle interventions aimed at weight loss, diet change, and increased physical activity, as well as with pharmacological therapy, though the latter appears to be less effective and more prone to adverse effects. In

addition to the research presented from these clinical trials, many of the interventions tested have since been translated to the community setting, where results are promising.

Among the clinical trials that studied the impact of lifestyle – diet and physical activity – in preventing the development of diabetes amongst those who are already high-risk or pre-diabetic, the earliest was published in 1991. The Malmo Feasibility Study (Eriksson & Lindgarde, 1991) invited 260 individuals previously identified as having impaired glucose tolerance (IGT) to participate in a diabetes prevention trial. The 181 who agreed to participate were included in the treatment group, while the 79 who did not enroll became the non-randomized control. The treatment group received dietary advice (reduced caloric intake, less sugar, more fiber, and more unsaturated fats) and an increase in physical activity. The results from the 5 year study period showed a conversion to diabetes in 10.6% of the intervention subjects as compared to 28.6% of the control group. Directly accounting for the significant decrease in progression from IGT to diabetes was an improvement in glucose tolerance. However, improvement in glucose tolerance was shown to be closely associated with both weight loss and increased physical activity to equal degrees (Eriksson & Lindgarde, 1991). This finding would heavily influence the direction of future intervention studies in diabetes prevention.

The next and strongest early evidence of diabetes prevention in the form of lifestyle intervention came in 1997 with the publication of the Da Qing IGT and Diabetes Study (Pan, et al., 1997). The objective of the Da Qing study was to demonstrate the efficacy of lifestyle intervention in delaying the development of diabetes in IGT individuals. Across 22 clinics in Da Qing, China, 577 IGT individuals were enrolled in study and followed for 6 years, or until diabetes developed. Enrolled subjects were randomized to one of four study groups – diet only,

exercise only, diet plus exercise, or control, who were given basic information, but did not receive any direct instruction. Following the 6 year follow up period, results from the study showed a diabetes incidence rates 25-50% below that of the control group (Pan, et al., 1997). Of those in the control group, 67.7% developed diabetes over the course of the study, as compared to 43.8, 41.1, and 46% in the diet only, exercise only, and diet plus exercise groups, respectively. These results were seen in both lean and obese individuals, indicating that although all subjects were classified as IGT, baseline BMI was not a factor in the efficacy of the intervention efforts. As the first randomized controlled clinical trial to demonstrate a significant reduction in diabetes incidence amongst individuals with IGT, the results from the Da Qing were inherently much stronger than those from the Malmo Study and would continue to fuel efforts in diabetes prevention research. However, in both studies, significant decreases in diabetes incidence were observed, indicating that even moderate lifestyle changes could have a great impact on reducing one's risk for developing diabetes.

Drawing from the evidence presented from these early clinical trials in China and Sweden, two larger, more comprehensive trials were carried out in the United States and in Finland – the Diabetes Prevention Program (DPP) and the Finnish Diabetes Prevention Study. In the United States, the Diabetes Prevention Program (DPP) sought to determine if lifestyle intervention or pharmacological therapy could effectively prevent or delay the onset of diabetes in individuals with IGT, or who were already at a very high risk for diabetes (Diabetes Prevention Program Research Group, 1999) (Diabetes Prevention Program Research Group, 2002). Over the course of three years, 3234 study participants were randomly assigned to one of three study groups – metformin, lifestyle, or placebo. The placebo group received no intervention aside from standard lifestyle recommendations, which included written information

and an annual individual assessment for the duration of the intervention. The metformin group received the same standard lifestyle recommendations along with an 850mg dose of, metformin, an oral antidiabetic therapy that lowers blood sugar through the suppression of glucose in the body. The lifestyle group received an intensive 16-lesson curriculum designed to help participants achieve goals of improved diet and exercise. Lifestyle group members were expected to perform 150 minutes of physical activity each week and to achieve a weight loss of at least 7% by the end of the intervention period. With a participation prerequisite of being considered at high-risk for diabetes development, the study participants displayed similar baseline characteristics, including all measured diabetes risk factor (The Diabetes Prevention Program Research Group, 2000) (Diabetes Prevention Program Research Group, 2002).

In looking at the results from the DPP study, the incidence of diabetes was 58% and 31% lower in the lifestyle and metformin groups than in the placebo group. Average weight loss was 5.6 kg in the lifestyle group, 2.1 kg in the metformin group as compared to 0.1 kg in the placebo group. Additionally, the incidence of diabetes was 39% lower in the lifestyle intervention group than in the group receiving metformin. All results were determined to be statistically significant and were similar in both men and women and across all racial groups. While the incidence of diabetes did rise in each of the three study groups, when compared to that of the placebo group, the incidence rates in both the metformin and lifestyle groups were significantly reduced throughout the follow-up period.

The implications of the DPP study results were particularly great for the United States, in that they indicated the positive findings from earlier studies abroad could be applied in the United States as well, in which the population is uniquely diverse. Their results indicated that millions of high-risk individuals living in the United States could either delay or avoid the

development of type 2 diabetes through weight loss achieved by low calorie diets and regular physical activity. Furthermore, prior to this study, research had not been able to demonstrate that drugs used to treat diabetes, such as metformin, are effective methods of diabetes prevention as well. Results from the DPP study showed metformin to effectively prevent the onset of diabetes, though less effectively than the intensive lifestyle intervention and with greater risk for adverse effects (Diabetes Prevention Program Research Group, 2002). Still, for those individuals for whom an intensive lifestyle intervention is not possible, this possibility would be especially important.

