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September 26, 2008

The Honorable Edward M. Kennedy  
Chairman  
The Honorable Michael B. Enzi  
Ranking Member  
Committee on Health, Education, Labor, and Pensions  
United States Senate

The Honorable John D. Dingell  
Chairman  
The Honorable Joe Barton  
Ranking Member  
Committee on Energy and Commerce  
House of Representatives

Subject: *Health-Care-Associated Infections in Hospitals: Number Associated with Medical Devices Unknown, but Experts Report Provider Practices as a Significant Factor*

Health-care-associated infections (HAI) in hospitals can be expensive to treat and, according to the Department of Health and Human Services' (HHS) Centers for Disease Control and Prevention (CDC), HAIs are estimated to be one of the top 10 causes of death in the United States. HAIs can be caused by bacteria or viruses, which may be introduced to a patient through the use of a device used to treat them, such as a needle or tube to deliver medicine, fluids, or blood. Common HAIs that are often associated with the use of medical devices are urinary tract infections (UTI), surgical site infections (SSI), pneumonia, and bloodstream infections (BSI). A number of federal agencies within HHS, including CDC and the Agency for Healthcare Research and Quality (AHRQ), currently collect HAI-related data for a variety of purposes. Nearly half of the states also require public reporting of hospital HAI rates, according to a summary report of these state laws.<sup>1</sup>

The Food and Drug Administration Amendments Act of 2007<sup>2</sup> requires us to conduct work on HAIs in hospitals associated with medical devices.<sup>3</sup> The act defines these infections as those that are acquired while an individual is a patient at a hospital and were neither present nor incubating prior to the patient's receiving services in the hospital. Specifically, the act

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<sup>1</sup>Consumers Union, "State Hospital Infection Disclosure Laws," available at <http://www.stophospitalinfections.org/learn.html> (accessed July 30, 2008).

<sup>2</sup>Pub. L. No. 110-85, § 229, 121 Stat. 823, 858.

<sup>3</sup>The act uses the term nosocomial infections instead of HAIs. However, for consistency with our previous work, we use the term HAIs in hospitals. See GAO, *Health-Care-Associated Infections in Hospitals: Leadership Needed from HHS to Prioritize Prevention Practices and Improve Data on These Infections*, GAO-08-283 (Washington, D.C.: Mar. 31, 2008).

requires us to report on the number of HAIs in hospitals attributable to new and reused medical devices and on the causes of such infections. As agreed with the committees of jurisdiction, in this report we examine two questions: (1) What is known from available federal and state data about the number of HAIs in hospitals associated with the use of medical devices? (2) What factors affect the occurrence of HAIs in hospitals associated with the use of medical devices?

To obtain information about the number of HAIs in hospitals associated with the use of medical devices, we identified available federal data sources at four HHS agencies—AHRQ, CDC, the Centers for Medicare & Medicaid Services (CMS), and the Food and Drug Administration (FDA)—and reviewed a summary report of available state data sources.<sup>4</sup> We interviewed relevant officials responsible for these federal data sets to determine the extent to which they included information specifically on HAIs in hospitals associated with the use of medical devices, how these data were collected, and whether the data were nationally representative. To identify the factors affecting the occurrence of HAIs in hospitals associated with the use of medical devices, we conducted a literature review and interviewed infection control experts. For the literature review, we identified 38 relevant articles from nearly 200 peer-reviewed scientific studies and medical literature published since 2000 and examined them to determine the significant risk factors and how these factors varied for different HAIs in hospitals. In addition, on the basis of our literature review and recommendations from officials at several federal agencies, professional associations, and advocacy groups, we identified 11 experts to interview about factors that affect the occurrence of HAIs in hospitals. When interviewing these experts, we asked them to identify causes of HAIs in hospitals from among those listed in the mandate and to identify any additional known causes.<sup>5</sup> We further relied on the literature review and these interviews to identify related prevention strategies. We conducted this performance audit from March 2008 through August 2008, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

