Improving outcomes for diverse populations disproportionately affected by diabetes: Final results of Project IMPACT: Diabetes

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Abstract

Objective: To improve key indicators of diabetes care by expanding a proven community-based model of care throughout high-risk areas in the United States.

Design: Observational, multisite, pre–post comparison study.

Setting: Federally qualified health centers, free clinics, employer worksites, community pharmacies, departments of health, physician offices, and other care facilities in 25 communities in 17 states, from June 2011 through January 2013.

Participants: 1,836 patients disproportionately affected by diabetes representing diverse ethnicities, insurance statuses, and social and economic backgrounds.

Intervention: Pharmacists were integrated into local, interdisciplinary diabetes care teams and provided customized diabetes education and medication consultations to patients.

Main outcome measures: Clinical measures included glycosylated hemoglobin (A1C), body mass index, systolic and diastolic blood pressures, low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C), triglycerides, and total cholesterol. Process measures included smoking status, eye examination status, foot examination status, and influenza vaccine status.

Results: Pharmacist patient care services for those underserved or disproportionately affected by diabetes resulted in a statistically significant and clinically relevant decrease in mean A1C levels (–0.8%). Other outcome indicators were below target levels at baseline and decreased significantly but not by clinically relevant amounts (LDL-C, –7.1 mg/dL; triglycerides, –23.7 mg/dL, and total cholesterol, –8.8 mg/dL). The mean increase in HDL-C (+0.6 mg/dL) was not statistically significant or clinically relevant. Among evaluable patients who were not at target for process measures at baseline, 51.7% of 453 patients received eye examinations, 72.0% of 271 patients received foot examinations, 41.7% of 307 patients received influenza vaccinations, and 9.3% patients of 270 quit smoking during the project. Of the communities involved in the study, 92% intend to sustain pharmacists' services.

Conclusion: Project IMPACT: Diabetes results show significant improvement in patients' clinical outcomes and demonstrate that all patients, even those with tremendous barriers to appropriate diabetes care, benefit from patient-centered, interdisciplinary health care teams that include pharmacists.

Keywords: Diabetes, pharmacist, interdisciplinary team, collaborative care, health outcomes.

J Am Pharm Assoc. 2014;54:477–485.
doi: 10.1331/JAPhA.2014.13240

Received December 6, 2013, and in revised form March 24, 2014. Accepted for publication May 3, 2014.

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Disclosure: Benjamin M. Bluml and Lindsay L. Watson are employed by APhA Foundation. Jann B. Skelton, Patti Gasdek Manolakis, and Kelly A. Brock served as consultants to APhA Foundation throughout the duration of Project IMPACT: Diabetes. The authors declare no other conflicts of interest or financial interests in any product or service mentioned in this article, including grants, gifts, stock holdings, or honoraria.

Funding: Project IMPACT: Diabetes was conducted by APhA Foundation with financial support from and in partnership with Bristol-Myers Squibb Foundation's Together on Diabetes initiative.

Acknowledgments: To Kandace Fleming and Rebecca Romaine from the University of Kansas Center for Research for their contributions to statistical analysis, and to the diabetes care teams and innovative leaders in each of the 25 communities for their dedication to improving people's health.

Previous presentation: There have been no previous presentations of the final results included in this manuscript. Interim results were presented at the National Minority Quality Forum 10th Annual Health Disparities Leadership Summit, Washington, DC, April 22, 2013.

According to the American Diabetes Association (ADA), diabetes affects an estimated 25.8 million Americans and is a contributing factor in more than 231,000 deaths annually.[1,2] Approximately 18.8 million Americans are aware they have a diagnosis of diabetes, while about 7 million are unaware and have not yet been diagnosed.[1,2]

Despite advances in prevention and treatment, the prevalence of diabetes in the United States increased by 128% from 1988 to 2008.[2] An estimated 1.9 million American adults aged 20 years and older are newly diagnosed with diabetes each year, which translates to more than 5,200 individuals being diagnosed with diabetes each day.[1,2] The epidemic of diabetes continues to spiral out of control. If the present trend continues, as many as 1 in every 3 American adults will have diabetes by 2050.[2]

The costs associated with diabetes are astounding. ADA estimates the economic cost of diabetes in the United States is $245 billion annually, including $176 billion in direct costs and $69 billion in indirect costs (e.g., disability, reduced productivity, premature mortality).[2] Medical expenses for people with diabetes are more than two times higher than for those without the disease.[1,2] According to recent estimates, 1 of every 10 health care dollars is spent treating diabetes and its complications. These costs will only increase if the diabetes epidemic continues to grow.[2]

At a Glance

Synopsis: This multisite, observational, pre–post comparison study evaluated the impact of pharmacist integration into interdisciplinary health care teams on patients with diabetes in 25 underserved and at-risk communities across the United States. Clinical results indicate that the 1,836 study participants experienced significant improvements in key diabetes indicators, with clinically relevant improvements in mean glycosylated hemoglobin (A1C). Improvements were also seen from baseline to study end in the number of patients quitting smoking and receiving influenza vaccines and eye and foot examinations. Overall, 92% of communities intended to sustain this type of pharmacist patient care services at study end.

