

Evidence-Based DIABETES MANAGEMENT™

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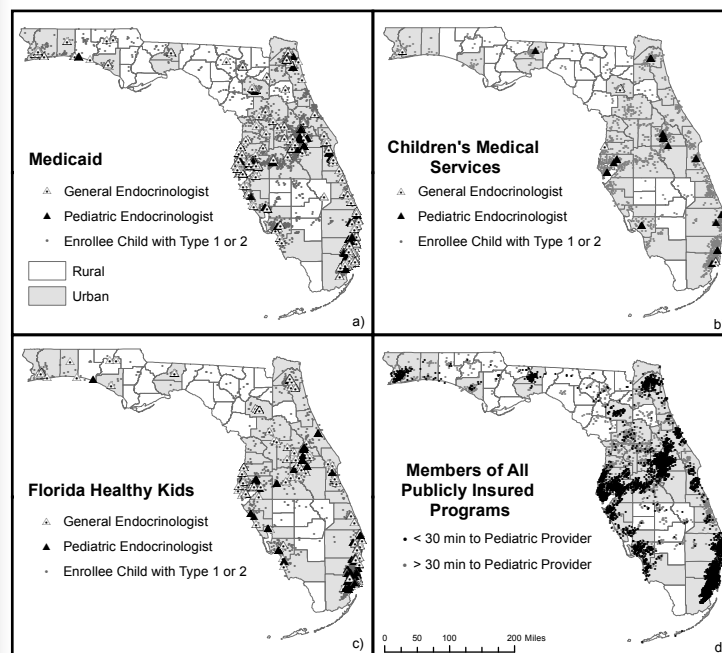
ORIGINAL RESEARCH

Geographic Access to Endocrinologists for Florida's Publicly Insured Children With Diabetes

Ashby F. Walker, PhD; Jaclyn M. Hall, PhD; Elizabeth A. Shenkman, PhD; Matthew J. Gurka, PhD; Heather L. Morris, PhD; Michael J. Haller, MD; Henry J. Rohrs, MD; Kelsey R. Salazar, MPH; and Desmond A. Schatz, MD

ABSTRACT: Enrollment files, eligibility files, and claims/encounter data were used to identify 7233 children with diabetes in Florida's public insurance programs to examine driving times they encounter to reach in-network endocrinologists who serve publicly insured children with diabetes in Florida; the children are categorized by sociodemographic characteristics. Average driving times to pediatric endocrinologists were ≤30 minutes for children in urban areas but ≥70 minutes for children in rural communities. White children faced the longest driving times; only 56% were ≤30 minutes from a pediatric endocrinologist. These data reinforce the importance of outreach strategies for families in rural areas and demonstrate that spatial barriers, alone, do not fully elucidate racial/ethnic disparities in pediatric diabetes.

FIGURES 1A-D. Travel Distance to In-Network Endocrinologists by Public Insurance Program and Rural/Urban Location for Children With Type 1 and Type 2 Diabetes in Florida



For LEGEND, see SP109

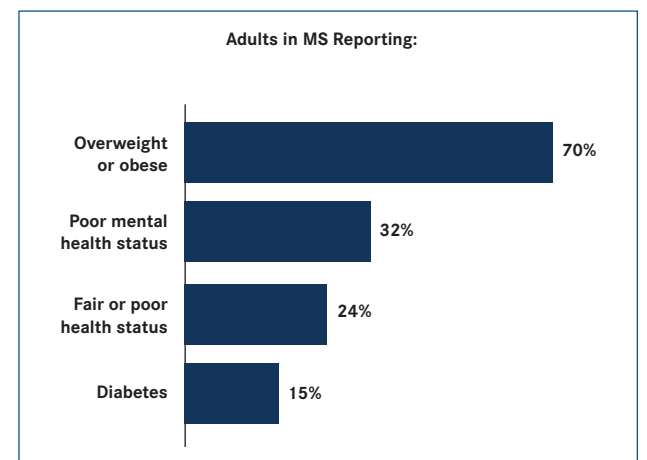
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COMMENTARY

The Potential of a Population Health Strategy to Improve Healthcare Outcomes and Reduce Costs for Medicaid Programs

David J. Zielak, PhD

FIGURE 1. The Status of Health in Mississippi



Source: Kaiser Family Foundation

THE RISING COST OF healthcare in the United States is a concern not only for individuals and families but also for corporations and both state and federal governments. This is particularly true of Medicaid programs across the country. The ever-escalating costs of medical goods and services are driving up the cost of Medicaid programs and making it difficult for state governments to fund their portion of the program.¹ State legislatures are increasingly faced with making difficult choices of funding the Medicaid program at the expense of other, equally important priorities.

Partly driven by healthcare funding pressure, as well as the Affordable Care Act, the concept of the “triple aim” was proposed by Berwick and colleagues in 2008.² The triple aim describes 3 linked and concurrent goals for healthcare delivery: improved care for individuals, improved health of populations, and reduced per-capita costs. Medicaid managed care programs have adopted the concept of the triple aim and attempt to achieve these goals by case management, which directs Medicaid recipients to the most appropriate setting for the healthcare that is needed,

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SPECIAL ISSUE

ACCESS AND ADHERENCE

MARCH 2018

VOLUME 24 ISSUE 4

FROM THE CHAIRMAN

SP106 ORIGINAL RESEARCH Geographic Access to Endocrinologists for Florida's Publicly Insured Children With Diabetes

ASHBY F. WALKER, PHD; JACLYN M. HALL, PHD; ELIZABETH A. SHENKMAN, PHD; MATTHEW J. GURKA, PHD; HEATHER L. MORRIS, PHD; MICHAEL J. HALLER, MD; HENRY J. ROHRS, MD; KELSEY R. SALAZAR, MPH; AND DESMOND A. SHATZ, MD

SP110 COMMENTARY The Potential of a Population Health Strategy to Improve Healthcare Outcomes and Reduce Costs for Medicaid Programs

DAVID J. DZIELAK, PHD

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Access and Adherence: Building Blocks of Care



HENNESSY

"YOU HAVE DIABETES."

Patients who hear these words wonder, "What now?" Fortunately, there are more choices than ever to help manage this disease, through a combination of diet, exercise, good sleep, and therapies, both new and old.

We also know more about prediabetes, and starting April 1, 2018, Medicare will launch the first preventive program to help beneficiaries at risk of progressing to type 2 diabetes. It's a revolution in care that could improve the lives of seniors and bend the cost curve for taxpayers.

In recent years, we've seen advances that tell us some therapies may also prevent heart attacks, heart failure, and lower the risk of early death. This is truly exciting. But none of this happens if people with diabetes lack the basics: access to care, and adherence to therapy. In this issue of *Evidence-Based Diabetes Management*[™], we talk about these critical topics.

Two articles in this issue address the critical role that geography plays in access to care. Dan Sheeran of HealthSlate discusses the decision by CMS to offer the Medicare Diabetes Prevention Program (DPP) as an in-person program only, at least for now. Beneficiaries can access virtual programs on a limited basis only for make-up sessions, and perhaps this will pave the way for virtual Medicare DPP programs in the future. Virtual providers have argued that beneficiaries in rural areas will never have equal access without their services.

Authors led by Ashby F. Walker, PhD, present a study showing how travel distance from a provider affects access to an endocrinologist among children with diabetes in Florida, and the role this plays in disparities in health outcomes. As former Mississippi Medicaid Director David J. Dzielak, PhD, writes, geography and poverty present hurdles to good care. Population health strategies, such as a public-private partnership pursued in his state to address diabetes and preterm births, can produce good results. But these programs are not simple; they require investment in technology and systems to achieve the savings that will come by identifying high-risk patients.

Multiple factors affect adherence. It has behavioral components, and it may be influenced by side effects, education and population health strategies. But cost is a factor, too. Our coverage of a class action lawsuit over insulin pricing filed more than a year ago shows the complexity of this issue, which FDA Commissioner Scott Gottlieb, MD, addressed in recent remarks. No matter the outcome, it appears the case will shed light on the relationships among pharmaceutical firms and pharmacy benefit managers (PBM), which have become powerful agents in our system. The case unfolds as 2 giant payer-PBM mergers are pending. We will be watching, and we thank you for reading. ♦

Sincerely,

Mike Hennessy, Sr.
CHAIRMAN AND CEO

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FROM THE EDITOR-IN-CHIEF

Guidance That Allows for Higher A1C Misses the Mark



GABBAY

DIABETES IS COMPLICATED.

It can occur at different times across the lifespan, both in otherwise healthy people and in those who have other comorbidities. These differences call for care plans that are both personalized and patient-centered, for this crucial reason: day-to-day management of diabetes is done largely by the patient.

It is curious, then, what message the American College of Physicians (ACP) hoped to send to people living with diabetes with a March 6, 2018, guidance published in *Annals of Internal Medicine*, which says most adults with type 2 diabetes (T2D) can aim for glycated hemoglobin (A1C) targets between 7% and 8%. Separately, it says clinicians should consider deintensifying medication for those with A1C levels less than 6.5%.¹ The American Diabetes Association, the American Association of Clinical Endocrinologists, the American Association of Diabetes Educators, the Joslin Diabetes Center, and the Endocrine Society joined together to strongly oppose the ACP guidance, saying this message overlooks the years of work by professional organizations with a particular interest in diabetes care to create current guidelines.²

What is the objective of a guideline? A guideline seeks to ensure optimal care in the setting where it is delivered. For most people with diabetes, especially those with T2D, that setting is the primary care clinic (this is one reason why the ACP guidance has caused such alarm). From the perspective of the diabetes specialist, the ACP not only gives less weight to recommendations from professionals who specialize in diabetes care, but the guidance also completely ignores new therapies now available to achieve tighter glycemic goals, such as the sodium glucose co-transporter-2 inhibitors and the glucagon-like peptide-1 receptor agonists. These agents can significantly lower cardiovascular disease risk and do not cause hypoglycemia, a traditionally limiting factor intensive glucose control. When insurance will pay, some patients can take newer therapies with metformin in convenient combination formulations.

To me, the greatest surprise in the ACP recommendations is the lack of concern for our younger patients with T2D. Data from CDC show T2D incidence is occurring at younger ages, but with today's treatments, these patients should have decades of life ahead of them. And while the evidence of glucose control in pregnancy was not reviewed, do we want to invite an increase in unplanned pregnancies among mothers who have A1C levels above 8%?

The fine print in the *Annals* article may say each patient should consult with his or her doctor, but with adherence already a challenge, some patients will only see the headline and stop taking their medication. Shortly after the ACP

announcement, a colleague shared that her father, in India, was delighted that he can now stop taking his diabetes drugs, so the change has already had an international impact.

The authors reviewed earlier studies concluding that targeting A1C to below 7% had little to no benefit in reducing the progression of microvascular or macrovascular events. This statement paints a misleading picture of equal risk of complications in all patients with diabetes, ignores what medications they were treated with, and assumes “treat-to-target” is the focus of diabetes care. Authors of the *Annals* article acknowledge their guidance does not consider results from cardiovascular outcomes trials, which have shown that newer therapies reduce the risk of cardiovascular disease and heart failure, the most common cause of morbidity and mortality in patients with diabetes, and one that brings significant costs to the healthcare system.

This should be of interest to health plans. So, too, should a statement from ACP President Jack Ende, MD, MACP, who told a news outlet that patients' A1C targets “are being used now as a performance measure.”³ This is true, but if getting patients to goal is proving difficult for some, the answer should be to find new therapeutic or behavioral strategies for patients who are struggling—not to move the goal posts.

Will there always be some patients with T2D who have difficulty bringing their A1C level below 7%? Yes. But payers should see this as the exception, not the norm. If not, there is great concern that many patients will remain at A1C levels above 8%, which puts them at increased risk for complications, including cardiovascular disease. Joslin Diabetes Center and professional societies that have long advocated for tighter glycemic control stand ready to share best practices with our fellow clinicians in primary care, to do what is best for patients. ♦

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Robert A. Gabbay, MD, PhD, FACP
EDITOR-IN-CHIEF

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ORIGINAL RESEARCH

Geographic Access to Endocrinologists for Florida's Publicly Insured Children With Diabetes

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continued from cover

Introduction

Youth with type 1 and type 2 diabetes (T1D and T2D) from low socioeconomic status (SES) households are at a greater risk than others for many negative health outcomes related to glycemic control, including higher hospitalization rates for very serious complications like diabetic ketoacidosis and elevated risk for diabetes-related morbidity and mortality.¹⁻¹⁴ Moreover, race and ethnic minority status further compounds disparate outcomes in diabetes for non-Hispanic blacks and Hispanics.⁶⁻¹⁵ Despite the need for interventions to improve health outcomes for economically vulnerable pediatric populations with T1D and T2D,^{16,17} there is a paucity of research that explicates barriers that may be unique to these children and their families.

