

Life or Death: A Sociotechnical Analysis of the Factors that Influence the Cost of Insulin

A Research Paper submitted to the Department of Engineering and Society

Presented to the Faculty of the School of Engineering and Applied Science
University of Virginia • Charlottesville, Virginia

In Partial Fulfillment of the Requirements for the Degree
Bachelor of Science, School of Engineering

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Spring, 2022

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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STS Research Paper

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Emergence of Diabetes and Insulin Conundrum

Type 1 and Type 2 Diabetes resulted in 79,000 deaths in the United States in 2020 and has plagued mankind for centuries, with limited solutions to address disease progression since its discovery in Ancient Egypt in 1500 BC (*Explore Diabetes in the United States | 2020 Annual Report*, n.d.; Lakhtakia, 2013). Diabetes is categorized as a syndrome of impaired carbohydrate, fat and protein metabolism due to insulin sensitivity or inability to secrete insulin that can lead to fluctuations between hypoglycemic, low blood sugar, and hyperglycemic, high blood sugar, conditions within the body (Hall & Guyton, n.d.). When left untreated the inability to control glucose levels has been known to compromise vascular integrity that can lead to large systemic complications such as retinopathy, retina failure, nephropathy, loss of kidney function, and neuropathy, nerve dysfunction, which all greatly decrease quality of life and can cause death (Corliss et al., 2020; *Diabetes Complications | ADA*, n.d.; *Diabetic Neuropathy | NIDDK*, n.d.; Lim, 2014). After centuries of diabetic's survival being limited to a few years on a strict low carbohydrate diet, Sir Frederick Banting discovered insulin, which reversed the symptoms of diabetes and prevented development of those large systemic complications. This revolutionary discovery transformed treatment of diabetes as improved purification and the bioengineering of slow acting insulin made it widely available to those afflicted (*Insulin 100 Years*, n.d., p. 100; Quianzon & Cheikh, 2012). Dr. Banting refused to put his name on the patent for insulin, selling it for a \$1 in an attempt to help all diabetics with affordable access to a life-saving necessity

(Belluz, 2019). However, the story of diabetes and its treatment is not a fairytale with a happy ending for those who suffer from it.

Pharmaceutical companies within the United States gained access to the patents, creating their own unique analogue insulins. The creation of new insulin analogues offered the biopharmaceutical companies the ability to competitively set prices of insulin as they see fit, forcing diabetic individuals to pay the chosen price in order to survive (Cefalu et al., 2018). The cost of insulin has tripled in the last decade, leading to out-of-pocket costs doubling for those afflicted in the US (Belluz, 2019; *Insulin's Out-Of-Pocket Cost Burden To Diabetic Patients Continues To Rise Despite Reduced Net Costs To PBMs*, n.d.; Meiri et al., 2020). The high price of insulin has created a complex problem in the lives of diabetic individuals around affordability and accessibility that must be solved; for failure to do so will result in unnecessary death and suffering. In the sociotechnical analysis of the interconnected parts of the scientific community, biopharmaceutical industry and public policy will highlight the power of innovation and the necessary ethical and moral decisions needed to protect the most vulnerable, in the way insulin pricing has currently failed to do so. Wicked Problem framing will be applied to understand how insulin is utilized as a technological fix to address diabetes, but harming those afflicted due to exorbitant costs as a result of various interconnected actors in the social and scientific fields. It is a necessity to delve into deeper analysis of the current system of treating diabetic patients and determine an optimal solution that prioritizes health and safety while addressing the financial burden the current system employs. In order to evaluate the impact of high insulin prices due to biopharmaceutical industrial decisions and the impact on the lives of diabetic patients one must answer the question: In what ways are the current prices of diabetic treatment and testing options determined by pharmaceutical stakeholders within a for-profit healthcare system harming

diabetic individuals by decreasing quality of life and what solutions exist to remedy this in an equitable way?

Background Information

Origin of the Unknown

Inscribed on papyrus in the heart of Egypt in the 1500s are references to individuals who suffered from “too great emptying of urine” (Karamanou et al., 2016; Lakhtakia, 2013). While in India, patients were diagnosed with a symptom that received the name *madehumeha* or honey urine, after ants would be placed near the spot of urination and move to the direct spot when attracted to the sweetness of the urine (Das & Shah, 2011; Trowell, 1982). Then in a small region of Greece called Cappadocia, a physician named Aretaeus coined the term diabetes, from the Greek word siphon, for a disease that caused constant flow of urine (Quianson & Cheikh, 2012). These were the first seeds in human history of the pathology behind diabetes, the origin of understanding for what would one day become one of the world’s most prevalent and deadly diseases. Today we know that diabetes can be categorized into two types. Type 1 is an autoimmune response in which the pancreatic islets are destroyed and can not make insulin and Type 2, where insulin deficiency or defective insulin release result in insulin resistance (Tan & Cheah, 1990). In 2018 in the US, 34.1 million individuals suffered from both Type 1 and 2 diabetes, while in 2020, 102,188 deaths due to diabetes occurred (*Centers for Disease Control and Prevention*, 2022). From times of old to present day, diabetes has marched forward to a steady drum beat that has brought only pain, suffering and possible death in its wake. Yet, in the distance we have the glimmering beacon of hope, the discovery of insulin.

