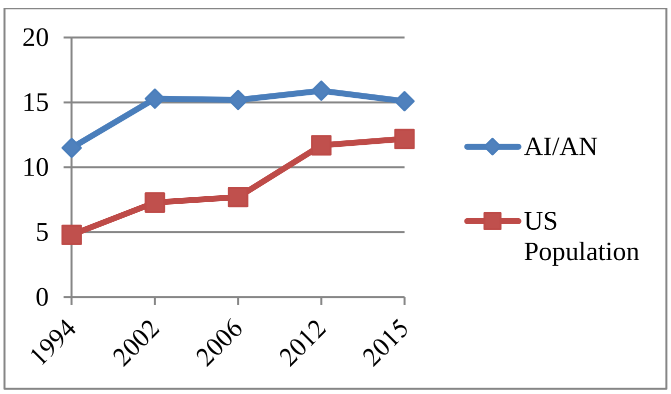
ASPE
ISSUE BRIEF

THE SPECIAL DIABETES PROGRAM FOR INDIANS: ESTIMATES OF MEDICARE SAVINGS[1]

May 10, 2019

The Special Diabetes Program for Indians (SDPI) was established by Congress in 1997 in response to a growing diabetes epidemic in the American Indian and Alaska Native (AI/AN) population. Between 1994 and 2002, the prevalence of diabetes grew from 11.5 percent to 15.3 percent of the adult AI/AN population (see Figure 1).

Figure 1: Age-adjusted* prevalence of diagnosed diabetes in AI/AN and US populations



Sources:
1994, 2002: CDC Morbidity and Mortality Weekly Report, 2003[2]
2006, 2012: IHS SDPI Report to Congress 2014[3]
2015: CDC National Diabetes Statistics Report 2017[4]
* 1994 – 2012 data are age ≥20, standardized to 2000 Census; 2015 data are age ≥18, standardized to 2015 Census; US population includes AI/AN population (0.08% - 2.00%)

[1] We estimate savings to the Medicare fee-for-service program resulting from the decrease in diabetes-related end-stage renal disease in American Indian and Alaska Native populations following the establishment of the Special Diabetes Program for Indians

[2] Diabetes prevalence among American Indians and Alaska Natives and the overall population – United States, 1994-2002; https://www.ncbi.nlm.nih.gov/pubmed/12894056

[3] https://www.nihb.org/sdpi/docs/05022016/SDPI_2014_Report_to_Congress.pdf

[4] https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf

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SDPI is a $150 million/year grant program that currently provides funding to 301 Indian health programs for diabetes prevention and treatment services. Grantees are required to implement at least one of the program's evidence-based best practices, but interventions are otherwise designed by individual grantees, allowing grantees to focus on locally identified priorities. Long-term, intensive efforts by the Indian Health Service (IHS) and its tribal and urban Indian organization partners (I/T/U)[5] to prevent both diabetes and its complications, such as end-stage renal disease (ESRD), in AI/AN people have had an effect: there have been no further increases in the prevalence[6] of diabetes since 2011,[7] and from 1996 to 2013, there was a 54 percent decrease in the incidence[8] of diabetes-related end-stage renal disease (ESRD-DM) in AI/AN adults. ESRD-DM is a serious medical condition that requires expensive treatment and that qualifies most[9] individuals at any age for Medicare coverage.

Previous work has found that improvements in chronic kidney disease care, as supported by SDPI, have resulted in lower rates of ESRD incidence in AI/AN diabetics.[10] In this paper, we estimate the potential savings to the Medicare program that accrued from the reduction in cases of ESRD-DM during 2006-2015, in order to gain a better understanding of the potential savings that have resulted from SDPI.[11] Although not analyzed, this program may also generate savings for the Indian Health Service and other payers, e.g., by preventing diabetes and other complications of diabetes such as retinopathy or hospitalizations.[12] Given uncertainty regarding what the incidence rate of ESRD-DM would have been in the absence of improvements in diabetic care we present two scenarios. In one scenario, we assume that in the absence of improvements in diabetic care the incidence of ESRD-DM in the AI/AN population during 2006-2015 would have grown at the same rate as was observed in white populations. In a more conservative scenario, we assume a constant incidence rate from what was observed for the AI/AN population in 2000, three years after the Special Diabetes Program for Indians was implemented. Finally, given uncertainty regarding what proportion of the reduction in the incidence rate may be attributable to SDPI, we also estimated a range of cost savings attributable to SDPI under each of these scenarios.

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[5] Federally recognized tribes access AI/AN-specific and general health services through the IHS (I), tribal programs (T) that operate their own health care services and/or urban Indian health clinics (U), referred to as the I/T/U system.

[6] Prevalence is a measure of the total number of individuals with a given condition at a point in time, while incidence is a measure of the number of individuals that are newly diagnosed with a condition over a period of time

[7] https://tinyurl.com/yxkrdkan

[8] https://tinyurl.com/yxn7wlge

[9] To qualify for Medicare based on having ESRD, patients must also accumulate a sufficient amount of work history individually or through a spouse or parent to qualify for Social Security Disability Insurance (SSDI) or Social Security Retirement Benefits or Railroad Retirement benefits or railroad disability annuity.

[10] Narva, A. S. (2008). Reducing the burden of chronic kidney disease among American Indians. *Advances in chronic kidney disease*, *15*(2), 168-173.

[11] The amount spent on SDPI during this ten-year period was $150 million x 10 years = $1.5 billion. Savings attributable to SDPI during this ten-year period are the result of cumulative effects of SDPI since it was established. However, the savings estimates presented in this paper should not be interpreted as estimates of the total return on the $1.5 billion investment in the program as they do not take into account other potential sources of savings such as preventing diabetes and other complications of diabetes such as retinopathy and the benefits that accrue to patients from avoiding these life altering conditions.

[12] Analyses showing reductions in diabetic retinopathy and hospitalizations in AI/AN populations include https://tinyurl.com/y68nm967 and https://tinyurl.com/y6luop25.

Key Findings

- The incidence of ESRD-DM has declined substantially for the AI/AN population since the SDPI was established.
  - The incidence of ESRD-DM declined from 324.4 per million AI/AN in 2000 (more than double the incidence for the white population in 2000) to 192.7 per million in 2015 (just above the rate for the white population in 2015, 150.4).

- Scenario 1: If the incidence of ESRD-DM in the AI/AN population had grown at the same rate as in white populations, there would have been approximately 2,602 additional diagnosed cases of ESRD-DM among AI/AN individuals during 2006-2015.
  - The amount of estimated savings from averted cases of ESRD-DM over this ten-year period attributable to SDPI ranges from $208 million (assuming 40 percent of savings were attributable to SDPI) to $520 million (assuming 100 percent of those savings were attributable to SDPI).

- Scenario 2: If the incidence of ESRD-DM in the AI/AN population remained the same as what was observed in 2000, there would have been approximately 2,256 additional diagnosed cases of ESRD-DM among AI/AN individuals during 2006-2015.
  - The amount of estimated savings from averted cases of ESRD-DM over this ten-year period attributable to SDPI range from $174 million (assuming 40 percent of the savings were attributable to SDPI) to $436 million (100 percent of those savings were attributable to SDPI).

I. Introduction

As of 2017, CDC data suggest there are 30.3 million Americans living with diabetes, approximately 9.4 percent of the U.S. population. While type 2 diabetes has been increasing in all racial/ethnic populations in the U.S., it has been especially prevalent in the American Indian/Alaska Native population, with rates twice that of the non-Hispanic white population.[13] Between 1994 and 2002, the prevalence of diabetes in the AI/AN population grew from 11.5 percent to 15.3 percent, a 33 percent increase.[14] In response to the growing epidemic, Congress established the SDPI in 1997 to provide grants for diabetes prevention and treatment activities at I/T/U sites across the country. In addition, SDPI facilitates a comprehensive program of training, technical support, clinical tools, and data collection and analysis at a national level. SDPI has contributed directly and indirectly to the development of care management and treatment approaches that have become standards in I/T/U diabetes care, some of which are transferrable to other high-risk populations.