In addition to basic primary care needs shared by all pediatric populations, a critical feature to achieving optimal health for children and adolescents living with diabetes is having regular access to pediatric endocrinologists. The American Diabetes Association recommends that children and adolescents with T1D and T2D visit a specialist at least four times a year.¹⁸ Children who do not meet these recommended guidelines for routine care with pediatric endocrinologists often have less-than-optimal glycemic control and higher rates of associated health risks.^{18,19} Moreover, though studies are limited in this area, public health insurance status has been identified as a risk factor for irregular pediatric endocrinology clinic attendance^{19,20} and for underuse of specialists in general, especially for non-Hispanic blacks.²¹

A rising scarcity of pediatric endocrinologists and a growing demand for their services²²⁻²⁴ compound difficulties that economically vulnerable families face in utilizing healthcare specialists who may be located considerable distances from their residences. Despite Family and Medical Leave Act protections, service sector jobs that are common among working-poor families rarely allow for adequate paid leave time; subsequently, a significant loss of income results when time away from work is taken to accommodate routine medical visits.²⁵⁻²⁷ Rural families are disproportionately poorer than urban families, and they are also at a greater

disadvantage in important ways that could negatively affect their health.^{28,29} Adequate access to healthcare is significantly correlated with distance, an inability to obtain a driver's license, and the lack of access to reliable transportation. All these factors negatively affect attendance of regular check-ups.^{30,31} Thus, the recommended standard of care of four visits to pediatric endocrinology a year presents a potential obstacle for low-SES families living with diabetes.

To better understand barriers of geographic access to pediatric endocrinologists, our study examined proximity to in-network providers of publicly insured children as a measure for access to endocrinology care among adolescents living with T1D and T2D in the state of Florida. This analysis also examined how socio-contextual factors such as urban versus rural location, race, and ethnic minority status shape geographic access as a key determinant in the complex construct of access to care. To our knowledge, there has not been a systematic attempt to document the distance that publicly insured children with diabetes in the state of Florida need to travel for access to potential endocrinologists. Florida is one of the four largest states in the United States with significant racial and ethnic diversity, and it ranks among the top three states for the number of low-income children (those from households earning less than 200% of the Federal Poverty Level).³² Moreover, Florida has been identified as one of the top four states with persistent pronounced disparities in access to healthcare.³³

Methods

This study relied on a cohort of publicly insured children from Florida's Title XIX and XXI programs, which include Medicaid, MediKids, Children's Medical Services Managed Care Plan (CMS), and the Florida Healthy Kids Program (FHKP or Florida's Children's Health Insurance Program, Title XXI), along with the 2015 provider directories for endocrinology of each program. All protocols in this study were approved by the Institutional Review Board-01 at the University of Florida and by the agencies represented in the research, including the Florida Agency for Health Care Administration and the FHKP. This study qualified as a

TABLE 1. Cohort Characteristics and Eligibility Criteria for Florida's Title XIX and XXI Programs

	Florida Healthy Kids (FHK) (n = 1279)		Children's Medical Services (CMS) (n = 1579)		Medicaid (n = 4454)		Overall (n = 7310)	
Program Description	Title XXI or Children's Health Insurance Program (CHIP). For children aged 5-18 years from households at > 133% to <201% of the Federal Poverty Level (FPL).		Title XIX and XXI programs for children with special healthcare needs who are under age 21 years from households at <201% of the FPL.		Title XIX program including MediKids (aged 1-4 years) and Medicaid (aged 5-18 years) from households up to 133% of the FPL. Children under age 1 with household income less than 200% of FPL are also eligible.		FHK, CMS, and Medicaid combined encompass Florida's overall KidCare program.	
Age, Years: Mean (SD)	13.6 (±3.28)		12.0 (±4.62)		11.8 (±4.87)		12.2 (±4.62)	
Gender	Male	45.8%	Male	48.7%	Male	47.1%	Male	47.2%
	Female	54.3%	Female	51.4%	Female	53.0%	Female	52.8%
Diabetes Status	Type 1	65.8%	Type 1	72.5%	Type 1	44.3%	Type 1	54.1%
	Type 2	34.3%	Type 2	27.5%	Type 2	55.7%	Type 2	45.9%
Race and Ethnicity	Hispanic	31.5%	Hispanic	16.8%	Hispanic	35.2%	Hispanic	30.6%
	Black	9.9%	Black	20.3%	Black	24.2%	Black	20.9%
	White	23.1%	White	24.7%	White	24.0%	White	24.0%
	Other	2.7%	Other	2.9%	Other	3.2%	Other	3.0%
	Unknown	32.9%	Unknown	35.1%	Unknown	12.5%	Unknown	21.5%

*Note: Total percentages may not sum to 100 due to rounding. FHK indicates Florida Healthy Kids.

retrospective review of existing data and operated under a waiver of informed consent. Enrollment files and eligibility files, along with claims/encounter data for each program, were used to identify children with diabetes using the following inclusion criteria: Children were defined as individuals aged 19 years or less who had any claims with *International Classification of Diseases, Ninth Revision, Clinical Modification* diagnosis (primary or secondary) code of T1D or T2D during the year. SAS 9.4 (SAS Institute, Inc; Cary, North Carolina) was used for analysis. Information about eligibility for each insurance program is provided in **Table 1**.

To our knowledge, a critical review of the provider directories available to publicly insured families has not been performed, nor are there studies in which directories have been carefully examined and verified prior to mapping. A systematic examination of the endocrinology provider directories available from health plans for each public health insurance program was conducted to verify that the specialists listed were, indeed, endocrinologists, and to further confirm their credentialing. Each provider's license and specialization were verified using both the Florida Department of Health (FL-DOH) practitioner profile search and the National Provider Identifier (NPI) registry. Providers were categorized as PE (pediatric endocrinology), GE (general/adult endocrinology), OE (other endocrinology; eg, reproductive endocrinology), or not applicable (providers whose licenses were not clear and active, who practiced in medical specialties other than endocrinology, or whose specialty could not be conclusively determined by the search(es)).

Provider addresses were entered into an online search for verification using a combination of the FL-DOH profile search and Google Maps. When registry searches yielded ambiguous results regarding addresses or specialty categorization, the *U.S. News and World Report Find a Doctor*³⁴ search tool was used to make a final determination. Each provider entry was verified by a second coder who consulted both FL-DOH and NPI registries. In the few instances in which a discrepancy arose between coders, an arbiter was used to make a final call. For a point of general comparison, the total number of pediatric endocrinology providers listed as in-network for each program was compared with the number of pediatric endocrinologists practicing in each county, as determined by use of the FL-DOH directory.

Using data on race and ethnic minority status as reported by members' families and addresses of the identified cohort available through the enrollment and eligibility files, members were geocoded using the industry-leading Navteq 2015 ESRI StreetMap Premium location software (Environmental Systems Research Institute, Inc. Redlands, CA). Geocoding is the process of determining the spatial location (latitude and longitude) of a residence from the written address.³⁵ Of all the members in the cohort, 95% were able to be geocoded to their street address number. Of the remaining 5%, which were able to be located only generally (at the centroid of their ZIP code), 77% of these addresses were post office boxes, and therefore not eligible

for street-level location. Provider addresses were also geocoded using the verified provider directories, and all providers' locations were successfully found geocoding.

ArcMap ESRI Network Analyst and StreetMap Premium data were used to measure the driving time from each member residence to both the closest in-network endocrinologist and to the closest in-network pediatric endocrinologist. Average drive times to a participating endocrinologist for members of each public health insurance program. Rural counties were identified as having less than 100 persons per square mile, based on the 2010 US Census, as defined by 2015 Florida Statute 381.0406 2015.³⁷ Adequate proximity was considered to be no more than 30 minutes driving time to a provider; the 30-minute limit has been used to identify areas with poor healthcare coverage in other studies.³⁶

Results

A total of 7233 children in the identified cohort were mapped to available endocrinology providers:

- 4395 for Medicaid and MediKids
- 1562 for CMS
- 1276 for the FHKP

Demographic characteristics of the cohort are presented in Table 1. In brief, the cohort included the following children:

- 54% with T1D
- 46% with T2D
- Mean age of 12.2 years (± 4.62)
- 47% male
- 24% white
- 31% Hispanic
- 21% black
- 3% other race/ethnicity
- 21% of unknown race/ethnicity.

The relatively high percentage of Hispanics is reflective of the overall population characteristics of the state of Florida, where approximately 29% of all children are Hispanic/Latino and the Hispanic population is the third-highest in the United States.³²

Members of each program were mapped to available providers (**Figures 1a-d**). The distances to available providers were examined for each program, according to provider type (PE versus GE/OE, and then "any" representing the driving distance to any type of endocrinologist). The findings from the provider directory analysis were thus used to create a typology for geocoding output and to calculate proximity to a location with at least one provider. Key to this analysis was examining possible variations in driving distances depending on whether a member lived in a rural or urban location, and to see how this relationship between distance and location type varied by race and ethnic minority status (**Table 2** and **Table 3**). As expected, rural populations represented a smaller proportion of the overall cohort and were more commonly non-Hispanic white. Ninety-five percent of non-Hispanic black members resided in urban counties, and the members in densely urban, southeast Florida were 60% Hispanic.

In all, members in urban areas for all programs tended to have similar driving times to pediatric endocrinologists or to any endocrinologist. For urban members in the FHKP, driving time to any endocrinologist was an average of 12 minutes (13 to a pediatric endocrinologist); for CMS members, driving time was 29 minutes (30 to a pediatric endocrinologist); and for Medicaid members, driving time was 13 minutes (18 to a pediatric endocrinologist). However, for rural families, driving times were significantly longer. Average driving times for rural families were as follows: For members in the FHKP, driving time to any endocrinologist was 59 minutes (70 to a pediatric endocrinologist); for CMS members, driving time was 75 minutes (75 to a pediatric endocrinologist); and for Medicaid members, driving time was 60 minutes (72 to a pediatric endocrinologist).

When driving times were examined according to race and ethnic minority status, non-Hispanic white families faced the longest driving times overall (34 minutes to a pediatric endocrinologist compared with 18 for Hispanics and 20

TABLE 2. Driving Times to Closest In-Network Endocrinologist by Program and Rural/Urban Location

	Florida Healthy Kids			Children's Medical Services Plan			Medicaid		
	Rural ^a	Urban	Overall	Rural ^a	Urban	Overall	Rural ^a	Urban	Overall
Count Routed	57 (4.5%)	1219 (95.5%)	1276 (100%)	86 (5.5%)	1476 (94.5%)	1562 (100%)	262 (6.0%)	4100 (94.0%)	4362 (100%)
Mean minutes to pediatric endocrinologist	70	13	21	75	30	33	72	18	21
Mean minutes to any endocrinologist	59	12	14	75	29	32	60	13	16
Members with <30 minutes to a pediatric endocrinologist (percent)	5 (8.7%)	1004 (82.4%)	1009 (79.1%)	4 (4.7%)	866 (58.6%)	870 (55.7%)	5 (1.9%)	3413 (83.2%)	3418 (78.4%)
Members with <30 minutes to any endocrinologist (percent)	7 (12.3%)	1144 (93.8%)	1151 (90.2%)	4 (4.7%)	901 (61.0%)	905 (57.9%)	89 (34.0%)	3802 (92.7%)	3891 (89.2%)

^aRural counties were identified as having less than 100 persons per square mile based on the 2010 US Census classifications.

TABLE 3. Driving Times to Closest In-Network Endocrinologist by Race, Ethnicity Minority Status, Rural/Urban Location

	Non-Hispanic Black			Hispanic			Non-Hispanic White		
	Rural ^a	Urban	Overall	Rural ^a	Urban	Overall	Rural ^a	Urban	Overall
Count Routed (percent)	72 (4.8%)	1431 (95.2%)	1503 (100%)	74 (3.5%)	2132 (96.7%)	2206 (100.2%)	164 (9.5%)	1555 (90.5%)	1719 (100%)
Mean minutes to pediatric endocrinologist	68	18	20	75	16	18	71	30	34
Mean minutes to any endocrinologist	59	17	19	68	12	14	60	21	25
Members with <30 minutes to a pediatric endocrinologist (percent)	4 (5.6%)	1200 (83.9%)	1204 (80.1%)	3 (4.1%)	1859 (87.2%)	1862 (84.4%)	5 (3.0%)	950 (61.3%)	955 (55.5%)
Members with <30 minutes to any endocrinologist (percent)	27 (37.5%)	1260 (88.1%)	1287 (85.6%)	10 (13.5%)	1947 (91.3%)	1957 (88.7%)	51 (31.1%)	1244 (80.0%)	1295 (75.3%)

^aRural counties were identified as having as less than 100 persons per square mile based on the 2010 US Census classifications.
* Note: Total percentages may not sum to 100 due to rounding.

the state to accommodate the ever-growing need. Finally, disparities in health outcomes associated with race and ethnic minority status in pediatric diabetes cannot be solely attributed to issues of geographic access, as the vast majority of non-white urban families who are at risk for negative diabetes-related outcomes live within minutes of in-network endocrinologists.

