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A COMPARATIVE STUDY BETWEEN THE UNITED STATES AND UNITED KINGDOM  
HEALTHCARE SYSTEMS FOCUSING ON TYPE II DIABETES

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## ABSTRACT

Type II Diabetes is a disease prevalent worldwide, most notably in the United States and the United Kingdom. Boasting two largely different healthcare systems, surveys were conducted addressing provider and patient attitudes and feelings towards different practices and policies in each country. Surveys were completely anonymous. Of the 140 participants surveyed, 49% (69 participants) were from the United Kingdom, 49% (69 participants) were from the United States, and 2% (2 participants) were from an unknown country and were thus excluded from the rest of the study. Of the 19 providers surveyed, 26% (5 participants) were from the United Kingdom, 69% (13 participants) were from the United States, and 5% (1 participant) were from an unknown country and thus excluded from the rest of the survey. Results suggested the initial hypothesis was not correct. It was found the United States and the United Kingdom would both be able to learn from one another in regards to practice, but the implications of the study for policy and governmental procedure was a little more muddled. It was determined additional research would be needed to ensure adequate revisions to existing governmental policies.

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## **Chapter 1**

### **Introduction**

#### **Why do a study on Type II Diabetes?**

Type II Diabetes remains the 7<sup>th</sup> leading cause of death in the United States and has been on the rise for years. Per the American Diabetes Association, 1.4 million Americans are diagnosed with diabetes each year. This includes children, adults and senior citizens. Furthermore, in 2012 86 million Americans over the age of 20 had “prediabetes,” which was an increase from the previous year of 79 million, and in 2013 diabetes cost the United States a remarkable \$245 billion.<sup>1</sup>

But Type II Diabetes is not only ravaging the United States. It is also affecting other countries, such as the United Kingdom. Per Diabetes UK, there are 4 million people living with diabetes in the United Kingdom and an expected 1 in 16 have diabetes, diagnosed and undiagnosed. Furthermore, around 700 people a day are diagnosed with diabetes in the United Kingdom, which is the equivalent of one person every 2 minutes. Since 1996, the number of people diagnosed with diabetes in the UK has more than doubled from 1.4 million to 3.5 million, and by the year 2025 it is expected that 5 million UK citizens will have diabetes.<sup>2</sup>



## **Why do a study on the United States and United Kingdom healthcare systems?**

The United States and the United Kingdom have vastly different healthcare systems, most notably with the socialization of healthcare in the United Kingdom. Is there one thing that one healthcare system does that yields more positive results than the other? Can the United States learn from the United Kingdom's success or vice versa? This study aims to look at the prevention, treatment and patient outcomes across these two healthcare systems, looking specifically at why these statistics regarding diabetes are so high. The goal of this study is to analyze patients and healthcare providers and see if there is a blend of the United States and United Kingdom healthcare systems that can produce more favorable and positive statistics in the realm of Type II Diabetes.

## **What is the purpose of this study?**

This study aims to analyze the differences between the United States and United Kingdom healthcare systems by looking at the prevention and treatment measures for Type II Diabetes. This study aims to determine whether one method of healthcare is superior to the other when providing care for Type II Diabetics so that each healthcare system can implement new treatment and prevention plans to provide better care for their patients. The hypothesis is such that while the United Kingdom will have better prevention measures, the United States will boast better treatment plans and governmental policies.

## **Thesis Structure**

What follows in the subsequent chapters of this thesis is background information on the Diabetes (Type I and Type II) the United States and United Kingdom healthcare system structures, the methods of the study conducted, the results of the study conducted, a discussion on what the results mean, and a short conclusion. Within the discussion, implications on healthcare policy and healthcare practice will be explored based upon the results collected from the surveys conducted in each country. Study limitations and additional areas of research will also be discussed before a short conclusion revisiting the main points.

## **Chapter 2**

### **Background Information**

#### **What is Diabetes?**

The Center for Disease Control and Prevention defines diabetes as a “condition in which the body does not properly process food for use as energy”.<sup>3</sup> All parts of the body require energy to function, and our bodies acquire this energy through the food we eat. When we eat, our bodies digest the food first in the stomach by mixing it with acids. Once digested chemically in the stomach, the chyme produced passes through the small intestine where the nutrients are released into the bloodstream and made available for the rest of the body.<sup>4</sup> One of the key compounds that is released is called glucose. Glucose is the product of broken down carbohydrates such as sugar and starches.<sup>4</sup> However, for our bodies to use glucose for energy, it needs insulin.

Insulin is a hormone that is made by the pancreas in the human body. It allows the body to capitalize on the glucose that is found in the carbohydrates found in the food we eat, and helps the body to regulate the level of glucose that is found in the blood. It prevents glucose levels from getting too high (hyperglycemia) or from getting too low (hypoglycemia). Insulin is often described as the “key” which unlocks the cell to allow sugar to enter the cell and be used for energy. Since cells in the body cannot access glucose directly, cells in the pancreas called beta cells are signaled to make insulin when blood glucose levels get too high. The insulin produced by the beta cells then attaches to cells and signals them to absorb the glucose or sugar from the bloodstream.<sup>5</sup>

If there is more sugar in the body than what the body needs, insulin will help the body store the excess glucose for later use. The body generally stores the sugar in the muscles.<sup>5</sup> Insulin does this by turning excess glucose into larger packages called glycogen. When lower levels of glucose are detected in the blood, it signals the pancreas to call upon its reserves of glycogen to keep glucose levels within check. Almost all body cells need proteins to work and grow as well as fat to protect nerves and muscles, however, both can be used as an energy source when the body is in a hypoglycemic state.<sup>4</sup>

Rises and falls in blood glucose levels happen many times throughout the day and night. When the body is working as it should, it keeps blood glucose levels within a normal range by producing more or less insulin. The normal range for blood glucose levels is between 70 and 120 milligrams per deciliter, however it is not uncommon for the blood sugar in a healthy person to spike to 180 mg/dL right after a meal, or to drop as low as 70 mg/dL when fasting for several hours.<sup>4</sup>

With diabetes, one of three malfunctions has occurred: either the body has stopped making insulin all together, the body has slowed down its production of insulin, or the body is no longer able to use its own insulin.<sup>4</sup> When this happens, several things can occur.

First, since glucose can no longer enter the cells because the insulin is not there to act as a key, the body can begin to experience a state of hyperglycemia or high blood sugar. This occurs when glucose levels in the body continue to rise. Once levels begin to surpass 180 mg/dL, the body will try to bring the blood sugar level back within normal range. The kidneys are an important component of this as the body tries to rid itself of the excess glucose through the urine. This often leads to the patient urinating more than usual, and thus produces an increase in thirst.

Other symptoms of hyperglycemia can include blurry vision, headaches, and a general feeling of illness.<sup>4</sup>

As the excess glucose is lost to the urine, the patient will notice decreased levels in energy as losing sugar through urine is also losing energy that could be available for the cells of the body to use or store. Because of this, a person may feel fatigued and hungry as well as experience a sudden drop in weight. When the body does not have enough glucose to use for energy, it reverts to burning body fat. The burning of body fat results in ketone byproducts. As these ketones build up within the body, a patient can experience a life-threatening condition called diabetic ketoacidosis.<sup>4</sup>

For a person who has been diagnosed with diabetes, the focus of treatment is to control blood glucose levels so these symptoms and conditions do not occur. The goal is to keep blood glucose levels between the 70-120 mg/dL normal range. The methods for obtaining this goal are different for each kind of diabetes because each one involves a different malfunction in the body. The main two types of diabetes are Type I Diabetes and Type II Diabetes.

### **Type I Diabetes**

Commonly referred to as Juvenile Diabetes, Type I Diabetes is an autoimmune disease in which the pancreas stops producing insulin completely. It most commonly strikes children and adults at a young age, hence giving it the nickname Juvenile Diabetes. It comes on suddenly, causing symptoms such as extreme thirst, frequent urination, sudden weight loss, and lethargy. There are an estimated 1.25 million Americans and 400,000 Britons living with Type I Diabetes.<sup>6</sup> In the U.S. over 40,000 people are newly diagnosed each year, most whom are

children. The patients diagnosed with Type I Diabetes can manage their condition with daily injections of insulin at every meal, however, there is no cure for Type I Diabetes.

In contrast to Type II Diabetes, Type I Diabetes is not a product of poor diet or inactivity, but rather a genetic disorder in which the body's immune system attacks itself. In doing so, the body destroys the insulin-producing cells in the pancreas known as the beta cells.<sup>7</sup> It is unknown what triggers this autoimmune response in the body of the individuals affected, however, it is believed to be a trait that is passed down through families. Certain individuals are more genetically prone than others. In many cases, a patient's family has a history of autoimmune disorders. While family members may not have had Type I Diabetes specifically, they may have had other autoimmune disorders such as psoriasis, rheumatoid arthritis, and vasculitis. Recent studies have found a small correlation between the onset of Type I Diabetes following a viral infection.<sup>8</sup> Infections such as mumps, rubella, cytomegalovirus, measles, influenza, encephalitis, polio, and Epstein-Barr virus have been linked with the onset of Type I Diabetes, however no substantial evidence that any of these viruses cause Type I Diabetes has been reported.<sup>8</sup> There have also been other rare instances in which injury to the pancreas from toxins, trauma, or surgical removal of part of the pancreas has resulted in Type I Diabetes, however, these situations are often the minority.<sup>8</sup>

Since the pancreas no longer produces insulin due to the damage of the beta cells, living with Type I Diabetes is a constant challenge. Through multiple daily injections of artificial insulin with pens, syringes, or pumps, it is up to the patient to accurately monitor their blood glucose levels.<sup>9</sup> Carbohydrate counting is extremely important as this, in conjunction with their blood sugar levels, tells the patient how much insulin to take at any given time. After the initial diagnosis, there may be a "honeymoon" period in which the blood sugar can be controlled with

little to no insulin.<sup>10</sup> However, this phase does not last and lifelong insulin therapy is always required. Types of insulin for management range from rapid-acting to long-acting to intermediate.<sup>10</sup>

The goal of Type I Diabetes is to keep blood sugar levels as close to normal as possible and to delay and prevent complications that may arise later in life. While insulin injections allow a person with Type I Diabetes to stay alive, they do not cure the disease, nor do they prevent the disease from developing. Type I Diabetes is a serious disease that is often difficult to manage, however, treatment options are improving with the advancement of modern technology, and Type I Diabetics can lead full, active, and normal lives.

## **Type II Diabetes**

Type II Diabetes is the more commonly known type of diabetes, and is often what people think of when they hear diabetes mentioned. In contrast to Type I Diabetes, the pancreas of a Type II Diabetic still produces insulin, however it may not produce enough insulin or the body may not respond to the insulin that is produced.<sup>11</sup> Consequently, Type II Diabetics are not generally insulin dependent like Type I Diabetics. Type II Diabetes typically develops later in life after the age of 40, however, it has recently become more frequent with children. While genetics does play a part in the cause of Type II Diabetes, it is not the sole culprit as in Type I Diabetes. Lifestyle plays a major role and conditions such as obesity, poor diet, and lack of exercise are main contributors.<sup>12</sup> Treatment normally involves blood sugar monitoring, oral medication, and sometimes insulin therapy. However, the biggest treatment most often prescribed is lifestyle changes such as healthy eating and regular exercise.<sup>13</sup> In the United States,

there are an estimated 29.1 million Americans living with Type II Diabetes, equating to 9.3% of the population, and more than 1.4 million new diagnoses are made each year.<sup>14</sup> In the United Kingdom, there are an estimated 4 million individuals living with the condition, representing 6% of the entire country's population.<sup>15</sup> There are an estimated 415 million people living with diabetes in the world, and the United States and the United Kingdom are leaders in this domain.

The greatest causes of Type II Diabetes, as mentioned before, are lifestyle habits. While there are many risk factors such as age, pregnancy, stress, genetics, and race, the single best predictor of Type II Diabetes is weight.<sup>16</sup> Almost 90% of the individuals diagnosed with Type II Diabetes are overweight, particularly around the middle part of their bodies. Being overweight creates added pressure on the body's ability to use insulin properly to control blood sugar levels, and often leads to insulin resistance.<sup>16</sup> When the fat, liver, and muscle cells in the body do not correctly respond to insulin, blood sugar does not get into the cells to be stored for energy. When sugar does not enter the cells, sugar builds up in the blood stream causing hyperglycemia.<sup>17</sup> Symptoms of Type II Diabetes may not appear for several years; however, early symptoms are generally caused by the hyperglycemia experienced from high blood sugar. These symptoms include hunger, fatigue, blurred vision, and increased thirst.<sup>17</sup>

Unlike Type I Diabetes, Type II Diabetes is somewhat curable. The short-term goal is to first lower the patient's high blood glucose levels. This is often done with oral medications and occasionally insulin therapy.<sup>17</sup> Once this is under control, the long-term goals involve preventing further complications and health problems that often arise from Type II Diabetes. Treatments in this regard generally involve lifestyle changes. Incorporating a good diet is often at the heart of this dealing. A high-fiber, low-fat diet including fruits, vegetables, and whole grains is often prescribed. Patients are also advised to eat fewer refined carbohydrates, sweets, and animal



products that may be high in cholesterol.<sup>13</sup> Along with diet, regular aerobic exercise is also suggested. Aiming for at least 30 minutes of exercise five days a week is ideal, as exercise not only helps lower blood sugar levels but also is crucial in other health aspects such as cardiovascular health.<sup>13</sup> While Type II Diabetes is reversible, most patients are advised to still monitor their blood sugar levels occasionally. As blood sugar levels can be unpredictable, careful monitoring is the only way to make sure that levels stay within the targeted range. The frequency of checks is often unique to each patient and is something that is agreed upon by the patient and their doctor.<sup>13</sup>

### **United Kingdom Healthcare System**

Launched in 1948, the United Kingdom National Health Service (NHS) was born out of the idea that good healthcare should be accessible to all, regardless of social status or wealth. This ideal has been at the heart of the NHS, and is one of their core principles as the country implements one of the largest socialized healthcare systems in the world. Except for a few changes such as certain prescription medications, optical services, and dental services, the NHS has remained free for United Kingdom citizens since its inception in 1948. It covers everything from routine screenings, long-term conditions, transplants, emergency treatment, and even end of life care. Servicing more than 64.6 million people in the United Kingdom, including 54.3 million citizens in England alone, the NHS sees and treats over 1 million patients every 36 hours.<sup>18</sup>

Together with the United States Department of Defense, McDonalds, Walmart, and the Chinese People's Liberation Army, the NHS is one of the world's largest workforces.<sup>18</sup> Ranked in the top 5 largest workforces in the world, the NHS employs more than 1.5 million people. Of

these, the clinical staff includes 150,273 doctors, 40,584 general practitioners, 314,966 nurses, 18,862 ambulance staff, and 111,127 hospital and community medical and dental staff.<sup>19</sup> The NHS is the largest aspect of the British government by far, and ranks above 10 other countries (Australia, Canada, France, Germany, Netherlands, New Zealand, Norway, Sweden, Switzerland, and the United States) in terms of efficiency and equity according to the 2014 Commonwealth Fund.<sup>20</sup>

Funding for the NHS comes directly from taxation. The Health and Social Care Act of 2012 moved the responsibility of funding the program from the Department of Health to a shared commitment between NHS England and NHS Improvement. When it was first founded, the NHS had a budget of £437 million. Today, the overall NHS budget is around £116.4 billion with NHS England contributing £101.3 billion.<sup>18</sup> This budget is expected to increase to almost £120.2 billion by the year 2019, as the average health expenditure per capita in the United Kingdom has risen from £1,868 to £2,057 since 2011.<sup>19</sup>

### **United States Healthcare System**

Unlike the United Kingdom, the United States does not have a uniform health system, no universal health care coverage, and only recently was legislation enacted that required healthcare coverage for almost everyone in the United States. Rather than implementing one national health service, or single-payer national health system, or a multi-payer universal health system, the United States employs a hybrid model of all three.<sup>21</sup> Most health care, even if publicly financed, is delivered privately. In 2014, 238.2 million people in the United States had coverage, equating to 89.6% of the total United States population. 66% of these individuals were workers who were

covered through a private health insurance plan and 36.5% of these individuals received insurance through the government through programs such as Medicare, Medicaid, or Veterans Administration.<sup>21</sup> Furthermore, as of 2014, nearly 32.9 million people in the United States had no health insurance or way of receiving care.<sup>21</sup>

In recent years, the topic of healthcare in the United States has been one of great debate with the implementation of the Affordable Care Act, more commonly known as ObamaCare. On March 23, 2010, President Obama signed the Patient Protection and Affordable Care Act into law.<sup>22</sup> Under the law, people in the United States who do not qualify for an exemption are required to obtain a minimum amount of healthcare coverage. Essentially, the provisions of the Affordable Care Act aim to provide better and more affordable coverage for all United States citizens. Specifically, the law focuses on improving healthcare nationwide, providing more effective healthcare, offering more affordable choices for healthcare, reforming the way insurers and providers offer services, removing barriers that prevent individuals from obtaining healthcare, and providing incentives such as tax breaks so employers cover their workers' healthcare.<sup>23</sup> This law was met with a considerable amount of backlash by the Republican Party of the American two-party system. Consequently, with the election of President Donald Trump, Congress is considering repealing and replacing the Affordable Care Act in 2017.<sup>22</sup>

In regards to spending and cost of healthcare, the United States is notorious for being the largest spender of healthcare in the world. In 2014, the United States spend an average of \$9,523 per capita and had a total national expenditure of \$3.0 trillion.<sup>24</sup> This accounted for 17.8% of the Gross Domestic Product (GDP) for that year and costs had increased 5.8% from the previous year.<sup>25</sup> 33% of this cost was covered by private health insurances, while 20% was covered by Medicare, 17% by Medicaid, and 11% from out of pocket spending.<sup>25</sup> For the years 2015-2025,

healthcare costs in the United States are expected to grow at an average rate of 5.8% per year, which is 1.3% faster than the Gross Domestic Product per year over this period.<sup>25</sup> Given the Affordable Care Act's major coverage expansions and premium subsidies, it is predicted that 47% of national health spending will be covered by the government by 2025.<sup>25</sup>

## **Chapter 3**

### **Methods**

#### **Population**

The sample for the public survey was drawn from a variety of sources. These sources included online public Type II Diabetes forums and social media. The survey was completely anonymous and researchers did not request any personal information such as name, address, ethnic background, or gender. Of the 140 participants surveyed, 49% (69 participants) were from the United Kingdom, 49% (69 participants) were from the United States, and 2% (2 participants) were from an unknown country and were thus excluded from the rest of the study. The sample frame was completely random and subjects were selected based upon their nationality and whether they or someone they knew had been diagnosed with Type II Diabetes.

The sample for the provider survey was also drawn from a variety of sources. These sources included personal emails, phone calls, and social media. This survey was also completely anonymous and researchers did not request any personal information such as name, address, degree, ethnic background, or gender. However, researchers did request job title, number of years in practice, and country in which they practice. Of the 19 healthcare providers surveyed, 26% (5 participants) were from the United Kingdom, 69% (13 participants) were from the United States, and 5% (1 participant) were from an unknown country and thus excluded from the rest of the survey. The average length of time working as a healthcare provider was 10.38 years for the United States and 23.2 years for the United Kingdom. The average length of time working with Type II Diabetes was 10 years for the United States and 16.2 years for the United

Kingdom. The range of specialties and professions included Physician, Nurse, Physician Assistant, Paramedic, Nursing Assistant, and specialists. The sampling frame for this survey was also completely random and subjects were selected based on their country of practice.

It should be noted that these surveys do not include all healthcare providers or Type II Diabetic patients in the United States and the United Kingdom. Therefore, any generalizations that are drawn from these surveys are limited to those who responded to the surveys and should not be taken as an all-inclusive generalization for each country.

### **Sampling**

Poor responses to surveys have been repeatedly reported for these types of studies. Recommendations for overcoming these problems include using graphics and various question writing techniques, putting the interesting questions first, making the questions user-friendly, using bold letters, reducing the length of the survey, explaining that the respondent's identity was completely protected and anonymous, and using mixed mode surveys.<sup>26</sup> However, regardless of these recommendations, it was found that response rates were still generally poor, especially in regards to healthcare providers.

Nevertheless, these recommendations were still considered. Various questions and question types were created and the questions were made user friendly by using a scale of 1 to 10. This scale was also incorporated to decrease the amount of time and effort the survey would take to complete. Respondents were also informed that the survey was completely confidential and anonymous and the main questions were placed towards the beginning of the surveys.

There were some differences between the Public Survey and the Provider Survey due to the nature of the subjects being surveyed. Because physicians are a more homogenous group

than those of the public, they may not require large samples to ensure that the data recorded is valid. Thus, the goal for the number of provider responses from each country was 5 and the goal for the number of public responses from each country was 50. The survey for the providers was also slightly longer based on the assumption that those with more education would be more inclined to participate in a longer survey than those with lower levels of education. The types of questions for the provider survey also included more open-ended question as opposed to the public scaled questions. This was done under the thought process that providers would have more desire to elaborate on their answers and would be more interested the study. Realizing this, the questions were made accordingly.

