

GOVERNMENT OF THE DISTRICT OF COLUMBIA

DEPARTMENT OF HEALTH



HEALTH REGULATION AND LICENSING ADMINISTRATION

# Patient Safety Reporting System District of Columbia

Annual Report  
Fiscal Year  
2012

FOR THE REPORTING PERIOD OF:

OCTOBER 1, 2011 – SEPTEMBER 30, 2012

Prepared January 2013 by:

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## **Executive Summary**

### **I. Improving Healthcare Delivery in the District of Columbia**

In December 2006, the District of Columbia passed the Medical Malpractice Amendment Act of 2006. The act requires that any licensed healthcare provider or medical facility must report adverse events, which include the 28 serious reportable events defined by the National Quality Forum (NQF) as events that are unambiguous (identifiable and measurable), serious (resulting in death or significant disability), and usually preventable. In 2009, the act was amended to require that adverse event reports must be reported within 60 days of their occurrence. In January 2010, a web-based adverse event reporting system was implemented in the ongoing effort to improve healthcare delivery. Starting in October 2010, District facilities were required to report central-line-associated bloodstream infections (CLABSIs) in intensive care units (ICUs) through the National Healthcare Safety Network (NHSN) system instead of the web-based system, allowing the epidemiologists at the District of Columbia Department of Health to monitor and validate infection rates for District facilities and contributing District information to the Centers for Disease Control and Prevention's (CDC) national database. The current users of the reporting systems include hospitals (acute care, long-term acute care, pediatric, psychiatric, and rehabilitation) and ambulatory surgical facilities. Adverse event reports are submitted to the Department of Health through their subcontractor, ECRI Institute, and are confidential, with patient information not required. ECRI Institute analyzes the web-based reports, identifies patterns or trends, recommends methods to reduce systematic adverse events, provides technical assistance to healthcare providers and medical facilities, and disseminates information and advice on best practices through various methods. The District of Columbia Department of Health Center for Policy, Planning and Evaluation's Division of Epidemiology - Disease Surveillance and Investigation provides information from the NHSN reports to ECRI Institute to include in the analysis.

This fifth annual report provides an update on the District of Columbia Patient Safety Reporting System, including an overview of the program's offerings, analysis of adverse event reports, and descriptions of the most significant findings from the reporting period of October 1, 2011, through September 30, 2012.

### **II. Data Collection—Patterns and Trends in Adverse Event Reports**

Collecting and analyzing reports of adverse events is a vital component of the District of Columbia's goal to improve healthcare delivery. During the reporting period of October 2011 through September 2012, the District's healthcare providers and medical facilities submitted a total of 216 events in fiscal year (FY) 2012 to the District of Columbia Department of Health. Seventy-five adverse event reports were submitted to the District of Columbia Patient Safety Reporting System, and 141 reports of CLABSI<sup>1</sup> were submitted to the CDC's NHSN (which is managed by the District of Columbia Department of Health Center for Policy, Planning and Evaluation's Division of Epidemiology - Disease Surveillance and Investigation). Acute care hospitals, which are the majority of the facilities required to report, submitted 177 (82%) of the reports; 4 (2%) were submitted by rehabilitation hospitals, 3 (1%) were submitted by psychiatric facilities, 31 (14%) were submitted by long-term acute care facilities, and 1 (0.5%) was submitted by ambulatory surgical centers. Analysis of the 75 adverse events, not including CLABSIs, revealed 4 (5%) of the reports involved a patient death.

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<sup>1</sup> CLABSI data is from CDC's NHSN, which is managed and provided by the District of Columbia Department of Health's Health Center for Policy, Planning and Evaluation's Division of Epidemiology - Disease Surveillance and Investigation.

The Department of Health continued to adopt NQF's list of 28 serious reportable events from 2006 as a classification system for reportable events during FY 2012; it is under discussion whether the updated NQF list from 2011 will be adopted going forward. The most commonly reported event types, representing 204 (94%) of reports submitted, were CLABSI, pressure ulcers, falls, retained foreign objects, and other events.

Highlights of the data submitted to the Department of Health for the reporting period of October 2011 to September 2012 include the following:

- A total of 216 event reports were received.
- The majority of reports, 177 (82%), were submitted by acute care hospitals.
- There were 14 event types reported this fiscal year.
- The CLABSI rate was 1.61 per 1,000 central-line-days.

The adverse event reports submitted by healthcare providers and medical facilities in the fifth year of the District's reporting program represent a sustained effort by District healthcare providers and medical facilities. Over the past two years, facilities have proven to be more engaged with the program and have shown more interest in the ongoing initiatives and custom feedback.

## Introduction

### I. The District's Patient Safety Reporting System

The District's Patient Safety Reporting System's goals include:

- Promoting patient safety
- Improving the culture of safety
- Learning from and preventing adverse events
- Providing feedback and best practices to District facilities

One of the chief goals of any reporting program is to prevent the occurrence of similar adverse events in the future. Aggregating adverse event data gathered from facilities and providers throughout the District is a powerful tool in identifying trends undermining safe and effective healthcare. The web-based adverse event reporting system provides access to aggregate data at the District level and at the ECRI Institute Patient Safety Organization (PSO) national level. Analysis of the information received through the District's reporting program will serve as the basis for meaningful insights, lessons learned, and best practices that can improve patient safety. For three of the frequently reported event types—CLABSI, retained foreign objects, and pressure ulcers—this report discusses what we have learned about the causes and presents strategies for helping to prevent these events from reoccurring.

Aside from the annual report, in FY 2012, the District of Columbia Patient Safety Reporting System offered the following benefits in which members could engage:

- **Patient safety webinars**—Offered quarterly and included the following topics:
  - The Hidden Source of Infection
  - The Physician Practice: Strategies for Reducing Risks and Improving Patient Safety
  - Best Practices for Managing Medical Product Hazards and Recalls
  - Your Falls Data and Strategies: Learn a New Pearl from your Peers
  - New Reporting System Training (offered 3 times)
- **Quarterly Navigators**—Patient safety advisory articles offered quarterly, which include a *National Navigator* article and a *District Navigator* article. Articles have been provided on the following topics over FY 2012:
  - **National:**
    - Sterile Processing Department's Role in Patient Safety
    - Events from Inadequate Orientation and Training
    - Patient Safety and the Environment of Care
    - Bariatric Patient Safety
  - **District:**
    - Medical Devices and Pressure Ulcers
    - Sitters
    - A Piece of the Patient Safety Puzzle: "Other" Events
- **Custom feedback on adverse events**—Resources and best practices are provided back to the facilities directly on selected adverse event reports, and they are offered more in-depth

research if warranted. Facilities may also request feedback on specific topics. The following are some of the topics in which feedback was provided during FY 2012:

- Amniotic Fluid Embolism
  - Blood Incompatibility
  - Blood Volume in Pediatric Patients
  - Discharge Medications
  - Elective Termination of Pregnancy
  - Falls
  - Handoff Communication
  - Harm Score Scales
  - Home Medications
  - Patient Medical Equipment
  - Pressure Ulcers
  - Retained Foreign Objects
  - Retained Guidewires
  - Sexual Assault
  - Suicide
  - Wrong-Site Nerve Block
- 
- **Root-cause analyses and corrective action plans (CAPs)**—If a thorough root-cause analysis and CAP are submitted along with an event, it is analyzed through ECRI Institute’s root-cause analysis review process and then the facility can be provided with a report to further assist them in improving their process.
  
  - ***Patient Safety Membership Update***—A monthly electronic newsletter that compiles updated patient safety news over the past month.
  
  - ***Patient Safety E-Alerts***—Unplanned special notices on major patient safety issues that have been seen at a national level. Topics in FY 2012 included:
    - Insulin Administration and Nutritional Therapy—It’s More Than Counting Carbs, It’s Communication and Coordination
    - Retained Foreign Objects—It’s Not the Robot’s Fault
    - Electrosurgical Burns—Don’t Get Burnt: Have High-Quality Contact

## Data Collection and Analysis

### I. Reportable Events

The District has mandated the reporting of adverse events by a broad range of healthcare providers and medical facilities. Adverse events that were required to be reported include the 28 NQF serious reportable events from the 2006 list. During this past fiscal year, CLABSIs continue to be reported to CDC's NHSN, which is managed by the District of Columbia Department of Health's Health Center for Policy, Planning and Evaluation's Division of Epidemiology - Disease Surveillance and Investigation. Since January 2010, hospitals and ambulatory surgical centers have been required to report adverse events and CAPs using the web-based reporting system. A standardized adverse event reporting form is available to all other medical facilities and healthcare providers for this purpose. Reports must be submitted within 60 days of the occurrence of an adverse event. The Department of Health collects and analyzes the reports, providing an annual report that includes summary data and recommendations. The Medical Malpractice Amendment Act contains well-defined confidentiality provisions related to reporters and information provided to the system administrator. This annual report compiles and provides analysis on both the CLABSI data from NHSN, as well as the NQF events submitted to the web-based reporting system.

