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Don Wright, MD, MPH
Deputy Assistant Secretary for Healthcare Quality
US Department of Health and Human Services
200 Independence Avenue, SW
Room 719B
Washington DC 20201

Attention: Draft Tier 2 Modules, HAI Action Plan

Dear Dr. Wright:

The Association for Professionals in Infection Control and Epidemiology (APIC), an international association comprised of over 13,500 infection preventionists, wishes to thank the Department of Health and Human Services (HHS) for the opportunity to provide input into the draft Tier 2 modules of the HHS Action Plan to Prevent Healthcare-Associated Infections (The Action Plan). We applaud HHS for its collaborative process in conjunction with all relevant agencies in producing this document, as well as organizations like ours, which bring significant experience to the mission to prevent infections and improving patient safety.

APIC supports the efforts of our members as they work to prevent healthcare-associated infections through a variety of avenues. Among these efforts are: sharing best practices for preventing, identifying, monitoring, and treating healthcare-associated infections, as well as the collection of meaningful data for internal improvement and public reporting. We welcome the opportunity to continue to share our expertise with HHS as the Action Plan continues to develop and offer the following comments on the Tier 2 modules.

Section A: Ambulatory Surgical Centers (ASCs)

General comments

- APIC suggests updating the wording "infection control" to "infection *prevention and* control" throughout the document.
- The HHS Plan states: "ASCs may benefit from regular access to a certified infection preventionist." However, Standard §416.51(b) Infection control program, already requires that the program is "(1) Under the direction of a designated and qualified professional who has training in infection control. The ASC must designate in writing, a qualified licensed health care professional who will lead the facility's infection control program" and later notes "that certification in infection control, such as that offered by the Certification Board of Infection Control and Epidemiology Inc. (CBIC), while highly desirable, is not required, so long as there is documentation that the individual has

training that qualifies the individual to lead an infection control program." Therefore, although APIC strongly supports and encourages infection preventionists (IPs) to pursue board certification in Infection Prevention & Control (CIC®) from the Certification Board of Infection Control & Epidemiology (CBIC), and given the rapid growth of ASCs and a limited supply of IPs with CIC, we instead feel this process metric must continue to be aligned with the Centers for Medicare and Medicaid Services (CMS) standard interpretation which requires the ASC to have a designated IP who can demonstrate qualification through ongoing education and training. The infection control program (IPC) overseen by the IP will need resources, i.e. staffing, that is adequate to accomplish the tasks required for the infection prevention and control program at the ASC. This needs to be commensurate with an infection prevention/control risk assessment that includes information from the population served and care, treatment and services provided. The ASC risk assessment can be used to identify the need to access external consultants as appropriate. The less prescriptive language involving a board certified IP is also consistent with the Joint Commission (TJC) accreditation requirements.

- APIC supports assessing performance using outcome metrics such as the surgical site infection (SSI) rate; reoperations for infection, bleeding and other complications; and hospitalizations for infection or other surgical complications.
- There is a critical need to monitor adverse events, including infections, related to specific medical and surgical procedures performed in ASCs.
- Assessment of patient and procedure risk factors, as well as the means to prevent or ameliorate the risks, is needed.
- Published evidence from surveys of ASCs [Schaefer MK, et al. JAMA 2010;303:2273-9] has identified a need to assure personnel in ASCs have received education and training on core IPC principles. APIC has considerable expertise in this regard and feels this should be emphasized.
- APIC recommends the use of the term "personnel" rather than staff as this encompasses the surgeon/owner and any consultants that might be needed in addition to employees. In terms of timeline for implementation, this process-focused measure should precede outcome measurement.
- APIC also encourages engagement of the patient receiving care from the ASC relative to perioperative responsibilities and post-procedure instructions on what to watch for as possible complications, and whom to notify if they occur.
- APIC applauds the collaboration between the Centers for Disease Control and Prevention (CDC) and CMS in development and use of the Infection Control Work Sheet (ICWS) survey tool and offers the following suggested additions to the tool:

<u>Comments on ICWS</u>

- *Part 1*: In question #15 we recommend defining what is meant by an "explicit infection control program".
- *Part 2 Section II -- Injection practices*:
    - E – We recommend adding the word "secure" so that pre-drawn medications are secure until used on a patient.