A New Hope: Insulin

Death was all but guaranteed for centuries when afflicted by diabetes. A plethora of treatments were attempted, to no avail. Finally, it was discovered in various places worldwide that fasting, low calorie diets, carbohydrate-free diets and eventually sugar free diets all reduced diabetes progression and reduced the speed that mortality was reached (Vecchio et al., 2018). However, some of these restrictive diets prescribed extreme caloric deficits, some as low as 450 calories a day, which combatted diabetes but eventually resulted in starvation (*The History of a Wonderful Thing We Call Insulin* / ADA, n.d.). No ideal treatment existed, and no answers appeared in sight.

Then in 1922 the world would be forever changed by a miraculous scientific breakthrough. Dr. Frederick Banting, Charles Best and John Mcleod designed experiments with dogs in which they removed the pancreas of some dogs, leading to the development of diabetes and rising glucose levels. These increased glucose levels could be combatted through the intravenous injection of the dogs own pancreatic extract, called *isletin*, to lower glucose levels (Quianson & Cheikh, 2012). Following this discovery, J.B Collip joined the group to purify *isletin* or as we know it now, insulin. Once purified the insulin was used with promising results on diabetic patients, allowing for the ability to control the dangerous and deadly high blood sugar spikes that had once meant almost certain death. Finally, a treatment had arrived that could allow diabetics to live their lives safely, and only improved in efficiency as purification and yield improvements were made.

Realizing that insulin could change countless lives for the better, Dr. Banting and his colleagues made a selfless choice in a push towards mass production. They believed it was unethical for doctors to profit off of something that could save lives, as Dr. Banting famously said “Insulin does not belong to me, it belongs to the world.” He and the other researchers did

not want their names attached to any patents and they sold the patent rights to the University of Toronto for \$1 each (*100 Years*, n.d.). The University of Toronto came to an agreement with Eli Lilly in 1922 to begin large-scale production of insulin (*Discovery of Insulin at University of Toronto / Heritage U of T*, n.d.). Fast forward to today, when demand for insulin to combat diabetes has never been higher and three companies within the United States have risen to the challenge, Eli Lilly, Novo Nordisk and Sanofi (Knox, 2020). Now a treatment exists, produced in vast quantities for individuals who suffer from diabetes. A storybook ending on the chapter on treatment of diabetes, the focus can be moved to a cure. However, this is far from a happy ending, under the façade of mass production and focus on care and human compassion is the real and ugly truth. Three companies control the insulin market that diabetics are dependent on for survival, meaning that whatever prices are chosen, individuals will be forced to pay, and these prices are only rising.

Cerberus: The Three Headed Monster

Eli Lilly, Novo Nordisk and Sonafi control 99% of the insulin market by value and 96% of the insulin market by volume (Beran et al., 2019). This leaves the three of them in an interconnected web of control over quantity, quality and increased prices. However, they are not the only influence. There is a complicated stakeholder network from pharmacies, pharmacy benefit managers (PBMs), insurance companies, wholesalers and the three drug companies that influence the price the consumer is paying. The problem begins at the top and trickles down. The list price of Eli Lilly's human insulin analog, Humalog, has risen 138% (2009-2015), while for Novo Nordisk the Novolog insulin vial has increased 353% (2001-2016) and Novolog FlexPen has increased 270% (2003-2016) (Cefalu et al., 2018). In 1999 Humalog cost \$21, now it costs \$332 in 2019 (Rajkumar, 2020). The Big Three use three justification for the cost barrier: There

is a high cost of development, the nature increases are a result of the free market economy within the US and natural inflation and lastly these costs allow for renewed innovation to invent new insulin-based products that best help the consumers and will lower costs (Rajkumar, 2020).