In summary, multiple federal programs and states collect data on HAIs in hospitals, but none of the data sources we identified provide a national estimate of the number of all HAIs in hospitals associated with medical devices. At the federal level, three HHS agencies, AHRQ, CDC, and CMS, specifically collect or have collected HAI-related data in databases maintained by separate programs, such as CDC's National Healthcare Safety Network (NHSN) program and CMS's Medicare Patient Safety Monitoring System (MPSMS). However, limitations in the scope and collection methods for these databases preclude them from developing a national estimate of HAIs in hospitals associated with medical devices. For example, CDC's NHSN data are not drawn from a representative sample of hospitals nationwide. Similarly, the infection rates included in the MPSMS are based on the experiences of a representative sample of Medicare fee-for-service beneficiaries and are not

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<sup>4</sup>Consumers Union, "State Hospital Infection Disclosure Laws," available at <http://www.stophospitalinfections.org/learn.html> (accessed July 30, 2008).

<sup>5</sup>The Food and Drug Administration Amendments Act of 2007 included the following possible causes: reprocessed single-use devices, handling of sterilized medical devices, in-hospital sterilization of medical devices, health care professionals' practices for patient examination and treatment, hospital-based policies and procedures for infection control and prevention, hospital-based practices for handling of medical waste, and other causes.

representative of the experiences of other Medicare or non-Medicare patients. Also, because the HAI-related information in two of these federal databases is gleaned from patient discharge and other medical records, the quality of the data is dependent on the accuracy with which the information was documented. Finally, although a Consumers Union summary report indicates that nearly half of the states mandate public reporting of hospital HAI rates, a number of factors limit the generalizability and usefulness of the state-reported rates.

Improper patient examination and treatment practices by health care professionals, such as the improper insertion of urinary catheters, are the most significant factor affecting the occurrence of HAIs in hospitals associated with medical devices, according to most medical experts we interviewed. Certain in-hospital sterilization techniques and improper handling of sterilized medical devices were also commonly identified as significant causes of such infections, as was the inherent risk of using medical devices, which can introduce bacteria into the body. Our review of medical literature corroborated many of the risk factors cited by the experts and identified additional factors. For example, patient characteristics such as old age, diabetes, or compromised immune systems were frequently cited in the literature as risk factors. In terms of preventing HAIs, improved hygiene, such as appropriate hand-washing, and the use of barrier precautions, such as caps and gloves, were commonly identified strategies.

In commenting on a draft of this report, HHS suggested that the report would be enhanced by providing a more detailed discussion of HAIs caused by reusable medical devices but acknowledged the difficulties in doing so. HHS also provided technical comments, which we incorporated as appropriate. HHS's comments are reprinted in the enclosure.

## **Background**

Within HHS, three agencies currently collect or have collected data on HAIs in hospitals associated with medical devices in databases maintained by separate programs: AHRQ's Healthcare Cost and Utilization Project (HCUP), CDC's NHSN, and CMS's MPSMS.<sup>6</sup> In addition, FDA's Manufacturer and User Facility Device Experience Database (MAUDE) collects reports of deaths or serious injuries related to the use of medical devices, a small number of which may involve HAIs. In addition to the data collection efforts of these federal agencies, nearly half of the states require public reporting of HAI rates.

Among the federal agencies, CDC's NHSN collects information from hospitals that voluntarily report data on five HAIs associated with medical devices: central-line-associated bloodstream infections (CLABSI), ventilator-associated pneumonia (VAP), catheter-related UTIs, SSIs, and postprocedure pneumonia.<sup>7</sup> In its 2006 annual report, NHSN calculated national rates for

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<sup>6</sup>For additional information regarding these three databases and their limitations, see [GAO-08-283](#). According to a CMS official, data on HAIs in hospitals associated with medical devices were collected from 2002 through 2007.

