The new CDC methodology

And the pursuit of an updated guideline for the prevention of SSI.

BY GEORGE ALLEN, PhD, CIC, CNOR

Preventing surgical site infection (SSI) continues to be of considerable importance to the nation in general and for infection preventionists (IPs) in particular, as the number of surgical procedures continues to increase,[1,2] public reporting and quality improvement requirements expand,[3,4] reimbursement shrinks[5], and patients requiring surgery get sicker and present for surgery with more complex co-morbidities.[6]

This illustration depicts a three-dimensional (3D) computer-generated image of four multidrug-resistant *Pseudomonas aeruginosa* bacteria. *P. aeruginosa* is a common cause of healthcare-associated infections including pneumonia, bloodstream infections, urinary tract infections, and surgical site infections. Some strains of *P. aeruginosa* have been found to be resistant to nearly all or all antibiotics including aminoglycosides, cephalosporins, fluoroquinolones, and carbapenems. About 13 percent of severe healthcare-associated infections caused by *P. aeruginosa* are multidrug resistant, meaning several classes of antibiotics no longer cure these infections.

PHOTO CREDIT: CDC/Melissa Brower

The Centers for Disease Control and Prevention (CDC) published the first recommendations for preventing SSI in 1983.[7,8] The first guideline addressed only incisional wound infections with recommendations based primarily on expert opinion. The 1985 revision added new information on pre-operative hair removal and operating room ventilation[9]. While the 1999 guideline was the first to adopt the term "surgical site infection,"[10] it was also notable for citing more than 2,500 publications. The latest updated draft guideline for the prevention of surgical site infection, 2013, was published in the Federal Register for public comment in January 2014 and opened up again for public comment in April (with comments due back in early May).[11] The structure of this draft guideline is organized along two main sections:

1. The **Core Section** provides recommendations that are applicable across the spectrum of surgical procedures; and
2. The procedure-specific section provides recommendations for a single high-volume, high-burden procedure—**prosthetic joint arthroplasties.** Prosthetic joint arthroplasties were chosen as the focus because approximately 1.2 million arthroplasties are performed in the U.S. each year,[12] and these procedures are associated with high cost and increasing SSI.[13]

Core Section questions

PARENTERAL ANTIMICROBIAL PROPHYLAXIS (AMP)

What are the most effective strategies for administering parenteral AMP to reduce the risk of SSI?

NON-PARENTERAL ANTIMICROBIAL PROPHYLAXIS

What are the most effective strategies for administering non-parenteral antimicrobial prophylaxis at the surgical incision to reduce SSI?

GLYCEMIC CONTROL

How do perioperative blood glucose and hemoglobin A1C levels impact the risk of SSI, and what are the optimal perioperative target levels in diabetic and non-diabetic patients?

NORMOTHERMIA

How safe and effective is the maintenance of perioperative normothermia in reducing the risk of SSI?

What are the most effective strategies for achieving and maintaining perioperative normothermia?

OXYGENATION

In patients with normal pulmonary function, how safe and effective is the perioperative use of increased fraction of inspired oxygen (FiO_2) in reducing the risk of SSI?

What is the optimal target FiO_2 to reduce the risk of SSI; how and when should it be administered?

ANTISEPTIC PROPHYLAXIS

What are the most effective strategies for preparing the patient's skin prior to surgery to reduce the risk of SSI?

How safe and effective is antiseptic irrigation prior to closing the surgical incision?

How safe and effective is repeat application of an antiseptic skin preparation agent to the surgical site immediately prior to closing the surgical incision?

Federal Register. Draft guideline – Centers for Disease Control and Prevention Draft Guideline for the Prevention of Surgical Site Infection. A notice by the CDC 1/29/2014. Available at: www.federalregister.gov/articles/2014/01/29/2014-01674/draft-guideline-centers-for-disease-control-and-prevention-draft-guideline-for-the-prevention-of Accessed April 4, 2014

The approach employed to grade the quality of evidence is an important methodological feature of the guideline. It is important to keep this in mind because it impacts the formulation of recommendations.

This article will explain the application of the new methodology in the context of the development of the new draft SSI guideline. It is important to note that the SSI guideline has not yet been finalized and is a work in progress (as of press time).

