Healthcare Associated Infections

2013 Report to the Washington State Legislature

April 2014

Division of Disease Control and Health Statistics

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Executive Summary

Healthcare associated infections (HAI) are infections that develop during, or soon after, care in a hospital, clinic, doctor's office, long-term care facility, or home-visit by a health professional. These types of infections have long been recognized as a serious and partially preventable problem. According to the Centers for Disease Control and Prevention (CDC) in 2009, there were 1.7 million healthcare associated infections every year. These infections affect 5 percent of all patients admitted to a hospital, add $26 billion to $33 billion in excess costs, and contribute to 99,000 related deaths annually. At the national Road Map to Eliminate HAI 2013 Action Plan Conference, CDC indicated there was a 44 percent reduction achieved by 2012 in central-line associated bloodstream infections, a 20 percent decrease in surgical site infections, and declines in invasive methicillin-resistant *S. aureus* (MRSA). However, progress wasn't as well-defined with catheter-associated urinary tract infections or *Clostridium difficile (C. difficile)* infections.

State and federal programs have begun new strategies to advance efforts toward preventing HAI during the past 10 years. The U.S. Department of Health and Human Services (HHS) is now in its second phase of a national HAI Action Plan. The CDC identified healthcare associated infections as one of six "winnable battles." As a leader among state programs, Washington has addressed key aspects of these recommended federal initiatives and has successfully completed all requirements outlined in our state law. The history of our program is laid out in Appendix B.

Under RCW 43.70.056, the state Department of Health oversees hospital reporting of central-line associated bloodstream infections (CLABSI) in all in-patient areas where patients typically stay at least 24 hours. The department also monitors specific types of surgical site infections (SSI), which now includes abdominal hysterectomy, colon resection, open chest cardiac, total hip replacement, and total knee replacement procedures. We also perform a thorough validation process to ensure the accuracy of rates reported on our public information website.

In this report we summarize the:

- Current hospital HAI reporting requirements;
- Department's anticipated actions and recommendations on new reporting requirements;
- Method by which the department ensures reliable quality in hospital reporting.

We began the legislative rule-making process this year to add reporting of *C. difficile* infections to align with existing Centers for Medicare and Medicaid Services (CMS) reporting requirements for hospitals. World-wide, *C. difficile* has been an increasing cause of severe and even fatal diarrhea, often following the use of certain antimicrobial drugs. We propose adding the best method to report. The information gained will help guide the best possible use of those drugs and aid in other infection prevention decisions.

Recommendations supported in our broadly representative Healthcare Associated Infections Advisory Committee are summarized in this table:

Recommendations		
TOPIC	**ACTION**	**RATIONALE**
MRSA screening of patients admitted to every adult or pediatric ICU, per RCW 70.41.430.	In the future, consider amending RCW 70.41.430 to cover all multiple drug resistant organisms (MDRO), including MRSA (testing based on risk assessment).	MRSA is not the only important drug resistant germ. Allowing each hospital to use their annual risk assessment to tailor their screening of MDRO is a better approach than regulating each MDRO separately. It's cost effective and provides needed flexibility. Oversight of the adequacy of their annual risk assessment process, potentially as part of regulatory inspection, is appropriate to include as part of the department's role.
Future extension of HAI reporting requirements to types of health care settings other than hospitals (e.g. ambulatory surgery, dialysis, skilled nursing & other long-term care facilities, home IV service providers, etc.).	In the future, consider new legal authority to include all facilities that provide the same services as acute care hospitals. Rulemaking is needed to expand the types of healthcare settings that are mandated to report HAI.	RCW 43.70.056 doesn't provide authority to extend reporting requirements beyond acute care hospitals to all facilities that present similar risks.
Broaden allowable uses of special grant account.	If authority is extended to include other types of facilities, broaden the allowable uses of the special grant account as authorized in the original 2007 version of RCW 43.70.056.	Expanding the allowable uses of special grant funding would allow us to support hospital infection control programs as well as strengthen HAI prevention programs in other settings. This supports our goal to enhance the effectiveness of public reporting.

I. Background

Healthcare associated infections (HAI) have long been recognized as a serious problem. These infections develop during, or soon after, care in a hospital, clinic, doctor's office, nursing home, or home-visit by a health professional. According to the CDC in 2009, an estimated 1.7 million HAI occur every year. These infections affect 5 percent of all patients admitted to hospitals, add $26 billion to $33 billion in excess costs, and contribute to 99,000 deaths annually (Scott, pp 1-13). This September, at the national Road Map to Eliminate HAI 2013 Action Plan Conference, CDC indicated there was a 44 percent reduction achieved by 2012 in central-line associated bloodstream infections, a 20 percent reduction seen in surgical site infections, reductions in invasive MRSA. However, progress wasn't as clear in catheter-associated urinary tract infections or *C. difficile* infections.

Over the past decade, state and federal programs have started new strategies to advance work toward preventing HAI. The U.S. Department of Health and Human Services (HHS) is now in its second phase of a national HAI Action Plan.[1] CDC identified HAI as one of six "winnable battles" on which to focus its efforts. As a leader among state programs, Washington has successfully completed all requirements in the 2007 legislation and addressed key aspects of recommended federal initiatives. See Appendix B and C for details.

2013 Legislative Action on HAI

The Revised Code of Washington (RCW 43.70.056) was amended in the 2013 legislative session and incorporated recommendations of the 2011 HAI report to the legislature:

RCW 43.70.056 Prior Versions	RCW 43.70.056 Amended in 2013
Department required to submit a report once in 2011 to the legislature based on recommendations of its advisory committee, findings of recent scientific and medical publications, and current methodologies of national organizations.	Department required to submit a report to the legislature biennially.
Central-line-associated bloodstream infection reporting limited to ICU cases.	Reporting expanded to all in-patient areas where patients normally stay at least 24 hours.
Ventilator-associated infections to be reported.	Ventilator reporting requirement eliminated.
Surgical site infection reporting to include abdominal and vaginal hysterectomy, total hip or knee replacement, and open chest cardiac procedures.	List changed to abdominal hysterectomy and colon surgery (to match CMS), along with total hip or knee and open chest cardiac procedures.
Department had rule making authority to delete or modify conditions required for reporting.	Rule-making authority extended to also add new reporting requirements when the department

[1] The HHS Action Plan (hhs.gov/ash/initiatives/hai/actionplan/) is available online.

RCW 43.70.056 Prior Versions	RCW 43.70.056 Amended in 2013
	considers it necessary to align state with federal requirements.

HAI Advisory Committee

The HAI Advisory Committee includes individuals representing:

- Health professions (hospital epidemiology and infection control, infectious diseases and other physician specialties, nursing, hospital administration and health care quality improvement);
- Rural, urban, and teaching hospitals from all geographic regions of the state;
- Associations (hospital, medical, nursing, infection control professionals, patient safety and community health alliance);
- Third-party payers;
- Public consumer patient safety advocates.

It's important to note that many of the infection prevention initiatives in the state are run by our partners who sit on the advisory committee. It's difficult to link single activities to overall outcomes for patients. However, the collaborative effort of all participants in Washington's HAI Program, HAI Advisory Committee, and individual associations and facilities have been beneficial. See Appendix B for details and the list of committee members. The committee doesn't include representation of other types of care settings (e.g. long-term care facilities, ambulatory surgical facilities, dialysis facilities, providers of outpatient home-care for central lines). The department has engaged in collaborative projects to promote infection prevention capacity in those other settings. We are not currently expanding reporting requirements to other settings at this time, nor do we have the authority to do so under RCW 43.70.056. However, it is appropriate to evaluate the future expansion of reporting to ambulatory surgery centers, dialysis facilities, skilled nursing and other long-term care facilities, and home intravenous service providers.

National Activity

The introduction of state HAI reports is the newest addition to a growing number of public information resources about hospital performance. These reports started appearing about ten years ago in response to states' legislative action. Several states started reporting just one or two types of infections, while others started with more comprehensive plans (GAO, pp 1-49). Some consumer advocates for patient safety, such as the Consumers Union Safe Patient Project and

contributors to the CDC Safe Healthcare web forum[2] (a moderated blog in which individuals can express their experience) want an even wider range of information as quickly as possible,

Two other important national organizations that actively promote patient safety are the National Quality Forum (NQF) and CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC). NQF is a nonprofit organization that works to improve the quality of American healthcare.

State reporting requirements should align as closely as possible with current guidance by national experts in hospital epidemiology and infection control, as is provided by CDC's HICPAC (McKibben et al, pp 580-587). HICPAC is a select group of experts in hospital epidemiology and infection control. They provide advice and guidance to CDC and the Secretary of HHS that are used to develop national prevention strategies and guidelines. HICPAC also includes representation from professional associations that focus efforts toward the prevention of HAI. With mandatory public reporting through state health departments, the Council of State and Territorial Epidemiologists (CSTE) is one such association that has emerged as an important influence on HAI initiatives.

We also recognize that federal agencies and national consumer advocacy groups are expecting more as state government HAI programs mature. This is clear in the HHS Action Plan. HHS has said that state HAI programs are the foundation of its plans, with the expectation being that states will move beyond rate reporting to promote and coordinate regional prevention activities in their action plans.

