SPECIFIC AIMS (Example 1)

Patient safety is of utmost importance in all health care deliveries, including [redacted] care. To avoid potential harm and improve [redacted] treatment success, [provider]'s must obtain an up-to-date medical and medication history of their patients. Recent studies revealed discrepancies of medical conditions in the electronic [redacted] record ([redacted]) versus electronic health record (EHR)[1] [2] [3-5] and delays in obtaining additional medical information from physicians [6]. Incomplete patient medical history could compromise [redacted] care and increase the risk of potential adverse events. Possible reasons for such gaps are patients failing to accurately recall their medical history and physician offices' delays, and vague responses to [providers]. These concerns have escalated due to the COVID-19 pandemic, with [providers] relying on their patients regarding the disease and vaccination histories to prevent disease transmission.

Large healthcare organizations (HCO) such as [redacted] schools and [redacted] implement integrated [redacted] EHRs[7] [8, 9] [10-12] [13] and consolidate care document architecture (C-CDA) to improve care coordination and [redacted] health. However, deploying such systems alone will not resolve the current barriers because the relevant patient-specific information may be fragmented across different HCOs, stored in various EHR sections. Like [redacted], [providers] will not have timely access to pertinent information to practice safe [redacted] care if they must scan through a patient's EHR or C-CDA to obtain relevant information. In addition, most [redacted] practices are not affiliated with HCOs and cannot access their patients' EHR. The emergence of community and vendor-supported health information exchanges (HIEs) and the consolidation and display of pertinent information offers a huge opportunity to allow [providers] to access their patients' medical history on time and facilitate HIE between [providers].

Our *long-term goal* is to improve communication and referrals between [providers] to improve patient care and promote screening and preventive management of chronic diseases. This proposal aims to develop and evaluate a usable patient medical summary (PMS) imported from the [redacted] Health Information Exchange (XHIE) that updates a [redacted] clinician about their patients' medical history. Our *central hypothesis* is that the PMS will have a higher percentage of complete and up-to-date medical information, which will reduce the average time required to assess a [redacted] patient case and determined by [providers] to be clinically useful. The proposed study will lay the foundation for an interprofessional [redacted] care delivery that enhances [redacted] and overall care among the US population, promotes preventive management, and reduces [redacted] care costs. To achieve our objectives, we propose the following three specific aims.

Specific Aim 1: Validate the [redacted] of information items that contribute to the PMS to assess a patients' medical status. We will conduct key informant interviews with XX [providers] who believe in integrating [redacted] and [redacted] care and two focus groups with 10 [providers] to assess the timeliness and relevance of information items during [redacted] care. The outcomes of this Aim are a list of validated information items that will contribute to the PMS and a formal description of the factors affecting implementing a PMS application via HIE in [redacted] practices.

Specific Aim 2: Develop prototypes that integrate the PMS with an EDR through [redacted] methods. We will customize the existing [redacted] functions and workflows in EDR based on the PMS template developed in Aim 1 and design and build the PMS application by implementing the [redacted] standard. We hypothesize that both the customized [redacted] module and the [redacted] based PMS application will fit into the [providers'] workflow and address barriers to access critical patient medical history information on time without information overload.

Specific Aim 3: Evaluate the effectiveness and efficiency of the PMS with [providers]. Using [methods redacted], we will evaluate the information organization and navigation, relevance, and efficiency of PMS versus [redacted] in obtaining timely patient medical history with XX [providers]. We hypothesize the PMS information is [redacted] to assess a patient's health than the existing methods of gathering a patient's medical history.

This proposal is significant because the historical divide between [redacted] and [redacted] have prevented [redacted] and [redacted] professionals from working towards a common goal to improve patient care and population health. This application is innovative because it builds new technological solutions that connects even solo- and small group [redacted] practices with community health information exchanges to access their patients' medical information and improve patient care. The outcomes of this proposal will lay the foundation for [providers] to access PMS via health information exchanges, facilitate bidirectional communication with providers to promote patient safety, improve screening for chronic diseases, and enhance the US population's [redacted] health.

