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Clinical Pearls of Antimicrobial Stewardship and Infection Prevention & Control

Presented by:
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Objectives

At the completion of this activity, the participant will be able to:

- Recognize the intent of the Centers for Medicare & Medicaid Services (CMS) Mega Rule as it relates to the Infection Prevention and Control Program (IPCP)
- Identify the Centers for Disease Control (CDC) Core Elements for an effective Antimicrobial Stewardship Program (ASP)
- Recognize the role of a robust Immunization Program
- Identify collateral damage of antimicrobial use including adverse drug events, drug interactions and clostridium difficile
- Recognize the role of probiotics, cranberry, and ascorbic acid

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- Dr. Milito has no disclosures to report

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The CMS Perspective

- Nursing home residents are at risk for adverse outcomes or collateral damage associated with the inappropriate use of antibiotics that may include but are not limited to the following:
  - Increased adverse drug events and drug interactions (e.g., allergic rash, anaphylaxis, or death)
  - Serious diarrheal infections from C. difficile
  - Disruption of normal flora (e.g., this can result in overgrowth of Candida such as oral thrush)

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The CMS Perspective (Continued)

- Infection Prevention and Control Program (IPCP) includes an Antibiotic Stewardship Program (ASP)
  - ASP is not a stand-alone program
- Antibiotic resistance has emerged as a national healthcare concern
- Even appropriate use of antibiotics can contribute to antibiotic resistance

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Assessment Question #1

Discussion

- An effective Infection Prevention and Control Program (IPCP) includes an Antimicrobial Stewardship Program (ASP) and Immunizations.
- True or False

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Preventing Spread of Illness Related to Multi-Drug Resistant Organisms (MDROS)

- Methicillin Resistant Staphyloccocus Aureus (MRSA)
- Vancomycin Resistant Enterococci (VRE)
- *Clostridium difficile*
- *Pseudomonas aeruginosa*
- Extended Spectrum Beta Lactamase (ESBL)
- Carbapenem Resistant Enterobacteriaceae (CRE)

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Regulatory Support

- §483.80

F880	Infection Prevention & Control	483.80(a)(1)(2)(4)(e)(f)
F881	Antibiotic Stewardship Program	483.80 (a)(3)
F882	Infection Preventionist Qualifications/Role	483.80(b)(1)-(4)(c)
F883	Influenza and Pneumococcal Immunizations	483.80(d)(1)(2)

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CMS Mega Rule Phase 2

Effective Date: November 28, 2017

Infection Prevention & Control Program (IPCP)

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Components of an IPCP

- Polices & Procedures
- Program oversight
- Infection Preventionist (IP)
- Surveillance
- Education
- Antibiotic Review
- Immunization Program

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Individual Risk Factors for Developing an Infection

- Medications: corticosteroids and chemotherapy
- Compromised host defenses: decreased or absent cough reflex – aspiration pneumonia
- Thinning skin - pressure injuries
- Decreased tear production - conjunctivitis
- Vascular insufficiency – wounds
- Coexisting chronic diseases (Diabetes, Arthritis, Cancer, COPD, Anemia)

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Individual Risk Factors for Developing an Infection (Continued)

- Decreased cognition
- Impaired response to infection (cell mediated responses)
- Bedfast
- Invasive devices
- Increased frequency of toxicity – decreased liver and kidney function
- Complications from invasive diagnostic procedures and skin/bloodstream/infections

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Institutional Risk Factors for Developing an Infection

- Pathogen exposure (handrails & equipment)
- Common air circulation
- Decorative water displays
- Direct/Indirect contact with others
- Hospital admission or emergency department visit
- Improper hand hygiene, glove use, or food handling

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Standard Precautions

- Applicable to:
  - Hand hygiene and the use and disposal of gloves
  - Safe injection practices
  - Use of personal protective equipment
  - Resident placement
  - Care of environment, textiles, laundry, equipment
  - Infectious waste: sharps, biohazard waste bags

Reference: SHEA/Epic Guideline Infection prevention and control in the long-term care facility. Infect control Hosp Epidemiology 29 (9); pg. 803

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Transmission Based Precautions

- **Contact Precautions:** gloving and gowning, private room preferred, cohorting acceptable
  - Reusable items cleaned and disinfected
  - Soap and water hand washing – no hand sanitizer
  - C. difficile
- **Droplet Precautions:** mask when within 3 feet of a resident infected with a disease spread by droplets (influenza, pertussis, meningococcal disease, private room preferred cohorting acceptable)
- **Airborne Precautions:** used when diseases are spread by fine particles spread by air current (Varicella Zoster, Tuberculosis, measles), includes use of a test-fitted N-95 respirator, eye protection, private room required

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CMS Mega Rule
Phase 2

Effective Date: November 28, 2017

Antimicrobial Stewardship Program (ASP)

18-month moratorium – financial penalties

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The Antibiotic Stewardship Program in Relation to Pharmacy Services

- The assessment, monitoring, and communication of antibiotic use shall occur by a licensed pharmacist.
- A pharmacist must perform a medication regimen review (MRR) at least monthly, including review of the medical record and identify any irregularities, including unnecessary drugs
- **This review must include a review of the resident's medical chart**

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CMS Mega Rule
Phase 1 – November 28, 2016

§483.45(d) Unnecessary Drugs

- Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used-
  - (1) In excessive dose (including duplicate drug therapy; or
  - (2) for excessive duration; or
  - (3) without adequate monitoring; or
  - (4) without adequate indication for its use; or
  - (5) in the presence of adverse consequences which indicate the dose should be reduced or discontinued; or
  - (6) any combinations of the above

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Antimicrobial Stewardship

- Steward:
  Verb
  1. Manage or look after
- Stewardship:
  Noun
  1. the conducting, supervising, or managing of something; especially: the careful and responsible management of something entrusted to one's care.
- Antimicrobials – bacteria, viruses, fungi, and parasites

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ASP Presidential Executive Order

Combating Antibiotic-Resistant Bacteria

- Issued by President Obama on September 18, 2014
- Establishes national and governmental recognition of one of the greatest global threats to human kind
  Antibiotic misuse is now an official national security priority
- Established a National Task Force in charge of combating antibiotic-resistant bacteria
  - Multi-departmental effort
  - Developed a 5-Year National Action Plan

Reference: The White House. Executive Order – Combating Antibiotic-Resistant Bacteria.

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ASP

Why should we be involved?

- 23,000 residents die each year as a direct result of an antibiotic resistant infection in nursing homes.
- Up to 70% of nursing home residents receive antibiotics annually
- Roughly 20-50% of antibiotics are prescribed inappropriately
- Nearly 50% of antibiotics prescribed in nursing homes may be given longer than necessary

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Case Discussion- We will build upon this as we proceed through the presentation

- Ciprofloxacin 500 mg PO every 12 hours

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The CDC Core Elements for Nursing Homes

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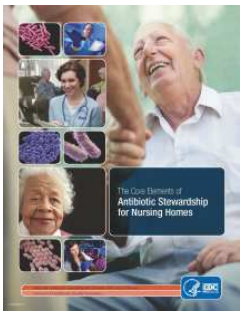

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Summary of Core Elements for Antibiotic Stewardship in Nursing Homes

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Summary of Core Elements for Antibiotic Stewardship in Nursing Homes

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Checklist for Core Elements of Antibiotic Stewardship in Nursing Homes

- The following checklist is a companion to the Core Elements of Antibiotic Stewardship in Nursing Homes. The CDC recommends that all nursing homes take steps to implement antibiotic stewardship activities. Before getting started, use this checklist as a baseline assessment of policies and procedures that are in place. Then use the checklist to review progress in expanding stewardship activities on a regular basis (e.g., annually). Over time, implement activities for each element in a step-wise fashion.

Reference: The Core elements of antibiotic stewardship for nursing homes. Checklist. CDC Cs250066-A

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Checklist for Core Elements of Antibiotic Stewardship in Nursing Homes (Continued)

Reference: The Core elements of antibiotic stewardship for nursing homes. Checklist. CDC Cs256066-A

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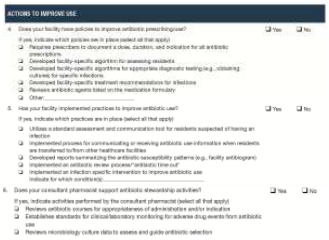
Checklist for Core Elements of Antibiotic Stewardship in Nursing Homes (Continued)



Reference: The Core elements of antibiotic stewardship for nursing homes. Checklist. CDC Cs256066-A

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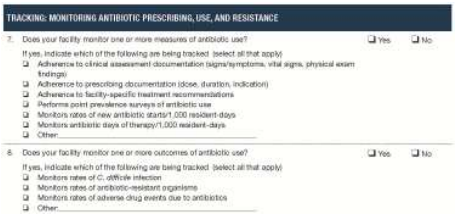
Checklist for Core Elements of Antibiotic Stewardship in Nursing Homes (Continued)



TRACKING: MONITORING ANTIBIOTIC PRESCRIBING, USE, AND RESISTANCE

7. Does your facility monitor one or more measures of antibiotic use? ❑ Yes ❑ No

If yes, indicate which of the following are being tracked (select all that apply)
- ❑ Adherence to clinical assessment documentation (signs/symptoms, vital signs, physical exam findings)
- ❑ Adherence to prescribing documentation (dose, duration, indication)
- ❑ Adherence to facility-specific treatment recommendations
- ❑ Performs point prevalence surveys of antibiotic use
- ❑ Monitors rates of new antibiotic starts/1,000 resident-days
- ❑ Monitors antibiotic days of therapy/1,000 resident-days
- ❑ Other: _____

8. Does your facility monitor one or more outcomes of antibiotic use? ❑ Yes ❑ No

If yes, indicate which of the following are being tracked (select all that apply)
- ❑ Monitors rates of *C. difficile* infection
- ❑ Monitors rates of antibiotic-resistant organisms
- ❑ Monitors rates of adverse drug events due to antibiotics
- ❑ Other: _____

Reference: The Core elements of antibiotic stewardship for nursing homes. Checklist. CDC Cs256066-A

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Checklist for Core Elements of Antibiotic Stewardship in Nursing Homes (Continued)

REPORTING INFORMATION TO STAFF ON IMPROVING ANTIBIOTIC USE AND RESISTANCE

9. Does your facility provide facility-specific reports on antibiotic use and outcomes with clinical providers and nursing staff? ❑ Yes ❑ No

