

Disparities between Quality of Diabetic Care due to Income Differences

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By

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On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

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Introduction

Diabetes is a rising epidemic in the United States and the simultaneously amassing wage gap has prevented people from seeking equal qualities of healthcare (Riddle & Herman, 2018). Over 16 million people in the United States currently suffer from diabetes, a number that expands to over 200 million across the globe. The diabetic population is anticipated to be 366 million by 2030, globally (Margolis, et. al., 2011). This disease interests me as a couple of my family members have or have had Type II diabetes, the form often resulting from dietary habits, exercise routines, and frequently is in conjunction with hereditary predispositions (Centers for Disease Control and Prevention, 2019). In addition, witnessing the differences in approaches of their diabetic care between different family members due to financial insecurities has provided motivation for this research. A case study of a new treatment option coming to the market for diabetic care, such as Microporous Annealed Particle (MAP) Hydrogel for use in diabetic wound healing, can be analyzed to understand the landscape of disparities in this healthcare field. The technical project of Growth Factor Release from Microporous Annealed Particle (MAP) Hydrogel to Improve Wound Healing was completed in parallel with this research as the Capstone degree requirement in Biomedical Engineering.

This technical topic is related to the human and social dimensions that are explored in this research because the project of MAP gel optimization can be applied to diabetic foot ulcer care. These chronic wounds that many diabetes patients develop, if not properly cared for, can result in limb amputations (Brem & Tomic-Canic, 2007). Therefore, as a possible emerging treatment for these dangerous wounds, similar to other emerging technologies, it is vital to consider how it will affect the entire diabetes patient population, including whether all income brackets will have access to this technology. I focus on the effect of financial insecurity in diabetes care using the

framework of *techno-politics* with an additional focus on the importance of *inclusive innovation* for the technical project case study. This research uncovers how financial insecurity affects a lower-income diabetic patient's quality of care and treatment options in the United States of America.

Case Context

Diabetes is a growing concern in the United States of America. The central stakeholders to this social and human issue of inequality in diabetic healthcare are infinite, but the ones most affected by the politics and technology of diabetic care are the patients themselves, individuals on Medicare and Medicaid, individuals on private insurance plans, doctors, hospital systems, the government, especially the agencies that have influence over healthcare policy, tax payers and families of patients. The framework of *techno-politics* is used to understand each stakeholder's perspective on diabetic care and how politics, particularly those relating to healthcare coverage and healthcare policy, impacts the relationships between these stakeholders. In addition, the technology component of techno-politics is analyzed to understand how policies typically develop around technologies to create order. The predictive technical case study that is developed is on how policy affects MAP gels and the treatment's availability to the public after it has been approved by the Food and Drug Administration (FDA).

Thus, it is crucial to first understand the context of the case that is explored. Between 10% and 15% of diabetes patients will develop or currently suffer from diabetic foot ulcers (DFUs). Diabetic foot ulcers can result from acute or chronic cutaneous disruptions to the skin, arterial complications, including cardiovascular blockages, peripheral neuropathy, or nerve damage, or a combination of these factors (Margolis, et. al., 2011). Patients with DFUs experience numerous resulting effects including decreased mobility, sleep deprivation, depression, anxiety and possible

requirement of limb amputation (Pop & Almquist, 2017). Further, DFUs and their symptoms are associated with a 5-year mortality rate equal to or greater than the mortality rate of individuals with prostate or breast cancer (Margolis, et. al., 2011).

There are few clinical treatments for DFUs and other diabetic wounds. This unmet clinical need is only expected to grow. Because of the range of factors that contribute to DFUs, these wounds are difficult to treat. Current treatment options for DFUs include tissue removal, negative pressure therapy, and topical applications (Margolis, et. al., 2011) (Pop & Almquist, 2017). However, these therapies are still ineffective for a substantial fraction of the patient population. Ultimately, they do not promote a healthy environment for tissue regeneration, rather they only attempt to alleviate the side effects of diabetes and DFUs (Pop & Almquist, 2017).