Before we consider this latest draft guideline and especially its methodological approach, it is worthwhile to remind ourselves that the principles of epidemiology are the foundation of IPs' practice of identifying sources of infection, and based on which evidence is translated into practice. Epidemiology centers on three factors within any population setting: the host, the agent, and the environment. The **host** represents the population, the **agent** is the health concern in question, and the **environment** is the geographical area of interest.

Epidemiology is a scientific discipline with sound methods of scientific inquiry at its foundation; it is data driven and relies on a systematic and unbiased approach to the collection, analysis, and interpretation of the data. Researchers look for cause-effect relationships within the host-agent-environment triad, collect data, provide the information needed to track correlations, and establish probabilities based on the results from the body of studies.

The new approach and structure of the SSI guideline may appear provocative to some and conservative to others; however, it rigorously embraces the principles of epidemiology. It is also intended to serve as a targeted way to provide timely guideline development and updates as new knowledge is acquired, without requiring the rewriting of the whole guideline.

METHODOLOGY

Beginning in 2010, the CDC and Hospital Infection Control Practices Advisory Committee (HICPAC) implemented a new process for developing guidelines based on using an evidence-based methodology.[14] This new methodology includes:

Prosthetic Joint Arthroplasty Section questions

BLOOD TRANSFUSION

How do perioperative blood transfusions impact the risk of SSI in prosthetic joint arthroplasty patients?

SYSTEMIC IMMUNOSUPPRESSIVE THERAPY

How does systematic corticosteroid or other immunosuppressive therapy impact the risk of SSI in prosthetic joint arthroplasty patients?

What are the most effective strategies in managing systemic corticosteroid or other immunosuppressive therapy perioperatively to reduce the risk of SSI in prosthetic joint arthroplasty patients?

What is the optimal duration of postoperative AMP to reduce the risk of SSI in prosthetic joint arthroplasty patients who are on systemic corticosteroid or other immunosuppressive therapy?

INTRA-ARTICULAR CORTICOSTEROID INJECTIONS

How do preoperative intra-articular corticosteroid injections impact the risk of SSI in prosthetic joint arthroplasty patients?

What are the most effective strategies for managing the preoperative use of intraarticular corticosteroid injections to reduce the risk of SSI in prosthetic joint arthroplasty patients?

ANTICOAGULATION

What are the most effective strategies for managing perioperative venous thromboembolism (VTE) prophylaxis to reduce the risk of SSI?

ORTHOPAEDIC SPACE SUIT

How safe and effective are orthopaedic space suits in reducing the risk of SSI in prosthetic joint arthroplasty patients, and which healthcare personnel should wear them?

ANTIMICROBIAL PROPHYLAXIS DURATION WITH DRAIN USE

What is the optimal duration of postoperative AMP to reduce the risk of SSI in prosthetic joint arthroplasty in the presence of a drain?

BIOFILM

What are the most effective strategies to reduce the risk of biofilm formation and SSI in prosthetic joint arthroplasty patients?

Federal Register. Draft guideline – Centers for Disease Control and Prevention Draft Guideline for the Prevention of Surgical Site Infection. A notice by the CDC 1/29/2014. Available at: https://www.federalregister.gov/articles/2014/01/29/2014-01674/draft-guideline-centers-for-disease-control-and-prevention-draft-guideline-for-the-prevention-of Accessed April 4, 2014

1. Generating key questions based on the opinions of experts;
2. Performing targeted systematic reviews of the best evidence currently available; and
3. Providing an explicit link between the evidence and the resulting recommendations

using the **Grading of Recommendations Assessment, Development, and Evaluation (GRADE)** method.[15]

The GRADE method is a system that determines the strength of the recommendations (Table 1) based on the assessed rigor of the individual studies and the quality of the evidence proffered by these studies. The largest weight is placed on high-quality randomized prospective studies; observational studies can also be included but are usually assigned an initial grade and overall quality grade of low. The quality of research studies, therefore, is graded on a hierarchical model

TABLE 1. HICPAC CATEGORIZATION SCHEME FOR RECOMMENDATIONS

Category 1A	A strong recommendation supported by high to moderate quality evidence suggesting net clinical benefits or harms.
Category 1B	A strong recommendation supported by low-quality evidence suggesting net clinical benefits or harms, or an accepted practice (e.g., aseptic technique) supported by low to very low-quality evidence.
Category 1C	A strong recommendation required by state or federal regulation.
Category II	A weak recommendation supported by any quality evidence suggesting a tradeoff between clinical benefits and harm.
No recommendation/ unresolved issue	An unresolved issue for which there is low to very low-quality evidence with uncertain tradeoffs between benefits and harms.

