Pharmacists as Stewards: Strategies for Effective Antimicrobial Stewardship

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iCARE PHARMACY SERVICES

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Goal

- Upon completion of this activity, the pharmacist should be able to design an antimicrobial stewardship program for a variety of practice settings.

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Learning Objectives

- At the conclusion of this presentation, the pharmacist should be able to:
  - Explore the threat of antimicrobial resistance on health systems and patient outcomes
  - Classify antibiotic-resistant organisms according to the CDC threat levels
  - Identify the four objectives of an antimicrobial stewardship program
  - Identify the CDC core elements of hospital, outpatient, and nursing home antimicrobial stewardship programs
  - Describe the role of pharmacists and available training opportunities in antimicrobial stewardship
  - Provide recommendations for implementing an effective antimicrobial stewardship program

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Abbreviations

- AmpC-E = AmpC-producing Enterobacterales
- ASP = antimicrobial stewardship program
- CDC = Centers for Disease Control and Prevention
- CDI = *Clostridioides difficile* infection
- CRAB = carbapenem-resistant *Acinetobacter baumannii*
- CRE = carbapenem-resistant Enterobacterales
- CRPA = carbapenem-resistant *Pseudomonas aeruginosa*
- DRNG = drug-resistant *Neisseria gonorrhoeae*
- DTR = difficult-to-treat resistance
- ESBL-E = extended-spectrum β-lactamase-producing Enterobacterales
- MDR = multidrug-resistant
- MRSA = methicillin-resistant *Staphylococcus aureus*
- VISA = vancomycin-intermediate *Staphylococcus aureus*
- VRE = vancomycin-resistant *Enterococcus*

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Outline

- Antimicrobial resistance in the United States
- CDC's list of threatening pathogens
- Bad bugs
- Few new drugs
- Antimicrobial stewardship
- Core elements of antimicrobial stewardship
- Role of the pharmacist
- Training opportunities for the pharmacist
- Recommendations for implementing an antimicrobial stewardship program
- Future directions: Beyond antibiotics

https://www.cdc.gov/drugresistance/index.html

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Sir Alexander Fleming

"… the microbes are educated to resist penicillin and a host of penicillin-fast organisms is bred out … the thoughtless person playing with penicillin is morally responsible for the death of the man who finally succumbs to infection with the penicillin-resistant organism. I hope this evil can be averted."

New York Times. 26 June 1945:21

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Antimicrobial Resistance in the United States

- ~2.8 million antibiotic-resistant infections
- ~35,000 people died as a result of their infection
- ~223,900 people required hospitalization because of CDI
- ~12,800 people died as a result of CDI

https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf

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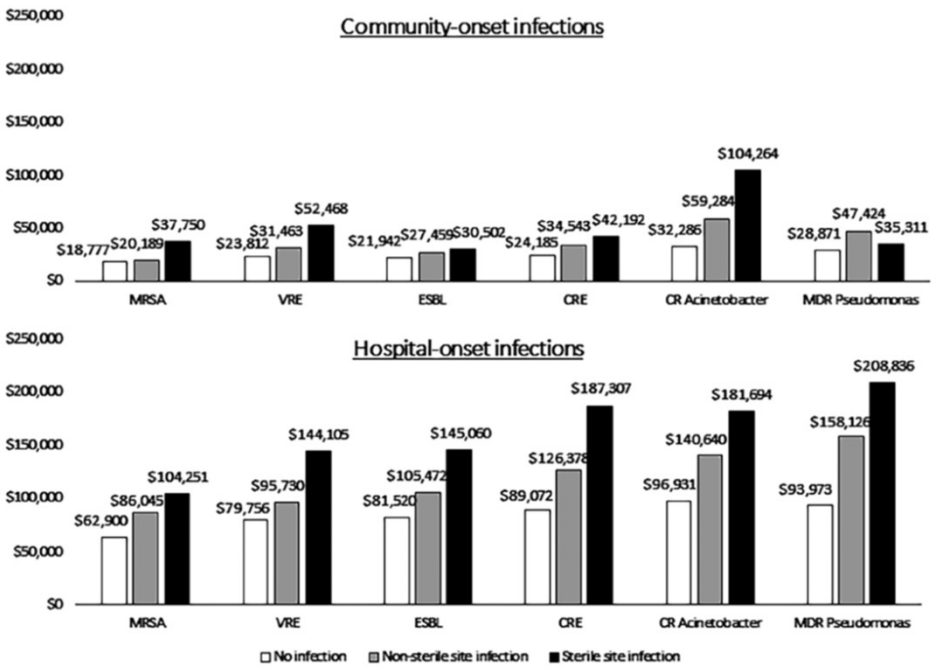