Analysis: *Project IMPACT: Diabetes is the first national research initiative to demonstrate that pharmacists working in community-based diabetes care teams can significantly improve clinical markers for a diverse population of primarily uninsured and underinsured patients who are disproportionately affected by the disease. Integrating pharmacists' services into Project IMPACT: Diabetes care teams improved access to care and provided a degree of health equity for the disadvantaged patients included in the study. The intention to sustain the Project IMPACT: Diabetes model underscores the perceived value of pharmacist patient care services.*

Diabetes is a complex disease that requires early identification, effective treatment, and focused management to prevent serious complications.[1,3] If diabetes goes undetected and untreated, or is uncontrolled with treatment, the risks for heart disease, stroke, blindness, neuropathy, amputation, renal disease, periodontal disease, and premature death significantly increase.[1,2] Ongoing management of diabetes is multifaceted and requires substantial patient self-management, including adhering to prescribed medications; monitoring blood glucose levels; obtaining recommended vaccinations; completing routine dental, foot, and eye examinations; and maintaining a healthy diet and lifestyle.[3]

ADA guidelines strongly recommend support of diabetes patient self-management, which has been shown to improve health outcomes and lower health care costs.[3] Because the management of diabetes is complicated, patients need access to a comprehensive team of health care professionals who work collaboratively to help them manage all aspects of the disease.

Pharmacists are ideally positioned for integration into multidisciplinary health care teams that help patients manage chronic diseases. More than 93% of Americans live within 5 miles of a community pharmacy, which provides patients with consistent access to pharmacists.[4] Previous research has documented the positive impact of pharmacists' patient care services on clinical, humanistic, and economic outcomes.[5–16] Through programs such as the Asheville Project and American Pharmacists Association (APhA) Foundation's Patient Self-Management Program (PSMP) for Diabetes, community pharmacists have worked with patients to manage their diabetes, helping improve clinical outcomes.[5–8]

Employer-based programs, including the Diabetes Ten City Challenge, have engaged pharmacists to provide care for patients with diabetes and resulted in improved clinical outcomes, decreased hospitalizations and emergency department visits, and reduced health care costs.[7–9] Additionally, team-based approaches that integrate pharmacists into health care teams in primary care settings and patient-centered medical homes have been shown to successfully support patient self-management and lead to the achievement of treatment goals and positive health outcomes.[10–16]

In 2010, APhA Foundation partnered with Bristol-Myers Squibb Foundation as part of the Together on Diabetes initiative to launch Project IMPACT: Diabetes. The project engages pharmacists as integral members of the health care team to improve diabetes outcomes in diverse communities.

Objectives

Project IMPACT: Diabetes was designed to establish a nationwide program that would scale the proven APhA Foundation process model into communities across the United States that are disproportionately affected by

diabetes.[6] Consistent with previous APhA Foundation initiatives, the Project IMPACT: Diabetes approach integrates collaborative care with pharmacists, continuous quality improvement, use of patient self-management credentialing, and collection of a minimum data set.

The key objectives of Project IMPACT: Diabetes included the following:

- Expand a proven community-based model of care throughout high-risk areas in the United States.
- Improve key indicators of diabetes care in these communities.
- Scale the existing model nationally by establishing local peer-to-peer network mentoring.
- Establish a sustainable platform for permanent change by embedding guiding principles in each community that will drive diabetes care for years to come.

Target population

Project IMPACT: Diabetes focused on improving the care and expanding access to evidence-based practices for several heavily burdened populations:

- Areas with incidences of diabetes higher than that of the state average
- Patients with uncontrolled glycosylated hemoglobin (A1C), defined as values greater than 7%, and other indicators of uncontrolled blood pressure, hypercholesterolemia, or weight
- Patients with limited access to quality diabetes care because of geographic, financial, or other barriers
- Communities that show need, through lack of focused resources or diabetes-related programming, for implementation of enhanced diabetes care

Methods

The study evaluated implementation strategies and patient care results in 25 disproportionate share communities across the United States. Through Project IMPACT: Diabetes, each community increased access to patient-centered, team-based care designed to improve clinical, process, and self-management measures related to diabetes care; increased collaboration among physicians, pharmacists, and other members of the health care team; and potentially prevented costly diabetes-related complications, including amputations, blindness, and glucose excursions (hypoglycemia/hyperglycemia) that could lead to hospital visits.