In addition to diabetes, the SDPI has implications for other conditions, such as ESRD-DM, end stage renal disease primarily caused by type 2 diabetes. Poorly controlled diabetes is a major risk factor for developing chronic kidney disease (CKD) and CKD may progress to ESRD, which requires treatment by dialysis or kidney transplant for survival.[15] While CKD patients are often not aware of their deteriorating kidney function until kidney disease is quite advanced, ESRD has significant negative implications for a patient's quality of life, resulting in trouble concentrating, muscle cramps, generalized itching, and extreme fatigue, among other conditions.[16] Even ESRD that is well treated with dialysis is associated with heart disease, bone disease, arthritis, nerve damage, infertility, and malnutrition.[17] Hence, reducing the incidence of ESRD has benefits beyond the reduction in kidney failure.

Type 2 diabetes is the leading cause of ESRD in the U.S., but the AI/AN ESRD population has a higher proportion of ESRD-DM than does the ESRD population of any other racial or ethnic group. Two out of every three AI/AN cases of ESRD are primarily caused by diabetes[18] and patients with ESRD require regular dialysis or kidney transplantation, both of which are expensive treatments covered by Medicare. By statute, Medicare extends coverage under Parts A (coverage for care obtained in facilities) and B (coverage for ambulatory care services, drugs administered in an outpatient settings, and durable medical equipment) to the majority[19] of patients, regardless of age, who have ESRD.

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[13] 15.1% AI/AN versus 7.4% non-Hispanic white population (ages 18 and up) CDC 2017 Diabetes Statistics Report http://dpacmi.org/documents/2014-National-Diabetes-Report-web.pdf

[14] https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5230a3.htm

[15] Patients with less than approximately 60% of kidney function meet diagnostic criteria for chronic kidney disease. Patients with less than 15% of kidney function are described as having kidney failure. Patients with kidney failure treated with dialysis or transplant as described as having End Stage Renal Disease (ESRD).

[16] https://www.niddk.nih.gov/health-information/kidney-disease/kidney-failure/choosing-treatment

[17] Ibid

[18] As of 2013; https://www.cdc.gov/vitalsigns/pdf/2017-01-vitalsigns.pdf

[19] To qualify for Medicare based on having ESRD, patients must also accumulate a sufficient amount of work history individually or through a spouse or parent to qualify for Social Security Disability Insurance (SSDI) or Social Security Retirement Benefits or Railroad Retirement benefits or railroad disability annuity.

Since Congress created SDPI in 1997, substantial gains in relevant health outcomes have been observed within the AI/AN population. For instance, the average annual growth in diabetes prevalence decreased by almost three quarters when comparing average growth in 2001-05 (2.2 percent) to 2006-14 (0.6 percent), and there has been no increase in the prevalence of diabetes in the AI/AN population since 2011. Moreover, the adjusted incidence of ESRD-DM in the AI/AN population declined from 584.6 cases per million in 2000 to 321.9 cases per million in 2015, or 45 percent.[20] The ability to prevent high cost conditions such as ESRD has important savings implications for the Medicare program, given the average annual cost of treatment for ESRD in 2015 ranged from $25,320 for maintenance in kidney transplant recipients to $89,037 for patients on dialysis.[21]

Because of the structure of the program, it is difficult to determine how much of the decline in ESRD-DM is due to the SDPI. Each SDPI Community Directed Grant funds a grantee- designed intervention that addresses locally identified priorities. Although grantees are required to implement and report on at least one of the SDPI evidence-based *Diabetes Best Practices*, [22] these are broad strategies that fall under prevention and/or treatment, such as tracking glycemic control or screening for retinopathy, and are easily folded into the larger intervention strategy. The interventions themselves are highly specific to what each community has determined are their priorities. Given that the interventions funded by the SDPI are so varied (i.e., it is hard to identify what may be working) and because all AI/AN individuals are free to visit any federal or tribal facility for care and some of the information, such as treatment algorithms, is made publicly available (i.e., it is not possible to distinguish individuals by receipt of treatment), it is not possible to evaluate how the SDPI, as whole, affected a patient or population. For additional details on the program, please see Appendix II.

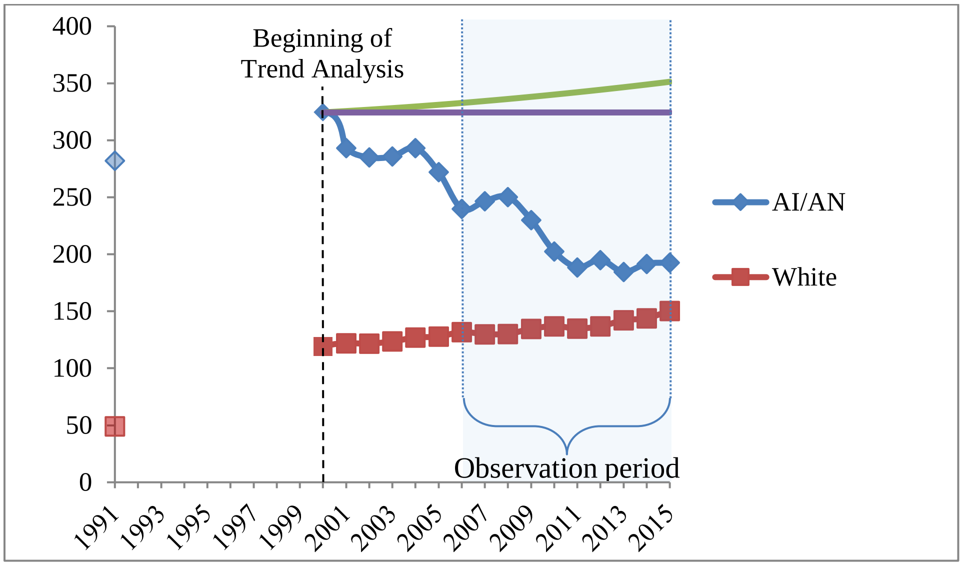
Although it is not possible to determine with certainty how much of the decline in ESRD-DM is attributable to SDPI, nothing else has impacted diabetes resources across the Indian health system as much as SDPI over the past 20 years and improved outcomes in the AI/AN population far surpass those observed for other races (described in greater detail below). In the following sections, we calculate a range of estimates of how much savings may have accrued as a result of the program between 2006 and 2015, based on various assumptions regarding what incidence rates would have been in the absence of diabetic care improvements and what proportion of estimated savings from averted cases of ESRD-DM may be attributable to the SDPI program.

[20] These values are adjusted for age and sex to make a comparison with other ethnicities more clear. The incidence rates used in this analysis, which are taken from the 2017 USRDS Annual Data Report Reference tables, are unadjusted.
[21] USRDS 2017 Annual Data Report, www.usrds.org
[22] https://www.ihs.gov/sdpi/sdpi-community-directed/diabetes-best-practices/

II. Estimating Averted Cases of ESRD-DM

The incidence of ESRD-DM in the AI/AN population was rapidly increasing prior to 1996.[23] Figure 2 below illustrates that in 2000, the AI/AN population had a much higher incidence of ESRD-DM than the white population, 324.4 per million AI/AN population versus 118.7 per million white population. After 2000, the incidence of ESRD-DM substantially decreased in the AI/AN population, while slightly increasing in the white population. The green line shows what the incidence in the AI/AN population would have been if it had followed the same trajectory as the white population starting three years after SDPI was implemented. This is the first scenario presented in the Key Findings. This trend line suggests that in 2015, the AI/AN incidence could have been 351.3 per million population. Instead, it was 192.7 per million population. We approximate how many cases of ESRD-DM were avoided between 2006 and 2015 under this scenario by comparing this counterfactual trend line to the actual AI/AN trend line. In addition, to provide a more conservative estimate, we also estimate a second scenario assuming the AI/AN incidence of ESRD-DM during this period remained at 324.4 per million, which is the rate of incidence in 2000 (this is represented by the purple line in Figure 2). We approximate averted ESRD-DM cases using the same methodology as Scenario 1, now using the purple line as the counterfactual trend line.