This research offers the first detailed account of actual driving times faced by families in Florida's public health insurance programs when in need of an endocrinologist. The methodological approach to this analysis is comprehensive: Most existing studies on geographic distance focus on adult and general populations, Euclidian distance (straight line), and primary care settings (rather than specialists). This study uses a state-of-the-art software to estimate driving times and breaks down analyses to program-specific, in-network specialists.

Limitations

There are several limitations to this work. Future studies on underserved populations would benefit from including complete information about the race/ethnicity of members. Given that families are not required to provide this information on applications for public health insurance, 21% of the study population's race/ethnicity was unknown. Also, this study cannot speak to member-level experiences with driving time and the degree to which it is perceived as a barrier. Rural residents may perceive distance as less of a barrier if the provider is within close proximity of routes they regularly travel.³⁰ Finally, though existing research indicates that publicly insured children and non-Hispanic black children are most at risk for underutilizing routine endocrinology care¹⁹⁻²¹ these findings cannot speak to actual utilization rates as they are beyond the scope of this study.

Conclusions

Reducing disparate health outcomes in diabetes will require multi-level interventions, but basic access to care is paramount. More research is needed to better explicate barriers for nonwhite families living in close proximity to available providers, and to test other mechanisms through which rural children at great distance from providers can receive care. We posit that entities working to improve health outcomes for children with T1D and T2D intentionally partner with state agencies that administer public health insurance programs when developing new interventions, as their enrollment files provide a robust way of identifying and reaching economically vulnerable children within a state. The pioneering efforts of this study will undoubtedly contribute to future studies that examine actual utilization rates and outcomes data alongside geographic access and contributing barriers. ♦

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for non-Hispanic blacks). Further, only 56% of the non-Hispanic white families were less than 30 minutes from a pediatric endocrinologist, compared with 84% of Hispanics and 80% of non-Hispanic blacks.

Systematic categorization of the providers listed in the Medicaid provider directories, which include both adult and pediatric endocrinologists due to Medicaid Managed Medical Assistance plans serving both populations, indicated that rural areas suffer from a dearth of practicing endocrinologists. Medicaid providers in the state served 36 of 67 counties, and among those, only six counties were classified as rural. To ascertain whether rural counties had other pediatric endocrinologists that simply were not available to publicly insured children in the state of Florida (eg, providers who do not accept these types of insurance programs), a county-level search was conducted through the FL-DOH registry to enumerate the total number of active licensed practitioners with a specialty in pediatric endocrinology in the state of Florida.

Overall, rural counties that were lacking providers for publicly insured children tended not to have any practicing pediatric endocrinologists at all. Findings from the FL-DOH registry demonstrate that the primary practice locations of the 107 providers listed as active, licensed pediatric endocrinologists in Florida at the time of analysis represented only 20 out of 67 counties statewide. Among those 20 counties, only one county was classified as rural. The instances where pediatric endocrinologists existed but were not available to publicly insured members were in urban hubs (eg, Miami) where families had more options for providers who *did* accept public forms of health insurance. Therefore, the issue of limited availability of endocrinology providers in rural areas of the state is not unique to public insurance status, but representative of a systemic lack of providers overall.

Discussion

For publicly insured children with T1D and T2D living in urban areas, average driving time to an

endocrinologist was 30 minutes or less. Conversely, publicly insured rural children faced driving times of one hour or more when traveling to see available endocrinologists. Notably, non-Hispanic white families had the longest driving times compared with Hispanics or non-Hispanic blacks, which may be best explained by the geographic distribution of these ethnicities among the publicly insured population. Based on US Census data, we expected Hispanic and non-Hispanic black children to have the shortest driving times due to demographic patterns of urban hubs like Miami, Orlando, Jacksonville, and Tampa. Results from this geospatial analysis provide new insight into the specific disparity in driving distances faced by rural, publicly insured families who need pediatric diabetes care, and how these times vary according to race and ethnic minority status.

The implications of these findings are important. Our analysis demonstrates that rural families utilizing public health insurance in the state of Florida face disproportionate barriers in access to pediatric endocrinologists. The costs associated with traveling an hour or more, 4 times a year, to see a specialist for routine care are likely to be considerable for low-income families. These findings reinforce calls for efforts to reach families affected by diabetes and living in rural communities through telemedicine and other novel outreach modalities.^{38,39} Additionally, our findings clarify that lack of access to specialists in rural areas is not a problem specific to the publicly insured; rather, this is an overall problem facing any child living with diabetes in rural counties of Florida.

While this distance constitutes a barrier for all children living in rural areas who require an endocrinologist's care, the economic vulnerability of publicly insured children presents multiple unique hardships that may augment the difficulty of seeking endocrinology care. The presence of a specialist in a rural area is associated with better health outcomes,⁴⁰ but there simply are not enough endocrinologists in rural pockets of

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ABOUT THE AUTHORS

Ashby F. Walker, Ph.D. is affiliated with the University of Florida Diabetes Institute and the Department of Health Services Research, Management and Policy, Gainesville, Florida. Michael J. Haller, MD, Henry J. Rohrs, MD, and Desmond A. Schatz, MD, are affiliated with the University of Florida Diabetes Institute and the Department of Pediatrics, Gainesville, Florida. Jaclyn M. Hall, Ph.D., Matthew J. Gurka, Ph.D., and Heather L. Morris, Ph.D., are affiliated with the Institute for Child Health Policy and the Department of Health Outcomes and Biomedical Informatics, University of Florida, Gainesville. Elizabeth A. Shenkman, Ph.D., is affiliated with the Department of Health Outcomes and Biomedical Informatics, The Institute for Child Health Policy, and the Department of Pediatrics at the University of Florida, Gainesville. Kelsey R. Salazar, MPH, is affiliated with the Health Care Improvement Foundation in Philadelphia, Pennsylvania.

FOR CORRESPONDENCE

Ashby F. Walker, PhD, University of Florida Diabetes Institute, PO Box 100309, Gainesville, FL 32610. Email: afwalker@ufl.edu.

AUTHOR CONTRIBUTIONS

AFW served as principal investigator (PI) for the study, designed the study, secured IRB-01 approval for the study, provided oversight for data delivery and management, secured the Data Use Agreement with Florida's Agency for Health Care Administration, coordinated all communications related to this project, and wrote the article. DAS contributed to the study design, served as co-PI for the Pediatric working group with AFW reviewed findings, and reviewed and edited the article. BAS served as PI on the External Quality of Review contracts with Florida and thus provided access needed for the research, contributed to the study design, and reviewed and edited the article. JMH served as the spatial geographer for the study, conducted all mapping and related output, wrote the methodology for the mapping, and reviewed and edited the article. HLM provided oversight of the provider directory work for CMS, provided input on the study design, helped create all demographic tables, and reviewed and edited the article. MJG served as the biostatistician for the research, reviewed data, and reviewed and edited the article. MJH and HJR provided oversight for the study design, provided continual expertise about the provider directory analysis, reviewed data, and reviewed and edited the article. KRS contributed to the literature review, had all oversight of research coordinators working on the provider directory analysis, wrote the methodology for the provider directory analysis, and reviewed and edited the article.

AFW is the guarantor of this work, and as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of data analysis.

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FIGURES 1A-D LEGEND.

Figures 1a-c show geocoded residence of each child with type 1 and type 2 diabetes from urban or rural county and locations to closest general endocrinologist and pediatric endocrinologist. Figure 1d shows all publicly insured children with type 1 or type 2 diabetes and driving time to pediatric endocrinologists. In order to ensure privacy, for these figures we implemented a random shift for each enrollee location symbol of a random direction and random distance between 1 and 5000 meters.

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COMMENTARY

The Potential of a Population Health Strategy to Improve Healthcare Outcomes and Reduce Costs for Medicaid Programs

David J. Dzielak, PhD

continued from cover



DZIELAK
David J. Dzielak, PhD, is an integrative cardiovascular physiologist whose research has focused on the neural control of the circulation and the role of immune mechanisms in cardiovascular disease.

limiting duplicative or unnecessary procedures and relying heavily on generic drugs. While this approach has seen positive results in containing costs, it is still unclear whether the overall health of the population is improving. Perhaps a slightly different focus could produce even greater results. That focus incorporates the concept of population health.

The term *population health* was coined by Kindig and Stoddart in 2003.³ Their original definition was concerned with the health outcomes of a group of individuals. While there is no single overarching definition of population health, the focus on health outcomes seems to be the unifying factor in this still-emerging discipline. For me, the whole tenet of population health is to understand the health risks of individuals and design interventions that mitigate the risk in an attempt to halt or stabilize the progression of the health condition or disease moving forward. Keeping people healthy by focusing specifically on their health conditions should lead to a healthier population and subsequently a lower cost of care. How do we do this, and where do we begin?

The first step is to understand the current health status of the individuals enrolled in the program. On the surface, this may sound like a fairly easy task, but it is not (**Figure 1**). Most Medicaid programs have large quantities of data residing in their Medicaid Management Information System (MMIS) regarding claims payments for their beneficiaries. This data set is very important to the understanding of the health status of the individual. However, no matter how well this data set is mined, it will not be sufficient to get a clear picture of the overall health status of the individual. MMIS data will provide some information, but it is not the whole picture.

For a true health-status picture to emerge, the MMIS data (which contain medical claims data for point-of-care visits as well as pharmacy data) must be merged with available electronic health record (EHR) data. Once this is done, a clearer picture of the health status of an individual will begin to emerge. These individuals can then be stratified into risk categories based on their overall health status. Those with the least risk for adverse health outcomes or disease progression can be stratified on one end of the spectrum and those with the greatest risk for adverse health outcomes on the other.

Once this is done, gaps in care can be identified and addressed. In addition, targeted strategies for interventions can be developed and implemented. This sounds logical and practical, right? But it is easier said than done, particularly in the Medicaid population.

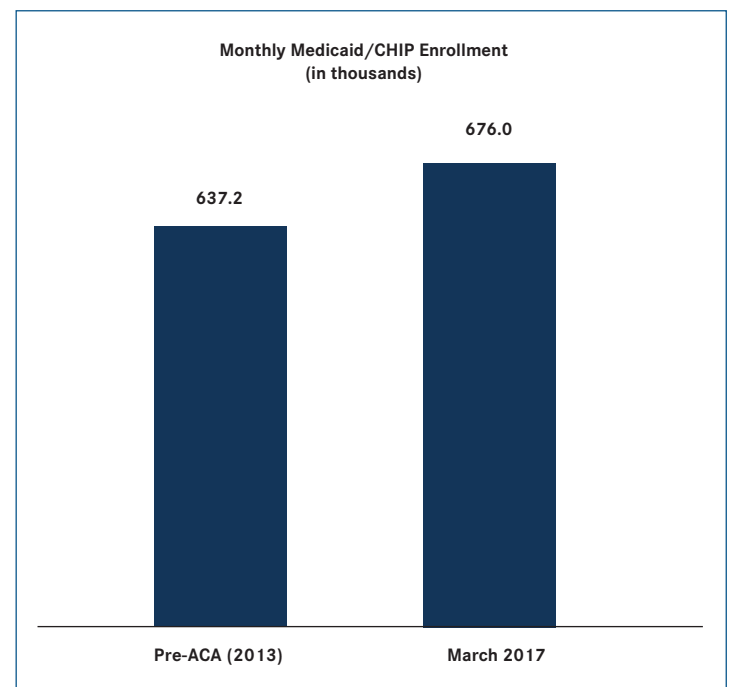
Eligibility for Medicaid is based on resources relative to some measure of the federal poverty level or disability status. The social determinates of health, such as food insecurity, the availability of fresh fruits and vegetables, adequate housing, safety concerns, limited educational opportunities, and environmental factors all work to negatively affect the health status of Medicaid beneficiaries. A population health approach in a middle-class or more affluent population is a challenge; add in the complex interaction of poverty and health, and it becomes an even greater

challenge for those receiving healthcare benefits through a Medicaid program.

