

Goal 1: Slow the Emergence of Resistant Bacteria and Prevent the Spread of Resistant Infections

Detect, Protect & Innovate

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Director

National Center for Emerging and Zoonotic Infectious Diseases

Centers for Disease Control and Prevention

Antibiotic Resistance

Some Major Gaps

- Limited national, state, and federal capacity to detect, prevent and respond to urgent and emerging antibiotic resistance threats
- Data on antibiotic use in human healthcare and in agriculture are not systematically collected
- Programs to improve antibiotic prescribing are not widely implemented in the United States
- Currently no systematic international surveillance of antibiotic resistance threats

National Momentum on Antibiotic Resistance

CDC's AR Threat Report (2013)

CDC's FY 15 Detect and Protect Initiative (2014)

National Strategy on Combating Antibiotic-Resistant Bacteria (CARB) & President's Council of Advisors on Science and Technology Report (2014)

CDC's FY 16 Antibiotic Resistance Solutions Initiative (2015)

National Action Plan for CARB (2015)

White House
Antibiotic Stewardship Forum (2015)

Presidential Advisory Council
on CARB (2015)



CDC's Public Health Portfolio for Antibiotic Resistance

Three core activities across AR threats
(healthcare-associated, foodborne, and community pathogens)



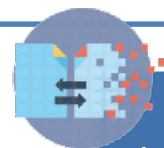
Prevention

- Develop evidence-based guidelines
- Assist in outbreak response
- Implement prevention strategies with states and partners
- Conduct applied research to inform prevention



Stewardship

- Track antibiotic use, especially in healthcare settings
- Provide research tools and guidance on improving antibiotic use
- Improve consumer and provider education



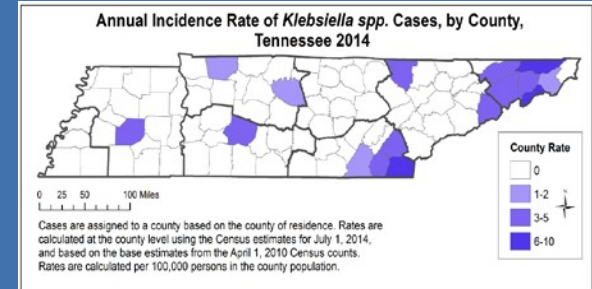
Surveillance

- Implement real-time data systems for tracking and quality improvement
- Define risk populations
- Provide national and international laboratory expertise, testing, and diagnostic capacity

Public Health Infrastructure is Needed for AR Prevention in Healthcare

- Healthcare and public health domains often separate
 - High variability in oversight, surveillance, mutual understanding
- Existing foundation to expand AR prevention:
 - State Healthcare-associated Infections (HAI) Programs and Coordinators
- State health departments can play a unique and critical role in preventing HAI/AR infections