Setting

Twenty-five communities were selected through a competitive application process that evaluated communities on their patient population, resources, information accessibility, team motivation and education, plan for incentive alignment, previously demonstrated success, and leadership. The communities engaged local stakeholders, modified existing programs, and used other community resources to implement local models of care for patients with diabetes. Figure 1 displays the distribution of the participating communities overlaid on the Centers for Disease Control and Prevention's (CDC) Behavioral Risk Factor Surveillance System map for people who have been told they have diabetes.[17] Table 1 lists the names of the communities, their locations, and descriptive information about the type of partnering organizations.

Study design

Project IMPACT: Diabetes is a multisite, observational, pre–post comparison study evaluating the impact of quality-improvement activities on the clinical outcomes of patients with diabetes. The Western Institutional Review Board approved the study and granted a waiver of informed consent.

Patients participating in the study were enrolled from June 1, 2011, to January 31, 2012. Each participant was evaluated for 1 year after enrollment or until January 31, 2013. The corresponding baseline data collection period extended up to 180 days before the start of the study period for clinical measures and 365 days before the start of the study period for process measures. To be eligible for enrollment, patients had to have a diagnosis of diabetes, be newly initiated on diabetes therapy, or be maintained on diabetes therapy but poorly controlled (e.g., A1C >7%).

Each community, led by at least one community champion, adapted APhA Foundation's structure and process model to accommodate the local process of care,[6] which could include physicians, nurse practitioners, physician assistants, specialist providers, organizational administration, health benefits managers, *promotoras* (lay Hispanic/Latino community members with specialized health education training), patient advocates, and others who affect how care is received in the community.

The common thread through all participating communities was that pharmacists and patients were integrated into the care team and clinical progress was quantified and recorded. As members of the team, pharmacists educated patients on the pathology of diabetes and how medications work to improve health; taught insulin injection techniques and the importance of medication adherence; promoted healthy lifestyles; and reinforced health goals and monitored progress toward those goals.

In addition to involving one-on-one consultations with pharmacists, local care models varied in their inclusion of such offerings as group educational classes, grocery store food tours, exercise programs, joint visits with patients by a combination of providers (e.g., pharmacists, physicians, dietitians, nurse practitioners), and a variety of patient incentives (e.g., bus passes, grocery store gift cards, discounted or free healthy lunches at

employer worksites, discounted copayments for antidiabetic medications and supplies). Specific information about the composition of the health care teams and how pharmacists were integrated into the different communities is available at www.projectimpactdiabetes.org and included in a companion article in this issue of *JAPhA*.[18]

Changes in clinical performance measures were assessed at baseline and then according to practice guidelines for a period of 1 year. For an individual patient's data to be included in the project evaluation, a minimum of two documented postenrollment visits at least 90 days apart was required. Clinical measures included hemoglobin A1C, body mass index (BMI), systolic/diastolic blood pressure, low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C), total cholesterol, and triglycerides. Each patient was also assessed on key process measures for the care of patients with diabetes, including foot examination status, eye examination status, influenza vaccination status, and smoking status.

At baseline, all enrolled patients completed the Knowledge Assessment from APhA Foundation's PSMP for Diabetes to gauge their knowledge strengths and areas for improvement.[19] Based on their answers to the 36-question assessment, patients earned achievement levels of "beginner," "proficient," or "advanced." Assessment responses were also used to help pharmacists and other providers customize patient education to meet individual needs.

A postproject survey was fielded to communities to collect information about the types of partnering health care workers, formalized collaborative relationships, and sustainability of the clinical services.

Data collection

The minimum data set was standardized across all 25 communities, and a common data collection tool was provided to streamline data organization and reporting. Community members were responsible for collecting the minimum data set elements through chart extraction, point-of-care testing, or other methods. Data were deidentified. Clinical changes from the baseline period to the 12-month intervention period, process measures, and patient self-management proficiency were assessed. Each patient served as his or her own control for comparative analyses.