Umscheid CA, Agarwal RK, Brennan PJ. Updating the guideline development methodology of the Healthcare Infection Control Practices Advisory Committee (HICPAC). Am J Infect Control 2010; 38:264-73.

LEARN MORE ABOUT SSI PREVENTION AT APIC 2014 IN ANAHEIM, CALIFORNIA

HICPAC GUIDELINES ON PREVENTION OF SSI, 2014

When: June 8, 2014
Presenter: Dale W. Bratzler, DO, MPH
Learning objectives: Describe the methodology used to develop HICPAC practice guidelines; demonstrate understanding of the key recommendations for prevention of surgical site infections; discuss opportunities for ongoing research on prevention of surgical site infections.

NHSN SURGICAL SITE INFECTIONS: REVIEW OF THE 2014 SSI PROTOCOL AND CASE STUDIES

When: June 9, 2014
Presenters: Katherine Allen-Bridson, RN, BSN, MScPH, CIC; Janet E. Brooks, RN, BSN, CIC
Learning objectives: Identify the latest requirements, published standards, and recommended practices for safe and effective reprocessing of reusable patient care items; discuss the challenges and practicality of meeting reprocessing standards and recommendations in a small facility using real life examples; discuss creative strategies for success in the ambulatory surgery center sterile processing area.

OUTSIDE THE BOX FOR SSI REDUCTION: PARTNERING WITH SKILLED NURSING

When: June 8, 2014
Presenter: Daniel R. Field, RN, CIC
Learning objectives: Quantify the potential contribution of skilled nursing facility care in the hospital SSI rate; articulate why applying infection prevention resources beyond the confines of the facility is a good return-on-investment; discuss strategies to elicit skilled nursing facility participation both to allow hospital infection preventionists to identify opportunities for improvement, and to implement the resulting recommendations.

CHOOSING A SURGICAL SITE INFECTION REDUCTION INTERVENTION IN THE ABSENCE OF AN OUTBREAK OR CLUSTER

When: June 7, 2014
Presenter: Jeanne A. Yegge, RN, BSN, MPH, CIC
Learning objectives: Describe the method used to identify gaps in compliance with known surgical site infection prevention recommended practices; identify objectives, measures and weights used in the Kepner-Tregoe decision analysis tool; describe the method used to choose a surgical site infection reduction intervention in the absence or an outbreak or cluster.

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of evidence. Cohort studies provide the lowest level of evidence while meta-analyses provide the highest. Meta-analysis is a research method that systematically combines pertinent qualitative and quantitative study data from several selected studies to develop a single conclusion that has greater statistical power than the single component studies. With meta-analyses, the component studies are analyzed individually.

A panel of content experts first developed a preliminary list of key questions from a review of the 1999 CDC SSI guidelines, solicited feedback from other content experts, and put the key questions in final form after vetting them additional content experts and HICPAC members. There were eight key questions in the Core Section covering antimicrobial prophylaxis (AMP)-parenteral; antimicrobial or antiseptic prophylaxis-topical; glycemic control; normothermia; oxygenation; and skin preparation. In the Prosthetic Joint Arthroplasty Section, there were 11 key questions covering blood transfusion; systemic immunosuppressive therapy; immunosuppressive therapy-intra-articular corticosteroid injections; anticoagulation, orthopedic space suit; antimicrobial prophylaxis duration with drain use; and biofilm.

After generating and vetting the key questions, the panel conducted a literature search from MEDLINE, EMBASE, CINAHL, and the Cochrane Library databases between 1998 (when the previous guideline searches ended) through June 2011 for the Core Section, and December 2011 for the Prosthetic Joint Arthroplasty Section.