### II. Reports by Event Type

In the fifth reporting period, which covers events submitted between October 1, 2011, and September 30, 2012, District medical facilities and healthcare providers submitted 216 reports to the Department of Health. The most frequently reported types of events were CLABSIs, pressure ulcers, falls, retained foreign objects, and other events, representing 204 (94%) of the reports submitted. Figure 1 summarizes the reports submitted by event type. Figure 2 provides a comparison between the number of events reported during this fiscal year and the previous fiscal year.

**Figure 1. Number and Percentage of Reports by Event Type in FY 2012**

Event Category	Event Type	No.	%
<b>Surgical Events</b>	1A - Surgery performed on the wrong body part	1	0.5
	1B - Surgery performed on the wrong patient	0	0
	1C - Wrong surgical procedure performed on a patient	0	0
	1D - Unintended retention of a foreign object in a patient after surgery or other procedure	10	4.6
	1E - Intraoperative or immediately postoperative death in an American Society of Anesthesiologists (ASA) class I patient	1	0.5
<b>Product or Device Events</b>	2A - Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility	0	0
	2B - Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended	1	0.5
	2C - Patient death or serious disability associated with intravascular air embolism that occurs while the patient is being cared for in a healthcare	0	0

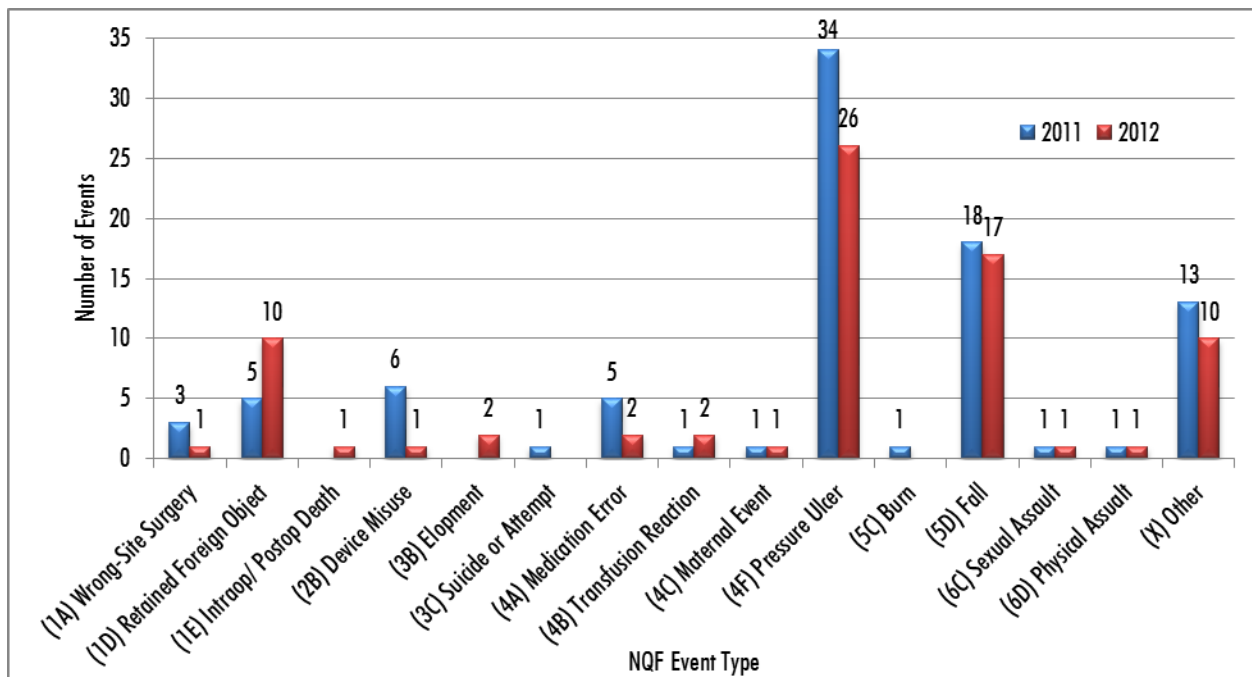
Event Category	Event Type	No.	%
	facility		
<b>Patient Protection Events</b>	3A - Infant discharged to the wrong person	0	0
	3B - Patient death or serious disability associated with patient leaving the facility without permission	2	0.9
	3C - Patient suicide or attempted suicide resulting in serious disability while the patient is being cared for in a healthcare facility	0	0
<b>Care Management Events</b>	4A - Patient death or serious disability associated with a medication error	2	0.9
	4B - Patient death or serious disability associated with a hemolytic reaction (abnormal breakdown of red blood cells) due to the administration of ABO/HLA-incompatible blood or blood products	2	0.9
	4C - Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while the patient is being cared for in a healthcare facility	1	0.5
	4D - Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility	0	0
	4E - Death or serious disability associated with failure to identify and treat hyperbilirubinemia in newborns	0	0
	4F - Stage III or IV pressure ulcers acquired after admission to a healthcare facility	26	12.0
	4G - Patient death or serious disability due to spinal manipulative therapy	0	0
	4H - Artificial insemination with the wrong donor sperm or wrong egg	0	0
<b>Environmental Events</b>	5A - Patient death or serious disability associated with an electric shock while the patient is being cared for in a healthcare facility	0	0
	5B - Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances	0	0
	5C - Patient death or serious disability associated with a burn incurred from any source while the patient is being cared for in a healthcare facility	0	0
	5D - Patient death or serious disability associated with a fall while the patient is being cared for in a healthcare facility	17	7.9
	5E - Patient death or serious disability associated with the use of restraints or bedrails while the patient is being cared for in a healthcare facility	0	0
<b>Criminal Events</b>	6A - Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider	0	0
	6B - Abduction of a patient of any age	0	0
	6C - Sexual assault on a patient within or on the grounds of a healthcare facility	1	0.5
	6D - Death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the grounds of a healthcare facility	1	0.5



Event Category	Event Type	No.	%
Healthcare-Associated Infections	7 - Central-catheter-associated bloodstream infection <sup>1</sup>	141	65.3
"Other" Event Type Reported	X - "Other" non-NQF type of event reported	10	4.6
<b>Total</b>		<b>216</b>	<b>100.1*</b>

\* Total percentage is greater than 100 due to rounding.

**Figure 2. Comparison of Number of Event Types (excluding CLABSI)**



This bar chart, Figure 2, details the event types that had one or more events reported in that category and shows a comparison between FY 2011 and FY 2012. Since the web-based system started in the middle of FY 2010, these past two years, FY 2011 and FY 2012, provide a comparison of data that was solely submitted online. Overall, the most significant increase in the number of events reported occurred with retained foreign objects. The most significant decrease in the number of events reported occurred with pressure ulcers. This change in the number of events reported may reflect a change in reporting or a decrease or increase in the number of events that occurred. Figure 3 shows a comparison of CLABSI events, which reveals a significant decrease; however, central-line-days are an important variable in comparing CLABSI events and are used to determine CLABSI rates. This information will be further detailed in the "Guidance and Recommendation" section.

During the FY 2012 reporting period, there continued to be 14 total event types reported, which was increased from 9 event types previously in FY 2010. The 14 event type categories changed slightly, as this year included both the elopement and intraoperative/postoperative death NQF event types.

