MEDSTAR HEALTH RESEARCH AND DIABETES INSTITUTES

MedStar Diabetes Pathway Ongoing Chart Review Protocol

Michelle Magee, MD Principal Investigator

Sub-Investigators
Alex Montero MD, MPH
Debra Thayer, CRNP, CDE
Maranda Jackson-Parkin, PhD, CRNP
Mihriye Mete, PhD

Gretchen Youssef, MS,RD, CDE and Carine Nassar, MS,RD, CDE
Program Managers

June 1.2016

MedStar Diabetes Pathway Ongoing Chart Reviews

I- Background.

The MedStar Diabetes Pathway (MDP) early pilot program has generated evidence that an innovative technology-enabled "Boot Camp" approach to the delivery of diabetes survival skills education and medication management has a significant impact on glycemic control and healthcare utilization measures. The MDP is a 12 week Diabetes "Boot Camp" technology-enabled intervention which will offer learner-centered survival skills self-management education (DSSE) and algorithm-driven diabetes medications (DM) titration by Endocrinologist-supervised Certified Diabetes Educators (CDE), NPs and PharmDs. The program has been offered at 5 MedStar Medical Group (MMG) Primary Care Practices in FY 15-16 to high risk adults with uncontrolled type 2 diabetes who have a hemoglobin A1C (A1C) level -a marker of average blood glucose (BG) levels in the 2-3 months prior to the time the test is done- which is at or above 9% - considered to be poor control, and 1 or more additional risk factors for poor health outcomes. The program has been well received by MedStar Primary Care Providers and their diabetes patients.

Patients who consent to join the program attend two 1:1 visits with a CDE followed by "virtual" visits via telephone/texting. DSSE is tailored to baseline DM knowledge and medication adherence deficits. An FDA cleared cellular-enabled blood glucose (BG) monitoring system (Telcare BGM®) auto- transmits BGs to a provider dashboard in near-real-time. The CDE reviews BGs and contacts patients at minimum weekly to discuss and make adjustments to DM medications and/or lifestyle, until BG targets are reached. The patient then returns to his/her Primary Care Provider (PCP) with any further ongoing DM management recommendations.

Ninety-eight (98) patients with uncontrolled type 2 diabetes have completed the MedStar Diabetes Pathway Boot Camp. A1C, a measure of average blood glucose control over the 2-3 months prior to the test being done, was checked at baseline and then after 3 months follow-up. Admissions and resource utilizations were measured for the period 6 months before baseline and then recorded between baseline and 3 months and between 3 months and 6 months. For comparison of A1C improvement, patients were matched to controls at a 1:3 ratio on age, sex, race/ethnicity, insurance group, and baseline A1C. The difference in improvements of A1c between a case and its matched control was tested. Utilization has not yet been captured for controls.

Clinical and Health Resources Utilization Outcomes.

- **A1C Performance**.

Blood glucose control improvement, as measured by change in A1C results is shown below.

Table 1: Change in A1C

	Boot Camp Cases	Control Cases	P value
Baseline A1C (%)	11.35 (1.86)	11.41 (1.71)	0.439
3 month A1C (%)	8.31 (1.52)	9.77 (1.98)	<0.001
Change in A1C (%)	-3.08 (2.01)	-1.64 (1.97)	<0.001
Percent A1C lowering	27%	14%	

The 3.08 % lowering of A1C among Boot Camp patients is highly clinically important. In comparison, most drug trials where A1C lowering is measured, there is typically reduction in A1C of 0.5-1.5% depending upon the drug or drugs being tested[1]. Furthermore, a 1% absolute reduction in A1C can be correlated with an approximately 15% reduction in risk for myocardial infarction[2]. The fact that lowering in A1C was also seen among control cases is not completely unanticipated. Per current standard care, when a patient presents with a markedly elevated A1C the physician caring for him/her would implement measures to help improve control which explains the concurrent fall in A1C over time. These results show that the Boot Camp intervention effectively doubled A1C lowering when compared to controls.

- **Health Resource Utilizations.**

Utilization for urgent care visits, urgent PCP visits, hospitalizations, and Emergency Department (ED) visits due to diabetes, taken in the 6 months before the listed time is shown in Table 2.

Table 2. Health Resource Utilizations

	Baseline (n)	3 months		6 months		
	Number	Number	% Reduction	Number	% Reduction	P value
Urgent Care Visits	3	0		0		0.109
Urgent PCP Visits	13	1	91%	1	92%	0.002
Hospitalizations	9	1	88%	3	66%	0.207
ED Visits	18	1	94%	2	88%	<0.001

There is an association between time and urgent PCP visits and ED visits. This means that for those patients enrolled in the program there appears to be a reduction over time in urgent PCP visits and ER visits following program completion. The number of hospitalizations was low overall and does show a trend for reduction over time.

Summary of Findings.

This pilot evidence demonstrates a significant impact on glycemic control and healthcare utilization measures as the result of a concise, focused DM education and medication management intervention.

