Improving Adult Immunization across the Continuum of Care: Making the Most of Opportunities in the Ambulatory Care

2016 ICHP Spring Meeting– East Peoria, IL– April 8, 2016

2016 MPA Health-Systems Spring Seminar – Missoula, MT – April 30, 2016

2016 LSHP 2016 Annual Meeting– New Orleans, LA– May 27, 2016

This activity is sponsored by the American Society of Health-System Pharmacists (ASHP).

Supported by an educational grant from Merck

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Activity Overview

According to the National Foundation for Infectious Diseases (NFID), more than 50,000 adults in the United States die from vaccine-preventable diseases or their complications each year, and nearly 36,000 people die from complications of seasonal influenza. The current comprehensive U.S. adult immunization schedule includes vaccination for 16 infectious diseases. Despite the availability of these vaccines, many adults remain unvaccinated against preventable infectious illnesses.

Health care professionals who work in the ambulatory care setting have an opportunity to screen unimmunized patients at risk for vaccine-preventable diseases and intervene. In order to be most effective, health care professionals must remain abreast of the frequently updated recommendations for adult immunization from the Centers for Disease Control and Prevention Advisory Committee on Immunization Practices. This symposium will highlight the latest recommendations for four important adult vaccines: influenza, pneumococcal, herpes zoster, and tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap) vaccines. Vaccination strategies for specific immunocompromised patients and immunization considerations for health care personnel will also be discussed.

Learning Objectives

After the conclusion of this application-based educational activity, participants should be able to

- Outline current adult vaccination recommendations for the influenza; pneumococcal; tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap); and herpes zoster vaccines.
- Provide recommendations for vaccinations in adult immunocompromised patients.
- Recommend vaccines for healthcare personnel and strategies to optimize coverage.
- Outline approaches to improve adult vaccination rates across all populations in the ambulatory care setting.

Continuing Education Accreditation

The American Society of Health-System Pharmacists is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This activity provides 1.0 hour (0.1 CEU – no partial credit) of continuing pharmacy education credit (ACPE activity # 0204-0000-16-423-L01-P).

Participants will process CPE credit online at http://elearning.ashp.org/my-activities. CPE credit will be reported directly to CPE Monitor. Per ACPE, CPE credit must be claimed no later than 60 days from the date of the live activity or completion of a home study activity.

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Faculty

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Dr. Williams earned his Bachelor of Science in pharmacy and Doctor of Pharmacy degrees at the University of Kentucky in Lexington. He is a board-certified pharmacotherapy specialist, as well as a certified asthma educator. He has received fellow recognition from the American Society of Health-System Pharmacists, American College of Clinical Pharmacy, and American Pharmacists Association.

Dr. Williams focuses his practice, teaching, and research on the management of patients with pulmonary and infectious diseases. He is a member of the National Asthma Education and Prevention Program Coordinating Committee of the National Heart, Lung, and Blood Institute and several other boards.

Dr. Williams has published research papers and book chapters in the area of pulmonary diseases and infectious diseases, and he regularly speaks on these topics at national and international professional programs. He has trained thousands of pharmacists and students about pulmonary, infectious disease, and immunization sciences, as well as practice considerations related to these topics.

Improving Adult Immunization across the Continuum of Care: Making the Most of Opportunities in the Ambulatory Care Setting

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Dr. Weber received his Bachelor of Arts from Wesleyan University, his Medical Degree (M.D.) from the University of California, San Diego, a Master of Public Health (M.P.H.) from Harvard University, and completed his medicine residency and infectious disease fellowship at Massachusetts General Hospital. He is Board-Certified in Internal Medicine, Infectious Disease, Critical Care Medicine, and Preventive Medicine. He is a fellow of the Infectious Diseases Society of America (FIDSA) and fellow of the Society for Healthcare Epidemiology of America (FSHEA).

His research interests include the epidemiology of healthcare-associated infections, new and emerging infectious diseases, control of drug resistant pathogens, immunization practices (especially of healthcare personnel), zoonotic diseases, and epidemiology of tuberculosis. He is the Society for Healthcare Epidemiology of America (SHEA) representative to the Advisory Committee of Immunization Practices (ACIP) and has also served on several working groups of the ACIP.

Dr. Weber has published more than 200 scientific papers in the peer-reviewed literature. In addition he has published 4 monographs and more than 200 book chapters, editorials, and short papers. He serves as Associate Editor for Infection Control and Hospital Epidemiology (ICHE).

Improving Adult Immunization across the Continuum of Care: Making the Most of Opportunities in the Ambulatory Care Setting

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- Dennis M. Williams, Pharm.D., BCPS, AE-C, FASHP, FCCP, FAPhA, declares his spouse is a stockholder of GlaxoSmithKline plc.
- David J. Weber, M.D., M.P.H., FIDSA, FSHEA, declares he is a speaker and consultant for Merck and Pfizer, Inc.
- All other planners report no financial relationships relevant to this activity.

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Disclosures

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Objectives

- Outline current adult vaccination recommendations for the influenza; pneumococcal; tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap); and herpes zoster vaccines.
- Provide recommendations for vaccinations in adult immunocompromised patients.
- Recommend vaccines for healthcare personnel and strategies to optimize coverage.
- Outline approaches to improve adult vaccination rates across all populations in the ambulatory care setting.

Greatest Public Health Achievements in the U.S.

1900-1998

- **Vaccination**
- **Motor vehicle safety**
- **Safer workplaces**
- **Control of infectious diseases**
- **Decline in deaths from coronary artery disease and stroke**
- **Safer and healthier foods**
- **Healthier mothers and babies**
- **Family planning**
- **Fluoridation of drinking water**
- **Recognition of tobacco use as a health hazard**

CDC. MMWR. 1999; 48:241-243.

2001-2010

- **Vaccination**
- **Prevention and control of communicable diseases**
- **Tobacco control**
- **Improved maternal and infant health**
- **Motor vehicle safety**
- **Cardiovascular disease prevention**
- **Occupational safety**
- **Cancer prevention**
- **Childhood lead poisoning prevention**
- **Public health preparedness and response**

CDC. MMWR. 2011; 60:619-623.

Value-Based Purchasing and Vaccines-Centers for Medicare and Medicaid Services (CMS)

- Vaccines coverage is incorporated as a measure
  - Influenza immunization (IMM-2) is a clinical care – process measure
  - Pneumococcal (IMM-1) (Pneumococcal) is currently suspended (voluntary reporting)
  - Global Immunization Measure also in effect
  - Influenza vaccine coverage for healthcare personnel (OP-27) planned for CY 2016
- Planned reduction (or withheld) by CMS in Drug Related Group (DRG) payments is 2% for FY 2017
- Influenza immunization measure (IMM-2) may be removed for FY 2018, but continue to be included in the Hospital Inpatient Quality Reporting (IQR)

CMS VBP FY 2017 and CMS 1607-P. www.cms.gov. (accessed 2015 October)

Home Health Value-Based Purchasing Measures

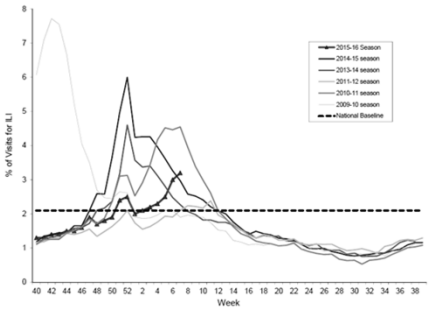
- Quality measures starter set for CY 2016 includes vaccines
  - Influenza, pneumococcal, and herpes zoster vaccine for beneficiaries
  - Influenza vaccine for healthcare personnel

Source: Docket No. CMS 1625P

Seasonal Influenza

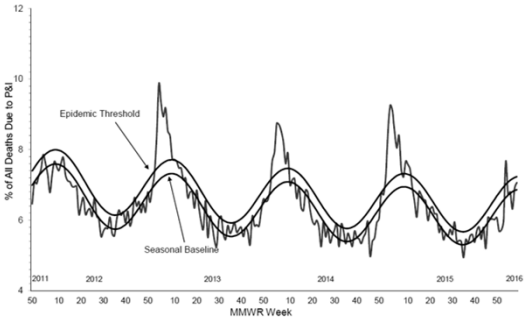
- An epidemic of influenza occurs annually in the United States
- Characterized by
  - Increase in rates of influenza-like illness (ILI)
  - Followed by increases in hospitalizations
  - Followed by increases in influenza-associated mortality

Surveillance of Influenza-like Illness by Season



CDC. Weekly U.S. Influenza Surveillance Report. www.cdc.gov/flu/weekly/index.htm (accessed March 2016)

Pneumonia and Influenza Mortality by Season



CDC. Weekly U.S. Influenza Surveillance Report. www.cdc.gov/flu/weekly/index.htm (accessed March 2016).

Influenza Vaccine Recommendations 2015-16

- Routine annual influenza vaccination is recommended for all persons ≥6 months of age who do not have contraindications
- Advisory Committee on Immunization Practices (ACIP) does not recommend a preference for any specific product
  - Committee also recommends that vaccination should not be delayed in order to obtain a specific product if an appropriate one is available

Centers for Disease Control and Prevention. *MMWR* .2015; 64(30); 818-825.

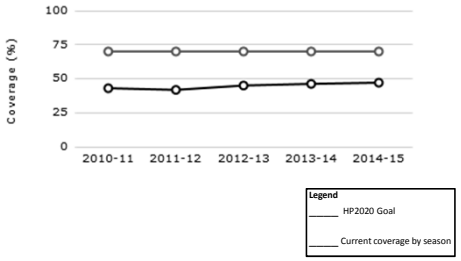
Influenza Vaccine Composition 2015-16

- Trivalent products
  - A/California/7/2009 (H1N1)-like virus
  - A/Switzerland/9715293/2013 (H3N2)-like virus*
  - B/Phuket/3073/2013-like (Yamagata lineage) virus*
- Quadrivalent products
  - B/Brisbane/60/2008-like (Victoria lineage) virus

* New for 2015-16

Centers for Disease Control and Prevention. *MMWR.* 2015; 64(30); 818-825.

Influenza Vaccination Coverage, U.S.



CDC.www.cdc.gov/flu/fluvaxview/reportshtml/reporti1415/trends/index.html (accessed 2015 Oct).

Influenza Vaccine Effectiveness (VE) Estimates, 2005-15

Influenza Season[1]	Reference	Study Site(s)	No. of Patients[2]	Adjusted Overall VE (%)	95% CI
2004-05	Belongia 2009	WI	762	10	-36, 40
2005-06	Belongia 2009	WI	346	21	-52, 59
2006-07	Belongia 2009	WI	871	52	22, 70
2007-08	Belongia 2011	WI	1914	37	22, 49
2009-10	Griffin 2011	WI, MI, NY, TN	6757	56	23, 75
2010-11	Treanor 2011	WI, MI, NY, TN	4757	60	53, 66
2011-12	Ohmit 2014	WI, MI, PA, TX, WA	4771	47	36, 56
2012-13	McLean 2014	WI, MI, PA, TX, WA	6452	49	43, 55
2013-14	Unpublished	WI, MI, PA, TX, WA	5990	51	43, 58
2014-15	ACIP presentation, Flannery	WI, MI, PA, TX, WA	4913	19	7, 29

CDC. http://www.cdc.gov/flu/professionals/vaccination/effectiveness-studies.htm (accessed 2015 Oct).

Interactive Case 1

- Mavis is a 65 year old female patient who was recently diagnosed with COPD. She is at the clinic and is being evaluated for vaccine needs. She reports that she hasn't received vaccines regularly during the past 20 years because she has had a fear of needles.

Interactive Case 1 (continued)

- Mavis asks about her options for the influenza vaccine which has been recommended for her. She reports that she has received the flu shot sporadically over the past years because of her fear of needles.

What option for influenza vaccine should be offered to Mavis?

a. Intradermal influenza vaccine
b. Intranasal influenza vaccine
c. Oral influenza vaccine
d. Intramuscular influenza vaccine

Influenza Vaccine Products 2015-16

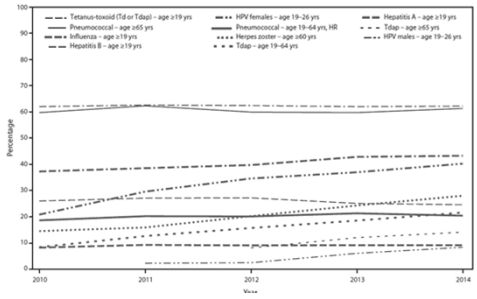
- Inactivated Influenza Vaccine, Trivalent (IIV3)
  - Intramuscular, Standard Dose
  - Intramuscular, High Dose
- Inactivated Influenza Vaccine, Quadrivalent (IIV4)
  - Intramuscular, Standard Dose
  - Intradermal, Standard Dose
- Live Attenuated Influenza Vaccine, Quadrivalent (LAIV)
  - Intranasal
- Inactivated Influenza Vaccine, Trivalent, cell-culture-based (ccIIV3)
  - Intramuscular, Standard Dose
- Recombinant Influenza Vaccine, Trivalent (RIV3)
  - Intramuscular, Standard Dose

Centers for Disease Control and Prevention. *MMWR*. 2015; 64(30):818-825.

Improving Influenza Vaccination Coverage-Clinician Role

- Recommend and advise
  - Use status as knowledgeable clinician
  - Individualize message
- Educate and increase awareness
  - Public and individual
  - Campaigns and promotions
- Serve as resource for information and services
  - Address myths, utilize facts
  - Provide clinics at convenient times and in various settings

Vaccine Coverage, Ages ≥19 years NHIS 2010-14



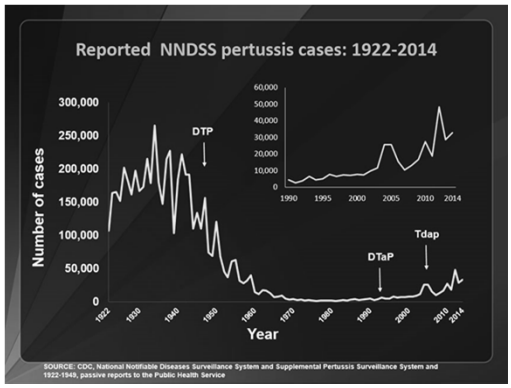
Centers for Disease Control and Prevention. *MMWR* . 2016; 65(1):1-40.

Interactive Case 1: Part 2

- Mavis, our 65 year old patient, is also advised that a tetanus booster is needed.
- She reports that she hasn't received a tetanus shot for 30 years.
- She is a new grandmother with a one month old granddaughter.

What tetanus-containing vaccine is recommended for Mavis?

a. DTaP (Diphtheria, tetanus, and acellular pertussis)
b. Td (Tetanus and diphtheria)
c. Tdap (Tetanus, diphtheria, and acellular pertussis)



Centers for Disease Control and Prevention. http://www.cdc.gov/pertussis/surv-reporting.html (accessed 2015 Oct 12).

See enlargement, p. 15

Pertussis Cases

Total Cases
2013: n=28639
2014: n=32971

Reported Case Profiles, By Age

Age	No. of Cases	%	Age Inc /100,000
< 6 mos	3,330	(10.1)	169.0
6-11 mos	875	(2.7)	44.4
1-6 yrs	6,082	(18.5)	25.1
7-10 yrs	5,576	(16.9)	34.0
11-19 yrs	11,159	(33.8)	29.6
20+ yrs	5,839	(17.7)	2.2
Unknown	110	(0.3)	N/A
Total	**32,971**	**(100.0)**	**10.4***

*Total age incidence per 100,000 calculated from 32,861 cases with age reported.

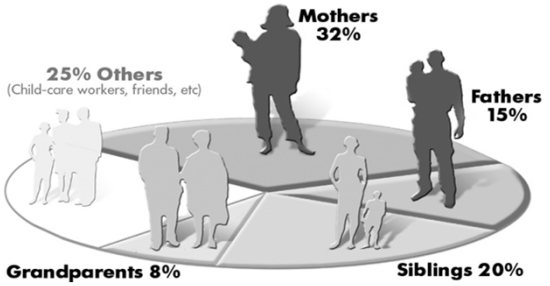
Reported Pertussis Deaths

Age	Deaths*†
Infants, aged < 3 mos	8
Infants, aged 3-11 mos	1
Children, aged 1-4 yrs	2
Adults, aged 55+ yrs	2
Total	**13**

*Deaths reported through NNDSS to CDC.
†9 of the 13 deaths were male.

CDC. 2014 Final Pertussis Surveillance Report. Sept 18, 2015/64(36). www.cdc.gov/mmwr/preview/mmwrhtml/mm6436a8.htm?s_cid=mm6436a8_w

Source of Infant Pertussis Infection (n=264)



Created with data from Bisgard K, et al. *Pediatric Infect Dis J.* 2004; 23:985-9.

Tdap Recommendation

- Single dose of Tdap is recommended for all individuals age ≥ 11 years
- Td booster recommended every 10 years

Tdap in Pregnancy Recommendations

- Recommended during pregnancy
  - Administer during every pregnancy
  - Target at 27-36 weeks gestation
  - If not given, administer immediately postpartum
- Rationale
  - Maximizes maternal antibody response and passive antibody transfer to infant
  - Consistent with cocooning strategy to protect newborns and infants

Centers for Disease Control and Prevention. *MMWR*. 2013; 62(07): 131-135.

Tetanus-containing Vaccine Recommendations

Age	Vaccine	Recommendation
Birth through 6 years	DTaP	5 dose series: 2, 4, 6, 15 to 18 months, and 4 to 6 years
7 through 10 years	Tdap	Administer one dose if child has not completed pediatric series
11 through 18 years	Tdap	Administer as first 'tetanus' booster at any time if not received
19 years and older	Tdap or Adult Td	Administer Tdap if not yet received, and Adult Td every 10 years as tetanus booster
Pregnancy	Tdap	Administer during each pregnancy, preferably between 27 and 36 weeks gestation
Health Care Personnel	Tdap or Adult Td	Administer Tdap if not yet received, and Adult Td every 10 years as tetanus booster

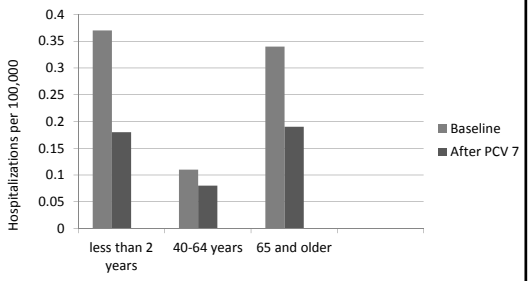
Pneumococcal Disease

- Caused by *Streptococcus pneumoniae*
- A leading cause of vaccine-preventable morbidity and mortality
- Commonly presents as
  - Pneumonia
  - Invasive disease (bacteremia and meningitis)

Available Pneumococcal Vaccines

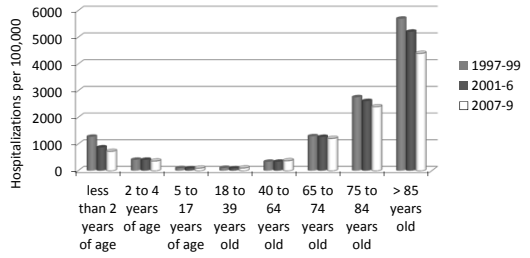
- 23-valent pneumococcal polysaccharide vaccine (PPSV23)
  - Polysaccharide-based vaccine, indicated for
    - Individuals age 65 years and older
    - Individuals with asthma or smokers ages 19 and older
    - Individuals with selected chronic diseases (including immunocompromising conditions), ages 2 to 64 years
- 13-valent pneumococcal conjugate vaccine (PCV13) (12 strains overlap with PPSV 23)
  - Protein conjugate-based vaccine, indicated for
    - Primary series for children younger than 2 years
    - Individuals age 65 years and older
    - Individuals with selected immunocompromising conditions, ages 6 to 64 years

Pneumococcal Meningitis In-Hospital Deaths, 1994-2004



Tsai CJ et al. *Clin Infect Dis*. 2008; 46:1664-72.

Hospitalization Rates for Pneumonia



Griffin MR et al. *N Engl J Med*. 2013; 369:155-63.

CDC Pneumococcal Vaccine Recommendations for Adults, ages > 19 years*

Risk group	Underlying medical condition	PCV13 Recommended	PPSV23 Recommended	PPSV23 Revaccination 5 yrs after first dose
Immunocompetent persons	Chronic heart disease†		✓	
	Chronic lung disease§		✓	
	Diabetes mellitus		✓	
	Cerebrospinal fluid leak	✓	✓	
	Cochlear implant	✓	✓	
	Alcoholism		✓	
	Chronic liver disease, cirrhosis		✓	
	Cigarette smoking		✓	
Persons with functional or anatomic asplenia	Sickle cell disease/other hemaglobinopathy	✓	✓	✓
	Congenital or acquired asplenia	✓	✓	✓
Immunocompromised persons	Congenital or acquired immunodeficiency¶	✓	✓	✓
	Human immunodeficiency virus infection	✓	✓	✓
	Chronic renal failure	✓	✓	✓
	Nephrotic syndrome	✓	✓	✓
	Leukemia	✓	✓	✓
	Lymphoma	✓	✓	✓
	Hodgkin disease	✓	✓	✓
	Generalized malignancy	✓	✓	✓
	Iatrogenic immunosuppression**	✓	✓	✓
	Solid organ transplant	✓	✓	✓
	Multiple myeloma	✓	✓	✓

* PCV recommendations also include children, ages 6 through 18 years; Both PCV 13 and PPSV 23 are universally indicated, ages 65 and older

www.cdc.gov/vaccines/vpd-vac/pneumo/vac-PCV13-adults.htm.

Interactive Case 1: Part 3

Mavis is also a candidate for a pneumococcal vaccine. She has no recent history of pneumococcal vaccination. What should be administered today?

a. PCV 13
b. PPSV 23
c. Both PCV 13 and PPSV 23

Pneumococcal Vaccines Caveats for Sequencing

- PPSV23 indications are broader
  - When > 1 dose is indicated, interval between doses is 5 years
  - Some patients could receive up to 3 PPSV doses in a lifetime
- For individuals age 65 years and older
  - PCV13 first, followed by PPSV23 in 1 year
- When PCV13 and PPSV23 indicated < 65 years
  - PCV13 first, followed by PPSV23 in 8 weeks

www.cdc.gov/vaccines/vpd-vac/pneumo/vac-PCV13-adults.htm.

Herpes Zoster and HZ Vaccine

- 50% lifetime risk for episode
  - Age-associated, with greatest risk ≥60 years
  - 1 million cases annually in U.S.
- Current vaccine reduces risk of shingles episode by 51% and of post herpetic neuralgia (PHN) by 66.5%
  - Severity of zoster and PHN episodes also lessened
- Declining protection against shingles with age, but PHN protection is preserved

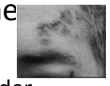
Data from registry study and www.immunize.org

Interactive Case 1: Part 4

Mavis has become interested in getting maximum protection against vaccine-preventable diseases. She reports never having chickenpox as a child but wonders if she should get the herpes zoster vaccine. What would you advise?

a. Yes
b. No

Herpes Zoster and HZ Vaccine



- Live attenuated virus vaccine
- Administer to adults at age 60 years or older
- Number needed to treat (NNT) to prevent one additional case of zoster is 1/(11.12 per 1000 pt-yr - 5.42 per 1000 pt-yr) or 175 people
- An inactivated, adjuvant subunit vaccine (HZ/su) in clinical trials
  - Requires 2 doses (2 months apart)
  - Exhibits 97% efficacy and higher ADR profile compared with current vaccine

Photo courtesy of CDC and Oxman MN et al. *N Engl J Med.* 2005; 352:2271-84 and Lal H et al. *N Engl J Med.* 2015; 372:2087-96.

Vaccine Recommendations for Immunocompromised Patients

- Recommendations available from CDC and various specialty practice groups
- Populations include cancer patients, HIV, SOT, HSCT, and others on chronic immunosuppressive therapies
- Largely concordant; however some variances are present

SOT=Solid organ transplant
HSCT=Hematopoietic stem cell transplantation

Interactive Case 2
Planned Immunosuppression

- Betty P. is a 59 year old Caucasian woman who has end-stage renal disease (ESRD) secondary to poorly controlled type 2 diabetes. She attends dialysis 3 times a week.
- She is currently treated with insulin, and is undergoing evaluation for a kidney transplant.
- A consult is requested regarding appropriate vaccinations to consider based on this plan.

