NATIONAL ADVISORY COUNCIL
CONCEPT CLEARANCE

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Title of Initiative: Comprehensive Care for Adults with Type 2 Diabetes Mellitus from Populations Experiencing Health Disparities

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Objectives: This initiative will support research to develop and test multi-level strategies to effectively implement recommended guidelines of comprehensive clinical care for individuals with Type 2 diabetes from populations experiencing health disparities and optimize patient engagement and self-management.

Background: Current national statistics reveal an overall prevalence of diabetes mellitus (all types) at 14.3% of the population [1]. The prevalence of diabetes mellitus among racial/ethnic minorities has consistently been significantly higher (more recently in the 20.6%-23.5% range or 2-3 times higher) than that of non-Hispanic Whites (NHWs) (11.3%), and is on the rise [1,2]. In addition, the prevalence of self-reported diabetes mellitus in rural areas is 17% higher than in metropolitan areas [3,4], 20-55% higher in SGM than non-SGM individuals [5,6], and inversely associated with income and socioeconomic status [1,7,8].

Although Type 2 diabetes (the most common form of diabetes mellitus) is strongly associated with cardiovascular (CV) complications (coronary artery disease, peripheral vascular disease, stroke and cardiomyopathy), it is also associated with long-term microvascular diseases (retinopathy, nephropathy), neuropathy, and others (e.g., hypoglycemia, infections, and pregnancy-related complications). Over the last decade, the association of diabetes with cognitive decline [9-11] and cancer [12-16] has gained attention. Therefore, comprehensive diabetes care guidelines for optimal glycemic control and prevention of complications have been established and are annually updated [17-26].

The limited existing data on diabetes-related complications in U.S. populations with health disparities point towards a significant risk and burden of complications. For instance, African Americans have four times, and Asians and Pacific Islanders have 1.5 times increased risk for diabetic retinopathy (DR) than NHWs. Individuals from rural settings may have 21% greater risk of DR than those living in urban settings [4]. The prevalence of DR in Hispanics/Latinos could be up to 46.9% and for American Indians/ Alaska Natives 45.3% [4]. The NHANES trends during 1988-2010 showed that the percentage of African Americans, Mexican Americans and other Hispanics with hemoglobin A1c (A1C) <7% or <8%, or blood pressure 130/80 or <140/90, or LDL <100 mg/dL and/or on statin therapy, was significantly lower than NHWs [27]. Hispanic/Latinos, African Americans and American Indians/Alaska Natives have 1.3-1.5 times risk for major amputations than NHWs [28], and Medicaid beneficiaries have 21.1-25.1% increased odds of having major or minor amputations compared to Medicare beneficiaries [29]. On the other hand, African Americans and Hispanics/Latinos are 20-30% more likely to receive endovascular interventions or open bypass than NHWs, whereas American Indians are 40% less likely to receive either treatment [28].

In 2017, the American Diabetes Association reported that the U.S. annual cost of diabetes management totaled $317 billion, which was attributed to $237 billion in health care costs and $90

billion in costs due to lost productivity [30]. Diabetes-related health care costs are mostly driven by hospitalizations [31-34], most of which are considered preventable [31,32,35,36]. Some racial/ethnic minority populations experience significantly increased odds for preventable hospitalizations [31,32,35,37], including higher than expected 30-day readmission rates for African Americans and Hispanics [31,35].

Completion rates of all or some of the recommended clinical assessments for persons with diabetes (e.g., A1C/lipid/blood pressure targets, annual retinal exam, foot exam, urine albumin and estimated glomerular filtration rate, influenza/pneumonia vaccines and others) [17-26] tend to be 10-30% lower for racial/ethnic minority populations than for NHWs [38-40]; 17% in rural settings [3] and 7-11% in the U.S. territories Puerto Rico, USVI and Guam [40]. These lower completion rates may in part explain the increased odds for preventable hospitalizations and readmissions mentioned above.

Patient-centered models of care, like the chronic care model (CCM), have been recommended as effective frameworks for optimal diabetes care [18,26,41-43]. The six elements of the CCM [20,41,42] include community resources/built environment (including policies), health care organization (quality-oriented culture), clinician decision support, clinical information system, patient self-management support (e.g., decision-making support, patient-clinician communication, patient-reported outcomes), and delivery system design (team-based, coordinated and proactive care). This framework has been expanded to address primary prevention of diabetes and incorporate future research into clinical practice [43].

