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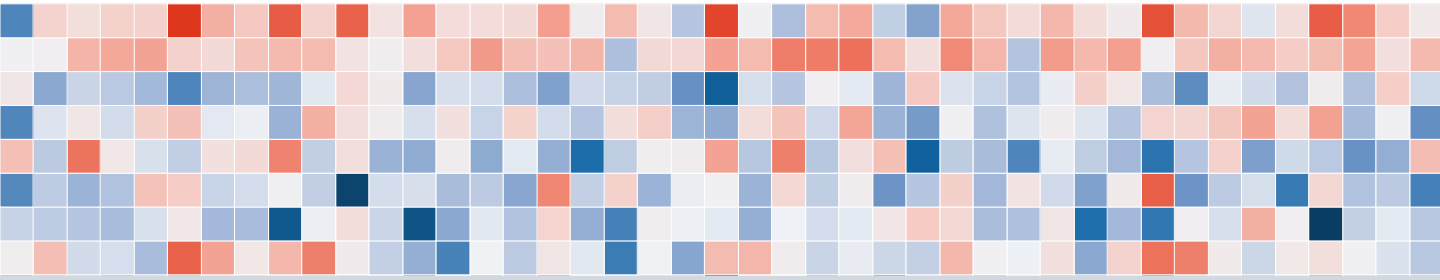

Spending on Individuals with Type 1 Diabetes and the Role of Rapidly Increasing Insulin Prices

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Insulin Prices Were the Primary Driver of Rapid Increases In Spending on Type 1 Diabetics

Type 1 diabetes is a chronic condition affecting approximately 1.5 million Americans.[1] In individuals with type 1 diabetes, the pancreas stops producing insulin. Insulin is the hormone that breaks down sugar in the blood so that it can be used by the body's other cells as fuel. As a result, type 1 diabetics must adhere to a lifelong insulin regimen that includes administering insulin through either injections or an insulin pump. Insulin is a complex drug that is not available in generic form, though competing versions are available for some insulin products. The cause of type 1 diabetes is unknown and there is no cure.

There has been a flurry of news reports sharing stories of individuals with diabetes rationing their insulin because they cannot afford higher and higher prices.[2] These anecdotes are consistent with findings of researchers documenting price increases on diabetic therapies, specifically insulin, over the last several years.[3] In response, there has been increased interest in policy circles. In May 2018 the American Diabetes Association testified before Congress on this issue,[4] and in October 2018 the Minnesota Attorney General filed suit against insulin makers for price gouging.[5]

In This Brief

We used health care claims data to investigate trends in total health care spending on individuals with type 1 diabetes between 2012 and 2016. We found a rapid increase in total health care spending, driven primarily by gross spending on insulin that doubled over the period. During that time insulin use rose only modestly. While the composition of insulins used shifted, the price of all types of insulin and insulin products increased, with point-of-sale prices roughly doubling on average between 2012 and 2016. We conclude that increases in insulin spending were primarily driven by increases in insulin prices, and to a lesser extent, a shift towards use of more expensive products.

A note on drug rebates and coupons: We did not have information on manufacturer rebates or coupons for insulin, because this information is proprietary and not publicly available. Thus, we measured gross spending using the point-of-sale prices that are reported on a claim for a prescription drug. Rebates and coupons result in lower net spending (for both payers and patients). Although we cannot incorporate data on rebates and coupons into our analysis of total spending or prices, we do provide an illustrative example of their effect – which still indicates that rising insulin prices were the largest driver of spending growth for this population.

Insulin Drove More Than $6,000 Increase In Gross Health Care Spending From 2012-2016

We examined gross per-person spending by type of service – inpatient, outpatient, professional procedure, insulin, and non-insulin pharmacy – over 2012 to 2016.

In 2016, individuals with type 1 diabetes spent $5,705 per-person on insulin.

- Gross spending on insulin accounted for 31% of the $18,494 in total per-person spending.
- Per-person spending on non-insulin pharmacy services was $4,119 (22%), which includes diabetic supplies, as well as other prescription drugs.
- Medical spending accounted for the remaining 47%, and reflected $2,116 in inpatient (11%), $3,481 in outpatient (19%), and $3,073 in professional procedure (17%) spending per person.

