

Ambulatory Surgical Facilities Infections Stakeholder Group Report

June 2009



Division of Epidemiology, Health Statistics, and Public Health Laboratories

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Executive Summary

In 2007 the Washington State Legislature passed Second Substitute House Bill (2SHB) 1106, *An Act Relating to the Reporting of Infections Acquired in Healthcare Facilities*, codified as RCW 43.70.056. This law requires acute care hospitals to report certain healthcare-associated infections to the National Healthcare Safety Network of the Centers for Disease Control and Prevention. Hospitals are required to report central line-associated bloodstream infections, ventilator-associated pneumonias, and surgical site infections. The Washington State Department of Health will make the infection rates of Washington hospitals available to the public in an annual report.

The legislation directed the Department of Health to create a stakeholder group to review available infection control protocols at ambulatory surgical facilities (ASFs) and make recommendations on whether these facilities should be required to report healthcare associated infections. This report presents the recommendations of the Ambulatory Surgical Facilities Infections Stakeholder Group, the recommendations from the department, and a review of relevant literature.

Since the 1980s the number of ambulatory surgical facilities and the range of procedures performed in these facilities have increased dramatically. This growth has been possible through advances in minimally invasive surgical techniques, safer forms of anesthesia, and more effective pain control. This growth has also led to questions about infections from procedures in these surgery facilities and the department was asked to study the issue in 2SHB 1106.

The department convened a stakeholder group representing Washington's ambulatory surgical facilities and other stakeholders. This stakeholder group recommends infection reporting for certain procedures regardless of the setting in which those procedures are performed. The group expressed a commitment to quality of care, respect for the value of transparency expressed in legislation, and a willingness to report surgical infection rates using the same standard definitions as used by hospitals. Consumers should expect safe outcomes whether or not the surgical procedure is performed in the hospital or ambulatory setting. However, including ASFs under the existing reporting requirements would not result in any data because only one ASF in Washington performs a procedure identified in 2SHB 1106.

At this time, the department recommends that ASFs should not be required to report healthcare-associated infections. The department suggests waiting until we can evaluate our experience with hospital reporting requirements and the public's use of infection data. The agency also recommends strengthened application of the existing notifiable conditions rule (chapter 246-101 WAC) to detect and report any outbreaks of infections in surgery centers.

Background

Public concern about medical errors and patient safety has increased dramatically since the publication of an influential Institute of Medicine (IOM) report, *To Err is Human*, in 2000.¹ That report focused on hospitals, but initiated changes that affected all healthcare settings. In response to public concerns prompted by the institute's report, and specific concerns about infections raised by groups such as the Consumers Union, a growing number of states have legislated mandatory public reporting of healthcare-associated infection rates by hospitals. Many states have extended these requirements to improve patient safety in other healthcare settings. Over the past five years, 29 states have mandated some form of infection reporting by healthcare facilities. Some states have included ASF among those required to report.

Recent national newspaper and television reports of serious infection outbreaks in outpatient clinics further reflect public concern. These incidents typically involved lack of adherence to nationally recognized infection prevention practices, resulting in unsafe injection and equipment reuse practices. They exposed hundreds of patients to low but unacceptable risk, and often required massive follow-up testing programs to confirm whether hepatitis or human immunodeficiency viruses were transmitted. Reports identify negligent infection prevention practices as a root cause of the inappropriate practices. Although outpatient surgical facilities have largely operated without state oversight or regulation, recent events led many states, including Washington, to consider or institute regulation. Effective May 18, 2009 the Centers for Medicare and Medicaid required surgery centers to establish a program for identifying and preventing infections. Beginning July 1, 2009 Washington will begin licensing surgery centers.

In 2007 the Washington State Legislature passed Second Substitute House Bill (2SHB) 1106, *An Act Relating to the Reporting of Infections Acquired in Healthcare Facilities*, codified as RCW 43.70.056. This law requires acute care hospitals to report certain healthcare-associated infections to the National Healthcare Safety Network of the Centers for Disease Control and Prevention. Hospitals are required to report central line-associated bloodstream infections, ventilator-associated pneumonias, and surgical site infections. The Washington State Department of Health will make the infection rates of Washington hospitals available to the public in an annual report.

The legislation directed the department to create a stakeholder group to review available infection control protocols at ambulatory surgical facilities (ASFs) and make recommendations on whether these facilities should also be required to report healthcare associated infections.

Increasing Extent of Outpatient Surgical Care

Since the 1980s the number of facilities known as outpatient, day surgery, ambulatory surgical centers (ASCs) or ambulatory surgical facilities, and the range of procedures performed there have increased dramatically. Ambulatory surgical facilities is a new term introduced by the Washington State Legislature in 2007; ambulatory surgical centers is an established term for the definition and regulation of these facilities by the Centers for Medicare and Medicaid (CMS). Advances in minimally invasive surgical techniques, safer forms of anesthesia and more effective

¹ LT Kohn, JM Corrigan, MS Donaldson (Eds.), *To Err is Human: Building a Safer Health System*, National Academy Press, Washington, DC, 2000.

pain control have made the growth of these facilities possible. By the 1990s over 50 percent of all surgeries were performed in an ambulatory setting; today, this has increased to nearly 80 percent.² Just as the number of Medicare-certified ambulatory surgical centers has grown exponentially, from over 400 in 1982 to nearly 5,000 in 2007, payments by the CMS to these facilities are expected to reach record levels, totaling almost \$3 billion in 2008.^{3,4} The extent of procedures performed outside facilities not certified by Centers for Medicare and Medicaid (including physicians' offices) is unknown.

The majority of Medicare-certified ambulatory surgical centers are for-profit, freestanding facilities located in urban areas.⁵ In the United States, 63 percent of ASFs operate as multi-specialty facilities, the rest as single-specialty units most commonly specializing in ophthalmology and gastroenterology.⁶ The most commonly reimbursed procedures performed in freestanding ASCs are cataract removal and lens replacement, colonoscopy, and other eye procedures.⁷

There are currently two regulatory bodies with oversight of ASFs: state licensing organizations and CMS.⁸ Effective May 18, 2009 the Centers for Medicare and Medicaid required surgery centers to establish a program for identifying and preventing infections, maintaining a sanitary environment, and reporting results to appropriate authorities. Beginning July 1, 2009, the Washington State Department of Health will start licensing surgery centers. Regulations for surgery centers include standards for infection control (WAC 246-330-176).

Standards for licensure, other than Medicare Conditions of Participation, vary by state. Surgery centers can seek accreditation from three independent bodies: The Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organization), the Accreditation Association for Ambulatory Health Care, and the American Association for Accreditation of Ambulatory Surgical Facilities. Twenty-five states and the District of Columbia require or recognize accreditation of certain types of ASF (Arizona, California, Delaware, District of Columbia, Florida, Georgia, Indiana, Kansas, Maryland, Montana, Nebraska, Nevada, New

² H Vila Jr., R Soto, AB Cantor, et al., "Comparative Outcomes Analysis of Procedures Performed in Physician Offices and Ambulatory Surgery Centers," *ARCH SURG*, 2003;138:991-995.

³ A Winters, "Comparing the Mix of Patients in Various Outpatient Surgery Settings," *HEALTH AFFAIRS*, 2003;22(6):68-75.

⁴ "Section 8: Ambulatory Care," *A Data Book: Healthcare spending and the Medicare program*, MEDPAC, 2008:111, http://www.medpac.gov/documents/Jun08DataBook_Entire_report.pdf, accessed 17 September 2008.