- F – We recommend adding more specific language to clarify if single dose vials can be used more than once on the same patient, and to address the issue of incremental dosing required during a single surgical case.
- I – We recommend defining the time needed to disinfect the vial septum with an appropriate disinfectant for at least 15 seconds as studied by Kaler & Chinn, (*Successful disinfection of needleless access ports: A matter of time and friction. JAVA 2007;12:140-3.*)
- J – Information from different sources is inconsistent on what date to put on the vial. CMS says to date the vial when first opened. However, The Joint Commission says to re-label the vial with a new expiration date, which they indicate should be 28 days after the vial is opened. CDC indicates to use the expiration date of the vial but does not differentiate between unopened and opened vials. This discrepancy in recommendations may be a cause for error by a user who may not know which date to use or what a data on a vial means. We recommend that the tool specify which date to put on the vial and encourage CDC to collaborate with CMS and TJC to develop a consistent recommendation. We also recommend that the tool specify that dating is required only for sterile injectable products and does not apply to nonsterile oral medications used at the ASC.
- We recommend that the tool specifically note that bags of normal saline cannot be used to prefill flush syringes in the ASC.
- We recommend that the common practice of spiking single use vials to allow for reuse should be included as an unsafe practice.

- *Part 2 Section III – High-level disinfection and sterilization*
  - E – The tool does not address the issue of rinsing with either sterile water or tap water followed by an alcohol rinse. Because this is a very important step prior to drying, we recommend this be included.
  - We recommend that this tool address the issue of "flash sterilization", using very clear and concise language, to avoid any confusion.
  - We recommend adding a question to the High-Level Disinfection section D. c. on quality control related to use of high level disinfectants. For example, some manufacturers of test strips used for assessing minimum effective concentration recommend quality control testing of the test strip.
- *Part 2 Section IV – Environmental Infection Control*
  - We recommend that CMS work with the Environmental Protection Agency (EPA) and professional organizations representing IPs like APIC and the Society for Healthcare Epidemiology of America (SHEA) to explore interpretations of label language that reflects current research and clinical practice regarding noncritical surface contact time for low level disinfection. For example, one might be able to demonstrate a surface has been cleaned and therefore the conditions differ from that to which the laboratory testing was performed prior to EPA registration.
  - We recommend specifying the frequency of full terminal cleaning.
- *Other comments related to the tool*
  - APIC recommends that the tool become integrated into the ASC survey process as a mandatory component.

- We strongly recommend continued use of this tool, but given the concerns about sustainability due to lack of certainty in funding, we recommend requiring that this tool be completed and documented annually by an infection preventionist and shared with governance for the ASC as part of the quality assessment and performance improvement program.
- We recommend that CMS investigate merging the inspection criteria outlined in the tool in the ASPEN system (or other existing CMS application) as a 3-5 year goal. If ASPEN is not feasible, then CMS should investigate another electronic data capture system that could facilitate data integration with ASPEN findings.

Comments on Surveillance & Outcome Measurement

- Before we can move toward comparative analysis, it is necessary to obtain baseline data. None exists currently for the specific ASC population. We therefore encourage issuance of requests for proposals by the Agency for Healthcare Research and Quality (AHRQ) to researchers to study opportunities and challenges in use of health claims data from ASCs. This could identify a roster of candidate procedures for which epidemiologic surveillance systems can be developed. In addition, this may identify procedures for which the incidence of complications is too low (e.g. gastrointestinal endoscopy - 1 complication / 1.8 million endoscopies) to be cost effective for inclusion in a surveillance program.
- We recommend that ASCs be encouraged to conduct a baseline and annual risk assessment thereafter from which candidate procedures can be identified for inclusion in the facility's SSI surveillance program. Candidate procedures can focus on high risk, high volume, and/or high morbidity procedures and should also span the age spectrum.
- We recommend that HHS consider utilizing input from the Colorado HAI Advisory Committee, and other states that are piloting outcome measurement, on lessons learned in the incorporation of ASCs in the mandatory HAI reporting process prior to enacting any broad mandate for collection and disclosure.
- Any surveillance system proposed needs to be able to be adaptable by ASCs with limited resources and technology and should be in sync with existing state requirements to avoid duplication.
- When considering the use of AHRQ data for measurement of HAIs, we recommend that this data not be used exclusively but instead be used in concert with other existing measures, such as the National Healthcare Safety Network (NHSN).
- We recommend that CMS clarify the surveillance timelines for implants. Experience with monitoring implants suggests that 30 days is not adequate for monitoring SSIs in this population. We suggest developing a timeline to require an extended timeframe for surveillance expectations in subsequent years. Most of these infections present in the first few months, but the majority will not present in the first 30 days, so the current surveillance timeline will be inadequate in capturing data that accurately reflects the SSI issue.
- We applaud the recognition of the need for validation of the SSI data.
- We applaud the work being done with electronic data mining and the NHSN collaboration. Development of a core set of elements for electronic medical records is the foundation for this entire process to be meaningful.