<sup>7</sup>Hospitals submit data to the NHSN database using a uniform set of definitions.

three of these HAIs—CLABSI, VAP, and catheter-related UTI—and reported the rates by hospital unit, including various types of intensive care units (e.g., burn, surgical, medical).<sup>8</sup> For example, NHSN reported a rate of 2.9 CLABSIs per 1,000 central line days in medical intensive care units.<sup>9</sup> CMS’s MPSMS includes information on the rates of HAIs in hospitals associated with three medical devices, including catheter-related UTIs, catheter-related bloodstream infections, and VAP. To calculate these rates, a CMS contractor extracted information from the medical records of a representative sample of certain fee-for-service Medicare beneficiaries. AHRQ’s HCUP database collects discharge data from all the community hospitals in 39 participating states. The states voluntarily report these data, which include information on the number of infections associated with certain medical devices, including CLABSI and catheter-associated UTI.<sup>10</sup> Collected data are categorized either as the principal condition or complication a patient had during his or her hospitalization or as one of several conditions or complications. Finally, FDA’s MAUDE includes reported incidents of serious injuries and deaths that medical devices have or may have caused or contributed to, which manufacturers, importers, and user facilities are required to report to FDA.<sup>11</sup> MAUDE also includes reports of adverse events voluntarily submitted to FDA.<sup>12</sup>

### **Available Federal and State Data Do Not Provide a National Estimate of HAIs in Hospitals Associated with Medical Devices**

Although multiple federal agencies and states collect data on HAIs in hospitals, limitations in the scope of the information they collect in their databases or their collection methods have precluded the development of national estimates of all HAIs in hospitals associated with medical devices. Among the federal data sources, CDC’s NHSN database provides the most clinically detailed information about HAIs in hospitals, and its procedures for identifying patients with these HAIs draw on the wider range of clinical information available while patients are still in the hospital, as opposed to retrospective reviews of patient medical records after discharge. However, the utility of its data in developing a nationwide estimate has been limited for at least two reasons, specifically its limited scope and its use of a nonrepresentative sample. For example, the NHSN does not collect information on all HAIs in hospitals associated with medical devices; however, in its 2006 annual report, it calculated

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<sup>8</sup>According to a CDC official, the agency will update these HAI rates in NHSN’s 2007 annual report, which the agency plans to publish at the end of 2008, based on data submitted by 621 hospitals. The increased participation is largely due to recent state mandates that require hospitals to report HAI data to NHSN. For example, although hospitals may continue to join NHSN voluntarily, 89 percent of the facilities that joined NHSN in 2007 and 2008 were in states that required participation through a mandate.

<sup>9</sup>Jonathan R. Edwards et al., “National Healthcare Safety Network (NHSN) Report, Data Summary for 2006, issued June 2007,” *American Journal of Infection Control*, vol. 35, 290-301 (2007). The rate of 2.9 CLABSIs per 1,000 central line days was calculated by dividing the aggregate number of reported instances of CLABSI (489) by the total number of days central lines were used (170,719) for all hospitals reporting such data, and multiplying this number by 1,000.

<sup>10</sup>HCUP encompasses a set of related databases, one of which is the Nationwide Inpatient Sample (NIS). NIS contains data from 5 million to 8 million hospital stays from about 1,000 hospitals. According to an AHRQ official, NIS approximates a 20-percent stratified sample of U.S. community hospitals drawn from the participating states, which represent 90 percent of hospital discharges across the United States.

<sup>11</sup>Manufacturers and importers are also required to report device malfunctions to FDA.

<sup>12</sup>Medical device user facilities, manufacturers, importers, and distributors must all maintain records of adverse events.

national rates by hospital unit for three such HAIs—CLABSI, VAP, and catheter-related UTI.<sup>13</sup> In addition, the sample of hospitals used in the 2006 annual report was not necessarily representative of hospitals nationwide, as a random sample would be. The sample included 211 hospitals, which voluntarily submitted data to NHSN. Further, hospitals that reported to NHSN may vary in the scope of their data collection efforts. For example, hospitals can collect data on different infections and monitor HAIs in different units within their hospitals.<sup>14,15</sup>