Figure 3. Comparison of Number CLABSI<sup>1</sup>

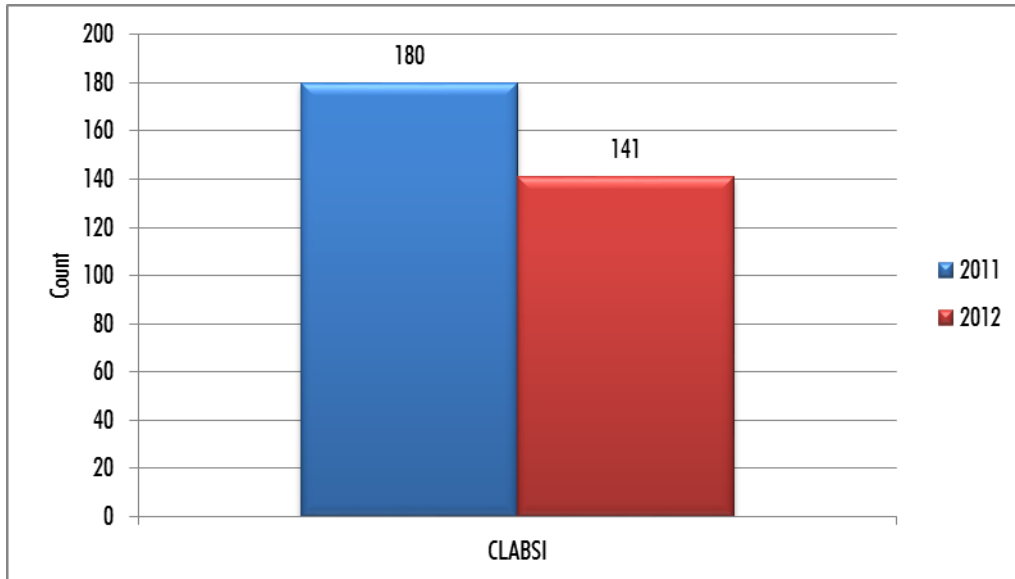
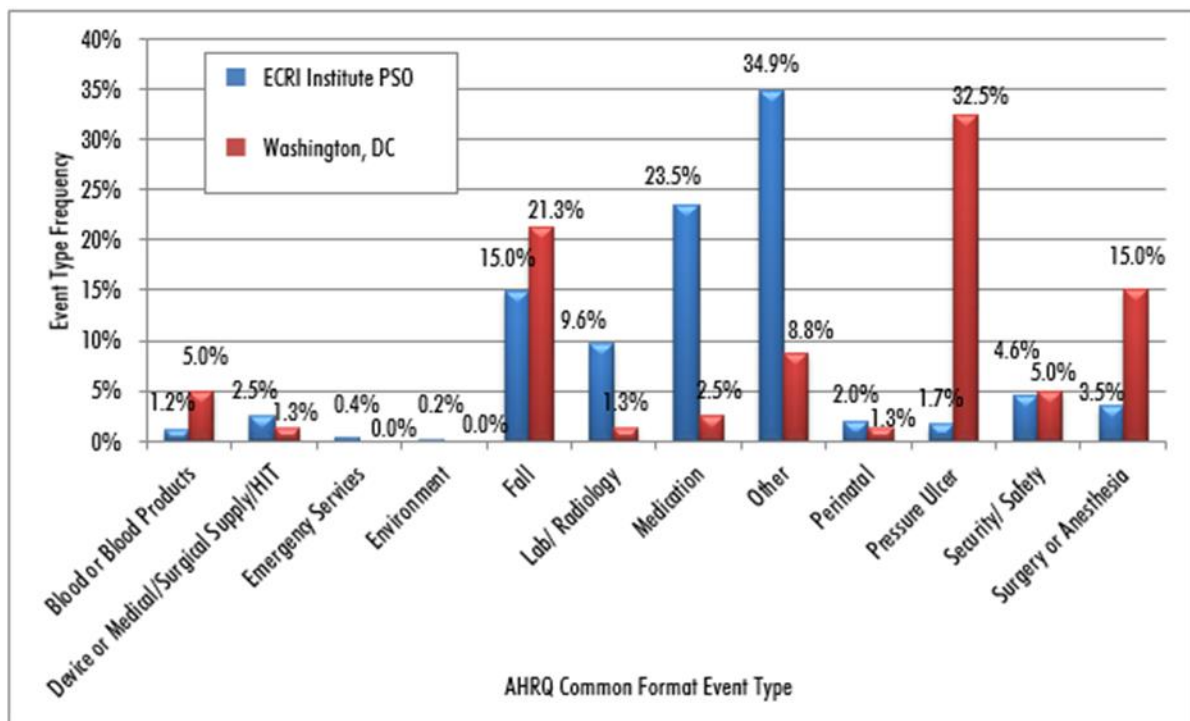


Figure 4. Comparison of Event Type Frequency<sup>1,2</sup>



<sup>2</sup> ECRI Institute PSO Database. Component of ECRI Institute, Plymouth Meeting, Pennsylvania.

Figure 4 shows a comparison of event categories reported by District facilities between October 1, 2011, and September 30, 2012, and those in the ECRI Institute PSO system overall aggregate. It should be noted that this graph cannot be considered a benchmark, as the ECRI Institute PSO system is a voluntary national event reporting database, whereas the District of Columbia Patient Safety Reporting System requires mandatory reporting of adverse events. These event types are categorized according to the Agency for Healthcare Research and Quality's (AHRQ) Common Formats rather than NQF event types.

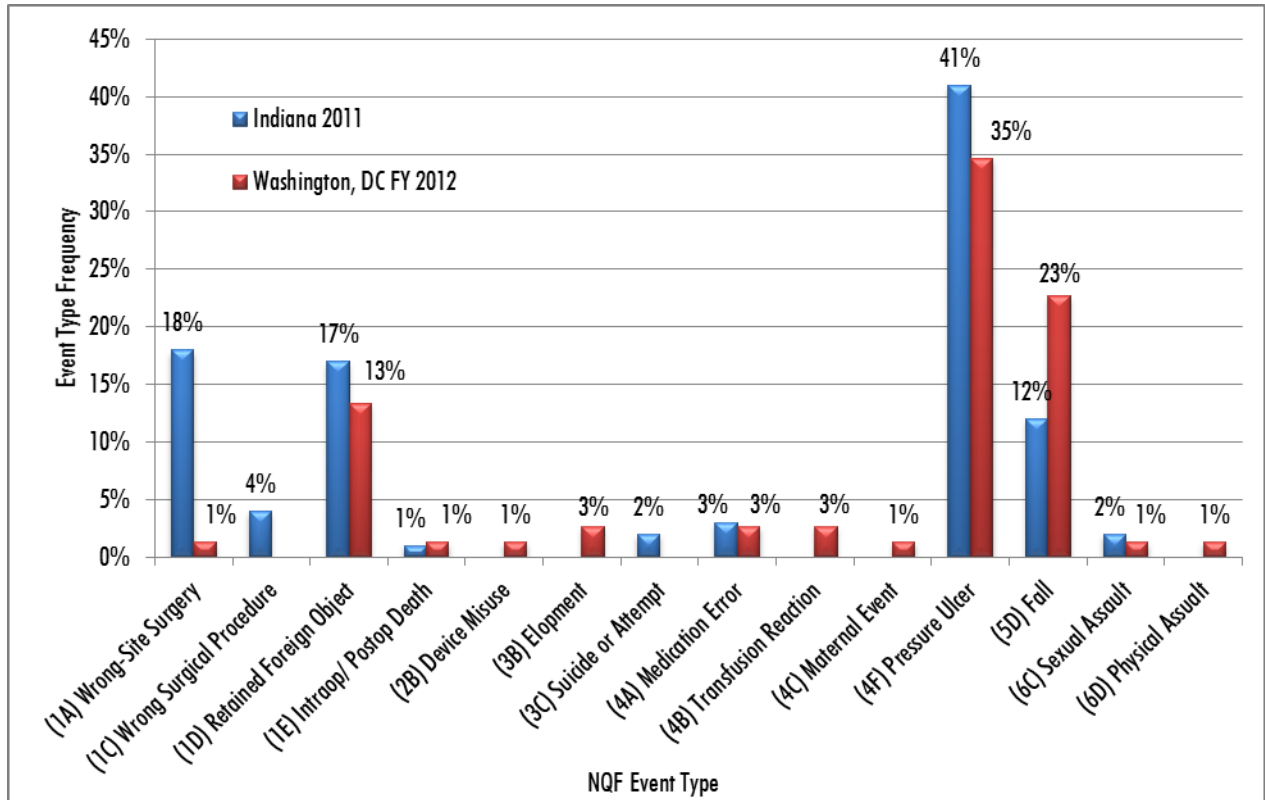
When viewed in this fashion, and excluding healthcare-associated infections and CLABSI, the District's top event categories were pressure ulcers, falls, surgery or anesthesia, other events, blood or blood products, and security/safety. The top reported events in the ECRI Institute PSO database were other events, medication errors, falls, lab/radiology, security/safety, and surgery or anesthesia. Although many categories have similar reporting frequencies, pressure ulcers clearly stand out as the most frequently reported event in the District (32.5%), whereas they were reported 1.7% of the time in the ECRI Institute PSO aggregate. In addition, medication errors were apparent 23.5% of the time in the reports to ECRI Institute PSO and only make up 2.5% of the District's reports. These comparisons were also very similar to those in FY 2011. However, it is difficult to draw conclusions when comparing mandatory versus voluntary reporting programs. The District's best benchmark is comparing each fiscal year's data to past years' data (see Figures 2 and 3).

