



# Health Watch USA<sup>sm</sup> Newsletter

[www.healthwatchusa.org](http://www.healthwatchusa.org) Oct. 1, 2017

Member of the National Quality Forum and a designated  
"Community Leader"

for Value-Driven Healthcare by the U.S. Dept. of Health and Human Services

## Healthcare Acquired Infections



### **New Study By Lead Author of The Reduced MRSA Study Finds Chlorhexidine Bathing Did NOT Lower MRSA on General Hospital Floors, Except in Patients With Medical Devices.**

Healio Infectious Disease News: "We found that, in general units outside the ICU, only patients with central lines and other medical devices derived a benefit from chlorhexidine bathing, researcher Susan S. Huang, MD, MPH, from the University of California, Irvine School of Medicine, told Infectious Disease News. (Dr. Huang was the lead author on

the REDUCE MRSA Study which popularized unit-wide daily chlorhexidine bathing in the ICU setting.) <https://www.healio.com/infectious-disease/mrsa/news/online/%7B91bde5c-d4c7-426d-97f7-b42169472618%7D/daily-chlorhexidine-does-not-reduce-mrsa-vre-in-lower-risk-patients>

HW USA does not feel these results are surprising. One of the fundamental articles regarding chlorhexidine bathing was the REDUCE MRSA study which has significant concerns regarding the integrity of this research and was a topic of Reuters New Agency by Pulitzer Prize winning investigative reporter Deborah Nelson. <http://www.reuters.com/investigates/special-report/usa-superbugs-research/>

Links to Health Watch USA's peer-reviewed articles and presentations on the REDUCE MRSA Study can be found at the end of this newsletter. BAD DATA - BAD POLICY - DEAD PATIENTS

## Medical Devices



Picture of a Hip Implant showing multiple areas of chromium cobalt corrosion. Corrosion such as this can be associated with elevated cobalt levels and encephalopathy. [Click on the picture to enlarge.](#)

### **Hip Implant Adverse Events - FDA PEAC Committee.**

Linda Radach testifies before the FDA Patient Engagement Advisory Committee on the dangers of chromium cobalt hip implants along with patient safety

concerns with the FDA medical device approval process and post market adverse event reporting..  
Oct. 12, 2105 YouTube Video: <https://youtu.be/HbBtNXVpcek>

**Medical Device Presentations:**

- 1) Dr. Stephen Tower, Complications of Wear or Corrosion of Chromic-Cobalt Hip Implants. Health Watch USA Conference. Nov. 4, 2016. YouTube Video: <https://youtu.be/CpaQliphWAM>
  
- 2) Amanda Rusmisell, The Essure Problems Group and Dangers Associated With the Essure Contraceptive device. Health Watch USA Meeting. Jan. 18, 2017. YouTube Video: <https://youtu.be/zSVe5MQLTeA>
  
- 3) Hooman Noorchashm MD, PhD on the morcellation disaster: A root cause analysis and perspective. YouTube Video: <http://youtu.be/n6226ic0Mpk>

## HW USA OpEd Healthcare Reform

Lexington Herald Leader: "The answer to healthcare reform is simple, you must lower health care costs. Either instill true provider competition or give more power to the purchasers with a variation of a single-payer system. In our present political climate, a pragmatic solution may be Medicare-Advantage-For-All." <http://www.kentucky.com/opinion/op-ed/article180025376.html>



Lexington Herald Leader: "Some regular community contributors to the Herald-Leader Opinion pages attended a March luncheon. Seated left to right: Rick Maynard, Remi Bellocq, Dr. Kevin Kavanagh, Teri Carter and Jillean McCommons. Standing left to right: Mike Rivage-Seul, John Barber, Ron Formisano, Marty Solomon, Roger Guffey, Larry Webster and Richard Dawahare." [Click on the picture to enlarge.](#)

Read more here: <http://www.kentucky.com/opinion/op-ed/article155755144.html>

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## Health Watch USA's 2017 Healthcare Quality & Patient Safety Conference



### The Setting Of Strong Quality Standards & Research Integrity

Nov. 3rd, 2017 at the Four Points Sheraton, Lexington, KY

**Speakers to Include:**

- Joycelyn Elders, MD: Past U.S. Surgeon General

- Deborah Nelson: Pulitzer prize winning investigative reporter presenting on conflicts-of-interest and infectious disease policy. Associate Professor Investigative Journalism. University of Maryland.  
Resume: <https://merrill.umd.edu/about-merrill/staff-faculty/deborah-nelson/>
- Ivan Oransky, MD -- Distinguished Writer in Residence, New York University & Co-Founder of "Retraction Watch" presenting on Characteristics and Findings of Retracted Peer-Reviewed Scientific Manuscripts.  
Resume: <https://journalism.nyu.edu/about-us/profile/ivan-oransky-md/>
- Lisa McGiffert, Consumer Union's Safe Patient Project, presenting on Patient Safety and Healthcare Accountability.  
Resume: <http://consumersunion.org/experts/lisa-mcgiffert/>

To register for the event go to: <http://www.healthconference.org/payment.htm>

To download the brochure: [http://www.healthconference.org/2017conference\\_downloads/Brochure.pdf](http://www.healthconference.org/2017conference_downloads/Brochure.pdf)

For more information go to: [www.healthconference.org](http://www.healthconference.org)

