


Slide 1

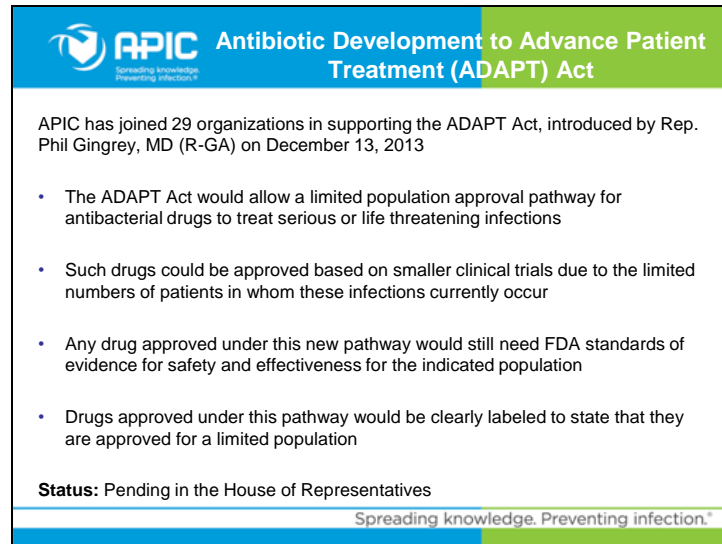


**Chapter Legislative Representatives
Government Affairs Update**

April 2014

Spreading knowledge. Preventing infection.®

As the APIC Chapter Legislative Representative, I will be updating you on the work of the APIC Public Policy Committee and news on federal initiatives that impact infection preventionists and our work.



The slide features a blue and green header with the APIC logo and the text "Antibiotic Development to Advance Patient Treatment (ADAPT) Act". The main content is white with a black border, containing a paragraph and a bulleted list. A blue and green footer at the bottom contains the APIC slogan "Spreading knowledge. Preventing infection."

APIC Antibiotic Development to Advance Patient Treatment (ADAPT) Act

APIC has joined 29 organizations in supporting the ADAPT Act, introduced by Rep. Phil Gingrey, MD (R-GA) on December 13, 2013

- The ADAPT Act would allow a limited population approval pathway for antibacterial drugs to treat serious or life threatening infections
- Such drugs could be approved based on smaller clinical trials due to the limited numbers of patients in whom these infections currently occur
- Any drug approved under this new pathway would still need FDA standards of evidence for safety and effectiveness for the indicated population
- Drugs approved under this pathway would be clearly labeled to state that they are approved for a limited population

Status: Pending in the House of Representatives

Spreading knowledge. Preventing infection.®

In February, APIC joined the Infectious Diseases Society of America and 29 other organizations to support the Antibiotic Development to Advance Patient Treatment (ADAPT) Act. The legislation was introduced by Representatives Phil Gingrey (R-GA) and Gene Green (D-Texas) and aims to encourage antibiotic development and address the growing threat of antibiotic resistance.

The ADAPT Act would help accelerate the development of new treatments through the limited population antibacterial drug pathway, which would allow new drugs to be approved in limited and specific patient populations.

In order to move this legislation forward in Congress, look for a letter from APIC in the coming weeks asking for our members to join us by sending a letter to Congress in support of the legislation.

APIC Spreading Knowledge. Preventing Infection.[®]

CDC Vital Signs: Antibiotic prescribing in hospitals

Vital Signs
Making Health Care Safer
Antibiotic Rx in Hospitals: Proceed with Caution
Antibiotic resistance is a growing public health problem. Prescribing antibiotics for the wrong infection, at the wrong dose, or for too long can lead to antibiotic resistance. Making sure antibiotics are used in the best way possible is key to preventing antibiotic resistance.

1 in 2
One-third of all antibiotic prescriptions for urinary tract infections and vancomycin include a potential error – given without proper testing or evaluation, or given for too long.

3x
Prescribing practices vary widely between hospitals and doctors within a hospital. According to CDC, doctors in some hospitals prescribed 3 times as many antibiotics as doctors in other hospitals.

30%
Reducing the use of high-risk antibiotics by 30% can lower *C. difficile* infections by 26%.

Improving antibiotic prescribing in hospitals
Key elements for improving the care of antibiotic prescribing practices:

1. Leadership commitment
2. Accountability
3. Drug expertise
4. Tracking prescribing and antibiotic resistance patterns
5. Regularly reporting to staff prescribing and antibiotic resistance patterns

CDC recommends that hospitals institute an antibiotic stewardship program that includes:

- Leadership commitment
- Accountability
- Drug expertise
- Taking at least one prescribing improvement action
- Tracking prescribing and antibiotic resistance patterns
- Regularly reporting to staff prescribing and antibiotic resistance patterns
- Education

Spreading knowledge. Preventing infection.[®]

CDC's March *Vital Signs* highlighted the effect poor prescribing habits can have on the ability to protect patients from unnecessary risk and preserve the power of antibiotics. The report found that approximately one-third of the time, prescribing practices to treat urinary tract infections and prescriptions for vancomycin included a potential error – given without proper testing or evaluation, or given for too long. In addition to the potential errors, prescribing practices vary widely between hospitals and doctors within a hospital. According to CDC, doctors in some hospitals prescribed 3 times as many antibiotics as doctors in other hospitals.