In comparison with another mandatory reporting system, the Indiana Medical Error Reporting System's report for 2011 noted 100 NQF events reported from a total of 291 facilities required to report. Indiana's medical error reporting system is also based on NQF's serious reportable events. Although there are many more facilities required to report, when broken down by event type percentages, Indiana's top reported events were similar to the District of Columbia Department of Health's in that they include pressure ulcers (41%), falls (12%), and retained foreign objects (17%). However, Indiana's top reported event types also include wrong-site surgery (18%), whereas the District of Columbia had one wrong-site surgery reported in FY 2012. Figure 5 shows a comparison of NQF event report type frequency from the District of Columbia for FY 2012 and Indiana's 2011 reporting year; the percentages are based on the total number of events, excluding CLABSI.<sup>3</sup>

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<sup>3</sup> Indiana State Department of Health. Indiana Medical Error Reporting System: final report for 2011 [online]. 2012 Oct [cited 2012 Dec 12]. [http://www.in.gov/isdh/files/2011\\_MERS\\_Report.pdf](http://www.in.gov/isdh/files/2011_MERS_Report.pdf).

**Figure 5. Comparison of Event Type Frequency (excluding CLABSI)<sup>3</sup>**



### III. Reports by Level of Harm

The 2006 list of NQF’s serious reportable events includes events that resulted in serious disability or death.<sup>4</sup> However, if adopted in the future, the 2011 list of NQF serious reportable events changes the language from “serious disability” to “serious injury” in applicable event types.<sup>5</sup> Not all reportable events necessarily imply the same degree of harm, and it is often useful to distinguish among degrees of harm. To this end, the harm scale developed by the National Coordinating Council for Medication Error Reporting and Prevention continues to be applied to the event reporting system, and 75 events could be categorized based on the information provided. The 141 CLABSI events that the Department of Health provided from NHSN does not include information on level of harm and therefore those events could not be included in this analysis.<sup>1</sup> Figure 6 summarizes the level of harm among the 75 reports, and Figure 7 provides a graph of the percentage of the level of harm identified.

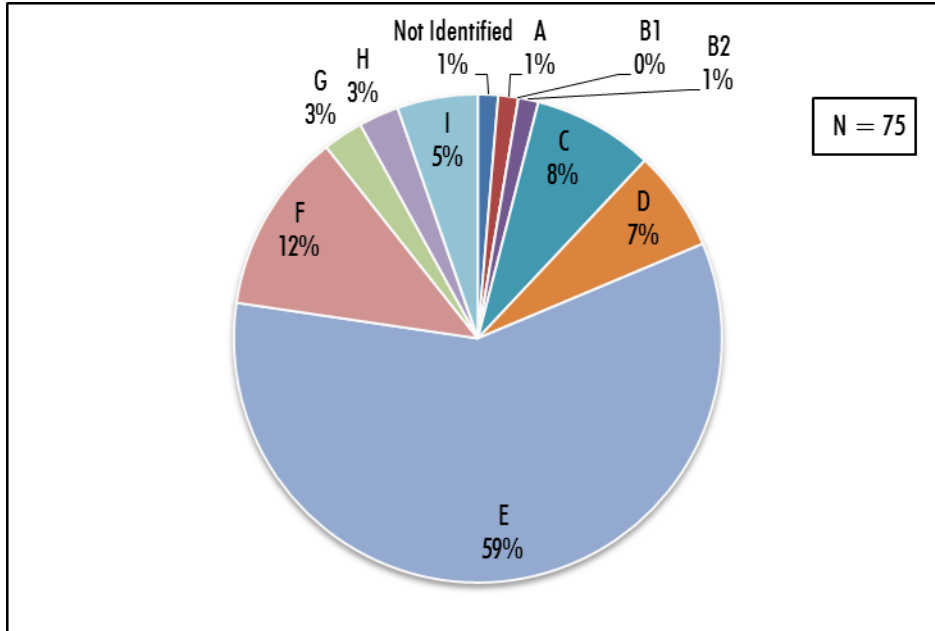
<sup>4</sup> National Quality Forum. Serious reportable events in healthcare—2006 update [online]. 2007 Mar [cited 2012 Dec 07]. [http://www.qualityforum.org/Publications/2007/03/Serious\\_Reportable\\_Events\\_in\\_Healthcare%E2%80%932006\\_Update.aspx](http://www.qualityforum.org/Publications/2007/03/Serious_Reportable_Events_in_Healthcare%E2%80%932006_Update.aspx).

<sup>5</sup> National Quality Forum. Serious reportable events in healthcare—2011 update: a consensus report [online]. 2011 [cited 2012 Dec 12]. <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=69573>.

**Figure 6. Number and Percentage of Reports by Level of Harm (FY 2012, excluding CLABSI)**

<b>Harm Score</b>	<b>Description</b>	<b>Reports</b>	<b>%</b>
<b>A</b>	Circumstances that could cause adverse events (e.g., look-alike medications, confusing equipment, etc.)	1	1
<b>B1</b>	An event occurred but it did not reach the individual (“near miss” or “close call”) because of chance alone	0	0
<b>B2</b>	An event occurred but it did not reach the individual (“near miss” or “close call”) because of active recovery efforts by caregivers	1	1
<b>C</b>	An event occurred that reached the individual but did not cause harm and did not require increased monitoring (an error of omission, such as a missed medication dose, does reach the individual)	6	8
<b>D</b>	An event occurred that required monitoring to confirm that it resulted in no harm and/or required intervention to prevent harm	5	7
<b>E</b>	An event occurred that contributed to or resulted in temporary harm and required treatment or intervention	44	59
<b>F</b>	An event occurred that contributed to or resulted in temporary harm and required initial or prolonged hospitalization	9	12
<b>G</b>	An event occurred that contributed to or resulted in permanent harm	2	3
<b>H</b>	An event occurred that resulted in a near-death event (e.g., required ICU care or other intervention necessary to sustain life)	2	3
<b>I</b>	An event occurred that contributed to or resulted in death	4	5
Reports with harm score not identified		1	1
<b>Total</b>		<b>75</b>	<b>100</b>

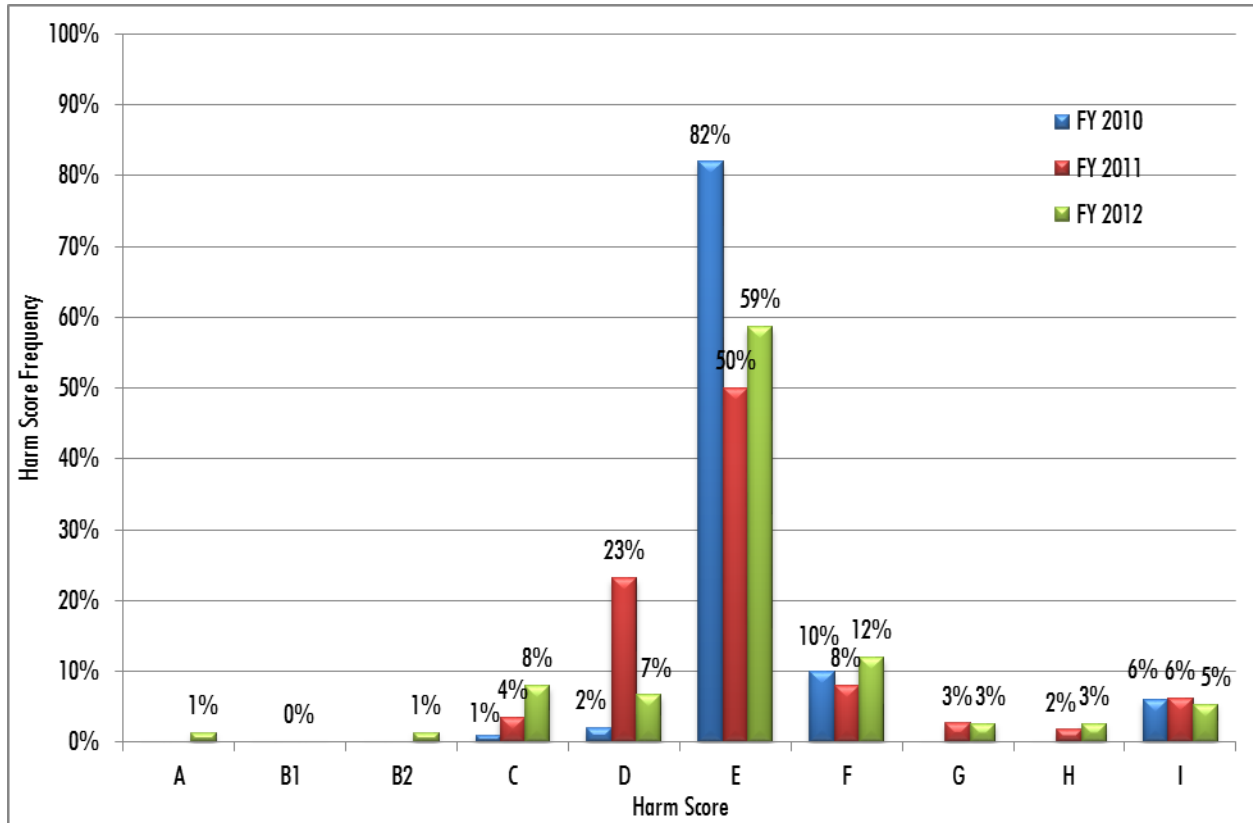
**Figure 7. Percentage of Reports by Harm Score (FY 2012, excluding CLABSIs)**