If yes, indicate which of the following are being tracked (select all that apply)
- ❑ Measures of antibiotic use at the facility
- ❑ Measures of outcomes related to antibiotic use (i.e., *C. difficile* rates)
- ❑ Report of facility antibiotic susceptibility patterns (within last 18 months)
- ❑ Personalized feedback on antibiotic prescribing practices (to clinical providers)
- ❑ Other: _____

EDUCATION

10. Does your facility provide educational resources and materials about antibiotic resistance and opportunity for improving antibiotic use? ❑ Yes ❑ No

If yes, indicate which of the following are being tracked (select all that apply)
- ❑ Clinical providers (e.g., MDs, NPs, PAs, PharmDs)
- ❑ Nursing staff (e.g., RNs, LPNs, CNAs)
- ❑ Residents and families
- ❑ Other: _____

Reference: The Core elements of antibiotic stewardship for nursing homes. Checklist. CDC:Cs250066-A

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Assessment Question #2

Case Discussion

- Ciprofloxacin 500 mg PO every 12 hours. What is needed for this order?
  - A. Duration
  - B. Diagnosis
  - C. 7-day reassessment
  - D. All of the above

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Antibiogram

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Antibiogram

- What is an antibiogram?
  - A table that contains susceptibility information that defines a specified period of time
- Why is it important?
  - Raise awareness of antimicrobial resistance
  - Helps to determine optimal empiric therapy
  - Provides opportunities to evaluate antibiotic usage

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Antibiogram

- Who should be involved?
  - Members of the microbiology staff
  - Pharmacists
  - Physicians
  - Others

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Challenges

- Challenges in obtaining an antibiogram:
  - Lab participation
  - Education of staff
  - Inaccurate due to small isolate number

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January – December 2017

	# of Isolates	Amox/Clav	Ampicillin	Ampicillin / Sulbact	Aztreonam	Cefazolin	Cefoxitin	Ceftriaxone	Cefuroxime	Ciprofloxacin	Clindamycin	Erythromycin	Gentamycin	Imipenem	Levofloxacin	Nitrofurantoin	Oxacillin	Penicillin	Piperacillin	Ticar /Clav (Timen)	Tobramycin	Trimeth/Sulfa	Vancomycin
	Numbers are the % of isolates susceptible / systemic infections																						
GRAM NEGATIVE																							
E. coli	485	95	62	65	97	94	98	98	95	46			94	99	46	96			64	93	94	86	
Kl. oxytoca	24	79	8	62	83	46	79	83	79	75			88	100	92				58	67	75	88	
Kl. pneumoniae	108	99	10	87	95	94	95	95	90	94			96	100	95				83	94	95	91	
Pr. mirabilis	58	100	82	83	94	92	100	100	100	85			83	100	86				83	100	85	86	
P. aeruginosa	66				74		93	29		60			84	88	60				70	72	97		
GRAM POSITIVE																							
E. faecalis	138		98							57		6			60	99		99					100
E. faecalis VRE	4		100							0		0			0	100		100					0
E. faecium	18		21							16		8			16	100		16					100
E. faecium VRE	30		17							0		0			0	100		14					0
S. agalactiae	60		100								85				100	100		100					100
S. aureus	130	98	18	98		99		99		87	86	75	100		86	100	100	18				100	100
S. aureus MRSA	151	0	0	0		0		0		23	35	7	99		25	100	0	0				99	100
S. epidermidis	78	22	3	22		21		21		23	48	21	67		24	100	22	3				50	100
S. pneumoniae	17	100						88				94			100	100		81				88	100

Reference: http://www.cdc.gov/abcs/reports-findings/downloads/antibiogram-method.pdf

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Antibiogram – Things to Consider

- What is the % of MRSA isolates?
- What is the E. Coli susceptibility to the quinolones?
- What is the Pseudomonas susceptibility to the quinolones?
- Are the carbapenems holding strong?

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FDA Warning for Quinolones

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Fluoroquinolone Warning

- The U.S. Food and Drug Administration approved safety labeling changes for fluoroquinolones to enhance warnings about their association with disabling and potentially permanent side effects and to limit their use in patients with less serious bacterial infections.
- FDA safety review found that both oral and injectable fluoroquinolones are associated with disabling side effects involving tendons, muscles, joints, nerves and the central nervous system. These side effects can occur hours to weeks after exposure to fluoroquinolones and may potentially be permanent.
- FDA-approved fluoroquinolones include: levofloxacin (Levaquin), ciprofloxacin (Cipro), ciprofloxacin extended-release tablets, moxifloxacin (Avelox), ofloxacin and gemifloxacin (Factive)
- The labeling changes include an updated Boxed Warning and revisions to the Warnings and Precautions section of the label about the risk of disabling and potentially irreversible adverse reactions that can occur together.
- Reserve fluoroquinolones for patients who do not have other available treatment options for acute bacterial sinusitis, acute bacterial exacerbation of chronic bronchitis and uncomplicated urinary tract infections.

Reference: FDA Drug Safety Communication: FDA updates warnings for oral and injectable fluoroquinolone antibiotics due to disabling side effects. FDA.gov

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Case Discussion

Assessment Question #3

- Which of the following is incorrect regarding the use of Ciprofloxacin 500 mg PO every 12 hours x 10 days (UTI)

A. Ciprofloxacin is a good empiric choice to treat uncomplicated UTI based on the antibiogram.
B. 3-5 days is a more appropriate duration for uncomplicated UTI treatment.
C. Ciprofloxacin is renally cleared.
D. Nitrofurantoin might be a better choice

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CMS Mega Rule Phase 3

Effective Date: November 28, 2019

Infection Preventionist (IP)

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Infection Preventionist (IP)

- Leader of the IPCP
- Qualified by education, training, experience, certification
  - CMS/CDC program to be released Spring 2019
- A member of the facility's quality assurance and performance improvement (QAPI) committee
- Report infection data, analyze information, implement and monitor the plan

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A Robust Immunization Program is Necessary

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Healthy People 2020

The Department of Health and Human Services has introduced this initiative to improve overall health and disease prevention in the United States, with specific goals to meet by the year 2020.

For Healthy People 2020, there are numerous categories of goals related to various disease and public health programs, including immunization and infectious diseases.

Goal vaccination rates for those 65 years of age or older by the year 2020 are:
Influenza: 90%
Pneumococcal: 90%
Zoster: 30%
* There is no goal related to reduction in pertussis in the elderly population

Source: Healthy People 2020 immunization and infectious diseases objectives. Office of Disease Prevention and Health Promotion. Last updated July 3, 2017. Available at https://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases/objectives.

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Immunizations

- The administration of pneumococcal and influenza vaccine, in accordance with national recommendations; facilities must follow the CDC and ACIP recommendations for vaccines
- As necessary, determine if the facility developed influenza and pneumococcal vaccine policies and procedures, including the identification and tracking/monitoring of all facility residents' and employees' vaccination status
  - Reason for declination
  - Received at another location
  - Rate (percentage) not number

Reference: CMS-20054 (5/2017)

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Assessment Question #4

Case Discussion

- Part of a robust immunization program includes:
  - A. Prevnar 13 should be given after Pneumovax 23 in a pneumococcal naive 66 year old.
  - B. Shingrix is administered as one IM injection
  - C. All of the above
  - D. None of the above

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Collateral Damage

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Collateral Damage

- *Clostridium difficile*
- Drug-drug Interactions
- Adverse drug reactions

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Clostridium Difficile

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- **What** is *C. difficile* infection (CDI)?
- **Why** is it important?
- **How** can we treat it and prevent it?

Reference: Emily Heil, PharmD, BCPS-AQ ID (2016). C. Difficile; Antimicrobial Stewardship in LTPAC

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Clostridium Difficile

- Gram-positive, anaerobic spore-forming, toxin-producing bacterium
- Most common infectious cause of health-care associated diarrhea in developed countries
- Associated with increased length of hospital stay, health care costs, morbidity and mortality
- Risk Factors
  - Antimicrobial agents (most common)
  - Advanced age
  - Hospitalization or residence in a long-term care facility
  - Cytotoxic chemotherapy
  - Immunosuppressive treatment
  - Acid suppressing medications

Reference: Emily Heil, PharmD, BCPS-AQ ID (2016). C. Difficile; Antimicrobial Stewardship in LTPAC

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Most Common CDI Causing Antimicrobial Agents

- Clindamycin
- Ampicillin/Amoxicillin
- 2nd or 3rd generation cephalosporins
- Fluoroquinolones

Reference: Bassetti M, et al. Expert Rev Anti Infect Ther 2012;2012;10(12):1405-23.; Cohen SH, et al. Infect Cont Hosp Epidemiol 2010;31(5):431-55.; Gerding, DN. Clin Infect Dis 2004;38:646-47.