State HAI Antibiotic Resistance Programs: Situational Awareness



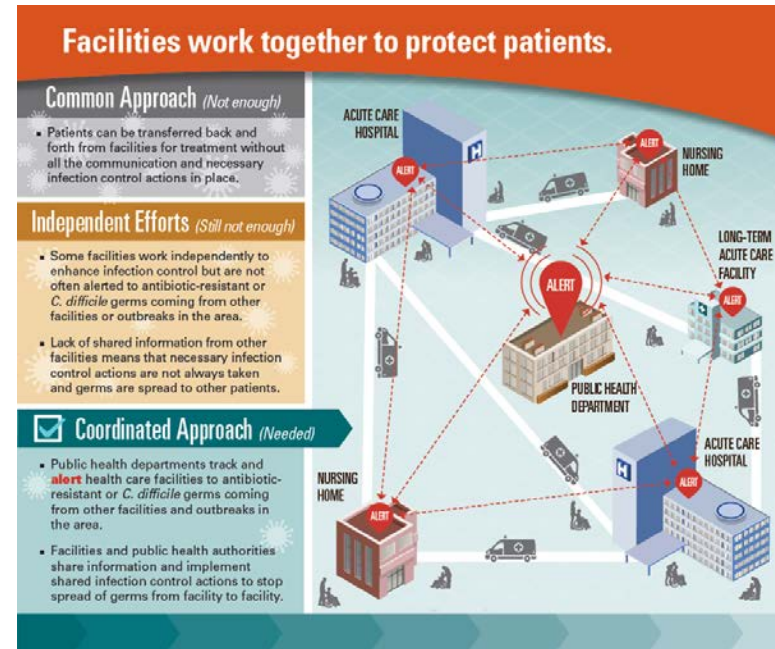
Making Health Care Safer

Stop Spread of Antibiotic Resistance

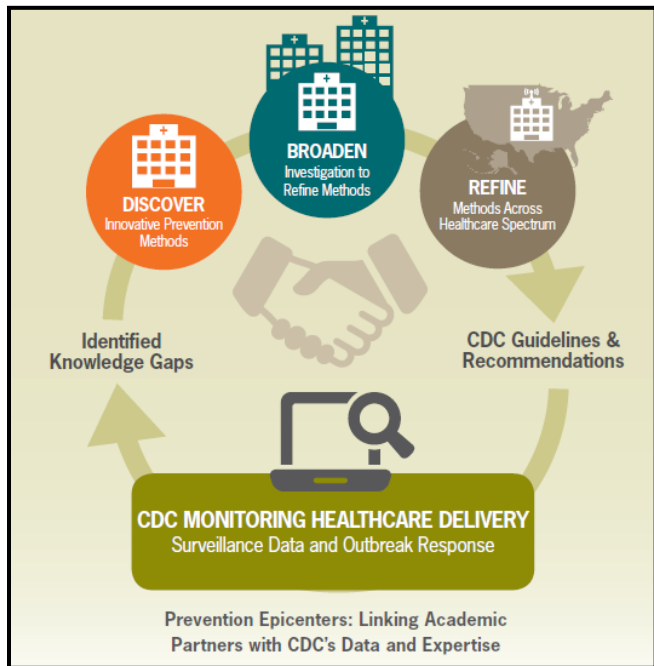
AUGUST 2015

CDC
Vitalsigns™

- Lack of coordination between facilities can put patients at increased risk
 - More patients get infections when facilities do not work together
- Public health authorities and health care facilities should work together to share experiences and connect patient safety efforts
 - Up to 70% fewer patients will get CRE over 5 years if facilities coordinate to protect patients



Innovation in Public Health Intervention: CDC Prevention Epicenters Program

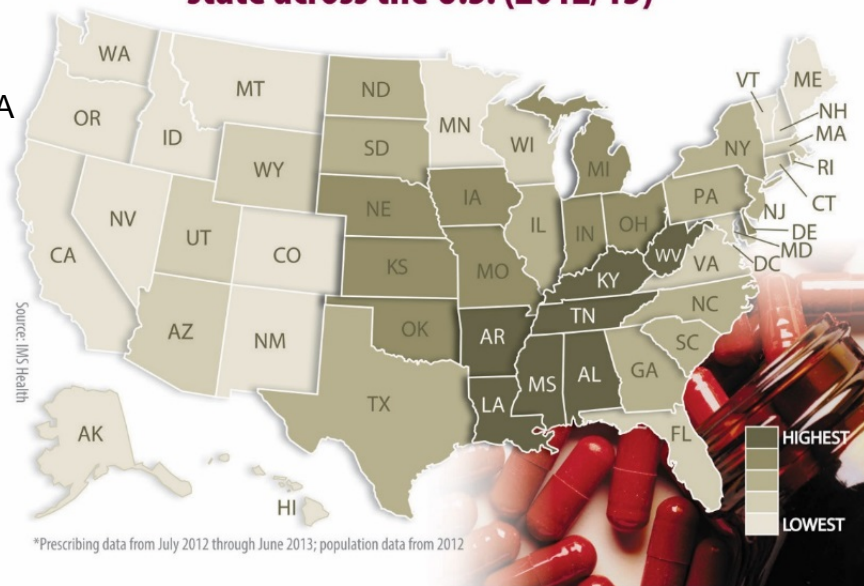


- Unique research program in which CDC collaborates with academic investigators to conduct innovative infection control and prevention research
- This collaboration protects patients by filling prevention knowledge gaps identified by CDC's outbreak response and surveillance data
- Accomplishments:
 - Widespread adoption of bathing with antiseptic soap as a best practice stemming from a CDC Epi-Center-wide trial; novel intervention reduced MRSA risk by nearly 40%, first identified by one CDC Epi-Center
 - Success found in reducing CRE bloodstream infections by 56% in long-term acute care hospitals using a bundled approach of prevention strategies
 - Forthcoming environmental study

Tracking Antibiotic Use

- Evaluating antibiotic prescribing trends and establishing national targets for reducing inappropriate antibiotic use
 - Implement antibiotic stewardship programs in hospitals including the VA
 - Develop clinical decision support for appropriate prescribing in VA outpatient settings
- Implementing hospital reporting of antibiotic use to the National Healthcare Safety Network (NHSN)
 - Developed a risk-adjusted summary measure for antibiotic use, with health system partners, for endorsement by the National Quality Forum
- Implementing HAI prevalence surveys that include assessments of antibiotic use and resistance in hospital and long-term care settings through CDC's Emerging Infections Program

Antibiotic prescribing rates by state across the U.S. (2012/13)*



Tools and Research for Stewardship

- Creating tools and guidance for stewardship, e.g., CDC core elements for antibiotic stewardship programs in hospitals and nursing homes
- Working with partners to support innovation to implement antibiotic stewardship
 - Implement antibiotic “time outs”
 - Work with state health departments, particularly where antibiotic use is highest, to establish new local partnerships to improve antibiotic use



Consumer and Provider Engagement

- White House Forum on Antibiotic Stewardship
 - Over 150 organizations across human and animal health (representing inpatient and outpatient healthcare settings, patient advocates, diagnostic & pharmaceutical manufacturers, food producers & retailers, veterinary societies and organizations)
 - Government-wide collaboration (CDC, AHRQ, CMS, FDA, USDA, DOD, VA) to support implementation and acceleration of National Action Plan
- Annual *Get Smart About Antibiotics Week*
 - Expanded partnerships in 2015
 - Opportunity to follow up on White House Forum commitments to antibiotic stewardship

National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB)

