

# Antimicrobial Stewardship in the Long-Term Care Setting

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# Disclosures and Present Commitments

Employed by Melinta Therapeutics

Shareholder, Johnson & Johnson and The Medicines Company

Chair, Arizona Department Health Services, Antimicrobial Stewardship Subcommittee

Member, CLSI Subcommittee on Revisions to M39-A4 (approved guideline): “Analysis and Presentation of Cumulative Antimicrobial Susceptibility Test Data”

# A Difficult Task Ahead

Implementing effective antimicrobial stewardship in LTCFs is associated with challenges distinct from those faced by hospitals: generally care for elderly populations who are vulnerable to infection, have prescribers who are often off-site, and have limited access to timely diagnostic testing.

CDC CORE ELEMENTS and TJC Measurements of Performance are nearly identical to those for ACH/CAH, but environments are very different (resources, turnover, front-line HCPs, expertise).

Physicians practicing in LTC will be exposed to similar measures in their local hospitals.

Reinforcement will occur in all healthcare settings, including community and office practices.

Little or nothing significant will happen unless there is leadership from “the top” (my opinion).

Will risk of penalties (expected in 2020 or 2021) provide incentive to change the antimicrobial use culture?

# CDC “Antibiotic Resistance Threats Report” is a valuable resource to identify key pathogens

## U.S. engagement in study of antibiotic resistance

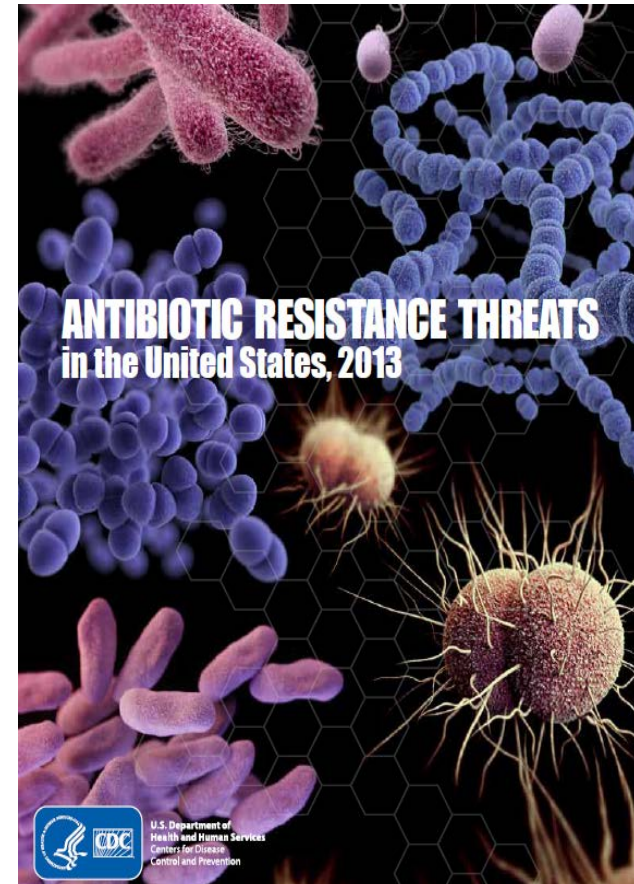
The U.S. Centers for Disease Control and Prevention (CDC) estimates that antibiotic resistance is responsible for more than 2 million infections and 23,000 deaths each year in the United States, at a direct cost of \$20 billion and additional productivity losses of \$35 billion.

Report divided 18 pathogens into “urgent threats” (3), “serious threats” (12), and “concerning threats”.

Assess these for your institution:

- Are they the same target pathogens?
- Utilize graphics in your presentations

Technical and methodological issues may under-estimate incidence, number of infections, and attributable mortality.

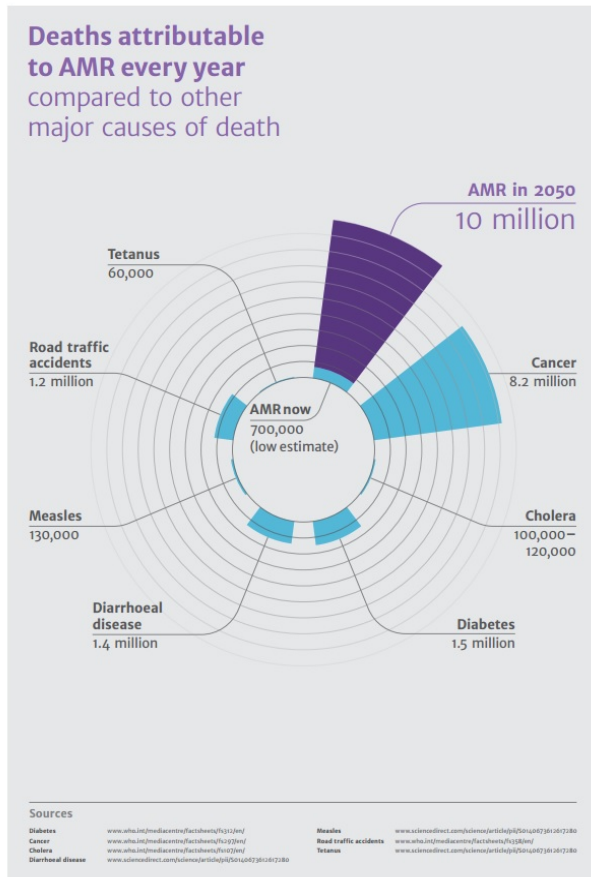


# Concern for antimicrobial resistance is increasing globally

Annual deaths globally due to antimicrobial resistance (AMR) pathogens are expected to exceed the sum contribution from cancer plus diabetes by 2050.