Despite these justifications a person with diabetes will need multiple vials per month to survive (2-4) and may have to pay some fraction out of pocket if they have insurance or possibly all if they do not. If someone cannot afford insulin to lower their blood sugar eventually it rises to a level that is so high the pH of the blood turns acidic, killing all of their cells and resulting in death, a completely preventable disease state known as diabetic ketoacidosis. Therefore, it is a necessity that diabetic individuals have continuous access to insulin without affordability as a barrier. Shrouded in mystery are these three behemoths, controlling the landscape of the US insulin market, and at the bottom are those who face the repercussions of rising costs daily. Solutions must be found to help diabetics.

STS Framework

Wicked Problem Framing

German design theorist Host Rittel and American urban designer Melvin M. Webber introduced the framework of the wicked problem in 1973. A wicked problem is a difficult social or cultural problem that is multifaceted with complexity as a result of the number of actors involved, the problem being hard to understand, differing opinions on the topic, economic or political impact and the intertwinement of the problem with other problems (*Dilemmas in a General Theory of Planning* / SpringerLink, n.d.). The elevated price of insulin represents a wicked problem within the framework of the United States healthcare system as a result of various stakeholders involved, the diversity in public and private opinions on the topic, and no clear solutions that alleviate the concerns of pharmaceutical companies about scientific progress

versus the necessity of diabetic patients to fundamentally survive (Seager et al., 2012). This problem occurs daily, for millions of people across the US and causes unimaginable pain and suffering that can be avoidable. Fundamentally, insulin appears as the perfect technological fix. From a scientific standpoint it can lower blood glucose levels after diabetic's eats, preventing diabetic ketoacidosis, while taking what was once a guaranteed death sentence and turning it into a life of challenge but with possibilities to fully live it. Yet, the quantity of insulin needed, frequency of treatments and overall cost negatively impact the lives of those with diabetes. Not only do they face the stress and responsibility of monitoring their glucose levels diligently and treating them properly at all times to limit the development of future complications, but they also must face the stress of how they will afford insulin and where the money to do so will come from. Therefore, a greater analysis of the system and wicked problem in which diabetic's medical needs are inadequately being addressed due to limitations on accessibility to insulin as a result of exorbitant prices is needed. An improved understanding of the problem can foster solutions or pathways forward that empower and help the individuals who need it the most. Either in the form of treatments outside of insulin or ways in which insulin becomes accessible and affordable so that diabetic individuals can focus on living life and not living to buy insulin. Thus, a solution of any type that is explored must be human centric. It must be focused on compassion and care for individuals with diabetes. It can recognize the complexity of actors, history and the political and economic system that the problem is ingrained in, but it needs to ensure a better path ahead. In America, life, liberty and pursuit of happiness are inalienable rights at the core of who we are, and in this wicked problem, individuals with diabetes can not pursue happiness if they face the current prices of insulin. That fundamental failure will be explored in a new path forward through a sociotechnical analysis of the wicked problem.

Foundational Wicked Problem Analysis of Diabetes in the US

Wicked problems are not uncommon in today's world. The United States healthcare system is one at its core, unable to provide equitable and affordable to individuals across the nation regardless of identity, socioeconomic status or region of settlement. However, it is also tasked with facing wicked problems, from the Spanish Flu to the Covid-19 Pandemic and a variety of everyday procedures. Fundamentally they are faced with trying to optimize patient health and quality of life before, after and during all of these events and are consistently improving over time with innovation and introspection. Past STS scholars have analyzed some of these wicked problems faced by the US healthcare system to both reflect on how the processes were executed and occurred, if they were optimal and what improvements could be made or lessons learned for the future. One such analysis was by Dr. Kerr and Dr. Glantz of the Sansum Diabetes Research Institute in which they analyzed diabetes as a whole as a wicked problem.

The focus of Dr. Kerr and Dr. Glantz was to aim for a resolution with the least bad outcomes for the majority. Primarily they wanted to focus diabetes as not only biologically different and unique across people but psychosocially as well, which would impact technology and care to form more compassionate solutions tailored to uniqueness of individuals. To combat the wicked problem that is diabetes, the goal is the creation of a digital diabetes ecosystem that is equitable. Taking into account personal consumer choices, factors such as physiological, behavioral, psychological and environmental, finally social preferences and genetic data paired with clinician workloads and empathy for the diabetic individual the system would be ideal to determine best path of care and most affordable while thoroughly informing patients (Kerr & Glantz, 2020). However, despite their sweeping claims of a diabetes digital ecosystem to help solve the wicked problem that is diabetes, the argument falls short. There is no description of

what form this technology would take, how it would be applied and even in what practical applications could it be used to legitimately improve the quality of life of diabetics. This solution is an attempt to solve a wicked problem, but shows how complex they can be and how theoretically a solution may seem good but practicality and execution are far different. These lessons are imperative in the pursuit of solving the facet of the wicked problem that is exorbitant insulin prices. A solution must be thorough and foundationally strong while practical and at the core better the lives of those who are suffering the most. There is no more time to theorize solutions or talk about hypotheticals as individuals die, actionable and legitimate paths forward must be explored as well. The analysis must ensure that the lives of people in pain are better tomorrow than they are today.

