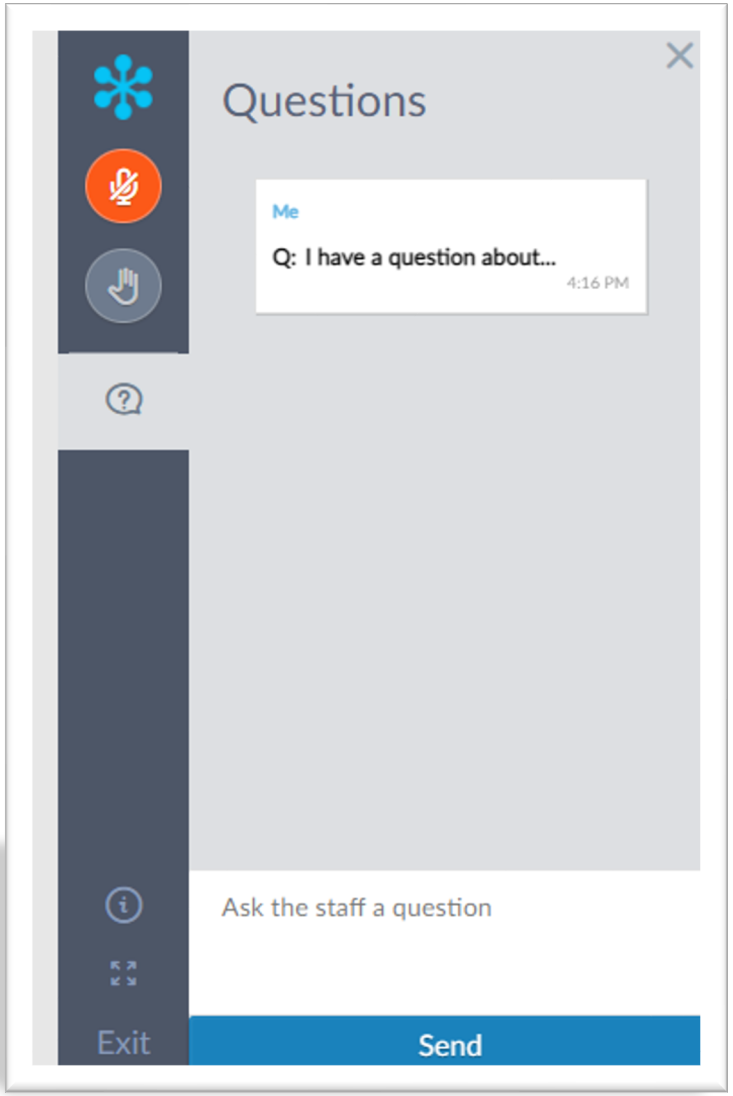
New Year, New Antimicrobial Requirements for Hospitals

INFECTIOUS DISEASE CONNECT SPONSORED WEBINAR

DECEMBER 7, 2022

Webinar Housekeeping

- This webinar will be recorded, and a recording link will be emailed afterwards
- All lines will be kept in listen only mode
- Copies of today's slides are available by clicking the document icon located on the right of your screen
- Please use the "questions" feature at the bottom of your attendee screen to submit questions – these will be answered during our Q&A
- If we can't get to everyone's questions in the allotted time, ID Connect will provide attendees with a "Frequently Asked Questions" write-up in the coming weeks



Today's Agenda

- Rationale for The Joint Commissions (TJC) New and Revised 2023 Antimicrobial Stewardship (AMS) Requirements

- What These AMS Changes Mean for Hospitals and Penn Medicine

- How Hospital Pharmacies and Pharmacists Can Prepare for TJC AMS Changes

- Question and Answers for Hospital Executives, Clinicians, and Patients

Today's Presenters

Dr. Tiffany Wiksten, DNP, RN, CIC
Associate Director, Standards Interpretation, TJC

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Matt Davis, PharmD
Infectious Disease Clinical Pharmacist, Infectious Disease Connect

Dave Zynn
CEO, Infectious Disease Connect

The Joint Commission

Antibiotic Stewardship: A Review of The Joint Commission Standards

Tiffany Wiksten, DNP, RN, CIC
Associate Director
Standards Interpretation Group

December 7, 2022

The Joint Commission

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The Joint Commission Disclaimer

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Why Were the Standards Updated?

The Joint Commission

Optimizing the use of antibiotics is a patient safety priority

Antibiotic stewardship programs play a critical role in supporting appropriate antibiotic prescribing practices and reducing antibiotic resistance

Align with:

- Federal regulations
- Current recommendations from scientific and professional organizations

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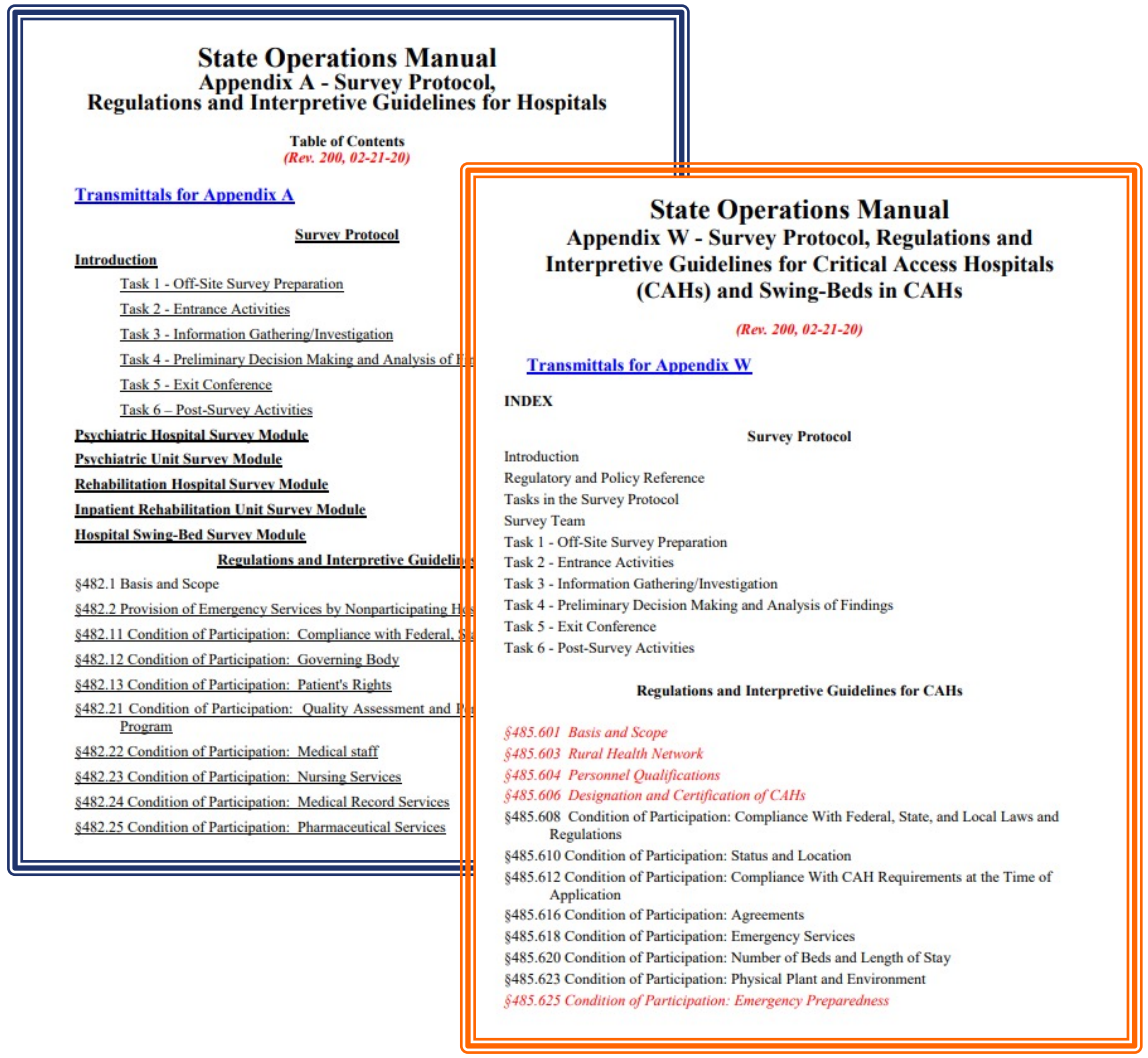
CMS Condition of Participation