Data analysis

Because of the many factors that influenced care delivery within each of the 25 communities, we believed that an analysis controlling for some of the major differences among participants would provide the most conservative and accurate determination of intervention impact. To shape the analysis, we assumed that study participants within a community who experience the same pharmacist interventions are likely more similar than participants from different communities. SAS Proc Mixed (SAS Institute, Inc., Cary, NC) was used to run

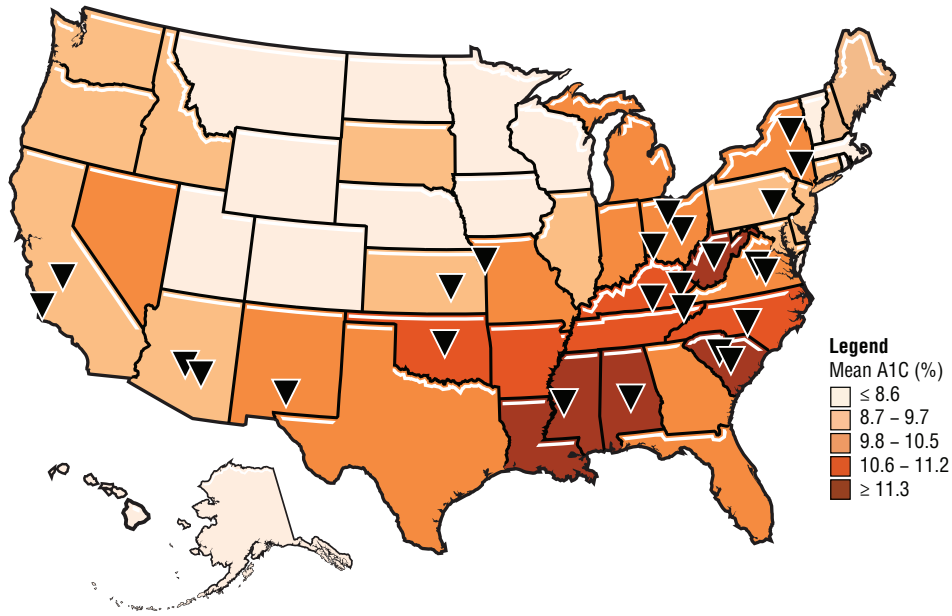

Figure 1. Distribution of Project IMPACT: Diabetes communities (▼) across states categorized according to mean glycosylated hemoglobin (A1C) values of residents with diagnosed diabetes

Source of A1C data: Centers for Disease Control and Prevention's Behavioral Risk Factor Surveillance System map for people who have been told they have diabetes.[17]

Table 1. Project IMPACT: Diabetes partnering organizations and communities

Community name/description	City	State
Appalachian College of Pharmacy Mobile health clinics, physician offices, and community pharmacies	Oakwood	VA
Ball's Food Stores and Deffenbaugh Industries Self-insured employer with supermarket pharmacy chain	Kansas City	KS
Central Ohio Diabetes Association Diabetes organization	Columbus	OH
Centro de Salud Familiar La Fe, Inc. Federally qualified health center[b]	El Paso	TX
County of Santa Barbara Public Health Department Department of health[b]	Santa Barbara	CA
CrossOver Healthcare Ministry Free clinic[a]	Richmond	VA
Daily Planet Free clinic	Richmond	VA
Eau Claire Internal Medicine and Cooperative Health Pharmacy Federally qualified health center[a]	Columbia	SC
Eau Claire Cooperative Health Centers Federally qualified health center[a]	Columbia	SC
El Rio Community Health Center Federally qualified health center[b]	Tucson	AZ
Fink's Pharmacy Independent community pharmacy	Essex	MD
Jefferson County Department of Health Department of health[a]	Birmingham	AL
Kroger Pharmacy, City of Cincinnati, and TriHealth Self-insured employer with supermarket pharmacy chain	Cincinnati	OH
Mountain States Health Alliance and Dispensary of Hope Federally qualified health center	Johnson City	TN
Ohio State University College of Pharmacy Medical clinic[a]	Columbus	OH
Paramount Farms and Komoto Pharmacy Self-insured employer with independent community pharmacy[b]	Lost Hills	CA
Pascua Yaqui Reservation of the El Rio Community Health Federally qualified health center	Tucson	AZ
Price Chopper Pharmacy Supermarket pharmacy chain	Schenectady	NY
University of Kentucky and St. Claire Regional Medical Center Self-insured employer with independent community pharmacies	Morehead	KY
University of Mississippi School of Pharmacy and Diabetes Care Group Physician office practice	Jackson	MS
Variety Care Federally qualified health center[b]	Oklahoma City	OK
West Virginia Health Right Free clinic	Charleston	WV
Wichita Public Schools and Dillons Pharmacy Self-insured employer with supermarket pharmacy chain	Wichita	KS
Wingate University School of Pharmacy Community pharmacies	Wingate	NC
Zufall Health Center Federally qualified health center[b]	Dover	NJ

[a]Mainly black population.
[b]Mainly Hispanic population.

hierarchical linear mixed models to handle the nesting of participants within communities. Additionally, observations (baseline and most recent) were made of the participants who were cared for by the organizations within those communities in this multilevel model.

