
MRSA SURVIVORS NETWORK

FDA STAPH WORKSHOP

September 5, 2014

Jeanine R. Thomas

Founder/ President

MRSA Survivors Network

Why Use Active Detection and Isolation to Reduce MRSA Infections ?

*Over 300 evidence-based studies and over 500 Abstracts support ADI

*Entire Countries use ADI:

Scandinavia, W. Australia & the Netherlands (<1% prevalence)

Why Use Active Detection and Isolation to Reduce MRSA Infections ?

Only two major studies with arguably poor designs. STAR*ICU and the JAMA-Swiss Study found Surveillance did not work.(1)

Compared to numerous before and after studies (1) along with well controlled studies out of Northwestern University (2) and Geneva Switzerland (3) which found surveillance to be vital in the prevention bundle.

1. Kavanagh KT, et al. PMID 24100502
2. Robicsek A, et al. PMID 18347349
3. Lee AS, et al. PMID 24056477

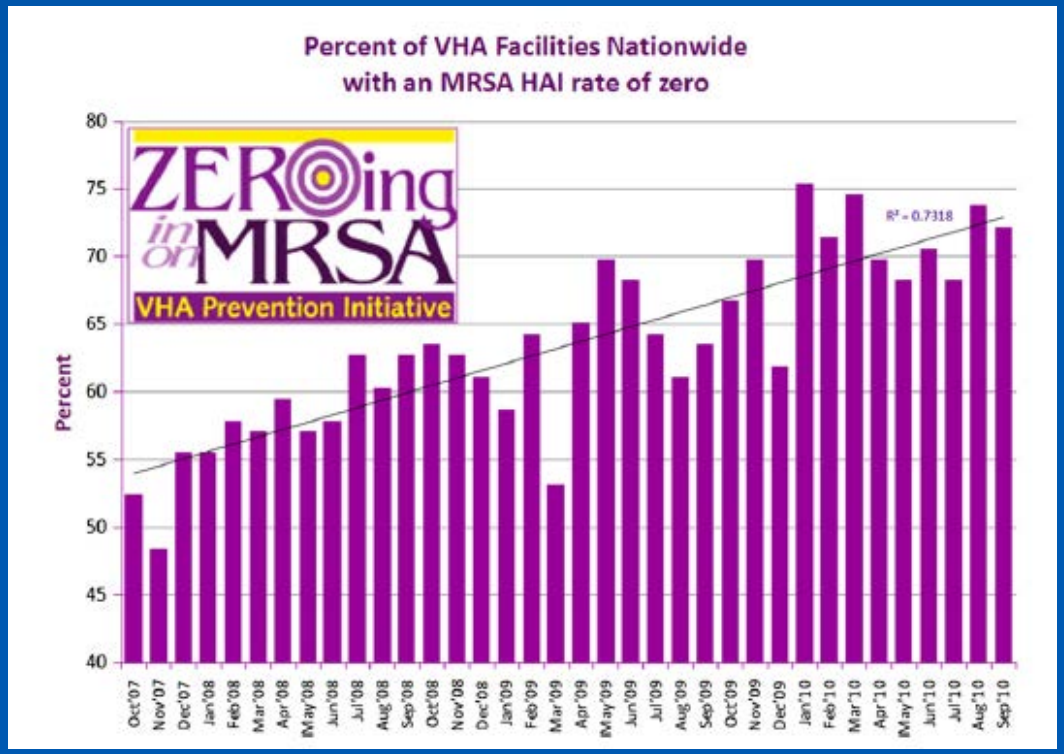
MRSA Testing Issues - US

- Northern Europe has <5% of *S. aureus* represented by MRSA; 50% in the US
- During last 10 years US guidelines did not consider active screening as essential
- By 2012, 59% of hospitals perform screening
- CDC recommends CRE and HIV screening
- AHRQ published comprehensive review (2013)
  - ~~2~~ 1 reports showed no screening benefit
  - 41 reports showed benefit of screening

