August 10, 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
Mailstop E-68, 1600 Clifton Road, NE
Atlanta, Georgia 30333
www.cdc.gov/ncidod/hip/isoguide.htm
Email: 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 Michigan Society for Infection Control (MSIC) 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*. MSIC represents over 400 members who promote infection control in acute care, long term care, home care, mental health, public health, correctional facilities, and health care product organizations and facilities.

MSIC 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 in health care facilities, implementation of bloodborne pathogen standards, and prevention of sharps injuries in hospitals. We have also offered input or comment to other CDC documents including the smallpox response plan and influenza immunization as well as the Guidelines for Environmental Infection Control in Healthcare Facilities, 2003, Guidelines for Disinfection and Sterilization in 2002, and the Guidelines for Preventing Healthcare-associated Pneumonia, 2003. We are gratified to see how carefully comments are considered and adopted.
Although this is an update of existing guidelines, we are appreciative of the enormous challenge involved in reviewing current knowledge regarding preventing transmission of infectious agents in multiple healthcare settings. The result is an excellent and practical document for use in our hospitals.

Detailed comments are appended in Table 1 but we would like to highlight several important concerns.

- *Standard precautions*. We applaud the effort to promote *standard precautions* (SP), intended to "provide a unified infection approach to multi-drug resistant organisms (MDROs), replacing prior pathogen-specific recommendations" and using "expanded precautions when the route of transmission is not completely interrupted by SP."

  - In that light, we encourage the CDC to promote a focus on using symptoms of illness to initiate SP, considering appropriate staffing, general emphasis of hand and respiratory, hygiene and functional engineering controls, truly relying on the principle of using basic standard precautions.

- *Appendix B- MDRO* Although the authors intent in positioning MDRO issues as an appendix may have been to provide balance, the very elements addressed in the appendix that would add that balance and lessen the perceived emphasis on MDRO do not appear with sufficient impact in the text and recommendations. The net effect is a focus on MDRO in the main document that may result in underestimating the primary role of SP.
  - We prefer elements of Appendix B be incorporated into the main section of this document as it offers a better perspective. Specifically this includes the discussion of a direct comparative study of standard versus contact precautions, (page139), a perspective on the MDRO control literature (page 142) and lack of nation/local consensus on optimal strategy to control MDRO (pages 144-45).

- *Control of (MDROs)* Emerging pathogens and MDROs are a challenge to all our hospitals and we appreciate the in-depth examination of the evidence available to date to control the transmission of infectious agents—both antimicrobial susceptible and resistant. Given the limited resources for competing healthcare needs it is crucial that maximum flexibility be afforded in the guidelines when recommending labor/cost intensive control measures that may work in some institutions, some of the time.[1-5] The literature review and recommendations emphasize elements of "active surveillance culturing" (ASC) and CDC should highlight a message that approaches ASC as a tool reserved for investigating clusters of infection. This tool, when combined with molecular epidemiology to analyze cross transmission of related clones can be powerful, as opposed to *routine* use. Consensus on optimal control measures however in U.S. health care facilities or on a global level remains elusive.[6] Given the controversy over efficacy interventions such as ASC, it is important that CDC maintain a broader, epidemiologic" perspective.

  Sustainable interventions will likely require public policy, development of new anti-infectives,[7] education, surveillance, antimicrobial stewardship and consideration of techniques from other fields such as hazard analysis & critical control point (HACCP) techniques (http://www.cfsan.fda.gov/~lrd/haccp.html). For example there are several studies in the literature that utilize HACCP and more broad performance improvement principles to prevent cross transmission of a wide range of pathogens, not just MDROs.[3,8-13] By way of example, one aspect involved in the dynamics of cross transmission has been studied to identify critical control points that will interrupt transmission of both susceptible and resistant microorganisms.[14] In addition, changes in processes of care (e.g., limiting duration of post operative antibiotic prophylaxis) and changes in patient care equipment can prevent transmission or development of infection of all pathogens within healthcare facilities.[15,16]
  - We support a systems approach to control MDROs, as has been applied to other patient safety problems 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 care of patients on isolation precautions and we are concerned that significant expansion of ASC will run counter to high quality patient care.[17-21]