Nelson RE et al. Clin Infect Dis. 2021;72(Suppl 1):S17-26

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CDC's List of Pathogens Posing Urgent Threats

Carbapenem-resistant *Acinetobacter baumannii* (CRAB)
Candida auris
Clostridioides difficile
Carbapenem-resistant Enterobacterales (CRE)
Drug-resistant *Neisseria gonorrhoeae* (DRNG)

https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf

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CDC's List of Pathogens Posing Serious Threats

Drug-resistant *Campylobacter*	Drug-resistant *Salmonella* serotype Typhi
Drug-resistant *Candida*	Drug-resistant *Shigella*
ESBL-producing Enterobacterales (ESBL-E)	Methicillin-resistant *Staphylococcus aureus* (MRSA)
Vancomycin-resistant *Enterococcus* (VRE)	Drug-resistant *Streptococcus pneumoniae*
MDR-*Pseudomonas aeruginosa*	Drug-resistant *Mycobacterium tuberculosis*
Drug-resistant nontyphoidal *Salmonella*	

https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf

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CDC's List of Pathogens Posing Concerning Threats

- Erythromycin-resistant group A *Streptococcus*
- Clindamycin-resistant group B *Streptococcus*

https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf

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CDC's List of Pathogens on the Watch List

- Azole-resistant *Aspergillus fumigatus*
- Drug-resistant *Mycoplasma genitalium*
- Drug-resistant *Bordetella pertussis*

https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf

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Question

- Which pathogens are posing urgent threats according to the CDC?
  - **A) *C. difficile* and CRE**
  - **B) *C. difficile* and MRSA**
  - **C) CRE and VRE**
  - **D) MRSA and VRE**

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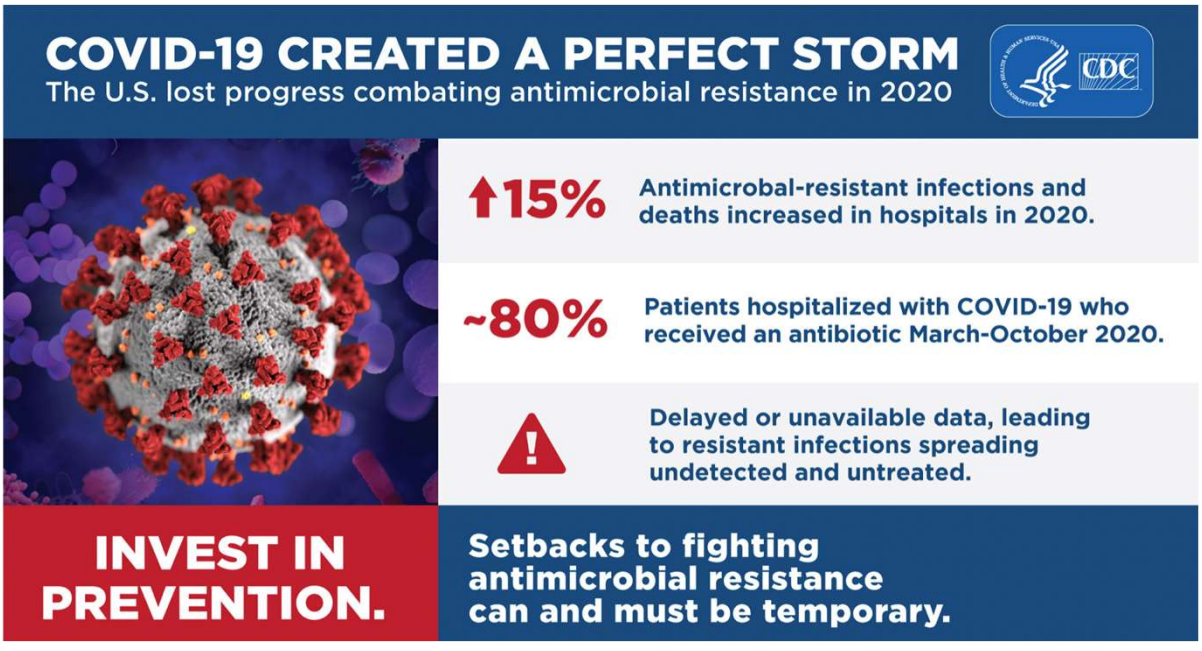