⁵ "Section 3F: Ambulatory Surgical Center Services," *Report to the Congress: Medicare Payment Policy*, MEDPAC, 2004: 183-202, http://www.medpac.gov/publications/congressional_reports/Mar04_Ch3F.pdf, accessed 12 May 2008.

⁶ K Bryant, "Chapter 13: Freestanding Ambulatory Surgery Units," *Day Surgery: Development and Practice*, International Association for Ambulatory Surgery, London, 2006: 281-298.

⁷ "Ambulatory Surgical Centers Payment System," MEDPAC, 2007. http://www.medpac.gov/documents/MedPAC_Payment_Basics_07_ASC.pdf, accessed 12 May 2008.

⁸ Ambulatory Surgery Center Association, "Ambulatory Surgical Centers: A Positive Trend in Health Care," <http://www.ascassociation.org/advocacy/AmbulatorySurgeryCentersPositiveTrendHealthCare.pdf>, accessed 12 May 2008.

Hampshire, New Jersey, New Mexico, New York, North Carolina, Ohio, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Virginia and Wyoming).⁹

Nine of the 29 states that have mandated reporting of healthcare-associated infections include surgery centers within the same laws as hospitals and other healthcare facilities. Some, including Washington, have proposed consideration of reporting by ambulatory surgical facilities.

Literature Review

The Department of Health conducted a review of the literature on infections associated with ambulatory care settings and shared this review with the stakeholder group. A detailed summary of the literature is provided in Appendix B.

The literature review supports the following conclusions:

Operations in surgery centers are shorter, less invasive or complicated, and their patients tend to be younger and healthier compared to people who have surgery in a hospital.

1. Fewer studies report on the ASF setting, and fewer still on surgery in physicians' offices, compared to the number of studies published about infection risks in hospitals.
2. Health care records from national healthcare systems in other countries document lower risk and lower infection rates in out-patient ASF care relative to in-patient hospital care.
3. The impact of different surveillance (infection tracking) methods by different health care providers creates problems in calculating infection rates. Comparison of rates cannot be meaningful unless all facilities follow patients long enough and well enough to detect infections.
 - a. Historically, hospitals first relied upon either passive or active surveillance during the period between a patient's admission and discharge from hospital.
 - i. It became recognized that relying on passive methods (e.g., waiting for clinicians to report cases of infection) was inferior to active methods (e.g., having infection control professionals monitor laboratory reports and clinical records).
 - ii. As lengths of hospitalization progressively decreased, the number of surgical site infections first evident only after discharge from the hospital increased.
 - b. Hospitals that monitor their patients before and after discharge (post-discharge surveillance) are more likely to detect all infections than those that maintain surveillance only until discharge. Effective May 18, 2009, the Centers for Medicare and Medicaid required that surgery centers they certify have a program that includes investigation of infections.
 - i. Some hospitals add post-discharge surveillance to their usual in-patient infection surveillance.
 - c. Since the length of stay in a surgery center is so short, post-discharge surveillance is the only way they can monitor the outcome of their patients.

⁹ Accreditation Association for Ambulatory Health Care, <http://www.aaahc.org>, accessed 29 September 2008.

- i. Methods of post-discharge surveillance vary. Some ASFs in Washington use telephone calls, postcards, lists sent to surgeons, or various other means.
 - ii. A voluntary survey conducted by the Washington Ambulatory Surgery Center Association (WASCA) includes information on how some of Washington's ASFs conduct infection surveillance.
 - d. The most cost-effective or best method for post-discharge surveillance by hospitals or ASFs remains a subject of debate.
4. In the past, variation in surveillance methods and its accuracy between facilities did not interfere with each facility's ability to monitor internal trends. Now that public reporting is required, such differences complicate inter-facility comparisons.
5. Clear threats to public health have been evident in occasional serious outbreaks in surgery centers, like the recent hepatitis C incident in Nevada (p. 23). These outbreaks become evident because they result in unusual infections in people who have no other risk exposures, unusually large numbers of cases, or both (see Appendix B). The vast majority of such outbreaks have been due to inadequate attention to infection prevention standards, such as:
 - inappropriate reuse of needles, syringes, or other sharps;
 - improper control of multiple-dose vials;
 - lax hand hygiene and environmental sanitation practices;
 - failure to follow proper cleaning and disinfection procedures with endoscopes (used inside the body) or endoscope accessories.

These outbreaks are distinct from the rare surgical site infection that will occur among hundreds or even thousands of operations in surgery centers. The actual number of patients affected in these outbreaks is relatively small given the large numbers of outpatient procedures performed each year in the United States, but is still unacceptable.
6. Research indicates adding infection surveillance and reporting adds cost, so actual benefits achieved must be carefully considered in order to make best use of limited resources to achieve infection control and overall quality of care.

The Washington Ambulatory Surgical Center Association Survey

The Department of Health worked with the Washington Ambulatory Surgery Center Association (WASCA) to develop a survey to find out more about practices in Washington ASFs. Washington Ambulatory Surgery Center Association independently conducted the survey and the results can be found in Appendix C. The survey describes the types of surgeries performed at surgery centers and outcomes from those surgeries.

Ambulatory Surgical Facilities Infections Stakeholder Group

As required by 2007 legislation, Second Substitute House Bill 1106, *An Act Relating to the Reporting of Infections Acquired in Healthcare Facilities*, the department convened a stakeholder group to review available data regarding existing infection control protocols at ASFs and make a recommendation on whether such facilities should report infections similar to hospitals. This stakeholder group included representatives from ASF, hospitals, national surgical management groups, healthcare payer organizations, and the Department of Health. The group's membership included infection control professionals, epidemiologists, nursing staff, facility management, and healthcare providers. Its members are listed in Appendix A.

In 2008 this group met three times over five months to discuss current facility standards and practices, and participate in a structured process to develop its recommendations. This report presents the final recommendations of the Ambulatory Surgical Facilities Infections Stakeholder Group.

Recommendations from the Ambulatory Surgical Facilities Infections Stakeholder Group

The stakeholder group recommends that:

- Infections from serious surgical procedures should be reported regardless of the setting in which those procedures are performed, hospital, surgery center, or physician's office.
 - Any person or facility licensed to conduct surgical operations should be required to report in order to ensure consistent quality of care regardless of setting.
 - The legislature should specify surgical procedures that warrant public reporting regardless of care setting.
- Washington's definition of ambulatory surgical facilities (ASFs) under RCW 70.230.010 (facilities providing invasive surgical services without overnight stay but excluding offices maintained for the practice of dentistry or offices where general anesthesia is not employed) excludes many offices where surgery occurs. ASF should be defined to include dentistry and procedures conducted under conscious sedation or regional as opposed to only general anesthesia, that all out-patient surgery settings are covered.
- Evidence-based national guidelines or standards should lead the definition of procedures chosen for reporting. The stakeholder group noted that none of the infection sites specified in the current legislation occur in the vast majority of ASFs, with the possible exception that total hip or knee replacement is starting to be done in a surgery center. The stakeholder group did not further specify what other procedures should be reported, nor criteria by which procedures could be judged to warrant public reporting.

In order to support infection reporting, as well as ensure patient safety, the group further recommends that management in all ASFs should be responsible for designating a specific individual who would be responsible for seeing that all Centers for Disease Control and Prevention (CDC) Class I infection control guidelines are followed. Recognizing the national shortage of experienced infection control professionals, the group further recommended that the department and WASCA work together to provide educational materials and develop affordable infection surveillance courses for ASF administrators and nursing staff.