The original sample size was to recruit approximately 50 patients and 5 providers from each country for a total goal of 110 responses, however additional responses were accepted. Equal numbers of males and females were attempted; however, this was not a large factor in the study. Furthermore, while the population surveyed was majority white, patients and providers of diverse backgrounds were also considered and recognized.

Sampling and recruitment took place via paper and pencil and a website called SurveyMonkey©. Local diabetes support groups, healthcare professionals, and social media platforms were also used for this purpose. Facebook, phone calls, and emails were used to inquire about participation. No reference was made in oral or written reports that could link participants to the study. The survey did not ask for any information that would identify who the responses belonged to. Participants were informed of the content of the study during the consent process to ensure their ease with the research situation in terms of intrusiveness and other potential abstract forms of discomfort. The Pennsylvania State University's Office for Research Protections, the Institutional Review Board and the Office for Human Research Protections in

the Department of Health and Human Services may review records related to this research study. In the event of any publication or presentation resulting from the research, no personally identifiable information was shared because participant names are in no way linked to their responses.

### **Data Collection**

The researcher prepared, revised, and polished a cover letter that was provided at the beginning of every survey. This cover letter provided the participant with all their rights in taking the study and explained the anonymity of the study. Databases were formulated through the main surveying method (SurveyMonkey.com ©) and results were kept in excel sheets on the researcher's private and locked computer. These databases tracked the responses to each question and ensured that the responses to each survey were completely anonymous. Finally, the last page of the survey provided contact details for the main researcher and encouraged participants to get in touch with the researcher in case any questions arose.

Implied consent was obtained from participants at the time of completing the survey. A consent document was provided to ensure that each participant understood the study and terms of participating in the survey. The document did not need to be signed as implied consent was used. Each participant was given the opportunity to ask questions and decline participation if they so desired. To minimize coercion or undue influence, all participants will be told that their participation in the study is completely voluntary and their decision to either participate or not will be confidential at the time they complete the survey.

To collect data included with this study, anonymous surveys were utilized to determine whether one country's healthcare system offered benefits in the treatment of Type II Diabetes



that the other one lacked. All methods and plans were passed by The Pennsylvania State University Institutional Review Board before beginning any research. Contact with several Pennsylvania State University faculties were maintained throughout the project. Any observed or reported harm (adverse event) experienced by a subject or other individual, which in the opinion of the investigator is determined to be (1) unexpected; and (2) probably related to the research procedures was agreed to be reported to the IRB, however, none occurred.

The surveys were split into two categories, public and provider, with public referring to the patient population and provider referring to the doctors, nurses, and allied healthcare that assisted in treatment. The study used the surveys to generate culturally framed insight into the way that Type II Diabetes is prevented and treated in the United States and the United Kingdom. Individuals who were either patients or providers in the United Kingdom and the United States were recruited. Data collection involved a series of one-time surveys discussing patient's attitudes towards the care they've been provided and providers attitudes and treatment protocols. Completing the survey took everyone approximately 10 minutes.

Data was collected from several locations including Leeds, England, Leicester, England, State College, PA, USA, and Williamsport, PA, USA. To collect and report the data several inclusion criteria were established. The patients were preferably Type II Diabetics who had received care from either the United Kingdom or the United States healthcare systems. Healthcare providers were required to have taken care of Type II Diabetic patients in either the United Kingdom or the United States. Participants were also required to be over the age of 18 and must be able to understand and communicate in English. Exclusion criteria were also established for the surveys. Individuals too frail or ill to complete the surveys were excluded as

well as individuals under the age of 18 and not a citizen of either the United States or the United Kingdom.

### **Assessment Variables**

There were three primary assessment variables for this study: (1) attitudes towards a respondent's personal healthcare system and whether respondents felt there was room for improvement, (2) the general education of the public in regards to Type II Diabetes, and (3) generally treatment protocols of Type II Diabetes in each country. Attitudes were assessed through a variety of questions and mostly included a ranked scaled of 1 to 10 on topics such as satisfaction, care, and education made available to the public. Education was defined as the extent to which the public and providers were made aware of new treatments, prevention measures, and new research. Finally, general treatment protocols were assessed on the Provider Survey via a multiple-choice question. Throughout the questionnaires, each area was assessed and evaluated mainly on a ranked scaled of 1 to 10. Additional question regarding attitudes and personal opinions were evaluated using open-ended questions and providers were also given the opportunity to provide any additional information they thought would be beneficial for the study.

### **Analytical Approach**

The analyses for the surveys were done using Excel Spreadsheets©. A T-test was used to analyze the statistical relevance between United States and United Kingdom responses for both the public and providers. For the questions where ranking on a scale of 1 to 10 was involved, basic statistics such as mean, median, mode, and standard deviation were also calculated. These

values were then compared with each other to reach a conclusion. For the open-ended questions, responses were compared with each other between both countries.

## Chapter 4

### Results

#### Public Survey Results

Of the 177 individuals who responded to the Public Survey, 78% were eligible to complete the questionnaire based on the inclusion and exclusion criteria set forth in the “Methods” section (Figure 1: Public Survey Question, Eligibility Question 1). Of these 138 individuals, 49% (69 participants) were from the United Kingdom and 49% (69 participants) were from the United States (Figure 2: Public Survey Results, Eligibility Question 2).

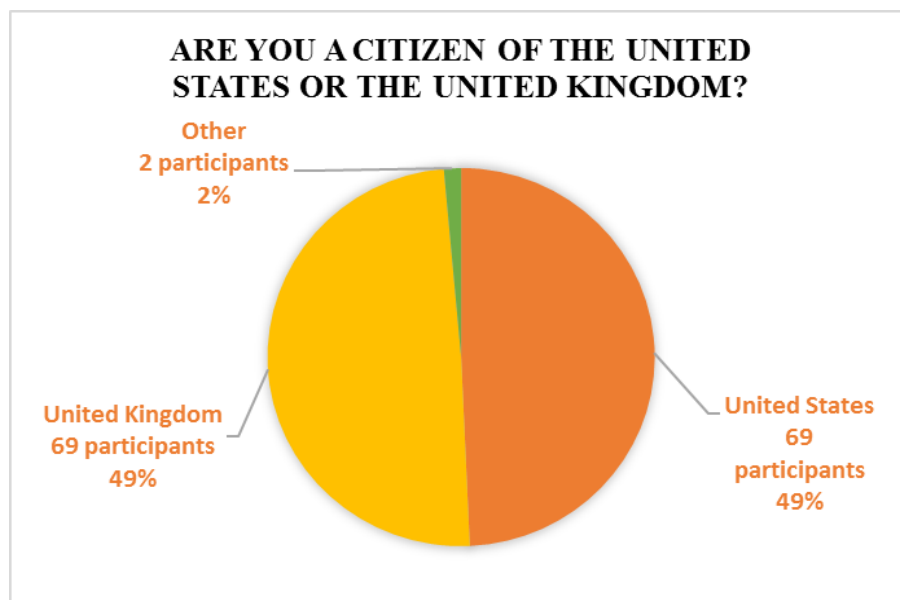


Figure 1: Public Survey Results, Eligibility Question 1

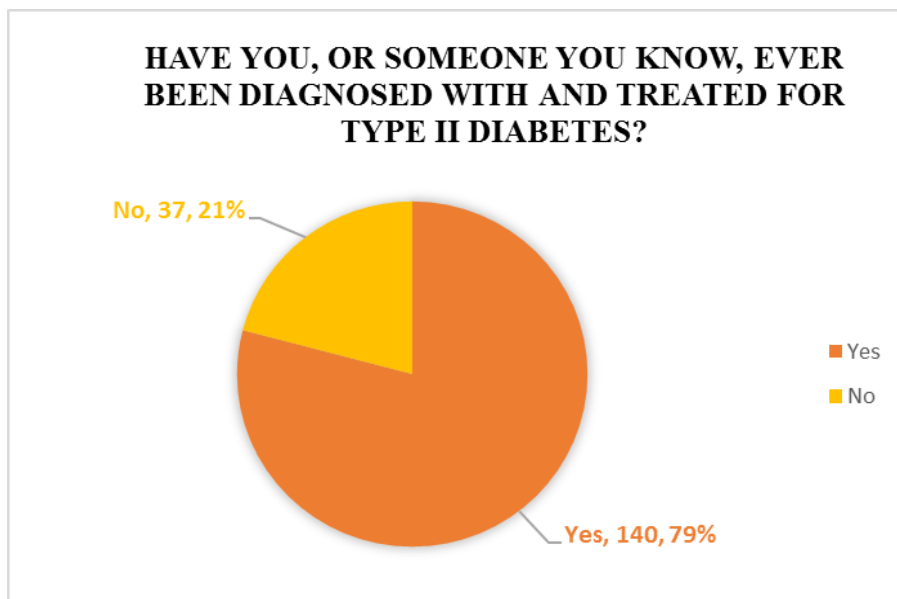


Figure 2: Public Survey Results, Eligibility Question 2

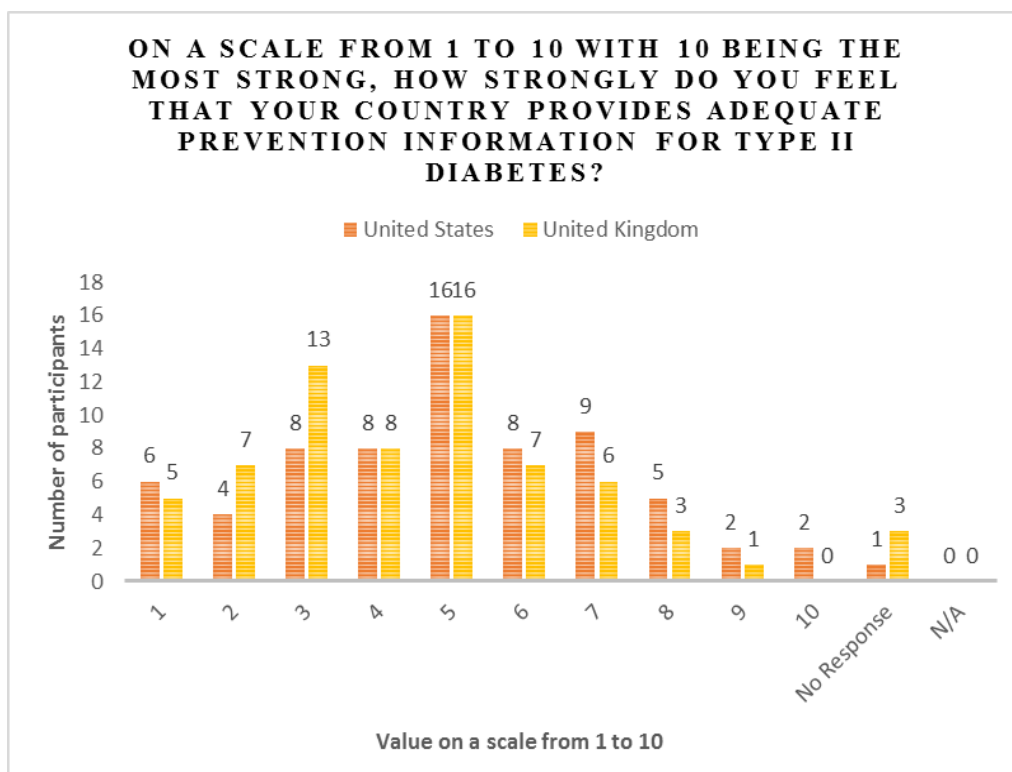


Figure 3: Public Survey Results, Question 1

Question 1 of the survey assessed how strongly participants felt that their country provided adequate information about Type II Diabetes on a scale from 1 to 10 (Figure 3: Public

Survey Results, Question 1). The United States responded with an average assessment of 4.985 with a standard deviation of 2.26 and the United Kingdom responded with an average assessment of 4.358 with a standard deviation of 1.94 (Table 1: Public Survey Results Statistical Analysis). The T-test value between the two countries for Question 1 was 0.086339 which suggests that the difference between the two sets of results is significant (Table 1: Public Survey Results Statistical Analysis).<sup>27</sup>

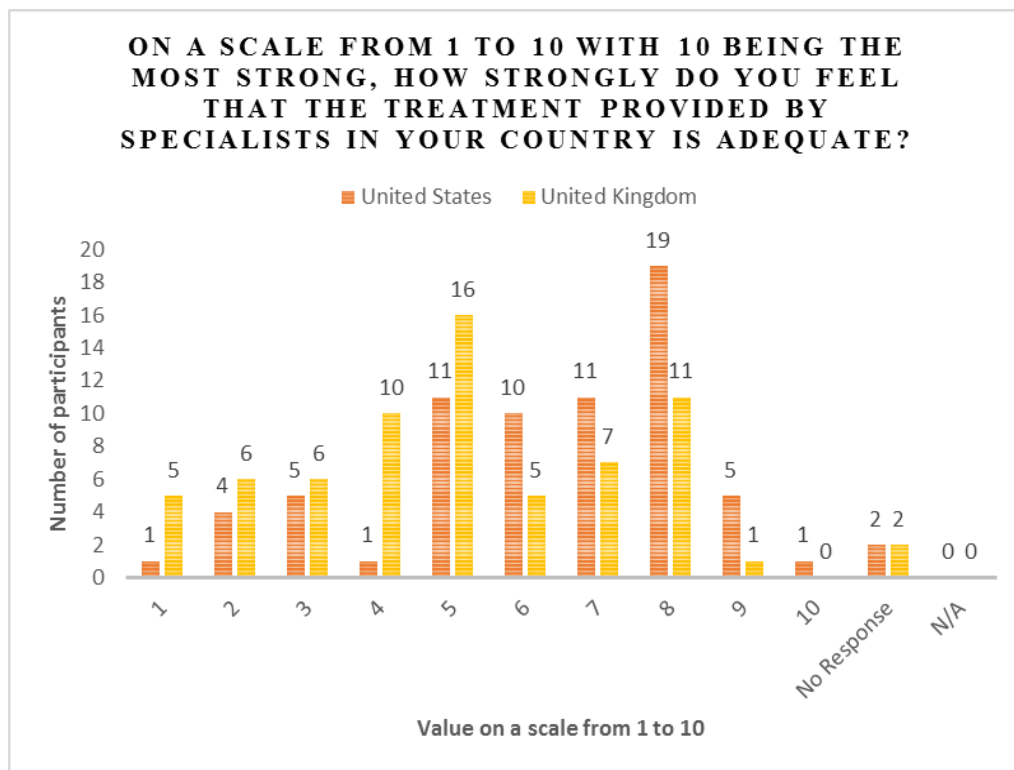


Figure 4: Public Survey Results, Question 2

The second question looked at how strongly the public felt that the treatment provided by their healthcare system was adequate based on a scale of 1 to 10 (Figure 4: Public Survey Results, Question 2). The United States' average response was 6.28 with a standard deviation of 2.09 and the United Kingdom's average response was 4.94 with a standard deviation of 2.19

(Table 1: Public Survey Results Statistical Analysis). The T-test value for Question 2 between the 2 countries was 0.000391 which also suggest that difference between the two values is noteworthy (Table 1: Public Survey Results Statistical Analysis).

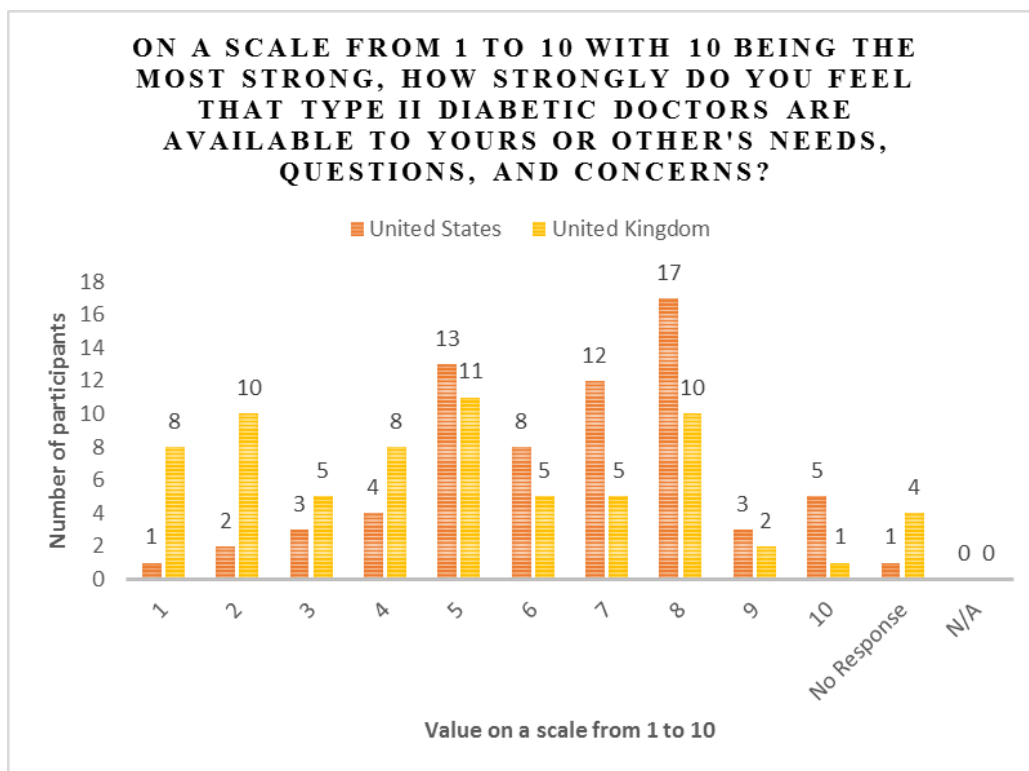


Figure 5: Public Survey Results, Question 3

Question 3 of the Public Survey aimed to assess how receptive and available patients felt their providers were to their needs, questions, and concerns on a scale of 1 to 10 (Figure 5: Public Survey Results, Question 3). The United States responded with an average of 6.471 with a standard deviation of 2.06 and the United Kingdom responded with an average of 4.662 and a standard deviation of 2.53 (Table 1: Public Survey Results Statistical Analysis). The T-test score for this question was rather small at  $1.52 \times 10^{-5}$  (Table 1: Public Survey Results Statistical

Analysis). This also suggests that the data obtained from this question had some statistical relevance.

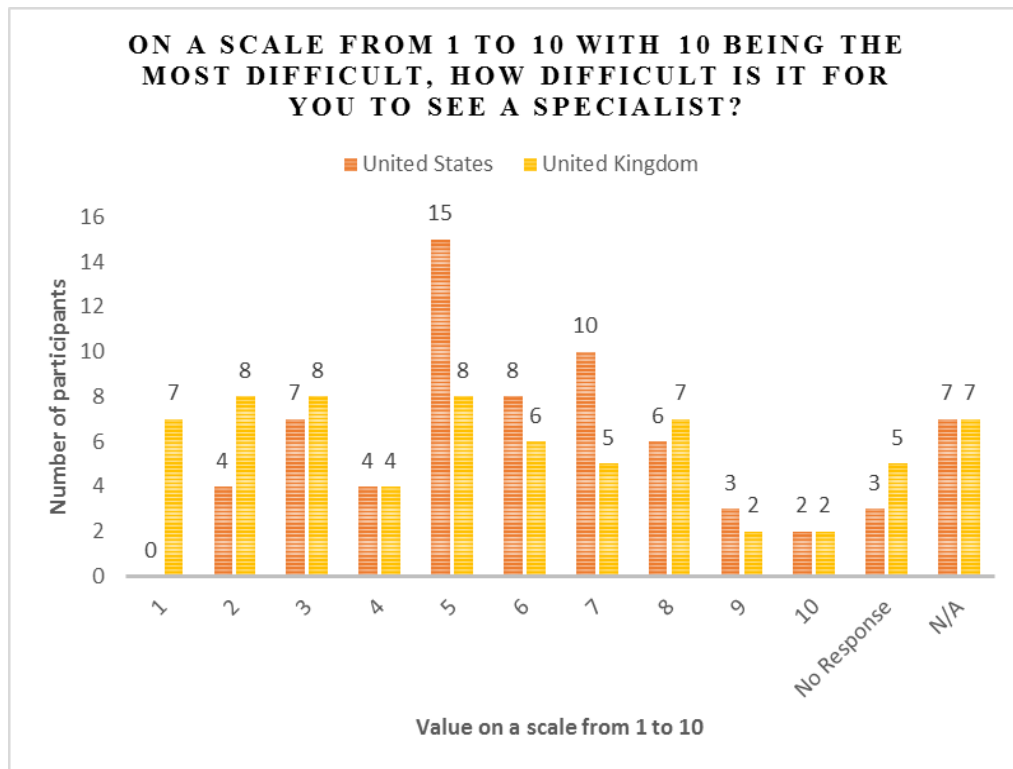


Figure 6: Public Survey Results, Question 4

The fourth question asked participants to rate on a scale of 1 to 10 how difficult it was for them to see and schedule an appointment with a specialist (Figure 6: Public Survey Results, Question 4). The average score for the United States was 5.64 with a standard deviation of 2.61 and the average score for the United Kingdom was 4.80 with a standard deviation of 2.95 (Table 1: Public Survey Results Statistical Analysis). The T-test for this question was 0.57416 which suggests that this may be a result of chance and the difference is not significant (Table 1: Public Survey Results Statistical Analysis).



