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Rationale, design, and implementation of a cluster randomized trial using certified diabetes educators to intensify treatment for glycemia, blood pressure and lipid control: REMEDIES *4D*

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ABSTRACT

Background: Evidence supports that adequate treatment of hyperglycemia, hypercholesterolemia, and hypertension can reduce morbidity and mortality in people with diabetes, however achieving treatment goals remains elusive. The majority of diabetes care occurs in the primary care setting; however there are often missed opportunities for timely intervention during office visits. This paper describes a systematic redesign of current diabetes treatment in primary care by implementing evidence-based protocols.

Materials/methods: This is a cluster randomized controlled trial using certified diabetes educators (CDEs) to intensify therapeutic management. Fifteen primary care practices from the University of Pittsburgh Medical Center were recruited. Practices were randomized to intervention (implementation of diabetes management protocols) or usual care. Eligibility criteria included diagnosis of type 2 diabetes at least one year prior to baseline and an A1C $\geq$7%, LDLc $\geq$100 mg/dl or blood pressure $\geq$130/80 mm Hg which were the goal levels established by the American Diabetes Association at study inception. Treatment was intensified according to preapproved protocols. Participants also received diabetes education during their visits. Research assessments were done at baseline, three, six and twelve months. Clinical visits were scheduled between research visits, as needed, to adjust medications. Primary outcomes were achievement of glycemic, blood pressure, or lipid control goals. Secondary outcomes included quality of life, medication and diabetes care satisfaction, medication adherence, and cost-effectiveness.

Conclusions: Results from this study will provide the evidence to support expanded roles for CDEs in primary care. Using this model to deliver diabetes care may offer a more cost-effective approach for diabetes management.

1. Introduction

Approximately 29.1 million Americans are living with diabetes [1], and this number is expected to soar to 48.3 million by 2050 [2]. As the prevalence of the disease rises, the incidence of diabetes complications [3] will likewise escalate under the current acute care model for disease

Abbreviations: NDMP, nurse directed management protocols; CDE, certified diabetes educator; REMEDIES *4D*, REdesigning MEDication Intensification Effectiveness Study for Diabetes.

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management. Since diabetes is a progressive disease [4], those who currently have diabetes will require more resources from an already burdened health care system. A new effective and efficient model for diabetes care is needed to manage the increased disease burden.

Evidence supports that adequate treatment of hyperglycemia [4,5], hypercholesterolemia [6–9] and hypertension [10,11] can reduce the incidence of diabetes complications and is cost-effective or even cost-saving [12], yet achieving treatment goals remains elusive. Access to care does not appear to be the major barrier but rather a result of missed opportunities for timely intervention during office visits. This is known as clinical inertia, which is a failure to initiate or titrate therapy when indicated [13], or failure to perform a needed service [14,15]. Efforts to understand this phenomenon showed that approximately 75% of clinical inertia could be attributed to the physician [16]. Given the multitude of tasks that need to occur in a time-constrained primary care visit, enhancing the roles and responsibilities of other team members to support primary care providers may offer a solution.

The American Diabetes Association Standards of Care recommend goals of A1C less than 7%, blood pressure less than 140/80 mm Hg, and LDLc less than 100 mg/dl [17] however, only one in five adult diabetes patients are controlled to these levels [18]. Successful diabetes care demands attention to a multitude of preventive care services and self-management requirements that cannot be addressed during a brief office visit. A health care model emphasizing planned care, with a focus on preventive practices and appropriate evidence-based treatment for risk factors, as well as addressing psychosocial and self-management needs is essential.

According to the comparative effectiveness recommendations from the Institute of Medicine, examining redesign strategies is a health care system priority topic, as is comparing the effectiveness of using allied health providers for chronic conditions [19]. Existing studies primarily focus on nurse case management where nurses facilitate or coordinate care to help the patient achieve the best outcomes [20–22]. These nurses, however, are seldom empowered to make therapeutic changes. A recent review showed that diabetes management independently directed by nurses or pharmacists using evidence-based treatment protocols significantly improved the levels of glucose, lipids and blood pressure [23]. This report describes the design and implementation of a certified diabetes educator (CDE)-driven model for intensifying treatment of glucose, blood pressure, and lipid control for patients with type 2 diabetes using evidence-based treatment protocols in community-based primary care practices.

2. Material and methods

2.1. Study design

This effectiveness trial, REdesigning MEDication Intensification Effectiveness Study for Diabetes (REMEDIES *4D*), began in January 2012, with recruitment completed in February 2014. Follow-up is currently underway. REMEDIES *4D* is a multi-practice, cluster-randomized controlled trial [24,25], evaluating the effectiveness of implementing standardized protocols on patient outcomes compared to usual diabetes care in primary care practices. The one-year intervention implemented diabetes management protocols modified and updated from the "Diabetes Disease Management Program for Registered Nurses" by Davidson et al. at Charles R. Drew University [26]. In REMEDIES *4D*, trained CDEs deliver diabetes care and implement treatment intensification, following detailed approved protocols and algorithms [26]. The University of Pittsburgh Institutional Review Board approved the study.

2.2. Practice recruitment

Eligible primary care practices were owned by the University of Pittsburgh Medical Center, and included primary care (internal, general, or family medicine) practices with at least fifty people with diabetes. All practices had an electronic medical record. The process of practice recruitment is pictured in Fig. 1. The medical director who oversees these practices (FS) made the initial contact with thirty-four practices via email in January 2012, providing information about REMEDIES *4D*. Meetings were scheduled to discuss the study and to obtain informed consent from providers. The principal investigator, CDEs and study coordinator met with the physician(s), office managers, and office staff. If the practice was interested, the informed consent was reviewed and signed by all physicians in the practice. Following consent, practices were stratified into three groups according to the number of people with diabetes in the practice (under 200, 200–500, greater than 500). Practices were then randomly assigned, by flip of a coin, to either intervention or usual care. We used the practice size to account for the number of people with diabetes in the practice so that a more balanced patient recruitment could be achieved.

The goal was to recruit twenty practices. As practices refused, other practices were sent invitations to participate. Fifteen practices agreed to participate in the study. In total, 59 providers were recruited from 15 practices (57 physicians and 2 physician assistants). Three of the practices were in urban settings with the remainder in the suburbs. All but one practice and two or more providers (range 2–11, average 4 per practice). Two-thirds of the practices had nursing staff, while all practices had medical assistants, clerical support and access to a case manager from a local health plan. Prior to the study, there were no CDEs working in the practice, although certified diabetes education programs were available at local hospitals.

2.3. Sample size

Sample size estimates were calculated using PASS 10.0 [27] and incorporated the multi-level cluster design of the study. Estimations were based on the mean difference in A1C of 1%, LDLc of 20 mg/dl, and systolic blood pressure (SBP) of 5 mm Hg between the two study groups. Four parameters were used in sample size estimation at alpha of 0.05 (two-sided) and beta of 0.2, including 1) the number of clusters/practices per group, 2) the difference between the group mean levels, 3) the intracluster correlation coefficient (ICC), and 4) the standard deviation. Usually, values of an ICC