Figure 2: Incidence per million of ESRD-DM in AI/AN and White populations



Sources:
1991: USRDS 1994 Annual Data Report[24] https://www.usrds.org/download/1994/ch04.pdf
2000-2014: ASPE analysis of USRDS 2017 ADR Reference Tables https://www.usrds.org/reference.aspx

[23] Incidence of diabetes-related ESRD increased from 80.6 per million in 1983 to 118.2 per million in 1987; because these incidence rates are not age adjusted, only include Medicare patients, and may not match the USRDS methodology, they are not included in Figure 2: Muneta et al, "Diabetic End-Stage Renal Disease Among Native Americans" 1993.

[24] The 1991 data points are for general reference, showing that even in 1991, the incidence of ESRD was much higher among AI/AN than whites. However, in 1994, USRDS only included Medicare patients; full incidence rates of ESRD-DM in AI/AN or white populations were unavailable. Because these data are not comparable to the post-2000 data analyzed in this study, the 1991 data points are not connected to the incidence rate curves.

III. Estimating Medicare Savings from Averted Cases of ESRD-DM

To estimate the amount of savings to the Medicare program resulting from our estimates of averted cases of ESRD-DM, we estimate what Medicare expenditures would have been for ESRD care if the averted cases of ESRD-DM estimated for each of the two scenarios presented in Section II had not been averted. To estimate expenditures given these cases were averted, we assign zero expenditures to averted cases that were not age-eligible for Medicare coverage. For averted cases that were eligible for Medicare coverage by qualifying based on age, we assume that all averted cases developed diabetes, and we estimate Medicare expenditures based on how many of these individuals are assumed to develop CKD due to their diabetes, since CKD treatment increases the cost of treating a person with diabetes. Previous literature has found that approximately 35 percent of patients with type 2 diabetes have CKD[25] and we base our final estimates of savings on this approximation, which we consider a conservative estimate given the likelihood of higher quality diabetes management (than in a nationally based average) preventing the progression to CKD and because it is possible that some of the averted cases of ESRD never developed diabetes.[26] After totaling Medicare expenditures on averted cases that did not progress to ESRD-DM, we subtracted these expenditures from our estimate of what expenditures would have been if these cases had progressed to ESRD-DM to estimate savings to the Medicare program for averted cases of ESRD-DM, overall (not necessarily attributable to SDPI). For additional detail on how these estimates were developed, please see Appendix I: Methodology.

Table 1 displays these ten-year (2006-2015) savings estimates. The net savings to Medicare from averted cases of ESRD-DM under Scenario 1 is estimated to have been $520.4 million and under Scenario 2, $435.9 million.

Table 1[27]: Estimated Medicare expenditures for ESRD care had ESRD-DM not been averted, estimated expenditures for averted cases assuming all averted cases developed diabetes and 35% were treated for CKD, and estimated net savings over ten years 2006-2015

	Estimated Medicare expenditures for ESRD care over ten years	Estimated Medicare expenditures for 65% diabetics and 35% CKD over ten years	Estimated Net Savings to Medicare from averted cases of ESRD-DM
Scenario 1: Growth at White rate	$640.2 million	$119.9 million	$520.4 million
Scenario 2: 2000 incidence	$540.1 million	$105.2 million	$435.9 million

Source: ASPE analysis

[25] Based on NHANES data from 2005-2008;
Thomas, Cooper, Zimmet *Changing Epidemiology of Type 2 Diabetes Mellitus and Associated Chronic Kidney Disease* (Nature Reviews, Nephrology 2016)
For additional detail on estimated savings when this assumption is varied, please see Appendix I: Methodology.
[27] Please see Appendix I for additional detail on methodology

IV. What Proportion of Savings May Be Attributable to SDPI?

The savings estimates presented in this paper are calculated based on reductions in AI/AN ESRD-DM incidence that have occurred in recent years. However, the degree to which diabetic care improvements attributable to funding provided by the SDPI have contributed to this trend remains unknown.

Figure 2 shows a downward trend in AI/AN ESRD-DM incidence starting in 2000, which is three years after the establishment of the SDPI. Data available before 2000 are not reliable,[28] but it is likely the incidence rates were higher or rising, given the rapidly rising prevalence of diabetes (see Figure 1). As with many new programs, it likely took a few years before the SDPI began to have an effect on diabetes. However, SDPI played an important role in the dissemination of treatment strategies developed by the IHS Kidney Disease Program in the late 1980s and early 1990s. Prior research has shown these strategies had a downward impact on the incidence of ESRD in AI/AN with diabetes. [29]

The design of the SDPI grant program makes it difficult to evaluate its contribution to the decline in incidence that has occurred since 2000. The program gives grants to I/T/U sites in exchange for having them provide diabetes prevention and treatment services. Because AI/AN individuals are free to visit any provider and often see multiple providers including non-I/T/U providers, it is difficult to isolate and compare those who were exposed to SDPI strategies and those who were not. In addition, the programs and strategies (e.g., specific treatment algorithms) that SDPI promotes are made freely available by the IHS Division of Diabetes Treatment and Prevention over the IHS website to the general public (to maximize the reach of the program), meaning the effects of the program are not limited to those receiving grants, making it difficult to identify a comparison group that is not affected by the program. Given uncertainty regarding the SDPI's contribution to the decline in incidence, we apply a range of multiplying factors to the savings estimate generated above that attribute varying degrees of savings to the SDPI, as displayed in Table 2.

Table 2: Attributing varying degrees of savings from averted ESRD-DM between 2006 and 2015 to the SDPI

	If AI/AN ESRD-DM incidence grew at rate of that of the white population	If AI/AN ESRD-DM incidence stayed constant since 2000
100%	$520.4 million	$435.9 million
80%	$416.3 million	$348.7 million
60%	$312.2 million	$261.5 million
40%	$208.2 million	$174.4 million

Source: ASPE analysis

[28] USRDS publishes an Annual Data Report (ADR) and corresponding reference data files that estimate incidence of ESRD. The 2017 ADR reference files only date back to the year 2000 for variables of interest to this study. Previous reference files included earlier years of data but were found to have errors.
[29] Narva, A. S. (2008). Reducing the burden of chronic kidney disease among American Indians. *Advances in chronic kidney disease*, *15*(2), 168-173.

V. Conclusion

The original objective of SDPI was to address what had been a growing public health epidemic of diabetes in the AI/AN population occurring prior to 2000. Diabetes typically requires ongoing medical management and if not controlled can lead to a variety of debilitating and often life threatening complications such as ESRD. In the years that followed implementation of SDPI, the prevalence of diagnosed diabetes in the AI/AN population stopped increasing and there has been a remarkable decline in the incidence of ESRD. This study considers how this particular public health gain has translated into savings for the Medicare program, which can be considered a secondary benefit. Public health gains from avoiding other complications of diabetes may have resulted in additional savings.

Under our relatively conservative assumption that the incidence rate of ESRD-DM in the AI/AN population would have remained at the rate observed in 2000 absent greater attention devoted to addressing diabetes in this population, we estimate that the overall reduction in ESRD-DM cases occurring between 2006 and 2015 resulted in accumulated savings to the Medicare program of $435.9 million. When we attribute a relatively conservative 40 percent of the reduction in ESRD-DM to SDPI, we estimate that SDPI resulted in accumulated savings to the Medicare program of $174 million. Varying these assumptions by considering (1) a higher incidence rate of ESRD-DM in the absence of extra attention devoted to treating diabetes in the AI/AN population and (2) greater attribution of the reduction in the incidence of ESRD-DM to SDPI, we estimate that the accumulated Medicare savings resulting from SDPI may have been as high as $520.4 million.

Appendix I: Detailed Methodology for Calculating Savings from Averted AI/AN Cases of ESRD-DM

We limited our analysis to medical care expenditures and savings that accrue to the Medicare program. In addition to these implications for the Medicare program, ESRD has significant implications for individuals with the condition. ESRD can result in losing employment, deteriorating energy and health, decreasing overall quality of life, and significantly shortening lifespan. If the impact of these factors were taken into account, our savings estimates would be substantially higher.