Wicked Problem of Insulin Pricing

There are wicked problems globally, and domestically. In a wide range of disciplines and areas of life. The United States Healthcare system has and is facing countless from the Covid-19 pandemic to antibiotic resistant bacteria in hospitals impacting patient care. It is time for a new analysis utilizing the framework of the wicked problem within the realm of US healthcare and patient health, the price of insulin negatively impacting diabetic lives. Individuals with families and friends, hopes and dreams, young and old and from every walk of life imaginable are facing a battle with diabetes daily. An understanding of their experience on a daily basis must be explored, psychologically, physically, socially and economically. Then intertwined in this is the wicked problem of insulin and how this impacts the diabetic experiences in all facets. Expanding past the lives of diabetics the roles of stakeholders like insurance companies, pharmacies, wholesalers, pharmacy benefit managers, and the Big Three insulin manufacturers make an intricate mesh of wants and needs that have to be unpacked and explored. Finally, the influence

of economic policies and pressure and political foci as both factors of the problem and avenues for solutions can be intertwined in analysis. By breaking down the problem into these areas a greater understanding can be achieved, targeted areas that solutions can be focused on can be identified and hopefully an improvement in lives can be made. This novel STS analysis using wicked problem framing can have untold potential for the betterment of lives by emphasizing compassion for those who have suffered long enough

Research Question and Methods

In what ways are the current prices of diabetic treatment and testing options determined by pharmaceutical stakeholders within a for-profit healthcare system harming diabetic individuals?

Three methodological approaches are applied to address the research question and generate equitable solutions that enable diabetic individuals to afford insulin. The three methods are documentary research methods, wicked problem framing and discourse analysis.

Documentary and discourse analysis includes ample resources for evidence that succinctly describes the background of how we have arrived at the problem, the reason this is a problem and how deeper analysis and application of a science and technology framework during a sociotechnical analysis can bring about changes that improve quality of life for diabetics. These analyses will require focus on specific keywords at the core with variations to gather a broad and robust depth of resources to create an unbiased and holistic analysis of the high prices of insulin. Primarily the keywords were “high insulin prices,” “effect of insulin prices on diabetics,” “cause of high insulin prices.” Wicked problem framing is at the core of addressing the research question. The sheer volume of actors, research, prevalence and societal implications of diabetes and the biases the reader may have if they come from within the United States healthcare system,

or not, means this problem has countless layers. By focusing on diabetic experience, flowing into how the current system is flawed and dabbling in solutions of other countries or even those hypothesized from courts of law and the political systems to the halls of science, a common understanding of the problem and solutions can be reached. This problem may not have just one solution, it may take multiple approaches assembled in unison to break it down. More importantly it will take inspiring and convincing individuals that high insulin prices are extremely detrimental to the lives of diabetic individuals and that everyone must stand up and seek remedying this problem together. At the core of this wicked problem is a larger conversation on compassion, human worth and our integrity. Will we stand beside those who need us the most and lift them up, or leave them to fight the darkness alone.

Results and Discussion

The cost of insulin in the United States is exorbitant. The high pricing of insulin places immense financial and emotional distress onto diabetic individuals, as they navigate the tightrope of life trying to balance their chronic disease and the everyday expectations and demands of being a member of society. Diabetic individuals pursue high health risk activities to make insulin last, especially rationing supplies to last longer while making money to continue purchasing it and staying alive. These prices are determined by the three manufacturing companies who control the market, intertwined in a complicated web of retailers, pharmacy benefit managers (PBMs) and diabetic patients that have exacerbated the problem. List prices continue to rise, and diabetic individuals are tasked with facing it with minimal support. In other global countries, healthcare changes and governmental effort and policies have equitably controlled the insulin market to be priced reasonably with price caps and other solutions. Furthermore, within the United States policies and awareness are growing with rapid focus and sound goals on enacting

change. The intertwining of all solutions options will offer fundamental groundwork towards progress that can be achieved. While acknowledgement of current limitations, and future progress display that even with this groundwork it is only a start to fixing the problem and far more work needs to be done. Fundamentally diabetes is a wicked problem due to complicated forces that lead to the problem, no clear and easy solutions and even when attempts to fix it are applied, they have been in small increments. Innovative solutions are necessary to make it possible that one-day diabetic patients will have full and easy access to insulin and be able to do so at a fraction of the current mental and financial cost, allowing them to pursue countless other endeavors in life that lead to happiness. The diagnosis of diabetes will no longer be a ball and chain, representing years of hyper focus and stress but instead be just a part of one's identity with far reaching access to solutions. No longer will diabetes be a slow march to complications or death, but simply a footnote in the broad and beautiful vibrant lives of individuals who will be far more than labelled by the disease they are afflicted by.