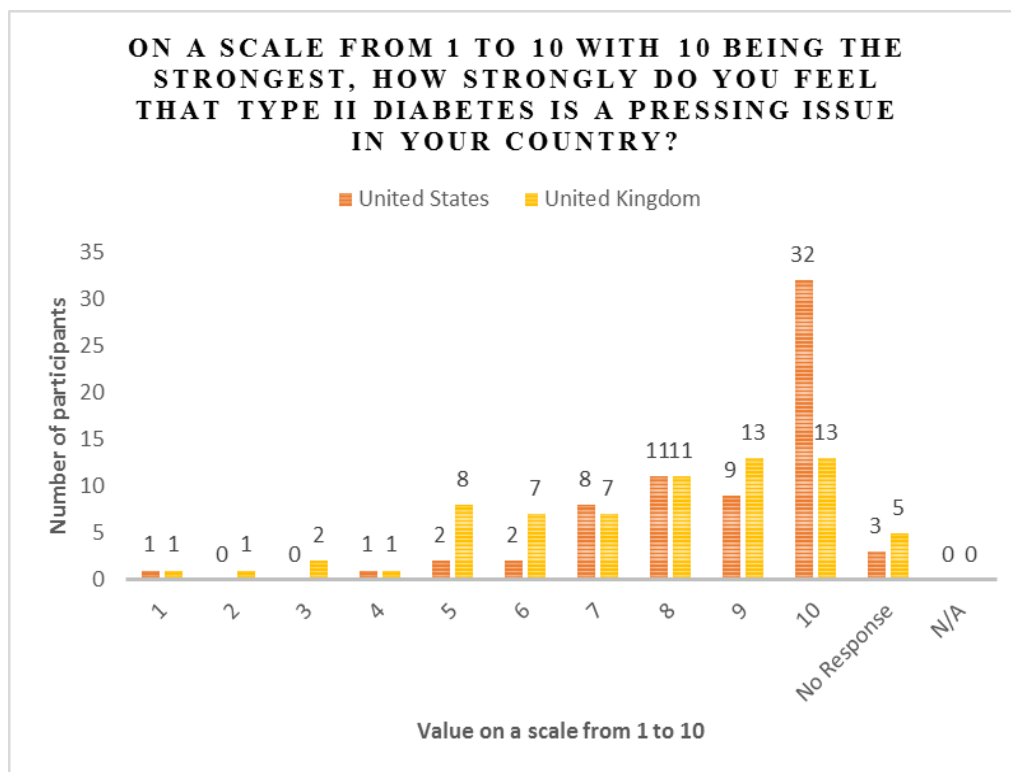
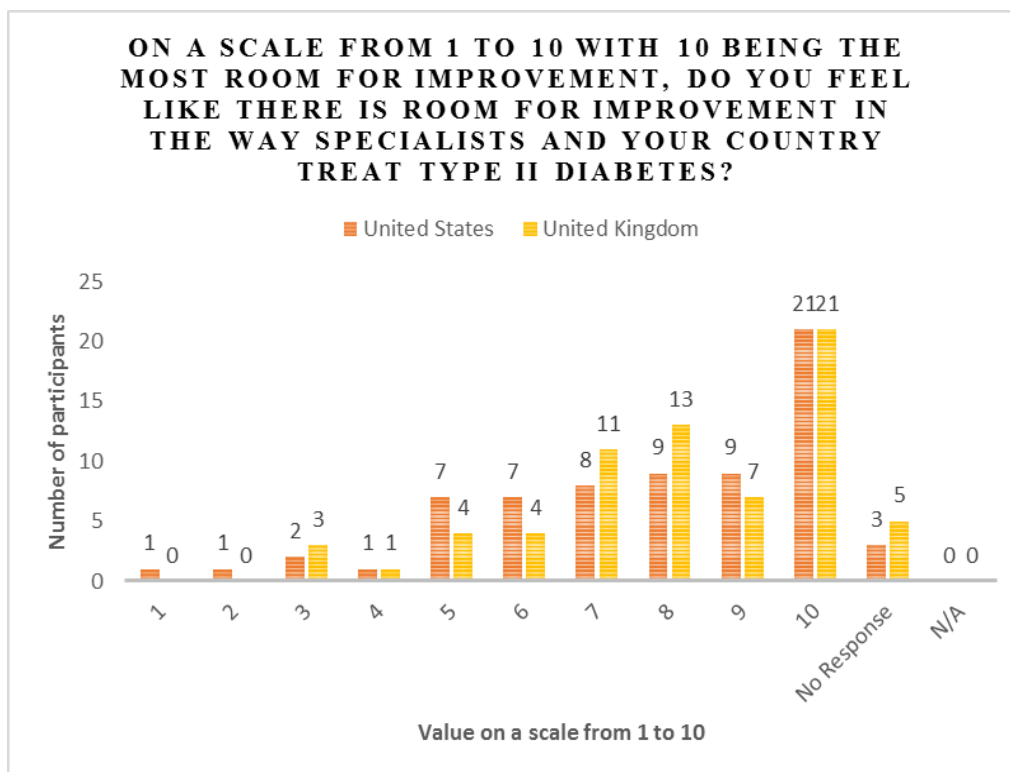


Figure 7: Public Survey Results, Question 5

Question 5 assessed how strongly the public felt that Type II Diabetes was a pressing issue in their country on a scale from 1 to 10 (Figure 7: Public Survey Results, Question 5). The public of the United States responded with an average of 8.67 and a standard deviation of 1.78. Meanwhile, the United Kingdom's public responded with an average of 7.48 and a standard deviation of 2.20 (Table 1: Public Survey Results Statistical Analysis). The T-test value for the fifth question of the public survey was 0.001055 suggesting that the data from this question possessed a large degree of statistical relevance (Table 1: Public Survey Results Statistical Analysis).



**Figure 8: Public Survey Results, Question 6**

The sixth question of the study for the public asked participants to rank how strongly they felt that there was room for improvement in the way specialists and their healthcare system treats Type II Diabetes (Figure 8: Public Survey Results, Question 6). For this question, the average score for the United States was 7.71 with a standard deviation of 2.28. The United Kingdom's public responded with an average of 7.98 and a standard deviation of 1.97 (Table 1: Public Survey Results Statistical Analysis). The T-test value for this question was 0.467294 (Table 1: Public Survey Results Statistical Analysis). While quite a bit higher than the most of the other questions for this survey, this value is still within the range that makes it statistically relevant however some degree of chance for the results of this question may be involved.

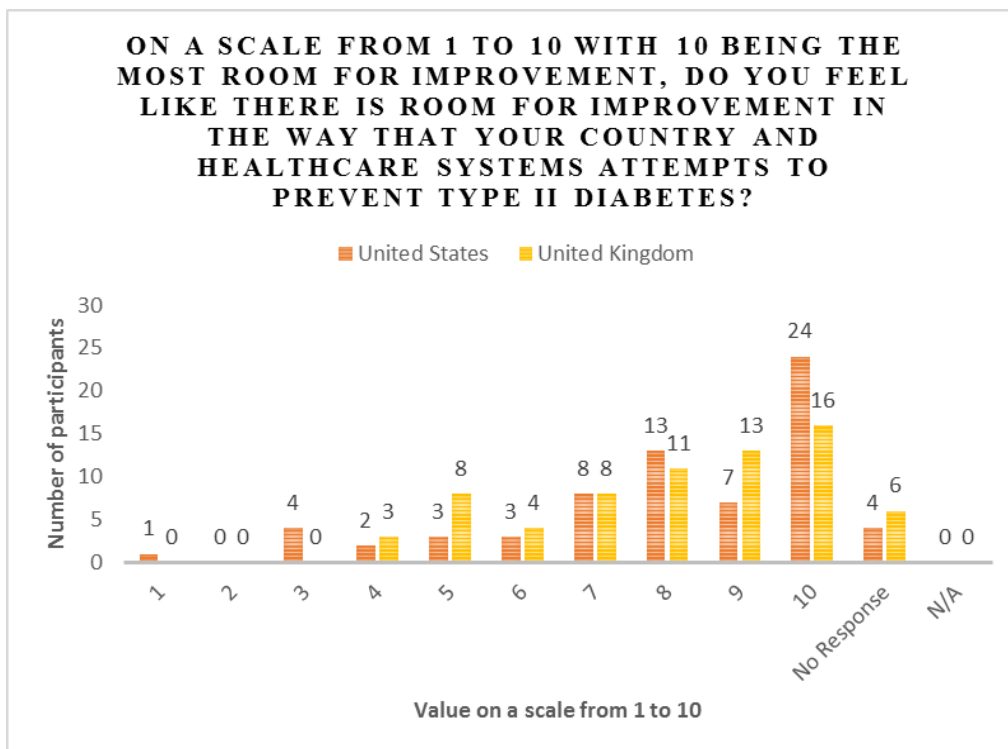
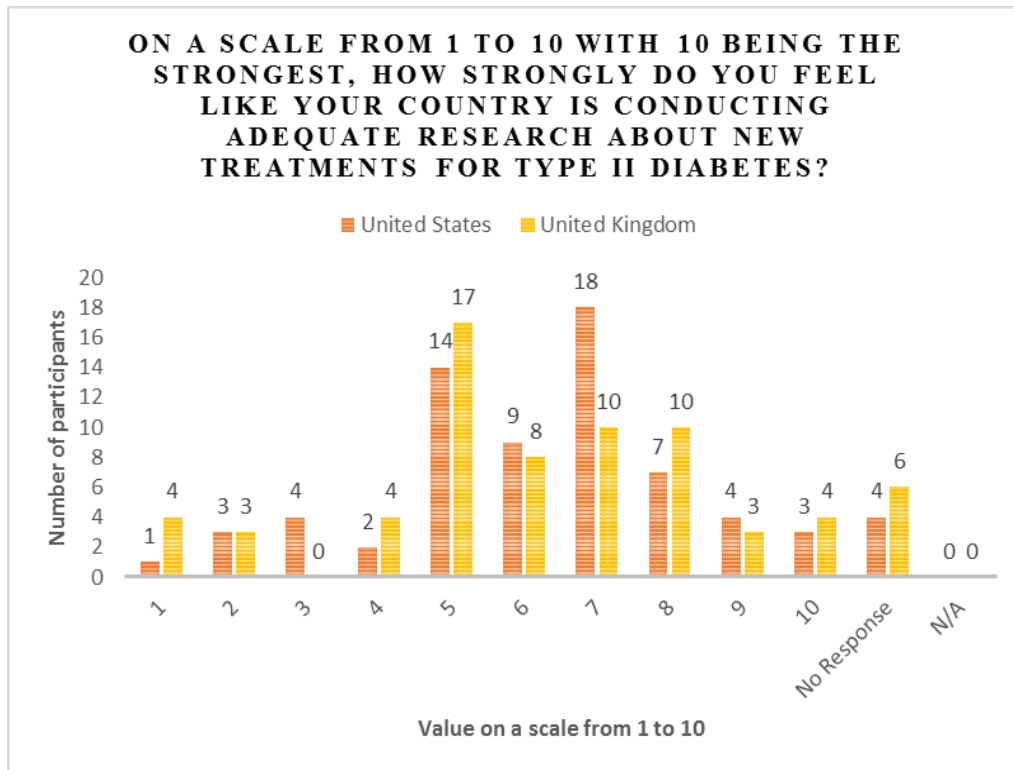


Figure 9: Public Survey Results, Question 7

Question 7 asked respondents to rank how strongly they felt there was room for improvement in the way their country attempted to prevent Type II Diabetes (Figure 9: Public Survey Results, Question 7). The United States responded with an average score of 7.95 and a standard deviation of 2.27 while the United Kingdom reported an average of 7.89 with a standard deviation of 1.88 (Table 1: Public Survey Results Statistical Analysis). The T-test value for this question was the highest of the Public Survey results at 0.86043 (Table 1: Public Survey Results Statistical Analysis). This suggests that the difference between the two values is not statistically significant and that the results of likely a product of chance.



**Figure 10: Public Survey Results, Question 8**

The final question of the Public Survey asked respondents to rank how adequately they thought their country was conducting research on Type II Diabetes on a scale from 1 to 10 (Figure 10: Public Survey Results, Question 8). The United States public responded with an average rating of 6.14 and a standard deviation of 2.01. Meanwhile, the United Kingdom reported an average of 5.97 and a standard deviation of 2.28 (Table 1: Public Survey Results Statistical Analysis). The T-test value for this question was 0.655517 and while lower than Question 7 this value also suggests that the difference between the two values is not statistically significant.

Table 1: Public Survey Results Statistical Analysis

QUESTION NUMBER	UNITED STATES				UNITED KINGDOM				T-TEST
	AVERAGE	MEDIAN	MODE	STANDARD DEVIATION	AVERAGE	MEDIAN	MODE	STANDARD DEVIATION	
1	4.985	5	5	2.262561	4.358	5	5	1.943922	0.086339
2	6.279	7	8	2.086528	4.94	5	5	2.18753	0.000391
3	6.471	7	8	2.062245	4.662	5	5	2.532766	1.52E-05
4	5.644	5	5	2.610227	4.793	5	5	2.950147	0.57416
5	8.667	9	10	1.783112	7.484	8	10	2.203836	0.001055
6	7.712	8	10	2.278766	7.984	8	10	1.971964	0.467294
7	7.954	8	10	2.2737	7.889	8	10	1.884667	0.86043
8	6.138	6	7	2.01461	5.968	6	5	2.278711	0.655517

### Provider Survey Results

Of the 19 healthcare professionals who completed the Provider Survey, 95% (18 participants) could be included in the study based upon the exclusion criteria that was set forth in the “Methods” section. Of those 19 participants, 26% (5 individuals) were from the United Kingdom, 69% (13 individuals) were from the United States, and 5% (1 individual) was from a country other than the United States or the United Kingdom (Figure 11: Provider Survey Results, Eligibility Question 1). The 5% from a third country were excluded from finishing the survey and as such 18 individuals were assessed.

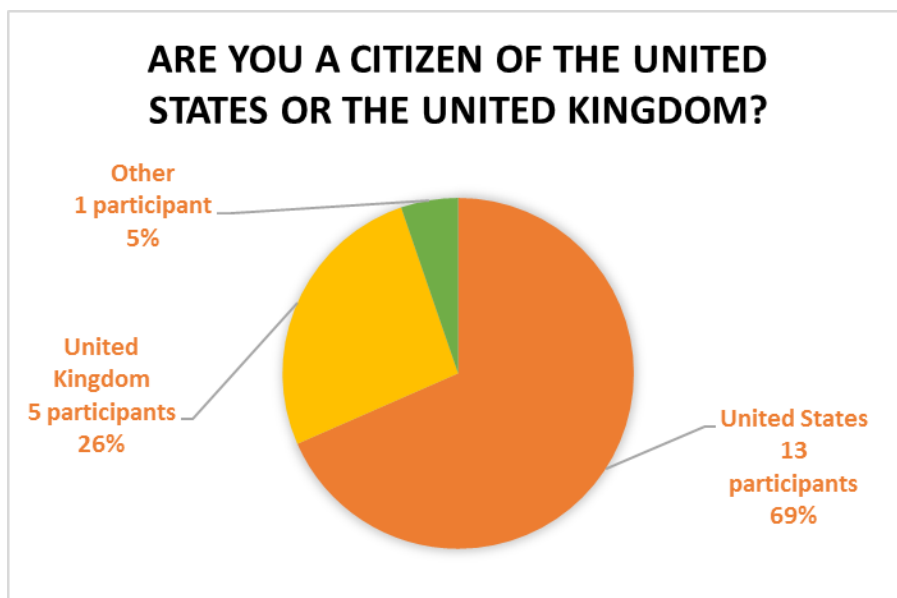


Figure 11: Provider Survey Results, Eligibility Question 1

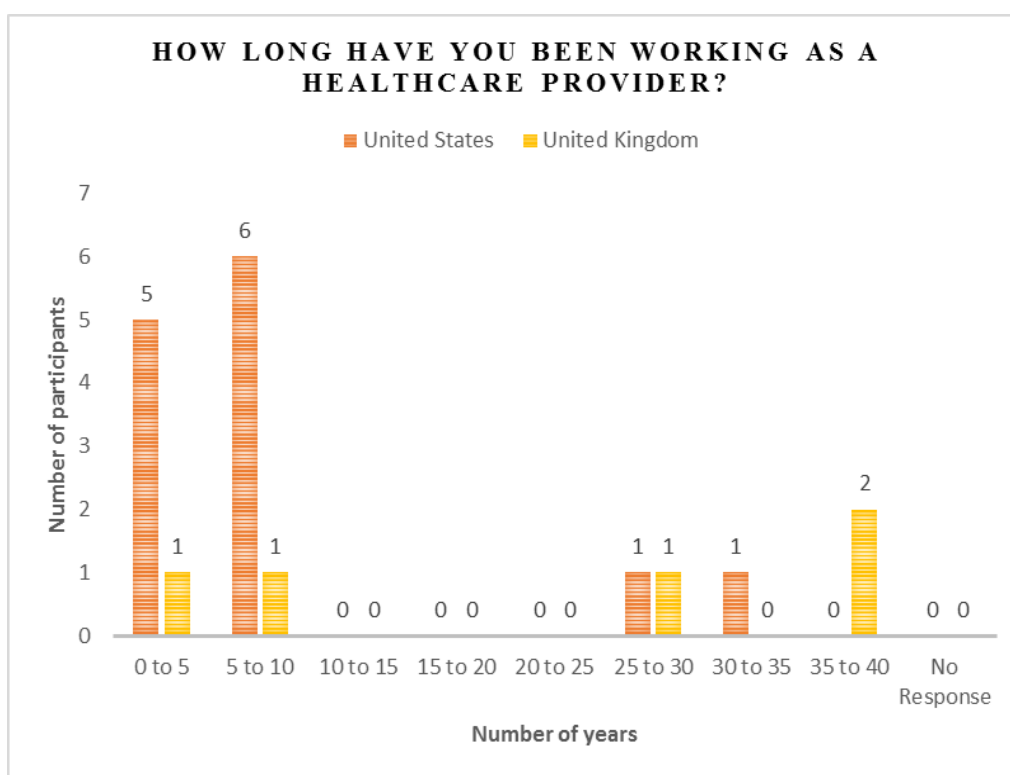


Figure 12: Provider Survey Results, Question 1

Question 1 of the Provider Survey asked participants how long they had been working in a healthcare related field (Figure 12: Provider Survey Results, Question 1). This question was

used to better understand the population being evaluated. Participants were asked to choose one of the options from a multiple-choice list that included 5 year brackets from 0 years to 40 years (Figure 12: Provider Survey Results, Question 1). The United States population responded with an average of 10.38 years with a standard deviation of 11.10 and the United Kingdom responded with an average of 23.2 years and a standard deviation of 15.99. The T-test value between these two sets of data was 0.154793 (Table 5: Provider Results Statistical Analysis). This value suggests that the differences between the two sets of data is not significant and is most likely a result of chance.

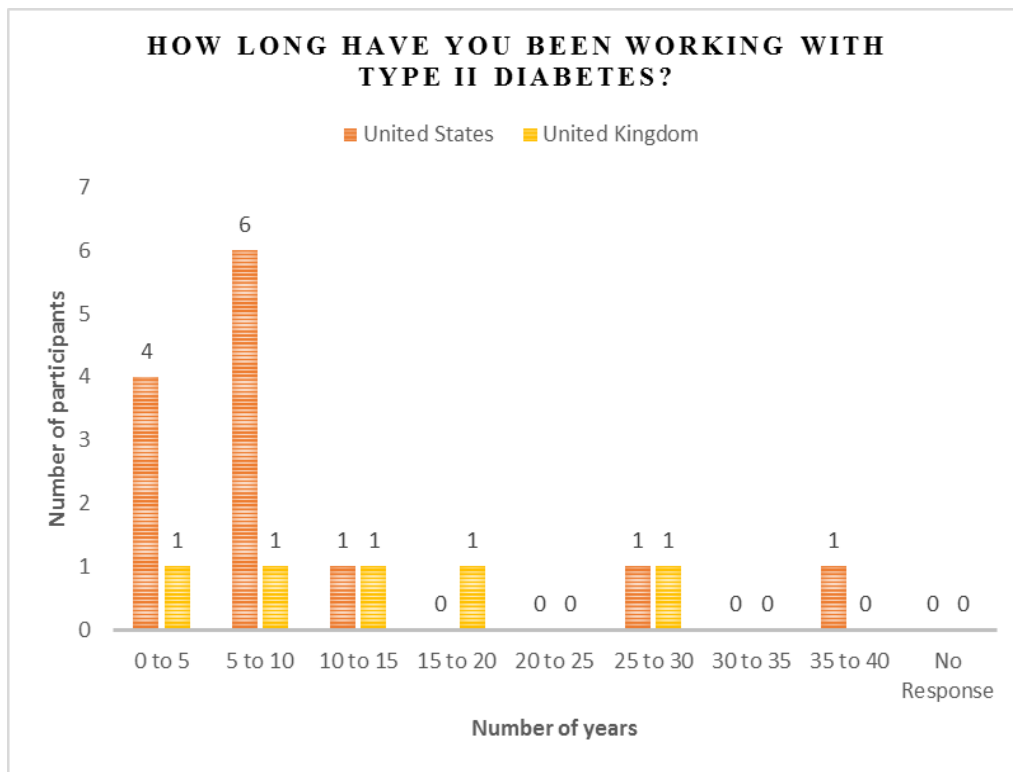


Figure 13: Provider Survey Results, Question 2

The second question of the survey asked participants how long they had been working with Type II Diabetes (Figure 13: Provider Survey Results, Question 2). This question, like

question 1, also aimed to assess the validity of the population. Participants were once again asked to respond to a multiple-choice question and choose one of several brackets from 0 to 40 years broken into possible answers of 5 years (Figure 13: Provider Survey Results, Question 2). For this question, the United States responded with an average of 10 years with a standard deviation of 11.64 while the United Kingdom responded with an average of 16.2 years and a standard deviation of 13.22. The T-test value for this question was 0.371621 (Table 5: Provider Results Statistical Analysis). Like question 1, this value also suggests that the difference between the two country's responses is not statistically relevant and is most likely a result of chance.