KT Kavanagh et al. AAC DOI10.1128/AAC.01839-13, 2013

NorthShore University HealthSystem

VA Healthcare Continued Program



$p<0.0001$ from start to end

- Between 2007 and 2010 there was a 38% increase in the number of hospitals with no MRSA infections

SM Kravolic et al. AJIC 41:456-8, 2013

NorthShore University HealthSystem

Research for the Effectiveness of Chlorhexidine is Controversial

Allegations of Industrial Influence

- Questions of Conflict-of-Interest and Industrial Influence first arose around a major study published in the NEJM (2010) regarding the effectiveness of a chlorhexidene-Alcohol antiseptic. (1,2)
- This study was part of a $40 million Dept. of Justice Settlement with CareFusion and an alleged 11 million dollar kickback. (3)

1. Brian J. Influential patient safety board cut ties with doc before CareFusion kickbacks case. Mass Device. Jan. 22, 2014.
2. Allen M. Hidden Financial Ties Rattle Top Health Quality Group. Propublica. Jan. 28, 2014
3. Department of Justice. CareFusion to Pay the Government $40.1 Million to Resolve Allegations That Include More Than $11 Million in Kickbacks to One Doctor. Jan. 9, 2014.

Change in Metrics Raise Concerns

Changes to NCT00980980 on 2012_06_19

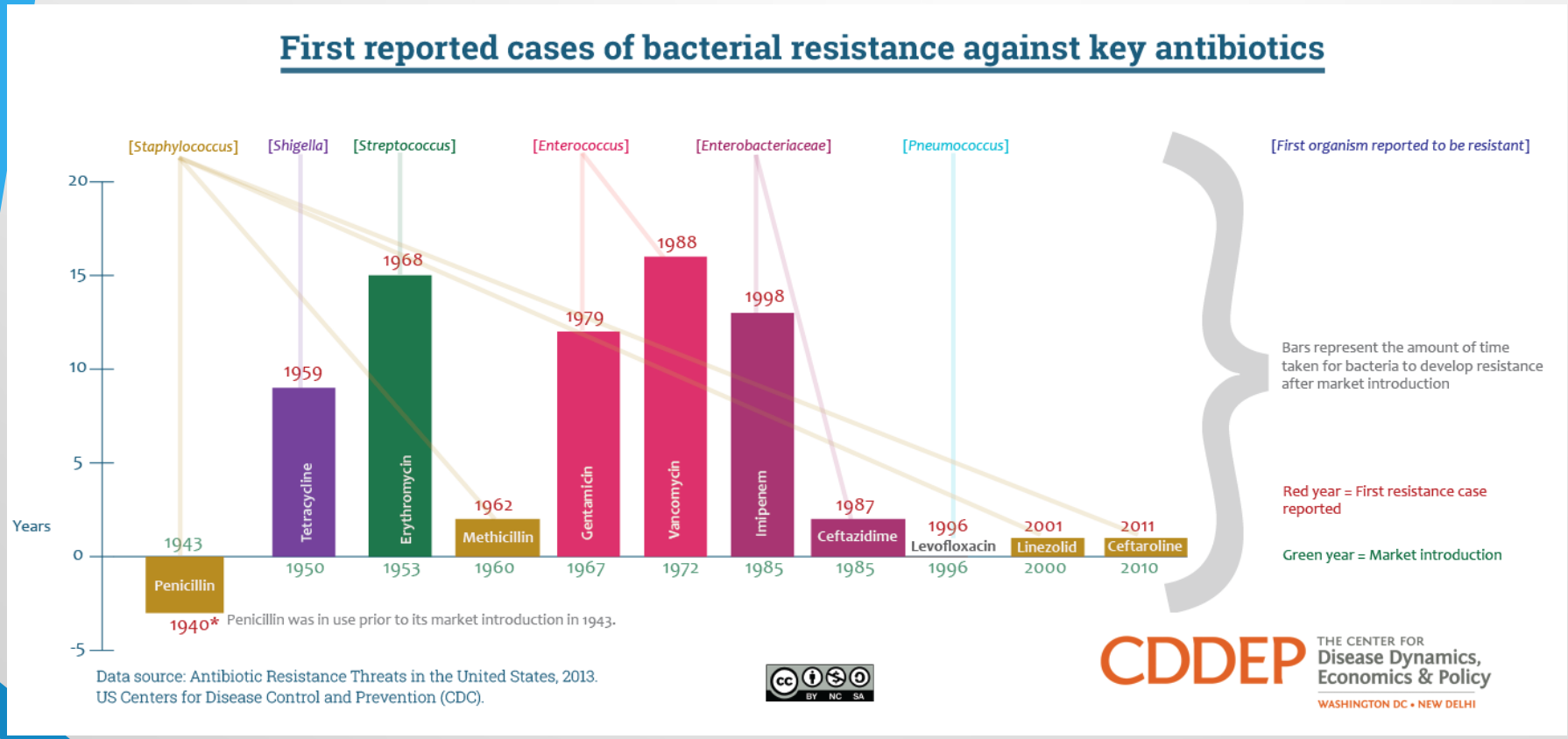
Type of info changed: Protocol, Misc.