MAP gel provides a microporous and controllable porosity structure as well as a degradable wound healing environment that promotes cellular network formation, including cell-cell adhesion and cell-extracellular matrix adhesion and signaling, and vascularization, or formation of blood vessels (Griffin & Weaver, 2015). The clinical goal of MAP gel is a one-time injection applied topically to a wound and upon annealing, or hardening, of the gel, healing times and health of the tissue would improve (Griffin & Weaver, 2015). MAP gel has already proven to be a more successful alternative to standard poreless hydrogels (Griffin & Weaver, 2015). In addition, it has demonstrated two other key improvements, including decreased inflammation and increased integration with healthy tissue. Therefore, the aim of this project is to continue to build upon the success that MAP gel has already had in order to continue to advance the best possible solution to the unmet clinical need of diabetic wound healing. The overarching goal of our project is to develop a MAP-Epidermal Growth Factor (EGF) formulation that can be applied in a murine wound healing model, that improves chronic wound healing through enhanced regeneration with

MAP hydrogel. This research ties together the technical and social components of ensuring that a new biomedical technology is inclusive and will be available for all patients if it is the best option for treatment.

Analysis of Diabetic Care through a Techno-Political Lens

The theories of *techno-politics* and *inclusive innovation* support the analysis of diabetic care, specifically MAP gel for wound healing applications that is addressed in the technical component. The main human and social dimension that is of issue is how politics in the United States, especially in relation to the coverage that Medicare and Medicaid offer, impact a diabetic patient's choices in treatment and quality of care (Kumar & Berlin, 1998). This can be analyzed through the research of the total number of different options for various treatment plans of diabetes, including blood sugar monitoring, insulin costs, medicines to lower A1C and blood sugar, and the treatment of side-effects, which wound healing would fall under. The total number of options can then be compared to the number of options that are covered under Medicaid in order to understand the coverage of diabetes treatment options for those of lower income. In addition, an analysis of whether the best options are covered by Medicaid adds to a complete understanding of whether healthcare politics affects a diabetic patient's quality of care.

Winner (1980) argues that technologies can be judged not only on how they succeed in generating efficiency and productivity, but also whether they generate power for good or for bad in society, thus resulting in politics. Therefore, through this *techno-politics* theory that Winner has built, the object under analysis in this research project will be both diabetic care in its entirety as well as the aforementioned case study of MAP gel. It is determined whether there are positive or negative power dynamics created through Medicare and Medicaid's coverage of specific treatments. Power dynamics are forces that propel people to have more or less influence over a

situation. In addition, power dynamics and political influence may arise if Medicare and Medicaid choose to cover treatments that are not of as high quality as other available options. The second part of the analysis via the *techno-political* framework is an understanding of how policies arise concerning a new biomedical technology. In order to provide this predicative analysis, case studies similar to MAP gel are looked at to understand the contributing factors to whether the treatment was covered by Medicaid in a particular state and how the government regulated the treatment.

Amadei (2014) describes that the appraisals of communities, or the inspection of a community in order to understand their daily struggles, can aid in the instruction of how communities can stand to improve their quality of life by leveraging their own talents and resources. This book chapter is utilized to understand communities in which diabetes healthcare affects. The guidelines and methodology can be applied to communities, defined for this research as individual states, who experience higher rates of diabetes or poor quality of care to understand what factors in their state may be encouraging these trends. This demonstrates whether they are predisposed to have higher rates of diabetes due to the quality of their life and availability of healthcare. The analysis of the diabetic care landscape through Amadei's description of the appraisals of communities supports a definition of inclusive innovation because if the availability of diabetic care treatments is not decided with these communities and their inherent strengths and struggles in mind then it is not inclusive innovation.

To support the framework of inclusive innovation are the key arguments that Wiebe E. Bijker offers. He states that the focus of technological culture used to be how to study it, but now it has become how to build the culture around technology (Bijker, 2017). The argument that is critical to this analysis is when Bijker states that we must invest in the future of technology. This is not to say we must spend more money developing technologies themselves, but rather investing

in preliminary research on how they will affect society. Bijker urges us to invest in constructing technological worlds rather than allow them to passively develop (Bijker, 2017). In this research, these arguments are utilized by drawing a connection between Bijker's argument and how we must plan in advance for new and emerging healthcare technologies in order to carry out inclusive innovation. I utilize it in order to make a connection to my technical report in describing that before a technology like MAP gel is available in the clinic, the implications of its use and availability to all groups of people, including lower income patients, for diabetic wound healing must be considered.