The stakeholder group also recognized a need to educate the general public (not just patients) about the risk of infection and its prevention in healthcare facilities. It recommends that the department and Washington Ambulatory Surgery Center Association work together to provide educational materials on infection control (e.g. asepsis and antisepsis, safe injection practices, etc.) and general care in ASFs so the public has realistic expectations about their local surgery center's infection prevention practices, as well as an actual track record of infection rates.

With regard to transparency, the group supports alignment with measures recommended by national bodies such as the National Quality Forum (NQF), periodic review and refocusing of a list of surgical procedures for which infections or other complications should be reported and work toward consistent application of surgical site infection definition across all settings. It was noted that many ASFs use Current Procedural Terminology (CPT) codes while hospitals and some ASFs use International Classification of Diseases Adapted (ICDA) codes to identify procedures for medical record and billing purposes; it should be possible to translate across the coding schemes to identify procedures regardless of settings, but it is not reasonable to identify procedure-related infections from these administrative codes in medical record abstracts. The state of Washington should make recommendations to these organizations at a national level, and national guidelines should lead to the development of a list of surgical procedures reportable by all healthcare facilities, hospitals, ambulatory surgical facilities, or physician's office using the same definitions of surgical site infection. Consistent with recommendations from these national organizations, reporting of compliance with infection prevention measures should be considered for reporting.

Department of Health Recommendations on Reporting in Ambulatory Surgical Facilities

Second Substitute House Bill 1106 requires that hospitals to report central line-associated bloodstream infections, ventilator-associated pneumonias, and surgical site infections following coronary artery bypass graft, total hip or knee replacement, and abdominal or vaginal hysterectomy. Additionally, hospitals must submit data to the National Healthcare Safety Network (NHSN) in accordance with its definitions, methods, and procedures. The legislation also required the Department of Health to report the stakeholder group recommendations as to whether ASFs should be required to report healthcare-associated infections similar to hospitals.

The Department of Health recommends that ASFs should not be included within the current central line or ventilator-associated infection reporting requirements. The department agrees with the stakeholder group that infections from surgical procedures should be reported regardless of the setting in which those procedures are performed. However, reporting requirements for central line and ventilator-associated infections are not relevant to ASFs since facility staff do not insert or maintain central lines. Ventilators are used in ASFs only during surgical anesthesia, and the associated risk of infection during anesthesia is very low. This is not the type of ventilator use covered in CDC reporting of ventilator-associated pneumonia so it would not be reported under the provisions of 2SHB 1106.

At this time, the department does not recommend that the legislature apply reporting requirements for surgical site infections to ASFs at this time. This is consistent with the *Essentials of Public Reporting of Healthcare-Associated Infections: A Tool Kit*,¹⁰ which recommends the following surgical procedures as reasonable options for public reporting: coronary artery bypass surgery, colon resection, total hip and total knee arthroplasty, laminectomy, and total abdominal hysterectomy.

The National Quality Forum lists the same surgical procedures with the exception of laminectomy, and also limits surgical site infection rate reporting to deep wound infections resulting from these procedures as elective surgery.¹¹ Few if any of the procedures included in 2SHB 1106 are performed in surgery centers. We've been able to locate just one ASF in the state that performs any of the procedures listed in 2SHB 1106 (total knee replacement).

The department suggests waiting until the department can evaluate of its experience with Washington's hospitals under current reporting requirements and public use of infection data, before applying the reporting requirements to ASFs.

Hospital infection control programs generally are defined departments with dedicated staff unlike their ASF counterparts. Lessons learned from solving problems of adding computer-linked reporting systems with hospitals might ease the burden and transition for ASF. Also, the computer system to which hospitals need to link to, the National Healthcare Safety Network (NHSN), has only recently incorporated ambulatory care into its network.

¹⁰ Published by The Healthcare-Associated Infection Working Group of the Council of State and Territorial Epidemiologists (CSTE), CDC, Society for Healthcare Epidemiology of America (SHEA) and Association for Professionals in Infection Control and Epidemiology (APIC) Joint Public Policy Committee, 2007.

¹¹ National Quality Forum, 2008.

The department also suggests that technical problems be addressed before ASFs are included under the reporting requirements, specifically concerning:

- use of post-discharge surveillance,
- accounting for differences in the severity and complexity of underlying diseases treated in different facilities (the so-called case-mix complexity adjustment), and
- confirmation that reported rates are sufficiently reliable for comparison purposes (validation of surveillance accuracy).

Differences in case-mix make comparison of rates between hospitals complicated and potentially misleading, so comparisons between in-patient versus out-patient facilities could be even more challenging. Case-mix refers to complexity of underlying conditions among patients in different facilities that make some more prone to adverse outcomes than others. Meaningful comparison also requires assurance that there is similar likelihood of infections being detected and reported among all facilities. Until post discharge surveillance becomes more standard, comparisons are more difficult. Time to resolve these issues will help to ensure that more meaningful comparisons between hospitals and ASFs can be provided in the future.

The Department of Health recommends that ambulatory surgical facilities report healthcare associated infections through the existing Washington Administrative Code, chapter 246-101 WAC, “Notifiable Conditions.”

The department recognizes that the threat to public health from surgery centers in other states has been from significant outbreaks of disease, not small differences in infection rates. In recommending against having ASFs report healthcare associated infections, we recognize the need for a suitable alternative to safeguard public interests.

Since ASFs expect nearly zero infections, we recommend they consider one event as the epidemic or outbreak threshold for reporting under the notifiable conditions rule. If a higher than usual rate is documented and deemed acceptable (e.g., as in surgical site infection following hernia repair), the reporting threshold could be set higher. Under existing law, this reporting would include all surgical site infections as well as blood-borne viral infections such as hepatitis B or HIV, which covers the complete range reported in the outbreak literature.

The Notifiable Conditions rule requires that health care facilities notify the local health department of outbreaks or suspected outbreaks of various diseases including nosocomial infections, but historically there has not been an emphasis on nosocomial infections. This rule defines “health care facilities” as including “clinics or other settings where one or more health care providers practice;” “nosocomial infection” as “an infection acquired in a hospital or other health care facility;” and “outbreak” to mean “occurrence of cases of a disease or condition in any area over a given period of time in excess of the expected number of cases.”

Local health officers or local health departments review each reported case of a confirmed or suspected notifiable disease and conduct an outbreak investigation when necessary. The local health department notifies the department of such cases upon completion of their investigation. Under this model, local health departments would relay reports of infections from ASFs to the Department of Health. The Department’s Healthcare Associated Infections Program would offer the support of its professional consultants in infection control to aid in the investigation and the review of infection control practices at any involved facilities. Further discussions would be

necessary to establish these working relationships. Potential benefits of this approach would include:

- strengthening compliance with the state's existing notifiable conditions system,
- promoting collaboration between elements of the state's public health system.
- initiating infection control practice reviews more promptly, since they would become components of outbreak investigations.

Potential impact on local health jurisdictions could be minimized if the department provides education and expert assistance to any required field investigation. Few infections are expected to occur at each ASF. The impact on ASFs also should be minimal because they already are expected to conduct post-discharge surveillance and report any suspicious findings to their local health jurisdiction.

Finally, underreporting of notifiable conditions is an issue that would need to be addressed. Coordinated efforts from ASF licensing and accrediting organizations can help address this issue by ensuring that policies, procedures and defined responsibilities are in place as a condition of successful licensure or membership application.

Policy Alternatives Considered But Not Adopted

The department considered and rejected four alternative approaches:

Licensing inspection to include review of the infection control program, followed by no additional requirements. Licensing inspections will include a review of infection control programs during infrequent inspection visits.