Between 2012 and 2016, gross insulin spending per person increased by $2,841.

Figure 1: Annual Spending per Person for People with Type 1 Diabetes, 2012 to 2016

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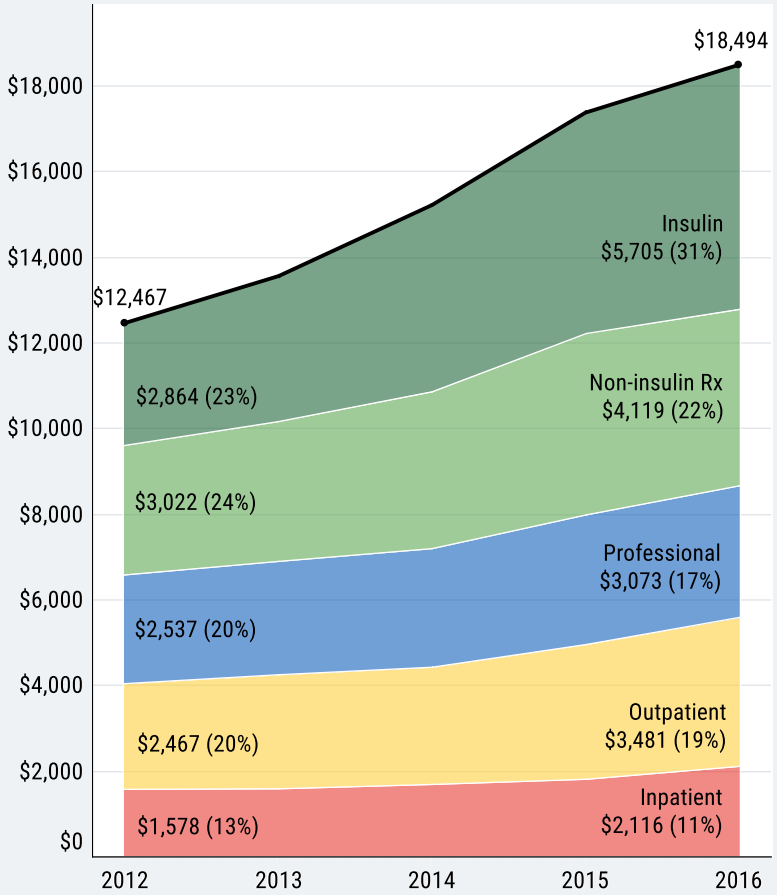


- The increase in gross spending on insulin accounted for 47% of the $6,027 increase in total per-person spending over the period.
- The increase in gross spending on insulin was larger than any other category, nearly doubling between 2012 and 2016.
- Non-insulin prescription drug and outpatient spending per-person had the next largest increases rising $1,097 and $1,014, respectively.

Overview Of Insulin Types

There are two types of insulin: basal (intermediate or long-acting) and mealtime (short or rapid-acting). The amount of insulin an individual requires and the timing of administering each type of insulin varies depending on a person's weight, carbohydrate intake, activity level, and how quickly their body absorbs insulin. Most individuals with type 1 diabetes have insulin regimens that include a basal and a mealtime insulin. There are also combination products, which include both.

Each insulin product contains one active ingredient (except for combination products). There are two broad categories of active ingredients, traditional human insulins and synthetic insulin analogs. Insulin analogs are modified in laboratories to produce formulations that have the potential of providing better blood sugar control.[7]

In general, each active ingredient had exactly one brand name as of 2016. The exceptions are human insulins and the basal insulin glargine, for which follow-on products had been approved. See Table 1 for insulins available as of 2016.

