

genetic loci (via look up-GWAS) in the histological NLP cohort

**METHODS/STUDY POPULATION:** We will utilize the Million Veteran Program Biobank where a total of 10,959 subjects have been identified using liver biopsy reports in the EMR via CPT codes. Cases will be based on i) steatosis, steatohepatitis, inflammation or fibrosis in liver biopsy reports with ii) exclusion of other causes of liver disease. Controls will be comprised of the general VA population. In collaboration with the Applied NLP and Precision Medicine groups at the VA Informatics and Computing Infrastructure(VINCI); we will attempt to create and validate a histological cohort of NAFLD in the MVP database by: 1)Annotation of biopsy reports for the NLP algorithm 2)Automation/training of the NLP algorithm We will then perform a multi-ancestry genetic lookup of previously established genetic loci among the cases identified.

**RESULTS/ANTICIPATED RESULTS:** Recently published data: the MVP NAFLD research led by Dr. Chang and Dr. Vujkovic had first validated a proxy NAFLD phenotype based on chronic alanine aminotransferase elevation (cALT). A GWAS was then performed using this phenotype which revealed 77 loci of genome-wide significance including 10 established NAFLD- and 52 ALT-associated SNPs were identified. Replication in external Liver Biopsy and Imaging Cohorts validated 17 SNPs of which 9 were novel. Preliminary data on Liver Biopsy reports: Using CPT codes for Liver Biopsy we estimated a total of 10,959 unique patients and 18,812 notes in the MVP biobank. We anticipate 2,000-3,000 NAFLD cases (based on the prevalence of NAFLD in the general population). Initial review reveals 90% concordance between analysts for the purposes of developing an NLP.

**DISCUSSION/SIGNIFICANCE:** NAFLD is a major cause for morbidity and mortality in liver disease. Gold standard for diagnosis is based on biopsy. GWAS studies with biopsy proven phenotypes are limited. The study will aim to isolate a histologically defined NAFLD cohort in MVP to conduct further GWAS that can provide new clinically relevant knowledge for future research.

## Contemporary Research Challenges

74

### Development and content validation of a tool to assess quality of primary care practice

Carolyn A. Berry, Lorraine Kwok, Margaret Paul, Stephanie L. Albert, Saul Blecker, Donna Shelley  
New York University Grossman School of Medicine

**OBJECTIVES/GOALS:** Primary care practices struggle to identify which combination of care structures and processes need to be implemented to improve practice performance and subsequently, patient outcomes. The goal of this study is to develop and validate a tool to assess care structures and processes that are associated with better quality and patient outcomes.

**METHODS/STUDY POPULATION:** Data from a scoping review, Delphi study, and qualitative interviews with high-performing primary care practices contributed to the development and content validation of the Tool for Advancing Practice Performance (TAPP). From these sources we identified 314 items representing care structures (e.g., care team makeup, use of electronic health records) and processes (e.g., care coordination, panel management). We developed criteria

for deleting and rescuing items and received input from our expert panel to refine the pool of items. We eliminated items that were redundant and lacked clarity/specificity. The tool was further modified based on feedback from cognitive interviewing and pilot testing with practice managers, quality improvement leaders, and physicians from primary care practices.

**RESULTS/ANTICIPATED RESULTS:** The pool of 314 items was winnowed to 188 after applying criteria for deleting and rescuing items. During the expert review, 70 items were eliminated and 8 new items were added, resulting in a working tool of 126 items. We conducted eight cognitive interviews with the 126-item tool and received feedback on the content, item structure, and language, which led to the elimination of 13 items that were poorly or incorrectly understood by respondents. We also modified the language of 23 items for clarity. After cognitive interviewing, the resulting tool comprised 113 items. Fifteen practices piloted the tool and no additional items were eliminated. We modified the instructions for completing the tool and resolved technical issues related to online administration.

**DISCUSSION/SIGNIFICANCE:** TAPP is a novel tool for assessing care structures and processes that are associated with better quality and patient outcomes in primary care settings. The tool can be used by researchers and primary care clinicians to identify areas for improvement in practice performance and patient outcomes related to chronic disease prevention and management.