Condition of Participation: Infection Prevention and Control and Antibiotic Stewardship Programs

The hospital (CAH) must have active hospital-wide programs for the surveillance, prevention, and control of HAIs and other infectious diseases, and for the optimization of antibiotic use through stewardship. The programs must demonstrate adherence to nationally recognized infection prevention and control guidelines, as well as to best practices for improving antibiotic use where applicable, and for reducing the development and transmission of HAIs and antibiotic resistant organisms. Infection prevention and control problems and antibiotic use issues identified in the programs must be addressed in collaboration with the hospital-wide quality assessment and performance improvement (QAPI) program.



State Operations Manual
Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals

Table of Contents
(Rev. 200, 02-21-20)

Transmittals for Appendix A

Survey Protocol

Introduction
- Task 1 - Off-Site Survey Preparation
- Task 2 - Entrance Activities
- Task 3 - Information Gathering/Investigation
- Task 4 - Preliminary Decision Making and Analysis of F
- Task 5 - Exit Conference
- Task 6 – Post-Survey Activities

Psychiatric Hospital Survey Module
Psychiatric Unit Survey Module
Rehabilitation Hospital Survey Module
Inpatient Rehabilitation Unit Survey Module
Hospital Swing-Bed Survey Module

Regulations and Interpretive Guidelin

§482.1 Basis and Scope
§482.2 Provision of Emergency Services by Nonparticipating H
§482.11 Condition of Participation: Compliance with Federal, S
§482.12 Condition of Participation: Governing Body
§482.13 Condition of Participation: Patient's Rights
§482.21 Condition of Participation: Quality Assessment and P Program
§482.22 Condition of Participation: Medical staff
§482.23 Condition of Participation: Nursing Services
§482.24 Condition of Participation: Medical Record Services
§482.25 Condition of Participation: Pharmaceutical Services

State Operations Manual
Appendix W - Survey Protocol, Regulations and Interpretive Guidelines for Critical Access Hospitals (CAHs) and Swing-Beds in CAHs

(Rev. 200, 02-21-20)

Transmittals for Appendix W

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Survey Protocol

Introduction
Regulatory and Policy Reference
Tasks in the Survey Protocol
Survey Team
Task 1 - Off-Site Survey Preparation
Task 2 - Entrance Activities
Task 3 - Information Gathering/Investigation
Task 4 - Preliminary Decision Making and Analysis of Findings
Task 5 - Exit Conference
Task 6 - Post-Survey Activities

Regulations and Interpretive Guidelines for CAHs

§485.601 Basis and Scope
§485.603 Rural Health Network
§485.604 Personnel Qualifications
§485.606 Designation and Certification of CAHs
§485.608 Condition of Participation: Compliance With Federal, State, and Local Laws and Regulations
§485.610 Condition of Participation: Status and Location
§485.612 Condition of Participation: Compliance With CAH Requirements at the Time of Application
§485.616 Condition of Participation: Agreements
§485.618 Condition of Participation: Emergency Services
§485.620 Condition of Participation: Number of Beds and Length of Stay
§485.623 Condition of Participation: Physical Plant and Environment
§485.625 Condition of Participation: Emergency Preparedness

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R³ Report | Requirement, Rationale, Reference

A complimentary publication of The Joint Commission

Issue 35, June 20, 2022

Published for Joint Commission-accredited organizations and interested health care professionals, *R3 Report* provides the rationale and references that The Joint Commission employs in the development of new requirements. While the standards manuals also may provide a rationale, *R3 Report* goes into more depth, providing a rationale statement for each element of performance (EP). The references provide the evidence that supports the requirement. *R3 Report* may be reproduced if credited to The Joint Commission. Sign up for email delivery.

New and Revised Requirements for Antibiotic Stewardship

Effective January 1, 2023, new and revised antibiotic stewardship requirements will apply to all Joint Commission–accredited hospitals and critical access hospitals. The 12 elements of performance (EPs) are included in the "Medication Management" (MM) chapter (Standard MM.09.01.01) and expand upon the current expectations for antibiotic stewardship programs in the hospital setting.

According to the Centers for Disease Control and Prevention, there are at least 2.8 million antibiotic-resistant infections each year, and more than 35,000 people die as a result. When *Clostridioides difficile (*a bacterium that can cause deadly diarrhea and is associated with antibiotic use) is included in the analysis, there are more than 3 million infections and 48,000 deaths.[1] Optimizing the use of antibiotics is a patient safety priority, and antibiotic stewardship programs play a critical role in supporting appropriate antibiotic prescribing practices and reducing antibiotic resistance. As a result, The Joint Commission made several revisions to Standard MM.09.01.01, which include updates to align with federal regulations and current recommendations from scientific and professional organizations.

https://www.jointcommission.org/-/media/tjc/documents/standards/r3-reports/r3_antibioticstewardship_july2022_final.pdf

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Updated Antimicrobial Stewardship Standards

Go into effect 1/1/2023

12 new and revised elements of performance that address antibiotic stewardship

- "New" requirements have not been directly addressed previously
- "Revised" include a combination of editorial changes and clarifications
- Elements of Performance will now apply to all accredited hospitals

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Standards Comparison

Current

MM.09.01.01 The hospital has an antimicrobial stewardship program based on current scientific literature

EP1: Organizational priority

EP2: Educates staff and LIPs

EP4: Multidisciplinary team

EP5: Core elements

EP6: Organization approved protocols

EP7: Collects, analyzes and reports data

EP8: Take action on improvement opportunities

For Deemed Organizations

EP9: Individual(s) appointed by the Governing Body to lead

EP10: Organizational coordination

EP11: Leadership responsibilities

Effective 1/1/2023

MM.09.01.01 The hospital has an antimicrobial stewardship program based on current scientific literature

NEW EP10: Financial resources

EP11: Physician and/or Pharmacist to lead ASP

EP12: Key responsibilities

EP13: Multidisciplinary committee

EP14: Coordination among all components

EP15: Documents evidence-based use of antibiotics

NEW EP16: Monitors antibiotic use

NEW EP17: Implements strategies to optimize prescribing

NEW EP18: Implements evidence-based guidelines

NEW EP19: Evaluates adherence to one evidence-based guideline

EP20: Collects, analyzed and reports data

EP21: Take action on improvement opportunities

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Key Updates

Allocating financial resources to support the antibiotic stewardship program

Appointing a leader of the antibiotic stewardship program and outlining responsibilities

Establishing a multidisciplinary committee to oversee the antibiotic stewardship program

Implementing a hospital-wide antibiotic stewardship program to address inappropriate antibiotic use

Evaluating adherence to evidence-based guidelines for the most common indications

Collecting, analyzing, and reporting data about the antibiotic stewardship program