The Hidden Cost of Insulin

The diabetic experience is one filled with intense responsibility focused around monitoring and treatment. Failure to continuously adhere to the stressful pressure of maintaining their glucose levels and overall health can result in a plethora of complications. To combat these, there are two areas of focus for diabetic individuals that often come with excessive cost.

The first is monitoring glucose levels consistently every day over the course of a lifetime through self-monitoring of blood glucose (SMBG) or continuous glucose monitoring (CGM). SMBG consists of blood testing, in which the skin is pricked to draw blood which is then placed on a test strip and read in a small meter to give a quantified value of the individuals glucose level in that exact moment (Yeaw et al., 2012). It is recommended individuals complete the process four

or more times per day, meaning in a year an individual will check their blood glucose levels a minimum of 1,460 times (“Self-Monitoring of Blood Glucose,” 2002). Self-monitoring results in consistent and prolonged pain due to pinpricks and excessive emotional trauma with the pressure to constantly monitor over the course of a lifetime. CGM entails the use of a sensor worn by the individual that is inserted subcutaneously and measures glucose levels within the interstitial fluid every 1-5 minutes before transmitting the data to a receiver (a separate device or phone) that allows the user to consistently know the results (Maiorino et al., 2020; Rivera-Ávila et al., 2021). Depending on the type and cost of the device the reports can come daily, hourly or every few minutes. CGMs can range in cost from \$160-\$500 a month (\$1920-\$5000 per year) while SMBGs costs about \$4380 per year (Shi & Hellmund, 2020; *When You Can't Afford a Continuous Glucose Monitor*, 2021). In order to monitor their glucose levels diabetic individuals, face a consistent financial and emotional burden to do so.

The second area of focus to prevent long-term complications is the treatment applied when glucose levels are too high or low by the individual. The normal range for glucose is 70 mg/dL to 99 mg/dL, slight variations above and below occur, however in diabetic individual's drastic changes happen above and below and that can be dangerous (*Blood Glucose Test*, n.d.). When glucose levels are too low, below 70 mg/dL, the body needs more glucose and the individual must eat more carbohydrates or protein to provide the body with the necessary nutrients it needs (*Hypoglycemia (Low Blood Glucose) | ADA*, n.d.). High levels of glucose occur when the body has too much glucose within the bloodstream and it is not being adsorbed or used by the cells as a result of insulin malfunction or lack of production (*Hyperglycemia (High Blood Glucose) | ADA*, n.d.). Therefore, diabetic individuals must use insulin injections to lower their glucose levels to normal ranges to prevent complications and possible death (McDonnell &

Umpierrez, 2012). The cost of insulin, as previously stated, is financially burdening. From 2012 to 2016, the price of all insulin treatment products increased 15-17% per year (Cefalu et al., 2018). The average out of pocket cost for all Americans over the course of a year from 2014-2017 was \$474, and \$1288 for those who were uninsured (Glyed, 2020). The high cost of insulin causes extreme stress for diabetic individuals as they face high prices for small doses of a necessary medication to survive.

Monitoring and treatment for diabetes can cost an individual thousands of dollars a year and both are a necessity to survive. The pharmaceutical company increase in insulin prices have been seen as the average yearly cost of insulin for consumers has risen from \$2864 to \$5705 per year or \$250-\$475 per month from 2012 to 2016 (Spending on Individuals with Type 1 Diabetes and the Role of Rapidly Increasing Insulin Prices, n.d.; Willner et al., 2020). In the United States the median salary of all workers 15 and older is \$41,535 (Bureau, n.d.). That means to afford insulin a person would have to spend 6.9%-13.7% of their entire yearly income, that's without the cost of insurance, food, housing and utilities.. Therefore, to be a diabetic person within the United States means to live a life of constant financial burden. Avoidance of financial pressure leads individuals to pursue risk heavy processes to make their insulin last longer while they earn money to purchase it, better known as rationing. Insulin rationing is pursued as individuals risk short- and long-term consequences to make their insulin last a few days or weeks until they have enough money to purchase more (Willner et al., 2020). During rationing, diabetic individuals take less insulin when their levels are high, returning glucose levels to low high levels to extend the time period of how often they purchase insulin. Others change their nutrition and eat low carbohydrate or high protein with no carbohydrate diets, others skip meals entirely or supplement with heavy exercise. Sometimes individuals can receive money from friends or family members,