FY 2016 President's Budget

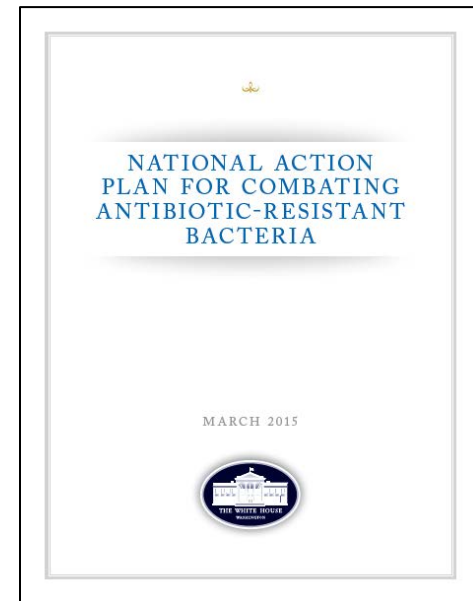
+\$264 million

- State HAI/AR Prevention (Protect) Programs
- Antibiotic stewardship activities
- Detect Network of AR Regional Labs

+\$14 million

- National Healthcare Safety Network (NHSN)

Supports implementation of CDC's activities under the National Strategy and National Action Plan



Thank you

FDA Activities to Slow the Emergence of Resistant Bacteria and Prevent Spread of Resistant Infection (Goal I)

Peter Lurie, MD, MPH
Associate Commissioner for
Public Health Strategy and Analysis
Office of the Commissioner
Food & Drug Administration

September 29, 2015

Overview of FDA Activities Related to AMR

- Surveillance
- Research & development
- *New product development for human drugs*
 - Streamlining regulatory processes
- *Minimizing resistance in veterinary practice and agriculture*
 - Eliminate the use of medically important antibiotics for growth promotion in animals and bring other uses of medically important antibiotics under veterinary oversight
- *Stakeholder Outreach*

New Product Development for Human Drugs

- *Streamline regulatory processes for updating and approving or clearing antibiotic susceptibility testing devices so that clinicians receive up-to-date interpretive criteria to guide antibiotic drug selection (Goal 1.1.5)*
- Updating breakpoints used to categorize patient bacteria as susceptible or resistant to particular antibacterial drugs
- FDA considering the role of Standards Development Organizations
- An FDA website, rather than product labeling, could provide breakpoint information
- FDA providing technical assistance on legislative proposals

Minimizing Resistance Related to Veterinary Practice and Agriculture

- *Implement FDA GFI #213 to eliminate the use of medically important antibiotics for growth promotion in animals and bring other in feed and in-water uses of medically important antibiotics under veterinary oversight (Objective 1.2.1)*
- GFI #213 finalized December 2013; presented a road map for animal drug companies to voluntarily:
 - Remove production indications from the FDA-approved labels for medically important antimicrobial drugs
 - Change marketing status to require Veterinary Feed Directive (VFD); finalized June 2015
- Use for growth promotion/without veterinary oversight will become illegal

Minimizing Resistance Related to Veterinary Practice and Agriculture

- *Optimize public awareness about progress toward eliminating the use of medically important antibiotics for animal-growth promotion (Objective 1.2.4)*
- All animal drug companies have committed in writing to make such changes by December 2016
- 32 of 293 products already withdrawn; 4 have been relabeled
- FDA website lists affected products and current status with periodic updates (updated August 2015)

Minimizing Resistance Related to Veterinary Practice and Agriculture

- *Identify, develop, and revise key agricultural practices that allow timely and effective implementation of interventions that improve animal health and efficient production (Objective 1.3.3)*
- Approximately 30% of medically important antibiotics used in feed and water have at least one use with indefinite duration; this is not consistent with judicious use
- Many of these products are not currently marketed and many may be removed from the market once the changes under Guidance #213 are fully implemented
- For disease prevention, use should be appropriately targeted to animals at risk for a specific disease and duration should be limited and risk-based
- FDA is examining the specific animal health conditions with open-ended or long-term durations and will determine whether alternative approaches are preferable

Stakeholder Outreach

- *Develop and implement educational outreach efforts to ensure that veterinarians and animal producers receive information and training to support and implement changes (Objective 1.2.3)*
- *Develop, implement, and measure the effectiveness of evidence based educational outreach to veterinarians and animal producers to advance antibiotic stewardship and judicious use of antibiotics in agricultural settings (Objective 1.3.1)*
- VFD brochures webinars, website pages, public meetings, stakeholder calls, etc.
- Working on GFI #120: describes the Veterinary Feed Directive (VFD) requirements for veterinarians, feed manufacturers, animal producers, and other parties in Q and A format
- Developing guidance on standardized format for the VFD Form

Stakeholder Outreach

- *Foster collaboration and public-private partnerships with public health, pharmaceutical, and agricultural stakeholders to facilitate identification and implementation of interventions to reduce the spread of resistance (Objective 1.3.2)*
- Engaging with stakeholder groups to develop plans for educating those affected by GFI #213 and the VFD Final Rule
- Consulting with educational institutions to incorporate key elements of GFI #213 into curricula
- Collaborating with USDA/APHIS to develop a VFD training module for the USDA/APHIS veterinary accreditation program
- Engaging with state agencies/organizations (e.g., NASDA, AAVSB, AAFCO)

THANK YOU

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VA



U.S. Department
of Veterans Affairs

Combating Antibiotic-Resistant Bacteria

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and Prevent the Spread of Resistant Infections**

**Gary A. Roselle, MD, FACP,
Director, National Infectious Diseases Service
Veterans Health Administration, VA Central Office**