CDC. COVID-19: U.S. Impact on Antimicrobial Resistance, Special Report 2022

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	Resistant Pathogen	2017 Threat Estimate	2018 Threat Estimate	2019 Threat Estimate	2017-2019 Change	2020 Threat Estimate and 2019-2020 Change
URGENT	Carbapenem-resistant *Acinetobacter*	8,500 cases 700 deaths	6,300 cases 500 deaths	6,000 cases 500 deaths	Stable*	7,500 cases 700 deaths **Overall: 35% increase*** **Hospital-onset: 78% increase***
URGENT	Antifungal-resistant *Candida auris*	171 clinical cases†	329 clinical cases	466 clinical cases	▲ Increase	754 cases **Overall: 60% increase**
URGENT	*Clostridioides difficile*	223,900 infections 12,800 deaths	221,200 infections 12,600 deaths	202,600 infections 11,500 deaths	▼ Decrease	Data delayed due to COVID-19 pandemic
URGENT	Carbapenem-resistant Enterobacterales	13,100 cases 1,100 deaths	10,300 cases 900 deaths	11,900 cases 1,000 deaths	▼ Decrease*	12,700 cases 1,100 deaths Overall: Stable* **Hospital-onset: 35% increase***
URGENT	Drug-resistant *Neisseria gonorrhoeae*	550,000 infections	804,000 infections	942,000 infections	▲ Increase	Data unavailable due to COVID-19 pandemic
SERIOUS	Drug-resistant *Campylobacter*	448,400 infections 70 deaths	630,810 infections	725,210 infections	▲ Increase	Data delayed due to COVID-19 pandemic‡ 26% of infections were resistant, a 10% decrease
SERIOUS	Antifungal-resistant *Candida*	34,800 cases 1,700 deaths	27,000 cases 1,300 deaths	26,600 cases 1,300 deaths	▼ Decrease*	28,100 cases 1,400 deaths **Overall: 12% increase*** **Hospital-onset: 26% increase***
SERIOUS	ESBL-producing Enterobacterales	197,400 cases 9,100 deaths	174,100 cases 8,100 deaths	194,400 cases 9,000 deaths	▲ Increase*	197,500 cases 9,300 deaths **Overall: 10% increase*** **Hospital-onset: 32% increase***
SERIOUS	Vancomycin-resistant Enterococcus	54,500 cases 5,400 deaths	46,800 cases 4,700 deaths	47,000 cases 4,700 deaths	Stable*	50,300 cases 5,000 deaths **Overall: 16% increase*** **Hospital-onset: 14% increase***

CDC. COVID-19: U.S. Impact on Antimicrobial Resistance, Special Report 2022

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	Resistant Pathogen	2017 Threat Estimate	2018 Threat Estimate	2019 Threat Estimate	2017-2019 Change	2020 Threat Estimate and 2019-2020 Change
SERIOUS	Multidrug-resistant *Pseudomonas aeruginosa*	32,600 cases 2,700 deaths	29,500 cases 2,500 deaths	28,200 cases 2,400 deaths	▼ Decrease*	28,800 cases 2,500 deaths Overall: Stable* **Hospital-onset: 32% increase***
SERIOUS	Drug-resistant nontyphoidal *Salmonella*	212,500 infections 70 deaths	228,290 infections	254,810 infections	▲ Increase	Data delayed due to COVID-19 pandemic‡ 14% of infections were resistant, a 3% decrease
SERIOUS	Drug-resistant *Salmonella* serotype Typhi	4,100 infections <5 deaths	4,640 infections	6,130 infections	▲ Increase	Data delayed due to COVID-19 pandemic‡ 85% of infections were resistant, a 10% increase
SERIOUS	Drug-resistant *Shigella*	77,000 infections <5 deaths	215,850 infections	242,020 infections	▲ Increase	Data delayed due to COVID-19 pandemic‡ 46% of infections were resistant, a 2% increase
SERIOUS	Methicillin-resistant *Staphylococcus aureus*	323,700 cases 10,600 deaths	298,700 cases 10,000 deaths	306,600 cases 10,200 deaths	Stable*	279,300 cases 9,800 deaths Overall: Stable* **Hospital-onset: 13% increase***
SERIOUS	Drug-resistant *Streptococcus pneumoniae*	12,100 invasive infections 1,500 deaths†	See pathogen page if comparing data over time	12,000 invasive infections 1,200 deaths	Stable	Data delayed due to COVID-19 pandemic
SERIOUS	Drug-resistant Tuberculosis (TB)	888 cases 73 deaths†	962 cases 102 deaths	919 cases	Stable	661 cases Decrease‡
CONCERNING	Erythromycin-resistant group A *Streptococcus*	5,400 infections 450 deaths†	See pathogen page if comparing data over time	6,200 infections 560 deaths	▲ Increase	Data delayed due to COVID-19 pandemic
CONCERNING	Clindamycin-resistant group B *Streptococcus*	13,000 infections 720 deaths†	See pathogen page if comparing data over time	15,300 cases 940 deaths	▲ Increase	Data delayed due to COVID-19 pandemic