Identifying opportunities to improve the antibiotic stewardship program and act

Editorial revisions (renumbering EPs, clarifying language, and adding notes)

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Summary

Ensure that the antimicrobial stewardship program has organizational support

Support the implementation of Antimicrobial Stewardship activities

Use the data that is collected for analysis and evaluation to guide improvement activities

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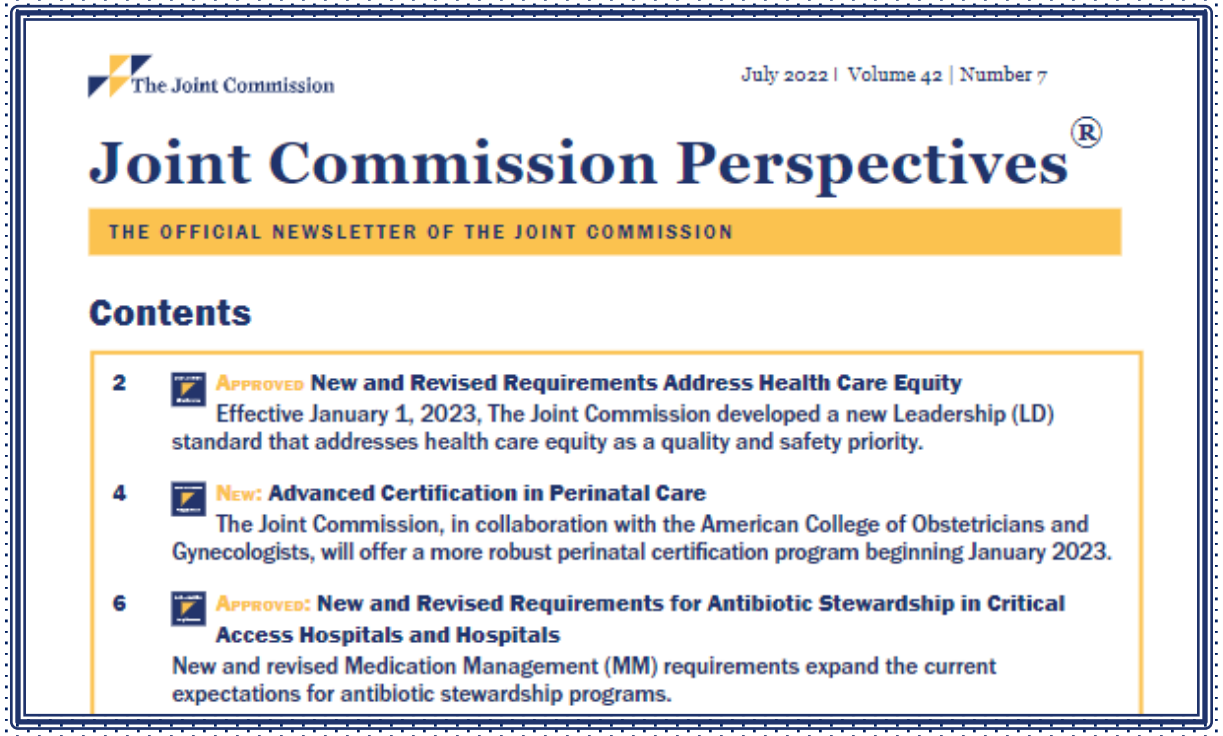
Additional Resources



The Joint Commission

July 2022 | Volume 42 | Number 7

Joint Commission Perspectives®

THE OFFICIAL NEWSLETTER OF THE JOINT COMMISSION

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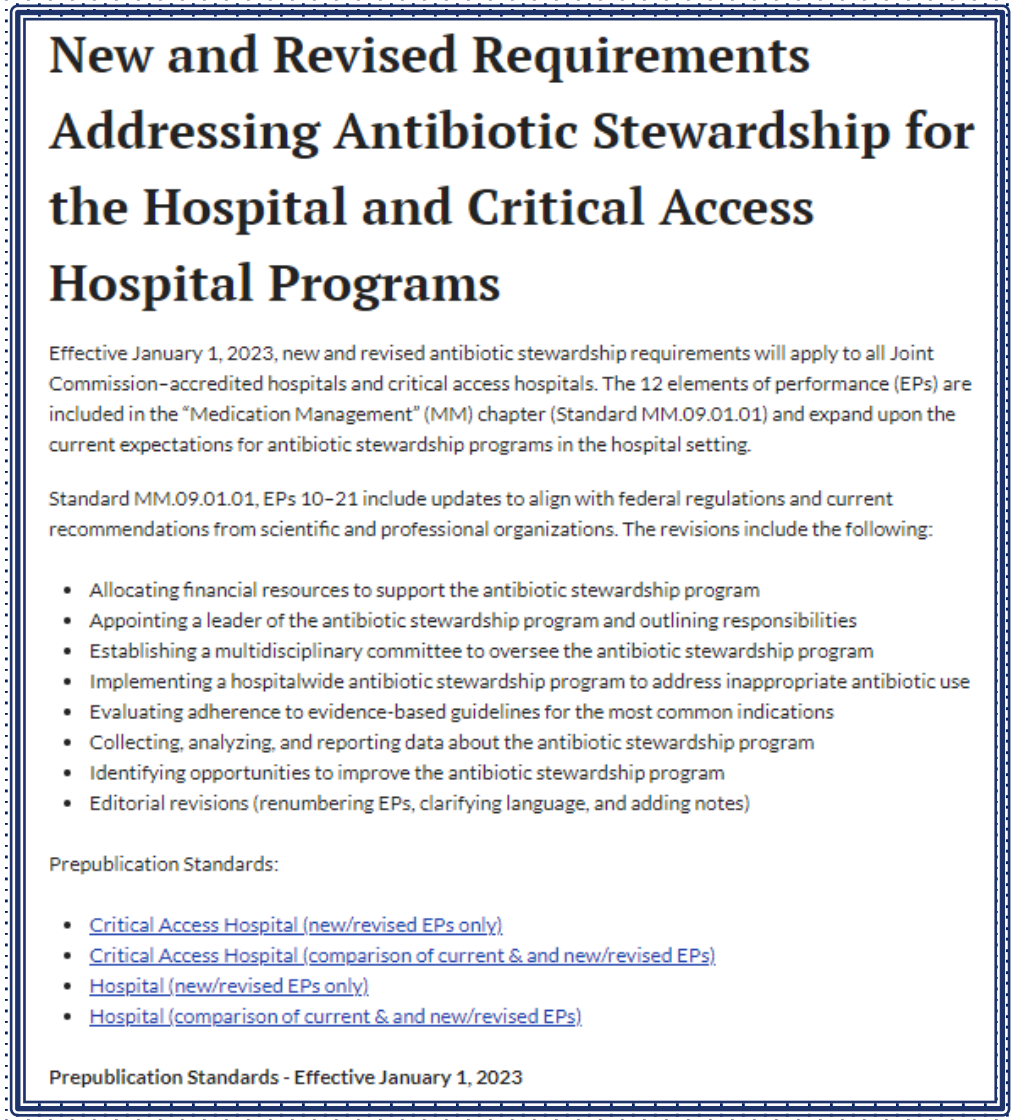
2 APPROVED **New and Revised Requirements Address Health Care Equity**
Effective January 1, 2023, The Joint Commission developed a new Leadership (LD) standard that addresses health care equity as a quality and safety priority.

4 NEW: **Advanced Certification in Perinatal Care**
The Joint Commission, in collaboration with the American College of Obstetricians and Gynecologists, will offer a more robust perinatal certification program beginning January 2023.