This death rate could result in a reduction of 2% to 3.5% in Gross Domestic Product (GDP) globally; it could cost the world up to 100 trillion USD.

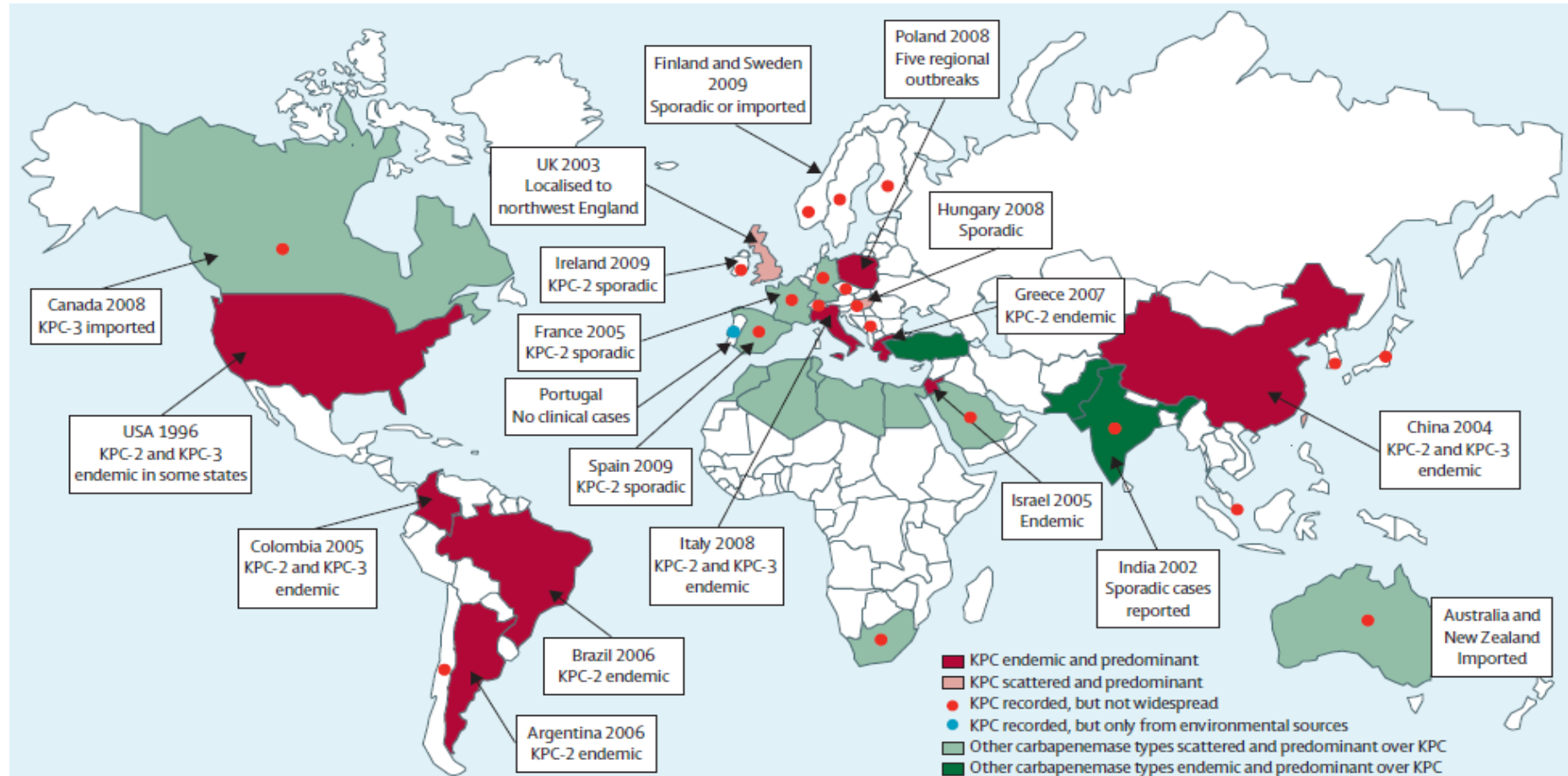
The estimates are conservative and based on studies which examine a subset of drug-resistant bacteria and public health issues which do not consider social and healthcare costs.