Published in 2003, the Finnish Diabetes Prevention Study (DPS), involved 522 middle-aged, overweight subjects with IGT were identified and randomized into either the intervention or control group (Lindstrom, et al., 2003). Study subjects in the control group received general dietary and exercise advice at baseline with annual physical examinations throughout the study period. Subjects in the intervention group received individualized dietary counseling from a nutritionist as well as offerings for circuit training sessions in addition to being advised to increase physical activity. The goals of the intervention were to reduce body weight (> 5%) and saturated fat consumption (<10% of total energy), while increasing physical activity (4 hours/week) and intake of fiber (>15g/1000 kcal). Results showed the intervention group to have a significant reduction in body weight as compared to the control group (-4.2 kg vs. -0.8 kg), and reduction in waist circumference as well (-4.4 cm vs. -1.3 cm), effectively reducing the risk for diabetes by 58% in the intervention group as reported by the DPS. Supporting these results further, diabetes was diagnosed in 27 subjects from the intervention group as compared to 59 subjects in the control group. This reduction in risk and incidence was directly associated with changes in lifestyle (Lindstrom, et al., 2003). In terms of long term effect, after a 3 years,

the intervention group still showed a reduction in body weight (3.5 kg) that was greater than that of the control group (0.9 kg) (Lindstrom, et al., 2003) and after 4 years, study subjects who had achieved the greatest increase in physical activity were 65% less likely to develop diabetes (Laaksonen, et al., 2005), indicating that this particular lifestyle change may be especially influential to reducing diabetes risk.

Since the publications of the DPP and the DPS, only one other clinical trial has been published demonstrating the efficacy of lifestyle intervention in preventing or delaying the onset of type 2 diabetes. This particular study from Japan was published in 2005 included 458 IGT males subjects who were randomly assigned using a 4:1 ratio to either a standard (control) or intensive intervention group (Kosaka, Noda, & Kuzuya, 2005), resulting in 356 participants in the standard intervention group and 102 participants in the intensive intervention group. Standard intervention group participants received basic instruction on how to maintain a healthy BMI with diet and exercise. Intensive intervention group participants were given detailed and personalized instructions on reducing or maintaining BMI through diet and exercise and received these instructions every 3-4 months. Over the course of the 4 year study period, the cumulative incidence of diabetes was 9.3% in the standard intervention group and 3.0% in the intensive intervention group, indicating the total reduction in the risk for diabetes to be 67.4% (Kosaka, Noda, & Kuzuya, 2005).

Assessing this body of research it is clear that aspects of lifestyle intervention, namely weight loss and increased physical activity, have measured success in preventing or delaying the onset of diabetes. Other studies have focused on an alternate mechanism of intervention and tested the efficacy of various pharmacological therapies. The earliest of such studies came from a Chinese journal in 2001 (Wenying, et al., 2001) testing the effects of both acarbose and

metformin, both of which work to suppress the release of glucose into the blood stream. In this 3 year study, 321 subjects over the age of 25 and with IGT were chosen. Participants were randomly assigned to one of four groups – control, diet plus exercise, acarbose, and metformin. The control group received standard education on diabetes prevention, the diet plus exercise group received an individually designed diet and exercise program in addition to yearly educational visits, and both the acarbose and metformin groups received oral doses of the respective medications. Results showed that, when compared to the control group in this study, both acarbose and metformin appeared to be very effective with risk reductions by 88% and 77%, respectively (Wenying, et al., 2001).

The efficacy of acarbose was further supported by the Study to Prevent Non-Insulin-Dependent Diabetes Mellitus (STOP-NIDDM), which showed a 36.4% reduction in diabetes incidence with acarbose therapy. The efficacy of metformin was further supported as well with the publication of the DPP, as described earlier (Diabetes Prevention Program Research Group, 2002). Results from this extensive study showed metformin to reduce diabetes incidence by 31%, although its efficacy was limited, particularly in those over the age of 60 or with a BMI lower than 30. However, in those subjects ages 24-44 or with a BMI greater than 35, treatment with metformin proved to be as effective as the intensive lifestyle intervention as designed by the DPP (Diabetes Prevention Program Research Group, 2002). Unfortunately, the DPP published in 2003 that results from metformin were not maintained after treatment stopped and reported progression to type 2 diabetes after withdrawal from therapy (The Diabetes Prevention Program Research Group, 2003).

Heymsfield et al., tested the efficacy of Orlistat, a gastrointestinal lipase inhibitor, with the specific hypothesis that when combined with moderate dietary intervention, it would improve

glucose tolerance and prevent the worsening of the diabetes status in obese adults more effectively than dietary intervention alone (Heymsfield, et al., 2000). Combining results from prior studies in the US (Davidson, et al., 1999) and the United Kingdom (Sjöström, et al., 1998), which demonstrated that Orlistat and dietary intervention promoted significant weight loss, they desired to determine whether or not this weight loss, when maintained for a long period of time, could also lead to an improved glucose tolerance and rate of diabetes onset in obese individuals. Results from the study showed subjects receiving Orlistat to have achieved greater weight loss than those receiving dietary intervention only (control group). Over 52% of those receiving Orlistat lost 5% or more of their initial body weight (vs. 37% in the control group) and over 30% lost at least 10% of their initial body weight (vs. 16.7% in the control group). This difference between groups was statistically significant (Heymsfield, et al., 2000). More telling, however, was the fact that among those who had impaired glucose tolerance (IGT) at the start of the study, a much greater percentage of those treated with Orlistat had a normal glucose tolerance at the end of treatment as compared to the control group (71% vs 49%). Additionally, only 3% of those in the Orlistat treatment group progressed to diabetic status, whereas nearly 8% in the group without Orlistat treatment developed diabetes. The implications of this study and others like it were especially great for diabetes prevention in the United States, in that vast numbers of adults in the U.S. are in a state of impaired glucose tolerance. Identifying ways to prevent progression to diabetes from an IGT state could therefore be enormously impactful for a large number of Americans (Heymsfield, et al., 2000).