Interactive Case 2
Planned Immunosuppression

- Ms. P.'s record indicates that she received the pneumococcal vaccine (PPSV23) five years prior, a Td booster 4 years ago, and the hepatitis B vaccine series 2 years ago prior to beginning dialysis.
- She received the 2015-16 influenza vaccine in January 2016.

Interactive Case 2

Which of following vaccines would <u>not</u> be recommended for Ms. P prior to her transplant?

a. Tdap
b. PCV 13
c. Hepatitis A
d. Polio

Interactive Case 2
Planned Immunosuppression

- Based on her planned kidney transplant, Ms. P should receive the following prior to transplant if possible:
  - Inactivated influenza vaccine
  - Hepatitis A
  - Tdap
  - PCV 13, followed by PPSV 23 in 8 weeks
  - Herpes Zoster vaccine at least 4 weeks prior to transplant
- Consult CDC and IDSA guidelines for recommendations

IDSA=Infectious Diseases Society of America

Vaccine Recommendations and Strategies for Health Care Workers

Rationale for Assuring HCP Immunity to Vaccine-Preventable Diseases

- Protect HCP
  - HCP have higher risk than general public of acquiring the following: hepatitis B (blood and body fluid exposure), measles (ED personnel), pertussis (exposure to children), invasive meningococcus (microbiologists), influenza (direct patient care)
  - Also protects HCP's families, if HCP acquires infection
- Protect patients
  - Infected HCP have initiated and propagated multiple nosocomial outbreaks
  - HCP have infected patients prior to onset of rash/symptoms: Measles, mumps, rubella, pertussis, and influenza
  - Chronically infected HCP have infected patients (hepatitis B)

Recommended Adult Immunization Schedule: U.S., 2016

Figure 2. Vaccines that might be indicated for adults aged 19 years or older based on medical and other indications[1]

VACCINE ▼ INDICATION ►	Pregnancy	Immunocompromising conditions (excluding HIV infection)[4,5,6,8]	HIV infection (CD4+ count (cells/µL))[4,5,6,9] < 200	HIV infection (CD4+ count (cells/µL))[4,5,6,9] ≥ 200	Men who have sex with men (MSM)	Kidney failure, end-stage renal disease, on hemodialysis	Heart disease, chronic lung disease, chronic alcoholism	Asplenia and persistent complement component deficiencies[4,9,10]	Chronic liver disease	Diabetes	Healthcare personnel
Influenza[2]	1 dose annually										
Tetanus, diphtheria, pertussis (Td/Tdap)[7]	1 dose Tdap each pregnancy	Substitute Tdap for Td once, then Td booster every 10 yrs									
Varicella[7,8]	Contraindicated	2 doses									
Human papillomavirus (HPV) Female[7,11]	3 doses through age 26 yrs			3 doses through age 26 yrs							
Human papillomavirus (HPV) Male[7,11]	3 doses through age 26 yrs			3 doses through age 21 yrs							
Zoster[8]	Contraindicated	1 dose									
Measles, mumps, rubella (MMR)[7,8]	Contraindicated	1 or 2 doses depending on indication									
Pneumococcal 13-valent conjugate (PCV13)[7,8]	1 dose										
Pneumococcal polysaccharide (PPSV23)[8]	1, 2, or 3 doses depending on indication										
Hepatitis A[7,8]	2 or 3 doses depending on vaccine										
Hepatitis B[7,8]	3 doses										
Meningococcal 4-valent conjugate (MenACWY) or polysaccharide (MPSV4)[7,8]	1 or more doses depending on indication										
Meningococcal B (MenB)[7,8]	2 or 3 doses depending on vaccine										
Haemophilus influenzae type b (Hib)[7,8]	3 doses post-HSCT recipients only	1 dose									

Covered by the Vaccine Injury Compensation Program | Recommended for all persons who meet the age requirement, lack documentation of vaccination, or lack evidence of past infection; zoster vaccine is recommended regardless of past episode of zoster | Recommended for persons with a risk factor (medical, occupational, lifestyle, or other indication) | No recommendation | Contraindicated

CDC. http://www.cdc.gov/vaccines/schedules/hcp/adult.html. Accessed 2016 March.

See enlargement, p. 15

Proof of Immunity for HCP

Vaccine	Birth before 1957	MD Dx	+ Serology	Self Report	Documented Vaccination
Mumps	✓[1]	Yes[3]	✓	No	✓
Measles	✓[1]	Yes[3]	✓	No	✓
Rubella	✓[1,2]	Yes[3]	✓	No	✓
Varicella	No	Yes	✓	No	✓
Hepatitis B	No		≥10 MIU/mL[4]	No	✓
Pertussis	No	No	No	No	✓
Influenza	No	No	No	No	✓

[1]Consider immunization of HCP born before 1957, recommend during an outbreak; [2]All HCP of childbearing potential should be immunized; [3]requires lab confirmation; [4]Obtain 1-2 months post last vaccine dose

Weber DJ, Schaffner W. *Infect Control Hosp Epidemiol*. 2011; 32:912-4.

Assessing Immunity to Vaccine-Preventable Diseases in HCP

- Assess immunity at start of professional school
  - Obtain appropriate serologies (if cost effective)
  - Provide appropriate vaccines (counsel if vaccine(s) cannot be provided)
- Assess immunity at start of employment
  - Obtain appropriate serologies (if cost effective)
  - Provide appropriate vaccines (counsel if vaccine(s) cannot be provided)
- Assess immunity annually
  - Review of medical records for incomplete immunization series
  - Review of current job description
  - Influenza vaccine
  - Need for boosters/additional doses (e.g., meningococcal)

Impact of Strategies to Improve HCP Influenza Vaccination

Intervention and study	Preintervention immunization rate, %	Postintervention immunization rate, %	Overall change in vaccination rate, %	Randomized, controlled trial of intervention	Implemented with other interventions
Declination					
Polgreen et al [23]	54	65	+11	No	Yes
Bertin et al [25]	38	55	+17	No	Yes
Ribner et al [27]	43	65	+22	No	Yes
Mandatory vaccination					
Virginia Mason [37]	30	98	+68	No	Yes
BJC HealthCare [39]	71	99	+28	No	Yes
Education and promotion					
Harbarth et al [31]	13	37	+24	No	Yes
Thomas et al [32]	8	46	+38	No	Yes
Mobile cart					
Sartor et al [29]	7	32	+25	No	Yes
Cooper et al [30]	8	49	+41	No	Yes
Incentives (raffle) [35]	38[a]	42	NS	Yes	Yes
Educational letter from leadership [36]	38[a]	39	NS	Yes	Yes
On-site expert education [33]	21[a]	22	NS	Yes	Yes

Talbot T et al. *Clin Infect Dis*. 2009; 49:773-779.

See enlargement, p. 16

Society for Healthcare Epidemiology of America (SHEA) Guideline: 2010 Update

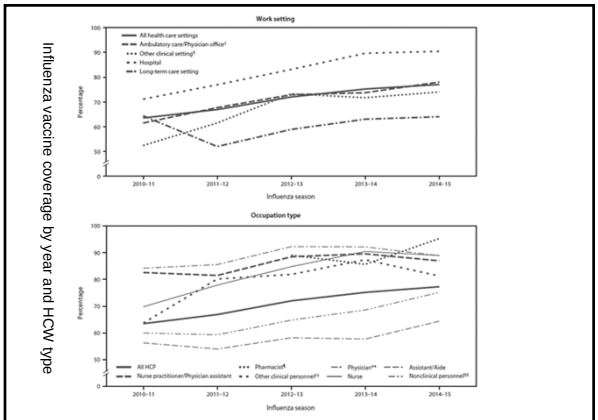
- No endorsement of requiring unvaccinated persons to wear a mask
- Use of declination forms should not be viewed as primary method for increasing vaccination rates
- Recommendations for coverage include ALL HCP (contract workers, volunteers, students, product vendors, independent practitioners)
- Exemptions to vaccine mandates should only be allowed for medical contraindications
- SHEA does not endorse religious exemptions or philosophical exemptions
- SHEA endorses that influenza vaccination should be a condition of employment

Impact of "Mandatory" Influenza Requirements

Reported institutional-level seasonal influenza vaccination coverage of pre- and post-requirement influenza seasons among US hospitals.[a]

Characteristic	Hospitals no.	Pre-requirement season Mean coverage (95% CI)	Post-requirement season Mean coverage (95% CI)
Overall	228	62.0 (59.8–64.2)	76.6 (74.5–78.8)
Vaccination coverage, pre-requirement season			
<50%	44	37.8 (35.9–39.7)	62.4 (56.7–68.2)
50–64%	84	57.6 (56.7–58.4)	73.3 (70.2–76.4)
65–79%	67	71.8 (70.8–72.9)	83.0 (80.6–85.4)
80+%	33	88.4 (86.5–90.3)	91.8 (88.0–95.7)
Consequences imposed for vaccine refusal			
Yes, termination	18	72.1 (66.6–77.7)	94.5 (93.5–95.5)
Yes, other[b]	105	63.5 (60.1–66.8)	81.9 (79.0–84.9)
No	105	58.8 (55.9–61.6)	68.3 (65.7–71.0)
Post-requirement season			
2007–2008, or before[c]	74	54.5 (50.8–58.2)	67.0 (64.1–69.8)
2008–2009	38	60.1 (54.4–65.9)	71.4 (66.2–76.7)
2009–2010	71	65.4 (61.9–68.8)	85.1 (81.8–88.3)
2010–2011	45	68.7 (63.1–74.2)	83.2 (79.3–87.0)
Location[d]			
Urban	131	59.0 (56.2–61.7)	75.8 (72.9–78.8)
Rural	97	66.2 (62.5–69.9)	77.7 (74.5–81.0)

Miller BL et al. Vaccine. 2011; 29:9398-9403.



Influenza vaccine coverage by year and HCW type

Centers for Disease Control and Prevention. *MMWR* . 2015; 64(36): 993-9.

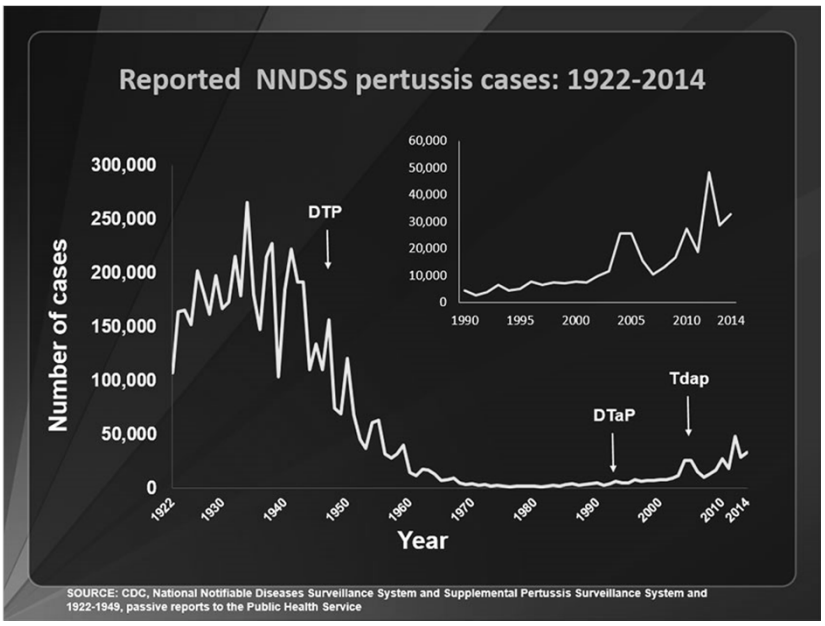
See enlargement, p. 16

Challenges/Issues for the Future in Preventing Healthcare-Associated Influenza

- Implementing vaccination as a condition of employment
  - Push back from unions and Equal Employment Opportunity Commission (EEOC)
  - Questions regarding effectiveness of HCP immunization (e.g., Cochrane review)
- Achieving ≥90% coverage without "mandates"
- Improving coverage of the following groups:
  - Students/trainees/volunteers
  - HCP in nursing homes and assisted living facilities
  - Contract workers
- Assessing HCP vaccine coverage outside of hospitals (e.g., nursing homes, students)
- Should non-vaccinated HCP wear a face mask while in clinical areas?
- Should HCP ≥65 years of age receive high titer vaccine?
- Should HCP preferentially receive quadrivalent vaccines?

Key Takeaways

- Vaccines have had a significant impact on reducing morbidity and mortality from vaccine-preventable diseases
  - Vaccine coverage rates are part of quality measures
  - Adults should be routinely screened for vaccine needs
- Health care personnel have a responsibility to be up to date with personal vaccinations to promote health and protect patients
  - Evidence-based strategies should be used to promote institutional policies regarding vaccinations for health care personnel
- Great opportunities and unmet needs exist with improving vaccine coverage rates and improving health



Centers for Disease Control and Prevention. http://www.cdc.gov/pertussis/surv-reporting.html (accessed 2015 Oct 12).

Recommended Adult Immunization Schedule: U.S., 2016

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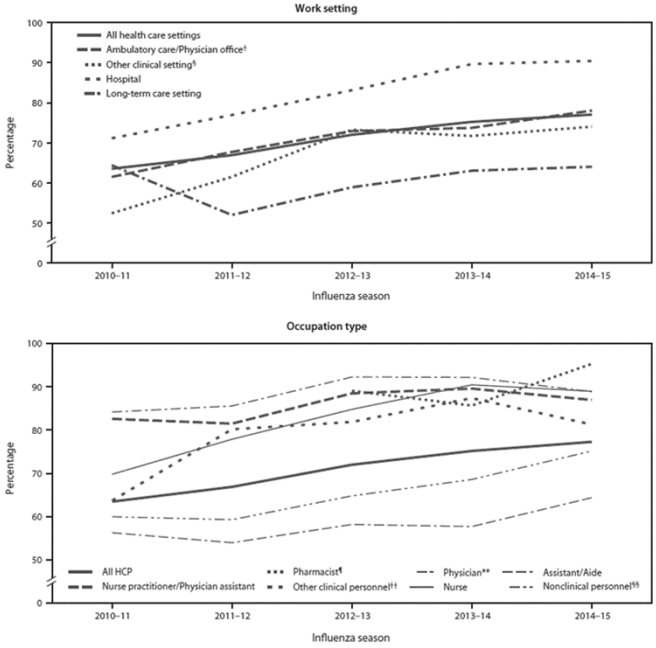

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Self-Assessment Questions

The questions included in this presentation are listed below as a learner assessment tool. You may wish to note the correct answers and rationale as you follow along with the speaker.

Interactive Case 1: Part 1

- Mavis is a 65-year-old female patient who was recently diagnosed with COPD. She is at the clinic and is being evaluated for vaccine needs. She reports that she hasn't received vaccines regularly during the past 20 years because she has had a fear of needles.
- Mavis asks about her options for the influenza vaccine which has been recommended for her. She reports that she has received the flu shot sporadically over the past years because of her fear of needles.

1. What option for influenza vaccine should be offered to Mavis?
    a. Intradermal influenza vaccine.
    b. Intranasal influenza vaccine.
    c. Oral influenza vaccine.
    d. Intramuscular influenza vaccine.

Interactive Case 1: Part 2

- Mavis, our 65 year old patient, is also advised that a tetanus booster is needed.
- She reports that she hasn't received a tetanus shot for 30 years.
- She is a new grandmother with a one month old granddaughter.

2. What tetanus-containing vaccine is recommended for Mavis?
    a. DTaP (Diphtheria, tetanus, and acellular pertussis).
    b. Td (Tetanus and diphtheria).
    c. Tdap (Tetanus, diphtheria, and acellular pertussis).

Interactive Case 1: Part 3

3. Mavis is also a candidate for a pneumococcal vaccine. She has no recent history of pneumococcal vaccination. What should be administered today?
    a. PCV 13.
    b. PPSV 23.
    c. Both PCV 13 and PPSV 23.

Interactive Case 1: Part 4

4. Mavis has become interested in getting maximum protection against vaccine-preventable diseases. She reports never having chicken pox as a child but wonders if she should get the herpes zoster vaccine. What would you advise?

    a. Yes.
    b. No.

Improving Adult Immunization across the Continuum of Care: Making the Most of Opportunities in the Ambulatory Care Setting

Interactive Case 2
Planned Immunosuppression

- Betty P. is a 59-year-old Caucasian woman who has end-stage renal disease (ESRD) secondary to poorly controlled type 2 diabetes. She attends dialysis 3 times a week.
- She is currently treated with metformin and insulin, and is undergoing evaluation for a kidney transplant.
- A consult is requested regarding appropriate vaccinations to consider based on this plan.
- Ms. P.'s record indicates that she received the pneumococcal vaccine (PPSV23) five years prior, a Td booster 4 years ago, and the hepatitis B vaccine series 2 years ago prior to beginning dialysis.
- She received the 2014-15 influenza vaccine in January 2015.

5. Interactive Case 2
   Which of following vaccines would <u>not</u> be recommended for Ms. P prior to her transplant?

Answers
1. d
2. c
3. a
4. a
5. d

Online CE Access:
Using an Enrollment Code

Pharmacists and Technicians:
Per ACPE, CPE credit must be claimed **no later than 60 days** from the date of the live activity or completion of a home study activity. All ACPE accredited activities which are processed on the eLearning site will be reported directly to CPE Monitor. To claim pharmacy credit, you must have your NABP e-Profile ID, birth month, and birth day. If you do not have an NABP e-Profile ID, go to www.MyCPEMonitor.net for information and application. Please follow the instructions below to process your CPE credit for this activity.

1. Type the following link into your web browser to access the e-Learning site: **http://elearning.ashp.org/my-activities**
2. If you already have an account registered with ASHP, log in using your username and password.

   If you have not logged in to any of the ASHP sites before and/or are not a member of ASHP, you will need to set up an account. Click on the **Register** link and follow the registration instructions.
3. Once logged in to the site, enter the enrollment code for this activity in the field provided and click **Redeem**.

   Note: The Enrollment Code was announced at the end of the live activity. Please record the Enrollment Code in the grid below for your records.
4. The title of this activity should now appear in a pop-up box on your screen. Click on the **Go** button or the **activity title.**
5. Complete all required elements. A green ✔ should appear as each required element is completed. You can now claim your credit.
6. Available credit(s) will appear beneath the completed required activities. Look for your profession in the list of available credits and click the appropriate **Claim** button. You might have to click to see more credit options if you don't see your profession listed.

   CPE Credit for Pharmacists and Technicians: To claim continuing pharmacy education (CPE) credit, you will need to enter your NABP e-Profile ID, birth month, and birth day. Once you have entered this information the first time, it will auto fill in the future. Please note: All CPE credit processed on the eLearning site will be reported directly to CPE Monitor.
7. Review the information for the credit you are claiming. If all information appears to be correct, check the box at the bottom and click **Claim**. You will see a message if there are any problems claiming your credit. Your credit will be reported directly to CPE Monitor.

Date of Activity	Activity Title	Enrollment Code	Credit Hours
	Improving Adult Immunization across the Continuum of Care: Making the Most of Opportunities in the Ambulatory Care Setting		1.0

NEED HELP? Contact eLearning@ashp.org

Read the Room: Using Emotional Intelligence Principles to Optimize Your Personal Interactions

Jennifer Tryon, PharmD, MS

The speaker has no conflict of interest to declare.

Objectives

- Define Emotional Intelligence (EI) as it relates to being an influential leader
- Identify situations in your work environment where high EI can improve interpersonal interactions and outcomes
- Identify methods to improve your people skills by improving your EI
- List pitfalls to being an emotionally intelligent leader

Audience Poll

- How many of you know what EI is, or at least can describe it to the person next to you?

Definition

- *From a scientific (rather than a popular) standpoint, emotional intelligence is the ability to accurately perceive your own and others' emotions; to understand the signals that emotions send about relationships; and to manage your own and others' emotions. It doesn't necessarily include the qualities (like optimism, initiative, and self-confidence) that some popular definitions ascribe to it.*
  - *John D. Mayer, Harvard Business Review, 1990*

Ovans A. How Emotional Initelligence Became a Key Leadership Skill. *HBR*. 2015; Apr 28: 1-6

EI's Importance to Business Leadership

- *The most effective leaders are all alike in one crucial way: they all have a high degree of what has come to be known as emotional intelligence… Without it a person can have the best training in the world, an incisive, analytical mind, and an endless supply of smart ideas, but he still won't make a great leader.*
  - *Daniel Goleman, What Makes a Leader. HBR, 1998*

Ovans A. How Emotional Initelligence Became a Key Leadership Skill. *HBR*. 2015; Apr 28: 1-6

Big L Leader……. Little L leader

Formal/Titles

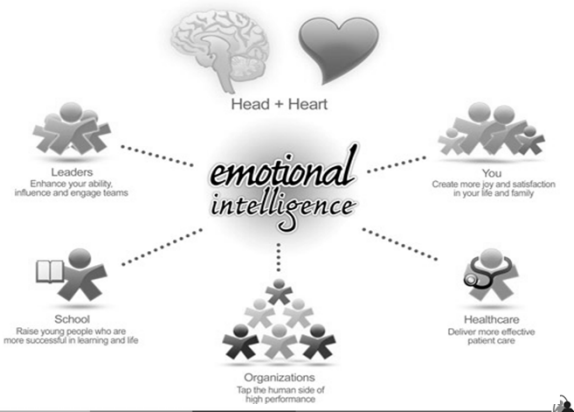
Every Pharmacist

How does EI apply to you?

