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CLOUD Japan: Prospective Multi-Hospital Study to Determine the Population-Based Incidence of Hospitalized Clostridium difficile Infections

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Abstract : Clostridium difficile (C. difficile) is the most common cause of antibiotic-associated diarrhea and infectious diarrhea in healthcare settings. Japan has an aging population; the elderly are at increased risk of hospitalization, antibiotic use, and C. difficile infection (CDI). Little is known about the population-based incidence and disease burden of CDI in Japan although limited hospital-based studies have reported a lower incidence than the United States. To understand CDI disease burden in Japan, CLOUD (Clostridium difficile Infection Burden of Disease in Adults in Japan) was developed. CLOUD will derive population-based incidence estimates of the number of CDI cases per 100,000 population per year in Ota-ku (population 723,341), one of the districts in Tokyo, Japan. CLOUD will include approximately 14 of the 28 Ota-ku hospitals including Toho University Hospital, which is a 1,000 bed tertiary care teaching hospital. During the 12-month patient enrollment period, which is scheduled to begin in November 2018, Ota-ku residents > 50 years of age who are hospitalized at a participating hospital with diarrhea (> 3 unformed stools (Bristol Stool Chart 5-7) in 24 hours) will be actively ascertained, consented, and enrolled by study surveillance staff. A stool specimen will be collected from enrolled patients and tested at a local reference laboratory (LSI Medience, Tokyo) using QUIK CHEK COMPLETE® (Abbott Laboratories). which simultaneously tests specimens for the presence of glutamate dehydrogenase (GDH) and C. difficile toxins A and B. A frozen stool specimen will also be sent to the Pfizer Laboratory (Pearl River, United States) for analysis using a two-step diagnostic testing algorithm that is based on detection of C. difficile strains/spores harboring toxin B gene by PCR followed by detection of free toxins (A and B) using a proprietary cell cytotoxicity neutralization assay (CCNA) developed by Pfizer. Positive specimens will be anaerobically cultured, and C. difficile isolates will be characterized by ribotyping and whole genomic sequencing. CDI patients enrolled in CLOUD will be contacted weekly for 90 days following diarrhea onset to describe clinical outcomes including recurrence, reinfection, and mortality, and patient reported economic, clinical and humanistic outcomes (e.g., health-related quality of life, worsening of comorbidities, and patient and caregiver work absenteeism). Studies will also be undertaken to fully characterize the catchment area to enable population-based estimates. The 12-month active ascertainment of CDI cases among hospitalized Ota-ku residents with diarrhea in CLOUD, and the characterization of the Ota-ku catchment area, including estimation of the proportion of all hospitalizations of Ota-ku residents that occur in the CLOUD-participating hospitals, will yield CDI population-based incidence estimates, which can be stratified by age groups, risk groups, and source (hospital-acquired or community-acquired). These incidence estimates will be extrapolated, following age standardization using national census data, to yield CDI disease burden estimates for Japan. CLOUD also serves as a model for studies in other countries that can use the CLOUD protocol to estimate CDI disease burden.

Keywords : Clostridium difficile, disease burden, epidemiology, study protocol
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