Research Question and Methods

The question that is addressed is: How does financial insecurity affect an individual's quality of care and treatment options for patients of lower income who suffer from diabetes in the United States of America?

Two central methods of evidence collection were employed in order to draw conclusions on the research question. The first data source used was primary data, specifically data from the American Diabetes Association, the Centers for Disease Control and Prevention through the U.S. Department of Health & Human Services and the Agency for Healthcare Research and Quality. I transcribed the data from the Diabetes State Burden Toolkit (Centers for Disease Control and Prevention, 2016). The categories collected from the CDC were more numerous than those listed, but those utilized as evidence for this research are:

- Overall rate of prevalence per 100 residents of each state
- Cost per patient annually in 2013 for each state
- Cost per 65+ year old patient annually in 2013 for each state

In addition, the percentage of the population for each state that were under the poverty line in 2016 is from primary source data from the U.S. Census Bureau, U.S. Dept. of Commerce, 2016 (FactsMaps, 2020). In addition, other income metrics were obtained including the average annual Social Security income of citizens over 65 in each state from Moneywise (Whiteman, 2019). Lastly, a measure of the average “Real Income” per household was obtained. This metric uses the average income by state and then accounts for both cost of living as well the value of money in each geographical region of the country (Mulhere, 2018).

From there, I delved into whether there are associations between the prevalence of diabetes in a state and the percentage of the population under the poverty level in that state. I analyzed the available treatment options regulated through state policies for the states that were both above the national average for prevalence of diabetes and above the national average for the percentage of the population under the poverty threshold, which is 12.7% of the population under the poverty line and every 9.4 persons out of 100 with diabetes. Two of these states, including Alabama and Mississippi are highlighted as case studies.

In addition, I used the Diabetes State Burden Toolkit data to analyze the cost of diabetes care in historically poorer states as compared to historically wealthy states in order to know whether there is a disproportionate relationship. If a state is historically financially insecure, one would hypothesize that the cost of their care would be decreased in order for the citizens to still have access to it. This is an important method because it gives a national scope of the care of diabetes and how well medicine in the United States is serving all of its patients of different backgrounds and income brackets that suffer from diabetes. *Techno-politics* informs the analysis of the whether there are power dynamics created through the coverage of Medicaid because the

lack of coverage of basic necessities for the care of diabetes allows for the deduction of whether there is equality amongst different income levels (Winner, 1980).

As the central purpose of this research is to draw connections to the human and social dimensions of a technical project, the second method of data collection that addresses inclusive innovation is interviews with diabetes advocacy groups. The groups that were contacted and willing to participate in interviews were Diabetes Advocacy, JDRF (Juvenile Diabetes Research Foundation), and the American Diabetes Association (ADA) of Greater Washington to understand their perspectives on disparities in quality of care of diabetic patients. Diabetes Advocacy and ADA were available via email communication, while I was able to speak over the phone with JDRF. The four main questions that were posed to interviewees were: “What do you believe to be the biggest hurdle that diabetics face in their daily life and their overall journey with this disease?”, “Are there any areas of diabetic healthcare that you see disparities between qualities of care between different patients? If so, what areas are most affected?”, “From your experience, have you seen a trend in the demographics of those potentially negatively affected by the cost of diabetes healthcare?”, and “Do you believe (or have seen from your advocacy work) that a person's type of insurance (be that private, Medicare or Medicaid) has affected their diabetes care and their access to it (i.e. choice in doctors or treatment/medication options)?”.