- EI applies to everyone
  - Professional and home
- Developing EI makes a difference in your success (and your failure)
- It's everyone's responsibility (boss, colleague, individual)

Topic Significance

- With every person to person interaction our brains engage in a symphony of emotions (with associated neural linkups)
- Science shows that nourishing relationships have beneficial impacts on our health, while toxic ones can act like a slow poison in our body



Calvin & Hobbes

Recognizing People with High EI

- Understand and manage emotions
- They make better leaders
- Deal with stress
- Overcome obstacles
- Inspire others to work toward common goal
- Manage conflict with less fallout
- Build stronger teams
- Happier at work

McKee A. How to Hire for Emotional Intelligence. *HBR*. 2016; Feb 5; 1-5

The Five Components of Emotional Intelligence

Self-Awareness	Self-Regulation	Motivation	Empathy	Social Skill
Ability to recognize and understand your moods, emotions, and drives, and their effect on others	Ability to control/redirect disruptive impulses and moods; the propensity to suspend judgment- to think before acting	A passion to work for reasons that go beyond money or status; a propensity to pursue goals with energy and persistence	Ability to understand the makeup of other people; skill in treating people according to their emotional reactions	Proficiency in managing relationships and building networks; an ability to find common ground and build rapport

The Five Components of Emotional Intelligence at Work. HBR Web site. https://hbr.org/visual-library/2004/01/the-five-components-of-emotional-intelligence-at-work Published 2004. Accessed February 29, 2016

Education Contributes to EI

- Focus of schools focuses on knowledge and problem solving
- Greater benefit may be derived from learning social skill development
- Technology automate processes; people with soft skills can compliment and add synergy
- New approach: facts for home study, class for effective communication and interaction

Miller CC. Why What You Learned in Preschool Is Crucial at Work. *The New York Times Company*. 2015; Oct 16: 1-4

Job Market

- Increasing markets and pay affiliated with more social and thinking skills
  - Doctors, engineers
- Increasing markets for social skills but not math skills
  - Lawyers and child-care workers
- Declining markets require neither social or math skills
  - Manual labor

Miller CC. Why What You Learned in Preschool Is Crucial at Work. *The New York Times Company*. 2015; Oct 16: 1-4

ICHP and IL Chapters of ACHE 2016 Spring Meeting

Identify the signs: EI is Lacking

- Clueless, brutish, socially oblivious
- Walking through the busy pharmacy and the person in front of you stops suddenly in the middle of the space
- Working for a boss who tells you she wants to include you in a decision making process but then tells you what the decision is

ICHP and IL Chapters of ACHE 2016 Spring Meeting

Seinfeld

https://www.youtube.com/watch?v=u3k7lykTWTk

ICHP and IL Chapters of ACHE 2016 Spring Meeting

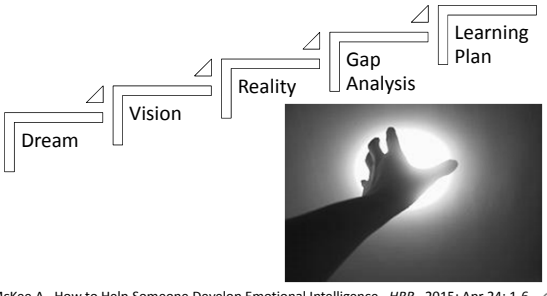
EI in the Pharmacy Environment

- Goal: Establish a healthy, happy, productive work environment
- EI skills can be developed but it requires personal commitment
  - Linked to a lifetime of neurological and psychological development
  - Require competency development (self control)
  - You must *want* to change your EI
- Pitfalls
  - Can't tell someone to change and expect results
  - Personal versus public perception of improvement

Wilkins MM. Signs That You Lack Emotional Intelligence. *HBR*. 2014; Dec 31: 1-6

ICHP and IL Chapters of ACHE 2016 Spring Meeting

Improving EI – Path to Action



McKee A. How to Help Someone Develop Emotional Intelligence. *HBR*. 2015; Apr 24: 1-6

ICHP and IL Chapters of ACHE 2016 Spring Meeting

Improving EI

- A personal vision of their future
- Identify the misalignment between the approach and the vision
- Reform habits

McKee A. How to Help Someone Develop Emotional Intelligence. *HBR*. 2015; Apr 24: 1-6

Example

- Resident with knowledge and passion for pharmacy work but off putting style
- Not my problem
- Bull in a china shop at work and at home
- Lacked empathy
- Unintended outcome
  - Impact on relationships
  - Progressive discipline
  - Possible termination

- Goal: Relearn how to care about people

The Village Approach

- Self-development journey
- Can't do it alone
  - People need kind and supportive people
  - Setbacks are inevitable
  - Confidence and commitment may wane
  - Who is on your board of Directors
- Have or find a mentor

Identify the Correct Path to Action for Improving EI

A Vision - Dream - Reality - Gaps - Plan

B Plan - Dream - Vision - Reality - Gaps

C Dream - Vision - Reality - Gaps - Plan

D Reality - Gaps - Dream - Vision - Plan

EI Uses in Conflicts

- Two components of conflict
  - Facts
  - Emotions
- Processing our environmental and emotional queues leads to behavior

Wilkins MM. Signs That You Lack Emotional Intelligence. *HBR*. 2014; Dec 31; 1-6

Conflict Gone Bad

- Emotional leakage
  - Feelings bottled up result in unintended, poorly articulated feelings
- Examples
  - Frustrating day leads to yelling at your kids
  - Your boss has no clue and is constantly assigning projects; you decide you're not following up and you don't tell them

Wilkins MM. Signs That You Lack Emotional Intelligence. *HBR*. 2014; Dec 31; 1-6

Fact or Emotion

- Sue is a top performing pharmacist who is the "go to" for oncology projects and knowledge. She updates her new boss routinely about project outcomes but before she can tell the punchline her boss tells her what to do. The approach is different from that of Sue every time. Sue gets frustrated, feels devalued, and decides not to update her boss. In her mind she decides to turf many of the issues to her "all knowing guardian". If things get much worse she may look for another job.
- Fact or Emotion?
- What are the consequences?

Seize Your Destiny

- Choose to behave in an emotionally intelligent manner
- Identify fact versus emotion
- Read your environment
  - Crossed arms, facial expressions, etc
- Understand the impact of your emotions
  - Criticism and nitpicking
  - Energy, creativity, big picture thinking

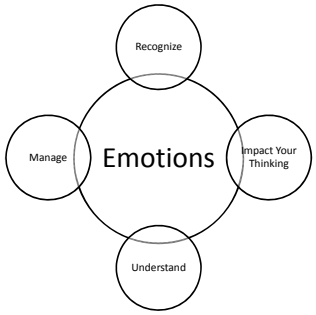
Wilkins MM. Signs That You Lack Emotional Intelligence. *HBR*. 2014; Dec 31; 1-6

Seize Your Destiny

- Emotions are important
  - Don't suppress them
  - Outcomes affect relationships, physiological effects, and memory
- "Emotions aren't just the result of a workplace conflict. In fact, emotions usually *are* the conflict."

Wilkins MM. Signs That You Lack Emotional Intelligence. *HBR*. 2014; Dec 31; 1-6

Applying EI to Difficult Conversations



Wilkins MM. Signs That You Lack Emotional Intelligence. *HBR*. 2014; Dec 31; 1-6

Emotional Agility

- It's normal to have feelings
  - Can't always be stoic and check your feelings at the door
  - Criticism, doubt, fear
- Anticipate problems and issues to identify solutions
- Problem: get hooked and emotional energy is sapped

David S, Congleton C. Emotional Agility. *HBR*. 2013: Nov; 125-128

Signs You Should Work On EI?

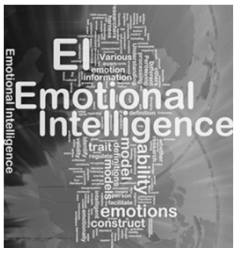
- Others don't get the point -- frustration
- Surprised at others' sensitivity to your jokes (they're overreacting)
- Being liked is overrated
- Quick to give opinions and defend to death
- Hold others to same high expectations
- Blame others for issues on team
- Annoyed others expect you to know how they feel

Wilkins MM. Signs That You Lack Emotional Intelligence. *HBR*. 2014; Dec 31: 1-6

Calvin

Calvin and Hobbs:
https://www.google.com/search?q=calvin+and+hobbes+emotional+intelligence&biw=1188&bih=542&source=lnms&tbm=isch&sa=X&ved=0ahUKEwjPgrTp6MHLAhWK8CYKHVUVAGsQ_AUIBigB#tbm=isch&q=calvin+and+hobbes+self+aware

Improving Your EI



- Get feedback
- Intent versus impact
- Press the pause button
- Wear both shoes

Wilkins MM. Signs That You Lack Emotional Intelligence. *HBR*. 2014; Dec 31: 1-6

Self Talk

- Internal voice/messaging
  - That was a dumb idea
  - This new tie is awesome
- Emotional Pause
  - Not suppressing or bottling emotions up
- Free your inner thoughts so you can engage in productive results
- Leads to professional success

PROBLEM

- Those who need it most are the least likely to realize it
- Essential to be a star performer
- Requires commitment to skill development

Wilkins MM. Signs That You Lack Emotional Intelligence. *HBR*. 2014; Dec 31: 1-6

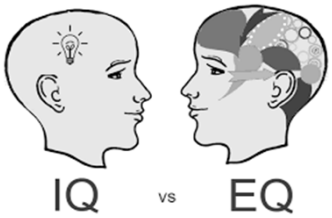
The Other Side of the EI Coin

- Pitfalls are not apparent, but there are counterarguments
- EI is not the only path to being a successful business leader
  - Have excellent expertise (strategist, forecaster, etc)
  - Hire people skills

Ovans A. How Emotional Initelligence Became a Key Leadership Skill. *HBR*. 2015; Apr 28: 1-6

Other Leadership Requirements

- IQ
- Technical Skills



Qualities of Great Managers

- What do employees value most in their managers? (Google researchers)
  - Technical Expertise
  - Personal connection
    - Made time for one-on-one meetings
    - Helped employees with problems
    - Interested in their lives

Miller CC. Why What You Learned in Preschool Is Crucial at Work. *The New York Times Company*. 2015; Oct 16: 1-4

Which skillset do most successful leaders have in common

A High Emotional Intelligence (EI)
B High Intelligence Quotient (IQ)
C Low Emotional Intelligence (EI)
D Low Intelligence Quotient (IQ)

Be Fierce, Commit to Developing EI

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8. David S, Congleton C. Emotional Agility. *HBR*. 2013: Nov; 125-128

"Reducing adverse drug event risks for geriatric patients by optimizing prescribing for selected medication records"

Amy Maxfield, BS Pharm
Heather Harper, PharmD, BCPS

Conflict of Interest Statement

- The speakers have no actual or potential conflict of interest in relation to this presentation

Pharmacist and Technician Objective

- State opportunities to leverage the electronic health record (EHR) to provide age appropriate dosing for geriatric patients

Site

- 616 bed tertiary care medical center located in Peoria, Illinois
- Teaching affiliate of the University of Illinois College of Medicine at Peoria
- Level 1 Adult and Pediatric Trauma Center
- Currently 80+ pharmacists on staff

Objective of Study

- To improve age-appropriate prescribing for selected medications in patients over 65 years old to decrease the potential for adverse drug events (ADEs)

Background

- 2014 - OSF Gero-Palliative Care Initiative
  - System-wide project with representation from many disciplines
  - Team members asked to develop and implement a project to improve the care of older adults
  - Pharmacy medication project
    - Noted inappropriate prescribing on inpatient units
    - Decided to focus project on improving appropriate prescribing of selected medications

Medication Selection

- Which medications to target?
  - BEERs list
    - 1991 – 12 clinicians led by Dr. M. Beers
    - Focus on two key areas
      - Meds that should be avoided
      - Meds that should be used with extra caution
- How many medications to target?
  - All meds on the BEERs list?
  - Small test of change to assess impact

Medication Selection

- Amitriptyline
- Cyclobenzaprine
- Diphenhydramine (oral and IV)
- Glimepiride
- Glipizide
- Glyburide

Leveraging the EHR

Age Based Contexts

- Medication records can be configured by age
- OSF uses 5 age contexts
  - Neonate (0-30 days)
  - Infant (1 month- 1year)
  - Pediatric (1 year – 14 years)
  - Adult (14 years – 65 years)
  - Geriatric (65 years +)

Age Based Contexts

- 75 year old
- 62 year old

Methods

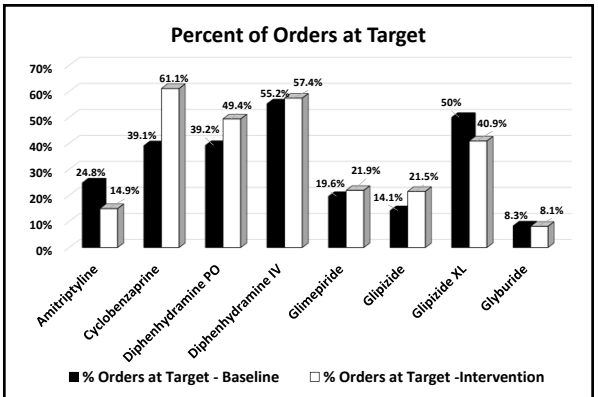
- Reviewed current entries in the EHR
- Determined target dose ranges and made changes to default dose/frequency
- EHR orders reports obtained for two six month periods for baseline and follow up
- Percentage of medication orders within target dose range were measured for patients 65 years and older

Methods

Medication	Target Initial Dose
Amitriptyline	10mg
Cyclobenzaprine	5mg
Diphenhydramine PO	12.5mg or 12.5mg-25mg
Diphenhydramine IV	12.5mg or 12.5mg-25mg
Glimepiride	1mg
Glipizide	2.5mg
Glipizide XL	2.5mg
Glyburide	1.25mg

Results

- Positive changes seen for 5 of 7 medications in the percentage of orders within target range



Limitations

- Age based dosing applied to new orders only
- Small number of medications selected
- p values not calculated

Summary

- Improved compliance achieved with provider ordering of cyclobenzaprine, oral/IV diphenhydramine, glimepiride, and glipizide for patients over 65 years
- Although not specifically measured, the risk of ADEs was reduced by adjusting default doses and frequencies of selected medications
- Next steps include reviewing post–op order sets for appropriateness

Assessment

Age based contexts are one means of improving age appropriate medication dosing for geriatric patients.

A. True

B. False

References

1. American Geriatrics Society 2015 Beers Criteria Update Expert Panel. American Geriatrics Society 2015 updated Beers criteria for potentially inappropriate medication use in older adults. *J Am Geriatr Soc* 2015 Oct 8. doi: 10.1111/jgs. 13702. [epub ahead of print].
2. Lexi-Comp. Accessed August 2014.

Economic impact of adverse drug events resulting in patient harm using hospital chargemaster data in 2014-2015

Bryan C. McCarthy Jr., Pharm.D., M.S., BCPS
Assistant Director, Ambulatory Clinical and Infusion Services
University of Chicago Medicine

The speaker has no conflict of interest to disclose.

University of Chicago Medicine

Primary Objective

- Identify the economic impact of adverse drug events resulting in harm on cost of hospitalization and length of stay

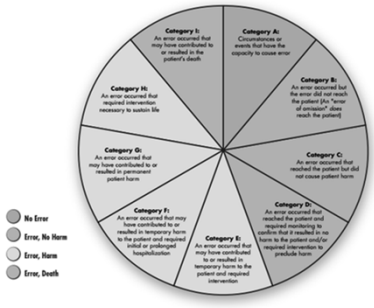
Background

- Adverse drug event is "an injury resulting from the use of a drug.
  - ADE includes harm caused by the drug (adverse drug reactions and overdoses) and harm from the use of the drug (including dose reductions and discontinuations of drug therapy)."[1]
- Cost of hospitalization and length of stay for hospitalized patients experiencing an ADE have been previously determined in the late 1990s and early 2000s to be significantly higher than for those who did not.[2-4]
  - Recent related publications citing this research have applied health care inflation rate factors to costs to promote external validity of their conclusions.[5,6]

Methods

- Retrospective analysis of ADEs experienced by hospitalized patients between April 2014 – May 2015
  - Voluntary reporting system
  - Hospital-based cost accounting system
- Two investigators rate each ADE based on NCC-MERP Index for Categorizing Medication Errors to determine severity
- For ADEs categorized as "E" or above, match a control group with varying numbers of patients based on:
  - Hospitalization during study period
  - MS-DRG
  - Age (+/- 2 years)
  - Gender

NCC MERP Index for Categorizing Medication Errors



Methods

- Cost of hospitalization and length of stay for case and control patient hospitalizations determined using the hospital-based cost accounting system
- Independent two sample Mann-Whitney U test to determine statistically significant differences among patients who experienced an adverse drug event resulting in harm vs. those who did not
- Exclusion criteria:
  - ADE experienced prior to admission
  - Multiple ADEs during single hospitalization
  - ADE attributed to unknown/unidentified medication
  - No identifiable controls available
  - Duplicate data from two sources

Results

Patient Hospitalization Demographic Information

		Case Group (n=242) n, %	Control Group (n=3279) n, %
Age			
	<15	24, 9.9%	566, 17.3%
	15-29	20, 8.3%	194, 5.9%
	30-44	27, 11.2%	154, 4.7%
	45-64	**108, 44.6%**	**1523, 46.4%**
	≥65	63, 26.0%	842, 25.7%
Gender			
	female	113, 46.7%	1016, 31.0%
	male	**129, 53.3%**	**2263, 69.0%**

Results

Frequency of Adverse Drug Events by Therapeutic Classification of Medication

Therapeutic Classification	Frequency (n, %)	Therapeutic Classification	Frequency (n, %)
Anti-anemia drugs	2, 0.8%	Calcium antagonists	1, 0.4%
Antibiotics	22, 9.1%	Cardiac Drugs	4, 1.7%
Anticoagulants	6, 2.5%	**Corticosteroids**	**34, 14.0%**
Anticonvulsants	4, 1.7%	Diagnostic Agents	4, 1.7%
Antidepressents	1, 0.4%	Electrolytes	1, 0.4%
Antidiabetic Agents	7, 2.9%	Hypotensive Agents	2, 0.8%
Antidiarrhea Agents	1, 0.4%	Immunosuppressive Agents	7, 2.9%
Anti-emetics	3, 1.2%	Local Anesthetic	3, 1.2%
Antihistamines	1, 0.4%	Opiate Antagonists	1, 0.4%
Anti-inflammatory Agents	1, 0.4%	**Opiates**	**28, 11.6%**
Antilipemic Agents	1, 0.4%	Parathyroid hormones	1, 0.4%
Antimanic agents	3, 1.2%	Sedatives and hypnotics	1, 0.4%
Antineoplastic Agents	**82, 33.9%**	Skeletal muscle relaxants	1, 0.4%
Antiprotozoals	1, 0.4%	Sympathomimetic agents	1, 0.4%
Antituberculars	1, 0.4%	Vasodilating Agents	3, 1.2%
Benzodiazepines	5, 2.1%	Vitamin K	1, 0.4%
Bronchodilators	8, 3.3%		

Results

Total Cost of Hospitalization and Length of Stay Between Patient Hospitalizations with ADE Resulting in Harm and No ADE Resulting in Harm

Group		n	Total Cost of Hospitalization ($) (Median, IQR)	p-value	Length of Stay (days) (Median, IQR)	p-value
All	Case	242	19,444, 13,481-40,580	***0.044***	5.0, 5.0-11.0	***0.005***
	Control	3279	17,173, 12,500-27,125		5.0, 4.0-7.0	
Antineoplastic agents	Case	82	18,616, 14,896-29,546	0.536	5.0, 5.0-8.8	0.893
	Control	1611	17,827, 17,021-27,703		5.0, 4.9-7.7	
Corticosteroids	Case	34	16,822, 10,967-38,621	0.339	5.0, 4.0-7.8	0.235
	Control	306	14,244, 11,207-19,008		4.6, 3.7-5.3	
Opiates	Case	28	23,415, 14,283-56,356	0.251	7.0, 4.8-16.0	0.251
	Control	381	18,004, 12,370-28,787		5.2, 4.2-7.2	
Age ≥65	Case	63	16,485, 13,575-24,664	0.878	5.0 , 7.5-4.0	0.806
	Control	842	17,692, 13,382-19,572		5.0, 4.2-5.9	
Age <65	Case	179	20,095, 13,327-43,994	***0.027***	5.0, 5.0-12.0	***0.002***
	Control	2423	17,101, 12,050-27,603		5.0, 4.0-7.4	

*Interquartile Range

Conclusion

- Total cost of hospitalization and length of stay is significantly higher for patients experiencing ADEs resulting in harm than those who did not

Limitations

- Investigator bias
- Select case and/or control patient hospitalizations may have experienced (additional) undocumented or unidentified ADE
- Additional variables that influence total cost of hospitalization and length of stay

Acknowledgements

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  PGY-2 Ambulatory Care Resident, Indiana University Health
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  Medication Safety Pharmacist, Mass General Hospital
- Eric Wenzler, PharmD
  Research Fellow, University of Illinois at Chicago
- Andrew M. Davis, MD, MPH, FACP
  Section of General Internal Medicine, University of Chicago Medicine

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Questions

bryan.mccarthy@uchospitals.edu

Basement to Bedside: Expanding Patient Care Roles in Pharmacy

Panelists:
Scott Drabant, RPh, FASCP
Jessica DiGioia, CPht
Megan Fleischman, PharmD, BCACP

Objectives

At the end of this presentation, pharmacist and technician participants should be able to:

- **Describe the role of the pharmacist and/or technician in transition of care, inpatient Medication Therapy Management (MTM), and within a patient-centered medical home (PCMH).**
- **List resources required to start a transitional service, MTM program, and a PCMH.**
- **Identify potential barriers to increasing patient care roles for the pharmacist and/or technician.**
- **Discuss strategies for optimizing medication therapy and patient adherence.**

Polling question

1. What is your current practice setting?
   A. Community Setting
   B. Inpatient Setting
   C. Outpatient Clinical Setting within an Institution
   D. Outpatient Clinical Setting Stand Alone
   E. Managed Care Organization
   F. Other Setting

Polling question

2. What percentage of time do you spend delivering direct patient care services in a given day?
   A. 0%
   B. 5-10%
   C. 20-30%
   D. 50%
   E. >50%

Basement to Bedside: Expanding Patient Care Roles in Pharmacy Medication Therapy Management (MTM)

Scott Drabant, RPh, FASCP
MTM / Clinical Pharmacist
Centegra Health System
McHenry, Illinois

Conflict of Interest

Unfortunately the Speaker has no actual or potential conflicts of interest in relation to this presentation

What are we going to talk about?

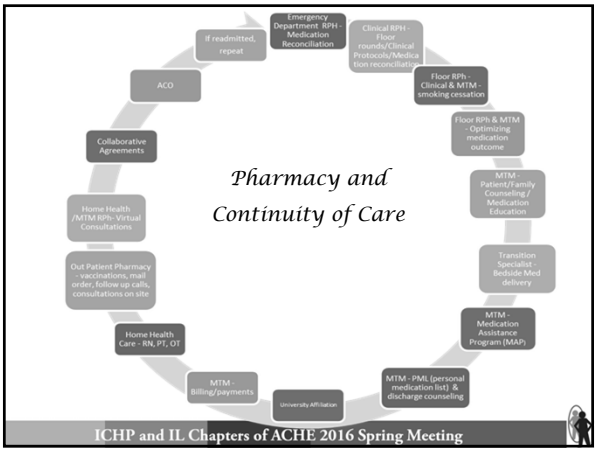
- Discuss steps to transition the pharmacist from “basement to the bedside”
- Focus on the role of MTM in a inpatient hospital setting
- How do we educate, empower and advocate for optimal medication outcomes?

Centegra Health System

McHenry

Huntley

Woodstock



Transition from "Basement to Bedside" Patient's Perspective

Current

- Development and implementation of clinical programs, ABX, anticoag., PCA, TPN dosing, Smoking cessation
- MTM program
- Pharmacists on the on the floors – clinical, rounding, med. rec., teaching, etc.
- Pharmacists in the ED
- Ownership of Medication Reconciliation
- Medication Assistance Program (MAP)
- Transition specialists – discharge medications at bedside
- MTM Virtual consults with home health

Transition from "Basement to Bedside"

In the Works

- Billing and Payments
- LTC consulting
- Collaborative agreements
- ACO

So what actually is inpatient MTM?

MTM services focus on identifying, preventing and solving medication related problems and to optimize medication outcomes – regardless of the setting.

Inpatient MTM: Pharmacist Responsibilities

- Medication reconciliation
- Comprehensive medication review
- Provision of patient-centered action plan
- Assessment of medication adherence
- Education and training
- Hospital discharge counseling
- Discharge medications at bedside
- Transitions of care (post-hospitalization)
- Continuum of care with chronic care services
- Monitor and evaluate response to care

How did we start the MTM program?

✓Proposal for an inpatient metabolic syndrome screening and an outpatient diabetic clinic.