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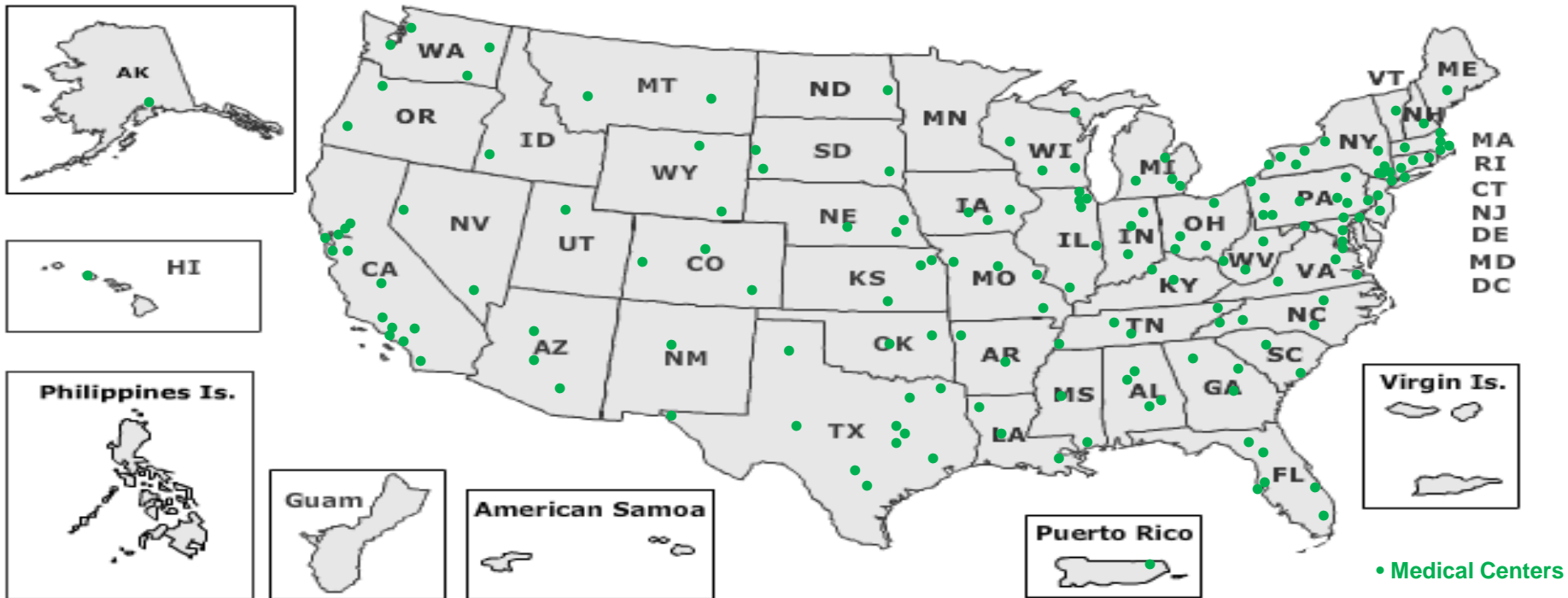
Defining
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Largest Integrated Health Care System in US

Over **1700** sites of care

Over **150** Medical Centers

Serving **8.76 million** veterans a year



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VHA's CARB Goal 1 Efforts

- VHA Multidrug-Resistant Organism Prevention Initiative
 - Taskforce chartered 2007
 - VHA Directive 2010-006
- VHA Antimicrobial Stewardship Initiative
 - Taskforce chartered 2011
 - VHA Directive 1031
- VA Inpatient Evaluation Center (IPEC)
 - Reporting and quality monitoring system established 2005



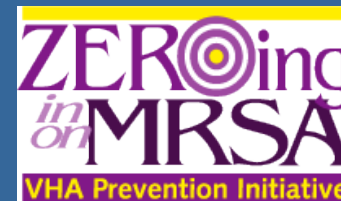


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VHA's Multidrug-Resistant Organism Prevention Initiative

- Methicillin-Resistant *Staphylococcus aureus* Prevention Initiative
 - Acute care October 2007
 - Long term care August 2008
- *Clostridium difficile* Prevention Initiative
 - Acute care March 2012
 - Long term care October 2013
- Carbapenem-Resistant Enterobacteriaceae Prevention Initiative
 - Newest initiative
 - Acute and long term care simultaneously March 2015