In order to account for the longer-term costs of ESRD-DM, we tracked individual yearly cohorts of newly diagnosed AI/AN ESRD-DM cases beginning with the 2006 cohort and ending with the 2015 cohort throughout the observation period (2006-2015).

Below is a more detailed description of the steps that we followed to calculate our expenditure estimates:

A. Estimate number of cases of AI/AN ESRD-DM diagnosed in each cohort year had incidence rate not fallen

   a. Scenario 1: if AI/AN ESRD-DM incidence were to grow at the same rate[30] as white ESRD-DM incidence starting in 2000 (Table 3)[31]

Table 3: Estimated ESRD-DM incidence and cases assuming growth observed in the white population

Cohort-year	AI/AN population in that year (in millions)	Incidence rate if white growth (cases per million population)	Cases in population if white growth (incidence rate multiplied by total AI/AN population)
2006	1.8	332.7	598.9
2007	1.9	334.4	635.4
2008	1.9	336.2	638.8
2009	1.9	338.1	642.4
2010	2.0	340.1	680.2
2011	2.0	342.1	684.3
2012	2.0	344.3	688.6
2013	2.1	346.5	727.7
2014	2.1	348.9	732.6
2015	2.2	351.3	772.9

Source: ASPE analysis based on USRDS 2017 Annual Data Report; IHS annual report

[30] $y = -0.0454306x^2 + 1.018415x + 323.381585$, where x=time=year-1999; this is the quadratic curve fitted to white data, shifted up to match AI/AN rates in 2000

[31] Substituting the years 2006-2015 into the rate equation

b. Scenario 2, if AI/AN ESRD-DM incidence had remained at the 2000 AI/AN incidence rate (324.4 per million population[32]). Estimated number of cases displayed in Table 4, Column 5.

Table 4: Estimated and Averted AI/AN ESRD-DM cases in full population

Cohort-year	Observed Incidence Rate (cases per million)	Observed cases (observed incidence multiplied by the total AI/AN population)	Estimated cases based on white growth (see Table 1)	Estimated cases if incidence unchanged from 2000 (based on incidence rate of 324.4 per million population)	Averted cases based on white growth (column 4 minus column 3)	Averted cases based on 2000 incidence (column 5 minus column 3)
2006	239.9	431.8	598.9	583.9	167.1	152.1
2007	246.6	468.5	635.4	616.4	166.9	147.8
2008	250.3	475.6	638.8	616.4	163.3	140.8
2009	230.2	437.4	642.4	616.4	205.0	179.0
2010	202.5	405.0	680.2	648.8	275.2	243.8
2011	188.6	377.2	684.3	648.8	307.1	271.6
2012	195.1	390.2	688.6	648.8	298.4	258.6
2013	184.6	387.7	727.7	681.2	340.1	293.6
2014	191.7	402.6	732.6	681.2	330.1	278.7
2015	192.7	423.9	772.9	713.7	348.9	289.7

Source: ASPE analysis and 2017 USRDS Reference tables

B. Subtract observed incidence of ESRD-DM diagnosed in AI/AN from alternative incidence rates calculated in previous step to calculate number of averted cases

The observed incidence rate of ESRD-DM diagnosed among AI/AN for each year was multiplied by the AI/AN treated population of that year (as reported by IHS) to approximate observed cases. The estimated incidence rates of each year are also multiplied by the AI/AN treated population of each year to approximate the estimated number of cases assuming growth in incidence observed in the white population and unchanged incidence rates (as in A-a and A-b).

C. Estimate costs of ESRD care in each year for averted cases over ten years assuming same growth in incidence observed in white population (Scenario 1)

The cost of treating ESRD varies by treatment modality.[33] Patients are eligible for Medicare while they have ESRD. For those patients who are treated with dialysis only, Medicare continues to treat them for the rest of their lives. For those patients who receive a transplanted kidney, Medicare continues to treat them for an additional 3 years, at which point they are no longer considered to have ESRD and lose Medicare coverage unless otherwise eligible. The

[32] Unadjusted incidence of reported ESRD with diabetes as the primary cause; https://www.usrds.org/reference.aspx
[33] Prices are not year-adjusted

annualized per person per year (PPPY) Medicare costs of dialysis, first transplant year, and subsequent transplant maintenance years are displayed in Table 5 below. We can see that PPPY costs have increased over the ten years for all treatment modalities, although not steadily.

Table 5: Average annual PPPY Medicare cost for AI/AN population with all-cause ESRD

Year	PPPY Cost for Dialysis Patient	PPPY Cost for Patient in Transplant Year	PPPY Cost for Patient in Maintenance Year
2006	$63,808	$104,261	$19,654
2007	$65,513	$109,865	$20,698
2008	$68,086	$102,627	$22,271
2009	$74,380	$113,265	$22,086
2010	$75,766	$116,937	$21,670
2011	$75,353	$116,195	$22,397
2012	$73,830	$115,439	$21,067
2013	$74,021	$119,103	$21,735
2014	$74,882	$118,539	$25,214
2015	$76,089	$115,495	$23,384

Source: USRDS 2017 Annual Data Report Reference Tables K10-K12, model 2
Note: These costs refer to the average total PPPY cost of care for AI/AN individuals with ESRD and therefore include the cost of treatment for any comorbidities

Dialysis is the most common form of treatment.[34] Patients on dialysis often visit dialysis centers to have their blood filtered through a dialyzer three days a week with each session lasting 4-6 hours, although some patients opt for home-based hemodialysis. In 2015, the average PPPY spending on an AI/AN hemodialysis patient was $76,089, up from $63,808 in 2006.[35] This annual cost continues until the patient stops dialysis, either due to receiving a kidney transplant or death. Despite socioeconomic barriers to accessing dialysis such as transportation costs, AI/AN populations do relatively well on dialysis, such that AI/AN have greater patient survival on dialysis than does the white population.[36] Table 6 displays the observed percentage of each cohort that is exclusively treated by dialysis in each calendar year and Table 7 displays the observed percentage of each cohort that dies on dialysis in each calendar year.

[34] We use the cost of hemodialysis done at a dialysis facility performed by a professional for all dialysis for simplicity. This is the most common dialysis treatment (89.5% of all dialysis in 2014); hemodialysis can also be self-administered in a facility or done at home and continuous ambulatory peritoneal dialysis (CAPD) and continuous cycling peritoneal dialysis (CCPD) are alternative options to hemodialysis. Prices among the modalities vary, CCPD/CAPD tend to cost less but have higher rates of complications
[35] USRDS 2017 Annual Data Report Reference Tables
[36] The 1999 US Renal Data System reports a mortality rate for prevalent dialysis patients of 196.7 per 1000 patient-years for the white population and 162.4 per 1000 patient-years for Al/AN; Narva, A. Kidney Disease in Native Americans, 2002

Table 6: Observed percentages of each year's cohort that is on dialysis through the full year

Cohort-Year	All-Cause ESRD	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9
2006	1,007	89.5%	75.4%	61.8%	50.2%	41.0%	33.7%	27.9%	22.7%	18.3%	14.9%
2007	1,046	91.4%	77.2%	62.6%	52.4%	43.9%	35.6%	28.7%	23.0%	18.5%	
2008	1,114	88.2%	73.1%	62.5%	52.4%	44.2%	36.5%	28.9%	23.2%		
2009	1,208	91.8%	78.9%	66.6%	56.1%	46.4%	38.7%	30.3%			
2010	1,166	92.4%	80.7%	68.5%	58.0%	48.1%	40.1%				
2011	1,162	91.9%	80.1%	70.3%	57.1%	48.2%					
2012	1,212	90.4%	77.7%	66.3%	56.5%						
2013	1,228	90.4%	78.7%	66.1%							
2014	1,245	91.2%	78.3%								
2015	1,248	90.9%									

