

**Healthcare-associated Infections Advisory Committee Meeting
April 14, 2011, Sacramento, California 10:30am-3:30pm**

Meeting Summary

Attendance

Members Present: Kim Delahanty (Chair), Mike Butera, Raymond Chinn, Enid Eck, Annemarie Flood, Lilly Guardia-LaBar, Brian Lee, Mike MacLean, Lisa McGiffert, Mary Mendelsohn, Roberta Mikles, Carole Moss, Rehka Murthy, Frank Myers, Terry Nelson, Shannon Oriola, Debby Rogers, Dawn Terashita, Francesca Torriani, Lisa Winston, David Witt, Kathy Wittman

Members Not Present: Alicia Cole, Eric Frykman, Daniel Gross, Michael Langberg

Department Staff: Linda Becker, Sue Chen, Pam Dickfoss, Loriann DeMartini, Lynn Janssen, Cheryl Kalson, Vickie Keller, Ralph Montano Theresa Nelson, Jorge Palacios, Kevin Riley, Maria Sperber, Jon Rosenberg, Dirk Winston

Agenda Item/Discussion	Follow-up
<p>Call to Order and Introductions</p> <p>HAI-AC Chair Kim Delahanty convened the meeting.</p> <p>Introductions were made of those present and on the teleconference lines.</p> <p>The Chair announced that the agenda order would be modified following the review of minutes to address the implementation plan for reporting SSIs in California as presented by Kevin Riley, Deputy Director of CDPH.</p>	
<p>Review of Rules of Order</p> <p>The Chair briefly reviewed the active rules of order used by the HAI-AC, including following the queue, speaking clearly, respecting speaker opinions, muting phones if on the teleconference line, limiting comments to two minutes, and not repeating statements which have already been made.</p> <p>The HAI Advisory Committee's mission is to give recommendations to CDPH on implementing the statutory mandates for the prevention of HAIs and the associated morbidity and mortality from HAIs. The Committee is neither a regulatory nor a punitive body.</p> <p>The public will be invited to comment after each topic today.</p>	
<p>Public Story</p> <p>There was no public story given at this meeting.</p>	

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<p>Approval of Minutes</p> <p>Motion to approve February 17, 2011 HAI-AC minutes (with corrections provided).</p> <ul style="list-style-type: none"> ➤ Motion—Delahanty ➤ Second—Mendelsohn ➤ Motion Passed (19 yes, 0 no, 1 abstention) 	<p>Minutes will be corrected by CDPH and posted to the HAI Program website.</p>
<p>Surgical Site Infection (SSI) Reporting Update—K. Riley, Chief Deputy Director, California Department of Public Health</p> <p><u>Background:</u> CDPH was invited to a meeting with Senator Alquist on April 11, 2011 regarding the release of AFL 11-23, which was based on the Advisory Committee’s recommendations and accepted by CDPH for Surgical Site Infection (SSI) reporting. The Senator expressed concern that the Department was not fully implementing the statutory provisions of SB 1058. Senator Alquist asked CDPH to re-evaluate the content of AFL 11-23 and provide feedback within the next two weeks regarding CDPH’s intent to fulfill the legislative mandate.</p> <p>HSC Section 1288.55 (a) (3), which was added to SB 1058, requires that health facilities shall report to CDPH on a quarterly basis:</p> <p>“...all health-care-associated surgical site infections of deep or organ space surgical sites, health-care-associated infections of orthopedic surgical sites, cardiac surgical sites, and gastrointestinal surgical sites designated as clean and clean-contaminated, and the number of surgeries involving deep or organ space, and orthopedic, cardiac, and gastrointestinal surgeries designated clean and clean-contaminated.”</p> <p>Dr. Riley asked for input from the Committee as to how to address Senator Alquist’s request.</p> <p><u>Discussion of Senator Alquist’s Response to CDPH Plans for SSI Reporting</u></p> <p>Committee Chair Kim Delahanty provided a brief history outlining the Committee’s efforts and the decisions that were made, based on research and evidence, to ensure patient safety. The Committee believes that valid and robust data is critical for making the best recommendations and implementation for patient safety. The Committee acknowledges the challenges that come with this commitment.</p> <p>The Committee addressed two major concerns: 1) That the reporting process as it stands now will negatively impact patient safety and, 2) How the Committee will recommend implementing the SSI module for public reporting.</p> <p>Specifically, the Committee is concerned that the ICD-9-CM codes are not easily mapped and hospitals are still learning how to input denominator data. Small errors have large impacts and the learning curve for hospital Infection Preventionists (IPs) is steep. Data needs to be validated and the training program for hospital IPs must be adjusted. Poor data will result in adverse decisions which will negatively impact</p>	<p>CDPH will re-evaluate AFL 11-23 and send out a corrected AFL that reflects adherence to the statutory provisions of SB 1058</p> <p>HAI-AC will send a letter to CDPH advising their concerns and recommendations for the reporting of all SSIs</p>

