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2019-2020 Incentive Grant Recipient  
Final Report

## **Introduction**

News headlines like “Americans are dying because they can’t afford insulin,” “Insulin's High Cost Leads To Lethal Rationing,” and “Americans Cross Border Into Mexico To Buy Insulin” have been circulating media platforms for years.<sup>1,2,3</sup> Although there has been an influx of new and innovative oral and non-insulin medications, over 7.4 million Americans with diabetes are using at least one formulation of insulin to help control their blood glucose.<sup>4</sup> As over 4,000 Americans are diagnosed with diabetes every day, insulin use in the United States will continue to increase.<sup>5</sup>

The cost of insulin over the past ten years has nearly tripled.<sup>6</sup> In a study using national survey data to analyze the expenditures and price of diabetes medications in the United States found that the cost per milliliter of insulin increased from \$4.34 in 2002 to \$12.92 in 2013.<sup>6</sup> Additionally, this study demonstrated that the total expenditure on insulin exceeded the total expenditure of all other diabetes medications combined in 2013.<sup>6</sup>

For insured patients between 2000 and 2010, out-of-pocket insulin costs nearly doubled.<sup>7</sup> Another patient population that is negatively impacted by insulin prices are uninsured patients. Despite efforts by the 2010 Affordable Care Act to improve health insurance access and affordability, 28.5 million Americans did not have insurance in 2017.<sup>8</sup> Patients without insurance are typically having to pay the list price, or close to it, for insulin, unless they are able to be enrolled in a Prescription Assistant Program or rebate from the manufacturer. In some cases, patients are not eligible for assistance depending on factors such as their income, state regulations and the specific insulin they are using, leaving them without a potentially life-saving medication.

Cost related non-adherence (CRN) is defined as not filling or taking medications because of cost related concerns.<sup>9</sup> Examples of CRN include, not filling a medication because it costs too much, skipping doses to make the medication last longer or taking a smaller dose of the medication to make it last longer due to cost. According to a Centers for Disease Control survey in 2015, patients with diabetes were more likely to reduce the dose of medication they were using or delay medication use when compared to those who do not have diabetes.<sup>10</sup> The most reported driving factor for these medication modifications was to save money.<sup>10</sup> By not using a dose of insulin that will appropriately control their blood sugar or delaying the use of insulin all together, patients are placed at a higher risk of serious complications associated with uncontrolled diabetes.

Diabetic ketoacidosis is a severe complication of uncontrolled diabetes that results from a build-up of acidic ketones in the bloodstream due to a lack of insulin. In a study whose objective was to identify the cause of diabetic ketoacidosis (DKA) in patients at a large urban hospital, 57 patients were admitted in the hospital for moderate to severe DKA.<sup>11</sup> All of the patients included in the study analysis were African American. Of the cases of moderate to severe DKA, 67% were precipitated due to insulin cessation.<sup>11</sup> Of the patients who stopped taking insulin, 43% of

patients reported they had no money to buy the insulin and 7% reduced the dose of insulin to save money.<sup>11</sup> In another study looking at the cause of recurrent DKA in inner-city minority patients, insulin discontinuation due to lack of money to buy insulin or reducing insulin dose to make it last longer were also the leading causes of DKA.<sup>12</sup>

Insulin access is important to assess in underserved patients. The social determinants of health are conditions in the environments in which 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.<sup>13</sup> Social determinants of health impact an individuals' risk of developing diabetes and their ability to control the disease. Those with lower income & lower education are 2-4 times more likely to develop diabetes.<sup>14</sup> Those with economic instability are less likely to have control of their diabetes.<sup>14</sup>

At the Charitable Pharmacy of Central Ohio (CPCO), the mission is to provide affordable and appropriate pharmacy services for people who are vulnerable in the community. CPCO utilizes a pharmacy model that provides medication and extensive education to patients to improve medication access and quality of life. It is uniquely positioned as it is the only pharmacy in Franklin County, Ohio that provides services to patients regardless of their ability to pay and qualifies patients for up to 12 months at a time. CPCO serves those living at or below 200% of the Federal Poverty Level (FPL) who are uninsured or underinsured for prescription medications. Despite having multiple sources for patients to access insulin including donated insulin, bulk-replenishment programs and purchased insulin, pharmacists at CPCO identified that patients are still facing barriers to insulin access.

