Inequity Surrounding Insulin Prices and its Impact on American Citizens

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Introduction

Medication prices for chronic illnesses are increasing rapidly, making it extremely difficult for patients to manage and treat their disorders. While insurance can cover a significant portion of it, out of pocket costs are unaffordable for most. High market prices of insulin have created a cycle of improper diabetic management, specifically in uninsured Americans, which created an inability for proper holistic treatment for those with Diabetes Mellitus. Those who are uninsured are facing a crisis in which they are forced to decide between taking a life saving medication or paying their weekly bills. The United States is one of the only nations lacking in regulation for the price of insulin. Therefore, life saving drugs should be made affordable for all, insured or uninsured, as we have a moral obligation to do whatever we can to keep people alive and their bodies functioning properly.

Diabetes and Insulin in the Body

Diabetes Mellitus, commonly referred to as Type 1 and Type 2 Diabetes, is a growing health concern globally. In the United States, the prevalence of Type 1 Insulin Dependent Diabetes is increasing rapidly. Diabetes is a chronic illness that impacts the daily life of the patient and their family members. In the United States, “an estimated 1.3 million U.S. adults are living with T1D and about 40,000 new cases are diagnosed annually (Willner, et al., 2020).” It can be classified as a series of metabolic conditions associated with hyperglycemia and caused by partial or total insulin insufficiency (Egan et. al, 2019) which causes the affected to become insulin dependent. Those who are impacted by Diabetes Mellitus must adhere to a regimen of proper diet, exercise and glucose management. In Type 1 Diabetes, the pancreatic cells are destroyed by the body’s autoimmune inflammatory mechanism. This leads to a complete insulin

deficiency in the body. While there are many hypotheses that are being considered, Diabetes Mellitus is idiopathic in its origin, which is often a factor in delayed diagnosis and treatment.

Insulin is a critical medication for those who have Diabetes Mellitus. Without it, the individual would develop deadly elevated blood sugar levels. Insulin manages the levels of blood glucose by working within the body to help absorb the glucose in the bloodstream. In the case of diabetes, the deficit of insulin creates a lack of glucose absorption by the cells, and creates high levels of unabsorbed, circulating insulin. When a person is in a state of high blood sugar, it is classified as hyperglycemia, and has very adverse effects. According to Willner, "Over time, even short episodes of hyperglycemia can precipitate microvascular complications including heart disease, kidney failure, blindness, nerve damage, lower limb amputations, and potentially fatal diabetic ketoacidosis" (Willner, et. al, 2020)". If a person was to go without insulin, even for a few days, death would be imminent.

When a patient does not have the proper insulin levels in the body, they will go into diabetic ketoacidosis (DKA), which can also be referred to as hyperglycemic shock. This crisis occurs when the serum levels of glucose in the blood reach over 240 mg/dL. Normal levels of fasting glucose should be under 100mg/dL. DKA has been determined to be "the leading cause of mortality among children and young adults with type 1 diabetes, accounting for ~50% of all deaths in this population" (Vellanki, 2018). Between 2000 and 2014, over 30 million adults and children were hospitalized because of DKA, with the rates increasing 6.3% each year (Vellanki, 2018). These statistics emphasize the original claim that as insulin prices rise, more Americans are having difficulty controlling their diabetes, which is causing a drastic rise in DKA diagnoses,

as well as other complications. When a person is unable to control their blood glucose, due to a lack of insulin, they "will die from hyperglycemia within days or weeks (Beran, et. al, 2016). When the body cannot maintain its normal functioning, it will begin to shut down very rapidly. This will eventually lead to organ damage such as heart and kidney failure, blindness and diabetic retinopathy and nerve damage.

Social Determinants of Health

The social determinants of health can be described as the "conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks" (US Department of Health and Human Services). It can be divided into five major categories, which are: economic stability, education access and quality, health care access and stability, neighborhood and built environment, and social and community context. According to Hill, "research has demonstrated that social determinants are associated with the disproportionate development of chronic conditions and challenges encountered with managing them" (Hill, et. al, 2013). Focusing specifically on economic stability, when a diabetic is unable to afford their insulin, they will begin to mismanage their chronic illness.

Economic stability has been discovered to be one of the major factors of the social determinants of health that impacts the control of Diabetes Mellitus. Those who are suffering from a chronic illness and are considered to be on or below the poverty line, have a more intense financial burden as the effects of poverty become exacerbated due to the high medication prices. Those who are on the poverty line, specifically those who are uninsured, may not have the

resources that they need to manage their condition, such as having "adequate housing, nutritious food, and health care services" (Hill, et. al, 2013). All of these factors can tie together to create, all around, an improper holistic management of Diabetes Mellitus.