The reports submitted ranged from a harm score of A (1%), circumstances that could cause adverse events (e.g., look-alike medications, confusing equipment, etc.), to I (5%), an event occurred that contributed to or resulted in death. The majority of the events were categorized as a harm score of E (59%), an event that resulted in temporary harm and required treatment or intervention, which is consistent with the minimal harm score severity level described in the NQF events.

Harm score frequency during this reporting period differs from FY 2010 and FY 2011, with a significant increase in reports submitted with lower-level harm scores, including harm levels A, B2, C, and D (see Figure 8). Considering NQF serious reportable events are typically a harm score of E or above, this shows that District facilities continue to be more engaged in the program and are now voluntarily reporting events that did not cause harm and are not mandatory to report.

**Figure 8. Comparison of Harm Score Frequency**



#### **IV. Report Quality**

During the FY 2012 reporting period, there was an increase in the quality of reports in terms of overall completion of the web-based event report form as well as the quality of the information provided. The “Event Description” field is a free-text field on the web-based form and can capture the most important details of the event when completed. Of the 75 reports from the District of Columbia Patient Safety Reporting System, excluding CLABSIs, 97% had adequate or thorough event descriptions. This has shown to be an improvement that coincided with the implementation of the electronic reporting system.

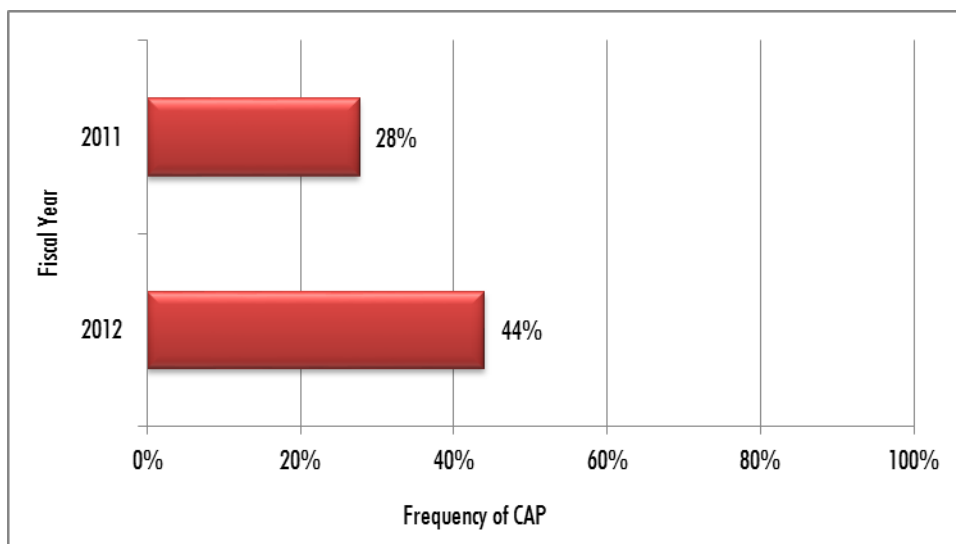
#### **V. Root Causes and Corrective Action Plans in Reports**

The District requires the submission of a CAP as a follow-up to the reported adverse event; a root-cause analysis can be submitted if applicable or if the facility would like a review. Ideally, an adverse event is handled in the following manner:



A CAP describes how the facility or provider plans to prevent or reduce the risk of similar events in the future and should be based on the findings from the event investigation. The investigation of an event must look beyond the direct patient care provider to identify causes embedded in the system. Of the 75 reports submitted, not including CLABSIs, 44% included a CAP submission, which is an increase of 18% from FY 2011. Figure 9 indicates the percentage of CAPs submitted for the reported events during FY 2011 and FY 2012, excluding CLABSIs. Although some reports identified contributing factors or root causes, there were no complete root-cause analyses submitted for review during FY 2012. In FY 2011, 8% of adverse events included a root-cause analysis submission, and in FY 2010, 1.5% of events included one.

**Figure 9. Frequency of CAP Submissions (excluding CLABSIs)**



A total of 33 (44%) of the reports submitted, excluding CLABSIs, had a CAP included. There was initially a significant decline in the CAPs received when the event submission changed from paper to electronic; however, we are beginning to see a rise in compliance. There is an additional field within the reporting system labeled “Supplemental Information” that some facilities have found as an easy way to incorporate their action plans. This also allows the event details and the action plans to be stored in the same location. Currently, some facilities use this method and others continue to submit their CAPs via



secure communication. If you would like to use the reporting system to enter a CAP but have not completed the root-cause analysis and CAP at the time of submission, you may always go back and update a report.

## **Guidance and Recommendations**

The Department of Health is charged with providing facilities and providers with recommended methods to reduce systematic adverse events and disseminating information and advice on best practices. The following is a summary of three of the frequently reported event types that discusses what we have learned about these events and presents strategies for helping to prevent them from reoccurring. The three event types that will be presented are:

- CLABSIs
- Unintended retention of a foreign object in a patient after surgery
- Stage III and IV pressure ulcers acquired after admission to a healthcare facility

As required by the Medical Malpractice Amendment Act, the information is deidentified and anonymous with regard to the facility, provider, and patient. Root causes, contributing factors, and preventive strategies identified by healthcare facilities and providers are shared. Finally, recommended best practices are provided to further assist facilities and providers in improving healthcare delivery in the District.

### **I. Central-Line-Associated Bloodstream Infections**

In January 2010, a web-based adverse event reporting system was implemented in the ongoing effort to improve healthcare delivery. Starting in October 2010, District facilities were required to report CLABSIs in ICUs through the NHSN system instead of the web-based system, allowing the epidemiologists at the District Department of Health to monitor and validate infection rates for District facilities and contributing District information to the CDC's national database. The following data was provided by the District of Columbia Department of Health Center for Policy, Planning and Evaluation's Division of Epidemiology - Disease Surveillance and Investigation.

District healthcare facilities reported 87,651 central-line-days and 141 CLABSIs in their ICUs, resulting in a CLABSI rate of 1.61 infections per 1,000 central-line-days during FY 2012 (see Figure 10). Although not directly comparable to NHSN figures, the district CLABSI rate may nonetheless serve as an approximate baseline. Last year's CLABSI rate was 2.04 during FY 2011; therefore, there was a significant decrease in the CLABSI rate this fiscal year.<sup>1</sup>

