ENQUIRE 2019 – Cluster 16 - Healthcare Delivery/Patient Outcomes

This report details the changes in scientific scope for study sections evaluated under the ENQUIRE process in 2019 as part of Cluster 16. ENQUIRE integrates data and input from multiple stakeholders – the external scientific community, extramural programs at NIH, and CSR staff. An external panel of accomplished scientists, each with broad expertise and experience with multiple study sections was convened and asked to recommend changes necessary to facilitate the identification of high impact science, with special consideration of emerging science. Second, a panel of NIH extramural staff was convened and asked to focus on review process and concerns raised by the external recommendations. Additional input was provided by the CSR Advisory Council and by CSR staff in drafting of study section guidelines. Finally, to test the practicality of the recommended changes and the likely size of resulting study sections, CSR performed mock application referral using the new guidelines.

These changes will be implemented for grant applications submitted for Oct 2020 grant deadlines and **beyond.** New slates will be developed for each new standing panel to ensure expert review of the topics within each. Those who are members of currently existing panels with time remaining in their term will be to be asked to continue to serve, on one of the newly formed panels.

Evaluated Study Sections

Behavioral Medicine: Interventions and Outcomes (BMIO) Biomedical Computing and Health Informatics (BCHI) Community-Level Health Promotion (CLHP) Clinical Management of Patients in Community-based Settings (CMPC) Dissemination and Implementation Research in Health (DIRH) Health Disparities and Equity Promotion (HDEP) Health Services Organization and Delivery (HSOD) Nursing and Related Clinical Sciences (NRCS) Psychosocial Risk and Disease Prevention (PRDP)

Formed Study Sections

Biobehavioral Medicine and Health Outcomes (BMHO)

Clinical Data Management and Analysis (CDMA)

Clinical Informatics and Digital Health (CIDH)

Clinical Management in General Care Settings (CMGC)

Healthcare and Health Disparities (HHD)

Health Promotion in Communities (HPC)

Health Services: Quality and Effectiveness (HSQE)

Interdisciplinary Clinical Care in Specialty Care Settings (ICSC)

Implementation Science in Health and Healthcare (ISHH)

Lifestyle Change and Behavioral Health (LCBH)

Organization and Delivery of Health Services (ODHS)

Biobehavioral Medicine and Health Outcomes - (BMHO)

The Biobehavioral Medicine and Health Outcomes Study Section (BMHO) reviews applications that examine the interface of psychological/behavioral processes with biological, physiological, and neurological processes underlying a range of diseases and conditions across the human lifespan at the individual or small group level. Applications may use biopsychosocial and behavioral methods in conjunction with clinical approaches in order to improve health outcomes of diseases or conditions and reduce related morbidity and mortality. The study section does not review applications using animal models, or studies with a primary focus on the community level, health services/health systems, or population-level variables or sample sizes.

- Studies focusing on behavioral or psychological approaches or responses to physiological or biological conditions, symptoms, or reactions to diseases or disorders.
- Studies focusing on the integration of behavioral and psychological approaches with medical/clinical approaches to improve health and manage disease/disabling conditions (including screening, rehabilitation, post-surgery care, medication adherence, treatment compliance, and symptom management).
- Studies focusing on investigating the role of physical activity, weight control, nutrition, selfregulatory and executive function in disease self-care, and quality of life, particularly when examined in the context of biomarkers and physiological responses to conditions or treatments.
- Studies focusing on behavioral, psychological, pharmacological, or social responses to interventions designed to reduce stress, distress or pain secondary to medical conditions or surgical procedures, including diagnosis or treatment of somatic diseases and conditions.
- Studies focusing on changes in quality of life/well-being and psychosocial adjustment related to biological or physiological diseases or treatments.
- Studies to test relevant applied mHealth and bioinformatic interventions focusing on individualor small group-level behavioral approaches, including adaptive designs and clinical interventions addressing disease management and outcomes with a behavioral/psychological component.

Clinical Data Management and Analysis - (CDMA)

The Clinical Data Management and Analysis Study Section (CDMA) reviews applications that develop computing technology, simulation/data models, and technical software intended for eventual translation of research or novel findings into clinical decision support tools and technology. Applications to CDMA should have major methods development, integration related to clinical use (integrating clinical/biological and genomics) or data mining and analytics method development. Studies that propose the adaptation of previously developed computing methodology, simulation models, and technical software into behavioral interventions, patient services, or other population-based or precision health-based research should be assigned to other study sections.

