Antimicrobial Stewardship Guideline Updates & Legal Responsibility to Your Patients

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Disclosure

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Learning Objectives

List the key components of an antimicrobial stewardship program in the acute health care setting

Describe targeted measures to improve antimicrobial use in your institution

Understand the legal responsibility/liability faced by a pharmacist in the acute care setting with respect to antimicrobial stewardship
It started in the West

California Senate Bill 1311

Presidential Executive Order

The Joint Commission Prepublication Requirements effective January 1, 2017

New Antimicrobial Stewardship Standard
SB 1311

Legislation in California began in 2006
- vague, less than 50% of hospital enacted ASP programs

September 2014 SB 1311
- Adopt and implement by July 1, 2015
- Guidelines established by the federal government and professional organizations

Key Elements
- Adopt and implement
- Evaluate
- Develop
- Appoint
- Report
Presidential Executive Order

National Action Plan for Combating Antibiotic-Resistant Bacteria (September 18, 2014)

Goals:

- Slow and prevent resistance
- Strengthen National Surveillance
- Advance diagnostic testing
- Accelerate research and development
- Improve International Surveillance
Presidential Executive Order

National Action Plan for Combating Antibiotic-Resistant Bacteria

Threats: Urgent (3)

1. C. difficile
2. Carbapenem-Resistant Enterobacteriaceae
3. Neisseria gonorrhoea
Presidential Executive Order

National Action Plan for Combating Antibiotic-Resistant Bacteria

Threats: Serious (12)
1. Multidrug resistant (MDR) Acinetobacter
2. Drug-resistant Campylobacter
3. Fluconazole-resistant Candida
4. Extended spectrum ß-lactamase (ESBL) producing Enterobacteriaceae
5. Vancomycin-resistant Enterococcus
6. MDR Pseudomonas aeruginosa
7. Drug resistant non-typhoidal Salmonella (notifiable to the CDC)
8. Drug resistant Salmonella typhi (notifiable to the CDC)
9. Drug resistant Shigella (notifiable to the CDC)
10. Methicillin-resistant Staphlococcus aureus (MRSA)
11. Drug-resistant Streptococcus pneumoniae (notifiable to the CDC)
12. Drug resistant Tuberculosis (notifiable to the CDC)
Presidential Executive Order

National Action Plan for Combating Antibiotic-Resistant Bacteria

Threats: Of Concern (3)

1. Vancomycin-resistant *Staphylococcus aureus* (VRSA)
2. Erythromycin-resistant Group A *Streptococcus*
3. Clindamycin-resistant Group B *Streptococcus*
Joint Commission **New** ASP Standard

Effective January 1, 2017

Leadership established ASP as a priority

Education: staff, licensed practitioners, patients, and their families

Core elements
- Leadership
- Accountability
- Drug expertise
- Action
- Tracking
- Reporting
- Education
ASP Structure

Key members
◦ Infectious disease physician
◦ Clinical pharmacist with infectious disease training
◦ Clinical microbiologist
◦ Information system specialist
◦ Infection control professional
◦ Hospital epidemiologist

Purpose
◦ Coordinated interventions to improve and measure the appropriate use of antimicrobial agents by promoting the selection of the optimal drug regimen including dosing, duration of therapy, and route of administration

Dellit 2007 CID
Barlam 2016 CID
ASP Activities

- Monitoring Resistance
- Appropriate Use
- Infection Prevention
IDSA, SHEA & PIDS Updates to ASP

Updated recommendations for Implementing an Antibiotic Stewardship Program – Focus on interventions

Practical playbook building off their previous recommendations

- Recognition that resistance results in increased morbidity, mortality, and cost of health care
- IDSA initially published guidelines in 1988
- Joined forces with SHEA in 1997

IDSA: Infectious Diseases Society of America
SHEA: Society for Healthcare Epidemiology of America

Dellit 2007 CID
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ASP The Role of the Pharmacist

Core member of a multidisciplinary team often co-director

Infectious disease training
- Certification
- Post-graduate training program

Drug expert
- Limit inappropriate use
- Optimize antimicrobial selection
- Dosing
- Route of administration
- Duration of therapy
- Limit unwanted consequences
ASP The Role of the Pharmacist

- Prospective audit with intervention and feedback
- Formulary restrictions and preauthorization
- Guidelines and clinical pathways
- De-escalation of therapy
- Parenteral to oral conversions
Melvin Eason (60 y.o.) was being treated for venous thromboembolic disease with warfarin at the VA in Jackson, Mississippi.

Mr. Eason’s warfarin dosing was being managed by Dr. Alice Paysinger, a clinical pharmacist for the VA.

Mr. Eason was scheduled to undergo dental extractions.

Dr. Paysinger instructed Mr. Eason to hold his warfarin for five days before the extractions, then resume the warfarin at higher doses than normally prescribed for three days after the extractions.

Mr. Eason was also instructed to inject himself with enoxaparin for three days prior to and three days after the extractions.
A couple of weeks after the procedure, Mr. Eason’s INR measured 5.5, and 5.72 upon retest.

Dr. Paysigner instructed him to skip the warfarin for four days, then restart at a lower dose and scheduled him to return to the clinic in a week.