✓CMS core measures changed the landscape, but not the patients

- ✓AMI, CHF, PNE

Identification of Patients

- OPI (Opportunities for Improvement) report
- MTM Pharmacist Referrals (careful what you ask for)
  - Smoking cessation
  - Heart failure
  - COPD
  - M in the Box
    1. > 10 meds (1 point)
    2. problem medication (1 point)
    3. multiple chronic conditions, which at least one is HF, DM or COPD (1 point)
    4. Cause of admission related to medication issue (2 points)
    5. Difficulty understanding medication(s) or condition (2 points)
       - "yes" to any 2 questions
       - "yes" to question #4 or #5

Identification of Patients

- Home Health
- Care Coordination
  - LACE tool
    - **L**ength of stay
    - **A**cute (emergent) admission
    - **C**omorbidity (Charlston comorbidity index score)
    - **E**mergency department visit in past 6 months

MTM Consults

CENTEGRA HOSPITAL - MCHENRY
Heart Failure Consult

HF Consult

[redacted] | DOB: [redacted] | Age: 69Y | Sex: Female

Room: VIR | Bed: 11
Order Status: New Order
Cancel reason:

Priority: | Frequency: ONCE | Order #: 17 | Visit #: [redacted] | MRN: [redacted]
Routine
Start Date/Time: 02/25/2016 19:18 | Ins: | HT: 68.0 | WT: 168.87 | SMKR: Current every day smoker

Admitting problem:CHEST PAIN, TIAS S, AFIB W/RVR | DX: | Transportation:
Ordering Phys.: STENSON, KERSTIN | Attending Phys.: STINSON, | Pt Type: INPATIENT

Instructions:

ALLERGIES: Adhesive Bandage
Tetanus
adhesive tape
bee venom (honey bee)
morphine

If 0 Allergies look to Patient Profile for a complete list of allergies

Clinical Alerts: -

Patient Encounters & Education

- **Medication literacy (keep it simple)**
- **AIDET**
  - **A**cknowledge
  - **I**ntroduce
  - **D**uration
  - **E**xplanation
  - **T**hank
- **PML (personal medication list)**
- **File of Life**
- **MAP (medication assistance program)**

PML (Personal Medication List)

CentegraHealthSystem

Medication Therapy Management

"To educate, empower and advocate for optimal medication outcomes"

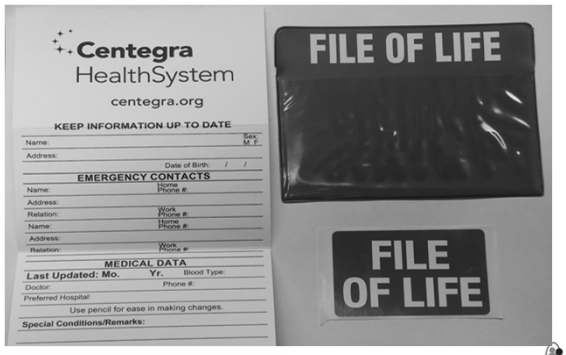
2/5/2016

Patient: xxxx	Vaccinations: ✓pneumonia ✓influenza ✓Tdap Zostrix
Allergy: Demerol – aggressive behavior; Dilaudid - Confusion	Healthcare Provider: Scott Drabant, RPh, FASCP 815-759-4421 815-759-4427 (fax) sdrabant@centegra.com

MEDICATION LIST

Medication generic (BRAND)	Why are you taking this medication	Common Side Effects	Special Instructions	Dose	Frequency (Times)
aspirin (BAYER ASPIRIN)	Heart headache pain prevention	•stomach ache	•Take with water •Take it with meals	81 mg	Morning
clopidogrel bisulfate (PLAVIX)	Prevent blood clots	•prolonged bleeding •rash •itching	•Take this medicine by mouth with a drink of water •May take this medicine with or without food	75 mg	evening
amlodipine besylate (NORVASC)	Heart Blood Pressure	•swelling of feet/ankles •dizziness •fast heart beat	•Take with water •Do NOT take with grapefruit	10 mg	Morning
hydralazine hydrochloride (APRESOLINE)	Heart / Blood Pressure (relaxes blood vessels)	•flushing •chills •dizziness	•Take with water •Take your medicine at regular intervals	100 mg	Morning, evening and at bedtime

File of Life



Team Approach

Physicians (cardiologist)
Nurses
Pharmacy Technicians
Discharge coordinators
Home Health intake coordinators
Transitional Specialists

Resources

- **APhA/ASCP: National Certification Training Program for Pharmacist**
- **The Pharmacist's Guide to Compensation for MTM Services**
- **Fundamentals of Geriatric Pharmacotherapy – An Evidence-Based Approach**
- **UCLA Intensive Couse in Geriatric Medicine**

Basement to Bedside: Expanding Patient Care Roles in Pharmacy Transitions of Care

Jessica DiGioia, CPht
Transitional Care Specialist
Centegra Health System
McHenry, Illinois

The speaker has no conflict of interest to declare.

Transitions of Care Centegra Care Connections

http://centegra.org/service/other-services/pharmacy-gift-shop/

Role of a Transition Specialist (TS)

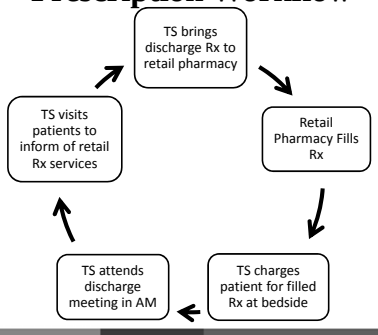
Review TS JDR: high level

- Certified Pharmacy Technician
- Critical thinking skills
- Great customer service
- Ability to interact with health care team
- Reliability
- Technical skills
- Communication skills

Resources

– Pharmacist
– Pharmacy Technicians
– Technical Requirements
– Leadership Support
– Care Coordination Interaction
– Physician Support
– Marketing

Transition Specialist and Prescription Workflow



Transition Specialist and Prescription Workflow

Additional Activities:

- Coordinate one-on-one education from MTM pharmacist
- Order and arrange for home medical equipment to be delivered prior to discharge
- Schedule follow-up appointments with Centegra health care providers

Basement to Bedside: Expanding Patient Care Roles in Pharmacy Patient-Centered Medical Home

Megan Fleischman, PharmD, BCACP
Clinical Assistant Professor
Patient Centered Medical Home Committee Chair
University of Illinois at Rockford
Practice Site: L.P. Johnson Family Health Center; PCMH Level 3 Recognition

Conflict of Interest

I have no actual or potential conflict of interest in relation to this activity.

Patient Centered Medical Home

- National Committee for Quality Assurance (NCQA) awards accreditation
- "The patient-centered medical home is a way of **organizing primary care** that emphasizes **care coordination** and **communication** to transform primary care into "**what patients want** it to be." Medical homes can lead to **higher quality** and **lower costs**, and can **improve patients' and providers' experience** of care."
- "Patients in medical homes receive the right care, in the right amount, at the right time. "

PPC-PCMH Content and Scoring

Standard 1: Access and Communication	Pts
A. Has written standards for patient access and patient communication**	**4**
B. Uses data to show it meets its standards for patient access and communication**	**5**
	9

Standard 2: Patient Tracking and Registry Functions	Pts
A. Uses data system for basic patient information (mostly non-clinical data)	2
B. Has clinical data system with clinical data in searchable data fields	3
C. Uses the clinical data system	3
D. Uses paper or electronic-based charting tools to organize clinical information**	**6**
E. Uses data to identify important diagnoses and conditions in practice**	**4**
F. Generates lists of patients and reminds patients and clinicians of services needed (population management)	3
	21

Standard 3: Care Management	Pts
A. Adopts and implements evidence-based guidelines for three conditions **	**3**
B. Generates reminders about preventive services for clinicians	4
C. Uses non-physician staff to manage patient care	3
D. Conducts care management, including care plans, assessing progress, addressing barriers	5
E. Coordinates care/follow-up for patients who receive care in inpatient and outpatient facilities	5
	20

Standard 4: Patient Self-Management Support	Pts
A. Assesses language preference and other communication barriers	2
B. Actively supports patient self-management**	**4**
	6

Standard 5: Electronic Prescribing	Pts
A. Uses electronic system to write prescriptions	3
B. Has electronic prescription writer with safety checks	3
C. Has electronic prescription writer with cost checks	2
	8

Standard 6: Test Tracking	Pts
A. Tracks tests and identifies abnormal results systematically**	**7**
B. Uses electronic systems to order and retrieve tests and flag duplicate tests	6
	13

Standard 7: Referral Tracking	PT
A. Tracks referrals using paper-based or electronic system**	**4**
	4

Standard 8: Performance Reporting and Improvement	Pts
A. Measures clinical and/or service performance by physician or across the practice**	**3**
B. Survey of patients' care experience	3
C. Reports performance across the practice or by physician **	**3**
D. Sets goals and takes action to improve performance	3
E. Produces reports using standardized measures	2
F. Transmits reports with standardized measures electronically to external entities	1
	15

Standard 9: Advanced Electronic Communications	Pts
A. Availability of Interactive Website	1
B. Electronic Patient Identification	2
C. Electronic Care Management Support	1
	4

**Must Pass Elements

NCQA Measuring quality

1

http://www.ncqa.org/Programs/Recognition/Practices/PatientCenteredMedicalHomePCMH/PCMH2014ContentandScoringSummary.aspx

PCMH Recognition

- Recognition is offered at three levels:
  - Level 1 – basic (25-49 points)
  - Level 2 – intermediate (50-74 points)
  - Level 3 – advanced (75-100 points)

Previsit Audit

- Patient: _____ Date of Birth: ____ PCP: ____
- *Date of last diabetic visit: ___ Number of visits within the last year: _____
- *Date of last visit: _____* Reason for visit: _____
- B/P: _____
- Last hospitalization: _____ Diagnosis: _____
- *DM1: _____ *DM 2: _____
- *Last A1c/Result: ___ *LDL/Result: ___ CMP/BMP: ___
- SCR_____ *Urine microalbumin/ Result: _____
- Does patient do blood sugar monitoring: No: __ Yes: __, frequency_____

Previsit Audit

- *Last noted evidence of diabetic education: ___
- Referrals: Ophthalmology ____Podiatry:___Other____
- *Last in-office foot exam with monofilament: _____
- *Problems with obtaining or taking medications: No: ____ Yes: ____, specify _____
- *Barriers to care: _____
- * Barriers to learning: _____
- If smoker, evidence of smoking cessation education/ date: _____ Non smoker_____
- Immunizations: Flu:_ Pneumonia:_ Zostavax:_ TDAP:_
- Co-morbidities: _____

Previsit Audit

- Screening tests up to date (If needed): Pap smear: _____ Mammogram: _____
- Colonoscopy: _____ Prostate exam: _____ Dexa scan_____
- AAA screen(if smoking HX male.65) _____
- Next office visit needed: _____ Appointment scheduled: _____

Care Plan

UNIVERSITY OF ILLINOIS COLLEGE OF MEDICINE AT ROCKFORD | MY PLAN TO MANAGE DIABETES

1. Choose one or more:
2. I made this plan to: (choose one or more)
   - ☐ Lower my blood sugars to goal
     a. Fasting 80-____ mg/dL
     b. After meals <____ mg/dL
   - ☐ Lower my hemoglobin A1c to < ___%
   - ☐ Lose weight
   - ☐ Decrease low blood sugar reactions
   - ☐ Lower my risk of complications like _____
   - ☐ Another goal I want to reach: _____

Care Plan

3. I will do this by:

What:	How much:	When:
(e.g. walking	*for 30 minutes*	*5 days per week)*

4. This change is?
   1 ..... 5 10
   Not important | Somewhat important | Very important

5. How likely are you to to do the above things prior to your next appointment?
   1 ..... 5 10
   Not very likely | Somewhat sure | Very likely

PATIENT'S SIGNATURE _____ CLINICIAN'S SIGNATURE _____

Current Roles for Pharmacists in the PCMH

Collaborative Drug Therapy Management (CDTM)	• Disease management via protocol where physician allows RPh to monitor and modify pharmacotherapy and offer lifestyle counseling
Comprehensive Medication Management	• Medication therapy management (MTM): CMR, PMR, MAP
Preventative care	• Immunizations • Medicare wellness visits

Berdine, et al. *Ann Pharmacother* 2012;46:723-50.

Current Roles for Pharmacists in the PCMH

Medication Reconciliation	• High risk patients and those in transitional states of care • Communicate findings to all practitioners involved in care
Monitor population registries for potential intervention	• Assist the medical team in qualifying for financial incentives by meeting and exceeding performance measures
Assist with accreditation of the practice as a PCMH	• Potential administrative role

Berdine, et al. *Ann Pharmacother* 2012;46:723-50.

Current Roles for Pharmacy Technicians in PCMH

Assist pharmacist in serving patients	• Collect and communicate patient-specific data • Perform technical aspects of dispensing • Direct patient questions to appropriate health team member
Maintain medication and inventory control systems	• Maintain appropriate supply of medication and medical equipment • Perform inventory and remove overstock/expired/discontinued medications
Participate in administration / management of pharmacy practice	• Coordinate communication throughout practice setting • Communicate with third-party payers • Use and maintain patient information, point-of-care technology, and dispensing technology

The Council on Credentialing in Pharmacy. Washington, DC, February 2009. Available at: http://www.PharmacyCredentialing.org/Contemporary_Pharmacy_Practice.pdf

Comprehensive Medication Management in a PCMH

- Standard of Care
- Does not need to be a pharmacist
  - Qualification to review: "Health professionals that possess this knowledge, an understanding of the **comprehensive taxonomy of drug therapy problems**, and the ability to apply the **rational and systematic decision-making process** for drug therapy are capable of providing medication management"
- Referrals to pharmacist services can be similar to specialist referrals
  - Internal or external

PCPCC Medication Management Task Force. Resource Guide. June 2012. Available at: http://www.pcpcc.net/files/medmanagement.pdf

Comprehensive Medication Management in a PCMH

Process	Documentation
Assess patient's medication related needs	Describe patient's medication experience (Beliefs and approaches) List medications *with* indications, allergies, immunizations
Identify patient's medication related problems	List problems to be addressed
Develop individualize care plan	Document Measureable outcomes (personalized) Interventions (personalized)
Follow-up evaluation to determine *actual* outcomes	Follow-up plan

Continue evaluation until outcomes achieved

PCPCC Medication Management Task Force. Resource Guide. June 2012. Available at: http://www.pcpcc.net/files/medmanagement.pdf

Comprehensive Medication Management in a PCMH

- One approach
  - Maximize number of patients seen by pharmacist
    - Encourage working at top of their license
  - Similar referral triggers to MTM
    - Target patients with need for higher levels of medication intervention
  - Increased need for pharmacy technicians?
- All patients can benefit from pharmacist review and intervention

PCPCC Medication Management Task Force. Resource Guide. June 2012. Available at: http://www.pcpcc.net/files/medmanagement.pdf

Payment Options in Illinois

- Medication Therapy Management
- CMS annual wellness visits
- 'Incident to' requirements
  - Clinic billing has 5 levels of E/M codes
    - Bill under 99211 only
  - Institution billing is under a "Facility fee"
    - APC codes cover hospital outpatient services
  - Chronic Care Management (CCM)
  - Transitions-of-Care Management (TCM)

Relaxed supervision requirement

Resources

- PCMH
  - NCQA has information on accreditation
  - Patient Centered Primary Care Collaborative
- Billing information
  - Fiscal intermediary for CMS billing: www.NGSmedicare.com
  - CMS (https://www.cms.gov) and Medicare Learning Network
  - Individual commercial plans for their rules and reimbursement

Audience Activity

- Think about a service you would like to implement at your practice site
  - Expanding a current service
  - Offering a new service
- Take a minute to write down your barrier(s) to implementing this service

Questions for Panel

When implementing new patient care services, what real or potential barriers exist?

Questions for Panel

What strategies do you use to optimize medication therapy and patient adherence?

Audience Questions

?

	Poster Session I, Friday, April 8, 2016 5:30-6:30pm, Fon Du Lac DEF	**ACPE UAN: 0121-0000-16-043-L04- P 0121-0000-16-043-L04-T**	**as of March 25, 2016**
Poster #	**Titles**	**Poster Presenter(s)**	**Poster Category**
1	The role of tenofovir in preexposure prophylaxis of herpes simplex virus type 2: a systematic review	Julia Silver, PA-S2, Master of Medical Sciences Candidate Michael Fotis, RPh, BSPharm	**Original - Research Complete**
2	Analysis of Risk Factors and Antipsychotic Usage Patterns Associated with Terminal Delirium in a Veteran Inpatient Hospice Population	Emily Ellsworth, PharmD	**Original - Research in Progress**
3	Efficacy, nephrotoxicity, and incidence of Clostridium difficile infection with broad spectrum antibiotic regimens in patients with nosocomial pneumonia	Kaitlyn B. Kalata, PharmD	**Original - Research in Progress**
4	Evaluation of a Protocol used to Screen and Control Glycemic Levels Following Total Orthopedic Knee and Hip Surgeries.	Patrick Hammond, PharmD	**Original - Research in Progress**
5	Evaluation of a Pilot Benzodiazepine Taper Clinic in Veterans with Concurrent Opioid Use	Julie Bucek Cabrera, PharmD, PGY1	**Original - Research in Progress**
6	Impact of pharmacists within a multidisciplinary team on chronic obstructive pulmonary disease (COPD) readmission rates	Leigh A. Moffett, PharmD, BCPS	**Original - Research in Progress**
7	A Performance Improvement Approach to Implementing a Pharmacist-led Medication Education Program in a Community Hospital	Stacy Thomas Scaria, PharmD Dusica Szczybura, PharmD	**Original - Research in Progress**

	Poster Session I, Friday, April 8, 2016 5:30-6:30pm, Fon Du Lac DEF	ACPE UAN: 0121-0000-16-043-L04- P 0121-0000-16-043-L04-T	as of March 25, 2016
8	Redesigning PGY1 Pharmacy Residency Interview Structure	Hailey P. Soni, PharmD	**Original - Research in Progress**
9	Global Initiatives to Streamline Pharmacy Education and Workforce Development	Abby A. Kahaleh, BPharm, MS, PhD, MPH	**Encore**
10	Comparison of Pharmacist and Physician Attitudes and Knowledge of Pain Management	Lauren Pestka, PharmD Candidate	**Student - Research in Progress**
11	Phytopharmacological evaluation of chamomile (Matricaria recutita L.) for indirect modulation of the endocannabinoid system	Kristine Manlimos, PharmD Candidate Nidhi Patel, PharmD Candidate	**Student - Research in Progress**
12	Retrospective analysis of osteoporosis risk factors among the Chinese population	Anna Aidonis, PharmD Candidate Hemangini Shah, PharmD Candidate	**Student - Research in Progress**

Poster #: 1 **Poster Session I, Friday, April 8, 2016**

Category: Original - Research Complete

Title: The role of tenofovir in preexposure prophylaxis of herpes simplex virus type 2: a systematic review

Abstract:

Purpose: Herpes simplex virus type 2 (HSV-2) is among the most common sexually transmitted infections, affecting approximately 417 million sexually active adults worldwide [1]. HSV-2 is the leading cause of genital ulcers, and is associated with pain, itching, negative social stigma and increased risk for HIV-1 [2]. Current preventative measures include barrier methods, abstinence, and chronic antiviral suppressive therapy for HSV-2 positive patients. There is not currently a vaccination or medication for preexposure prophylaxis (PrEP) for HSV-2. The purpose of this study is to assess the efficacy of the nucleotide reverse-transcriptase inhibitor, tenofovir, in the preexposure prophylaxis of HSV-2.

Methods: Data sources included PubMed, Cochrane Library and Embase between 1966-2015. Search terms included, " tenofovir prevention herpes virus". A total of 222 articles resulted. Inclusion criteria were set as randomized controlled trials with human participants conducted over the last 5 years, which yielded 2 studies. The main outcome measured is HSV-2 seroconversion.

Results: In one study, the incidence rate of HSV-2 was 10.2 cases per 100 person years with pericoital application of tenofovir gel, compared to incidence rate of HSV-2 of 21.0 cases per 100 person-years with placebo gel, NNP = 9.8 [3]. A second study resulted in an incidence rate of HSV-2 of 5.6 cases per 100 person years with oral tenofovir-based PrEP, compared to 7.7 cases per 100 person years with placebo, NNP = 37.1 [4].

Conclusion: Tenofovir-based therapy significantly reduced HSV-2 seroconversion in two double-blinded, randomized controlled trials. Periocoital tenofovir gel resulted in a 51% decrease in HSV-2 seroconversion, while oral tenofovir-based therapy resulted in a 30% decrease in HSV-2 seroconversion, suggesting that topical therapy is more effective in preventing HSV-2 seroconversion compared to oral therapy, although future studies comparing topical and oral tenofovir therapy for PrEP of HSV-2 are needed. Limitations of the studies are as follows: neither study was originally designed to assess the effect of tenofovir on HSV-2 acquisition thus randomization at study enrollment was not stratified by HSV-2 status; the studies do not use the same formulation of tenofovir and neither study assesses the timing of HSV-2 acquisition in relation to plasma tenofovir levels. This systematic review suggests that there is a potential role of tenofovir to prevent HSV-2 acquisition, which could reduce genital ulcers, pain, social stigma and HIV risk associated with HSV-2.

1. Looker, K.J., et al., Global and Regional Estimates of Prevalent and Incident Herpes Simplex Virus Type 1 Infections in 2012. PLoS One, 2015. 10(10): p. e0140765. 2. Tan, D., Potential role of tenofovir vaginal gel for reduction of risk of herpes simplex virus in females. Int J Womens Health, 2012. 4: p. 341-50. 3. Abdool Karim, S.S., et al., Tenofovir Gel for the Prevention of Herpes Simplex Virus Type 2 Infection. N Engl J Med, 2015. 373(6): p. 530-9. 4. Celum, C., et al., Daily oral tenofovir and emtricitabine-tenofovir preexposure prophylaxis reduces herpes simplex virus type 2 acquisition among heterosexual HIV-1-uninfected men and women: a subgroup analysis of a randomized trial. Ann Intern Med, 2014. 161(1): p. 11-9.

Submitting Author: Michael Fotis

Organization: Northwestern University Feinberg School of Medicine

Authors: Primary Author: Julia Silver PA-S2; Master of Medical Sciences Candidate; Northwestern University Feinberg School of Medicine

Poster #: 2 **Poster Session I, Friday, April 8, 2016**

Category: Original - Research in Progress

Title: Analysis of Risk Factors and Antipsychotic Usage Patterns Associated with Terminal Delirium in a Veteran Inpatient Hospice Population

Abstract:
Purpose: The purpose of this study is to (1) Identify risk factors for terminal delirium in a VA inpatient hospice population (2) Assess usage patterns of antipsychotics in terminal delirium (3) Describe nursing assessment, non-pharmacological and pharmacological interventions, and documentation of terminal delirium

Methods: This is a retrospective case-control study of patients who expired in the Edward Hines, Jr. VA Hospital Community Living Center (CLC) under the treating specialty "NH hospice" during the period of October 1, 2013 to September 30, 2015. Cases are defined as patients who were treated with antipsychotics for terminal delirium within the last two weeks of life. Controls are defined as patients who were not treated with antipsychotics for terminal delirium within the last two weeks of life. All patients enrolled under the treating specialty "NH Hospice" will be evaluated with the exclusion of living hospice patients and patients discharged to receive home hospice care prior to death. Patients' medical records will be reviewed from two weeks prior to death until the recorded death date during which the following will be assessed from the medical record as available: age, terminal diagnosis, time interval cancer diagnosis and death, war era, comorbid conditions, prescribed antipsychotic medications, other medications potentially contributing to delirium, documentation for antipsychotic use, non-pharmacological interventions, and date of death.

Results: Research in progress

Conclusions: Research in progress

Submitting Author: Emily Ellsworth

Organization: Edward Hines, Jr. VA Hospital

Authors: Emily Ellsworth, PharmD., Kevin Bacigalupo, PharmD., BCPS, Kavita Palla, PharmD., BCPS, Seema Limaye, M.D., Margaret Walkosz, ACHPN, GNP-BC, Sandra Szczecinski, BSN, Katie Suda, PharmD, M.S. All authors employed by Edward Hines, Jr. VA Hospital.

Poster #: 3 **Poster Session I, Friday, April 8, 2016**

Category: Original - Research in Progress

Title: Efficacy, nephrotoxicity, and incidence of Clostridium difficile infection with broad spectrum antibiotic regimens in patients with nosocomial pneumonia

Abstract:

PURPOSE: Vancomycin plus piperacillin-tazobactam is a broad-spectrum antibiotic regimen chosen as empiric therapy for a multitude of infections. Recent data suggests that this combination may increase the risk of nephrotoxicity when compared to vancomycin alone, or when compared to vancomycin plus an alternative beta-lactam antibiotic, such as cefepime. Recently, as a result of these studies and due to recommendations by pharmacy, prescribing at Edward Hines, Jr. VA Hospital has begun to shift from using vancomycin plus piperacillin-tazobactam to a regimen of vancomycin plus cefepime with or without metronidazole for anaerobic coverage. This regimen has been chosen for many infections, but most commonly for the nosocomial pneumonias: hospital-acquired pneumonia (HAP), healthcare-associated pneumonia (HCAP), and ventilator-associated pneumonia (VAP). This change in prescribing practices raises many important questions. First, in terms of aspiration pneumonia and VAP, what is the difference in efficacy between vancomycin plus piperacillin-tazobactam and vancomycin plus cefepime plus metronidazole? Additionally, in terms of nosocomial pneumonia without mention of aspiration, what is the difference in efficacy between vancomycin plus piperacillin-tazobactam and vancomycin plus cefepime? Finally, what is the difference in the rates of nephrotoxicity and Clostridium difficile infection associated with these regimens?