Review on Antimicrobial Resistance. Antimicrobial Resistance: Tackling a Crisis for the Health and Wealth of Nations. 2014. Accessed: December 2016. <https://amr-review.org/Publications>

Tackling drug-resistant infections globally: Final report and recommendations. Accessed December 2016 <https://amr-review.org/>

# Epidemiologic features of *Klebsiella pneumoniae* carbapenemases is an example of global surveillance



KPC = *Klebsiella pneumoniae* carbapenemase

Munoz-Price LS, Poirel L, Bonomo RA, et al. *Lancet Infect Dis.* 2013;13:785-96.

# Antibiotic resistance is an adverse drug event

## ASHP definition of an adverse event:

“Any unexpected, unintended, undesired, or excessive response to a drug that: 1) requires discontinuing the drug (therapeutic or diagnostic); 2) requires changing the drug therapy; 3) requires modifying the dose (except for minor dosage adjustments); 4) necessitates admission to a hospital; 5) prolongs stay in a health care facility; 6) necessitates supportive treatment; 7) significantly complicates diagnosis; 8) negatively affects prognosis; 9) results in temporary or permanent harm, disability, or death.”

## FDA definition of a serious adverse event (related to drugs or devices):

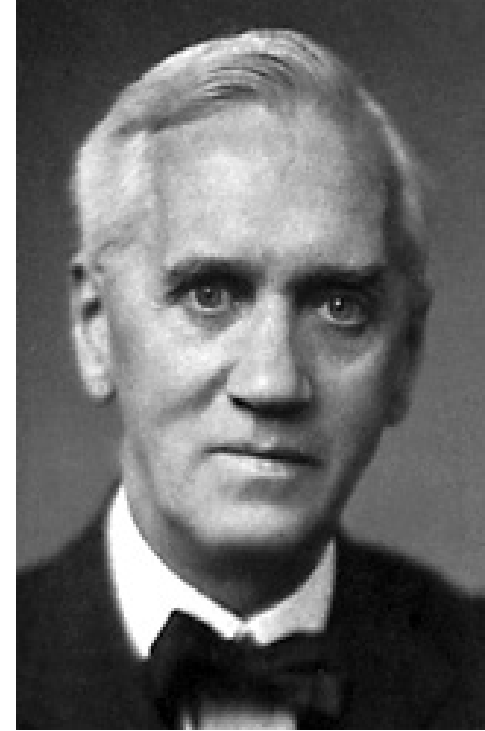
Events in which “the patient outcome is death, life-threatening (real risk of dying) condition, hospitalization (initial or prolonged), disability (significant, persistent, or permanent), congenital anomaly, or required intervention to prevent permanent impairment or damage.”

## World Health Organization (WHO) definition of an adverse drug reaction:

“Any response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function.”

# Words to heed from decades past

“The public will demand [the drug and]...then will begin an era...of abuses. The microbes are educated to resist penicillin and a host of penicillin-fast organisms is bred out which can be passed to other individuals and perhaps from there to others until they reach someone who gets a septicemia or a pneumonia which penicillin cannot save. In such a case, the thoughtless person playing with penicillin treatment is morally responsible for the death of the man who finally succumbs to infection with the penicillin-resistant organism. I hope the evil can be averted”.