Source: Acumen analysis of Medicare data

Table 7: Observed percentages of each year's cohort that dies while on dialysis

Cohort-Year	All-Cause ESRD	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9
2006	1,007	7.4%	11.7%	10.6%	8.5%	7.0%	6.1%	4.9%	4.4%	3.6%	2.9%
2007	1,046	6.9%	11.5%	11.3%	8.7%	6.4%	6.5%	5.4%	4.5%	3.5%	
2008	1,114	9.1%	12.7%	9.0%	8.5%	6.9%	6.3%	6.9%	4.6%		
2009	1,208	6.8%	10.5%	9.5%	8.4%	7.9%	6.4%	6.0%			
2010	1,166	6.1%	9.1%	8.4%	9.0%	7.7%	6.8%				
2011	1,162	6.2%	9.4%	7.9%	10.8%	7.9%					
2012	1,212	7.4%	10.9%	8.8%	8.3%						
2013	1,228	8.1%	9.6%	10.5%							
2014	1,245	7.6%	10.9%								
2015	1,248	7.5%									

Source: Acumen analysis of Medicare data

For those receiving kidney transplants, in 2015, average first year spending on an AI/AN transplant patient was $115,495 (See Table 5).[37] After the first year of receiving a transplant, a functioning graft must be maintained through immunosuppressant drugs. By statute, if a graft is successfully maintained for 3 years, the patient no longer qualifies for Medicare by ESRD alone. Very few patients with an ESRD diagnosis start their treatment with an immediate transplant (see Table 8). Most patients must wait a few years before they may qualify for a transplant. Some patients will be treated with dialysis before even being referred for a transplant qualification evaluation. Once patients qualify for transplantation, they are placed on a waiting list to receive a kidney. Ethnic minorities, residents of rural or other geographically disadvantaged areas, and patients with lower socioeconomic status have been known to face delayed referrals, if they are referred at all.[38] AI/AN populations served by IHS may face one or more of these disadvantages. Table 8 shows the number of all-cause ESRD diagnoses in AI/AN populations each year, and how many of the patients received kidney transplants in each year. We use the counts in Table 8

[37] USRDS 2017 Annual Data Report Reference Tables
[38] HRSA, Educational Guidance on Patient Referral to Kidney Transplantation https://optn.transplant.hrsa.gov/resources/guidance/educational-guidance-on-patient-referral-to-kidney-transplantation/

to calculate the percentages of ESRD patients that receive transplants in each calendar year and then multiply these percentages by the number of averted cases in each year estimate the number of transplants that would have occurred in the averted cases.

Table 8: Observed number of transplants among AI/AN for each cohort of all-cause ESRD in each subsequent year

Cohort-Year	All-Cause ESRD	Immediate First Year Transplants	After 1 yr	After 2 yrs	After 3 yrs	After 4 yrs	After 5 yrs	After 6 yrs	After 7 yrs	After 8 yrs	After 9 yrs
2006	1,007	31	20	20	27	24	13	12	7	10	6
2007	1,046	18	23	23	15	24	20	16	11	13	
2008	1,114	30	15	11	19	16	15	9	16		
2009	1,208	18	18	25	26	23	15	30			
2010	1,166	18	18	28	16	29	13				
2011	1,162	22	22	13	23	13					
2012	1,212	26	12	23	20						
2013	1,228	19	17	22							
2014	1,245	16	9								
2015	1,248	20									

Source: ASPE aggregation of Acumen analysis of Medicare data

In order to estimate the costs of the averted cases, we assume the ratio of dialysis to transplants to post-transplant maintenance that was observed under all-cause ESRD in AI/AN applies to the averted ESRD-DM cases as well. Whenever necessary, we round down in order to keep the estimate of cost savings conservative. Because re-transplants have been observed to be rare (11 cases over the ten-year period studied), we do not consider them in our analysis. Similarly, reversions to dialysis, although less rare (the highest number of dialysis after transplant patients was 21, ten years after diagnosis) are also not taken into account. Had we considered these situations, our savings estimates would have been higher. We assume three years of maintenance costs (after the transplant year) for each transplant. By multiplying the percentages of transplants in Table 8 to our estimates of averted cases in Scenario 1, we calculate the number of transplants in each year that were averted in Scenario 1. Table 9 displays these results. The total number of transplants performed over ten years for the cases that were averted assuming the same growth in incidence observed in the white population is approximately 201. Table 10 reorganizes the Table 9 estimates of averted transplants by calendar year (CY) and multiplies by the calendar year price to find that the averted costs of the first year of kidney transplantation over the ten year study period was **$23,214,782**.

Table 9: Estimated number of averted transplants assuming growth in incidence observed in the white population based on observed percentages

Cohort-Year	Averted Cases (White)	Immediate First Year Transplants	After 1 yr	After 2 yrs	After 3 yrs	After 4 yrs	After 5 yrs	After 6 yrs	After 7 yrs	After 8 yrs	After 9 yrs
2006	167.1	5.1	3.3	3.3	4.5	4.0	2.2	2.0	1.2	1.7	1.0
2007	166.9	2.9	3.7	3.7	2.4	3.8	3.2	2.6	1.8	2.1	
2008	163.3	4.4	2.2	1.6	2.8	2.4	2.2	1.3	2.4		
2009	205.0	3.1	3.1	4.2	4.4	3.9	2.6	5.1			
2010	275.2	4.3	4.3	6.6	3.8	6.8	3.1				
2011	307.1	5.8	5.8	3.4	6.1	3.4					
2012	298.4	6.4	3.0	5.7	4.9						
2013	340.1	5.3	4.7	6.1							
2014	330.1	4.2	2.4								
2015	348.9	5.6									

Source: ASPE analysis, Acumen analysis of Medicare Data

Table 10: Estimated number and cost of averted transplants assuming growth in incidence observed in the white population in each calendar year

	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
2006	5.1	3.3	3.3	4.5	4.0	2.2	2.0	1.2	1.7	1.0
2007		2.9	3.7	3.7	2.4	3.8	3.2	2.6	1.8	2.1
2008			4.4	2.2	1.6	2.8	2.4	2.2	1.3	2.4
2009				3.1	3.1	4.2	4.4	3.9	2.6	5.1
2010					4.3	4.3	6.6	3.8	6.8	3.1
2011						5.8	5.8	3.4	6.1	3.4
2012							6.4	3.0	5.7	4.9
2013								5.3	4.7	6.1
2014									4.2	2.4
2015										5.6
Total #	5.1	6.2	11.4	13.4	15.3	23.1	30.8	25.2	34.8	36.0
CY PPPY Cost	$104,261	$109,865	$102,627	$113,265	$116,937	$116,195	$115,439	$119,103	$118,539	$115,495
Total $	$535,902	$680,064	$1,168,922	$1,517,751	$1,786,797	$2,681,781	$3,550,904	$3,006,160	$412,7528	$415,8975

Source: ASPE analysis, Acumen analysis of Medicare Data, USRDS 2017 Annual Data Report Reference Tables

To calculate maintenance costs in each calendar year, we sum the calendar year transplants from the previous three years ("maintenance years") and multiply by the price of graft maintenance in that year, as seen in Table 11. The first three years of the study period have low numbers of maintenance years because we only consider the maintenance costs of transplants performed during the study period. The averted cost to Medicare due to maintenance costs during the study period is **$15,095,739**.

Table 11: Estimated number and cost of maintenance years assuming growth in incidence observed in the white population in each calendar year

	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
CY Transplants	5.1	6.2	15.8	18.7	24.2	40.2	56.3	46.8	66.2	69.0
Maintenance Years	0.0	5.1	11.3	27.1	40.6	58.6	83.0	120.7	143.3	169.3
CY PPPY Cost	$19,654	$20,698	$22,271	$22,086	$21,670	$22,397	$21,067	$21,735	$25,214	$23,384
Maintenance Years $	$0	$106,388	$252,330	$598,972	$880,452	$1,313,136	$1,748,772	$2,623,415	$3,612,662	$3,959,613

Source: ASPE analysis, Acumen analysis of Medicare Data, USRDS 2017 Annual Data Report Reference Tables

Multiplying the percentages in Table 6 by the estimated number of averted cases (displayed again in the second column of Table 12), we calculate the number of full dialysis years that were averted under Scenario 1, also displayed in Table 12. The total number of dialysis years over the 2006-2015 study period is approximately 7,636. Similarly, using the percentages in Table 7, we know the number of dialysis deaths over the period is approximately 986. Table 13 displays the number of full dialysis years, dialysis deaths, and the price of dialysis for each calendar year. We assume half the cost of a full year of dialysis as an approximation for the cost of dialysis in the last year of life. The averted cost to Medicare due to full dialysis years during the study period is **$565,354,613**. The same due to half dialysis years (dialysis deaths) during the study period is **$36,571,617**.