Table 1: Basal and Mealtime Insulins Available in 2016

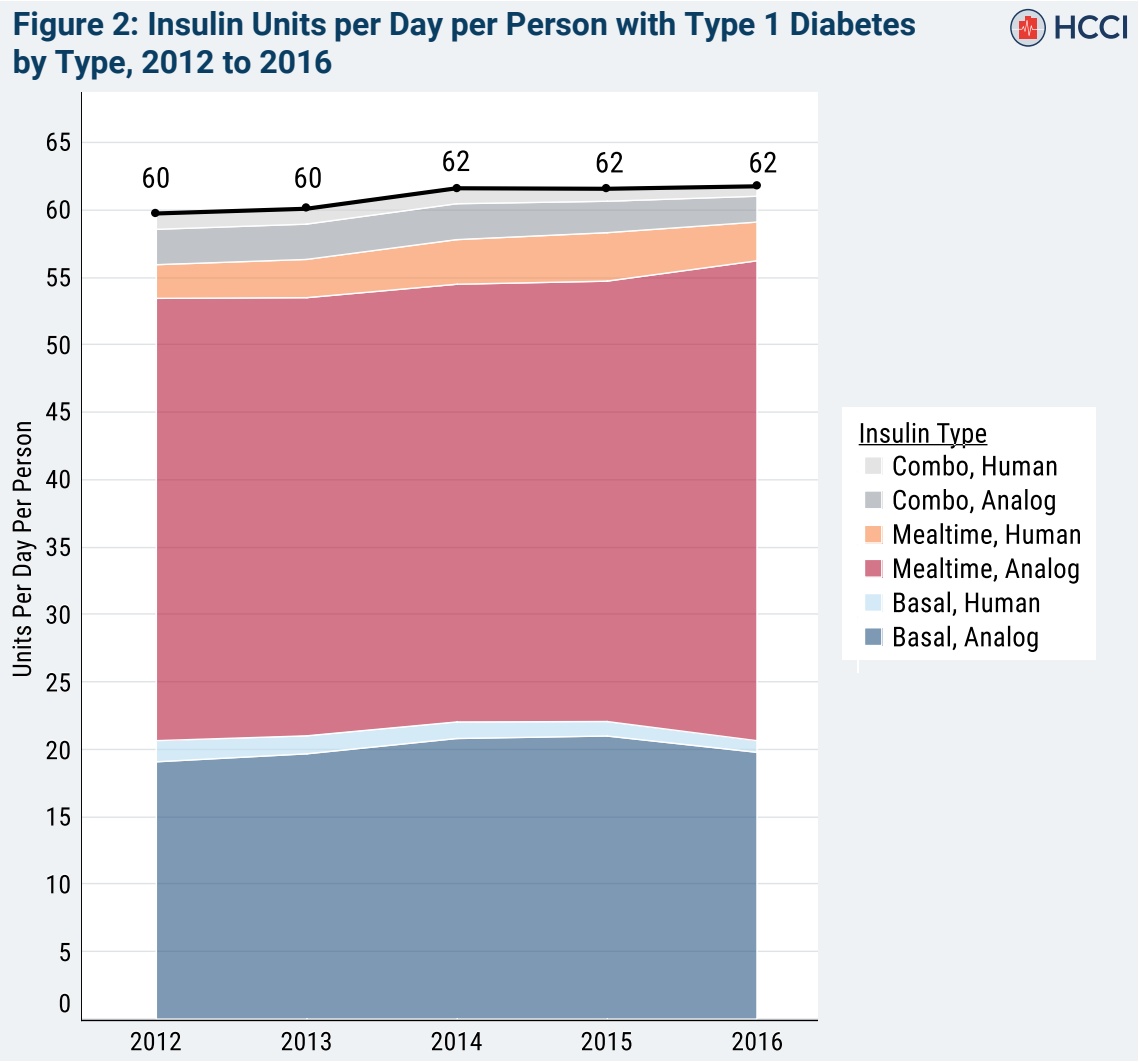
Basal Insulins
Traditional human insulins
▪ Humulin® N/Novolin® N (NPH)
Synthetic insulin analogs
▪ Lantus®/Toujeo®/Basaglar® (glargine) ▪ Levemir® (detemir) ▪ Tresiba® (degludec)
Mealtime Insulins
Traditional human insulins
▪ Humulin® R/Novolin® R (regular insulin)
Synthetic insulin analogs
▪ Apidra® (glulisine) ▪ Humalog® (lispro) ▪ Novolog® (aspart)

Average Daily Insulin Use By Type 1 Diabetics Rose by Only 3%

To measure changes in insulin use, we grouped insulins by type and whether the active ingredient was a human or analog insulin. We then summed the total units across all prescriptions filled in the year. (Insulin units provide a standardized measure that can be used to compare different types and strengths of insulin in a reliable way.) For ease of interpretation, we divided the total units by the number of days in a year to get a daily average.