# Seven CORE ELEMENTS of antimicrobial stewardship programs

Leadership Commitment

Accountability

Drug Expertise

Actions to support optimal antibiotic use

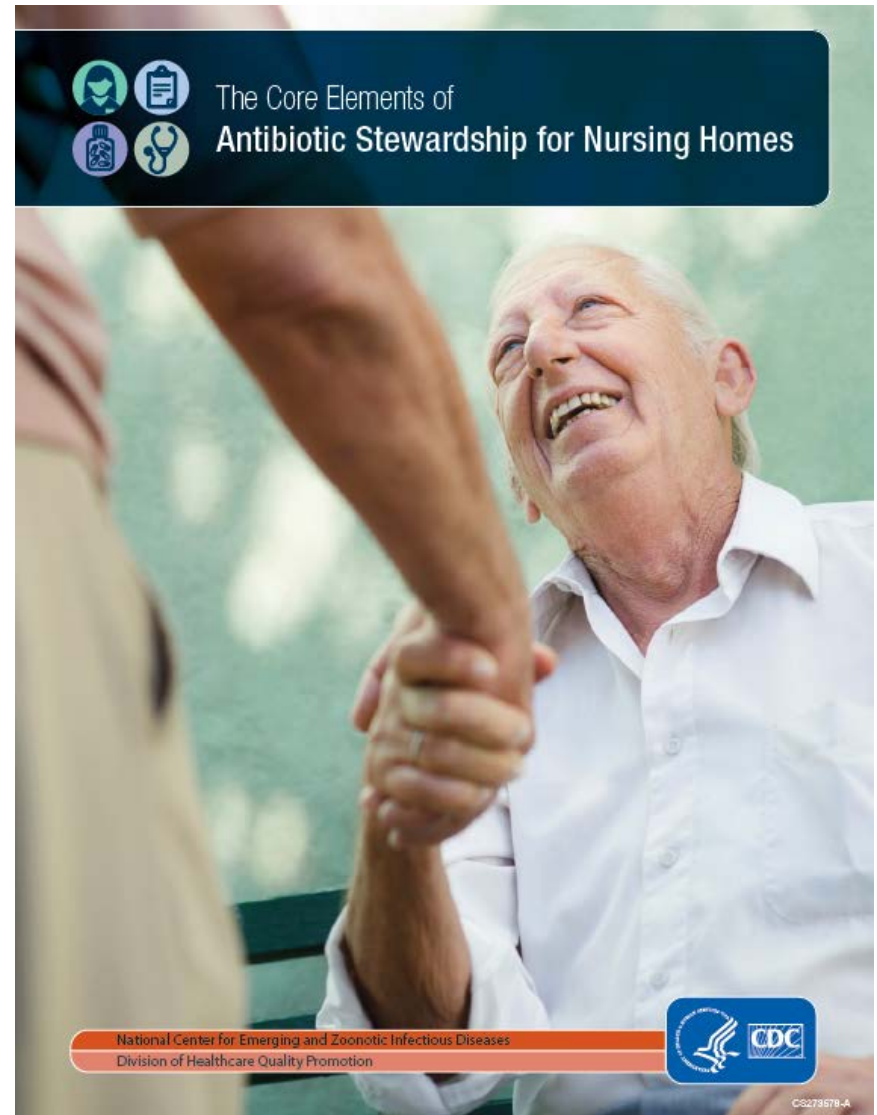
Tracking

Reporting

Education

CDC. The Core Elements of Antibiotic Stewardship for Nursing Homes.  
<https://www.cdc.gov/longtermcare/prevention/antibiotic-stewardship.html>

CDC. Core Elements of Hospital Antibiotic Stewardship Programs.  
<http://www.cdc.gov/getsmart/healthcare/implementation/core-elements.html>.



# National Quality Forum Playbook is an essential guide to overcoming barriers and challenges



## Antibiotic Stewardship in Acute Care: A Practical Playbook

NATIONAL QUALITY FORUM  
NATIONAL QUALITY PARTNERS  
ANTIBIOTIC STEWARDSHIP ACTION TEAM

1. **Leadership Commitment:** Dedicate necessary human, financial, and information technology resources.
2. **Accountability:** Appoint a single leader responsible for program outcomes who is accountable to an executive-level or patient quality-focused hospital committee. Experience with successful programs shows that a physician leader is effective.
3. **Drug Expertise:** Appoint a single pharmacist leader responsible for working to improve antibiotic use.
4. **Action:** Implement at least one recommended action, such as systemic evaluation of ongoing treatment need after a set period of initial treatment (i.e., “antibiotic time out” after 48 hours).
5. **Tracking:** Monitor process measures (e.g., adherence to facility-specific guidelines, time to initiation or de-escalation), impact on patients (e.g., *Clostridium difficile* infections, antibiotic-related adverse effects and toxicity), antibiotic use, and resistance.
6. **Reporting:** Report the above information regularly to doctors, nurses, and relevant staff.
7. **Education:** Educate clinicians about disease state management, resistance, and optimal prescribing.

# CORE ELEMENTS: a national survey via NHSN of ACHs

Core Element	National
Leadership Commitment	67.7%
Accountability	76.6%
Drug Expertise	89.4%
Action	94.9%
Tracking	81.1%
Reporting	86.0%
Education	66.1%

- National survey began in 2014; CAHs joined in 2015.
- Reported according to 2015 National Healthcare Safety Network (NHSN) Annual Hospital Survey (4,569 hospitals with average bed size of 164).
- In 2014, 40.9% of hospitals reported having an ASP with all 7 core elements; in one year, that percent increased to 48.1%.
- In 2015, amongst hospitals with at least 200 beds, all 7 core elements were met 66.1% (AZ, 41%).
- Written leadership commitment (6-fold increase of having all 7 core elements), salary support, teaching status, and bed size were independent predictors of an ACH meeting all core elements.

# **APPROVED: New Antimicrobial Stewardship Standard**

The Joint Commission recently announced a new Medication Management (MM) standard for **hospitals, critical access hospitals, and nursing care centers**. Standard MM.09.01.01 addresses antimicrobial stewardship and becomes **effective January 1, 2017**.



Official Publication of Joint Commission Requirements

## **New Antimicrobial Stewardship Standard**

APPLICABLE TO NURSING CARE CENTERS

**Effective January 1, 2017**

**Medication Management (MM)**

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### **Standard MM.09.01.01**

The organization has an antimicrobial stewardship program based on current scientific literature.

# Eight standards, including the 7 CORE ELEMENTS

(with 4 standards which require documentation)

1. Leaders establish antimicrobial stewardship as an organizational priority.
2. The organization educates staff and licensed independent practitioners involved in antimicrobial ordering, dispensing, administration, and monitoring about antimicrobial resistance and antimicrobial stewardship practices. Education occurs upon hire or granting of initial privileges and periodically thereafter, based on organizational need.
3. The organization educates residents, and their families as needed, regarding the appropriate use of antimicrobial medications, including antibiotics.
4. The organization has an antimicrobial stewardship multidisciplinary team that includes certain members, when available in the setting.
5. **D** The organization's antimicrobial stewardship program includes the CDC's 7 core elements.
6. **D** The organization's antimicrobial stewardship program uses organization-approved multidisciplinary protocols.
7. **D** The organization collects, analyzes, and reports data on its antimicrobial stewardship program.
8. **D** The organization takes action on improvement opportunities identified in its antimicrobial stewardship program.