The Washington State HAI Program has made a strong start (see Appendix B for details):

- Met the original requirements of RCW 43.70.056.
- Gained favorable recognition at national and international levels. This is evident in our success on grant opportunities. For example, when we collaborated with the state's designated Quality Improvement Organization to bring acute and long-term care facilities together in potentially self-sustaining local communities of care. Though several states validate the quality and accuracy of infection reporting by hospitals, we're the only state that validates in a manner consistent with international quality standards.
- Advanced the science through publications and presentations, with studies conducted in partnership with research faculty in universities across North America.

As a leader among state programs, Washington has successfully completed all activities required by the 2007 legislation and addressed key aspects of recommended federal initiatives. See Appendix B and C for details.

Activity	Status
CLABSI Reporting	All eligible hospitals started reporting in 2008. Annual rates have been reported on our public website since 2009. Reporting expanded beyond hospital ICU areas in 2013 to include all in-patient areas where patients normally stay at least 24 hours.
SSI Reporting	Start date postponed in 2010 by House Bill 2828. All eligible hospitals started reporting in August 2013.
Validation	Conducted annual CLABSI validation since 2009. We're now pilot testing an SSI component to add in 2014.
Prevention Projects with Stakeholder Partners	Stakeholder organizations on our advisory committee led prevention collaborative groups. We participate when appropriate. The department also launches projects with partners when we see unmet needs (e.g. projects to bridge acute and long-term facilities to promote regional collaboration).
CDC State Prevention Status Reports	We consistently rank as showing activity in all essential components.
Engagement in rule making	We initiated the rule making process in November 2013 to consider adding *C. difficile* to the reporting requirements.

HAI Program Scope: Adding Other Healthcare Settings

The department's anticipated rule making for changes in reporting requirements for acute-care hospitals are described in Section III of this document.

Stage 2 of the national HHS HAI Action Plan focuses on including other types of health care settings. An ever-increasing number of services are being provided in out-patient and home-care settings. For example, future reporting of health care-associated community-onset CLABSI among those receiving outpatient or home intravenous therapy care of central lines may provide a more complete picture of the risk and areas for action.

CMS reporting requirements have added HAI events for outpatient dialysis and long-term care facilities. CDC has added modules for long-term care skilled nursing facilities, ambulatory surgical facilities and dialysis facilities. The department has no immediate plan to recommend extending state HAI rate reporting requirements to these other care settings now but will examine this more closely in the future. The prevention value of public reporting of HAI information is

unproven. At this time, we believe it is better to require reporting of a small number of conditions and ensure that the information is accurate and trustworthy. However, in order to provide the full picture of HAI, it may be necessary to expand surveillance beyond hospitals to include all settings where patients have central lines or surgical procedures. The HHS Stage 2 national action plan focuses on these other settings. In the future, we may recommend adding new legal authority giving the department the ability to expand requirements into other settings when the evidence demonstrates support for reporting additional facility types.

II. HAI Reporting Currently Required of Hospitals

Hospitals are impacted by federal and state HAI reporting requirements. The current and proposed CMS Inpatient Prospective Payment System (IPPS) federal requirements are listed in Appendix D. Inpatient Prospective Payment System (IPPS) is an incentive pay-for-reporting program. Washington enacts the following reporting requirements through RCW 43.70.056, RCW 70.41.430, and Chapter 246-101 WAC:

RCW 43.70.056	RCW 70.41.430	Chapter 246-101 WAC
Requires reporting central-line associated bloodstream infection data for all in-patient units. Surgical site infection data are also needed for colon resection, abdominal hysterectomy, total hip or knee, and open chest cardiac procedures.	Requires report of methicillin-resistant *S. aureus* (MRSA) infections through CHARS (Comprehensive Hospital Abstract Reporting System).	Requires reporting "outbreaks of disease that occur or are treated in the health care facility." Also requires reporting of "rare diseases of public health significance."

Recommendation for Statutory Changes

We recommend that RCW 70.41.430 be modified to permit each hospital to determine which patients should be screened for which particular MDRO based on the individual hospital's annual risk assessment. If this change is made, the Department of Health should be given responsibility for formally assessing the adequacy of annual risk assessment process during review of hospital infection control programs.

Background and Supporting Information

Chapter 246-101 WAC contains a provision for adding the reporting of "other rare diseases of public health significance." For example, we used this provision in 2013 to establish voluntary reporting of carbapenem-resistant Enterobacteriaceae (CRE). Enterobacteriaceae includes several types of bacteria that normally inhabit the healthy intestine. However, they're capable of infecting the urinary tract, wounds, the bloodstream and other body areas. Carbapenems are a class of antibiotic that's the last treatment option for very serious infections. CRE first appeared in other countries and appeared in the United States soon after carbapenems were introduced. Additional information about CRE is detailed in Appendix E.

RCW 70.41.430 requires hospitals to screen patients for MRSA within 24 hours of admission to adult or pediatric intensive care units, and to any other care units identified as high risk by each facility's own risk assessment reviews. Prior to an amendment in 2013, RCW 43.70.056 also required the department's advisory committee to make an annual recommendation on whether current science supports expanding pre-surgical screening for MRSA prior to open chest cardiac, total hip and total knee elective surgeries. Expert task forces of our advisory committee and HAI

Program recommended in 2011 that it shouldn't be universally required. While such screening could be helpful in some facilities, it wouldn't be effective or cost effective in others. That recommendation still stands (Courville et al, pp 152-159; Schweizer et al., pp 1-13).

The department and its HAI Advisory Committee support a change to RCW 70.41.430 to allow each hospital to make decisions on MDRO screening based on its own annual risk assessment. We've identified four reasons for this recommendation:

- Screening is only one of several approaches to preventing transmission of MRSA. Promising new approaches exist that may be more cost-effective. The original recommendation to screen and isolate was based on information available at the time. However, knowledge from studies described in Appendix E now makes a different approach worthwhile.

- Washington state hospitals are maintaining low rates of central-line associated bloodstream infection and of MRSA infection relative to the past decade and rates reported by other states.[2]

- There are other emerging pathogens that are of equal or even greater concern today (for example CRE), and

- The capacity to afford and to process screening cultures is limited. Hospital epidemiology and infection control programs need to be able to shift resources quickly in response to changing conditions.

RCW 70.41.430 requires hospitals to conduct an annual risk assessment, which is not a uniformly defined process. We recommend the annual risk assessment process be formally measured during review of infection control programs. The focus should be on whether each hospital maintains an adequate assessment process, not on any given hospital's current incidence or prevalence rate of MDRO infections. While specific details would require additional discussion and can be addressed through departmental policy or rule rather than statute, there are four elements that assessment of an annual hospital HAI risk assessment process should cover:

1. Is the hospital's infection control program informed by a clinical laboratory that uses methods consistent with current Clinical and Laboratory Standards Institute (CLSI) and CDC guidance on susceptibility testing so that drug resistance can be detected?

[2] Washington State's standing relative to other states is evident in CDC's 2009 *First State-Specific Healthcare-Associated Infections Summary Data Report* and subsequent annual *National Healthcare-Associated Infections Standardized Infection Ratio Report* series for all years since 2009.

2. Is communication between the laboratory, infection control program and clinical staff timely and reliable so that appropriate MDRO precautions can be started without undue delay?
3. Does the hospital epidemiology and infection control program regularly review its past years' experience regarding outbreaks, cross-infection episodes, etc. involving various MDROs?
4. Does the hospital epidemiology and infection control program regularly review trends in past year's screening cultures and results of any special studies done to identify high-risk areas or patient groups?

Whether adequacy of annual risk assessment process should be the responsibility of the department's regulatory program, or part of the HAI Program's annual validation visit protocol, or both also remains to be determined.

III. Intent to Add, Delete or Modify Reporting Requirements by Rule

This section describes the department's current thinking about HAI reporting recommendations based on federal and state agency requirements, review of the related scientific literature, and discussions with our HAI Advisory Committee.

Department of Health's Perspective on Expanding Reporting Requirements

We recognize the importance of balancing workload for a reporting facility against the value of information to the public and our ability to improve patient safety. We anticipate expanding reporting requirements as we learn more about important gaps in current reporting, or the value of adding reporting on emerging new infectious diseases of public health concern. We expect to eliminate unsuccessful requirements where we see an existing measure not serving its intended purpose well, for example, ventilator-associated pneumonia was eliminated in 2013 for reasons explained in Appendix E.

There are many critical gaps in current knowledge about mandatory public reporting. There are questions about whether the types of information being provided are the best way to support the public in making decisions about their health care. We've engaged with research faculty at universities across North America to identify and address those gaps. Evidence that public reporting has had significant impact on preventing infection is lacking, but it may be premature to expect to prove it has a significant impact on infection rates given the short time the programs have been in place (Fung et al., pp 111-123; Shekelle et al., pp 1-46; Stone, pp-417-422; Ellingson, presentation; Sheps and Birnbaum, pp 96-154; Linkin et al., 844-846; Pakyz and Edmond, pp 780-784).

The department and advisory committee agree that the highest priority is to implement effective prevention methods. The department also believes focusing on reporting that can be done thoroughly, meaningfully, and with validation of the data. It's important for physicians to have confidence in our HAI rate reports as they guide their patients through informed consent discussions prior to invasive procedures.

Another valuable source of information for assessing healthcare quality is an All-Payer Claims Database (APCD). ADCD are providing consumers access to patient safety and quality reports to make informed healthcare decisions. Washington State has an APCD currently maintained by the Washington Health Alliance. Further expansion of the Washington APCD will allow access to data that is already being collected for administrative uses to allow quality measurement.