SPECIFIC AIMS (Example 2)

Genomic medicine has led to the discovery of underlying genetic contributions to hundreds of rare, hereditary disorders.[18,19] However, as we work to maximize care for our patients, gaps in our understanding persist that leave those suffering from many rare diseases without [redacted]. I draw on the [redacted] definition of [redacted], meaning [definition redacted].[20] The [syndromes redacted], some of the most prominent rare genetic diseases, are a prime example of such a failure. Patients with [syndrome redacted] regularly undergo a long diagnostic odyssey of X-X years.[18,21] During this period, clinicians may downplay or even dismiss their [symptoms redacted], leading patients to report negative experiences and distrust in clinical encounters.[16,22] Feeling [redacted], they may avoid healthcare and pursue potentially dangerous alternatives in attempts to manage their chronic symptoms, leading to adverse health outcomes. While patients with the classical type of [syndrome redacted] may receive a molecular diagnosis, that is not possible for patients with [syndrome redacted], as the genes underlying [syndrome redacted] are still unknown, despite ongoing research.[23] Nonetheless, little work has focused on the experiences and views of such patients or their clinicians.[24] Nor is it known how the potential of a molecular diagnosis changes outcomes for patients with these various types of [syndrome redacted]. Some work has been done to measure communication of [redaction]. [Redacted] has been shown to improve quality of care for at least some patient populations[25] and may even [redacted].[26] Furthermore, [redacted] training has been shown to have immediate positive [redacted] impact for patients.[27] However, there is a persistent gap in our understanding of how patients with [syndrome redacted] – as well as other rare diseases – come to [redacted] and how [redacted] can be countered. Therefore, research is urgently needed to identify and evaluate ways to improve such patients' [redacted] and that [redacted]'s role in timely, empathic, and ethically sound care.

The goal of the proposed study is to characterize the [redacted] of patients with [syndrome redacted] and their clinicians regarding the role of molecular diagnosis in [redacted] of patients with rare diseases, and to use those insights to develop strategies to improve [redacted] among this population. My central hypothesis, based on my own prior research,[6,16] is that [redacted] directly contribute to an increasingly troubled patient–provider relationship, and that a molecular diagnosis may alleviate some of those troubles while exacerbating others. I propose to test this hypothesis by contrasting experiences of both patients and providers with regards to [syndrome redacted] patients with a molecular diagnosis ([syndrome redacted]) and those without ([syndrome redacted]). This proposal will incorporate qualitative data from interviews coupled with quantitative data from surveys to better understand the issues at play in this and similar patient populations' diagnostic odysseys. The three aims of this project will look at patients' (A1) and providers' (A2) perspectives, and then integrate them to develop strategies for a simple but concrete communication intervention (A3), which research suggests has a strong likelihood of effecting meaningful and positive change.[28] The proposal's three aims are as follows:

Specific Aim 1: To characterize the events and interactions that affect [redacted] among patients as they pursued an [syndrome redacted] diagnosis. We will conduct in-depth, qualitative interviews (Aim 1a), and a survey (Aim 1b), identified through the [Syndrome] Registry, in order to identify differences in this experience between receiving a molecular ([syndrome redacted]) and a clinical ([syndrome redacted]) diagnosis.

Specific Aim 2: To characterize the [redacted] of clinicians to understand the challenges they face in caring for patients with such complex clinical cases. We will conduct in-depth, qualitative interviews with clinicians in primary care and specialists from [redacted] and [redacted] (Aim 2a), and a vignette-based survey to assess variability in perceptions of legitimacy of complaints between the two patient cohorts, with and without a molecular diagnosis (Aim 2b).

Specific Aim 3: To develop strategies to improve [redacted] among patients with rare diseases. We will use methods adapted from those used by the National Academies[29,30] to convene a longitudinal working group of 10-15 stakeholders – patients, clinicians, and implementation scientists. This group will discuss outcomes of A1 and A2, and will work collaboratively and iteratively over four sessions to identify approaches for a concrete, pragmatic communication intervention, informed by ELSI research, to improve [redacted] for patients living with [syndrome redacted] and similar disorders.

Our distinctive use of quantitative and qualitative communication research methods in applied ELSI research and our innovative adaptation of the National Academies' approach will provide the experience and data to serve as a robust foundation for a comprehensive and independently funded research program designed to reduce the burdens and barriers faced by patients with rare diseases. At the end of the award period, I will be well positioned in my career as a research scientist studying the ethics and communication issues of genomic medicine in practice.

