DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

JAN 18 2013

Michael A. Carome, M.D.
Sidney M. Wolfe, M.D.
Public Citizen's Health Research Group
1600 20th Street, NW
Washington, DC 20009

Dear Drs. Carome and Wolfe:

In September, you wrote to the Secretary of Health and Human Services concerning the occurrence of infections caused by the multidrug-resistant bacteria, carbapenem-resistant *Klebsiella pneumoniae* (KPC), at the Clinical Center of the National Institutes of Health (NIH) in Bethesda, Maryland. You asked that the Secretary arrange for an independent inquiry into decisions made by Clinical Center officials as to when and whom to notify of the KPC cluster. Your letter suggested that this inquiry be conducted by the Department's Office of Inspector General (OIG). The Secretary referred your concerns to my office; with this letter, we are advising you of our findings.

Background

The index patient for the KPC outbreak was transferred to the Clinical Center on June 13, 2011, from a hospital in New York. She was colonized with KPC prior to admission at the Clinical Center and was placed in contact isolation upon review of her medical charts. Surveillance testing did not reveal any other instances of the KPC isolate until August 5th, several weeks after the index patient had been discharged (on July 15th). Thereafter, additional instances of colonization, or active infection, were detected at a rate of, on average, 1 per week, totaling 17 cases as of January 2012. During those months, and since, NIH launched numerous infection detection and control measures to identify and contain transmission. We understand that Public Citizen does not question the nature or sufficiency of those measures. Instead, your letter asks why the Clinical Center did not report the presence of the KPC cluster to officials outside the Clinical Center. Broadly, the letter cites failures to report to governmental entities (at the Federal, State, and local levels); incoming patients to the Clinical Center; and the public at large. We address each of these below.

Reporting to Federal and State Authorities:

- Federal Authorities—Centers for Disease Control and Prevention; Agency for Healthcare Research and Quality

Direct hospital reporting of health-care-associated infections (HAI) to the Centers for Disease Control Prevention's (CDC) National Health Safety Network (NHSN) is not required by CDC. Some States mandate that NHSN be used as the operational system for reporting under their State HAI reporting laws. Maryland is among these States. The Maryland requirements are addressed in more detail below, but in short, the Clinical Center is not subject to Maryland State regulation.

Clinical Center officials confirmed that they did not report the KPC cluster through the NHSN.[1] However, the Clinical Center was in repeated contact with CDC for advice and consultation during the outbreak. In September 2011, a Clinical Center official discussed the outbreak with a member of CDC's Division of Healthcare Quality Promotion, National Center for Emerging and Zoonotic Infectious Disease, who is responsible for antimicrobial surveillance activities (including the NHSN). In November, the Clinical Center consulted with CDC's Director and Deputy Director of the Division of Healthcare Quality Promotion concerning the continued transmissions at the Clinical Center. In early December, at the Clinical Center's invitation, a CDC expert on KPC epidemiology came onsite to assess the Clinical Center's response to the KPC cluster and offer additional suggestions. Thus, we found that NIH did not conceal the outbreak of KPC at the Clinical Center from CDC; instead, Clinical Center officials informed multiple CDC officials of the KPC cluster and consulted with them on infection control measures during the outbreak.

We inquired and learned that the Clinical Center does not currently report information on "patient safety events" to a Patient Safety Organization (PSO). The Agency for Healthcare Research and Quality maintains a list of PSOs that are authorized to collect and analyze data on patient safety events. This reporting is voluntary. Clinical Center officials indicated that they had hesitated to participate in a PSO because, as patients of a research facility, the Clinical Center patient population was unique. They are currently considering affiliating with a PSO.

- Maryland State Public Health Authorities

The NIH campus is a Federal enclave; Maryland ceded jurisdiction over this property to the United States in 1953. Under the Constitution (Art. I, 8, cl. 17), Congress exercises "exclusive

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[1] Recently, the Centers for Medicare & Medicaid Services' (CMS) Hospital Inpatient Quality Reporting Program required hospitals participating in this program to use NHSN as the tool to report data on certain infections (e.g., central-line-associated bloodstream infections). These CMS reporting requirements are tied directly to Medicare reimbursements. Since the Clinical Center does not accept Medicare or Medicaid reimbursement, the CMS reporting requirement does not apply.