METHODS: This study is a retrospective, electronic chart review of patients with nosocomial pneumonia. Eligible patients for screening will be identified via a fileman search of patients using ICD codes and active orders of piperacillin-tazobactam plus vancomycin, cefepime plus vancomycin, or cefepime plus vancomycin plus metronidazole. Inclusion criteria for the study include male and female patients ≥ 18 years of age with a clinical diagnosis of nosocomial pneumonia, who had a baseline serum creatinine obtained within 24 hours of admission, and who received one of these broad-spectrum antibiotic regimens for at least 48 hours. Patients will be excluded if they are receiving chronic dialysis or have a diagnosis of end stage renal disease. The primary outcome being evaluated is clinical efficacy of antibiotic regimens, which is reflected as improvement in two of the following three clinical symptoms (fever, leukocytosis/leukopenia, purulent secretions) at 48 hours. A secondary endpoint will be the incidence of Clostridium difficile infection, which is reflected as a positive Clostridium difficile toxin B PCR test with diarrhea (three or more unformed stools passed in 24 hours) or histopathological findings of pseudomembranous colitis within 14 days of starting antibiotics. An additional secondary endpoint of acute kidney injury, defined as an increase in serum creatinine ≥50% from baseline, an increase in serum creatinine of ≥0.3 mg/dL, or a urine output <0.5mL/kg per hour for >6 hours, will also be evaluated. Data collection will include demographics (age, race), classification/etiology of pneumonia, temperature, WBC count, blood pressure, pulse rate, sputum production, use of broad-spectrum antibiotic regimens (dose, route, duration), number of days on oral or IV antibiotics in the 14 days prior, concomitant use of nephrotoxic drugs, clinical improvement (documented in progress notes) and documented adverse drug reaction or allergy to antibiotics.

RESULTS: Research in progress.

CONCLUSIONS: Research in progress.

Submitting Author: Kaitlyn Kalata

Organization: Edward Hines, Jr. VA Hospital

Authors: Kaitlyn B. Kalata, Pharm.D., Sue Kim, Pharm.D., BCPS, Ursula C. Patel, Pharm.D., BCPS, AQ-ID, Raymond Byrne, Pharm.D., BCPS. All authors are employees of Edward Hines, Jr. VA Hospital.

Poster #: 4 **Poster Session I, Friday, April 8, 2016**

Category: Original - Research in Progress

Title: Evaluation of a Protocol used to Screen and Control Glycemic Levels Following Total Orthopedic Knee and Hip Surgeries.

Abstract:
Purpose: Perioperative hyperglycemia can affect a patient's recovery following orthopedic surgery by increasing the risk of complications including infection and by increasing patient length of stay. Currently, our institution does not have a standardized glucose management protocol for this patient population. The objective of this study is to implement a protocol that can effectively manage patient's glucose levels post-operatively and decrease the rate of post-op infections in patients who have undergone a total orthopedic knee or hip surgery.

Methods: Patients undergoing elective orthopedic knee or hip surgery will first have Hemoglobin A1c labs drawn during preadmission testing. Patients with an A1c <8 will undergo surgery as planned while patient with an A1c >8 will be referred to their primary care physician to help manage their glucose levels. Their surgery will be postponed until the patient can provide documented glucose logs demonstrating glucose control and management over a 4 week period. Once patients undergo surgery their glucose level will be managed by a P&T approved protocol using a sliding scale or basal plus correction method of insulin administration. Both non-diabetic and diabetic patient's glucose will be managed by this protocol. This study will compare the management of patient glucose levels prior to and after the initiation of the protocol. The primary outcome of the study is the rate of post-operative infection. Secondary outcomes include the average glucose on post-operative days 0, 1, 2, and 3. Other outcomes include nursing satisfaction and number of patients who are found to have new onset diabetes.

Results: Research in Progress

Conclusions: Research in Progress

Submitting Author: Patrick Hammond

Organization: Presence St. Joseph Medical Center

Authors: Patrick D. Hammond, PharmD. Presence St. Joseph Medical Center, Joliet Rishita Shah, PharmD. Presence St. Joseph Medical Center

Poster #: 5 **Poster Session I, Friday, April 8, 2016**

Category: Original - Research in Progress

Title: Evaluation of a Pilot Benzodiazepine Taper Clinic in Veterans with Concurrent Opioid Use

Abstract:
Purpose: Opioid pain relievers are implicated in nearly 17,000 overdose deaths in the United States. This is over a 100% increase in rates over the first decade of this century. Thirty-one percent of these deaths involved the concurrent use of benzodiazepine sedatives. In late 2013, the Department of Veterans Affairs (VA) launched the Opioid Safety Initiative to reduce the use of opioids among veterans. While the initiative drew attention to clinical considerations regarding the risk of co-administration, a recent medication use evaluation concluded that over 700 Veterans had active outpatient prescriptions for both a benzodiazepine and an opioid at a single VA facility. As a result, a pilot benzodiazepine taper clinic will be implemented at Edward Hines, Jr. VA Hospital in January 2016 in collaboration with the Hines Primary Care and Mental Health Providers to reduce the number of veterans on high dose benzodiazepines and concurrent opioid therapy. An order set for the treatment of insomnia will also be created and integrated into the electronic medical record system in February 2016 at Edward Hines, Jr. VA Hospital to promote and facilitate the use of non-benzodiazepine evidence-based treatment of insomnia. The primary purpose of this quality assurance and quality improvement project is to evaluate potential benefits and barriers to implementing a multidisciplinary benzodiazepine taper clinic at Edward Hines, Jr. VA Hospital.

Methods: The project will assess the reduction in high dose benzodiazepines for the pilot clinic patients. The magnitude and time to dose reduction(s) will be evaluated. High dose benzodiazepines will be defined as total daily doses of temazepam >20 mg, diazepam >10 mg, clonazepam >1 mg, lorazepam >2 mg, and alprazolam >1 mg. Patients receiving opioids for cancer pain, patients receiving a benzodiazepine for back spasms in spinal cord patients, hospice patients, and patients with severe mental health disorders (i.e. bipolar disorder, psychosis) will be excluded. Time spent in preparation for clinic visits, patient contact hours, and time spent for follow up will be logged. Self-reported patient compliance with treatment plans and patient clinic cancellations will be recorded. Additionally, the project will track the use of the newly implemented order set for the treatment of insomnia.

Results: Research in Progress

Conclusion: Research in Progress

Submitting Author: Julie Cabrera

Organization: Edward Hines Jr., VA Hospital

Authors: 1. Julie Bucek Cabrera, Pharm.D., PGY1 Pharmacy Practice Resident, Edward Hines Jr., VA Hospital 2. Julie Stein, Pharm.D., VHA-CM, Associate Chief of Pharmacy Clinical & Education Programs, Director of PGY1 Pharmacy Residency, Edward Hines Jr., VA Hospital 3. Sue Kim, Pharm.D., BCPS, Clinical Pharmacy Specialist, Edward Hines Jr., VA Hospital

Poster #: 6 **Poster Session I, Friday, April 8, 2016**

Category: Original - Research in Progress

Title: Impact of pharmacists within a multidisciplinary team on chronic obstructive pulmonary disease (COPD) readmission rates

Abstract:
Purpose: In FY2015, the Centers for Medicare and Medicaid Services (CMS) expanded the existing algorithm accounting for readmission of patients to include those admitted for an acute exacerbation of chronic obstructive pulmonary disease (AECOPD). The Medicare Hospital Readmissions Reduction Program (HRRP) penalizes hospitals for excess early readmissions of patients with AECOPD. Currently, the penalty is in place for all-cause 30 day readmissions. The purpose of this study is to evaluate the impact of pharmacists within a multidisciplinary team on chronic obstructive pulmonary disease (COPD) readmission rates.

Methods: Patients were identified at admission to University of Chicago Medicine using an algorithm that identified documented COPD. On admission, a medication history was performed by a pharmacist or student pharmacist during which five COPD-focused questions were asked to each patient. The patients were then seen by the pulmonary advanced practice nurse (APN). After being seen by the APN, the pharmacy department provided inhaler education utilizing the teach-to-goal (TTG) method. Once the patient was discharged, a follow up appointment was scheduled within approximately seven to ten days with the pulmonary APN. During this follow up appointment, the pharmacy department provided further inhaler education using TTG. The primary endpoint of this study was COPD readmission in 30 days. The secondary endpoints were to show an increase in completed medication histories and an improvement in patients' inhaler techniques using the TTG method. COPD readmission rates were determined by reporting from the hospital's quality department. Improvement in patients' inhaler techniques was evaluated through a systematic scoring system which allowed for the comparison of initial and final inpatient technique scores.

Results: Research in progress. Preliminary data collection comparing scores before TTG session and after TTG session in the inpatient setting shows the average increase in TTG score was 4.9 points for the MDI inhaler (percentage change 20.3%). For the tiotropium inhaler, the average increase in the TTG score was 6 (percentage change of 20%).

Conclusions: Research in progress.

Submitting Author: Leigh Moffett

Organization: University of Chicago Medicine

Authors: Leigh A Moffett, PharmD, BCPS, University of Chicago Medicine, PGY2 Internal Medicine Pharmacy Resident Jennifer Szwak, PharmD, BCPS, University of Chicago Medicine, Clinical Pharmacist Specialist, Internal Medicine, PGY2 Internal Medicine Residency Program Director

Poster #: 7 **Poster Session I, Friday, April 8, 2016**

Category: Original - Research in Progress

Title: A Performance Improvement Approach to Implementing a Pharmacist-led Medication Education Program in a Community Hospital

Abstract:

Purpose: The Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey is a standardized questionnaire that has become an important indicator of the patient's view of perceived care. The study site was underperforming in the medication-related survey questions: "How often did hospital staff tell you what the medication was for?" and "How often did hospital staff describe possible side effects in a way you could understand?". The Pharmacy Department wanted to implement an intervention to improve patient satisfaction in this domain. The purpose of the study was to determine the impact of a pharmacist-led medication education program on the medication-related HCAHPS scores.

Methods: The study was conducted at a small community hospital from July to December 2015. All pharmacists and student pharmacists received competency and training to ensure uniformity in the medication education sessions. Patients from two medical-surgical units were targeted to receive medication counseling by a pharmacist or student pharmacist with priority given to those with heart failure, on an oral anticoagulant or receiving 6 or more medications. Nursing home patients and patients with altered mental status were excluded from receiving the intervention. At the end of the month, data was reviewed and changes were made to the process to improve to the target goal of five counseling sessions per day. The primary outcome was change from baseline on medication-related HCAHPS scores. A secondary outcome was number of documented counseling sessions performed, tracked on a daily basis on a department quality improvement board and trended monthly.

Results: The 2015 HCAHPS results regarding the question about explaining medication indications improved by 8% and the scores regarding the question about side effects improved by 36% when comparing the pre and post implementation of the medication education service. 392 patients were counseled as part of the pharmacist-led medication education program with an average of 65 sessions performed per month.

Conclusion: As shown in the study, pharmacist medication counseling can make an impact on the medication-related HCAHPS scores. Medication education is an important aspect of patient communication in the inpatient setting and the launching of this service enhanced patient understanding of the indications and side effects of their medications as measured by these scores.

Submitting Author: Stacy Scaria

Organization: Tenet Healthcare - Westlake Hospital

Authors: Stacy Thomas Scaria, PharmD Clinical Pharmacist Tenet Healthcare - Westlake Hospital Deanna McMahon Horner, PharmD, BCPS Clinical Pharmacy Manager Chicago Market, Tenet Healthcare - MacNeal, Weiss, West Suburban, Westlake Dusica Jovic Szczybura, PharmD Clinical Pharmacist Tenet Healthcare - Westlake Hospital Amita Healthcare - St. Alexius Medical Center Charlene Hope, PharmD,

MS, BCPS Quality and Safety Pharmacy Manager Chicago Market, Tenet Healthcare - MacNeal, Weiss, West Suburban, Westlake

Poster #: 8 **Poster Session I, Friday, April 8, 2016**

Category: Original - Research in Progress

Title: Redesigning PGY1 Pharmacy Residency Interview Structure

Abstract:
Purpose: The structure of our PGY1 residency interview day was redesigned to increase objectivity in candidate evaluations and exposure of candidates to the activities in our department while decreasing the preceptor time commitment.

Methods: In 2015 the PGY1 recruitment team incorporated multiple mini interviews (MMI), interdisciplinary rounds and a departmental activity in the interview days for PGY1 residency candidates for the 2015 recruitment season. Each multiple mini interview assessed specific qualities deemed to be essential in pharmacy residency training and utilized standardized evaluation tools. In 2016, the interview day was again restructured to adjust the time candidates spend rounding, eliminated one of the MMIs and implemented a one-on-one discussion session with the candidates and a current resident. Following the interviews, candidates were sent an electronic survey to evaluate their satisfaction with the interview day and the new structure. Descriptive statistics were used to describe the survey results from 2015 and survey results from 2016 are pending. Preceptor time for interview days in 2015 and 2016 will be compared with the amount of time required of preceptors in previous years.

Results: In 2015 a total of 72 candidates were interviewed and 49 completed the post-interview survey. The activities that left the highest positive impression during the interview day were the introduction section, departmental activity and traditional interview sessions. The majority of candidates (84%) stated that the interview day increased their desire to pursue residency training at University of Chicago and felt that time was adequately appropriated between activities. Preceptor time for candidate interviews decreased by 72% (600 hours vs 168 hours) and from 7.1 hours per candidate to 2.3 hours per candidate. With the new structure, the number of candidates per day was increased allowing us to decrease the number of interview days by 36%. Results from 2016 are in progress.

Conclusion: The restructuring of the interview day in 2015 provided resident a positive impression of our residency program while requiring fewer preceptor hours dedicated to interviewing. These results will be compared and new conclusions drawn off of the research conducted on the 2016 interview cycle.

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Organization: University of Chicago

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Poster #: 9 **Poster Session I, Friday, April 8, 2016**

Category: Encore

Title: Global Initiatives to Streamline Pharmacy Education and Workforce Development

Abstract:
Purpose: To evaluate trends and developments in pharmacy education that impact and influence national and global design and delivery - To examine national and global initiatives and resources that both drive and support curricular changes and international collaborations

Methods: The educational experts describe national and global initiatives to best streamline Competencies for pharmacy education. Specifically, the experts highlight programs for pharmacy education and workforce development that have been successfully implemented and assessed to assure the quality of pharmacy education on the global level.

Results: Descrptions of the following six frameworks and initiatives will be presented. Here is a list of national and global resources: 1. The Global Competency Framework; 2. FIPEd Strategic Plan; 3. WHO-UNESCO-FIP Education Initiative Development Team; 4. ACPE"s International Certification Quality Criteria "Standards"; 5. Pillars and Foundation of Educational Quality; and 6. Global Competency Framework.

Conclusions: Several national and global initiatives have used the FIP and. ACPE resources were successful in advancing pharmacy education and assuring its quality. Future initiatives will further streamline global

Submitting Author: Abby Kahaleh

Organization: Roosevelt University College of Pharmacy

Authors: 1. Abby A Kahaleh, BPhrm, MS, PhD, MPH-RUCOP 2. Mike Rouse, BPharm (Hons)-ACPE 3. Ian Bates, PhD-FIP 4. Andreia Bruno, PhD

Poster #: 10 **Poster Session I, Friday, April 8, 2016**

Category: Student - Research in Progress

Title: Comparison of Pharmacist and Physician Attitudes and Knowledge of Pain Management

Abstract:
Purpose: The purpose of this research is to further explore pharmacists' attitudes and knowledge of pain management and education, then compare and contrast it to the following study: Primary Care Physicians' Knowledge And Attitudes Regarding Prescription Opioid Abuse and Diversion (Hwang et al., 2015). We are therefore conducting this survey through pharmaceutical organizations targeting licensed pharmacists. The data collected can then be compared and contrasted to a recently published study that targeted primary care physicians on the issue of prescription opioid diversion. By comparing and contrasting these two studies together, we will be able to assess the current viewpoint spectrum regarding pain management from various health care professions and recommend new implementations into the education of pain management to construct consistency in the continuity of care throughout the health care system. Furthermore, it is wise to note that the focus of this study is not on prescription drug abuse, but on how to properly manage pain through education and alternative therapies such as mindfulness. Mindfulness is a particular alternative therapy that originates from the Buddhist practice and was further developed in the 1970's by psychologists. Mindfulness can be described as "paying attention in a particular way; on purpose, in the present moment, and nonjudgementally." As this definition implies, mindfulness involves attention and awareness to the present moment in an intentional manner and in an objective manner that attempts to remove judgment from one's initial response to experiences. The idea is that a mindful person will be able to assess his or her situation in a reasonable manner that will allow him or her to make the best decision to attain a desirable outcome. Dispositional mindfulness describes the innate characteristic to be mindful. In this study, mindfulness can used as an educational tool by the prescribing physician or distributing pharmacist to enable the patient to make conscience therapeutic decisions. Through this education, it may enhance medication efficiency by reducing a growing development tolerance to pain medications.

Methods: This is a cross-sectional study where all participants will be given a questionnaire consisting of questions utilizing a 4-point likert scale. A likert scale uses a fixed choice response format and is designed to measure attitudes or opinions. The survey will be administered through SurveyMonkey sent by listservs of pharmaceutical organizations that will target pharmacist in the current practice of pharmacy. The data will then be taken and be analyzed for statistical significance and compared to other healthcare providers knowledge and attitudes toward pain management.

Results: Research in Progress

Conclusions: Research in Progress

Submitting Author: Lauren Pestka

Organization: Chicago State University College of Pharmacy

Authors: Rebecca M. Castner, PharmD, is a Clinical Assistant Professor of Pharmacy Practice at Chicago State University College of Pharmacy (CSU-COP) Diana Isaacs, Pharm.D., BCADM, BCPS, is a Clinical Assistant Professor of Pharmacy Practice at Chicago State University College of Pharmacy (CSU-COP)

Lauren H Pestka, Associates of Science, is a 4th year pharmacy student at Chicago State University College of Pharmacy

Poster #: 11 **Poster Session I, Friday, April 8, 2016**

Category: Student - Research in Progress

Title: Phytopharmacological evaluation of chamomile (Matricaria recutita L.) for indirect modulation of the endocannabinoid system

Abstract:
Purpose: German chamomile (Matricaria recutita L.) has been known to be a useful antidepressant and anxiolytic in humans. Clinical trials demonstrate the role of the endocannabinoid system in modulating emotional homeostasis. The objective of our research was to identify compounds in chamomile that indirectly modulate the endocannabinoid system through inhibition of the endocannabinoid catabolizing enzymes, fatty acid amide hydrolase (FAAH) and monoacylglycerol lipase (MAGL). The identification of compound(s) interacting with the endocannabinoid system will provide lead compounds with therapeutic potential against various mood disorders.

Methods: A bioassay-guided fractionation approach was adopted. Whereas chamomile powder was initially extracted with methanol followed by fractionation with hexane, chloroform, ethyl acetate, and methanol. All fractions were fingerprinted using high performance liquid chromatography. The fractions were evaluated for FAAH inhibition using an in vitro microplate assay. In the initial screening, the hexane showed the highest activity. The fraction was further subjected to bioassay-guided chromatography until a pure active compound was isolated and identified. All fractions were also evaluated for inhibition of the MAGL enzyme.

Results: Research in progress. Throughout our experiments, we were able to identify one active compound, linoleic acid. Our current and future research aim at identifying the remainder of compounds and their evaluation in animal models.

Conclusions: Though our research is still in progress, our experiments demonstrate a procedure that can be replicated for any other herbs of interest. We are still in an early phase of our chamomile project, and many active compounds are yet to be isolated and identified. However, we were able to reliably demonstrate FAAH and MAGL inhibition activity, which show that chamomile has a role in modulating the endocannabinoid system and supports its use as an herbal dietary supplement for depression and anxiety.

Submitting Author: Kristine Manlimos

Organization: Chicago State University College of Pharmacy

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Poster #: 12 **Poster Session I, Friday, April 8, 2016**

Category: Student - Research in Progress

Title: Retrospective analysis of osteoporosis risk factors among the Chinese population

Abstract:
Purpose: Assess effects of weight, cigarette smoking, and alcohol intake, on bone mineral density, measured as T-score, among the Chinese population in Chicago's Chinatown neighborhood. -Determine if length of stay in the US has any impact on BMD.

Methods: A retrospective analysis will be conducted using data collected at Midwest Asian Health Association (MAHA) in Chicago's Chinatown neighborhood from August 2013 to August 2015. Data from 200 participants will be reviewed. MAHA, located in Chicago, is a community-based, non-profit 501 (c)(3) organization that provides community outreach education, screenings, immunizations and linkage to care in collaboration with community-based organizations, health care providers and academic institutions to reduce health disparities for the Asian population. The majority of the health fair attendees lack or have limited health insurance. For the last two years, pharmacy school students from Chicago State University College of Pharmacy have partnered with MAHA to offer free bone mineral density screening during MAHA's monthly health fair. During these events, MAHA collected demographic information of each participant as part of their record keeping in order to properly assess the participants' risk of osteoporosis. These demographic information include age, sex, height weight, social and family history. Bone health-bone density screenings were offered to men and women aged 20 years and older using the Lunar AchilllesTMQuantitative Ultrasound System provided by the College of Pharmacy at Chicago State University. All participants signed a consent form to be part of the health screenings. Descriptive analysis will be used to report demographic and fracture risk factors. A correlation analysis will be used to describe the relationship between length of stay in the US, weight, smoking status, and alcohol consumption and BMD.

Results: Research in Progress

Conclusion: Research in Progress

Submitting Author: Anna Aidonis

Organization: Chicago State University College of Pharmacy

Authors: Cindy Leslie A. Roberson, Pharm.D., BCACP. Employment: Access at Holy Cross Health Center and Clinical Assistant Professor at Chicago State University. Anna Aidonis, Pharm.D. 2016 Candidate. Employment: Walgreens Pharmacy Hemangini Shah, Pharm.D. 2016 Candidate

2015 Regulatory Year in Review: Planning for 2016

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- Accreditation and regulatory are the foundation for patient safety and performance excellence, but some are more problematic than others.
- Today, we'll review accreditation/regulatory changes and challenges from 2015 and look at what's ahead in 2016.

Faculty

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Disclosure Information

- Jodi Eisenberg has no relevant financial or nonfinancial relationships to disclose.

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Objectives

1. Articulate new standards, revisions to existing standards and survey process and problematic standards outlined in the 2015 Regulatory Year in Review
2. Describe a recommended strategy for assessing or successfully mitigating 2015 problematic standards
3. Describe how addressing the problematic standard using a recommended strategy positions organizations for effective and reliable delivery of safe, high-quality patient care

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CMS Update

Important Note: The foundation of every voluntary accrediting organization's standards are the CMS Conditions of Participation.

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CMS Problematic Topics

Based on CMS Data through 2015 Quarter 4

- Medication Administration
- EMTALA, Emergency Department Log, Emergency Services
- Content, Form and Retention of Record
- Contracted Services
- Data Collection and Analysis (QAPI)
- Facilities, Supplies, Equipment Maintenance
- Governing Body
- Infection Control
- Life Safety/Maintenance of Physical Plant
- Medical Staff Structure, Organization, Management

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Regulatory Visits Future State

CMS

- General certification
- Complaint visits
- Focused visits: Infection Control, Discharge Planning, QAPI, Emergency Preparedness, EMTALA

Medicare Survey and Certification

(Dollars in Thousands)

	FY 2014 Final	FY 2015 Enacted	FY 2016 President's Request	FY 2016 +/- FY 2015
BA	$375,330,000	$397,334,000	$437,200,000	+$39,866,000

https://www.cms.gov/About-CMS/Agency-Information/PerformanceBudget/Downloads/FY2016-CJ-Final.pdf

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CMS News for 2015

- **Infection Control, Discharge Planning, Quality Assessment and Performance Improvement (QAPI) *CMS Survey & Certification Memo 15-12 published 11/26/14***

QAPI

- Activities & Projects
- PI focus on high risk areas
- Selection process for indicators, initiatives
- Proportional to scope and complexity of services and operations
- Governing body, Medical Staff, Senior Administrators involvement in QAPI

Infection Control/Prevention

- Resources
  - –Infection Control Officer
  - –Policies and procedures
- QAPI systems related to Infection Prevention and Control
- Infection Control training
- Competency assessment
- Supervision

Discharge Planning

- Policies and procedures
  - –Evidence of discharge planning activities
- Reassessment and QAPI
  - –Review process and track readmissions
  - –Tracer
    - Chart reviews of how discharge planning occurred

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CMS News for 2015

- *Revised guidance related to new and revised regulations for hospitals, ambulatory surgical centers, rural health clinics and federally qualified health centers CMS Survey & Certification Memo 15-22 published 1/30/15*
  - *Dietician/qualified nutrition professional may order with MD authorization*
  - *Ordering of outpatient services by non-medical staff members*
  - Accrediting organization (AO) seeking CMS approval of its hospital accreditation program must demonstrate that it has standards for utilization review and that its standards meet or exceed the Medicare standards.