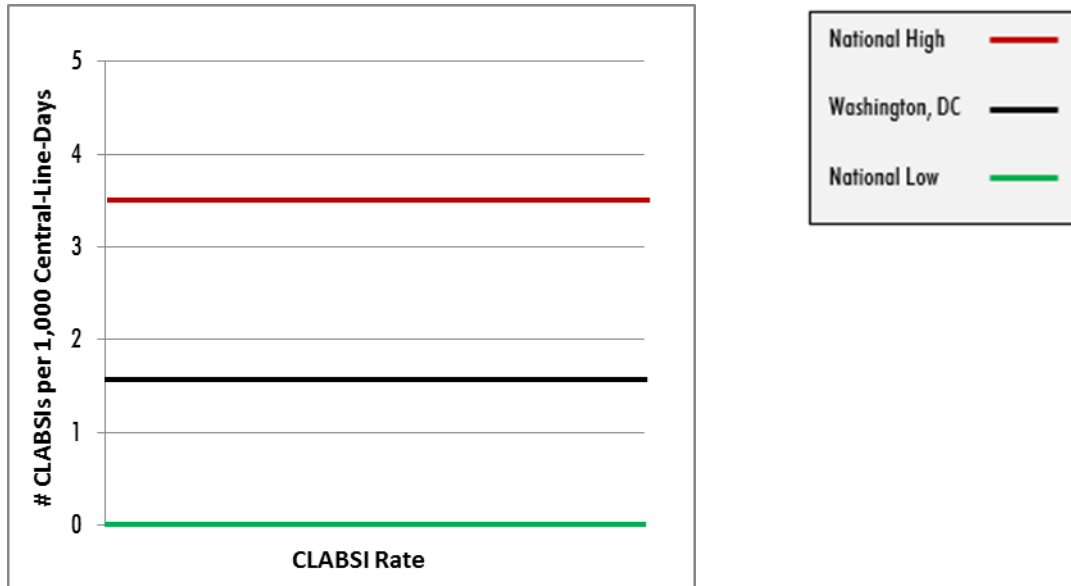
NHSN's data summary for 2010 reports the national incidence (or infection rate) of CLABSIs in hospital critical care units ranges from 0.0 to 3.5 infections per 1,000 central-line-days,<sup>6</sup> depending on the type of hospital unit.<sup>7</sup> Comparing the FY 2012 CLABSI rate in District ICUs with NHSN national figures required collecting data not only on the infections but also on the number of patients in each District ICU that had central-line catheters during the same time period.

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<sup>6</sup> Central-line-days are calculated on each critical care unit by counting the number of patients with a central line each day. At the end of the month, the daily totals for each unit are added up for monthly totals.

<sup>7</sup> Dudeck MA, Horan TC, Peterson KD, et al. National Healthcare Safety Network (NHSN) report, data summary for 2010, device-associated module [online]. 2011 [cited 2012 Dec 07]. [http://www.cdc.gov/nhsn/PDFs/dataStat/NHSN-Report\\_2010-Data-Summary.pdf](http://www.cdc.gov/nhsn/PDFs/dataStat/NHSN-Report_2010-Data-Summary.pdf).

Figure 10. Number of CLABSI Reports per 1,000 Central-Line-Days (FY 2012)<sup>1,7</sup>



CLABSI data in ICUs were reported from the 29 units in the District, which included:<sup>1</sup>

- long-term acute care
- medical cardiac critical care
- medical critical care
- medical/surgical critical care
- neonatal critical care
- neurosurgical critical care
- pediatric cardiothoracic critical care
- pediatric medical/surgical critical care
- surgical cardiothoracic critical care
- surgical critical care

### Recommendations

Focusing on strategies for the insertion and maintenance of a central venous catheter may assist in CLABSI prevention. The Michigan Health and Hospital Association Keystone Center for Patient Safety and Quality completed a successful project on CLABSI prevention that included the following strategies:<sup>8,9</sup>

- Insertion checklist
- Hand hygiene
- Skin preparation with chlorhexidine
- Proper site selection

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<sup>8</sup> Pronovost P, Needham D, Berenholtz S, et al. An intervention to decrease catheter-related bloodstream infections in the ICU. *N Engl J Med* 2006 Dec 28;355(26):2725-32.

- Maximal barriers
- Evaluating the need for continued use of the central line
- Protocol for maintenance of the central line

After insertion, a central venous catheter is cared for by many different staff members and accessed numerous times, which creates a risk for a CLABSI if care is not optimal. According to the Pennsylvania Patient Safety Authority, some points to consider with maintenance of central venous catheters include:<sup>9</sup>

- Disinfection of hubs, caps, and needleless connectors
- Skin antisepsis
- Occlusive dressing (which includes chlorhexidine)

### **Additional Resources**

- Joint Commission. NPSG 7: healthcare-associated infections from the bedside to the C-suite [slide presentation online]. 2011 Jun [cited 2012 Dec 7]. [http://jointcommission-lms.org/1900\\_00\\_HAI\\_NPSG\\_7/data/downloads/npsg-7\\_hai\\_kuhnny+soule\\_june2011-handout.pdf](http://jointcommission-lms.org/1900_00_HAI_NPSG_7/data/downloads/npsg-7_hai_kuhnny+soule_june2011-handout.pdf).
- Pennsylvania Patient Safety Authority. Assessment of program for prevention of central-line associated bloodstream infections [online]. 2011 [cited 2012 Dec 7]. <http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/clabsi/Pages/observation.aspx>.
- Society for Healthcare Epidemiology of America, Infectious Diseases Society of America. Compendium of strategies to prevent healthcare-associated infections in acute care hospitals [online]. 2008 [cited 2012 Dec 7]. <http://www.shea-online.org/about/compendium.cfm>.

## **II. Unintended Retention of a Foreign Object in a Patient after Surgery**

Retained foreign objects (RFOs), also called retained surgical items (RSIs), within a patient's body after a surgical or interventional procedure, are medical errors that constitute a serious breach of trust between patients and their medical caregivers and institutions. Organizations that set standards for patient safety and quality in medical settings have identified the postintervention retention of foreign objects as a hospital-acquired condition that is a serious preventable event (NQF), a sentinel event (Joint Commission), and an occurrence for which the Centers for Medicare and Medicaid Services will not reimburse hospitals or providers for associated sequelae.<sup>10</sup>

No medical team intends to leave sponges, needles, instruments, or device fragments within a patient's wound or body cavity after a medical procedure. Yet this human error continues to occur at an estimated rate of an RFO/RSI for every 5,500 operations performed, according to a 2008 study.<sup>11</sup> Although there are certain patient and intraprocedural characteristics that place patients at a higher

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<sup>9</sup> Davis J. Central-line-associated bloodstream infection: comprehensive, data-driven prevention. Pa Patient Saf Advis [online] 2011 Sep [cited 2012 Dec 7]. [http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2011/sep8\(3\)/Pages/100.aspx](http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2011/sep8(3)/Pages/100.aspx).

<sup>10</sup> Martindell D. Update on the prevention of retained surgical items. Pa Patient Saf Advis [online] 2012 Sep [cited 2012 Dec 3]. [http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2012/Sep;9\(3\)/Pages/106.aspx](http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2012/Sep;9(3)/Pages/106.aspx).

<sup>11</sup> ECRI Institute. The case of the missing sponge: practice variation is culprit. *Risk Manage Rep* 2012 Jun;31(3):4.

potential risk for occurrence of an RFO/RSI event (e.g., high body mass index, unplanned changes in procedure or multiple simultaneous procedures, significant blood loss or other emergency),<sup>11</sup> mitigating these risks depends upon a commitment to teamwork and communication, as well as standardization of surgical item counts and use of technology to supplement item accounting. Surgical and interventional teams rely on counting of surgical items before, during, and after a procedure—an excellent risk reduction strategy, considering that intraprocedural surgical count discrepancies elevate the risk to patient safety as much as 100 times<sup>12</sup>—but given that thousands of objects and instruments are used in any kind of surgery, counting discrepancies are inevitable.<sup>11</sup>

The question is, how do surgical teams respond to, reconcile, and reduce the risks of these discrepancies, as well as create processes that support the *accounting for*, rather than merely the counting of, every surgical item that is introduced into the sterile field, a distinction that has been made by Verna C. Gibbs, M.D., in her national surgical safety project NoThing Left Behind.<sup>13</sup> A comprehensive response to the problem of RFOs/RSIs comprises attention to team communication, continuous situational awareness of all team members, and standardization of procedures wherever possible, in addition to the traditional counting and wound examination protocols and use of adjunct technology such as radiopaque items, radio-frequency and bar-code scanning, and use of x-ray imaging intra- or postoperatively to scan for inadvertently retained items.

## Recommendations

Preventing incidents of RFOs/RSIs is related to “fundamental issues of communication, hierarchy, and teamwork,” in addition to improvements to technology and policies and procedures, according to Mayo Clinic Department of Surgery Vice Chair of Quality and Safety Robert Cima, M.D., M.A.<sup>11</sup> Indeed, the approaches developed by the Association of periOperative Registered Nurses (AORN) in practice guidelines revised in 2010 and described in detail by Goldberg and Feldman in the February 2012 *AORN Journal*<sup>14</sup> address both the technological and human factors that are central to successful implementation of preventive RFO/RSI strategies. The following is a detailed summary of Goldberg and Feldman’s recommendations for healthcare institutions on how to apply the AORN revised best practices directly in the operative or interventional procedure settings.