In general, CMS defines which HAI events hospitals must report (see Appendix D), and CDC defines technical aspects of related data reporting requirements. We regularly analyze CMS and CDC infection reporting requirements and evaluate the benefits of their measures. We have

aligned state requirements with measures that are beneficial, but have presented better alternatives to those that are not. In selecting accountability measures to add, the following principles guide our decisions:

- The measure should reflect conditions (of which includes not only HAI but also unintended negative consequences of an HAI prevention strategy) for which ability to prevent is a realistic expectation;
- The measure should be practical, readily understandable, and meaningful for its intended audience;
- The measure should be used to inform the public and facilities for quality improvement; and
- The reporting system should be one that we can validate annually for completeness and accuracy.

There are a number of CMS IPPS event categories that we don't plan to incorporate into state reporting. Other categories adopted by CMS do fit our criteria, but involve as yet unresolved technical issues. A brief summary is presented here, and more detailed technical information is presented in Appendix E.

Plan to Adopt	Do Not Plan to Adopt	For Further Consideration
Clostridium difficile disease	• Catheter-associated urinary tract infection • MRSA bacteremia LabID event	• Influenza immunization rate in staff • Consider recommending RCW 70.41.430 be changed to improve flexibility in dealing with all MDRO • Consider recommending addition of assessment of the facilities' annual risk assessment to compliance monitoring.

CMS Categories the Department Does Plan to Adopt

C. difficile associated diseases present certain technical difficulties in case definition and risk adjustment, but it's a major public health concern and collecting these data offer a baseline assessment of the burden of CDAD in Washington. *C. difficile* lives in the bowel, spreads to the environment from bowel movements, can survive on surfaces for very long periods of time by forming spores, and reach others on unwashed hands or contaminated items. Some strains of *C. difficile* produce toxins, and some toxin-producing strains produce more bowel-damaging toxin than others. Two events are needed to produce the disease. The first event is becoming colonized

with a toxin-producing strain of this organism. It's impossible to know the time and place of acquiring the strain because people can't be tested before and after each encounter they may have with other colonized individuals or contaminated environmental surfaces. The second event is disruption of normal intestinal bacteria during treatment with an antibiotic that permits *C. difficile* to flourish. The toxin then produced by some strains damages the intestine and this causes the disease. Time and place of disease onset is easy to recognize. However, the two event process leads to the difficulty of distinguishing between "healthcare-acquired healthcare-onset," "healthcare-acquired community-onset," "community-acquired healthcare-onset," and "community-acquired community-onset" categories. Also, some hospitals tend to treat more patients who are more likely to be colonized. Therefore, some form of risk adjustment is necessary to make disease rates comparable. We have initiated the rule making process to explore ways of dealing with these issues through public hearing and other sources of information.

CMS Categories the Department Does Not Anticipate Adopting

Catheter-associated urinary tract infections (CAUTI) have been one of the most common types of HAI, and there is considerable potential for prevention activities. However, we don't plan to make it required under state rules. Briefly:

- The vast majority of these infections produce no symptoms, don't require treatment, spontaneously resolve after a catheter is removed, and have no noticeable effect on additional hospital cost or length of stay. These "asymptomatic" infections wouldn't be counted.

- National Healthcare Safety Network (NHSN) recently changed its case definition to include cases only serious enough to require treatment. This narrower new definition excludes most CAUTIs. The cases that do break through to cause serious infection often because of other urinary tract abnormalities. Since some hospitals treat a higher proportion of patients prone to having such abnormalities than others, this makes comparison by simple CAUTI rates less meaningful.

The CMS IPPS program also includes MRSA bacteremia LabID event. Again, for reasons detailed in Appendix E, we don't plan to make it required under state rules:

- The LabID option is a simplified way of reporting that only records laboratory results – a positive culture for MRSA. Previous attempts to define a MRSA rate weren't able to distinguish between actual infection and the presence of bacteria on the body without producing disease (many people are colonized in this way). Limiting this to presence of MRSA in a normally sterile site (blood) makes it easier to identify a positive culture as evidence of infection.

This doesn't distinguish between infections in those who were previously colonized with MRSA or had a preexisting MRSA infection that extended to the bloodstream.

- This metric does not measure how many patients were MRSA-free on admission then became infected while in hospital. Without clinical and genetic fingerprinting information, it can't meaningfully indicate whether MRSA spread from one person to another.

CMS Categories That Warrant Further Consideration

There are several issues related to CMS reporting categories that warrant further consideration but for which we do not support an immediate rule change.

- MRSA has captured the largest amount of public attention, but there are other important MDRO that also present a serious threat to patients. Public health has dealt with some of these, but now needs to consider more cost-effective ways of monitoring and controlling all MDRO under one coordinated framework. We're discussing with our advisory committee how to recommend changes in RCW 70.41.430 to provide hospitals more options for tailoring screening strategies based on their annual risk assessment for all MDRO.

- CMS also includes health care personnel influenza vaccination rate in its IPPS categories. This began in 2013 for hospitals and is scheduled for 2014 in other settings. In its initial year, the hospital reporting deadline was midway during the usual immunization campaign so it's not an accurate indication. Our advisory committee will discuss whether adding this as a requirement in the future might be worthwhile.

- There is continued discussion at various levels about whether compliance with prevention practices might be a worthwhile addition. CMS and other accreditation agencies include assessment of prevention practice compliance in their facility surveys. Prevention practice is much easier to measure than infection outcome in ambulatory care facilities. However, there's no consensus on reporting compliance with prevention practices at this time.

- The Surgical Care Improvement Project (SCIP) set of measures similarly records percentage compliance with a set of best practices for preventing surgical site infection. While widely reported as compliance with individual items, the value in complying with some, but not all SCIP measures has been challenged by research findings.

IV. Process Used to Evaluate the Quality and Accuracy of Reporting

The department verifies that all hospitals report the correct infections. Our approach is consistent with the methods for acceptance sampling used by all other industries in line with the international standard ISO 2859. Our protocol differs from the approaches currently used by CMS and CDC. It was developed before the recent release of a CDC method, and we continue to use our method because it's an efficient use of resources and meets International Organization for Standardization (ISO) standards. Four divisions of the American Society for Quality noted that Washington is the only state HAI program following the international conventions (Fortuna et al., pp 611-614), and two other countries (Israel and Belgium) have requested our information for use in their national programs. Only three or four states perform any form of annual validation, and we're the only state meeting the ISO standard.

Our method is fully described in a technical reference manual (available upon request). We have used this method in annual validation of central line-associated bloodstream infection (CLABSI) reporting since January 2010. We piloted a similar method in 2013 for annual evaluation of the quality in surgical site infection (SSI) reporting. Our annual method involves:

- Shared responsibility
    - Every hospital participates in an "internal" self-assessment component.
    - We conduct on-site reviews of selected hospitals based on the results of their "internal" assessment and other factors.
    - We work with each hospital to ensure they maintain the pre-specified standards for quality in HAI detection and reporting.

- Validation
    - The sample size for the number of medical records we review in each hospital has been selected to ensure adequate power to detect substandard performance if it exists.
    - It is efficient, minimally burdensome for hospitals, and has revealed improvement opportunities appreciated by our hospital partners.
    - During each validation verification visit, we check to see whether reporting to National Healthcare Safety Network (NHSN) from each hospital visited misses or misclassifies too many HAI events such that a corrective action plan would be required. We offer suggestions where we see opportunities to share "best practices," unlike other states. We also maintain a pass/fail standard to ensure we can stand behind the accuracy of rates we report to the public.

In addition, during our annual update to the public information website, we double check for any gaps in the monthly data submitted during the report period and troubleshoot any problems with the hospital. If our data analysis identifies any issues, we work with the hospital to review the clinical details of the HAI case to confirm all cases satisfy the NHSN definition criteria.

V. List of Abbreviations

AMSCoS	Antimicrobial Stewardship Consortium of Seattle
APIC	Association for Professionals in Infection Control and Epidemiology, Inc.
APCD	All-Payer Claims Database
ARRA	American Reinvestment and Recovery Act
CAUTI	Catheter-associated urinary tract infection
CDAD	*Clostridium difficile* associated disease
CDC	U.S. Centers for Disease Control and Prevention
CHARS	Comprehensive Hospital Abstract Reporting System
CLABSI	Central line-associated bloodstream infection
CMS	Centers for Medicare and Medicaid Services
CRE	Carbapenem-resistant Enterobacteriaceae
CSTE	Council of State and Territorial Epidemiologists
CUSP	Comprehensive Unit-Based Safety Program
ESBL	Extended-spectrum beta-lactamase
HAC	Hospital-acquired condition
HAI	Healthcare associated infection
HHS	U.S. Department of Health and Human Services
HICPAC	Healthcare Infection Control Practices Advisory Committee
ICU	Intensive care unit
IHI	Institute for Healthcare Improvement
IPPS	Inpatient Prospective Payment System
ISO	International Organization for Standardization
MDRO	Multiple-drug-resistant organisms
MRSA	Methicillin-resistant *Staphylococcus aureus*
NHSN	National Healthcare Safety Network
NQF	National Quality Forum
PSO	Patient Safety Organization
QIO	Quality Improvement Organization
RCW	Revised Code of Washington
SCIP	Surgical Care Improvement Project
SHEA	Society for Healthcare Epidemiology of America
SIR	Standardized Infection Ratio
SSI	Surgical site infection
TJC	The Joint Commission
VAP	Ventilator-associated pneumonia
VRE	Vancomycin-resistant enterococci

VI. Appendixes

Appendix A: References

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Appendix B: Program History and Healthcare Associated Infections (HAI) Advisory Committee Membership List

In 2007, the Washington State Legislature passed Second Substitute House Bill 1106. Codified as RCW 43.70.056 requires acute care hospitals to report certain healthcare-associated infections to the CDC's National Healthcare Safety Network (NHSN). NHSN is a secure data sharing network for reporting healthcare associated infections. It provides users with standardized case definitions and methods that CDC has been refining for more than 40 years. The majority of state programs use NHSN to obtain publicly reported infection rates. In addition, NHSN has been used as an international model for creating reporting systems and by the Centers for Medicare and Medicaid Services (CMS) as their source for obtaining infection rates for the CMS Hospital Compare website and other purposes.