There is limited data assessing the insulin access crisis in underserved populations. The purpose of this study is to explore insulin access in an urban underserved population who fill prescriptions at a charitable pharmacy. Insulin access poses a crisis for many uninsured and underinsured patients, leaving some with no choice but to switch between insulin products from month to month or completely go without insulin altogether. Insulin is a vital medication, and going without it can lead to microvascular and macrovascular complications associated with diabetes as well as an increase in morbidity and mortality. Before we can start to improve access to insulin for patients, we must first identify what barriers they experience throughout the process. Specific objectives of this study are to 1) identify methods patients are using to access insulin; 2) identify barriers to insulin access; 3) identify shared characteristics of patients with insulin access issues; and 4) explore the extent to which problems with insulin access impact a patient's need to connect with acute health care services.

## **Methods**

This observational study was intended to be descriptive in nature. Data was gathered from an electronic survey using Qualtrics<sup>SM</sup>. Inclusion criteria included English and Spanish speaking subjects who presented to the Charitable Pharmacy of Central Ohio (CPCO) to fill prescriptions during the study timeframe, were diagnosed with diabetes and were supposed to be using insulin. Patients were excluded if they were less than 18 years of age and did not speak English or Spanish.

All patients who presented to the CPCO between 1/13/2020 and 3/9/2020 received a screening document when they signed into the waiting room. This document was available in both English and Spanish. The screening document asked the following questions: Do you speak English or Spanish? Do you have diabetes? Are you currently using or supposed to be using insulin? These screening documents were anonymous and were not collected by study personnel. The purpose of the screening document was solely for patients to identify with inclusion criteria.

The bottom of the recruiting document gave directions to patients, so that if they answered yes to the three aforementioned questions and had not previously completed the survey, they were directed to a laptop station in a semi-private area of the pharmacy to complete the survey. Potential participants chose whether or not to take the survey.

The first question of the survey was used to assess the patient’s primary language. Immediately following this question, the participants were asked to provide informed consent, electronically, before completing the rest of the survey. The same questions utilized on the screening document were asked again in the electronic survey to confirm that participants had self-identified to inclusion criteria appropriately. To avoid subject risks, no protected health information or potentially identifiable data was collected. There was no additional participation beyond the electronic survey. Each question in the electronic survey was optional and participants were able to skip any questions they did not want to answer. Participants that did not answer the first four screening questions on the electronic survey were not be included in data analysis.

The survey instrument included multiple choice questions, including validated survey questions from the Medicare Beneficiary Survey to assess for cost-related nonadherence.<sup>16</sup> In addition, questions were asked to gather information around methods used by participants to access insulin, barriers to insulin access, and the impact of poor insulin access.

This research was determined to be exempt by The Ohio State University (OSU) IRB. Descriptive statistics were used to summarize survey responses. In brief, categorical data are presented as counts (n) and frequencies (%).

## Results & Discussion

Demographics and baseline information is presented in Table 1.

<b>Demographics (n =52)</b>	
Preferred Language	English - 52 (100%)
Diabetes Type	Type I – 4 (7.7%) Type II – 45 (86.5%) I don’t know – 1 (1.9%) Did not answer – 2 (3.8%)
Race	White – 13 (25.1%) African American – 32 (61.5%) Other – 6 (11.5%) Did not answer – 1 (1.9%)

U.S Residency Status	U.S resident – 18 (34.6%) U.S. citizen – 33 (63.5%) Neither – 1 (1.9%)
Age	25-34 years – 1 (1.9%) 35-44 years – 3 (5.8%) 45-54 years – 11 (21.2%) 55-64 years – 28 (53.8%) 65-74 years – 8 (15.4%) 75+ years – 1 (1.9%)
Insurance Status	Medicaid – 6 (11.5%) Medicare – 17 (32.7%) Medicaid & Medicare – 6 (11.5%) Private Insurance – 6 (11.5%) No insurance - 16 (30.8%) Did not answer – 1 (1.9%)
Highest Level of Education	11th grade or less – 3 (5.8%) High school or GED – 25 (48.1%) Some college or associates or technical training – 19 (36.5%) College graduate – 4 (7.7%) Graduate degree – 1 (1.9%)
Home	Owned/bought by self – 7 (11.5%) Rented – 40 (76.9%) Occupied without payment – 5 (9.6%) No permanent residence – 1 (1.9%)

Over half of study participants were between the ages of 55-64 years and predominately stated their race was either Black/African American or White. At CPCO, nearly 50% of all patients identify as Black/African American and the majority of patients served are 50 years of age or older. The majority of study participants (52%) used CPCO as a source of insulin access for at least one type of insulin, 29% reported using an “other” community pharmacy, 10% utilized a medication assistance program and 8% reported purchasing insulin at Walmart.