We anticipated that health outcomes would change once participants had been exposed to the intervention and that there would be inherent differences among participants of the various knowledge groups as defined by the PSMP. The initial model included a fixed effect for time, a fixed effect for credential group, and an interaction between group and time. Because researchers expected there to be differences among organizations, random effects for time and intercept for each organization were also included in the model. Effect sizes were calculated using least-squares means for the effects of interest (time or credential) and the observed standard deviation of the total sample during baseline for between-group comparisons. Effect sizes within group comparisons were calculated for significant findings using the observed standard deviations and the estimated correlation between time points from the model.[20] The a priori level of significance was set at $P < 0.05$.

Results

The total engaged population comprised 2,280 patients who completed a knowledge assessment during the enrollment period and were aged 18 years or older. A total of 453 individuals (19.9%) withdrew from the project for various reasons; of those, 154 met the inclusion criteria (Table 2).

The total evaluable population comprised 1,836 patients from 25 communities. Table 3 provides a participant breakdown by demographics and proficiency level distributions of baseline self-management knowledge.

Patients had a mean of 5.2 visits with pharmacists, either one on one or in collaboration with other health care team members, with visits averaging 39.4 minutes in length (42.4 minutes for the first visit and 38.9 minutes for subsequent visits). The mean number of days enrolled in the program was 333 (SD = 109).

Clinical results for the evaluable population indicated that patients experienced significant improvements in key diabetes indicators. Matched baseline and final measures are in Table 4. Clinical results showed statistically significant and clinically relevant decreases in mean A1C of 0.8%. Other values fell by statistically significant amounts, but since their means were below target at baseline (ADA treatment goals for systolic blood pressure, diastolic blood pressure, LDL-C, and HDL-C were <140 mm Hg, <80 mm Hg, <100 mg/dL, and >40 mg/dL, respectively[21]), the decrements were not clinically relevant: LDL-C of 7.1 mg/dL, triglycerides of 23.7 mg/dL, and total cholesterol of 8.8 mg/dL.

A significant relationship was observed in the multilevel modeling between PSMP achievement level and A1C at baseline. Baseline A1C was 9.2% in the beginner group (n = 622), 8.9% in the proficient group (n = 721), and 8.8% in the advanced group (n = 324). During the study, A1C values decreased significantly ($P < 0.001$) by 0.9%, 0.8%, and 0.6% in the beginner, proficient, and advanced groups, respectively.

Process measures were also improved in the evaluable population during the evaluation period. Of the

Table 2. Patient withdrawal from program participation

Withdrawal situation	No. participants: Total population (n = 2,280)	No. participants: Evaluable population (n = 1,836)
Withdrew in first 90 days	126	5
Reasons for withdrawal		
Lost to follow-up	95	32
No longer covered by health plan	93	56
Moved or no longer had access to transportation	38	13
Personal reasons	37	9
Lacked motivation to continue	31	20
Unspecified	20	12
Did not want to comply with treatment requirements	13	7
Total withdrawals	453	154

Table 3. Participant demographics and baseline knowledge

Characteristics	Participants (n = 1,836) n (%) (unless otherwise noted)
Age (years), mean ± SD	54.1 ± 11.1
Race/ethnicity	
White	760 (41.4%)
Black	448 (24.4%)
Hispanic	394 (21.5%)
Native American	88 (4.8%)
Asian	15 (0.8%)
Pacific Islander	11 (0.6%)
Other	27 (1.5%)
Not specified	93 (5.1%)
Gender	
Women	1,050 (57.2%)
Men	786 (42.8%)
Baseline Knowledge Assessment[a]	
Beginner	679 (37.0%)
Proficient	802 (43.7%)
Advanced	355 (19.3%)

[a]Baseline Knowledge Assessment measured by Patient Self-Management Credential for Diabetes (Source: Reference 19).