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CMS News for 2015

- CRE Alert Survey & Certification Letter 15-32
  - Reports of bacterial infections caused by CRE in patients who underwent scope procedures.
  - Safety Communications from FDA, CMS, TJC, CDC and others
  - Meticulously follow the manufacturer's instructions for reprocessing duodenoscopes
  - Adhere to nationally recognized multi-society consensus guidelines
- ***FDA** Safety Communication related to Duodenoscope Processing published 2-2015 updated 3-4-2015*
- ***CDC** guideline – CRE contamination on duodenoscopes or any other scopes with an elevator mechanism – updated August 2015*
- ***TJC** Quick Safety Issue 11 published March 2015*

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CMS revised guidelines for pharmaceutical services

- Survey and certification letter 16-01 Hospital, October 30, 2015
- Standards of practice for safe sterile compounding based on USP 797
- Guidelines for immediate-use CSPs (compounded sterile preparations – this includes solutions used in the OR)
- Guidelines for determining the beyond-use date for CSPs
- The pharmacy director must have documented training or expertise in hospital pharmacy practice and management.
- If the hospital has a drug storage area instead of a pharmacy, only pre-packaged medications that require no further preparation at the point of care are used.
- If using an outside compounding facility must qualify with FDA's Current Good Manufacturing Practice
- Non-compliance could be scored at the CLD level.

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CMS Discharge Planning Proposed Rule Change

- Develop a discharge plan within 24 hours of admission or registration
- Complete a discharge plan before the patient is discharged or transferred
- Applies to all inpatients and certain outpatients including those receiving moderate sedation or anesthesia
- Discharge instructions provided to all patients discharged home
- Medication reconciliation required
- Transferred patients – facility receives medical information
- Hospitals and critical access hospitals establish a post-discharge follow-up process

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TJC Updates

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Decreasing the number of Standards and Elements of Performance Review and Evaluation

- Goal is to streamline the standards and elements of performance
- Elements of performance are being evaluated for:
  - Relevance to quality and safety
  - Duplication
  - Addressed through other laws and regulations
  - Relate to processes that should be based on organizational discretion
- No CMS CoPs will be impacted.
- Slated for implementation July 2016

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TJC Sentinel Event Alerts and Safety Tips

Important Note: While these SE Alerts are published by TJC, they have application to all providers regardless of accreditor.

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Most Frequently Reported Sentinel Events

- Wrong patient, site, or procedure
- Unintended retention of foreign objects
- Suicide
- Falls
- Delay in treatment
- Operative/postoperative complication
- Other unanticipated events
- Perinatal death/injury
- Medication error
- Fire-related events

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Sentinel Event Alert 54: Safe Use of Health Information Technology

- Potential contributing factors leading to health IT sentinel events
  - Human – computer interface (33%)
  - Workflow and communication (24%)
  - Clinical content (23%) – design or data issues
  - Internal organizational policies, procedures, and culture (6%)
  - People (6%) – training; failure to follow established processes
  - Hardware and software design issues (6%)
  - External factors (1%)
  - System measurement and monitoring (1%)

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of Health Information Technology

- Improvement strategies:
  - Culture of safety, high reliability, and effective change management
  - Process improvement:
- Routinely review downtime and reactivation policies
- Utilize proven methodologies such as FMEA, to proactively identify risks in the system
- Limit the number of patient records that can be displayed at the same time on the same screen
- Assure all screens and printouts include patient identification information
- Provide patient access to their electronic records for information as well as accuracy
- Ongoing safety assessments to assure safe performance

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Sentinel Event Alert 54: Safe Use of Health Information Technology

- Leadership
  - Evaluate workflow processes prior to implementing technology solutions
  - Involve users in the system planning
  - Choose system interfaces that easily align
  - Improve the ability of systems to reliably and accurately exchange data
  - Monitor effectiveness based on metrics
- Issues
  - Boxes checked by mistake
  - Boxes checked in advance of an activity that later does not occur
  - Automated time stamp does not reflect time of the activity
  - Automated communication links do not occur
  - Copying and pasting errors

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Cybersecurity

Three defensive strategies to protect health information:

- Mitigate threats before they enter your network
- Discover threats that have entered or attempted to enter your system
- Respond to threats that have breached your network

New risk area: Ransomware

- Type of harmful program or malware that allows the attacker to take control of a personal medical device such as a pacemaker, or infusion pump
  - FDA issued recommendations in 2014 to device manufacturers on cybersecurity issues during product development including malware, security patches, and software updates

California hospital paid $17,000 ransom in bitcoins to hackers

By Tribune news services · Contact Reporter

FEBRUARY 17, 2016, 10:51 PM

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Quick Safety Tips: Transcription-related patient safety risks

- Vulnerabilities of current documentation processes:
  - Improper use or expectations of SRT capabilities
  - Degradation of translation accuracy over time
  - No standards for style, grammar, and readability
  - Minimal standards for certification
  - Lack of continuing education of transcriptionists
  - Unclear roles and standards for editors of transcribed notes
- Use of voice or speech recognition technology (SRT)
  - Critical error rates for speech recognition proofreading and editing
  - High percentage of errors prior to physician sign-off with still a significant number after sign-off
  - Inaccuracy of voice recognition related to voice accent and tone
- Physician as editor – no guarantee errors will be found

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Quick Safety Tips: Transcription-related patient safety risks

- Safety Improvement Strategies:
  - Implement performance improvement methodologies in the medical record/transcription departments
  - Establish proofreading requirements
  - Address outsourcing and offshoring
  - Establish guidelines for handling discrepancies, blanks, quality of documentation produced when using free-text entry via keyboard or speech recognition
  - Report documentation events that impact patient safety
- Unedited documentation errors:
  - Age transcribed as AIDS
  - 40 mg Lasix transcribed as 400 mg Lasix
  - No episodes of unconsciousness transcribed as episodes of unconsciousness
  - BID transcribed as TID

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Sentinel Event Alert 49: Safe use of opioids

Heightened attention by the Health and Human Service addressing opioid-drug related overdose, death and dependence

- Press release issued March 26, 2015

Priorities:

- Providing training and educational resources, including updated prescriber guidelines, to assist health care professionals in making informed prescribing decisions and address overprescribing of opioids
- Expanding use of Medication-Assisted Treatment (MAT) combining medication with counseling and behavioral therapies to treat substance use disorders
- TJC survey focus: Review of prescribing, administration, and monitoring

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Quick Safety Alert Issue 14: At risk obstructive sleep apnea patients

- Often experience complications when receiving sedatives (opioids) or general anesthesia
- Safety recommendations:
- Screen and identify Obstructive Sleep Apnea
- Add sleep apnea questions as part of the initial nursing assessment
- Assess use of sedating medications and narcotics
- Use of continuous pulse oximetry
- Use of supplemental oxygen or positive airway pressure device
- Positioning

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ECRI Top 10 Patient Safety Concerns for 2015

- Alarm hazards: inadequate alarm configuration policies and practices
- Data integrity: incorrect or missing data in the EHR and other health IT systems
- Managing patient violence
- Mix-up of IV lines leading to misadministration of medications
- Events related to medication reconciliation
- Failure to conduct independent double checks
- Opioid events
- Inadequate reprocessing of endoscopes and surgical instruments
- Inadequate handoffs related to patient transport
- Medication errors related to pounds and kilograms

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2015 /16 Safety issues in the news

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Focus Areas and Challenging Standards

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Infection Control (CMS 42.CFR.482)

TJC IC.02.02.01 – The hospital reduces the risk of infections associated with medical equipment, devices, and supplies. Implements infection prevention and control activities (#2 most frequently scored)

- Endoscope cleaning and storing
- Current and comprehensive policies (Manufacturer's Guidelines)
- Low level disinfection (frequency / risk assessment)
- High level disinfection
- Sterilization
- Staff competence (not documented / not done)

Findings / dependent on severity and prevalence:

- Likely to result in Condition level finding
- May escalate to Immediate Threat to Health and Safety

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Infection Control

Common Findings:

- Not performing the manufacturer's recommended quality control on the Cidex OPA strips when a new container was opened.
- Not monitoring the temperature of the Cidex OPA solution as recommended by the manufacturer.
- Expired unopened containers of Cidex test strips.
- SPD: "washer/disinfection" machines in the decontamination area did not have formal processes for water/wash and thermal temperature monitoring and QC measures for protein removal from instrumentation using TOSI testing as recommended by the manufacturer.
- Laryngoscope blades and oral airways stored unprotected in carts and transport bags
- Instruments double packaged with folds in the inner package
- Manufacturer's equipment cleaning schedule not followed
- Single use disposable brushes being reused

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FDA Safety Communication Sept. 17, 2015: Infections associated with reprocessed flexible bronchoscopes

Failure to follow manufacturer's instructions for reprocessing:

- Lack of pre-cleaning at point of use
- Failure to perform thorough manual cleaning before HLD
- Failure to flush or brush channels
- Use of expired detergent or HLD
- Insufficient flushing, rinsing and or drying after HLD
- Persistent device channel kinks or bends
- Channel wall scratches, divots, or crevices
- Holes, cracks, other imperfections in the distal end
- Use of device despite residual material in the instrument or suction channels

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need for healthcare facilities to review procedures for cleaning, disinfecting, and sterilizing reusable medical devices

Advisory alert released September 11, 2015

Recommendations:

- Training:
  - upon hire or prior to performing activities (At least once a year)
  - When new devices or protocols are introduced including changes in the manufacturer's instructions
  - Demonstrate competency with device processing through direct observation validation prior to functioning independently; maintain documentation of trainings and competencies
- Accessible Information - Copies of manufacturer's instructions readily available to staff and any surveyor; including instructions for use of chemical disinfectants
- Audit and Monitor all reprocessing steps – provide routine feedback to staff

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President Obama Press Release March 27, 2015

Focus on combatting antibiotic-resistant bacteria

- 5 Goals:
  - Slow emergence
  - Strengthen surveillance efforts to combat resistance
  - Advance development and use of rapid and innovative diagnostic tests for identification and characterization of resistant bacteria
  - Accelerate basic and applied research and development for new antibiotics and therapies
  - Improve international collaboration and capacities for antibiotic resistance prevention, surveillance, control, and research and development

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President Obama Press Release March 27, 2015

Focus on combatting antibiotic-resistant bacteria

- Outcomes:
  - Establishment of antibiotic stewardship programs in all acute care hospitals
  - Reduction of inappropriate use by 50% in outpatient settings and 20% in inpatient settings
  - Establishment of State Antibiotic Resistance Prevention Programs to monitor regional MDRO with feedback and assistance to health care facilities
  - Eliminate the use of medically important antibiotics for growth promotion in food producing animals

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Medication Management (Pharmaceutical Services CMS 25.CFR.482)

- TJC MM.01.01.03 EP 1 / Identify in writing high alert and hazardous medications.
  Consider if any of the following medications are being used:
  - Carcinogens
  - Toxic agents
  - Reproductive toxins
  - Irritants/corrosives
  - Hepatotoxins, nephrotoxins, neurotoxins
  - Agents which damage the lungs, skin, eyes, or mucous membranes
  - Agents that act on the hematopoietic system

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Medication Management (Pharmaceutical Services CMS 25.CFR.482)

Identify High risk exposure points in the process:

- Medication mixing
- Infusion
- Disposal
- Spill management
- Waste containment

Communicate appropriate cautions:

- Absorption from hazardous waste most often occurs through contact with the skin and contaminated surfaces

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Medication Management (Pharmaceutical Services CMS 25.CFR.482)

Surveyors will expect to see:

- Appropriate product labeling
- Safe process from receipt through disposal
- Dedicated storage area with appropriate hazard alerts
- A process for monitoring process from receipt through disposal to validate compliance
- All staff, including facilities and distribution staff, interacting with these medications should be thoroughly trained regarding:
  - » Inherent toxicity and possible health risks
  - » How to respond to spills, accidents, inhalation, and personal contact
  - » Use of Personal Protection Equipment

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Management(Pharmaceutical Services CMS 25.CFR.482)

MM.03.01.01 Medication storage

Stored according to manufacturer's recommendations

- Temperature management
- Vaccines

Secured/Authorized access

- Diversion risk?
- Who has access?
- Staff access after transfer/termination
- Based on organizational policy and state regulation
- Locked in accordance with law and regulation
- Disposal – use of large bins; patches
- Job descriptions/policy – inclusion of access authorization

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Medication Management(Pharmaceutical Services CMS 25.CFR.482)

MM.04.01.01 Medication orders are clear and accurate

- *Policy* on required elements of a complete order
- *Policy* addresses when an indication is required in the order
- *Policy* addressing precautions to take for ordering look alike/ sound alike names
- *Policy* includes actions to take when orders are incomplete, illegible or unclear

Protocols/Order Sets/Standing Orders:

- Routine review and approval by the medical staff, nursing, and pharmacy
- Review for consistency with nationally recognized and evidence-based guidelines
- Date, time, and authentication by the ordering practitioner or other practitioner responsible for care

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Medication Management/Pharmaceutical Services (CMS 23.CFR.482)

MM.05.05.01 Pharmacist review for appropriateness of all medication orders

- Reviewed for allergies and sensitivities
- Food-drug interactions
- Appropriateness of the medication, dose, frequency, and route
- Any impact as indicated by lab values
- Therapeutic duplication (focus on pain and antiemetic medications – decision tree reference in clinical record)
- Any contraindications
- Any issues are clarified with the prescriber before dispensing

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Management/Pharmaceutical Services (CMS 23.CFR.482)

TJC MM.05.01.07 Staff prepare medications in a clean, uncluttered, and functionally separate.

TJC MM.05.01.09 Medication containers are labeled whenever medications are prepared but not immediately administered (NPSG.03.04.01)

- Label includes in a standardized format:
  - Name, strength, and amount if not apparent from the container;
  - Date prepared
  - Expiration date when not used within 24 hours;
  - Expiration time when expiration occurs in less than 24 hours;
  - Diluent for all compounded IV admixtures

- Verify all medications both verbally and visually by two individuals when the person preparing the medication is not the person administering (NPSG.03.04.01)

- All medications and solutions on and off the sterile field and their labels are reviewed by entering and exiting staff responsible for managing the medications (NPSG.03.04.01)
- Dispensed in most ready to use form:
  - Recommend Use of single dose vials - If using multi-dose vials, ensure appropriate labeling and storage
  - Splitting tablets – only if scored

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Medication Management: Bulk contrast Update

FDA approved bulk contrast system for use in CT

- New dosage form designed and labeled for multi-patient use in the CT suite in conjunction with an automated contrast injection system or a contrast management system. It can also be used with a syringe-based CT injection system and transfer set designed for multi-patient use.
- *Only approved transfer sets* which allows filling of multiple sterile, single-use-only syringes with a syringe-based power injector system from one container in the CT suite may be used; use of a laminar flow hood is not required. Each syringe would be used for one patient only.

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Medication Management: Bulk contrast Update

TJC Standards Surveyed:

- The IBP contrast system is used only in the CT suite and stored according to manufacturers' recommendations. (MM.03.01.01, EP 2)
- The IBP contrast system is used according to the manufacturers' recommendations: i.e. The IBP is used in conjunction with a syringe-based power injection system or approved contrast management system for multiple patient use. (MM.03.01.01, EPs 2 & 7, MM.05.01.07, EP 2, MM.05.01.09, EPs 1, 2, 3 & 5 and IC.02.01.01, EP 1)
- Staff are educated on the IBP contrast system for use in CT. (HR.01.05.03, EPs 1, 4, 5, 6, & 7)
- Staff are competent to use the IBP contrast system for use in CT. (HR.01.06.01, EPs 1, 2, 5, 6, & 15)

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Provision of Care (CMS 23 and 24.CFR.482)

TJC PC.01.02.03 – The hospital assesses and reassesses the patient based on defined *time frames*

- H&Ps
- H&P update
- Timeframes for assessments and reassessments are defined in writing
- Reassessed based on the plan of care and/or change in condition

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Provision of Care (CMS 13.CFR.482)

TJC PC.01.03.01 – The hospital plans the patient's care.

- Plan of care reflects the patients needs based on the assessment and reassessment
- The plan is based on the patient's goals and the time frames necessary to meet those goals
- Staff evaluate the patient's progress based on the established goals
- Goals and plans are revised based on patient needs

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Provision of Care (CMS 22/23/Various.CFR.482)

TJC PC.02.01.03 – Provision of care based on services ordered or prescribed, and in accordance with law and regulation

- Obtain or renew orders prior to providing care, treatment, or services
- Provide care treatment, or services based on the most recent patient order
- Of note: Providing care without orders can result in the individual's loss of licensure and the organization can lose their accreditation

Survey Findings:

- Initiating protocols without orders
- Protocol orders not initiated when ordered
- Initiating treatment without orders
- Verbal orders not documented in the medical record

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Provision of Care (CMS 13.CFR.482)

TJC PC.02.02.11 – Resuscitation services are available throughout the hospital. (#7 frequently scored clinical standard)

- Appropriate to patient population: Pediatric /Adult supplies
- Malignant hyperthermia supplies
- Supplies in date (within and on top of cart)

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Provision of Care (CMS 23 and 52.CFR.482)

TJC PC.03.01.03 – Care before operative or other high risk procedures, including those requiring moderate or deep sedation or anesthesia.

- Pre-sedation/pre-anesthesia assessment
- Immediate reassessment
- LIP plans or concurs with the plan for sedation or anesthesia
- Pre-anesthesia evaluation completed and documented within 48 hours prior to surgery
  - 48 hours begins at the time the patient is moved to a designated recovery area
  - Can be done by anyone who is authorized to administer anesthesia - does not need to be the same practitioner that did the assessment
  - The evaluation *should not* begin until the patient is sufficiently recovered from the acute administration of the anesthesia so as to participate in the evaluation, e.g., answer questions appropriately, perform simple tasks, etc.

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Provision of Care (CMS 23 and 52.CFR.482)

An immediate post-op progress note is acceptable until the full report can be written or dictated within a time frame defined by the organization

Note must include:

- Name of the primary surgeon and assistants
- Procedure performed
- Description of findings
- Estimated blood loss
- Specimens removed
- Post operative diagnosis

The progress note must be entered into the record before the patient is transferred to the next level of care.

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Provision of Care – Discharge Planning (CMS 43.CFR.482)

TJC PC.04.01.01 – 04.01.07 and PC.04.02.01:

- 7 day a week coverage/access
- Lack of comprehensive plan
- Lack of implementation of the plan
- Poor transfer communication
- Looking for:

• Ongoing review of the discharge plan
• Tracking of readmissions process
  - Identification of potential readmissions
  - Review of 1-2 inpatients that were readmissions
  - Review of 1-2 closed records looking for a discharge evaluation plan

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Medical Staff

- MS.08.01.01 FPPE
  - Initial privileging of a new provider
  - New privilege for an existing medical staff member
  - Lack of specific documentation to base an evaluation
- MS.08.01.03 OPPE
  - Performance data did not have a correlating recommendation
  - Lack of evidence the performance data was reviewed by the Chairman

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Leadership (CMS 12.CFR.482)

TJC LD.01.03.01 The governing body is ultimately responsible for safety and quality of care, treatment, and services

- Scored when there are trends and patterns which could impact patient safety or staff safety
- Scored when there is a CMS Condition Level Deficiency

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Human Resources (CMS 11.CFR.482)

TJC HR.01.02.05 The hospital verifies staff qualifications.

- Primary source verification
- At time of hire and time of license /certification/registration renewal

TJC HR.01.06.01 Competency

- Lack of job specific competency documentation
- Contract staff

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Record of Care (CMS 24.CFR.482)

TJC RC.01.01.01 – The hospital maintains a complete and accurate record for each individual patient (#5 most frequently scored standard)

- Entries are timed
- Entries are dated
- Legibility
- Leaving fields blank versus documenting “non-applicable”

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Patient Rights (CMS 13 and 24.CFR.482)

TJC RI.01.03.01 Informed consent :
- Policy includes how the informed consent is obtained and documented.
  - Acceptable examples:
    - On a pre-approved form
    - Progress notes
    - Elsewhere in the record
  - Identifies the specific care, treatment, and services that require informed consent in accordance with law and regulation
  - Any exceptions to obtaining informed consent
  - Describes the process used to obtain informed consent

Findings include:
- Multiple consents/conflicting information (RI.01.03.01)
- Consent not signed by the patient, no documentation addressing patient's ability to sign (RI.01.02.01)
  - Content not written in terms patient understands (RI.01.01.03)
  - Non-English speaking patients/literacy (RI.01.01.03)
  - Signatures not timed and dated (RC.01.01.01)

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Emergency Management

CMS Survey & Certification - Emergency Preparedness

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/index.html?redirect=/surveycertemergprep/

TJC:

- EM.01.01.01 The organization **engages in planning activities** prior to developing its Emergency Operations Plan
- EM.02.01.01 The organization **has an Emergency Operations Plan**
- EM.03.01.01 **Evaluate the effectiveness** of the emergency management planning activities
- EM.03.01.03 **Evaluate the effectiveness** of the emergency operations plan

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Environment of Care (CMS 41.CFR.482)

TJC EC.02.02.01 The hospital manages risks related to hazardous materials and waste.
- For managing hazardous materials and waste, the hospital has the permits, licenses, manifests, and safety data sheets required by law and regulation.
- OSHA required staff training on the Safety Data Sheet labels by December 1, 2013.
- Minimum training includes:
  - Type of information the employee would expect to see on the new labels including: product identifier, signal word indicating severity of the hazard and the alert, pictogram, hazard statement, precautionary statement, name, address, and phone number of the manufacturer, distributor, or importer
- Chemo gloves tested to the correct level of permeation safety (D6978 for chemotherapy permeation; F739-12 for liquids and gases)

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Environment of Care (CMS 41.CFR.482)

TJC EC.02.06.01 Maintain a safe, functional environment
Findings are related to:
- Maintain ventilation, temperature, and humidity levels suitable for care, treatment and services provided
- Ventilation – do doors hang open due to air pressure? Odors?
- Temperature – complaints of too hot / too cold?
- Humidity – are there areas > 60% RH which promote mold? Window condensation? < 20% creates the risk of static electricity and possibility of a fire
- Pharmacy Clean Room and Anteroom: appropriate ventilation, temperature, humidity, cleanliness (Log Completed by pharmacy and environmental services)
- Unsecured oxygen tanks
- Locked doors – no keys
- Emergency patient call cords ineffective

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Environment of Care (CMS 41.CFR.482)

- EC.02.06.01 Ventilation systems
- Ventilation system does not provide the correct pressure relationships
- Endoscopy process rooms should always be negative to the egress corridor
- Soiled utility rooms should always be negative
- Rule of thumb – the cleanest location should be more positive versus the dirty area should be negative
- Correct number of air changes per hour
- *Findings in this EP will generate a condition level deficiency. If corrected at the time of survey the finding may be reduced to a condition level finding.*
- Best practice: continuous airflow monitoring

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Environment of Care (CMS 41.CFR.482)

- TJC EC.02.06.01 - Medical Gas Safety
- Storage (requirements do not apply to "in use" cylinders:
- Secured to a stretcher is "in use"
- Properly racked (in storage)
- Empty cylinders are not considered part of the 12 allowed in storage
- Empty and full must be physically racked separately
- Partial designation organization's choice; CMS only recognizes full and empty

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Life Safety/NFPA Life Safety Code

- TJC LS.02.01.20 Maintain the integrity of the means of egress
- Corridor clutter – the following items are allowed:
- Crash carts
- Isolation carts when in use
- Chemo carts when in use

TJC LS.02.01.30 Building features protect individuals from the hazards of fire and smoke

- Doors not latching
- Door gaps

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Life Safety/NFPA Life Safety Code

- LS.02.01.35 Systems for extinguishing fires
- Sprinkler heads are free from corrosion, foreign materials and paint.
- Sprinkler system piping is not used to support any other item, i.e. nothing can be draped on top of it.
- All ceiling tiles in place
- Fire extinguishers not blocked
- Quick response sprinklers mixed with other types in patient sleeping smoke compartments
- Appropriate signage

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OSHA – Workplace Violence

- New web page released in December focusing on employers and worker strategies with tools for preventing workplace violence in the health care setting
- Strategies:
- Management commitment and worker participation
- Worksite analysis and hazard identification
- Hazard prevention and control
- Safety and health training
- Documentation and program evaluation

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Be Prepared

It's not about the SURVEY!