CDC. COVID-19: U.S. Impact on Antimicrobial Resistance, Special Report 2022

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	Threat	Change in Rates or Number of Infections***			
		2020 vs. 2019	2021 vs. 2020	2022 vs. 2021	2022 vs. 2019
URGENT*	Hospital-onset CRE	▲ Increase	▲ Increase	— Stable	▲ Increase
URGENT*	Hospital-onset Carbapenem-resistant *Acinetobacter*	— Stable	— Stable	— Stable	▲ Increase**
URGENT*	Clinical Cases of *C. auris*	▲ Increase	▲ Increase	▲ Increase	▲ Increase
SERIOUS*	Hospital-onset MRSA	▲ Increase	— Stable	▼ Decrease	— Stable
SERIOUS*	Hospital-onset VRE	▲ Increase	▲ Increase	— Stable	▲ Increase
SERIOUS*	Hospital-onset ESBL-producing Enterobacterales	▲ Increase	— Stable	— Stable	▲ Increase
SERIOUS*	Hospital-onset MDR *Pseudomonas aeruginosa*	▲ Increase	▲ Increase	— Stable	▲ Increase

* Threat level for each pathogen, as categorized in CDC's *Antibiotic Resistance Threats in the United States, 2019*.
** There was no statistically significant difference in rate of hospital-onset carbapenem-resistant *Acinetobacter* in 2020, 2021, and 2022 when compared to the previous year. However, there was a statistically significant increase in rate of hospital-onset carbapenem-resistant *Acinetobacter* in 2022 when compared to 2019.
*** Hospital-onset rates were described using multivariable models for all threats except *C. auris*. Please note that in above table, stable indicates there was no statistically significant increase or decrease, decrease indicates a statistically significant decrease where $p<0.05$, and increase indicates a statistically significant increase where $p<0.05$, for all threats except for *C. auris*. Increases or decreases in *C. auris* were indicated by changes in the number of clinical cases reported nationally without hypothesis testing.

https://www.cdc.gov/antimicrobial-resistance/data-research/threats/update-2022.html

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Bad Bugs!

- ***E****nterococcus faecium* (VRE)
- ***S****taphylococcus aureus* (MRSA, VISA)
- ***K****lebisella pneumoniae/Escherichia coli* (ESBL-E, CRE)
- ***A****cinetobacter baumannii* (CRAB)
- ***P****seudomonas aeruginosa* (CRPA, MDR/DTR-*P. aeruginosa*)
- ***E****nterobacter cloacae* (ESBL-E, AmpC-E, CRE)

Boucher HW et al. Clin Infect Dis. 2009;48:1-12

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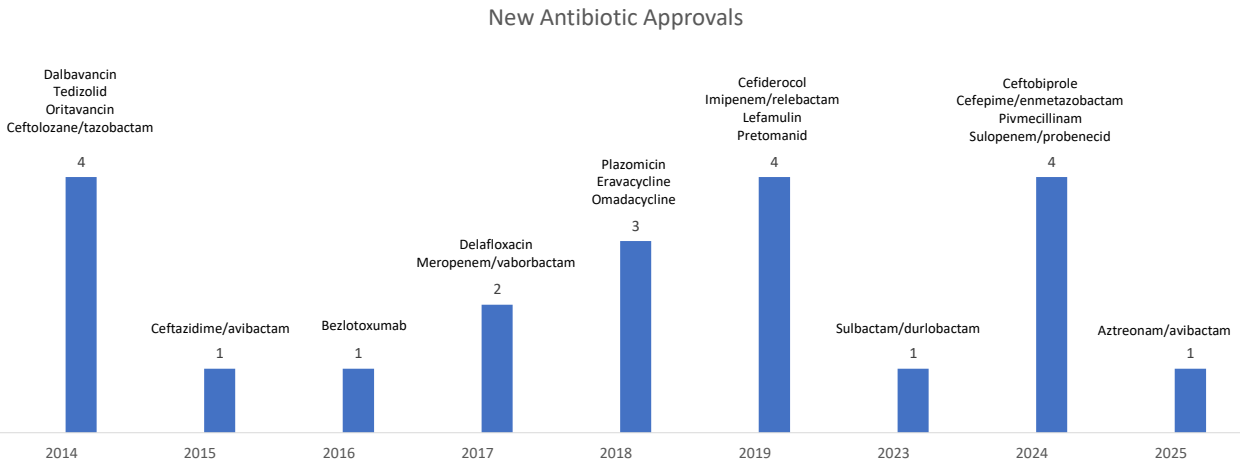
Few New Drugs!