The panel first screened titles and abstracts. Full text articles were then reviewed if they were: 1) relevant to one or more of the key questions; 2) inclusive of clinical practice guidelines, systematic reviews, or primary study designs meeting the inclusion criteria (randomized control trial [RTCs] for the Core and Prosthetic Joint Arthroplasty Sections, and observational studies for the

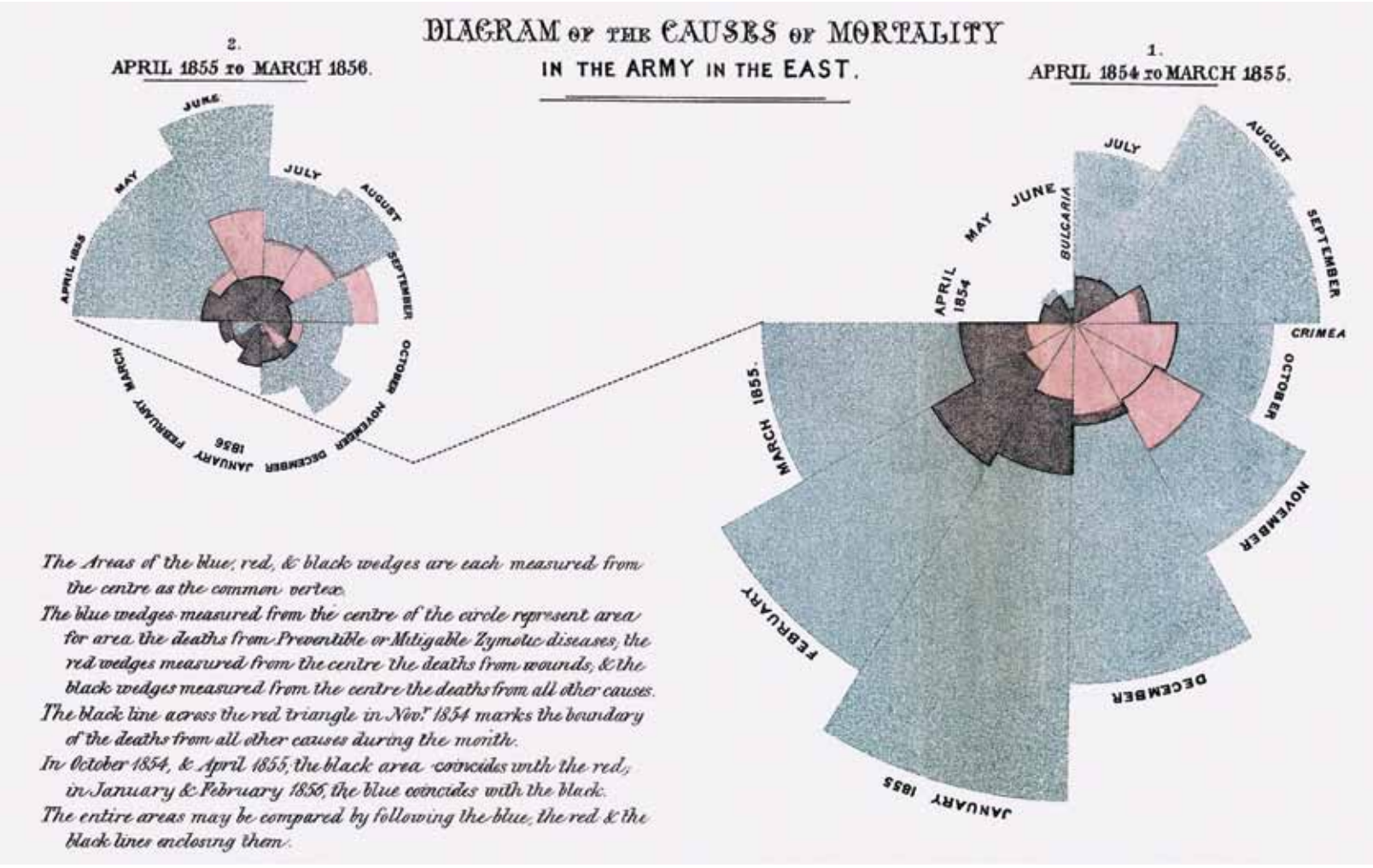
Prosthetic Joint Arthroplasty Section—only when the key questions were not adequately addressed by the initial search); 3) written in English; and 4) available as full text studies. Animal studies and basic science studies were excluded from all topics except Biofilm. Two independent reviewers screened these full text articles; disagreements were resolved by discussion. Subsequently, the panel reviewed a draft bibliography, suggested additional references, and then progressed through the title/abstract and full review process as above. Data abstraction and synthesis followed; finally, the draft was updated and released for public comment in January 2014 and again in April 2014.