Another study published in 2002 addressed the efficacy of Troglitazone. The specific objective of the study was to determine whether reducing insulin resistance through the use of Troglitazone would effectively alleviate the demand on pancreatic β -cells, thus delaying or

preventing the onset of diabetes in high-risk Hispanic women (Buchanan, et al., 2002). A sample of 266 Hispanic women were randomly selected from a pool of potential subjects identified to be high-risk by the existence of gestational diabetes mellitus in the previous 4 years, as well as an impaired glucose tolerance that predicted the development of diabetes within 5 years. Each of the 266 women were randomly assigned to either receive placebo or troglitazone therapy. Both placebo and therapy groups received dietary and exercise recommendations as well. The results from this study showed that of those high-risk Hispanic women who were treated with Troglitazone rather than the placebo, there was a 50% reduction in diabetes incidence. Furthermore, this protection from diabetes onset continued for 8 months following the end of therapy, indicating that treatment with Troglitazone actually preserved β -cell function, allowing for adequate compensation to insulin resistance for some time post-treatment. Unfortunately, due to documentation of severe adverse events in the form of liver toxicity (Gale, 2006) in numerous studies, Troglitazone was withdrawn from the U.S. market in 2000 and from other markets internationally as well. The implications of these results are therefore reduced to very little, although the concept of using pharmacological therapy to further target insulin resistance is still of great interest and is still being researched.

The Diabetes Reduction Assessment with Ramipril and Rosiglitazone Medication (DREAM) trial was published in 2006 and investigated the drug Rosiglitazone's ability to prevent diabetes in individuals at high risk of for developing the disease (The DREAM Trial Investigators, 2006). The study involved 5,269 high risk adults who were randomly assigned to either receive Rosiglitazone therapy, or a placebo. Results showed that treatment with Rosiglitazone for 3 years reduces diabetes risk by 60% and increases the likelihood of regression to normoglycaemia in those with IGT or with impaired fasting glucose. However, despite these

benefits and a substantial delay in onset of diabetes, rosiglitazone also resulted in a 37% increase in adverse cardiovascular events. While this finding did not quite meet the level of statistical significance, it was high enough to spark concern among some researchers. Therefore, it may become much more important that the adverse effects of pharmacological therapy for diabetes prevention be further researched, especially if this type of intervention should ever be undertaken for a lifespan (The DREAM Trial Investigators, 2006).

In regards to diabetes prevention in the AI/AN population, the literature shows a strong focus on lifestyle and environmental interventions. Drawing on the positive findings from studies described above, many community-based programs aimed at the prevention of diabetes and diabetes risk factors, such as obesity, have attempted to successfully translate the findings into practice within the culturally specific environments of AI/AN communities. While, by nature, these studies are not randomized clinical trials, they do provide potential insight into the translation of prevention methods to the AI/AN population.

In 1994, a lifestyle intervention program called the Kahnawake Schools Diabetes Prevention Project (KSDPP) was implemented in the Mohawk community in Canada (Paradis, et al., 2005). Running the span of 8 years, the KSDPP aimed to study the effectiveness of a school-based diabetes prevention intervention program on certain primary diabetes risk factors, including body size, physical activity levels, and diet, in elementary school children ages 6 to 11 in the Mohawk community. Within the schools, the KSDPP employed a health education curriculum involving topics on type 2 diabetes, healthy nutrition (including traditional foods), and physical fitness. Community activities included the use of advertisements in local newspapers and on local radio stations, promotional events, and family activities. Using a participatory approach in the development of the program, in which there was a substantial

emphasis on community ownership and community decision-making at all levels of the intervention, including program planning, delivery and evaluation, researchers sought to involve community members and leaders to the highest degree. The impact of the intervention was assessed in two ways –through the changes in outcome measures in the intervention as relative to the comparison community (from years 1994-1996), and through the changes in outcome measures in the intervention community over time (1994-2002). Early results from the intervention showed some success in reducing observed risk factors for type 2 diabetes, including a slower rate of increase in subscapular and triceps skinfolds in the intervention group as compared the control (though this did not translate to a slower rate of increase in BMI), decreased consumption of soft drinks and key high fat foods and high sugar foods, and increased levels of physical activity. However, despite these improvements, the primary objective to reduce the prevalence of obesity was not achieved in the study population. Increases in adiposity occurred in the intervention community throughout the study period (Paradis, et al., 2005). A number of outside factors, including the concurrent introduction of satellite television in the community, increased availability of fast food, and an unfortunate cut in physical education classes due to budget constraints, were cited by community members as potential explanations for the overall lack of results, making it difficult to quantify the true impact of the KSDPP intervention. This particular publication would make clear that while prior randomized experiments have shown evidence of the preventive impact of lifestyle intervention, translating that evidence would be challenging. Researchers suggested that a longer intervention period, more intensive programs, and different types of interventions would be necessary to achieve the long-term lifestyle changes needed to see a true impact in diabetes risk factors (Paradis, et al., 2005).