Research Gaps: The implementation and effectiveness of the full CCM -or some variations- in the management of Type 2 diabetes has been studied in different populations and settings in the U.S. [42,45-55]. Significant improvement in clinical outcomes [42,45-48,55], cardiovascular risk score [47,48], and completion rates of recommended tests [50,53] have been demonstrated. At the same time, some studies have demonstrated improvement in glycemic control with the integration of cultural competence at the self-management [55] and community resources levels [48], but no consistently observed improvement with interventions at the delivery system level [48,55], low adherence at the clinician decision support level [49], and lack of effectiveness at the clinical information level [51]. In some of these studies, the percentage of patients from racial/ethnic minority groups ranged between 1% and 13% [44,45,47], and very few studies were dedicated to developing and testing the CCM or similar models of diabetes care for populations experiencing health disparities [46,53-55]. Among the latter, significant improvement in A1C, blood pressure, lipids and ACEI/aspirin/statin intake were observed among uninsured patients attending an acute care setting, most of whom were from racial/ethnic minority populations [46]. Other studies have evaluated culturally-tailored community-engagement interventions for Latinos without linking them to the health care system or clinician [53-55], primarily focusing on the self-management element.

Effective implementation of and adherence to recommended guidelines of care [e.g., assessment of risk of diabetes-related complications, setting optimal glycemic goals and control of CV risk factors, designing a treatment plan, medical/dental/nutritional referrals, immunizations and other preventive services] is urgently needed for individuals with diabetes from populations experiencing health disparities. Effective strategies would be expected to impact health across all populations in a positive way, while potentially generating new information and research hypotheses on treatment effectiveness and precision medicine.

Previous and ongoing NIH efforts in this area: The NIDDK has established the NIDDK Diabetes Centers program, which does not directly fund major research projects. The proposed initiative does not represent an overlap with this NIDDK program. The NIDDK has also issued the funding opportunity announcements (FOAs) *Evaluating Natural Experiments in Healthcare to Improve Diabetes Prevention and Treatment* (PAR-17-178), and *Addressing Health Disparities in NIDDK Diseases* (PA-18-412). The former FOA does not focus on the implementation and testing of health care delivery. Under the latter FOA no studies involving disparities in the implementation or comparative effectiveness of recommended diabetes care guidelines have been funded.

Other FOAs addressing implementation of health care delivery or promotion of patient adherence to treatment include: *Improving Patient Adherence to Treatment and Prevention Regimens to Promote Health* (PA-18-722), *AHRQ Health Services Research Demonstration and Dissemination Grants (R18)* (PA-18-793), and *Dissemination and Implementation Research in Health* (PAR-19-274). None of these initiatives specifically looks at research in the implementation of diabetes care guidelines.

Description of the Initiative: This initiative will support innovative multidisciplinary and multi-level research designed to develop and/or test interventions to optimize Type 2 diabetes care for populations experiencing health disparities concordant with evidence-based guidelines. Proposed projects would be expected to develop and/or test patient-centered strategies, which in addition to optimal glycemic control, would aim at completing other recommended guidelines (e.g., annual eye/foot and urine albumin exam, optimal blood pressure control, intake of ACEI/statin/aspirin and influenza/pneumonia vaccines). The effect of the implementation of these strategies and guidelines on quality of life, optimal care of comorbidities, and prevention of short- and long-term complications, including hospitalizations, are also of interest.

Areas of interest and potential study designs include but are not limited to:

- Multi-level interventions that promote a proactive care delivery (consider health IT and comorbidities) – Identify intermediate factors that mediate or contribute to health or effectiveness of treatment outside of the clinical setting
- Interventions involving clinician decision support, adherence to recommended guidelines, patient/family unit decision-making, and adherence to treatment and self-management (especially for older adults)
- Innovative multi-level strategies to implement guidelines of care within the context of challenging housing- and/or work-related conditions or settings
- Health care coordination between traditional and non-traditional health care settings (e.g., pharmacies, fire stations, other community resources)
- Studies that evaluate the effectiveness of individualization of guidelines of care based on age (e.g., older adults), sex/gender, race/ethnicity, urban/rural settings, pregnancy status, comorbidities, and state of progression of the disease, including prioritization and integration of guidelines of care in the context of comorbidities
- Studies that address implicit bias strategies/practices across different levels in the health outcomes/care continuum
- Analyses and sub-analyses on sustainability, actual and/or projected health care costs, and prevention of hospitalizations and other complications. In addition, analyses of costs of interventions could assess the costs and access of medications, health care payer policies, health

insurance and health care system protocols and processes, availability of subspecialty care, and payment models.

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