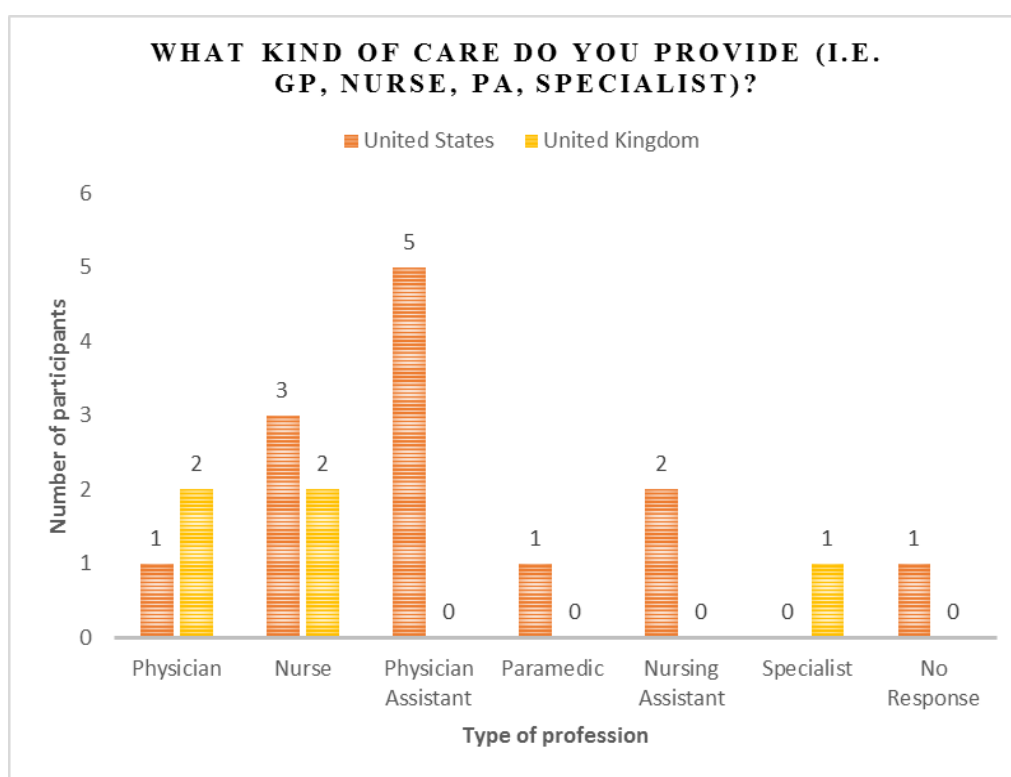


Figure 14: Provider Survey Results, Question 3

Question 3, like question 1 and question 2, attempted to gather more information about the population being studied by asking the respondents what their profession was (Figure 14:



Provider Survey Results, Question 3). This question was open-ended and respondents had the opportunity to submit their job title to the survey. Responses received included Physician, Nurse, Physician Assistant, Paramedic, Nursing Assistant, and Specialist. The United States population for this survey included 1 Physician, 3 Nurses, 5 Physician Assistants, 1 Paramedic, 2 Nursing Assistants, 0 Specialists, and 1 unknown. For this survey, the United Kingdom population included 2 Physicians, 2 Nurses, 0 Physician Assistants, 0 Paramedics, 0 Nursing Assistants, 1 Specialist, and 0 unknowns (Figure 14: Provider Survey Results, Question 3).

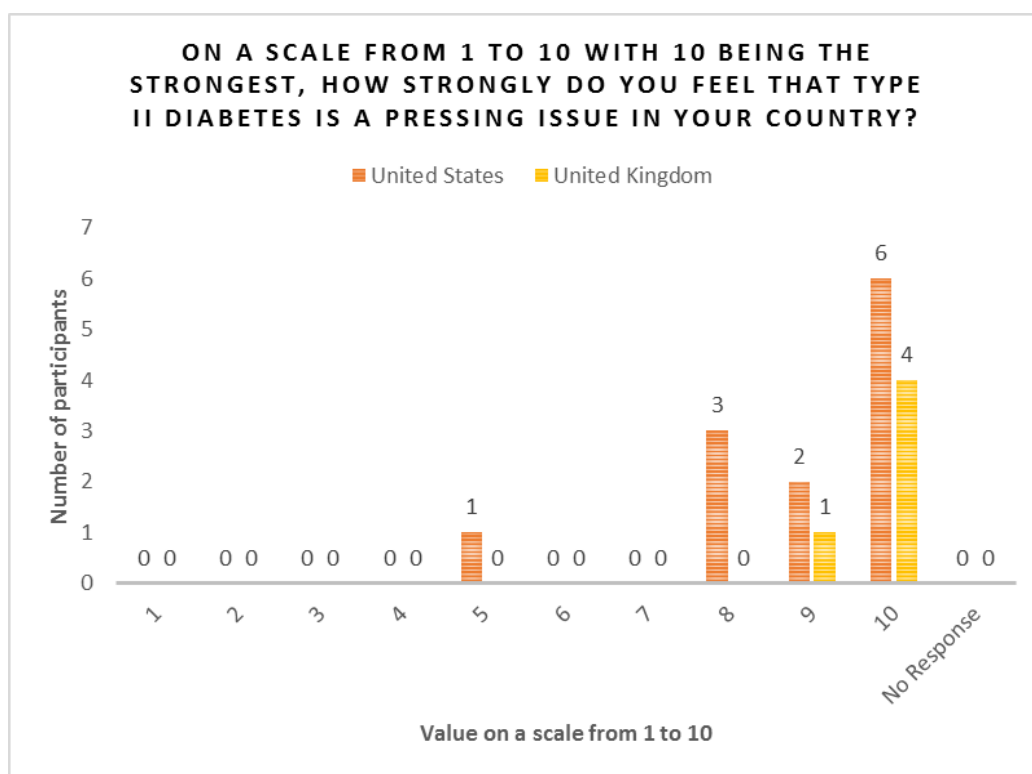


Figure 15: Provider Survey Results, Question 4

Question 4 of this survey was the first question that truly assessed healthcare providers' attitudes regarding Type II Diabetes. This question asked respondents to rank on a scale of 1 to 10 how strongly they felt Type II Diabetes was a pressing problem in their country (Figure 15:

Provider Survey Results, Question 4). For this question, the United States responded with an average of 8.917 and a standard deviation of 1.51. Conversely, the United Kingdom responded with an average of 9.8 and a standard deviation of 0.45 (Table 5: Provider Results Statistical Analysis). The T-test value for this question was 0.061125, and while only slightly higher than 0.05 still suggests that the difference between these two datasets is not statistically significant and could be a result of chance (Table 5: Provider Results Statistical Analysis).

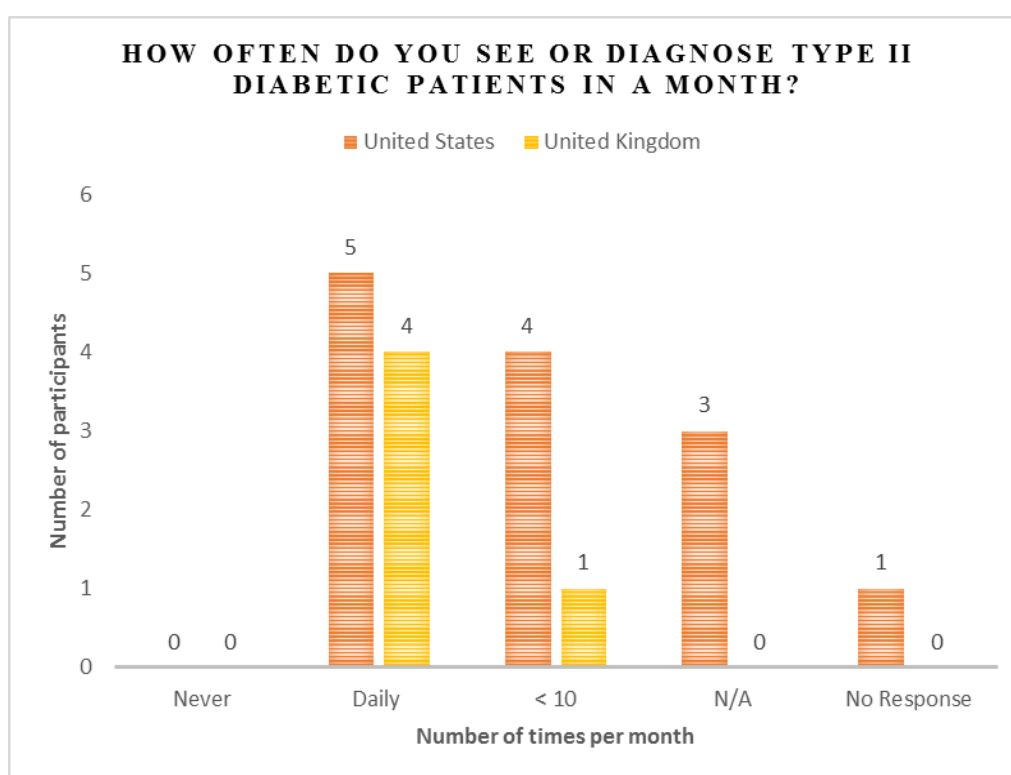


Figure 16: Provider Survey Results, Question 5

The fifth question of the survey attempted to evaluate how often the responding healthcare providers treated someone with Type II Diabetes in the average month. Respondents were asked to choose one of four multiple choice responses that included “Never”, “Daily”, “<10”, and “N/A” (Figure 16: Provider Survey Results, Question 5). Of these options, 0 United

States respondents stated that they saw Type II Diabetic patients never, 5 stated that they saw Type II Diabetic patients daily, 4 stated that they saw Type II Diabetic patients less than 10 times per month, 3 stated that the question did not apply to them, and 1 respondent did not answer (Figure 16: Provider Survey Results, Question 5). Similarly, 0 United Kingdom respondents reported that they never see Type II Diabetic patients, 4 stated that they see Type II Diabetic patients daily, and 0 stated that this question did not apply to them (Figure 16: Provider Survey Results, Question 5).

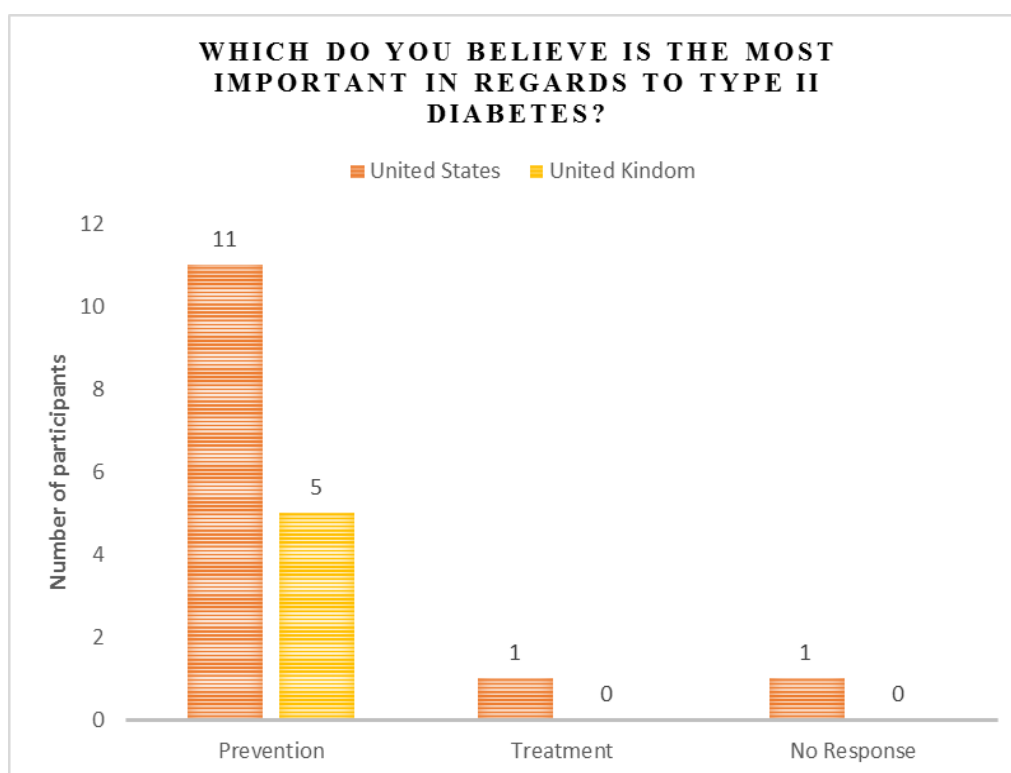
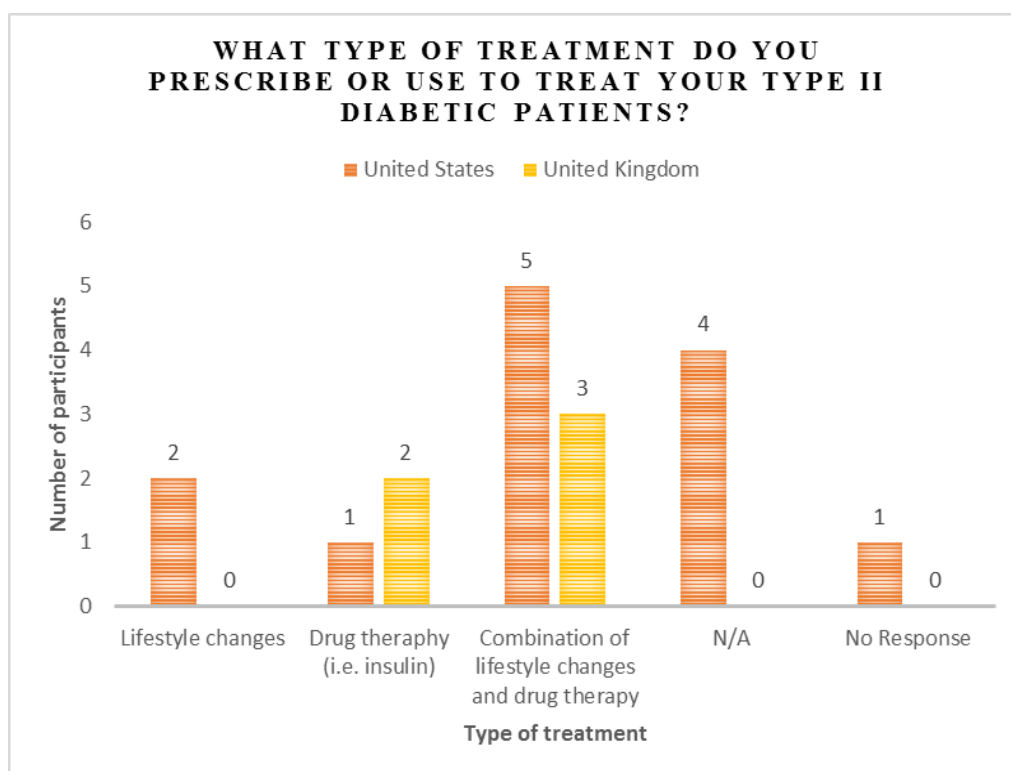


Figure 17: Provider Survey Results, Question 6

Question 6 of the Provider Survey wanted to examine healthcare providers' attitudes and opinions towards providing care for Type II Diabetic patients. The question asked respondents to choose whether they felt that treatment or prevention was more important in treating Type II

Diabetes (Figure 17: Provider Survey Results, Question 6). For this question, 11 United States respondents reported that they felt prevention was most important, 1 responded that they felt treatment was most important, and 1 respondent did not respond. Similarly, 5 United Kingdom respondents reported that they felt prevention was most important and 0 reported that they felt treatment was most important (Figure 17: Provider Survey Results, Question 6).



**Figure 18: Provider Survey Results, Question 7**

The seventh question of the survey continued with the ideas of question 6. This question asked respondents to answer a multiple-choice question regarding what kinds of treatment they provide to their Type II Diabetic patients. Respondents had the following four answer options for this question: lifestyle changes, drug therapy (i.e. insulin), combination of lifestyle changes and drug therapy, and not applicable (Figure 18: Provider Survey Results, Question 7). Of the

respondents from the United States, 2 reported that they prescribe only lifestyle changes, 1 reported that they prescribe only drug therapy, 5 reported that they prescribe a combination of both, 4 responded that the question was not applicable to them, and 1 respondent did not respond. Of the respondents from the United Kingdom, 0 reported that they prescribe only lifestyle changes, 2 reported that they prescribe only drug therapy, 3 reported that they prescribe a combination of both, and 0 responded that the question did not apply to them (Figure 18: Provider Survey Results, Question 7).