Washington hospitals were originally required to report central line-associated bloodstream infections (CLABSI) that occur in intensive care units and ventilator-associated pneumonia to NHSN. The department publicly reports annual infection rates from this data through its HAI's website. The website has been available to the public since the end of 2009 and is updated at least once every year.

In 2010 Substitute House Bill 2828, amended RCW 43.70.056, to postpone the reporting of surgical site infections (SSI) to NHSN until hospitals are able to align their reporting capacity with the standards set by NHSN (Cummings et al., Abstract #827). Since then, hospitals have been establishing the electronic systems required by CMS and the federal Meaningful Use program that significantly ease the burden of surgical event reporting. RCW 43.70.056 requires the department to assure the accuracy of hospital reporting. We pilot tested a validation method in 2013 to ensure accuracy and completeness of SSI reporting, which will be added to our existing annual CLABSI validation protocol in 2014 and will add annual validated SSI rates to our website as soon as possible.

RCW 43.70.056 originally required the department to submit a report to the legislature in 2011 on additional mandated infection reporting requirement recommendations. The report is based on the recommendations of our HAI Advisory Committee, the findings of recent scientific and medical publications and the current methodologies of national organizations. Amendment of RCW 43.70.056 in the 2013 legislative session introduced the following changes in accord with recommendations of our 2011 report:

1. The department is to submit a report to an appropriate committee of the Legislature biennially.
2. The scope of central-line-associated bloodstream infection reporting expanded from only intensive care units to also include all in-patient care areas where patients normally stay at least 24 hours.

3. The ventilator-associated infection reporting requirement was discontinued.

4. The list of surgical procedures for which surgical site infection reporting is required was changed to include and exceed those required by CMS.

5. New rule making authority was given to the department to expand the list of reportable conditions in future for the purpose of staying aligned with CMS requirements.

The department consistently has taken a constructive approach on setting mandatory reporting requirements. We recognize the importance of balancing workload for a reporting facility against information valuable to the public and the ability of public health agencies to advance patient safety. As we learn more about important gaps in current reporting, or the value of adding reporting on emerging new infectious diseases of public health concern, we anticipate expanding current requirements. Where we see an existing measure not serving its intended purpose well, we anticipate eliminating unsuccessful requirements (i.e. ventilator-associated pneumonia). At the time of our 2011 report, there was no evidence yet that public reporting has significant impact on preventing infections (Fung et al, pp 111-123; Shekelle, et al., pp 1-46; Stone, pp 417-422). That is still the case (Ellingson, presentation; Linkin et al., pp 844-846; Pakyz and Edmond, pp 780-784). However, it is premature to expect to be able to measure impact on infections (Sheps and Birnbaum, pp 96-154). There are many critical gaps in current knowledge about mandatory public reporting concerning whether the right kind of information is being provided in the most effective manner to address what different segments of a public audience can use in a practical way. We have engaged with research faculty at universities across North America to identify and address those gaps through collaborative research studies (Sheps and Birnbaum, pp 96-154). From work with these research partners, we do emphasize that it seems premature to expect to be able to prove public reporting has significant impact on infection rates. In our own Universities Council research collaborative, we've identified a research agenda that starts with confirming whether content and form of public reporting meets actual needs of its intended audience, then whether that information delivery leads to "knowledge translation" (influencing the way people think and communicate), then finally to whether that alignment leads to measurable improvement. Universities Council is a group of research faculty members spanning a wide range of academic disciplines at universities across North America who have agreed to collaborate with us addressing critical knowledge gaps. Our collaborative's past and present studies in what is at least a five-year research agenda is still focused on the first of these aspects.

Priority should be placed on requiring only categories of reporting that can be done thoroughly, meaningfully, and with validation so that hospitals can develop infection reduction plans based on credible data. The Advisory Committee agreed that the highest priority is to implement effective prevention methods. The department also believes this approach is important in enabling physicians to indicate our rate reports as being trustworthy when they guide their patients through informed consent discussions prior to invasive procedures. The department's anticipated rule making plans concerning changes in reporting requirements are described in Section III of this document.

It is important to note that many of the infection prevention initiatives in Washington State are run by our partners who sit on the Advisory Committee. The department focuses its own effort on oversight of credible reporting, assisting facilities and local health jurisdictions in investigation of suspected HAI outbreaks or emergence of unusual pathogens, and providing consultative expertise in hospital epidemiology and infection control. This provides our partners with information to help them prioritize, plan and monitor projects they conduct with hospitals, long-term care facilities, ambulatory care facilities and dialysis centers. For example, the Antimicrobial Stewardship Consortium of Seattle (AMSCoS) is working to promote best practices for prudent antimicrobial use in order to provide patients with optimal therapeutic outcomes while reducing the emergence of drug resistant organisms. Local chapters of the Association for Professionals in Infection Control and Epidemiology (APIC) provide education day events for infection control professionals in hospitals and ambulatory care clinics. The Surgical Outcomes Research Center at University of Washington (SORCE, http://uwsurgery.org/index.php?option=com_flexicontent&view=items&cid=79&id=248&Itemid=209) leads projects and studies intended to optimize the quality of surgical outcomes throughout the state, which more recently encouraged and enabled launch of a Strong For Surgery (www.strongforsurgery.org) resource. Strong for Surgery helps patients and their physicians start earlier with simple actions that can improve the likelihood of good surgical outcomes. The state's designated Quality Improvement Organization (QIO), Qualis Health, provides education in continuous quality improvement methods. It also facilitates collaborative projects in hospitals and long-term care facilities on a wide range of adverse event topics including methicillin-resistant *Staphylococcus aureus* [MRSA] and *C. difficile* prevention, antimicrobial stewardship, and improving inter-facility communication at the time of patient transfer to ensure continuity of care. The Washington State Hospital Association a designated Patient Safety Organization runs a Comprehensive Unit-Based Safety Program (CUSP), a Safe Tables Program, and a Hospital Engagement Network in the CMS Partnership for Patients to promote advancement of best practices collaborations in a wide range of adverse event topics including central line, ventilator, urinary tract and surgical site infection.

It is difficult to link single activities to achievement of overall outcomes for patients. However, the collaborative effort of all participants in Washington State's HAI Program, HAI Advisory Committee, and individual associations and facilities has been beneficial. CLABSI rates reported for hospitals are not only very close to zero but are also among the lowest reported by any state. Although it has been noted that states conducting validation tend to have higher CLABSI rates than states that do not validate the accuracy of reporting (Arnold, CSTE Annual Conference 2013), Washington State consistently stands out as having a credible validation program and CLABSI rates among the lowest in the nation as evidenced by CDC's annual National and State Healthcare-Associated Infections Standardized Infection Ratio Reports. Very few states report ventilator-associated pneumonia (VAP) rates, and it is impossible to validate the accuracy of VAP reporting, so while Washington State VAP rates also are very close to zero we cannot determine on how they compare nationwide. We do not yet have sufficient data to determine performance in preventing SSI.

HEALTHCARE ASSOCIATED INFECTION ADVISORY COMMITTEE MEMBERS

Roy Almeida, DrPH, MT(ASCP) Director, Epidemiology & Infection Control Providence Sacred Heart Medical Center & Children's Hospital Spokane, WA	**John Barnett** (until July 2013) President AARP Washington State Kirkland, WA
Penny Becker, PhD Infection Control Coordinator Olympic Medical Center Port Angeles, WA	**Susie Dade, MPA** Deputy Director Puget Sound Health Alliance Seattle, WA
Marisa D'Angeli, MD, MPH Medical Epidemiologist Washington State Department of Health Shoreline, WA	**E. Patchen Dellinger, MD** Professor, Vice Chairman and Chief Division of General Surgery, Dept. of Surgery University of Washington Health Sciences Seattle, WA
Timothy Dellit, MD Associate Medical Director Harborview Medical Center Seattle, WA	**Angela Dickson, RN, CIC** Infection Preventionist PeaceHealth St. John Medical Center Vancouver, WA
Sharon Eloranta, MD Medical Director, Quality & Safety Initiatives Qualis Health Seattle, WA	**Linda L. Foss, PhD, RN** (Until July 2013) Executive Director, Inspections and Investigations Department of Health Tumwater, WA
Janie Garris, RN, MN Director, Infection Control and Employee Health Group Health Cooperative Seattle, WA	**Susan Gustafson, RN, CIC** Infection Prevention Program Director Multicare Health System Tacoma, WA
Howard E. Jeffries, MD, MBA, MPH (Until July 2013) Medical Director, Continuous Performance Improvement Seattle Children's Hospital Seattle, WA	**Thomas Locke, MD, MPH** Health Officer Clallam and Jefferson Counties Port Angeles, WA
Miriam Marcus-Smith, RN, MHA Program Director, Washington Patient Safety Coalition Foundation for Health Care Quality Seattle, WA	**Michael Matlock, MD** (until 2014) Medical Consultant to Epidemiology Providence St. Peter Hospital Olympia, WA