Table 4. Mean clinical measures for participants in Project IMPACT: Diabetes[a]

Measure	Baseline LS mean (SE)	Most recent LS mean (SE)	Change	*P* value	Effect size (Cohen's d)[b]
A1C (n = 1,667) (%)	9.0 (0.1)	8.2 (0.1)	-0.8	<0.001	0.41
Body mass index (n = 1,701) (kg/m^2)	34.9 (0.3)	34.8 (0.3)	-0.1	0.097	
Systolic blood pressure (n = 1,713) (mmHg)	131.7 (0.9)	130.6 (0.9)	-1.2	0.254	
Diastolic blood pressure (n = 1,713) (mmHg)	78.9 (0.8)	78.2 (0.7)	-0.7	0.274	
LDL-C (n = 1,216) (mg/dL)	98.6 (1.6)	91.4 (1.5)	-7.1	<0.001	0.17
HDL-C (n = 1,285) (mg/dL)	43.6 (0.6)	44.2 (0.6)	0.6	0.164	
Triglycerides (n = 1,290) (mg/dL)	207.8 (9.4)	184.0 (8.8)	-23.7	<0.001	0.13
Total cholesterol (n = 1,299) (mg/dL)	179.4 (2.3)	170.7 (2.2)	-8.8	<0.001	0.20

Abbreviations used: A1C, glycosylated hemoglobin; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol; LS, least squares.
[a]Sample size varies among clinical measures based on number of patients with at least two data points ≥90 days apart.
[b]Cohen's original rules of thumb indicate that d = 0.2 is "small," d = 0.5 is "medium," and d = 0.8 is "large" (Source: Reference 20).

453 patients (39.9% of the total population) who did not have an eye examination on record at baseline, 51.7% completed one during the 12-month evaluation period. Of the 271 patients (21.5% of the total population) who did not have a foot examination on record at baseline, 72.0% had one completed during the project. Of the 307 patients (27.5% of the total population) who did not have an influenza vaccine on record at baseline, 41.7% received one during the 12-month evaluation period. Of the 270 patients who were smokers at baseline, 9.3% quit smoking during the project; 2.8% of documented nonsmokers regressed.

The postproject survey revealed that 417 health care team members participated in care delivery, including 126 pharmacists, 96 physicians, 37 nurse practitioners, 32 medical assistants, 22 dietitians, 21 patient/health advocates, 12 specialists, 11 social workers, 6 behavioral therapists, 6 physician assistants, and 48 other health care professionals. More than one-half (52%) of the 25 communities had collaborative practice agreements in place to facilitate interdisciplinary care.

Regarding the financial viability of services, 40% of communities indicated that pharmacists or pharmacies were compensated for the clinical services they provided. An overwhelming majority (92%) of communities indicated that they intend to sustain the Project IMPACT: Diabetes model or the services established through the project, with 14 of 15 respondents (93%) noting that reimbursement for pharmacists' clinical services would make the model more easily sustainable.

Discussion

The final results of Project IMPACT: Diabetes expand our understanding of the pivotal role pharmacists play on interdisciplinary diabetes care teams. The Asheville Project,[5] APhA Foundation's previous research on diabetes,[6–8] and similar studies conducted at universities, clinics, and health systems during the past decade[9–16] have all presented compelling cases for integrating pharmacists into the unique care teams of their study-specific populations. Project IMPACT: Diabetes is the first comprehensive, practice-based research initiative to demonstrate that pharmacists working in community-based diabetes care teams can significantly reduce A1C levels and other clinical markers of diabetes for patients of various economic, social, and insurance statuses in diverse communities across the United States.

Based on the settings in which care was delivered, the patient population engaged in Project IMPACT: Diabetes primarily comprised uninsured or underinsured individuals with access to safety net and free clinics. The patient population also included insured individuals such as schoolteachers and other educational staff, hospital personnel, city employees, sanitation engineers, and farm workers, among others. Regardless of insurance status, patients faced many barriers to affording and/or accessing routine diabetes care, including housing instability; food insecurity; limited access to consistent, reliable means of transportation; low literacy and health literacy; and/or inability to prioritize diabetes self-management in their daily lives. Ethnic, cultural, social, and economic diversity influenced the care that was delivered on a local level, as health care teams in each community customized their approach to be sensitive to the health beliefs and needs of their specific populations.

During the 1-year patient care period, patients visited their pharmacist an average of 5.2 times at an average of 39.4 minutes per visit, for a total average of 205 minutes (or nearly 3.5 hours) of pharmacist consultation. These visits, which were typically in addition to patients' routine appointments with other health care professionals, provided important opportunities for more customized education and personal support in effective diabetes management.

Pharmacists are highly accessible health care providers with practice locations in nearly every community throughout the country,[4] making them ideally positioned to provide services to all types of patients. The integration of pharmacists' patient care services within Project IMPACT: Diabetes care teams improved access

to care and facilitated a degree of health equity for patients receiving care within participating communities. For most disadvantaged individuals with diabetes, this type of care is not readily accessible in the current health care system.