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Clostridium Difficile Symptoms

- Profuse watery or green mucoid, foul smelling diarrhea
- Cramping abdominal pain
- In the most severe cases, patients can have life-threatening pseudomembranous colitis, toxic megacolon, bowel perforation, and death
- Antibiotic associated CDI usually begins 4-10 days after starting antibiotic therapy

Reference: Emily Heil, PharmD, BCPS-AQ ID (2016). C. Difficile; Antimicrobial Stewardship in LTPAC

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Clostridium Difficile

250,000
INFECTIONS PER YEAR

14,000
DEATHS

1,000,000,000
IN EXCESS MEDICAL COSTS PER YEAR

THREAT LEVEL URGENT

Reference: Emily Heil, PharmD, BCPS-AQ ID (2016). C. Difficile; Antimicrobial Stewardship in LTPAC

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Testing and Diagnosis

- Molecular Test – PCR Assay Testing
  - *Clostridium difficile* DNA Toxin Assay for toxin B gene has sensitivity and specificity of 95%
  - Remember that the test is picking up the toxin gene, **does not** distinguish between colonization and infection
- Glutamate Dehydrogenase (GDH) Antigen Test
  - Rapid test (<1 hour), high sensitivity (negative result effectively rules out CDI) but non-specific to antigen so must be combined with toxin detection or PCR
- Toxin AB Enzyme Immunoassay (EIA)
  - Detects the presence of toxins A & B, lower sensitivity and specificity than the PCR based testing

Reference: Emily Heil, PharmD, BCPS-AQ ID (2016). C. Difficile; Antimicrobial Stewardship in LTPAC

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Testing Guidelines

- Perform testing for
  - New diarrhea (>= 3 unformed stools in 24 h)
  - Clearly worsening diarrhea in those with chronic GI conditions
  - Suspected ileus due to *C. difficile*
- Only test unformed diarrheal stool (i.e., stool that takes the shape of the container), unless patient has ileus

Reference: Emily Heil, PharmD, BCPS-AQ ID (2016). C. Difficile; Antimicrobial Stewardship in LTPAC

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Testing Guidelines (Continued)

- DO NOT test if
  - Diarrhea due to tube feeds, laxatives or other bowel regimen
  - Sepsis or leukocytosis without GI symptoms or signs
- DO NOT repeat testing as a test of cure
  - Molecular tests can remain positive for weeks after treatment

Reference: Emily Heil, PharmD, BCPS-AQ ID (2016). C. Difficile; Antimicrobial Stewardship in LTPAC

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Medical Management

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Treatment Recommendations

Clinical Definition	Clinical Data	Recommended Treatment [a]	Strength of Recommendation/ Quality of Evidence
Initial episode, non-severe	Leukocytosis with a white blood cell count of ≤15 000 cells/mL and a serum creati-nine level <1.5 mg/dL	• VAN 125 mg given 4 times daily for 10 days, OR • FDX 200 mg given twice daily for 10 days • Alternate if above agents are unavailable: Metronidazole, 500 mg 3 times per day by mouth for 10 days	Strong/High Strong/High Weak/ High
Initial episode, severe[b]	Leukocytosis with a white blood cell count of ≥15 000 cells/mL or a serum creatinine level >1.5 mg/dL	• VAN 125 mg 4 times per day by mouth for 10 days, OR • FDX 200 mg given twice daily for 10 days	Strong/High Strong/High
Initial episode, fulminant	Hypotension or shock, ileus, megacolon	• VAN 500 mg 4 times per day by mouth or by nasogastric tube. If ileus, consider adding rectal instillation of VAN. Intravenously administered Metronidazole (500 mg every 8 hours) should be administered together with oral or rectal VAN, particularly if ileus is present.	Strong/Moderate (oral VAN); Weak/Low (rectal VAN); Strong/Moderate (intravenous metronidazole)

Reference: Clinical Practice Guidelines for *Clostridium difficile* Infection • CDC 2018

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Treatment Recommendations (Continued)

Clinical Definition	Clinical Data	Recommended Treatment [a]	Strength of Recommendation/ Quality of Evidence
First recurrence	…	• VAN 125 mg given 4 times daily for 10 days if metronidazole was used for the initial episode, OR • Use a prolonged tapered and pulsed VAN regimen if a standard regimen was used for the initial episode (eg, 125 mg 4 times per day for 10–14 days, 2 times per day for a week, once per day for a week, and then every 2 or 3 days for 2–8 weeks), OR • FDX 200 mg given twice daily for 10 days if VAN was used for the initial episode	Weak/Low Weak/Low Weak/Moderate
Second or subsequent recurrence	…	• VAN in a tapered and pulsed regimen, OR • VAN 125 mg 4 times per day by mouth for 10 days followed by rifaximin 400 mg 3 times daily for 20 days, OR • FDX 200 mg given twice daily for 10 days, OR • Fecal microbiota transplantation[c]	Weak/Low Weak/Low Weak/Low Strong Moderate

Abbreviations: FDX, fidaxomicin; VAN, vancomycin.
[a]All randomized trials have compared 10-day treatment courses, but some patients (particularly those treated with metronidazole) may have delayed response to treatment and clinicians should consider extending treatment duration to 14 days in those circumstances.
[b]The criteria proposed for defining severe or fulminant Clostridium difficile infection (CDI) are based on expert opinion. These may need to be reviewed in the future upon publication of pro-spectively validated severity scores for patients with CDI.
[c]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.

Reference: Clinical Practice Guidelines for *Clostridium difficile* Infection • **CDC 2018**

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Testing Guidelines

- **Discontinue** the offending antimicrobial, if possible
- **Do not** administer antiperistaltic agents (e.g., loperamide)
- **Discontinue** proton pump inhibitors (PPIs), if possible
- **Discontinue** bowel regimens!

Reference: Emily Heil, PharmD, BCPS-AQ ID (2016). C. Difficile; Antimicrobial Stewardship in LTPAC

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Novel Therapies: Fecal Microbiota Transplantation (FMT)

- The process of taking stool from a healthy donor and placing it into the GI tract of a patient
- Goal is to restore the healthy gut microbiota by replenishing the intestinal ecosystem of the patient with the microbiota of the healthy donor
- Increasingly popular in the clinical arena and the public media
- Introduction of detrimental microbes during fecal transplantation is a concern

Reference: Emily Heil, PharmD, BCPS-AQ ID (2016). C. Difficile; Antimicrobial Stewardship in LTPAC

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Novel Therapies: Bezlotoxumab (BEZ)(Continued)

- Monoclonal antibiody
- Safe and effective in preventing CDI recurrence
- High cost

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Infection Prevention

- Wash your hands with soap and water!
  - Alcohol based hand sanitizers do not kill *C. difficile* spores
- Enteric pathogen isolation
  - Contact isolation with gowns and gloves
  - Handwashing required before and after resident visit
- Bleach-based room cleaning

Reference: Emily Heil, PharmD, BCPS-AQ ID (2016). C. Difficile; Antimicrobial Stewardship in LTPAC

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Assessment Question #5

Case Discussion

- Antimicrobials that can contribute to C. diff are:
  - A. Clindamycin
  - B. Ceftriaxone
  - C. Quinolones
  - D. All of the above

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Significant Drug-Drug Interactions

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Azole Antifungals and Warfarin Interactions

- High severity drug interaction
- Azole antifungals increase the effect of warfarin
  - Fluconazole
  - Itraconazole
  - Ketoconazole
  - Miconazole
  - Posaconazole
- Monitor INR
- Prescriber may lower the dose of warfarin when the antifungal is initiated

Reference: Emily Heil, PharmD, BCPS-AQ ID (2016). C. Difficile; Antimicrobial Stewardship in LTPAC

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Cephalosporins and Warfarin Interactions

- Second and third generation cephalosporins might increase the effect of warfarin
- High severity interactions
  - Cefotetan
- Moderate severity interaction
  - Cefazolin
  - Cefoxitin
  - Ceftriaxone
- Monitor INR when therapy is started or stopped

Reference: Emily Heil, PharmD, BCPS-AQ ID (2016). C. Difficile; Antimicrobial Stewardship in LTPAC

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Fluoroquinolones and Warfarin Interactions

- May increase the response to warfarin
- High severity interactions
  - Ciprofloxacin
  - Levofloxacin
  - Moxifloxacin
  - Norfloxacin
  - Ofloxacin
- Monitor INR when any fluoroquinolone is started or stopped

Reference: Emily Heil, PharmD, BCPS-AQ ID (2016). C. Difficile; Antimicrobial Stewardship in LTPAC

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Macrolide Antibiotics and Warfarin Interactions

- May increase the response to warfarin
- High severity interactions
  - Azithromycin
  - Clarithromycin
  - Erythromycin
- Monitor INR when any macrolide is started or stopped

Reference: Emily Heil, PharmD, BCPS-AQ ID (2016). C. Difficile; Antimicrobial Stewardship in LTPAC

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Penicillin Antibiotics and Warfarin Interactions

- May increase the response to warfarin
- High doses of IV penicillins
- Moderate severity drug interactions
  - Amoxicillin, Amoxicillin/Clavulanate
  - Ampicillin, Ampicillin/Sulbactam
  - Penicillin G, Penicillin G Benzathine, Penicillin G Procaine
  - Piperacillin, Piperacillin/Tazobactam
  - Ticarcillin/Clavulanate

Reference: Emily Heil, PharmD, BCPS-AQ ID (2016). C. Difficile; Antimicrobial Stewardship in LTPAC

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Tetracyclines and Warfarin Interactions

- May increase the response to warfarin
- Moderate severity interactions
  - Demelocycline
  - Doxycycline
  - Minocycline
  - Tetracycline **(Monitor INR when tetracycline is started or stopped)**

Reference: Emily Heil, PharmD, BCPS-AQ ID (2016). C. Difficile; Antimicrobial Stewardship in LTPAC

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Trimethoprim/Sulfamethoxazole (TMP/SMX) Interactions

- TMP/SMX
  - Frequently prescribed for Urinary Tract Infections (UTIs)
  - Over 20 Million prescriptions per year in the U.S.
  - May increase the effect of warfarin
  - R and S isomer activity

Reference: Emily Heil, PharmD, BCPS-AQ ID (2016). C. Difficile; Antimicrobial Stewardship in LTPAC

75

Trimethoprim/Sulfamethoxazole (TMP/SMX) Interactions

- Warfarin
  - High severity of drug interaction, <u>even with short courses of therapy</u>
  - Avoid use if possible
  - Some prescribers lower the dose of warfarin by 25%-50%
    - Monitor INR when Trimethoprim/Sulfamethoxazole is started or stopped

Reference: Emily Heil, PharmD, BCPS-AQ ID (2016). C. Difficile; Antimicrobial Stewardship in LTPAC

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Trimethoprim/Sulfamethoxazole (TMP/SMX) Interactions with ACE Inhibitors (ACEI's) and Angiotension II Receptor Blockers (ARBs)

- TMP/SMX can reduce the excretion of potassium
- 80% of resident taking TMP/SMX have an increase in serum potassium
  - This increase in potassium can place a resident at risk for hyperkalemia when also taking an ACEI or ARB
  - May lead to an unnecessary hospitalization or death

Reference: Emily Heil, PharmD, BCPS-AQ ID (2016). C. Difficile; Antimicrobial Stewardship in LTPAC
TMP-SMX induce hyperkalemia in patients receiving inhibitors of the renin-angiotensin system. Antoniolu, T, et al. Arch Intern Med 2010.