Marcia Patrick, RN, MSN, CIC (Until August 2013) APIC National Board Member Tacoma, WA	**Fran Petersen, RN, MSN, CIC** Infection Control/Quality Manager Lourdes Medical Center Pasco, WA
Susan Peterson Associate Director, Legislative and Regulatory Affairs Washington State Medical Association Olympia, WA	**Gary Preston, PhD** Epidemiologist Healthcare Management Alternatives, Inc. Vashon, WA
Steve Saxe, MHA, FACHE Office Director, Health Professions and Facilities Department of Health Tumwater, WA	**Will Shelton, M(ASCP), CIC** Director, Epidemiology and Employee Health Swedish Medical Center Seattle, WA
Barbara Soule, RN, MPA, CIC Infection Control Professional Olympia, WA	**Carol Wagner, RN** Vice President, Patient Safety Washington State Hospital Association Seattle, WA
Sally Watkins, PhD, RN Assistant Executive Director, Nursing Practice, Education and Research Washington State Nurses Association Seattle, WA	**Nancy Whittington, RN CIC** Lead Clinical Healthcare Epidemiologist University of Washington Medical Center Seattle, WA
Ethan Crawford, Jr. AARP Washington State	**J. Elaine Albert, MD, MHA** Director of Patient Safety Division of Pediatric Critical Care Medicine Seattle Children's Hospital Seattle, WA
Yanling Yu, PhD Washington Advocates for Patient Safety	

Appendix C: HAI Program Achievements

Fulfillment of RCW 43.70.056 Requirements, National and International Recognition

The Washington State HAI Program has:

- Met the original requirements of RCW 43.70.056.
    - Convened a broadly representative advisory committee.
    - Enrolled all eligible hospitals in a reporting network on schedule.
    - Ensured hospitals are reporting all required information.
    - Created a website to report hospital rates to the public.
    - Established a program to validate the accuracy of hospital reports.
    - Made new recommendations through required reports to the legislature.
- Gained favorable recognition at national and international levels.
    - Our applications for funding through the American Reinvestment and Recovery Act (ARRA), Epidemiology and Laboratory Capacity (ELC) and Affordable Care Act (ACA) HAI grant opportunities have been very successful. This brought over $1,000,000 in additional funding to Washington State. Over half went to hospitals for strengthening their infection surveillance and prevention capacity; the remainder supported project positions in our HAI Program to provide services for hospitals, long-term care facilities, and others.

    - Our projects have gained national attention and support. For example, with the state's designated Quality Improvement Organization, Qualis Health, as a partner, we conducted a pilot project in 2011. It launched regional collaborative groups of long-term care facilities around their community's hospital in what we hope could become a self-sustaining model independent of government facilitation. This novel approach to align an entire continuum of care toward sharing best practices for preventing the spread of multiple-drug resistant organism (MDRO) infections attracted the attention of U.S. Dept. of Health and Human Services Region X Administration. Region X entered our model into a 2012 HHS internal competition; among the 41 nation-wide applicants, 18 were funded including Region X. This resulted in a contract from Region X Administration to the department to replicate our model by offering train-the-trainer sessions in all the other Region X states. Our Region X project brought an additional $50,000 to Washington State to cover all expenses associated with this work.

- We are the only state that has validated the quality and accuracy of infection reporting in a manner consistent with the pertinent international standard for such work (ISO 2859[3]). Many state programs have struggled to find a practical and affordable way to do validation, and most do not perform any annual validation. Our annual validation program has been working well since 2009 with all applicable hospitals in Washington to ensure their reporting meets our defined standards for completeness and accuracy. A description of our experience using this approach was accepted for presentation at the Decennial International Conference on Healthcare-Associated Infections and the Council of State and Territorial Epidemiologists (CSTE) annual conference in 2010. We subsequently were invited to share our method as a featured member of a panel on validation convened by CDC for the 2013 CSTE Annual Conference. We are acknowledged by leaders from four divisions of America's foremost organization for expertise in quality methodology the American Society for Quality's Healthcare, Statistics, Audit and Management divisions as the only state conducting our validation sampling in a manner consistent with standards agreed upon by certified quality specialists across all other industries (Fortuna et al., pp 611-614).

- Partnership with research faculty in universities across North America our Universities Council expanded our ability to address important knowledge gaps facing all state HAI public reporting programs. Studies conducted with these partners have been reported in papers accepted for presentation in major conferences and publication in leading journals. (See Appendix B.)

- A growing number of people nationally and internationally have asked for our assistance in establishing a validation process with their hospitals. The validation technical reference manual documents our methods to confirm accuracy of hospital reporting for CLABSI was distributed by NHSN to other states. Healthcare professionals who specialize in HAI at Harvard University and its teaching hospitals, two Southern California hospitals affiliated with the University of California, and California's State HAI Program became very interested in our 2013 SSI validation component work. They volunteered to collaborate with us in sharing information and pilot testing the new SSI protocol. Also in 2013, the State of Israel's health ministry requested a formal visit to discuss implementing our protocol in their national program. The Scientific Institute of Public Health in Belgium requested a copy of our validation technical reference manual for their national program.

[3] The nature of ISO 2859 and its pertinence to this work is fully explained in our validation protocol technical reference manual, available upon request.

Conference Presentations & Posters:

- Birnbaum D, Cummings MJ, Guyton K, Schlotter J. Public Reporting of Hospital Performance Data. Poster. Northwest Patient Safety Conference, Washington Patient Safety Coalition, Seattle Washington, June 2009.

- Birnbaum D, Cummings MJ, Guyton K, Schlotter J, Kushniruk A. Designing Public Web Information Systems with Quality in Mind: Public Reporting of Hospital Performance Data. 1st Canadian Quality Congress & 13th World Congress for Total Quality Management, Vancouver, British Columbia, August 2009.

- Birnbaum D, Van Buren J. Applying Continuous Improvement In Public Reporting: What Should Governments Report To Their Citizens About The Quality Of Healthcare-Associated Infection Prevention In Their Hospitals? 1st Canadian Quality Congress & 13th World Congress for Total Quality Management, Vancouver, British Columbia, August 2009.

- Eloranta S, Wagner C, Birnbaum D. Aligning to Eliminate Healthcare Associated Infections. QualityNet Conference, Centers for Medicare and Medicaid Services, Baltimore Maryland, December 2009.

- Benneyan J, Best A, Birnbaum D, Borycki E, Goeschel C, Jarvis W, Kushniruk A, Mazor K, Pronovost P, Sheps S. Enlisting University Partners to Address Knowledge Gaps Facing State Healthcare Associated Infection (HAI) Programs. Abstract #825, Fifth Decennial International Conference on Healthcare-Associated Infections, Atlanta Georgia, March 2010.

- Cummings J, Zarate R, Birnbaum D. Surgical Site Infection Reporting Readiness: A Survey of Washington State Hospitals. Abstract #827, Fifth Decennial International Conference on Healthcare-Associated Infections, Atlanta Georgia, March 2010.

- Zarate R, Cummings J, Birnbaum D. A Practical Method to Validate the Accuracy of State-Wide Hospital Infection Surveillance. Abstract #842, Fifth Decennial International Conference on Healthcare-Associated Infections, Atlanta Georgia, March 2010.

- Birnbaum D, Marfin A, Zarate R. SIR, You've Led Me Astray! Abstract #849, Fifth Decennial International Conference on Healthcare-Associated Infections, Atlanta Georgia, March 2010.

- Furkay L, Birnbaum D. Lessons from Washington State's Healthcare Associated Infections and Adverse Reporting Programs, Northwest Patient Safety Conference, Seattle Washington, May 2010.

- Bell S, Benneyan J, Best A, Birnbaum D, Borycki EM, Gallagher TH, Goeschel C, Jarvis B, Kushniruk AW, Mazor KM, Pronovost P, Sheps S. Mandatory Public Reporting: Build It and Who Will Come? Information Technology & Communications in Health international conference, Victoria BC, February 2011.

- Birnbaum D. Mandatory Public Reporting: Build It and Who Will Come? Washington Medical Librarians Association annual meeting, Kenmore WA, March 2011.

- Birnbaum D. Public Reporting: The Need for Standardization and Validation. Society for Healthcare Epidemiology of America annual scientific meeting, symposium session on Expanding the Research Agenda for Infection Prevention, Dallas Texas, April 2011.

- Zarate R, Birnbaum D. Post-Discharge Surgical Site Infection Surveillance in Washington Acute Care Hospitals. Poster, Northwest Patient Safety Conference, Washington Patient Safety Coalition, Seattle Washington, May 2011.

- Birnbaum D, Schwien T. Regional Multiple Drug Resistant Organism Prevention Collaborative Collaboration. Northwest Patient Safety Conference, Washington Patient Safety Coalition, Seattle Washington, May 2011.