Comments on SCIP measures

- APIC agrees that use of applicable and appropriate SCIP measures be considered. However, we recognize that the following measures do not apply to ASCs as these procedures are not performed in this setting and therefore the measures cannot be extrapolated to other surgeries.
    - Glucose control for cardiac surgeries.
    - Normothermia in colorectal surgeries.
- Many of the surgeries in ASCs do not require prophylactic antibiotics.
- We recommend that HHS consider issues with timing of Vancomycin in this setting as it takes a longer time to administer and these cases will not be able to be scheduled in the early morning if compliance is expected.
- SCIP measures do not adequately address the pediatric population.

Comments on Education

- APIC's expertise in infection prevention and control can enhance and support the educational efforts currently planned for ASCs. We welcome the opportunity to continue our collaboration with HHS to assist in this effort and we look forward to further discussions on this area.

Additional Stakeholders

- APIC recommends the addition of key groups as essential contributors in the planning process for this plan, including anesthesiologists, nurse anesthetists, sterile processing professionals, and perioperative organizations.

Section B: End-Stage Renal Disease (ESRD) Facilities

We recommend that a correction be made to this module. Under "Priority Module 3 – Recommendations for Appropriate maintenance of Vascular Catheters" the 4th bullet states "use of polymyxin B/ bacitracin/ gramicidin (e.g., Polysporin ® Triple) or povidone-iodine antiseptic ointment at the hemodialysis catheter exit site after catheter insertion and at the end of each dialysis session. Select an ointment that does not interact with the material of the hemodialysis catheter." Please change "HICPAC *Category IA*" to "HICPAC *Category II*".

In addition, APIC recommends adding the following to the ESRD recommendations:

General comments

- Ensure consistency between the ESRD Module and other existing guidance documents on infection prevention in ESRD facilities. We recommend that HHS review APIC's Dialysis Infection Elimination Guide, Medication/Infection Safety Position Paper, and CDC's Guideline for Hemodialysis as existing guidance that may be useful.
- Require a dedicated infection preventionist for each dialysis unit or, at a minimum, ensure that the individual in each dialysis unit responsible for infection prevention receives initial and ongoing training, such as that available through APIC.

- Clarify and elaborate on the role of the individual responsible for infection prevention in hemodialysis units.
- Add to the influenza and pneumococcal disease prevention section a requirement for respiratory etiquette for employees and patients in hemodialysis units.
- Offer 1-dose of pneumococcal polysaccharide vaccine to adult dialysis patients and a one-time booster dose, for those vaccinated prior to age 65, after 5 years have elapsed.
- Include a requirement for patient education relative to prevention of healthcare-associated infections.
- Ensure that metrics are harmonized with NHSN dialysis surveillance program. Using the example of access-related bacteremia, the NHSN event to which this measure refers is "access-*associated* bacteremia," not "access-*related* bacteremia" and best term would be "access-associated bloodstream infection (BSI)". Harmonization should include denominators and reporting frequencies.
- Revise message from "Fistula First" to "Fistula First and Catheter Last" to avoid use of catheters instead of grafts. An unintended consequence of the "Fistula First" initiative has been an observed increase in central line use and associated central line-associated bloodstream infection (CLABSI) risk.
- Require education in medical schools, nursing schools, and renal fellowships relative to ensuring access pre-dialysis to reduce central catheter utilization and the associated risk of CLABSI.
- Require that dialysis certification tests include questions relative to infection prevention. Ensure that study guides on infection prevention in ESRD facilities are available to staff.
- Require hepatitis C testing be recommended to dialysis patients and that CMS cover this screening test.