CDC estimates that reducing the use of high-risk antibiotics by 30% can lower *C. difficile* infections by 26%. CDC recommends that hospitals have an antibiotic stewardship program in place to reduce instances of inappropriate antibiotic prescribing.

The release of the March *Vital Signs* coincides with CDC's announcement of a new antibiotic resistance initiative, that will focus on the four core actions called for in CDC's Antibiotic Resistance Threat Report: detection of antibiotic resistance; response to outbreaks; prevention of infections; discovery of new antibiotics and diagnostic tests for resistance. The initiative aims to reduce the threats of seven antibiotic resistant organisms, including carbapenem-resistant *Enterobacteriaceae* (CRE), by improving detection through regional laboratories and strengthening antibiotic prescribing practices.

Stay tuned to future updates to find out how APIC members can help promote this CDC initiative by sending a letter to their member of Congress in support of funding for these efforts.

National Action Plan to Prevent Healthcare-Associated Infections Current Progress and Proposed Targets for 2020						
Measure	Data Source	Baseline Years	Baseline Data	2013 Target	Progress	Proposed Target for 2020
Reduce central-line associated bloodstream infections (CLABSI) in ICU and ward-located patients	CDC/ NHSN	2006-2008	1.0 SIR	50% reduction or .50 SIR	44% reduction or .56 SIR (2012)	50% reduction from 2015 baseline ¹
Reduce catheter-associated urinary tract infections (CAUTI) in ICU and ward-located patients	CDC/ NHSN	2009	1.0 SIR	25% reduction or .75 SIR	2% increase or 1.02 SIR (2012)	25% reduction from 2015 baseline ²
Reduce the incidence of invasive healthcare-associated methicillin-resistant Staphylococcus aureus (MRSA) infections	CDC/EIP/ ABC	2007-2008	27.08 infections per 100,000 persons	50% reduction or 13.5 infections per 100,000 persons	31% overall reduction or 18.6 infections per 100,000 persons (2012)	75% reduction from 2007-2008 baseline ³
Reduce facility-onset methicillin-resistant Staphylococcus aureus (MRSA) in facility-wide healthcare	CDC/ NHSN	2010-2011	1.0 SIR	25% reduction or .75 SIR	3% reduction or .97 SIR (2013)	50% reduction from 2015 baseline
Reduce facility-onset Clostridium difficile infections in facility-wide healthcare	CDC/ NHSN	2010-2011	1.0 SIR	30% reduction or .70 SIR	2% reduction or .98 SIR (2012)	30% reduction from 2015 baseline
Reduce the rate of Clostridium difficile hospitalizations	AHRQ/ HCUP	2008	11.6 hospitalizations with C. difficile per 1,000 discharges	30% reduction	13.6 hospitalizations per 1,000 discharges (2012 Projected)	30% reduction from 2015 baseline
Reduce Surgical Site Infection (SSI) admission and readmission	CDC/ NHSN	2006-2008	1.0 SIR	25% reduction or .75 SIR	20% reduction or .80 SIR (2012)	30% reduction from 2015 baseline

¹ Infections from Mucosal Barrier Injury (MBI) will be excluded from the calculation
² The target will reflect aggregate data, but interim assessments of the rate will also be stratified by ICUs and non-ICUs in order to better understand the areas needed for improvement
³ This is a Healthy People 2020 Goal

Abbreviations:
 CDC/NHSN - Centers for Disease Control and Prevention's National Healthcare Safety Network
 CDC/EIP/ABC - Centers for Disease Control and Prevention's Emerging Infections Program Network
 Active Bacterial Core Surveillance; AHRQ/HCUP - Agency for Healthcare Research and Quality
 Healthcare Cost and Utilization Project; SIR - Standardized Infection Rate

Spreading knowledge. Preventing infection.™



The U.S. Department of Health and Human Services released proposed targets and metrics for the National Action Plan to Prevent Healthcare-Associated Infections, as virtually all of the previous targets and metrics expired December 2013.

A national stakeholder meeting was held in September 2013 and helped shape the proposed targets along with a federal steering committee of HAI prevention experts from federal agencies.


The proposed targets would set 2015 as the new baseline, with the exception of invasive MRSA, which was included in the federal government’s Healthy People 2020 goals and has an existing 2007-2008 baseline, which has not expired.

This table outlines the proposed new targets for 2020, alongside the most recent progress on the measures to date.

The APIC Public Policy Committee has drafted comments on the draft targets, which are available on Public Policy section of the APIC website under “What’s New”.