6 APPROVED: **New and Revised Requirements for Antibiotic Stewardship in Critical Access Hospitals and Hospitals**
New and revised Medication Management (MM) requirements expand the current expectations for antibiotic stewardship programs.



New and Revised Requirements Addressing Antibiotic Stewardship for the Hospital and Critical Access Hospital Programs

Effective January 1, 2023, new and revised antibiotic stewardship requirements will apply to all Joint Commission–accredited hospitals and critical access hospitals. The 12 elements of performance (EPs) are included in the "Medication Management" (MM) chapter (Standard MM.09.01.01) and expand upon the current expectations for antibiotic stewardship programs in the hospital setting.

Standard MM.09.01.01, EPs 10–21 include updates to align with federal regulations and current recommendations from scientific and professional organizations. The revisions include the following:

- Allocating financial resources to support the antibiotic stewardship program
- Appointing a leader of the antibiotic stewardship program and outlining responsibilities
- Establishing a multidisciplinary committee to oversee the antibiotic stewardship program
- Implementing a hospitalwide antibiotic stewardship program to address inappropriate antibiotic use
- Evaluating adherence to evidence-based guidelines for the most common indications
- Collecting, analyzing, and reporting data about the antibiotic stewardship program
- Identifying opportunities to improve the antibiotic stewardship program
- Editorial revisions (renumbering EPs, clarifying language, and adding notes)

Prepublication Standards:

- Critical Access Hospital (new/revised EPs only)
- Critical Access Hospital (comparison of current & and new/revised EPs)
- Hospital (new/revised EPs only)
- Hospital (comparison of current & and new/revised EPs)

Prepublication Standards - Effective January 1, 2023

https://www.jointcommission.org/standards/prepublication-standards/new-and-revised-requirements-addressing-antibiotic-stewardship-for-hospital/

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Additional Resources

https://www.jointcommission.org/resources/patient-safety-topics/infection-prevention-and-control/antibiotic-stewardship/

https://www.jointcommission.org/standards/standard-faqs/hospital-and-hospital-clinics/medication-management-mm/000002449/

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The Joint Commission Antibiotic Stewardship Requirements

How Changes Impact Your Hospital

Keith Hamilton, MD FACP FSHEA
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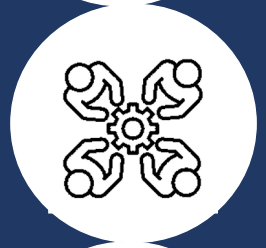
Director of Undergraduate Medical Education
Department of Medicine, Perelman School of Medicine

TJC Revisions

Commitment/Collaboration



Team Building

Action and Impact

Tracking and reporting

Education and expertise

TJC Revisions

Commitment/Collaboration

Team Building

Action and Impact

Tracking and reporting

Education and expertise

- **Requirement**: The hospital establishes antibiotic stewardship as an organizational priority through support of its antibiotic stewardship program.
- **EP10**: The hospital allocates financial resources for staffing and information technology to support the antibiotic stewardship program.
- **EPI11**: The governing body appoints a physician and/or pharmacist…as the leader(s) of the antibiotic stewardship program…. The appointment(s) is based on recommendations of medical staff leadership and pharmacy leadership.

Commitment and Collaboration

"Accountability is the glue that ties commitment to the result" – Bob Proctor

- Support for antibiotic stewardship lead(s)
  - Financial support
  - Protected time
  - Clear reporting structure (e.g. chief medical, quality, or pharmacy officer)
  - Job description of lead(s) approved by medical board or similar committee
- Develop or update a hospital policy mapped to the Joint Commission Elements of Performance (EP)
  - Approved by hospital medical board or similar committee
- Support information technology resources for antibiotic stewardship
  - Software and personnel

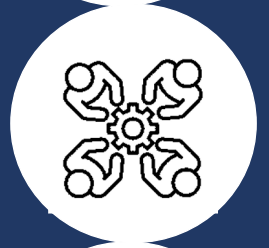
Written Administrative Support and Association with Comprehensive ASP

RR 7.2 (95% CI 6.1-8.4)

Pollack LA, et al. CID 2016.

TJC Revisions

Commitment/Collaboration



Team Building

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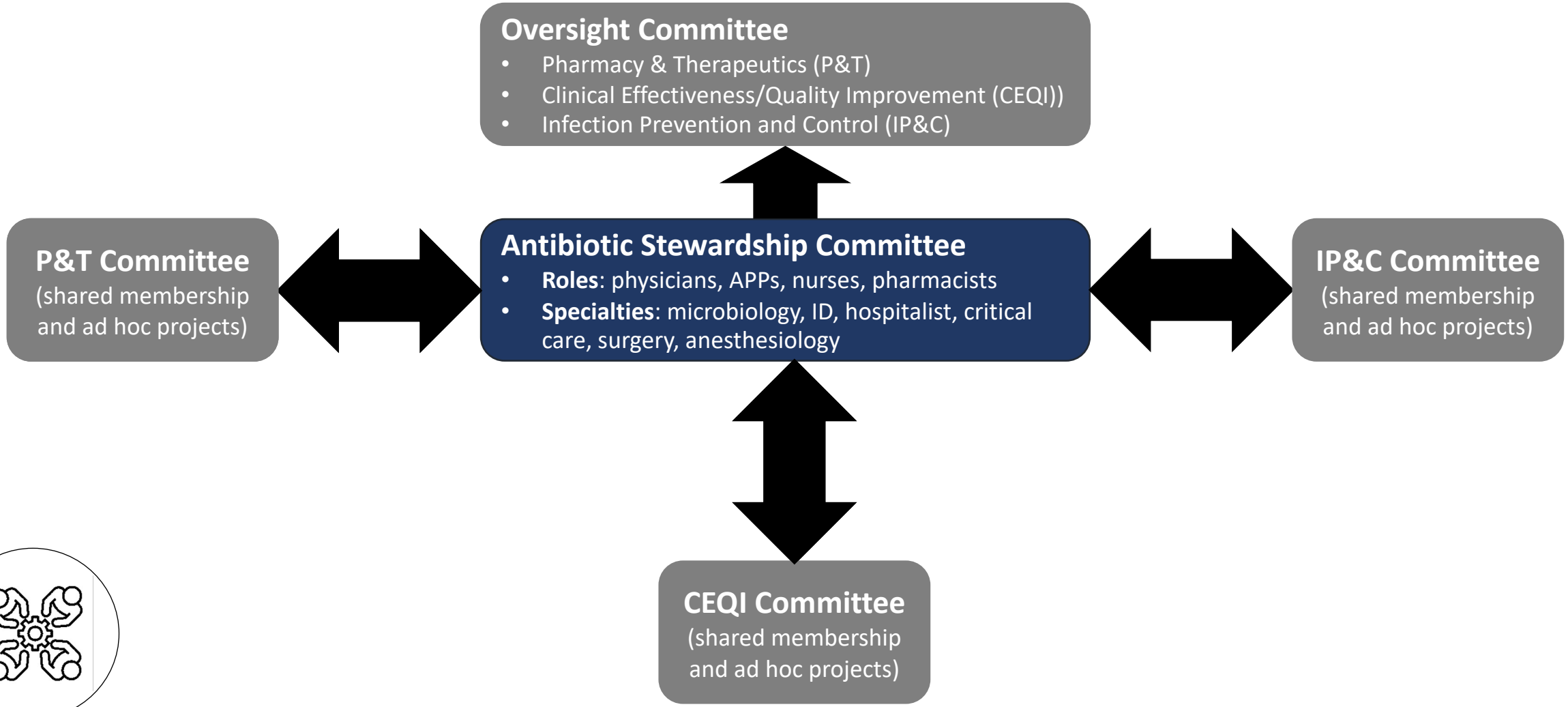
- **EP12**: The leader(s) of the antibiotic stewardship program is responsible for…**[c]ommunicating and collaborating** with the medical staff, nursing leadership, and pharmacy leadership, as well as with the hospital's infection prevention and control and quality assessment and performance improvement programs on antibiotic use issues….
- **EP13**: The hospital has a multidisciplinary **committee** that oversees the antibiotic stewardship program [may include part-time/consultant staff and can occur remotely].
- **EP14**: The antibiotic stewardship program demonstrates **coordination among all components of the hospital responsible for antibiotic use and resistance**, including, but not limited to, the infection prevention and control program, the quality assessment and performance improvement program, the medical staff, nursing services, and pharmacy services.