75

### Effect of probiotic supplementation on intestinal permeability in subjects with overweight and obesity: A systematic review of randomized controlled trials

Zachary DiMattia<sup>1</sup>, Janhavi Damani<sup>1</sup>, Connie J. Rogers<sup>2</sup>

<sup>1</sup>Penn State University, <sup>2</sup>University of Georgia

**OBJECTIVES/GOALS:** Obesity is associated with gut dysbiosis, inflammation, and increased intestinal permeability. Probiotic consumption may reverse these outcomes. The goal of this study is to evaluate the evidence linking probiotic consumption to changes in intestinal permeability in subjects with overweight or obesity.

**METHODS/STUDY POPULATION:** Articles were searched in Pubmed, Web of Science, and CAB Direct through February 2022 using search terms: intestinal permeability, overweight or obesity, and probiotic supplementation. 694 articles were exported, and 289 duplicates were identified. Titles and abstract were screened in the 405 remaining references by two investigators to determine eligibility. Eligible studies had data extracted on study participant characteristics, probiotic strain used, probiotic dosage, length of intervention, and intestinal barrier outcomes. Results were summarized in tabular form based on intestinal permeability response to probiotics. Quality of the studies was assessed based on Cochrane-Risk of Bias' tool (RoB2).

**RESULTS/ANTICIPATED RESULTS:** Thirteen eligible studies were identified. Probiotic genera included Akkermansia, Bifidobacterium, Lactobacillus, Streptococcus, Lactococcus, and Bacillus. Single strain probiotics were used in 3 studies, while the other 10 used multi-strain formulas. Dosage and length of probiotic supplementation ranged from 2.4 x 10<sup>7</sup> to 5 x 10<sup>10</sup> CFU/person/day and 3 to 26 weeks, respectively. The most widely used gut permeability outcomes were serum lipopolysaccharide (LPS) (n=10) and mixed sugar solution consumption with urine analysis (n=6). Five of the 10 studies reported decreases in serum LPS following probiotic consumption, while the other 5

showed no effect. Urinary lactulose/mannitol ratio decreased in 1 of the 4 studies, and urinary lactulose percent decreased in 2 studies. DISCUSSION/SIGNIFICANCE: Probiotic supplementation may be remediating an obesity-induced increase in intestinal permeability as evidenced from the effect on serum LPS and mixed sugar solution assays. However, additional studies are needed to further clarify which strain of probiotic bacteria is most effective and the optimal intervention length in subjects with obesity.

76

### Methods and Perceptions of Success for Patient Recruitment in Decentralized Clinical Trials\*\*

Brian Miyata, Barbara Tafuto, Nadina Jose  
Rutgers University

OBJECTIVES/GOALS: Patient recruitment, enrollment, and retention continues to be one of the leading barriers to successful clinical trials, and results do not always reflect the diversity of the general population. This systematic review aims to assess the impact of decentralized methods on recruitment, retention, and diversity on recent clinical research. METHODS/STUDY POPULATION: A systematic search of the literature, using databases such as PubMed, Cochrane Library and EMBASE to find publications reporting on the aspect of recruitment in decentralized clinical trials was performed. The titles and abstracts of the publications were assessed, excluded those lacking sufficient or pertinent information regarding decentralization in clinical trials. The remaining publications were reviewed for those reporting sufficient data regarding the impact of decentralization on the aspect of recruitment in clinical trials to be included in the focused analysis. Studies reporting on participant retention and diversity in addition to recruitment were emphasized. RESULTS/ANTICIPATED RESULTS: This systematic search returned 13 studies highlighting the role of decentralized clinical trial methods impacting participant recruitment, retention, and diversity in clinical trials. Out of the 13 studies, 10 reported improved recruitment using virtual or decentralized methods, and 7 of these reported improvements when compared alongside with traditional methods. 7 studies reported a positive impact on participant retention, with 4 of these directly comparing decentralized methods with traditional methods. Lastly, of these studies, 5 were reported to have trended towards diversity in the demographics of the sample population, including race or geographic location. DISCUSSION/SIGNIFICANCE: Related reviews have stated a lack of published comparable data to determine if DCTs (Decentralized Clinical Trials) improved recruitment and retention. Results suggest this review addresses such a gap, by providing data on how decentralized methods can benefit recruitment and retention, potentially highlighting a new standard.