- In 2016, average daily insulin use was 62 units, a 2 unit (3%) increase from 2012. In comparison, insulin spending per-person just about doubled over the same period.
- Daily usage of mealtime insulins increased by 3 units, whereas units of basal insulin used remained constant, and use of combination insulins decreased by 1 unit.
- Analog insulins accounted for more than 90% of use during each year in the period.
- Use of analog insulins increased slightly from 2012 to 2016.

Figure 2: Insulin Units per Day per Person with Type 1 Diabetes by Type, 2012 to 2016



The Insulin Products Used Changed Over Time: Active Ingredient

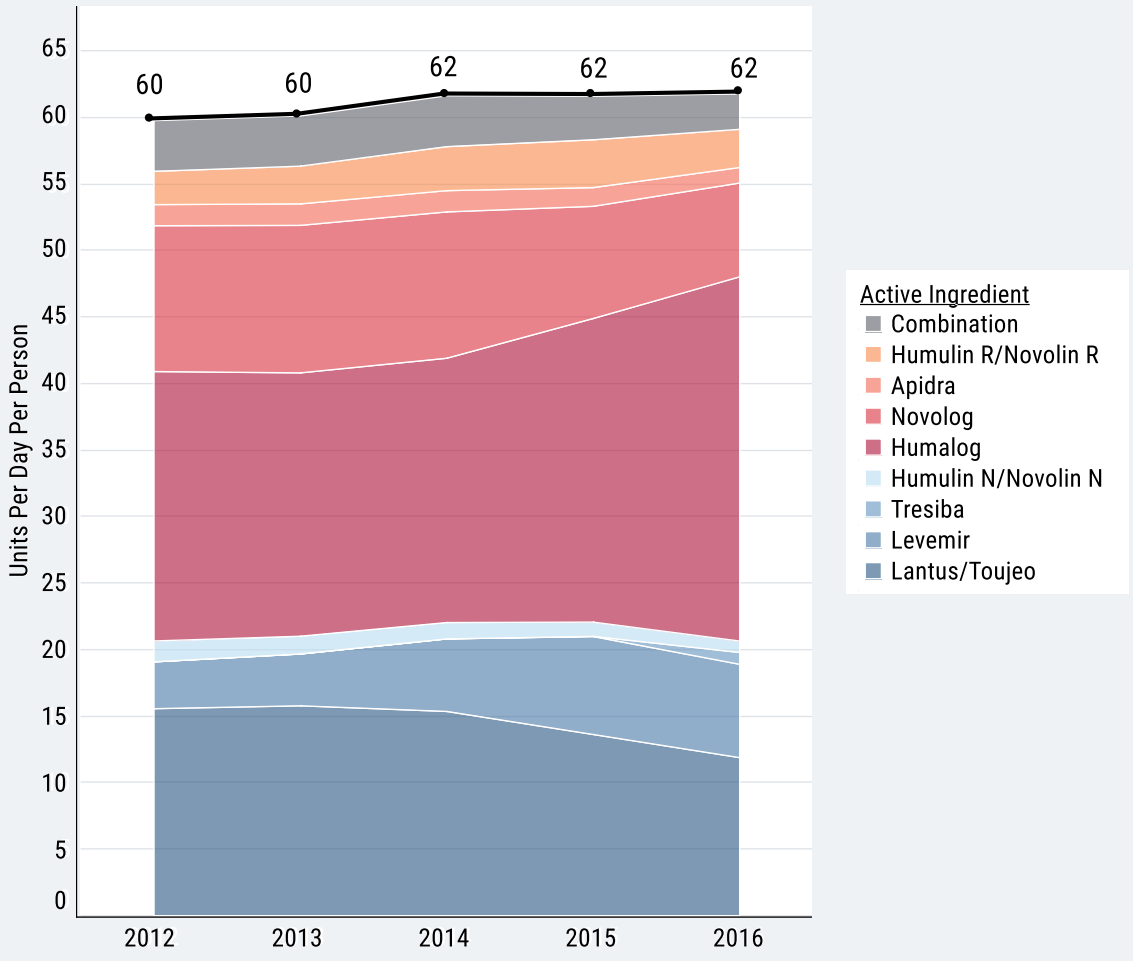
Among basal and mealtime insulins there are several distinct human and analog insulin products. The products differ in their active ingredient and the mechanism used for delivery. To further examine utilization trends, we categorized products along each of these dimensions.