77

Antimicrobials that Inhibit the Effect of Warfarin

Dicloxacillin	Griseofulvin	Nafcillin
Oxacillin	Rifampin	Rifabutin

- Monitor INR when started or stopped

Reference: Emily Heil, PharmD, BCPS-AQ ID (2016). C. Difficile; Antimicrobial Stewardship in LTPAC

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Other Oral Anticoagulants that May Interact with Antimicrobials

1

Apixaban

- Reduce dose by 50% with strong inhibitors: itraconazole, ketoconazole, ritonavir, clarithromycin

2

Dabigatran

- Reduce dose to of Dabigatran to 75mg BID with ketoconazole

3

Rivaroxaban

- Avoid ketoconazole, itraconazole, posaconazole; use with caution with clarithromycin and fluconazole
- Use erythromycin with caution in residents with mild to moderate renal impairment.

Reference: Emily Heil, PharmD, BCPS-AQ ID (2016). C. Difficile; Antimicrobial Stewardship in LTPAC

79

What Should Facility Staff Do When an Antimicrobial is Prescribed in the Presence of Warfarin?

1. When taking a phone order for an antimicrobial, remind the prescriber when the resident is taking warfarin
2. Before the prescriber hangs up, ask if there is an order to monitor the INR
3. Never remove an antimicrobial from an emergency kit without checking if the resident is also taking warfarin

Reference: Emily Heil, PharmD, BCPS-AQ ID (2016). C. Difficile; Antimicrobial Stewardship in LTPAC

80

What Should Facility Staff Do When an Antimicrobial is Prescribed in the Presence of Warfarin?

4. Vigilantly monitor the resident for signs of bruising or bleeding Q shift
5. Report INRs to the prescriber immediately if above or below the target INR
6. Only use antimicrobials for the minimum duration of therapy based on the infection type, its severity, and the condition of the resident

Reference: Emily Heil, PharmD, BCPS-AQ ID (2016). C. Difficile; Antimicrobial Stewardship in LTPAC

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Assessment Question #6

Case Discussion

- Patient takes Ciprofloxacin 500 mg PO every 12 hours x 10 days (UTI) and is taking Warfarin 2.5 mg PO daily. Which of the following is true:
  - A. Order more frequent INR
  - B. Hold warfarin x 2 days
  - C. Ciprofloxacin can potentiate the INR
  - D. All of the above

82

Adverse Drug Reactions

83

Risks of Using Unnecessary Antimicrobials

- Drug-induced diarrhea – *Clostridium difficile*
- Nausea
- Drug-drug interactions
- Renal toxicity
- Increased Antimicrobial Resistance
- Anaphylactic and other allergic reactions
- Cardiotoxicity via QT prolongation [Macrolides/Quinolones]
- Blood Dyscrasias
- Rash, Skin Reactions, Stevens-Johnson Syndrome
- Musculoskeletal toxicity (tendonitis/tendon rupture) [Quinolones]

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Assessment Question #7

Case Discussion

Ciprofloxacin 500 mg PO every 12 hours x 10 days. CrCl = 25 ml/min

A. Keep dose the same
B. Decrease dose to 250 mg
C. Extend the interval to 18 hours
D. B & C

85

A Few More “Pearls”

86

Cranberry

87

Cranberry

- 2009 Guidelines state insufficient evidence to recommend for prophylaxis in catheterized patients
- 2012: Cochrane review of 24 studies (4472 patients) concluded:
  - Juice does not appear to have a benefit
  - Cranberry tablets/capsules appeared to trend towards prevention of UTI but was not significant possibly due to lack of potency
- 2012 and 2016 RCTs in Female Nursing Home Residents:
  - 2012: 80 residents → possible dose-dependent (max PAC dose 108 mg) decrease in *E. coli* bacteriuria but findings not significant
  - 2016: 185 women (low recurrence risk)→No difference in bacteriuria + pyuria vs. placebo

Reference: Hooton et al, CID 2012;50:625-33. ; Bianco et al, J Am Geriatr Soc 2012;60:1180-81
Jepson et al, Cochran review 2012;10; Juthani-Mehta et al, JAMA 2016; 18:1879-87

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Cranberry: Summary

- Potential mechanism: Proanthocyanidins (PAC) (Ellura) help reduce bacterial adhesion (dose-dependent) → Mostly studies with *E. coli*
- Continued mixed results
  - Studies use various doses of PAC and formulations (juice versus capsules with standardized PAC)
  - Often dose of PAC may be too low
  - Study outcomes are all different and thus difficult to compare and group together
    - Incidence of recurrent UTI, incidence of pyuria+bacteriuria, UTI definitions are variable, younger populations of pre-menopausal women versus LTCF
- Needs
  - Active "ingredient"?
  - Further study in high-risk recurrent UTI patients using a high enough dose and duration
  - Strict UTI definition (clinical versus micro) in LTCFs

LaPlante KL, Gill CM, Rowley D. Cranberry Capsules for Bacteriuria plus Pyuria in Nursing Home Residents. Letter JAMA. 2017 ;317(10):1078

89

Ascorbic Acid

90

Ascorbic Acid (Vitamin C)

- Possible mechanism: decrease urinary pH
- Only two studies have been reported with contradictory results
- 1996 study in 38 spinal cord injury patients taking 500 mg 4x daily → only 13 completed study and no significant decrease in urine pH was observed
- 2007 study in 100 pregnant women taking a multivitamin with 100 mg ascorbic acid reported less UTI symptoms versus those taking multivitamin without ascorbic acid
  - Very low dose, unclear if urine cultures were done
- Cannot recommend ascorbic acid for prevention of UTI

Castello et al. Spinal Cord 1996;34:592-3;
Ochoa Bayt, et al. Arch Obstet Ginecol Enged 2007; 85:283-7

91

Probiotics

92

What is the role of probiotics in primary prevention of CDI?

There are insufficient data at this time to recommend administration of probiotics for primary prevention of CDI outside of clinical trials.

Reference: Clinical Practice Guideline for Clostridium difficile Infection CID 2018:XX

93

What is the role of probiotics for the prevention of CDI recurrences?

Several probiotics have shown promise for the prevention of CDI recurrence however, as yet, none has demonstrated significant and reproducible efficacy in controlled clinical trials.

Reference: Clinical Practice Guidelines for Clostridium difficile Infection CID 2018: XX

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Assessment Question #8

Case Discussion

- This resident develops C. difficile. The provider orders a probiotic and metronidazole.
  - A. Probiotics have been shown to be effective in treating C. difficile
  - B. Metronidazole is a good choice for the initial treatment of mild-moderate C. difficile
  - C. Droplet precautions should be started
  - D. None of the above

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Summary of Clinical Pearls

96

Clinical Pearls

1. Implement one policy, monitor one process, and measure one outcome as per the CDC Core Elements
2. Nitrofurantoin is a good choice to treat *E. coli* and can be used if CrCl is 30 ml/min and above
3. Prevnar13© is given first in residents who are 65 and older and pneumococcal naïve
4. Do not repeat testing as a test of cure for CDI
5. TMP/SMX can contribute to hyperkalemia
6. Fluoroquinolones should not be used for uncomplicated infections due to resistance, side effects, and adverse events
7. Cranberry does not appear to have a benefit for preventing UTI's – more studies to follow
8. Ascorbic acid can not be recommended for prevention of UTI
9. Probiotics may help to prevent a second recurrence of CDI
10. Pharmacists are the drug experts!

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Thank You!!

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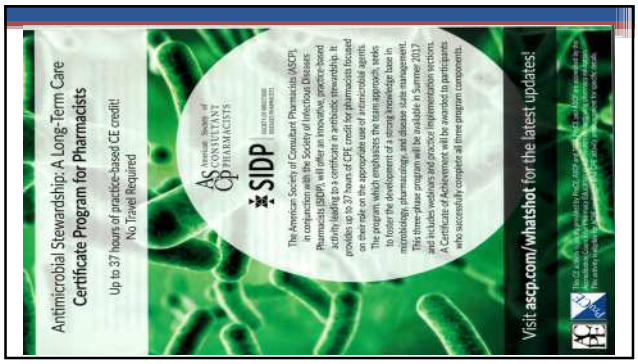
Resources


Antimicrobial Stewardship: A Long-Term Care Certificate Program for Pharmacists
Up to 37 hours of practice-based CE credit!
No Travel Required
SIDP
The American Society of Consultant Pharmacists (ASCP), in conjunction with the Society of Infectious Diseases Pharmacists (SIDP), will offer an innovative, practice-based activity leading to a certificate in antibiotic stewardship. It provides up to 37 hours of CPE credit for pharmacists focused on their role on the appropriate use of antimicrobial agents. The program, which emphasizes the team approach, seeks to foster the development of a strong knowledge base in microbiology, pharmacology, and disease state management. This three-phase program will be available in Summer 2017 and includes webinars and practice implementation sections. A Certificate of Achievement will be awarded to participants who successfully complete all three program components.
Visit ascp.com/whatshot for the latest updates!

UNIVERSITY of MARYLAND SCHOOL OF PHARMACY

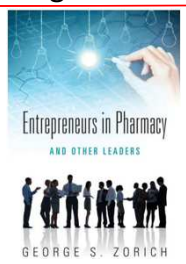
Pharmapreneurship

Natalie D. Eddington, PhD

Learning Objectives

- At the end of this lecture, attendees will be able to:
  - Define pharmapreneurship™ and recognize its distinction from entrepreneurship
  - Identify innovative thinking related to pharmacy and characteristics of an effective pharmapraneurial mindset
  - Identify opportunities to introduce pharmapreneurial thinking in teaching, research, and practice
  - Identify therapeutic and scientific challenges that benefit from a pharmapreneurism approach

Entrepreneurs in Pharmacy George S. Zorich



The Mindset of Entrepreneurs: The Pharmacist's Perspective

- Opportunists who are smart but practical
- Passionate about their ideas
- Usually not at the "top" of the class
- Pharmacists are cautious and are not risk takers
- Entrepreneurs by nature are risk takers whereas pharmacists are usually reserved and risk averse

G.S. Zorich

Entrepreneurs in Pharmacy

Dan Buffington
President
Clinical
Pharmacology Services

Erin Albert
Founder, Pharm LLC and Yuspie LLC
Pharmacy Podcast Network

Curt Mueller
Mueller Sports Medicine

Entrepreneurs in Pharmacy

Navneet Puri
Founder of Nevakar
Leader in specialty pharmaceutical company (injectable, ophthalmic spaces)

Gordon J. Vanscoy
CEO, PantherRx
Leader in specialty pharmacy for rare and devastating conditions

Katie MacFarland and Brian Zorn
Smart Pharma
Commercial and strategic consulting for Biotech/Biopharm companies

Why Pharmapreneurship™?

