PROJECT TITLE:

Prospective validation of readmission risk score and interventions to prevent readmission in patients with decompensated cirrhosis

Short title: Cirrhosis readmissions

IMPROVEMENT TEAM DETAILS:

Co-Primary Investigators, Key Contacts:
Antoinette Pusateri, MD[1]
Khalid Mumtaz, MBBS, MSc[2]
Co- Investigators:
Sean Kelly, MD[2]
Adam Hanje, MD[2]
Kyle Porter, MAS[3]

Department of Internal Medicine, The Ohio State University Wexner Medical Center, Columbus, OH[1]
Division of Gastroenterology, Hepatology, and Nutrition, The Ohio State University Wexner Medical Center, Columbus, OH[2]
Center of Biostatistics, The Ohio State University, Columbus, OH[3]

The team as enumerated above will consist of the Co-PI's, resident physician Dr. Antoinette Pusateri and attending physician hepatologist Dr. Khalid Mumtaz. They will oversee all aspects of the project from IRB and grant preparation and management, hiring and training a case manager, recruiting patients, organizing and analyzing data, communicating with team, and generating final project analyses and manuscript/presentation preparation. Other Co-I's include attending physician hepatologists (Drs. Sean Kelly, Adam Hanje) who will aid in the identification of eligible patients and manuscript formation. Gastroenterology statistician (Mr. Kyle Porter) will help in analyzing the data. The case manager (TBD) will physically recruit and consent patients, assign patients to intervention versus standard of care arms, enter patient data into RedCap database, call patients weekly for one month after index admission to see if they have been readmitted, and arrange outpatient follow up for those in the intervention arm as applicable.

PROJECT GOALS, STATEMENT ON ALIGNMENT WITH MISSION OR ORGANIZATIONAL PRIORITIES:

In line with the OSUWMC mission statement of improving the lives of Ohioans with research, education and patient care, successful completion of this research project will accomplish a triple aim of 1) reducing 30-day readmission rate in our patients with decompensated cirrhosis (DC) admitted to the OSUWMC Hepatology Service from 27% to 19% from June 1, 2019 to May 31, 2020 through our case manager intervention versus standard of care 2) reducing costs associated with 30-day readmission in these patients and 3) prospectively validating and enhancing the Mumtaz readmission risk score to more closely predict those patients with DC who are at higher risk of readmission. In the future we hope to 1) collaborate with other centers managing patients with DC in order to identify and recruit patients into a multicenter prospective cohort who are eligible for participation into cross-sectional consortium protocols and 2) generate and analyze additional novel, evidence-based interventions for prevention of 30-day readmission in patients with DC. Ultimately these findings will work to reduce the cost of care, enhance quality of care, decrease calendar year mortality, and improve safety and quality of life in patients with DC across the United States.

PROJECT NARRATIVE & STRATEGY:

PROBLEM OR GAP IN QUALITY: BACKGROUND AND SIGNIFICANCE

Burden and mortality related to cirrhosis is increasing in United States

Cirrhosis of liver is a chronic, progressive disease affecting close to 5 million Americans (1). Cirrhosis has been reported to be the 8th leading cause of death with estimated over 40,000 deaths annually in the United States (2). A study of the burden of gastrointestinal, liver and pancreatic diseases in the United States revealed liver diseases had the highest mortality at 3.1% overall, with more than half of deaths from all non-malignant GI disease attributable to liver disease (3). In addition to high mortality, cirrhosis can have high morbidity. The sequelae of cirrhosis are often managed through hospital admissions and include volume overload, portal hypertensive bleeding, hepatic encephalopathy (HE), electrolyte imbalances, renal failure, spontaneous bacterial peritonitis (SBP) and other infections. Hospitalizations for chronic liver disease have increased 25% over the last 10 years. These hospitalizations added up to $4 billion in aggregate cost in 2014.

Readmissions add to the cost and mortality in cirrhosis

Since hospital readmission in general is a large burden on the American healthcare system, the government established the Hospital Readmissions Reduction Program (HRRP) in 2011, wherein 30-day mortality and 30-day readmission rates for Medicare patients were measured for patients with acute myocardial infarction, heart failure, or pneumonia (4). In United States, liver disease had the highest rate of all-cause 30-day readmission with 20,936 readmissions per 139,971 index admissions, with a median charge per index stay of $29,692 and a median charge per readmission of $30,607(3). Many studies have demonstrated the exceptionally high readmission rate (20-37%) and associated morbidity and mortality for patients with cirrhosis (5-14). Studies have demonstrated readmissions to be associated with a variety of clinical factors such as higher MELD score (5, 7, 8, 13, 15), cirrhosis related complications (6, 7, 14, 15) including HE (8, 11), diabetes (5, 8, 15), and higher serum creatinine (5, 6). Mortality has been shown to be higher in those with early readmission than without readmission (5, 7, 12, 13, 15). Cirrhosis is not yet a disease entity included in the HRRP, despite the aforementioned associated costs and it being demonstrated to be an independent predictor of 30-day readmission just like congestive heart failure, peripheral vascular disease and metastatic cancer (16). However, with increasing expenses associated with cirrhosis, it is also expected to be included into HRRP program.

Future novel approaches are needed to prevent readmissions in DC

There have been several small studies on successful interventions for reducing readmission in DC patients. Morales et al found that through their HEPACONTROL program wherein a hepatology specialist gave a close follow up exam within 7 days after discharge, there was a reduction in 30-day admission, 60-day mortality and rate of emergency department visits and associated costs (17). Morando et al demonstrated that follow up with a “care management check-up” group as opposed to “standard outpatient care” reduced 30-day readmission (15.4% versus 42.4%), reduced 12-month mortality (23.1% versus 45.7%) and saved almost 1500 euros per patient month of life (18). Similarly, Kanwal et al demonstrated lower risk of death in group of patients with early follow up within the first 7 days of discharge (9). Interventions could also include those aimed at providers. Johnson et al showed that targeted educational efforts for house staff and standardized order sets significantly decreased 30-day hospital readmission rates for patients with chronic liver disease presenting with acute upper GI bleed (19). Tapper et al demonstrated that development of a checklist for HE protocol, standard SBP treatment and prophylactic measures integrated into the electronic medical record and order entry system reduced odds of 30-day readmission overall (from 37.9% to 26.6%) and for patients with HE (from 39.2% to 27.6%) (20).

PILOT DATA AND PREVIOUS WORKS

We have recently published a series of papers on the important issue of early readmission in patients with DC. We found that patient with DC with ascites have a 33% chance of 30-day readmission. Younger patients, with public insurance, nonalcoholic cirrhosis and increased number of comorbidities who underwent paracentesis are at increased risk of readmission (21). HE plays an important role in readmission in patients with DC. We studied the independent predictors of 30-day readmission and developed a readmission risk model in patients with HE. Nearly one-third of patients with HE were readmitted within 30-days, and early readmission adversely impacted healthcare utilization and calendar-year mortality. With our proposed simple risk assessment model, patients at high risk for early readmissions can be identified to potentially avert poor outcomes (22).

Finally, we developed and validated a comprehensive readmission risk score for all patients with DC called the Mumtaz score (http://mumtazreadmissionriskscore.com/). This score is based on the National Readmission Database (NRD) patients’ demographic, administrative information, clinical features, interventions and disposition. We divided the population of patients at the time of discharge into low, medium and high risk of readmission based on variables from the index admission. The Mumtaz score highlights the need for targeted interventions in high risk patients in order to decrease rates of readmission within this population. This study had some limitations inherent to administrative database analysis research. First, this study relies on ICD9-CM codes for establishing diagnoses. Theoretically, under/miscoding can lead to misclassification bias. Second, NRD does not capture medications or laboratory values. Therefore, we could not assess the effect of medications/polypharmacy/medication compliance on 30-day readmission. In addition, variables such as MELD or Child Turcotte-Pugh scores which reflect the severity of cirrhosis could not be used.

Hence there is a need for prospective validation of our risk score and additional variables to improve its validity. Moreover, there is a need to prospectively intervene in high risk group and reduce the rate of early readmission in patients with DC. Prospective validation of a risk score for readmission in patients with DC has never been reported. We speculate that our prospectively validated risk score will accurately identify patients with DC at a higher risk of 30-day readmission. Prospective use of various interventions at the time of discharge in this cohort of patients will also be helpful in reducing early readmissions.

PROJECT AIMS:
As discussed above, our triple aim includes:

1. reducing 30-day readmission rate in our patients with decompensated cirrhosis (DC) admitted to the OSUWMC Hepatology Service from 27% to 19% from June 1, 2019 to May 31, 2020 through our case manager intervention versus standard of care
2. reducing costs associated with 30-day readmission in these patients. Furthermore we aim to show that readmissions at OSUWMC are less expensive than readmissions at outside hospitals.
3. prospectively validating and enhancing the Mumtaz readmission risk score to more closely predict those patients with DC who are at higher risk of readmission.

RESEARCH PLAN
The study cohort will consist of group of patients with DC admitted at The Ohio State University Wexner Medical Center, a tertiary care university medical center from June 1, 2019 to May 31, 2020. The Department of Quality and Patient Safety of OSUWMC will provide a Quality Data Release for this project and the project will get IRB approval.

All patients admitted to the inpatient service will be screened by the case manager; those who meet inclusion criteria will be approached for study consent (Table 1). If the patient consents for the study, the case manager will evaluate the patient and assess for liver frailty score and SIPAT score. Consented patients will be randomly assigned to either the intervention (INT) arm or the standard of care (SOC) arm in a 1:1 ratio. The case manager will proceed to collect the following data on all patients using the Electronic Medical Record (EMR; Figure 1). These data include:

- Demographics including age, sex, insurance type, income based on the zip code
- Hospitalization data including date of index admission, reason for admission, length of stay (LOS), discharge disposition, associated cost
- etiology of cirrhosis including alcoholic and non-alcoholic (viral, non-alcoholic fatty liver disease, autoimmune, primary biliary cirrhosis, primary sclerosing cholangitis or cryptogenic)
- complications of cirrhosis {presence of acute kidney injury (AKI), HE, ascites, variceal bleeding, SBP, HRS, coagulopathy, portal hypertension, hepato-pulmonary syndrome (HPS), hepatocellular carcinoma (HCC)}
- procedures performed during admission including esophago-gastro-duodenoscopy (EGD), paracentesis, transjugular intrahepatic portosystemic shunt (TIPS) and hemodialysis (HD)
- Elixhauser comorbidity index
- Discharge medications
- Laboratory data including serum creatinine, total bilirubin, INR, sodium, dialysis within last 2 weeks; CTP and MELD-Na score can be calculated from this data.

The case manager will evaluate each patient's EMR and call each patient enrolled in either arm weekly for one month post index discharge to find out if the patient has been readmitted at our or other hospital. For the patients in the INT arm, at the time of discharge, the case manager will help the patient set up an outpatient hepatology follow up appointment within 7 days of discharge. The study coordinator will also arrange outpatient paracentesis appointment if applicable and make sure that patient is discharged on rifaximin and or SBP prophylaxis. Upon the weekly phone call, study coordinator will reassess all the interventions. For the patients in the SOC arm, the study coordinator will call to find out if the patient has been readmitted or not (Figure 1).