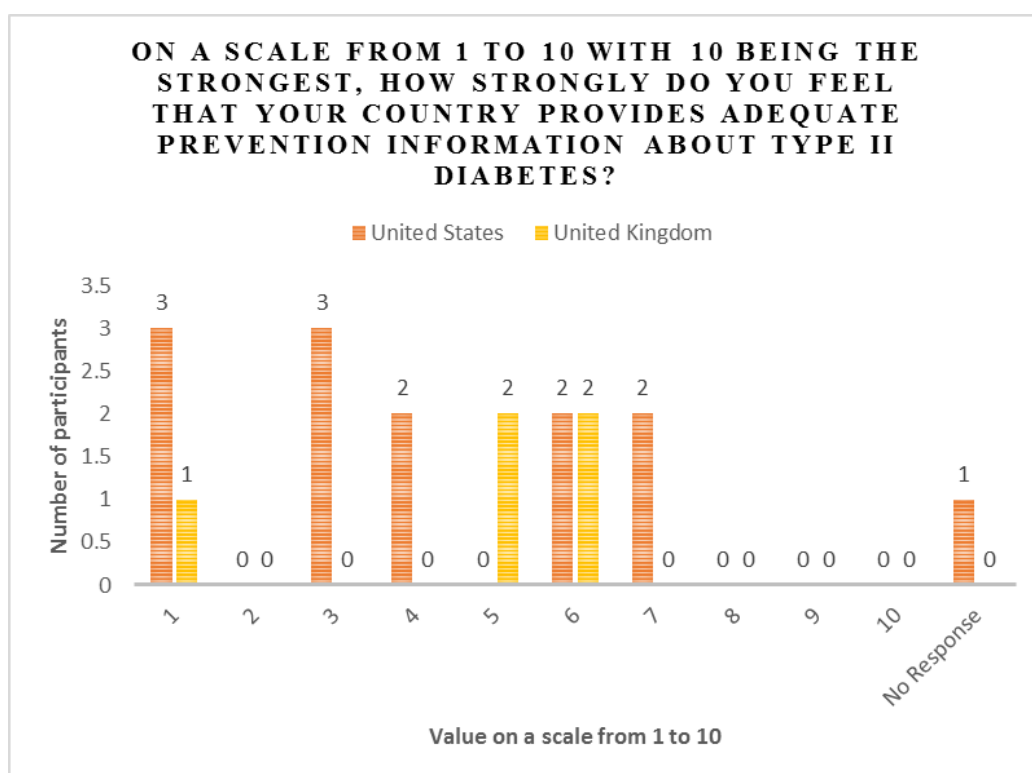
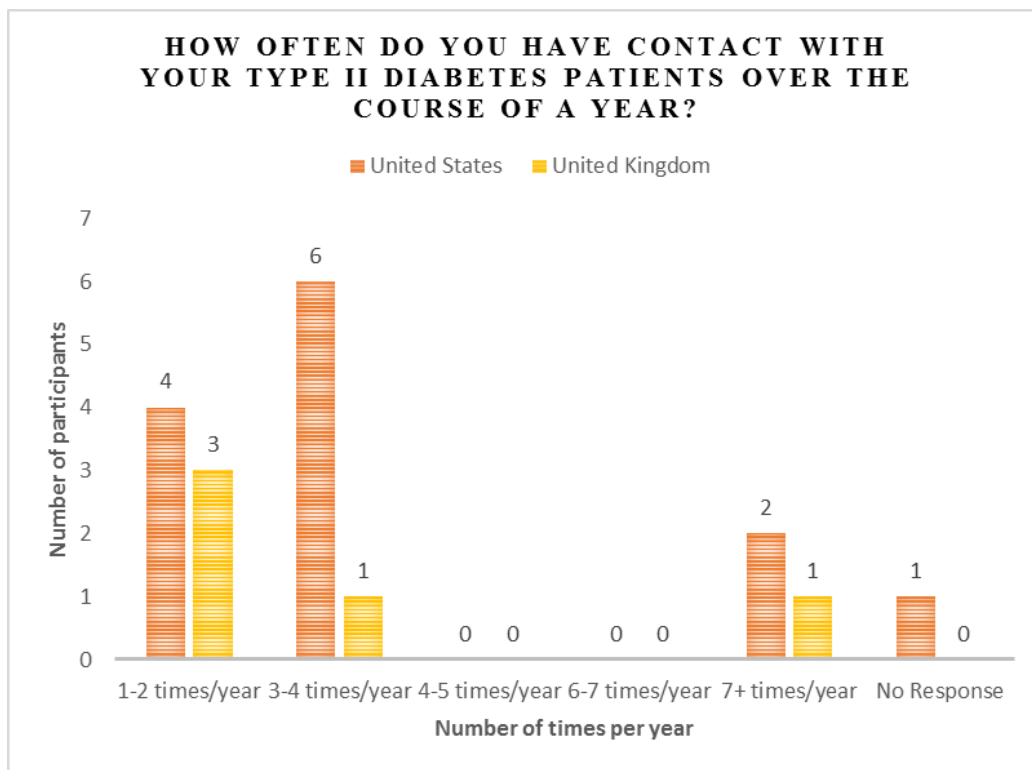


Figure 19: Provider Survey Results, Question 8

Question 8 asked healthcare providers to report on a scale of 1 to 10 how strongly they felt their country provided adequate prevention information about Type II Diabetes (Figure 19: Provider Survey Results, Question 8). The United States providers responded with an average

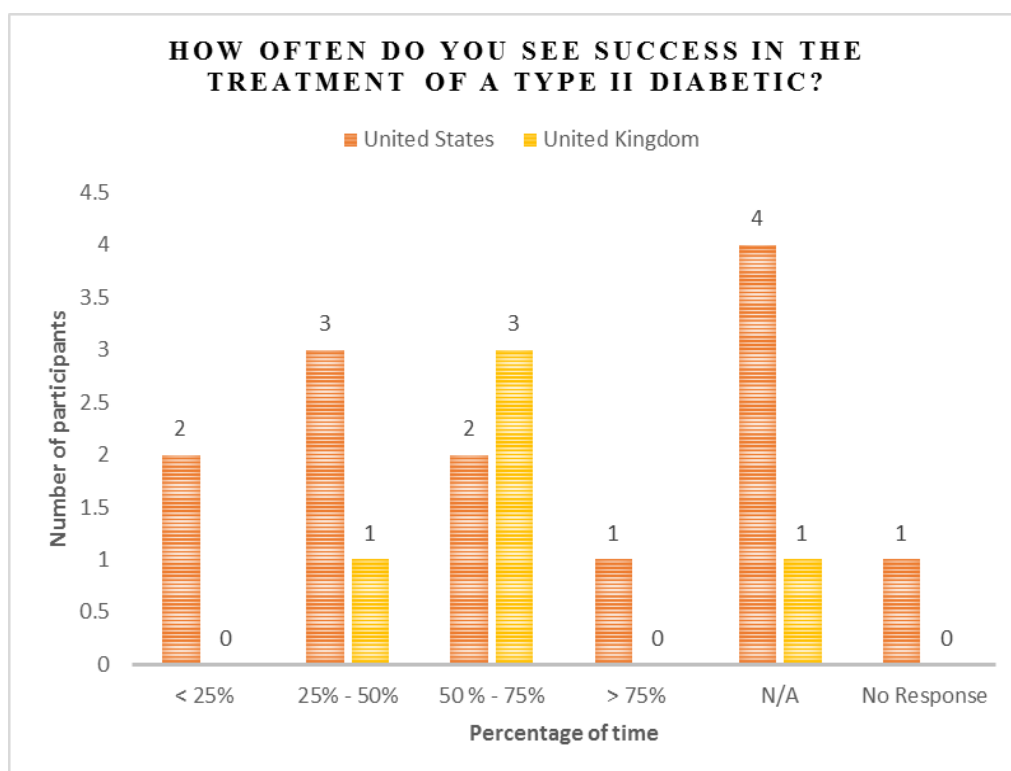
score of 3.83 and a standard deviation of 2.25 while the United Kingdom providers responded with an average of 4.6 and a standard deviation 2.07. The T-test value for this question was 0.516997 (Table 5: Provider Results Statistical Analysis). This value, while only just barely, suggests that the differences between these two sets of data is not statistically significant and could be a result of chance, however, given the number of respondents from each country, this assessment could be slightly unreliable.



**Figure 20: Provider Survey Results, Question 9**

Question 9 of the survey asked respondents how many times a year they saw one diabetic patient. This was a multiple-choice question and participants had 5 options from which to choose (Figure 20: Provider Survey Results, Question 9). 4 respondents from the United States replied with 1-2 times per year, 6 replied with 3-4 times per year, 0 replied with 4-5 times per year, 0

replied with 6-7 times per year, 2 replied with 7+ times per year, and 1 participant did not respond. From the United Kingdom, 3 respondents chose 1-2 times per year, 1 respondent chose 3-4 times per year, 0 respondents chose 4-5 times per year, 0 respondents chose 6-7 times per year, and 1 respondent replied 7+ times per year (Figure 20: Provider Survey Results, Question 9).



**Figure 21: Provider Survey Results, Question 10**

The tenth question was geared to evaluate patient outcomes. This multiple-choice question asked providers to respond to how often they saw success with their Type II Diabetic patients. Respondents had five options from which to choose: < 25% of the time, 25% - 50% of the time, 50% - 70% of the time, > 75% of the time, and not applicable (Figure 21: Provider Survey Results, Question 10). For this question, 2 United States respondents reported that they

saw success less than 25% of the time, 3 reported they saw success 25% - 50% of the time, 2 reported they saw success 50% - 75% of the time, 1 reported they saw success more than 75% of the time, 4 responded that the question was not applicable to them, and 1 respondent provided no response. Conversely, 0 United Kingdom respondents reported they saw success less than 25% of the time, 1 reported they saw success 25% - 50% of the time, 3 reported they saw success 50% - 75% of the time, 0 reported they saw success more than 75% of the time, and 1 reported that the question was not applicable to them (Figure 21: Provider Survey Results, Question 10).

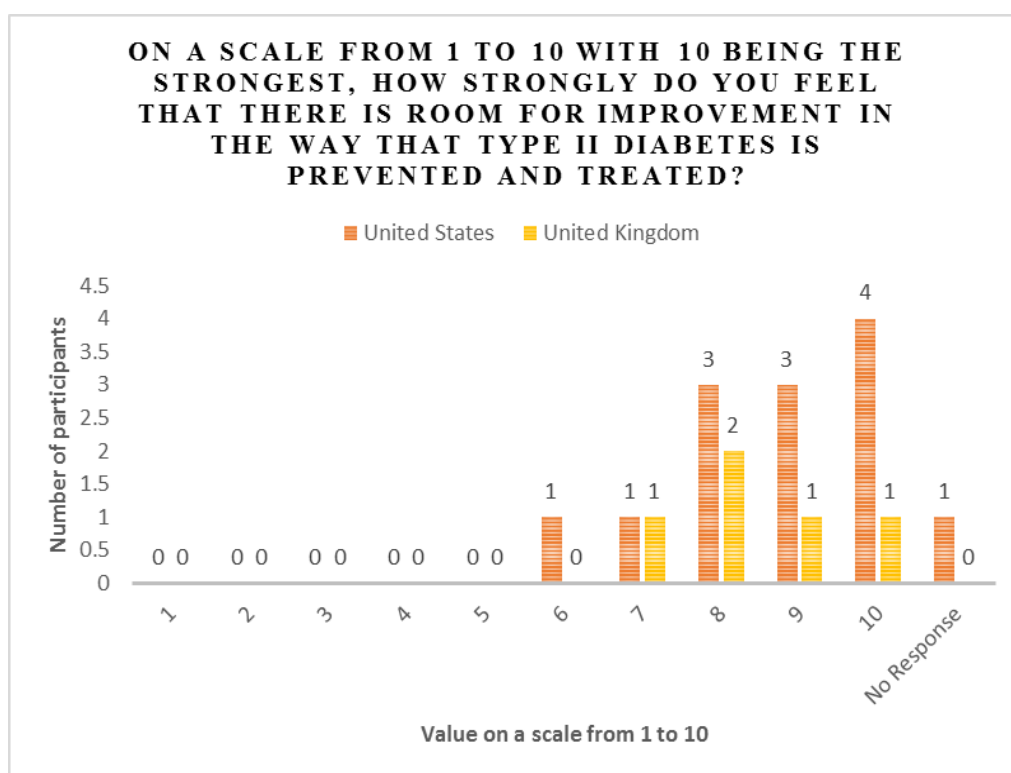
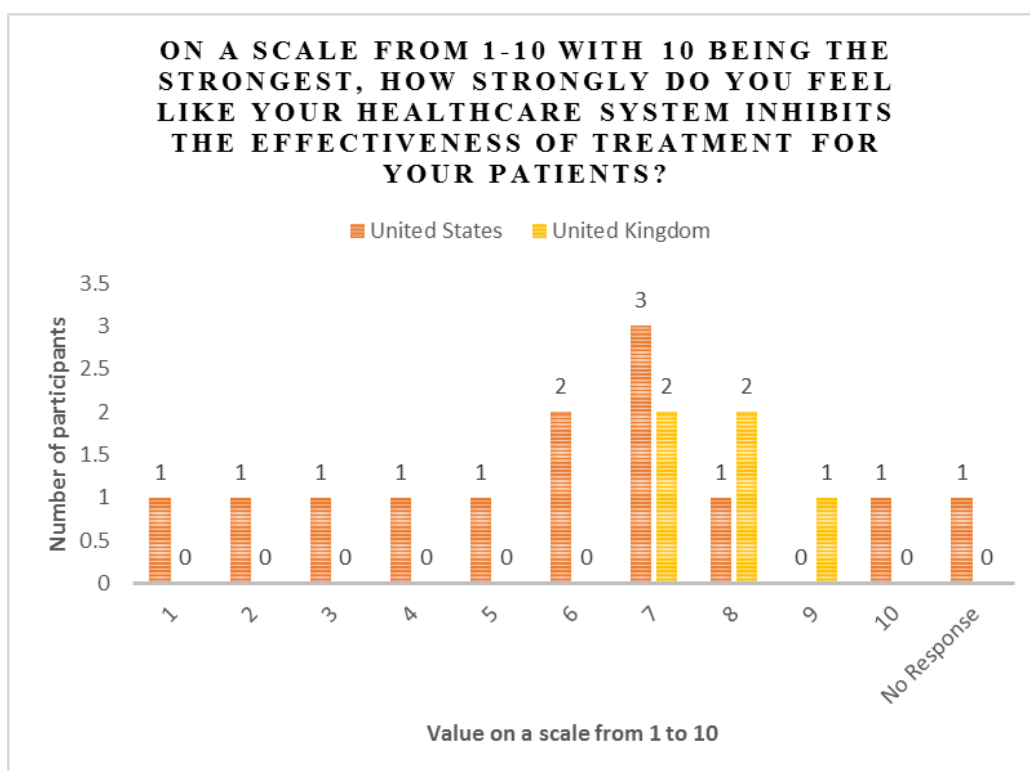


Figure 22: Provider Survey Results, Question 11

Question 11 asked healthcare respondents to rate on a scale of 1 to 10 how strongly they felt that there was room for improvement in the way Type II Diabetes is prevented and treated (Figure 22: Provider Survey Results, Question 11). For this question, the United States



responded with an average of 8.67 with a standard deviation of 1.30 while the United Kingdom responded with an average of 8.4 and a standard deviation of 1.14. The T-test value for the eleventh question was 0.684145 (Table 5: Provider Results Statistical Analysis). This value suggests that there is no statistical relevance between the responses from each country and that these values may be the result of chance.



**Figure 23: Provider Survey Results, Question 12**

The twelfth question of the survey asked participants to rate on a scale of 1 to 10 how strongly they felt their healthcare system inhibited the effectiveness of treatment for their patients (Figure 23: Provider Survey Results, Question 12). The United States reported an average of 5.5 for this question with a standard deviation of 2.61. In contrast, the United Kingdom reported an average of 7.8 with a standard deviation of 0.84 (Table 5: Provider Results

Statistical Analysis). The T-test value for this question was 0.015662 which suggests that the differences between these two sets of data is of statistical relevance and is not a result of chance (Table 5: Provider Results Statistical Analysis).

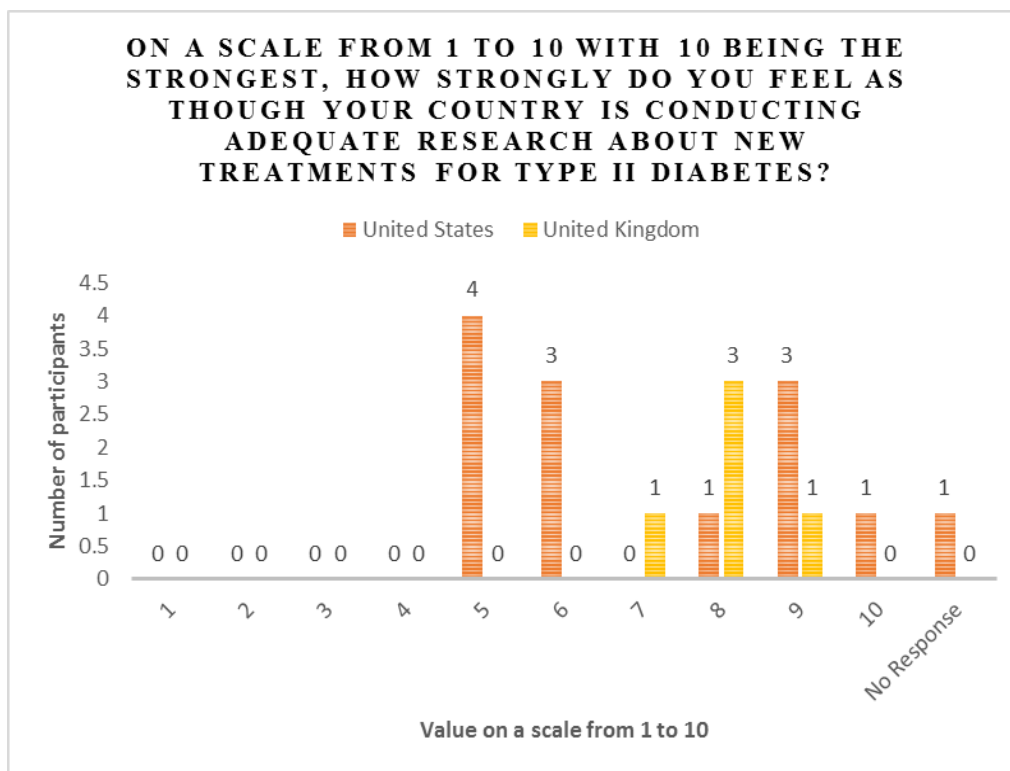


Figure 24: Provider Survey Results, Question 13

Question 13 of the provider survey asked respondents to report on a scale of 1 to 10 how strongly they felt their country was conducting adequate research regarding new treatments for Type II Diabetes (Figure 24: Provider Survey Results, Question 13). The United States posted an average of 6.92 and a standard deviation of 1.93 while the United Kingdom posted an average of 8 and a standard deviation of 0.71. The T-test value for this question was 0.111376 (Table 5: Provider Results Statistical Analysis). This value suggests that the difference between these two countries was most likely a result of chance and that the difference is not statistically relevant.

Table 2: Provider Survey Results, Question 14

**If you could change one thing about the way your healthcare system treats Type II Diabetics, what would it be and why?**

<b>United States</b>	<b>United Kingdom</b>
Provide better access to care for patients who lack financial and cognitive resources	Greater focus on prevention
Increasing emphasis on preventing DMII; exercise no fast food etc.	Greater focus on lifestyle- behavior change, option for VLCDs, Activity on prescription
It is difficult to get adequate cost coverage for insulin and medication	personal budgets to offer gym/personal trainers rather than expensive new drugs to patients with diabetes. Funding to continue only whilst patient succeeding to avoid additional medication
More follow up with new onset diabetes	Promote group learning as I feel peer support helps.
Better education because when treating the patients, their families and themselves seem to be unaware of the disease process.	Better advice on Dietary changes and the role of Carbs in diet
More patient education is needed regarding long term effects of diabetes if not managed appropriately.	
Be more persistent with weight loss and diet changes in order to avoid using medications to treat it	
Cost of medications and testing supplies	
Higher emphasis on life style changes and less reliance on pharmacotherapy	
Better insurance coverage	

Table 3: Provider Survey Results, Question 15

**Do you think that another country has a better treatment and prevention procedure for Type II Diabetes? If so, which country and why? If not, why?**

United States	United Kingdom
I would say any other country that has a better culture and exercise and healthier diet. I think the US has problems due to cultural differences that lead to more obesity and inactivity.	Not sure
I believe other countries don't serve the same types of school lunches as America serves	No - I think the UK is a leader in research, just how to deliver the change.
Switzerland and Canada. Comes down to cost and promotion of healthy living	not aware of one but suspect there will be other countries doing much better with limiting advertising, access to unhealthy foods etc.
I really have no idea	Not sure
Unknown. Heather countries probably have natural prevention!	Not sure anyone has it sorted
I don't know about other countries and their treatment of diabetes	
Yes, countries with better access to health care have earlier detection rates and better disease control	

Table 4: Provider Survey Results, Question 16

**Do you have any additional comments that you think would be beneficial to my research?**

<b>United States</b>	<b>United Kingdom</b>
I think the US does well in treatment of insured patients as far as meds, but patients are not active enough and do not often make the needed lifestyle changes.	Good luck with your research
Education is key!	
Compliance of the patient appears to be a very significant factor for DM.	

The last 3 questions of the survey were all open-ended questions that allowed respondents to provide their own opinions and ideas regarding the question being asked. Question 14 asked respondents if there was one thing they could change about the way their healthcare system treats Type II Diabetes, what would it be and why. United States participants responded with answers such as “provide better access to care for patients who lack financial and cognitive resources”, “more follow-up with new onset diabetes” and “more patient education is needed regarding long term effects of diabetes if not managed appropriately” (Table 2: Provider Survey Results, Question 14). Responses from the United Kingdom included “greater focus on prevention”, “promote group learning” and “better advice on dietary changes and the role of carbs in diet” (Table 2: Provider Survey Results, Question 14). Question 15 asked participants if they thought another country had a better treatment and prevention procedure for Type II Diabetes than their own country. American healthcare professionals responded with answers such as “I would say any other country that has a better culture and exercise and healthier diet”,

“Switzerland and Canada” and “countries with better access to health care have earlier detection rates and better disease control” (Table 3: Provider Survey Results, Question 15). British healthcare professionals responded with answers such as “Not sure”, “No, I think the UK is a leader in research, just how to deliver the change” and “Not sure anyone has it sorted” (Table 3: Provider Survey Results, Question 15). The last question of the survey asked respondents if they had any additional comments they thought would be beneficial to the study. American responses included answers such as “I think the US does well in treatment of insured patients as far as meds, but patients are not active enough and do not often make the needed lifestyle changes”, “education is key” and “compliance of the patient appears to be a very significant factor for DM”. Conversely, there was one response to this question from the United Kingdom and it was “Good luck with your research” (Table 4: Provider Survey Results, Question 16).