Our History Informs Our Future

- The University of Maryland School of Pharmacy's nearly two-century history has established it as the home of pharmapreneurship.
- In looking at the School's rich history, we are without a doubt the American birthplace of pharmapreneurship.
- Faculty and alumni have consistently contributed to our pharmapreneurial history - creating uniform standards for the profession and for the education of future pharmacists and researchers.

ACPE Accreditation Standards

- 4.3 Innovation/entrepreneurship: Presentation/discussion sessions with local pharmacists who have established innovative practices that meet community needs (e.g., immunization/travel immunization, specialized compounding, mobile pharmacies serving the homeless), participation in programs that recognize the development of innovative professional business plans

Why Pharmapreneurship?
Our History Informs Our Future

George Avery Bunting
Class of 1899
Founder
Noxzema, CoverGirl Cosmetics, and Noxell Corp.

Louis Dohme
Class of 1857
Co-founder
Merck, Sharp, and Dohme

Alpheus Sharp
Class of 1842
Co-founder
Merck, Sharp, and Dohme

Why Pharmapreneurship?
Our History Informs Our Future

Victoria G. Hale, BSP '83, PhD
Founder and CEO
OneWorld Health
Medicines360

Felix A. Gyi, BSP '83, PharmD, MBA
Executive Chair and Founder
Chesapeake Research Review

Robert W. Henderson, BSP '63
Founder and Chair
Nutramax Laboratories

Why Pharmapreneurship?
Our History Informs Our Future

Calvin H. Knowlton, PhD '93, Mdiv
Co-founder
Tabula Rasa Healthcare
Founder, Chair, and CEO
CareKinesis, Inc.

Ellen H. Yankellow, BSP '73, PharmD '96
President and CEO
Correct Rx Pharmacy Services

John M. Gregory, BSP '76, DPS (hon) '02
Chair and CEO
Gregory Pharmaceutical Holdings
Founder
King Pharmaceuticals
Managing Partner
SJ Strategic Investments

Define pharmapreneurship and understand its distinction from entrepreneurship

What is Pharmapreneurship?

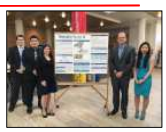
- Represents our commitment to supporting and best positioning our world class faculty, our wonderful students, and our exceptional staff to achieve their career aspirations and therefore address our nation's health care, research, policy, and societal needs.

Pharmapreneurship

- We have trademarked the term *pharmapreneurship* to describe our pharmacy entrepreneurs.
- Defines our expertise, influence, and impact, such as UMSOP-derived businesses and social entrepreneurs, both inclusive of health care, research, community, and policy initiatives
- We continue to drive significant social, research, and policy shifts in health care – we want enhanced national recognition for our efforts.

Why Pharmapreneurship? Students!!!

- Our students have a passion to innovate, problem solve, and compete – enhancing their critical thinking skills
- University-wide annual clinical skills competition and NCPA Business Plan competitions, regulatory science competition, UMB entrepreneurial fellows
- Student led organizations – Entrepreneur & Innovation Network



Pharmapreneurship Among Our Faculty

- Encouraging and investing in our faculty to more purposely innovate to create impactful solutions to problems in health care, research, education, and community engagement

UMSOP Pharmapreneurship

- University Pharmaceuticals of Maryland
- SILCS Bio
- PATIENTS/Learning Health Care Community
- MS in Regulatory Science, Pharmacometrics, Palliative Care, Health Services Research
- Patients, Pharmacist, Partnerships (P^3)
- ATRIUM
- Mass Spectrometry Center
- Pharmaceutical Research Computing
- Maryland Poison Center
- America's Got Regulatory Science Talent Competition
- NCPA Business Plan Competition
- Clinical Care Competition
- NIIMBLE

We have interest, and we have examples.

How do we institutionalize them and provide more opportunities?

Identify opportunities to introduce pharmapreneurial thinking in teaching, research and practice

Our Pharmapreneurial Initiatives

- A partnership with the University of Maryland Robert H. Smith School of Business and its Dingman Center for Entrepreneurship to offer a joint PharmD/MBA degree and to create a joint certificate program for pharmapreneurship
- Opportunities for students to participate in the Dingman Center's student-focused programs, including pitch contests and startup showcases, with plans to replicate these types of programs at the School of Pharmacy
- Funding from the Board of Visitors for our first-ever Pharmapreneur Fellows, who will work with UMB's Office of Research and Development and our faculty to gain valuable interdisciplinary experiences in pharmapreneurship and to develop their own pharmapreneurial innovations.

Our Pharmapreneurial Initiatives

- The creation of an innovation space called the Pharmapreneur's Farm to be located in Pharmacy Hall Atrium
- The appointment of the School's first pharmapreneurs-in-residence, who work with faculty, students, and staff to help them transform their pharmapreneurial dreams into reality.

In establishing pharmapreneurship as the umbrella of our current strategic plan, we will develop an infrastructure to support innovation opportunities for our faculty, students, and staff

UMSOP Pharmapreneur's Farm

Innovation Outside Pharmacy: Olin College of Engineering

- Founded in 1997 at Babson College
- Within five years, ranked within top five engineering programs
- No departments, no tenured faculty
- Focus on faculty-collaboration, student-centered learning
- Focus on entrepreneurship, creativity, critical thinking

Olin College of Engineering

Olin Curriculum Example

- Exercise in design
- Apply user-oriented collaborative design
- First semester project:
  - design new children's toys
  - work in small teams (4-5)
- Panel of judges
  - local 4th grade class
  - brutally honest feedback

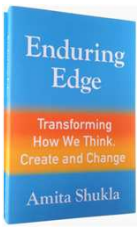
Develop a pharmapreneurial mindset

Pharmapreneur-in-Residence

- Greg Cangliosi, BA
  - Chairman and co-founder of Betamore
  - UMBC graduate (English)
  - Founder of several startups
  - On the board of Baltimore Development Corporation
  - Co-founder of Nucleus Ventures, LLC and Baltimore Angels
  - Passion for marketing and entrepreneurship

Pharmapreneur-in-Residence

- Amita Shukla, MBA
  - CEO of Vitamita, LLC
  - Harvard and Stanford graduate (biochemistry and business administration)
  - Founder of two startups
  - Principal at venture capital giant New Enterprise Associates (NEA) – invested in and worked with numerous start ups
  - Vice president of Amika Corp. – developed and commercialized novel research tools resulting in 10 patents
  - Passion for human health and expertise in entrepreneurship



"True intelligence rests not in mastering any one dimension of our mind but in balancing how we use all three."
-Enduring Edge

Enduring Edge

Transforming how we think, create and change

1D MIND

The 1D mind is our primal animal mind and the source of our basic impulses and instincts. Committed to a singular mission—our survival—it directs our focus to the urgent and short-term. Ever on alert for threats—real and imagined—the 1D mind harbors the 'fight or flight' or stress response and drives emotional reactions such as anger, anxiety and fear. It is guided by inputs from our senses and shaped by our past experiences. While the 1D mind is critical for survival, most of us tend to overuse it, falling prey to its weaknesses.

1D MIND

Being in the 1D mind is akin to driving a car through the city. It's fast and efficient, yet what you learn is limited because you are confined to roads.

Enduring Edge

Transforming how we think, create and change

2D MIND

The 2D mind is the seat of our rational and analytical thinking capabilities—our intellect. It relies on data and tangible, measurable inputs to drive analysis and decisions. The 2D mind is responsible for much of our productivity and progress in the world. The 2D mind's weakness is that it can lead to an over-reliance on data or analysis paralysis in solving complex challenges that require more creative and intuitive thinking. The 2D mind is also the seat of our ego, which tends to introduce judgment and binary (us vs. them) thinking into the mind.

2D MIND

Being in the 2D mind is akin to being a pedestrian. You can wander in and out of shops and restaurants and talk to locals, gaining a deeper, more nuanced experience.

Enduring Edge

Transforming how we think, create and change

3D MIND

The 3D mind is the source of our intuition, insights, and innovative and creative potential. It leads us to discover our passion, purpose and meaning and fosters compassion, empathy and connection. When we are in the 3D state, we lose track of time, place and self and experience deep inner calm, serenity and joy (i.e. being in flow or in the zone). The 3D mind is the catalyst for lasting change and the secret power of true leaders, visionaries, artists, innovators and change agents. Most of us use the 3D mind much less than possible.

3D MIND

eing in the 3D mind is akin to taking a elicopter ride. You gain a new erspective on the city, which an on-the- round view cannot reveal.

3D Mindset Test

https://vitamita.com/1d2d3dmind/

Link to test: http://www.surveygizmo.com/s3/3845368/1D2D3DMindQuiz

Implementation at UMSOP

- Pharmapreneurship Task Force
  - Define pharmapreneurship and aspects of education, research, practice and service
  - Survey entrepreneurial landscape at UMB, Baltimore, and beyond
  - Establish a timeline and milestones for implementation of pharmapreneurship curriculum
  - Establish external partnerships and opportunities
  - Create advisory board
  - Design survey instrument exploring attitudes, opportunities, and gaps in implementing pharmapreneurship as a core value
  - Determine IP policies to protect initiatives

Educational Initiatives

- PharmD Pharmapreneurship Pathway
  - Seminar series
  - Effective Leadership & Advocacy
  - Regulatory science competition
  - NCPA business plan competition
  - Communication course
  - Students work with faculty advisors to develop projects
  - Participate in Dolphin Tank and Shark Tank competitions
- Pharmapreneurship Seminar Series

Identify therapeutic and scientific challenges that benefit from a pharmapreneurship approach

SOP Faculty Shark Tank Competition June 2017

Three winning teams awarded $50,000 each to help support pioneering projects in each of the School's departments.

Shark Tank Competition

Design and Implementation of Novel Interactive Application to Enhance Learning of Antimicrobial Spectrum of Activity

- *Development of new training tools on antimicrobial spectrum and antimicrobial stewardship using an interactive, app-based platform.*

Innovation in Disability Research: Rethinking Healthcare for Complex Populations

- *Using pharmaceutical claims datasets (Medicare and Medicaid) to understand trajectories of pharmaceutical access, healthcare utilization patterns, and health outcomes among people with disability*.