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<p>patient safety. Several Committee members stated that IPs will be pulled from the bedside back into the office to record data, which will result in less time ensuring that staff is consistently following correct infection control procedures.</p> <p>A member noted that a phased-in approach to SSI reporting is expected to be implemented by CMS, which will begin mandatory reporting of SSIs using NHSN beginning January 1, 2012, but has not yet announced which procedures would be required.</p> <p>The Chair recapped the Committee's concerns thus far:</p> <ol style="list-style-type: none"> 1) The Committee acknowledges the need for robust, comparative, valid data 2) The Committee believe that more time is needed to phase-in the procedures because of the necessity for further clarification on what the surgical procedures mean and the time it will take for training hospital IPs as a steep learning curve is anticipated 3) The Committee's intent is to drive patient safety and not divert Infection Preventionists from the bedside where successful work is being done 4) The Committee will consider putting together a reference document of pros and cons, justifying the decisions made—a written submission to CDPH to potentially drive their recommendations forward. <p>Comment: Variance is the enemy of quality and that is why we have to be very careful about our definitions. I want CDC guidelines and NHSN definitions to be used.</p> <p>Comment: The legislation was clearly designed to improve patient safety. However, an unintended consequence of moving rapidly to implement all surveillance for all procedures is a decline in patient safety. Larger hospitals may be able to allocate resources to carry this out but what about the small and rural hospitals where the Infection Preventionist wears three hats?</p> <p>Comment: If you look at the progress over the past three to five years, it's been huge. We are attempting to change the culture of the hospital, therefore we need support from hospital administration, physician champions, and others or we will not succeed.</p> <p>Comment: The law allows reporting in two ways: We can use NHSN and go through that portal with the delays and the validation, but the law also allows this Committee to advise the CDPH if we don't go in that direction. I think It's something we should need to consider. It won't be the national standard, it'll be a lot of work but this may move us in that direction.</p> <p>Comment: I am troubled that quantity is trumping quality. The CDC has not endorsed this type of global reporting. The legislation does not allow pediatric hospitals to target their most challenging infections—ventricular shunts. By law you're forcing them to take away what they really should be doing.</p>	

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<p>Comment: California reports more indicators being publically reported than any other state in the country. Other states only report CLABSIs. We can certainly talk about more to roll-out in the future but it will have to be from a phased-in approach.</p> <p>The Chair thanked Dr. Riley for listening to the Committee’s concerns and outlined the following key points:</p> <ol style="list-style-type: none"> 1) The Committee wants robust, valid, transparent data that is comparable and therefore useful to consumers and to the hospitals so that they may make process improvements 2) Data must have a high level of confidence to advance patient safety 3) A timed approach is needed to phase in procedures 4) The Committee will identify the surgical procedures within the three categories and best approaches; the Committee will make recommendations to CDPH based on their expert knowledge base. 5) The Committee will provide written documentation to CDPH regarding justification of their recommendations and the pros and cons of the “all” approach, supported by evidence and research. The paper will include recommendations as to how to abide by the law and ensure patient safety. <p>Dr. Riley stated that Senator Alquist asked CDPH to re-evaluate the AFL and provide feedback within the next two weeks.</p> <p><u>Discussion of The White Paper to be addressed to CDPH</u></p> <p>A member stated that the law has been clear for quite some time and some of the members may want to send a minority statement to Senator Alquist along with the majority statement.</p> <p>The Committee acknowledged that the law does not address the more serious pediatric-based infections although pediatric hospitals are required to report the same categories to CDPH.</p> <ul style="list-style-type: none"> • Motion that the HAI Advisory Committee create a document in response to Senator Alquist, addressing her concerns regarding SSI reporting and implementation in California, outlining, based on the Committees’ expertise and review of the literature, the pros and cons of reporting all SSIs in the State of California, given the current state, and a proposed plan for rolling-in reporting as required under HSC Section 1288.55 the Orthopedic, Cardiac, and GI procedure categories. <ul style="list-style-type: none"> ➤ Motion—Flood ➤ Second—Oriola ➤ Motion Passed (16 yes, 1 no, 3 abstentions) 	

