

# NIMHD NATIONAL ADVISORY COUNCIL CONCEPT CLEARANCE FORM

**Council Date:** September 9-10, 2021

**Title of Initiative:** Innovative Health Care Models for Persons with Multiple Chronic Conditions from Populations that Experience Health Disparities

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**Objective** This initiative will support innovative, collaborative, and multidisciplinary research designed to study the effective integration and implementation of recommended guidelines of care and their impact on health outcomes of persons with multiple chronic conditions (MCCs) from populations that experience health/health care disparities. Projects would be expected to involve more than one component and/or more than one level of influence—based on [NIMHD Research Framework](#)—within existing health care models or through newly proposed health care models.

**Background** The increasing prevalence of U.S. adults with chronic diseases has posed several clinical and public health challenges. In particular, the proportion of U.S. adults attaining treatment and control goals has been persistently lower among persons from populations that experience health/health care disparities. Among the U.S. population with chronic disease, the prevalence of those with MCCs has significantly increased among some racial/ethnic minority populations, especially among those aged 45-64 years [1-3], and could be twice as high among adults living in poverty [1]. In addition, the rate of preventable hospitalizations and visits to the emergency department related to specific chronic conditions [4-16], and to MCCs [17-21] tends to be higher among populations that experience health disparities, and especially for those without health insurance or optimal health insurance coverage [22], and some rural communities [23]. The significant costs associated with these preventable events deepens the financial hardship experienced by many of these patients and their families [24], which could also be experiencing disabling complications associated with MCCs.

Workgroups led by the IOM [25,26] and HHS [27] have identified challenges associated with the attainment of recommended care goals for persons with MCCs, including: delivery system issues (for example, lack of or suboptimal care coordination and subspecialty referrals) [25-32]; limited understanding on the best integration or prioritization of guidelines of care within the context of coexisting conditions or risk factors, and the risk of polypharmacy and undesirable adverse events [27-29, 32]; patient-centered priorities (for example, patient's expected outcomes, quality of life, out-of-pocket affordability) [29]; and payment/reimbursement issues (for example, lack of reimbursement for some services). Also, the exclusion of persons with MCCs from clinical trials precludes the generation of necessary evidence that would inform the optimal integration of new treatments into real-life clinical settings [25-27]. At the same time, strategies to address these challenges, include "facilitating research to fill knowledge gaps," [27] "scaling up interventions that reach all people," and especially "disadvantaged populations disproportionately affected by chronic illness." [27,30]

Several health care models have been proposed that intend to incorporate broad approaches to the management of chronic diseases. The Chronic Care Model (CCM) [33] emphasizes on the assurance of productive interactions between the patient and the care team and proposes the integration of six elements—health care organization, community resources, patient self-management support, delivery system design, health care provider decision support, and clinical information system. The CCM catapulted the proposal of other health care models (for example, the eHealth Enhanced Chronic Health Care Model [34], the Community-Based Transition Model [35], the Model for Developing Complex Interventions in Nursing [36], the Home-Based Model [37], the Integrated Delivery Systems Model [38], Team-Based Care [39], Family Management Framework [40], and others [41-44]) in which components of the CCM have been expanded or enhanced. More recently, the Value-Based Care Model has gained increasing interest [45-47]. Some of these models—or interventions, in some of their components—have demonstrated improvements in disease-specific health outcomes or the facilitation of care coordination. Nonetheless, the impact of these models on attaining optimal control and prevention of complications associated with MCCs has not been fully tested or evaluated. Moreover, there has not been enough research evaluating the impact of these different health care models on health outcomes and health care costs for persons with MCCs from populations that experience health/health care disparities.

**Description of Initiative** As stated in the Objective, this initiative seeks to study the integration of guidelines of care for MCCs through interventions in existing or newly proposed health care models, and its impact on health outcomes in persons with MCCs from populations that experience health/health care disparities. This initiative in part parallels an active FOA presented to the NIMHD Council in February 2020 on Comprehensive Care for Adults with Type 2 Diabetes Mellitus from Populations with Health Disparities ([NOT-MD-20-026](#) and [PA-21-232](#)).