In regards to cost related non-adherence, 39% of participants reported in the last year they delayed getting their insulin filled due to cost, 33% reported they took a smaller dose of insulin to make it last longer due to cost and 30% of participants reported skipping doses of insulin to make it last longer due to cost. When each individual participant was analyzed, 25 out of 52 participants, or 48% of participants reported experiencing some form of cost related non-adherence in the last year. When asked if they had ever had to choose between filling their insulin or buying food, 28.8% of participants responded, yes. In a study assessing insulin access in a population that utilize an urban diabetes center, one in 4 patients experienced cost related non-adherence.<sup>15</sup> As nearly two in 4 patients experienced cost related non-adherence in this study, insulin access issues in the urban underserved population may be more prevalent than in the general population.

All participants had an annual household income at or below 200% of the federal poverty level (FPL) and 38% of participants had an annual household income below the FPL. Half of

participants reported they pay a copay for insulin, and of those, 70% also reported they experienced some form of CRN. Five participants reported paying a monthly copay between \$100 and \$200 and one participants reported paying a copay between \$200 and \$300. These copays accounted for 6-15% of their household income. Individuals are defined as underinsured if they have to pay  $\geq 5\%$  of their annual income towards healthcare costs.<sup>16</sup> The data collected in this study suggests that some patients are expected to pay 2-3 times that, demonstrating they are grossly underinsured.

Other barriers to insulin access besides cost included transportation and needing a new prescription. Fifteen percent of patients reported they had gone without insulin because they had no way to get to the pharmacy, and 37% of patients reported they went without insulin because they needed refills or their prescription expired. Of those that reported they ran out of refills, 95% of them reported they had a usual source of primary care. When looking at the reasons those 18 participants reported for running out of refills, a majority of patients stated that it took their doctor a couple days before they sent a new prescription. Another barrier that underserved patients might have to obtaining medication refills is that the clinic where they seek care is only open certain days of the week, which 11% of participants reported.

The original intent of this study was to use demographic data to calculate associations and test for statistical significance; however, due to COVID-19, data collection was halted abruptly, not allowing for an n powered to complete this analysis. When analyzing insurance status and incidence of CRN, 50% of those with Medicaid reported experiencing CRN, 41% with Medicare, 67% with dual coverage, 83% with private insurance and 37% with no insurance. Despite having prescription drug coverage, many participants reported cost as a barrier to insulin access. For uninsured patients, CPCO has programs such as bulk-replenishment programs and donated medications to assist patients in accessing insulin. Of the individuals with no insurance not experiencing CRN (63%), 40% reported filling their insulin at CPCO, which suggests some of these programs are helping to reduce CRN in uninsured patients.

To assess the impact of insulin CRN on an individuals' need to seek acute health care services, questions were asked about doctor visits, emergency room visits and hospitalizations. Doctor visits due to CRN were experienced by 21% of participants. 17% of participants reported going to the emergency room due to CRN in the last year, which accounted for at least 19 emergency room visits, as one participant reported going to the emergency room due to CRN more than 5 times in a year. Hospitalizations due to CRN were reported in 10% of patients accounting for 10 hospitalizations. In this patient population, an unnecessary or extra visit to their doctor due to insulin cost related non-adherence could create other financial strains, as these patients can often have difficulty finding transportation, as suggested by this study, or can struggle to pay for their visit copay. In addition, preventable emergency room visits and hospitalizations cost the healthcare system billions of dollars each year and these visits due to insulin cost related non-adherence are just adding to that cost.

Limitations of this study include that all data was collected at one site. While the intent was to assess insulin access specifically in an underserved population, data was only collected at one charitable pharmacy. There is also the potential for recall bias as patients were asked to think back over the past year. In addition, all of the information was patient reported. Another

limitation is also that all data was collected at the beginning of the year which could impact reported copays.

### Conclusion

Insulin cost related non-adherence in an urban underserved population was found to be higher than that experienced by other populations. The insulin access crisis is further increasing health care costs by forcing patients to visit their doctors more often, and attributing to emergency room visits and hospitalizations. Even with a variety of insulin access options, patients are still going without insulin and having to make difficult decisions, like choosing between food or filling their insulin.

Our goal is to share this information in aggregate with area health systems, community organizations, donors, policy makers, and the healthcare community nationwide, in order to provide more information about the problem and request support for solutions to insulin access that target the most vulnerable patients.

### Updates from Interim Report

The use of funds from the grant received through the APhA Foundation have changed since the interim report.

Report of Funds	
Amount Received	\$1,000
Amount Spent	70 gift cards purchased x \$10 = \$700
Amount Left	<b>\$300**</b>

\*\*The plan is to utilize the remaining funds to help with publication fees

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