**Table 5: Provider Results Statistical Analysis**

QUESTION NUMBER	UNITED STATES				UNITED KINGDOM				T-TEST
	AVERAGE	MEDIAN	MODE	STANDARD DEVIATION	AVERAGE	MEDIAN	MODE	STANDARD DEVIATION	
<b>1</b>	10.38	8	10	11.09646	23.2	27	N/A	15.99062	0.154793
<b>2</b>	10	7	8	11.64334	16.2	13	N/A	13.21741	0.371621
<b>4</b>	8.917	9.5	10	1.505	9.8	10	10	0.447214	0.061125
<b>8</b>	3.83	3.5	3	2.249579	4.6	5	6	2.073644	0.516997
<b>11</b>	8.67	9	10	1.302678	8.4	8	8	1.140175	0.684145
<b>12</b>	5.5	6	7	2.611165	7.8	8	7	0.83666	0.015662
<b>13</b>	6.92	6	5	1.928652	8	8	8	0.707107	0.111376

## **Chapter 5**

### **Discussion**

#### **Implications for Healthcare Practice**

Per the results of the public survey, Americans' satisfaction with the healthcare practice in their country was relatively higher than that of their British counterparts. This is what was expected and stated in the initial hypothesis. On the questions that asked participants to rank their opinions on a scale from 1 to 10, Americans consistently scored higher on the questions relating to healthcare practice while the British consistently scored the practices of their healthcare lower. However, opposed to the original hypothesis, the provider surveys showed that the outcome and treatment measures was much the same in both countries.

On the scale regarding the adequacy of the treatment provided by specialists in their country, Americans ranked their satisfaction as an average 6.279 with a 2.086528 standard deviation on a 10-point scale while the British ranked the same question at 4.94 with a standard deviation of 2.1875295 (Table 1: Public Survey Results Statistical Analysis). The t-test value for this question was 0.000391 suggesting that the results of this question were not a result of chance and the difference between the two scores is significant (Table 1: Public Survey Results Statistical Analysis). This perhaps suggests that the United Kingdom has something to learn from the United States in regards to how their patients feel in regards to the adequacy of the care they receive.

This may relate to the frequency of how often providers saw their patients or the type of treatment plan they prescribed. Per the results of questions seven and nine of the provider survey, American providers reported they saw their Type II Diabetic patients more over the course of a year compared to their British counterparts (Figure 18: Provider Survey Results, Question 7). American providers also stated that they prescribed a combination of drug therapy and lifestyle changes to their patients more than the British who, while prescribing mainly the same treatment plan, also seemed to rely more on drug therapy (Figure 20: Provider Survey Results, Question 9). In an effort to increase the satisfaction of the British public in regards to their healthcare, the United Kingdom could utilize the results found in the United States and perhaps increase the amount of contact they have with their patients over the course of a year as well as focus more on lifestyle changes as opposed to drug therapy.

The idea of being more available to patients and their needs is supported by several other findings from the patient survey. In regards to the availability of providers to the patient, the American public ranked their provider's availability as 6.471 with a standard deviation of 2.062245, while the British ranked their provider's availability as 4.662 with a standard deviation of 2.532766 (Table 1: Public Survey Results Statistical Analysis). The t-test value for the relationship between these two values was  $1.52E-5$ , also suggesting a high degree of significance (Table 1: Public Survey Results Statistical Analysis). This large difference suggests the higher degree of success in American healthcare practices in regards to patient satisfaction, and provides an area of improvement for British healthcare practices.

Likewise, the British also reported a higher value for the question asking participants to rank how much room they thought their country had in regards to treatment practices of Type II Diabetes. Americans reported an average value of 7.712 with a standard deviation of 2.278766



while British respondents reported an average of 7.984 and a standard deviation of 1.971954 (Table 1: Public Survey Results Statistical Analysis). While the Americans did post a lower value for this question, the t-test value for the comparison between the two averages was 0.467294, suggesting that the difference is not statistically significant and the results could be due to chance (Table 1: Public Survey Results Statistical Analysis). Regardless of this t-test value, it should still be noted that the British could learn from this particular question and perhaps employ more resources to improving treatment procedures in their country. Nevertheless, the t-test value of this question also suggests that this may be an area in which additional research will be needed before proceeding with any practice changes.

Conversely, however, the British ranked the difficulty they had in seeing a specialist as lower than that of the Americans. For the question regarding how difficult it was for a patient to see a specialist on a scale of 1 to 10, the British reported an average score of 4.793 with a standard deviation of 2.950147 while the Americans reported an average of 5.644 and a standard deviation of 2.610227 (Table 1: Public Survey Results Statistical Analysis). While the t-test value for this question was 0.57416 and suggested a large degree of this response was due to chance and is not statistically significant, it is still an important piece of information to acknowledge (Table 1: Public Survey Results Statistical Analysis). More research in this area would need to be conducted to determine the validity and relativeness of this question in regards to provider and specialist availability in each country.

Meanwhile, while Americans seemed to report a higher satisfaction with their healthcare, the British reported more success in the treatment of a Type II Diabetic patient. Comparatively, more British providers reported seeing success 50-75% of the time than Americans who favoured a success rate of 25-50% of the time (Figure 21: Provider Survey Results, Question 10).

This is supported by previous research mentioned in Chapter 2 in which the United Kingdom saw a lower prevalence of Type II Diabetes across its population than the United States.

While this success in treatment may be due to healthcare practices, it could also be related to cultural differences. From the personal experiences of this principal investigator spent in both countries, it was noted that the United Kingdom boasted a higher walking culture and a social culture vastly different from that of the United States. Community footpaths were readily accessible to the public in the United Kingdom, and the British seemed to make more use of these footpaths for daily commutes than did Americans. Furthermore, it was noted that Americans use food as a way in which to socialize with one another. This was rarely the case in the United Kingdom, with individuals choosing to socialize primarily around alcohol at local, walkable pubs as opposed to driving to restaurants for a sit-down meal. Overall, it appeared that the British lead less sedentary lives than those of their American counterparts. This theory is supported by the responses of several provider responses.

For question 15 of the provider survey which asked providers if they felt another country has a better treatment and prevention protocol than their own, an American response was as follows: “I would say any other country that has a better culture and exercise and healthier diet. I think the U.S. has problems due to cultural differences that lead to more obesity and inactivity” (Table 3: Provider Survey Responses, Question 15). This thought seemed to echo through the American responses for this question. Responses such as “I believe other countries don’t serve the same types of school lunches as America serves” and “Comes down to cost and promotion of healthy living” was common for Americans (Table 3: Provider Survey Responses, Question 15). Meanwhile, British responses consisted of “not sure” and “not sure anyone has it sorted” (Table 3: Provider Survey Responses, Question 15). This may be one area in which the United States

could improve their practices in treating Type II Diabetes. While both countries reported that prevention was more important than treatment, it appears the United States could learn from the United Kingdom in ways to carry out prevention practices (Figure 17: Provider Survey Results, Question 6).

Based on the results from each survey, it is apparent that both the United Kingdom and the United States have areas in which they can both improve. This is supported by the feelings of providers. Both American providers and British providers posted similar averages when asked to rank how much room there was for improvement in the way their country treats Type II Diabetes (Figure 22: Provider Survey Results, Question 11). The areas in which this change can be carried out are different for each country though. As predicted by the hypothesis, the United States seemed to be able to provide better treatment while the United Kingdom seemed to provide better prevention measures. Perhaps each country could learn from the other.

The United Kingdom can learn from the United States in regards to better treatment protocols. By employing more emphasis on a combination of drug therapy and lifestyle changes like the United States, they may see an increase in the way their patients feel in regards to the adequacy of the treatment they provide. Additionally, spending more time with patients also seemed to be a large area in which the United Kingdom could improve its practices. British respondents reported lower interactions with their providers over the course of a year in comparison to American respondents. This could be a large factor in the lower degree of patient satisfaction in the United Kingdom as opposed to the United States. While these are both important points, it is crucial to point out that while the United States healthcare system is a business built upon consumer happiness, the same cannot be said for the United Kingdom healthcare system. This could be an area in which the British could improve their system.

Conversely, it appears the United States could improve prevention measures. Based upon the lower prevalence of Type II Diabetes in the United Kingdom and the United States, combined with the personal experiences of the principle investigator and the responses to several provider survey questions, the United States could improve its current prevention practices by learning from the United Kingdom. While mass cultural changes are nearly impossible in a country of the size and magnitude of the United States, providers can begin to implement changes by encouraging their patients to seek less sedentary lifestyles and healthier diet choices. By modeling measures practiced in the United Kingdom, the United States may be able to observe a shift in the prevalence of Type II Diabetes throughout the country.

### **Implications for Healthcare Policy**

Contrary to the initial hypothesis that the United Kingdom would be able to benefit from policy reform more than the United States, it appears both countries could benefit from policy reform equally. With providers in both countries stating that they see and diagnose Type II Diabetic patients almost daily, and with both patients and providers stating that they believe Type II Diabetes is a pressing issue in their country, there appears to be obvious areas of reform which each country can employ (Figure 16: Provider Survey Results, Question 5, Figure 7: Public Survey Results, Question 5, Figure 15: Provider Survey Results, Question 4).

From the surveys conducted, both providers and patients seemed to feel that the key to reducing incidences of Type II Diabetes begins with their government's ability to provide adequate prevention education. In fact, of the healthcare providers surveyed, the clear majority cited prevention as significantly more important in the fight against Type II Diabetes than

treatment (Figure 17: Provider Survey Results, Question 6). However, when asked about the adequacy of their country to provide prevention information to the public, providers in the United States gave a low ranking of 3.83 with a standard deviation of 2.249579 while British providers gave a rank of 4.6 and a standard deviation of 2.073644 (Table 5: Provider Results Statistical Analysis). While the t-test value between these two values was a little high at 0.516997, and does suggest the relationship between these two values as insignificant and a result of chance, it does not take away from how each country can learn individually from their own country's results, regardless of how they compare to a foreign country. These values were echoed by the public, with Americans citing an average of 4.985 and a standard deviation of 2.262561 and the British citing an average of 4.358 and a standard deviation of 1.943922 for the same question (Table 1: Public Survey Results Statistical Analysis).

Furthermore, when asked how much room they believe their country has in improving how they prevent Type II Diabetes, the American public responded with an average of 7.954 and a standard deviation of 2.2737 while the British public responded with an average of 7.889 and a standard deviation of 1.884667 (Table 1: Public Survey Results Statistical Analysis). Once again boasting a high t-test value of 0.86043 for the relationship between the two values, the insignificance of the relationship between the two countries should not take away from what each country can learn individually.

Additionally, these numerical values were further solidified with the open-ended questions of the provider survey. Responses such as "more patient education is needed," "greater focus on prevention," and "better education because when treating the patients, their families and themselves seem to be unaware of the disease process" were common across both countries (Table 2: Provider Survey Results, Question 14). "Education is key!" seemed to be the largest

theme that was noted in all the open-ended responses (Table 4: Provider Survey Results, Question 16).

The results seen from both the providers and the public for each country suggests that the governments from both the United States and the United Kingdom could enact policies focusing on prevention and education of Type II Diabetes. While they cannot necessarily learn from each other in this aspect as originally hypothesized, the countries can learn from the results internally. Providers and patients in each country seem to be calling for more prevention measures to be taken. Perhaps enacting policy that creates a unit on Diabetes to be taught in public schools could remedy this. Not only would this be educating the youth of each country, but by assigning homework and sending home pamphlets with the children the government would be reaching the parents of these children as well. In regards to older patients, of which Type II Diabetes more commonly affects, the government could perhaps begin a campaign that involved send informational brochures and pamphlets to the homes of the elderly that educates them on Type II Diabetes.

While prevention and education seemed to be the largest theme throughout the surveys conducted, it was not the only area in which policy reform could be enacted. When surveyed about how strongly they feel their healthcare systems inhibit the effectiveness of treatment for their patients, American providers reported an average of 5.5 with a standard deviation of 2.611165 and British providers reported an average of 7.8 with a standard deviation of 0.83666 (Table 5: Provider Results Statistical Analysis). Interestingly, the t-test value for this question was 0.015662 and suggests a high degree of significance between the two values (Table 5: Provider Results Statistical Analysis). The values reported for this question are in line with the original hypothesis that while the United Kingdom will have better prevention measures overall,

the British healthcare system would be less effective than the United States system. However, limited British responses were observed when asked how providers thought their system could be improved (Table 2: Provider Survey Results, Question 14). While Americans responded with ideas such as “adequate cost coverage for insulin and medication” or “provide better access to care for patients who lack financial and cognitive resources”, there was almost no improvements suggested by the British providers (Table 2: Provider Survey Results, Question 14).

While it is easy to say that the British can learn from the American responses, it is not that simple. Because of the differences in the way each healthcare system is run, policy implications such as insurance coverage and accessibility to care works and functions differently in each country. One can speculate that making healthcare more affordable and accessible could help remedy this problem, however, more research in this area would need to be conducted to be more finite and specific in this decision.

In addition to education and accessibility to healthcare, providers and patients were also asked to rank how strongly they felt their country was conducting adequate research on Type II Diabetes (Figure 10: Public Survey Results, Question 8, Figure 24: Provider Survey Results, Question 13). Publicly, Americans reported an average of 6.138 with a standard deviation of 2.01461 and the British reported an average of 5.968 and a standard deviation of 2.278711 (Table 1: Public Survey Results Statistical Analysis). Similarly, American providers reported an average of 6.92 with a standard deviation of 1.928652 and British providers reported an average of 8 with a standard deviation of 0.707107 (Table 5: Provider Results Statistical Analysis).

While these numbers were not excessively low, they were not excessively high either. This is perhaps another area in which the British and American government could enact policy to increase the satisfaction of their constituents. Perhaps creating a committee that focuses solely on

Type II Diabetes would be beneficial, or by portioning a section of each country's budget specifically for Type II Diabetes research would be suitable. Furthermore, creating government grants for education for those conducting research in the field could amp up the desire of intellectually gifted citizens to begin their own studies within the field.

While practice improvement in each country closely followed the original hypothesis set forth, policy improvements in each country were not so clear cut. It was originally believed that the United Kingdom would have more to learn from the United States in this aspect, however, it seems they could each learn more internally rather than from foreign external sources and examples. Prevention measures and education reform seemed to be the biggest theme for which both countries could improve upon, while improvements in accessibility and research were also prevalent. Further research needs to be conducted in policy reform to provide a concrete direction of action.

### **Study Limitations**

It should be noted that several study limitations were observed in this project. Firstly, response rates for surveys are known for being notoriously low. This study was no exception. While the goals were met for each survey with a minimum of 50 patient participants from each country and 5 provider participants from each country, this in no means a large representation of each country. Secondly, the length of time and amount of resources available for this study were limited. As an undergraduate thesis, the same amount of resources could be not afforded as a full scale governmental or institutional study would be able to employ. Thirdly, the results of the study are prone to human error. As the surveys conducted were largely opinion based



surveys, it should be noted that the results may not be entirely accurate as humans are prone to differences in opinion. Many of the questions asked were based on relativity, and the experiences of one person may not be the same of another, thus provided a serious limitation for the study.

### **Additional Research**

As noted throughout this chapter, there are several areas in which additional research can be conducted. The main area for additional research in regards to practice was regarding accessibility to specialists. While it appeared that the British reported more difficulty seeing a specialist, the reasons why could be further researched to provide information for the British to improve upon. Additionally, in regards to policy, further research needs to be conducted in each country in regards to making healthcare both more affordable and accessible. While it was originally believed that each country could learn from the other in this aspect, it appeared that this was not the case. More internal studies will need to be conducted in each country to remedy the unique problems of each system.

## **Chapter 6**

### **Conclusion**

Type II Diabetes is an issue plaguing many countries around the world, the United States and the United Kingdom included. While each of these countries provide a different healthcare system to their citizens, both the United States and the United Kingdom both have areas for improvement in regards to healthcare practice and policy reform. The hopes of this study were to see if each country would be able to improve upon their faults by learning from the benefits of their foreign counterparts. However, while this seemed true for healthcare practice, it appeared the same could not be said for healthcare policy, providing areas of further research to be conducted.

The study operated by surveying at least 50 patients and 5 providers from each country. Race and ethnicity were not considered for this study; however, citizenship was. Participants were asked to rank several questions on a scale from 1 to 10 that assessed attitudes and preferences towards accessibility, effectiveness, and treatment of Type II Diabetes and healthcare in their respective countries. Providers were also asked to comment on their treatment protocols and procedures. The values from these questions were then compiled and basic statistical data, including a t-test, were performed for analysis.

The results were varied. The original hypothesis suggested that the United States would be able to learn from the United Kingdom in regards to prevention and practice measures, while the United Kingdom would be able to learn from the United States in regards to policy and healthcare structure measures. While it was apparent that the United States could learn about

prevention from the United Kingdom, it was not as one-sided as originally thought. Similarly, it was believed that the United Kingdom would be able to base improvements off a model provided by the United States. Contrary to the original hypothesis, this was not the case and it was observed that more internal studies would need to be conducted in order for each country to implement improvements to their healthcare systems and policies.

## **Appendix**

### **Supporting Documents**

#### **Thesis Proposal**

### A COMPARATIVE STUDY BETWEEN THE UNITED KINGDOM AND UNITED STATES HEALTHCARE SYSTEMS FOCUSING ON THE PREVENTION, TREATMENT, AND PATIENT OUTCOMES FOR TYPE II DIABETES

This thesis will look at the differences between the United Kingdom health care system and the United States health care system, however, more specifically it will focus on the pros and cons of each system in the treatment, prevention, and disease outcome for type two diabetes. Through surveys, interviews, and case studies, this thesis will not only compare the two health care systems, but also attempt to find if there is any connection between the way that people are treated and the outcome of the disease. Furthermore, care will be taken to analyze the differences in prevention measures as well as the treatment process. This thesis aims to determine whether one health care system is better than the other when providing care in relation to type two diabetes. The main goals of this thesis are outlined below.

- Assess the differences between the United States health care system and the United Kingdom health care system
- Analyze whether one system has an advantage over the other in the prevention and treatment of type two diabetes

In order to complete the thesis, I will conduct surveys to be distributed to patients and health care providers, and if possible conduct follow up interviews to gather more information. This thesis will also require extension background research on the way that each country's health care system operates as well as current statistics for each country regarding type

two diabetes. Through my exchange studies in the United Kingdom, surveys can be distributed and interviews can begin as soon as possible. Furthermore, through my connections with local hospitals, I can gather data for the United States portion. I aim to have all data collected by the beginning of the fall term so that the majority of my senior year can be spent organizing and analyzing the data to produce a final product for the thesis deadline. In conclusion, this thesis aims to offer a new perspective regarding health care systems and how they can affect scientific treatment of a disease, and I hypothesize that while the United Kingdom will have better prevention measures, the United States will boast better treatment plans and patient outcomes.

## Public Survey

**ANONYMOUS PUBLIC SURVEY**

*A COMPARATIVE STUDY BETWEEN THE UNITED STATES AND UNITED KINGDOM HEALTHCARE SYSTEMS FOCUSING ON THE PREVENTION, TREATMENT, AND PATIENT OUTCOMES FOR TYPE II DIABETES*

1. Have you, or someone you know, ever been diagnosed with and treated for Type II Diabetes?

YES or NO

2. Are you a citizen of the United Kingdom or the United States?

United Kingdom      United States      I am not a citizen of either country.

**IF YOU SELECTED “*I am not a citizen of either country*” PLEASE RETURN THE FORM BACK TO THE INTERVIEWER.**

3. On a scale from 1 to 10 with 10 being the most strong, how strongly do you feel that your country provides adequate prevention information for Type II Diabetes (i.e. lessons taught in school health classes, access to nutrition labels and exercise, and public announcements)?

1      2      3      4      5      6      7      8      9      10

4. On a scale from 1 to 10 with 10 being the most strong, how strongly do you feel that the treatment provided by specialists in your country is adequate (i.e. diet plans, blood sugar monitoring, and frequency of check-ups)?

1      2      3      4      5      6      7      8      9      10

5. On a scale from 1 to 10 with 10 being the most strong, how strongly do you feel that Type II Diabetic doctors are available to your needs, questions, and concerns?

1      2      3      4      5      6      7      8      9      10

6. On a scale from 1 to 10 with 10 being the most difficult, how difficult is it for you to see a specialist (i.e. how long it takes to get an appointment, how effectively you are referred to a specialist, etc.)?

1      2      3      4      5      6      7      8      9      10

7. On a scale from 1 to 10 with 10 being the strongest, how strongly do you feel that Type II Diabetes is a pressing issue in your country?

1      2      3      4      5      6      7      8      9      10

8. On a scale from 1 to 10 with 10 being the most room for improvement, do you feel like there is room for improvement in the way specialists and your country treat Type II Diabetes?

1      2      3      4      5      6      7      8      9      10

9. On a scale from 1 to 10 with 10 being the most room for improvement, do you feel like there is room for improvement in the way that your country and healthcare systems attempts to prevent Type II Diabetes (i.e. lessons taught in school health classes, access to nutrition labels and exercise, and public announcements)?

1      2      3      4      5      6      7      8      9      10

10. On a scale from 1 to 10 with 10 being the strongest, how strongly do you feel like your country is conducting adequate research about new treatments for Type II Diabetes?

1      2      3      4      5      6      7      8      9      10

11. If you could change one thing about the way that you, or someone you know, has been treated for Type II Diabetes, or the way that your country attempts to prevent Type II Diabetes, what would it be and why?