If a patient is readmitted within 30 days of index admission whether to OSUWMC or an outside hospital, the case manager will manually review the EMR and record reason for readmission, labs upon readmission and discharge, medications upon readmission and discharge, and associated cost of readmission. We will exclude planned readmissions such as for inpatient elective procedures including endoscopy, transarterial chemoembolization (TACE), TIPS, or observation for paracentesis as well as readmissions unrelated to DC including motor vehicle accidents.

POWER AND SAMPLE SIZE OF TARGET PATIENT POPULATION
Target recruitment for the study is 844 patients admitted to the hospital with decompensated cirrhosis on the Hepatology Service. Patients will be randomly assigned in a 1:1 ratio into INT or SOC arms. The 422 in the SOC arm will be used for prospective validation of the 30-day readmission risk model (Aim 3). The target sample size for the risk model validation is a minimum of 100 patients with events (30-day readmissions in this study) and 100 patients without events, based on recommendations from simulation studies (23, 24). Based on our previous study using the NRD administrative database, we expect a 30-day readmission rate of 27% among patients meeting inclusion criteria, which would yield 114 of 422

patients having 30-day readmission events and meet the target sample size. For the randomized intervention study (Aim 1 and 2), a total sample size of 844 (422 per group) will provide 80% power to detect a 30% decrease in 30-day readmission rate (from 27% to 19%) at a type I error rate of 0.05.

STATISTICAL ANALYSIS PLAN

Prospective validation of the risk model for 30-day readmission (Aim 3) will be performed using data from the patients in the standard of care arm. Risk scores will be calculated as described in the published risk score methodology based on patient age, primary payer, Elixhauser comorbidity, etiology of cirrhosis (alcoholic or non-alcoholic), ascites, hepatic encephalopathy, variceal bleeding, hepatocellular carcinoma, paracentesis during admission, hemodialysis during admission, and discharge disposition. A logistic regression model will be fit to the observed 30-day readmission outcome in the prospective validation cohort using the risk score as the independent variable. Validation will consist of an assessment of model discrimination using the c-index and an assessment of model calibration comparing observed and expected 30-day readmission rates for ranges of predicted probabilities and examining the calibration curve across the full range of probabilities. Assessment of the efficacy of intervention in reducing the 30-day readmission rate (Aim 1 and 2) will be performed using a chi-square test to compare the 30-day readmission rates between the two randomized groups.

MEASUREMENT STRATEGY

Our outcome measure is 30-day readmission rate and associated cost, aiming also to show readmissions to OSUWMC cost less than to outside hospitals. Our process measures include length of stay and 30-day readmission rate as predicted by original Mumtaz readmission score. Data for each patient will be collected by the case manager through using the EMR, written onto the data collection form and entered into the RedCap database.

We will not make changes in our intervention versus standard of care arm until 844 patients (422 in each arm) have been recruited. We will have bi-monthly data analyses discussed over email and monthly meetings with our Co-PI's, case manager and statistician to track recruitment progress, preliminary outcome and process measures and discuss any barriers to recruitment or data collection.

FEASIBILITY, TIMELINE, DELIVERABLES, FACILITATORS & BARRIERS

The project will begin June 1, 2019 to May 31, 2020. We aim to consent 70 patients per month and will check in on this progress at our monthly team meetings as described. By Spring 2010, we hope to have preliminary data to submit to the ACG or AASLD conference for oral presentation. By Summer 2020 we hope to have data analyzed to publish a manuscript stating our aims and conclusions. Around that same time, if the study shows the intervention of the case manager follow up decreases 30-day readmission significantly then we will work with our department to integrate permanently such case manager intervention into our clinical practice. Furthermore, based on data collection if other variables associated with 30-day readmission are elucidated and can be acted upon, initiatives arranging such interventions will be planned and analyzed using PDSA technique.

Facilitators for this project include the support of the Division of Gastroenterology and if fortunate to be awarded PSAG, the Office of Quality and Safety and their respective leadership. Our biggest barrier is that we do not currently have a case manager hired to perform the tasks as described above.

IMPLEMENTATION AND DISSEMINATION PLAN

We plan to implement and disseminate this information after successful completion of the project by presenting the results in front of hospital QI leadership, the Division of Gastroenterology leadership, Case Management leadership and the Department of Internal Medicine. Resources we will employ include placing the link to the refined Mumtaz readmission score on OneSource and as a dotphrase in EPIC for use in daily progress notes for patients with decompensated cirrhosis. We will ensure community and other stakeholder engagement and benefit by providing quarterly reports on reduction in admissions for patients with cirrhosis and associated costs and patient outcomes relative to pre-project implementation. Continued success with this project may require hiring more case managers to assist with follow up calls. We will also invite further qualitative improvement initiatives through provider feedback quarterly and can discuss testing them through PDSA cycle analysis.

SUSTAINABILITY PLAN

To aid in sustainability, given that the intervention truly does reduce readmission, we hope to hire several more case managers to help with the weekly follow up calls of our patients with DC for one month post admission and arrangement

of early hepatology follow up, outpatient paracentesis if applicable, and if indicated HE and SBP prophylaxis. Overall the Division of Gastroenterology will track readmissions for cirrhosis more closely and review quarterly, leading to sustainability of the plans we created through our study.

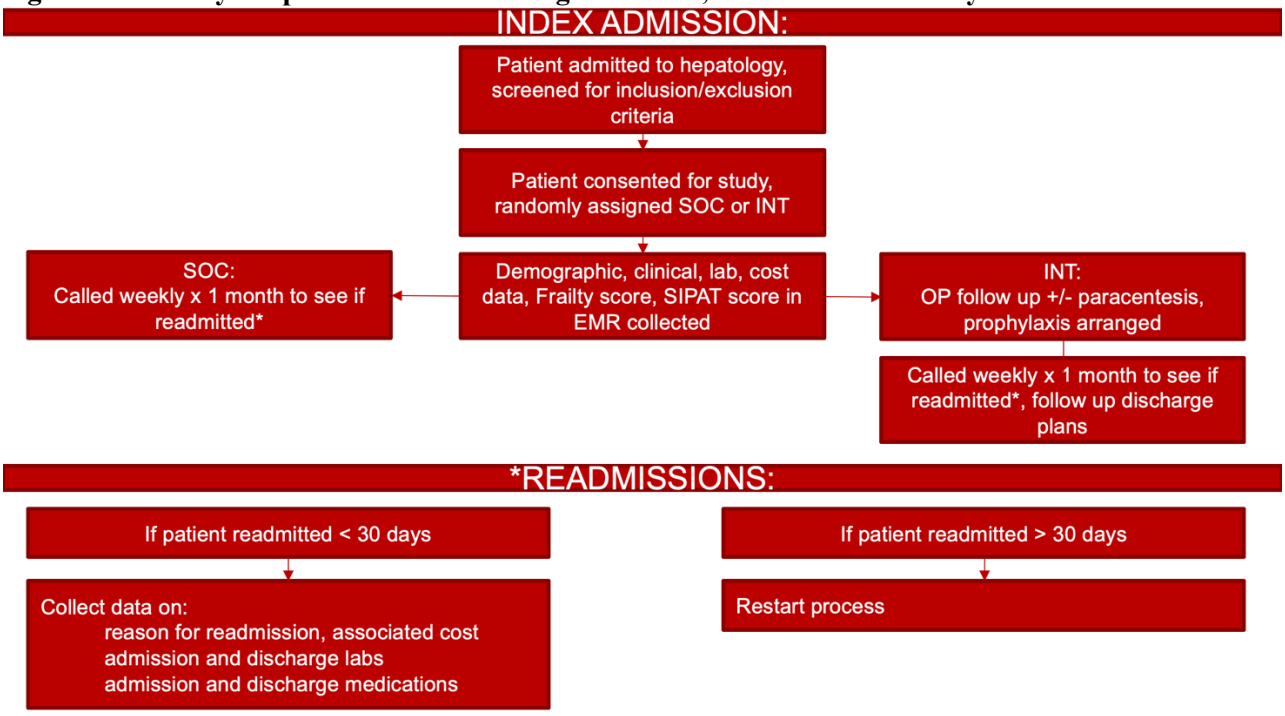
INTELLECTUAL PROPERTY

This project will involve intellectual property in that we are going to enhance the Mumtaz readmission score with a goal to make a smartphone application for it. It currently is available on MDCalc website.

Table 1. Study Inclusion and Exclusion Criteria

Inclusion:	**Exclusion:**
Admitted to inpatient service	Patients with compensated cirrhosis
Patients with known cirrhosis admitted with one or more decompensations including ascites, HE, SBP, hepatorenal syndrome, variceal bleeding, etc.	Patients with liver transplant
	Patients < 18 yo
	Admitted for liver or other organ transplant
	Admitted for elective surgery
	Admitted for non-cirrhosis issue (examples include motor vehicle accident)
	Died during index admission
	Elective admission for EGD, TIPS or TACE, paracentesis procedure)
	Discharged to hospice
	On mechanical ventilation during index admission

Figure 1. Pathway for patients with DC being consented, involved in our study



BIOSKETCHES:

Table of contents:

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Antoinette Josephine MJ Pusateri

eRA COMMONS USER NAME (credential, e.g., agency login): n/a

POSITION TITLE: Clinical Instructor House Staff, Resident Physician

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Start Date MM/YYYY	Completion Date MM/YYYY	FIELD OF STUDY
The University of Notre Dame; South Bend, Indiana	BS – magna cum laude	08/2010	05/2014	Biological Sciences & Theology
The Ohio State University College of Medicine; Columbus, Ohio	MD – cum laude	08/2014	05/2018	Doctor of Medicine
The Ohio State University Wexner Medical Center; Columbus, Ohio	Residency	06/2018	06/2021	Residency - Internal Medicine

A. Personal Statement

I am a first-year resident physician in the Department of Internal Medicine at The Ohio State University Wexner Medical Center pursuing a career in gastroenterology, hepatology and nutrition. I have conducted basic science, translational and clinical research in the field of gastroenterology throughout my undergraduate, medical school and residency training, which has produced presentations and publications as enumerated below. Even at this early stage in my clinical career, I have had the opportunity to rotate on our gastroenterology and hepatology services multiple times. I have witnessed first-hand the burden cirrhosis and its sequelae have on patients and their families, even relative to other chronic gastrointestinal diseases. In addition to the associated morbidity, mortality and high costs associated with readmission in patients with cirrhosis, I have observed the mental and emotional toll hospital readmissions take on patients. My undergraduate training in Biology and Theology instilled in me that to best care for my patients, I must tend to their physical, mental, and emotional needs. Through this study we will analyze how demographic, clinical and psychosocial factors impact readmission and ultimately design interventions to prevent readmission, bringing our patients with cirrhosis closer to living their best quality of life possible.