- Zarate R, Birnbaum D. Post-Discharge Surgical Site Infection Surveillance in Washington Acute Care Hospitals. Abstract #1060568. Council of State & Territorial Epidemiologists annual conference, Pittsburgh Pennsylvania, June 2011.

- Zarate R, Birnbaum D. Acute Care Hospital Risk Stratification Using Hierarchical Cluster Analysis. Abstract # 1060201. Council of State & Territorial Epidemiologists annual conference, Pittsburgh Pennsylvania, June 2011.

- Birnbaum D. HAI: What is the role of public health? West Coast Epidemiology 2011 Conference, Troutdale Oregon, October 2011.

- Tebaldi J, Lovinger P, Birnbaum D. Partnering to Meet the Challenge of Healthcare Associated Infections. 18th Annual Joint Conference on Health, Washington State Public Health Association, Vancouver WA, October 2011.

- Amini A, Birnbaum DW, Black B, Hyman DA. Public Reporting of Hospital Infection Rates: Ranking the States on Credibility and User Friendliness. Information Technology & Communications in Health International Conference, Victoria, British Columbia, February 2013.

- Matsuura GT, Birnbaum D, Son B, Schwien T. The assessment of antimicrobial stewardship electronic infrastructure capabilities within Washington State. Northwest Pharmacy Convention, Coeur d'Alene Idaho, May 2013

- Black B, Birnbaum DW, Hyman DA, Amini A. Public Reporting of Hospital Infection Rates: Ranking the States on Report and Website Content, Credibility, and Usability. Council of State & Territorial Epidemiologists annual conference, Pasadena CA, June 2013.

- Birnbaum D, Fortuna JA. Washington State's Experience Applying ISO 2859 Validation Methods To Healthcare Associated Infections (HAI) Reporting. Council of State & Territorial Epidemiologists annual conference, Pasadena CA, June 2013.

- D'Angeli M, Weissman S, Birnbaum D. State Public Health Laboratory – NIH-Funded Research Laboratory Collaboration For Carbapenem-Resistant Enterobacteriaceae Surveillance: A Model For Maximizing The Public Health Potential Of Taxpayer Money. Council of State & Territorial Epidemiologists annual conference, Pasadena CA, June 2013.

CSTE Position Statement

- Birnbaum D, Kainer M. Council of State & Territorial Epidemiologists Position Statement #11-SI-05: Prioritizing Electronic Reporting of Healthcare-Associated Infection Data. http://www.cste.org <http://www.cste.org> February (interim status) & June (ratified) 2011.

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- Birnbaum D, Van Buren J. Applying Continuous Improvement In Public Reporting: What should government reports do for quality improvement? CLINICAL GOVERNANCE 2010;15(2):79-91.

- Birnbaum D, Cummings MJ, Guyton K, Schlotter J, Kushniruk A. Designing Public Web Information Systems with Quality in Mind: Public Reporting of Hospital Performance Data. CLINICAL GOVERNANCE 2010;15(4):272-278.

- Zarate R, Birnbaum D. Validity of Self-Declared Teaching Status in Mandatory Public Reporting. INFECTION CONTROL & HOSPITAL EPIDEMIOLOGY 2010;31(12):1310-1311.

- Bell S, Benneyan J, Best A, Birnbaum D, Borycki EM, Gallagher TH, Goeschel C, Jarvis B, Kushniruk AW, Mazor KM, Pronovost P, Sheps S. Mandatory Public Reporting:

Build It and Who Will Come? STUDIES IN HEALTH TECHNOLOGY & INFORMATICS 2011;164:346-52.

- Reid P, Borycki EM. Emergence of a new consumer health informatics framework: introducing the healthcare organization. STUDIES IN HEALTH TECHNOLOGY & INFORMATICS 2011;164, 353-7.

- Birnbaum D, Zarate R, Marfin T. SIR, you've led me astray! INFECTION CONTROL & HOSPITAL EPIDEMIOLOGY 2011;32(3):276-282.

- Zarate R, Birnbaum D. Post-discharge surveillance practices of Washington State hospitals. INFECTION CONTROL & HOSPITAL EPIDEMIOLOGY 2012;33(1):87-89.

- Masters A, Birnbaum D. Addressing healthcare associated infections prevention through a fellowship training program: The CDC/CSTE applied epidemiology fellowship program. CLINICAL GOVERNANCE 2012;17(1):64-71.

- Tellez-Marfin A. Public Health Implications of Healthcare-Associated Infections: Problems & Prospects. CLINICAL GOVERNANCE 2012;17(2):101-108.

- Birnbaum D, Stricof R. State and Federal Legislative Interests. CLINICAL GOVERNANCE 2012;17(2):141-148.

- Birnbaum D. The U.S. Experience with Mandatory Public Reporting. CLINICAL GOVERNANCE 2012;17(2):113-123.

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Appendix D: Healthcare Facility HAI Reporting Requirements to CMS via NHSN, Current & Proposed

HAI Event	Facility Type	Reporting Start Date
CLABSI	Acute Care Hospitals Adult, Pediatric & Neonatal ICUs	January 2011
CAUTI	Acute Care Hospitals Adult & Pediatric ICUs	January 2012
SSI	Acute Care Hospitals: colon surgery & abdominal hysterectomy	January 2012
I.V. Antimicrobial Start	Dialysis Facilities	January 2012
Positive blood culture	Dialysis Facilities	January 2012
Signs of vascular access infection	Dialysis Facilities	January 2012
CLABSI	Long Term Care Hospitals	October 2012
CAUTI	Long Term Care Hospitals	October 2012
CAUTI	Inpatient Rehabilitation Facilities	October 2012
MRSA Bacteremia LabID Event	Acute Care Hospitals	January 2013
C. difficile LabID Event	Acute Care Hospitals	January 2013
Healthcare worker influenza vaccination	Acute Care Hospitals	January 2013
Healthcare worker influenza vaccination	Ambulatory Surgery Centers	October 2014
CLABSI	Adult & Pediatric Medical & Surgical Wards	January 2015
CAUTI	Adult & Pediatric Medical & Surgical Wards	January 2015
MRSA Bacteremia LabID Event	Long Term Care Hospitals	January 2015
C. difficile LabID Event	Long Term Care Hospitals	January 2015
SSI (future proposal)	Outpatient surgery, Ambulatory Surgery Centers	To be determined

Appendix E: Technical Detail Appendix

Role of NQF relative to CDC, HICPAC and CSTE; Reason for eliminating VAP

The National Quality Forum (NQF) is a nonprofit organization that works to improve the quality of American healthcare. NQF includes infection reporting as an accountability measure.[4] NQF has its own technical panels and sets standards that may be adopted by federal organizations such as CMS. However, some of its accountability measures are considered insufficiently proven by other expert groups. For example, ventilator-associated pneumonia rate (VAP) was an NQF-endorsed measure considered by other groups as unreliable for use as an accountability measure. Those concerns have been confirmed (Klompas, pp 237-239; Klompas, pp 408-410). Federal authorities recently replaced VAP with a combination of ventilator-associated condition (VAC), infection-related ventilator-associated complication (IVAC), possible ventilator-associated pneumonia and probable ventilator-associated pneumonia measures. It's not yet clear whether this combination will be sufficiently practical, reliable, suitable and understandable for use as a public accountability measure (Klompas, https://www.premierinc.com/safety/safety-share/archive.jsp).

NQF provides a general forum for any interested parties to comment on a broad range of quality issues; other organizations focus content experts on HAI issues alone. State reporting requirements should align as closely as possible with current guidance by national experts in hospital epidemiology and infection control, as is provided by CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC) (McKibben et al., pp 580-587). HICPAC is a select group of experts in hospital epidemiology and infection control. They provide advice and guidance to CDC and the Secretary of HHS that is used to develop national prevention strategies and guidelines. HICPAC also includes representation from professional associations that focus efforts toward the prevention of healthcare associated infections. With the advent of mandatory public reporting through state health departments, the Council of State and Territorial Epidemiologists (CSTE) is one such association that has emerged as an important influence on healthcare associated infections initiatives. Two years ago it formed a CSTE/CDC Standards Committee that is attempting to guide greater uniformity among state and federal public reports through an evidence-based national consensus approach.