Relying on licensing inspection in addition to placing greater on-going emphasis on Washington's notifiable disease reporting law is a more comprehensive plan.

1. Including ASFs along with hospitals under 2SHB 1106:

Although nine states have included these facilities in their mandatory reporting legislation, it's unclear that it provides meaningful data because their ASF Web sites displays rows and rows of zeros. They do not report the cost to collect this data, making it difficult to assess whether the end result is worthwhile.

Twenty other states have not included ASFs in their mandatory reporting legislation, the current evidence does not suggest sufficient public benefit to offset additional costs, burdens, and potential unintended consequences. An example of unintended consequence following mandatory reporting is the denial of service to higher-risk patients in New York who need heart surgery. Patients whose underlying condition makes them more likely to have poorer outcomes found it increasingly difficult to find surgeons and hospitals willing to accept them, because they might lower a surgeon's or facility's ranking.¹²

¹² S Jauhar, "The Pitfalls of Linking Doctors' Pay to Performance," *New York Times* Sept 9, 2008, <http://www.nytimes.com/2008/09/09/health/09essa.html?partner=rssnyt>, accessed 3 October 2008.

The stakeholder group is willing to have ASFs included, but sees a need for improvement of the legislation and remains concerned about largely undefined costs and benefits of infection reporting.

2. Review surgery provided at ASFs. Rotate through different, specific operations during successive periods each year, so all major types are examined in detail over time. An example is the French Centre inter-régional de coordination de la lutte contre les infections nosocomiales study approach (each surgical service providing detailed information about 200 consecutive operations annually during a three month period);

This approach has merit as an applied research project and internal continuous quality improvement method, but a state agency reporting requirement is too simple an instrument to facilitate the complexity of this type of review. Universities are more appropriate than state agencies to conduct research projects.

If the goal of mandatory public reporting is to drive improvements in patient safety, then collaborative project efforts between Washington Ambulatory Surgery Center Association, university-based researchers, and ASF-based healthcare professionals would provide more flexibility in changing the selection of surgical procedures studied in detail, matching study of procedures to specific quality objectives, and better fit the rapid-cycle needs of continuous quality improvement processes.

Appendix A

Ambulatory Surgical Facilities Infections Stakeholder Group Members

**Healthcare Associated Infections
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Appendix B
Literature Review

Literature Review

I. Differences between surgical procedures in ASF versus hospital in-patient settings.

Operative procedures in the ASF setting have been described as “generally shorter and not as invasive or complicated” compared to hospital in-patient surgical procedures.¹³ This, together with selection of relatively younger and healthier patients, implies that classification of operations performed in ASFs would rank at the low end on conventional scales used to predict surgical site infection risk.^{14,15,16} These scales have a long history of use in the hospital in-patient setting to provide meaningful comparisons, adjusting for the level of risk inherent in different types of surgery.

The most commonly used classification scale is the so-called NNIS scale,¹⁷ a four-point scale from the National Nosocomial Infections Surveillance system that adds one point each for:

- American Society of Anesthesiologists preoperative assessment ASA score >2 (ASA score 1 is a normal healthy patient, 2 is one with mild systemic disease, 3 is one with severe systemic disease that limits activity but isn't incapacitating, 4 indicates severe systemic disease that is a constant threat to life, 5 indicates moribund and not expected to survive without the operation);
- Identification of the surgical site as a contaminated or dirty procedure (formally defined options being clean [no inflammation is encountered, the respiratory, alimentary or genitourinary tracts are not entered, there is no break in aseptic operating theatre technique], clean-contaminated [the respiratory, alimentary or genitourinary tracts are entered but without significant spillage], contaminated [acute inflammation without pus is encountered, or there is visible contamination of the wound], or dirty [pus is present, or a previously perforated hollow viscus, or compound/open injuries more than four hours old.]); and
- Surgical duration exceeds the 75th percentile time for that procedure.

Many of these procedures in the ASF setting also utilize minimally invasive techniques, for instance, using endoscopes rather than large incisions. Infection rates associated with clean procedures, low risk patients, and endoscopes tend to be less than 1 percent regardless of setting, although documentation of such rates in large numbers of patients is more readily available from the literature of hospital-based programs. Fewer studies have been published from the ASF

¹³ Friedman, 2007.

¹⁴ EM Sloss, C Fung, BO Wynn, et al., “Further Analysis of Medicare Procedures Provided in Multiple Ambulatory Settings,” *MEDPAC*, 2006, http://medpac.gov/publications/contractor_reports/OCT06_Multiple_Ambulatory_CONTRACTOR.pdf, accessed 13 May 2008.

¹⁵ M Delgado-Rodriguez, M Sillero-Arenas, M Medina-Cuadros, et al., “Nosocomial Infections in Surgical Patients: Comparison of Two Measures of Intrinsic Patient Risk,” *INFECT CONTROL HOSP EPIDEMIOL*, 1997;18(1):19-23.

¹⁶ M Delgado-Rodriguez, et al., “Nosocomial Infections in Surgical Patients: Comparison of Two Measures of Intrinsic Patient Risk,” *INFECT CONTROL HOSP EPIDEMIOL*, 2006;27(8):825-8.

¹⁷ DH Culver, TC Horan, RP Gaynes, et al., “Surgical Wound Infection Rates By Wound Class, Operative Procedure and Patient Risk Index,” *AM J MED*, 1991;91(suppl3B):152-157.

operating room environment, and fewer still regarding outpatient procedures performed in a physician's office.

Studies based on infection surveillance from ASFs in several countries have been published, but less frequently than studies from the traditional hospital setting. One recent German study addresses value of the NNIS scale itself in the ASF setting. It documents that components of the NNIS index do not provide useful stratification of risk among 1,095 procedures in a freestanding outpatient surgery facility.¹⁸ It provides a discussion of its findings in context of a review of the literature, but no direct comparison to the same type of operation in comparable in-patients. This confirms the uniformly lower risk patients and procedures selected by ASFs, but does not permit direct comparisons. Another study, in a Canadian university teaching hospital, compares surgical site infection rates by prospective surveillance of 635 day surgery patients, using telephone contact with patients 30 days postoperatively, with similarly thorough surveillance on the same hospital's inpatient population. Seventy-one percent of their day surgery procedures were in the clean category, 28.5 percent clean-contaminated; on the other hand, just 84.3 percent of in-patient procedures were in those two categories, and the in-patient group had significantly more risk factors for infection such as being older, more likely to have malignancy, foreign body insertion, prior trauma, renal dialysis, preoperative shaving of the operative site, longer duration procedures. All rates reported in this study from the 1980s are higher than what one would expect today, but in relative terms the crucial finding is that the authors "conclude that day surgery infection rates are much lower than inpatient surgery infection rates at our facility, probably because of a relative absence of risk factors in the day surgery patient."¹⁹

II. Methods to detect and classify post-surgical infections

The accuracy of reports such as the German and Canadian works cited rests upon ability to monitor ASF patients after they leave the facility. There is more than one way to accomplish this monitoring, the best way is still not known, and these details of surveillance programs must be considered. A community hospital documented a clean wound surgical site infection rate of 0.76 percent among 2,060 ASF procedures carried out by 106 surgeons. Their surveillance system relied upon forms sent to each physician at the end of each month, to be returned the following month with indication of any infections noted postoperatively; average form return rate without prompting is reported as 90 percent with an increase to 95 percent after prompting by telephone if late.²⁰ This is consistent with a previous report of >90 percent response rate and <1 percent infection rate,²¹ and another older study reporting 99 percent response rate from 75 surgeons and 0.5 percent surgical site infection rate among 835 surgical procedures on 632 outpatients versus 1.3 percent infection rate among 832 on 625 in-patients documented by surgeon self-reports to monitor that one hospital's operating rooms (no differences described as statistically significant, and only 4 of 11 infections requiring readmission to hospital).²² A small number of even earlier studies report achievement of 55 percent to 100 percent return rates from post-discharge

¹⁸ S Hirsemann, D Sohr, K Gastmeier, et al., "Risk factors for surgical site infection in a free-standing outpatient setting," *AM J INFECT CONTROL*, 2005;33(1):6-10.