B. Positions and Honors
Catherine R. Lucey, MD Ambassador Award for Professionalism, The Ohio State University College of Medicine Graduation Award, May 2018

OSU Internal Medicine Award – "for exceptional aptitude in all phases of endeavor as a student of medicine entering the field of Internal Medicine or Internal Medicine/Pediatrics", May 2018

OSU Research Award and Scholarship 2017, The Eugene & Mona Gee Memorial Scholarship Fund

OSU College of Medicine Top 25% Scholarship 2017-2018

Gold Humanism Honor Society, Class of 2017, President, 2017-2018

OSU College of Medicine Class of 1966 Endowment Scholarship 2016-2017

OSU College of Medicine Professionalism Award 2016-2017

OSU College of Medicine Top 25% Scholarship 2016-2017

Landacre Research Honor Society, Class of 2016

OSU College of Medicine Leadership Award 2015-2016

Crohn's and Colitis Foundation of America 2015 Student Fellowship Research Award

Dr. Clotilde Bowen, MD Award of Excellence, 2014

The Glenna R. Joyce Full Academic Scholarship to the University of Notre Dame, 2010-2014

C. Contributions to Science
Publications
Pusateri, A.J. and Krishna, S.G, Pancreatic Cystic Lesions: Pathogenesis and Malignant Potential. *Diseases*. 2018. 6(2): pii: E50. PMID: 29899320

Thompson, M. D., Cismowski, M. J., Serpico, M., **Pusateri, A.,** & Brigstock, D. R. Elevation of circulating microRNA levels in obese children compared to healthy controls. *Clinical Obesity.* 2017; 7(4):216-221. PMID: 28397375

Pusateri, Antoinette J., Kim, Sandra, C., Dotson, Jennifer L., Balint, Jane P., Potter, Carol J., Boyle, Brendan M., Crandall, Wallace, V. Incidence, pattern, and etiology of elevated liver enzymes in pediatric inflammatory bowel disease (IBD). *Journal of pediatric gastroenterology and nutrition*. 2015; 60(5):592-597. PMID: 25493346

Pusateri, Antoinette and Shrader-Frechette, Kristin. Commentary: Flawed Scientific-Evidence Standards Delay Diesel Regulations. *Accountability in research.* 2015; 22(3):162-191. PMID: 25635848

Research Abstracts and Presentations

Orsagh-Yentis, Danielle, Bobbey, Adam, **Pusateri, Antoinette,** Bai, Shasha, Williams, Kent. Feasibility of a *Spirulina* breath test for measurement of gastric emptying in children age 6-18. Abstract submitted to Digestive Disease Week 2019.

Luthra, Anjuli MD, **Pusateri, Antoinette MD**, Yearsley, Martha MD, Schmidt, Carl MD, Krishna, Somashekar MD, MPH. P0246. Confocal Endomicroscopy of Solid Pseudopapillary Tumor of the Pancreas. Endoscopy Video Forum Presentation at: Amercian College of Gastroenterology; 2018 Oct; Philadelphia, Pennsylvania

Pusateri, Antoinette J., et al. Enhancing Collaboration between Future Sonologists and Sonographers:
An Ultrasound Interest Group (USIG) Outreach Initiative. Oral Presentation at: American Institute of Ultrasound
in Medicine; 2018 Mar; New York, New York.

Chang, Cindy D., Boulger, Creagh, **Pusateri, Antoinette,** et al. Infrastructure of the Ohio State University Ultrasound Interest Group (USIG) to promote Point-of-Care Ultrasound in Undergraduate Medical
Education. ePoster presented at: American Institute of Ultrasound in Medicine; 2017 Mar; Orlando, FL.

Pusateri, Antoinette J., et al. Tu2017 The Impact of Quality of Life Upon Transition Readiness in Adolescent
Patients With Inflammatory Bowel Disease (IBD). *Gastroenterology*. 2016; 150(4): S1007.

Scoville, Nicholas, **Pusateri, Antoinette,** Boulger, Creagh, Dschaak, Tyler, Singhal, Sara, Prats, Michael, Bahner, David. Intermediate Ultrasound: Going beyond the basics of ultrasound in medical student education. Poster presented at: World Congress on Ultrasound in Medical Education; 2016 Sept; Lubbock, TX.

Kilgore, Alexandra, **Pusateri, Antoinette,** Crandall, Wallace, Ardura, Monica. Infections in children receiving anti-TNF alpha therapies for inflammatory bowel disease. Poster presented at: North American Society of Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN); 2015 Oct; Washington, DC.

Pusateri, Antoinette, et al. P-172 Characterizing Frequency, Pattern and Etiology of Elevated Liver Enzymes in Pediatric Inflammatory Bowel Disease Patients: A 3-Year Retrospective, Single-Center Review. *Inflammatory Bowel Diseases.* 2013. 19:S95.

Pusateri, Antoinette J. and Velazquez, Peter. Biochemistry of mucosal antigen presentation in normal and colitic animals. Poster presented at: 41st Annual Autumn Immunology Conference; 2012 Nov; Chicago, IL.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors. Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **KHALID MUMTAZ, MBBS, MSc**

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE: Assistant Professor, Ohio State University, Columbus, Ohio

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Start Date MM/YYYY	Completion Date MM/YYYY	FIELD OF STUDY
Dow Medical College, Karachi, Pakistan.	MBBS	06/1987	12/1992	Bachelor of Medicine and Surgery
Aga Khan University, Karachi, Pakistan.	FCPS	11/1996	10/2000	Fellowship in Medicine
Aga Khan University, Karachi, Pakistan.	FCPS	11/2001	10/2004	Fellowship in Gastroenterology
Medical Council of Canada, Ontario, Canada	MCCEE	2011	2012	Medicine
Toronto General Hospital, University of Toronto, Toronto, Canada.	Fellowship Hepatology	01/2011	06/2012	Transplant Hepatology
University of Toronto, Toronto, ON, Canada	MSc	07/2012	06/2014	Clinical Epidemiology & Bio stats

A. Personal Statement

Currently, I am working as Senior Assistant Professor of Medicine and the Director of Clinical Research in section of Hepatology at The Ohio State University, Wexner Medical Center. I have the necessary procedural expertise, research skills and motivation to successfully carry out the proposed study. I got my training in Transplant Hepatology and Clinical Epidemiology at Toronto General Hospital, University of Toronto, Ontario Canada. My research interests in outcomes of liver diseases is reflected in my early and recently published peer reviewed papers. I have distinctive skillsets in biostatistics and have special interest in large-database analyses. I have unique training and research experience in population based databases. I belong to a group of very few gastroenterologists and Hepatologist, who have training in clinical epidemiology and practice clinical research. I primarily focus on following major areas of hepatology research.

1. Post Liver Transplantation (LT) outcomes: I have published 7 papers on various aspects of post LT outcomes, including Hepatitis C virus, post-transplant lymphoproliferative disorder, employment pattern,

cystic fibrosis, TIPS, obesity, etc. Two review articles were also published on topics of Combined Heart & Lung transplantation and Outcomes of liver transplantation in patients with hepato-renal syndrome.
2. Academic Center volume and LT outcomes: 3 papers were published identifying that outcomes of high center volume does not mitigate risk associated with high risk donor organ. Contrary to that, outcomes of simultaneous liver kidney transplant are dependent on the center volume; the higher the volume, the better the outcome.
3. Industry Initiated Trials: I am a Principal Investigator (PI) on three industry initiated trials (2 on the role of Obeticholic acid for Primary Sclerosing Cholangitis and Primary Biliary Cirrhosis and 1 on terlipressin for Hepato-renal syndrome) and Co-PI on nine trials at OSUWMC.
4. Readmission and liver cirrhosis: I recently presented 6 papers about the very important national theme of the role of readmission in healthcare at the 2017 Annual American College of Gastroenterology meeting. For the first time, we proposed a high national 30-day readmission rate, its predictors, and effects on mortality in patients with various complications like cirrhosis in our series of peer reviewed papers.

1) Sobotka LA, Modi RM, Vijayaraman A, Hanje AJ, Michaels AJ, Conteh LF, Hinton A, El-Hinnawi A, **Mumtaz K**. Paracentesis in cirrhotics is associated with increased risk of 30-day readmission. World J Hepatol. 2018 Jun 27;10(6):425-432.
2) Andrew J. Kruger, Fasika Aberra, Sylvester M. Black, Alice Hinton, James Hanje, Lanla F. Conteh, Anthony J. Michaels, Somashekar G. Krishna, **Khalid Mumtaz.** A Validated Risk Model for Prediction of Early Readmission in Patients with Hepatic Encephalopathy. Annals of Hepatology. September, Vol. 17 No. In Press 5, 2018: 00-00.
3) **Mumtaz K**, Issak A, Porter K, Kelly S, Hanje J, Michaels AJ, Conteh LF, El-Hinnawi A, Black SM, Abougergi MS. Validation of Risk Score in Predicting Early Readmissions in Decompensated Cirrhotic patients: A Model Based on the Administrative Database. Hepatology. 2018 Sep 15. doi: 10.1002/hep.30274.

Briefly, in these publications, we: (a) found that patient with decompensated cirrhosis (DC) with ascites have a 33% chance of 30-day readmission, (b) studied the independent predictors of 30-day readmission and developed a readmission risk model in patients with HE and finally, (c) developed and validated a comprehensive readmission risk score for all patients with DC called the Mumtaz score (http://mumtazreadmissionriskscore.com/). The Mumtaz score highlights the need for targeted interventions in high risk patients in order to decrease rates of readmission within this population.
With the current grant application, our goal is to prospectively validate Mumtaz score in patients admitted with DC at Ohio State University, Columbus Ohio. Moreover, we will study various interventions to reduce the rate of readmission in these patients.

B. Positions and Honors

Position and employments

Current appointment

2014 to present	Assistant Professor, Research Director, Section of Hepatology, at Ohio State University, Wexner Medical Center, Gastroenterology, Hepatology and Nutrition, Columbus, Ohio

Academic appointments

07/2012 –07/2014	Transplant Hepatologist & Gastroenterologist at Toronto General Hospital, University Health Network, University of Toronto, Toronto, Ontario, Canada.
12/2007 to 12/2010	Assistant Professor & Consultant Gastroenterologist, Department of Medicine, Aga Khan University Hospital (AKUH), Karachi, Pakistan
09/2004 –11/2007	Senior Instructor and Consultant Gastroenterologist in Section of Gastroenterology, Department of Medicine, Aga Khan University Hospital (AKUH), Karachi, Pakistan.

Other Experience and Professional Memberships

09/2018 to present Member American College of Gastroenterology

2016 to present Active Member, INSTITUTIONAL REVIEW BOARD (IRB), Ohio State University, Columbus, OH

2015 to present Director, Research Section of Hepatology, Ohio State University, Columbus, Ohio

2015- to present Editorial board member of World Journal of Hepatology

2014 to present Editorial board member of Ibnosina Journal of Medicine and Medical Sciences

2014 to present Peer reviewer of multiple journals including Cochrane Library, Transplantation, Expert Review of Gastroenterology & Hepatology, Hepatobiliary and Pancreatic Disorder International, Canadian Journal of Surgery, Annals of Hepatology, Journal of Clinical and Experimental Hepatology, BMJ Journal of Case Report, Journal Reviewer for BMC Gastroenterology, World Journal of Gastroenterology etc.

2008-2009 Exchange Fellowship of American College of Physicians at University of Pittsburgh Medical Centre, Pittsburgh, Pennsylvania, USA.