borrow insulin of diabetic friends or even try to contact programs and companies for free samples all in hope of having enough insulin to survive. None of these methods are perfect or are guaranteed to remedy the problem. The lack of insulin for diabetic individuals is unique. Someone with high cholesterol, asthma or increased blood pressure may be able to go a few hours, days or weeks without their medication without disastrous long-term complications or death as the individuals body uses hormones and feedback systems to self-correct and keep them alive (Rosenthal, 2019). Diabetics are not so lucky. When a diabetic does not produce insulin or they have insulin resistance, even a few hours gap can be deadly as glucose levels skyrocket and diabetic ketoacidosis can occur, that without immediate treatment leads to death. The only way to bring that glucose level down is with insulin, so without it, the individual is powerless. There are heartbreaking narratives around individuals who ration their insulin so severely that diabetic ketoacidosis occurs. One such example is the life of Alec Smith-Holt, who at the age of 26 phased out of his mother's health insurance and without any medical insurance had to purchase his insulin out of pocket. The price of insurance was too high to cover with a restaurant manager salary of \$35000, and he ended up passing away from diabetic ketoacidosis, 3 days before his next payday and without any insulin left in his home (Sable-Smith, 2018). There is no question that the high cost of insulin has tangible and dangerous repercussions on the lives of diabetics. Individuals forced to live and limit their whole lives around a chronic disease is devoid of any semblance of quality of life or happiness, the antithesis to the American dream and the expectation of the human experience. Change must come. Death or suffering at the hands of a system that seeks financial gain over individuals access to necessary medications is unacceptable.

Puppeteers of Pricing

The price of insulin is too high, leading to rationing and the development of long-term complications. Death, pain and suffering hidden behind a wall of immense financial burden. The problem is intertwined in a unique and complicated web of moving parts, each stakeholder driven by different desires and interests, with consumers often forgotten. The three large insulin producing drug companies, Eli Lilly, Novo Nordisk and Sonafi, provide insulin to the whole United States and set the list price of their insulin for both human and analog insulin options. The manufacturers then sell this product at a slight discount of the set list price to wholesalers, while also paying wholesalers a handling or distribution fee. Pharmacies then purchase the product from the wholesalers and sell it to consumers who pay for it either out of pocket or in conjunction with their health plan which they pay to have. Pharmacies are also reimbursed by Pharmacy Benefit Managers (PBMs) for prescriptions filled as well as receive copay coupons and fees and discounts paid by the manufacturers. PBMs are paid rebates and administrative fees by the manufacturer as well as a portion from the health plan of consumers for filling prescriptions and negotiating drug prices, where the health plan will also have a portion of the manufacturer rebate passed along to them through the PBMs (Cefalu et al., 2018; Van Nuys, 2021). The flow of insulin is pretty straightforward from manufacturer to consumer; however, the flow of money is far more difficult to follow with many stakeholder interests focused on retaining profit within a multilayered financial system for prescription reimbursement.

The money trail of insulin displays fundamental flaws at each level in the process of providing diabetics life-saving medication. The three largest PBM companies are Express Scripts, CVS Caremark and Optum RX, and are tasked with reducing pharmaceutical costs for insurance companies while providing consumers high quality medications that improve health outcomes (*How Insulin Pricing Works in the U.S.*, 2019). Primarily PBMs are tasked with

creation of formularies for health insurance companies which are lists of medication that the PBMs will help health insurance companies cover and thus get directly to clients; if a drug is not on the formulary, it will not be offered at a health insurance discount to consumers. Therefore, manufacturers have increased incentives to have their developed drugs on as many formularies as possible, to be sold to the most people and make the most profit. In a Senate Finance Committee examination of insulin prices by Charles Grassley and Ron Wyden, they found that in the early 2010's PBMs influenced the immense increase in insulin list prices. The reason for this change was the result of PBMs pitting the three big companies against each other to raise list prices which in turn raise profits for the PBMs through rebates, or else they would be excluded from PBM formularies (*Grassley and Wyden Insulin Report*, n.d.). Every time Eli Lilly, Novo Nordisk or Sonafi raised their list price the others followed suit to stay in favor with the PBMs by offering larger rebates and discounts, causing list prices to sky rocket (Knox, 2020). However, despite this change by manufacturers, the overall net price benefit they received did not increase the same as most of the stakeholders along the distribution chain gained more profit as each benefits from high list prices. From 2007 to 2016 the list price of insulin rose 252% while the net price to manufacturers increased to 102% in 2014 and fell to 57% by 2016 (Cefalu et al., 2018). Furthermore in 2014 to 2018 a cross-sectional study performed at USC of the high insulin pricing market, found that a hypothetical \$100 insulin expenditure within the insulin distribution chain caused profit shares for manufacturers to decrease by 33%, while increases were seen for wholesalers (74.7%), pharmacies (228.8%) and PBMs (154.6%). Therefore there is a noticeable change within the insulin market as the intermediaries make increased profit and manufacturers profit decreases per amount of insulin sold. Not only is it beneficial to manufacturers to raise list prices to increase their net prices and profits, it comes with the benefit of remaining on