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**Provider Survey**

**PROVIDER SURVEY**

*A COMPARATIVE STUDY BETWEEN THE UNITED STATES AND UNITED KINGDOM HEALTHCARE SYSTEMS FOCUSING ON THE PREVENTION, TREATMENT, AND PATIENT OUTCOMES FOR TYPE II DIABETES*

12. How long have you been working as a Type II Diabetic healthcare provider?

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13. In which country do you practice?

United Kingdom      United States      I don't practice in either country.

**IF YOU SELECTED "I don't practice in either country" PLEASE RETURN THE FORM BACK TO THE INTERVIEWER.**

14. What kind of care do you provide (i.e. general practitioner, nurse, specialist)?

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15. On a scale from 1 to 10 with 10 being the strongest, how strongly do you feel that Type II Diabetes is a pressing issue in your country?

1      2      3      4      5      6      7      8      9      10

16. How often do you see or diagnose new Type II Diabetic patients in a month? \_\_\_\_\_

17. Do you believe treatment or prevention is more important in regards to Type II Diabetes?

Treatment                      Prevention

18. What type of treatment do you prescribe to your Type II Diabetic patients?

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19. On a scale from 1 to 10 with 10 being the strongest, how strongly do you feel that your country provides adequate prevention information about Type II Diabetes (i.e. lessons taught in school health classes, access to nutrition labels and exercise, and public announcements) to the general public?

1      2      3      4      5      6      7      8      9      10



20. How often do you have contact with your Type II Diabetes patients over the course of a year?

1-2 times/year      3-40 times/year      5-6 times/year      7+ times/year

21. How often do you see success in treatment of a Type II Diabetic?

< 25%      25%-50%      50%-75%      > 75%

22. On a scale from 1 to 10 with 10 being the strongest, how strongly do you feel that there is room for improvement in the way that Type II Diabetes is prevented and treated?

1    2    3    4    5    6    7    8    9    10

23. On a scale from 1-10 with 10 being the strongest, how strongly do you feel like your healthcare system inhibits the effectiveness of treatment for your patients?

1    2    3    4    5    6    7    8    9    10

24. If you could change one thing about the way your healthcare system treats Type II Diabetics, what would it be and why?

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25. On a scale from 1 to 10 with 10 being the strongest, how strongly do you feel as though your country is conducting adequate research about new treatments for Type II Diabetes?

1    2    3    4    5    6    7    8    9    10

26. Do you think that another country has a better treatment and prevention procedure for Type II Diabetes? If so, which country and why? If not, why?

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27. Do you have any additional comments that you think would be beneficial to my research?

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**Thesis Protocol for IRB Approval****HRP-591 - Protocol for  
Human Subject Research****Protocol Title:**

Provide the full title of the study as listed in item 1 on the “Basic Information” page in CATS  
IRB (<http://irb.psu.edu>).

A Comparative Study between the United States and United Kingdom Healthcare Systems  
Focusing on the Prevention, Treatment, and Patient Outcomes for Type II Diabetes

**Principal Investigator:**

Name: Terry-anne Barbour

Department: Bachelors of Science in General Science – Biological Science and Health

Professions

Telephone: 570-974-8834

E-mail Address: tzb5212@psu.edu

**Version Date:**

Provide the date of this submission. This date must be updated each time the submission is provided to the IRB office with revisions.

March 7<sup>th</sup> 2016

### **Clinicaltrials.gov Registration #:**

Provide the registration number for this study, if applicable.

[Type text here]

### **Important Instructions for Using This Protocol Template:**

1. Add this completed protocol template to your study in CATS IRB (<http://irb.psu.edu>) on the “Basic Information” page, item 7.
2. This template is provided to help investigators prepare a protocol that includes the necessary information needed by the IRB to determine whether a study meets all applicable criteria for approval.
3. **Type your protocol responses below the gray instructional boxes of guidance language. If the section or item is not applicable, indicate not applicable.**
4. **For research being conducted at Penn State Hershey or by Penn State Hershey researchers only, delete the instructional boxes from the final version of the protocol prior to upload to CATS IRB (<http://irb.psu.edu>). For all other research, do not delete the instructional boxes from the final version of the protocol.**
5. When making revisions to this protocol as requested by the IRB, please follow the instructions outlined in the Study Submission Guide available in the Help Center in CATS IRB (<http://irb.psu.edu>) for using track changes.

### **If you need help...**

<b>University Park and other campuses:</b>	<b>College of Medicine and Hershey</b>
<p data-bbox="186 1501 771 1585"><a href="#">Office for Research Protections Human Research Protection Program</a></p> <p data-bbox="186 1606 511 1690">The 330 Building, Suite 205 University Park, PA 16802-7014</p> <p data-bbox="186 1711 397 1743">Phone: 814-865-1775</p> <p data-bbox="186 1764 381 1795">Fax: 814-863-8699</p> <p data-bbox="186 1816 430 1858">Email: <a href="mailto:irb-orp@psu.edu">irb-orp@psu.edu</a></p>	<p data-bbox="820 1501 1031 1533"><b>Medical Center:</b></p> <p data-bbox="820 1554 1161 1596"><a href="#">Human Subjects Protection Office</a></p> <p data-bbox="820 1617 1291 1648">90 Hope Drive, Mail Code A115, P.O. Box 855</p> <p data-bbox="917 1669 1112 1701">Hershey, PA 17033</p> <p data-bbox="917 1722 1364 1753">(Physical Office Location: Academic Support</p> <p data-bbox="820 1774 1039 1806">Building Room 1140)</p> <p data-bbox="820 1827 1039 1858">Phone: 717-531-5687</p>

	Fax number: 717-531-3937
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	Email: <a href="mailto:irb-hspo@psu.edu">irb-hspo@psu.edu</a>
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## Objectives

### Study Objectives

Describe the purpose, specific aims or objectives. State the hypotheses to be tested.

**Specific Aim:** This study aims to analyze the differences between the United States and United Kingdom healthcare systems by looking at the prevention and treatment measures for Type II Diabetes. This study aims to determine whether one method of healthcare is superior to the other when providing care for Type II Diabetics so that each healthcare system can implement new treatment and prevention plans to better care for their patients.

**Hypothesis:** While the United Kingdom will have better prevention measures, the United States will boast better treatment plans and patient outcomes.

### Primary Study Endpoints

State the primary endpoints to be measured in the study. Clinical trials typically have a primary objective or endpoint. Additional objectives and endpoints are secondary. The endpoints (or outcomes), determined for each study subject, are the quantitative measurements required by the objectives. Measuring the selected endpoints is the goal of a trial (examples: response rate and survival).

Not applicable

### Secondary Study Endpoints

State the secondary endpoints to be measured in the study.

Not applicable

## Background

### Scientific Background and Gaps

Describe the scientific background and gaps in current knowledge.

Type II Diabetes remains the 7th leading cause of death in the United States and has been on the rise for years. According to the American Diabetes Association, 1.4 million Americans are diagnosed with diabetes each year. This includes children, adults and senior citizens. Furthermore, in 2012 86 million Americans over the age of 20 had “prediabetes,” which was up from the previous year of 79 million, and in 2013 diabetes cost the United States a remarkable \$245 billion (Statistics About Diabetes, n.d.).

But Type II Diabetes isn’t only ravaging the United States. It is also affecting other countries, such as the United Kingdom. According to Diabetes UK, there are 4 million people living with diabetes in the United Kingdom and an expected 1 in 16 have diabetes, diagnosed and undiagnosed. Furthermore, around 700 people a day are diagnosed with diabetes in the United Kingdom, which is the equivalent of one person every 2 minutes. Since 1996, the number of people diagnosed with diabetes in the UK has more than doubled from 1.4 million to 3.5 million, and by the year 2025 it is expected that 5 million UK citizens will have diabetes (Diabetes UK: Facts and Stats, n.d.).

The United States and the United Kingdom have vastly different healthcare systems, most notably with the socialization of healthcare in the United Kingdom. Is there one thing that one healthcare system does that yields more positive results than the other? Can the United States learn from the United Kingdom’s success or vice versa? This study aims to look at the prevention, treatment and patient outcomes across these two healthcare systems, looking specifically at why these statistics regarding diabetes are so high.

The goal of this study is to analyze patients and healthcare providers and see if there is a blend of the United States and United Kingdom healthcare systems that can produce more favorable and positive statistics in the realm of Type II Diabetes.

#### Previous Data

Describe any relevant preliminary data.

Previous data regarding Type II Diabetes will be used from respectable sources such as the American Diabetes Association and Diabetes UK. Statistics from these sites will be used to help analyze the outcome and current findings on Type II Diabetes. I also plan to use previous data from respectable sources about patients' feelings towards their healthcare systems as well as how each healthcare system works in its respected country.

#### Study Rationale

Provide the scientific rationale for the research.

In order to effectively analyze the research question, I propose a combination of patient and healthcare provider surveys. These surveys will be conducted via paper and the internet through survey services such as SurveyMonkey. Surveys will be distributed throughout the United Kingdom, most notably in the area of Leeds and Leicester. They will also be distributed throughout the United States mainly in State College, PA and Williamsport, PA at local hospitals and diabetes centers, including places such as Williamsport Regional Medical Center and Divine Providence Hospital. I plan to approach healthcare providers individually and ask for their support as well as approach local diabetes support



groups for patient participation. All surveys will be anonymous in order to gain as honest a response as possible from each individual.

### Inclusion and Exclusion Criteria

Create a numbered list below in sections 3.1 and 3.2 of criteria subjects must meet to be eligible for study enrollment (e.g., age, gender, diagnosis, etc.). Indicate specifically whether you will include any of the following vulnerable populations: (You may not include members of these populations as subjects in your research unless you indicate this in your inclusion criteria.)

Review the corresponding checklists to ensure that you have provided the necessary information.

#### Adults unable to consent

Review “CHECKLIST: Cognitively Impaired Adults (HRP-417)” to ensure that you have provided sufficient information. HRP-417 can be accessed by clicking the Library link in CATS IRB (<http://irb.psu.edu>).

#### Individuals who are not yet adults (infants, children, teenagers)

If the research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research (“children”), review the “CHECKLIST: Children (HRP-416)” to ensure that you have provided sufficient information. HRP-416 can be accessed by clicking the Library link in CATS IRB (<http://irb.psu.edu>).

#### Pregnant women

Review “CHECKLIST: Pregnant Women (HRP-412)” to ensure that you have provided sufficient information. HRP-412 can be accessed by clicking the Library link in CATS IRB (<http://irb.psu.edu>).

#### Prisoners

Review “CHECKLIST: Prisoners (HRP-415)” to ensure that you have provided sufficient information. HRP-415 can be accessed by clicking the Library link in CATS IRB

<http://irb.psu.edu>).

Neonates of uncertain viability or non-viable neonates

Review “CHECKLIST: Neonates (HRP-413)” or “CHECKLIST: Neonates of Uncertain Viability (HRP-414)” to ensure that you have provide sufficient information. HRP-413 and HRP-414 can be accessed by clicking the Library link in CATS IRB (<http://irb.psu.edu>).

### Inclusion Criteria

List the criteria that define who will be included in your study.

Patients, preferably with Type II Diabetes, who have received care from either the United Kingdom or United States healthcare systems

Healthcare providers who have taken care of patients diagnosed with Type II Diabetes in the United Kingdom or the United States

Over the age of 18

A citizen of either the United Kingdom or the United States

Ability to understand and communicate in English

### Exclusion Criteria

List the criteria that define who will be excluded in your study.

Individuals too frail or ill to complete the interviews

Individuals under 18

Individuals who are not citizens of either the United Kingdom or the United States

Healthcare professionals who have not had experiencing treating or preventing Type II Diabetes

## Early Withdrawal of Subjects

### Criteria for removal from study

Insert subject withdrawal criteria (e.g., safety reasons, failure of subject to adhere to protocol requirements, subject consent withdrawal, disease progression, etc.).

Not applicable as the study only requires a one-time survey

### Follow-up for withdrawn subjects

Describe when and how to withdraw subjects from the study; the type and timing of the data to be collected for withdrawal of subjects; whether and how subjects are to be replaced; the follow-up for subjects withdrawn from investigational treatment.

Not applicable as the study only requires a one-time survey

## Recruitment Methods

### Identification of subjects

Describe the methods that will be used to identify potential subjects or the source of the subjects. If not recruiting subjects directly (e.g., database query for eligible records or samples) state what will be queried, how and by whom.

I will work with the population of Centre County and Lycoming County in Pennsylvania as well as the population of Yorkshire and the Midlands in England. I intend to recruit at least 50 patients and at least 5 health professionals from each country. Recruitment will take place via local diabetes support groups and individual outreach to healthcare professionals, as well as through a social media platform with a survey engine. The population is majority white; however, we plan to invite individuals of diverse backgrounds to participate.

#### Recruitment process

Describe how, where and when potential subjects will be recruited (e.g., approaching or providing information to potential subjects for participation in this research study).

The recruitment process will involve contacting local diabetes support groups and healthcare professionals via email, Facebook, phone to inquire whether they agree to participate in the study. From there I plan to distribute the surveys via paper and pencil as well as through the internet using a link to a survey on SurveyMonkey.

#### Recruitment materials

List the materials that will be used to recruit subjects. Add recruitment documents to your study in CATS IRB (<http://irb.psu.edu>) on the “Consent Forms and Recruitment Materials” page. For advertisements, upload the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.

I will be using paper and pencil as well as a link to a survey I created on SurveyMonkey to distribute materials.

### Eligibility/screening of subjects

If potential subjects will be asked eligibility questions before obtaining informed consent, describe the process. Add the script documents and a list of the eligibility questions that will be used to your study in CATS IRB (<http://irb.psu.edu>) on the “Consent Forms and Recruitment Materials” page.

To screen for eligibility, participants will be asked if they are over the age of 18. Each survey asks whether the participant is a citizen of the United States or the United Kingdom and whether or not they have Type II Diabetes.

### Consent Process and Documentation

Refer to “SOP: Informed Consent Process for Research (HRP-090)”, for information about the process of obtaining informed consent from subjects. HRP-090 can be accessed by clicking the Library link in CATS IRB (<http://irb.psu.edu>).

### Consent Process

#### Obtaining Informed Consent

#### Timing and Location of Consent

Describe where and when the consent process will take place.

From a participant perspective, any adult can provide consent.

Implied consent will be obtained from participants at the time of completing the survey. A consent document will be provided to ensure that the participant understands the study and terms of participating in the study. Participants will also be given an informed consent form to refer to. This document will not need signed as we are using implied consent. They will be given the opportunity to ask questions and decline participation. Please see the attached consent document to be supplied with the surveys.

#### Coercion or Undue Influence during Consent

Describe the steps that will be taken to minimize the possibility of coercion or undue influence in the consent process.

To minimize coercion or undue influence, all participants will be told that their participation in the study is completely voluntary and their decision to either participate or not will be confidential at the time they complete the survey.

#### Waiver or alteration of the informed consent requirement

If you are requesting a waiver or alteration of consent (consent will not be obtained, required information will not be disclosed, or the research involves deception), describe the rationale for the request in this section. If the alteration is because of deception or incomplete disclosure, explain whether and how subjects will be debriefed. Add any debriefing materials or document(s) to your study in CATS IRB (<http://irb.psu.edu>) on the “Supporting Documents” page. NOTE: Review the “CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)” to ensure you have provided sufficient information for the IRB to make these determinations. HRP-410 can be accessed by clicking the Library link in CATS IRB (<http://irb.psu.edu>).

Not applicable

## Consent Documentation

### Written Documentation of Consent

Refer to “SOP: Written Documentation of Consent (HRP-091)” for information about the process to document the informed consent process in writing. HRP-091 can be accessed by clicking the Library link in CATS IRB (<http://irb.psu.edu>).

If you will document consent in writing, describe how consent of the subject will be documented in writing. Add the consent document(s) to your study in CATS IRB (<http://irb.psu.edu>) on the “Consent Forms and Recruitment Materials” page. Links to Penn State’s consent templates are available in the same location where they are uploaded and their use is required.

We will use implied consent.

### Waiver of Documentation of Consent (Implied consent, Verbal consent, etc.)

If you will obtain consent (verbal or implied), but not document consent in writing, describe how consent will be obtained. Add the consent script(s) and/or information sheet(s) to your study in CATS IRB (<http://irb.psu.edu>) on the “Consent Forms and Recruitment Materials” page. Links to Penn State’s consent templates are available in the same location where they are uploaded and their use is required. Review “CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)” to ensure that you have provided sufficient information. HRP-411 can be accessed by clicking the Library link in CATS IRB (<http://irb.psu.edu>).

If your research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent.

We will provide a consent form, but for this study, it will not need to be signed. Consent will be implied when a participant completes the survey. Please see the Appendix for the consent form.

#### Consent – Other Considerations

##### Non-English Speaking Subjects

Indicate what language(s) other than English are understood by prospective subjects or representatives.

If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. Indicate the language that will be used by those obtaining consent.

Indicate whether the consent process will be documented in writing with the long form of the consent documentation or with the short form of the consent documentation. Review the “SOP: Written Documentation of Consent (HRP-091)” and the “Investigator Manual (HRP-103)” to ensure that you have provided sufficient information. HRP-091 and HRP-103 can be accessed by clicking the Library link in CATS IRB (<http://irb.psu.edu>).

Not applicable: Subjects must be able to communicate in English in order to participate in the study.



### Cognitively Impaired Adults

Refer to “CHECKLIST: Cognitively Impaired Adults (HRP-417)” for information about research involving cognitively impaired adults as subjects. HRP-417 can be accessed by clicking the Library link in CATS IRB (<http://irb.psu.edu>).

### Capability of Providing Consent

Describe the process to determine whether an individual is capable of consent.

Not applicable: We will not enroll any cognitively impaired adults in this study.

Not applicable: We will not enroll any cognitively impaired adults in this study.

### Adults Unable To Consent

Describe whether and how informed consent will be obtained from the legally authorized representative.

Describe who will be allowed to provide informed consent. Describe the process used to determine these individual’s authority to consent to research.

For research conducted in the state, review “SOP: Legally Authorized Representatives, Children and Guardians (HRP-013)” to be aware of which individuals in the state meet the definition of “legally authorized representative”. HRP-013 can be accessed by clicking the Library link in CATS IRB (<http://irb.psu.edu>).

For research conducted outside of the state, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the

procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of “children” in “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013).” HRP-013 can be accessed by clicking the Library link in CATS IRB (<http://irb.psu.edu>).

Not applicable

#### Assent of Adults Unable to Consent

Describe the process for assent of the subjects. Indicate whether assent will be required of all, some or none of the subjects. If some, indicate which subjects will be required to assent and which will not.

If assent will not be obtained from some or all subjects, provide an explanation of why not.

Describe whether assent of the subjects will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require subjects to sign assent documents.

Not applicable

Subjects who are not yet adults (infants, children, teenagers)

#### Parental Permission

Describe whether and how parental permission will be obtained. If permission will be obtained from individuals other than parents, describe who will be allowed to provide permission. Describe the process used to determine these individual’s authority to consent to each child’s general medical care.

For research conducted in the state, review “SOP: Legally Authorized Representatives, Children and Guardians (HRP-013)” to be aware of which individuals in the state meet the definition of “children”. HRP-013 can be accessed by clicking the Library link in CATS IRB (<http://irb.psu.edu>).

For research conducted outside of the state, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of “children” in “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013).” HRP-013 can be accessed by clicking the Library link in CATS IRB (<http://irb.psu.edu>).

Not applicable: subjects must be 18 years or older in order to participate in the study.

Assent of subjects who are not yet adults

Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent. When assent of children is obtained describe whether and how it will be documented.

Not applicable

HIPAA Research Authorization and/or Waiver or Alteration of Authorization

This section is about the access, use or disclosure of Protected Health Information (PHI). PHI is individually identifiable health information (i.e., health information containing one or more 18 identifiers)

that is transmitted or maintained in any form or medium by a Covered Entity or its Business Associate. A Covered Entity is a health plan, a health care clearinghouse or health care provider who transmits health information in electronic form. See the “Investigator Manual (HRP-103)” for a list of the 18 identifiers. HRP-103 can be accessed by clicking the Library link in CATS IRB (<http://irb.psu.edu>).

If requesting a waiver/alteration of HIPAA authorization, complete sections 6.2 and 6.3 in addition to section 6.1. The Privacy Rule permits waivers (or alterations) of authorization if the research meets certain conditions. Include only information that will be accessed with the waiver/alteration.

#### Authorization and/or Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

Check all that apply:

- X Not applicable, no identifiable protected health information (PHI) is accessed, used or disclosed in this study. [Mark all parts of sections 6.2 and 6.3 as not applicable]
- Authorization will be obtained and documented as part of the consent process. [If this is the only box checked, mark sections 6.2 and 6.3 as not applicable]
- Partial waiver is requested for recruitment purposes only (Check this box if patients’ medical records will be accessed to determine eligibility before consent/authorization has been obtained). [Complete all parts of sections 6.2 and 6.3]
- Full waiver is requested for entire research study (e.g., medical record review studies). [Complete all parts of sections 6.2 and 6.3]

Alteration is requested to waive requirement for written documentation of authorization (verbal authorization will be obtained). [Complete all parts of sections 6.2 and 6.3]

#### Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

Access, use or disclosure of PHI representing no more than a minimal risk to the privacy of the individual

Plan to protect PHI from improper use or disclosure

Include the following statement as written – DO NOT ALTER OR DELETE unless this section is not applicable because the research does not involve a waiver of authorization. If the section is not applicable, remove the statement and indicate as not applicable.

