



March 5, 2020

Dominic Mancini
Deputy Director
Office of Information and Regulatory Affairs
Office of Management and Budget
Washington, DC

Subject: Request for Emergency Review and Clearance

Dear Mr. Mancini:

Pursuant to Office of Management and Budget (OMB) procedures established at 5 CFR Part 1320, *Controlling Paperwork Burdens on the Public*, I request that the proposed information collection project, "Investigation of a cluster of extensively drug resistant shigellosis associated with a cruise ship" be processed in accordance with section 1320.13, Emergency Processing.

On February 13, 2020 CDC was notified by Australian public health authorities of four cases of infection with extensively drug-resistant (XDR) *Shigella* associated with Cruise X. The Miami, Florida-based Cruise X, left port on January 19, 2020 and returned on January 26, 2020. The cruise made stops in St. Maarten, Puerto Rico, and Haiti. The strain of *Shigella* that was reported by Australian health officials is of concern because of its resistance to all major treatment agents, including ampicillin, cotrimoxazole, ceftriaxone, ciprofloxacin, and azithromycin. On February 20, 2020, CDC notified state and local enteric disease epidemiologists of these cases, and asked states to notify CDC of any patients with *Shigella* infection who reported taking a cruise matching the characteristics of Cruise X. As a result of preliminary case finding, a total of nine U.S. cases were identified as associated with Cruise X. This included cases of both *Shigella sonnei* and *Shigella flexneri*, and at least one case with a resistance profile matching that of the Australian cases. As a result of preliminary case finding, which indicated multiple Cruise X associated cases of shigellosis, including a case of infection with the XDR strain, an investigation was initiated.

The goal of this investigation is to identify additional cases and better characterize cases of acute gastroenteritis and shigellosis associated with Cruise X. This will inform strategies to prevent introduction and transmission of XDR *Shigella* within the United States, and to identify future prevention strategies. CDC cannot reasonably comply with the normal clearance because the initial investigation suggests it is critical to rapidly begin collection of patient data from multiple states in order to identify individuals with infections and prevent transmission of this highly resistant organism within the United States.

Because the collection of patient data is projected to begin on March 13, 2020, accelerated OMB review is requested. Therefore, CDC requests a 90-day emergency clearance to launch collection of patient data.

Please provide an approval/disapproval determination of this request to collect information under an emergency clearance by close of business 3/12/2020.

Respectfully,

Rima F. Khabbaz, MD
Director, National Center for Emerging and Zoonotic Diseases
Centers for Disease Control and Prevention