Shark Tank Competition

Creating Data Analytic Solutions to Achieve Medication Therapy Outcomes

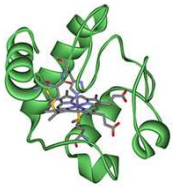
- *This project will build an integrated data analytic platform, with a special emphasis on identifying factors affecting medication therapy and linking patient care services.*

SOP Center on Metallotherapeutic Research

- *The Metallotherapeutics Research Center will address a gap in the area of drug development and regulatory sciences, and position the School as international recognized leader in research on metals in medicine and the environment.*

METALLOTHERAPEUTICS RESEARCH CENTER

- The mission of the Metallotherapeutics Research Center is to bring together researchers across disciplines who have a fundamental interest in metallotherapeutics, metals in biology, and the role of metals in the environment.
- We strive to improve human health and welfare by identifying new metalloprotein drug targets, developing new metal therapeutics, and improving current metal-based medications.



Innovation is Growing in Baltimore?

- Best-kept secret of the nation's innovation scene
- Ranked 20 hottest cities in tech
- Top three cities for women in technology
- Nearly 40 entrepreneurial support groups and co-working spaces
- Maryland ranked 3rd in Fast Company's listing of innovative states
- Maryland ranked 4th in number of startup per 1M residents

Center for Maryland Advanced Ventures

- **GOAL 1:** Pursue grant funding for the University of Maryland, including interdisciplinary grant funding.
  - **Industry Alliances**
  - **Joint UMB/UMCP large grants**
- **GOAL 2:** Expand technology transfer developed by the University of Maryland to the private sector.
  - **Maryland Momentum Fund**
  - **Life Sciences IP Fund**
  - **Medical Device IP Fund**
  - **Robert E. Fischell Institute for Biomedical Devices**
  - **President's Entrepreneurial Fellowships Create a USM-wide tracking technology transfer tracking system**
- **GOAL 3:** Encourage the development and location of University-created or sponsored technology companies in Baltimore City.
  - **The GRID** innovation center in the BioPark
    - **Small Business Development Center**
    - **IP and Entrepreneurship Clinic**
    - **I-CORPS**
    - **The Baltimore Fund**

UNIVERSITY OF MARYLAND
STRATEGIC PARTNERSHIP
MPOWERING THE STATE

The GRID

- Education and co-working space at UMB for students, entrepreneurs, faculty, and staff to connect and take on health and social challenges
- Founded by UM Ventures
  - Business incubator space
  - Business assistance programs
    - SBDC
    - Law School IP and Entrepreneurship Clinic
    - Community banks

Questions?

Pharmapreneurship

Self-Assessment Questions

1. Pharmapreneurship or pharmapreneurism is a course at the University of Maryland School of Pharmacy to prepare graduating PharmDs for the financial aspects of the profession of pharmacy.
    a. True
    b. False

2. List at least 3 steps in the Pharmapreneurship Pathway.
    a. From slide

3. Pharmapreneurship will allow significant opportunities for collaboration and networking to enhance the role of pharmacy throughout health care.
    a. True; this is a mission.
    b. False; it is solely business oriented.

4. A dedicated pharmapreneurism space at the School of Pharmacy is called

    _____.

Answers

1. False
2. From the slide: Seminar series, Effective leadership & advocacy, Regulatory science competition, Business plan competition, Communication course, Student developing projects, and Participate in Dolphin Tank and Shark Tank competitions.
3. True
4. Pharmapreneur's Farm

Intro to Becoming a Consultant Pharmacist

Windy Irwin, PharmD, BCGP

Objectives

- Define what a consultant pharmacist is and identify the role of pharmacist consulting in various settings.
- Recognize applicable federal regulations and guidance documents for consultant pharmacists in the long-term care setting
- Recognize challenges within the role of the consultant pharmacist, identifying effective strategies of medication management.
- Identify various resources available for consultant pharmacists

Consultant Pharmacist : Definition

- *"A consultant pharmacist is a pharmacist who works as a consultant providing expert advice on the use of medications or on the provision of pharmacy services to medical institutions, medical practices and individual patients"*

Consultant Pharmacist Overview

- Focuses on reviewing and managing medication regimens
  - Appropriateness
  - Effectiveness
  - Safety
- Various settings
- Identifies, resolves, preventative measures regarding medication related problems
- Classify patient-specific goals

Consultant Pharmacist Overview

- Educates proper use and administration, storage and disposal of medications
- Collaborates with interdisciplinary team of healthcare professionals
- Influential decision makers of medication use
- Time management skills, flexibility
- Communication skills essential
- Counseling and recommendations to patients, providers, caregivers
- Oversee medication distribution services

Consultant Pharmacist Roles

- Long-Term Care and Post Acute
- Mental Institutions
- Hospice Care Facilities
- Correctional Institutions
- Care facilities for Developmentally Disabled
- Acute Care Hospitals
- Dialysis Units
- Managed Care - telepharmacy
- Primary Care
- Assisted Living Facilities
- Specialty Pharmacy
- Home Health Care
- Group Homes and Addiction Centers
- Compliance Strategies
- Independent Consultant Pharmacist Business

- *Some states do require consultant pharmacists to obtain a separate license*

Consultant Pharmacist Services

- LTC, MRR
- MTM
- CMR
- Transitions of Care
- Medication Reconciliation
- Antimicrobial Stewardship
- Education
- Cost Savings Analysis
- Laboratory services
- Software Development
- Nutritional Services
- Clinical Research
- Chronic Care Management
  - Diabetes
  - HTN
  - COPD
- Disease Management Protocols
  - Diabetes
  - Pain
  - Bowel
  - Hypertension

Consultant Pharmacist Play an Important Role In Long-Term Care

- Adults living longer
- US population age 65 years and older expected to double within 25 years
- 72M >65 years old
- Consume considerable percentage of meds
- Need expert advice
- Advocate for senior care
- Specially trained to assist with long-term care patients & medication needs
- Seniors greater risk for medication related problems
  - Multiple chronic disease
  - Impacts of aging
  - Higher rate of both RX and OTCs

State Operations Manual
Appendix PP - Guidance to Surveyors for Long Term Care Facilities

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf

Medication Regimen Review

"Medication Regimen Review (MRR)" or Drug Regimen Review is a thorough evaluation of the medication regimen of a resident, with the goal of promoting positive outcomes and minimizing adverse consequences and potential risks associated with medication. The MRR includes review of the medical record in order to prevent, identify, report, and resolve medication-related problems, medication errors, or other irregularities. The MRR also involves collaborating with other members of the IDT, including the resident, their family, and/or resident representative.

Medication Regimen Review

F-755 Intent

§483.45(c)(1), (2), (4), and (5) The intent of this requirement is that the facility maintains the resident's highest practicable level of physical, mental and psychosocial well-being and prevents or minimizes adverse consequences related to medication therapy to the extent possible, by providing oversight by a licensed pharmacist, attending physician, medical director, and the director of nursing (DON).

Medication Regimen Review

F-756

§483.45(c) Drug Regimen Review. §483.45(c)(1) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist. §483.45(c)(2) **This review must include a review of the resident's medical chart.**

Medication Regimen Review

MRR policies and procedures should also address, but not be limited to:

MRRs for residents who are anticipated to stay less than 30 days

MRRs for residents who experience an acute change of condition and for whom an immediate MRR is requested after appropriate staff have notified the resident's physician, the medical director, and the director of nursing about the acute change

Medication Regimen Review

§483.45(c)(5) The facility must develop and maintain policies and procedures for the ***monthly drug regimen*** review that include, but are not limited to, time frames for the different steps in the process and steps the pharmacist must take when he or she identifies an irregularity that requires urgent action to protect the resident.

Medication Regimen Reviews

Definition

"Irregularity" refers to use of medication that is inconsistent with accepted standards of practice for providing pharmaceutical services, not supported by medical evidence, and/or that impedes or interferes with achieving the intended outcomes of pharmaceutical services.

An irregularity also includes, but is not limited to, use of medications without adequate indication, without adequate monitoring, in excessive doses, and/or in the presence of adverse consequences, as well as the identification of conditions that may warrant initiation of medication therapy.

(See reference to F757 Unnecessary Drugs which defines unnecessary drugs in opening regulatory language.)

Medication Regimen Reviews

F-757

§483.45(d) Unnecessary Drugs—General

Each resident's drug regimen must be free from unnecessary drugs.

An unnecessary drug is any drug when used— §483.45(d)

(1) In excessive dose (including duplicate drug therapy); or §483.45(d)

(2) For excessive duration; or Effective November 28, 2017 §483.45(d)

(3) Without adequate monitoring; or §483.45(d)

(4) Without adequate indications for its use; or §483.45(d)

(5) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or §483.45(d)

(6) Any combinations of the reasons stated in paragraphs (d)(1) through (5) of this section.

Medication Monitoring

Monitoring for Efficacy and Adverse Consequences

If the therapeutic goals are not being met or the resident is experiencing adverse consequences, it is essential for the prescriber in collaboration with facility staff, the pharmacist, and the resident to consider whether current medications and doses continue to be appropriate or should be reduced, changed, or discontinued.

Serum concentration monitoring may be necessary for some medications. Abnormal or toxic serum concentrations must be evaluated for dosage adjustments. If serum concentrations are within normal ranges, each resident should still be evaluated for effectiveness and side effects.

Medication Regimen Review

Transitions in care such as a move from home or hospital to the nursing home, or vice versa, increase the risk of medication-related issues.

Medications may be added, discontinued, omitted, or changed. It is important, therefore, to review the medications. Currently, safeguards to help identify medication issues around transitions in care and throughout a resident's stay include:

The pharmacist performing the medication regimen review, which includes a review of the resident's medical record, at least monthly

The pharmacist reporting any irregularities in a separate written report to the attending physician, medical director, and director of nursing

The attending physician reviewing and acting on any identified irregularities

Medication Regimen Review

F-758

§483.45(c)(3) A psychotropic drug is any drug that affects brain activities associated with mental processes and behavior.