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Antimicrobial Stewardship

- Fiduciary responsibility for all healthcare institutions across the continuum of care
  - ASPs should be required through regulatory mechanisms
  - Antibiotic use should be monitored in ambulatory healthcare settings
  - Education about resistance and stewardship must be accomplished
  - Antimicrobial use data should be readily available for both inpatient and outpatient settings
  - Research on antimicrobial stewardship is needed

SHEA, IDSA, PIDS. Infect Control Hosp Epidemiol. 2012;33:322-7

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Definition

- Coordinated interventions
  - Improve the appropriate use of antimicrobials
  - Measure the appropriate use of antimicrobials
- Promote the selection of the optimal antimicrobial regimen
  - **R**ight antimicrobial
  - **R**ight dose
  - **R**ight route of administration
  - **R**ight frequency of administration
  - **R**ight duration of therapy

5Rs

Dellit TH et al. Clin Infect Dis. 2007;44:159-77

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Objectives

- To achieve optimal clinical outcomes
- To limit the selective pressure on pathogens
- To minimize toxicity and other adverse events
- To reduce costs across the continuum of care

SHEA, IDSA, PIDS. Infect Control Hosp Epidemiol. 2012;33:322-7

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Question

- What is the primary objective of an ASP?
  - **A) To achieve optimal clinical outcomes**
  - **B) To decrease adverse effects**
  - **C) To eliminate the risk of CDI**
  - **D) To reduce healthcare costs**

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Core Elements of Hospital Stewardship

Leadership commitment	• Dedicate necessary human, financial, and information technology resources
Accountability	• Appoint a leader or co-leaders, such as a physician and pharmacist, responsible for program management and outcomes
Pharmacy expertise	• Appoint a pharmacist, ideally as the co-leader of the ASP, to help lead implementation efforts to improve antibiotic use
Action	• Implement interventions, such as prospective audit and feedback or preauthorization, to improve antibiotic use
Tracking	• Monitor antibiotic prescribing, the impact of interventions, and other important outcomes such as CDI and resistance patterns
Reporting	• Regularly report information on antibiotic use and resistance to prescribers, pharmacists, nurses, and hospital leadership
Education	• Educate prescribers, pharmacists, nurses, and patients about adverse reactions from antibiotics, resistance, and optimal prescribing

www.cdc.gov/antibiotic-use/healthcare/pdfs/hospital-core-elements-H.pdf

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Priorities for Hospital Core Element Implementation

Leadership commitment	• Antibiotic stewardship physician and/or pharmacist leader(s) have stewardship responsibilities in their contract, job description, or performance review
Accountability	• Antibiotic stewardship program is co-led by a physician and a pharmacist
Pharmacy expertise	• Antibiotic stewardship physician and/or pharmacist leader(s) have completed specialty training, a certificate program, or other training on antibiotic stewardship
Action	• ASP has facility-specific treatment recommendations for common clinical condition(s) and performs prospective audit/feedback or preauthorization
Tracking	• Hospital submits antibiotic use data to the NHSN Antimicrobial Use Option
Reporting	• Antibiotic use reports are provided annually to target feedback to prescribers. ASP monitors adherence to facility-specific treatment recommendations
Education	• No implementation priority identified

https://www.cdc.gov/antibiotic-use/core-elements/hospital/priorities.html

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Core Elements of Outpatient Stewardship

Commitment	• Demonstrate dedication to and accountability for optimizing antibiotic prescribing and patient safety
Action for policy and practice	• Implement at least one policy or practice to improve antibiotic prescribing, assess the results, and modify the approach as needed
Tracking and reporting	• Monitor antibiotic prescribing practices and offer regular feedback to clinicians, or ask clinicians to assess their own antibiotic prescribing practices
Education and expertise	• Provide educational resources to clinicians and patients on antibiotic prescribing, and ensure access to the necessary expertise for prescribing

www.cdc.gov/antibiotic-use/community/improving-prescribing/core-elements/core-outpatient-stewardship.html