Table 12: Estimated number of full dialysis years averted assuming the growth in incidence observed in the white population

Cohort -Year	Averted Cases (White)	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9
2006	167.1	149.6	126.0	103.3	83.9	68.5	56.3	46.6	37.9	30.6	24.9
2007	166.9	152.6	128.9	104.5	87.5	73.3	59.4	47.9	38.4	30.9	
2008	163.3	144.0	119.4	102.1	85.6	72.2	59.6	47.2	37.9		
2009	205.0	188.2	161.8	136.5	115.0	95.1	79.3	62.1			
2010	275.2	254.3	222.1	188.5	159.6	132.4	110.4				
2011	307.1	282.2	246.0	215.9	175.4	148.0					
2012	298.4	269.8	231.9	197.8	168.6						
2013	340.1	307.5	267.7	224.8							
2014	330.1	301.1	258.5								
2015	348.9	317.2									

Source: ASPE analysis, Acumen analysis of Medicare Data

Table 13: Estimated number and cost of dialysis years and dialysis deaths assuming growth in incidence observed in the white population in each calendar year

	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Dialysis Years	149.6	278.5	376.2	495.9	674.1	856.0	997.5	1155.4	1269.8	1383.2
Dialysis Deaths	12.4	31.1	51.8	67.7	79.2	98.3	121.6	152.0	176.3	196.1
CY PPPY Cost	$63,808	$65,513	$68,086	$74,380	$75,766	$75,353	$73,830	$74,021	$74,882	$76,089
Dialysis Years $	$9,542,486	$18,247,991	$25,610,549	$36,886,530	$51,070,830	$64,501,414	$73,643,948	$85,521,643	$95,082,917	$105,246,305
Dialysis Deaths $	$394,506	$1,017,640	$1,762,284	$2,519,336	$3,001,337	$3,704,112	$4,488,491	$5,623,764	$6,599,628	$7,460,519

Source: ASPE analysis, Acumen analysis of Medicare Data

We sum the total relevant costs from transplant years, maintenance years, dialysis years, and dialysis deaths to calculate the estimate of averted costs

- **$23,214,782**[due to transplant years] + **$15,095,739**[due to maintenance years] + **$565,354,613**[due to dialysis years] + **$36,571,617**[due to dialysis deaths] = **$640,236,751**

This totals to **$640,236,751** in averted expenditures had AI/AN ESRD-DM incidence grown at the same rate as that of the white population.

D. Estimate the costs of ESRD care for each year for the number of averted cases given unchanged incidence rates (Scenario 2)

We now repeat this process for Scenario 2 by multiplying the prices in Table 5 and the percentages developed from Tables 6-8 by the number of averted cases in each year had incidence rates remained unchanged since 2000 (the last column in Table 4). Table 14 displays the estimated number of transplants in each calendar year, which totals to approximately 91 over the ten-year period. As in Section C, we assume a maintenance period of three years after the year in which successful transplants occur. We calculate the number of maintenance years in each calendar year by summing the number of transplants in the previous three years. By this metric, we calculate that approximately 194 maintenance years were averted during the observation period, also displayed in Table 14. The averted cost to Medicare during the study period due to transplants is **$10,391,620** and the same due to maintenance is **$4,389,174**.

Table 14: Estimated number and cost of maintenance years given 2000 incidence in each calendar year

	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Transplants	3.1	3.7	6.9	7.7	7.8	10.8	13.1	10.5	13.1	13.8
Maintenance Years	0.0	3.1	6.8	13.7	18.3	22.4	26.4	31.8	34.4	36.8
CY PPPY Transplant Cost	$104,261	$109,865	$102,627	$113,265	$116,937	$116,195	$115,439	$119,103	$118,539	$115,495
CY PPPY Maintenance Cost	$19,654	$20,698	$22,271	$22,086	$21,670	$22,397	$21,067	$21,735	$25,214	$23,384
Transplant $	$320,962	$407,263	$705,863	$874,026	$916,621	$1,254,621	$1,515,964	$1,251,004	$1,556,177	$1,589,119
Maintenance $	$0	$63,718	$151,117	$301,768	$396,594	$502,436	$555,174	$690,484	$868,200	$859,682

Source: ASPE analysis, Acumen analysis of Medicare Data

Table 15 displays the estimated number of dialysis years and dialysis deaths in each calendar year, calculated by multiplying the Scenario 2 averted cases (see Table 4) by the percentages in Tables 6 and 7, respectively, and totaling over each calendar year. Given the unchanged incidence rate since the year 2000, there would have been 6,678 years of dialysis and 864 dialysis deaths during our 2006-2015 study period. The averted cost to Medicare due to full dialysis years during the study period is **$494,288,065**. The same due to half dialysis years (dialysis deaths) during the study period is **$32,032,421**.

Table 15: Estimated number and cost of dialysis years and dialysis deaths given year 2000 incidence in each calendar year

	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Dialysis Years	136.1	249.8	332.3	436.1	594.3	755.5	876.0	1010.1	1100.8	1187.3
Dialysis Deaths	11.3	28.0	45.9	59.7	69.8	86.7	107.0	133.1	153.5	169.2
CY PPPY Cost	$63,808	$65,513	$68,086	$74,380	$75,766	$75,353	$73,830	$74,021	$74,882	$76,089
Dialysis Years $	$8,686,151	$16,363,352	$22,623,957	$32,438,888	$45,028,522	$56,927,843	$64,677,612	$74,767,035	$82,432,599	$90,342,106
Dialysis Deaths $	$359,092	$916,982	$1,563,677	$2,219,629	$2,645,915	$3,267,883	$3,948,321	$4,924,336	$5,748,197	$6,438,389

Source: ASPE analysis, Acumen analysis of Medicare Data

As in section (C.), we sum the relevant costs of transplants, maintenance years, dialysis years, and dialysis deaths to find the total averted costs to Medicare.

- **$10,391,620**[due to transplant years] + **$4,389,174**[due to maintenance years] + **$494,288,065**[due to dialysis years] + **$32,032,421**[due to dialysis deaths] = **$541,101,280**

This totals to **$541,101,280** of averted Medicare expenditures had AI/AN ESRD-DM incidence remained at the 2000 rate.

E. Estimate Medicare expenditures if our estimates of averted cases of ESRD-DM in both scenarios had not been averted.

For the purposes of this analysis, we assumed that all AI/AN who were age 65 or older were covered by Medicare.[39] We did not take into account any other form of Medicare eligibility. Since we cannot observe the characteristics of individuals who had averted cases of ESRD, including their age, we applied the age distribution for all-race ESRD-DM to the averted AI/AN ESRD-DM case cohorts.[40] Given AI/AN populations tend to develop diabetes at earlier ages, using an all-race ESRD-DM age distribution skews the applied age distribution older than the actual distribution for AI/AN populations, placing a greater percentage of patients into Medicare and making our final estimates of net savings from averted cases of ESRD-DM more conservative (i.e., averted expenditures are lower for Medicare patients, since Medicare covers the cost of their diabetes and CKD care). The USRDS incidence reference table provides the age distribution of each all-race cohort diagnosed with ESRD-DM (table not shown). On average, of all those diagnosed within a given year, 46.8 percent are over age 65, 61.8 percent are over age 65 after five years, and 75.0 percent are over age 65 after 10 years. Table 16 shows how these percentages are applied to the cohorts in our analysis. Every cohort begins in year 0 with 46.8 percent of the cohort qualifying for Medicare based on age. After five years of observation, this percentage increases to 61.8 percent. The first cohort does not reach 75 percent over age 65 because this occurs after the completion of ten years and our observation period is only ten years.

[39] Census Bureau; 65+ in the United States; 2014, (based on 2010 data)
[40] AI/AN populations are small and recording the age distribution of AI/AN only would expose patients and violate HIPAA.