¹⁹ D Zoutman, P Pearce, M McKenzie, et al., "Surgical wound infections occurring in day surgery patients," *AM J INFECT CONTROL*, 1990;18(4):277-282.

²⁰ E Flanders, JR Hinnant, "Ambulatory surgery postoperative wound surveillance," *AM J INFECT CONTROL*, 1990;18(5):336-339.

²¹ CP Craig, "Infection Surveillance for Ambulatory Surgery patients," *QRB*, 1983;April:107-111.

²² JM Garvey, C Buffenmyer, RR Rycheck, et al., "Surveillance for Postoperative Infections in Outpatient Gynecologic Surgery," *INFECT CONTROL*, 1986;7(2):54-58.

surveillance contact; few studies provide direct comparison of inpatient versus ambulatory surgical site infection rates for the same surgical procedures during the same time period in the same community, and these earlier studies tend to let surgeons' define infection ad hoc rather than apply a uniform definition. Manian et al. simultaneously performed traditional in-house monitoring and surgeon self-reporting with the Centers for Disease Control and Prevention (CDC) infection definitions for a year to monitor 10,952 outpatient and 9,584 in-patient procedures at one facility; they report 78 percent response overall (ranging from 57-95 percent among 12 surgical specialties), with statistically significant differences between 0.11 percent surgical site infection rate among clean outpatient procedures versus 0.85 percent among in-patients, and 0.06 percent among clean-contaminated outpatient procedures versus 1.50 percent among in-patients.²³ Return rates are one aspect of post-discharge surveillance methods described in these studies; accuracy and predictive value are other important aspects, and in this regard a noteworthy study of 5,572 operative procedures documents low sensitivity, as well as low predictive value of positive reports, from patients (return rate of 33.4 percent compounded by false-positive reports due to minor wound complications that fail to meet criteria for surgical site infection) and surgeons (79 percent return rate, but many false-negative and false-positive responses).²⁴

Many of the current state mandatory public reporting laws recognize the CDC's NNIS system, which recently was transformed into the National Healthcare Safety Network (NHSN), as the best established system through which to gather healthcare-associated infection data from hospitals. However, neither NNIS nor NHSN have included provisions for enrolling freestanding ambulatory surgical facilities, only hospitals. NHSN plans to add an ambulatory surgery module, but has not yet unveiled details of its operation. In France, infection control has been coordinated through a national technical assistance committee for nosocomial infections (CTIN, Comité technique national de lutte contre les infections nosocomiales) and five interregional coordinating committees (C-CLIN, Centre inter-régional de coordination de la lutte contre les infections nosocomiales). The Paris-Nord C-CLIN reported results of an ambulatory surgery surveillance network project conducted in 1999-2000.²⁵ Their regional study of 5,183 patients documents a surgical site infection rate of 0.4 percent, with 93 percent of patients classified as 0 by the NNIS risk index scale, concluding that infectious risk is low in this setting and not associated with any recognized risk factors. In Canada, the national healthcare system provides record linkage that simplifies examination of return visits; a study of 17,638 consecutive ambulatory surgery patients at one major center in Toronto documents 193 readmitted to a hospital within 30 days of surgery (1.1 percent) of which just 26 were for complications (0.15 percent), of which just one or two appear related to surgical site infection serious enough to warrant return to an emergency room or admission to hospital.²⁶

The NNIS Risk Index has been shown to not perform well in the ASF setting. NHSN recognizes the need to adjust for patient case-mix and other relevant risk factors, but "there is currently no widely agreed upon, scientifically validated method for risk adjusting HAI indicators. Available

²³ FA Manian, L Meyer, "Comprehensive Surveillance of Surgical Wound Infections in Outpatient and Inpatient Surgery," *INFECT CONTROL HOSP EPIDEMIOL*, 1990;11(10):515-520.

²⁴ K Sands, G Vineyard, R Platt, "Surgical Site Infections Occurring after Hospital Discharge," *J INFECT DIS*, 1996;173:963-970.

²⁵ A Sewonou, C Rioux, F Golliot, et al., "Incidence of surgical site infection in ambulatory surgery: results of the INCISCO surveillance network in 1999-2000," *ANN CHIR*, 2002;127(4):262-267.

²⁶ G Mezei, F Chung, "Return Hospital Visits and Hospital Readmissions After Ambulatory Surgery," *ANN SURG*, 1999;230(5):721-727.

systems for assessing severity of illness, such as the Acute Physiology and Chronic Health Evaluation (APACHE) score or systems using discharge diagnoses, were designed to predict the risk of death rather than the risk of HAI acquisition and therefore are useful tools to adjust for differences in expected mortality among comparison groups. These systems, however, have not been validated to predict a patient's risk for developing a HAI."²⁷ Even if issues of case-mix risk adjustment are ignored, another fundamental problem remains that would confound meaningful comparison with hospital in-patient surgical site infection rates today; hospitals might have lower sensitivity surveillance programs relative to ASFs because the former may rely less on post-discharge surveillance than the latter. Most hospitals have not monitored the sensitivity and specificity of their infection surveillance programs, and the number using post-discharge surveillance methods in their overall program is not reported.

Historically, hospital in-patient infection surveillance programs have relied upon weekly inspection of surgical wounds and review of clinical records during each patient's hospital stay. As lengths of stay became progressively shorter, and distinctions were noticed between the nature of infections that became visible before versus after discharge from hospital, the importance of following surgical in-patients after discharge (so-called "post-discharge surveillance") became more apparent.^{28,29} It is important to remember that NNIS criteria have long defined surgical site infections as occurring within 30-day follow-up periods for cases in which there are no implanted foreign bodies, or one year if implants are involved.

NNIS, now NHSN, neither requires nor reports the number of participating hospitals with a post-discharge component in their comprehensive infection surveillance program. One study of surgical site infection following total hip and total knee replacement procedures at an integrated healthcare system documents infection rates below the NNIS all-hospitals average if their post-discharge-detected cases were excluded, but above that average if their post-discharge-detected cases were included.³⁰ This implies that SSI rates could be used without surveillance sensitivity concerns to monitor for trends over time within an individual facility, but comparisons between facilities or geographic regions could be confounded by differences in completeness of surveillance efforts.³¹

Those incorporating effective post-discharge surveillance would likely achieve higher sensitivity, so conceivably be expected to report higher infection rates relative to other facilities with less complete efforts, which could present a picture different from their true relative risk of infection. In the ASF setting, there is no alternative to some form of post-discharge surveillance. Options include providing surgeons with monthly lists of their recent operative patients so that each surgeon can self-report after those patients return for a post-discharge office visit; contacting

²⁷ ES Wong, ME Rupp, L Mermel, et al., "Public Disclosure of Healthcare-Associated Infections: The Role of the Society for Healthcare Epidemiology of America," *INFECT CONTROL HOSP EPIDEMIOL*, 2005;26(2):210-212.