It's important to note that the literature review search dates correspond to the beginning of the panel's process of updating the guideline. Per the April 11, 2014, HICPAC meeting, the CDC is considering examining more recent literature for the Core Section past the June 2011 cutoff date (as of press time).

Because of the unavailability of stronger evidence, the panel applied non-RCT, observational evidence to make recommendations

BELOW: **Florence Nightingale was a pioneer of epidemiological methodology, visual presentation of information, and statistical graphics. Her *"Diagram of the causes of mortality in the army in the East"* provided a visual representation of seasonal sources of patient mortality—including infection—in the military field hospital she managed.**

IMAGE CREDIT: Wikipedia Commons and www.royal.gov.uk/output/Page3943.asp.



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Decreasing cesarean section surgical site infection: An ongoing comprehensive quality improvement program, Frank R. Witter, Patricia Lawson, Janis Ferrell [April 2014 (volume 42 issue 4 Pages 429-431 DOI: 10.1016/j.ajic.2013.12.004)]

A polymicrobial outbreak of surgical site infections following cardiac surgery at a community hospital in Florida, 2011-2012, Duc B. Nguyen, Neil Gupta, Alison Abou-Daoud, Benjamin G. KleKamp, Chaz Rhone, Tiffany Winston, Trevor Hedberg, Ana Scuteri, Charlotte Evans, Bette Jensen, Heather Moulton-Meissner, Thomas Török, Sandra I. Berríos-Torres, Judith Noble-Wang, Alexander Kallen [April 2014 (volume 42 issue 4 Pages 432-435 DOI: 10.1016/j.ajic.2013.11.021)]

Assessing surgical site infection risk factors using electronic medical records and text mining, James D. Michelson, Jenna S. Pariseau, William C. Paganelli, March 2014 (volume 42 issue 3 Pages 333-336 DOI: 10.1016/j.ajic.2013.09.007)

Incidence and factors associated with surgical site infections in a teaching hospital in Ujjain, India, Ashish Pathak, Erika A. Saliba, Shailendra Sharma, Vijay Kumar Mahadik, Harshada Shah, Cecilia Stålsby Lundborg [January 2014 (volume 42 issue 1 Pages e11-e15 DOI: 10.1016/j.ajic.2013.06.013)]

A survey to examine patient awareness, knowledge, and perceptions regarding the risks and consequences of surgical site infections, Michael Anderson, Andy Ottum, Sara Zerbel, Ajay Sethi, Martha E. Gaines, Nasia Safdar [December 2013 (volume 41 issue 12 Pages 1293-1295 DOI: 10.1016/j.ajic.2013.02.007)]

Risk of methicillin-resistant *Staphylococcus aureus* surgical site infection in patients with nasal MRSA colonization, Lalit Kalra, Fabian Camacho, Cynthia J. Whitener, Ping Du, Margaret Miller, Crystal Zalonis, Kathleen G. Julian [December 2013 (volume 41 issue 12 Pages 1253-1257 DOI: 10.1016/j.ajic.2013.05.021)]

Epidemiology and outcomes of surgical site infections following orthopedic surgery, Guoqing Li, Fang-fang Guo, Yang Ou, Guang-wei Dong, Wen Zhou [December 2013 (volume 41 issue 12 Pages 1268-1271 DOI: 10.1016/j.ajic.2013.03.305)]