In addition, limitations in the scope and collection methods for CMS's MPSMS and AHRQ's HCUP databases have precluded the use of their data in developing a national estimate of HAIs in hospitals associated with medical devices. For example, in 2006 MPSMS reported rates of infection for three HAIs in hospitals: 5.35 percent of reviewed medical charts showed evidence of catheter-related UTIs, 2.80 percent showed evidence of catheter-related bloodstream infections, and 9.02 percent showed evidence of VAP infections. However, these rates were based on the experiences of a representative sample of Medicare fee-for-service beneficiaries and did not include other Medicare or non-Medicare patients. Further, because MPSMS data were extracted from medical records, the quality of the data depended on the accuracy with which the patient information was documented, according to a CMS official. Similarly, AHRQ's HCUP database relies on patient discharge records to collect information on the number of HAIs in hospitals associated with certain medical devices, including CLABSI and UTI. For example, data from 2006 showed an estimated 45,879 instances of catheter-associated UTI as one of several complications or conditions patients experienced and an estimated 21,123 instances as the principal complication or reason for admission. However, differences in how hospital staff assign discharge codes may result in inconsistent reporting of HAIs. Further, prior to 2008, the HCUP database did not include information about whether an infection was present on admission. As a result, the number of HAIs in the hospital could have been overstated in previous years as it may have included patients who were infected prior to their hospital stay, according to an AHRQ official. Finally, although a small portion of the incidents reported to FDA's MAUDE database may involve HAIs in hospitals, the principal purpose of the database is to identify devices whose safety and effectiveness warrant closer scrutiny and not to determine the frequency of HAIs in hospitals.

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<sup>13</sup>Edwards et al., "National Healthcare Safety Network (NHSN) Report, Data Summary for 2006, issued June 2007." NHSN reports national rates for other HAIs, including SSI and postprocedure pneumonia. However, SSI and postprocedure pneumonia rates were not calculated for the 2006 annual report due to insufficient data, but will be reported in NHSN's 2007 annual report, according to a CDC official.

<sup>14</sup>Despite these limitations, data from the National Nosocomial Infections Surveillance System—the predecessor to NHSN—were used, along with data from CDC's National Hospital Discharge Survey and the American Hospital Association Survey, to calculate the 2002 nationwide estimate of 1.7 million HAIs in hospitals. CDC officials estimated that over half of these infections were associated with the use of certain medical devices. CDC has no specific plans to update this number using a comparable methodology; however, the agency is exploring the feasibility of developing a national estimate of HAIs in the future using an alternative methodology that has been successful in other countries, according to a CDC official.

<sup>15</sup>Despite this flexibility, voluntary participation in NHSN involves fulfilling a number of requirements, including submitting a monthly reporting plan, adhering to the NHSN reporting protocol, and using NHSN surveillance methods.

Over 20 states mandate public reporting of hospital HAI rates, according to Consumers Union, and variation exists in the types of data they require hospitals to report.<sup>16</sup> For example, Missouri requires hospitals to report data on CLABSI, SSI, and VAP, while as of July 2008, Washington requires hospitals to collect data only on CLABSI. Because of the variation among state reporting requirements, data from individual states cannot be generalized, thereby limiting the usefulness of state data in determining a national estimate of HAIs in hospitals associated with medical devices.

### **Patient Examination and Treatment Practices Cited as the Most Significant Factor Affecting the Occurrence of HAIs in Hospitals**

The most significant factor affecting the occurrence of multiple types of HAIs in hospitals from among possible causes listed in the mandate is health care professionals' improper patient examination and treatment practices, according to the experts we interviewed. All 11 experts we interviewed identified health care professionals' improper patient examination and treatment practices as a factor, with 7 of the 11 medical experts identifying it as one of the most significant factors affecting the occurrence of HAIs in hospitals associated with medical devices. As a specific example of such practices, experts cited the improper insertion and maintenance of medical devices such as urinary catheters and central lines. In addition, about half of the medical experts identified certain in-hospital sterilization processes and improper handling of sterilized devices as potential causes of such infections. Specifically, the experts cited the inadequate preparation of a device for sterilization and the improper storage of sterile devices, which may result in their contamination, as examples of potential causes. Although the use of reprocessed single-use devices is on the list of potential causes included in the mandate, none of the experts we interviewed cited the use of reprocessed single-use devices as a factor contributing to HAIs in hospitals.<sup>17</sup> Beyond the list of potential causes included in the mandate, the medical experts we interviewed referred to other risk factors for developing HAIs in hospitals. For example, 8 of the 11 experts identified the intrinsic risk of using medical devices, including the inability to completely disinfect the area where a device is inserted, as a factor affecting the occurrence of HAIs in hospitals.