2007 to present Member of American Association for Study of Liver Disease (AALSD)

2007-2008 Research Committee Member of Single Topic Conference under the auspices of Asian Pacific Association for Study of Liver (APASL),

2005-2010 Research committee member of Pakistan Society for the Study of Liver Disease (PSSLD)

2003-2011 Member Asian Pacific Association for Study of Liver (APASL)

2003 to present Member Pakistan Society for the Study of Liver Disease (PSSLD), Pakistan

2003-2011 Member Pakistan Society of Gastroenterology (PSG), Pakistan

HONORS:

2018 Michael R. Grever Clinical Research Award, Ohio State University, Wexner Medical Center.

2017 THE GOOD TO GREAT AWARD, on my achievements at Ohio State University, Wexner Medical Center.

05/2012 Received the BEST ORAL PRESENTATION Award at 27th Annual Sheila Sherlock Liver Research Day, on presentation of *"Post-transplant lymphoproliferative disorder in adult Liver Transplant Patients" at* University of Toronto, Toronto, Canada.

2010 BEST TEACHER AWARD for my teaching services at AGA Khan University, Karachi, Pakistan.

2008-09 American College of Physician (ACP) Exchange Fellowship. (US$10,000.00)

04/2005 Travel Bursary of Euros 1000 for Best Paper presentation by the European Association for Study of Liver (EASL), Paris, France for presenting, "*A study of Efficacy of L-Ornithine L-Aspartate in Patients with Hepatic Encephalopathy.*

12/2004 Travel Bursary for Oral paper presentation by Asian Pacific Association for Study of Liver (APASL) in, New Delhi, India on presenting "*Distribution of HCV genotypes and response to treatment in Pakistani patients".*

09/2004 Travel Bursary of Euros 1000 for Best Paper presentation by United European Gastroenterology Federation (UEGF) in Prague, Czech Republic on presenting, *"An office based test for detection of current H. pylori infection: Is it valid?*

07/2003 Travel Bursary of euros 1000 for Best Paper presentation by the European Association for Study of Liver (EASL), in Geneva, Switzerland on presenting, *"A Study of Microbiological Profile and Mortality Predictors in Patients with Spontaneous Bacterial Peritonitis".*

05/2002	Gold Medal, awarded by Pakistan Society of Gastroenterology (PSG), in Karachi, Pakistan, on presentation of study entitled, "*Study of Factors Predicting Hyperkalemia in Patients with the Liver Cirrhosis".*
09/2002	Young Investigator Award (YIA) of US$ 1000.00 awarded by Asian Pacific Association for Study of Liver (APASL), in Taipei, Taiwan, on presenting, *"Epidemiology and Clinical Impact of Hepatitis Delta Virus Infection in Pakistan".*

C. Contributions to Science

Early Career

Since my early career at Aga Khan University (AKU), Toronto General Hospital, and now at The Ohio State University, I have been actively working as an academic gastroenterologist and hepatologist. I managed to publish studies on various important aspects of gastroenterology and hepatology during my tenure at AKU. **Viral hepatitis B, C and Delta** are prevalent in South East Asia but their precise distribution, genotypes, and clinical impact were not defined until my research endeavors.

1) **Mumtaz K** , Hamid SS, Adil S, Afaq A, Islam M, Abid S, Shah HA, Jafri W. Epidemiology and clinical pattern of hepatitis delta virus infection in Pakistan. *J Gastroenterol Hepatol.* 2005 Oct; 20(10):1503-7.
2) Faisal Wasim Ismail, Hasnain A. Shah, Saeed Hamid, Zaigham Abbas, Shahab Abid, **Mumtaz K**. Noninvasive predictors of large varices in patients hospitalized with gastroesophageal variceal hemorrhage. *Hepatol Int* (2008) 2:124–128.
3) **Mumtaz K**, Umair Syed Ahmed, Sadik Memon, Ali Khawaja, Tariq Moatter, Muhammad Tayyab Usmani, Saeed Hamid, Wasim Jafri. Virological and clinical characteristics of hepatitis delta virus in South Asia. *Virology Journal*. 2011; 8:312.
4) **Mumtaz K**, Saeed Hamid, Shahid Ahmed, Shamim Siddiqui, Tariq Moatter*, Anis Khan, Masashi Mizokami, Wasim Jafri. A Study of HBV Genotypes and its Correlation with Various Types of Hepatitis B Infections in Pakistan. *Hepatitis Monthly*. 2011;**11**(1):14-18**.**
5) **Mumtaz K,** Saeed Hamid, Tariq Moatter*, Shahab Abid, Hasnain A. Shah, M. Islam, Wasim Jafri. Distribution of HCV genotypes and response to treatment in Pakistani patients. *Saudi Medical Journal*: 2008 Nov;29(11):1671-3.

I published various important cohort studies in the field of hepatology on portal hypertension, Spontaneous Bacterial Peritonitis (SBP), pill-induced esophageal injury and safety and utility of Esophago-gastro-duodenoscopy (EGD).

1) **Mumtaz K**, Faisal Wasim, Wasim Jafri, Saeed Hamid, Hasnain Shah, Sajid Dhakam. Safety and Utility of Esophago-gastro-duodenoscopy in Acute Myocardial Infarction. *European Journal of Gastroenterology and Hepatology* 2008, Vol 20(1):51-55.
2) Kamani L, **Mumtaz K**, Ahmed US, Ali AW, Jafri W. Outcomes in culture positive and culture negative ascitic fluid infection in patients with viral cirrhosis: cohort study. *BMC Gastroenterology*. 2008 Dec 18;8(1):59.
3) Ismail F W, **Mumtaz K**, Chawla T, Jafri W. Gastric variceal bleed in a patient without liver cirrhosis: an unusual cause of haematemesis. *Singapore Med J* 2007; 48(6) : e171
4) **Mumtaz K**, Shahid Majid, Hasnain A. Shah, Kashif Hameed, Ashfaq Ahmed, Saeed Hamid, Shahab Abid, Wasim Jafri. Prevalence of Gastric Varices and Results of Sclerotherapy with N-butyl 2 cyanoacrylate for controlling acute Gastric variceal bleed. *World J Gastroenterol* 2007 February 28; 13(8): 1247-1251
5) Ismail FW, **Mumtaz K**, Shah HA, Hamid S, Abbas Z, Abid S, Anis K, Ahmad A, Jafri W. Factors predicting in-hospital mortality in patients with cirrhosis hospitalized with gastro-esophageal variceal hemorrhage. *Indian J Gastroenterol*. 2006 Sep-Oct; 25(5):240-3.

I participated in important innovative studies on diagnosis of H. Pylori infection, recurrence and recrudescence of H. pylori infection, Reloading Multiband Ligator for Esophageal Varices for reducing cost and developed the Bleeding Care Pathway.

1) **Mumtaz K**, Abid S, Yakoob J, Abbas Z, Hamid S, Islam M, Shah HA, Jafri W. An office-based serological test for detection of current Helicobacter pylori infection: is it useful? *Eur J Gastroenterol Hepatol*. 2006 Jan; 18(1):85-8.

2) Yakoob J, Abid S, Jafri W, Abbas Z, **Mumtaz K**, Hamid S, Ahmed R. Low rate of recurrence of Helicobacter Pylori infection in spite of high clarithromycin resistance in Pakistan. BMC Gastroenterol. 2013 Feb 21;13:33. doi: 10.1186/1471-230X-13-33.
3) Zaigham Abbas, Lubna Rizvi, Umair Syed Ahmed, **Mumtaz K**, Wasim Jafri. Cost Saving by Reloading Multiband Ligator for Esophogeal Varices: a proposal for the third world countries. *World Journal of Gastroenterology* 2008 Apr 14;14(14):2222-5.
4) **Mumtaz K**, Lubna Kamani, Wasim Jafri, Hasnain A. Shah, Saeed Hamid. Impact of a Bleeding Care Pathway in the Management of Acute Upper Gastrointestinal Bleeding. *Indian Journal of Gastroenterology*. 2011 Mar; 30(2):72-7.

Our group had a lot of success with landmark clinical trials in the areas of portal hypertension. We conducted trials on octreotide, terlipressin, N-acetyl Cysteine (NAC), etc.

1) Shahab Abid, Wasim Jafri, Saeed Hamid, , Mohammed Salih, Zahid Azam, **Mumtaz K**, Hasnain Ali Shah and Zaigham Abbas. Efficacy and Safety of Terlipressin Vs Octreotide as Adjuvant Therapy in Bleeding Esophageal Varices. *American Journal of Gastroenterology. Am J Gastroenterol* 2009; 104:617–623.
2) **Mumtaz K**, Azam Z, Hamid S, Abid S, Memon S, Ali Shah H, Jafri W. Role of N-acetylcysteine in adults with non-acetaminophen-induced acute liver failure in a center without the facility of liver transplantation. *Hepatol Int.* 2009 Aug 29.
3) Hasnain A. Shah, **Mumtaz K**, Wasim Jafri, Shahab Abid, Saeed Hamid, Ashfaq Ahmad, Zaigham Abbas. Sclerotherapy plus Octreotide Versus Sclerotherapy alone in the management of Gastro-esophageal Variceal Hemorrhage. *J Ayub Med Coll Abbotabad* 2005:17(1).

Post MSc Career

After completing my Masters in Clinical Epidemiology, my research skills are further polished and I published papers on my new set of research skills, i.e. meta-analyses and large database analyses such as United Network of Organ Sharing (UNOS), Nationwide Inpatient Database (NIS) and Nationwide Readmission Database (NRD).

1) **Mumtaz K**, Faisal N, Husain S, Morillo A, Renner EL, Shah PS. Universal prophylaxis or preemptive strategy for cytomegalovirus disease after liver transplantation: a systematic review and meta-analysis. Am J Transplant. 2015 Feb;15(2):472-81. doi: 10.1111/ajt.13044.
2) Bhaskaran A, **Mumtaz K**, Husain S. Anti-Aspergillus Prophylaxis in Lung Transplantation: A Systematic Review and Meta-analysis. Curr Infect Dis Rep. DOI 10.1007/s11908-013-0380-y.
3) Rania R, **Mumtaz K**, Renner EL. Efficacy of antiviral therapy for hepatitis C post liver transplant on cyclosporine versus tacrolimus: A systematic review and meta-analysis. Liver Transpl 19:36-48, 2013. doi: 10.1002/lt.23516.
4) **Mumtaz K**, Patel N, Patel V, Modi RM, Hanje AJ, Black SM, Krishna SG. Trends and Outcomes of Trans-arterial chemoembolization (TACE) for Primary Hepatocellular cancers (HCC): A National Survey. Hepatobiliary Pancreatic Disease International. December 2017; 16(6): 624-30.
5) Kruger AJ, **Mumtaz K**, Anaizi A, Modi RM, Hussan H, Zhang C, Hinton A, Conwell DL, Krishna SG, Stanich PP. Cirrhosis Is Associated with Increased Mortality in Patients with Diverticulitis: A Nationwide Cross-Sectional Study. Dig Dis Sci. 2017 Oct 6. doi: 10.1007/s10620-017-4782-9.
6) Modi RM, Li F, **Mumtaz K**, Hinton A, Lilly SM, Hussan H, Levine E, Zhang C, Conwell DL, Krishna SG, Stanich PP. Colonoscopy in Patients With Post myocardial Infarction Gastrointestinal Bleeding: A Nationwide Analysis. J Clin Gastroenterol. 2017 Aug 30.
7) Beal EW, Black SM, **Mumtaz K**, Hayes D Jr, El-Hinnawi A, Washburn K, Tumin D. High Center Volume Does Not Mitigate Risk Associated with Using High Donor Risk Organs in Liver Transplantation. Dig Dis Sci. 2017 Jun 1. doi: 10.1007/s10620-017-4639-2.
8) Tumin D, Beal EW, **Mumtaz K**, Hayes, D Jr., Tobias JD, Pawlik TM, Washburn KW, Black SM. Medicaid participation among liver transplant candidates after the Affordable Care Act Medicaid expansion. Journal of American College of Surgery. 2017 May 18. pii: S1072-7515(17)30454-4.