formularies of PBMs. Additionally, these price increases are deemed necessary as wholesalers, PBMs and pharmacies begin to profit more within the insulin distribution system and manufacturers still desire to profit as well. The problem with this complicated web however is that as each group fights to increase their profit, consumers are forced to pay more, at the price of their quality of life and survival as previously discussed. The cost of insulin is a wicked problem as multiple stakeholder interest's area driven by profit and the problem is exacerbated when paired with the desires of diabetic individuals to be allowed to live a normal and healthy life where the for-profit healthcare system and many actors provides an impenetrable boundary to a single solution.

Wonderful World and Insulin

There is no question that the price of insulin set by the interconnected web of stakeholders driven by profit is harming diabetic individuals' quality of life. However there has been no display of a clear and concise solution that helps diabetic individuals without disrupting all stakeholders' current processes and interests in a way that they would willing change rapidly. However, not all hope is lost as a global perspective on the insulin crisis within the US displays possible solution options.

The European Union as well as Canada are international entities that offer insulin to diabetic patients within their countries at a fraction of the cost of the United States. In 2018 within Canada the average insulin user spent \$725 per year versus \$3490 within the United States, a difference of 351%, and represents a monthly cost of \$60.42 versus \$290.83. Furthermore, over the period of 2016 to 2019, the cost of insulin rose 10.1% in the United States and only 0.01% in Canada (Schneider et al., 2022). Canada possesses a Patented Medicine Prices Review Board (PMPRB) that requires patented drugs to have sales and price data to be submitted

upon market introduction and semiannually after. The Review Board analyzes the price and if it is deemed too high, based on market evaluations and other metrics, the PMPRB will take measures to lower it. For insulin this creates a semi-cap like system that ensures that the manufacturers themselves are not determining the price, nor intermediaries, but a federal entity with only the public's best interest at heart. The average price of insulin of all types is \$98.70 within the US and approximately \$8.57 across Europe, a difference of 168% (*Cost of Insulin by Country 2022*, n.d.). There are three methods of pricing used in Europe, profit control in the UK, Reference pricing in Germany/Netherlands and Product price control most commonly everywhere else (Ess et al., 2003). Product price control is determined by manufacturers themselves but within a set of defined market stipulations, reference pricing allows for manufacturers to set a price at a reference price, above generic cheaper reimbursed drugs but not ridiculously high and lastly profit control where manufacturers determine a set price and balance with reimbursements to not exceed an exorbitant profit at the expense of consumers. The introduction of a Single European pharmaceutical market with parallel imports across the European Union also impacted pricing by ensuring all the countries had access at the same import price. Therefore, across Europe there are different pricing options starting from the same original import price, with governmental processes and policies to retain drug pricing at a reasonable amount. Most countries possess transparency laws in pharmaceutical pricing and oversight committees. These are fundamentally essential structures in ensuring patients' rights and equitable pricing occur.

Internationally the World Health Organization (WHO) is running a program where they will work with smaller insulin companies to prequalify the insulin they make for safe and efficient manufacturing processes. The WHO will then provide patients with direct contact to

these smaller insulin companies which will sell their products at a much lower list price than the three largest manufacturers (Kwong, 2020). Furthermore, they are pushing for more human based insulin production over pricier synthetic options as well as thoroughly regulating pricing and transparency in pricing set up (*New WHO Report Maps Barriers to Insulin Availability and Suggests Actions to Promote Universal Access*, n.d.). However, not every company especially the three biggest manufacturers will take part in these new avenues, yet they are a strong start. By providing more competition with quality insulin, individuals will be able to drive the big three to eventually lower prices to avoid losing market share.