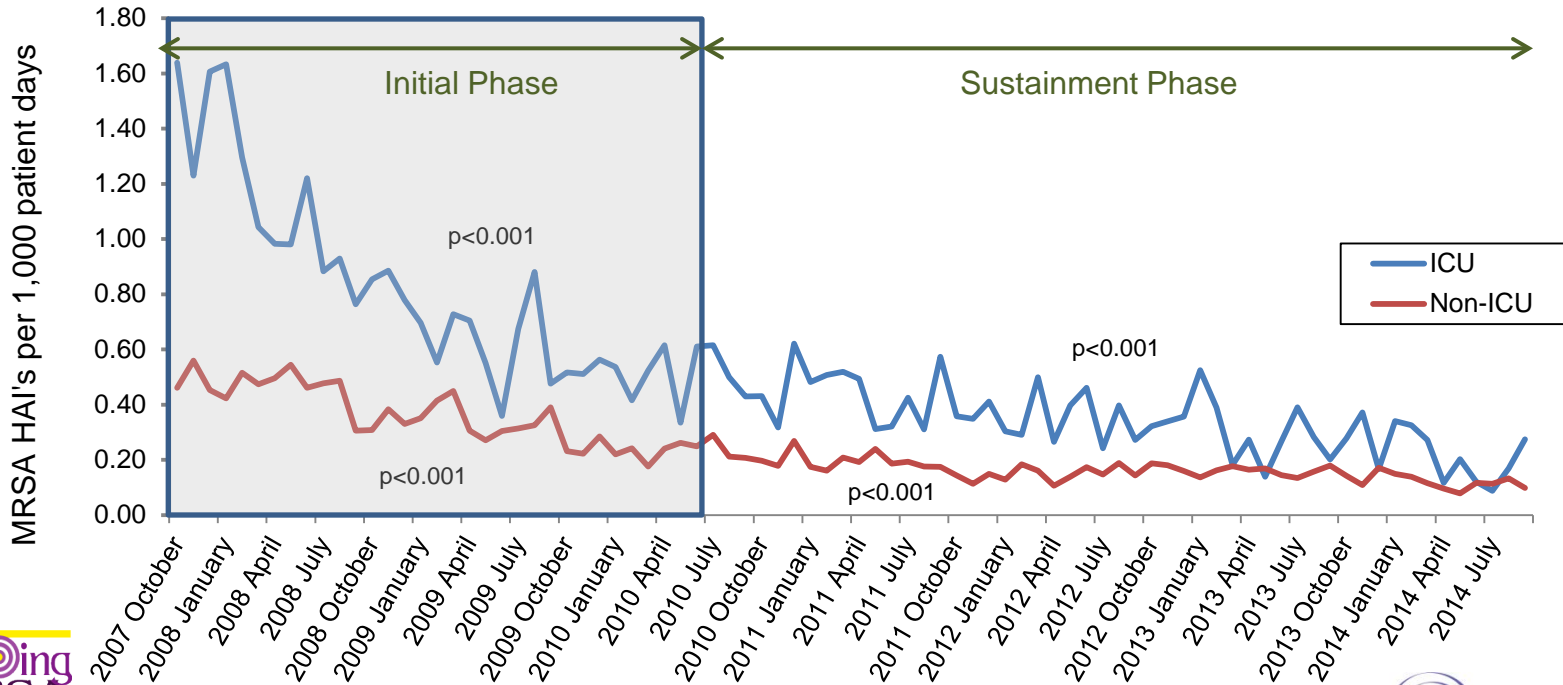


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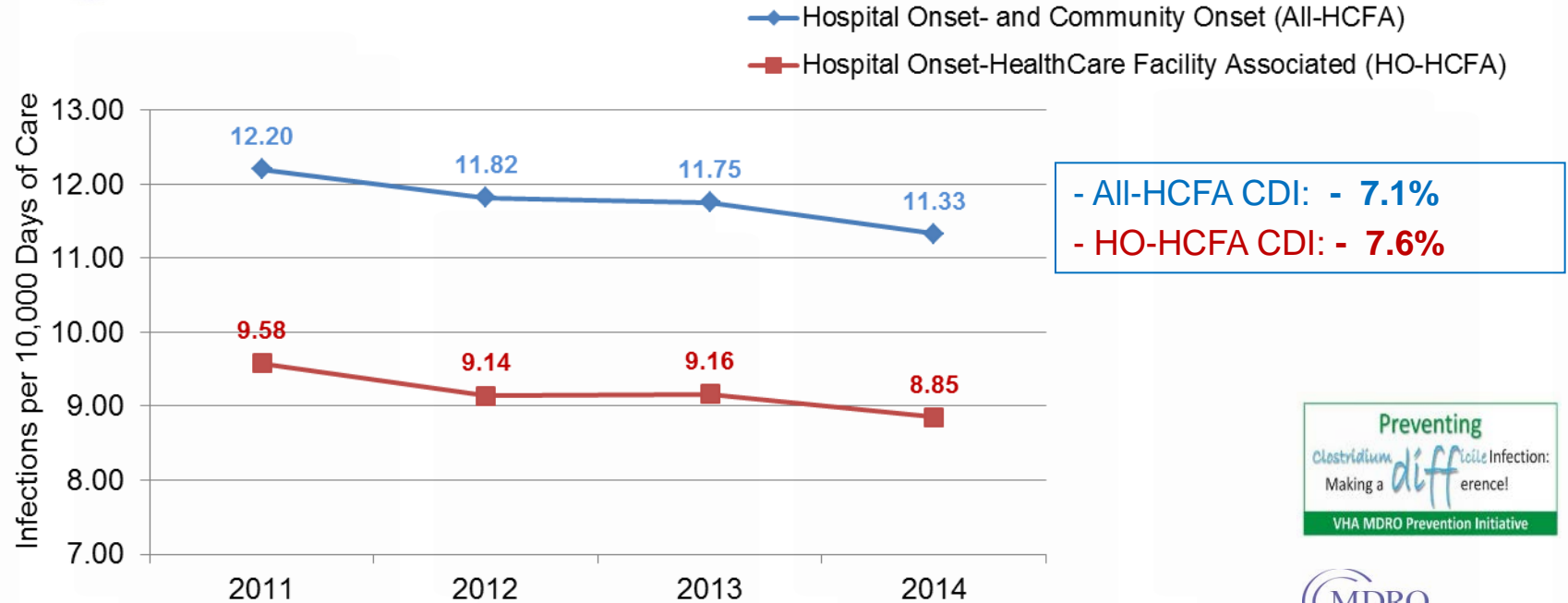


Methicillin-Resistant *Staphylococcus aureus* (MRSA) Healthcare-Associated Infections Oct. 2007 to Sep. 2014





C. difficile Infection Rates by Fiscal Year



From IPEC Data Cubes accessed 9/21/15





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VHA's Antimicrobial Stewardship Initiative