Complete List of Published Work in MyBibliography
(http://www.ncbi.nlm.nih.gov/pubmed/?term=mumtaz+k)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Sean G. Kelly, M.D.

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE: Assistant Clinical Professor

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Start Date MM/YYYY	Completion Date MM/YYYY	FIELD OF STUDY
Duke University	Bachelor of Science	08/1998	05/2002	Biological Anthropology and Anatomy
The Ohio State University	Medical Degree	07/2003	05/2007	Internal Medicine
The Ohio State University and Nationwide Children's Hospital	Residency	07/2007	06/2011	Internal Medicine and Pediatrics Program
University of Wisconsin	Fellowship	07/2012	06/2015	Gastroenterology, Hepatology and Nutrition
University of Wisconsin	Advanced Fellowship	07/2015	06/2016	Transplant Hepatology

A. Personal Statement

I decided to become a Gastroenterologist and Transplant Hepatologist late in my residency career. A rotation with Dr. Robert Kirkpatrick and Dr. James Hanje illustrated the unique disease process of patients with cirrhosis and changed my career path. Those physicians are now two of my five Transplant Hepatology colleagues. I have a diverse practice that involves Endoscopy, Hepatology, Liver Transplantation and Program Directorship. I am fortunate to have a career that allows me to impact the lives of patients and physicians in a number of ways.

B. Positions and Honors

Position	Institution
08/2016 – present	Assistant Clinical Professor The Ohio State University Wexner Medical Center 395 W. 12th Ave, 2nd floor Doan Tower Columbus, OH 43210
07/2015 – 06/2016	Fellow in Transplant Hepatology University of Wisconsin Hospital and Clinics 1685 Highland Ave. 4240-01A MFCB Madison, WI 53705
07/2012 – 06/2015	Fellow in Gastroenterology University of Wisconsin Hospital and Clinics 1685 Highland Ave. 4240-01A MFCB Madison, WI 53705
07/2011 - 07/2012	Hospitalist Physician Sound Physicians at Mount Carmel East Hospital Department of Medicine 6001 East Broad St. Columbus, OH 43213

Date	Honors
2017	Poster of Distinction - Wenzke KE, Kelly SG, Eickhoff JC, Lucey MR, Rice JP. Multidisciplinary liver transplant evaluation in patients with alcoholic liver disease – an alternative to the 'six month rule.' American Transplant Congress. Chicago, IL April 2017
2015	Fellowship Professionalism Award. Division of Gastroenterology and Hepatology, Department of Medicine, University of Wisconsin School of Medicine and Public Health. Awarded annually by the division faculty, fellows, and staff to one fellow
2015	David Wissler Research Day Award Winner Division of Gastroenterology and Hepatology, Department of Medicine, University of Wisconsin School of Medicine and Public Health. Awarded annually by the division faculty, fellows, and staff to one fellow for excellence in basic research
2011	Robyn D. Howson Memorial Award. Selected by Internal Medicine-Pediatrics residency
2009	Outstanding Resident Educator. Selected by medical students

2008	Outstanding Housestaff Teaching Award. Selected by medical students
2007	Grant Morrow Scholarship. Awarded for excellence in pediatric research for role in esophageal manometry and impedance project
2007	Graduated cum laude from medical school

C. Contributions to Science

Early Career – I originally had a focus on Pulmonary and Critical Care Medicine prior to a transition to Gastroenterology and Transplant Hepatology. My first publication was a survey study investigation factors surrounding ICU bed placement.

Graduate Career – My main research focus during Gastroenterology and Transplant Fellowship was focused on Palliative Care in End Stage Liver Disease.

Post-Graduate Career – I have maintained a research interest in Palliative Care in End Stage Liver Disease and additional projects are forthcoming. I was the Principal Investigator for an HCV treatment study for patients who failed prior HCV therapy. As the Assistant Gastroenterology Program Director, I am involved in the recruitment, development and mentorship of Gastroenterology fellows. I am also the lead Physician for Cyanoacrylate Injection for treatment of gastric varices at our institution.

D. Additional Information: Research Support and/or Scholastic Performance

Peer-Reviewed Articles	1. **Kelly SG**, Hawley M, O'Brien JM. Impact of bed availability on requesting and offering in-hospital intensive care unit transfers: a survey study of generalists and intensivists. Journal of Critical Care. 2013 Aug;28(4):461-8. Epub 2013 Jan 9. PMID 23312125. 2. **Kelly SG** and Rice JP. Palliative care for patients with end-stage liver disease: The role of the liver team. Clin Liver Dis. 2015 Jul;6(1):22-3. doi:10.1002/cld.474. 3. **Kelly SG**, Campbell T, Hillman LC, Said A, Lucey MR, Agarwal PD. The utilization of palliative care services in patients with cirrhosis who have been denied liver transplantation. Ann Hepatol. 2017 May - Jun;16(3):395-401. 4. Murphy CJ, Bhatt A, Chen W, Malli A, McGorisk T, **Kelly SG**. Syphilitic Hepatitis. The Lancet. 2017 Dec; 2(12): 920. 5. Motosugi U, Roldan-Alzate A, Bannas P, Said A, **Kelly SG**,

	Wieben O, Reeder SB. Four-Dimensional Flow MRI as a Marker for Risk Stratification of Gastroesophageal Varices in Patients with Liver Cirrhosis. *Radiology* 2018. https://doi.org/10.1148/radiol.2018180230 6. **Kelly SG**, Wenzke KE, Eickhoff JC, Lucey MR, Rice JP. Multidisciplinary liver transplant evaluation in patients with alcoholic liver disease – an alternative to the 'six month rule.' Under review.
Abstracts and Posters	1. Saha N, **Kelly SG**, Ledford C. Diagnosis of Pulmonary Embolism in a Schizoaffective Patient with Acute Renal Failure. American College of Physicians, Ohio Scientific Meeting. Columbus, OH. October 2009. 2. **Kelly SG**, Hawley M, O'Brien JM. Influence of Bed Availability on ICU Admission Requests. American Thoracic Society Meeting. New Orleans, LA. May 2010. 3. **Kelly SG** and Malas A. Septic cavernous sinus thrombosis associated with intravenous drug abuse in patient with persistent bacteremia. American College of Physicians, Ohio Scientific Meeting. Columbus, OH. October 2010. 4. **Kelly SG**, Hillman LC, Agarwal P. Palliative Care Utilization in ESLD Patients Denied Transplant Candidacy. American Association for the Study of Liver Diseases Conference. Boston, MA. November 2014. 5. **Kelly SG** and Said A. Assessing risk of Variceal Hemorrhage with PC-VIPR MRI. Division of Gastroenterology and Hepatology. David Wissler Memorial Research Competition. Madison WI. April 2015. 6. Motosugi U, Roldan A, **Kelly SG**, Spiel A, Said A, Reeder S. 4D-flow MRI for Risk Stratification of Gastroesophageal Varices in Cirrhotic Patients. University of Wisconsin School of Medicine and Public Health. Department of Medicine Research Day. Madison WI. May 2015. 7. **Kelly SG**, Ma X, Newton M, Agarwal P. Current knowledge of guidelines and barriers to HCC screening: A survey study of gastroenterologists and primary care physicians. American Association for the Study of Liver Diseases Conference. San Francisco, CA. November 2015. 8. Wenzke KE, **Kelly SG**, Eickhoff JC, Lucey MR, Rice JP. Multidisciplinary liver transplant evaluation in patients with alcoholic liver disease – an alternative to the 'six month rule.'

	American Transplant Congress. Chicago, IL April 2017. 9. Edd T, Chiles J, **Kelly SG**. Cirrhosis due to Budd Chiari Syndrome. Department of Internal Medicine Trainee Research Day. Columbus, OH May 2017
Book Chapters	1. Hazzard's Geriatric Medicine and Gerontology 7th edition. **Kelly SG**, Barancin C, Lucey MR. Chapter 91 – Hepatic Disease. Published in Fall 2016. 2. Hazzard's Geriatric Medicine and Gerontology 7th edition. **Kelly SG**, Rice JC, Benson ME, Lucey MR. Chapter 92 – Biliary and Pancreatic Disease. Published in Fall 2016.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Adam James Hanje	Associate Professor of Clinical Medicine
eRA COMMONS USER NAME (credential, e.g., agency login)	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
The Ohio State University	B.S.	06/1996	Interdisciplinary Study in Psychobiology
The Ohio State University	M.D.	06/2000	Medicine

Please refer to the application instructions in order to complete sections A, B, C, and D of the Biographical Sketch.

A. Personal Statement

As a formally trained Transplant Hepatologist and Director of Hepatology at a large academic institution, I have access to a large patient population. My goal is to build a program that provides sub-specialty care and access to novel therapies through clinical trials to an often underserved patient population. Specific areas of research interest include next generation treatments for viral hepatitis as well as utilization of loco-regional therapies and transplant in Hepatocellular Carcinoma. Specific areas of clinical interest include Acute Liver Failure and Drug-Induced Liver Injury.