The PSMP for Diabetes, which has been used in all previous APhA Foundation diabetes research, was employed to assist pharmacists in their initial assessment of patients and in determining the appropriate care strategy for individual participants.[18] Stratification of baseline A1C by achievement level in the multilevel modeling analysis revealed that a lower-credential achievement level predicts a higher baseline A1C. This psychometrically validated tool could be a valuable addition to diabetes care programs to stratify patients in the absence of A1C data, as well as to provide a mass customization approach when caring for populations of people with diabetes.

In addition to the statistically significant clinical improvement observed in this study, clinically relevant improvement was observed for A1C levels. According to CDC, every percentage point drop in A1C can reduce the risk of microvascular complications (eye, kidney, and nerve diseases) by 40%.[1] CDC also notes that comprehensive foot care programs can reduce the risk for costly amputations by 45%–85%.[1] In the present study, reduced risk of diabetes-related complications was noted for the 235, 194, and 170 patients who did not have eye examinations, foot examinations, or influenza vaccinations, respectively, at baseline but received them during the project, as well as for 26 people who quit smoking during the project.

The national aggregate data encompass local results that reflect varying implementation tactics employed by each community. Themes emerged across the communities that suggest core determinants of clinical and implementation success:

- Patient-centered collaboration among health care professionals
- Organizational buy-in for practice model change
- Individualized diabetes education based on PSMP results
- Accountability for patient success via outcomes monitoring, personal relationships with pharmacists, and adjustment of health care provider recommendations to address patients' specific barriers to success
- Customized incentive alignment for different populations, which may include reduced copayments; free medications or testing supplies; grocery store gift cards; transportation passes; or simply the ability to receive continuous care from an engaged health care provider
- Innovation driven by resource scarcity, with those communities with the fewest resources identifying and implementing innovative solutions to deliver high-quality care

Resource scarcity in the 25 communities is tightly coupled with the sustainability of pharmacists' services. With only 40% of communities able to incorporate reimbursement for pharmacists' services into their model, it would seem that resource scarcity (in the absence of continuing or new grant funding) would limit widespread ability to retain a pharmacist on the team. The model's lack of financial viability is primarily attributable to pharmacists' restricted compensation pathways for clinical and disease management services, which is due in part to their lack of recognition as providers in the Social Security Act.

An overwhelming majority (93%) of survey respondents believe that reimbursement would empower them to sustain the Project IMPACT: Diabetes model. Despite the questionable funding landscape, 92% of communities intend to sustain the services implemented as part of Project IMPACT: Diabetes because they believe the positive results warrant the added cost.

Limitations

The limitations of this research are rooted in three key areas: (1) lack of clinical relevance of the change in non-A1C clinical diabetes indicators; (2) variability of practice models and care delivery among the 25 communities; and (3) transience and poverty-related challenges of the diverse populations of patients in these disproportionately affected communities.

While improvements in LDL-C, triglycerides, and total cholesterol were statistically significant, they were associated with a small effect size. Additionally, a variety of factors may have influenced the ability to observe a statistically or clinically relevant response in clinical indicators other than A1C. Baseline mean measures for systolic blood pressure, diastolic blood pressure, LDL-C, and HDL-C were less than ADA treatment goals,[21] and this may have had an impact on clinical improvements. The 12-month study period may have been too short to observe a meaningful reduction in BMI. Health care teams encountered many patient barriers, including economic, social, and cultural factors, that interfered with patients' abilities to prioritize their health and focus on achieving broader health goals beyond blood sugar control.

Each community was encouraged to use or expand established interdisciplinary practice models or to develop new models to meet their unique needs and circumstances. As a result, wide variability exists among practices in how pharmacists interact with patients and health care team members. Additionally, variability in the types of patient and provider incentives employed across communities limits making comparative conclusions regarding the relative effectiveness of incentives.

Because of the patient barriers described above, 453 patients were lost to follow-up. Patients frequently missed appointments when they could not find or afford transportation. Addresses and contact numbers changed routinely for patients with transient living arrangements (e.g., moving among shelters and homes of family members) and disconnected phones. Future research that integrates transportation incentives and other proactive means for maintaining connection with patients at risk for homelessness or without reliable transportation could provide solutions and guidance generalizable to similar populations.

Conclusion

Project IMPACT: Diabetes enhanced patient-centered, team-based care delivery in 25 communities across the country that were underserved or disproportionately affected by diabetes. Employing the proven collaborative care model developed and used by APhA Foundation for 15 years, a team of providers that included pharmacists cared for patients with diabetes in these communities, enabling them to become better informed about their diabetes, learn how to self-manage their condition, and ultimately improve key clinical outcomes. These improvements, including a statistically significant and clinically relevant decrease in A1C levels, demonstrate that patients with diabetes may improve their overall health and potentially reduce their risk of major complications associated with the disease when they partner with their pharmacist for care.