At the next visit, his INR measured 1.05, the lowest it had been since Dr. Paysinger started treating him.

Medical records for that visit indicate that Mr. Eason would be out of town for the next three weeks (Christmas). Dr. Paysinger instructed Mr. Eason to take 1 tablet of warfarin that day, and a half tablet daily thereafter.

Mr. Eason was scheduled for a follow up appointment upon return from his trip.
History of Liability for the Clinical Pharmacist Jeffries v United States of America (2009) (continued)

• Mr. Eason suffered a massive stroke five days later, which left him in a near vegetative state.

• His daughter, Ms. Jeffries, subsequently commenced the lawsuit against the VA.

• Damages awarded were $609,164 for past expenses, $500,000 in non-economic damages, and $2,900,017 in future medical expenses (approx. $4 million total)
Joseph Oran Van Winkle (67) was admitted to the ICU at the VA in Albuquerque, New Mexico for septic shock on May 7, 2012

Blood cultures tested positive for S. aureus on May 8, 2012 and a report from the lab listed antibiotics that would be effective against Staphylococcus

Maureen Wood, MD concludes that blood culture results are a “false positive” and chooses to treat with Cefepime

Dr. Wood was accompanied on her daily rounds with an “unnamed pharmacist”

Mr. Van Winkle was discharged on May 13, 2012
Mr. Van Winkle was admitted to Artesia General Hospital on June 5, 2012 for dehydration and continued infection, and subsequently transferred back to the VA in Albuquerque.

Physicians at the VA diagnosed Mr. Van Winkle with severe right-sided endocarditis.

The infection resulted in a bacterial growth on one of heart valves and severe damage to the rest of the circulatory system.
The VA held a meeting with Mr. Van Winkle’s wife and daughter on the same day to inform them that a panel reviewing the medical records concluded that Mr. Van Winkle’s course of oral antibiotics was “not adequate or appropriate to treat his infection and that he should have been given intravenous antibiotics for four to six weeks”

The panel also found that the growth on Van Winkle’s tricuspid valve resulted from this failure to provide Mr. Van Winkle with appropriate antibiotics.

Mr. Van Winkle died on September 10, 2013
Gallegos v United States of America (2015) (continued)

The “unnamed pharmacist” was named as a defendant in the subsequent lawsuit initiated by Mr. Van Winkle’s daughter, Ms. Gallegos.

The United States of America filed a motion to dismiss, among other things, the “unnamed pharmacist” from the lawsuit.

The court rejected this motion citing the following arguments:

• That plaintiffs may sue non-physicians for medical malpractice

• That pharmacists “can absolutely commit malpractice, but only when acting within the scope of their job, which is to understand medications and their interactions” Second Tr. At 52:10-13 (Keegan)
Gallegos v United States of America (2015) (continued)

• That a pharmacist’s duty of care is likely created by a pharmacist who makes daily rounds with a physician, thus has a special relationship with the patient

• Unlike cases where a community pharmacist would be unfamiliar with the patient’s medical record, the “unnamed pharmacist” here would have likely reviewed the patient’s chart.

• The “unnamed pharmacist” either knew or should have known the results of the culture and that the drugs given to Mr. Van Winkle were not appropriate for his treatment because of the results of the culture.

• The “unnamed pharmacist” should have been recommended vancomycin
Gallegos v United States of America (2015) (continued)

• That several jurisdictions hold pharmacists liable for prescribing contraindicated drugs even when a physician prescribes them;

• Liability for failure to be alert for clear errors or mistakes on prescriptions, failure to warn patients or physicians of obvious inadequacies appearing on the face of the prescription which created substantial risk or serious harm

• The court admitted that, while it could not say as a matter of law that the pharmacist could not have known that the prescribed antibiotics would be ineffective, that this information may be borne out by expert testimony

• Therefore, since there is a basis for potential liability, the court refused to dismiss the “unnamed pharmacist” as a defendant preferring to allow evidence to be admitted to allow the jury to function as the finder of fact.

No. CIV 13-1055 JB/KBM
Test Questions

Presidential executive order list which of the following as urgent threats ASP

A. *C. difficile*

B. Carbapenem-Resistant *Enterobacteriaceae* (CREs)

C. *Neisseria gonorrhoea*

D. All of the above
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Test Questions

A pharmacist with infectious disease training may contribute to patient care by which of the following:

A. Filling orders as they are written

B. Questioning if the most appropriate therapy is being prescribed by the treating physician

C. Recommending all antimicrobial agents be added to the formulary without restriction to allow prescribing without hindrance

D. All of the above
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Test Questions

Select the correct statement:

A. Only physicians may be sued physicians for medical malpractice

B. Pharmacists can commit malpractice when acting within the scope of their job which is to understand medications and their interactions

C. The pharmacist does not create a duty of care on rounds

D. All of the above are correct
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References

1. California Senate Bill 1311
2. Presidential Executive Order
3. The Joint Commission Prepublication Requirements effective January 1, 2017
Session Code:

1. Write down the course code. Space has been provided in the daily program-at-a-glance sections of your program book.

2. To claim credit: Go to www.cshp.org/cpe before December 1, 2016.