# We know what we know, but not sure what we don't know....

Antibiotics are among the most frequently prescribed medications in nursing homes, with up to 70% of residents in a nursing home receiving one or more courses of systemic antibiotics when followed over a year.

Studies have shown that 40–75% of antibiotics prescribed in nursing homes may be unnecessary or inappropriate.

Harms from antibiotic overuse are significant for the frail and older adults receiving care in nursing homes. These harms include risk of serious diarrheal infections from *Clostridium difficile*, increased adverse drug events and drug interactions, and colonization and/or infection with antibiotic-resistant organisms.

**Antibiotic stewardship refers to a set of commitments and activities designed to optimize the treatment of infections while reducing the adverse events and collateral damage associated with antibiotic use – the unintended consequences of overuse**

# Additional Federal Actions: September 2014 Executive Order 13676: Combating Antibiotic-Resistant Bacteria

Sets forth policy to detect, prevent, and control illness and death

Establish a task force co-chaired by the Secretaries of Defense, Agriculture, and Health and Human Services Department (HHS)

Develop a five-year National Action Plan

Establish the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

Improve antibiotic stewardship and use of antibiotics by hospitals and other inpatient healthcare delivery facilities

Strengthen national surveillance systems and laboratory networks

Prevent and respond to infections and outbreaks

Promote new and next-generation antibiotics and diagnostics

Support cooperation of international antibiotic resistance efforts

# September 2014 (cont'd)

Sec. 5. Improved Antibiotic Stewardship. (a) By the end of calendar year 2016, HHS shall review existing regulations and propose new regulations or other actions, as appropriate, that require hospitals and other inpatient healthcare delivery facilities to implement robust antibiotic stewardship programs that adhere to best practices, such as those identified by the CDC. HHS shall also take steps to encourage other healthcare facilities, such as ambulatory surgery centers and dialysis facilities, to adopt antibiotic stewardship programs. <sup>1</sup>

The President's Council of Advisors on Science and Technology (PCAST) released its report to the President on Combating Antimicrobial Resistance in the U.S. with key recommendations focusing on antibiotic resistance policy, stewardship, and surveillance. <sup>2</sup>

<sup>1</sup> National Strategy to Combat Antibiotic-Resistant Bacteria, Report available at: [http://www.cdc.gov/drugresistance/pdf/carb\\_national\\_strategy.pdf](http://www.cdc.gov/drugresistance/pdf/carb_national_strategy.pdf)

<sup>2</sup> Report to the President on Combatting Antibiotic Resistance; available at: [https://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST/pcast\\_carb\\_report\\_sept2014.pdf](https://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST/pcast_carb_report_sept2014.pdf)



# Where do I start when antibiotic resistance is coming from so many sources?

Set up a meeting with Administrator, Medical Director, Director of Staff Development, Director of Nursing, and others who might be stakeholders

- Bring in examples of “Commitments to Support” letters as examples
- Draft a poster of the letter and picture of Medical Director and Staff – publically display

Begin to create a culture change – before you order that antibiotic, think about the consequences, they are real

Set standards and assign responsibilities; then develop program mission statement, goals and objectives

- Who will review antibiotic orders? How will outliers be handled?

Explore knowledge, behaviors and attitudes of nursing staff, AND environmental services

Bring in the consultant pharmacist, infection preventionist, and maybe the same from the local ACH to help (“your bugs are my bugs”), reference laboratories; get help from local health department officials and experts

Create networks of drug expertise – consultant pharmacists and friends. Get certified!