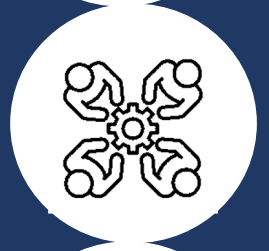
Team Building

"If everyone is moving forward together, then success takes care of itself" – Henry Ford



TJC Revisions

Commitment/Collaboration



Team Building

Action and Impact

Tracking and reporting

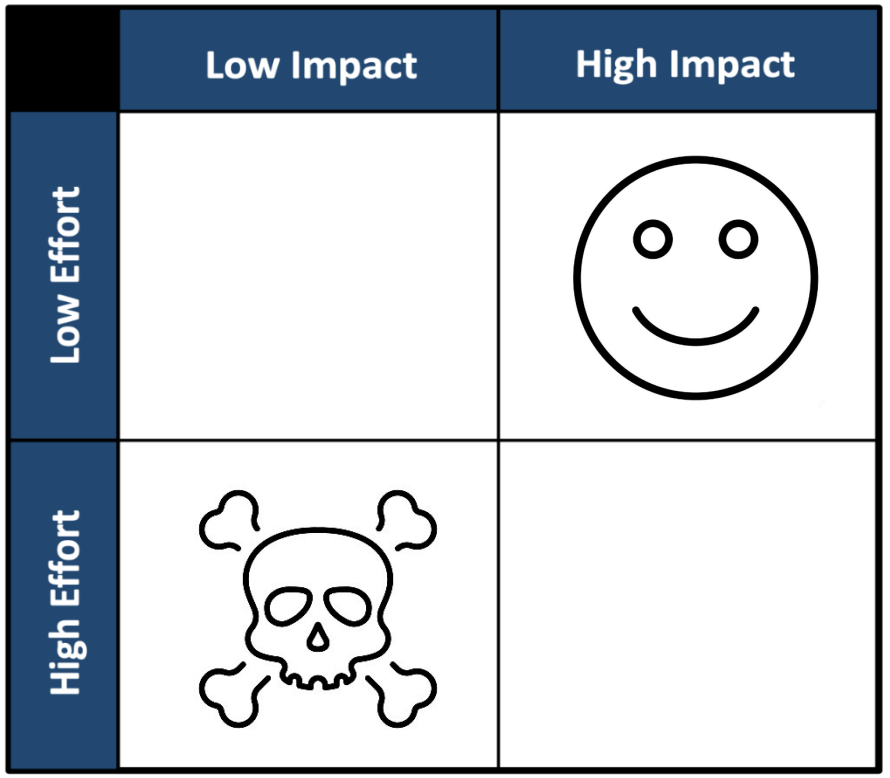
Education and expertise

- **EP12**: The leader(s) of the antibiotic stewardship program is responsible for…[d]eveloping and implementing a hospital-wide antibiotic stewardship program that is based on **nationally recognized guidelines** to monitor and improve the use of antibiotics…[and]…**[d]ocumenting antibiotic stewardship activities**….
- **EP17**: The antibiotic stewardship program implements one or both of…**[p]reauthorization [and/or] [p]rospective review and feedback** regarding antibiotic prescribing practices
- **EP18**: The antibiotic stewardship program implements **at least two evidence-based guidelines to improve antibiotic use for the most common indications**…based on national guidelines and also reflect local susceptibilities, formulary…, and the patients served
- **EP21**: The hospital takes **action on improvement opportunities** identified by the antibiotic stewardship program.

Action and Impact

"Nothing will work unless you do." – Maya Angelou

- Documenting stewardship activities
  - Consider maintaining an ongoing log of stewardship initiatives, interventions, and data
  - Consider mapping these activities to CDC Core Elements of Hospital Antibiotic Stewardship
- Action on improvement opportunities:
  - Target conditions with high rates of inappropriate prescribing
  - Consider a mini strategic plan process to identify and prioritize interventions

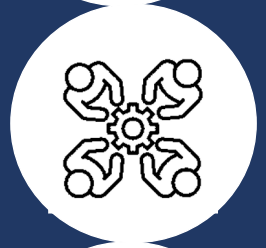


https://www.cdc.gov/antibiotic-use/core-elements/hospital.html

CDC Core Elements of Hospital Antibiotic Stewardship

TJC Revisions

Commitment/Collaboration



Team Building

Action and Impact

Tracking and reporting ➡

Education and expertise

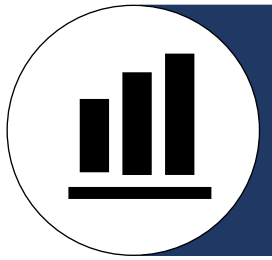
- **EP15**: The antibiotic stewardship program documents the **evidence-based use of antibiotics in all departments and services** of the hospital.
- **EP16**: The antibiotic stewardship program monitors the hospital's antibiotic use by analyzing data on **days of therapy per 1000 days present or 1000 patient days, or by reporting antibiotic use data to the National Healthcare Safety Network's Antimicrobial Use Option** of the Antimicrobial Use and Resistance Module.
- **EP19**: The antibiotic stewardship program evaluates **adherence (including antibiotic selection and duration of therapy, where applicable) to at least one of the evidence-based guidelines** the hospital implements.

EP20: The antibiotic stewardship program **collects, analyzes, and reports data to hospital leadership and prescribers**…Examples of antibiotic stewardship program data include antibiotic resistance patterns, antibiotic prescribing practices, or an evaluation of antibiotic stewardship activities.

Tracking and Reporting

"It is widely believed that you cannot manage what you cannot measure. It is also true that you cannot measure what you cannot define." – Richard Platt

- Start preparing to upload data to **National Healthcare Safety Network's (NHSN) Antimicrobial Use and Resistance (AUR)** "Option"
  - CMS will require reporting to NHSN module starting in calendar year 2024
- Syndromic stewardship and monitoring of guideline adherence (antibiotic selection and duration) is **challenging**
  - Can use ICD-10 codes for diagnoses of interest, but attribution to the individual antibiotic is difficult and cannot prospectively audit use by indication
  - Consider requiring prescribers enter antibiotic indication in the antibiotic order
  - Provider-selected indication can be used to identify indication-specific guideline discordance in real-time and to report antibiotic use by indication



Comparing Pneumonia Provider-Selected Antibiotic Indication v. ICD-10 Code

Specificity 96.3% v. 96.1%

Yang D, et al. SHEA 2023 [submitted].