²⁸ JA Weigelt, D Dryer, RW Haley, "The Necessity and Efficiency of Wound Surveillance after Discharge," *ARCH SURG*, 1992;127:77-82.

²⁹ M Delgado-Rodriguez, et al., "Nosocomial Infections in Surgical Patients: Comparison of Two Measures of Intrinsic Patient Risk," *INFECT CONTROL HOSP EPIDEMIOL*, 2001;22(1):24-30.

³⁰ S Barnes, C Salemi, D Fithian, et al., "An enhanced benchmark for prosthetic joint replacement infection rates," *AM J INFECT CONTROL*, 2006;34(10):669-72.

³¹ J Manniën, S van den Hof, C Brandt, et al., "Comparison of the National Surgical Site Infection surveillance data between The Netherlands and Germany: PREZIES versus KISS," *J HOSP INFECT*, 2007;66:224-231.

patients themselves by telephone or post card to inquire about any signs or symptoms of infection; relying upon hospital readmission or clinic visit records to detect serious infections; or antibiotic prescription records. However, the most cost-effective or best way to accomplish post-discharge surveillance for surgical site infections remains a subject of debate, and potentials in electronic data interchange remain largely unrealized.^{32,33,34,35,36,37,38}

Despite the relatively small number of publications and omission of ASFs from regional or national voluntary hospital infection surveillance networks, a statement of general guidance on surgical site infection surveillance in this setting is available.³⁹

“The strategy for surveillance of surgical site infections differs slightly from in-patient surveillance; however, it is necessary to evaluate infection trends, develop rates for new or more complex surgeries, and monitor changes in rates following interventions. Surveillance should include the following:

- Determining procedures to follow: Perform a risk assessment for high-volume, high-risk, problem-prone and historically problematic procedures. Perform a medical literature search for articles on the procedures that will be followed to determine a benchmark. Once enough data have been collected, an internal baseline rate can be determined.
- Developing case finding of effective data sources, such as medical records, letters to surgeons, and contact with the medical offices where patients receive post surgery care.
- Reassessing rates after changes in practice.”

III. Outbreaks of infection within this setting

Clear threats to public health have been evident in outbreaks more so than small changes in infection rates of ambulatory care facilities and the vast majority of such outbreaks have been due to clearly negligent practices. Inappropriate reuse of needles, syringes or other sharps; improper control of multiple-dose medication vials; lax hand hygiene and environmental sanitation practices; failure to follow proper cleaning and disinfection procedures with endoscopes or

³² Manian, 1990.

³³ RJ Sherertz, RD Marosok, RA Garibaldi, et al., “SHEA, APIC, CDC, SIS Consensus Paper on the Surveillance of Surgical Wound Infections,” *INFECT CONTROL HOSP EPIDEMIOL*, 1992;13(10):599-605.

³⁴ TH Holtz, RP Wenzel, “Post-discharge surveillance for nosocomial wound infection: A brief review and commentary,” *AM J INFECT CONTROL*, 1992;20(4):206-213.

³⁵ FA Manian, L Meyer, “Comparison of Patient Telephone Survey with Traditional Surveillance and Monthly Physician Questionnaires in Monitoring Surgical Wound Infections,” *INFECT CONTROL HOSP EPIDEMIOL*, 1993;14(4):216-218.

³⁶ K Sands, G Vineyard, R Platt, “Surgical Site Infections Occurring after Hospital Discharge,” *J INFECT DIS*, 1996;173:963-970.

³⁷ R Platt, DS Yokoe, KE Sands, et al., “Automated Methods for Surveillance of Surgical Site Infections,” *EMERG INFECT DIS*, 2001;7(2):212-216.

³⁸ ES Petherick, JE Dalton, PJ Moore, et al., “Methods for identifying surgical wound infection after discharge from hospital: a systematic review,” *BMC INFECT DIS*, 2006;6:170.

<http://www.biomedcentral.com/1471-2334/6/170>, accessed 22 May 2008.

³⁹ Friedman, 2007.

endoscope accessories are consistently found as root causes in such incidents.⁴⁰ Lapses in infection management control still result in large preventable outbreaks and exposure incident despite the fact that problems hampering infection surveillance and control in that setting; growth of outpatient care delivery volume; outbreaks; current and recommended practices in various office and clinic settings were described a decade ago.^{41,42} The references cited here are typical of other reviews and formal investigation reports that follow popular press accounts of incidents like the most recent in a Nevada endoscopy center.^{43,44}

The recent outbreak of hepatitis C among patients treated at a Las Vegas endoscopy clinic has highlighted the inherent risks associated with outpatient procedures. According to the Centers for Disease Control and Prevention (CDC), between 2007 and the first quarter of 2008, there were “five recognized syringe-reuse incidents in different states that have resulted in large numbers of patient notifications recommending testing for HIV, [hepatitis B], and [hepatitis C].”⁴⁵ Investigations conducted by the CDC of four outbreaks of hepatitis B and hepatitis C in outpatient healthcare facilities between 2000 and 2002 found that “unsafe injection practices, primarily reuse of syringes and needles or contamination of multiple-dose medication vials, led to patient-to-patient transmission.”⁴⁶ These investigation reports concluded that “healthcare workers did not adhere to fundamental principles related to safe injection practices, suggesting that they failed to understand the potential of their actions to lead to disease transmission. In addition, deficiencies related to oversight of personnel and failures to follow up on reported breaches in infection-control practices resulted in delays in correcting the implicated practices.”⁴⁷

Nebraska, Cancer Clinic, 2000-2002

“The largest outbreak of hepatitis C in North America, affecting 99 patients, was in 2002 in Nebraska, where patients in a cancer clinic were infected when a nurse used the same syringe on more than one patient.”⁴⁸ In October 2002, 612 patients of a cancer clinic in Fremont, Nebraska received notifications from the Nebraska Department of Health recommending testing for hepatitis C.⁴⁹ The outbreak report, which identifies the source of the infection as an infected patient from March 2000, holds a nurse, who reused

⁴⁰ RA Goodman, SL Solomon, “Transmission of Infectious Diseases in Outpatient Health Care Settings,” *JAMA*, 1991;265(18):2377-2381.

⁴¹ LA Herwaldt, SD Smith, CD Carter, “Infection Control in the Outpatient Setting,” *INFECT CONTROL HOSP EPIDEMIOL*, 1998;19(1):41-74.

⁴² S Balter, M Layton, K Bornschlegel, et al., “Transmission of Hepatitis B and C Virus in Outpatient Settings - New York, Oklahoma, and Nebraska, 2000-2002,” *MMWR*, 2003;52(38):901-906.

⁴³ Anon., “Nevada Hepatitis C Outbreak Tied to Las Vegas Clinic. Thousands Now at Risk for Hepatitis, HIV,” *News Inferno*, February 28, 2008, <http://www.newsinferno.com/archives/2647>, accessed 13 May 2008.

⁴⁴ CDC, “Acute Hepatitis C Virus Infections Attributed to Unsafe Injection Practices at an Endoscopy Clinic - Nevada, 2007,” *MMWR*, 2008; 57(19):513-517.

⁴⁵ M Bell, “CDC Statement for Nevada State Legislative Interim Session: Legislative Committee on Healthcare,” April 21, 2008, <http://www.cdc.gov/washington/testimony/2008/t20080421.htm>, accessed 12 May 2008.

⁴⁶ S Balter, M Layton, K Bornschlegel, et al., “Transmission of Hepatitis B and C Virus in Outpatient Settings - New York, Oklahoma, and Nebraska, 2000-2002,” *MMWR*, 2003;52(38):901-906.

