Form "EAST Multicenter Study Proposal"
Details #117 (submitted 10/14/2020)

Study Title	Social Determinants of Acute Abdomen Outcomes
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Are you a current member of EAST?	Yes
If you selected "No" above please identify a Sponsor that is an active EAST member:	
My Multicenter Study proposal is...	Retrospective
Use this area to briefly (1-2 paragraphs only) outline the burden of the problem to be examined	Social determinants of health are thought to play a role in influencing patient presentation and outcomes in a variety of conditions including EGS-related diseases. Unemployed patients undergoing elective spine surgery were found to have higher rates of 30-day readmission and poorer functional improvement at 1-year than patients who were employed. In the setting of diseases requiring emergency surgery, social support and socioeconomic status both had direct relationships with mortality and functional outcomes after hip fracture. With regards to EGS diseases, uninsurance independently predicts complexity of disease presentation and public insurance predicts higher rates of in-hospital mortality and 30-day readmission following EGS procedures. Similarly, patients from the lowest income quartile have a higher EGS mortality rate compared to patients from the highest income quartile. Despite the excess morbidity and mortality associated with emergency laparotomy during index hospitalization as well as post-operatively, little research has been done on the influence of social determinants of health on initial presentation and outcomes in this patient population. As such, we seek to investigate the relationship between social determinants and emergency laparotomy outcomes with respect to 30- and 90-day complications and readmission rates. We hypothesize that patients with lower social support and adverse local socioeconomic environment will present with more severe intra-abdominal contamination at the time of presentation and will have longer lengths of stay and higher incidence of complications and readmission, even after controlling for higher severity of disease.
Primary aim	To evaluate the association between social determinants of health and 30- and 90-day major a) complications and b) re-admissions

To evaluate the association between social determinants of health and illness severity at the time of presentation for acute abdomen with respect to a) degree of intra-abdominal contamination and b) sepsis at the time of initial presentation

Secondary aims

To evaluate the association between social determinants of health and index hospitalization a) length of stay and b) discharge disposition

Inclusion Criteria

•18 and older

•Primary diagnosis of hernias with gangrene, ischemic and infectious enteritis, perforated viscus, toxic colitis/enteritis, peritonitis, solid organ rupture, colorectal emergencies, bowel obstruction OR upper/lower GI bleed

•Primary procedure of laparotomy (e.g., for colon resection, laparotomy, lysis of adhesions, small bowel resection, strangulated hernia repair, ulcer repair) within 12 hours of initial contact with surgery team

Exclusion Criteria

•Prisoner

•No physical address provided

•Previous abdominal surgery within past 90 days of index operation

Therapeutic Interventions

Retrospective chart review only.

Primary Outcome

30 and 90-day complication and readmission rates

Secondary Outcomes

Degree of intra-abdominal contamination and systemic sepsis at presentation

Index hospitalization length of stay and discharge disposition

List specific variables to be collected & analyzed

Co-variates

Demographics: age, sex, race

Chronic comorbidities: e.g., DM, HTN, cirrhosis

Clinial presentation data: e.g., primary diagnosis, time to OR, transfer status

Dependent variables (predictors of interest)

Social capital: employment status at admission, educational level, insurance status as noted in hospital intake form or case management/social work notes

Social support: subjective measure (high, low, unknown) based on chart review of case management and/or social work notes with consideration of factors including patient's social support persons presence at bedside and/or mention of such persons, living situation, caretakers, patient-reported social support systems

Local socioeconomic stressors: Area deprivation index (ADI) will be used to capture socioeconomic distress. ADI is a composite measure of neighborhood-level disadvantage based on socioeconomic variables including income, education, employment, and housing quality within a given ZIP code such that a higher value corresponds to higher socioeconomic distress (33). ADI has been associated with adverse health outcomes in the settings of cardiovascular disease, cancer, and childhood mortality (34-39)

Independent variables (outcomes of interest)

Presentation severity: degree of contamination (phlegmon, free air, purulent contamination, feculent contamination, gangrenous viscera), surgical APGAR score, qSOFA score

Length of stay: in days, for only those who survived index hospital admission

Discharge disposition: home, home with services, rehab, SNF, LTAC, death

30- and 90- major complications: operative (e.g., wound complication, hematoma), systemic (e.g., renal, cardiac), mortality

30- and 90- re-admission: re-admitted to same hospital as index hospitalization or to other hospital

Outline the data collection plan and statistical analysis plan succinctly

Study staff as appointed by lead investigators at each participating site will abstract data from the electronic medical record for patients meeting inclusion criteria for 5 years prior to the study start date. While participating sites will have competing EMRs, those with access to shared data through the EMR (e.g., EPIC™ Care Everywhere) will be scanned to identify measures of interest, in particular re-admissions. While all-cause re-admissions will be recorded, there will be a variable to flag the admission as a direct EGS complication (e.g., wound dehiscence) vs other cause (e.g., PE). Data will be recorded into a HIPAA compliant REDCap database housed within the Ohio State University Center for Clinical Translational Sciences. Data on patients presenting during the COVID-19 pandemic related changes in EGS structures and processes will be flagged as such. Patient zip codes of residence will be recorded and will be linking to ADI data released by the University of Wisconsin.

Outline consent procedures here, if applicable

This is a retrospective chart review study and will use a waiver of consent.

Succinctly outline a risk/benefit analysis

Our study involves no more than minimal risk because it is a retrospective epidemiological study using information from the patients' electronic medical records to discern if social determinants of health result in adverse outcomes. This study leverages pre-existing information about patient outcomes, and therefore provides only minimal risk with regards to data confidentiality for the patients whose medical records we will analyze.

Include a brief listing of key references

See attached PDF proposal