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<p>Yes: Flood, Terashita, Rogers, Eck, MacLean, Torriani, Myers, Wittman, Delahanty, LaBar, Winston, Mendelsohn, Murthy, Chinn, Mikles, Oriola</p> <p>No: Moss</p> <p>Abstain: Witt, Butera, Nelson</p> <p><u>Discussion of the Implementation Plan</u></p> <p>The Chair announced a modification to the agenda, to defer the rest of the reports in order to continue the SSI discussion. As most of the Committee agreed to develop a White Paper with an implementation plan, the Chair requested that the Committee develop the draft now unless someone was opposed. There was no opposition.</p> <p>At the February 17, 2011 HAI AC meeting, a list of 17 operative procedures was distributed by Dr. Rosenberg for review and discussion as a starting point for reporting phase-in. The list had been compiled by Dr. Rosenberg to represent the cardiac, gastrointestinal, and orthopedic procedures available in NHSN.</p> <p>The Committee first considered the list of Operative Procedure Categories for mandatory reporting: GI, Cardiac and Orthopedic. The focus was to be only on meeting the mandate of the law but noted that, for the record, the Committee is restrained by what NHSN can accept.</p> <p>Implementation of Cardiac Procedures</p> <p>The Committee recognized that cardiac surgeries are not all appropriate for pediatric reporting, therefore it was agreed that the White Paper will include a separate pediatric section, which will be based on recommendations from the Pediatric SSI Reporting Subcommittee. For now, the Committee will focus on the mandate of the law. As the law does not define what constitutes a cardiac surgery, the Committee will use the NHSN categories to decide under the law what to use.</p> <p>In determining which procedures would be excluded from the Cardiac category, members identified pacemaker implantations, which are usually performed by a cardiologist (as opposed to a cardiac surgeon) in a cath lab (as opposed to an operating room). Percutaneous valve replacements were considered to be a broad procedure and difficult to include as there is no benchmark for comparison. Heart transplantation is an entirely different category because of the nature of transplantation; therefore, the Committee concluded that transplantation should be separate.</p> <p>A member suggested including the ICD9-CM codes, (e.g., 36.10 through 36.14 plus 36.19 for CBGB) for clarification, as the procedure codes are what determine cardiac surgery within the Cardiac category.</p> <p>As the Advisory Committee believed that some of the operative procedures did not fit the criteria as indicated in SB 1058, the following motions reflect the Committee's</p>	

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<p>recommended exclusions from the operative procedure categories, including justifications.</p> <p>Cardiac</p> <ul style="list-style-type: none"> • Motion to exclude pacemakers from the Cardiac category as the procedure is usually not performed by a surgeon in an operating room. <ul style="list-style-type: none"> ➤ Motion—Eck ➤ Second—Flood ➤ Motion Passed (14 yes, 2 no, 1 abstention) <p>Yes: Flood, Witt, Terashita, Rogers, Eck, Torriani, Myers, Delahanty, Winston, Mendelsohn, Chinn, Mikles, Oriola, Nelson</p> <p>No: Moss, McLean</p> <p>Abstain: LaBar</p> <p>Orthopedic</p> <ul style="list-style-type: none"> • Motion to include hip and knee prostheses in the Orthopedic category. Exclude RFUSN, ORIF, FUSN, and laminectomy which are either often traumatic procedures that do not fit the “clean and clean-contaminated” criteria, or are sometimes performed by Neurology, other times Orthopedics, which makes it impossible to risk stratify. <ul style="list-style-type: none"> ➤ Motion—Oriola ➤ Second—Winston ➤ Motion Passed (13 yes, 2 no, 3 abstention) <p>Yes: Flood, Witt, Terashita, Eck, Torriani, Myers, Wittman, Delahanty, Mendelsohn, Butera, Chinn, Mikles, Oriola</p> <p>No: Moss, MacLean</p> <p>Abstain: Rogers, LaBar, Nelson</p> <p>Gastrointestinal</p> <ul style="list-style-type: none"> • Motion to exclude rectal surgeries from the gastrointestinal category, as these are always considered a contaminated site in NHSN; also exclude appendectomies, which are frequently contaminated, and do not meet the criteria for clean and clean-contaminated. <ul style="list-style-type: none"> ➤ Motion—Wittman ➤ Second—Torriani ➤ Motion Passed (15 yes, 2 no, 1 abstention) <p>Yes: Flood, Witt, Terashita, Rogers, Eck, Torriani, Myers, Wittman, Delahanty, Mendelsohn, Butera, Chinn, Mikles, Oriola, Nelson</p>	