Active Ingredient

Figure 3 shows the average daily use for each active ingredient. Basal insulins are in the blue shades and mealtime insulins are in the red shades.

- Across the sample, individuals used 7 more units of Humalog® daily in 2016 than in 2012, while daily use of Novolog® declined by 4 units.
- Among basal insulins, daily use of Lantus®/Toujeo® declined by 4 units. This was offset by an increase in use of Levemir® and the adoption of Tresiba®, which came to market in 2015.

Figure 3: Insulin Units per Day per Person with Type 1 Diabetes by Active Ingredient, 2012 to 2016



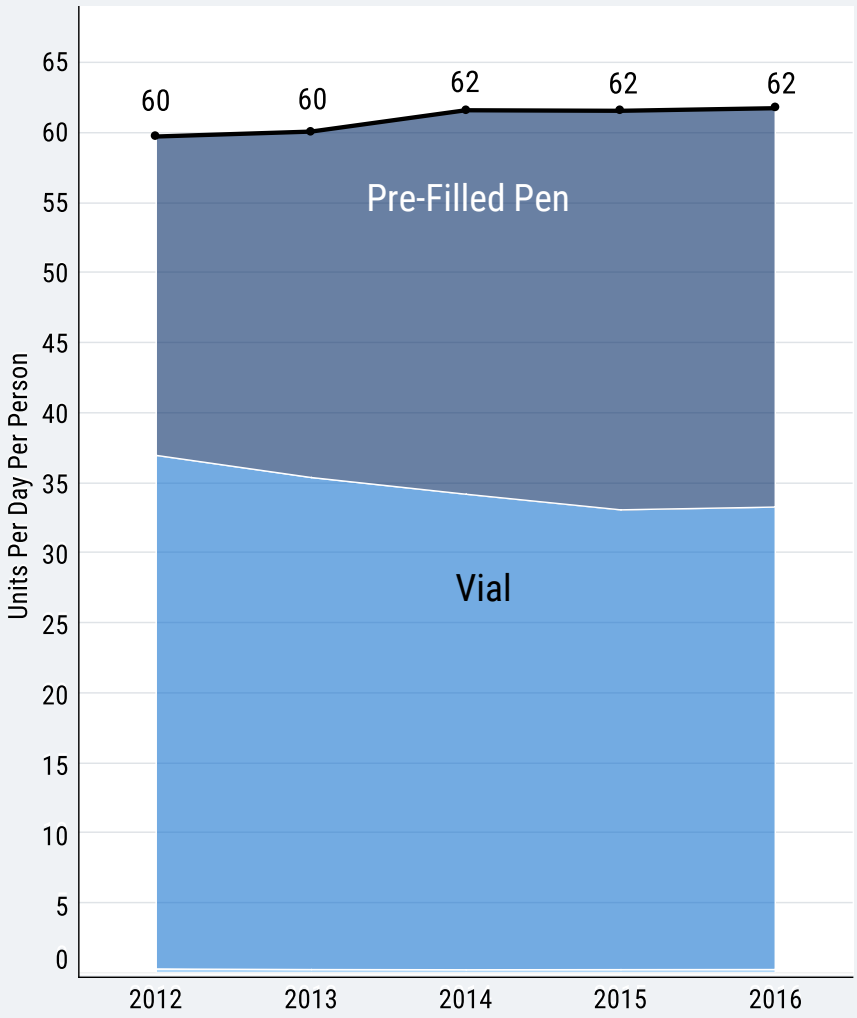
The Insulin Products Used Changed Over Time: Delivery Mechanism

Delivery Mechanism

Historically, insulin was available in a vial, and a syringe was used for administration. More recently, pre-filled insulin pens have become available. There are also reusable pens that take cartridges of insulin.