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Core Elements of Nursing Home Stewardship

Leadership commitment	• Demonstrate support and commitment to safe and appropriate antibiotic use in your facility
Accountability	• Identify physician, nursing, and pharmacy leads responsible for promoting and overseeing antibiotic stewardship activities in your facility
Drug expertise	• Establish access to consultant pharmacists or other individuals with experience or training in antibiotic stewardship for your facility
Action	• Implement at least one policy or practice to improve antibiotic use
Tracking	• Monitor at least one process measure of antibiotic use and at least one outcome from antibiotic use in your facility
Reporting	• Provide regular feedback on antibiotic use and resistance to prescribing clinicians, nursing staff, and other relevant staff
Education	• Provide resources to clinicians, nursing staff, residents and families about antibiotic resistance and opportunities for improving antibiotic use

www.cdc.gov/longtermcare/prevention/antibiotic-stewardship.html

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Question

- What are the seven core elements of a hospital ASP?
  - 1) ……
  - 2) ……
  - 3) ……
  - 4) ……
  - 5) ……
  - 6) ……
  - 7) ……

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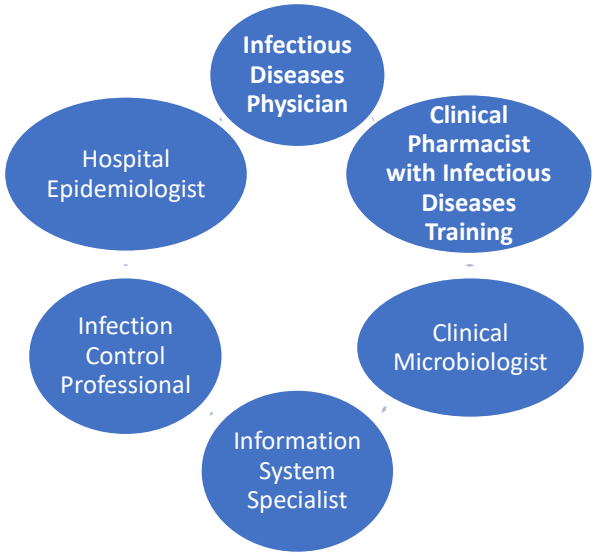
Role of the Pharmacist



Dellit TH et al. Clin Infect Dis. 2007;44:159-77

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Question

- A hospital ASP is usually co-directed by:
  - **A) a clinical pharmacist with infectious diseases training and the director of pharmacy**
  - **B) an infection control professional and the hospital epidemiologist**
  - **C) an infectious diseases physician and an infectious diseases pharmacist**
  - **D) an infectious diseases physician and the director of pharmacy**

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Training Opportunities for the Pharmacist

- PGY-1 pharmacy residency
- PGY-2 infectious diseases pharmacy residency
- Board certification in infectious diseases pharmacotherapy (BCIDP)
- Antimicrobial stewardship certificate programs
- Antimicrobial stewardship workshops

Board of Pharmacy Specialties
Ernst EJ et al. Pharmacotherapy. 2009;29:482-8

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Question

- Which program(s) is/are available specifically for pharmacists to improve their knowledge and skills in antimicrobial stewardship outside of residency training?
  - **A) ACCP/ASHP preparatory and recertification course for BCIDP**
  - **B) MAD-ID basic and advanced antimicrobial stewardship certificate programs**
  - **C) SIDP antimicrobial stewardship certificate program**
  - **D) SIDP recertification content for BCIDP**
  - **E) All of the above**

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Recommendations for Implementing an ASP

- Interventions
- Optimization
- Microbiology and laboratory diagnostics
- Measurement
- Special populations

Barlam TF et al. Clin Infect Dis. 2016;62:e51-77

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Interventions

Recommendations	Strength
Preauthorization and/or prospective audit and feedback	**Strong recommendation**
Didactic educational materials for stewardship	Weak recommendation
Facility-specific clinical practice guidelines	Weak recommendation
Specific infectious diseases syndromes	Weak recommendation

Barlam TF et al. Clin Infect Dis. 2016;62:e51-77

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Interventions

Recommendations	Strength
Reduce the use of antibiotics associated with a high risk of CDI	**Strong recommendation**
Prescribers to perform routine review of antibiotic regimens	Weak recommendation
Computerized clinical decision support	Weak recommendation
No antibiotic cycling	Weak recommendation