⁴⁷ *Ibid.*

⁴⁸ J Steinhauer, “77 New Cases of Hepatitis are Identified in Las Vegas,” *The New York Times*, May 9, 2008, <http://www.nytimes.com>, accessed 12 May 2008.

⁴⁹ B Lydick, “Hepatitis C Trial Begins,” *The Fremont Tribune*, Oct 2, 2005, <http://www.fremonttribune.com/articles/2005/10/04/news/news1.prt>, accessed 12 May 2008.

syringes to draw solution from a saline bag on multiple patients, responsible. Ninety-nine patients tested positive for hepatitis C as a result of the Nebraska clinic's negligent practices.⁵⁰

Oklahoma, Pain Remediation Clinic, 2002

"In August 2002, the Oklahoma State Department of Health (OSDH) was informed of six patients with suspected acute [hepatitis c] infection who had received treatment from the same pain remediation clinic. A preliminary investigation by OSDH found that a certified registered nurse anesthetist reused needles and syringes routinely during clinic sessions...A total of 69 [hepatitis C] and [hepatitis b] infections were identified that probably were acquired in the clinic."⁵¹

New York, Anesthesiologist's Office, 2008

"In New York, health officials have notified 11,000 former patients of a Long Island anesthesiologist's office for possible transmission of blood-borne diseases. It is believed transmission occurred because the physician reused syringes on multiple patients."⁵²

Michigan, Dermatologist's Office, 2007

In early 2007, in response to allegations of unsafe practices in a Michigan dermatologist's office, "the Kent County Health Department sent more than 13,000 letters to patients of Dr. Stokes, recommending testing for hepatitis B, hepatitis C and HIV. In response to these letters and the widespread media coverage of the trial, laboratory tests were conducted on samples collected from 776 individuals for possible exposure to these blood borne pathogens. These individuals were screened at free clinics sponsored by the Kent County Health Department and the Mid-Michigan District Health Department. Of these 776 patients, six (0.77 percent) were found to be positive for hepatitis C infection, none were positive for hepatitis B infection and none were positive for HIV infection."⁵³

Nevada, Endoscopy Clinic, 2008

"The Southern Nevada Health District has mailed more than 40,000 letters to patients of the Endoscopy Center of Southern Nevada, urging them to be tested for hepatitis and HIV. Health investigators estimate that 4 percent of the Endoscopy Center's patients will end up testing positive for hepatitis C."⁵⁴ "During the initial investigation, CDC and the Southern Nevada Health District (SNHD) observed dangerous practices known to have been implicated in previous hepatitis C virus transmission and that may have been ongoing for several years. These included reuse of syringes to access medications from a single dose vial, and the use of single dose vials for multiple patients."⁵⁵

⁵⁰ A Wells, "Public Health Crisis: 'Message of Hope' on Hepatitis," *Las Vegas Review-Journal*, May 23, 2008, <http://www.lvrj.com/news/16936876.html>, accessed 12 May 2008.

⁵¹ Balter, 2003.

⁵² Wells, 2008.

⁵³ Michigan Department of Community Health Press Release, "State Releases Findings in Stoke Investigation," May 2, 2008, <http://www.michigan.gov/mdch/0,1607,7-132--191242--,00.html>, accessed 12 May 2008.

⁵⁴ Wells, 2008.

⁵⁵ Bell, 2008.

New York, Dialysis Center, 2008

“A Manhattan dialysis center closed down after State Health Department inspectors found blood on chairs and machines and discovered that at least one patient had contracted hepatitis C because of the unsanitary conditions. More than 600 other patients treated at the center, going back nearly five years, were urged to get hepatitis and H.I.V. tests... Richard F. Daines, the state’s health commissioner, sent letters on Monday to 657 patients of the clinic going back to January 2004, the last time infection-control violations had been found, urging them to be tested for possible exposure to hepatitis C, hepatitis B and H.I.V. The clinic, which had 171 patients at the time of the inspection, agreed to pay for the testing, even if it is done by private doctors, officials said.”⁵⁶

In a setting where the infection rate is so low that there is a reasonable expectation of not seeing any postoperative infections in any given month, reporting of infection rates is not as useful as other approaches to detect and curtail adverse events as quickly as possible, not to mention strengthening effective management control that would prevent the negligent practices which place patients at unreasonable risk by contravening widely recognized and established infection control guidelines. Although nine states have included ASFs in their mandatory reporting programs, initial reports on such web sites tend to show large collections of zero percent rates. They do not indicate costs, workload implications or sources of funding to cover production of those numbers.

IV. Surgical procedures performed in physician offices

Less is known about surgical procedures performed in physician offices as distinct from freestanding ASC staffed by larger teams. However, there is evidence of higher morbidity and mortality risk, as one study documents a twelve-fold higher risk of injury and of death as a surgical outcome at Florida physicians’ offices.⁵⁷ This report based on two years of adverse event reports by physicians to the Florida Board of Medicine and by ASC to the Florida Agency for Health Care Administration documents perforation, cardiac and respiratory arrest, hemorrhage, and unspecified complications rather than infection per se, and discusses possible reasons for wide variations in other mortality studies of office-based surgery. Another study documents 13 deaths and 43 transfers to hospital over three years of Florida physician office reporting to that state’s Agency for Health Care Administration, but does not compute rates.⁵⁸ However, Coldiron et al. suggest that Vila et al. overestimate relative risk because only offices using general anesthesia submit case logs from which number of procedures is derived but a larger number of unregistered offices report adverse events to the Board of Medicine, and criteria for associating adverse outcomes with ASC are narrower than with physician offices. When Coldiron et al. adjust the numerators and denominators of Vila et al.s’ findings to reflect these concerns, the 12-fold statistically significant risk ratio diminishes to 2.7 without strong statistical significance (95 percent confidence intervals for relative risk change from 5.79-24.14 to 0.80-9.27 respectively). They note that the Florida data is the only “available prospective, verifiable data from mandatory reporting of office surgical infections to include the physician’s identity.”

⁵⁶ A Hartocollis, “Unsanitary Dialysis Center Shuts Down Over Hepatitis,” *The New York Times*, Sept 16, 2008, <http://www.nytimes.com>, accessed 17 Sept 2008.

⁵⁷ Vila, 2003.

⁵⁸ B Coldiron, E Shreve, R Balkrishnan, “Patient Injuries from Surgical Procedures Performed in Medical Offices: Three Years of Florida Data,” *DERMATOL SURG*, 2004;30(12):1435-1443.

V. Conclusions

Conclusions from this body of evidence are that:

- Post-discharge surveillance is the only way to detect adverse events following operations in ASFs, but the optimal form of post-discharge surveillance is not yet known.
- Conventional risk stratification inherent in the NNIS/NHSN system is not useful in the ASF setting where nearly 100 percent of operations are in risk class zero.
- Risk of surgical site infection has consistently been lower in the ASF setting when compared to in-patient or physician office settings, although relatively few comparative studies with well-documented case definitions are available.
- The expected rate of infection in this low-risk setting is <1 percent, and most outbreaks have been evident from investigation of otherwise unexplained blood borne viral infection (such as hepatitis B following negligent reuse of needles and syringes) or relatively large numbers of clustered cases with unusual bacterial pathogens (such as *Pseudomonas aeruginosa* following errors in reprocessing endoscopes or endoscope accessories).
- An internal quality assurance and improvement program should include targeted surveillance efforts to assess impact of changes in practice, addition of new higher-risk surgical procedures to the services offered, monitoring of procedures recognized as being problem-prone.

