AAOS
American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

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February 24, 2014

Tom Frieden, MD, MPH
CDC Director
Centers for Disease Control and Prevention (CDC)
1600 Clifton Rd.
Atlanta, GA 30333, USA

Re: **Docket No. CDC–2014–0003** - Centers for Disease Control and Prevention Draft Guideline for the Prevention of Surgical Site Infections

Dear Dr. Frieden:

On behalf of more than 18,000 board-certified orthopaedic surgeons, the American Academy of Orthopaedic Surgeons (AAOS/Academy) thanks the CDC for the opportunity to comment on the Draft Guideline for the Prevention of Surgical Site Infections (Guideline). The AAOS understands the significant resources required to undertake a project of this magnitude and lauds the CDC for its efforts.

The AAOS is committed to educating its members about the significant impact SSIs have on the healthcare system and patients. It is of the utmost importance to the Academy that its members engage in strategies that will reduce the incidence of SSIs, thus decreasing morbidity, mortality, and financial burden on the healthcare system and society. The Academy offers the following comments on the SSI Guideline.

Methodology

AAOS's Evidence-base Medicine Unit has reviewed the methodology used to develop the SSI Guideline and appreciates the CDC's efforts to base all recommendations on the best available evidence. In developing Clinical Practice Guidelines, the Academy believes guidelines should be prepared using a systematic, well-defined process that makes it possible for readers to scrutinize every aspect of the decision-making process, which should be as unbiased, transparent, and reproducible as possible.

The Academy raises two methodological points of concern:

1. The numerous conflicts reported by JP, JEM, EPD, KI, and JS (page 3)
2. Why 14 guidelines were included that were not identified in the initial literature review (page 25)

These two points do not necessarily mean that bias was introduced. The Academy recognizes the fact that it is difficult to have entirely disinterested parties in the development process and appreciates the CDC's efforts to

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acknowledge where the parties may have a conflict for the sake of transparency. Second, the workgroup introducing 14 guidelines that were previously unidentified by the initial literature search leads to three questions:

1. Is it possible other unidentified studies and/or guidelines were missed?
2. What criteria were used in identifying these guidelines?
3. Were there additional guidelines excluded by the workgroup during its second search?

Overall, the Academy believes that the guideline development process used was rigorous and unbiased.

Guideline Content

CORE section

Parenteral Antimicrobial Prophylaxis

Q1C. As the draft is currently written, the use of weight-based dosing is left unresolved, though the CDC cites several guidelines that support using weight-based dosing. Weight-based antibiotic dosing is currently supported by the Academy and the International Consensus Meeting on Periprosthetic Joint Infections[1,2,3].

Q1D. The safety and effectiveness of intra-operative re-dosing was left unresolved. Abdominal and perineal wound SSI and intra-abdominal abscess were the outcomes of interest used in this analysis. The Academy supports re-dosing of prophylactic antibiotics intra-operatively, when the length of surgery exceeds 1-2 half-lives of the antibiotic, or when there is excessive blood loss and/or fluid resuscitation (>2L)[1,4,5,6].

Q1E. There is a strong recommendation against the administration of prophylactic antibiotics after skin closure. AAOS supports the administration of prophylactic antibiotics up to, but no later than, 24 hours after completion of surgery[1]. The CDC recommendation was based on a meta-analysis using studies spanning cardiac, thoracic, vascular, ear, nose and throat, gynecologic, orthopaedic, and general surgical procedures. Considering population differences among specialties, the Academy does not believe it is prudent to draw broad generalizations that could potentially have a negative impact on orthopaedic patients. This raises the question: Will the CDC guidelines lead to limiting all prophylactic antibiotics to a single, pre-operative dose? There is an immense difference between “clean” surgical procedures in which an implant is not placed in a body cavity and other clean surgical procedures involving an implant. The bioburden required to result in a clinically significant SSI is much lower when an implant is used. The AAOS strongly urges the CDC to alter the language and grant latitude to surgeons to continue the antibiotics for 24 hours when an implant is utilized.

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Oxygenation

Q6A. Volume replacement is important to allow oxygen delivery to become manifest at the tissue level. What constitutes adequate volume replacement varies with respect to patient and surgical classification (trauma vs elective and obese vs non-obese, for example), and the Academy questions the strength of a 1A recommendation based on the available evidence. Recommendations are based on studies addressing colorectal, open appendectomy, emergency and elective laparotomy for a variety of general and gynecologic procedures. Not controlling for, nor taking into account, all confounding variables could lead to a spurious relationship.

Antiseptic Prophylaxis

Q8D. A Category II recommendation was given to the use of plastic adhesive drapes with or without antimicrobial properties suggesting it is not necessary for the prevention of SSIs. The International Consensus Meeting on Periprosthetic Joint Infections[2] recognized studies that found iodine impregnated skin incise drapes decreased skin bacterial counts, but there was no correlation established with SSI. Therefore, the group did not make a recommendation on whether or not use adhesive drapes. The Academy believes more research should be conducted in this area before recommendations are made.

<u>Prosthetic Joint Arthroplasty Section</u>

Blood Transfusion

Q11. No recommendation could be given regarding the perioperative management of blood transfusions for the prevention of SSIs in prosthetic joint arthroplasty. The guideline cites data (guideline citations 133-138, 140) that suggest allogeneic transfusion increases the incidence of SSI and autologous transfusions have no effect on the incidence of SSI. The Academy appreciates the CDC's efforts to identify gaps in the evidence and hopes this will drive future research endeavors that will resolve this issue.

Systemic Immunosuppressive Therapy

Q12. Based on the analysis, no recommendation was made regarding the perioperative management of systemic corticosteroid or other immunosuppressive therapy for the prevention of surgical site infection in prosthetic joint arthroplasty. With many conflicting recommendations, the Academy supports being mindful of the known side-effects of these agents and taking into account all individual patient factors when making a treatment decision. These factors include, but are not limited to, the use of more than one immunosuppressant and the presence of comorbidities that could lead to increasing patients' risks for developing SSIs. Again, the Academy

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thanks the CDC for its efforts to identify areas where conflicting evidence exists.

Orthopaedic Space Suit

Q18. No recommendation could be made on the safety and effectiveness of orthopaedic space suits on reducing the incidence of SSIs in prosthetic joint arthroplasty. The Academy feels that personal protection space suits are a helpful safety tool in protecting the surgical team from bodily fluids during procedures that have significant risk of splatter and atomization of fluids. There are also differences in the design and exhaust mechanisms of space suits that should be addressed. These may or may not have a negative impact on the incidence of SSI, but could prove to be protective to the surgical team. The Academy believes more research is needed in this area.

Conclusion

The AAOS shares concerns of the CDC and is committed to reducing the burden of SSIs. We again thank the CDC for its efforts and hope the Guideline on the Prevention of Surgical Site Infection will serve to reduce SSIs and highlight areas where further research is needed.

If you have any questions on the AAOS comments, please do not hesitate to contact our Medical Director, William O. Shaffer, MD, at (202) 546-4430 or shaffer@aaos.org

Sincerely,

Joshua J. Jacobs, MD
President, American Academy of Orthopaedic Surgeons

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