The Apache Healthy Stores (AHS) program was an environmental intervention conducted in the White Mountain and San Carlos Apache reservations from 2003-2005 (Gittelsohn, et al., 2005). Funded by the US Department of Agriculture, the intervention sought to change the food environment on the chosen reservations through working closely with small and large food stores to increase the number of healthy options and to then promote those foods both in the stores and in the community with the help of community media outlets. Ensuring a true community-based approach, AHS involved key members of the community in the planning and implementation of the program, including tribal administration, tribal members, store owners and managers, tribal health departments and in particular, those working in the diabetes prevention programs. The study design involved 20 food stores – 10 intervention stores and 10 control stores, where the intervention stores received a 12 month program that focused on different healthy foods. Trained staff worked with store owners and staff to increase the stocking of healthy foods, which were then promoted in the stores through the use of interactive sessions with shoppers, posters, flyers and promotional giveaways. Mass media and in-store promotions were also incorporated to further encourage the adoption of healthy food behaviors. Researchers measured the success of the program through increases in consumer knowledge, self-efficacy, intentions to buy healthy foods, purchase of healthy foods and use of healthy cooking methods. Drawing data from survey questions that were given before and after program took place to 176 individuals across the reservations, there were noted improvements in several of the success measures as a result of the AHS program – food knowledge increased 0.79 points in the intervention group, as compared to -0.25 points in the control group. Food self-efficacy increased 2.6 points in the intervention group versus 1.5 in control group. Food intentions also increased 1.2 points in the intervention group as compared to a 0.8 point increase in the control.

There were also positive results seen in the sales of promoted healthy foods in the intervention group as compared to the control. Sales of cooking spray increased 244% at the intervention stores, as compared to 149% at control stores. Sales of pretzels increased 150% in intervention stores, as compared to 131% at control stores. Sales of low sugar, high fiber cereals increased 18% in intervention stores, as compared to an actual decrease of 1% in control stores. Such improvements in the purchasing of healthy foods gives clear indication that changing the food environment is indeed possible. Researchers believed the combination of mass-media activities, promotional signage in stores at the point of purchase, in-store interactive sessions and the overall increased availability of healthy foods in the intervention stores allowed for a multidimensional approach that ultimately had a favorable effect on the psychosocial factors and food-related behaviors that often lead to obesity and diabetes. However, despite these program successes, improvements in health outcomes related to diabetes or obesity were not evaluated (Gittelsohn, et al., 2005) making it difficult to ascertain if these improvements in diet choices were substantial enough to translate to diabetes prevention. Regardless, the demonstration alone that that food environment and certain dietary behaviors can be changed on an AI/AN reservation was a notable achievement and valuable knowledge for future diabetes prevention efforts.

Published in 2008 and running from 2002-2006, another study focused on examining the effectiveness of a culturally influenced, low-intensity lifestyle intervention in young American Indian women (Thompson, et al., 2008). Designed as a randomized controlled trial, the intervention involved a study population of 200 urban AI/AN females ages 18 through 40, with a primary objective to reduce type 2 risk in young American Indian women. The intervention group participated in a five month program that involved monthly discussion groups focusing on

healthy eating, physical activity, goal-setting and social support. The primary outcomes for this study included dietary fat and vegetable consumption and self-reported physical activity. Secondary measures included cardiorespiratory fitness, insulin sensitivity, blood pressure, BMI, fruit intake and others. In the time immediately following the intervention, results showed significantly more women in the intervention group to have a loss in body weight than in the control group – 49% in the intervention group versus 34% of the control group, with a mean percentage loss of 3.2% and 3.9% respectively. At 18 months, however, just over a year after the intervention period, there was much less of a difference between groups, with only 59% of the intervention group having lost body weight as compared to 52% in the control group. In regards to improvements in physical activity, 64% of the intervention group and 70% of the control group already met the intervention recommendations for hours of vigorous activity per week at the start of the intervention. Among those in the intervention group who did not meet the recommendations at the start of the study, 38% were meeting the criteria a year into the intervention, as compared to 33% in the control group. It was unclear as to why there was ultimately an improvement in health benefits in both the control and the intervention groups, but researchers did report that nearly all participants were previously considering or already making lifestyle changes upon the start of the intervention, which could have positively influenced health behavior. Regardless, the impact of this study is that it suggests high intensity interventions in high-risk, already obese, or diabetic individuals are not the only way to prevent diabetes and its associated risk factors in a population. Subjects for this study were recruited without regard to weight or any other risk factors for type 2 diabetes, with the only health-related inclusion criteria being that they could not already have type 2 diabetes. Furthermore, the intervention itself was minimalistic, relying only on basic discussion of healthful behaviors in group settings, rather

than the more intensive and complex type of intervention usually used in diabetes prevention programs. These results indicate that a low-intensity intervention among younger individuals with a lower average risk for type 2 diabetes can have a positive impact, perhaps preventing the need for more expensive high-intensity interventions in the future (Thompson, et al., 2008).

CHAPTER 3

NATIONAL EFFORTS TO ADVANCE AI/AN HEALTH

3.1 Special Diabetes Program for Indians (SDPI)

In addition to clinical research, there have also been wide scale, government-funded programs aimed at addressing the growing epidemic of diabetes in the AI/AN population. Perhaps the most expansive and overarching of these programs is the Special Diabetes Program for Indians (SDPI). The SDPI was established by Congress in 1997 as a part of the Balanced Budget Act and currently provides funding to 404 Indian Health Service (IHS), Tribal, and Urban Indian health programs – essentially covering all federally recognized tribes in the United States. Using evidence-based and community driven approaches, the SDPI addresses both diabetes treatment and prevention through the development of two core components – Community Directed Diabetes Programs, and Initiatives. The Community Directed Diabetes Programs receive over \$100 million per year of the SDPI budget to design and implement interventions using known best practices in diabetes in a way that still addresses the priorities and needs of individual communities. The two Initiatives for the SDPI are the Diabetes Prevention Program and the Healthy Heart Project. Using research-based prevention and treatment interventions, each Initiative is organized to implement these successful interventions, collect data, and ultimately develop strategies for dissemination to other Indian health programs, thus broadening the impact and reach of the SDPI.