B. Positions and Honors

Medical Education and Positions

2000-2003	Residency and Internship, Internal Medicine, Ohio State University Hospitals
2003-2004	Chief Residency, Internal Medicine, Ohio State University Hospitals
2004-2007	Digestive Diseases Fellowship, Ohio State University Hospitals
2007-2008	Transplant Hepatology Fellowship, University of California, San Francisco Hospital
2008-	Assistant Clinical Professor of Medicine, The Ohio State University Hospitals
2009-	Department of Internal Medicine Core Liaison for Division of Gastroenterology, Hepatology and Nutrition, The Ohio State University Hospitals
2010-	Director of Hepatology, The Ohio State University Hospitals
2010-	Assistant Program Director, Division of Gastroenterology, Hepatology and Nutrition, The Ohio State University Hospitals
2017-	Associate Clinical Professor of Medicine, The Ohio State University Wexner Medical Center

Faculty Awards

2014-2015	Teacher of the Year Awarded to the top Faculty Teacher by the Internal Medicine House staff
2012-2013	Inpatient Faculty Teacher of the Year

	Awarded to the top Inpatient Faculty Teacher by the Internal Medicine House staff
2011-2012	Excellence in Teaching Awarded to the top 6 Faculty Teachers within the Department of Internal Medicine by the 3rd year Medical Students
2011-2012	Inpatient Faculty Teacher of the Year Awarded to the top Inpatient Faculty Teacher by the Internal Medicine House staff
2010-2011	Teacher of the Year Awarded to the top Faculty Teacher by the Internal Medicine House staff
2010-2011	Inpatient Faculty Teacher of the Year Awarded to the top Inpatient Faculty Teacher by the Internal Medicine House staff
2010-2011	Excellence in Teaching Awarded to the top 8 Faculty Teachers within the Department of Internal Medicine by the 3rd year Medical Students
2009-2010	Inpatient Faculty Teacher of the Year Awarded to the top Inpatient Faculty Teacher by the Internal Medicine House staff
2009-2010	Excellence in Teaching Awarded to the top 8 Faculty Teachers within the Department of Internal Medicine by the 3rd year Medical Students

Residency Program Honors

2006-2007	Clinical Fellow of the Year, Ohio State University Hospitals
2003-2004	Chief Resident, Ohio State University Hospitals
2001-2002	John Prior Award-Intern of the Year, Ohio State University Hospitals

Memberships

2004-	Member, Alpha Omega Alpha
2008-	Member, The Ohio State University Liver Transplant Quality Committee
2009-	Member, American Gastroenterological Association
2010-	Member, The Ohio State University, Division of Gastroenterology, Hepatology and Nutrition Finance Committee
2010-	Member, The Ohio State University, Division of Gastroenterology, Hepatology and Nutrition Fellowship Committee
2010-	Member, American Association for the Study of Liver Diseases

C. Selected Peer-reviewed Publications

1. Hanje AJ, Shamp JL, Thomas FB, Meis GM. Thalidomide-induced severe hepatotoxicity. Pharmacotherapy 2006; 26: 1018-22.
2. Hanje AJ, Fortune B, Song M, Hill DB, McClain CJ. The use of selected nutritional supplements and complementary and alternative medicine in liver disease. Nutrition in Clinical Practice 2006; 21: 255-72.
3. Hanje AJ, Pell LJ, Votolato NA, Frankel WL, Kirkpatrick RB. Case report: fulminant hepatic failure due to duloxetine hydrochloride. Clinical Gastroenterology and Hepatology 2006; 4: 912-7.
4. Hanje AJ, Patel T. Preoperative evaluation of patients with liver disease. Nature Clinical Practice Gastroenterology and Hepatology 2007; 4: 266-76.
5. Hanje AJ, Chalasani N. How common is chronic liver disease from acute drug induced liver injury? Gastroenterology 2007; 132: 2067-8.
6. Hanje AJ, Yao FY. Current approach to down-staging of hepatocellular carcinoma prior to liver transplantation. Current Opinion in Organ Transplant 2008; 13: 234-40.
7. Lee, WM, Hanje AJ, Michaels, AM. Controversies in Hepatology: The Experts Analyze Both Sides. N-Acetylcysteine for all non-acetaminophen acute liver failure. October 2010. Editor: Donald Jensen, M.D.. Publisher: PNS & WSS Incorporated dba SLACK Incorporated, Delaware Corporation, 6900 Grove Road, Thorofare, New Jersey 08086.

8. Chamarthi S, Raterman B, Mazumder R, Michaels A, Oza V, Hanje AJ, Bolster B, Jin N, White RD, Kolipaka A. Rapid Acquisition Technique for MR Elastography of the Liver. Magn Reson Imaging. 2014; 32: 679-83.
9. Beal EW, Albert S, McNally M, Shirley L, Hanje AJ, Michaels A, Black S, Bloomston M, Schmidt C. Indeterminate nodules discovered by surveillance imaging of the cirrhotic liver and risk of hepatocellular carcinoma. J Surg Oncol 2014; 110: 967-9.
10. Joshua R Peck, Nicholas Latchana, Anthony Michaels, Adam James Hanje, Alice Hinton, El-Mahdi Elkhammas, Sylvester M Black and Khalid Mumtaz. Diagnosis of morbid obesity may not impact healthcare utilization for orthotopic liver transplantation: A Propensity matched study. World Journal of Hepatology. In Press. Accepted Date: 2017-03-22 16:24

D. Research

Ongoing Research Support

13C-Methacetin Breath Test for the Prediction of Outcome in Acute Liver Failure (ALF-MBT)
Role: Study Co-Investigator, Site Principal Investigator
PI: Lee
Opened 2013
Status: Ongoing Enrollment

A Multi-Center Group to Study Acute Liver Failure
Role: Study Co-Investigator, Site Principal Investigator
PI: Lee
Opened 2013
Status: Ongoing Enrollment

Completed Research Support

SCARLET: A Prospective, Randomized Clinical Trial Comparing Blood Product Use and Bleeding Events During and After Endoscopic or Neurosurgical Procedures in Patients with Cirrhosis and Coagulopathy: Rotational Thromboelastrography (ROTEM) versus Conventional Therapy.
Role: Principal Investigator
Opened: 2015
Status: Closed

Acute Liver Failure Checklist Pilot Study: Development and Pilot of a Checklist for the Management of Acute Liver Failure in the Intensive Care Unit.
Role: Study Co-Investigator, Site Principal Investigator
PI: Fix
Opened 2012
Status: Closed

A Phase 3b, Multicenter, Randomized, Single-blind, Parallel Group Trial of the Effects of Titrated Oral SAMSCA (Tolvaptan)
Role: Co-Investigator
PI: Pesavento
Opened 2012.
Status: Closed

CPI-IFE-001: A Multi-Center, Double Blind, Randomized, Controlled Study to Determine the Safety and Pharmacokinetics of Ifetroban Injection in Hepatorenal Syndrome.
Role: Co-Investigator
PI: Michaels
Opened 2012

Status: Closed

A5294: A Prospective, Phase III, Open-Label Study of Boceprevir, Pegylated-Interferon Alfa 2b and Ribavirin in HCV/HIV Coinfected Subjects.
Role: Co-Investigator
PI: Koletar
Opened 2012
Status: Closed

A Randomized, Double-Blind, Controlled Study to Evaluate the Efficacy and Safety of the Combination of ABT-450/Ritonavir/ABT-267 (ABT-450/r/ABT-267) and ABT-333 With and Without Ribavirin (RBV) in Treatment-Naïve Adults with Genotype 1a Chronic Hepatitis C Virus (HCV) Infection (PEARL-IV).
Role: Principal Investigator
Opened May 2013
Status: Closed

Completed Research Support

A Randomized, Open-Label Trial of the Safety and Efficacy of DEB025/Alisporivir in Combination with Pegylated Interferon-α2a and Ribavirin (peg-IFNα2a/RBV) and Boceprevir in Combination with peg-IFNα2a/RBV in African American Treatment-Naïve Patients with Chronic Hepatitis C Genotype 1.
Role: Principal Investigator
Opened 2011
Status: Closed.

GS-US-256-0124: A Phase 2b, Randomized, Double-Blind, Placebo-Controlled Trial Evaluating Response Guided Therapy using Combinations of Oral Antivirals (GS-5885, tegobuvir, and/or GS-9451) with Peginterferon α2a and Ribavirin in Treatment Experienced Subjects with Chronic Genotype 1 Hepatitis C Virus Infection.
Role: Principal Investigator
Opened 2011
Status: Closed.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Porter, Kyle M

eRA COMMONS USER NAME (credential, e.g., agency login): PORTER363

POSITION TITLE: Senior Biostatistician

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Mount Vernon Nazarene University, Mount Vernon, OH	B.A.	1998	Theological Studies
The Ohio State University, Columbus, OH	M.A.S.	2003	Statistics

A. Personal Statement

I have the expertise, training, and experience necessary to successfully carry out the statistical components of the proposed research project. I have worked as a collaborative biostatistician at the OSU Center for Biostatistics for 13 years with experience in study design, data management, statistical analysis, statistical programming, technical writing, and team leadership. I have worked with databases large and small, prospective and retrospective, in a variety of areas including gastroenterology, oncology, sleep apnea, pharmacy, stress and pregnancy, pathology, veterinary medicine, and public health. I specialize in statistical methods including diagnostic classification, linear and non-linear mixed models, logistic regression, survival analysis, propensity score methods for observational studies, and large database analysis. I have co-authored over 90 publications.

For this proposed research project seeking to validate a risk scoring model for 30-day readmission in patients with decompensated cirrhosis and to evaluate an intervention to reduce 30-day readmission rates, my role will be to generate a randomization list; oversee data quality; perform and report on the proposed analyses; and conduct exploratory analyses in a responsible manner, noting the exploratory nature and the need for independent validation. Reproducible research will be a high priority throughout this study.

B. Positions and Honors

Positions and Employment

2002-2003 Teaching Associate, Department of Statistics, The Ohio State University, Columbus, OH
2003-2004 Research Associate, Battelle Memorial Institute, Columubs, OH
2004-2005 Researcher, Battelle Memorial Institute, Columbus, OH

2005-2006	Biostatistician I, Center for Biostatistics, The Ohio State University, Columbus, OH
2006-2013	Biostatistician II, Center for Biostatistics, The Ohio State University, Columbus, OH
2013-present	Senior Biostatistician, Center for Biostatistics, Department of Biomedical Informatics, The Ohio State University, Columbus, OH

Professional Activities

2005-present	Member, American Statistical Association
2005	Lab Instructor, Mulitlevel Modeling, Summer Program in Applied Statistical Methods, The Ohio State University
2006	Instructor, Introduction to SAS, College of Public Health, The Ohio State University
2006	Instructor, Introduction to SAS, Summer Program in Applied Biostatistical and Epidemiological Methods, The Ohio State University

C. Contributions to Science

1. Gastroenterology: I have collaborated in the role of biostatistician with the Division of Gastroenterology, Hepatology, and Nutrition in the Ohio State University Wexner Medical Center since January 2013, providing input on sample size and study design; grant preparation; statistical programming and data management; analysis of prospective, retrospective, and large database studies; and manuscript preparation. Analytical methods have included evaluation of measures of classification accuracy, survival analysis, linear mixed models, and logistic regression, among others. I have worked previously with Dr. Mumtaz on developing the risk model for 30-day readmissions for patients with decompensated cirrhosis.

a. Mumtaz K, Issak A, **Porter K**, Kelly S, Hanje J, Michaels AJ, Conteh LF, El-Hinnawi A, Black SM, Abougergi MS. Validation of Risk Score in Predicting Early Readmissions in Decompensated Cirrhotic patients: A Model Based on the Administrative Database. Hepatology. 2018 Sep 15. [Epub ahead of print].
b. Hussan H, Ugbarugba E, **Porter K**, Noria S, Needleman B, Clinton SK, Conwell DL, Krishna SG. The Type of Bariatric Surgery Impacts the Risk of Acute Pancreatitis: A Nationwide Study. Clin Transl Gastroenterol. 2018 Sep 12;9(9):179.
c. Krishna SG, Bhattacharya A, Li F, Ross WA, Ladha H, **Porter K**, Atiq M, Bhutani MS, Lee JH. Diagnostic differentiation of pancreatic neuroendocrine tumor from other neoplastic solid pancreatic lesions during endoscopic ultrasound-guided fine-needle aspiration. Pancreas. 2016;45(3):394-400.
d. Hussan H, Stanich PP, Gray DM 2nd, Krishna SG, **Porter K**, Conwell DL, Clinton SK. Prior bariatric surgery is linked to improved colorectal cancer surgery outcomes and costs: a propensity-matched analysis. Obes Surg. 2017; 27(4):1047-55.
e. Krishna SG, Bhattacharya A, Ross WA, Ladha H, **Porter K**, Bhutani MS, Lee JH. Pretest prediction and diagnosis of metastatic lesions to the pancreas by endoscopic ultrasound-guided fine needle aspiration. J Gastroenterol Hepatol. 2015; 30(10):1552-60.

