Short title: **SERPENS**
Title: Epidemiology and outcomes of Gram negative urosepsis
Number: GMA-EU-UROSEP-13-02

Design and Setting:

This is a prospective, longitudinal data collection as an ancillary study to the 2013 GPIU point prevalence study.

Participating hospitals will perform data collection with a goal of collecting complete hospital course data on 600 cases of urosepsis.

Objectives:

a. To describe the prevalence of organisms causing urosepsis and the prevalence of drug resistant organisms causing urosepsis.
b. To describe the clinical and economic burden of urosepsis caused by resistant Gram negative pathogens of interest
c. To characterize risk factors for urosepsis with resistant gram negative pathogens of interest
d. To examine the impact of initial inappropriate antibiotic therapy on clinical and economic outcomes

Patient Selection Criteria:

Patients with clinical diagnosis of urosepsis (presence of systemic inflammatory response with clinical signs of a bacterial infection involving the urogenital organs)

Data Collection:

Clinical and microbiological data are collected as well as information regarding clinical course and outcomes of interest.

- *Microbiological etiology of urosepsis*
  - ❖ Incidence of infection due to Gram negative pathogens of interest
    - Pseudomonas aeruginosa
    - Escherichia coli
    - Klebsiella pneumoniae, oxytoca
    - Enterobacter spp., Citrobacter spp., Serratia spp.
    - Proteus spp.
  - ❖ Rates of resistance among Gram negative pathogens of interest as reported by each site to commonly used agents such as quinolones and bactrim and in addition:
    - Pseudomonas aeruginosa (carbapenem, piperacillin/tazobactam, cefepime, ceftazidime)

  - Escherichia coli (ESBL, carbapenem, 3rd generation cephalosporin)
  - Klebsiella pneumoniae (ESBL, carbapenem, 3rd generation cephalosporin)

- *Characteristics of study population*
  - Demographics
  - Comorbidities
  - Prior antibiotic therapy
  - Prior hospitalization
  - disease factors including catheterization
  - Sepsis severity
  - Sepsis duration
  - Impact on quality of life
- *Antibiotic prescriptions*
- *Treatment adequacy (appropriate versus inappropriate empiric antibiotic therapy) as reported by clinician during data entry*
- *Urologic interventions*

Audit data fields measures:

- *Clinical data*
  - Clinical success/failure (time to symptom resolution, de-escalation/escalation, antibiotic switch)
  - Mortality (overall, infection related)
  - Impact of early appropriate vs. inappropriate empiric antibiotic therapy on clinical outcomes
    - Operational definitions for inappropriate versus appropriate therapy will be developed in the statistical analysis plan
- *Economic data*
  - Resource Utilization
  - Length of stay
  - Impact of early appropriate vs. inappropriate empiric antibiotic therapy on economic outcomes

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Statistical:

Data measured on a continuous scale will be expressed as mean, standard deviation, range, and median. Categorical data will be expressed as counts and percentages of patients in the categories. Chi-square or Fisher's tests will be used to test for statistical differences in categorical variables and T- or Mann-Whitney tests will be utilized for determination of statistical differences in continuous variables where appropriate.

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Trial Registration at clintrials.gov:
Please find the full description of the trial on the Clintrial.gov website:
https://clinicaltrials.gov/ct2/show/NCT02380170

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