When discussing the interventions for economic mismanagement of Diabetes Mellitus, it can be viewed through horizontal and vertical policies. Horizontal policies are interventions that are specific to the condition, while vertical policies are working to improve the economic standing that is causing the relation between poverty and uncontrolled diabetes management. Most of the time, lawmakers and doctors focus specifically on horizontal policies, and managing the crisis in front of them. However, it is becoming more prevalent that the relation between uninsured Americans and inability to afford insulin. This is a vertical issue, which needs to be addressed in society. Americans should be focused on addressing the initial problem before it happens, instead of looking to do damage control after. The prices of insulin are continuing to increase, making it incredibly difficult for those who are of a lower economic status to continue to treat their diabetes. Instead of working to lower the insulin cost, and prevent all secondary complications, the inaccessibility of insulin is forcing Americans to not treat their original illness, and instead focus on the side effects that come from high insulin levels.

Uninsured Americans and Insulin Prices

It has been estimated that 31.1 million United States citizens were uninsured at the start of 2021 (American Hospital Association, 2021). For this population, they either cannot afford to pay for insurance out of pocket, or they do not have a job that covers insurance for them. They are already struggling to make ends meet in this situation, and being uninsured adds to the

persistent problem of being unable to afford basic life necessities. When a chronic disease, such as diabetes, is factored into this situation, it becomes a daily struggle of choosing to purchase insulin or whether or not to buy groceries that week. No human should be forced to make a decision over things that they should have a right to. Picking between food or medication is a cycle that is hard to escape from, but it is something that many uninsured Americans face each day. There is almost never a time where this group of people feels economically secure enough to afford the things they need. The people who need the most help with insurance, those who cannot afford it on their own, are the ones who are faced with these difficult decisions.

The price of insulin is rapidly increasing in the United States each year. For those who are uninsured, insulin prices are not affordable, and they will often forego their medication in order to pay other bills. According to the Mayo Clinic, one small vial of Insulin Lispro, a form of rapid acting insulin, "used to cost $21 in 1999, costs $332 in 2019, reflecting a price increase of more than 1000%" (Rajkumar, 2020). Rapid acting insulin is used around mealtimes, as it has a very short onset, and can begin affecting the blood glucose levels at a fast enough rate to manage the incoming glucose from the meal. Depending on the severity of the patient's diabetes, a person could require anywhere between 3-6 vials of all types of insulin per month, totaling a minimum of between $996-1,992.

Comparing the cost of insulin in the United States with other nations, such as Canada, it is clear to see that there is a drastic difference in the price. Those with diabetes are a vulnerable population; they have no choice but to take their medication to survive. America has three companies which have monopolized the insulin industry, and are continuing to raise the prices

with little to no pushback. There are currently three insulin manufacturers in the United States which together control just under 100% of the insulin created out of the United States. These companies are Eli Lilly, Novo Nordisk, and Sanofi. They are aware of the high demand for insulin, as more people are being diagnosed each year, and they have the knowledge that the patients can either purchase their medication, or die (Rajkumar, 2020). There is little to no data on what the production cost of insulin is for the manufacturer. However, it has been estimated by Health Action International, that a year long supply of insulin costs the manufacturer between $78 and $133 dollars to sell (Lawrence, 2018). This is showing an immense inflation in the price between what the consumer pays, versus what it actually costs the manufacturer to make.

The discrepancy between the cost of insulin in the United States is reaching all time highs. Each person has a very different insulin demand, so the average prices for insulin are variable. According to the JAMA Internal Medicine, between “2010 and 2015, the monthly wholesale price of Humulin, the most popular insulin, rose to nearly $1100, up from $258 for the average patient” (Rosenthal, 2019). According to Schenider, the price of insulin has increased over 10% in the United States, while in Canada, there has only been an inflation of 0.01%. The United States is lacking a regulation of prices, with no control over how much companies can charge for a life saving drug. Unlike medications, such as Ibuprofen, there is no generic name for insulin. Ibuprofen has both a brand name, Advil, and a generic name. The brand name of Advil is always more expensive than the generic, store brand name. This allows for lower costs for the medication. Since insulin is a difficult drug to manufacture, there is nothing being made that is currently similar. This leaves no competition for the companies, which is allowing them to continually raise the price of insulin.

Difference in the Canadian Healthcare System

In Canada, there is a division of the government called the Patented Medicine Prices Review Board, which has instilled rules and regulations which prevent manufacturers from taking advantage of those with chronic illnesses. According to the Government of Canada, "The PMPRB protects and informs Canadians by ensuring that the prices of patented medicines sold in Canada are not excessive". This board works together with the universal healthcare of Canada, to help to keep prices of all prescription medications accessible to all of their citizens. All provinces of healthcare in Canada cover insulin in some form. While some insurances can cover more specific aspects of insulin, at its most basic level, insulin is completely covered for all people in Canada, both insured and uninsured.