- Computing and modeling of multi-source large-scale data that integrates clinical data with biological and genomics, such as bioinformatics for disease prediction, diagnosis, and individualized treatment; public health bio-surveillance systems; and management of integrated database related to clinical use.
- Studies to develop data mining and analytics methods including natural language processing; machine learning (deep learning)/artificial intelligence; ontologies; data simulation and modeling; computer visualization; and spatial/temporal modeling. Data sources would include, but are not limited to: clinical data (such as electronic health records, administrative data, claims data, patient/disease registries, health surveys, clinical trials data); clinical images (pathological, radiological, etc.) integrated with other data (such as EHRs); physiologic data (such as electrocardiograms (EKGs) and electroencephalograms (EEGs); omics data; environmental data; social media analytics; mHealth data; and clinical trials data.
- Studies to develop and validate systems, software or technologies for clinical data management; including data collecting, storage and sharing (cloud), data standardization and integration, and data privacy.

Clinical Informatics and Digital Health - (CIDH)

The Clinical Informatics and Digital Health Study Section (CIDH) reviews applications that develop, validate, and implement information technology-based approaches/tools for healthcare delivery, clinical decisionsupport in caring for individual patients, and clinician-patient data sharing. Applications are usually datacentric or scalable health IT interventions, large scale data validation and have clinical utility or applicability to health care by clinicians or precision health. The research areas include consumer health informatics, and mobile/wireless health (mHealth) and biosensor technology for clinical use. Applications often involve the development and application of computing and informatics technology to be disseminated to clinicians and patients or translating the newly found knowledge from big data analytics to support clinical decisions. Studies that propose the integration of computing, simulation models, and technical software into behavioral interventions, patient services, or other population- based research should be assigned to other study sections.

- Studies to develop consumer/patient health informatics for patient management, patient-care giver/clinician communication, and digital analytical tools in making information accessible to patients. Technologies include wireless medical devices, telemedicine, medical device data systems, health IT, device software functions such as mobile medical applications, artificial intelligence and machine learning in medical device, and software as medical device.
- Studies to develop informatics systems integrating data/information to improve patient and clinical workflow, such as testing and application of clinical informatics.
- Studies to develop, validate and apply to mobile and wireless health (mHealth); integration of
 mobile device design, software or smartphone App development; and use of sensor data
 integrated with clinical data for clinical decision support; use of mHealth or telehealth
 technology in patient monitoring, patient-provider communications, and adherence to
 treatment.
- Studies to address human-machine interface in the collection, storage, organization or retrieval of data for use in treatment, care, or management.

Clinical Management in General Care Settings - (CMGC)

The Clinical Management in General Care Settings Study Section (CMGC) reviews applications that identify, develop, and evaluate clinical management of patients from a provider perspective in general care settings, including home-based settings or ambulatory settings with care teams oriented around primary care, with the intent to guide care or inform clinical practice. The study section reviews applications that examine clinical management or symptom management of patients in general care settings, including rehabilitation, supportive care, and palliative care.

- Studies of clinical support and services for patient care and/or disability in primary care or home-based patient settings, including providing support for patient adherence to clinical treatment plans. Studies of patient and caregiver support in palliative or hospice care in community or home settings.
- Studies of survivorship care focused on improving patient care after treatment for lifethreatening illness or occurrence of multi-morbid illness.
- Studies of maternal and infant care before and after delivery, including families needing support in the context of pediatric, obstetrical and postpartum clinical care in generalized care settings, primary care, or home-base settings.
- Studies of informal or family caregivers who support the clinical management of patients with chronic health conditions or disabilities.
- Studies examining provider-patient/caregiver communication and/or clinical decision-making in generalized or home-based settings. This may include care planning in early phases of chronic or life-threatening illness, such as development of advanced care plans or directives.
- Studies to test relevant applied m-health, telehealth, and bioinformatic intervention studies to support patient care and/or self-management for chronic disease and/or disabilities, with the intent to guide care or inform clinical practice.

Healthcare and Health Disparities - (HHD)

The Healthcare and Health Disparities Study Section (HHD) reviews applications examining the systemic underpinnings of health care disparities closely associated with social, economic, and/or environmental disadvantage (race, ethnicity, gender, sexuality, socioeconomic status, age, geographic location, education level, disability status, immigrant status and a wide range of other vulnerable populations), and how social determinants of health relate to access to, use of, and effectiveness of health services and health promotion at the health systems level. Studies designed to address individual, community, and population-level disparities and/or cultural adaptations of existing interventions are better suited to other study sections.