Future Directions

- We recommend collaboration between all professional associations to ensure infection prevention is always included in practice guidelines for hemodialysis.

Research Directions

- Determine the role of surface disinfection in infection transmission, focusing specifically on minimum contact time to achieve low level disinfection.
- Best practices in dialysis access care and maintenance, including fistula techniques.
- Study the epidemiology and transmission dynamics of hepatitis B and C viruses (HBV, HCV), and multidrug-resistant organisms (MDROs) in this setting.
- Study the efficacy of new products, including antimicrobial locks and ultrapure dialysate, best skin disinfectants including bleach, and associated costs.
- Study the impact of antibiotic stewardship on resistance of bacteria.
- Develop prediction models for successful fistula placement, which may be better predictors of success than vein mapping alone.
- Study the association of training providers relative to staging of renal disease and the success of permanent access placement.
- Study the impact of patient education on the adverse outcomes associated with catheters, grafts and fistulas.

- Study the benefit of HBV isolation in dialysis units.
- Encourage basic research scientists to develop a vaccine against HCV vaccination for hemodialysis patients.
- Study the effect of mandatory healthcare personnel influenza vaccination on ESRD patient health and outcomes.
- Study the benefit of peritoneal dialysis and/or wider use of home dialysis as an alternative to central catheter placement prior to fistula maturation.

Information Systems and Technology

- Recommend designing CROWNWeb database for interface with NHSN.

Metrics and Evaluation

Possible ESRD module metrics for infection prevention:

- Vascular access: compliance with central line care and maintenance care bundle.
- CLABSI: compliance with NHSN definitions.
- Immunization: measure patient vaccination rates for HBV, influenza, and pneumococcal disease; measure employee vaccination rate for influenza.

Section C: Influenza Vaccination of Healthcare Personnel (HCP)

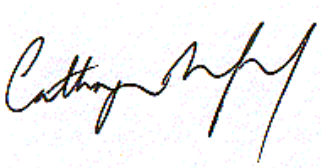
- APIC embraces the long term goal of 90% influenza vaccination rate among HCP in Healthy People 2020 and supports the working group's interim metric of 70%; however, we agree that this is a significant challenge, particularly in the broad spectrum of healthcare settings, including ASCs, in which coverage is currently below 50%.
- We agree with the Plan's focus on the importance of utilizing a consistent definition of HCP, particularly when measuring progress toward meeting the Plan's goals.
- We recommend that the Plan outline how measurement of HCP will be conducted, particularly outside of acute care settings where there has been a proposal to measure immunization as a part of existing voluntary quality reporting efforts.
- We support the HCP influenza vaccination goal for all settings. However, it is important to clarify how measurement will occur in all care settings and to work with stakeholders to support such efforts. We suggest that stakeholders from ambulatory and non-traditional care organizations be included in these discussions. Given the fact that most of our knowledge regarding vaccine acceptance is based upon acute and long term care experiences, it would be helpful to acknowledge and/or identify barriers which may be unique to other care settings.
- In our position paper "Influenza Immunization of Healthcare Personnel" APIC recommends that:
    - hospitals, long term care, and other facilities that employ healthcare personnel, implement a comprehensive strategy which incorporates all of the recommendations for influenza vaccination of HCP of the Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices (ACIP). As part of a comprehensive strategy, we

recommend that influenza vaccine be required annually for all healthcare personnel with direct patient care.

- As noted in the HCP module, although CDC, ACIP, and a number of stakeholder organizations have called upon healthcare facilities to implement multi-component interventions to increase vaccination rates, recent data still indicate that in 2009 62% of HCP reported receiving seasonal influenza vaccine, with only 37% reporting having received the pandemic A/H1N1 vaccine. The lack of significant progress in vaccination rates in recent years, coupled with the success of mandatory policies in a growing number of healthcare facilities, points to the importance of providing states with model legislation in this area. As such, we support the Plan's efforts to provide states who wish to legislate in this area with models for mandating influenza vaccination of HCP.

APIC appreciates the opportunity to provide comments on the draft Tier 2 modules for the HAI Action Plan, and we welcome the opportunity to review and provide input on future documents and tools that will be used in the prevention of healthcare-associated infections. If you have any questions or need additional information, please contact Lisa Tomlinson, Senior Director of Government Affairs, at 202-454-2606 or ltomlinson@apic.org.

Sincerely,



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