The Mississippi Division of Medicaid began investigating the potential of a population health approach to achieve better health outcomes and reduced cost in 2014. The Medicaid program continued to be a significant cost driver in Mississippi's state budget, in part because of enrollment growth (**Figure 2**). (According to the Kaiser Family Foundation, in 2017 Medicaid accounted for 12% of the state's general fund spending and 46% of all federal funds directed to the state.⁴) Newer, more innovative solutions had to be identified to control costs.

The public investment in the digitization of medicine, including Meaningful Use and Interoperability funding, set the stage to enable the Division of Medicaid to leverage clinical data generated through the delivery of care. By combining clinical EHR data and claims data from the MMIS, the stage was set to monitor health outcomes of Medicaid beneficiaries as well as the progress of the managed care plans to produce improved outcomes.

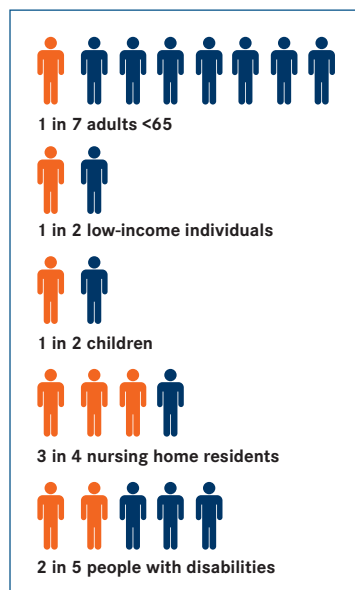
FIGURE 2. Monthly Medicaid/CHIP Since the Affordable Care Act



Source: Kaiser Family Foundation. CHIP indicates Children's Health Insurance Program.

The Mississippi Division of Medicaid partnered with the Delta Health Alliance (DHA) to perform a pilot program called the Mississippi Delta Medicaid Population Health Demonstration Project. The Mississippi Delta region is one of the most impoverished regions in the country, with a large Medicaid population⁵ and a high disease burden.⁶ DHA is a nonprofit 501(c)(3) whose mission

FIGURE 3. Mississippi Populations Covered by Medicaid, 2015



Source: Kaiser Family Foundation

is to research and identify the causes of poor health and lack of adequate educational opportunities as well as inform residents of the Mississippi Delta on how to adapt a healthier lifestyle.

Because the disease burden is high and the health status of the region is poor, this demonstration project had multiple disease conditions to choose from. In addition, because the region is

known for its poor health outcomes and lack of infrastructure, any model developed under these difficult conditions should be able to meet the challenges of any other region of the state.

One of the key elements of the study, as well as the power of the population health approach, is to identify individuals at risk for disease progression and implement strategies that will mitigate or perhaps reverse that progression. Two conditions were chosen to explore in this study, the progression of diabetes from its precursor form, prediabetes, to full blown type 2 diabetes (T2D) and preterm delivery. The incidence of obesity and the subsequent burden of T2D in the Mississippi Delta region is high. A clinical profile was developed of an individual progressing along the path of prediabetes to T2D. This profile was used as a template to identify those individuals meeting these clinical criteria.

The demonstration project used a proprietary population health platform developed by the Cerner Corporation to create a longitudinal record that contained Medicaid claims data and clinical EHR data for Medicaid beneficiaries in select clinics in the Mississippi Delta region. Using a predictive algorithm, risk scores for progression of prediabetes to T2D were developed for Medicaid beneficiaries receiving care at the select clinics. Targeted interventions were applied through intensive care management techniques.

Mississippi has a high burden of preterm birth. Preterm birth refers to babies born before 37 weeks of gestational age. The National Center for Health Statistics reports that 9.85% of the births in the United States are considered preterm.⁷ The preterm birth rate for Mississippi is one of the highest in the country, at 13.6%.⁸ Data at the Division of Medicaid show that the preterm birth rate for women receiving benefits is 18%.⁹ Therefore, the Medicaid population accounts for a disproportionate share of the high preterm birth rate in Mississippi.

Although the cause of approximately 50% of the preterm births is unknown, a wide variety of risk factors are known to play a role in the birth

outcomes. Some of the known causes of preterm birth are vaginal infections, short intervals between pregnancies, maternal stress, anxiety or depression, smoking, obesity, diabetes, and low socioeconomic status. In addition, African American mothers are almost twice as likely to have a preterm infant as white mothers in the United States.¹⁰

Prenatal care is integral to lowering the risk and rate of preterm births. Often access to prenatal care is tied to insurance coverage. It is worth noting that the socioeconomically disadvantaged women with higher risk factors for preterm birth do not become eligible for coverage until they are pregnant. Access to and timely attainment (in the first trimester) of care for women who were previously uninsured depend on a rapid enrollment for Medicaid benefits. Unsurprisingly, prenatal care in this population is often delayed.

Using the population health platform described above, longitudinal records were created, and predictive algorithms were applied for risk of preterm delivery for women who became pregnant. These women received intensive prenatal care as well as education that was related to risk factors such as infection, smoking, stress, and other lifestyle risks.

While the study is still ongoing, preliminary results indicated a considerable cost savings through the application of population health tools. Preventing the progression of prediabetes to T2D is estimated to save approximately \$9700 per year per individual.¹¹ Although the estimates vary on the cost savings of preventing preterm delivery, Mississippi Medicaid data show the average stay in the newborn intensive care unit for a preterm baby costs approximately \$57,000.

These preliminary results, which are exciting, need to be verified and repeated not only in other settings but also with other health conditions and disease states such as hypertension, heart failure, asthma, and metabolic syndrome. The care management model used in this approach is significantly high touch, but it is important to weigh the cost of the intervention against the healthcare outcomes achieved.

There is a heightened interest in the healthcare outcomes of managed care programs from the federal regulatory body, the Center of Medicaid and CHIP Services (CMCS), that oversees the Medicaid managed care programs. The recently promulgated Medicaid Managed Care Final Rule¹² puts a great deal more emphasis on state oversight and health outcomes. These new rules indicate that the federal government is now interested in the cost-to-benefit ratio and whether managed care can improve health outcomes and lower costs as a result. As the cost of healthcare and the cost of the Medicaid program at both the state and federal levels increase, there is likely to be further emphasis on cost containment as a product of improved health outcomes. Population health platforms offer a new tool that can be applied to achieve these results.

Of anecdotal interest is the fact that CMCS was very receptive to the concept of a population health approach to improving quality and outcomes in the Medicaid program. When the Mississippi Division of Medicaid submitted its Implementation Advanced Planning Document for enhanced funding for its population health initiative, it was received with great interest and approved within a 4-week time period, a short turnaround for proposals of this type.

In 2017, the Mississippi Division of Medicaid completed a reprocurement of its managed care program, adding contract language that requires managed care plans to implement a population health-based strategy as part of its ongoing operations. While debate continues over who should deliver managed care to the state's Medicaid recipients, the future seems to point toward a population health approach.

While the program is still in its infancy, there is significant potential for population health platforms to improve healthcare outcomes, which can not only lead to healthier, more productive individuals but also substantially lower the cost of healthcare in Medicaid programs. ♦

FINANCIAL DISCLOSURE

There are no conflicts to disclose.

ABOUT THE AUTHOR

David J. Dzielak, PhD, served as executive director of the Mississippi Division of Medicaid from January 2012 to December 2017. He is an integrative cardiovascular physiologist whose research has focused on the neural control of the circulation and the role of immune mechanisms in cardiovascular disease. He received his PhD from the University of Mississippi Medical Center (UMMC) in 1982 and returned to the medical school in 1987 after working in the private sector. At the time of his appointment as Medicaid director, he was UMMC's associate vice chancellor for Strategic Research Alliances; he helped the medical center secure more than \$74 million in congressional funding and played a major role in promoting technology transfer and biotechnology development with academic and business partners.

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COMMENTARY

How Technology Can Make CMS' Diabetes Prevention Program Viable

Dan Sheeran



SHEERAN
Dan Sheeran, is the CEO of Healthslate LLC.

APRIL 1, 2018, will mark the beginning of the Medicare Diabetes Prevention Program (MDPP).¹ In theory, this should be unalloyed good news. After all, the National DPP has been shown to lower diabetes risk by 71% for those 60 years or older at high risk.² With more than two-thirds of seniors in the high-risk category, the potential benefits in both human welfare and Medicare costs are enormous. Specifically, a DPP pilot led by the YMCA found the program saved \$2650 per Medicare beneficiary.³ However, that potential will be reached only if the program is made available in a manner that meets the diverse needs of different subpopulations and if program providers can deliver the program in a financially feasible manner.

Unfortunately, as was well documented by AJMC.com earlier this year, the rules ultimately adopted by CMS could well cause the program to fall short on both fronts.^{4,5} First, the lack of coverage for virtual delivery means diabetes prevention will be a realistic option only for people who live near an in-person program and who have the time, inclination, and travel resources to attend about 2 dozen DPP sessions in the first year. CMS intends to run a pilot study to determine whether virtual programs can deliver health outcomes comparable with those of in-person DPPs. But as many comments filed with CMS pointed out, several virtual programs have already demonstrated such ability in the required outcomes data submitted to the CDC. Importantly, while the pilot is conducted and evaluated, thousands of people who need education and support to avoid developing diabetes will go unserved.

Many operational and compliance requirements, such as the need for all MDPP lifestyle coaches to have a National Provider Identification and the necessity to provide an additional 2 years of maintenance sessions for each program group, will make it difficult for program providers to cover their costs.

Perhaps the greatest challenge stems from the reimbursement model CMS chose, which allocates a much higher percentage of total reimbursement to weight loss than has been the case in commercially insured programs. This will produce truly perverse motivations—providers may lose incentive to serve some of the populations who most need the program if that population's average weight loss has historically been below the 5% threshold required for most of the MDPP reimbursement. For example, African American women could face trouble finding programs because of lower-than-average weight loss in the DPP.⁶

Instead of reimbursing based on weight loss, particularly on weight loss in terms of outcomes-based remuneration, CMS could shift some of the reimbursement to validated attainment of the DPP's physical activity targets. Although several studies have demonstrated that physical activity can improve insulin sensitivity and thereby lower glucose levels,⁷ DPP providers are not reimbursed for helping participants achieve the physical activity targets and therefore may focus on it less than they could. Moreover, given that so many people have trouble losing weight and can easily get discouraged and quit, providing another metric that could help patients envision their own progress could improve long-term attention.

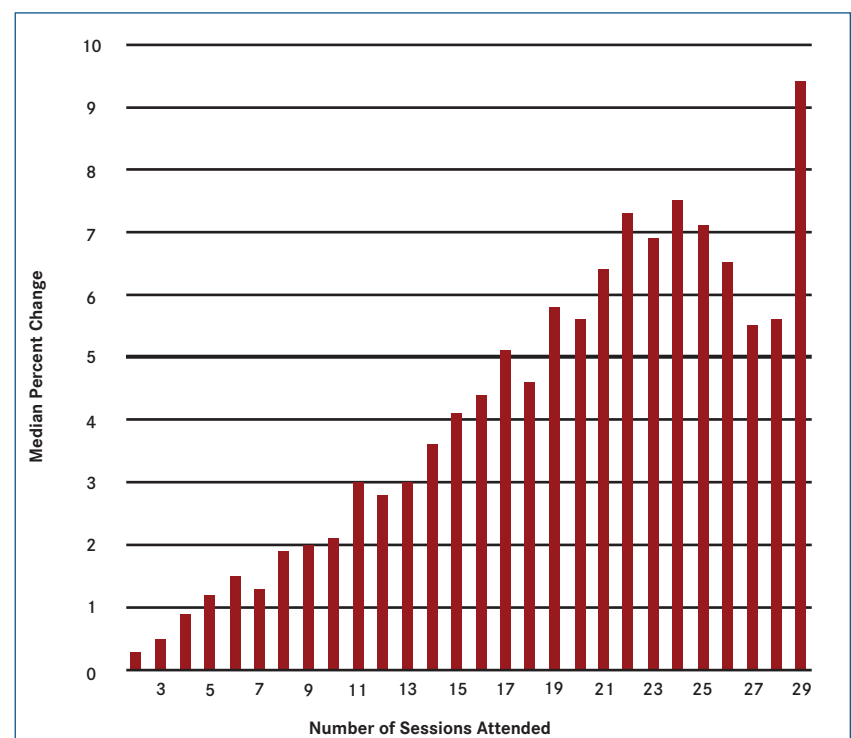
While fully digital programs will not be covered by the initial MDPP, digital tools can nevertheless play a crucial role in addressing, at least partly, many of these challenges. The key is to focus on digital as an adjunct, rather than an alternative, to in-person program delivery.