Legislation" over such enclaves; accordingly, the Clinical Center is not subject to licensure or regulation by the State of Maryland. Nonetheless, the Clinical Center, as a matter of practice, does choose to report communicable diseases in accordance with Maryland requirements. At the time of our review, there was no formal written policy establishing this voluntary practice. [2] However, in mid-November, NIH announced that it was negotiating an agreement under which the Clinical Center would voluntarily notify both the State and Montgomery County, Maryland, of occurrences of high profile diseases at the Clinical Center.

Briefly, Maryland law provides that the head of a covered institution must report to the State when he or she "has reason to believe that an individual on the premises of the institution has a condition or an infectious or contagious disease . . . that has been designated by the Secretary of Health and Human Services as reportable" (MD Code. Ann. Health-Gen § 18-201). Implementing regulations list 82 specific diseases and conditions that are reportable in Maryland (COMAR 10.06.01). KPC is not a listed disease or condition. The Clinical Center advised that in addition to reporting the listed ones, it also reports to the State any diseases or conditions that pose a health risk to the public. With the KPC outbreak, the Clinical Center did not identify such a public health danger because KPC has posed significant risk only to critically ill, hospitalized individuals with highly compromised immune systems or other serious illnesses. In addition, the disease was contained within certain wards of the Clinical Center. Further, KPC clusters are common in hospitals in many States, and KPC-producing bacteria have been reported to be endemic in hospitals in New York and New Jersey. Since the disease was not a designated reportable one since it was believed not to pose a danger to healthy people and given its prevalence in hospital settings, NIH did not report the cluster to the State.

Although the Clinical Center did not report the KPC cluster under the Maryland infectious disease reporting rules, it did notify the State Health Department and consulted with that office about the Clinical Center's actions to control transmission. In early December 2011, Clinical Center officials consulted with the Center for Surveillance, Infection Prevention and Outbreak Response in the Maryland Department of Health and Mental Hygiene (DHMH). Since then, there have been other contacts with the State concerning the cluster.

Clinical Center officials indicated that they had consulted with other Maryland hospitals and learned that there is no consistency on whether those facilities report KPC outbreaks. However, NIH has indicated that going forward, it will report clusters of KPC and other multidrug-resistant bacteria to Maryland unless and until State officials advise them that it is unnecessary.[3] With

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[2] We did find references to the practice in NIH materials. See, e.g., patient information materials at http://clinicalcenter.nih.gov/participate/patientinfo/legal.shtml, "Uses of Information Outside NIH." Reporting to State authorities is also listed as part of the job description for hospital epidemiology services employees.

[3] Clinical Center officials advised that in at least one instance in the past, they had been asked not to submit national surveillance reports. The Clinical Center's unique status as a research facility only, with disproportionate numbers of patients who are gravely ill and no public emergency department, can skew the reported data.

respect to reporting to county authorities, Clinical Center officials stated that like other Maryland hospitals, the Clinical Center relies on the Maryland DHMH to forward information on reportable communicable diseases to relevant counties. In this case, as set forth in press accounts, after NIH consulted with the State about the KPC cluster, the State did not share that information with Montgomery County. The Clinical Center has since consulted directly with county officials.

Recently, Maryland has begun requiring that certain HAIs be reported to the State via the NHSN. Clinical Center officials indicate that while they do report communicable disease information to State officials, they do not use NHSN. Again, because the Clinical Center is not licensed or regulated by the State, we found no legal requirement that the Clinical Center use this mechanism to alert State officials to HAIs.

Joint Commission

The Joint Commission (JC) inquired about the KPC outbreak in approximately September 2012. NIH responded with a written summary of its response to the outbreak. To date, the JC has expressed no additional concerns nor has it scheduled a "for-cause" survey in response to NIH's written summary. The JC also conducted its triennial accreditation survey of the NIH Clinical Center in September 2012. The onsite survey was conducted on September 7, 2012, and the Accreditation Quality Report was issued the following month. The Clinical Center remained "Accredited" and met all National Patient Safety goals, including those associated with reducing the risk of HAIs. The JC report, dated October 2, 2012, may be found at http://www.qualitycheck.org/qualityreport.aspx?hcoid=6266.