We appreciate CDC's effort to support organizations' need for flexibility as they consider their own experiences, but we have concern that some practices that are classified as Category IB negate that very flexibility, as well as the undermining the premise of using SP as a first approach. (See comments on categorization scheme below). An example may be found in the appended Table 1 (Part IV. Section V: A.4.g. Page 84g). In summary, recommendations that are based on a sheer volume of observational studies *cannot* replace those based on a well designed randomized trial.

- We urge CDC carefully consider in assigning categories of evidence (IB) for recommendations that support *routine* activities which not based on sufficiently strong- particularly when addressing "active surveillance culturing" or ACS, 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, we urge CDC 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. We know CDC is aware, but wish to reinforce that while their published guidelines are recommendations, quite often they become "codified" into regulatory language or adopted by accreditation agencies as standards.[22,23] The scientific evidence upon which Category I recommendations are based therefore should be strong, robust, and reproducible. Category IB is problematic. Often randomized, controlled trials are lacking for this category or studies cited reflect experience in a narrow spectrum of healthcare or reflect theoretical rationale. Since there is a far-reaching impact of recommendations in this category, we strongly advise a careful analysis of cited evidence and if insufficient or narrow in scope, a Category II be employed. We support the importance of evidence-based, scored guidance for science-based decisions, particularly in the light of the Institute of Medicine's (IOM) reports that encourage use of evidence-based practices to enhance patient and health care worker safety. HICPAC has been a leader in scoring recommendations based on evidence-based practices to enhance patient and health care worker safety and we would once again encourage review of the current categorization scheme for future guidelines. The entire issue of evidence-based guidelines has come under intense scrutiny, as you are fully aware, and we draw attention to a report, *Systems to Rate the Strength of Scientific Evidence*.[24]
  - We recommend a review of this report for elements that may useful to consider for future application in Healthcare Infection Control Practices Advisory Committee (HICPAC) guidelines when considering the impact of assigning a category. We acknowledge that significant gaps in the quality and quantity of research remain in the field of infection control/ healthcare epidemiology, however national consensus guidelines should remain adherent to principles of evidence-based health care and systematic review of the literature.[25-27]

- *Respiratory protection***.** It is clear that contradiction remain regarding the selection of appropriate respiratory protection and several recommendations imply that selection is based primarily on particle size. Particle size of biologic agents is but *one* component of the disease transmission chain and not the sole determinant of the type of respiratory protection. Disease transmission requires appreciation of several factors such as host susceptibility, level of respiratory hygiene, and administrative/engineering controls etc., 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.[28-29] We are pleased that CDC plans to address this issue more formally for a consistent approach to determining when a mask or particulate respirator may be appropriate under certain conditions.

- We strongly support a review of the function and quality of respirators, so that the benefits to healthcare personnel resulting from improvements in respirator design can be realized rather than complete reliance on fit-testing.

- *Staffing issues*: Our understanding of optimal staffing levels and skill mix to prevent healthcare-associated infections (HAI) is still evolving and we feel it premature to rate the available evidence as Category IB. Second, given the lack of a contemporary, objective quantification of the optimal ratio of ICP to facility bed size to ensure an effective infection prevention/control program we believe the recommendations should more clearly reflect that a staffing bed ratio is too imprecise.[30-31]

We have appended a table comments on a number of specific, technical concerns that apply to specific recommendations within the guidance.

If you have concerns or questions about these comments, please contact MSIC Advocacy Chair, Linda Scott (517-335-8284).

Teri Lee Dyke
Teri Lee Dyke (517-339-7840)
MSIC President 2004

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