Alternatives to MRSA Screening

Screening is only one of several approaches to preventing transmission of MRSA and promising new approaches exist that might be more cost-effective. For example, a growing body of evidence suggests that daily bathing of ICU patients using the antiseptic agent chlorhexidine, perhaps along with mupirocin nasal ointment, can significantly reduce transmission and infection by many MDRO including MRSA without prior screening (Climo et al., pp 1858-1865; Climo et al., pp 533-542; Huang et al., pp 1468-1471; Popovich et al., pp 889-890; Rupp et al., pp 1094-1100. Since those studies are unable to distinguish if or by how much the use of the antibiotic

4 Information about NQF is available at www.qualityforum.org

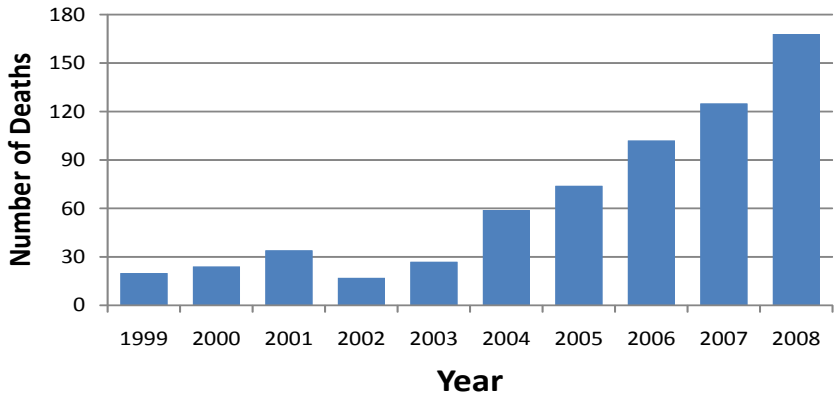
mupirocin adds to the effect of chlorhexidine alone, and potential for promoting resistance to antibiotics like mupirocin is a well-recognized concern, it's important to note that alternatives to the mupirocin nasal ointment also are being studied. For example, one group found intra-nasal application of the antiseptic chemical iodophor superior to mupirocin (Phillips et al, Abstract LB-3). Another found an entirely non-chemical alternative, an intranasal flash of ultraviolet light, to be highly effective (Wong Abstract). These non-antibiotic approaches are important because while bacteria frequently develop resistance to antibiotics they very rarely develop new resistance to antiseptics and disinfectants (Weber and Rutala, pp 1107-1119). We are not promoting widespread use of chlorhexidine and mupirocin as a requirement for all, but rather recognition that the original recommendation to screen and isolate was based on information available at the time while new knowledge now makes a different approach worthwhile.

MDRO – Especially CRE, *C. difficile*, MRSA

Carbapenem resistance in Enterobacteriaceae (CRE) organisms is a looming threat to public health, more widespread in some other countries, but now present in the United States. There are several different mechanisms by which bacteria can become resistant to this class of drugs, the most ominous being carbapenemase production (an enzyme that destroys the drug), which first appeared in the United States in 2001. There are now several different types of carbapenemases that vary in occurrence in different parts of the world but have all spread to the United States. These mechanisms are transmissible to other species of bacteria, so not only can these infections spread from patient to patient but the resistance elements can spread to even wider ranges of bacteria. Washington State is one of two states that have three types of carbapenemases reported; all other states have experienced fewer types. Fortunately, spread seems to have been controlled by infection control measures in all of the facilities where cases were detected and investigated, but we have not had any active monitoring programs in place. The department partnered with a Seattle hospital's federally funded microbiology research laboratory last year to increase our ability to study CRE bacteria; developed a voluntary reporting program that works for local health departments, healthcare facilities and laboratories; and we are in the process of coordinating with HAI programs in Oregon and California to combine forces against this impending public health threat (Anon., pp 1-4; D'Angeli et al., Poster).

C. difficile is a recognized public health threat in the United States and other countries. It also poses unique challenges for meaningful HAI reporting. California's HAI Program, which provided most of the case data that CDC used to propose a risk adjustment formula, requires *C. difficile* reporting and is presenting its own study to demonstrate its legitimate concerns about inadequacy of the current CDC risk adjustment formula (Datta et al., Abstract #2427). We know that the number of deaths in Washington State noted with *C. difficile* as an underlying cause steadily increased over a ten-year period:

Number of WA Deaths With *Clostridium difficile* Noted as "Underlying Cause of Death," 1999-2008

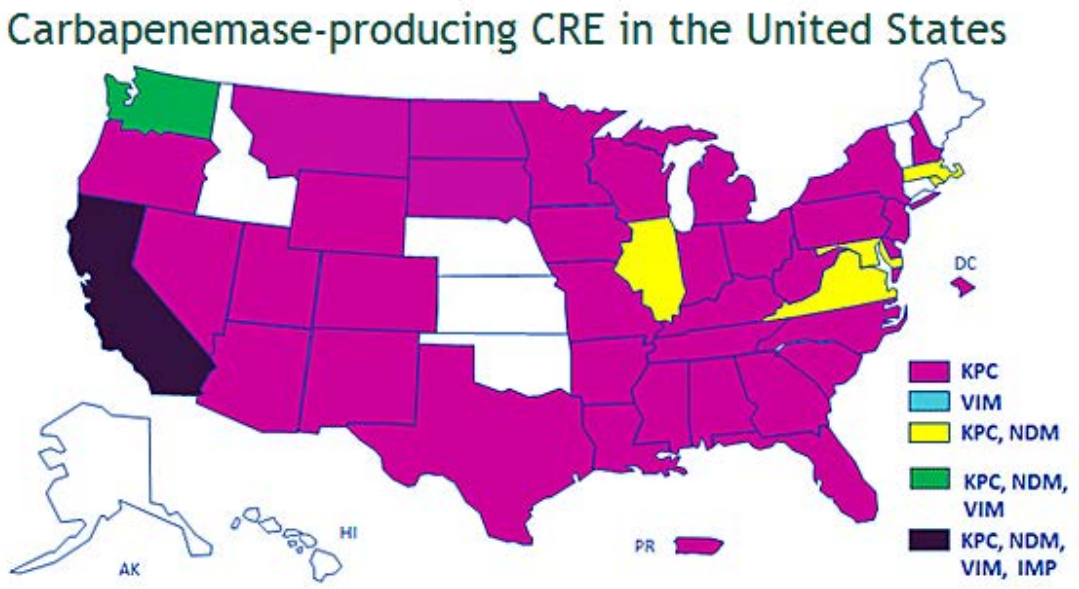


Source: Washington CHARS database.

A strain that produces much more toxin than others was first recognized in 1984. Since a 2002 outbreak in Quebec, Canada, that strain has been causing increased numbers of hospital- and community-acquired cases in the United States and other countries. We have lacked any effective and timely way to monitor *C. difficile* infections or to determine whether particularly dangerous strains are causing disease or death here. We intend to add *C. difficile* reporting via the NHSN LabID Event protocol by rule, consistent with the IPPS 2013 federal reporting requirement, after resolving the best approach to rate adjustment with California's program. We also will need to address Rhode Island's finding that the NHSN LabID approach consistently over-estimates the disease rate, but to a variable extent in different hospitals, since it doesn't incorporate clinical information or differences in stool culture practices (Baier et al, pp 653-655). Also, since clinical laboratories generally test for toxin rather than attempt to grow the bacteria from stool culture, they cannot send cultures of the bacteria to public health laboratories capable of determining which strains are involved. We are discussing this problem with our public health microbiology laboratories to see if there is a sustainable way for us to monitor which *C. difficile* strains are present among patients who have *C. difficile* associated disease.

C. difficile should be considered in the broader context of multiple-drug resistant organisms (MDRO). Rather than focus solely on one organism at a time (e.g.: *C. difficile*, MRSA), it is prudent to remember that new pathogens and new types of resistance are constantly emerging. "The threat of infections due to multidrug-resistant organisms (MDRO) is increasing. Methicillin-resistant *Staphylococcus aureus* (MRSA) has attracted the most attention, but multidrug-resistant gram-negative rods (MDR-GNR) are more menacing. No effective drugs are available to treat some life-threatening MDR-GNR infections, and there are few new antimicrobials in development." (Sandora and Goldmann, pp 2168-2170) Detecting the emergence of new MDRO early and stopping their spread through regional efforts before they

become widely entrenched, is critical to successful prevention. The emergence of a family of intestinal bacteria that became resistant to the carbapenem class of antibiotics through several different mechanisms (CRE bacteria with their IMP, KPC, NDM or VIM resistance genes) is one of the most serious recent public health threats (CDC, pp 165-170). The map below, taken from a CDC voluntary reporting effort and reproduced in our epiTREND report (Anon., pp 1-4), shows that California and Washington State have had more types of novel resistance mechanisms reported than other states. The department has addressed CRE surveillance by instituting voluntary case reporting under provisions of the state's notifiable conditions rule (Chapter 246-101 WAC) and augmenting our public health laboratory molecular typing capabilities through a new collaborative relationship with a National Institute of Health-funded research laboratory (D'Angeli et al., Poster).



Antibiotic stewardship is an important aspect of preventing both *C. difficile* associated disease and the development of drug resistance. To better inform stewardship efforts, the department's HAI Program has taken two initial steps. First, we collaborated with the state's pharmacy association and designated QIO to survey hospital pharmacy capability for electronically sharing antibiotic usage volume information (Matsuura et al, poster). If enough pharmacies across the state would be capable and interested in using the NHSN Antimicrobial Use and Resistance (AUR) module, we could work to establish a reporting network. Second, we participate in the Antimicrobial Stewardship Consortium of Seattle (AMSCoS) and are exploring ways to gather antibiotic resistance information from clinical laboratories. After we have a better understanding of the information sharing capabilities and concerns of pharmacies and laboratories, we will

consider whether it would be possible to gather, monitor and publish aggregated regional rates of antibiotic use and resistance. Our objective would be to provide timely information to our partners who run stewardship programs so that they can set priorities and evaluate impact as effectively as possible. While reporting of antimicrobial usage or resistance trends has not been identified as a proposed requirement by CMS to date, it is a topic of public health surveillance importance being actively explored by CDC and CSTE consistent with two of the original HHS HAI Action Plan Level I priorities ("Improve laboratory capacity to confirm emerging resistance in HAI pathogens…" "Enhance laboratory capacity for state and local detection and response to new and emerging HAI issues…").