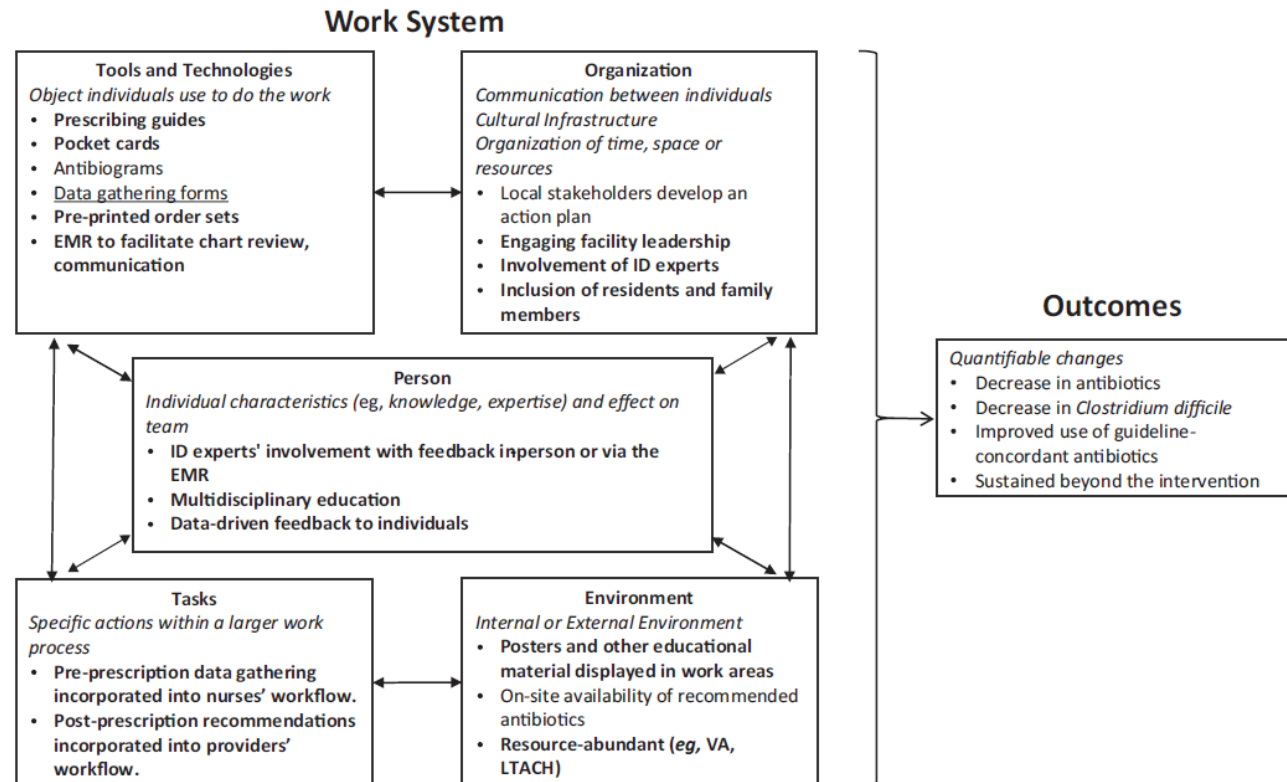
Implement policies – there are dozens! Focus on big issues – CDI and ASB

# A recent review of 20 successful ASPs in LTCF

Effective antimicrobial stewardship in long-term care is supported by 3 major elements:

- Incorporating multidisciplinary education
- Tools integrated into the workflow of nurses and prescribers that facilitate review of antibiotic use
- Involvement of infectious disease consultants.

Adaptation of the work system from the Systems Engineering Initiative for Patient Safety (SEIPS) model to antimicrobial stewardship interventions in LTC:



# Where do I start when antibiotic resistance is coming from so many sources? (cont'd)

Measure antibiotic use and specific outcomes of interest.

- Difficult to find data sometimes; manual data collection can be the only method available
- Avoid antibiotic purchase data – replace with DDDs or better yet duration of therapy (DOT)

Don't just create an antibiogram – use it! NHSN tracking of MRSA, CRE, CDI but there are other novel ways to create tools for presentation.

- Trend your data when possible

Report on the data collected; if everyone is part of the culture they need something in return for their cooperation

Educate clinicians about antibiotics and their use.

- Distinguish between colonization and infection
- Use recent reports from the CDC, NQF, SHEA, IDSA, CLSI, etc keeps resistance in focus – no need to reinvent the wheel
- Think about patients too, and their families

# Think about these high-level opportunities

What outcomes are of primary concern the first year?

- CDI, but beware of PCR data which may only suggest colonization
- ASB – rates of urine collection for culture, FQ use

Discuss the benefits of a “regional strategy” partnering with local ACHs

- Shared patient populations
- Identify nearby ACHs and participate in a “preferred status” list
- Agree to work with ACH to comply with CMS regulations on stewardship<sup>1</sup>

Strategies to sustain the ASP, including enduring educational materials (recorded and/or online webinars<sup>2</sup>, data collection tools, ASP metrics) for new staff.

Discuss approaches to behavioral interventions<sup>3</sup>

Navigate State Departments of Health to identify successful interventions

- Arizona Dept Health Services developed a pocket-size ASB guideline (<http://azdhs.gov/preparedness/epidemiology-disease-control/healthcare-associated-infection/advisory-committee/antimicrobial-stewardship/index.php#committee-resources>)

Transfer of care notifications for CDI, CRE, or other reportable infections/pathogens – place labels on chart so prescribers can be cautious

Be willing to set a course towards publication, especially in nursing journals<sup>4</sup>

1 Kullar R, Yang H, Grein J, Murthy R. Clin Infect Dis. 2018;66:1304-12. 2 Wilson B, Shick S, Carter R, et al. Am J Infect Control. 2017;45:466-70.  
3 Goldstein E, Goff D, Reeve W, et al. Clin Infect Dis. 2016;63:532-8. 4 Olans R, Olans R, DeMaria A.. Clin Infect Dis. 2016.62:84-9..

# “Hunt” for resources – adapt available innovations

## Breaking the Cycle Asymptomatic Bacteriuria



Urinary tract infection (UTI) is the most common indication for antibiotic use in post-acute care facilities and a significant proportion of this use is inappropriate and unnecessary. Asymptomatic bacteriuria (ASB) is prevalent in residents of post-acute care facilities and is frequently misidentified as a “UTI”.