Risk factors for neurosurgical site infection after neurosurgery in Rennes, France: Comparison of logistic and Cox models, Sylvie Buffet-Bataillon, Lauren Saunders, Boris Campillo-Gimenez, Claire Haegelen [December 2013 (volume 41 issue 12 Pages 1290-1292 DOI: 10.1016/j.ajic.2013.02.006)]

Surgical site infection prevention following total hip arthroplasty in Australia: A cost-effectiveness analysis, Katharina M.D. Merollini, Ross W. Crawford, Sarah L. Whitehouse, Nicholas Graves [September 2013 (volume 41 issue 9 Pages 803-809 DOI: 10.1016/j.ajic.2012.11.015)]

Antimicrobial prophylaxis may not be the answer: Surgical site infections among patients receiving care per recommended guidelines, Francesca M. Lee, Sylvia Trevino, Emily Kent-Street, Pranavi Sreeramoju [September 2013 (volume 41 issue 9 Pages 799-802 DOI: 10.1016/j.ajic.2012.11.021)]

for the Prosthetic Joint Arthroplasty Section. This can be seen as either a weakness or a major strength of this new process. It could have a significant impact on clinical practice because new evidence can quickly be disseminated and translated into practice as the recommendations are reviewed and updated in a timely manner. The new process is expected to accelerate research based on noted gaps where no recommendations can be made. In the past, it took an average of 10 years for updated recommendations to occur. The new structure has the potential to make updates easier by keeping the Core Section intact and updating the specific-focused sections. Thus, CDC will continue to apply this methodology for all future updates and drafts of guidelines.

FORMULATION OF THE RECOMMENDATIONS

There were three key inputs that went into developing recommendations:

- Values and preferences used to determine the "critical" outcomes
- Overall GRADE of the evidence for the "critical" outcomes
- Net benefits, net harms, or trade-offs that result from weighing the "critical" outcomes

Recommendations

- For or against (direction)
- Strong or weak (strength)

The panel utilized concepts of net benefits, net harms, or trade-offs that result from weighing the critical outcomes of the data abstraction, analysis, and synthesis. Data from studies meeting the strict inclusion criteria were extracted and placed into standardized evidence tables, one table for each clinical topic represented by the key questions. Extracted data was placed in the tables under the following categories: study

author, year, design, the risk of bias, objective, population, setting, sample size, interventions, and results of clinically relevant outcomes. The panel assessed risk of bias associated with each study and included the scores in the evidence tables. Studies were extracted into GRADE evidence tables most relevant to them and organized by individual key questions and sub-questions.

Meta-analyses were only performed when their use was deemed critical to a recommendation and only in circumstances in which the multiple studies had sufficiently homogenous populations, interventions, and outcomes. Systematic reviews (a synthesis of the relevant studies on a particular topic) were included if the individual studies in the review were in accordance with the study inclusion criteria. To avoid duplication of data, primary studies identified by the search were excluded if they were also included in a systematic review captured in the literature search.

CONCLUSION

Surgical site infections continue to be a major concern for IPs and the United States. This is one of the first CDC guidelines to be updated using this new methodology. The use of the best available evidence acquired through RCT as the framework for recommendations to prevent SSI can be seen as a step in the right direction and an apparent strength of this new process of issuing recommendations from HICPAC. Much of the evidence cited in previous recommendations was derived from studies that used quasi-experimental designs, also referred to as nonrandomized, pre- post-intervention study designs. Although these types of studies can provide valuable information regarding the effectiveness of various interventions, several factors can decrease the certainty of attributing improved outcome to a specific intervention.

Because the new implemented methodology—relying on strong experimental evidence—has resulted in no or limited evidence to support some previous recommendations in the case of SSIs, the CDC is considering ways to provide guidance that clinicians have requested. Future *Prevention Strategist* articles will detail those as they become available from the CDC.

Perhaps the most unusual feature of this document is that for a guideline it is not very 'prescriptive'; none of the recommendations use the phrase 'do not.' When there is not enough data to support a practice recommendation, the guideline states that no recommendations can be made regarding the safety and effectiveness. It is then up to the IPs and perioperative clinicians to use the guideline to implement practices and interventions that best serve their patients within their particular context. Such "open-endedness" may provide more room for individual practice but it does put the burden on the clinician to be well-versed and competent in habits of implementation science. PS

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The dissemination of this article is supported by an unrestricted educational grant from Ethicon, APIC Strategic Partner 2014.