Appendix C

Washington Ambulatory Surgical Center Association Survey

Washington Ambulatory Surgical Center Association Survey

Preface

The Department of Health worked with Washington Ambulatory Surgery Center Association (WASCA) on a survey to find out more about practices in Washington ASFs. The WASCA independently conducted the survey. The survey was sent to all known surgery centers in Washington, approximately 230 organizations. Forty-four percent responded.

Survey Notes

1. The survey was sent to approximately 230 surgery centers. Forty-four percent responded. It is not possible to tell whether the survey responders are typical of the entire industry or even what parts may be represented.
2. Confidence intervals were not determined, so the results do not reveal the precision with which estimates from this sample represent true values. Definitive conclusions should not be drawn from the survey results.
3. The facilities that did respond indicated confidence in their own ability to detect infections. However, when asked to indicate how many infections they detected in the past year (zero being an acceptable answer) half declined to answer this question.
4. From the data analysis, it is not possible to know whether the infections reported were in the types of procedures more prone to infection (e.g. hernia repair) or in the types where infection should be exceedingly rare (e.g. intraocular lens implants, colonoscopies, endoscopic joint operations, etc.). The results document that serious adverse events do occur (e.g. wrong procedure, wrong site, wrong patient, and deep rather than superficial infection), but we cannot determine the rates at which they occur in Washington's ASFs.
5. There may be misclassification among Current Procedural Terminology (CPT) codes included in the analysis as surgical procedures. For example, CPT code 64483 is included (that code denotes "Injection, anesthetic agent and/or steroid, transforaminal epidural; lumbar or sacral, single level"). Inconsistencies between tables reporting methods used by ASFs to detect post-surgical infections may also include misclassification.

WASCA Survey Process

In June 2008 the Washington Ambulatory Surgery Center Association (WASCA) contracted with Willard3 Communications, Inc. (W3C) to assist them in developing a Quality Research Initiative (QRI) survey for Washington Ambulatory Surgery Centers. W3C had successfully published a QRI in the state of Colorado and WASCA officials contracted with W3C to develop a similar initiative in Washington. WASCA also contracted with Applebaum Research to assist in developing the WASCA survey and to analyze the data results submitted by Washington ASCs. Applebaum Research has over 30 years of experience conducting research for the University of Colorado and has developed surveys for various groups across the country.

The Washington QRI survey was developed in cooperation with personnel from the Washington Department of Health in June of 2008 and consisted of 37 questions on ASC financial, quality of care and clinical data. ASCs were directed to report information for their most recently completed financial year and complete as much of the survey as possible.

The WASCA QRI survey was mailed in July 2008 to 230 ASCs throughout Washington. A self-addressed stamped envelope was included in the QRI packet that was mailed to Washington ASCs and recipients were asked to either use the self-addressed stamped envelope to return their responses or to fax them directly to a number included with the survey. The survey responses were anonymous. Three rounds of follow-up calls were made to all recipients of the survey in order to maximize return rates.

101 WASCA QRI questionnaires were remitted by Washington ASCs representing 44 percent of the Washington ASC industry. Questionnaires submitted did not always include responses to all questions. Incomplete or extreme data were excluded from our data analysis. Follow-up phone calls were made after data analysis was complete in order to determine possible response bias and develop an accurate representation of those ASCs that responded and those that didn't.

Survey results and raw data were forwarded to the Washington Department of Health in October of 2008. A detailed report of the survey's findings will be published by WASCA.

Any additional questions about the survey process or the findings should be directed to John Willard at willard3communications@yahoo.com

Summary of Major Findings

Outpatient Surgical Procedures and Patient Visits

- On average, 2,588 patients had outpatient surgical procedures at reporting facilities in 2007. This masks great variation in number of patients served across facilities. More than half of facilities reported serving fewer than 2,000 patients in 2007. In contrast, about one-fifth of facilities served 3,000 or more patients.
- The great majority of 2007 patient visits fell into American Society of Anesthesiologists (ASA) physical status categories 1 and 2. Half were in level 1 – normal health patient, and one-third were in level 2 – patient with mild systemic disease.
- Gastroenterology has by far the highest number of reported patient visits: 1,269 per facility on average. Orthopedics, ophthalmology, and pain management are also frequently used specialties. Very few patient visits fall into the oral surgery category – only .49 per facility on average.

Patient Satisfaction Surveys

- Most facilities conduct formal patient satisfaction surveys, primarily by mail. On average, facilities had a survey response rate of 47.4 percent to their most recent patient satisfaction survey, although response rates ranged from 3 percent to 100 percent. The vast majority of patients report that they had a positive overall experience. Most patient satisfaction surveys are conducted in-house.

Accreditation and Certification

- Two-fifths (43.6 percent) of facilities are currently accredited by Joint Commission on Accreditation of Healthcare Organizations (JCAHO), The Accreditation Association for Ambulatory Health Care (AAAHC) or American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF). Almost one-third of facilities are accredited by AAAHC, and approximately 10 percent are accredited by AAAASF and JCAHO. None of the facilities are accredited by Healthcare Facilities Accreditation Program (HFAP). Facilities were most recently accredited within the last three years.
- The great majority of facilities are Medicare-certified.

Policies and Staffing

- Almost half of facilities report they have a formal, written RN to patient staffing ratio for incubated patients. Of this group, most have a 1:1 staffing ratio, that is, one RN for each patient.
- Facilities employed 11 RNs on average in 2007. Slightly more than two-thirds employ 10 or fewer RN's.
- Four-fifths of facilities' RNs are ACLS-certified, approximately 16 percent are PALS-certified, and virtually none are PEARS-certified.
- Three-fifths report that their facility uses general anesthesia.
- Most facilities have a policy requiring "time out" prior to a procedure.

Post-Procedure Outcomes

- On average, facilities reported few transfers and status changes, either planned or unplanned. Facilities had 3.4 unplanned transfers and status changes on average, and .23 planned transfers and status changes.
- The most frequently cited reasons for unplanned transfers and status changes are surgical complications followed by post-operative pain.
- About two-thirds of facilities report that they capture information regarding unplanned return to the operating room or procedure room within 24 hours of procedure completion. A similar proportion report that they capture information regarding visits to the emergency room in connection with surgery performed at their facility.
- On average, 1.14 patients per facility experienced an unplanned return to the operating room or procedure room within 24 hours.
- Patients made an average of 3.25 visits to the emergency room in connection with surgery performed at reporting facilities.

Post-Operative Infections

- Three-quarters of facilities use CDC definitions for surveillance of wound infections. The most frequently used method for detecting post-surgical wound infections is surgeon self-report, followed by patient post-operative visits and periodic lists of patients sent to surgeons. Few facilities detect post-surgical wound infections by patient mail or e-mail.
- Almost all facilities have a high level of confidence in the accuracy of their facility's post-surgical/procedure wound infection report.
- On average, facilities reported 6.91 post-operative infections. Most of the reported postoperative infections were categorized as "superficial."
- Facilities reported virtually no sentinel events.

Characteristics of Facility

- On average, direct employee costs comprise 39 percent of facilities' direct operating costs, and medical supplies and pharmaceuticals comprise 23 percent of total operating costs.
- Most facilities serve Medicare and Medicaid patients. Two-thirds serve charity care patients, and half serve patients with bad debt.
- Almost one in five facilities report there are insurance companies that refuse to contract with their facility. Aetna and First Choice are most frequently cited.

Appendix D

References

References

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