[www.preventHAIAz.gov](http://www.preventHAIAz.gov)  
For comments or question please contact:  
[HAI@azdhs.gov](mailto:HAI@azdhs.gov)

### Common ways ASB masquerades as an infection requiring antibiotic treatment:

Masquerade Myths	Best Practice Response
A positive UA/C&S result (an organism name and susceptibility report; any colony count) is a “positive test that cannot be ignored	Up-to-date decision criteria require <b>both</b> a positive culture <b>and</b> specific clinical features
A positive UA/C&S result predicts “risk of later invasive infection” even when there are no symptoms/signs	Multiple studies show antibiotic Rx of ASB confers no benefit and does not prevent invasive disease
“Confused this morning ... start Cipro and get a UA/C&S”	Hold antibiotic; Assess for other reasons for confusion, such as medications
C&S result = 50,000 colonies <i>E. coli</i> ESBL+ “This is a superbug ... should be treated”	Multi-Drug Resistant Organism (MDRO) is not an indication for antibiotic Rx
100,000 colonies ... no symptoms or signs “This is a positive test ... can’t ignore it”	This is ASB, not a UTI; standardized definition of UTI requires a positive clinical (McGeer criteria) as well

<http://www.azdhs.gov/documents/preparedness/epidemiology-disease-control/healthcare-associated-infection/advisory-committee/antimicrobial-stewardship/asb-optimizing-use.pdf>

# Early experience with an ASP in 3 LTCFs with prescriptions for UTI – results with hopes for improvement

A quasi-experimental study targeting antibiotic prescriptions for UTI using time-series analysis with 6-month retrospective pre-intervention and 6-month intervention period at three community LTCFs.

The ASP team (infectious diseases (ID) pharmacist and ID physician) performed weekly prospective audit and feedback of consecutive prescriptions for UTI. Loeb clinical consensus criteria were used to assess appropriateness of antibiotics; recommendations were communicated to the primary treating provider by the ID pharmacist.

104 antibiotic prescriptions for UTI were evaluated during the intervention, and recommendations were made for change in therapy in 40 (38%), out of which 10 (25%) were implemented. Only eight (8%) residents started on antibiotics for UTI met clinical criteria for antibiotic initiation. An immediate 26% decrease in antibiotic prescriptions for UTI during the ASP was identified.

# Many resources are available at CDC.gov



## The Core Elements of Antibiotic Stewardship for Nursing Homes CHECKLIST



National Center for Emerging and Zoonotic Infectious Diseases  
Division of Healthcare Quality Promotion



### Core Elements for Antibiotic Stewardship in Nursing Homes What You Need to Know About Antibiotics in a Nursing Home

#### What are antibiotics?

Antibiotics are drugs used to treat infections caused by bacteria. They do not work for illnesses caused by viruses, like flu and most cases of bronchitis.



#### When are antibiotics necessary?

There are times when antibiotics are urgently needed; for example, to treat sepsis (e.g., when bacteria cause a severe infection of the bloodstream), pneumonia caused by bacteria, and meningitis caused by bacteria. Using antibiotics when they are not necessary increases the risk they will not work when needed most.



#### Can taking antibiotics be harmful?

Antibiotics, like any medications, can have minor side effects like upset stomach or a rash, as well as serious allergic reactions or dangerous interactions with other medications a person is taking. In particular, antibiotics put people at risk for a deadly type of diarrhea caused by *C. difficile*. Frequent or excessive use of antibiotics leads to developing bacteria that are resistant to those antibiotics. Antibiotic-resistant bacteria are harder to kill, and can cause untreatable infections. A person also can carry resistant bacteria without feeling sick (this is called "colonization"), but if that bacteria causes an infection, it can require more complex treatments and transfer to the hospital.



#### What is antibiotic stewardship?

Antibiotic stewardship refers to a set of commitments and actions designed to make sure patients receive the right dose, of the right antibiotic, for the right amount of time; and only when truly necessary. Improving antibiotic use will ensure these life-saving medications are effective and available when we need them.



#### Why is improving antibiotic prescribing practices important for nursing homes?

Nursing home residents have a higher risk of colonization with bacteria for many reasons. The presence of invasive devices such as urinary catheters and feeding tubes, wounds, and conditions that affect the bladder (e.g., diabetes or stroke) can all lead to colonization. Difficulties in separating colonization of bacteria from true illness in frail or older adults can lead to the overuse of antibiotics, which in turn drives antibiotic resistance.