Prevalence of Diabetes in Society

In 2006, Pfizer had completed a study focusing on the uninsured American, and the types of health conditions that they are commonly hospitalized for. In children with diabetes, 1,049 children have been hospitalized for a complication from this disorder. Complications usually arise from improper management, which is either due to a lack of insulin or a lack of ability to receive proper medical care. Out of all children who are hospitalized for a complication of diabetes, 4.1% of the children fall under the uninsured category. This places the uninsured child in the Top 20 reasons for them to be hospitalized while they are aged between 1-17. Over age 18, 22% of the uninsured hospital stays are related to adolescents who are experiencing complications with managing their diabetes. There are 22,975 uninsured adolescents who were hospitalized for this reason. For adults aged 40-64, 24,785 of them were hospitalized with diabetic complications, and 11% of them were uninsured. Diabetes impacts both insured and

uninsured people alike, however, these numbers could be lower for those who do not have insurance. These statistics are higher than necessary, as the percentage of uninsured diabetics with complications would decrease if they were given the opportunity to have low-cost insulin.

Typically, it is seen that high insulin prices are a concern for those who are uninsured. With insurance, insulin is at a more affordable cost. However, to those who have jobs who do not provide insurance, or if they cannot be on Medicare, these Americans face a life or death situation every day. Those who have "no insurance or a high deductible could have to pay at least $1,000 for a month's supply" (Caplan, 2021). This leaves these citizens no choice but to ration their insulin. Recent studies have found that around 25% of diabetics are rationing their insulin. In 2020, it was reported that 8.3 million people in the United States require insulin to help them regulate their blood glucose. That leaves over 2 million diabetics mismanaging their chronic illness (Hayes, et. al, 2020) simply because the medication that can keep them functioning properly, is unaffordable to them. When diabetes is improperly treated, the body begins to develop other adverse reactions and experience microvascular and systemic body failure.

In an article written by Fortune, the focus was given to Sa'ra Skipper, an uninsured American citizen who rationed her insulin, due to the high prices, and ended up in the emergency room. At the beginning of her story, she had a steady job which gave her insurance and other benefits. However, until her benefits kicked in, she had to pay her own insulin deductibles. She was left having to pay cash for her insulin, which totalled approximately $1,000 for her month supply; a price she could not afford with her current circumstance. She was still paying rent and other necessities of daily living. As she continued her recollection she reached her current state.

Now, a few years later, Sa'ra was unemployed, and had been recently admitted to the emergency room due to a lack of glucose control. When asked how she was going to manage, she said that her insulin stockpile will run out in the next month, but that she doesn't know what will happen after that. Without a job and without insurance she is at a standstill, and is being faced with making the decision of what necessities are most important for her to purchase. Uninsured Americans are put under severe stress and are being forced to put their lives at stake in order to continue paying their bills.

Comorbidities of Diabetes

Patients with diabetes are more likely to experience other complications, not related to insulin regulation. Since diabetes is a chronic illness, the entire body is impacted by the lack of insulin. It has been determined that 75% of adults who have diabetes, also have high blood pressure. The combination of Diabetes Mellitus and Hypertension can cause both macrovascular and microvascular side effects. The macrovascular system affects any of the large blood vessels in the body, which can lead to "coronary artery disease, myocardial infarction, stroke, congestive heart failure, and peripheral vascular disease" (Long, et. al, 2011). The microvascular components are when the small vessels are impacted. This damage will cause neuropathy, retinopathy and nephropathy (Long, et. al, 2011). Neuropathy occurs when the small nerves and vessels in the extremities are damaged, which can lead to numbness and tingling. Retinopathy and nephropathy are where the vessels of the retina and kidney, respectively, are damaged due inadequate perfusion. If left untreated, these complications will get worse, and the body will begin to deteriorate rapidly.

A recent study completed out of Tampa Bay, Florida has discovered that "patients with diabetes pay about $16,750 in medical expenses per year, which is an average of 2.3 times greater than their medical expenditures would have been without diabetes" (Joud, et. al, 2020). Since there are many comorbidities that exist with Diabetes Mellitus, there are many other protocols that a patient must also follow. Insulin is not the only treatment regimen for a majority of those diagnosed with diabetes. If a patient is uninsured, it is extremely difficult to follow each of the protocols recommended for them. Not only will they be having to find a way to pay for their insulin, but for medications for the macrovascular and microvascular complications as well. Due to the high price, diabetics begin to stop treatments that they believe are not as important or the most expensive. If they are already experiencing a financial crisis, such as not being able to afford rent or food, it is often discovered that their medication protocol is not considered a priority.

Conclusion

Insulin prices in America are rapidly increasing at an uncontrollable rate. Due to the lack of regulation for the three companies that create insulin, there is no limit to how expensive it can become. The high prices are leaving Americans no choice but to start rationing their insulin. However, since the body is fully dependent on external sources of insulin, when it is limited, rapid deterioration occurs. The uncontrolled glucose levels in the blood will begin to cause systemic complications, and can eventually lead to Diabetic Ketoacidosis and death. As Americans, we have a duty to give all people the opportunity to afford this medication. It is not an elective treatment, but one that is required to stay alive. We cannot justify allowing certain

populations of people to suffer, and possibly even die, due to the fact that the prices of insulin are high due to unregulated and monopolized companies.

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