The most obvious area where digital tools can help is with missed sessions. MDPP participants must attend 9 sessions in the first 6 months to remain enrolled and for DPP providers to even have the opportunity to earn a weight loss–based reimbursement. This makes sense given that, on average, participants who attend more sessions tend to lose more weight and keep it off longer. Specifically, for every additional session attended and every 30 minutes of activity reported, participants lose 0.3% of body weight. However, attending 9 sessions in person at preset times is not a practical reality for many participants (**Table**).

Fortunately, CMS is allowing up to 2 of those missed sessions to be made up “virtually.” While virtual delivery encompasses a variety of options, the most convenient choice for most participants and the most efficient for lifestyle coaches, is one in which the participant self-navigates an online version of the session at their own pace. HealthSlate⁸ and Solera Health,⁹ for example, partnered over a year ago to enable such a model through the SoleraONE platform for in-person DPP providers.

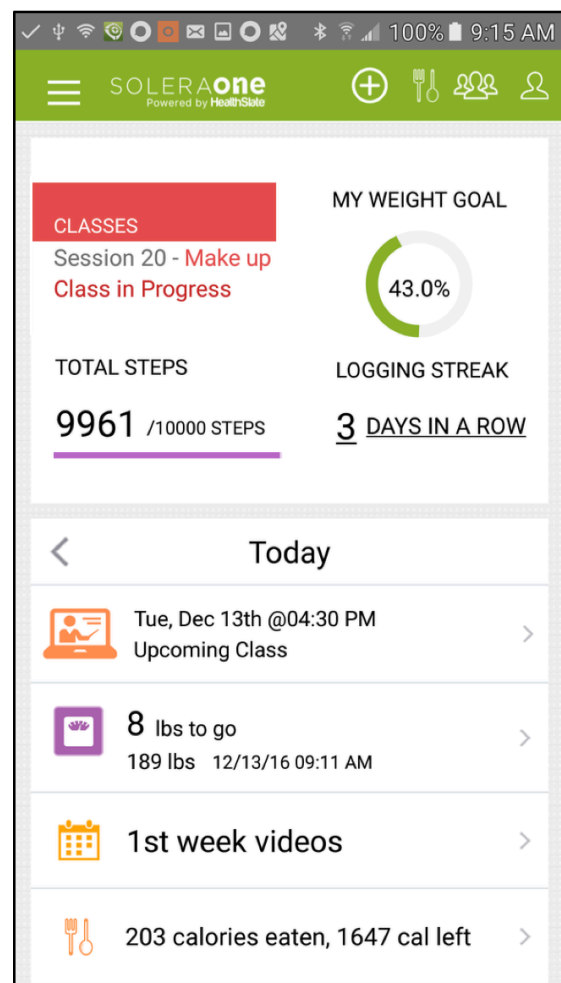
Another key way in which digital tools can contribute is by helping participants stay connected with one another and with their coaches between sessions. The Group page of the many DPP apps, including SoleraONE, typically offers a Facebook-like experience in which participants cheer one another's success and remind fellow

TABLE. Effect of Attendance on Weight Loss



Source: Ely EK, Gruss SM, Luman ET, et al. A national effort to prevent type 2 diabetes: participant-level evaluation of CDC's National Diabetes Prevention Program. *Diabetes Care*. 2017;40(10):1331-1341.

FIGURE. Virtual DPP App



Source: HealthSlate. DPP indicates Diabetes Prevention Program.

participants of the upcoming class. This is particularly valuable in the MDPP model, in which participants are expected to continue attending classes over a 3-year period.

Given the ability of physical activity to lower glucose, digital tracking of steps—whether by an app on the phone or a Fitbit-style tracker—could greatly

improve participants' outcomes, both directly and in self-perceived progress. Such digital step tracking is still not the norm in most in-person DPPs.

Perhaps the most significant contribution digital technologies can make to the MDPP is vastly improving our understanding of what's actually working and what isn't. Regardless of whether someone participates in person or virtually in a DPP session for 1 hour each week, their success is largely dependent on what they are doing during the other 167 hours of that week. By encouraging all MDPP participants log meals and weight via a mobile app, and having that app automatically track their steps, we provide lifestyle coaches with the data, insights, and tools to spot when participants are going off track and make it possible to intervene before it's too late. This tracking is further enriched, of course, when participants have an activity tracker such as a Fitbit or a connected scale, which prevents data entry errors in the logs by the participant and automatically uploads the data.

While lifestyle coaches can use digital tools to spot trends at the individual and small-group levels, companies like HealthSlate and Solera can analyze large data sets at the population level to answer questions like "Who is enrolling, and who isn't?" and "Who is succeeding and who isn't?" and "Why?" Advanced statistical techniques and machine learning algorithms can then be applied to this work, allowing continuous improvements in the delivery model.

All of this is standard operating procedure for digital vendors, but it is far from standard for in-person programs. Today, in-person DPPs remain largely operated, analyzed, and accredited in the same manner as they were before smartphones were invented. While Solera and HealthSlate are already empowering many in-person DPPs with digital tools, the national uptake of available technology is not happening fast enough. The missions of the MDPP and the National DPP would be well served

if the CMS and CDC were to more aggressively promote, or even require, use of digital tools by in-person DPPs. ♦

AUTHOR INFORMATION

Dan Sheeran is CEO of HealthSlate LLC, a CDC-recognized provider of diabetes prevention technology, content, and coaching services. HealthSlate is based in Seattle, Washington.

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More Americans Obese, Diabetic, New CDC Report Says

Allison Inzerro

NEW HEALTH STATISTICS FROM the US government paint a picture of a population that is more obese and more prone to diabetes than it was 20 years ago. On the bright side, however, more people have health insurance and cigarette smoking dropped. The early release of January to September 2017 data from the National Health Interview Survey, including estimates from 1997 to 2016, was published March 15, 2018. Included in the findings:

Obesity. The prevalence of obesity among US adults 20 years and older increased from 19.4% in 1997 to 31.4% in the latest report. Looking at just January to September of last year, adults aged 40 to 59 years of both sexes were the most likely to be obese (36.6%), but women were more likely to be obese if they were in the age range of 20 to 39 years (28.7% vs 24.5% for men). Black women were most likely to be obese

(48.9%) compared with Hispanic women (34.2%) and white women (29.4%). There was no significant difference in the prevalence of obesity by race and ethnicity groups among men.

Diabetes. Diabetes, which is known to be linked to obesity, also increased. The prevalence of diagnosed diabetes among adults 18 years and older increased from 5.1% in 1997 to 9.2% in 2010, and then more slowly from 2010 through January to September 2017. The age- and sex-adjusted prevalence of diagnosed diabetes was 12.9% for Hispanic adults, 7.0% for white adults, and 10.9% for black adults. The prevalence of diagnosed diabetes was lower among white adults compared with Hispanic and black adults. The prevalence of diagnosed diabetes among black adults was not significantly different from Hispanic adults.

Exercise. A little more than half (53.8%) of adults 18 years and older meet the 2008 federal physical activity guidelines for aerobic activity, but women are less likely than men to meet those guidelines in every adult age group.

Insurance. In January to September 2017, the percentage of persons uninsured was 9%, the same as 2016. In 2010, the percentage of persons uninsured was 16%. For children younger than 18 years, the uninsured percentage generally decreased from 13.9% in 1997 to 4.9% in the latest report. ♦

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ACCESS TO CARE

Applying Digital Technology in Clinical Trials to Improve Real-World Outcomes

Henry Anhalt, DO



ANHALT
Henry Anhalt, DO, is the vice president for medical affairs for Science 37.

AS THE INCIDENCE OF diabetes continues to climb, so does the overall cost of treatment, now estimated at \$245 billion a year in the United States.¹ This increasing burden on payers is forcing them to closely examine the real-world effectiveness of approved therapies. Payers also seek to understand how effective a therapy may be in an individual patient, using predictive analytics. This approach, often referred to as *precision medicine*, supports the use of the most cost-effective treatments as first-line choices.

To address the need for more effective treatments for diabetes, pharmaceutical companies are using the latest developments in biotechnology and genomic science to develop ever more advanced treatments with new mechanisms of action. While these therapies are often more expensive per unit than older ones, they also come with the promise of improving patient outcomes significantly enough to deliver reductions in both short- and long-term costs related to the disease.

Digital technology has become critical in driving more efficient and accurate data collection through all stages of research and development. The ease of use of digital technology is transforming clinical trials and providing data, such as patient-reported outcomes, that are much more reflective of how effective treatments are in the real world.

Traditional randomized controlled clinical trials call for the procedures and treatments to be conducted at brick-and-mortar research centers, which are artificial conditions not necessarily reflective of how the treatments will be used by patients in real life. It shouldn't be surprising that many of these clinical trials fail to provide the kind of data both providers and payers need to ensure the treatment will work for an individual patient.

As a result, patients may be prescribed a treatment that according to the clinical trials *should* be effective and that payers believe will be cost-effective—only to find it provides less than ideal outcomes in actual use. Payers thus can spend significant healthcare dollars on treatments that are likely to fail, when the right clinical trial data might have helped to direct providers to a truly effective option for a particular patient.

Digital Technology as the New Foundation

The application of the latest digital technology, including advanced data analytics, has allowed investigators to reimagine clinical trials that enable measurement of variables that have proved challenging to collect previously.

Making use of digital technology allows for the passive collection of data from a variety of different sources, including wearable sensors that measure amount of sleep, heart rate, and physical activity. Digital platforms also enable decentralized trials—which incorporate electronic consent, telemedicine capabilities, and accurate data collection conducted outside the research center, at a patient's home. These can produce data that are far more representative of what patients do with an experimental drug or device as they go about their normal activities.

Digital tools can also be employed for patient recruitment. At my company, we use a number of different digital strategies, including social media, to engage and recruit patients with a variety of medical conditions. Not only are these tactics useful to

recruit for *specific* trials, but they also allow us the opportunity to establish databases of micro communities for those patients interested in participating in *future* clinical trials.

Driving Better, More Inclusive Results

Another major hurdle in conducting clinical trials that produce reliable real-world data is identifying and enrolling an appropriate patient population. With traditional trials, patients who cannot travel to a research center are excluded from the pool. Since research centers are often located in larger urban areas, people who live in distant suburbs, or in more rural areas, simply don't or can't afford to participate because of factors such as out-of-pocket costs and the time commitment required. In-home clinical trials eliminate many of the barriers to participation and therefore allow far more representative patient populations access to the trial.

Artificial conditions in traditional clinical trials may not necessarily be reflective of how the treatments will be used by patients in real life. As a result, patients may be prescribed a treatment that according to the clinical trials should be effective and that payers believe will be cost-effective, only to find it provides less than ideal outcomes in actual use.

This is particularly important when it comes to the need to include people of color or ethnic minorities, individuals who are often seriously underrepresented in clinical trials.² In many cases, members of these communities have been shown to respond differently to a treatment that was deemed effective in a clinical trial in which they were not adequately represented. This is vital for evaluating diabetes treatments in the United States because of the disproportionate incidence of the disease among African Americans, Native Americans,³ and those of Latino or Hispanic⁴ descent.

The importance of including a more diverse population is clear when one considers the early experience with angiotensin-converting enzyme (ACE) inhibitors for the treatment and prevention of hypertension. The drugs were approved after the usual set of randomized controlled trials and appeared to demonstrate excellent results. The trials, however, were unable to recruit a significant number of African American patients—a group who not only suffers from hypertension at a much higher rate than the overall population but responds quite differently to ACE inhibitors. As a result, only after they were prescribed to African Americans was it discovered that ACE inhibitors did not work nearly as well for them as had been predicted by the clinical trials.⁵

Expanding Access to Care

Patients enrolled in decentralized trials enabled by digital technology and telemedicine receive healthcare in the convenience

of their home, giving them access to care they may not have had otherwise received. The clinical trial itself provides an opportunity to administer more general care for at-risk patients because the trial is effectively enforcing a schedule of interactions between the participant and the investigators.

An additional benefit is the potential access to innovative treatments provided by the trial itself. For patients suffering from a serious condition like diabetes, there is a chance for them to be treated with something they might otherwise not qualify to receive.

In summary, innovative companies like mine have invested in hiring physician scientists who have experience working across healthcare sectors including pharma, biotech, clinical care, and academia. This expertise, coupled with innovative digital technology, has enabled us to engage and recruit diverse populations of patients and execute trials efficiently, more reliably, and with more relevant outcomes reflecting real-world experience. The benefits to the patients include access to clinical trials and enhanced care through telemedicine in the comfort of their homes, the benefit to the payer includes data to support the value proposition of the therapy, and the benefit to our sponsors is in condensing timelines and accelerating time to market. ♦

AUTHOR INFORMATION

Henry Anhalt, DO, is the vice president for medical affairs for Science 37. He is a board-certified pediatrician and pediatric endocrinologist whose work focuses on novel approaches to research and treatment of people living with diabetes and metabolic disorders.