These responses add explanatory data that is critical for the interpretation of the descriptive statistics in order to ensure respect for people runs rampant through the Medicaid healthcare plans. I chose to include the quotes from respondents in the Results section based upon two criteria, including their emphasis that action must be taken to correct these disparities and their humanistic approach. The purpose of much social science research is to systematically gather evidence and draw conclusions. Then, the completed research is a critical component of advocacy groups' fights

against injustice and thus these two criteria are important if one were to use this research for activism. If patients do not feel as though their insurance fully covers their diabetic care needs, then this is an alarming sign that the systems have not been designed to meet the inclusive innovation requirements (Amadei, 2014). Incorporating a dimension like this is important for future advocacy purposes in order to emphasize the importance of creating change in this sphere of quality of care disparities.

Results

Financial insecurity affects an individual's quality of care, treatment options and access to healthcare for patients who suffer from diabetes in the United States of America. In addition, an individual's and community's lower income status increases their predisposition to diabetes. Although this research cannot identify absolute causation as no experiments were conducted and all possible reasons cannot be ruled out, it will establish striking trends such as an increase in the percentage of the population under the poverty line in a state is related to an increase in the prevalence of diabetes in the state. The explanatory data introduced by experts of the field, though, will offer more causation. This research also explores the apparent trend in gaps in state legislative policies for diabetic healthcare coverage in states in which the prevalence of diabetes is greater than the national average. Lastly, this research uncovered the opinions of advocacy groups, who are battling this national issue every day, who have attested to witnessing the horrors that financial hardships create for patients battling this lifelong disease.

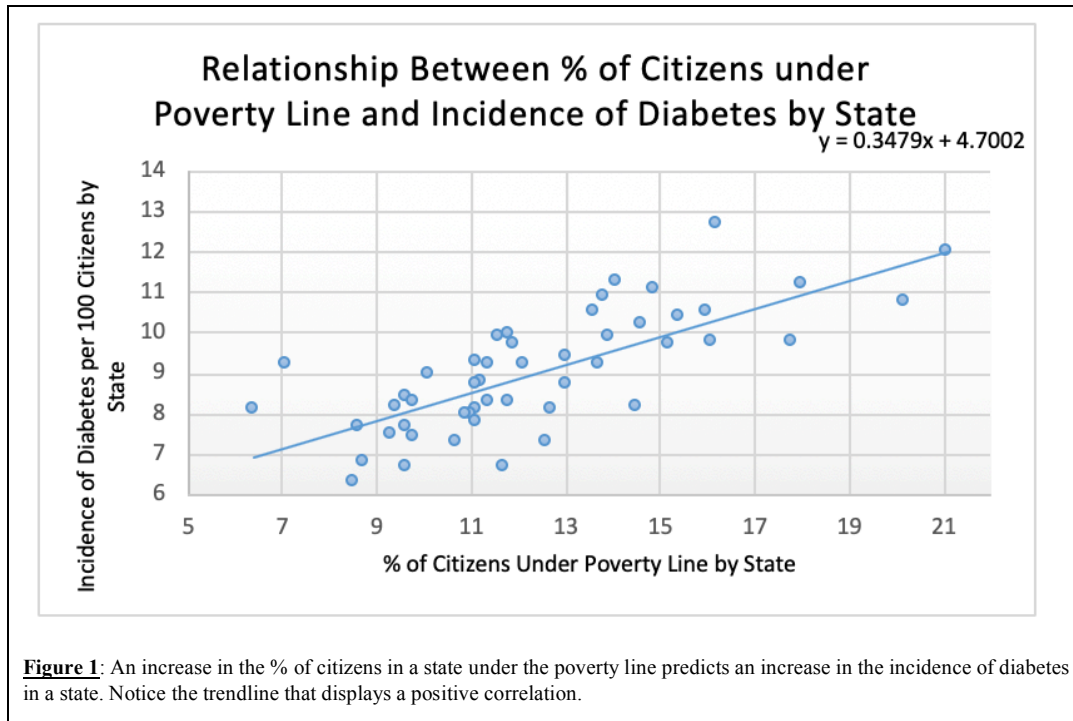
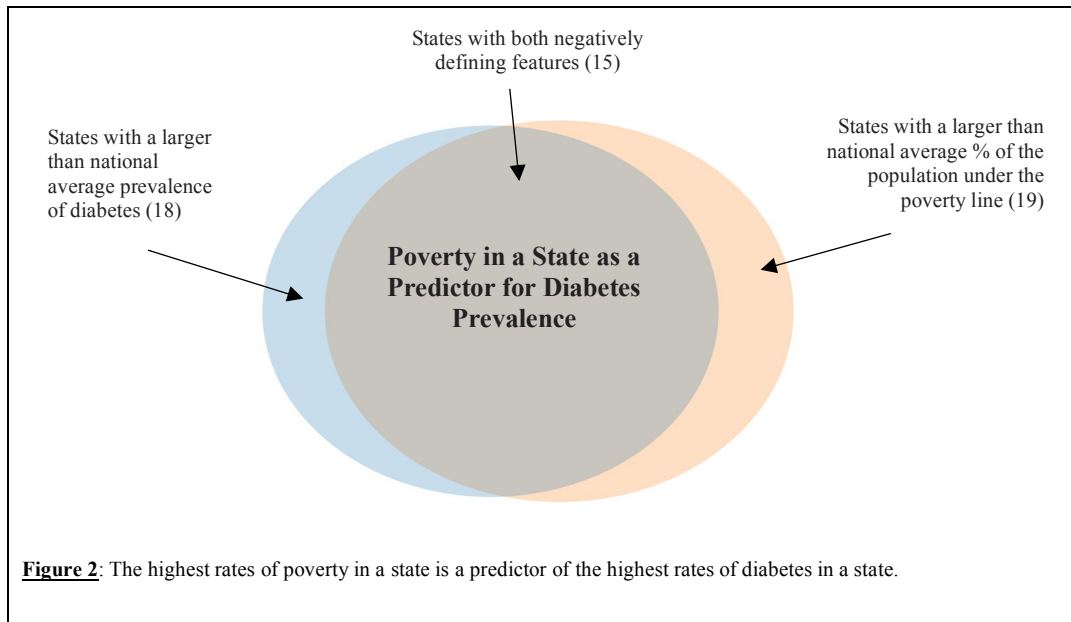