Phase 2.0 MedStar Diabetes Pathway Expanded Pilot

Building on the success of the MDP Phase 1.0 pilot, the next steps in expanding the program will be as follows:

- **Transition** of the Pathway from early feasibility pilot to the next phase as an expanded pilot program integrated within the MedStar Health System care delivery network and built upon a sustainable infrastructure (brick and mortar –plus- virtual components) across early adopter MMG practice sites.
- **Expand recruitment** to include high risk patients with uncontrolled type 2 diabetes, including those with a new diagnosis and A1C >9%, who have MedStar Emergency Department and/or Inpatient encounters
- **Spread** to additional targeted MedStar Medical Group (A&B) Primary Care Practices and/or to MedStar Managed Care Plan participants (MedStar Family Choice, MedStar Select)

As the MDP is transitioning into a clinical program offered at various MedStar sites, the MDP clinical team is reviewing the data collected during the pilot to improve the program and adapt it to various clinical settings in order to better serve the target patient population. It will be imperative to continue reviewing patient clinical outcomes as the program expands in order to insure continuous quality improvement of the program. This will be achieved through chart reviews of patients receiving diabetes care via the MDP.

III- Chart Review and Data Collection

MDP patients' chart review:

MDP target population:

Inclusion Criteria

- Active and established patient of a MedStar Medical Group Ambulatory Primary Care practice provider:
- Diagnosis of type 2 diabetes on EMR problem list for ≥1 year
- New diagnosis of type 2 diabetes with A1C≥9
- Active practice patient as evidenced by one or more visits to PCP in the past 12 months
- Age ≥ 21 to < 75 years
- A1C ≥ 9.0% at their last visit to MedStar Medical Home, ED or hospital admission.
- Primary Care Provider willing to have patient enter the program
- Patient is able and willing to participate in the program
- Proficient in English

-AND- one or more of the following high risk characteristics:

- Acute care encounter(s) including) ED visit(s) or hospital admission(s) in the past year with uncontrolled diabetes (BG> 200mg/dL or A1C >9%; severe hypoglycemia = BG <40mg/dL requiring assistance to treat)
- Evidence of low medication adherence as evidenced by no refills since one or more prescribed DM RXs "ran out" (based on last Rx for each DM med and time period was prescribed for on EMR/SureScripts medications list); or any other circumstance that has

been identified by the health care team which indicates poor adherence to prescribed medication.
- Does not meet HEDIS diabetes measures for two or more of: no MA/Cr, no DM retinal exam, no lipid profile
- SBP $\geq$140 mmHg
- LDL$\geq$100 mg/dL
- Depression diagnosis on problem list *(or depression medication on med list)*
- BMI >32

Exclusion Criteria

- Known history of DKA
- No MedStar PCP visit within past 12 months
- Endocrine or Diabetes Education consult referral order in the past 6 months which resulted in Endo visit(s) or DSME visit(s) documented in chart or self-reported by patient during initial screen
- Active additional medical issues which in the opinion of the care team would preclude concentrating on BG control and/or would predispose to ED visits and/or hospital admits independent of glycemic control, e.g.: severe CHF, severe COPD; severe mental illness.
- Resident of skilled nursing facility, nursing home or receiving home health care services.
- Active cancer in the preceding 3 years excluding nonmalignant basal cell cancer
- Supraphysiologic doses of glucocorticoids (hydrocortisone > 30mg/day; prednisone > 5-6mg daily; dexamethasone > 2mg daily).
- Pregnant or anticipates attempting conception in the following year
- Patient and/or custodial caregiver unwilling and/or unable to participate in program-related activities

The following data will be collected retrospectively from the charts of patients that complete the MDP.

- Demographics
- A1C baseline, at 3 month after baseline visit to assess impact of the pathway.
- Hypoglycemic events (BG<70 and <40) during the 6 months of enrollment in MDP
- Diabetes 2 go Knowledge test
- ED and hospital visits in 30 days and 90 days prior to and after the boot camp
- Referring MedStar Provider satisfaction with intervention
- Patient satisfaction with the MDP

In addition, the clinical team will also compare the clinical and utilization outcomes of patients enrolled in the MDP with those of a randomly selected control group consisting of MedStar

patients with elevated A1C levels. This will be done to allow a better assessment of the impact and effectiveness of the MDP.

Once the data is obtained, it will be de-identified prior to data analysis and reporting. Demographics will be reported as a group, i.e. percentage of patients within a certain age group or geographic area or with a certain type of insurance to insure equal access to the MDP, and help recruit underrepresented groups so they can also benefit from the program.

Data Management

The MedStar Health Research Institute will provide data management services for all aspects of the chart review process, including preparation of the program REDCap database, quality checks of data and developing processes for bringing data into REDCap from available data sources held by system partners which will be leveraged for the program. All data will be de-identified prior to presentation to the Biostatician for analysis.

Data Analysis and Reporting Plan

Data analysis will be performed by the MHRI Biostatistician. All data will be de-identified prior to submission to the biostatistician for analysis. Results will be reviewed for quality improvement purposes and will also be presented at national meetings. Additionally, one or more manuscripts will be prepared for submission to peer-reviewed journals.

References

1- Management of Hyperglycemia in Type 2 Diabetes: A Patient-Centered Approach Position Statement of the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD)**.** Silvio E. Inzucchi, MD,[1] Richard M. Bergenstal, MD,[2] John B. Buse, MD, PHD,[3] Michaela Diamant, MD, PHD,[4] Ele Ferrannini, MD,[5] Michael Nauck, MD,[6] Anne L. Peters, MD,[7] Apostolos Tsapas, MD, PHD,[8] Richard Wender, MD,[9] and David R. Matthews. Diabetes Care. 2012 Jun; 35(6): 1364–1379.

2- Turnbull FM, Abraira C, Anderson RJ, Byington RP, Chalmers JP, Duckworth WC, et al. Intensive glucose control and macrovascular outcomes in type 2 diabetes. Diabetologia 2009;52:2288–2298.