The results from Project IMPACT: Diabetes were observed across diverse practice settings, including self-insured employer settings, free clinics, federally qualified health centers, community pharmacies, physician offices, and other organizations. The study results show that pharmacist patient care services within community-based diabetes teams can improve the health of a diverse population of patients. Pharmacists are available in nearly every community across the United States and are therefore ideally positioned for integration into health care teams that help patients manage chronic diseases such as diabetes.

References

1. Centers for Disease Control and Prevention. National diabetes fact sheet, 2011. www.cdc.gov/diabetes/pubs/pdf/ndfs_2011.pdf. Accessed June 12, 2013.
2. American Diabetes Association. Fast facts: data and statistics about diabetes. http://professional.diabetes.org/admin/UserFiles/0%20-%20Sean/FastFacts%20March%202013.pdf. Accessed June 12, 2013.
3. American Diabetes Association. Standards of medical care in diabetes—2013. Diabetes Care. 2013;36(Suppl 1):S11–S66.
4. National Association of Chain Drug Stores (NACDS). 2011–2012 chain pharmacy industry profile. Alexandria, VA: NACDS;2011.
5. Cranor CW, Bunting BA, Christensen DB. The Asheville Project: long-term clinical and economic outcomes of a community pharmacy diabetes care program. J Am Pharm Assoc. 2003;43(2):173–184.
6. Garrett DG, Bluml BM. Patient self-management program for diabetes: first-year clinical, humanistic, and economic outcomes. J Am Pharm Assoc. 2005;45(2):130–137.
7. Fera T, Bluml BM, Ellis WM, et al. The Diabetes Ten City Challenge: interim clinical and humanistic outcomes of a multisite community pharmacy diabetes care program. J Am Pharm Assoc. 2008;48(2):181–190.
8. Fera T, Bluml BM, Ellis WM. Diabetes Ten City Challenge: final economic and clinical results. J Am Pharm Assoc. 2009;49(3):383–391.
9. Iyer R, Coderre P, McKelvey T, et al. An employer-based, pharmacist intervention model for patients with type 2 diabetes. Am J Health-Syst Pharm. 2010;67(4):312–316.
10. Ip EJ, Shah BM, Yu J, et al. Enhancing diabetes care by adding a pharmacist to the primary care team. Am J Health Syst Pharm. 2013;70(10):877–886.
11. Johnson KA, Chen S, Cheng IN, et al. The impact of clinical pharmacy services integrated into medical homes on diabetes-related clinical outcomes. Ann Pharmacother. 2010;44(12):1877–1886.
12. Jameson JP, Baty PJ. Pharmacist collaborative management of poorly controlled diabetes mellitus: a randomized controlled trial. Am J Manag Care. 2010;16(4):250–255.
13. Morello CM, Zadvorny EB, Cording MA, et al. Development and clinical outcomes of pharmacist-managed diabetes care clinics. Am J Health Syst Pharm. 2006;63(14):1325–1331.
14. McCord AD. Clinical impact of a pharmacist-managed diabetes mellitus drug therapy management service. Pharmacotherapy. 2006;26(2):248–253.
15. Wallgren S, Berry-Caban CS, Bowers L. Impact of clinical pharmacist intervention on diabetes-related outcomes in a military treatment facility. Ann Pharmacother. 2012;46(3):353–357.
16. Simpson SH, Majumdar SR, Tsuyuki RT, et al. Effect of adding pharmacists to primary care teams on blood pressure control in patients with type 2 diabetes: a randomized controlled trial. Diabetes Care. 2011;34(1):20–26.
17. Centers for Disease Control and Prevention. Behavioral Risk Factor Surveillance System survey data, 2011. http://apps.nccd.cdc.gov/gisbrfss/map.aspx. Accessed December 6, 2013.
18. Watson LL, Bluml BM. Integrating pharmacists into diverse diabetes care teams: implementation tactics from Project IMPACT: Diabetes. J Am Pharm Assoc. 2014;54:538–541.
19. American Pharmacists Association Foundation. Patient Self-Management Credential. www.aphafoundation.org/patient-self-management-credential-project. Accessed February 7, 2014.
20. Cohen, J. Statistical power analysis for the behavioral sciences. 2nd ed. Hillsdale, NJ: Lawrence Erlbaum Associates;1988:25.
21. American Diabetes Association. Standards of medical care in diabetes—2014. Diabetes Care. 2014:37(Suppl 1):S14–S80.