Figure 1 illustrates the striking trend that an increase in poverty in a state can predict an increased prevalence of diabetes in that state as well. This is the basis upon which policies of diabetic healthcare within a select number of states can be analyzed. This allows a selection of states that had both high rate of poverty and a high incidence of diabetes to be further examined. There are 18 states that have a rate of diabetes for every 100 people over the national average. There are 19 states that have a greater than national average percentage of the population that is under the poverty line (Semega, et. al., 2017; FactsMaps, 2020; CDC, 2016). 15 states fit the qualifications for both adverse categories, see Figure 2.



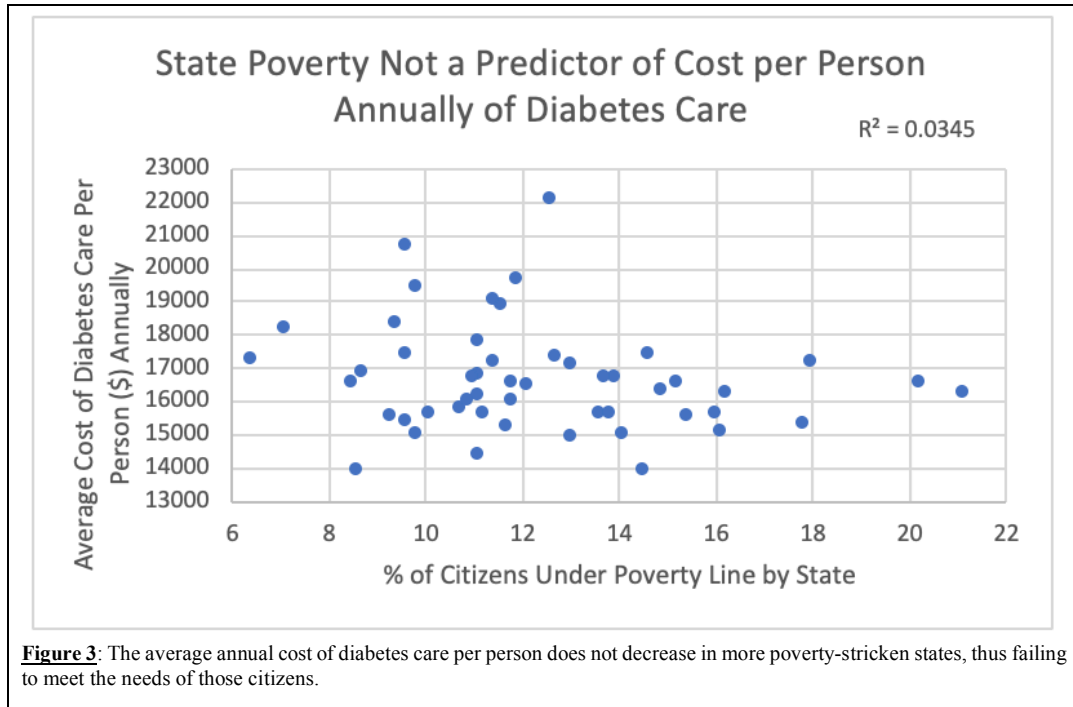
Of the fifteen states who have both above a national average of prevalence of diabetes and above average percentage of the population under the population line, there is evidence in the state legislative policies of seven of these states, including Alabama, Arizona, Arkansas, Georgia, Kentucky, Mississippi, and North Carolina, that points to attributable perpetuation of disparities of quality of care (Cauchi, 2016). These seven states all have instances of lack of mandated coverage for diabetes care. For instance, Alabama, the most detrimental of these seven in failing to protect the underserved diabetic population, has no mandated coverage or requirement of insurance plans for diabetes coverage. In addition, CHIP in Alabama, or Children's Health Insurance Program, which is a source of insurance coverage for uninsured children that do not qualify for Medicaid, requires copays for prescribed insulin, disposable needles, syringe combinations, and glucose strips (Cauchi, 2016). Restrictions on prescribed insulin, such as a maximum allowed number of units or combinations of prescriptions, in Alabama also exists. This lack of protection over vulnerable groups in Alabama, with every 12.7 out of 100 people suffering from diabetes (the highest in the nation) and 16.2% of their population under the poverty line (the third highest in the nation), can allow the disease to persist in communities untreated and thus

creating a poor quality of life. Patients that do not have these necessities covered must cover the costs themselves, which could result in decisions to forgo them.

The second state case study investigated is Mississippi with every 12 out of 100 people suffering from diabetes (the second highest in the nation) and 21.1% of their population under the poverty line (the highest in the nation). Although this state requires insurance providers to offer at least one policy with coverage of treatment of diabetes, the medications and supplies, such as insulin and needles, are not a required benefit (Cauchi, 2016). More concerning is the fact that disposable needles, syringe combinations and blood glucose strips are not covered for those citizens on Medicaid. There is also limited coverage for insulin, disposable needles, syringe combinations, and blood glucose strips for children on CHIP (Cauchi, 2016). This extreme gap in coverage severely diminishes the quality of care that financially insecure patients on Medicaid and CHIP are receiving through the state.

The next major uncovering is that there is no correlation ($R^2 = 0.0345$) between the poverty rate and the average annual cost of diabetes care per person by state, see Figure 3 for a visualization of the lack of relationship. This signifies that although an increased proportion of the population may not be able to afford the care, its subsequent cost does not decrease in order to meet the needs of the people. This phenomenon is explored further in the Discussion, but it is important to note that this is a key feature in analyzing the quality of care as it demonstrates that the cost out prices those who are financially insecure in historically poor states from accessing basic needs to fight their disease. The average percentage of household income required for one individual's cost of diabetes care annually is 29.45%. This extreme cost of care rises to 65.36% for those receiving Social Security checks and are aged 65 and older (Whiteman, 2019). In a household in which the income is below the poverty line, these families are already defined as struggling to make ends

meet, feed their families, pay the utilities, and afford rent. Therefore, if a third of their income must be used for diabetes care, this creates an unsustainable strain on a family that may force a patient to sacrifice the maintenance of their disease.