Since 1998, the SDPI has allowed the Indian health system and AI/AN communities to make enormous changes to the diabetes landscape, both in prevention and treatment efforts, and in areas and communities where very little resources previously existed. Access to treatment and

prevention services grew exponentially and the clinical and community outcomes have proven this to be extremely effective both in terms of health markers and reducing federal healthcare costs. In terms of clinical outcomes, the SDPI cites decreases in average blood sugar levels from 9% to 8% (as measured by the A1C test), decreased risk of cardiovascular disease via reduction of average LDL from 118 mg/dL to 94 mg/dL, better control of blood pressure with the average blood pressure being 131/75 mmHg and declining rates of diabetes-related kidney disease, which fell by 27.7%. They also cite community outcomes, including increases in primary prevention and weight management activities for children and youth as well as increased emphasis on healthy lifestyle behaviors in adults. The SDPI believes its impact has immense financial bearing as well, touting the declining incident rates of diabetes-related kidney disease, or end-stage renal disease (ESRD), as one of the greatest successes in this area. ESRD is the largest driver of Medicare costs, with the yearly costs of hemodialysis for one person sitting over \$87,000. Since the start of the SDPI in 1998, however, incidence rates of ESRD due to diabetes in the AI/AN population have fallen dramatically – nearly 28% from 1999 to 2006 – thus, resulting in significant cost savings for not only Medicare, but the Indian Health Service as well.

3.2 Notah Begay III Foundation

The Notah Begay III Foundation (NB3F) is another instrumental player in advocating for the advancement of AI/AN health within the U.S., particularly that of AI/AN youth. Notah Begay III, a 4-time winner on the PGA TOUR and the only full-blooded Native American professional golfer, began this foundation with the desire to address the negative impact of type 2 diabetes on tribal communities and Native Americans throughout the United States. It began in 2005 as a small golf program in New Mexico led by Notah's father, Notah Begay Jr., who aimed

to bring the game of golf to Native American youth – a sport usually out of reach for young people in AI/AN communities. He believed golf could be used to both provide character development and confidence, while also promoting healthier lifestyles for the Native American youth. The goal of the program was, therefore, to introduce these Native American youth to the positive impact sports can have on a young person's life, such as discipline, goal-setting, pride and health. As the scope and reach of the Notah Begay III Foundation (NB3F) expanded, however, additional programs were created in order to further address the prevention of obesity and type 2 diabetes in AI/AN communities.

In 2009 the foundation launched a comprehensive health and wellness program that would take significant steps towards ensuring a more holistic approach to fighting obesity and diabetes in AI/AN youth through the inclusion of four main components: nutrition education, greater access to healthy foods, leadership development and continued research to further inform prevention efforts. This integrated approach was designed to work together with effective physical activity programming in the communities in which it is implemented in order to achieve the greatest impact on obesity and diabetes prevention.

The foundation also began a soccer program in the San Felipe Pueblo that has since expanded to New Mexico, California, Oklahoma, Arizona and other states with high Native American populations. The mission of the NB3 Soccer Program is primarily to use the sport of soccer as a means of preventing obesity and diabetes, but also to foster the positive self-esteem and leadership development among Native American youth. Through the early work with the San Felipe Pueblo, the foundation found that the soccer program was especially influential in promoting parent involvement and community development. Furthermore, the NB3 foundation believes that soccer, as one of the world's more inexpensive sports with very little equipment

required, is an ideal program for AI/AN communities where poverty and lack of resources is endemic (Devoe, Darling-Churchill, & Snyder, 2008). This factor alone leads the NB3 foundation to believe that soccer and the NB3F Soccer Program hold the potential to become a major force for promoting physical activity and preventing obesity and diabetes in AI/AN youth.

Perhaps one of the most impactful programs under the NB3 Foundation, however, is the San Felipe Place-Based Program. In looking to develop “place-based” programs, or programs that are highly tailored to the specific culture, needs, and resources of a particular community, the NB3 foundation saw the San Felipe Pueblo as incredibly fertile ground to test this type of intervention, as their rates in childhood obesity were incredibly high – over 60% at the start of the program in 2005. NB3F committed to a long term presence in the San Felipe Pueblo with the goal of reducing the rate of childhood obesity by 50% by the year 2021. This particular program would combine the holistic elements of the health and wellness program with the highly engaging physical fitness elements of the soccer program to create NB3F’s most intensive and integrated approach to preventing obesity and diabetes. Beyond this, their goal was to use the knowledge gained to create model place-based programs that could then be replicated in other tribal communities, as well as to inform policy development at the tribal, state and national levels.

One of the cornerstones of the NB3F has been to establish and foster partnerships that allow for the sharing of expertise and resources to better serve the AI/AN youth population. There has also been great focus within the foundation on continued research on the subject of obesity and diabetes in AI/AN youth and evaluation of the programs designed by the foundation. Partnerships with such organizations as Johns Hopkins University, the Robert Wood Johnson Foundation and the Indian Health Service (IHS) are three of the biggest partnerships undertaken

by NB3F. Through these partnerships in particular, the NB3F has been able to evaluate key NB3F programs (Notah Begay III Foundation, 2013) (Johns Hopkins University, 2014), increase research capacity surrounding obesity and diabetes in AI/AN children, particularly in New Mexico (Crum, 2013), and use shared best practices to effectively implement new, culturally sensitive initiatives targeted at reducing rates of obesity and diabetes in AI/AN communities (Indian Health Service, 2013).