- Studies where the primary aim is to address or reduce systematic factors related to health and health care disparities in access to and utilization of care across dimensions of social, economic, and place-based disadvantage by race, gender, class, sexual orientation, gender identity and expression, immigrant status, and other disadvantaged groups.
- Health care-related research to assess multiple influences on health disparities at the healthcare systems level.
- Studies related to structural or systemic factors such as stigma and implicit or explicit bias that mediate the relationship between impact disadvantage and health care or service-related outcomes.
- Studies to investigate the role of technology, including mHealth designed specifically to address or ameliorate health disparities in access/utilization, particularly for rural and vulnerable groups.

Health Promotion in Communities - (HPC)

The Health Promotion in Communities Study Section (HPC) reviews applications that develop and test the efficacy and effectiveness of interventions with a community-oriented approach aimed at promoting health or moderating health risks in the general population. HPC also reviews application proposing interventions to address health implemented in community organizations or other non-clinical settings (e.g., schools, worksites, service delivery organizations). The following topic areas fit within the scope of this study section:

- Studies proposing interventions that utilize community resources, organizations, and information systems for outreach, health education, and service delivery; or interventions which use social and organizational networks as systems for intervention and services delivery.
- Studies looking at community or local environment characteristics; developing and evaluating interventions at the community level among the general population.
- Studies utilizing a community-based participatory research (CBPR) approach, experimental/quasi-experimental, and multi-level approaches, or mHealth technology where a specific community, community structure, or relationship to a local group/organization is a central consideration.

Health Services: Quality and Effectiveness - (HSQE)

The Health Services Quality and Effectiveness Study Section (HSQE) reviews applications that focus on the provision of health services, healthcare quality, effectiveness, and individual/patient health outcomes. Studies focus on the access/receipt/utilization of services, cost-effectiveness, and comparative effectiveness. Service receipt settings may include: home and community-based settings, hospitals, emergency rooms, ICUs, NICUs, operating rooms, nursing homes, palliative care settings, primary care, and community clinics.

- Studies focused on the interaction of patients and providers in the delivery of health care services and individual/population-level outcomes associated with service receipt.
- Studies that examine provider service modalities, alternative service systems and individual patient outcomes.
- Studies that examine pharmaco-epidemiology, pharmacoeconomics, pharmacovigilance, and individual patient outcomes.
- Studies that apply risk prediction modeling and clinical decision making to improve health service delivery (at the individual/patient level).
- Studies that focus on comparative effectiveness of existing interventions in health care services.

Interdisciplinary Clinical Care in Specialty Care Settings - (ICSC)

The Interdisciplinary Clinical Care in Specialty Care Settings Study Section (ICSC) reviews applications addressing the clinical management of patients in institutional and inpatient settings (such as hospitals, nursing homes, impatient facilities, and hospice care facilities), as well as patients in ambulatory settings receiving active specialty care or involving specialized/complex care teams. Studies should have direct patient care implications or be closely associated with clinical practice; applications with a strong biological, basic science, occupational health, or animal model focus are reviewed in other study sections. Examples of patient-care oriented disciplines that may be reviewed in the study section include, but are not limited to nursing, medicine, pharmacy and physical and rehabilitation medicine.

- Studies to assess patient-level outcomes in institutional or specialty care settings, or for patients with complex care needs; including inpatient settings, surgical centers, dialysis centers, or those undergoing active treatment or ongoing specialty or complex care.
- Studies on treatment modalities for patients and/or caregivers for acute, life-limiting, chronic illness occurring in institutional settings, or palliative and end of life care within the institutional setting.
- Clinical studies of symptom-management in institutional or specialty care settings such as pain, fatigue, stress, and depression, or functional status changes during the active treatment of an underlying condition (e.g., cancer, organ transplant, brain injury or other neurological insult, myocardial infarction or other coronary disease).
- Studies of perinatal care for mothers with complex needs managed in institutional or specialty care settings, mothers in active labor, and infants with complex needs including those treated in neonatal intensive care units (NICU). Studies of involved families and other informal caregivers are also included.
- Studies of transitions between institutional and home-based settings, including preparation for inpatient care or for discharge from hospital to home.
- Studies examining provider-patient communication and/or clinical decision-making in institutional, specialty care or institutional (not home) hospice settings.