Barlam TF et al. Clin Infect Dis. 2016;62:e51-77

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Preauthorization

- Advantages
  - Reduces initiation of unnecessary/inappropriate antibiotics
  - Optimizes empiric choices and influences downstream use
  - Prompts review of data/cultures at the time of therapy initiation
  - Decreases antibiotic costs
  - Provides a mechanism for rapid response to antibiotic shortages
  - Provides direct control over antibiotic use
- Disadvantages
  - Impacts use of protected agents only
  - Addresses empiric use to a much greater degree than downstream use
  - Results in loss of prescriber autonomy
  - May delay antibiotic therapy
  - Effectiveness depends on skills of the approver
  - Real-time resource intensive
  - Potential for manipulation of system
  - May simply shift to other antibiotics and select for different resistance patterns

Barlam TF et al. Clin Infect Dis. 2016;62:e51-77

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Prospective Audit and Feedback

- Advantages
  - Can increase visibility of the ASP and build collegial relationships
  - More data available for recommendations, enhancing uptake
  - Greater flexibility in the timing of recommendations
  - Can be done on less than daily basis if resources are limited
  - Provides educational benefits to clinicians
  - Maintains prescriber autonomy
  - Can address de-escalation of antibiotics and duration of therapy
- Disadvantages
  - Compliance voluntary
  - Typically labor-intensive
  - Success depends on the delivery method of feedback to prescribers
  - Prescribers may be reluctant to change therapy if patient is doing well
  - Identification of interventions may require IT support and/or purchase of computerized surveillance systems
  - May take longer to achieve reduction in targeted antibiotic use

Barlam TF et al. Clin Infect Dis. 2016;62:e51-77

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Question

- Which broad stewardship strategies provide the foundation for an ASP?
  - **A) Leadership commitment and accountability**
  - **B) Pharmacy expertise and education**
  - **C) Preauthorization and prospective audit and feedback**
  - **D) Tracking and reporting**

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Optimization

Recommendations	Strength
Pharmacokinetic monitoring for aminoglycosides	**Strong recommendation**
Pharmacokinetic monitoring for vancomycin	Weak recommendation
Alternative dosing strategies of broad-spectrum β-lactams	Weak recommendation
Use of oral versus intravenous antibiotics	**Strong recommendation**
Allergy assessments in patients with "allergy" to β-lactams	Weak recommendation
Shortest effective duration	**Strong recommendation**

Barlam TF et al. Clin Infect Dis. 2016;62:e51-77

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Microbiology and Laboratory Diagnostics

Recommendations	Strength
Develop antibiograms	**Strong**
Selective and cascade reporting of susceptibility results	Weak
Rapid viral testing for respiratory pathogens	Weak
Rapid diagnostic testing on blood specimens	Weak
Serial procalcitonin testing in the ICU	Weak
Fungal markers in hematologic malignancies	Weak

Barlam TF et al. Clin Infect Dis. 2016;62:e51-77

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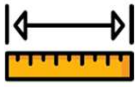
Measurement



Recommendations	Strength
Monitor antibiotic use using days of therapy (DOT) in preference to defined daily dose (DDD)	Weak
Measure antibiotic costs based on prescriptions or administration instead of purchasing data	Good practice
Use measures that consider the goals and size of the syndrome-specific intervention	Good practice

Barlam TF et al. Clin Infect Dis. 2016;62:e51-77

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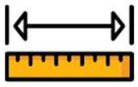
Measurement



- Process measures
  - Excess days of therapy
  - Duration of therapy
  - Proportion of patients compliant with facility-based guideline or treatment algorithm
  - Proportion of patients with revision of antibiotics based on microbiology data
  - Proportion of patients converted to oral therapy
- Outcomes measures
  - Hospital length of stay
  - 30-day mortality
  - Unplanned hospital readmission within 30 days
  - Proportion of patients diagnosed with hospital-acquired CDI or other adverse events related to antibiotics
  - Proportion of patients with clinical failure

Barlam TF et al. Clin Infect Dis. 2016;62:e51-77

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Special Populations

Recommendations	Strength
Febrile neutropenia in hematology-oncology patients	Weak
Antifungals in immunocompromised patients	Weak
Unnecessary use of antibiotics in nursing homes	Good practice
Antibiotic treatment in terminally ill patients	Good practice