### Recommendation 1: Multidisciplinary Approach Supports Patient Safety

***Successful implementation of the AORN recommended practices for RSI prevention requires a “consistent multidisciplinary approach during all surgical and invasive procedures.”<sup>15</sup>***

“Multidisciplinary” includes the circulating nurse, scrub person, surgeon(s) and assistants, anesthesia professionals, surgical techs, the radiology staff, and the environmental staff members who clean

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<sup>12</sup> Greenberg CC, Regenbogen SE, Lipsitz SR et al. The frequency and significance of discrepancies in the surgical count. *Ann Surg* 2008 Aug;248(2):337-41.

<sup>13</sup> NoThing Left Behind: a national surgical patient-safety project to prevent retained surgical items [website]. [cited 2012 Dec 3]. Gibbs V. <http://www.nothingleftbehind.org>.

<sup>14</sup> Goldberg JL, Feldman DL. Implementing AORN recommended practices for prevention of retained surgical items. *AORN J* 2012;95(2):205-19.

<sup>15</sup> Goldberg JL, Feldman DL. Implementing AORN recommended practices for prevention of retained surgical items. *AORN J* 2012;95(2):205-19. Citing: Association of perioperative Registered Nurses (AORN). Recommended practices for prevention of retained surgical items. In: AORN. *Perioperative standards and recommended practices*. Denver (CO): AORN, Inc.; 2011: 263-82.

operating room (OR) and interventional suites and may find discarded or dropped surgical items remaining in the area postprocedure. Communication among all of these team members throughout the procedure must be continuous, with each member aware of his or her role in accounting for the use and disposal of surgical items. With the AORN recommendations as a foundation, the authors suggest that institutions implement standardized systems for counting procedures, such as the timing of counts: initial/baseline, when OR staff are relieved, when new items are added to the sterile field, and during closing of the wound. Surgeons and their assistants should be encouraged (or required) to communicate and acknowledge verbally when counts are being done or when they are placing items into the surgical wound. Documentation of counts should also be standardized, for example, using whiteboards, needle and sponge counting containers, sorters, and hangers consistently so that individual variation from procedure to procedure and team to team is reduced. Multidisciplinary implementation of these practices provides opportunities for nurse and surgeon leaders to work together to develop guidelines for when and how counts should take place and invests everyone with responsibility for making the practices work. Including team members who are not always part of a surgical team, such as radiologists, into the implementation planning serves to solve missing-item problems proactively by showing radiology staff what typical surgical items that they should be looking for on radiographic images look like, for example, or informing environmental staff what they should do if they locate sponges, sharps, or instrument fragments when they are preparing the OR for the next case.<sup>14</sup>

### **Recommendation 2: Surgical Count—Soft Goods**

***Perform an initial count to establish a baseline. Count soft goods opened onto the sterile field and add them to the count documentation.***<sup>14</sup>

Establishing consistent procedures for counting and documentation of counted items is imperative for the success of this recommendation. Since soft goods such as sponges, gauze, and pledgets are among the most numerous and most commonly RFOs after surgery (and even after nonsurgical procedures such as a normal vaginal birth), the detailed procedures recommended by AORN focus on how to keep these items separated, orderly, and identifiable before and after use. Use of only radiopaque soft goods within the wound with confirmation of each item's radiopaque tag is recommended. Dressing sponges should be dispensed only after the final count is complete. Again, communication is key: verbal counting and acknowledgment, communication about any soft goods left in place for therapeutic packing and reconciling those counts, and counting in the same order every time. Visible counting aids such as pocketed sponge bags and whiteboard documentation increase awareness and visibility of these numerous items.<sup>14</sup>

### **Recommendation 3: Surgical Count—Sharps and Needles**

***“Sharps and other miscellaneous items that are opened onto the sterile field should be accounted for during all procedures for which [these items] are used.”***<sup>15</sup>

With these often small and delicate items whose visibility can be easily obscured within the surgical wound and the operative field, close attention to tracking of sutures and needles is necessary throughout the duration of surgical procedures. The circulator and scrub person should count these items when packages are opened and ensure that they both view the contents completely. Sharps should have appropriate containment devices, and the scrub should inspect items coming from the sterile field for possible breakage. Any team member should be able to request a time-out for wound inspection when a broken item is returned after use. Count discrepancies or breakage should be

acknowledged and radiologists notified of exactly what type of item is missing. There should be clear policies for informing patients about any retained sharps, as well as a policy determination of when unaccounted-for sharps will not be investigated radiographically (for example, when they are 10 mm in size or smaller).<sup>14</sup>

#### **Recommendation 4: Surgical Count—Instruments**

***Account for instruments on all procedures in which it is likely that an instrument could be retained. Conduct an initial count of instruments before sterilization [or decontamination] to provide an inventory.***<sup>15</sup>

This recommendation refers to streamlining instrument sets using tools such as preprinted count sheets or computerized inventories of surgical instruments according to the type of sterile processing for each set to be used. This is not the same as the initial surgical count. The focus is on standardization and involvement of ancillary services in maintaining accurate instrument accounting. The authors also recommend instrument accounting for minimally invasive surgical techniques such as laparoscopy and thoracoscopy.<sup>14</sup>

#### **Recommendation 5: Unretrieved Device Fragments**

***“Identify and reduce the risks associated with unretrieved device fragments.”***<sup>14</sup>

When a surgical or interventional device breaks during a procedure, at times it is determined to be safer to let the broken fragment remain in the wound rather than risk additional trauma to tissue or bone by attempting to remove it. Common examples include the guidewires used to place catheters or stents, drill tips used during orthopedic procedures, plastic sheaths, tissue stapler heads, bands, and screws—after soft goods, these are the most commonly retained postprocedure items.<sup>11</sup> Risk reduction for the patient and medical team include adding a line item for broken device fragments to the standard checklist for the final time-out so that it is brought to everyone’s awareness and intra-procedural verbal communication about the possibility or occurrence of a broken device fragment. The surgeon should speak with the patient about any unretrieved device fragment and explain the associated risks for infection or migration of the fragment, the implications for future diagnostic procedures (such as magnetic resonance imaging in the case of a metallic retained fragment), and risks and benefits of leaving the fragment in the wound versus attempting to remove it.<sup>14</sup>

#### **Recommendation 6: Standardization of Procedures and Radiographic Imaging for Patient Safety**

***Standardize procedures for the closing count to identify discrepancies as early as possible. Notify all members of the surgical or interventional team of discrepancies so that they can be investigated and reconciled promptly, with attention to avoiding prolonging of the duration of patient anesthesia.***<sup>14</sup>

Effective implementation of this recommendation depends upon open communication by the circulating nurse to the perioperative team about a count discrepancy—and a safety-centered response by the entire team to reconcile the variance, including verbal acknowledgment by the surgeon so that investigative and inspection actions can begin immediately. This is a critical time during a surgical (or interventional) procedure because wound closure might have to be suspended for adequate reconciliation of soft goods, sharps, and instrument counts to ensure that there is nothing unintended left in the wound. It is also possible that an intraoperative x-ray may be indicated. The condition of the

patient should determine the decision about intraoperative, postoperative, or no imaging to locate a missing surgical object.<sup>14</sup>

### **Recommendation 7: Adjunct Technology Evaluation and Use**

***Healthcare institution leadership, including surgeons, nurses, and risk managers, should consider the use of adjunct technologies that count and/or detect surgical items to supplement manual count procedures and develop a multidisciplinary process to evaluate these technologies.***<sup>14</sup>

The decisions about what kinds of surgical implements to purchase and use have traditionally been left up to surgical departments, but the authors recommend broader involvement of healthcare institution leadership, whose input might bring new perspectives and recommendations for efficiency, effectiveness, and cost control. For example, bar-code scanning or radio-frequency identification of individual items are adjunct technologies that make location and counting of these items much easier, but there are pros and cons associated with costs as well as considerations of sterilization/decontamination techniques that may change or require additional time or expense. Successful implementation of this AORN best practice should consider extraprocedural costs such as RFO/RSI cases not covered by insurers, legal costs, the cost of training in proper use of these technology-enabled materials, and the effect of such changes on OR time—such considerations mitigate toward multidisciplinary input at the outset of these purchasing decisions rather than after the fact.<sup>14</sup>

In summary, patient safety in prevention of RFO/RSI adverse events means having all affected contributors at the decision-making table because reducing individual process variation during any surgical or interventional procedure depends upon having every medical and environmental staff person aware, engaged, and invested in safety before, during, and after the surgical case closes. Goldberg and Feldman also note that there are additional recommended practices that deal with nursing competencies, policies and procedures, quality assurance, and proper documentation that merit institutional consideration.<sup>14</sup>