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Science 37, Novartis Sign Agreement to Advance Decentralized Clinical Trials

EBDM Staff

THE IDEA OF THE “site-less” clinical trial got a boost March 7, 2018, as Science 37 signed a strategic alliance with Novartis to support up to 10 new decentralized clinical trials over the next 3 years. This will increase the portfolio of Science 37's propriety platform, which uses mobile technology and telemedicine to reach patients remotely and keep trials ongoing.

In a statement, Science 37 said the collaboration will allow US-based trials to launch in oncology, dermatology, and neuroscience during 2018.

“We are excited to deepen our relationship with an industry leader in innovative drug development like Novartis,” said Noah Craft, MD, PhD, and co-founder and CEO of Science 37. “We are thrilled to launch this strategic alliance to accelerate our patient-centered scientific work together across these new therapeutic areas.”

The need to travel long distances to clinical trial sites has long been cited a reason why only 3% to 5% of cancer patients take part in clinical trials, and why certain subgroups, including young adults and minorities, are underrepresented

in trials. Overall, minorities account for less than 10% in clinical trials, and the share in some cancer trials can be less than 2%.

Science 37's proprietary technology allows pharmaceutical researchers to make participation from home possible. Novartis already has site-less trials with Science 37 ongoing for investigational treatments for acne, cluster headaches and nonalcoholic steatohepatitis, according to a statement from the pharmaceutical company.

“Novartis aims to run studies in ways that overcome many of the barriers patients face when deciding whether or not to enroll in clinical trials, like long journeys or extensive time spent at hospitals or trial sites,” Rob Kowalski, ad interim Head of Global Drug Development and Chief Medical Officer, said.

“With our shared vision of futuristic trials enabled by technology, we're excited to expand our collaboration with Science 37 to pioneer a new, patient-centric research model.” ♦



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ORIGINAL RESEARCH

Impact of a Pharmacist-Managed Diabetes Clinic on Quality Measures

Nadia J. Aneese, PharmD; Alexandra Halalau, MD; Sarah Muench, PharmD; Daniel Shelden, DO; Janna Fett, PharmD; Colleen Lauster, PharmD

PRECIS

This study evaluated a pharmacist-managed diabetes clinic (PMDC) to determine its impact on diabetes-related quality measures.

PURPOSE

A PMDC was created to assist with improvement of diabetes quality measures. The objective was to evaluate the PMDC impact on quality measures.

BACKGROUND

According to the CDC 2017 National Diabetes Statistics Report, diabetes was the seventh leading cause of death in 2015.¹ Additionally, diabetes is associated with significant morbidity leading to a high burden on healthcare costs. Tools are used to evaluate provider performance on this costly disease. The Healthcare Effectiveness Data and Information Set (HEDIS) developed by the National Committee for Quality Assurance (NCQA) is 1 tool with defined diabetes care criteria.² These criteria include current glycated hemoglobin testing (A1C), A1C control (<8%), current retinal or dilated eye exam, blood pressure control (<140/90 mmHg), and nephropathy monitoring.

The NCQA maintains Recognition Programs such as the Patient-Centered Medical Home designation for clinicians who adhere to medical evidence proven to provide high-quality care. Achieving high HEDIS scores is imperative for these NCQA Recognition Programs and has been associated with cost-effective practices and better health outcomes.^{2,3}

A pharmacist-managed diabetes clinic (PMDC) was created to assist with the improvement of diabetes quality measures. The criteria developed by HEDIS were used to evaluate care in our Outpatient Clinic (OPC). Studies have shown the benefits of PMDCs across different clinical settings, including attaining significant improvement of diabetes related parameters (A1C, blood pressure, lipids, etc) and reaching A1C goals more frequently.⁴⁻⁹ The objectives of this study were to evaluate the impact of a PMDC on HEDIS measures and to assess adherence to other diabetes standards-of-care recommendations.

METHODS

Study Design

This study was approved by the Beaumont Health Institutional Review Board as a retrospective cohort analysis of patients with type 1 diabetes (T1D) or type 2 diabetes (T2D). Patients followed in the PMDC were compared to those receiving standard clinic care (Figure 1).

Setting

The outpatient clinic (OPC) is a training site for 60 internal medicine (IM) and 15 combined medicine and pediatric (Med-Peds) residents. These residents serve as primary care providers (PCPs) for patients. The OPC manages more than 800 patients with diabetes.

Intervention

Prior to January 2015, 2 standard care options were available for diabetes management 1) PCPs managed their own patients with diabetes 2) referred patients to the multidisciplinary diabetes clinic (MDC). The MDC is comprised of an endocrinologist, medical residents, dietitians, and pharmacists. The focus is general diabetes care including physical exam, medication management, hypertension and lipid management, nephropathy screening, diabetic foot exams, and immunizations. Despite these services, the OPC had not been designated as a patient-centered medical home, thus identifying the need for improvement in diabetes-related HEDIS measures.

FIGURE 1. Study Protocol

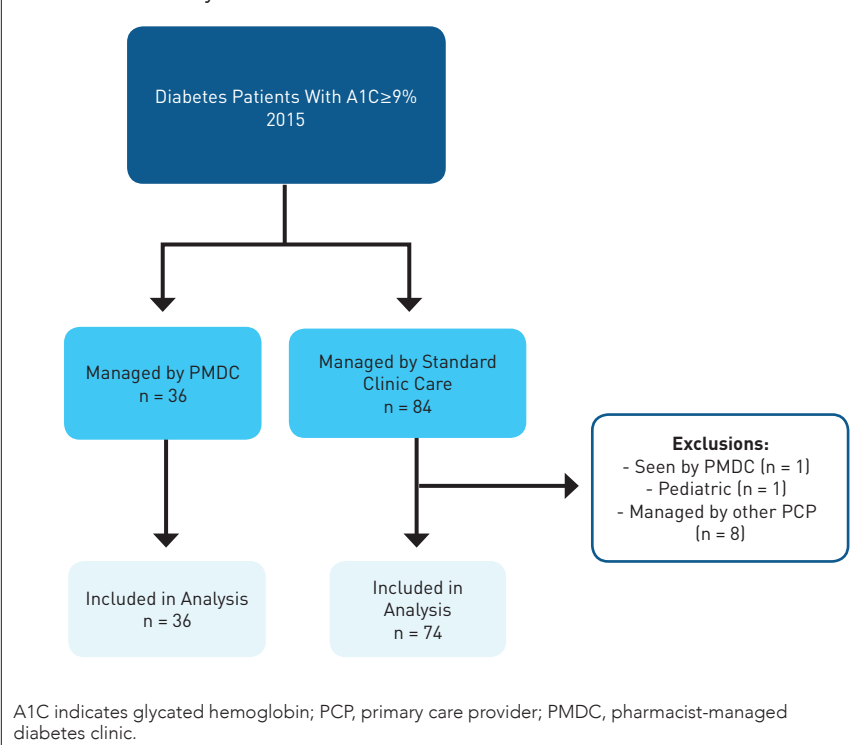
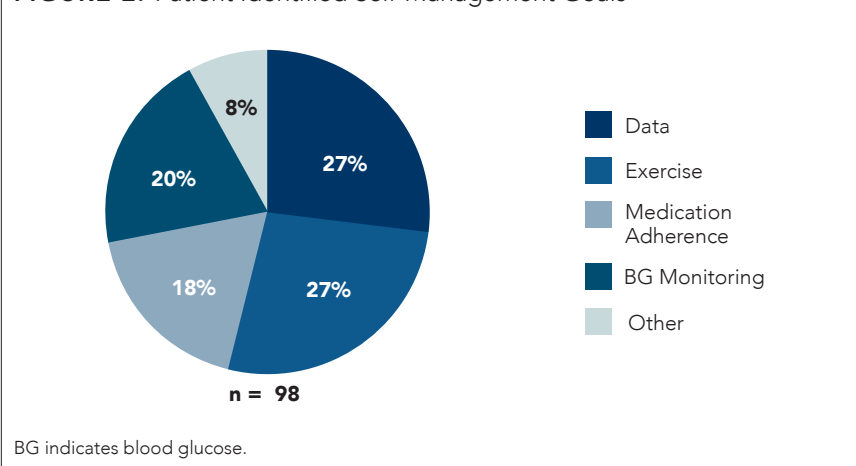


FIGURE 2. Patient Identified Self-Management Goals



The PMDC was created in January 2015 with the goal of assisting the OPC in attaining improved HEDIS measures in high-risk patients (those with an A1C $\geq 9\%$). This created a third option for diabetes management. The PMDC works in tandem with the standard care that patients receive in the OPC. Pharmacists in the PMDC work under a collaborative practice agreement to conduct visits with patients. During appointments, patients are asked to describe gaps in knowledge and identify their own self-management goals (Figure 2). These goals serve as the foundation for follow up. Patient education is reviewed at appointments (Table 1). Review of topics typically occurs over multiple appointments, depending on the individual's need.

TABLE 1. Diabetes Education Reviewed at PMDC Visits

What is Diabetes?	Monitoring BG and Glycemic Goals	Hyperglycemia and Hypoglycemia	Individualized Medication Review	Introduction to Lifestyle Changes
Pathophysiology	A1C goals	Definition	Mechanism of action	Diet: review of food groups and portion control
Signs and symptoms of diabetes	Pre- and postprandial BG goals	Symptoms	Administration instructions	Exercise: 30 minutes x 5 days/week
Introduction to diabetes complications	Importance of self-monitored BG	Causes	Review progressive nature of diabetes	
Individual care plan	Barriers to monitoring identified	Treatment	Adverse effects-monitoring and management	

A1C indicates glycated hemoglobin; BG, blood glucose; PMDC, pharmacist-managed diabetes clinic.

TABLE 2. Patient Characteristics

	PMDC (n = 36)	Standard (n = 74)	P-value
Age (years), mean ± SD	51 ± 12	51 ± 14	.96
Male, n (%)	19 (52.8)	30 (40.5)	.23
Weight (kg), median (25th, 75th)	95 (78, 123)	93 (77, 115)	.73
BMI (kg/m ²), median (25th, 75th)	33 (26, 41)	32 (28, 39)	.95
Type 2 Diabetes %	92	93	.72
Diabetes duration (years), median (25th, 75th)	10 (4, 14)	9 (4, 14)	.73
Newly diagnosed, n	1	4	
Unknown duration, n	2	13	
Baseline A1C, median (25th, 75th)	11.5 (10.3, 12.9)	10.6 (9.7, 11.9)	.033
Insulin therapy, n (%)	34 (94.4)	56 (75.7)	.017
Current smoker, n (%)	8 (22.2)	18 (24.7) ^a	.16

A1C indicates glycated hemoglobin; BMI, body mass index; PMDC, pharmacist-managed diabetes clinic; SD, standard deviation.
^an = 73

Participants

Eligible patients had an A1C $\geq 9\%$ between January 1, 2015, and September 30, 2015, and had to be ≥ 18 years old. Patients in the PMDC were identified through electronic health record (EHR) schedules. Standard clinic care patients were identified through a report that identified patients with diabetes assigned to a clinic PCP. Exclusion criteria for both groups were those that had not been seen by an OPC physician in 2015.

Data Collection

The following variables were collected: patient demographics, blood pressure (BP), and the following laboratory values: A1C, lipid panel, and microalbumin/creatinine ratio. Additionally, information regarding the patients' medication profile was collected such as antidiabetic, anti-hypertensive, and lipid-lowering regimens. Finally, factors related to medical follow up, such as number of office visits and hospitalizations, were reviewed. All laboratory parameters were evaluated between 3 to 6 months and 6 to 9 months after the baseline A1C was measured in 2015.

Endpoints

The primary endpoints were the absolute change in A1C from baseline to 3 and 6 months and percent of patients who reached an A1C goal of less than 8% at either 3 or 6 months. If patients had readings at both 3 and 6 months, the most recent A1C was used. If patients only had readings at 3 months then that was included. Secondary endpoints included BP $< 140/90$ mmHg measured at 3 or 6 months, current retinal or dilated eye exam, current nephropathy screening,

and appropriateness of medication use with angiotensin-converting-enzyme inhibitors (ACE-inhibitors) or angiotensin receptor blockers (ARBs) and statins. Patients were deemed to have appropriate use of medications if agents prescribed were indicated based upon current diabetes recommendations and agents not prescribed were contraindicated due to allergies or adverse effects.