Barlam TF et al. Clin Infect Dis. 2016;62:e51-77

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Question

- Which antibiotic stewardship strategy is a strong recommendation in the IDSA/SHEA guidelines?
  - **A) Develop, disseminate, and implement facility-specific clinical practice guidelines for common infectious diseases syndromes.**
  - **B) Implement pharmacokinetic monitoring and adjustment programs for vancomycin.**
  - **C) Implement preauthorization and/or prospective audit and feedback.**
  - **D) Use rapid diagnostic testing on blood specimens in addition to conventional methods.**

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Question

- Which statement is true regarding de-escalation of antibiotic therapy?
  - **A) It focuses on changing from an initial narrow-spectrum agent to empiric broad-spectrum therapy.**
  - **B) It focuses on changing monotherapy to combination therapy.**
  - **C) It is a subclass of the formulary restriction and preauthorization strategy.**
  - **D) It targets the causative pathogen, resulting in decreased antimicrobial exposure and cost savings.**

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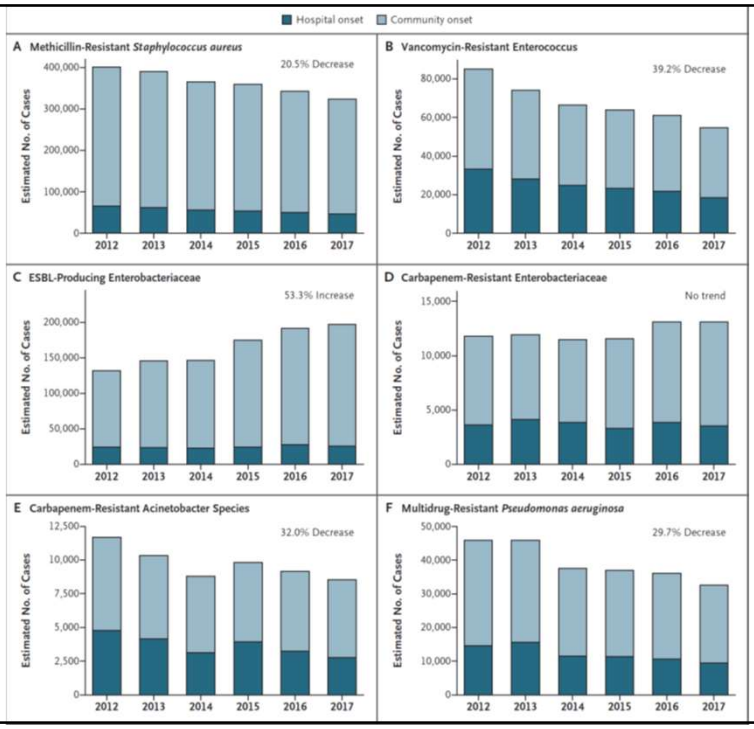

Jernigan JA et al. N Engl J Med. 2020;382:1309-19

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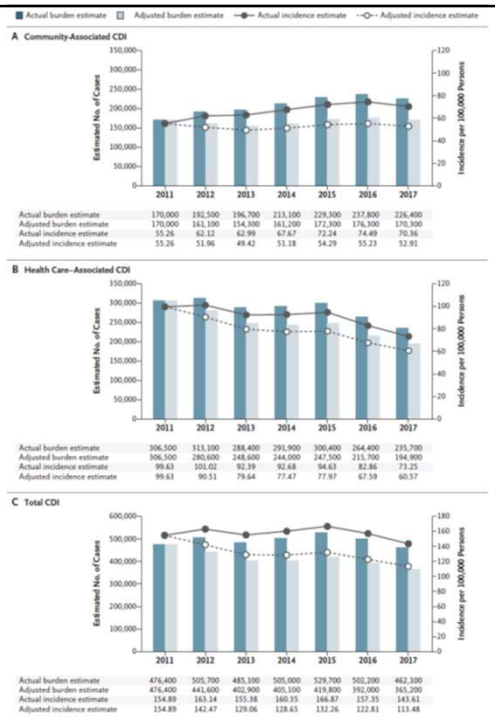

Guh AY et al. N Engl J Med. 2020;382:1320-30

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Future Directions: Beyond Antibiotics

- Bacteriophage therapy
- Monoclonal antibodies
- Microbiome-based therapies

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Miyamoto Musashi

"The warrior, in accordance with his aims, maintains various weapons and knows their characteristics and uses them well."

The Book of Five Rings

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Take Home Message

- Protection is better than restriction
- Less is more
- Oral is the new IV
- Shorter is better
- X (twitter) is the new textbook

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Practicum

- Which antimicrobial stewardship strategies or initiatives would you like to implement at your practice site?

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Key References and Readings

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