It's about the PATIENTS!

Continuous Patient Readiness

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Ongoing compliance

Be aware of THE BASICS that make your work areas safe

Consider periodic monitoring of any standards compliance issues observed in your unit.

Surveyor's interview follows the course of care, treatment and the services provided – be able to articulate what you do and how you do it per your own policy and procedure.

You are not in this alone – understand the dynamics of your care team – evaluate the interconnections between disciplines, departments and services and be able to demonstrate how you work together to provide care, treatment and services in a safe and efficient way.

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Questions?

Contact Jodi Eisenberg at jodi.eisenberg@vizientinc.com for more information.

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ICHP 4/9/16 Presentation

2015 Regulatory Year In Review: Planning for 2016

Post-test

The foundation of all voluntary accrediting organization's standards are:

A. Federal Compliance Code
B. CMS Conditions of Participation
C. EMTALA
D. None of the above

Based on the new fiscal budget, the future state of regulatory visits will:

A. Increase and expand
B. Be limited to focused visits on Infection Control, Discharge Planning, QAPI, Emergency Preparedness, EMTALA
C. Decrease in frequency
D. All of the above

In 2015, safety alerts regarding bacterial infections in patients who underwent scope procedures were published by:

A. FDA
B. CMS
C. TJC
D. CDC
E. All of the above

Identify the strategies that leadership can implement to help ensure the safe use of health information management (select all that apply).

A. Evaluate workflow processes prior to implementing technology solutions
B. Involve users in the system planning
C. Choose system interfaces that easily align
D. Monitor effectiveness based on metrics

Recent communication included in the _____ discussed the establishment of antibiotic stewardship programs in all acute care hospitals:

A. CMS S&C Memo
B. Obama Press Release
C. FDA Safety Alert
D. CDC Communication

Women in Leadership

DESPINA KOTIS, PHARMD, FASHP

THE SPEAKER HAS NO CONFLICT OF INTEREST TO DISCLOSE.

"We need a new generation of leaders – men and women – who willingly embrace their opposites."

TONY SHWARTZ, BLOGS.HBR.ORG OCTOBER 30, 2012

Objectives

To describe gender style differences and leadership authenticity.

To create succession planning and development programs for emerging leadership for women

To describe nature of the leadership gender sea change

To appraise implications of the demographic patterns

Satya Nadella

CEO, Microsoft

"It's not really about asking for the raise but knowing and having faith that the system will actually give you the right raises as you go along…Because that's good karma, It'll come back. Because somebody's going to know: That's the kind of person that I want to trust. That's the kind of person that I want to really give more responsibility to. And in the long-term efficiency, things catch up."

Grace Hopper Celebration of Women in Computing Conference

October 9, 2014

Executive Leadership

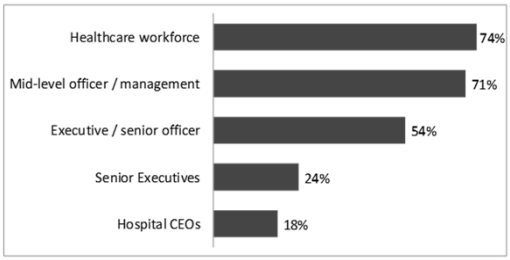
CEOs ranked top issues facing hospitals:

1. Financial challenges
2. Healthcare reform implementation
3. Governmental mandates
4. Patient safety and quality
5. Care for the uninsured
6. Patient satisfaction
7. Physician-hospital relations
8. Population health management
9. Technology
10. Personnel shortages
11. Creating an accountable care organization

Source: Top Issues Confronting CEOs: 2013. American College of Healthcare Executives. Retrieved February 2014. www.ache.org/pus/research/ceoissues.cfm

Gender and Healthcare Leadership

Women continue to be under-represented at top levels of leadership.



Sources: Bureau of Labor Statistics (2011), EEOC Employer Information Report for Hospitals (2011), American Hospital Association (2010), American College of Healthcare Executives (2013).

Gender and Healthcare Leadership

Study conducted in partnership with the Women's Leadership Center at Kennesaw State University Coles College of Business

- 282 quantitative responses to online survey
- 157 women, 125 men in leadership levels from Director to CEO
- 58% secular non-profits, 21% religious non-profits, 9% government, 7% for-profits, 5% other
- 38% > 10,000 employees; 22% between 5,000 and 9,999 employees; 32% between 1,000 and 4,999 employees; 8% fewer than 999 employees
- 52% urban, 36% suburban, 12% rural

Career Paths

Women and men in leadership positions have different work histories and educational backgrounds.

Educational Background: All Leaders	
Men	**Women**
MBA (25.4%)	MBA (19.1%)
MD (25.5%)	MHA (14.6%)
MHA (12.7%)	MSN (12.7%)
Bachelors (5.6%)	Bachelors (10.8%)

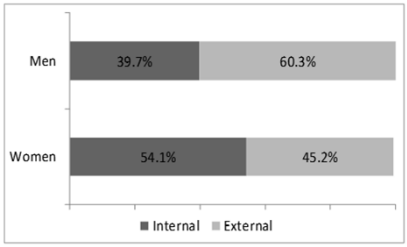
Functional Background: All Leaders	
Men	**Women**
Medicine (35.7%)	Nursing (43.9%)
Finance (16.7%)	Medicine (9.6%)
Administration (14.3%)	Finance, HR, Admin (6.4% each)

Among CEOs in the survey:

- 53% of women CEOs have nursing backgrounds.
- 43% of men CEOs come from general administration.

Career Paths

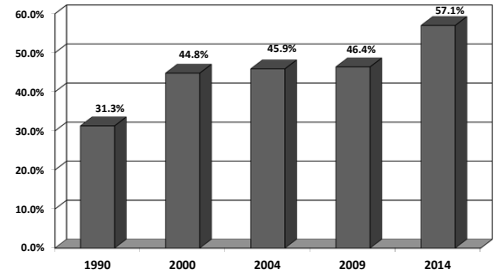
Women are more likely to be promoted internally than hired externally.



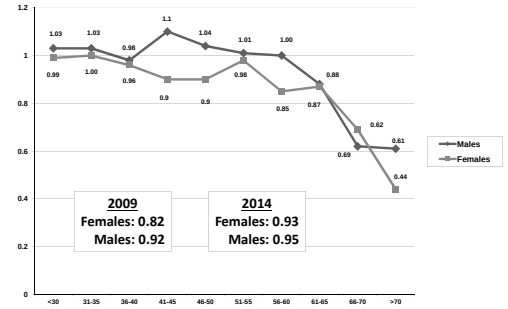
Career Paths

Women tend to stay at an organization longer than their male peers.

Percent of Actively Practicing Pharmacists that are Female: 1990-2014



Mean FTE Contributions by Age & Gender



Women Pharmacy Leaders

39.1% UHC AMC Directors of Pharmacy

35.4% Multihospital System CPOs

30.7% College of Pharmacy Deans

32.7% ASHP Accredited Residency Program DOPs

59.3% ASHP Accredited Residency Program RPDs

57.8% Health System Pharmacy Admin Residents

Leadership Competencies

Leadership Competencies	Male	Female	t	Sig.
Takes Initiative	49.8	56.4	-13.67	0.00
Displays High Integrity and Honesty	49.9	54.7	-9.78	0.00
Drives for Results	50.6	55.2	-9.53	0.00
Practices Self-Development	51.3	56.0	-9.51	0.00
Develops Others	51.1	55.1	-8.14	0.00
Inspires and Motivates Others	51.6	55.1	-7.35	0.00
Builds Relationships	51.2	54.5	-6.70	0.00
Collaboration and Teamwork	52.1	54.5	-4.96	0.00
Champions Change	51.6	54.0	-4.96	0.00
Establishes Stretch Goals	51.7	54.1	-4.77	0.00
Solves Problems and Analyzes Issues	52.0	52.7	-1.38	0.17
Communicates Powerfully and Prolifically	52.9	53.4	-1.14	0.26
Connects the Group to the Outside World	52.3	52.1	0.34	0.73
Innovates	52.6	52.2	0.96	0.34
Technical or Professional Expertise	52.1	51.1	2.10	0.04
Develops Strategic Perspective	53.7	51.2	5.06	0.00

ZENGER/FOLKMAN

Factors Valuable to Career Success

Women cited specific factors as more helpful to their careers than men did, including:

- Leadership abilities
- Involvement in professional or community organizations
- Networking within their organizations
- Having sponsors to endorse them
- Access to flexible work practices
- Support from family members

Challenges to Career Advancement

Women identified challenges to career advancement:

- Lack of supportive supervisors
- Exclusion from informal networks
- Lack of senior role models "like me"
- Inhospitable culture/biased attitudes
- Failure of senior leadership to help advance someone "like me"
- The need to prioritize family over work

Men identified different challenges to career advancement:

- Unwillingness to change organizations / companies
- Having an ineffective leadership style
- Lack of significant general or line management experience

The Next Level- Key Element
Sponsor/Sponsorship

- To be a bold promoter of another
- To shepherd another's aspirations
- "Your next role will be…"
- "I am recommending you for…"

Sponsorship

- **It matters**
  - Critical to accelerating a woman's career
  - Sponsors work as catalysts:
    - Provide access to essential networks
    - Highlight your achievements to senior-level executives
    - Recommend you for key assignments

SOURCE: Catalyst. Catalyst study shows sponsorship is key to women's success. Retrieved on February 2, 2016 at http://www.catalyst.org/media/catalyst-study-shows-sponsorship-key-women%E2%80%99s-success

Diablo Cody

Academy Award Winner for Best Screenplay, - Juno

"I'd say that it's natural to be scared, and that can fuel a lot of your adventures in life. [And] there will always be people who find a strong woman off-putting. You can't allow them to determine your fate. You have to tune out that kind of static and just be bold, be true to who you are. I do my best work under pressure, when I'm a little bit frightened—plus it just makes life more fun! You know, there's something to be said for adrenaline when you're tackling the unknown"

Vanity Fair, September 2014

Christine Lagarde

Managing Director of the International Monetary Fund
First female Finance Minister of France 2007-2011
First female Chairman of a major global law firm

"Although I think the fact that I was a woman helped to get this job," she admits. "It would have been hard [after the scandal] to give it to another French *man*."

She now feels growing responsibility to embrace women's issues. "I am so often the only woman in the room and I feel I should talk about it."

She said when she got to the IMF she found silo-thinkers," she explains. "They thought that things like women's contribution to the economy, or climate change, or income inequality, didn't matter. But it does."

Financial Times September 12, 2014

New Lipid-Lowering Drugs: PCSK9 Inhibitors

Blockbusters or Bust?

Jody Mallicoat, BS, PharmD
PGY1 Pharmacy Resident
OSF Saint Francis Medical Center, Peoria, IL

The speaker has no actual or potential conflicts of interest in relation to this presentation.

What's our starting point?

Had you heard of PCSK9 inhibitors prior to this presentation?

A. Yes
B. No

Why You Should Care

- Two recently FDA-approved medications
  - alirocumab and evolocumab
  - bococizumab in the pipeline
- Novel mechanism resulting in potent LDL reduction
- Extensive clinical trial data
- Potential for great impact on public health
- Cost to patients and payers

Outline

- Current treatment guidelines for LDL reduction in hypercholesterolemia
- Mechanism of action of PCSK9 inhibitors
- Features of PCSK9 inhibitors
- Efficacy and safety data from clinical trials
- Place in therapy
- Cost

In a world without PCSK9 inhibitors…

CURRENT HYPERCHOLESTEROLEMIA TREATMENT GUIDELINES

2002 ATPIII Guidelines[1]

The higher the risk of cardiovascular disease…

- Atherosclerotic disease
- Risk factors such as smoking, hypertension, diabetes

…the more aggressive the LDL goal

2013 ATPIV Guidelines[2]

- Statin therapy
  - Dose intensity determined by presence of atherosclerotic cardiovascular disease or cardiovascular risk (ASCVD risk calculator)
- Adjunctive therapy if
  - Baseline LDL above 190 mg/dL
  - Inadequate response to statin
- Nonstatin therapy if contraindication to statin

Aren't Statins Enough?

- Atherosclerotic disease is still the leading cause of morbidity and mortality in developed countries.[3]
- Nearly **60 million** Americans are estimated to have LDL ≥160 mg/dL
  - Only **26%** of patients are receiving a high-intensity statin
  - Only **1/3** of very high-risk patients achieve an LDL <70 mg/dL in surveys conducted both within and outside of the U.S.

Aren't Statins Enough?

- Up to **40%** of patients receiving statins are not able to reach target LDL goals following current guideline recommendations.[4]
  - Residual risk
  - Statin intolerance
  - Non-compliance
  - Suboptimal dosing
  - Familial hypercholesterolemia

Adjunctive Therapy

Lack of demonstrated reduction in cardiovascular events when used in addition to a statin

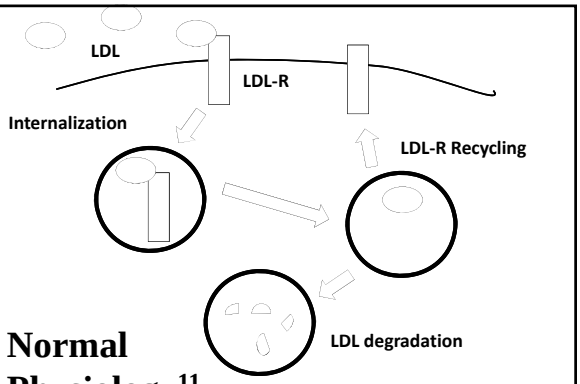
Trial	Drug, Population
ACCORD[5]	Fenofibrate, Type II Diabetes
AIM-HIGH[6]	Niacin, CVD and LDL <70mg/dL
HPS2-THRIVE[7]	Niacin + laropiprant, atherosclerotic vascular disease
ILLUMINATE[8]	Torcetrapib, high cardiovascular risk

IMPROVE-IT Trial[9]

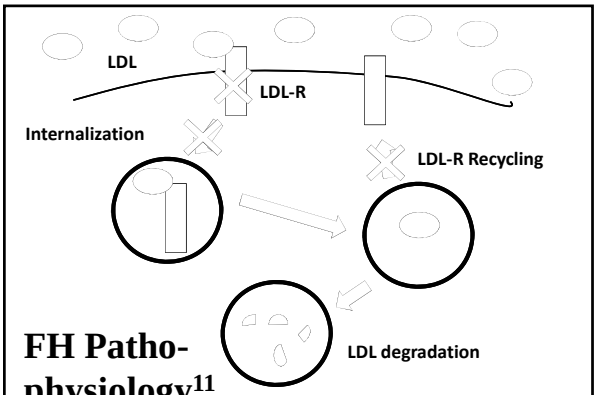
- 18,114 patients, acute coronary syndrome
- Ezetimibe + statin therapy reduced LDL levels and improved CV outcomes
  - Reduced LDL by 15.8 mg/dL, p<0.0001
  - Reduced primary endpoint over 6 years
  - Absolute risk reduction of 2%, HR of 0.936 (0.89 to 0.99, p=0.016), NNT of 50
- Limitation, used 40 mg simvastatin which is moderate intensity

Familial Hypercholesterolemia[10]

- ASCVD risk calculator likely underestimates risk in patients with FH.
- With the same lipid parameters and cardiac risk factors, patients with FH have greater risk.



Normal Physiology[11]



FH Patho-physiology[11]

Familial Hypercholesterolemia[10,12-13]

- Heterozygous forms: receptor function impaired ~50%
  - LDL levels 3x normal
  - 1 in 250 to 300 people
  - 40% experience cardiovascular events by age of 50
- Homozygous forms or compound heterozygous: receptor function impaired ~70-90%
  - LDL levels 4-8x normal
  - 1 in a million people
  - Accelerated atherosclerosis with cardiovascular events as early as childhood

FH Guidelines 2011[14]

- Patients with LDL ≥190 mg/dL require drug therapy to reduce LDL by ≥50%.
- LDL may need to be lowered to <100 mg/dL in patients with atherosclerotic disease, diabetes, family history of early coronary heart disease, or current smoking.
- Statins initially
- Can add ezetimibe, niacin, and bile acid sequestrants to intensify therapy

Familial Hypercholesterolemia[15]

- Combination therapy is often required.
  - Atorvastatin 80 mg daily
  - Homozygous FH→28% LDL reduction
  - LDL receptor negative→14% LDL reduction
  - Defective LDL receptors→41% LDL reduction

Familial Hypercholesterolemia

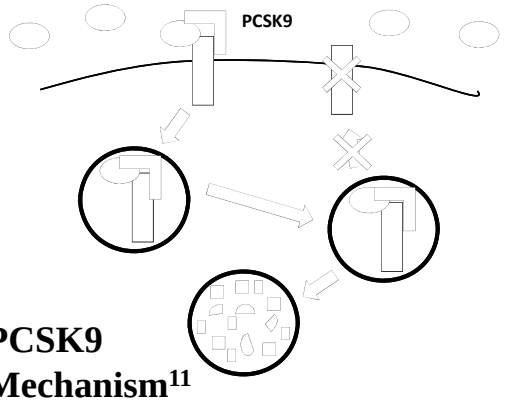
- Ezetimibe[15]
  - Can reduce LDL levels by 20%
- Lomitapide and ApoB antisense oligonucleotide[10]
  - Both reduce LDL by 25-40%,
  - REMS for both drugs—hepatotoxicity
- Lipoprotein apheresis[15]
  - Used in combination with other drugs
  - Reduces LDL by 45%

A Novel Mechanism To Meet An Unmet Need

PCSK9 INHIBITORS

PCSK9[11]

- **Proprotein convertase subtilisin/kinexin type 9**
- Enzyme that modulates the density of LDL receptors
- Produced in all people
  - May be a mechanism to maintain LDL receptor density equilibrium in normal individuals
- Statins, through an unknown mechanism, increase PCSK9 levels



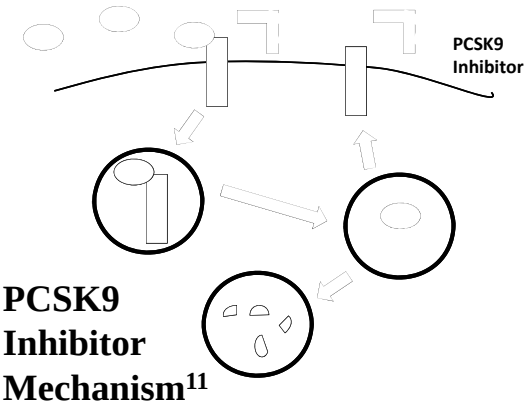
PCSK9 Mechanism[11]

PCSK9

- Loss of function PCSK9 mutations→ decreased LDL receptor degradation→ lower LDL levels[16]
  - 15-28% reduction in LDL-C
  - 47-88% reduction in CHD events
- Logically, inhibiting PCSK9 prevents LDL receptor degradation and preserves LDL receptor recycling to the hepatocyte surface

PCSK9 Inhibitors

- Fully human monoclonal antibodies to PCSK9
- Dose-dependent inhibition



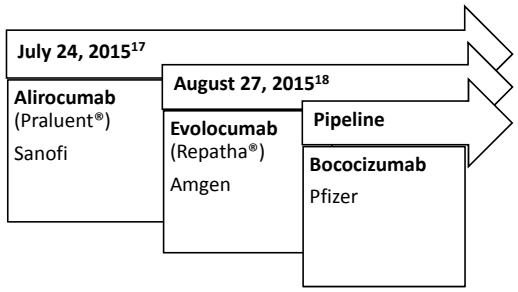
PCSK9 Inhibitor Mechanism[11]

Learning Assessment

How do PCSK9 inhibitors reduce LDL levels?

A. Reduce LDL receptor recycling
B. Reduce LDL absorption in the gut
C. Inhibit LDL receptor degradation
D. Inhibit synthesis of LDL cholesterol

Race To The Market



PCSK9 Inhibitors[19-20]

	Alirocumab	Evolocumab
Indications	Heterozygous FH in combination with a statin Hypercholesterolemia in patients with atherosclerotic CVD in combination with a statin	Heterozygous FH in combination with a statin Hypercholesterolemia in patients with atherosclerotic CVD in combination with a statin Homozygous FH in combination with other LDL-lowering drugs

PCSK9 Inhibitors[19-20]

	Alirocumab	Evolocumab
Dosing	75 mg SC Q2 weeks Max: 150 mg SC Q2 weeks	140 mg SC Q2 weeks or 420 mg SC monthly
Dosage Form	75 mg/mL or 150 mg/mL pen or prefilled syringe	140 mg/mL prefilled auto-injector

PCSK9 Inhibitors[19-20]

	Alirocumab	Evolocumab
Storage	Refrigerate, do not freeze, do not shake	Refrigerate, do not freeze, do not shake, protect from light
Administra-tion	Allow to warm to room temperature for 30-40 minutes Use within 24 hours SC injection into thigh, abdomen, or upper arm Rotate injection sites	Allow to warm to RT for 30 minutes Use within 30 days SC injection into thigh, abdomen, or upper arm Rotate injection sites

PCSK9 Inhibitors[19-20]

	Alirocumab	Evolocumab
Contra-indications	Hypersensitivity	Hypersensitivity, latex allergy
Adverse Effects	Common: injection site reactions, nasopharyngitis, influenza Serious: allergic reaction	Common: injection site reactions, influenza, nasopharyngitis, upper respiratory tract infection Serious: rash, urticaria

PCSK9 Inhibitors[19-20]

	Alirocumab	Evolocumab
DIs	No known DIs	No known DIs
Monitoring	LDL 4-8 weeks of initiation or dose change	LDL 4-8 weeks of initiation or dose change
PK	T_{max}: 3-7 days Metabolism: protein degradation $T_{1/2}$: 17 to 20 days	T_{max}: 3-4 days Metabolism: protein degradation $T_{1/2}$: 11 to 17 days

Learning Assessment

A patient is newly prescribed a PCSK9 inhibitor. Which of the following is a correct statement you could use to counsel the patient?

A. Store your medication at room temperature and rotate injection sites.
B. Allow medication to come to room temperature over 30 minutes and rotate injection sites.
C. Refrigerate your medication and shake to bring to room temperature
D. Refrigerate your medication and consistently inject at the same site

Efficacy, Safety, Cardiovascular Outcomes

WHAT THE DATA SHOW

Efficacy

Extensively studied in phase II and III clinical trials

Two meta-analyses in 2015

- Navarese et al.[21]
  - 24 randomized controlled trials, n=10,159 patients
  - Lipid, safety, and clinical outcomes
- Li et al.[22]
  - 20 randomized controlled trials, n=9,880 patients
  - Lipid and safety outcomes

Lipid-lowering Effects

Lipoprotein effects	Navarese *et al.*[21] n=10,159, 24 RCTs	Li *et al.*[22] n=9,880, 20 RCTs
LDL	**-47.9% (-69.6 to -25.4)**	**-65.29 mg/dL (-72.1 to -58.5)**
Total Cholesterol	-31.5% (-46.4 to -16.6)	-60.0 mg/dL (-70.0 to -50.1)
HDL	6.3% (5.6 to 7.0)	3.40 mg/dL (3.12 to 3.68)
Lp(a)	-25.5% (-30.2 to -27.7)	-0.94 mg/dL (-1.12 to -0.77)

Lipid-lowering Effects

Navarese et al.[21]

Comparator	Mean Difference in LDL (95% CI)	p-value
All comparators	-47.49% (-69.4 to -25.35%)	P<0.001
Placebo	-58.77% (-61.03 to -56.51%)	P<0.001
Ezetimibe	**-36.71% (-39.28 to -33.06)**	P<0.001

Why The Extra Indication For Evolocumab?