**Presentation videos for the 2016 Conference are now online.**

To view the conference presentations: Go To:

[https://www.youtube.com/playlist?list=PLKKV6p\\_etRmPhxndxzrvt7yeE-ICUmqzK](https://www.youtube.com/playlist?list=PLKKV6p_etRmPhxndxzrvt7yeE-ICUmqzK)

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## Health Watch USA Articles and Presentations Regarding the Reduce MRSA Study and Research Integrity - BAD DATA - BAD POLICY - DEAD PATIENTS

### Peer Reviewed Articles on Integrity Concerns with the REDUCE MRSA Study.

1. A Perspective on How the United States Fell Behind Northern Europe in the Battle Against Methicillin Resistant Staphylococcus Aureus. Antimicrobial Agents and Chemotherapy. (Ahead of Print. Oct. 7, 2013.) Dec. 2013 57(12):5789-5791. PMID: 24100502 <http://aac.asm.org/content/57/12/5789.full.pdf>  
  
Reply to "Planned Analyses of the REDUCE MRSA Trial" Kevin T. Kavanagh, Daniel M. Saman and Yanling Yu Antimicrob. Agents Chemother. 2014, 58(4):2486. DOI: 10.1128/AAC.02821-13. <http://aac.asm.org/content/58/4/2486.long>
2. Viewpoint: A response to "Screening and isolation to control methicillin-resistant Staphylococcus aureus: sense, nonsense, and evidence", Antimicrobial Resistance and Infection Control 2015, 4:4 (5 February 2015) <http://www.aricjournal.com/content/pdf/s13756-015-0044-9.pdf>
3. A perspective on the principles of integrity in infectious disease research. Journal of Patient Safety. Mar. 24, 2016. [http://journals.lww.com/journalpatientsafety/Fulltext/2016/06000/A\\_Perspective\\_on\\_the\\_Principles\\_of\\_Integrity\\_in.1.aspx](http://journals.lww.com/journalpatientsafety/Fulltext/2016/06000/A_Perspective_on_the_Principles_of_Integrity_in.1.aspx)

4. Kavanagh KT, Abusalem S, Calderon LE. The incidence of MRSA infections in the United States. Is a more comprehensive tracking system needed? Antimicrobial Resistance and Infection Control. April 7, 2017. Free Access: <https://aricjournal.biomedcentral.com/articles/10.1186/s13756-017-0193-0>

## **Presentations Regarding Integrity Problems With The REDUCE MRSA Study.**

1. Kevin Kavanagh, MD, MS provides a short comment on chlorhexidine research integrity, WHO recommendations for surgical antisepsis and FDA medical device approval. Presidential Advisory Council on Combating Antibiotic Resistant Bacteria (PACCARB) - Sept 14, 2017  
<https://youtu.be/W1XHZqqVuhs>  
Written Comment: <http://www.healthwatchusa.org/HWUSA-Presentations-Community/PACCARB-WrittenComments/20170914-Written-Comment.pdf>
2. Kavanagh KT. Health Watch USA Comments on chlorhexidine, surveillance and public disclosure of conflicts of interest in the confrontation of the antibiotic bacterial resistance epidemic. Presidential Advisory Council for Combating Antibiotic Resistant Bacteria. Mar. 30, 2016. Washington, DC.  
YouTube Video: <https://youtu.be/iG1aQZftqb0>  
Written Comment: <http://www.healthwatchusa.org/HWUSA-Presentations-Community/PACCARB-WrittenComments/20160330-Written-Comment.pdf>
3. Kavanagh KT. MRSA Surveillance, Concerns Regarding Chlorhexidine and Bacterial Resistance. SFAR (Stakeholder' Forum in Antibiotic Resistance) Conference. Oct. 9, 2014. Philadelphia, PA. YouTube Video <https://youtu.be/MC7ztSASvuc>
4. Kevin T. Kavanagh, MD - Board Chairman of Health Watch USA discusses the current status of MRSA Epidemiology, Surveillance and Chlorhexidine. Health Watch USA Conference; Nov. 10, 2014. <http://youtu.be/dgsQatT4f8l>

There have been other concerns regarding chlorhexidine usage. These have included NQF recommendations:

- Conflict of Interest, Dr, Charles Denham and the Journal of Patient Safety. J Patient Saf. 2014 Dec;10(4):181-185. PubMed PMID: 25408235.  
[http://journals.lww.com/journalpatientsafety/Fulltext/2014/12000/Conflict\\_of\\_Interest,\\_Dr\\_Charles\\_Denham\\_and\\_the.1.aspx](http://journals.lww.com/journalpatientsafety/Fulltext/2014/12000/Conflict_of_Interest,_Dr_Charles_Denham_and_the.1.aspx)

Finally, concerns regarding numerous studies which have compared Chlorhexidine plus Alcohol to Iodine alone. In addition, the WHO meta-analysis appears to to have serious integrity questions. View Presentation:

- Matthias Maiwald, MD, discusses research integrity problems with research on the efficacy of the antiseptic chlorhexidine. Specific topics relate to incomplete reporting of methodology, errors in data interpretation, clinical equipoise and bias in meta-analyses. Specific attention is given to WHO indications for the surgical antisepsis. YouTube URL: <https://youtu.be/8YDMQjjnn7g>

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