3.3 National Diabetes Education Program

The National Diabetes Education Program (NDEP) is another federally-sponsored program that utilizes both public and private partners in their efforts to improve diabetes management and outcomes, promote early diagnosis of diabetes and ultimately prevent the onset of diabetes in the U.S. Founded in 1997, NDEP is supported by more than 200 partner organizations, led primarily by the National Institute of Diabetes and Digestive and Kidney Diseases of the National Institutes of Health and the Division of Diabetes Translation of the Centers for Disease Control and Prevention. NDEP has a number of objectives, which include increasing awareness and knowledge of the seriousness of diabetes and its risk factors, decreasing the number of Americans with undiagnosed diabetes, facilitating the efforts to improve diabetes-related health care and to reduce the health disparities in those populations that are disproportionately burdened by diabetes. While they focus on a number of populations within the U.S., one of the populations of interest for the NDEP are those populations disproportionately burdened by diabetes and its complications, including AI/AN populations, making it a recipient of much of their outreach efforts. One such effort was a toolkit published in 2011 entitled *Living a Balanced Life with Diabetes*. Containing culturally appropriate

materials representing many different tribal nations, the toolkit was designed to help health care professionals better understand and navigate the psychosocial issues and emotional needs of American Indians/Alaska Natives living with diabetes such as depression, self-esteem, anger, and substance abuse.

3.4 Native Diabetes Wellness Program

Established in 1998 as a part of the Center for Disease Control's Division of Diabetes (CDC) Translation, the Native Diabetes Wellness Program (NDWP) works develop and support programs specifically designed to advance AI/AN health and address the health inequities revealed so starkly by the rates of diabetes in AI/AN communities (Division of Diabetes Translation, 2013). With guidance from the Tribal Leaders Diabetes Committee and through partnership with the IHS, NDWP uses a variety of culturally competent methods to organize, share data, and evaluate programs that work to support better health practices and policies to within AI/AN communities. Using an upstream approach, the program collaborated not only with such larger organizations as the IHS's Division of Diabetes Treatment and Prevention and the National Institute of Health, but with tribal colleges, communities and leaders as well, in efforts to offer culturally competent programs and materials that would focus on the inequities that perpetuate the diabetes epidemic in Indian Country.

One such inequity is in the access to healthful foods on reservations and in tribal communities. With funding support from CDC, the NDWP began the Traditional Foods Project in 2009. Based on a 5 year grant and cooperative agreements with 17 tribal communities, this project worked to establish programs in each community that would strive to restore local, traditional foods and physical activity as a way to support traditionally-oriented, sustainable and

ecological approaches to diabetes prevention, all while strengthening the immense need for social support for community members. The Traditional Foods Project also aimed to revive and even create stories of healthy traditional ways to be shared in homes, schools and communities. Finally, the project worked to engage community members to continually monitor the program's progress, looking for opportunities for improvement and enhanced sustainability, and also to participate in health promotion activities when available.

NDWP also developed a series of four educational books entitled "Eagle Books" that for elementary school children on traditional ways of being healthy and preventing type 2 diabetes. Brought to life by animal characters, these books were created in response to the burden of diabetes among AI/AN communities and the subsequent need to develop effective education and prevention materials for AI/AN children. With the creation of the Eagle Books, the NDWP hoped to reintroduce to AI/AN children the joy of physical activity, eating healthy foods, and learning from their elders about traditional ways of being healthy.

3.5 Awakening the Spirit: Pathways to Diabetes Prevention & Control

Awakening the Spirit's is a community-based program launched in 1999 by the American Diabetes Association (ADA) in partnership with the IHS's Division of Diabetes Treatment and Prevention that seeks bring awareness of diabetes and diabetes management to AI/AN communities in a way that will not only encourage AI/AN individuals to make healthy food choices and be more active, but will also embolden the drive and spirit to fight diabetes. Reflecting the heart of its mission, Awakening the Spirit presents three truisms on its web site – no one should have to fight diabetes alone, people with diabetes can manage it, and people with diabetes can live full lives. Awakening the Spirit accomplishes this partially through education

and disseminating educational materials to empower tribal members and leaders on the importance of community wellness. It also places great emphasis as an organization on advocating nationally and locally to urge Congress to continue funding for tribal diabetes education programs in tribal communities, providing a number of resources for AI/AN individuals who wish to join in the effort. Furthermore, the leadership of Awakening the Spirit is entirely volunteer-based, representing numerous tribal communities, thus giving it a unique perspective and ground-up approach that ensured the program met the intricate needs of each community.

3.6 Cherokee Choices

Launched in 1999, the Cherokee Choices program was created with funds from CDC's Racial and Ethnic Approaches to Community Health (REACH) program as a community-based intervention to address the growing rates of diabetes in the Eastern Band of Cherokee Indians living in the mountainous area of North Carolina (Bachar, et al., 2006). Cherokee Choices sought to mobilize and enable the community to better confront both the environmental and biological elements of the heightened risk for diabetes in the Cherokee people. Furthermore, in order to maximize improvements in behavior and lifestyle choices and reduce the risk of diabetes, the program was designed with traditional AI/AN values and stakeholder involvement at its core. Cherokee Choices has demonstrated several beneficial changes in the community, showing that improvements in health can be achieved in a tribal setting through targeted, hands-on programs in a variety of settings.

The primary components of the program included a mentoring program for elementary school students, a worksite wellness program for adults working in tribal offices, and a wellness

program for members of tribal churches. The elementary school mentoring program consisted of four experienced mentors who worked with the students and staff to increase awareness of the seriousness of diabetes, encourage physical activity, provide useful knowledge about proper nutrition and teach stress-management skills. They also worked through lesson plans within the classroom to instill within the students a greater sense of self-esteem, cultural pride and emotional well-being. The worksite wellness program was organized into teams of workers at various tribal offices who were provided a challenge to increase their amount of physical activity per week, and also to participate in weekly educational and support activities. Participants were further encouraged by the incentive of prizes for those groups with the highest attendance at such activities as healthy cooking demonstrations, exercise classes, supermarket tours and stress-management workshops, conducted by qualified nutritionists, dietitians and fitness professionals. For the wellness program in churches, health professionals worked with five churches, encouraging members to participate in activities to improve diet, raise awareness of health services available to tribal members, and to increase physical activity. Additionally, a social marketing strategy was put in place to support the three primary components, which included television advertisements and a documentary series.