"This is one of the first CDC guidelines to be updated using this new methodology."

References

1. Hall MJ, DeFrances CJ, Williams SN, Golosinsskiy A, Schwartzman A. 2007 National Hospital Discharge Survey. National health statistic reports; no 29. 2010; Available at: www.cdc.gov/nchs/data/nhsr/nhsr029.pdf Accessed April 4, 2014.
2. Cullen KA, Hall MJ, Golosinskiy A. Ambulatory Surgery in the United States, 2006. National health statistics reports; no 11. Revised. 2009; Available at: www.cdc.gov/nchs/data/nhsr/nhsr011.pdf Accessed April 4, 2014.
3. U.S. Department of Health and Human Services. HHS Action Plan to prevent healthcare associated infections: Appendix G. Available at: www.hhs.gov/ash/initiatives/hai/actionplan/. Accessed April 4, 2014.
4. U.S. Department of Health and Human Services. Centers for Medicare & Medicaid Services. 42 CFR Parts 412, 413, 415, et al. Medicare Program; Hospital Inpatient Prospective payment System for Acute Care Hospitals and Long-term Care Hospital Prospective payment System Changes and FY2011 Rates; Provider Agreements and Supplier Approvals; and Hospital Conditions of Participation for Rehabilitation and Respiratory Care Services; Medicaid Program: Accreditation for Providers of Inpatient Psychiatric Services; Final Rule 2010; Available at: http://edocket.access.gpo.gov/2010/pdf/2010-19092.pdf. Accessed April 4, 2014.
5. U.S. Government Printing Office. The Deficit Reduction Act of 2005. Available at: www.gpo.gov/fdsys/pkg/BILLS-109s1932enr.pdf Accessed April 4, 2014.
6. Fry DE, Fifty ways to cause surgical site infection. *Surgical Infections.* December 2011; 12(6):497-500.
7. Polk HC, Jr., Simpson CJ, Simmons BP, Alexander JW. Guidelines for prevention of surgical wound infection, *Arch Surg* 1983; 118:1213-7.
8. Simmons BP. Guideline for prevention of surgical wound infections. *Am J Infect Control* 1983; 11:133-43.
9. Garner JS. CDC guideline for prevention of surgical wound infections, 1985. Supersedes guideline for prevention of surgical wound infections published in 1982. (Originally published November 1985). Revised. *Infect Control* 1986; 7:193-200.
10. Mangram AJ, Horan TC, Pearson ML, Silver LC, Jarvis WR. Guideline for prevention of surgical site infection, 1999. Centers for Disease Control and Prevention (CDC) Hospital Infection Control Practices Advisory Committee, *Am J Infect Control* 1999;27:97-132.
11. Federal Register. Draft guideline – Centers for Disease Control and Prevention Draft Guideline for the Prevention of Surgical Site Infection. A notice by the CDC 1/29/2014. Available at: www.federalregister.gov/articles/2014/01/29/2014-01674/draft-guideline-centers-for-disease-control-and-prevention-draft-guideline-for-the-prevention-of Accessed April 4, 2014.
12. Kurtz S, Ong K, Lau E, Mowat F, Halpern M. Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2013. *The Journal of Bone and Joint Surgery American Volume* 2007;89:780-5.
13. Kurtz S, Lau E, Watson H, Schmier JK, Parvizi J. Economic burden of periprosthetic joint infection in the United States. *The Journal of Arthroplasty* 2012;27:61-5 e1.
14. Umscheid CA, Agarwal RK, Brennan PJ. Updating the guideline development methodology of the Healthcare Infection Control Practices Advisory Committee (HICPAC). *Am J Infect Control* 2010;38:264-73.
15. GRADES Working Group. Available at: www.gradeworkinggroup.org/index.htm. Accessed April 4, 2014.

After the guideline is finalized and released, *Prevention Strategist* will be publishing a useful overview of the updated SSI guideline in the fall issue.