- Highly active National Antimicrobial Stewardship Taskforce
- Development of national resources for local use
 - Monthly educational teleconference series
 - Sanford Guide® On-line
 - Stewardship SharePoint® Site
 - Numerous example policies
- 49 VA facilities successfully reporting to NHSN's Antimicrobial Use module

Example Policies

Multi-disciplinary Antimicrobial Stewardship Business Plan

Intravenous to Oral Conversion Tool

Avoidance of Double Anaerobic Coverage

Intervention to Improve Outcomes for Patients with *C. difficile* Infection

Stewardship Monitoring of Outpatient Parenteral Antimicrobial Therapy

Vancomycin De-escalation

Workload Documentation Guidance

Broad-Spectrum Gram-Negative De-escalation

Pneumonia Duration of Therapy

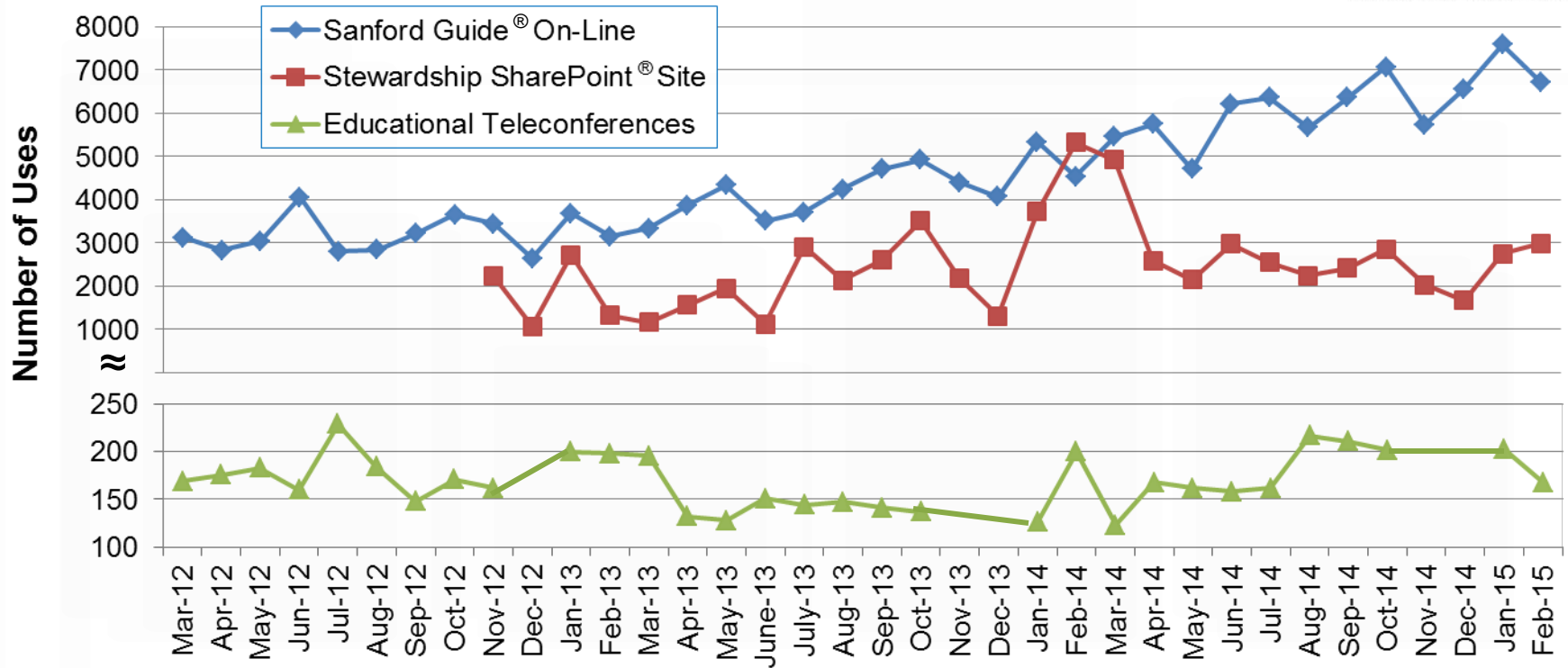
Outpatient Upper Respiratory Tract Infections (URIs)