Patients

We found no legal requirement that NIH advise all incoming patients of the KPC occurrence in the Clinical Center. NIH has nonetheless revised its "Patient Education" materials on its patient Web site to specifically advise patients concerning the KPC cluster and other potential HAIs. Generally, these materials set forth basic information concerning HAIs and multidrug-resistant bacteria in a hospital setting. The Web site advises patients of the occurrence of KPC at the Clinical Center. It outlines infection control precautions to prevent transmission of these bacteria and encourages patients to "speak up" about safety concerns, take personal precautions against transmission, report prior exposures to multidrug-resistant bacteria, and report any symptoms. The patient education materials also notify Clinical Center patients that they may have cultures taken to test for multidrug-resistant bacteria; cultures may be taken monthly or, in some wards, as frequently as every few days. A copy of the notice is enclosed.

Clinical Center officials confirmed, as stated in the media, that decisions with respect to whether and in what detail to advise patients of the presence of a KPC cluster in the Clinical Center were made largely by the Principal Investigator (PI) in charge of the particular research protocol, because Clinical Center officials determined that each PI was best positioned to assess the risks to his/her particular patients. The Clinical Center did test whole-hospital rectal surveillance

cultures once per month and more frequently for patients in wards where the risk of infection was highest. Clinical Center officials advised that staff informed patients of the reason for the swabs at the time they were taken. Also, after the story appeared in the media, the Clinical Center issued a "bed-to-bed" memorandum to all inpatients.

Public

We found no legal obligation for a hospital to notify the community at large of the presence of a particular infection in the facility. However, as noted above, NIH recently announced that it was negotiating an agreement to voluntarily notify local county officials of occurrences of high profile diseases at the Clinical Center.

Conclusion

OIG found no violation of any legal requirements with respect to reporting the KPC cluster at the Clinical Center. The Clinical Center, as a matter of policy and not law, opts to report to Maryland public health authorities in accordance with State requirements. [4] Maryland law does not list KPC among reportable communicable diseases or conditions. Clinical Center officials concluded that the cluster posed little or no health risk to the public because KPC has posed significant risk only to individuals with compromised immune systems and the outbreak was contained in certain wards of the Clinical Center. Hospital epidemiology staff consulted informally with other hospitals and were advised that those facilities also do not consistently report KPC to State public health authorities. For these reasons and because of the prevalence of the disease, the Clinical Center did not report the cluster to Maryland. Although the Clinical Center officials did not report the KPC cluster through State or Federal surveillance systems, they did inform both CDC and the Maryland DHMH of the outbreak and sought advice on possible interventions. A KPC expert from CDC came onsite to the Clinical Center to confer.

The Clinical Center advised that going forward, in the interest of supporting the efforts of the Maryland DHMH to track and respond to infectious disease outbreaks in the State, the Clinical Center will consult with Maryland DHMH authorities about all high profile infections occurring in the hospital and will notify the Maryland DHMH whenever outbreaks of infections that might present a risk to the public health occur in the Clinical Center. In addition, in order to ensure communication with public health authorities in Montgomery County and in keeping with the understanding that the Maryland DHMH notifies local public health authorities about issues relevant to their localities, the Clinical Center will also maintain an open line of communication with the Montgomery County Department of Health and Human Services about issues likely to generate community interest.

We found no legal obligation for the Clinical Center to inform all incoming patients or the public at large concerning the KPC cluster, although the agreement under development will provide for notification to local county officials. Finally, the JC inquired about the KPC outbreak in

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[4] The NIH policy is not a written one; however, NIH is now negotiating an agreement that will address notification of State and county officials of outbreaks in the Clinical Center.

September 2012; NIH responded with a summary of its response to the outbreak; and the JC has not expressed additional concerns.

Given the results of our review, OIG does not plan to take additional action in this matter. OIG has conducted extensive work in the general area of reporting and prevention of adverse events, work that has included hospital-acquired infections. While we do not currently plan any additional evaluation of the Clinical Center's actions with respect to the KPC cluster, this information will be highly useful as OIG continues to build on and shape future studies in the area of patient safety.

We hope that this information is helpful to you. If you have questions, please contact Erin Bliss, Director of External Affairs, at 202-205-9523 or Erin.Bliss@oig.hhs.gov.

Sincerely,

Daniel R. Levinson
Inspector General

Enclosure