### **CAPs Submitted for Retained Foreign Object Events**

One-half of the RFO cases submitted to the PSO involved retained items that are categorized as soft goods, such as sponges, gauze, and gloves. These events occurred during minimally invasive procedures (e.g., laparoscopy, vaginal birth) rather than open surgical procedures. The other half of cases involved broken device fragments left behind unintentionally or intentionally to reduce the risk of further surgical exploration. These events are consistent with national trends in RFO/RSI incidence type, though no determination can be made about comparative local RFO/RSI incidence rates. One CAP and one root-cause analysis were submitted. These plans focused on how and when to use placeholders and landmark items such as prep stick sponges and how to document and count these items during the procedure. The CAP also recommended a policy change and supplemental education on use of placeholders and pneumo-occluders during total vaginal hysterectomy. Education of OR staff was recommended. A growing number of RFO/RSI events have been associated with increases in minimally invasive surgical procedures, and the obstetric/gynecological literature has cited the need for attention to soft goods accounting during labor and delivery or other gynecological surgery. Retained guidewire and sheath fragment cases could be due to escalating catheter-based procedures. These are trends that should be monitored by risk management, patient safety, and healthcare institution leadership with a view toward increasing multidisciplinary planning and decision support for implementing the kinds of evidence-based standards and procedures described in this report.



## Additional Resources

- Centers for Medicare and Medicaid Services. Conditions for Coverage (CfCs) and Conditions of Participations (CoPs) [online]. [cited 2012 Dec 5]. <http://www.cms.gov/Regulations-and-Guidance/Legislation/CfCsAndCoPs/index.html?q=hospital+acquired+conditions>.
- Conway PH, Berwick DM. Improving the rules for hospital participation in Medicare and Medicaid. *JAMA* 2011 Nov 23;306 (20):2256-7.
- Edel EM. Surgical count practice variability and the potential for retained surgical items. *AORN J* 2012 Feb;95(2):228-38.
- Joint Commission Resources. Foreign objects retained after surgery [online]. [cited 2012 Nov 26]. <http://www.jcrinc.com/Foreign-Objects-Retained-After-Surgery>.
- National Quality Forum. Serious reportable events in healthcare—2011 update: a consensus report [online]. 2011 [cited 2012 Dec 12]. <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=69573>.
- Norton EK, Micheli AJ, Gedney J, et al. A nurse-led approach to developing and implementing a collaborative count policy. *AORN J* 2012 Feb;95(2):222-7.
- RP summary: recommended practices for prevention of retained surgical items. *AORN J* 2012 Feb;95(2):220-1.

## III. Stage III and IV Pressure Ulcers

Stage III and IV pressure ulcers are considered serious reportable events and have been added to the list of hospital-acquired conditions whose treatment will no longer be reimbursed by Medicare. Stage III and IV pressure ulcers include pressure ulcers with full-thickness tissue loss and full-thickness tissue loss with exposed muscle, tendon, or bone. The Department of Health received 26 reports of stage III or IV pressure ulcers, down from 34 reports last year. This was the most frequently reported NQF event type in FY 2010 and FY 2011, and it continued to be the most frequently reported event type in FY 2012.

## Recommendations

Although the majority of pressure ulcers reported in FY 2011 were sacral ulcers, a few this fiscal year, as well as a few in the past, were related to tracheostomies. In a two-year span from January 2010 to January 2012, eight device-related pressure ulcers were reported by the District of Columbia Patient Safety Reporting System, and these involved bi-level positive airway pressure masks, braces, casts, and tracheostomy tubes. Based on various studies, some considerations for the prevention of pressure ulcers related to devices such as tracheostomies, casts, braces, helmets, and others include the following:<sup>16</sup>

- Frequently and thoroughly perform skin and neurovascular assessments tailored to the type of device.<sup>22,17</sup>
- Inspect the area around and underneath the device, and keep the area clean.<sup>18</sup>

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<sup>16</sup> ECRI Institute PSO. Medical devices and pressure ulcers. *District of Columbia PSO Navigator* 2012 Aug; 3(2):1-2.

<sup>17</sup> Black JM, Cuddigan JE, Walko MA, et al. Medical device related pressure ulcers in hospitalized patients. *Int Wound J* 2010 Oct;7(5):358-65.

- Pay close attention to those patients at risk for edema and those who are immobilized or cannot feel the pressure.<sup>23</sup>
- Loosen and remove the device (if possible) each shift.<sup>23</sup>
- Develop procedures for performing and documenting inspection of these devices.<sup>19</sup>
- Educate staff on pressure ulcer identification.<sup>24</sup>
- Ensure devices are properly fit to the patient, and include fit checks in procedures and the correct department to contact if assistance is needed.<sup>23,24</sup>

### **CAPs Submitted for Pressure Ulcers**

CAPs submitted with these reports were of the most robust action plans submitted over FY 2012. They address pressure ulcers of various types including but not limited to bed sores such as sacral or heel ulcers, tracheostomy-related ulcers, and ulcers from casts. Some of the strategies put in place by facilities to prevent device-related pressure ulcers included the following:

- Educating staff on risks involved with tracheostomy tubes and proper skin assessments
- Reviewing post-op tracheostomy care with staff
- Involving a wound care specialist in the selection of the tracheostomy tube type
- Reviewing and adjusting current tracheostomy inventory
- Initiating wound consult on all patients with tracheotomy tubes
- Educating staff on tracheotomy care documentation and completing audits
- Reviewing procedures for suture removal with tracheotomy tubes

### **Additional Resources**

- Boesch RP, Myers C, Garrett T, et al. Prevention of tracheostomy-related pressure ulcers in children. *Pediatrics* 2012 Mar;129(3):e792-7.
- European Pressure Ulcer Advisory Panel and National Pressure Ulcer Advisory Panel (EPUAP and NPUAP). *Prevention and treatment of pressure ulcers: quick reference guide*. Washington (DC): National Pressure Ulcer Advisory Panel; 2009.
- Improving the safety of negative-pressure wound therapy. *Pa Patient Saf Advis* [online] 2011 Mar [cited 2012 Dec 7]. [http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2011/mar8\(1\)/Pages/18.aspx](http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2011/mar8(1)/Pages/18.aspx).
- Institute for Healthcare Improvement (IHI). Prevent pressure ulcers [online]. [cited 2012 Dec 7]. <http://www.ihl.org/explore/PressureUlcers/Pages/default.aspx>
- National Pressure Ulcer Advisory Panel (NPUAP) [website]. Washington (DC): NPUAP. <http://www.npuap.org>.
- Skin and soft-tissue infections in long-term care. *Pa Patient Saf Advis* [online] 2011 Mar [cited 2012 Dec 7]. [http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2011/mar8\(1\)/Pages/34.aspx](http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2011/mar8(1)/Pages/34.aspx).

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<sup>18</sup> Apold J, Rydrych D. Preventing device-related pressure ulcers: using data to guide statewide change. *J Nurs Care Qual* 2012 Jan-Mar;27(1):28-34.

<sup>19</sup> Jacobson TM, Tescher AN, Miers AG, et al. Improving practice: efforts to reduce occipital pressure ulcers. *J Nurs Care Qual* 2008 Jul-Sep;23(3):283-8.

## **Conclusion**

Medical facilities and providers in the District continue to take important steps in reducing the number of adverse events by submitting adverse event reports under the Medical Malpractice Amendment Act of 2006. The focus of the District's Patient Safety Reporting System is to analyze events to better understand how and why adverse events occur. Dissemination of lessons learned and best practices will facilitate system changes that consistently promote the delivery of safe patient care. The success of the reporting program continues to rely on the willingness of healthcare facilities and providers to disclose NQF events and submit meaningful reports. In 2013, the District will have continued opportunities to benefit from custom feedback to support this objective. The vision for the reporting system is to provide a tool for quality improvement and education. The delivery of safe patient care is the ongoing goal of the program, and 2013 will usher in the next phase of this important effort.

### **Technical Credits**

This report was prepared for the Department of Health by ECRI Institute. ECRI Institute, a nonprofit organization, dedicates itself to bringing the discipline of applied scientific research in healthcare to uncover the best approaches to improving patient care. As pioneers in this science for over 40 years, ECRI Institute marries experience and independence with the objectivity of evidence-based research. More than 5,000 healthcare organizations worldwide rely on ECRI Institute's expertise in patient safety improvement, risk and quality management, and healthcare processes, devices, procedures, and drug technology.