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CHAPTER 4

DISCUSSION AND RECOMMENDATIONS

4.1 Gaps in Knowledge

As the burden of diabetes in the United States has risen exponentially in recent decades, there have been many published studies on the epidemiology of diabetes in AI/AN populations. This has allowed for a greater understanding of the disease as a whole, as well as how it is impacting the AI/AN population. However, the number of published diabetes prevention clinical trials focused on the AI/AN population is still considerably lacking. Even amongst those clinical trials that exist, there are even fewer that have evaluated the long-term effectiveness of prevention interventions in regards to diabetes-related health outcomes. In order to know and understand the true effectiveness of diabetes intervention in AI/AN communities, there is first, a great need for more clinical trials that evaluate prevention efforts extensively and over longer periods of time. With at least one study showing that initial positive outcomes in the intervention population were not maintained over time (Paradis, et al., 2005), it has been demonstrated that success at the conclusion of the intervention does not necessarily translate to long-term success. Secondly, there must also be a consistent focus on observing the impact of interventions on diabetes-related health outcomes. Several of the studies found in the literature report positive results, demonstrating that specific intervention markers were met, but neglect to obtain data on the changes seen in actual health outcomes. Other studies report the impact on health outcomes, but fail to do so over long periods of time. Both aspects are needed to truly understand whether or not an intervention or program is successful in preventing diabetes in a population. Therefore,

more research is needed that shows the measured benefits of these programs by including long-term assessments of health outcomes directly related to type 2 diabetes.

There are very similar holes seen in the research surrounding pharmacological intervention, particularly in the length of evaluation period. As described earlier, several studies have shown that glucose-lowering drugs are effective in delaying the onset of diabetes, but, with the exception of metformin, none have been given for longer than 3 years. What's more, results from these studies also show that once pharmacological therapy is discontinued, the incidence of diabetes rises (The Diabetes Prevention Program Research Group, 2003) (Phung, Sood, Sill, & Coleman, 2011). Therefore, in order to truly know the efficacy of intervention with pharmacological therapy, it is essential that researchers carry out interventions for a longer period of time, providing sufficient follow up once treatment has ceased. Furthermore, considering the evidence presented thus far, it is likely that successful pharmacological intervention will require adherence to long-term treatment. With this in mind, it will also be important to have a greater body of research on the extent of adverse effects seen with each potential drug. If they cannot be avoided, can they be effectively mitigated? Finally, newer drugs and combination drug regimens are continuing to emerge as promising options to reduce diabetes risk and incidence, but they are under-researched. More research is therefore needed around these newer possibilities.

There is also great need for more research on type 2 diabetes in AI/AN children. This area of the diabetes epidemic is especially concerning and, if left as is, paints a rather ominous picture for the future of AI/AN communities. It is therefore critical that diabetes prevention focus on this population in particular, in the development of both epidemiological research and clinical trials that address the unique environment of school-aged children. However, effective

interventions for preventing diabetes in AI/AN children cannot be designed until the epidemiology of the disease within this group is better understood, so that must be the priority. One area of particular focus could be in the correlation between exposure to diabetes in utero and the early onset of diabetes in childhood as referenced by prior studies (Dabelea, Hanson, Roumain, Knowler, & Pettitt, 1998). Such a potential link could have a substantial impact on understanding the rising rates of childhood diabetes, especially in AI/AN children where the chance of being exposed is inherently higher due to the higher rates of diabetes in the adult AI/AN population as a whole. In terms of prevention efforts, more long-term evaluations of clinical trials are needed to further understand what program aspects and designs are the most effective in AI/AN children. School-based programs seem to be the focus of most interventions seen in the literature, but the research would benefit from a greater exploration of the possibilities of exposure through the home environment as well.

Another suggested area for development is diabetes prevention in the AI/AN population living outside of rural reservation communities. In terms of cultural sensitivity, it appears to be well understood that for a particular intervention to be successful, it must be intentionally designed to meet the needs and traditions of the culture of the population. Nearly every intervention found in the literature, successful or unsuccessful, considered the specific cultural environment of the participating population in the study design. However, the overwhelming majority of these studies were conducted in AI/AN populations living in rural reservation communities (Thompson, et al., 2008). These studies are extremely valuable and provide useful insight into addressing diabetes prevention in such a challenging and culturally specific environment as an AI/AN reservation, but they fail to address a large portion of the AI/AN population that have migrated from reservations to urban areas in which the particular cultural environment is

incredibly diverse. In fact, according to the 2010 Census, the majority (78%) of the AI/AN population now live outside of AI/AN areas or reservations (U.S. Census Bureau, 2012).

Therefore, for these people, there is a great need for more research, both in the gathering of information and in the development of prevention programs that address the unique challenges of the extreme cultural diversity of their urban surroundings.

A final area for suggested development would be to further define and understand the moment at which intervention is most effective in reducing diabetes risk in AI/AN populations. More specifically, must intervention be reserved for those individuals who are already displaying risk factors for developing diabetes or could it be equally effective to implement a less formal, less intensive intervention in a population before they become high-risk? A better understanding of the answer to this question could mean much lower-cost interventions and programs with the same level of impact on AI/AN population over time. Most diabetes prevention programs that are currently in place restrict the enrolling of low-risk individuals with the argument that resources must be used for those who need them the most. However, if it was demonstrated that lower scale and less intensive interventions implemented in a low-risk population were effective in lowering the rates of diabetes in a population over time, extreme cost savings in diabetes prevention could be possible.