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<p>No: Moss, MacLean</p> <p>Abstain: LaBar</p> <p>Note: A list of the 10 operative procedures recommended by the Committee is attached to this Meeting Summary.</p> <p><u>Drafted Letter to CDPH from the Advisory Committee</u></p> <p>The Advisory Committee Chair requested that due to the time constraints, the Committee draft the following letter to CDPH. Annemarie Flood presented the completed draft:</p> <p>“The HAI Advisory Committee respectfully wishes to address the Senator’s concerns regarding the implementation of Health and Safety Code 1288.55 (a) (3), regarding reporting of surgical site infections.</p> <p>It is the considered opinion of the Advisory Committee, based on their collective expertise, that the following meets the regulation and the intent of HSC Section 1288.55 (a) (3).</p> <p>This document addresses adult acute care facilities only. In its current state, NHSN does not readily address the special needs and risks of the pediatric population. The Pediatric SSI Subcommittee will determine, based on their risk assessment, recommendations for pediatric SSI reporting.</p> <p>What we have recommended is consistent with the surgical procedures as required by the law, that NHSN categorizes in the cardiac, GI, and orthopedic procedures, and what NHSN is currently able to accept.</p> <p>This is a living document that may change as NHSN defines further procedures.</p> <p>The procedures identified in this document were considered to be consistently performed in operating rooms with a frequency of >25 clean or clean-contaminated procedures in most hospitals in California.</p> <p>By using these procedures for reporting, this will provide meaningful, robust, transparent, and comparative data that can be risk-adjusted. This, in turn, will provide useful and meaningful guidance for the citizens of California.</p> <p>There are limitations to these lists, as NHSN does not provide risk-adjusted comparative rates for all procedures that can be performed in a hospital.</p> <p>The Committee is concerned that there may be unintended consequences as a result of a rapid implementation in the reporting of all of these procedures immediately. NHSN denominator data is time-intensive and is often inputted manually by the IP, taking that resource away from implementing infection prevention strategies at the bedside.</p>	

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<p>To that end, we respectfully request that hospitals be allowed to continue the paper reporting of SSI and gradually roll-in entering these procedures into NHSN, with the intent that all hospitals will report all procedures by the end on 2012.”</p> <p>Attachments: NHSN Operative Procedure Categories, FY 2010 most recent version; HAI-AC’s Cardiac, Orthopedic, and Gastrointestinal exclusions recommendations/justifications</p> <p><u>Discussion of Timeframe for Implementing the SSI Reporting</u></p> <p>Comment: We could recommend a roll-out as late as November for the last data set with an aggregate rate for the State, but if everything has to be in by the end of the year, I suggest we evaluate the first four months while continuously reviewing the data, begin training the hospital IPs, then adjust training for the last months of the data, which won’t be as robust, but at least we can come up with aggregate data and address some of the issues.</p> <p>Comment: There are no additional physical procedures beyond what was previously approved by the HAI-AC for the remainder of 2011. Beginning in 2012, we could institute a process to ensure the accuracy and reliability of SSI reporting for the procedures identified by the HAI-AC in 2011.</p> <p>The SSI Subcommittee may recommend to the Committee additional procedures or processes for selection of those procedures at the hospital level.</p> <p>Comment: Perhaps in April, May June, hospitals can report hips or CABGs then add another procedure, for example, colon surgeries, in July.</p> <p>Comment: All agreed: We’ll do hips and CABGs in April. In May we should be able to add knee replacements, and in June, the hospitals can add colon surgeries.</p> <p>Comment: You can’t add a new procedure every month.</p> <p>Comment (Oriola): I make a motion to continue with hips and CABGs as identified in the AFL. In July 2011, hospitals can enter colon, then through Dec. 2012 the subsequent procedures that are defined as “all” will be phased in based on risk assessment how they will be phased in. All will be in through December 2012.</p> <p><u>Discussion</u></p> <p>Comment: A suggestion: Is it burdensome to think we can continue with the paper reporting and then phase in NHSN? For me, the paper reporting is easier. We will continue to work on NHSN but we (hospital IPs) will continue with the paper reporting until we can get everyone up to speed.</p> <p>(Shannon Oriola withdrew her motion)</p> <p>Comment (LaBar): The motion is to continue to use the paper submission form for public reporting purposes as hospitals concurrently phase in NHSN reporting.</p>	