TJC Revisions

Commitment/Collaboration

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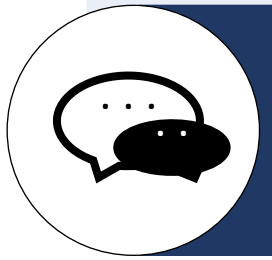
Tracking and reporting

Education and expertise

- **EP11**: The governing body appoints a physician and/or pharmacist who is **qualified through education, training, or experience** in infectious diseases and/or antibiotic stewardship as the leader(s) of the antibiotic stewardship program.
- **EP12**: The leader(s) of the antibiotic stewardship program is responsible for…[p]roviding **competency-based training and education** for staff, including medical staff, on the practical applications of antibiotic stewardship guidelines, policies, and procedures

Education and Expertise: Building Expertise

Course	CME and/or CPE Credit	Free
CDC Antibiotic Stewardship Training Series	☑	☑
IDSA Antimicrobial Stewardship Curriculum for ID Fellows		$
MAD-ID Antimicrobial Stewardship Certificate Program	☑	$
SHEA Antibiotic Stewardship Training Course	☑	$
SHEA Implementation Science	☑	$
SHEA Primer on Healthcare Epidemiology/Antimicrobial Stewardship	☑	$
SIDP Antimicrobial Stewardship Certificate Programs	☑	$
Stanford University Antimicrobial Stewardship	☑	☑



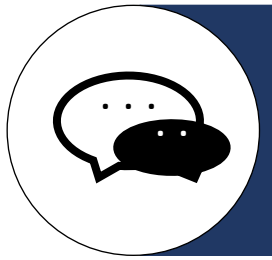
Courses that Offer Training in

Antibiotic Stewardship

Education and Expertise: Training Staff

Education is not the learning of facts but training the mind to think – Albert Einstein

- Competency-Based Education (CBE):
  - Learner competencies are determined prior to developing curriculum
  - Curriculum is designed to promote mastery of competencies
  - Often learner-directed where learners have some choice in curriculum
  - Learner assessment required to confirm competency, not regurgitation of facts
- Steps:
  1. Determine competencies
  2. Design curriculum based on competencies
  3. Determine what competency means (completing training, answering questions, etc.)
  4. Assess that education has had an impact (prospective audit and feedback, data review, etc.)
- Examples:
  - On-boarding learning modules for providers based on CBE
  - WHO has an extensive competency-based stewardship education module (see below)



https://openwho.org/courses/AMR-competency

WHO Antibiotic Stewardship

Antimicrobial stewardship: a competency-based approach. *JAC Antimicob Resist*. 2020. doi:10.1093/jacamr/dlaa006.

Standard MM09.01.01 Revisions & Pharmacy Implications

MATT DAVIS
INFECTIOUS DISEASE CONNECT
PHARMD

Pharmacists as Core ASP Contributors

E.P. 10. The hospital allocates financial resources for **staffing** and IT to support the ASP. **(NEW)**

E.P. 11. The governing body appoints a **qualified** physician and/or **pharmacist** as the leader(s) of the ASP.

E.P. 12. The leader(s) of the ASP is responsible for the following:

- **Documenting antibiotic stewardship activities**, including any new or sustained improvements
- **Communicating and collaborating** with the medical staff, nursing leadership, and **pharmacy leadership**, IP&C, QAPI on antibiotic use issues

E.P. 13. A multidisciplinary committee oversees the ASP composed of medicine, **pharmacy**, IP&C, nursing, microbiology, IT, and QAPI.

E.P. 14. The ASP **coordinates across all parties** responsible for AU and resistance, including […] **pharmacy services**.

E.P. 15. The ASP **documents the evidence-based use of antibiotics** in all departments and services of the hospital.

E.P. 16. The ASP **monitors the hospital's AU** by monitoring DOT/1000 days present or patient days, or by reporting AU data to NHSN. **(NEW)**

E.P. 17. The ASP **implements pre-authorization and/or prospective audit and feedback** to improve antibiotic prescribing. **(NEW)**

E.P. 18. The ASP implements at least two evidence-based guidelines to improve antibiotic use for the most common indications. **(NEW)**

E.P. 19. The ASP **evaluates adherence** to at least one of the evidence-based guidelines the hospital implements. **(NEW)**

E.P. 20. The ASP **collects, analyzes, and reports data to hospital leadership and prescribers.**

E.P. 21. The hospital takes action on improvement opportunities identified by the ASP.

Infectious Disease Connect

AU = antibiotic use; IP&C = infection prevention and control; IT = information technology; QAPI = quality and performance improvement
https://www.jointcommission.org/-/media/tjc/documents/standards/r3-reports/r3_antibioticstewardship_july2022_final.pdf

How Can Pharmacists/Pharmacies Prepare

SIDP
SOCIETY OF INFECTIOUS DISEASES PHARMACISTS

Certifications:
Acute Care Pharmacists
Long-Term Care Pharmacists
Research Mini-Series

SIDP Education Center:
Journal Club Series
CPE/BCIDP credit
SIDP meeting content

Toolkits/Resources:
COVID-19 monoclonal and oral antiviral
Vancomycin AUC
Public education resources

MAD-ID
MAKING A DIFFERENCE IN INFECTIOUS DISEASES®

Certifications:
Basic
Advanced (content delivered at annual meeting)

Tool/Resources:
Vancomycin AUC calculators (free and paid)
Monthly newsletter
Annual ID conference

bps BOARD CERTIFIED INFECTIOUS DISEASES PHARMACIST
accp American College of Clinical Pharmacy
ashp

Certifications:
Board certification in infectious diseases pharmacy (BCIDP)

Training/Recertification Materials:
ACCP/ASHP materials (member discounts)
Recertification materials

Podcasts

Breakpoints
The SIDP Podcast

febrile

PGY-2 training in infectious diseases is **NOT REQUIRED**

https://sidp.org/home
https://mad-id.org/
https://febrilepodcast.com/
https://www.bpsweb.org/bps-specialties
https://www.rxcertifications.org/infectious-diseases/certification-preparation
https://www.sidp.org/Podcasts

How Can Pharmacists/Pharmacies Prepare

Allocate staffing/dedicated time for processes

- **Prospective audit and feedback – *few hours to full FTE(s)***
- Pre-authorization processes

Work with IT to create actionable reports

- Antibiotic monitoring for audits/restrictions
- **Antibiotic use tracking for analysis and reporting**

Develop and document formulary and guideline changes

- **≥ 2 pathways (Examples: UTI, SSTI, CAP, *C. difficile*, ASB)**

Infectious Disease Connect

ASB = asymptomatic bacteriuria CAP = community-acquired pneumonia;
SSTI = skin and soft tissue infection; UTI = urinary tract infection

Key Responsibilities: Prospective Audits

"Preauthorization and/or prospective audit and feedback are a ***core component of any stewardship program***. Programs should decide whether to include one strategy or both based on availability of resources, but some ***implementation is essential.***"

Barlam TF et al. ***Clinical Infectious Diseases*** 2016. DOI: 10.1093/cid/ciw118

Pharmacist (primary)

Physician ("backup")