Study sample size

All diabetes patients that were enrolled in PMDC between January 1, 2015, and September 30, 2015, were included. They were compared with diabetes patients that were receiving regular care, at a ratio of approximately 1:2.

Statistical analysis

Descriptive statistics were used for data collected and examined separately for both groups. Categorical variables were reported as counts and frequencies, and Pearson's Chi-square tests or Fisher's Exact tests were used. Continuous variables were examined for normality and non-parametric data. Wilcoxon tests were used for all continuous variables as they were not normally distributed.

RESULTS

A total of 110 patients were included (Figure 1); 36 patients were managed by the PMDC and 74 by standard clinic care. Patients in both groups were well matched in terms of baseline characteristics, with the exception of baseline A1C and insulin use (Table 2). PMDC patients had a higher median baseline A1C of 11.5% versus 10.6% ($P = .033$). Insulin use was 94.4% in the PMDC group versus 75.7% in the standard care group ($P = .017$).

Primary endpoints

Figure 3 depicts the change in A1C for both groups. At 3 months, the A1C improved by 2.2 points in the PMDC group compared to 0.9 points in the standard group ($P = .006$). At 6 months, the A1C improved with 3.2

points in the PMDC group compared to 1.2 points in the standard group ($P = .044$).

The percentage of patients with a follow-up A1C at 3 months was 67% in the PMDC group compared to 50% in the standard group (Table 3). At 6 months, 53% in the PMDC and 55% in the standard group had a follow-up A1C. Of the patients with follow-up data, 50% in the PMDC and 30% in the standard group reached an A1C goal of $< 8\%$ by 3 or 6 months. The difference between groups was not statistically significant (OR 2.31 [95% CI, .90, 5.95]; $P = .08$).

Secondary endpoints

The difference between groups for the percent of patients reaching blood pressure goals or receiving eye exams was not significant (Table 4). A higher percentage of patients in the PMDC group had nephropathy screening (97.2%) compared to the standard group (79.7%, $P = .015$).

Regarding medication appropriateness, 97.2% of patients in the PMDC group and 100% of patients in the standard group were appropriately prescribed ACE-inhibitors or ARBs. Appropriate use of statins was seen in 94.4% in the PMDC group vs 91.9% in the standard group ($P = 1.00$) (Table 4).

DISCUSSION

PMDCs have proven to be advantageous in diabetes care.⁴⁻⁹ Similarly, our PMDC contributed to positive outcomes related to diabetes quality measures. Overall, patients in the PMDC had a 3.2 point decrease in A1C at 6 months. Although a significant change, the study did not show a statistically significant difference in the percent of patients reaching a A1C of $< 8\%$. The number of patients with available

TABLE 3. Primary Endpoints

	PMDC (n = 36)	Standard (n = 74)	P-value
Patients with A1C n (%)			
3 months	24 (67)	37 (50)	–
6 months	19 (53)	41 (55)	–
	PMDC (n = 28)	Standard (n = 53)	P-value
Patients reached A1C goal <8% by 3 or 6 months, n (%)	14 (50)	16 (30.2)	.08

A1C indicates glycated hemoglobin; PMDC, pharmacist-managed diabetes clinic.

TABLE 4. Secondary Endpoints

	PMDC (n = 36)	Standard (n = 74)	P-value
Patients meeting BP goal, n (%)	28 (77.8)	53 (71.6)	.49
Patients with current eye exam, n (%)	19 (52.8)	32 (43.2)	.35
Patients with current kidney screening, n (%)	35 (97.2)	59 (79.7)	.015
Medication appropriateness ACE-inhibitor/ARB Statin therapy	35 (97.2) 34 (94.4)	74 (100) 68 (91.9)	.33 1.00

ACE indicates angiotensin-converting enzyme; ARB, angiotensin receptor blockers; BP, blood pressure; PMDC, pharmacist-managed diabetes clinic.

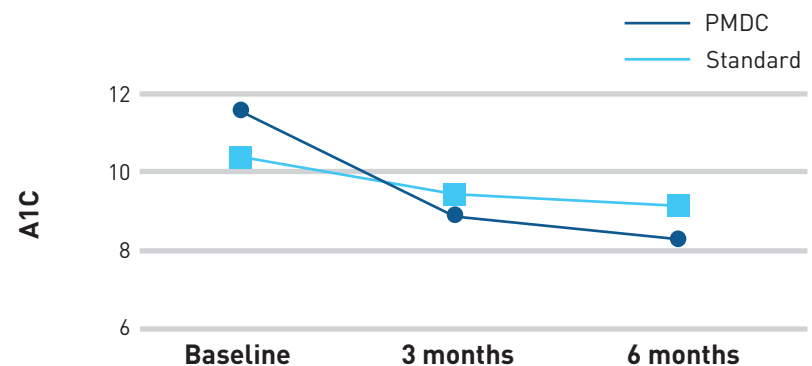
TABLE 5. Medical Follow Up

	PMDC	Standard	P-value
Diabetes-related hospitalizations, n (%)			
0	29 (80.6)	56 (75.7)	.28
1-2	5 (13.9)	15 (20.3)	
3-4	2 (5.6)	2 (2.7)	
5	0	1 (1.4)	
Number of diabetes-related clinic appointments			
Median (25th, 75th)	3 (3, 6)	3 (2, 5)	.19
Min to Max	1 to 15	0 to 10	
Percent missed appointment			
Median (25th, 75th)	15 (9, 22)	16 (6, 22)	.86
Min to Max	0 to 46	0 to 53	
Number of PMDC appointments^a			
Median (25th, 75th)	3 (2, 4)		
Min to Max	1 to 14		

^aNot included in diabetes-related clinic appointments
Max indicates maximum; Min, minimum; PMDC, pharmacist-management diabetes clinic.

A1C data at 3 and 6 months (Table 3) was lower than desired in both groups. This may be related to the percentage of missed appointments (Table 5.) However, the missed appointment rate seen in the OPC was consistent with reported rates at other residency teaching clinics.¹⁰ The lack of data and the missed appointment rate may have impacted the observed difference between groups.

Pharmacists have been valuable members of the MDC for years. They provide recommendations for medication titration and patient education alongside the multidisciplinary group. The role of the pharmacist in the PMDC and MDC differ, which may explain the benefit seen with the PMDC. One dif-

FIGURE 3. Primary Endpoint: Change in A1C

Endpoints	PMDC	Standard	P-value
Baseline to 3 months Min to Max	-2.2 -9.8 to 0.3	-.9 -6.6 to 2.6	.006
Baseline to 3 months Min to Max	-3.2 -7.1 to 2.9	-2.2 -8.1 to 3.3	.004

A1C indicates glycated hemoglobin; Max, maximum; Min, minimum; PMDC, pharmacist-managed diabetes clinic.

ference is that the PMDC pharmacist conducts the full 30-60-minute appointment, whereas in the MDC the pharmacist spends approximately 15 minutes with the patient. This PMDC appointment may have allowed for more detailed patient-centered diabetes education. In the PMDC, pharmacists encouraged patients to identify self-management goals and allowed patients to set the foundation for follow-up visits. The PMDC was comparable with the pharmacist-managed clinic reported by Kelly and Rodgers,⁶ who also incorporated a management plan with patient- and pharmacist-identified management goals. While they were unable to show statistical significance in their A1C reduction compared to control, they did show a positive trend. As the state of the current healthcare system evolves, patient-centered care is crucial for improving chronic disease management.

The percentage of patients with current retinopathy screening was lower than desired in both treatment groups. Although patients are frequently referred for diabetic retinopathy screening by their physicians or pharmacists, follow up was often low. Nephropathy screening was improved in the PMDC group compared to the standard group. This finding has also been supported in the literature.⁹ Pharmacists in the PMDC follow a specific checklist at the initial appointment to keep track of diabetes standards, such as nephropathy screening, which may have explained the difference between the groups.

There were limitations to this study. At the evaluation time points of 3 and 6 months, a smaller amount of follow-up data was available. This may be related to the rate of missed appointments in general, but it also affects the percent of patients reaching the goal. If authors assumed that any patient without data did not reach the goal, the overall number of patients reaching the target A1C would be less. Additionally, as this study was a chart review, the results are dependent upon documentation in the institution's charting system. Lastly, a snapshot method was used to determine if patients had reached their target BP—a practice that payers use when evaluating HEDIS measures. However, patients may have been at their target immediately before or after the snapshot value, and this may not accurately reflect overall BP control.

Based on this study, areas for process improvement were identified. To improve rates of retinopathy screening, clinic pharmacists are now working with the institution's eye clinic to better streamline an appointment process for patients with diabetes. Efforts to schedule these annual retinopathy screenings immediately after a clinic visit were initiated. The eye clinic being located within the same building improved coordination of appointments, which may alleviate concerns of transportation, work-related time off, or other matters.

It was noted that many patients in the standard group were referred to the PMDC, however appointments to the PMDC were not made. Improving the referral process will also require coordination with clinic registration to ensure referrals made for the PMDC are carried out. Additional education to the medical residents on the PMDC referral process may improve this.

CONCLUSION

The addition of a PMDC had a positive effect on the change in A1C of patients with diabetes. A higher percentage of patients in the PMDC were able to reach a target A1C of <8%. Rates of nephropathy screening were also improved with the PMDC. Patients in both groups were ordered appropriate medications in regard to other diabetes standards of care. Overall, retinopathy screening in this patient population is open to improvements. ♦

AUTHOR INFORMATION:

Nadia J. Aneese, PharmD, is with Huron Valley Physicians Association of Ann Arbor, Michigan. Alexandra Halalau, MD, is with Beaumont Hospital, Royal Oak, Department of Internal Medicine, Royal Oak, Michigan. Sarah Muench, PharmD, Janna Fett, PharmD, and Colleen Lauster, PharmD, are with Beaumont Hospital, Royal Oak, Department of Pharmaceutical Services, Royal Oak Michigan. Daniel Sheldon, DO, is chief resident at Beaumont Hospital, Royal Oak, Department of Internal Medicine.

CORRESPONDING AUTHOR:

Colleen Lauster, PharmD
Colleen.lauster@beaumont.org

Beaumont Hospital, Royal Oak
Department of Pharmaceutical Services
Beaumont Hospital, Royal Oak, Michigan
3601 West 13 Mile Road
Royal Oak, MI 48073

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IN FOCUS

Out-of-Pocket Costs for Insulin Are a Problem. Litigants in Case Disagree on Who Is at Fault

Mary Caffrey



GOTTLIEB

As the case proceeds, FDA Commissioner Scott Gottlieb, MD, told a gathering of America's Health Insurance Plans that the complexity of rebates "help conceal their corrosion on our system—and their impact on patients."

AFTER A YEAR IN COURT, the leading insulin manufacturers and the attorneys suing them agree: Some people with diabetes pay a lot of money out of pocket for the hormone that keeps them alive.

They disagree, however, on whether laws have been broken and who should be blamed. The insulin manufacturers argue the problem of rising prices is beyond the court's ability to solve.

Soon judges overseeing the 14-month-old suit will decide whether they agree. With a stay lifted in the case, the insulin companies have filed a scathing motion to dismiss the racketeering claims lodged against them.

But in doing so, the drugmakers admit that consumers' sticker shock is real. It's just not the manufacturers' fault, they argue. And it's definitely not a crime.

"Defendants acknowledge that pharmaceutical pricing is an important issue, especially given how recent trends in the design of insurance benefits have affected certain patients' out of pocket costs," states the joint motion filed on March 9, 2018, by attorneys for Novo Nordisk, Sanofi, and Eli Lilly.¹

If allowed to proceed, the case could finally shed light on the role of pharmacy benefit managers (PBMs), who may be the plaintiffs' ultimate target. The lead attorneys have followed a strategy that will allow them to gather evidence while fighting the pharmaceutical firms and use it later in a suit against the PBMs. Not everyone agrees with this approach, however.