For example, Barbara from Diabetes Advocacy added her expertise by offering the viewpoint that:

“Unless you have wonderful insurance that will never disappear, you must always be concerned about the high cost of staying alive. In the US, we are seeing more and more people living with diabetes having to ration their insulin. That is absurd. Imagine living in a first world country and not being sure if you can afford the medication that will keep you alive? This is sadly the reality for too many people living with diabetes. For those who can cover their insulin costs, the cost of the technology that optimizes their health can still be prohibitive. This is wrong and adds more stress to an already stressful condition.”

Thus, as is evident through this explanatory data, Barbara's experience advocating for these underserved patients, although some people could live better lives through the lifesaving powers of insulin and other advances in diabetic healthcare, often they are not able to afford these treatments (B. Wagstaff, personal communication, February 27, 2020). This creates an enormous difference in the quality of care between those that can and cannot afford to fight their disease.

In addition, Laura Keller from the American Diabetes Association of Greater Washington added this important point to the conversation over disparities in quality of care:

“I think that unfortunately we still see disparities due to lack of insurance or quality of insurance. Often this mirrors socio-economic disparities and access. If you have a better job with employee sponsored health insurance you have more access and lower cost which usually equates to better care.”

These statements illustrate that before healthcare is even at play in this situation, an individual's job has an enormous impact on someone's ability to have equal access. Often, those of higher socio-economic status have access to higher paying jobs, which often provide enhanced healthcare insurance plans to give them a higher quality of care.

Discussion

The theories of *techno-politics* and *inclusive innovation* structure the analysis of diabetic care across the United States of America. Politics in the United States, especially in relation to the coverage that Medicaid and CHIP, influences the insurance coverage offered from state governments for those of a lower socioeconomic status, offer, and impacts a diabetic patient's choices in treatment and quality of care (Kumar & Berlin, 1998). The case studies of states that had policies that did not protect people of lower socioeconomic from receiving full benefits and coverage of their diabetes care needs is an example of *techno-politics* in action because both

policies have arisen around healthcare technologies and a negative power dynamic is created that ostracizes citizens out of equal qualities of care (Winner, 1980). The politics of state government's choices in their legislative or lack of legislative action in protecting socioeconomically vulnerable groups and its subsequent negative power stance over this demographic by out pricing them from their healthcare needs has created disparities in quality of diabetic care across the country (Winner, 1980).

In addition, the analysis of the cost of care that is relatively constant across the country, despite varying levels of poverty is an example of a collective group of technologies – diabetes care as a whole – which does not meet Amadei's (2014) definition of inclusive innovation, which is designing a technology, infrastructure or a system with the input from those that are facing the problems and will be using it. State legislative governments in poverty-stricken states such as Alabama and Mississippi have not designed policies for Medicaid and CHIP with the input of their socioeconomically insecure citizens, otherwise they may be more comprehensive and not require out of pocket costs that they cannot afford. For instance, Sarah Brawley, the outreach coordinator at JDRF acknowledged that the main problem newly diagnosed families face is the prospect of how they will pay for this lifelong disease when insurance plans and policies are constantly changing (S. Brawley, personal communication, March 4, 2020).

Identifying the limitations of research such as this is important in order for future investigators to build upon the work that has been done thus far. The two central shortcomings of this research are the limited number of interviews conducted. I was able to contact a representative from Diabetes Advocacy and JDRF individuals representing advocacy groups. If more time or resources were available, these interviews could have been greater in number and more comprehensive. For instance, it is evident after conducting the limited number of interviews that

advocacy groups tend to already have a biased perspective on diabetic care. If they did not believe that patients faced troubles related to their quality of care, then their mission and work would be not purposeful. Thus, expanding these interviews towards the perspectives of doctors, other healthcare providers, insurance company representatives, and more policy makers would be important.