Audit key antimicrobials

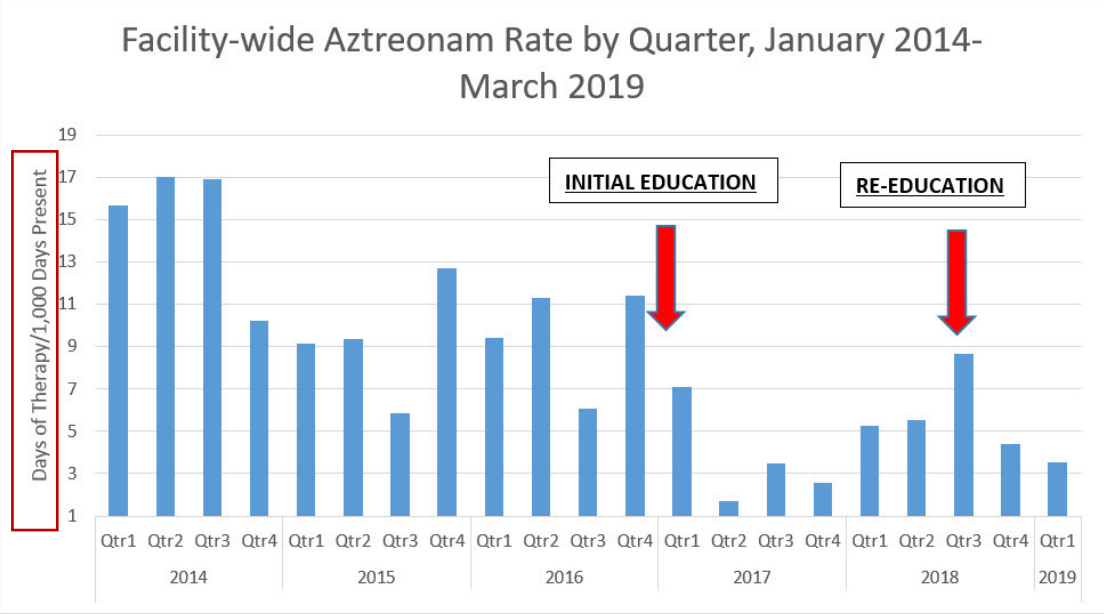
Assure appropriate dose, spectrum, duration, safety, formulary/guidelines

Provide intervention and feedback/education to primary teams

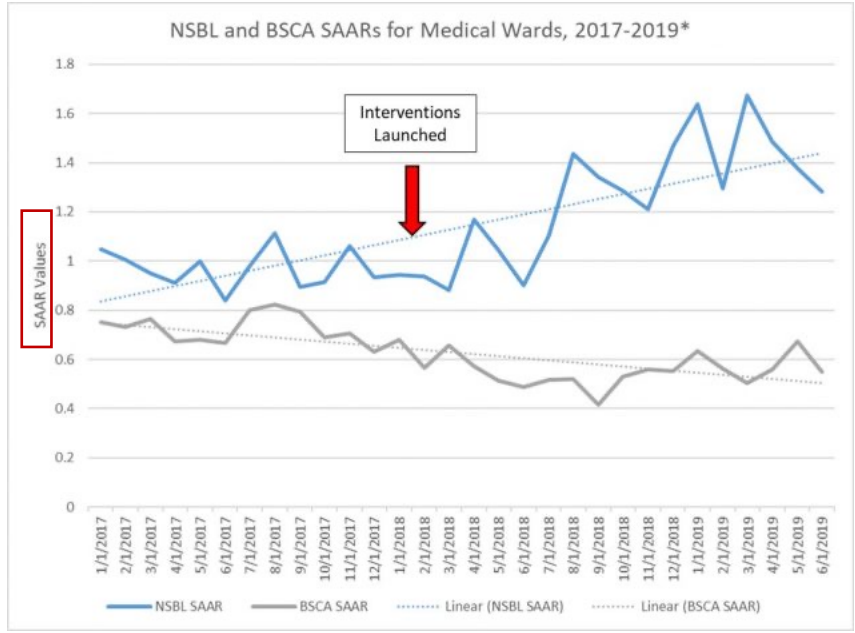
Most challenging

Applicable E.P.'s: **10, 12, 15-19, 21**

Key Responsibilities: Metrics and Analysis



Tracking antimicrobial use provides critical insight into local utilization patterns and feedback on effectiveness of ASP quality improvement initiatives.



Antimicrobial use data can be uploaded into CDC's NHSN platform to compare local data to a national benchmark for context.

Common ASP pharmacist responsibilities

Applicable E.P.'s: **10, 12, 15, 16, 19-21.**

https://www.cdc.gov/nhsn/au-case-xamples/reducing-aztreonam-use.html https://www.cdc.gov/nhsn/au-case-examples/multiple-interventions.html

Key Responsibilities: Guidelines/Formulary

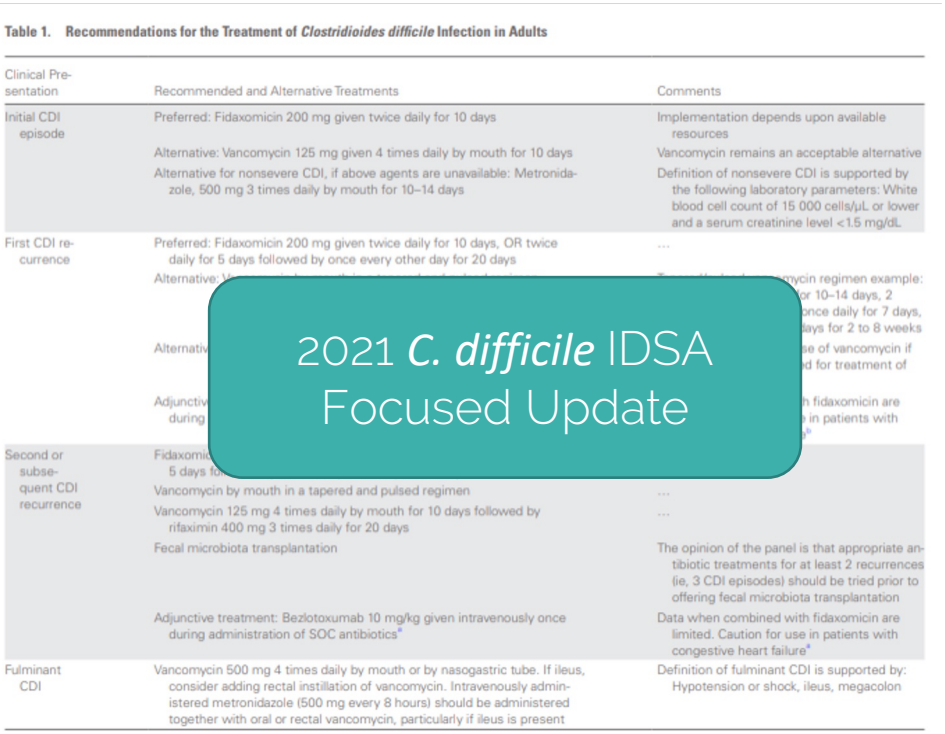
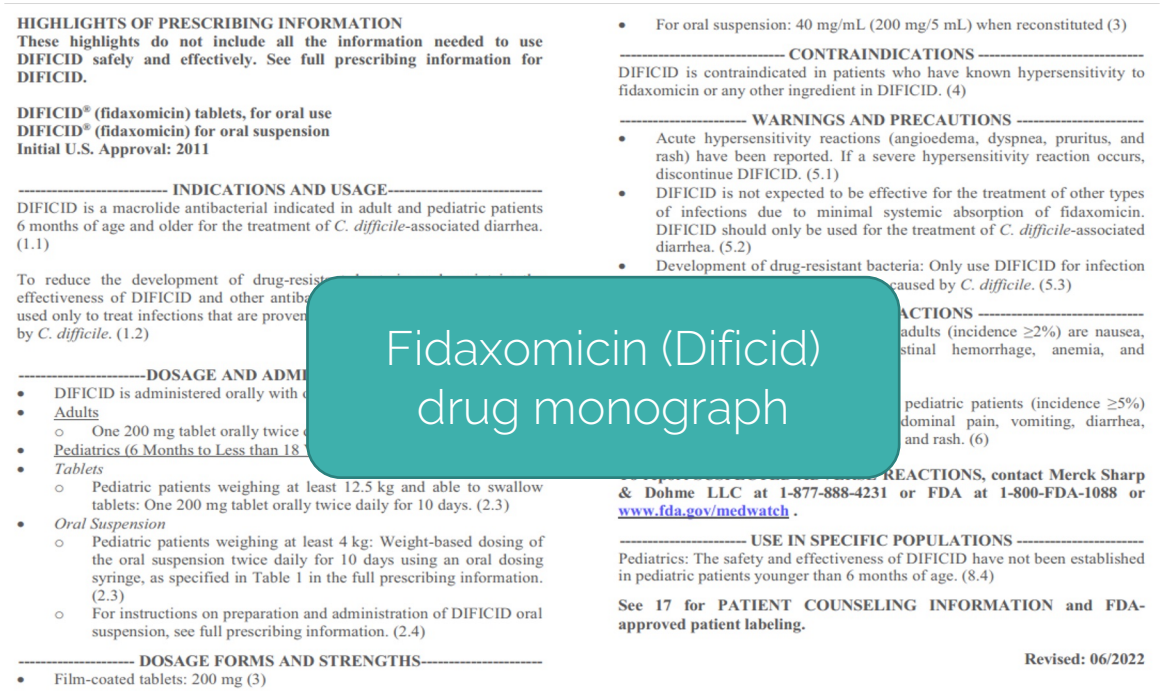