Table 16: Approximated percentages of Medicare-enrolled individuals based on all-race age distribution

Cohort-Year	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9
2006	46.8%	46.8%	46.8%	46.8%	46.8%	61.8%	61.8%	61.8%	61.8%	61.8%
2007	46.8%	46.8%	46.8%	46.8%	46.8%	61.8%	61.8%	61.8%	61.8%	
2008	46.8%	46.8%	46.8%	46.8%	46.8%	61.8%	61.8%	61.8%		
2009	46.8%	46.8%	46.8%	46.8%	46.8%	61.8%	61.8%			
2010	46.8%	46.8%	46.8%	46.8%	46.8%	61.8%				
2011	46.8%	46.8%	46.8%	46.8%	46.8%					
2012	46.8%	46.8%	46.8%	46.8%						
2013	46.8%	46.8%	46.8%							
2014	46.8%	46.8%								
2015	46.8%									

Source: ASPE analysis of USRDS incidence reference tables

By multiplying the percentages in Table 16 by the number of averted cases in each cohort year, we can estimate the number of individuals within each cohort year that were eligible for Medicare based on their age. We sum these estimates for each calendar year as displayed in Table 17.

Table 17: Number of Medicare patients in each calendar year

	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Scenario 1: assuming white growth	78.2	156.3	232.7	328.7	457.5	626.3	790.9	974.6	1159.8	1364.4
Scenario 2: assuming 2000 incidence	71.2	140.4	206.3	290	404.1	554	697.2	855.8	1013	1185.2

Source: ASPE analysis

We then multiply the number of Medicare patients in each calendar year by the PPPY average total healthcare costs of AI/AN individuals with diabetes or CKD (displayed in Table 18) in order to estimate a range of the costs to Medicare from averted cases.

Table 18: Approximate PPPY Medicare costs by calendar year for diabetes and CKD in AI/AN

	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Diabetes	$12,821	$13,717	$14,857	$15,104	$15,591	$16,181	$16,167	$16,095	$17,906	$18,155
CKD	$19,904	$22,365	$21,638	$24,201	$27,198	$24,817	$23,809	$23,852	$23,359	$26,624

Source: ASPE analysis of USRDS 2017 Reference Tables

In both scenarios we do not approximate mortality, but assume all averted cases live through the ten-year period. In addition, some of the averted cases may not have developed either diabetes[41] or CKD. Not taking these factors into account makes our savings estimates more conservative.

[41] In addition to promoting approaches to treat individuals who have developed diabetes, the SDPI also promotes strategies to prevent individuals from developing diabetes.

Scenario 1: Assuming the growth in incidence observed in the white population

- 35% CKD and 65% diabetes: **$119,883,979**
- All diabetes: **$102,847,269**
- All CKD: **$151,523,585**

Scenario 2: Assuming 2000 incidence rate

- 35% CKD and 65% diabetes: **$105,215,722**
- All diabetes: **$90,250,409**
- All CKD: **$133,008,447**

F. The final step in our calculations is to calculate the difference between estimated costs had the averted cases cohorts developed ESRD-DM (calculated in sections C and D) versus estimated costs given they did not develop ESRD-DM (calculated in section E) to generate estimates of overall savings to the Medicare program during the 2006-2015 period. Table 19 shows the estimated net savings over ten years was between $489 and $537 million under Scenario 1 (i.e., had AI/AN ESRD-DM incidence grown at the same rate as that of the white population). If AI/AN ESRD-DM incidence had stayed at the 2000 level (Scenario 2), we estimate a net savings of between $408 and $451 million.

Table 19: Estimated Medicare expenditures on ESRD-DM, diabetes, or CKD care over ten years, and estimated net savings to the Medicare program over ten years (2005-2014)

	Estimated Medicare expenditures for ESRD care over ten years	Estimated Medicare expenditures for diabetic care over ten years	Estimated Medicare expenditures for CKD care over ten years	Estimated Medicare expenditures for 65% diabetics and 35% CKD over ten years	Estimated range of net savings to Medicare from averted cases of ESRD-DM	Estimated range of net savings to Medicare from averted cases of ESRD-DM
Scenario 1: White growth	$640,236,751	$102,847,269	$151,523,585	$119,883,979	$488,713,166 - $537,389,482	$520,352,772
Scenario 2: 2000 incidence	$541,101,280	$90,250,409	$133,008,447	$105,215,722	$408,092,833 - $450,850,871	$435,885,558

Source: ASPE analysis

Key Assumptions and Limitations:

Although implementation of SDPI began in 1997, we chose to begin this study's trend analysis in the year 2000 for two main reasons. First, we wanted to account for various time lags, including the time involved in implementing SDPI (SDPI is a complex system of grants and initiatives, the development of which would not have been instantaneous) and the time it takes for new diabetes treatment and prevention interventions to have an effect on ESRD-DM prevalence rates. It is our understanding that some interventions supported by SDPI may have already been in development prior to implementation of the program. Still, we believe that implementation of SDPI substantially advanced existing efforts and generated new opportunities for intervention. Second, the systems through which diabetes and ESRD-DM data were collected in both AI/AN and non-AI/AN populations improved over time and we believe reference data vintages that include years of data prior to 2000 are not sufficiently reliable or comparable to those that include more recent years of data. Because data prior to the year 2000 are not analyzed or displayed in this study, it is not immediately obvious that the 2000 ESRD-DM incidence rate in AI/AN is not the peak of AI/AN incidence over time, although other internally consistent vintages have suggested it is not.[42] Regardless, the estimates are sensitive to the choice of initial year. Had we chosen to start trend analysis in a later year, our savings estimates would have been lower.

Ideally, if we had had access to a sufficient number of years of reliable data prior to 1997, we would have employed a difference-in-difference analysis. A difference-in-difference approach could have demonstrated how the SDPI had affected AI/AN ESRD-DM incidence growth by comparing how quickly ESRD-DM incidence grew in AI/AN populations (versus white populations) before and after SDPI.

Finally, all-cause ESRD trends in most non-white racial or ethnic groups decreased over the time period studied.[43] However, trends for ESRD-DM differ from all-case ESRD and declines in ESRD-DM have been substantially greater for AI/AN populations relative to other non-white racial or ethnic groups. Given the incidence of ESRD-DM among AI/AN diabetics is most closely mirrored by that among white diabetics,[44] we believe the ESRD-DM incidence in the white population is the appropriate counterfactual in Scenario 1.

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[42] 2016 USRDS reference data tables

[43] All-cause ESRD incidence in Native Hawaiians / Pacific Islanders increased over time, 2018 USRDS Annual Data Report, Figures 1.5 and 1.12

[44] As of 2013; https://www.cdc.gov/mmwr/volumes/66/wr/mm6601e1.htm

Appendix II: Background on the components of the Special Diabetes Program for Indians

In 1997, as part of the Balanced Budget Act, Congress established the Special Diabetes Program for Indians (SDPI) in order to prevent and treat diabetes in the AI/AN population, which is disproportionately affected by the condition. SDPI is currently a $150 million per year grant program authorized through September 30, 2019. The FY 2020 Budget proposes to extend funding for two years through FY 2021, at $150 million each year.

Because SDPI has been running for the past twenty years, various components have come in or out of use.

Community Directed Grants

SDPI currently funds direct interventions in the form of Community Directed Grants. These interventions are designed by individual grantees, allowing them to focus on locally identified priorities. Clinical interventions may include paying for diabetes or related medication or hiring more clinicians; prevention interventions may include providing education about nutrition or increased frequency of testing.

Starting in 2001, in order to be eligible for SDPI, grantees are required to choose and implement at least one of SDPI *Diabetes Best Practices* and report on a corresponding key measure. IHS developed SDPI *Diabetes Best Practices* to reflect the most current research about diabetes. Most of the 18 *Best Practices* are prevention/treatment practices applicable to the general population. The screening for latent tuberculosis (TB), however, is specific to the AI/AN population because latent TB is still common in the AI/AN community and diabetes is a risk factor for the progression of latent TB to active TB.

