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Association

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August 13, 2004

Patrick J. Brennan, MD  
Healthcare Infection Control Practices Advisory Committee  
Resource Center  
Attention: IsoGuide  
Division of Healthcare Quality Promotion  
Centers for Disease Control and Prevention  
1600 Clifton Road, NE, Mailstop E-68,  
Atlanta, Georgia 30333  
[www.cdc.gov/ncidod/hip/isoguide.htm](http://www.cdc.gov/ncidod/hip/isoguide.htm)  
Email: [isocomments@cdc.gov](mailto:isocomments@cdc.gov)

Re: Centers for Disease Control and Prevention: Draft Guideline for Isolation Precautions:  
Prevention of Infectious Agents in Healthcare Settings, 2004

Dear Dr. Brennan:

On behalf of the American Hospital Association (AHA), its 4,700 member hospitals and health care systems, and 31,000 individual members, we welcome the opportunity to comment on the Centers for Disease Control and Prevention's (CDC) *Draft Guideline for Isolation Precautions: Prevention of Infectious Agents in Healthcare Settings 2004*.

The AHA has worked with the CDC and other federal agencies to improve safety by encouraging health care facilities to develop and sustain infection control and safety strategies. We remain actively involved in multiple efforts, such as the prevention of transmission of tuberculosis (TB) in health care facilities, implementation of bloodborne pathogen standards, and prevention of sharps injuries in hospitals. We also have offered input or comment to other CDC documents including the smallpox response plan and other Healthcare Infection Control Practices Advisory Committee (HICPAC) guidelines. We are pleased with the careful consideration our comments have received and the fact that the CDC has adopted many of our recommendations.

While the *Draft Guideline for Isolation Precautions* is an update of existing guidelines, we recognize the enormous challenge involved in reviewing the state of current knowledge on preventing transmission of infectious agents in multiple health care settings. The result is an excellent and practical document for use in our hospitals.



Overall, we support the guidelines as drafted; however, we do have six key concerns with the current draft, which are articulated below. In addition, we have provided an attachment that includes our specific, technical concerns that apply to the CDC's recommendations (Table 1) as well as the list of referenced footnotes that are cited both in this letter and in Table 1.

## **KEY CONCERNS**

### **Standard Precautions**

We fully endorse the concept of "standard precautions" (SP) as currently developed in the updated guidelines. That is, use of standard precautions as the universal approach to infection control with an increased emphasis on "respiratory hygiene/cough etiquette," should enhance current efforts to effectively control infection transmission with basic interventions.

We believe that the principal underlying strategy for successful control of infections is adherence to SP. In health care and many other fields, safety has been significantly improved only when systemic changes were implemented, and using SP is such a systematic approach that will minimize the potential for patients to become infected by various organisms, including MDRO. It is an approach that can be implemented throughout the hospital by clinicians, administrators, and other employees and can involve patients and family members. Such a systemic approach will serve to reinforce the "culture of safety" hospitals are seeking to develop and maintain.

We fully support the terminology change which clarifies that SP are intended to "provide a unified infection approach to MDROs, replacing prior pathogen-specific recommendations" and, concur with the use of "expanded precautions" when the route of transmission is not completely interrupted by SP.

**The AHA encourages the CDC to further emphasize the importance of initiating SP based on patient symptoms of illness, considering appropriate staffing, importance of hand and respiratory hygiene, and functional engineering controls. Such emphasis, when positioned in a "culture of safety," will result in a better general understanding of the effectiveness of interventions that are not dependent on pathogen-specific information, and reflect the principle of using SP as the universal approach to controlling infection. Specific suggestions to better promote SP are listed in Table 1.**

### **Appendix B – MDRO**

Appendix B describes a number of critical factors that reduce the emergence of MDRO. However, these issues need to be incorporated into the main text of the guidelines if they are to be viewed as an organizational responsibility. For example, the critical role of judicious use of antimicrobial agents is such a factor in Appendix B that needs to be brought into the main guideline text. The AHA strongly supports the appropriate use of antibiotics within the health care setting and the monitoring of antimicrobial resistance patterns. This activity is key among multiple strategies to reduce emergence of resistant microbes. The medical staff and others have a significant responsibility for implementing appropriate guidelines and protocols for use of antimicrobials, as opposed to indiscriminate prescribing practices that are frequently permitted.

This is but one item that may lead to confusion on the part of users of the guideline if the MDRO section remains an appendix. In our attached table, we have identified other critical elements that we believe should be highlighted in the main text of the guidelines.

**The AHA recommends that key elements of Appendix B be incorporated into the main section of this document to enhance understanding. Specifically, this would include the discussion of a judicious use of antimicrobial agents (page 137), direct comparative study of standard versus contact precautions (page 139), a perspective on the MDRO control literature (page 142), and the lack of national/local consensus on optimal strategy to control MDRO (pages 144-45).**

### **Control of MDROs**

Emerging pathogens and MDROs are a challenge to all hospitals and we appreciate the in-depth examination of the evidence on how to control the transmission of infectious agents. Given the limited available resources in hospitals for many critical and competing health care priorities, it is crucial that maximum flexibility be afforded in the guidelines when recommending labor and cost intensive control measures that may not be universally needed.<sup>1-5</sup>

Thus, we are particularly concerned with the CDC's recommendations emphasizing elements of "active surveillance culturing" (ASC). We appreciate that this tool, when combined with molecular epidemiology to analyze cross transmission of related clones, can be powerful, but it also is time and resource intensive. It is not the most efficacious choice for routine infection surveillance. **The CDC should highlight ASC as a tool reserved for investigating clusters of infection, and not for routine use.** Consensus on optimal infection control measures in the U.S. and on a global level remains elusive.<sup>6</sup> Given the controversy and disagreement over the efficacy of interventions such as ASC, it is important that efficient and effective surveillance methods continue to be options for hospitals and other facilities to use.