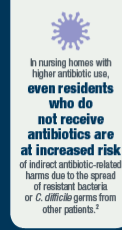
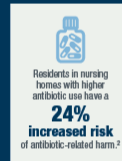
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### Core Elements for Antibiotic Stewardship in Nursing Homes Creating a Culture to Improve Antibiotic Use in Nursing Homes

#### Why is Antibiotic Stewardship Important for Nursing Homes?

- Antibiotics are some of the most commonly prescribed medications in nursing homes.
  - Over the course of a year, up to 70% of nursing home residents get an antibiotic.
- Roughly 40% to 75% of antibiotics are prescribed incorrectly.
  - In nursing homes, high rates of antibiotics are prescribed to prevent urinary tract infection (UTI) and respiratory tract infection (RTI). Prescribing antibiotics before there is an infection often contributes to misuse.
  - Often residents are given antibiotics just because they are colonized with (carrying) bacteria that are not making the person sick. Prescribing antibiotics for colonization contributes to antibiotic overuse.
- When patients have poor communication skills, insufficient health literacy, or resistance to change, it can be difficult to implement antibiotic stewardship programs in nursing homes.
  - Antibiotic-related hospitalizations.
  - Current nursing home regulations require review and monitoring of antibiotic use.



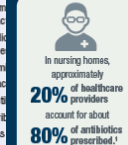
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Division of Healthcare Quality Promotion

#### What Can I Do?

- Share formal or informal antibiotic stewardship information with staff and residents.
- Commit resources to antibiotic stewardship.
- Identify and engage antibiotic stewardship champions.
- Have clear policies on antibiotic use.
- Establish monitoring and feedback systems.
- Develop faculty and staff education on antibiotic stewardship.
- Review and update antibiotic stewardship policies.
- Print and distribute antibiotic stewardship materials.
- Provide access to antibiotic stewardship resources.
- Partner with other nursing homes in the community.

<sup>1</sup> Steinhilber LJ, Joseph G, et al. *JAMA Intern Med.* 2013;173:1001-1006.  
<sup>2</sup> Daneman, N et al. *Worldwide Antibiotic Resistance in Nursing Homes.* *JAMA Intern Med.* 2013;173:1001-1006.



Current nursing home regulations (e.g., F-tag 441, F-tag 229, F-tag 428) already include requirements to review and monitor antibiotic use.

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### Core Elements for Antibiotic Stewardship in Nursing Homes Leading Antibiotic Stewardship in Nursing Homes

#### Who are the Antibiotic Stewardship Leaders in Nursing Homes?

- Medical Director
- Director of Nursing
- Consultant Pharmacist

#### What are their Roles?



##### Medical Directors can:

- Set standards for antibiotic prescribing practices for all healthcare providers prescribing antibiotics.
- Oversee adherence to antibiotic prescribing practices.
- Review antibiotic use data and ensure best practices (e.g., the right drug at the right dose for the right amount of time) are followed.



##### Directors of Nursing can:

- Establish standards for nursing staff to assess, monitor and communicate changes in a resident's condition that could impact the need for antibiotics.
- Use their influence as nurse leaders to help ensure antibiotics are prescribed only when appropriate.
- Educate front line nursing staff about the importance of antibiotic stewardship and explain policies in place to improve antibiotic use.



##### Consultant Pharmacists can:

- Provide education to staff about the different types of antibiotics and their uses.
- Review antibiotic prescriptions as part of the drug regimen review for new medications and ensure they are ordered appropriately.
- Establish laboratory testing protocols to monitor for adverse events and drug interactions related to use of antibiotics and other high risk medications.
- Review microbiology culture results and provide feedback to prescribers on initial antibiotic selection to let them know if it is the right drug to treat the infection or if the bacteria may be resistant to the antibiotic.

<sup>1</sup> Daneman, N et al. *Prolonged Antibiotic Treatment in Long-Term Care.* *JAMA Intern Med.* 2013;173:1001-1006.



Centers for Disease Control and Prevention  
National Center for Emerging and Zoonotic Infectious Diseases

National Center for Emerging and Zoonotic Infectious Diseases  
Division of Healthcare Quality Promotion



# Summary: Ideas on how to preserve current antibiotics and solve the problems of antibiotic overuse?

Estimated that annual deaths in the US due to increasing antibiotic-resistant infections will climb 30-fold by 2050 (~320,000). This equates to \$20 bill excess healthcare costs and \$35 bill in lost productivity annually.<sup>1</sup>

So....

Challenge clinicians why individual and collective contributions to overuse is an ethical issue and what specific moral questions it raises<sup>2</sup>

Make a case for regulatory mandates to convince hospital administration to fund and staff ASPs<sup>3</sup>

Develop processes and outcome measures which are tied to prescriber accreditation<sup>3</sup>

Require certification, coursework, and ongoing educational modules on antibiotic use<sup>3</sup>

Embrace quality-of-care improvements and disease-state management as part of a continuous quality improvement effort; abandon costs as the primary goal of ASPs<sup>4</sup>

Discuss with HCPs strategies which blend Locke's individualism and Rousseau's collectivism<sup>5</sup>

1 Hampton T. JAMA. Published online June 3, 2015, News & Analysis; 2 Littmann J et al. Public Health Ethics. 2015;1-16; 3 Policy Statement SHGEA, IDSA, PIDS. Infect Control Hosp Epidemiol. 2012;33:322-7; 4 Dodds-Ashley E et al. Clin Infect Dis.2014;59(suppl 3):S112-21; 5 Flanders S, Saint S. JAMA Internal Med. Published online March 4, 2014