Our literature review largely corroborated many of the risk factors cited by the experts and identified additional risk factors. For example, similar to the examples cited above, a number of articles identified health care professionals' improper patient examination and treatment practices and handling of sterilized medical devices as causes of HAIs in hospitals. In addition, half of the articles we reviewed referred to the inherent risk of using medical devices, which can introduce bacteria into the body. The increased risk of infection based on patient characteristics such as old age, diabetes, or compromised immune systems was also cited in more than one-third of the reviewed articles. Other risk factors cited in articles were specific to certain HAIs in hospitals. For example, risk factors specific to CLABSI included the design of the device, such as the materials a catheter is made from and the location on a patient's body where a catheter is inserted, and risk factors specific to VAP included the prolonged duration of mechanical ventilation.

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<sup>16</sup>Consumers Union, "State Hospital Infection Disclosure Laws," available at <http://www.stophospitalinfections.org/learn.html> (accessed July 30, 2008).

<sup>17</sup>Further, one of our recent reports found that available data, while limited, did not indicate that reprocessed single-use medical devices present elevated health risks to patients. See *Reprocessed Single-Use Medical Devices: FDA Oversight Has Increased, and Available Information Does Not Indicate That Use Presents an Elevated Health Risk*, GAO-08-147 (Washington, D.C.: Jan. 31, 2008).

The medical experts and literature highlighted a variety of strategies to prevent the occurrence of HAIs in hospitals associated with the use of medical devices. Three specific prevention strategies—barrier precautions, such as caps, gowns, and gloves; general hygiene measures, such as appropriate hand washing technique; and the use of antimicrobial-coated or antimicrobial-impregnated devices—were the strategies most frequently identified through our expert interviews and our literature review. Other strategies, such as the use of disinfectants, particularly chlorhexidine gluconate, and reducing unnecessary use of medical devices, were also often identified. Finally, bundling prevention strategies, a practice whereby a number of prevention strategies are implemented together, was identified as an additional strategy to prevent the occurrence of HAIs in hospitals. For example, some of the bundled prevention strategies for VAP cited in the literature included elements related to bed elevation and oral hygiene. Although a number of effective prevention strategies exist, the need for evidence-based research on effective prevention techniques for HAIs in hospitals associated with medical devices was identified by several medical experts and studies. In addition, to help reduce HAIs in hospitals, we previously recommended that HHS identify priorities among effective evidence-based practices for infection control and prevention.<sup>18</sup>

### **Agency Comments and Our Evaluation**

In its written comments, HHS stated that the report correctly points out the extent of surveillance conducted for single-use, disposable devices, such as urinary catheters. HHS also said a limitation is that the report combines single-use devices and reusable devices and that the report would be improved by clarifying the distinction between these types of devices. HHS further suggested that the report would be enhanced by including a more detailed discussion of HAIs caused by reusable medical devices. However, HHS acknowledged, and we agree, that very little is known about infections caused by reusable devices. Therefore, it was not feasible to discuss reusable devices separately because no data sources focused on or explicitly included these devices. Nevertheless, HHS's point is important in that it highlights another area in which knowledge is lacking about medical devices and HAIs.

HHS also provided technical comments, which we incorporated as appropriate. HHS's comments are reprinted in the enclosure.

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We are sending copies of this report to the Secretary of Health and Human Services. We will also make copies available to others on request. In addition, the report will be available at no charge on GAO's Web site at <http://www.gao.gov>.