Attorneys representing 71 patients—who have not been certified as a class—argue that rebates are paid to the nation's 3 largest PBMs to keep brands on formulary, inflating insulin prices and harming consumers when their health plans do not uniformly pass discounts through at the pharmacy counter. Multiple suits were merged into a case called Insulin Pricing, which claims the transactions between pharmaceutical companies and PBMs amount to a series of illegal schemes.² Although PBMs were not sued, their role in the pharmacy chain is discussed at length by both sides—and it's drawing scrutiny from well beyond the obscure federal courthouse in Trenton, New Jersey, where the case ended up after it was filed in Massachusetts.³

The drug manufacturers say the plaintiffs fail to show how insulin prices reflect rebates, and they portray the current system as something beyond their ability to change. "As plaintiffs recognize, manufacturer rebate payments are not unique to the sales of insulin. It is how the entire branded pharmaceutical industry functions. As a result, the relief plaintiffs seek would not only require this Court to regulate the sales of insulin, but also would have an impact on the entire pharmaceutical industry at large," the joint motion states.¹

Against this backdrop, regulators are taking notice. Two days before the manufacturers filed their motion, FDA Commissioner Scott Gottlieb, MD, took aim at rebates and the effect on consumers during an address to America's Health Insurance Plans (AHIP).⁴ Amid proposed mergers between CVS and Aetna⁵ and Cigna and Express Scripts⁶, Gottlieb said, "The very complexity and opacity of these schemes help to conceal their corrosion on our system—and their impact on patients. In the long run, the interests of patients, providers, and manufacturers are not well served by these arrange-

ments, precisely because these practices encourage large list price increases to fuel the pricing schemes."

"And so," Gottlieb said, "we continue to see a backlash against these Kabuki drug-pricing constructs—constructs that obscure profit taking across the supply chain that drives up costs; that expose consumers to high out-of-pocket spending; and that actively discourage competition."⁴

The Plaintiffs Line Up

Attorney Steve Berman made headlines in sources from *The New York Times*⁷ to business outlets⁸ to medical publications⁹ when he filed the putative class action in the US District Court for the District of Massachusetts on January 30, 2017, citing a federal racketeering statute created to go after figures in organized crime. The filing alleged the 3 companies increased "benchmark" insulin prices 150% over 5 years, acting in "lock step" to pay rebates to PBMs.³

"People living with diabetes are practically imprisoned under the price hikes and sadly are resorting to extreme measures to afford the medication they need to live," said Berman, the managing partner of Hagens Berman, best known for his prosecutions that contributed to the \$206 billion master settlement agreement with the tobacco companies.¹⁰

Berman was racing the clock to beat other plaintiffs to court. Another firm based in Seattle, Washington, Keller Rohrback, was preparing an insulin pricing case led by plaintiff Julia Boss, the mother of a child with type 1 diabetes and head of the Type 1 Diabetes Defense Foundation (T1DF).¹¹ After considering a filing with Hagens Berman, Keller Rohrback filed *Boss v CVS Health* in Trenton on March 17, 2017.¹²

Insulin Pricing was delayed for months while various plaintiffs' attorneys fought for control of the case. Boss' determination to sue PBMs from the start, not later—and her disagreement with Hagens Berman on this point—was among the reasons she and Charles Fournier, vice president of T1DF, cut ties with Keller Rohrback, causing a stay in late January.¹³ Filing pro se, Boss still seeks to add PBMs to the case; on March 16, 2018, she asked the court to reconsider its consolidation order, so that PBMs could be sued on a separate track.¹⁴

"Our goal is to realign the interests of payers and consumers. That means passing through rebates and basing cost-sharing on actual net cost to plan for specialty/brand drugs and supplies. A payer who has no perverse incentive to inflate list prices can instead use its negotiating power to exert downward pressure on both list and net prices for analog insulin, glucagon and test strips, returning these to competitive levels," Boss said in an email to *The American Journal of Managed Care*® (AJMC®).

In February, a group representing Medicare Advantage and other health plans joined the fray, saying it will use big data tools to prove its case. An attorney involved in the entity, MSP Recovery, told AJMC® in an interview that the entity will be aided by an ability to draw insights from data drawn from up to 100 health plans.

Enrique G. Serna, of Serna & Associates of San Antonio, Texas, said the pooled health plan data will allow MSP Recovery to show

connections between rising insulin prices and outcomes like incidence of diabetic ketoacidosis, hospital admissions, and prescriptions being abandoned at pharmacy counters. He said the data are especially compelling in regions of the country with high rates of diabetes. Referring to defendants, Serna said, “We have access to information that they don’t.”

A Year of Delays

For people living with diabetes who use insulin, going to court promised a window into pricing—something that Congress tried to achieve without success.¹⁵ During a protest in 2017 at Eli Lilly headquarters, a company spokesperson called insulin pricing “a complex problem to solve” and said that with rebates, net prices have actually gone down.¹⁶ Financial reports have portrayed all 3 insulin manufacturers as under intense pricing pressure in recent years, and the companies laid off thousands of employees in 2016 and 2017.¹⁷

Days after the Massachusetts filing, the suit was refiled in the US District Court of New Jersey, where it is now assigned to US District Judges Lois H. Goodman and Brian R. Martinotti.¹⁸ Asked about the move, Hagens Berman spokesperson Ashley Klann said in an email the most important one was a related investors’ suit against Novo Nordisk that was being heard in Trenton.¹⁹ A February 2017 statement from Hagens Berman said filing the insulin case in the same jurisdiction as the existing investors’ suit helped avoid a multidistrict litigation petition, “which would have slowed the case’s progress.”²⁰

Berman and James Cecchi of New Jersey-based Carella Byrne refiled the insulin case, while Cecchi was simultaneously representing investors who were suing Novo Nordisk over disappointing earnings, alleging that earlier reports had been inflated through “collusive price fixing” of the company’s insulin with PBMs.

Despite the jockeying for control, Serna said this decision by Berman prevented an even longer delay. Besides Keller Rohrback, both Weitz & Luxenberg, which has ongoing litigation involving sodium-glucose cotransporter-2 inhibitors, and Berman DeV-alerio also made bids to control the case. The latter 2 firms claimed Berman’s representation of a drug wholesaler, FWK Holdings, against Sanofi in Massachusetts represented a conflict of interest; they said Berman would have to argue that Sanofi had kept the price of insulin artificially high through wholly different behavior than it used to harm consumers during the same time frame.²¹ That argument was rejected, and in September 2017, the various insulin cases were consolidated, with Berman and Cecchi named interim co-lead counsel.²²

A Dispute Causes a Stay

Records show that Keller Rohrback’s efforts to collaborate with Hagens Berman ended when Berman would not agree to include the PBMs as defendants. In fact, Keller Rohrback attorneys told

the court this strategy was one reason the firm should be named lead counsel: “We have no objection to working with Hagens Berman in this case, but [Keller Rohrback] and its clients strongly believe that the PBMs play a central role in the conspiracy and must be named defendants.”²³

Keller Rohrback also brought in one of New Jersey’s best-known trial attorneys, Michael Critchley, as local counsel; his recent cases include a major patent ruling involving pembrolizumab (Keytruda). He remains counsel to several plaintiffs in *Insulin Pricing*.

As outlined in their January 30, 2018, letter, Berman and Cecchi are using a legal mechanism called a tolling agreement that allows them “to include one or more of the PBMs as party defendants” as long as this is done “within 180 days after this court has adjudicated all motions to dismiss in *Insulin Pricing*.” The letter says they can gather evidence from PBMs during the *Insulin Pricing* suit.²⁴ The MSP Recovery suit uses a tolling mechanism as well.

“As plaintiffs recognize, manufacturer rebate payments are not unique to the sales of insulin. It is how the entire branded pharmaceutical industry functions. As a result, the relief plaintiffs seek would not only require this Court to regulate the sales of insulin, but also would have an impact on the entire pharmaceutical industry at large.”

But in an email to *AJMC*[®], Fournier wrote that he and Boss had hired Keller Rohrback specifically because they disagreed with this approach. Berman and Cecchi’s filings reveal the strain over this issue. Accounts differ on how much the disagreement caused Boss to part ways with Keller Rohrback, which, having not been named co-lead counsel, ultimately signed on with the tolling strategy. Berman and Cecchi filed a consolidated complaint on December 26, 2017, that left Boss out.² While they acknowledged that Boss has a child with diabetes, Berman and Cecchi wrote, “The opinion of one individual with limited experience in the pharmaceutical industry and no proffered experience with complex civil litigation should not dictate the litigation strategy for the entire class.”²⁴

The MSP Recovery case runs parallel to the patient claims. After initially filing suit in Texas, on February 15, 2018, MSP Recovery refiled in New Jersey,²⁵ seeking damages in part under the Medicare Secondary Payer Act.²⁶ Spokesperson Diana Diaz said in an interview that the act allows health plans to sue entities, such as auto insurers and pharmaceutical manufacturers, if counsel can prove their actions caused Medicare plans to overspend on emergency room treatment, hospital stays, or other care. The filing alleges that defendants and “unnamed co-conspirators” caused prices to increase through a scheme similar to that outlined in the other suits, citing the False Claims Act and the Anti-Kickback

Statute. The case reads, “The Affordable Care Act provides that ‘a person need not have actual knowledge...or specific intent to commit a violation.’”

Meanwhile, Keller Rohrback continues to represent other plaintiffs in related cases that involve pricing for glucagon²⁷ and test strips²⁸. *Prescott v CVS Health* alleges that Abbott, Johnson & Johnson, Bayer, Roche, and Ascensia, along with the PBMs, took part in a pricing scheme tied to CMS’ competitive bidding program for test strips, which a study in *Diabetes Care* found put Medicare beneficiaries at risk.²⁹ As of March 2, 2018, Boss was listed as a pro se litigant on those cases as well.

Asked to comment on the split with their attorney, Fournier wrote in an email, “During our initial case assessment, we identified payers as key actors in that control the allocation of manufacturer rebates,” and that this and other issues had to be explored.

Despite the pro-consumer pitch of the announcement that UnitedHealthcare will directly pass rebates on to consumers³⁰—which Gottlieb referenced in his AHIP remarks—Fournier said this development only shows that payer-PBM nexus has everything to do with what is paid at the pharmacy counter. “In light of defendant UnitedHealth’s announcement...on rebate pass-through, our own counsel’s refusal to proceed on our rebate pass-through claims against PBM/insurer defendants makes no sense,” he wrote.

The RICO Act

Insulin Pricing spells out a series of claims against each insulin maker, charging each with “designing and implementing the scheme” that involved sharing information with PBMs to set benchmark prices and establish rebates. “By subsequently failing to disclose such practices to the individual consumers,” each company and the PBMs “engaged in a fraudulent and unlawful course of conduct, constituting a pattern of racketeering activity.” The MSP Recovery case also cites racketeering claims.

But not everyone agrees that the Racketeer Influenced and Corrupt Organizations (RICO) Act is the best tool. In an online paper, economist Larry Abrams, PhD, a critic of PBMs, wrote that he is skeptical of RICO’s applicability in *Insulin Pricing*. The situation is not pure price fixing, he said, but coordination between pharmaceutical companies and PBMs, on whom they depend for market access.³¹

“We think the coordination is not overt, but a ‘follow-the-leader’ understanding developed independently over the years. Pharma understands that a move to list price significantly below a competitor only reduces their ability to compete on gross rebates in the second round of this two-step bargaining process,” Abrams wrote.

In the motion to dismiss, attorneys led by Michael Griffinger of Gibbons, based in Newark, New Jersey, mounted a multipart objection to the RICO claim—the most basic point being that consumers do not buy insulin from drug manufacturers directly, something they say is an “insurmountable obstacle” under the law. They also argued that “allegedly excessive pricing is not fraudulent” and



Clarkson S. Fisher Federal Courthouse,
Trenton, New Jersey

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that nowhere in their complaint do the plaintiffs make a direct tie between benchmark prices and rebates paid to PBMs.

In fact, the drug firms argued, “to the extent that insured consumers are unhappy that they do not receive the benefit of rebates paid to their insurers and PBMs, their complaint is not with the defendants.”¹¹

The Investors' Suit

Meanwhile, the investors' suit, which gave Berman and Cecchi the New Jersey foothold to control *Insulin Pricing*, has progressed. In November, Seeger Weiss and Carella Byrne filed new arguments³² on why the case should not be dismissed, alleging that during 2015 and 2016, Novo Nordisk made false statements about the size and role of rebate payments to PBMs and overstated the superiority of its new long-acting insulin, Tresiba.

Novo Nordisk's attorneys, Davis Polk & Wardwell of New York City and Gibbons, rejected those arguments in a December 18, 2017, statement supporting their earlier motion to dismiss.³³ They argued that Novo Nordisk “met its publicly disclosed financial guidance for 2015 and 2016” and that the plaintiffs failed to make their case that the company intentionally misled investors. “Even accepting as true that individuals in different business units disagreed about some aspect of budgeting or forecasting, that is not indicative of fraudulent intent,” the statement said.

A spokesperson for Hagens Berman said a dismissal of the investors' suit would have no bearing on *Insulin Pricing*. *The American Journal of Managed Care*[®] sought comments from representatives at Carella Byrne and Gibbons but did not receive a response. ♦

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