While SDPI funds are used to adopt at least one *Best Practice*, those funds are not limited to use for *Best Practices*. Any evidence-based strategy for diabetes prevention or treatment qualifies as a reasonable use of grant dollars.

SDPI Demonstrations and Initiatives

In 2004, Congress established SDPI demonstration project program as an additional component of SDPI in order to translate the most recent diabetes prevention and treatment research into real-world interventions that are locally and culturally appropriate. The first round of demonstration projects were referred to as SDPI Diabetes Prevention Program Demonstrations (2004-2010), the second round were called SDPI Diabetes Prevention Program Initiatives (2010-2016). Each round had two types of programs designed to focus on different issues within the AI/AN community: SDPI Diabetes Prevention Program (SDPI DP) focused on preventing diabetes in at-risk AI/AN individuals and SDPI Healthy Heart Program (SDPI HH) focused on reducing risk of cardiovascular disease in diabetic AI/AN individuals.

SDPI DP intervention was designed based on a prior NIH-funded Diabetes Prevention Program (DPP) clinical trial, findings from which were published in 2002. The NIH DPP was a randomized controlled trial which divided 3,234 overweight and pre-diabetic study participants into three groups: a control group, which took a placebo pill each day, a metformin (medication to help control blood sugar) group, and a lifestyle intervention group, which was given training on nutrition, physical activity, and behavior modification with the goal of losing a moderate amount of body weight and maintaining the loss. The NIH DPP found that the lifestyle intervention group experienced the sharpest reduction in the likelihood of developing diabetes post-treatment. SDPI DP used the same 16-session lifestyle curriculum (adapted for AI/AN patients) and compared their results with the NIH DPP study control group to evaluate their success. Although the population enrolled in SDPI DP was demographically different from the population enrolled in the NIH DPP trial, for the purposes of comparing results from SDPI DP to the NIH DPP, the evaluation population of SDPI DP was limited to those with the same non-racial characteristics as patients eligible for the NIH DPP trial. These characteristics included age, BMI, fasting blood glucose and oral glucose tolerance ranges. SDPI DP initially funded 36 Indian Health Service / Tribal / Urban Indian Health Program (I/T/U) health programs. This demonstration resulted in a significantly reduced eight-year risk of developing diabetes, as well as significant weight loss, increased physical activity, improved consumption of healthy foods, lower blood pressure, lower glucose levels, and improved health-related quality of life compared to the NIH-DPP placebo/control group. In 2010, the lessons learned from SDPI DP demonstration were incorporated into the follow-on SDPI DP Initiatives program with the purpose of continuing prevention and disseminating strategies learned from the first round. Similar to the demonstration, SDPI DP Initiative population exhibited lower rates of diabetes post-treatment than the NIH DPP placebo group, suggesting successful implementation.[45] As of May 2014, 4,549 patients had completed lifestyle classes and follow-up assessment.[46]

SDPI Healthy Heart Program (SDPI HH), the companion to SDPI DP, addresses the issue of cardiovascular disease, a leading cause of death in diabetic patients. SDPI HH initially funded 30 I/T/U programs in order to implement an intensive, clinic-based case management intervention to reduce cardiovascular risk factors in diabetic patients. The program showed success in reducing a number of cardiovascular disease risk factors: decrease in smoking, eating healthy foods once or more per week, eating unhealthy foods once or less per week, and regular physical activity. These changes were also associated with improvements in the clinical risk factors such as blood pressure, LDL, and triglycerides. The follow-on SDPI HH Initiative 2010-2016 continued this work, including dissemination of lessons learned from the demonstration. As of May 2014, 2,174 participants had completed follow-up assessments.

[45] Although the post-treatment rate of diabetes was somewhat higher in SDPI DP study population compared to the NIH-DPP lifestyle intervention group, the AI/AN population has greater baseline risk of diabetes than the multi-race population drawn enrolled in the NIH DPP clinical trial, so this finding was not unexpected.

[46] https://www.nihb.org/sdpi/docs/05022016/SDPI_2014_Report_to_Congress.pdf

Diabetes Audit

SDPI has indirectly improved data collected on diabetic AI/AN patients. The IHS Diabetes Care and Outcomes Audit (Audit) is an aggregated dataset that includes most, if not all, AI/AN diabetic patients who are treated through the IHS federal or tribal network. Although some smaller versions of the Audit predate SDPI, the first national data were collected electronically in 1997 around the start of SDPI. Some SDPI funding supported establishment of electronic health records (EHRs). The implementation of EHRs made it easier for grantees to submit their data to the Audit, which improved reporting. Beginning in 2004, SDPI grantees, including those focusing solely on prevention, are now required to report data to the Audit.

The Diabetes Audit includes a variety of patient characteristics, blood sugar levels, medications taken, and frequency of visits, among other information. This information is used to track diabetes outcomes in a number of ways including prescriptions of ACE inhibitors or ARBs, blood pressures, hemoglobin A1Cs, urine albumin-to-creatinine ratios, comorbidities, and other measures.

Diabetes Treatment Algorithms & Standards of Care and Clinical Practice Recommendations

SDPI indirectly contributed to the standardization of treatment for diabetes and comorbidities through the distribution and promotion of two systems: the diabetes treatment algorithms and the standards of care and clinical practice recommendations. These were both designed for primary care or general practitioners who may not have the expertise or training necessary to treat diabetes-related complications.

As early as in the late 1980s, tribal-based physicians developed diabetes treatment algorithms. These were distributed by hard copy, but came into wider use when SDPI began centralizing diabetes knowledge on the IHS website. Since grantees visit the IHS website to download the SDPI grant applications and submit data, posting the diabetes treatment algorithms on the website has helped foster their dissemination. Posting this information supports efforts to standardize treatment and potentially reduce referrals to specialists, although these outcomes have not been analyzed to date. There are currently 6 separate algorithms for treating common conditions or comorbidities associated with diabetes.[47] These algorithms are applicable to the general population, but are specific to AI/AN communities in the medication regimens they recommend: medications are available through the national core formulary, which are the required medications for IHS clinics to have available.

The standards of care and clinical practice recommendations were developed specifically for the AI/AN population, which has some health differences from the general population. These recommendations provide guidance in a centralized repository on a number of conditions related to diabetes. These recommendations are useful for clinicians that are new to working with AI/AN populations or who have not kept up with the latest recommendations specific to diabetic care. For example, pregnant women are generally tested for gestational diabetes somewhere

[47] https://www.ihs.gov/diabetes/clinician-resources/dm-treatment-algorithms/

between 24 and 28 weeks, but IHS standards of care recommend AI/AN pregnant women are tested much earlier for undiagnosed pre-pregnancy diabetes, which would require a different treatment than diabetes that developed during pregnancy.

Continuing Education

SDPI indirectly contributes to keeping AI/AN health care providers educated and up to date on the latest research on diabetes care. This is done through webinars and trainings, IHS Area-wide meetings or conferences, and Area Diabetes Consultants.

The IHS division of Diabetes Treatment and Prevention sponsors regular webinars from experts in the field. SDPI pays for the staff that runs the webinars, for filing the paperwork necessary to qualify these trainings for CME/CE credits, and for promoting these trainings. Some of these trainings are required of SDPI grantees. Area-wide meetings or conferences facilitate the spread of professional knowledge and allow health care providers to compare notes on how to deal with common situations. The most recent conference was national in order to disseminate information from SDPI Initiatives; the Diabetes in Indian Country Conference took place in Albuquerque from Sept 19th-21st, 2017 and registration had to be cut off after almost 1000 attendees due to the size of the venue. The next conference will take place in August 2019 in Oklahoma City and organizers have chosen a larger venue to accommodate the expected attendance. In addition, SDPI funds Area Diabetes Consultants (ADC); an ADC is a health care professional with expertise in diabetes that serves as a support for a single IHS Area. The 12 IHS Areas are supported by 12 ADCs who are also the project officers for the Community Directed Grants. They coordinate information flow between local and national Indian health systems, conduct site visits to check for program improvement, provide diabetes training and resources to health care professionals, and work with the IHS division of diabetes to translate the latest scientific research into locally and culturally appropriate intervention ideas.