In the future, I would change my approach by incorporating more geographically diverse perspectives. If the research question is poised to answer how the disparities affect “patients of lower income who suffer from diabetes in the United States of America”, then gathering the thoughts of those across the country with differing insurance coverages, healthcare providers, backgrounds, income levels, and perspectives on this issue would be important. For instance, I would incorporate rural, inner city, and suburban perspectives in a more systematic, random and structured way, rather than researching diabetes advocacy groups and healthcare advocacy groups in Washington, D.C.

This research is a fundamental part of my training as a future engineer. It will greatly aide me in advancing my upcoming engineering practice in order to remain focused on the mission of my company. In July 2020, I will be working for Amgen, a biotech/pharmaceutical company, at their manufacturing site in Rhode Island. The company prides itself on its mission of “To serve patients”. Therefore, because of the insights and perspectives I have uncovered through this research, I will be able to keep in mind those that are considered underserved patients and communities. Although during my first two years in a Rotational Program, I will not necessarily be making decisions that directly affect these people, indirectly the decisions and work I do may one day affect those that Amgen serves. Therefore, I will carry with me a viewpoint centered on

empathy and compassion for those suffering from diseases with limited resources to aid in their fights.

The theories and analysis of disparities in quality of diabetic care due to socioeconomic status can be applied to innumerable cases across the world and in the United States. One particularly important trend is the increased rate of death and complications for women of African American descent in comparison to Caucasian women during pregnancy and childbirth. Just as diabetes has targeted a lower socioeconomic demographic, this healthcare issue has negatively affected a racial demographic. The morbidity rate for African American women is four times higher than for Caucasian women during pregnancy and child birth. In addition, this problem is escalating as evidenced by the fact that the morbidity rate for African American pregnant women is higher than it was two decades ago (Taylor, et. al., 2019). If one were to analyze this through a techno-political lens, it could be argued that due to the lack of strong and sustainable healthcare practices, healthcare surveillance programs, and data collection in these communities, these women are underserved and thus are at a higher risk because they are not on the receiving end of the power of new healthcare practices, thus creating power dynamics for the worse.

Conclusion

By uncovering broad and systemic issues of policies failing to protect patients across the country to first-hand accounts of advocacy groups who are fighting for increased education, awareness, and cost reformations, this research shows that disparities exist in the quality of care for patients of varying socioeconomic levels exists. The two most significant takeaways from these developments are that it is important to understand the strong negative power dynamic that patients often faceoff against and that if one intends to develop a new product for the healthcare market, be that diabetes care or not, they must analyze whether it is inclusive and will meet all people's

needs. First, patients must deal with the institutional power of insurance and government provided insurance, such as Medicaid. If they are unaware of their available options, what is covered by their plan, or potential copays associated with visits, medications, or devices, then they may be put in an uncomfortable decision on whether to properly care for their disease or meet their family's daily basic needs such as food and housing. In a first world country, deemed one of the most affluent in the world, this is a severely unethical dilemma to allow these people to suffer with unequal quality of care for a disease that they cannot afford and did not choose.

As briefly highlighted above, there is much potential for future researchers to build upon the work that has been done. It would be important to next incorporate first-hand accounts from residents of states with poor policy protections, such as Alabama or Mississippi. If one understood the daily decisions they make, such as rationing their insulin or making healthcare decisions based on cost, one could develop a fuller understanding of how exactly socioeconomic status effects the disparities in quality of care. How do they decide between providing food for the family or ensuring that they are caring for themselves through proper diabetes medications? These are the types of questions that may be uncovered through first-hand accounts of diabetes patients in underserved communities. In addition, speaking to legislators to understand if there are any other ways that they are working to protect these vulnerable populations would be important. By asking questions such as "How do you ensure that those underrepresented communities that are often silenced do to economic barriers are properly protected when you examine healthcare legislation?"

Overall, this research has uncovered much, but with over 34 million Americans currently suffering from diabetes, there is much work to be done to eliminate negative power dynamics and protect those that do not have the means to fight for basic human decency and respect (CDC, 2019). In order to arrive at a future where socio-economic status and one's quality of insurance plan does

not designate whether they are able to afford and receive the newest and most advanced treatment plans, we must act now to raise up the voices of those who are often silenced to the leaders who are making healthcare policy decisions.

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