For the purposes of this Concept, chronic diseases of interest are those with the highest prevalence and/or greatest burden of morbidity, disability, and/or mortality in populations that experience health disparities. These include obesity, diabetes and its complications, cardiovascular diseases (including coronary artery disease, heart failure, peripheral

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vascular disease, and stroke), cardiovascular or cardiometabolic disease risk factors (e.g., hypertension, hypercholesterolemia/dyslipidemia, smoking, prediabetes), cancer and its complications, chronic respiratory diseases—especially chronic obstructive pulmonary disease and asthma—sleep disordered breathing, cognitive decline (including Alzheimer’s disease and related dementias), chronic liver disease and cirrhosis, chronic kidney disease (including end-stage kidney disease), substance use disorders, osteoarthritis, systemic lupus erythematosus and its associated complications, and mental health conditions (including anxiety and depression).

Although most studies on MCCs have focused on adults, some studies have highlighted the emerging needs of children with chronic diseases. Therefore, projects focused on children are also of interest.

The initiative will support interventions (especially multi-component or multi-level interventions), clinical trials (including cluster-randomized trials, pragmatic trials), quasi-experimental studies, natural experiments (e.g., impact of policy), mixed-methods, and evaluation of proposed strategies or health care models.

### **Research Priorities**

Areas of interest include but are not limited to:

- Multi-component, multi-level studies in existing models or in newly proposed health care models that explore the integration of guidelines of care and health outcomes based on:
  - Patients’ characteristics: age, sex/gender, race/ethnicity, pregnancy status, state of progression of the disease (e.g., newly diagnosed compared to advanced disease stage), and social determinants of health (e.g., as defined in the [Phen-X Toolkit](#)).
  - Health care settings’ characteristics: urban or rural location, resources, personnel.
- Clinician decision-making and/or health care system strategies on prioritizing or integrating guidelines of care.
- Research on strategies to integrate guidelines of care for patients at greater risk for non-adherence or adverse events, including persons with cognitive impairment, and/or complex illnesses and health regimens, and/or challenging housing or work-related conditions.
- Studies that test and evaluate hybrid health care models [for example, combination of health care setting and a non-health care setting (e.g., workplace), or group-based models of care (e.g., Centering Pregnancy)].
- Studies that test and evaluate strategies or models that promote proactive health care delivery and how this enhances patient self-management, timely continuity of care, patient/caregiver-clinician shared decision making, care coordination, medical specialty referrals and/or shared patient care in health care settings with limited resources and clinical personnel. The role of health information technology, including telehealth, in proactive health care delivery is of interest.
- Studies that identify and evaluate the impact of contextual factors outside of the clinical/health care settings on the effectiveness of models of care. Some of these contextual factors include:
  - Ongoing community interventions; community resources and services.
  - Transportation, housing, and other sectors.
  - Local, state, and federal health care and non-health care policies (e.g., laws/policies regarding insurance coverage, eligibility for services, workplace safety, sick leave).
- Studies that evaluate the impact of changes in individual health care insurance coverage on access to and affordability of needed pharmacotherapy and self-monitoring devices and supplies, utilization of and quality of health care services, timely evaluation by subspecialists, and other services.
- Research that tests and evaluates health care coordination between traditional and alternative settings (e.g., pharmacies, fire stations, other community resources) and its impact on utilization of and quality of health care services, and/or health outcomes.
- Health economic sub-analyses (embedded into primary studies, and not limited to) on: the sustainability of the integration or implementation of guidelines of care, including actual and/or projected health care costs of the full implementation of evidence-based care guidelines for MCCs; attainment of health outcomes goals; prevention of adverse events, hospitalizations and other complications; quality of life; access to and costs of medications and self-management supplies and devices; and availability of sub-specialty care health care within the context of health care payer policies on coverage of and payment for services, health care system protocols and processes, and payment models.

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