These drugs include, but are not limited to, drugs in the following categories:

Anti-psychotic

Anti-depressant

Anti-anxiety

Hypnotic

Medication Regimen Reviews

Psychotropic Drugs

•

§483.45(e) Psychotropic Drugs. Based on a comprehensive assessment of a resident, the facility must ensure that

§483.45(e)(1) Residents who have not used psychotropic drugs are not given these drugs unless the medication is necessary to treat a specific condition as diagnosed and documented in the clinical record

§483.45(e)(2) Residents who use psychotropic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these

- §483.45(e)(3) Residents do not receive psychotropic drugs pursuant to a PRN order unless that medication is necessary to treat a diagnosed specific condition that is documented in the clinical record; and
- §483.45(e)(4) PRN orders for psychotropic drugs are limited to 14 days. Except as provided in §483.45(e)(5), if the attending physician or prescribing practitioner believes that it is appropriate for the PRN order to be extended beyond 14 days, he or she should document their rationale in the resident's medical record and indicate the duration for the PRN order.
- §483.45(e)(5) PRN orders for anti-psychotic drugs are limited to 14 days and cannot be renewed unless the attending physician or prescribing practitioner evaluates the resident for the appropriateness of that medication.

Psychoactive Medication Use

Potential Adverse Consequences

The facility assures that residents are being adequately monitored for adverse consequences such as:

General: anticholinergic effects which may include flushing, blurred vision, dry mouth, altered mental status, difficulty urinating, falls, excessive sedation, constipation

Cardiovascular: signs and symptoms of cardiac arrhythmias such as irregular heart beat or pulse, palpitations, lightheadedness, shortness of breath, diaphoresis, chest or arm pain, increased blood pressure, orthostatic hypotension

Metabolic: increase in total cholesterol and triglycerides, unstable or poorly controlled blood sugar, weight gain

Neurologic: agitation, distress, EPS, neuroleptic malignant syndrome (NMS), parkinsonism, tardive dyskinesia, cerebrovascular event (e.g., stroke, transient ischemic attack (TIA)

Psychoactive Medication Use

§483.45(d) Unnecessary drugs and 483.45(c)(3) and (e) Psychotropic Drugs

The intent of this requirement is that:

Each resident's entire drug/medication regimen is managed and monitored to promote or maintain the resident's highest practicable mental, physical, and psychosocial wellbeing

The facility implements gradual dose reductions(GDR) and non-pharmacological interventions, unless contraindicated, prior to initiating or instead of continuing psychotropic medication

PRN orders for psychotropic medications are only used when the medication is necessary and PRN use is limited

Pharmacist's Review Overview

Whether the physician and staff have noted and acted upon possible medication-related causes of recent or persistent changes in the resident's condition such as worsening of an existing problem or the emergence of new signs or symptoms.

Some examples of changes potentially related to medication use that could occur include:
–
Anorexia and/or unplanned weight loss, or weight gain
–
Expressions or indications of distress, or other changes in a resident's psychosocial status
–
Bowel function changes including constipation, ileus, impaction
–
Confusion, cognitive decline, worsening of dementia (including delirium); o Dehydration, fluid/electrolyte imbalance
–
Excessive sedation, insomnia, or sleep disturbance
–
Falls, dizziness, or evidence of impaired coordination
–
Headaches, muscle pain, generalized aching or pain
–
Rash, pruritus
–
Spontaneous or unexplained bleeding, bruising
–
Urinary retention or incontinence

F-755

§483.45(a) Procedures. A facility must provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident
§483.45(b) Service Consultation. The facility must employ or obtain the services of a licensed pharmacist who—
§483.45(b)(1) Provides consultation on all aspects of the provision of pharmacy services in the facility
§483.45(b)(2) **Establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation**
§483.45(b)(3) Determines that drug records are in order and **that an account of all controlled drugs is maintained and periodically reconciled**

Resources are available to facilitate evaluating medication concerns related to the performance of the MRR, such as:

- *U.S. Department of Health and Human Services, Food and Drug Administration (FDA) http://www.fda.gov/medwatch/safety.htm.*
- *American Society of Consultant Pharmacists (ASCP) http://ascp.com/;*
- *American Medical Directors Association – The Society for Post-Acute and Long-Term Care Medicine (AMDA) http://www.paltc.org/;*
- *National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) http://www.nccmerp.org;*
- *American Geriatrics Society (AGS) http://www.americangeriatrics.org; and CMS or the U.S. Department of Health and Human Services. CMS is not responsible for the content of pages found at these sites. URL addresses were current as of the date of this publication.*

Consultant Pharmacist Role –AL setting

- Majority of AL residents need assistance with medications
  - Challenges-financial, social, safety, sense of autonomy
- Residents-self administration or not?
  - Many not able due to physical, memory or cognitive difficulties
  - Quarterly evaluations by delegating nurse
  - Assessment form available
- Transitions of Care
- Varies state to state
- (Maryland): AL facility ***shall*** arrange for a licensed RPH to conduct on-site review of medications and physician orders at least every six months for any resident receiving 9 or more medications including OTCs and PRNs

Challenges

- Time management
- Scheduling
- Communication, people skills
- Rapidly evolving
- Caseload, Bed load
- Travel
- Flexibility-cancellations, changes
- LTC-changes turn-over

Challenges

- Environment
  - Location to work
  - Distractions
  - Internet Connection
  - Locked units
  - Audits-accessibility
  - Bathroom
  - Meal prep
- Inexperience
- Regulations and Guidelines
- Staying Up to Date
- Lack of knowledge
  - BCGP
  - Webinars
  - Conferences
  - Professional Associations

Resources

- www.ascp.com
  - Practice Resource Centers
  - SENIORX Solutions
  - Journal, Products, Webinars
- www.americangeriatrics.org
- www.cdc.gov
- www.cms.gov
- www.pharmacytimes.com
- Beer's List of Potentially Inappropriate medications for Older Adults
- Black Box Warnings

References

- www.ascp.com
- www.cms.gov
- www.cdc.gov
- www.hqi.solutions
- www.pharmacytimes.com

Thank you!

Questions?

Becoming A Consultant Pharmacist
Self-Assessment Questions

Assessment: Answer Key--- Highlighted in Yellow

1. Consultant pharmacist responsibilities include the following:
    a. Identification of preventative measures regarding medication-related problems
    b. Classify patient-specific goals
    c. Education on proper use and administration, storage and disposal of medications
    d. All of the above

2. Regulations and Guidelines to Surveyors for long-term care facilities can be located in the State Operations Manuel (True or False)

3. MRR review must include review for unnecessary medication use. Each resident's drug regimen in a long-term care facility must be free from unnecessary drugs described as the following except:
    a. Excessive dose
    b. Use without adequate monitoring
    c. Establish a system of records of receipt and disposition of all controlled drugs
    d. Medication use in the presence of adverse consequences

4. Seniors are at greater risk for medication related problems due to the following:
    a. Multiple chronic diseases
    b. Higher rate of both prescription medications and OTC agents
    c. Cost of living
    d. Both a and b

5. Services of consultant pharmacist may include the following:
    a. Cost savings analysis
    b. Antimicrobial Stewardship
    c. Software Development
    d. All of the above

6. Consultant pharmacist additional certification and licensing is required in most states (true or false).

7. Medication Regimen Review (MRR) must be performed according to the following:
    a. Requires that the facility develop multiple levels of oversight
    b. Medication Regimen Review must be performed once a month by licensed pharmacist or registered nurse.
    c. MTM review can be performed in place of MRR review.
    d. Facility must develop and maintain policies and procedures for the monthly drug-regimen review that include, but are not limited to, time frames for the different steps in the process and steps the pharmacist must take when he or she identifies an irregularity that requires urgent action to protect the resident.

8. Challenges to becoming a consultant pharmacist include the following:
    a. Planning / scheduling
    b. Travel
    c. Lack of experience or knowledge
    d. All of the above

The Ps and Qs of Pain Assessment and Management

Maryland Chapter ASCP
25th Annual Conference
August 3, 2018

David H. Jones, RPh, FASCP
*dhj***Rx***Consulting*

Objectives

- To identify key impacts of uncontrolled pain
- Recognize proper utilization of tools to assess level of pain
- Identify collaboration opportunities for the development and implementation of interventions to manage pain, including the selection of appropriate medication and the use of non-drug alternatives.

Definitions

- Pain is a complex subjective and unpleasant sensation derived from sensory stimuli and modified by memory, expectations, and emotions"

  The Merck Manual of Geriatrics
- Pain is always and completely subjective
- "Pain is just what the patient says it is."

  American Geriatric Society

Start With P

The Ps of Pain to Ponder

Precipitating Factors

- Age
- Arthritis
- Circulation
- Immobility
- Neuropathy
- Comorbidities
- Surgery
- Wounds

Pain Is

- Present
- Persistent
- Prevalent
- Personal
- Punishing
- Physical, Psychological

The Presence of Pain

- Over 80% of patients in Long Term Care report pain
- The patients' perception of pain may differ from that of caregivers
  - Perhaps 60% of the time
    - *CMS data*
- CDC reports that 11% of adults experience daily pain

The Persistence of Pain

- Over ¾ of LTC patients in pain are not treated to relief
- Nearly half of patients are still having pain at time of next assessment
- Can be disease specific
  - 70 to 90 %, cancer
  - 50%, HIV
- DHHS survey: 50% of those over 60 report ongoing pain over the last month

The Prevalence of Pain

- Overall prevalence of bothersome pain, nearly 52% of overall elderly population
- 74.9% reported pain at multiple sites
- No significant difference in prevalence among age groups
  - Ages 65 to over 90
- 58% of women; 48% of men

Prevalence and Impact of Pain Among Older Adults, Pain, 2013; 154 et seq)

Pain is Personal

- Cognition
- Depression
- Anxiety
- Sleep disturbance
- Behaviors
- Lack of will to participate

Pain is Punishing

- Risk to Fall
- Decreased ADLs
- Decubitus risk
- Slower recovery or healing
- “I just cannot take it.”
- Pain score of 86
- 72% noted restrictions in movement when pain is present

(Pain 2013 in NIH study)

The Patients

Primum Non Nocere!
(First, Do No Harm)

Hippocrates

Use the Q

- Quality
  - Of the pain
  - Of our response
  - Of the outcome
- Questions
- A Ladder vs. a Queue

Quality Awareness and Improvement

- Care process for pain management
- Pain Recognition
- Effective, consistent assessment of pain
- Management of pain
  - Non-drug
  - Drug
- Monitoring, reassessing, and revising of care plan