There are options within the United States of possible legislation on setting a price cap for insulin list prices or providing consumers more support to purchase insulin at cheaper prices. By taking into account the success and options offered in the European and Canadian pharmaceutical markets as well as the WHO's recommendations an intertwined composite of solutions can be applied to begin addressing the wicked problem.

Solutions in Sight

There are various methods applied across Europe, Canada and internationally to address the exorbitant pricing of insulin that are rampant within the US. It has also been displayed that it is a fundamental problem in the United States and is negatively affecting diabetic lives. A composite solution applied to the wicked problem will offer a fundamental groundwork to begin addressing the problem that can be expanded on in the future with optimal success. Within Canada and the EU there are large review boards that oversee all pharmaceutical pricing including insulin. The United States would benefit from this. While the FDA approves pharmaceuticals for human use and has a specific three tier process for authentication there is no oversight into pricing after certification. Therefore, the creation of a group that takes patient's

rights into account primarily and company profit secondarily to determine optimal pricing would be a huge step in the right direction. Globally the WHO and other countries have passed pharmaceutical transparency acts in which greater clarity on intermediary effects on pricing occur. Within the US system there is a large profit and monetary benefit to the intermediaries that fundamentally oppose the option to lower prices for diabetics. Therefore, analysis of these systems and better regulation and control by a governmental institution or policies will benefit diabetic individuals. Lastly, the option of a price cap or benefits to smaller insulin companies can allow for a more competitive market as well as cheaper insulin options that would benefit the most people. While these solutions can not solve the entire wicked problem of exorbitant pricing, they would offer greater regulation, understanding and begin lowering prices while further policy analysis, governmental institution design and financial processes can be explored that benefit diabetic individuals the most in affording insulin and having a higher quality of life without hindering future advances or improved research and pharmaceutical design.

Limitations and Future Expansion

The application of a sociotechnical analysis around the high price of insulin displayed the gross inequity in diabetic experiences in purchasing insulin and the for-profit interest of the healthcare system and countless stakeholders. However, it was not without limitations in application. The sole stakeholders analyzed were manufacturers, wholesalers, pharmacies, PBMs, health plans and consumers. There is a far larger web of stakeholders involved including doctors, governmental policymakers, insurance companies, and loved ones of diabetic individuals. The stories, interests and impact of high insulin prices on these groups can further illuminate the problem and further reveal the complicated pathway to solutions. Other limitations include deeper policy analysis within both the United States and other countries with lower

insulin prices that would highlight core difference in healthcare structure of more socialized systems versus the for-profit system within the United States. Many of the solutions offered hinge on a desire and focus to move to more socialized approaches to help diabetic individuals with the high cost of insulin, however that would hinge on the political mobility, choices and policies both currently and their projected change in the future. Despite these limitations, the current analysis sets a strong foundation of identifying the problem, unpacking the insulin distribution change and core elements of how high prices exist and offer a medley of solutions that in pairing could begin the process of creating a better solution to the current wicked problem of high insulin prices.

There is ample expansion to this sociotechnical analysis that can be applied. The first is the correction to the limitations by expanding on further stakeholders and greater policy analysis within the US and globally to maximize the solutions applied. A greater level of research on manufacturer and intermediaries profits off of insulin pricing would be beneficial, as would insurance company/Medicaid/Medicare impact on insulin prices for individuals. Improved focus on human insulin versus analog insulin as well as short-term versus long-term insulin and pricing impact and variations should also be focused on. Older methods of diabetic treatment should not be excessively priced and hurting diabetics quality of life. All of these areas of focus would lead to an improved narrative and understanding of high insulin prices on the lives of diabetic individuals and improved solutions the create a life of higher quality.

Conclusion

The high cost of insulin is dangerous and deadly as it impacts diabetics quality of life negatively as many individuals turn to rationing to survive and make their insulin last. There are countless shareholders from manufacturers to PBMs, wholesalers and pharmacies interlocked in

a unique and intricate relationship and pricing process that have led prices to rise to exorbitant levels. The sheer volume of shareholders and the United States healthcare system built in a for profit model has created a problem with no clear and concise solution. Therefore, an analysis of the current global systems that lower pharmaceutical prices paired with America policy options displayed a few opportunities to lower insulin prices. Setting a price cap on insulin, improving transparency of the flow of money and rebates in the insulin process as well as possibly capping the amount intermediaries can profit in set percentages of list prices can ensure insulin prices stay at set levels that are more equitable. Utilizing these options in tandem can start the process of lowering insulin prices and improving diabetic lives. More importantly it must begin a conversation within the United States that we must keep working to lower insulin prices, lower most drug prices and even possibly reform and improve our healthcare system so that this never happens again and that the system helps individuals in the best way it can.

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