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<ul style="list-style-type: none"> • Motion that hospitals implement the requirements of AFL 11-23 by December 2011 and continue the paper reporting of SSIs while anticipating the overall implementation of SB 1058. <ul style="list-style-type: none"> ➤ Motion—LaBar ➤ Second—Witt ➤ Motion Passed (13 yes, 2 no, 0 abstention) <p>Yes: Flood, Witt, Terashita, Eck, Torriani, Myers, Wittman, Delahanty, LaBar, Butera, Chinn, Mikles, Oriola</p> <p>No: Moss, MacLean</p> <p>Abstain: None</p> <ul style="list-style-type: none"> • Motion to completely phase-in NHSN by December 31, 2011 <ul style="list-style-type: none"> ➤ Motion—LaBar ➤ Second—Witt ➤ Motion Does Not Pass (2 yes, 9 no, 2 abstention) <p>Yes: Moss, LaBar</p> <p>No: Flood, Terashita, Eck, LacLean, Myers, Wittman, Delahanty, Mikles, Oriola</p> <p>Abstain: Butera, Nelson</p> <ul style="list-style-type: none"> • Motion that hospitals roll-in their NHSN reporting of the identified SSI procedures so that these procedures are in the database by December 31, 2012; The order of roll-in will be based on a hospital’s particular risk assessment. <ul style="list-style-type: none"> ➤ Motion—Flood ➤ Second—Oriola ➤ Motion Passed (12 yes, 0 no, 0 abstention) <p>Yes: Flood, Moss, Witt, Terashita, Eck, Myers, Wittman, Delahanty, LaBar, Butera, Mikles, Oriola</p> <p>No: None</p> <p>Abstain: None</p> <p>All information will be added to the paper reporting, as it is with CLABSI reporting. The Committee does not want to be too prescriptive regarding which procedures are rolled-in and when, thus it will be based on a hospital’s particular risk assessment.</p> <p>Dr. Rosenberg observed that there is nothing in the legislation that refers to after January 2012 and that the Advisory Committee may want to consider an Addendum report that would be issued to the public in July 2012. Given that SSI infections can occur up to a year after surgery, it will take more than a year to get a full set of data.</p>	

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<p>This is particularly true in regards to hip prosthesis.</p> <p>Although the Advisory Committee has decided on specific recommendations for abiding by the mandate when reporting of SSIs, the letter will still be sent to CDPH as it memorializes the concerns of the Advisory Committee.</p> <ul style="list-style-type: none"> • Motion that the letter should be adopted by the Committee and sent to CDPH as documentation of their work, concerns, and recommendations. <ul style="list-style-type: none"> ➤ Motion—Flood ➤ Second—Oriola ➤ Motion Passed (13 yes, 1 no, 0 abstention) <p>Yes: Flood, Witt, Terashita, Eck, MacLean, Myers, Wittman, Delahanty, LaBar, Butera, Mikles, Oriola, Nelson</p> <p>No: Moss</p> <p>Abstain: None</p> <p>The Committee recognizes that CDPH will determine whether the letter should be forwarded to Senator Alquist, as that is not a decision for the Advisory Committee to make.</p> <p>Due to the importance of the SSI reporting recommendations discussion, the Chair determined that the Subcommittee Reports, the Title 22 Procedural Review presentation, and the HAI-AC bylaws discussion will be held over until the next HAI-AC meeting.</p>	
<p>Action Items</p> <ul style="list-style-type: none"> • Minutes will be corrected by CDPH and posted to the HAI Program website • CDPH will re-evaluate AFL 11-23 and release a corrected AFL that reflects adherence to the statutory provisions of SB 1058 • HAI-AC will send a letter to CDPH advising their concerns and recommendations for the reporting of all SSIs 	
<p>Future Meetings</p> <p>The next HAI-AC meeting will take place on June 9 from 10:30 AM to 3:30 PM in Sacramento</p>	

Acronyms

AFL	All Facilities Letter
CDC	Centers for Disease Control and Prevention
CDPH	California Department of Public Health
CLABSI	Central Line Associated Blood Stream Infection
FUSN	Fusion (i.e., immobilization of spinal column)
GI	Gastrointestinal
HAI AC	Healthcare Associated Infections Advisory Committee
HSC	Health and Safety Code
IP	Infection Preventionist
NHSN	National Healthcare Safety Network
ORIF	Open Reduction Internal Fixation
RFUSN	Refusion of Spine
SSI	Surgical Site Infection