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<sup>18</sup>GAO-08-283, 41.

If you or your staffs have any questions about this report, please contact me at (202) 512-7114 or [bascettac@gao.gov](mailto:bascettac@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Key contributors to this report were Susan Anthony, Assistant Director; Lisa Motley; Roseanne Price; Sari B. Shuman; and Stephen Ulrich.



Cynthia A. Bascetta  
Director, Health Care

Enclosure



Enclosure

**Comments from the Department of Health and Human Services**



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for

Washington, DC 20201

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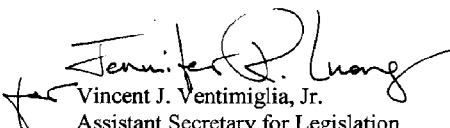
Cynthia Bascetta  
Director, Health Care  
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Dear Ms. Bascetta:

Enclosed are comments on the U.S. Government Accountability Office's (GAO) report entitled: "Health-Care-Associated Infections in Hospitals: Number Associated with Medical Devices Unknown, but Experts Report Provider Practices as a Significant Factor" (GAO 08-1091R).

The Department appreciates the opportunity to review this report before its publication.

Sincerely,

  
for Vincent J. Ventimiglia, Jr.  
Assistant Secretary for Legislation

Attachment

**COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE U.S. GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: HEALTH-CARE-ASSOCIATED INFECTIONS IN HOSPITALS" (GAO-08-1091R)**

**General Comments:**

Thank you for the opportunity to review and comment on the GAO report, Health-Care-Associated Infections in Hospitals: Number Associated with Medical Devices Unknown, but Experts Report Provider Practices as a Significant Factor (GAO-08-1091R).

**Single Use Versus Reusable Devices**

A limitation of this report is that it combines, and hence equates, two very different types of medical devices. The report focuses on infections due to urinary catheters, vascular catheters and ventilators, and is correct in pointing out that there is quite a bit of surveillance conducted for these types of infections. However, the report does not point out that these devices are exclusively single use, disposable devices (in the case of the ventilator, the portions that contact the patient are single use and disposed or between patients) that are left in patients for prolonged periods of time. These devices are very different from other devices such as colonoscopes and surgical instruments that are used for time limited procedures (i.e. they are not left in patients for long periods of time), re-used on multiple patients and are cleaned and disinfected between uses.

We believe the report would be improved by providing more clarity on the different types of devices and discussing each type separately. In addition, the top paragraph on page 2 makes a distinction between "new and used medical devices." We suggest considering instead explaining the difference between disposable, single use devices and reusable devices.

**Identification of Infections from Reusable Devices**

Much is known about both the numbers of, and risk factors for, infections associated with the disposable devices and we would agree that there are surveillance systems in place that do provide some estimates about how often these occur. However, very little is known about infections caused by the reusable devices. The report highlights the availability of the FDA's MAUDE system, but points out various limitations in the ability of this system to provide information on healthcare associated infections. To these, we would add the important fact that often times healthcare providers do not know when a particular infection is associated with a device and thus would be unable to report this information through a surveillance system.

Special investigative efforts are often needed to associate a HAI with a particular reusable device. Public health officials at state and federal levels have been involved in investigations of outbreaks of healthcare associated infections of unknown etiology which turned out to be caused by contaminated, reusable medical devices. These infections were not reported as device-associated infections, because the etiology was not known until after the investigation occurred. Published investigations have shown that

**COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE U.S. GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: HEALTH-CARE-ASSOCIATED INFECTIONS IN HOSPITALS" (GAO-08-1091R)**

these types of infections can be due not only to problems with the handling, cleaning and disinfection of the devices, as is mentioned in the report, but also to defects in the devices themselves.

We believe that the report would be enhanced by including a more detailed discussion of the issues of infections caused by reusable medical devices. It should be noted that investigations of these infections have led to a variety of improvements, not just in the handling, cleaning and disinfection devices in healthcare, but also in device design. The investigation of these types of device-associated infections remains an important part of improving the overall safety of medical devices.

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