77

### METHODS FOR IDENTIFYING FILIPINO GENDER MINORITIES AND MENTAL HEALTH RISKS IN ELECTRONIC HEALTH RECORDS

Charlene Bumanglag, Stephanie Mikhail, Renee Rumler, James Davis, Deborah Goebert,  
University of Hawaii, John A. Burns School of Medicine

OBJECTIVES/GOALS: Aim 1: To explore methodologies to identify gender minorities, and Filipinos, separately, in an electronic health record system. Aim 2: To characterize the similarities and differences in demographic, socioeconomic, and mental health of Filipinos gender

\*\*Brian Miyata has been added as an author. An addendum detailing this update has also been published (doi:10.1017/cts.2023.593).

minorities compared to Native Hawaiian Pacific Islanders, and White/ European Americans. METHODS/STUDY POPULATION: This study was approved by the University of Hawaii Institutional Review Board. Cross-sectional retrospective data were obtained from a collaborative community clinic's electronic health record system. Patients were age 18 and older with a clinical diagnosis for gender dysphoria and from Native Hawaiian Pacific Islander, White/ European American, and Filipino backgrounds. RESULTS/ANTICIPATED RESULTS: Preliminary data revealed that 11% of the clinical population were diagnosed with gender dysphoria (N=373) with 57.6% (n=215) who met the inclusion criteria with complete health registration forms. Patients were from Filipino (21.8%), Native Hawaiian Pacific Islander (23.3%), White/ European American (31.6%), and multiethnic (23.3%) backgrounds. Most patients reported mental health (e.g., depression) conditions (50.6%-64.7%). Further statistical analyses will reveal if Filipinos have higher or lower levels of anxiety, depression, and suicide risks than Native Hawaiian Pacific Islander, and White/ European American gender minority individuals. DISCUSSION/SIGNIFICANCE: In Hawaii, one person dies by suicide every two days; suicide is the lead cause of fatal injuries. Study findings can inform future methodology studies to identify gender minorities and develop culturally relevant gender affirming mental health programs for gender minorities.

78

### Pharos: A Novel Mapping Software to Identify Cell Network Signal Strength for Mobile Health Epidemiology

Carson Moore<sup>1</sup>, Govert van Dam<sup>2</sup>, Maurice Odiere<sup>3</sup>, David Wright<sup>1</sup>, Thomas Scherr<sup>1</sup>

<sup>1</sup>Vanderbilt University, <sup>2</sup>Lieden University Medical Center, <sup>3</sup>Kenya Medical Research Institute Centre for Global Health Research

OBJECTIVES/GOALS: The aim of this study was to design and implement the Pharos application to map the cellular network support structure around Lake Victoria in Western Kenya. Additionally, the Pharos app was used to collect images of disease-relevant vector and plant life surrounding the study sites to train a computer vision algorithm to map disease-relevant areas. METHODS/STUDY POPULATION: Pharos was provided to a 4-person team of healthcare workers. The app was pre-loaded on both iOS and Android devices to be used during the course of normal field activity. Pharos ambly collects network data and the team was asked to capture images of landmarks relevant to their work in schistosomiasis control. The field team traveled to 4 counties of differing schistosomiasis risk surrounding Kisumu, Kenya in autumn 2022 and will return to these areas in early spring 2023. Cell signal indicators (upload and download speed) were collected and asynchronously uploaded to a database for further analysis. Additionally, all landmark images (cell network towers, landmarks (e.g. schools, churches, public centers), plant life, vectors, and water bodies) were recorded and tagged with GPS coordinates and time stamps. RESULTS/ANTICIPATED RESULTS: Iterative development powered by small, informal, user-centered focus group discussions with the field team led to several key adaptations to the Pharos software. On the first deployment, 1,297 unique upload and download events were recorded across 3 Kenyan cell providers and 1 American provider. 1,197 data points were collected in Kenya using both Android and iOS devices using several versions of the Pharos application. 154 unique landmarks were photographed, but a distinct difference in landmark recording was observed between devices, prompting a transition to iOS-only data collection. Of the landmarks recorded, the majority (120, 77.9%) were landmarks or cell network towers, while 22.1% were water bodies, plant