- Vials remained the most common delivery method, making up 53% of use in 2016.
- Use of pre-filled insulin pens increased over the period, rising from 38% of use in 2012 to 46% in 2016.
- Cartridges represented less than 1% of insulin used in each year.

Figure 4: Insulin Units per Day per Person with Type 1 Diabetes by Delivery Method, 2012 to 2016



Prices Increased Steadily For All Types Of Insulin Products: Basal Insulins

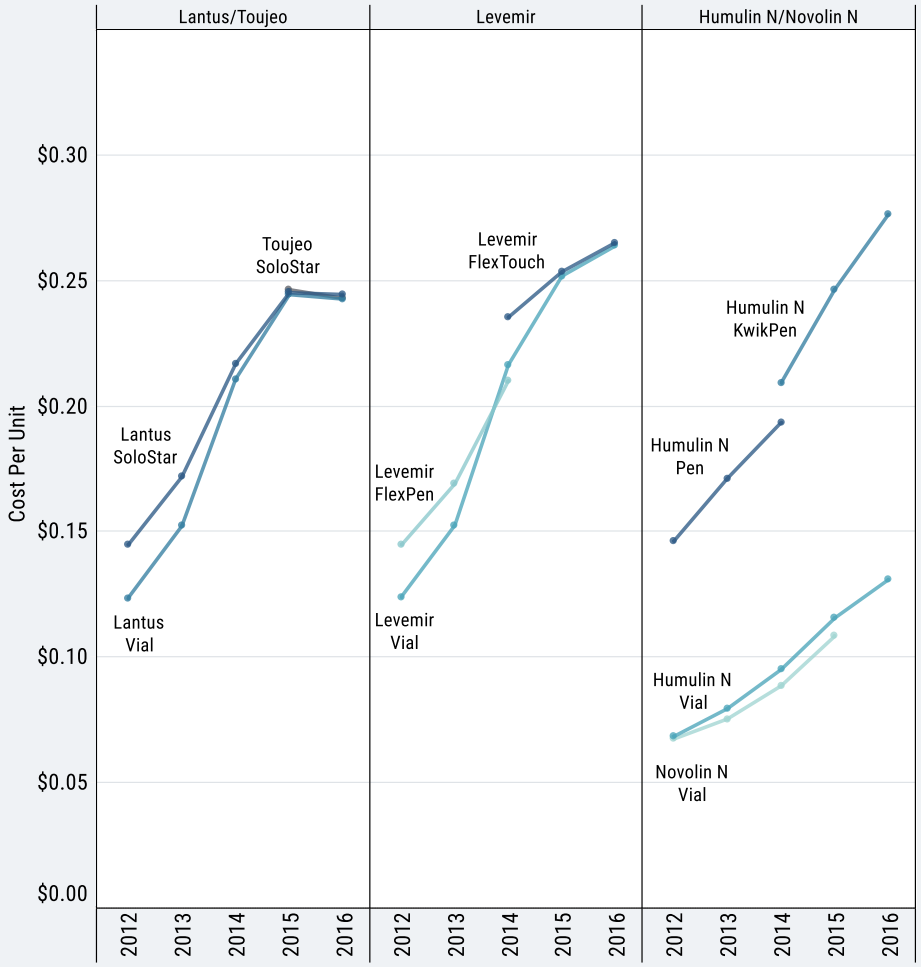
Changes in spending can be driven by changes in use and/or changes in prices. We observed little change in total use over the period but did see the composition of insulins shift. To examine whether use of more expensive products or higher prices drove gross spending increases, we calculated the price per unit of insulin for each NDC code. This standardization allows for comparison across vials and pre-filled pens, which usually contain different amounts of insulin in each package, and across insulins of different concentrations.

The price of all insulin products increased between 2012 and 2016. The average point-of-sale price nearly doubled, rising from $0.13 per unit to $0.25 per unit. That translates to an increase from $7.80 a day in 2012 to $15 a day in 2016 for someone using an average amount of insulin (60 units per day).

In Figure 5a, the average price per unit for basal insulins are plotted.