Not applicable

Plan to destroy identifiers or a justification for retaining identifiers

Describe the plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research. Include when and how identifiers will be destroyed. If identifiers will be retained, provide the legal, health or research justification for retaining the identifiers.

Not applicable

Explanation for why the research could not practicably be conducted without access to and use of PHI

Provide an explanation for why the research could not practicably be conducted without access to and use of PHI.

Not applicable

Explanation for why the research could not practicably be conducted without the waiver or alteration of authorization

Provide an explanation for why the research could not practicably be conducted without the waiver or alternation of authorization.

Not applicable

### 6.3 Waiver or alteration of authorization statements of agreement

By submitting this study for review with a waiver of authorization, you agree to the following statement – DO NOT ALTER OR DELETE unless this section is not applicable because the research does not involve a waiver or alteration of authorization. If the section is not applicable, remove the statement and indicate as not applicable.

Protected health information obtained as part of this research will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other permitted uses and disclosures according to federal regulations.

The research team will collect only information essential to the study and in accord with the ‘Minimum Necessary’ standard (information reasonably necessary to accomplish the objectives of the research) per federal regulations.

Access to the information will be limited, to the greatest extent possible, within the research team. All disclosures or releases of identifiable information granted under this waiver will be accounted for and documented.

## Study Design and Procedures

### Study Design

Describe and explain the study design.

The study will use surveys to determine whether one country's healthcare system offers benefits in the treatment of Type II Diabetes that the other one lacks. These personal surveys will then be combined with current statistics to determine if there is any areas of improvement that each country can analyze based on the success of the other country to insure more positive outcomes and quality care for their citizens and patients.

### Study Procedures

Provide a description of all research procedures being performed and when they are being performed (broken out by visit, if applicable), including procedures being performed to monitor subjects for safety or minimize risks. Include any long-term follow-up procedures and data collection, if applicable.

Describe where or how you will be obtaining information about subjects (e.g., medical records, school records, surveys, interview questions, focus group topics, audio or video recordings, data collection forms, and collection of specimens through invasive or non-invasive procedures to include the amount to be collected and how often). Add any data collection instruments that will be seen by subjects to your study in CATS IRB (<http://irb.psu.edu>) in the "Supporting Documents" page.

EXAMPLE: Visit 1 or Day 1 or Pre-test, etc. (format accordingly)

Provide a description as defined above and format accordingly.

The study will use surveys to generate culturally framed insight into the way that Type II Diabetes is prevented and treated in the United States and the United Kingdom. I will recruit individuals who are either patients or providers in the United Kingdom (specifically Leeds and Leicester) and the United States (specifically State College, PA and Williamsport, PA). Data collection will involve a series of one-time surveys discussing patient's attitudes towards the care they've been provided and providers attitudes and treatment protocols. Completing the survey should take each individual approximately 10 minutes. Please see the Appendix for surveys.

EXAMPLE: Visit 2 or Day 2 or Post-test, etc. (format accordingly)

Provide a description as defined above and format accordingly.

Not applicable

#### Duration of Participation

Describe the duration of an individual subject's participation in the study.

It will take about 10 minutes for each individual to complete the survey. Participants will only be surveyed once.

#### Subject Numbers and Statistical Plan



## Number of Subjects

Indicate the total number of subjects to be accrued.

If applicable, distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects needed to complete the research procedures (i.e., numbers of subjects excluding screen failures.)

Total number of participants is 110. This includes at least 50 patients from each country and at least 5 healthcare providers from each country.

## Sample size determination

If applicable, provide a justification of the sample size outlined in section 8.1 – to include reflections on, or calculations of, the power of the study.

Not applicable

## Statistical methods

Describe the statistical methods (or non-statistical methods of analysis) that will be employed.

All data will be coded into an excel spreadsheet by the lead investigator in order to keep all data together and to most effectively analyze results. Two files will be used, one for providers and one for patients. Subsequently, two sheets in each file will be used, one for the United States and one for the United Kingdom.

## Confidentiality, Privacy and Data Management

For research being conducted at Penn State Hershey or by Penn State Hershey researchers only, the research data security and integrity plan is submitted using “HRP-598 – Research Data Plan Review Form Application Supplement”, which is available in the Library in CATS IRB (<http://irb.psu.edu>). Refer to Penn State College of Medicine IRB’s “Standard Operating Procedure Addendum: Security and Integrity of Human Research Data”, which is available on the IRB’s website. In order to avoid redundancy, for this section state “See the Research Data Plan Review Form” in section 9.0 if you are conducting Penn State Hershey research and move on to section 10.

For all other research, in the sections below, describe the steps that will be taken to secure the data during storage, use and transmission.

#### Confidentiality

##### Identifiers associated with data and/or specimens

List the identifiers that will be included or associated with the data and/or specimens in any way (e.g., names, addresses, telephone/fax numbers, email addresses, dates (date of birth, admission/discharge dates, etc.), medical record numbers, social security numbers, health plan beneficiary numbers, etc.).

If no identifiers will be included or associated with the data in any way, whether directly or indirectly, please indicate this instead.

None

Use of Codes, Master List

If identifiers will be associated with the data and/or specimens (as indicated in section 9.1.1 above), describe whether a master record or list containing a code (i.e., code number, pseudonyms) will be used to separate the data collected from identifiable information, where that master code list will be stored, who will have access to the master code list, and when it will be destroyed.

If identifiers are included or associated with the data as described in section 9.1.1 above, but no master record or list containing a code will be used, it will be assumed by the IRB that the investigator plans to directly link the identifiers with the data.

None

#### Storage of Data and/or Specimens

Describe where, how and for how long the data (hardcopy (paper) and/or electronic data) and/or specimens will be stored. NOTE: Data can include paper files, data on the internet or websites, computer files, audio/video files, photographs, etc. and should be considered in the responses. Refer to the “Investigator Manual (HRP-103)” for information about how long research records must be stored following the completion of the research prior to completing this section. HRP-103 can be accessed by clicking the Library link in CATS IRB (<http://irb.psu.edu>).

Please review [Penn State’s Data Categorization Project](#) for detailed information regarding the appropriate and allowable storage of research data collected according to [Penn State Policy AD71](#). Although the IRB can impose greater confidentiality/security requirements (particularly for sensitive data), the IRB cannot approve storage of research data in any way or using any service that is not permissible by [Penn State Policy AD71](#).

All data will be coded into an excel spreadsheet by the lead investigator in order to keep all data together and to most effectively analyze results. Two files will be used, one for providers and one for patients. Subsequently, two sheets in each file will be used, one for the United States and one for the United Kingdom. Data will be kept for three years after the study is complete. All recorded data will be stored securely via a locked computer, and will be made available only to persons conducting the study. Final results will be kept on the PIs secured password protected computer and stored indefinitely.

#### Access to Data and/or Specimens

Identify who will have access to the data and/or specimens. This information should not conflict with information provided in section 9.1.1.1 regarding who has access to identifiable information, if applicable.

Not applicable

#### Transferring Data and/or Specimens

If the data and/or specimens will be transferred to and/or from outside collaborators, identify the collaborator to whom the data and/or specimens will be transferred and how the data and/or specimens will be transferred. This information should not conflict with information provided in section 9.1.1.1 regarding who has access to identifiable information, if applicable.

Not applicable

#### Subject Privacy

This section must address subject privacy and NOT data confidentiality.

Indicate how the research team is permitted to access any sources of information about the subjects.

Describe the steps that will be taken to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on whom they interact with or to whom they provide personal information.

Describe what steps you will take to make the subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed. "At ease" does not refer to physical discomfort, but the sense of intrusiveness a subject might experience in response to questions, examinations, and procedures.

No reference will be made in oral or written reports that could link participants to the study. The survey does not ask for any information that would identify who the responses belong to. Participants will be informed of the content of the study during the consent process in order to ensure their ease with the research situation in terms of intrusiveness and other potential abstract forms of discomfort. The Pennsylvania State University's Office for Research Protections, the Institutional Review Board and the Office for Human Research Protections in the Department of Health and Human Services may review records related to this research study. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared because participant names are in no way linked to their responses.

#### Data and Safety Monitoring Plan

This section is required when research involves more than Minimal Risk to subjects. As defined in "SOP: Definitions (HRP-001)", available in the Library in CATS IRB (<http://irb.psu.edu>), Minimal Risk is

defined as the probability and magnitude of harm or discomfort anticipated in the research that are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For research involving prisoners, Minimal Risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons. Please complete the sections below if the research involves more than minimal risk to subjects OR indicate as not applicable.

#### Periodic evaluation of data

Describe the plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe.

Not applicable

#### Data that are reviewed

Describe the data that are reviewed, including safety data, untoward events, and efficacy data.

Not applicable

#### Method of collection of safety information

Describe the method by which the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls and with subjects).

Data will be collected via surveys, one for patients and providers. See appendix for sample surveys.

#### Frequency of data collection

Describe the frequency of data collection, including when safety data collection starts.

Not applicable

#### Individuals reviewing the data

Identify the individuals who will review the data. The plan might include establishing a data and safety monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor.

Terryanne Barbour

Dr. Mark Sceigaj

Dr. Ronald Markle

#### Frequency of review of cumulative data

Describe the frequency or periodicity of review of cumulative data.

As needed to analyze and formulate a conclusion.

#### Statistical tests

Describe the statistical tests for analyzing the safety data to determine whether harms are occurring.

Not applicable

#### Suspension of research

Describe any conditions that trigger an immediate suspension of research.

Not applicable

### Risks

List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects' participation in the research. For each potential risk, describe the probability, magnitude, duration, and reversibility. Consider all types of risk including physical, psychological, social, legal, and economic risks. If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable. If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant. If applicable, describe risks to others who are not subjects.

Please keep in mind that loss of confidentiality is a potential risk when conducting human subject research and should be addressed as such.

Patients may experience a loss of confidentiality, although the risk is minimal as no identifiers will be collected. Patients may feel slight psychological discomfort when discussing personal issues related to their medical history or healthcare experiences. We do not expect discomfort, if any, to be serious. If participants become extremely uncomfortable describing their experiences, they will not be required to continue to describe them.

### Potential Benefits to Subjects and Others

### Potential Benefits to Subjects



Describe the potential benefits that individual subjects may experience from taking part in the research. If there is no direct benefit to subjects, indicate as such. Compensation is not considered a benefit. Compensation should be addressed in section 14.0.

Subjects may find the experience interesting and potentially beneficial to have the opportunity to discuss their experiences being treated for Type II Diabetes by their country's healthcare system. The subjects' participation will help us to gain important understanding of how Type II Diabetes is treated and prevented in the United States and the United Kingdom and whether one country can learn from the other based on each other's successes.

#### Potential Benefits to Others

Include benefits to society or others.

The results of this study will be used to create culturally appropriate interventions for the current and future populations.

#### Sharing Results with Subjects

Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject's primary care physicians) and if so, describe how it will be shared.

We will share the results via peer-reviewed manuscripts and written reports via the Penn State Schreyer Honors College thesis database online.

#### Subject Stipend (Compensation) and/or Travel Reimbursements

Describe the amount and timing of any subject stipend/payment or travel reimbursement here. If there is no subject stipend/payment or travel reimbursement, indicate as not applicable.

If course credit or extra credit is offered to subjects, describe the amount of credit and the available alternatives. Alternatives should be equal in time and effort to the amount of course or extra credit offered.

If an existing, approved student subject pool will be used to enroll subjects, please indicate as such and indicate that course credit will be given and alternatives will be offered as per the approved subject pool procedures.

Not applicable

Economic Burden to Subjects

Costs

Describe any costs that subjects may be responsible for because of participation in the research.

Not applicable

Compensation for research-related injury

If the research involves more than Minimal Risk to subjects, describe the available compensation in the event of research related injury.

If there is no sponsor agreement that addresses compensation for medical care for research subjects with a research-related injury, include the following text as written - DO NOT ALTER OR DELETE:

It is the policy of the institution to provide neither financial compensation nor free medical treatment for research-related injury. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. Costs for the treatment of research-related injuries will be charged to subjects or their insurance carriers.

For sponsored research studies with a research agreement with the sponsor that addresses compensation for medical care for research-related injuries, include the following text as written - DO NOT ALTER OR DELETE:

It is the policy of the institution to provide neither financial compensation nor free medical treatment for research-related injury. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. Such charges may be paid by the study sponsor as outlined in the research agreement and explained in the consent form.

Not applicable

Resources Available

Facilities and locations

Identify and describe the facilities, sites and locations where recruitment and study procedures will be performed.

If research will be conducted outside the United States, describe site-specific regulations or customs affecting the research, and describe the process for obtaining local ethical review. Also, describe the

principal investigator's experience conducting research at these locations and familiarity with local culture.

Surveys can be completed in private without the need of an interviewer. Paper surveys will be distributed to support groups and providers as requested. Locations includes Leeds, England and Leicester, England as well as State College, PA, USA and Williamsport, PA, USA.

Feasibility of recruiting the required number of subjects

Indicate the number of potential subjects to which the study team has access. Indicate the percentage of those potential subjects needed for recruitment.

Prior research indicates that data saturation should be reached during proposed recruitment period following the sampling strategy previously outlined. Similar data collection projects conducted as part of a health assessments, suggest that this is an appropriate approach to recruitment.

PI Time devoted to conducting the research

Describe how the PI will ensure that a sufficient amount of time will be devoted to conducting and completing the research. Please consider outside responsibilities as well as other on-going research for which the PI is responsible.

The PI will be in the United Kingdom for a total of 6 months to gain adequate data, after which she will be returning to the United States to finish her undergraduate degree where she will have the opportunity to gather the United States participants.

Availability of medical or psychological resources

Describe the availability of medical or psychological resources that subject might need as a result of their participation in the study, if applicable.

Not applicable

#### Process for informing Study Team

Describe the training plans to ensure members of the research team are informed about the protocol and their duties, if applicable.

Not applicable

#### 17.0 Other Approvals

##### 17.1 Other Approvals from External Entities

Describe any approvals that will be obtained prior to commencing the research (e.g., from cooperating institutions, community leaders, schools, external sites, funding agencies).

Communication with local support groups and hospitals are in process, but each group contacted seems more than willing to participate.

##### 17.2 Internal PSU Committee Approvals

Check all that apply:

Anatomic Pathology – Hershey only – Research involves the collection of tissues or use of pathologic specimens. Upload a copy of the Use of Human Tissue For Research Form on the “Supporting

Documents” page in CATS IRB. This form is available on the IRB website at:

<http://www.pennstatehershey.org/web/irb/home/resources/forms>

Animal Care and Use – All campuses – Human research involves animals and humans or the use of human tissues in animals

Biosafety – All campuses – Research involves biohazardous materials (human biological specimens in a PSU research lab, biological toxins, carcinogens, infectious agents, recombinant viruses or DNA or gene therapy).

Conflict of Interest Review – All campuses – Research has one or more of study team members indicated as having a financial interest.

Radiation Safety – Hershey only – Research involves research-related radiation procedures. All research involving radiation procedures (standard of care and/or research-related) must upload the Radiation Review Form on the “Supporting Documents” page in CATS IRB. This form is available on the IRB website at: <http://www.pennstatehershey.org/web/irb/home/resources/forms>

IND/IDE Audit – All campuses – Research in which the PSU researcher holds the IND or IDE or intends to hold the IND or IDE.

Scientific Review – Hershey only – All investigator-written research studies requiring review by the convened IRB must provide documentation of scientific review with the IRB submission. The scientific review requirement may be fulfilled by one of the following: (1) external peer-review process; (2) department/institute scientific review committee; or (3) scientific review by the Clinical Research Center

Advisory committee. NOTE: Review by the Penn State Hershey Cancer Institute Scientific Review Committee is required if the study involves cancer prevention studies or cancer patients, records and/or tissues. For more information about this requirement see the IRB website at:

<http://www.pennstatehershey.org/web/irb/home/resources/investigator>

## 18.0 Multi-Site Research

If this is a multi-site study (i.e., the study will be conducted at other institutions each with its own principal investigator) and you are the lead investigator, describe the processes to ensure communication among sites in the sections below.

### 18.1 Communication Plans

Describe the plan for regular communication between the overall study director and the other sites to ensure that all sites have the most current version of the protocol, consent document, etc. Describe the process to ensure all modifications have been communicated to sites. Describe the process to ensure that all required approvals have been obtained at each site (including approval by the site's IRB of record). Describe the process for communication of problems with the research, interim results and closure of the study.

All sites will be provided with a copy of the surveys, consent information, and this protocol document.

### 18.2 Data Submission and Security Plan

Describe the process and schedule for data submission and provide the data security plan for data collected from other sites. Describe the process to ensure all engaged participating sites will safeguard data as required by local information security policies.

Not applicable

### 18.3 Subject Enrollment

Describe the procedures for coordination of subject enrollment and randomization for the overall project.

Not applicable

### 18.4 Reporting of Adverse Events and New Information

Describe how adverse events and other information will be reported from the clinical sites to the overall study director. Provide the timeframe for this reporting.

Not applicable

### 18.5 Audit and Monitoring Plans

Describe the process to ensure all local site investigators conduct the study appropriately. Describe any on-site auditing and monitoring plans for the study.

Not applicable

### 19.0 Adverse Event Reporting

#### 19.1 Reporting Adverse Reactions and Unanticipated Problems to the Responsible IRB

By submitting this study for review, you agree to the following statement – DO NOT ALTER OR DELETE:



In accordance with applicable policies of The Pennsylvania State University Institutional Review Board (IRB), the investigator will report, to the IRB, any observed or reported harm (adverse event) experienced by a subject or other individual, which in the opinion of the investigator is determined to be (1) unexpected; and (2) probably related to the research procedures. Harms (adverse events) will be submitted to the IRB in accordance with the IRB policies and procedures.

## 20.0 Study Monitoring, Auditing and Inspecting

### 20.1 Auditing and Inspecting

By submitting this study for review, you agree to the following statement – DO NOT ALTER OR DELETE:

The investigator will permit study-related monitoring, audits, and inspections by the Penn State quality assurance program office(s), IRB, the sponsor, and government regulatory bodies, of all study related documents (e.g., source documents, regulatory documents, data collection instruments, study data etc.). The investigator will ensure the capability for inspections of applicable study-related facilities (e.g., pharmacy, diagnostic laboratory, etc.).

## 21.0 Future Undetermined Research: Data and Specimen Banking

If this study is collecting identifiable data and/or specimens that will be banked for future undetermined research, please describe this process in the sections below. This information should not conflict with information provided in section 9.1.1 regarding whether or not data and/or specimens will be associated with identifiers (directly or indirectly).

### 21.1 Data and/or specimens being stored

Identify what data and/or specimens will be stored and the data associated with each specimen.

Responses to surveys by patients and providers.

#### 21.2 Location of storage

Identify the location where the data and/or specimens will be stored.

Data will be stored on the computer of the PI and will be password protected.

#### 21.3 Duration of storage

Identify how long the data and/or specimens will be stored.

Data will be stored for 2 years.

#### 21.4 Access to data and/or specimens

Identify who will have access to the data and/or specimens.

The PI will have access to data. Dr. Mark Sceigaj and Dr. Ronald Markle will also have access upon request.

#### 21.5 Procedures to release data or specimens

Describe the procedures to release the data and/or specimens, including: the process to request a release, approvals required for release, who can obtain data and/or specimens, and the data to be provided with the specimens.

Data will be released the digression of the PI by requests through email, telephone, and in person.

#### 21.6 Process for returning results

Describe the process for returning results about the use of the data and/or specimens.

Not applicable

#### 22.0 References

List relevant references in the literature which highlight methods, controversies, and study outcomes.

Diabetes UK: Facts and Stats. (n.d.). Retrieved February 15, 2016, from

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## ACADEMIC VITA

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**Terry-anne Barbour**  
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**Education:** Pennsylvania State University  
**Major(s) and Minor(s):** General Science, B.S.  
**Honors:** General Science, Health Policy Administration

**Thesis Title:** A Comparative Study between the United States and United Kingdom Healthcare Systems Focusing on Type II Diabetes  
**Thesis Supervisor:** Dr. Mark Sciegaj

### **Work Experience**

**Date:** July 2016 - Present

**Title:** Patient Care Technician

**Description:** Provided care to patients in UPMC Susquehanna Williamsport Emergency Department. Skills including phlebotomy, ECG collection, and CPR are utilized.

**Institution/Company:** UPMC Susquehanna, Williamsport, PA

**Supervisor's Name:** Jessica Laidacker

**Grants Received:** Schreyer Honors College Study Abroad Grant

**Awards:** Dean's list multiple semesters

**International Education:** Spring 2016 Semester Abroad – Leeds, England