**The AHA supports a systems approach to controlling MDROs, as has been applied to other patient safety problems in a culture of safety. This is a more logical strategy that integrates well with overall patient safety and performance improvement programs. Such an approach has revealed that there are deficiencies and unintended consequences in the care of patients on isolation precautions and we are concerned that significant expansion of ASC will run counter to high quality patient care.**<sup>17-21</sup>

Further, we appreciate the CDC's effort to support health care facilities need for flexibility as they consider their own experiences, but we are concerned that some practices that are classified in the draft as Category of Evidence IB (i.e., "Strongly recommended for implementation and supported by some experimental, clinical, or epidemiologic studies and a strong theoretical rationale") negate that very flexibility and undermine the premise of using SP as a universal approach. An example may be found in the appended Table 1 (Part IV. Section V: A.4.g. Page 84g). Recommendations that are based on a sheer volume of observational studies *cannot* replace those based on a well-designed randomized trial.

**The AHA urges the CDC to carefully consider the strength of the scientific evidence in assigning a category of evidence for recommendations that support *routine* activities – particularly when addressing ACS, staffing, or other recommendations for which no randomized study has been reported to date.**

**Evidence Used For Category Assignment And Associated Regulatory/Accreditation Issues**

On a closely related issue, the AHA strongly urges the CDC to re-evaluate the *method* of categorizing recommendations based on strength of scientific evidence as well as other variables such as theoretical rationale, application and cost effectiveness.

Although the CDC's published guidelines are only recommendations, often they become "codified" into regulatory language or adopted by accreditation agencies as standards.<sup>22,23</sup> Thus, the scientific evidence for Category I recommendations should be strong, robust and reproducible. However, we have found that there are inconsistencies in the evidence that is used (or not) for specific recommendations. As noted above, Category IB is especially problematic. Often randomized, controlled trials are lacking for this category. The cited studies may reflect experience in a narrow spectrum of health care or reflect theoretical rationale. Since there is a far-reaching impact of recommendations in this category, the AHA strongly urges a careful analysis of cited evidence and reclassification to Category II, as appropriate.

The AHA supports the importance of evidence-based, scored guidance for science-based decisions. HICPAC has been a leader in scoring recommendations based on evidence-based practices to enhance patient and health care worker safety. To continue its leadership in this area, HICPAC should review the Agency for Healthcare Research and Quality's (AHRQ) Evidence-Based Practice Center report, *Systems to Rate the Strength of Scientific Evidence*.<sup>24</sup>

**The AHA urges the CDC and HICPAC to adopt the relevant elements from AHRQ's report for future work on guidelines. We acknowledge that significant gaps in the quality and quantity of research remain in the field of infection control/ health care epidemiology. However, national consensus guidelines, such as those developed for the CDC by HICPAC, should adhere to principles of evidence-based health care and systematic review of the literature.**<sup>25-27</sup>

**Respiratory Protection**

We are concerned by the CDC's focus on particle size as the primary component that would determine respiratory protection selection. Particle size of biologic agents is only one component of the disease transmission chain. Disease transmission requires appreciation of several other factors such as host susceptibility, level of respiratory hygiene, and administrative/engineering controls, and not solely size of microbial laden particles. Analysis of the literature requires looking at the epidemiology and successful use of masks over many years for diseases as disparate as Varicella zoster, TB and, most recently, SARS-CoV.<sup>28-29</sup>

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We are pleased that the CDC plans to address this issue more formally in order to develop a consistent approach to determining the circumstances under which a mask or particulate respirator may be appropriate.

**The AHA strongly supports such a review of the function and quality of respirators, so that the benefits to health care personnel resulting from improvements in respirator design can be realized instead of the current complete reliance on fit-testing.**

#### **Staffing Issues**

As noted above, the AHA strongly encourages the CDC to continue approaching infection control as an essential component of a culture of safety. Therefore, while we acknowledge and appreciate the leadership role provided by infection control personnel, they are part of a broader team that share responsibility for controlling and eradicating risks of infection.

The guidelines do not appear to adequately recognize the responsibility of other staff in health care organizations that play a critical role in controlling infectious risks. The AHA believes health care organizations must be accountable for developing broad strategies to control infection-related risks. This point needs to be emphasized by the CDC, especially since an understanding of optimal staffing levels and skill mix to prevent health care-associated infections in facilities is still evolving.

**In terms of staffing ratios, it is premature to rate the available evidence as Category IB. Given the lack of a contemporary, objective quantification of the optimal ratio of infection control professionals to facility bed size to ensure an effective infection prevention control program, we believe the guidelines should not include recommendations of staffing based on a bed ratio.**<sup>30-32</sup>

Thank you for the opportunity to provide comments on this important document. If you have concerns or questions about these comments, please call me or the AHA's Roslyne Schulman at (202) 626-2273.

Sincerely,

Rick Pollack  
Executive Vice President

Attachment