CMS Measures the Department Does not Plan to Adopt at this time

The department does not anticipate adopting reporting of catheter-associated urinary tract infection category (CAUTI). The most common type of hospital-acquired infection is urinary tract infections. Research shows that this is an area where simple measures could have a major effect on the frequency of infections (Meddings et al., pp 550-560; Saint et al., pp 243-250; Saint et al., pp 333-341). The vast majority of catheter-associated urinary tract infections produce no symptoms, do not require treatment, spontaneously resolve after the catheter is removed, and have no noticeable effect on additional hospital cost or length of stay (Graves et al., pp 280-292). Most are asymptomatic; a smaller proportion, 30 percent or less, become symptomatic (producing pain or fever that requires treatment) and often because of other urinary tract abnormalities. An even smaller proportion (four percent or less) extends to produce bloodstream infection (Saint and Lipsky, pp 800-808).

NHSN recently limited its case definitions to include in CAUTI only cases as serious enough to require treatment. This narrower new definition excludes most of these infections, which makes it difficult to compare hospitals where there may be differences in the types of patients, and urine culture clinical practices, and complicates comparison of rates before versus after the definition change. As such, we do not believe that CAUTI rates would show much difference between hospitals and would not be a meaningful measure of how well this type of infection is prevented.

CMS has made reporting of CAUTI required (see Appendix C) as a hospital-acquired condition (HAC), but this does not necessarily make CAUTI a good metric for state reporting. There are two major components to the CMS action for prevention of CAUTI:

- As an incentive to put more emphasis on prevention, CMS announced in 2008 that it would no longer pay costs associated with complications they deem preventable. This includes several types of infections, including CAUTI. The impact of this policy change has been questioned (Meddings et al., pp 550-560).
- CMS 2010 rules indicate that CMS plans to publish CAUTI information as one of a number of HACs on its Hospital Compare website.

As an alternative to reporting CAUTI, some members of the Advisory Committee thought adding hospital compliance with CAUTI prevention practices would be more beneficial. This approach is consistent with the limited research related to preventing CAUTI; however, a nationally accepted set of prevention practices has not yet been defined. We could consider adding compliance with prevention practices for CAUTI in the future once a national standard for this is available. The department, in agreement with its Advisory Committee, does not recommend having hospitals report CAUTI as a state requirement.

We also do not feel that the CMS-mandated MRSA bacteremia LabID event rate is sufficiently meaningful to add to our state reports. Bacteremia (the presence of bacteria in the bloodstream) can be primary (as captured by our reporting of central-line associated bloodstream infections) or secondary (in which bacteria causing infection elsewhere in the body break through to the bloodstream). Primary bloodstream infections are preventable and suitable for an accountability measure. Secondary bloodstream infection has more to do with deterioration in a patient's underlying condition than with infection prevention programs. Proponents consider MRSA bacteremia because isolation of MRSA from normally sterile blood is easier to interpret as an infection (as distinct from colonization) than isolation of MRSA from other body sites. Proponents desire a metric that would show if patients are not infected or colonized with MRSA on admission but become positive later while in hospital, as an indication of potentially ineffective MRSA surveillance and prevention procedures in the hospital. However, this is not what the MRSA bacteremia LabID event actually measures because it does not incorporate sufficient clinical information. Therefore, we do not consider it to be a meaningful indicator of the effectiveness of hospital-infection prevention programs.

Issues for future consideration

First, methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant enterococci (VRE), extended-spectrum beta-lactamase (ESBL) enteric bacteria and other emerging drug-resistant pathogens like *Acinetobacter* spp. are a recognized public health concern (Cohen et al, pp 901-913). While MRSA has captured the largest amount of public attention, we know these other MDROs are present in Washington State, but we have no systematic monitoring in place. We recognized CRE when a hospital in this state provided care for a patient infected by *Klebsiella pneumoniae* resistant to all antibiotics usually used to treat such infections because of a resistance mechanism not previously reported in the United States (CDC, p 1212). Recognizing the importance of tracking these potentially dangerous MDROs, many Washington hospitals already keep lists of MDRO infected patients but do not report these infections in a manner that allows sharing of information among healthcare facilities, NHSN, and public health agencies. RCW 70.41.430 requires all hospitals to screen all patients upon admission to certain care units for MRSA, but does not give them an option to tailor their screening strategy based upon annual risk assessment with consideration of other MDRO. Screening patients for MRSA who are newly admitted to specific hospital areas can be cost-effective (Fuller et al., pp 1-327), but it is not optimal to deal with one MDRO at a time through statute. We are discussing with our advisory committee how RCW 70.41.430 could be amended to be more inclusive in scope

while giving hospitals more flexibility to focus their screening resources in response to their annual risk assessment findings.

Second, Inpatient Prospective Payment System (IPPS) requires participating hospitals to report the percentage of their staff that is immunized against influenza, but started this new 2013 requirement with deadlines midway through the immunization season. That choice of initial deadline means any 2013 rate published by CMS may not reflect all who receive vaccine during the entire immunization season. We will discuss with our Advisory Committee whether adding influenza immunization rates after 2013 might be a worthwhile addition to the state public reporting.

Third, we also will continue discussing with our advisory committee the relative merits of reporting compliance in each facility with other infection prevention strategies. Compliance with basic infection prevention measures applies to all settings, including ambulatory surgical facilities, home care services and long-term care facilities. The increasing federal emphasis on prevention collaboratives (groups of facilities pooling their efforts to define, evaluate and implement best practices) supports the concept of adding a mix of best practice prevention compliance measures that would be pertinent to safe care in all settings.

Focusing on prevention practices is consistent with addressing the following issues:

- Most of our hospitals are already using the Institute for Healthcare Improvement (IHI) "bundles" approach. "Bundles" are sets of prevention practices that when used together have been proven to reduce the occurrence of specific types of infections.
- Hand hygiene (hand washing, hand sanitizer rubs and appropriate glove use) is important in all settings. Direct observation of compliance with those measures is recognized as the "gold standard" measure. Self-reporting of hand hygiene compliance is noted as having "poor validity in several studies"; similarly, monitoring the use of hand hygiene product per patient-day "…does not capture the appropriate denominator… cannot provide information about which indications for hand hygiene are being followed, or which types of staff members are in best/worst compliance. Not able to assess technique…") (Haas and Larson, pp 6-14). The most effective way to monitor compliance with hand hygiene practices is direct observation. Many infection control programs lack the staffing necessary to conduct observations.
- Influenza and pneumococcal immunization strategies have shifted to emphasize patient and employee vaccination in healthcare facilities that serve high-risk segments of the population.
- CMS surveys prevention practices activity in long-term care facilities and some clinic facilities. Following newspaper reports of disease exposures and outbreaks due to negligent practices, CMS recently increased support for infection control guidelines and inspection activity to include ambulatory surgery facilities.

- Several other states are directing the attention of their health department toward HAI prevention needs of their long-term care facilities. Some, for example, are launching initiatives to combat emerging drug resistance on a regional basis instead of only within individual institutions. This is because they recognize that long-term care facilities provide a reservoir through which colonized patients bring resistant organisms to and from hospitals during acute care episodes.
- RCW 70.230.100 requires licensing surveys of ambulatory surgical facilities every eighteen months. Monitoring and reporting of best practice prevention compliance measures may support licensing survey efforts.
- If ambulatory surgerial facilities perform any of the procedures identified by CMS and state law for public reporting, then those facilities logically should be subject to the same reporting requirements as hospitals.

The national Surgical Care Improvement Project (SCIP) is a set of prevention practices that are intended to lower the risk of surgical site infections. SCIP reports a set of individual "best practice" statements. Compliance scores for each individual practice item are commonly shown on public reports; however, SCIP needs reconsideration as a useful prevention measure. An important study found that only compliance with the complete set of prevention practices is associated with lower infection risk (Stulberg et al., pp 2479-2485). The SCIP set of prevention practices should be considered as an all or none, rather than a single-item, rating for hospitals and ambulatory surgery facilities.

The department recognizes the potential value of adding injection safety, asepsis, antisepsis, and immunization reporting measures. Public confidence has been affected by news reports from other states concerning inappropriate injection needle and single-patient drug vial reuse, faulty instrument disinfection, and low immunization rates. It is too early, at this time, to recommend specific measures for public reporting related to these practices. There are several possible directions we need to explore with a wider group of stakeholders. For example, we need to consider compliance with IHI "bundles" as a possible metric for preventing ventilator-associated pneumonia, surgical site infection, and central line-associated bloodstream infection wherever these types of care are provided. We also should consider use of patient and staff annual influenza immunization rates as a metric for hospitals, clinics and long-term care facilities.

Fourth, as noted in Section I, RCW 43.70.056 does not give the department authority to impose HAI reporting requirements on types of healthcare facilities other than hospitals and our Advisory Committee does not include representation of other types of facilities. In response to the second stage HHS HAI Action Plan, as detailed in Appendix C, CMS is now imposing reporting requirements on other types of facilities. If CMS adds reporting requirements for types of surgical procedures commonly performed in ambulatory surgical facilities, our HAI Program has no means to extend mandatory public reporting requirements so that the public could see uniform reports on all facilities performing those surgical procedures. To align state with federal requirements in that situation would require creation of a similar new law dealing with

ambulatory surgical, dialysis and long-term care facilities. Such legislation also should consider covering providers of outpatient home-care for central lines since many CLABSI events are present on admission to hospital according to our own data and a model for extending coverage to home-care service providers exists in Nebraska.