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Monthly Use of Resources



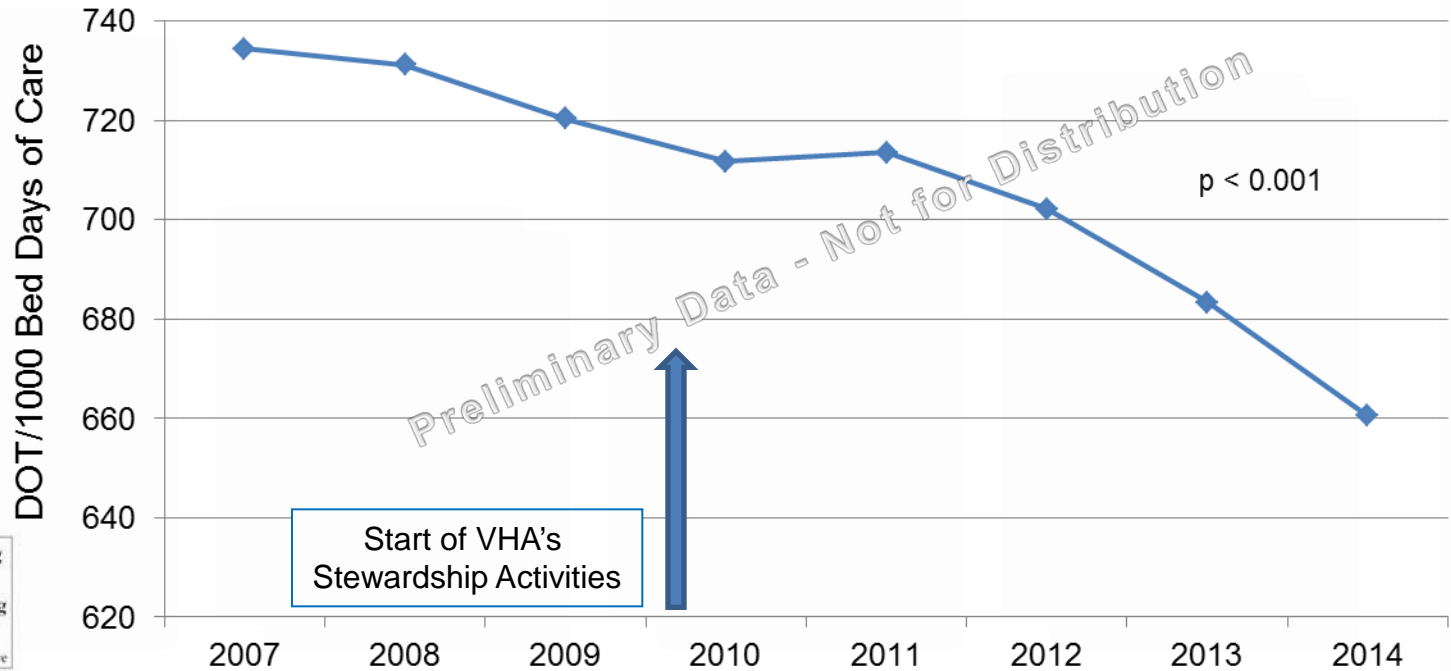
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Inpatient Antibiotic Days of Therapy per 1000 Bed Days of Care by Calendar Year



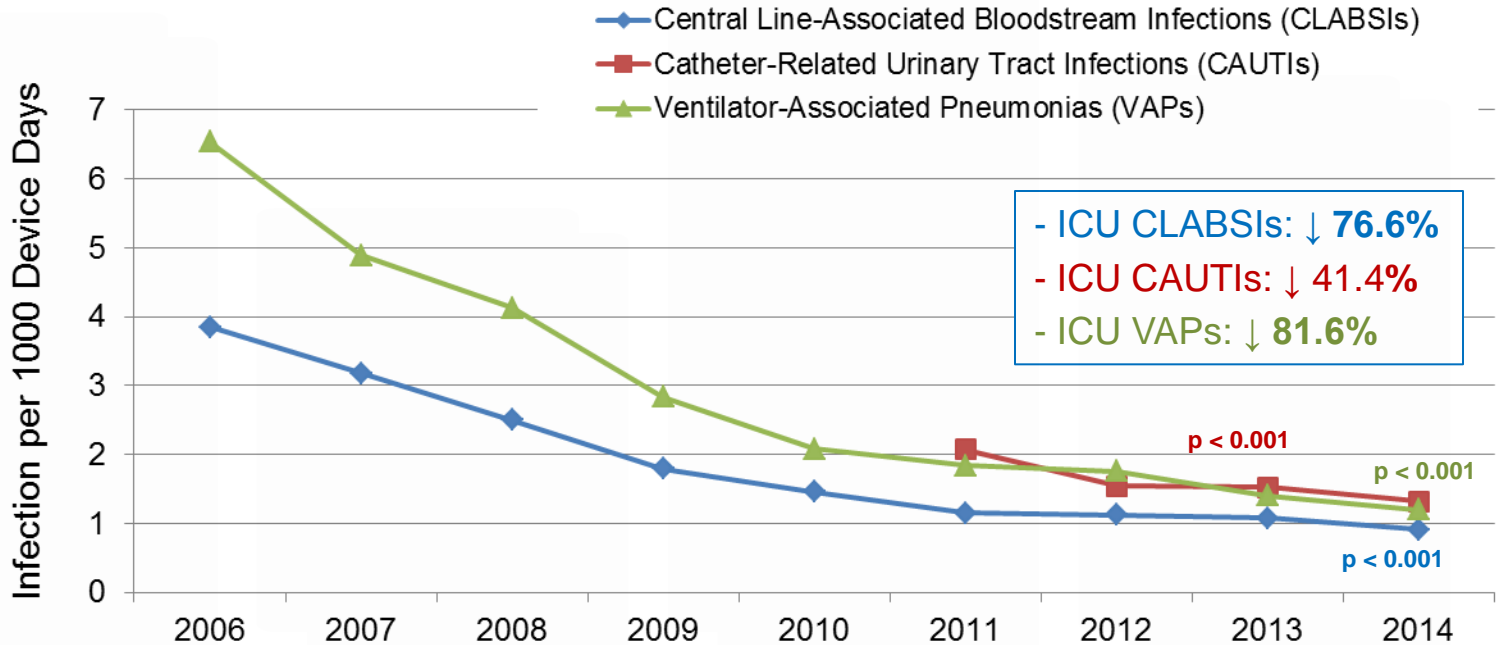
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Intensive Care Unit Device-Related Infection Rates by Fiscal Year