Implementation Science in Health and Healthcare (ISHH)

The Implementation Science in Health and Healthcare (ISHH) Study Section reviews applications that identify, develop, and evaluate dissemination and implementation theories, strategies and methods designed to integrate evidence-based health interventions into public health, clinical, and community settings. Applications reviewed in ISH should have a major methods, strategy, or theoretical development component in implementation science in order to understand how interventions are implemented and measure implementation outcomes in public health, clinical, and community settings. Studies that test effectiveness of evidence-based interventions with a focus on evaluating intervention outcomes rather than implementation outcomes (e.g., testing of specific implementation strategies) are reviewed in other study sections. Additionally, applications proposing basic science, pre-clinical, or clinical research perspectives are reviewed in other study sections. The following topic areas fit within the scope of this study section:

- Studies that focus on the testing of theories, models and conceptual frameworks for dissemination and implementation processes and outcomes (e.g. feasibility, fidelity, penetration, acceptability, sustainability, uptake, and costs) with approaches that emphasize resources of local care settings and the needs of multiple stakeholders (i.e. people or organizations who have an interest in the research project or are affected by its outcomes).
- Studies to examine the organization, adoption and integration of efforts to implement evidencebased practices, mobile health (mHealth) applications or platforms, or guidelines into practice for health care providers, patients, organizations, and communities.
- Studies to explore innovative approaches to identify, understand and develop strategies for overcoming barriers to the adoption, adaptation, integration, scale-up, and sustainability of evidence-based interventions, tools, policies, and guidelines.
- Studies to understand circumstances that create a need to stop or reduce ("de-implement") the use of interventions that are ineffective, unproven, low-value, or harmful.
- Studies that examine the integration of multiple evidence-based interventions in order to create an evidence-based system of care.
- Studies to explore strategies to impact organizational structure, climate, culture, and processes to enable dissemination and implementation of clinical/public health information and effective clinical/public health interventions.
- Studies to develop advance dissemination and implementation science measures and methods that assess the ability of an approach to move evidence into practice in various settings.

Lifestyle Change and Behavioral Health - (LCBH)

The Lifestyle Change and Behavioral Health Study Section (LCBH) reviews applications focusing on the adoption or uptake of health promoting behaviors or lifestyle changes to reduce health risks or to recover from diseases, conditions, or treatments at the individual or small group level. Applications typically use psychosocial and behavioral methods designed to improve well-being, delay disease onset, or to maintain recovery from diseases across the human lifespan. The study section does not review applications using animal models, or studies with a focus on community-level or population-level variables.

- Studies focusing on promotion of healthy lifestyles in individuals (e.g. physical activity, body weight control and maintenance, healthy dietary intake, management of sleep, alternative medicine methods such as yoga and Tai chi, self-care) to reduce risks or delay disease onset, as well as maintaining recovery from diseases including cancer, cardiovascular and diabetic diseases, and other chronic conditions across the life span.
- Studies on cultural adaptations of interventions or approaches to reduce risks and health disparities in diverse populations.
- Studies with relevant applied mHealth and bioinformatic interventions involving individual- or small group-level lifestyle change components, including adaptive designs interventions addressing health promotion and risk reduction.

Organization and Delivery of Health Services - (ODHS)

The Organization and Delivery of Health Services Study Section (ODHS) reviews applications focused on the organization and delivery of health services from a systems level, including health care financing, insurance, access, utilization and the provision of health services at the population level. Many studies will rely on large administrative data sources (e.g. Medicare, Medicaid, SEER etc.).

- Studies to examine the structure of health care organizations (range of services) and delivery systems, and their performance and efficiency.
- Studies to examine the structure of hospital or other healthcare systems (size and service capacity), hospital performance measures, and hospital operations.
- Studies to develop practice guidelines and operational research in health care organizations and examine health care provider characteristics.
- Studies to examine physician performance, practice networks, and physician payment practices and systems.
- Studies to examine health system access including cost of care, health care financing, and the financial costs at the population level.
- Studies to examine health plans and health insurance coverage, scope, costs, eligibility, benefits, and reimbursement.
- Studies to understand implications of health policy changes for health care systems, providers and organizations.
- Studies to examine the organization and delivery of pharmaceutical services.
- Studies to utilize risk prediction tools and clinical decision making at the provider and systems level.
- Studies that use implementation science principles to focus on the delivery of services at the systems-level or state-level. This includes studies using systems science methods (agent-based modeling, social networking analysis, simulation modeling and system dynamics modeling).