2. Oncology: I have worked as biostatistician in collaboration with investigators from the Ohio State University Comprehensive Cancer since starting at the Center for Biostatistics in 2005. My involvement has run the course of the research endeavor, from study design to data analysis to reporting results. I have helped design laboratory experiments, animal experiments, clinical trials, and retrospective studies. Analyses have included survival analysis, linear and non-linear

mixed models, IC50 estimation, prediction models, and combination drug synergy analysis, among others. I contributed to the design and proposal of biostatistics cores for 4 currently funded program project grants (2 P01s, 1 P30, 1 P50).

a. Segkos K, **Porter K**, Senter L, Ringel MD, Nabhan FA. Neck Ultrasound in Patients with Follicular Thyroid Carcinoma. Hormones & cancer. 2018; 9(6):433-439.
b. Nabhan F, **Porter K**, Lupo MA, Randolph GW, Patel KN, Kloos RT. Heterogeneity in Positive Predictive Value of RAS Mutations in Cytologically Indeterminate Thyroid Nodules. Thyroid. 2018; 28(6):729-738.
c. Valenciaga A, Grubbs EG, **Porter K**, Wakely PE Jr, Williams MD, Cote GJ, Vasko VV, Saji M, Ringel MD. Reduced Retinoblastoma Protein Expression Is Associated with Decreased Patient Survival in Medullary Thyroid Cancer. Thyroid. 2017; 27(12):1523-1533.
d. Nabhan F, **Porter K**, Senter L, Ringel MD. Anti-thyroglobulin antibodies do not significantly increase the risk of finding iodine avid metastases on post-radioactive iodine ablation scan in low-risk thyroid cancer patients. J Endocrinol Invest. 2017; 40(9):1015-21.

3. Other: I have also served as lead biostatistician for the Stress and Health in Pregnancy research program, a sleep apnea research program, and the OSU Medical Center Department of Pharmacy research program in all stages of research, applying a wide variety of statistical methods.

a. Dumanian GA, Potter BK, Mioton LM, Ko JH, Cheesborough JE, Souza JM, Ertl WJ, Tintle SM, Nanos GP, Valerio IL, Kuiken TA, Apkarian AV, **Porter K**, Jordan SW. Targeted Muscle Reinnervation Treats Neuroma and Phantom Pain in Major Limb Amputees: A Randomized Clinical Trial. Annals of surgery. 2018.
b. Khayat RN, Varadharaj S, **Porter K**, Sow A, Jarjoura D, Gavrilin MA, Zweier JL. Angiotensin Receptor Expression and Vascular Endothelial Dysfunction in Obstructive Sleep Apnea. American journal of hypertension. 2018; 31(3):355-361.
c. Christian LM, Beverly C, Mitchell AM, Karlsson E, **Porter K**, Schultz-Cherry S, Ramilo O. Effects of prior influenza virus vaccination on maternal antibody responses: Implications for achieving protection in the newborns. Vaccine. 2017; 35(39):5283-90.
d. Elefritz JL, Bauer KA, Jones C, Mangino JE, **Porter K**, Murphy CV. Efficacy and safety of a colistin loading dose, high-dose naintenance regimen in critically ill patients with multidrug-resistant gram-negative pneumonia. J Intensive Care Med. 2017; 32(8):487-93.

Full Pubmed Bibliography:
https://www.ncbi.nlm.nih.gov/sites/myncbi/18APMx8b5t25a/bibliography/54233144/public/?sort=date&direction=descending

D. Additional Information: Research Support and/or Scholastic Performance

Ongoing Research Support

P30 CA16058 Pollock (PI) 12/01/2004 -11/30/2020
OSU Comprehensive Cancer Center Support Grant

The goal is to support the programs, services, research, and administration of the OSU Comprehensive Cancer Center. The overall CC Program goal is to conduct research to reduce the incidence, mortality and morbidity of cancer, which is accomplished by employing a transdisciplinary research team approach.
Role: Biostatistician

PO1 CA124570 Ringel (PI) 07/01/2008 - 03/31/2019
Genetic and Signaling Pathways in Epithelial Thyroid Cancer
The primary goal of this P01 is to improve the outcomes and lives of patients with thyroid cancer by identifying genetically "at-risk" individuals allowing for early diagnosis and prediction of tumor behavior, new pathways that influence cancer development and progression, and improving outcomes of patients with metastatic disease by improving existing therapies or validating new treatment targets
Role: Biostatistician

RO1 CA227847 Ringel (PI) 04/01/2018 - 03/31/2023
Role of p21-activated kinases in thyroid cancer
Metastatic progressive PTC is an incurable disease. We have identified a potentially important new pathway downstream of BRAF that may be involved PTC progression. Our goal is to determine the relevance of the pathway in vivo, clarify the mechanism by which the pathway is activated, and test several novel compounds that block pathway activation with a goal to determine if PAK is a viable therapeutic target for patients with BRAF-mutated PTC.
Role: Biostatistician

R01 NR013661 Christian (PI) 08/07/2013 - 07/31/2019
Maternal Stress, Obesity, and Influenza Virus Vaccine Immunogenicity in Pregnancy
This study tests the hypotheses that psychosocial stress and obesity substantially impair maternal antibody responses and antibody levels in newborns following maternal influenza vaccination in pregnancy. The goal is to identify and quantify the impact of novel risk factors for poor immune protection from vaccination in two populations vulnerable to influenza complications: pregnant women and infants. This study will determine if it is justified to re-evaluate influenza vaccine recommendations for pregnant women with specific risk factors.
Role: Biostatistician

Completed Research Support

R56 HL127079 Khayat (PI) 09/15/2016 – 08/31/2017
Pharmacological approach to cardiovascular risk in OSA
This study will evaluate the mechanism of endothelial dysfunction in patients with OSA and test a pharmacological approach to minimize cardiovascular risk in patients who do not use CPAP. The findings will advance the understanding of vascular disease in sleep apnea, a major cause of morbidity and mortality in this population. The result will be immediately applicable to planning needed randomized controlled trials evaluating the effects of treatment of sleep apnea on cardiovascular disease.
Role: Biostatistician

R21 HL106283 Khayat (PI) 03/01/2011 - 02/28/2014

The Microcirculation in OSA
This study will evaluate the mechanism of endothelial dysfunction in patients with OSA. The findings will advance the understanding of vascular disease in sleep apnea, a major cause of morbidity and mortality in this population. The result will be immediately applicable to planning needed randomized controlled trials evaluating the effects of treatment of sleep apnea on cardiovascular disease.
Role: Biostatistician

P01 CA125066 Kinghorn (PI) 12/01/2006 - 04/30/2018
Discovery of Anticancer Agents of Diverse Natural Orgin
It is the overall goal of the integrated studies of this program project to discover novel chemicals from selected tropical rainforest plants, as well as cyanobacteria and fungi, for development as cancer chemotherapeutic agents, particularly for tumors that can not be cured by present treatment methods.
Role: Biostatistician

P50 CA168505 Ringel (PI) 09/25/2013 - 07/31/2018
The primary goal of The Ohio State University / M.D. Anderson Thyroid Cancer SPORE is to improve the outcomes and lives of patients with thyroid cancer by identifying genetically "at-risk" individuals allowing for early diagnosis and prediction of tumor behavior, developing new approaches to minimize side effects of treatments, and developing better biomarkers and treatment options for progressive metastatic disease.
Role: Biostatistician

BUDGET

THE OHIO STATE UNIVERSITY
CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE

Program Director/Principal Investigator (Last, First, Middle): Pusateri, Antoinette Josephine MJ

DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY	FROM June 1, 2019	THROUGH May 31, 2020

List PERSONNEL *(Applicant organization only)*
Use Cal, Acad, or Summer to Enter Months Devoted to Project
Enter Dollar Amounts Requested *(omit cents)* for Salary Requested and Fringe Benefits

NAME	ROLE ON PROJECT	Cal. Mnths	Acad. Mnths	Summer Mnths	INST.BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	TOTAL
Pusateri & Mumtaz	PD/PI	12	12	3	0	0	0	
Kyle Porter	Statistician	12	12	3	0	3,148	0	3,148
Case Manager**	CM	12	12	3	0	36,852	0	36,852
SUBTOTALS →						40,000		40,000

CONSULTANT COSTS n/a	0
EQUIPMENT *(Itemize - if applicable and based on guidelines in the RFA)* n/a	0
SUPPLIES *(Itemize by category)* n/a	0
TRAVEL n/a	0
INPATIENT CARE COSTS n/a	0
OUTPATIENT CARE COSTS n/a	0
ALTERATIONS AND RENOVATIONS *(Itemize by category)* n/a	0
OTHER EXPENSES *(Itemize by category)* **Case manager is research staff personnel and has not been named at this time	0
CONSORTIUM/CONTRACTUAL COSTS — DIRECT COSTS	0
SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD *(Item 7a, Face Page)*	$ 40,000
CONSORTIUM/CONTRACTUAL COSTS — FACILITIES AND ADMINISTRATIVE COSTS	0
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD	$ 40,000

CCTS Budget Form v.2 December 2017

BUDGET JUSTIFICATION:

PERSONNEL

Co-Primary Investigators Antoinette Pusateri, MD & Khalid Mumtaz, MBBS MSc (effort = 12 calendar months, 3 summer months) – While we will not be compensated for our time, we will oversee all aspects of the project, including: selecting and training the Case Manager to perform the job as described; promoting the project and recruitment to the Hepatology primary inpatient team and attendings (listed as Co-investigators); conducting bi-monthly data analysis and monthly team meetings to discuss progress and data collected in our RedCap database; processing the data for national conference presentation and manuscript submission at the time of study conclusion; implementing quality improvement initiatives shown to reduce readmission from this study and testing additional QI initiatives identified as being promising from this study.

TBD Case Manager (effort = 12 calendar months, 3 summer months) - We will be hiring a case manager who will be recruiting patients for the study, entering data into the RedCap for the study, and performing the weekly follow up calls a month after index admission as described above for the entire study year. As enumerated in the budget form, this individual will be payed $36852 for the year.

Statistician Kyle Porter (effort = 12 calendar months, 3 summer months) - We will have a statistician who has already established for us our power and sample size and statistical analysis plana and will work with us through the study year to process our data as collected in RedCap. As enumerated in the budget form, this individual will be payed $3148 for the year.