- Prices were similar regardless of the delivery mechanism among basal insulins containing the same active ingredient.
- Traditional human insulin products were cheaper than insulin analogs, except for the Humulin® N KwikPen introduced in 2014.
- The unit price did not vary across different concentrations of insulin within the same active ingredient. Toujeo®, which is a more concentrated version of Lantus®, was nearly identical in price.

Figure 5a: Price per Unit of Insulin by Product Family, 2012 to 2016 (Basal Insulins)



Prices Increased Steadily For All Types Of Insulin Products: Mealtime Insulins

We performed the same analysis for mealtime insulins, calculating the price per unit for each NDC code. In Figure 5b, the average price per unit for mealtime insulins are plotted. Trends for mealtime insulins were similar to those observed for basal insulins.

- Among mealtime insulins, vials were cheaper than insulin packaged in other types of delivery mechanisms.
- Traditional human insulin products were cheaper than insulin analogs.
- The unit price did not vary across different concentrations of insulin within the same active ingredient. Vials of Humulin® R and Humulin® R U-500, which is five times more concentrated, were similarly priced per unit of insulin.

Figure 5b: Price per Unit of Insulin by Product Family, 2012 to 2016 (Mealtime Insulins)

What Do Changes In Insulin Prices Look Like From A Patient Perspective?

To illustrate how an individual might have been impacted by insulin price increases, consider a person with the following insulin regimen:

- Once or twice a day basal insulin: Lantus® SoloStar, 30 units total on average
- Mealtime insulin at meals: Humalog® Pen, 30 units total on average throughout the day

This person would use one Lantus® and one Humalog® pen every 1-2 weeks and require at least seven boxes of each over the year. In 2012, their annual insulin spending would have been approximately $3,200, growing to $5,900 in 2016.[8] Table 2 provides the average point-of-sale prices for the most common products in our sample. Table 2 also provides the 5-year percent change for products available in all years. The median price increase among these products was 92 percent.

Table 2: Prices for Common Insulin Products, 2012 to 2016

	Product	Delivery	Description	Average Price per Product ($)					5-yr Chg. (%)
				2012	2013	2014	2015	2016	
Basal	Humulin N	Vial	10mL, 100 units/mL	68	79	95	116	131	93%
		Pen	5 pens, 3mL each, 100 units/mL	219	257	290			
		KwikPen	5 pens, 3mL each, 100 units/mL			314	370	415	
	Novolin N	Vial	10mL, 100 units/mL	67	75	89	108		
	Lantus	Vial	10mL, 100 units/mL	123	152	211	244	243	98%
		SoloStar Pen	5 pens, 3mL each, 100 units/mL	217	258	325	368	367	69%
	Levemir	Vial	10mL, 100 units/mL	124	152	216	252	264	113%
		FlexPen	5 pens, 3mL each, 100 units/mL	217	253	315			
		FlexTouch	5 pens, 3mL each, 100 units/mL			353	380	398	
	Toujeo	SoloStar Pen	3 pens, 1.5mL each, 300 units/mL				333	328	
	Tresiba	U-100 Pen	5 pens, 3mL each, 100 units/mL					440	
		U-200 Pen	3 pens, 3mL each, 200 units/mL					524	
Mealtime	Humulin R	Vial	10mL, 100 units/mL	68	80	96	116	132	94%
		U-500 Vial	20mL, 500 units/mL	563	804	961	1152	1319	134%
		U-500 KwikPen	2 pens, 3mL each, 500 units/mL					513	
	Novolin R	Vial	10mL, 100 units/mL	68	79	93			
	Apidra	Vial	10mL, 100 units/mL	97	124	169	209	240	147%
		SoloStar Pen	5 pens, 3mL each, 100 units/mL	196	244	332	408	466	138%
	Humalog	Vial	10mL, 100 units/mL	127	147	178	213	241	90%
		Cartridge	5 cart., 3mL each, 100 units/mL	235	271	334	398	449	91%
		Pen	5 pens, 3mL each, 100 units/mL	247	285	346	415	469	90%
		KwikPen	2 pens, 3mL each, 200 units/mL					381	
	Novolog	Vial	10mL, 100 units/mL	127	146	176	209	237	87%
		Cartridge	5 cart., 3mL each, 100 units/mL	242	275	333	397	443	83%
		FlexPen	5 pens, 3mL each, 100 units/mL	247	286	344	409	461	87%

How Might Manufacturer Rebates and Coupons Affect Spending Analysis?