SPECIFIC AIMS (Example 3)

Over 4.4 million Americans receive home health services after hospital or rehabilitation facility discharge to improve function, foster independence, promote health-related quality of life and sense of well-being (QoL), and decrease unnecessary hospital or nursing home stays. Among these patients, > 80% are 65 years or older, most manage at least two chronic conditions, and nearly 70% report subjective cognitive decline (SCD).[1-1] SCD is an early clinical sign of Alzheimer's disease and related dementia (ADRD).[2-4] SCD is associated with diminished activity performance,[5-7] poor QoL,[8,9] and other adverse health outcomes (e.g., depressive symptoms).[8,10]

Home health patients with SCD require more time, structure, and guidance to complete tasks and adjust to new skills and environments. Without support, they often lose their sense of control, have fewer personal choices,[11] and disengage from *meaningful activities*.[12,13] Meaningful activities are self-identified activities based on the individual's previous life experiences, sense of intentionality, and goals to remain involved in desired activities and personal relationships.[14,15] In older adults, engagement in meaningful activities is associated with better physical and mental health, QoL, reduced risk of cognitive decline and mortality.[14,16,17] Poor engagement in meaningful activities results in rapid patient decline[18] that may otherwise be preventable. For those with SCD who are at risk of declining and progressing to preclinical ADRD,[19] new care delivery models that promote engagement in meaningful activities to enhance patient outcomes are needed. Because informal caregivers are usually unprepared, lack confidence in their new caregiver role, and have difficulty providing support,[1,20] it is vitally important to include these caregivers in new care delivery models.

We propose a new home health care delivery model in partnership with Kindred at Home (KAH) Gentiva Health Services, a division of Humana that encompasses 400 sites across 40 states. Our proposed telephone-delivered care model, Daily Engagement in Meaningful Activities-Professional (DEMA-Pro) is a *Positive Health* intervention[21] that is strengths-based, family-centered, and tailored to patient/caregiver goals and values. DEMA-Pro addresses the core problem of diminished engagement in meaningful activities among SCD patients at home by: 1) coaching patient-caregiver dyads to problem-solve; 2) teaching the dyads self-management and communication skills; and 3) enhancing naturally occurring patient-caregiver interactions necessary to accomplish self-identified, mutually agreed upon goals. DEMA-Pro builds on five preliminary studies of the DEMA intervention[22-28] that demonstrated high feasibility, acceptability, and positive preliminary effects on health outcomes (physical function, mood, and QoL).[27,28] DEMA-Pro will be refined for delivery by home health services staff to patients with SCD and their informal caregivers.

The purpose of this R61/R33 grant proposal is to conduct a pragmatic cluster randomized controlled trial (RCT) of DEMA-Pro to improve outcomes in home health service patients with SCD. In the R61 phase, we will establish the organizational structure and processes and pilot test DEMA-Pro in 4 KAH home health service facilities. In the R33 phase we will conduct a full pragmatic RCT in 40 KAH facilities to compare DEMA-Pro to usual care. In accordance with pragmatic trial principles, we will primarily use existing data sources including electronic Medicare OASIS (Outcome and Assessment Information Set) data to characterize the cohort and measure outcomes**. R61 and R33 Specific aims** are:

R61 Phase (12 months)

Aim 1. Establish the organizational infrastructure and programmatic processes needed to conduct a pragmatic cluster-randomized control trial of the DEMA-Pro intervention versus usual care. A Steering Committee will lead the project and coordinate the activities of 3 Work Groups: Regulatory and Operations; DEMA-Pro Intervention Protocol; and Data Management and Analysis.

Aim 2. Pilot test the DEMA-Pro training protocol in 4 KAH North Region locations and refine as indicated.

R33 Phase (48 months).

Forty KAH home health services sites will be randomized to DEMA-Pro or usual care. DEMA-Pro site home health services staff will be trained as DEMA-Pro coaches who will work with home health service leaders to: (1) consolidate home health services DEMA-Pro procedures; (2) train and educate staff; and (3) facilitate DEMA-Pro coaching with patients and their family caregivers. The implementation period will be 18 months and all enrolled patients will be followed for 12 months.

Aim 3. Compare outcomes of DEMA-Pro to Usual Care over 12 months.

Hypotheses (H). Compared to usual care, DEMA-Pro patients will have: H 3.1(primary) higher physical function; H 3.2 higher overall quality of life (i.e. Sense of well-being) (QoL); H 3.3 lower depression, and, H 3.4. lower rates of transfers to nursing home per 1000 person days.

Impact: By valuing and fostering a positive health model of care, an efficacious DEMA-Pro has potential to facilitate a paradigm shift in how elderly patients in the USA are cared for at home.