CONSULTANT COSTS
Not applicable
EQUIPMENT
Not applicable
SUPPLIES
Not applicable
TRAVEL
Not applicable
INPATIENT CARE
Not applicable
OUTPATIENT CARE
Not applicable
ALTERATIONS AND RENOVATIONS
Not applicable
OTHER EXPENSES
Not applicable

REFERENCES:

1. Services USDoHaH. Summary Health Statistics: National Health Interview Survey, 2016. 2016.
2. Murphy SL, Xu, J., Kochanek, K.D., Curtin, S.C. and Arias, E. Deaths: Final Data for 2015. 2017;66(6).
3. Peery AF, Crockett SD, Murphy CC, Lund JL, Dellon ES, Williams JL, et al. Burden and Cost of Gastrointestinal, Liver, and Pancreatic Diseases in the United States: Update 2018. Gastroenterology. 2018.
4. Services DoHaH. Medicare program; hospital inpatient value-based purchasing program. Final rule. 2011;76(88).
5. Berman K, Tandra S, Forssell K, Vuppalanchi R, Burton JR, Jr., Nguyen J, et al. Incidence and predictors of 30-day readmission among patients hospitalized for advanced liver disease. Clin Gastroenterol Hepatol. 2011;9(3):254-9.
6. Agrawal K, Kumar P, Markert R, Agrawal S. Risk Factors for 30-Day Readmissions of Individuals with Decompensated Cirrhosis. South Med J. 2015;108(11):682-7.
7. Volk ML, Tocco RS, Bazick J, Rakoski MO, Lok AS. Hospital readmissions among patients with decompensated cirrhosis. Am J Gastroenterol. 2012;107(2):247-52.
8. Bajaj JS, Reddy KR, Tandon P, Wong F, Kamath PS, Garcia-Tsao G, et al. The 3-month readmission rate remains unacceptably high in a large North American cohort of patients with cirrhosis. Hepatology. 2016;64(1):200-8.
9. Kanwal F, Asch SM, Kramer JR, Cao Y, Asrani S, El-Serag HB. Early outpatient follow-up and 30-day outcomes in patients hospitalized with cirrhosis. Hepatology. 2016;64(2):569-81.
10. Tapper EB, Halbert B, Mellinger J. Rates of and Reasons for Hospital Readmissions in Patients With Cirrhosis: A Multistate Population-based Cohort Study. Clin Gastroenterol Hepatol. 2016;14(8):1181-8 e2.
11. Singal AG, Rahimi RS, Clark C, Ma Y, Cuthbert JA, Rockey DC, et al. An automated model using electronic medical record data identifies patients with cirrhosis at high risk for readmission. Clin Gastroenterol Hepatol. 2013;11(10):1335-41 e1.
12. Orman ES, Ghabril M, Emmett TW, Chalasani N. Hospital Readmissions in Patients with Cirrhosis: A Systematic Review. J Hosp Med. 2018.
13. Morales BP, Planas R, Bartoli R, Morillas RM, Sala M, Cabre E, et al. Early hospital readmission in decompensated cirrhosis: Incidence, impact on mortality, and predictive factors. Dig Liver Dis. 2017;49(8):903-9.
14. Mumtaz K, Issak A, Porter K, Kelly S, Hanje J, Michaels AJ, et al. Validation of Risk Score in Predicting Early Readmissions in Decompensated Cirrhotic patients: A Model Based on the Administrative Database. Hepatology. 2018.
15. Ganesh S, Rogal SS, Yadav D, Humar A, Behari J. Risk factors for frequent readmissions and barriers to transplantation in patients with cirrhosis. PLoS One. 2013;8(1):e55140.
16. Picker D, Heard K, Bailey TC, Martin NR, LaRossa GN, Kollef MH. The number of discharge medications predicts thirty-day hospital readmission: a cohort study. BMC Health Serv Res. 2015;15:282.
17. Morales BP, Planas R, Bartoli R, Morillas RM, Sala M, Casas I, et al. HEPACONTROL. A program that reduces early readmissions, mortality at 60 days, and healthcare costs in decompensated cirrhosis. Dig Liver Dis. 2018;50(1):76-83.
18. Morando F, Maresio G, Piano S, Fasolato S, Cavallin M, Romano A, et al. How to improve care in outpatients with cirrhosis and ascites: a new model of care coordination by consultant hepatologists. J Hepatol. 2013;59(2):257-64.
19. Johnson EA, Spier BJ, Leff JA, Lucey MR, Said A. Optimising the care of patients with cirrhosis and gastrointestinal haemorrhage: a quality improvement study. Aliment Pharmacol Ther. 2011;34(1):76-82.
20. Tapper EB, Finkelstein D, Mittleman MA, Piatkowski G, Chang M, Lai M. A Quality Improvement Initiative Reduces 30-Day Rate of Readmission for Patients With Cirrhosis. Clin Gastroenterol Hepatol. 2016;14(5):753-9.
21. Sobotka LA, Modi RM, Vijayaraman A, Hanje AJ, Michaels AJ, Conteh LF, et al. Paracentesis in cirrhotics is associated with increased risk of 30-day readmission. World J Hepatol. 2018;10(6):425-32.
22. Kruger AJ AF, Black SM, Hinton A, Hanje J, Conteh LF, Michaels AJ, Krishna SG, Mumtaz K. A Validated Risk Model for Prediction of Early Readmission in Patients with Hepatic Encephalopathy. 2018;17.
23. Collins GS, Ogundimu EO, Altman DG. Sample size considerations for the external validation of a multivariable prognostic model: a resampling study. Stat Med. 2016;35(2):214
24. Van Calster B ND, Vergouwe Y, De Cock B, Pencina MJ, Steyerberg EW. A calibration hierarchy for risk models was defined: from utopia to empirical data. Journal of Clinical Epidemiology 2016(74):167-76.

LETTERS OF SUPPORT FROM DEPARTMENT CHAIR(S) OF PI(S) AS WELL AS THE EXECUTIVE SPONSOR

Table of contents:

Note: since we are only using IHIS for data extraction we do not need a letter of support from IHIS.

THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

February 27, 2019

Re: Dr. Khalid Mumtaz
Patient Safety Advancement Grant (PSAG) Application

Dear PSAG Scientific Review Committee:

I am pleased to provide this enthusiastic letter confirming my support as Division Director for the 2019 PSAG grant application entitled:

Prospective validation of readmission risk score and interventions to prevent readmission in patients with decompensated cirrhosis

This investigation is an initial submission of a grant from Dr. Khalid Mumtaz. He is proposing to prospectively validate a readmission risk score in patients with decompensated cirrhosis. Moreover, he will compare various interventions with standard of care in these patients to prevent readmission.

This current research proposal for a single center pilot study utilizes data from the patients with decompensated cirrhosis (DC) admitted at Ohio State University. This investigation seeks to prospectively validate his recently developed Mumtaz readmission risk score in adult patients with DC on a cohort of inpatients at a tertiary care university medical center. He is also planning to compare readmission rates between patients randomized to the intervention arm or standard of care (SOC) arm in patients with DC. A designated case manager will follow all the study patients with once weekly call for early readmission(s) for a month after discharge. Interventions in the form of early outpatient hepatology clinic follow-up, arrangement of outpatient paracentesis if needed, assuring that patients with hepatic encephalopathy (HE) are on rifaxamin and SBP prophylaxis at the time of discharge.

Dr. Mumtaz has recently published a series of paper on the important theme of readmission in patients with DC. In these publications, he has **(a)** found that patient with decompensated cirrhosis (DC) with ascites have a 33% chance of 30-day readmission, (b) studied the independent predictors of 30-day readmission and developed a readmission risk model in patients with HE and finally, (c) developed and validated a comprehensive readmission risk score for all patients with DC called the Mumtaz score (https://www.mdcalc.com/mumtaz-score-readmission-cirrhosis). The Mumtaz Score highlights the need for targeted interventions in high risk patients in order to decrease rates of readmission within this population.

This project has full support from the medical center and GHN Division as outlined below.

Dr. Mumtaz has divisional support for this single center pilot study. The Division of Gastroenterology, Hepatology and Nutrition (GHN) is an integral part of the main campus. It provides all gastrointestinal disease education and medical support for the medical center. The Division has 28 full time faculty MDs, 5 Certified Nurse Practitioners and 8 Administrative support staff. The GHN Division has over 20,000 sq. ft. of newly renovated space that includes the medical clinics where the patients with decompensated cirrhosis are managed by our inpatient service team. Our unit is equipped with GHN outpatient clinic and a 16 room endoscopy suite where various endoscopic procedures are performed on patients with cirrhosis.

The Ohio State University Wexner Medical Center
Department of Internal Medicine
Division of Gastroenterology, Hepatology and Nutrition

Faculty Office Tower
395 W. 12th Ave.
Suite 290
Columbus, OH 43210

Phone: 614-293-6255
Fax: 614-293-0861

THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

Dr. Mumtaz has my full support as Division Director for this research project and as Mentor for his academic career. While we believe this application is competitive for PSAG funding support, time will be allotted in Dr. Mumtaz's schedule to complete this research investigation. As a gastroenterologist, I am keenly aware of the global need for improving the readmission in patients with decompensated cirrhosis, and truly believe the proposed study represents a significant opportunity to improve our ability to prospectively validate Mumtaz readmission risk score and develop interventions to reduce readmissions.

On a personal note, Dr. Mumtaz, has essential ingredients for completing this research project, based on his research skills, credentials and work in this field. Dr. Mumtaz has more than 70 peer-reviewed publications including 17 publications as first author and 25 publications as senior author, 3 book chapters, and is participating in 12 clinical trials at Ohio State University, three of which he is the Principal Investigator. He has completed a total of 50 abstracts and has had a total of 48 oral and poster presentation at local, national and international meetings. Dr. Mumtaz has also been a regular judge of other science at the **Ohio American College of Physicians Posters** and **Annual Research Day** for the Wexner Medical Center. As pointed earlier, he published in the area of readmission is decompensated cirrhosis and has a lot of insight about this field. Therefore, I propose think that, Dr. Mumtaz clearly fulfills the requirements for PSAG grant for his research protocol.

Dr. Mumtaz has been awarded ACG Presidential Plenary presentations, American Association for Study of Liver Disease (AALSD) Oral Presentations, Travel bursaries, and numerous Posters of Distinction from numerous GI societies. In addition, he is the recipient of the Michael Grever Award for Clinical Research Excellence in Gastroenterology at The Ohio State University Wexner Medical Center.

I believe awarding him PSAG Grant is a next step in the matriculation of his academic career. It is my intention to continue mentoring Dr. Mumtaz, and plan to submit further grant proposals in the field of hepatology.

Thank you for considering this grant application from a leading researcher in Hepatology at Ohio. I personally can guarantee that he will be able to successfully complete this grant and make strides in improving the readmission rate and ultimately cost of care and mortality in patients with decompensated cirrhosis.

Sincerely,

Darwin L. Conwell, MD, MS
Professor of Medicine
Director, Division of Gastroenterology, Hepatology & Nutrition
The Ohio State University Wexner Medical Center

The Ohio State University Wexner Medical Center
Department of Internal Medicine
Division of Gastroenterology, Hepatology and Nutrition

Faculty Office Tower
395 W. 12th Ave.
Suite 290
Columbus, OH 43210

Phone: 614-293-6255
Fax: 614-293-0861