Dr. Carolyn Clancy, MD
Director, Agency for Healthcare Research and Quality
540 Gaither Road
Rockville, MD 20850

March 26, 2011

Dear Dr. Clancy:

We would like to comment on the AHRQ draft White Paper regarding MRSA and Surveillance, "Screening for Methicillin-Resistant Staphylococcus Aureus (MRSA)".
http://www.effectivehealthcare.ahrq.gov/ehc/products/228/1008/MRSA_Draft-Report_20120315.pdf

We are concerned that the White Paper is flawed in the analysis of the data and thus the conclusions it makes. This may have a disastrous effect by discouraging institutions from testing high-risk populations for MRSA carriage. Our review found that only four of the White Paper's studies were found to not observe a positive effect with surveillance. We believe the analysis of these four studies is flawed, one was even mis-referenced.

The White Paper's main bias is that the effectiveness of intervention was not a parameter in the ranking of the research papers. This was a major factor in two of only three studies which were ranked as "Good". We feel these two studies (Habarth, 2008, PMID 18334690 & Huskins, 2011, PMID 21488763) had significant flaws in their intervention, which produced their negative results. We strongly recommend that they should not be included in the analysis.

In the Huskins, 2011, study, it can be argued that effective intervention took place in less than 40% of the time. Our analysis found the following:

1) Surveillance test results were not available for five days.
2) Staff compliance with isolation protocols was poor (in the intervention group, gloves were used for a median of 82% of contacts, gowns for 77% of contacts, and hand hygiene after 69% of contacts).
3) In addition, 2993 of the 5434 ICU patients were eliminated from the study because their stay in the ICU was less than 3 days. This would be expected to increase the spread of MRSA in the ICU.

In the Harbarth, 2008 study, it can be argued ineffective intervention also took place. Our analysis found the following:

1. 44% of the patients in the study did not have surgery.
2. 120 patients (31% of carriers having surgery) were identified as MRSA carriers after surgical intervention but were included in the analysis.
3. Only 43% of the patients who were known to be MRSA carriers before surgery received appropriate antibiotics against MRSA.
4. Carriers were only placed in a, "flagged side or single rooms whenever available".
5. There is a question if the medical staff reliably follows institutional protocols with the article commenting that "especially in abdominal surgery, surgeons were reluctant to add vancomycin to the standard prophylactic regimen".

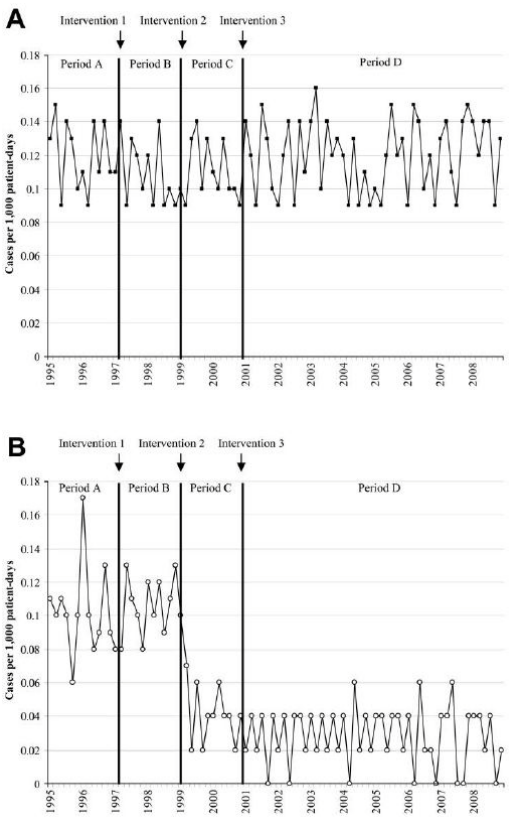
One has to wonder if not giving preoperative antibiotics effective against MRSA to patients known to be colonized with MRSA even violates basic standards of care.

In contradistinction, it can be argued that the Harbarth study even supports the need for surveillance since:

1) 5.1% of the patients who had MRSA on screening developed 43% of the MRSA infections.
2) All of the 26 patients who were identified as MRSA carriers on an outpatient basis underwent decolonization and had adequate prophylaxis. None of these patients developed an infection.

In addition, Leonhardt, et al., (2011, PMID 21768764) was listed as not showing a decrease in MRSA infections when the study actually found a decrease in MRSA infections from 0.27% to 0.15% comparing Universal Screening vs. Targeted Screening or a decrease of 44.4%. The main reason this study did not reach significance was because the experimental group was from a small hospital (167 beds) and the study's N was too small.

Of additional interest is the study of Rodriguez-Bano, et al., (2010, PMID 19845694). We believe this is a wrong reference since it does not deal with surveillance. The correct reference should be Rodriguez-Bano, et al., (2010, PMID 20524852). This article observed a significant decrease in both MRSA acquisition ($P < 0.001$) and bacteremia ($p < 0.01$). "The MRSA bacteremia rate decreased by 80%, whereas the rate of bacteremia due to methicillin-susceptible S. aureus did not change." To the right is a drop in MRSA bacteremia observed in Rodriguez-Bano, et al. (Period C represents the time period when active MRSA surveillance in patients and healthcare workers were performed in units where there was MRSA transmission. A: Shows no decrease in MSSA bacteremia, B: is the decrease found in MRSA Bacteria. Reference: Rodríguez-Baño J, et al. Figure 2, Infect Control Hosp Epidemiol. 2010 Aug;31(8):786-95.)