- HICPAC developed the draft Guideline for the Prevention of Surgical Site Infection (SSI) to update the 1999 SSI guidelines.
- For the new guideline, HICPAC used a different methodology for evaluating quality of evidence and determining strength of recommendations
 - This methodology resulted in significantly fewer practice recommendations than in the previous guideline
- APIC submitted comments to HICPAC on the draft guideline
 - Drafted in collaboration with the Practice Guidance Committee and the Public Policy Committee



Spreading knowledge. Preventing infection.®


APIC submitted comments to the CDC Healthcare Infection Control Practices Advisory Committee (HICPAC) Draft Guideline for the Prevention of Surgical Site Infection. A joint review by the APIC Practice Guidance and Public Policy Committees provides support for HICPAC’s efforts, but also notes that the methodology used to develop the guidelines resulted in significantly fewer practice recommendations than were included in the 1999 guidelines, which can make implementation of the guideline more challenging.

The HICPAC draft SSI guideline and APIC comments may be found in Public Policy section of the APIC website under “What’s New”.



Other Recent Public Policy Committee Activities

- **Judicious use of antibiotics in food-producing animals**
 - Submitted comments to FDA on updates to the Veterinary Feed Directive
- **Proposed rule on consumer antimicrobial hand soaps and body washes**
 - FDA proposed rule would require proof of safety and efficacy of OTC antimicrobial hand soaps and body washes
 - This rule would **not** impact products intended for healthcare facility use
- **Updated investigational new drug enforcement policy for fecal transplantation**
 - Draft policy would update FDA 2013 guidance on agency approval of fecal microbiota for transplantation



Spreading knowledge. Preventing infection.®

APIC Government Affairs staff reviews and monitors federal regulations for infection prevention implications. When appropriate, the Public Policy Committee will provide clinical expertise to draft comments on regulations and guidelines.


APIC recently submitted comments to the Food and Drug Administration (FDA) on the update to the Veterinary Feed Directive, which would allow veterinarians to better ensure that antibiotics are only used for therapeutic purposes in food producing animals. While the directive does not directly affect infection prevention, it is a part of FDA's efforts to promote the judicious use of antibiotics.

In addition the FDA has proposed a rule on consumer antimicrobial hand soaps that would require manufacturers of consumer hand soaps and body washes to provide evidence that products labeled as antimicrobial are both safe for everyday use and more effective than plain soap and water at preventing infections. If not, products would need to be reformulated and relabeled. A Public Policy Committee review group is currently preparing comments on this issue.

The Public Policy Committee is also reviewing an update to FDA's 2013 investigational new drug (IND) enforcement policy for fecal microbiota for transplantation (FMT). Previously, FDA reported that the agency would use discretion in enforcing the IND requirements. The updated enforcement policy would require:


- That treating provider obtain adequate informed consent from patient or his/her representative
- That the FMT is obtained from a donor known to either the patient or the provider
- The stool donor and stool are qualified by screening and testing.

Links to these proposed rules can be found on Public Policy section of the APIC website under "What's New".



What can you do to help?

From time to time APIC Government Affairs will ask members to contact their Members of Congress and weigh-in on issues affecting infection prevention. Your input helps APIC educate and influence legislators on the value of infection prevention programs.



State Tuned: Upcoming letter writing campaigns:


- Support the ADAPT Act – asking U.S. Representatives to cosponsor this legislation to accelerate the development of antibiotics
- Support funding for important CDC programs and initiatives:
 - NHSN and Prevention EpiCenters funding – annual campaign to support funding for CDC’s NHSN, Prevention EpiCenters and other HAI prevention programs
 - Antibiotic Resistance Initiative

Spreading knowledge. Preventing infection.®

APIC Government Affairs sometimes asks members to contact their Members of Congress on issues affecting infection prevention.

As your Chapter Legislative Representative, I will be asking chapter members to support two upcoming letter writing campaigns. The first campaign will be asking our U.S. Representatives to cosponsor the ADAPT Act, which would allow new antibiotics for emerging threats to be approved under a limited population pathway. The second campaign is APIC’s annual appropriations letter to ask Members of Congress to support funding for NHSN and other HAI prevention programs, including the CDC’s antibiotic resistance initiatives.

There is no need to worry about looking up legislators – APIC’s website has a handy program that populates all the necessary information. The only thing you have to do is fill in your name and address. APIC can only influence legislators when we speak with one voice about the work infection preventionists do to protect patients in their districts. Thank you for your support in these campaigns.



Additional Resources

CDC March 2014 Vital Signs, Making Healthcare Safer, Antibiotic RX in hospitals: proceed with caution
<http://www.cdc.gov/vitalsigns/pdf/2014-03-vitalsigns.pdf>

APIC comments on HICPAC draft SSI Guidelines
http://www.apic.org/Resource_/TinyMceFileManager/Advocacy-PDFs/APIC_comments_on_HICPAC_SSI_guidelines_2014.pdf

APIC comments on the Food and Drug Administration's Veterinary Feed Directive
http://www.apic.org/Resource_/TinyMceFileManager/Advocacy-PDFs/FDA_VFD_Proposed_rule_3-5-14.pdf

Spreading knowledge. Preventing infection.®

These are the pathways where you can find some of the documents referenced in these slides.