From IPEC Data Cubes accessed May 2015

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VHA's Future Plans

- Targeted guidance for MDROs as necessary
- Expansion of antimicrobial stewardship programs into long term care and outpatient areas of care
- Expand capabilities to share VHA data with key stakeholders

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29 SEP 15

Dr. David Smith

Deputy Assistant Secretary of Defense (Health Affairs)
Health Readiness Policy and Oversight



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Goal 1: DoD

- Broad-spectrum antibiotic usage has been shown to correlate with antibiotic resistance within *E. coli* and *Acinetobacter* spp. infections in the Military Health System (MHS)

Goal 1: DoD

- How best to answer the question of appropriate antibiotic use?
 - Multi-disciplinary Working Group to formalize antimicrobial policy and implementation
 - Analyzing data across system

Goal 1: DoD



- Multidrug-resistant organism Repository and Surveillance Network (MRSN)
 - Confirmatory center for all clinical isolates in DoD
 - Derives outcomes based on lab results & prescribing practices
 - Leading collaborative data linkage efforts with the Department of Veterans Affairs (patient safety and continuity of care)



Goal 1: DoD

- Armed Forces Health Surveillance Center-Global Emerging Infections Surveillance and Response System (AFHSC-GEIS)
 - Public health arm of the Defense Health Agency/DoD
 - Provides platform within the DoD to communicate commitments, data, and analytic summaries
 - Supports MRSN and other partner commitments to Stewardship

THANK YOU

Combating Antibiotic-Resistant Bacteria (CARB)

AHRQ's Contributions to the National Action Plan

Melissa A. Miller, B.S.N., M.D., M.S.

AHRQ

Center for Quality Improvement and Patient
Safety Division of Healthcare-Associated
Infections

AHRQ's Role in CARB

- Support research to develop improved methods for—
 - Reducing transmission of resistant infections
 - Promoting implementation of effective antibiotic stewardship (AS) to prevent the development of resistance
 - Reducing healthcare-associated infections (HAIs) in general
 - Reduce exposure to antibiotic-resistant infections
 - No infection = no need for antibiotic
- Support translation of research findings into tools health care providers can implement in multiple settings

Research Funding

- In 2015, AHRQ more than doubled funding of research supporting CARB-related efforts compared with 2014

Sub-Objective 1.1.4: Develop and pilot new interventions to address clinical and other drivers of emergence and spread of antibiotic resistance and antibiotic misuse.

- **3-year milestone:** AHRQ will sponsor research to develop improved methods and approaches for combating antibiotic resistance and conducting antibiotic stewardship activities in multiple health care settings, with a focus on long-term and ambulatory care centers, as well as acute-care hospitals

Prevention of Transmission

- New and ongoing projects to reduce transmission of—
 - Methicillin-resistant *Staphylococcus aureus* (MRSA) in households
 - *Clostridium difficile* (*C. difficile*) in hospitals
 - Carbapenem-resistant bacteria in hospitals

Antibiotic Use and Stewardship

- New and ongoing projects
 - Antimicrobial use in dialysis units
 - AS interventions in nursing homes
 - Personalizing antibiotic stewardship to the patient

Prevention of Resistant Infections

- New and ongoing projects to prevent or reduce resistant infections
 - Decolonization studies to reduce resistant infections in multiple settings
 - MRSA in long-term care
 - Reduction of *C. difficile* infection by improving appropriate antibiotic use for urinary tract infections in nursing homes

Translation of Research into Tools—AS

- Based on results of four previous studies in long-term care, AHRQ has created a guide for AS in nursing homes
 - Currently field-testing; wide availability 2016

Sub-Objective 1.1.4: Develop and pilot new interventions regarding antibiotic resistance and stewardship

- **3-year milestone:** AHRQ will support translation of research findings into antibiotic-resistance prevention tools that can be implemented by health care providers in long-term and ambulatory care settings as well as in hospitals

Toolkits for Reducing Resistant Infections

- Toolkit for reduction of *C. difficile* infections through antimicrobial stewardship—produced by the ERASE *C. difficile* project
- Carbapenem-Resistant *Enterobacteriaceae* (CRE) Control and Prevention Toolkit

CARB and HAIs

- Every HAI prevented represents—
 - One less episode of antibiotic use, and thus one less opportunity for development of resistance
 - One less exposure to a potentially resistant infection
- AHRQ's HAI Program combines supporting research on HAIs with promoting the wide-scale implementation of proven methods for preventing these infections

AHRQ Safety Programs

CUSP (Comprehensive Unit-based Safety Program) for—

- Central Line-Associated Bloodstream Infections (CLABSI) [completed]
 - Resulted in 41% reduction in CLABSI in >1,000 hospitals and more than 1,800 units
 - Number of units reporting zero rate CLABSI doubled (30% to 68%)
- Catheter-Associated Urinary Tract Infections (CAUTI) in Hospitals
- Surgery
- Ambulatory Surgery Centers
- Mechanically Ventilated Patients
- Long-Term Care

Furthering the CARB Research Agenda

Sub-Objective 1.1.4: 1-year milestone

- AHRQ and CDC will host a meeting of experts and stakeholders to consider knowledge gaps for prevention of antibiotic-resistant HAIs and identify potential interventions
 - AHRQ and CDC are holding regular conference calls for planning
 - Anticipate meeting in spring 2016

Thank You

- AHRQ's HAI Program: www.ahrq.gov/hai
- Questions: Melissa.Miller@ahrq.hhs.gov