Recognizing manufacturer rebates and coupons are not trivial,[6] we considered a case where rebates and coupons offset 50% of the gross cost of insulin in each year. This implicitly assumes that the costs offset by coupons or rebates change proportionately with any changes in the point-of-sale cost of insulin. In this case:

- The net increase in total spending per person would be $4,606, reflecting a $1,421 increase in spending on insulin.
- Increased spending on insulin net of rebates and coupons would account for 31% of the total increase in spending and would still be the category with the largest increase.
- On net, the average price of insulin would still have doubled between 2012 and 2016.

Table 3: Per-Person Spending by Category, 50% Rebate for Insulin, 2012 and 2016

Category	2012	2016	Change	Share of Change
Inpatient	$1,578	$2,116	$538	11.7%
Outpatient	$2,467	$3,481	$1,014	22.0%
Professional	$2,537	$3,073	$536	11.6%
Non-insulin Rx	$3,022	$4,119	$1,097	23.8%
Insulin	$1,432	$2,853	$1,421	30.8%
Total	$11,035	$15,641	$4,606	

Data and Methods

Analytic Sample: We studied individuals aged 18-64 with employer sponsored health insurance. We identified individuals with type 1 diabetes by adapting the classification tree model presented by Lo-Ciganic and colleagues.[9] Because we wanted to measure spending on medical care over a full calendar year, we restricted our sample to individuals with full-year of medical and prescription drug coverage. Given the important role of insulin in the treatment and management of type 1 diabetes, we further limited the sample to individuals who had at least one prescription for an insulin product in the year. This methodology resulted in between 13,800 and 16,200 type 1 diabetics per year in our sample.

Measure of Use: The days supplied field in the claims data is not a reliable measure of insulin use because use can vary widely day-to-day. We instead combined information on the insulin strength (units per mL) with the quantity field (expressed as mL of insulin) to calculate the total number of units a person obtained in a calendar year. We excluded prescriptions for Afrezza® (inhaled insulin) because the units are not equivalent to injected insulins. There were less than 200 fills for Afrezza® over the period in our sample.

Price Calculation: To calculate the point-of-sale price of individual insulin products, we used a subset of all filled prescriptions. First, we excluded combination products and restricted the analysis to the most common NDC code for each active ingredient and delivery mechanism. Next, we restricted the analysis to products that had at least 100 fills in a year. Therefore, some products that were available for purchase are not included, because we did not observe a sufficient number of fills in the year. We then summed the payments (allowed amounts) and units by year for each NDC code. To calculate the price per unit, we divided the total payments by the total units. We constructed prices per product by multiplying the unit price by the number of units in the package.

Limitations

It is possible that manufacturer rebates and coupons for insulin have increased as a share of list prices over the study period. In Medicare Part D, manufacturer rebates increased from 11.7% of total drug costs in 2012 to 19.9% of total drug costs in 2016.[10] Additionally, a report by the U.S. Department of Health & Human Services Office of Inspector General found that rebates offset approximately 20% of spending increases in Part D from 2011 to 2015.[11] If similar patterns exist for insulin products, our findings will overstate the percent change in spending and prices. Note, the analysis reflects claims from individuals with employer-sponsored insurance coverage. Individuals without insurance coverage would not benefit from lower prices resulting from manufacturer rebates.

In addition, we only have data on prescriptions filled where the individual reported their insurance coverage. If individuals purchased insulin over-the-counter or used an insulin discount program that cannot be combined with insurance when filling their prescription, it will not be reflected in our data, and therefore, excluded from this analysis.

Finally, several new insulin products have been approved since the end of the period of this study. In addition, products approved near the end of the period have likely increased in use. We are unable to assess the effects of these changes in the landscape of products available on spending, prices, and use in 2017 and 2018. That is, the trends reported in this brief cannot be reliably extrapolated to more recent years.

End Notes

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8. These back of the envelop calculations here are slightly above the averages we calculated for our sample, because the products used for our calculations are more expensive than average.

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