4.2 Promising findings from the literature

In looking at the diabetes prevention literature, there is strong evidence that both lifestyle and pharmacological intervention can be effective in reducing diabetes risk. In regards to lifestyle intervention, diabetes incidence can be reduced by programs aimed at weight loss, diet change, and increased physical activity (Diabetes Prevention Program Research Group, 2002)

(Pan, et al., 1997) (Tuomilehto, et al., 2001). Pharmacological therapy has also been shown to reduce diabetes incidence, though less effectively than lifestyle intervention, with metformin and some thiazolidinedones, namely rosiglitazone, demonstrating the greatest potential (Diabetes Prevention Program Research Group, 2002) (Wenying, et al., 2001) (Heymsfield, et al., 2000) (The DREAM Trial Investigators, 2006). Neither lifestyle nor pharmacological intervention are without limitation and numerous challenges, but with continued research clinical trials do suggest that prevention is possible.

In terms of diabetes prevention within AI/AN communities, the literature is much more limited, but amongst what is presented, there do appear to be particular aspects of program design that are especially influential to success. Interventions that engage multiple community settings, such as the household, schools, food stores and community organizations seem to have a broader and more substantial impact, perhaps due in part to the fact that working with multiple institutions allows for a much higher exposure of the intervention to the population of interest. The more saturated a community is with an intervention, the more effective it appears to be. It was also noted in several studies that including community members and leaders in the development and implementation of an intervention had a noticeable impact on its success. Involving a community in this way not only allows for the creation of a program that is sensitive to the culture and traditional values, but it also ensures that the program is sustainable in years to come. Lastly, the most successful interventions and programs incorporated into the design a large amount of personal and community support. In addition to focusing on healthful living, it is clear that providing individuals with emotional and social support makes for a much more effective intervention or program.

4.3 Challenges

There are many challenges in preventing diabetes in the AI/AN population. First and foremost, AI/AN individuals experience disproportionately high rates of diabetes and a significantly worse health status in general as compared with the rest of the United States. This in and of itself presents a situation that will be very difficult to address, as it is compounded by the historical lack of financial resources necessary to create and sustain an effective health care system. Without substantial improvements in the Native American Health Care System, researchers will find it difficult to instill long-term change in a community. Therefore, better infrastructure and ongoing financial support is needed.

Another major hurdle in reducing diabetes risk is the difficulty in translating successful clinical trials into successful community-based programs. Clinical trials effectively show what is possible, but it cannot be assumed that the results are easily converted into practice. The primary challenge is that the environment of a clinical trial is a stark contrast to that of a real, community-based environment. A subject in a clinical trial receives a great amount of attention from health care professionals, a continuous encouragement adhere to the intervention regimen, and in many cases, free resources such as access to exercise equipment. In a community-based program, however, this type of environment is rarely possible. Resources are spread thin over a much larger population and the concentrated attention on each individual participant is not realistic. This challenge persists across all populations, not just in AI/AN communities.

Perhaps the biggest challenge faced in diabetes prevention, however, is the fact that long-term success requires the ability to impart long-term, or even permanent, behavioral change. Unfortunately, outside of a clinical trial, behavior and lifestyle choices are the result of a vast array of factors, each extremely rooted in personal history, culture, perceptions, habits, and other

psychological factors. One study noted that the primary barriers to achieving behavioral change were not lack of knowledge of healthy dietary practices or the value of exercise, but rather a deep-rooted preference for unhealthy foods, large serving sizes, and more sedentary lifestyles (Hood, Kelly, Martinez, Shuman, & Secker-Walker, 1997). Expecting instant change in a person or a population over the duration of one intervention might, therefore, be unrealistic. More programs are needed that become permanent fixtures in communities and impart gradual, deep-rooted changes. Researchers and political leaders must work together to make the desired changes more achievable for the AI/AN population through increased access to services and prevention program support. Only then will desires turn to widespread action.

4.4 Recommendations

Diabetes in the AI/AN population presents a very serious and complex challenge for researchers and for public health officials in the United States. While ample epidemiological research has allowed for a fairly comprehensive understanding of the scope and epidemiology of the disease within this group, much is still left unanswered in regards to effective prevention and intervention. Clinical trials in less specific populations have demonstrated that prevention is possible through lifestyle and even pharmacological intervention. However, successful translation of these interventions to the AI/AN community setting continues to be an extreme challenge to researchers. Programs have been established in AI/AN communities that are demonstrating a positive impact, but more evidence is needed. Unfortunately, the long-term sustainability of successful programs and interventions depends upon supportive policies and without substantial evidence that any given program or intervention is successful, such policies will never take shape. Initiating and funding diabetes prevention will require a high level

confidence that society will benefit from it and that the cost of such programs are necessary to ultimately secure substantial cost savings in the future. Thus, it is imperative to find and publish evidence that community-based interventions will be effective. In order to accomplish this, researchers must continue to work to successfully translate promising findings from diabetes prevention clinical trials into real-life settings, and demonstrate the long-term health impact of those programs.

4.5 Conclusion

Despite the described challenges, limitations and knowledge gaps, diabetes prevention has proven to be possible. What's more, intervention at early stages and in lower risk individuals has proven to be impactful as well. While the long-term effect of this kind of study has not yet been evaluated, should it positively impact health outcomes for diabetes risk factors, the cost of programs and diabetes treatment could be significantly reduced. As the growing diabetes epidemic worsens the health of AI/AN communities and further burdens the nation's health care expenditures, such a possibility is yet another indicator that more research is needed that shows the long-term impact of prevention programs and interventions in all subsets of the AI/AN population. Much is left to learn in diabetes prevention and the research must continue. Finally, as more research is done and new findings on diabetes prevention emerge, it will be crucial that these findings are published and successfully translated into practice in AI/AN communities. Continued evidence of this type of success will be the greatest hope for greater funding and support in the years ahead.

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