UNDERSTANDING THE INCIDENCE OF DIARRHEA IN THE CITY OF LOUISVILLE: <u>C</u>ITY OF <u>LOU</u>ISVILLE <u>D</u>IARRHEA (CLOUD) STUDY

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KEY POINTS

- Research teams from the University of Louisville Center of Excellence for Research in Infectious Diseases (CERID) will work in each hospital to identify patients experiencing diarrhea [3 or more loose stools in a 24 hour period] and approach them with an invitation to enroll in the CLOUD study.
- Research team members will communicate the objectives of the study with staff, specifically nursing staff as they are critically involved in the physical care needs of patients with diarrhea.
- For patients who agree to the study, a stool specimen will be collected and sent to the CERID research laboratory for analysis.
- > Enrolled patients will be asked about the impact of diarrhea on their quality of life including mobility, self-care, usual activities, discomfort, and anxiety via a five-question survey.
- > After discharge, some patients may be contacted to follow up regarding the impact of diarrhea on their quality of life.

Diarrhea, regardless of its etiology, results in significant discomfort, morbidity and mortality among adults. For many reasons, diarrhea has been difficult to study and therefore difficult to understand, manage, and prevent. Further complicating this situation, some cases of diarrhea occur as a result of infection due to Clostridioides difficile (formerly known as Clostridium difficile) in what has now become one of the most common healthcare-associated infections and also one of the deadliest.

Fortunately, work is ongoing to develop a vaccine targeting *C. difficile*, but that work depends upon understanding the current burden of infection and the epidemiology of the disease.

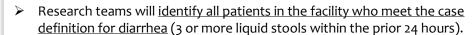
In order to understand the epidemiology of diarrhea in Louisville and the impact *C. difficile* and other pathogens have on its presence, the <u>City of Louisville Diarrhea</u> (CLOUD) study has been under development for the past year. In 2018 and early 2019, pilot studies were held in all nine Louisville adult hospitals, twenty long term care facilities, and a sample of outpatient clinics, emergency departments and urgent care settings.

These pilot studies helped determine how diarrhea can be identified and studied among patients receiving care in those settings, and the safe, efficient, and effective research practices that would be needed for a citywide study

approach. Results from the pilot studies have informed and guided development of the CLOUD study, poised to begin in September

2019 in all nine adult hospitals in the city of Louisville.

WHAT'S INVOLVED?





- Stool specimen will be analyzed in the CERID research lab and not the hospital laboratory.
- Research team members will review electronic health records seeking to identify patients admitted to the hospital who are experiencing diarrhea at the time of admission.
- Research team members will also visit patient care areas every day (Monday-Friday) to ask the nursing staff if they are aware of additional patients experiencing diarrhea.
- Research team members will adhere to the individual facility infection prevention and control policies, procedures, and practices.
- It is the intent of the research teams to ensure the study does not represent any disruption to care nor result in consumption of hospital resources.
- Perhaps the most important outcome of this study will be the identification of risk factors that can be used to focus provision of a soon-to-be released *C. difficile* vaccine.
- > We expect this study will provide new ideas for research and performance improvement ideas not currently recognized, and we look forward to cataloguing these questions and engaging in discussions regarding how individual projects and interests may be supported.





Founded in 2017, CERID, the Center of Excellence for Research in Infectious Diseases, is housed in the University of Louisville Division of Infectious Diseases. The mission of CERID is the generation of new knowledge through clinical and population-based research. To accomplish this mission, CERID seeks to actively and inclusively engage healthcare facilities, healthcare personnel, industry, and communities at large in research efforts that will result in improvements in the human condition.