Areas of Impact

- Pain
  - Pain Symptoms
  - Pain site
  - Control/pla revision
- Mood / sleep
  - Sleep cycle
  - Sadness, anxiety, apathy
  - Mood chenges
  - Resisting care
  - Behavior changes
- Depression
  - Initiative
  - Involvement
- Ability / function
  - Functional limitation in range of motion
  - Changes in ADL
  - Range of motion
  - Rehabilitation
  - Restorative Care
- Nutrition
  - Mouth pain
  - Difficulty swallowing
  - Weight Loss
- Skin
  - Lesions
  - Other skin problems
  - Foot problems

Impact of Pain on the Patient

Physical

- Decreased ambulation
- Risk to Fall
  - Gait disturbances
  - Deconditioning
- Contractures
- Decreased ADLs
- Bowel and Bladder changes
- Slowed healing

Impact of Pain on the Patient

Mental

- Cognitive Losses
- Depression
- Anxiety
- Behavior episodes
- Sleep disturbances
- Delirium
- Decreased sense of self worth

Impact: The Patient's Point of View

- Inability to enjoy social activity
  - 54%
- Feelings of depression
  - 32%
- Anxiety
  - 26%
- Impaired memory
  - 12%

Adapted from JAGS, 2016

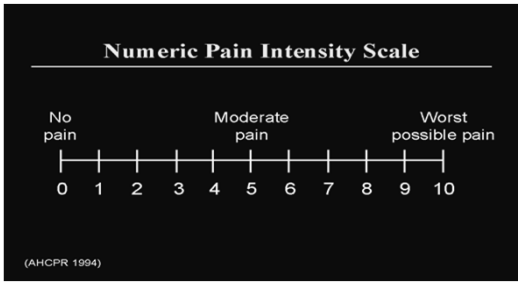
Pain Assessment

- Review medical, nursing, and drug history
- Include a focused pain history
  - Always include family and caregivers
- Review psycho-social concerns for contribution to pain and expression
- Review previous treatment regimens, effectiveness, family and patient satisfaction
- Consider each pain complaint separately

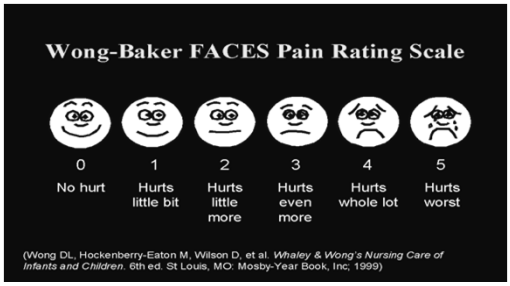
Assessment Tools

- Numerical Scale
- Faces
- Descriptors
- Verbal expressions
- Non verbal evidence
- Anything That Works, Everything Needed
- "The Fifth Vital Sign"

A Pain Assessment Scale



A “Faces” Pain Assessment Scale



FLACC Scale

- Face
- Legs
- Activity
- Cry
- Consolability

Scored 0,1,2 for each Category and totalled for final assessment

Valuable for non-responsive patients

Classification of Pain: Triage Interventions

- Acute: A Medical Emergency
  - Pain Score of 9 or 10 = Intervene NOW
- Recent onset
- Chronic (Maybe call it Persistent?)
  - Nociceptive: somatic, visceral
  - Neuropathic
  - Psychologically mediated
- Persistent Malignant
- Persistent Non-malignant

Other Signs of Pain

Verbal
- Sighing
- Moaning
- Groaning
- Crying
- Blowing
- Screaming
- Requests for help
- Requests for medication

Non Verbal
- Grimacing
- Guarded position
- Decreased ROM
- Rocking/ Rubbing
- Irritability
- Fatigued
- Anorexia
- Dehydration
- Confusion
- Resisting care

Questions to ask

- Location: Where does it hurt?
- Quality: What does it feel like?
- Timing: When does it occur?
- Severity: How bad is the pain?
- Exacerbation: What makes it worse?
- Palliative: What makes it better?
- Consequences: What does it keep you from doing or enjoying?

Action Plans

- Proactive, not reactive
- Consistent screening and assessment
- Appropriate intervention
- Prescribing
- DePrescribing

Pain Control: General Principles

- Believe the patient; include family & caregivers
- Partner with the patient, family, and caregivers
  - Always be aware of patient needs and satisfaction
- Balance drug and non-drug interventions
  - Must be complementary
  - Consider pain-free versus manageable
  - Contract for pain management
- Pain prevention beats treatment
- Pain is multidimensional and unique
- Keep the regimen as simple as possible

Adapted from American Pain Society, 2017

Principles for Analgesic Selection

Drugs are an essential consideration in pain management programs

- Choice of Drug
- Administration of Drug
- Establish Pain Management Goal
- Monitoring
  - Benefits
    - Effective
    - Efficacious
  - Changing needs
  - Adverse Drug Reactions

Principles for Analgesic Selection

Administration

- Use the appropriate medication
- Give adequate doses
- Titrate to individual needs
  - Patient response and satisfaction
  - Drug itself
    - Onset
    - Peak
    - Duration
- Dose Around The Clock, especially for persistent pain

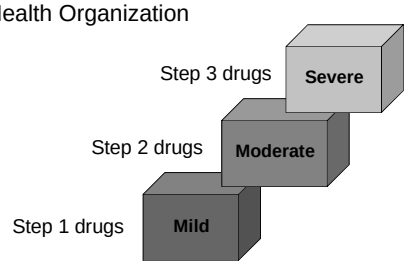
The “House” Protocol

“If I have a butt-load of pain, I need a butt-load of drugs”

Gregory House, MD 2008

Say WHO?

- World Health Organization



Quality Interventions to Consider

- Medications
  - Opioids
  - Non-opioids
- Non-drug interventions

Non-opioid Options

Non-narcotic drugs

- Acetaminophen
- NSAIDs
  - COX-2 Inhibitors
- Tramadol ?
- Low-Dose Naltrexone
- Adjuvant Drugs

Low-Dose Naltrexone (LDN)

- Demonstrated symptom reduction in a number of conditions
  - Fibromyalgia
  - Complex regional pain
  - Multiple sclerosis
  - Rheumatoid arthritis
  - Polymyalgia rheumatic
  - Neuropathy
- Central anti-inflammatory action

Clin. Rheumatology, 2014
Select patient responses

LDN Dosing

- 4.5 mg PO daily at bedtime
- Alternative 3 mg PO daily ay bedtime for MS
- General range 1.75 mg to 4.5 mf daily
- Treatment may start at 1.5 mg daily, with titration to benefit

Opioids: That Was Then

- Mentioned in Sumerian Pharmacopoeia 5000 BC
- "Among the remedies which it has pleased Almighty God to give to man to relieve suffering none is so universal and so efficacious as opium."

  Sydenham, 1680
- "Opioids are the major class of analgesics used in the management of moderate to severe pain because of their effectiveness, ease of titration, and favorable risk to benefit ratio"

  AHCPR Practice Guideline 2004

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Opioids 2018

- OMG! What to do?
- Effective and necessary for select patients
- Use lowest effective dose for shortest patient-beneficial duration
- Deprescribe/discontinue
- Well-defined benefit/risk evaluation
- Avoid co-prescribing
  - Benzodiazepines of special risk and concern

Based on CDC Guideline Statement 2017

Opioids

- Oxycodone
- Hydrocodone
- Fentanyl
- Morphine
- Codeine
- Meperidine
- Methadone
- Oxymorphone

Fear The Opioids

Adjuvant Drugs

- Neuropathic pain is a prime area where adjuvants can be powerful co-analgesics
- General Uses:
  - Enhance the efficacy of opioids or other analgesics
  - Treat concurrent symptoms that exacerbate pain
  - Treat pain not receptive to traditional analgesics
- May be used at any stage of treatment

Non-Drug Interventions Comfort Beats Discomfort

- Distraction
- Heat or Cold Application
- Massage
- Exercise
- Physical Therapy
- T.E.N.S.
- Acupressure
- Acupuncture
- Aromatherapy
- Biofeedback
- Other Therapies
  - Pet
  - Art
  - Music

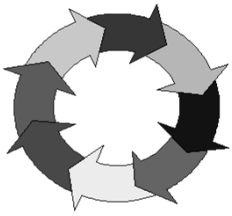
Combination Therapy May Help

The Pain Management Team

- Patient
- Family
- Administrator
- Medical Director
- Nursing
- Professional Nursing Assistants
- Staff Development
- Admissions Coordinators
- Attending Physicians
- Pharmacist
- OT, PT
- Dietitian
- Social Services
- Therapeutic Recreation
- Clergy
- Patient

Team Communications

We must complete the circle to be fully effective!



Ps & Qs; Let's Add Rs

- Regularly Monitor
- Respect the Patient
- Reassure Patient and Family
- Report to all the Team
- Revise as needed

And perhaps add Ss

- Systematic tracking
- Symptom review
- Support

A Closing Thought

"Giving a patient the information necessary to participate intelligently in his or her own pain management is empowering and provides the person with a sense of control in an otherwise difficult and unpredictable period of their lives"

Bruce Ferrell, MD

With thanks and acknowledgment

Primary resources:

- Agency for Healthcare Research and Quality
- American Medical Association
- American Pain Society
- American Society of Consultant Pharmacists
- Hospice and Palliative Nurses Association
- National Hospice Organization

Web Resources

- www.theacpa.org for chronic pain
- www.ascp.com
- www.ahrq.gov
- www.ashp.com
- www.aps.org
- www.jointcommission.org
- www.iasp-pain.org/PatientResources

Thank You!

"It does not matter how slowly you go, as long as you do not stop"

Confucius

- Are there any questions?

The Ps & Qs of Pain Assessment and Management

Self-evaluation Questions

1. Pain assessment and management depends on factors that are:
a. Objective
b. Subjective

2. Pain control is a prevalent concern for over half of the elderly population.
a. True
b. False

3. The FLACC Scale is useful only for very young patients.
a. True
b. False

4. Name at least 3 classifications of pain
a. Acute
b. Recent onset
c. Chronic or persistent
d. Malignant
e Non-malignant

5. Low-dose naltrexone is an FDA approved approach for genera pain control.
True
False

Answers

1. Subjective
2. True
3. False
4. Select from list
5. False