Table 1. Recommendations for the Treatment of *Clostridioides difficile* Infection in Adults

Clinical Presentation	Recommended and Alternative Treatments	Comments
Initial CDI episode	Preferred: Fidaxomicin 200 mg given twice daily for 10 days	Implementation depends upon available resources
	Alternative: Vancomycin 125 mg given 4 times daily by mouth for 10 days	Vancomycin remains an acceptable alternative
	Alternative for nonsevere CDI, if above agents are unavailable: Metronidazole, 500 mg 3 times daily by mouth for 10–14 days	Definition of nonsevere CDI is supported by the following laboratory parameters: White blood cell count of 15 000 cells/μL or lower and a serum creatinine level <1.5 mg/dL
First CDI recurrence	Preferred: Fidaxomicin 200 mg given twice daily for 10 days, OR twice daily for 5 days followed by once every other day for 20 days	…
	Alternative:	…ycin regimen example: …or 10–14 days, 2 …once daily for 7 days, …days for 2 to 8 weeks
	Alternati…	…se of vancomycin if …d for treatment of
	Adjunctiv… during	…h fidaxomicin are … in patients with
Second or subsequent CDI recurrence	Fidaxomi… 5 days fo…	…
	Vancomycin by mouth in a tapered and pulsed regimen	…
	Vancomycin 125 mg 4 times daily by mouth for 10 days followed by rifaximin 400 mg 3 times daily for 20 days	…
	Fecal microbiota transplantation	The opinion of the panel is that appropriate antibiotic treatments for at least 2 recurrences (ie, 3 CDI episodes) should be tried prior to offering fecal microbiota transplantation
	Adjunctive treatment: Bezlotoxumab 10 mg/kg given intravenously once during administration of SOC antibiotics[a]	Data when combined with fidaxomicin are limited. Caution for use in patients with congestive heart failure[a]
Fulminant CDI	Vancomycin 500 mg 4 times daily by mouth or by nasogastric tube. If ileus, consider adding rectal instillation of vancomycin. Intravenously administered metronidazole (500 mg every 8 hours) should be administered together with oral or rectal vancomycin, particularly if ileus is present	Definition of fulminant CDI is supported by: Hypotension or shock, ileus, megacolon

2021 *C. difficile* IDSA Focused Update



HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use DIFICID safely and effectively. See full prescribing information for DIFICID.

DIFICID® (fidaxomicin) tablets, for oral use
DIFICID® (fidaxomicin) for oral suspension
Initial U.S. Approval: 2011

---------- INDICATIONS AND USAGE----------
DIFICID is a macrolide antibacterial indicated in adult and pediatric patients 6 months of age and older for the treatment of *C. difficile*-associated diarrhea. (1.1)

To reduce the development of drug-resist… effectiveness of DIFICID and other antib… used only to treat infections that are proven… by *C. difficile*. (1.2)

----------DOSAGE AND ADMI…
- DIFICID is administered orally with …
- Adults
  - One 200 mg tablet orally twice …
- Pediatrics (6 Months to Less than 18 …
- *Tablets*
  - Pediatric patients weighing at least 12.5 kg and able to swallow tablets: One 200 mg tablet orally twice daily for 10 days. (2.3)
- *Oral Suspension*
  - Pediatric patients weighing at least 4 kg: Weight-based dosing of the oral suspension twice daily for 10 days using an oral dosing syringe, as specified in Table 1 in the full prescribing information. (2.3)
  - For instructions on preparation and administration of DIFICID oral suspension, see full prescribing information. (2.4)

---------- DOSAGE FORMS AND STRENGTHS----------
- Film-coated tablets: 200 mg (3)
- For oral suspension: 40 mg/mL (200 mg/5 mL) when reconstituted (3)

---------- CONTRAINDICATIONS ----------
DIFICID is contraindicated in patients who have known hypersensitivity to fidaxomicin or any other ingredient in DIFICID. (4)

---------- WARNINGS AND PRECAUTIONS ----------
- Acute hypersensitivity reactions (angioedema, dyspnea, pruritus, and rash) have been reported. If a severe hypersensitivity reaction occurs, discontinue DIFICID. (5.1)
- DIFICID is not expected to be effective for the treatment of other types of infections due to minimal systemic absorption of fidaxomicin. DIFICID should only be used for the treatment of *C. difficile*-associated diarrhea. (5.2)
- Development of drug-resistant bacteria: Only use DIFICID for infection …caused by *C. difficile*. (5.3)

…ACTIONS ----------
…adults (incidence ≥2%) are nausea, …stinal hemorrhage, anemia, and …

…pediatric patients (incidence ≥5%) …dominal pain, vomiting, diarrhea, … and rash. (6)

…REACTIONS, contact Merck Sharp & Dohme LLC at 1-877-888-4231 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch .

---------- USE IN SPECIFIC POPULATIONS ----------
Pediatrics: The safety and effectiveness of DIFICID have not been established in pediatric patients younger than 6 months of age. (8.4)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 06/2022

Fidaxomicin (Dificid) drug monograph

New medications must be evaluated for cost-effectiveness and concordance with updated national guidelines to develop institutional guidelines. **Minimum of two evidence-based guidelines** should be implemented with compliance monitored.

Applicable E.P.'s: **12, 14-21.**

Johnson S et al. *CID* 2021. DOI: DOI: 10.1093/cid/ciab549/
https://www.merck.com/product/usa/pi_circulars/d/dificid/dificid_pi.pd

Q & A

ANSWERS WILL BE SENT TO PARTICIPANTS WHOSE QUESTIONS ARE NOT ADDRESSED

Healthcare Leaders Are Wondering.....

- What penalties might hospitals face if they don't comply with new TJC AMS standards?
- What has provided the most help to Penn Medicine in its quest to improve its AMS reporting?
- What can clinical teams do to ensure they improve their communications and provide more timely AMS feedback?

Thank You for Joining Infectious Disease Connect

NEW YEAR, NEW ANTIMICROBIAL REQUIREMENTS FOR HOSPITALS

DECEMBER 7, 2022