	Before (Updated 2011_10_24)	After (Updated 2012_06_19)
1	<clinical_study>	<clinical_study>
	<measure>	<measure>
2	~~Nosocomial~~ MRSA Bloodstream ~~and Urinary Cultures~~	MRSA Bloodstream **Infection**
3	</measure>	</measure>
	<measure>	<measure>
4	~~Routinely reported central line associated blood stream infections (CLABSI).~~	**ICU-attributable All-pathogen Bloodstream Infection**
5	</measure>	</measure>
	<time_frame>	<time_frame>
6	~~18 months~~	**18-months**
7	</time_frame>	</time_frame>
	<last_release_date>	<last_release_date>
8	2011-10-24	2012-06-19
9	</last_release_date>	</last_release_date>
	</clinical_study>	</clinical_study>

From www.clinicaltrials.gov

Bacterial Resistance Concerns

Research for Daily Chlorhexidine Use Has a Real Risk of Worsening Bacterial Resistance



Multiple Studies Are Finding Reduced Susceptibility to Chlorhexidine

Patients bathed daily with chlorhexidine, organisms causing CLABSIs were more likely to have reduced chlorhexidine susceptibility.

Suwantarat N, et al. High prevalence of reduced chlorhexidine susceptibility in organisms causing central line-associated bloodstream infections. Infect Control Hosp Epidemiol. 2014 Sep;35(9):1183-6.

MRSA chlorhexidine resistance is an independent factor predictive of decolonization failure.

Lee AS, et al. Impact of combined low-level mupirocin and genotypic chlorhexidine resistance on persistent methicillin-resistant Staphylococcus aureus carriage after decolonization therapy: a case-control study. Clin Infect Dis. 2011 Jun 15;52(12):1422-30.

Research for Daily Chlorhexidine Use Has a Real Risk of Worsening Bacterial Resistance

- Because Chlorhexidine is used externally it affects the entire microbiome of the facility.
- The extremely drug resistant strain of Klebsiella can develop reduced susceptibility to Chlorhexidine.

Naparstek L, et al. Reduced susceptibility to chlorhexidine among extremely-drug resistant strains of Klebsiella pneumoniae. J. Hosp. Infect. 2012. 81:15–19.

SUMMARY

- WHO's April, 2014 Report on Antimicrobial Resistance (AMR) stated that antibiotic resistance is a major global health threat.

- Universal Decolonization has a real risk of increasing antibiotic resistance and potentially affecting the microbiome of not only the patient but also the facility.

ACTION NEEDED

- We need to study how we can get every single healthcare facility in the U.S. to implement Active Detection and Isolation (ADI) to control MRSA and use rapid testing.
- How much money has been given by different Federal Agencies to study MRSA vs for actual prevention?

SPECIAL THANKS TO

- **Dr. Kevin Kavanagh**
  Health Watch USA
- **Dr. Lance Peterson**
  NorthShore HealthSystems
- **Dr. William R. Jarvis**
  Jason & Jarvis Associates, LLC
- **Dr. Barry M. Farr**
  Professor Emeritus, UVA