We would recommend the following changes:

1) The studies of Habarth, et al., (2008, PMID 18334690 and Huskins, et al. (2011, PMID 1000373) should be eliminated from the data analysis along with being deleted from Tables 1, 6, 8, and 10.
2) Table 4 should list the study of Loenhardt, et al. as NS with a downward arrow.
3) The Reference to the article of Rodriguez-Bano, et al. needs to be corrected.
4) Table 10 needs to be corrected to list the results of Rodrigues-Bano, et al. to be significant and showing a decrease (downward arrow) in MRSA bacteremia and acquisition.

All of the research studies used to formulate the AHRQ draft White Paper's conclusion showed a decrease in MRSA transmission or infection when effective (eliminating the studies of Harbarth, et al, and Huskins, et al.) MRSA surveillance, isolation/decolonization was instituted. We feel this white paper provides strong evidence in favor of surveillance; and we strongly urge AHRQ and the CDC to take an active role in setting standards, which include at a minimum surveillance for all high-risk populations, preoperative patients and patients admitted to the ICU for the prevention of MRSA. Universal surveillance with effective isolation and intervention should also be performed on all patients entering a facility from communities with a high MRSA colonization rate in the general population.

As pointed out by Andreas Vos (BMJ, 2004, PMID:15345601): "Randomised controlled trials are useful for investigating a limited number of variables and when randomisation can be accomplished. Infection control measures are habitually complicated and depend on multiple factors. Therefore I still have some faith in the strength of common sense, microbiological experiments, and careful observation of success and failure when evaluating infection control measures."

After all, it took decades of research and arguing with the tobacco industry regarding the validity of studies which demonstrated health risks associated with tobacco use before effective action was taken that limited sales and secondhand smoke exposure. Despite the flaws that exist in biomedical research, Surgeon General Dr. Luther Terry acted much earlier and in 1964 determined that smoking is dangerous to your health. We strongly urge AHRQ to follow suit and set standards, calling for surveillance to be used as a major tool in combating the epidemic of healthcare associated infections.

Thank you for this consideration,

Kevin T Kavanagh, MD, MS, FACS (Board Chairman)
Helen Bukulmez, JD (Health Policy Analysist)
Health Watch USA
Somerset, KY
Phone 606-875-3642
healthwatchusa@gmail.com

Kathy Day, RN
Patient Safety Advocate
McCleary MRSA Prevention
www.mcclearymrsaprevention.com
Bangor, Maine

Michael Bennett
President the Coalition for Patient's Rights
Author of "My Father, An American Story of Courage, Shattered Dreams and Enduring Love."
Baltimore, MD
www.coalitionforpatientsrights.org

Julia A Hallisy, DDS
President
The Empowered Patient Coalition
www.EmpoweredPatientCoalition.org
San Francisco, CA

Jean Rexford
Connecticut Center for Patient Safety
PO Box 231335
Hartford, CT 06123-1335
http://www.ctcps.org/

Kerry O'Connell
Consumer Advocate
Denver, CO 80238

Lori Nerbonne, RN, BSN
6 Fieldstone Drive
Bow, NH 03304
New Hampshire Patient Voices
www.nhpatientvoices.org

Pat Mastors
Patient Advocate
Founder & CEO, Pear Health LLC
www.thepatientpod.com

Suzan Shinazy RN
Patient Advocate
Napa, CA.

Alicia R. Cole
Hospital-acquired Infection Survivor
Alliance for Safety Awareness for Patients
Sherman Oaks, Ca 91403
www.PatientSafetyASAP.org

Nancy Oliver
Patient Safety Advocate
Cincinnati, Ohio

Alan Levine
Health Care Advocate
Washington, DC

Jeanine Thomas
Founder/National Spokesperson for MRSA Survivors Network
Hinsdale, IL
http://www.mrsasurvivors.org/

Lisa McGiffert
Manager, Consumers Union Safe Patient Project
Austin, TX
lmcgiffert@consumer.org

Mary Brennan-Taylor
Patient Safety Advocate and daughter of MRSA victim Alice Brennan
Lockport, New York

Robert E. Oshel, Ph.D,
Retired Associate Director for Research and Dispute
National Practitioner Data Bank
Silver Spring, Maryland

Yanling Yu, Ph. D & Rex Johnson
Washington Patient Safety Advocates
Seattle, WA 98155

Patty Skolnik
Executive Director
Citizens for Patient Safety
Denver, CO 8023

Lee Tilson, JD
Patient Advocate, Attorney
4141 Commonwealth
Detroit, MI
www.rethinkingpatientsafety.com

Copies Sent To:

Donald Wright, MD, MPH -- Deputy Assistant Secretary for Healthcare Quality, Office of the Secretary, US Dept. HHS

Stephanie Chang, MD, MPH -- Director, Evidence-based Practice Program, Center for Outcomes and Evidence, AHRQ

Nancy Wilson, MD, MPH -- Joint Senior Advisor to Agency for Healthcare Research and Quality (AHRQ) and to the Office of the Secretary, US Dept. HHS

Stephanie Chang, MD, MPH -- Director, Evidence-based Practice Program, Center for Outcomes and Evidence, AHRQ

Jean Slutsky, PA, MSPH -- Director, Center for Outcomes and Evidence, AHRQ

Supriya Janakiraman, MD, MPH -- Task Order Officer, Center for Outcomes and Evidence, AHRQ