TESLA-B Trial[23]

- Randomized, double-blind, placebo-controlled, phase III trial
  - 50 patients, 12 years or older with homozygous FH who were on lipid-lowering therapy but not lipid apheresis
  - Randomized to either evolocumab 420 mg or placebo every 4 weeks for 12 weeks

Why The Extra Indication For Evolocumab?[23]

Polymorphism	LDL
Compound heterozygous FH with 2 defective alleles	MD -46.9% (-68 to -25.7)
Compound heterozygous FH with 1 defective and 1 receptor negative allele	MD -24.5% (-41.6 to -7.3)
LDL-receptor-negative mutations on both alleles and autosomal recessive homozygous hypercholesterolemia	**Increase in LDL over 12 weeks**

Adverse Events

Adverse Event	Navarese *et al.*[21] n=10,159, 24 RCTs	Li *et al.*[22] n=9,880, 20 RCTs
CK elevation	**OR 0.72 (0.54 to 0.96)**	Not reported
Composite of serious AEs	OR 1.01 (0.87 to 1.18)	RR 1.01 (0.88 to 1.17)
Discontinuation of therapy	Not reported	RR 1.07 (0.86 to 1.34)

Adverse Events

Zhang et al.[24]

- Meta-analysis that evaluated alirocumab and evolocumab safety separately
- Neither alirocumab nor evolocumab significantly affect the occurrence of the following as compared to placebo (p>0.26)
  - Adverse events in general
  - Adverse events leading to discontinuation
  - Musculoskeletal disorders
  - GI disorders

Adverse Events

Zhang et al.[24]

Adverse Effect	Alirocumab	Evolocumab
Injection site reactions	**RR 1.48 (1.05 to 2.09)**	RR 1.06 (0.67 to 1.67)
CK elevation >5X ULN	RR 0.72 (0.52 to 1.01)	RR 0.57 (0.21 to 1.51)
AST or ALT >3X ULN	RR 0.95 (0.26 to 3.47)	**RR 0.43 (0.20 to 0.93)**

Cardiovascular Outcomes

- No completed studies to date with cardiovascular outcomes as part of the primary analysis
- FOURNIER and ODYSSEY Outcomes trials for evolocumab and alirocumab
  - Sufficient design and duration to assess cardiovascular events
  - Final results not expected until 2018

Cardiovascular Outcomes

Navarese et al.[21]: mean follow-up 44 weeks

Outcome	+PCSK9i	-PCSK9i	OR (95% CI), p-value
All-cause Mortality	**0.31 %**	**0.53 %**	**0.45 (0.23 to 0.86), p=0.015**
Cardiovascular Mortality	0.19%	0.33%	0.50 (0.23 to 1.10), p=0.084
MI	0.58%	1%	0.49 (0.26 to 0.93), p=0.030
Unstable angina	0.04%	0.08%	0.61 (0.06 to 6.14), p=0.676

What The Data Appear To Show

- Profound reductions in LDL
- An apparently similar level of safety to background treatment
- A preliminary signal of survival benefit
  - No single RCT has been powered to show an effect on cardiovascular outcomes or mortality

Interpret with Caution

- Meta-analyses pooled data from the study level, not patient level
- Navarese et al. used fixed effects model
- Small number of events
- Duration of follow-up ranged from 2 months to 2 years
- Quantitative interaction

Who Might Benefit?

PLACE IN THERAPY

Place In Therapy: FDA Indications[19-20]

- Adjunctive therapy to diet and maximally tolerated statin therapy
- Adults with heterozygous FH or ASCVD who require additional LDL-lowering
- Evolocumab carries the added indication for patients with homozygous FH on other LDL-lowering therapies who require additional LDL-lowering

Place In Therapy: Hypercholesterolemia[25]

- Primarily competing against ezetimibe for adjunctive agent of first resort when maximally tolerated statins are insufficient
- Ezetimibe has a greater edge due to greater quality of evidence for cardiovascular event reduction
  - Longer time on market
  - Strong safety profile
  - Oral medication
  - Lower cost

Place In Therapy: Heterozygous FH[25]

- Difficult to say which is the adjunctive agent of first resort
  - PCSK9 inhibitors are clearly better able to reduce LDL concentrations than other adjunctive agents.
- The decision may be made by the clinician depending on the patient's LDL goal.

Place In Therapy: Homozygous FH[25]

- Statins and ezetimibe first line
- Evolocumab primarily competing against lipid apheresis
  - Except homozygous LDL-receptor-negative FH or autosomal recessive hypercholesterolemia→lipoprotein apheresis is superior option
- TESLA-B trial excluded patients receiving apheresis

Place In Therapy: Statin Intolerance[25]

- No labeled indication for patients intolerant of statins
- Potently decreases LDL in these patients either alone or in combination with ezetimibe

Learning Assessment

For which of the following patients would you most likely recommend a PCSK9 inhibitor?

A. Patient with FH experienced an MI at the age of 38, LDL is 120 mg/dL with atorvastatin 80 mg.
B. Patient has made diet changes, takes rosuvastatin 20 mg, and LDL is 70 mg/dL.
C. Patient takes atorvastatin 80 mg, is not compliant with insulin injections, and LDL is 100 mg/dL.
D. Patient reports nausea with statins and saw an ad on TV for these exciting new drugs.

The Real Question:

HOW MUCH DO THEY COST?

What's your guess?

How much do you think PCSK9 inhibitors cost per patient per year?

A. $100
B. $400
C. $1,400
D. $14,000
E. $140,000

Cost[26]

Current cost per year per patient

Alirocumab $14,600

Evolocumab $14,100

Estimated that 2.6 million U.S. individuals could potentially receive a PCSK9 inhibitor over the next 5 years

- $108 billion over 5 years
  - $19 billion FH
  - $15 billion CVD with statin intolerance
  - $74 billion for CVD with LDL not at target

Cost: ICER Report[26]

Institute for Clinical and Economic Review

- PCSK9 inhibitors should cost 85% less than current list price
- Typical cost-effectiveness ratio threshold: $100,000/QALY gained
  - To meet that threshold, yearly cost of between $3,615 to $4,811
- Even using a more generous threshold of $150,000/QALY gained
  - $5,200/year would be cost-effective

Cost: ICER Report[26]

- In order to not have to limit use in some way, drug cost would need to be $2,177, an 85% discount.
  - Make drugs more affordable
  - Cut costs elsewhere
  - Limit access

Cost To The Patient[27]

- Express Scripts
  - 25 million Americans
  - Will cover both agents—listed on National Preferred Formulary
- Have negotiated a lower price with drug manufacturers, though reported to not be as low as ICER report recommends
- Manufacturers will provide $5 copay cards and offer to cover up to $4,200/year in copays.

So…

BLOCKBUSTERS OR BUST?

Blockbuster?: Too Early to Tell

- Potential for great impact in reducing cardiovascular outcomes
  - Awaiting results of long-term studies
  - FOURNIER and ODYSSEY
- Strongest case for use in highest risk patients
- Impact on debate regarding reestablishment of LDL targets

Bust?: Too Early to Tell

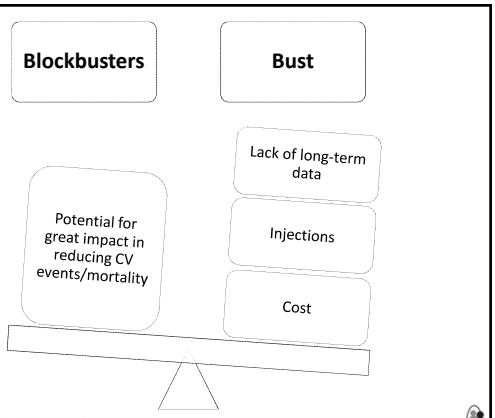
- High cost, chronic therapy
- No long-term safety or clinical outcome data
- Reasons PCSK9 inhibitors will not be used
  - Statin dose not yet optimized
  - Not following diet/exercise plan
  - Apprehensive about injections
  - Statin compliance
  - Patient will not be able to afford

What do you think?

Do you think PCKS9 inhibitors will be blockbusters or busts?

A. Blockbusters

B. Busts



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Stop the Bleeding! New Reversal Agents

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I have no actual or potential conflict of interest in relation to this activity.

Objectives for Pharmacists

- Review current strategies for the management of bleeding due to direct oral anticoagulants.
- Describe the characteristics and clinical trial data behind new reversal agents.
- Identify anticoagulation reversal agents in the pipeline.

Objectives for Pharmacy Technicians

- List currently available medications used to reverse bleeding caused by direct oral anticoagulants.
- Describe how new reversal agents are stored, prepared, and administered.
- Identify anticoagulation reversal agents in the pipeline.

Assessment Pre-test

Which of the following agents undergoing clinical trials may reverse the anticoagulant effects of factor Xa inhibitors, but NOT factor IIa inhibitors?

A. Aripizine (PER977)
B. Andexanet alfa (PRT064445)
C. Antihemophilic factor, PEGylated (BAX855)
D. Clazakizumab (ALD518)

CURRENT STRATEGIES

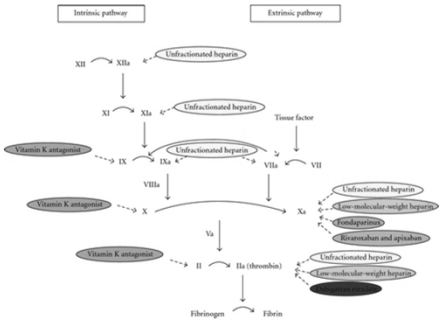
REVERSAL OF DIRECT ORAL ANTICOAGULANTS

Anticoagulation Guideline Recommendations

- Management of Atrial Fibrillation
  - dabigatran, rivaroxaban, or apixaban.
    - *Level of Evidence: B*
- Venous Thromboembolism Disease (VTE)
  - dabigatran, rivaroxaban, apixaban, or edoxaban over vitamin K antagonist (VKA) therapy.
    - *Grade 2B*
  - The risk that a major bleed will be fatal appears to be no higher for the direct oral anticoagulants (DOACs) than for VKA therapy.

January CT, et al. *J Am Coll Cardiol*. 2014;64(21):e1-76.; Kearon C, et al. *Chest*. 2016;149(2):315-52.

DOAC Mechanisms of Action



Moheimani F, Jackson DE. *ISRN Hematol.* 2011;2011:124610.

Anticoagulant Effect of DOACs

Coagulation test	anti-IIa	anti-Xa
PT	+	++
INR	+	++
aPTT	+	+
TT	++	-
ECT	++	-
anti-Xa (heparin)	-	++
chromogenic	++	++

PT, prothrombin time; INR, international normalized ratio; aPTT, activated partial-thromboplastin time; TT, thrombin time; ECT, ecarin clotting time.

- dabigatran
  - aPTT (curvilinear)
- rivaroxaban
  - PT (linear)
- apixaban
  - PT*, aPTT*
- edoxaban
  - PT*, aPTT (linear)

*Causes prolongation, but variability between laboratory reagents.

Di Minno G, et al. *Intern Emerg Med.* 2015;10:533-34.; Crowther M, Crowther MA. *Arterioscler Thromb Vasc Biol.* 2015;35:1736-45.

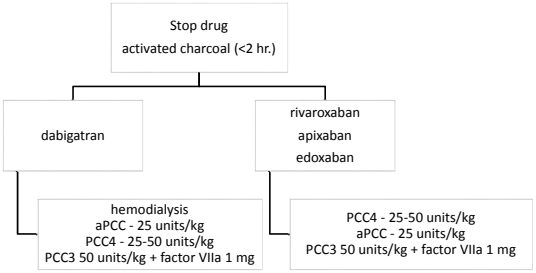
Patient Case

- 56 year old female
- PMH: DVT
- Meds: rivaroxaban 20 mg PO daily
- CC: MVA
- Dx: retroperitoneal hemorrhage (major bleed)
  - requires immediate surgical intervention

Which of the following would you recommend to try and reverse her rivaroxaban?

A. Hemodialysis
B. 4-factor prothrombin complex concentrate (KCENTRA®)
C. Idarucizumab (PRAXBIND®)
D. Cryoprecipitate

Reversal for Major Bleeding or Urgent Invasive Procedure



Nutescu EA, et al. *Am J Health Syst Pharm.* 2013;70(21):1914-29.

Concentrated Clotting Factor Products

Reversal Agent	Brand Names	Clotting Factor(s) Replaced	Activated?	Contains Heparin?
PCC3	Bebulin VH® Profilnine SD®	II, IX, and X	No	Yes No
PCC4	Kcentra®	II, VII, XI, and X	No	Yes
aPCC	FEIBA VH®	II, VII, XI, and X	Yes	No
rFVIIa	Novo-Seven®	VII	Yes	No

PCC3, 3-factor prothrombin complex concentrate; PCC4, 4-factor prothrombin complex concentrate; aPCC, activated prothrombin complex concentrate.

None of the concentrated clotting factor products are FDA-approved for reversal of bleeding due to DOACs.

Learning Assessment

What is the only FDA-approved medication for reversal of dabigatran?

A. Aripizine (PER977)
B. 4-factor prothrombin complex concentrate (KCENTRA®)
C. Activated 4-factor prothrombin complex concentrate (FEIBA VH®)
D. Idarucizumab (PRAXBIND®)

Reversal Strategies for DOACs

Crowther M, Crowther MA. *Arterioscler Thromb Vasc Biol*. 2015;35:1736-45.

DIRECT ANTIDOTE

REVERSAL OF DABIGATRAN

idarucizumab (PRAXBIND®)

- Humanized antibody fragment.
- ≈350-fold higher affinity to dabigatran versus dabigatran for thrombin.

Eikelboom JW, et al. *Circulation*. 2015;132:2412-22.

idarucizumab (PRAXBIND®)

Eikelboom JW, et al. *Circulation*. 2015;132:2412-22.

idarucizumab (*BI655075*) phase 1 trial

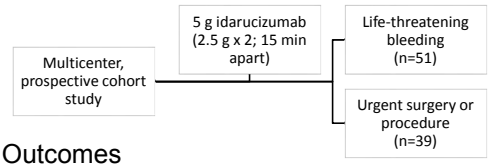
- Placebo-controlled, double-blind
- Healthy males age 18-45 years (n=47)
  - BMI 18.5-29.9 kg/m^2
- Dabigatran 220 mg PO daily x 3 days
- 3:1 ratio to idarucizumab or placebo
  - Idarucizumb: 1g, 2g, 4g, 5g + 2.5g
- Endpoints
  - adverse events
  - laboratory values

Glund S, et al. *Lancet*. 2015;386(9994):680-90.

idarucizumab – phase 1 trial

Glund S, et al. *Lancet*. 2015;386(9994):680-90.

idarucizumab – phase 3 trial RE-VERSE AD



- Outcomes
  - Reversal (%) of the anticoagulant effect of dabigatran after idarucizumab
  - Clinical and safety outcomes

Pollack CV Jr, et al. *N Engl J Med.* 2015;373(6):511-20.

RE-VERSE AD

Percentage of patients with normalized laboratory values.

dTT, dilute thrombin time; ECT, ecarin clotting time.

Percentage of patients with dabigatran concentrations near lower limit.

Pollack CV Jr, et al. *N Engl J Med.* 2015;373(6):511-20.

RE-VERSE AD

- Group A
  - Cessation of bleeding at 11.4 h
- Group B
  - 92% intra-operative hemostasis

Product	Total, No. (%)
Fresh frozen plasma	23 (25.6)
Cryoprecipitate	2 (2.2)
Activated PCC	4 (4.4)
4-factor PCC	0
Factor VIIa	0

PCC, prothrombin complex concentrate.

- 18 deaths overall
  - 5 fatal bleeds
- Thrombosis (< 72 h)
  - 1 patient only

Thrombotic event	Day
DVT and PE	2
DVT	7
DVT, PE, atrial thrombus	9
NSTEMI	13
Stroke	26

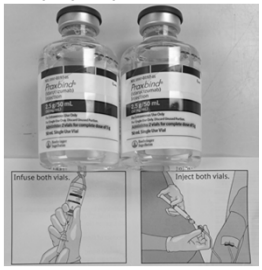
DVT, deep vein thrombosis; PE, pulmonary embolism; NSTEMI, non ST-segment elevation myocardial infarction

Pollack CV Jr, et al. *N Engl J Med.* 2015;373(6):511-20.

idarucizumab (PRAXBIND®)

- Mechanism
  - noncompetitive inhibitor
- Onset - minutes
- Labs - dTT, ECT, aPTT, TT
- Half-life - 4.4-8.1 h
- Interactions - none
- Storage - refrigerated
- Stability - 2 years
- Cost - $3500 (WAC)
- Repeat dosing?
- Co-administration of factor products?

Dosing: 5 g [2.5 g x 2 vials (50 mL/vial)]



Administration: rapid infusion or IV bolus

Eikelboom JW, et al. *Circulation.* 2015;132:2412-2422.

AGENTS IN THE PIPELINE

REVERSAL OF DIRECT ORAL ANTICOAGULANTS

andexanet alfa (*PRT064445*)

- Recombinant decoy protein, catalytically inactive and unable to bind to phospholipid membrane

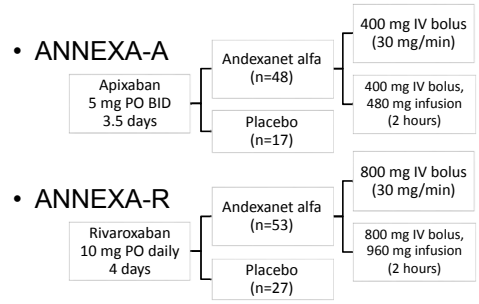
Ansell J. *Nat Med.* 2013;19(4):402-4.

andexanet alfa – phase 3 trials ANNEXA-A and ANNEXA-R

- Placebo-controlled, double-blind
- Healthy adults age 50-75 years
- 2 part studies
  - Part 1: IV bolus only
  - Part 2: IV bolus followed by 2 hour infusion
- Endpoints
  - Change (%) in anti-factor Xa activity
  - Drug concentrations, thrombin generation

Siegal DM, et al. *N Engl J Med.* 2015;373(25):2413-24.

andexanet alfa



Siegal DM, et al. *N Engl J Med.* 2015;373(25):2413-24.

ANNEXA-A and ANNEXA-R

Siegal DM, et al. *N Engl J Med.* 2015;373(25):2413-24.

ANNEXA-A and ANNEXA-R

Siegal DM, et al. *N Engl J Med.* 2015;373(25):2413-24.

ANNEXA-A and ANNEXA-R

- Factor Xa activity and thrombin generation restored
- Reduced unbound DOAC (apixaban and rivaroxaban)
  - NO thrombotic events seen
- Bolus and/ or infusion administration
- Biomarkers of anticoagulation return to placebo levels after 1 to 3 hours
- ANNEXA-4, phase 3b study underway [NCT02329327]

Siegal DM, et al. *N Engl J Med.* 2015;373(25):2413-24.; Lu G, et al. *Nat Med.* 2013;19(4):446-51.

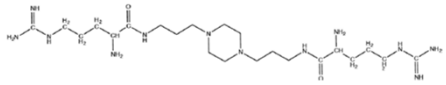
andexanet alfa

- Mechanism – recombinant decoy protein
- Dosing – differs based on DOAC agent
- Administration – IV bolus rate 30 mg/min
- Onset – minutes
- Half-life – approximately 1 h
- Interactions – unknown
- Storage – refrigerated
- Supplied – 50 mg/vial lyophilized powder (10 mg/mL)
- Potential to reverse edoxaban, LMWH, fondaparinux

Siegal DM, et al. *N Engl J Med.* 2015;373(25):2413-24.; Lu G, et al. *Nat Med.* 2013;19(4):446-51.

aripazine (*PER977*, ciraparantag)

- Small, synthetic, water-soluble, cationic molecule



- Non-covalent hydrogen bonding
  - charge-charge interactions

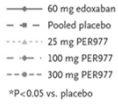
Ansell JE, et al. *N Engl J Med*. 2014;371(22):2141-42.

aripazine (*PER977*, cirapantag) phase 1 trial

PER977 5 mg or placebo	EDX + PER977 5 mg or placebo
PER977 15 mg or placebo	EDX + PER977 15 mg or placebo
PER977 25 mg or placebo	EDX + PER977 25 mg or placebo
PER977 50 mg or placebo	EDX + PER977 50 mg or placebo
PER977 100 mg or placebo	EDX + PER977 100 mg or placebo
PER977 200 mg or placebo	EDX + PER977 200 mg or placebo
PER977 300 mg or placebo	EDX + PER977 300 mg or placebo

Ansell JE, et al. *N Engl J Med*. 2014;371(22):2141-42.

aripazine (*PER977*, cirapantag) phase 1 trial



Ansell JE, et al. *N Engl J Med*. 2014;371(22):2141-42.

aripazine (*PER977*, cirapantag) phase 1 trial

- "…baseline hemostasis was restored from the anticoagulated state within 10 to 30 minutes after administration of 100 to 300 mg of PER977 and was sustained for 24 hours."

Ansell JE, et al. *N Engl J Med*. 2014;371(22):2141-42.

aripazine (*PER977*, ciraparantag)

- Mechanism – hydrogen bonding directly to anticoagulant
- Dosing – to be determined
- Administration – IV bolus rate 50 mg/min
- Onset – minutes
- Half-life – approximately 1.5 h
- Interactions – unknown
- Storage – room temperature
- Potential to reverse all DOACs, UFH, LMWH, fondaparinux
- Phase 2 study underway [NCT02207257]

Ansell JE, et al. *N Engl J Med*. 2014;371(22):2141-42.

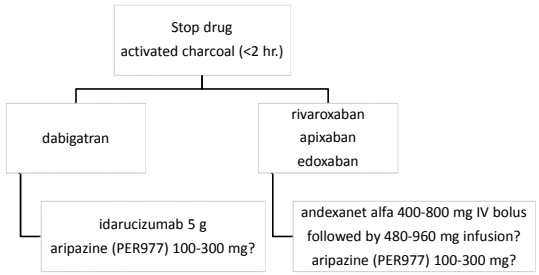
Activity of Reversal Agents

Anticoagulant	Idarucizumab	Andexanet alfa	Aripazine
Dabigatran	X	n/a	X
Rivaroxaban	n/a	X	X
Apixaban	n/a	X	X
Edoxaban	n/a	X	X
UFH	n/a	n/a	X
LMWH	n/a	X	X
Fondaparinux	n/a	X	X

UFH, unfractionated heparin; LMWH, low-molecular-weight heparin.

Some data inferred based on mechanisms of action versus actual study data.

Future Anticoagulant Reversal Proposed Protocol



Learning Assessment

Of the following anticoagulant reversal agents, FDA-approved or undergoing clinical trials, which is stored at room temperature?

A. Aripizine (PER977)
B. Andexanet alfa (PRT064445)
C. 4-factor prothrombin complex concentrate (KCENTRA®)
D. Idarucizumab (PRAXBIND®)

Assessment Post-test

Which of the following agents undergoing clinical trials may reverse the anticoagulant effects of factor Xa inhibitors, but NOT factor IIa inhibitors?

A. Aripizine (PER977)
B. Andexanet alfa (PRT064445)
C. Antihemophilic factor, PEGylated (BAX855)
D. Clazakizumab (ALD518)

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QUESTIONS?

Stop the Bleeding! New Reversal Agents

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I have no actual or potential conflict of interest in relation to this activity.

	Poster Session II, Saturday, April 9, 2016 9:30-10:30am, Fon Du Lac DEF	ACPE UAN: 0121-0000-16-047-L04- P 0121-0000-16-047-L04-T	as of March 25, 2016
Poster #	**Titles**	**Poster Presenter(s)**	**Poster Category**
13	Calcium and Vitamin D co-supplementation in Gestational Diabetes Mellitus	Christina Hill, PA-S2, Master of Medical Sciences Candidate Michael Fotis, RPh, BSPharm	**Original - Research Complete**
14	Sacubitril; Losartan the next treatment for heart failure?	Tara Marcus, PA-S2, Master of Medical Sciences Candidate Michael Fotis, RPh, BSPharm	**Original - Research Complete**
15	Digoxin and Time to Cardiac-Related Hospitalizations: A Retrospective Cohort Study	Stephanie Dwyer, PharmD, PGY1	**Original - Research in Progress**
16	Evaluation of fall risk in dementia patients on an atypical antipsychotic in the VA population	Lianna Serbas, PharmD, PGY1	**Original - Research in Progress**
17	Oral lorazepam for seizure prophylaxis in adult patients treated with high dose intravenous busulfan before hematopoietic stem cell transplantation: A retrospective study	Monica Timmerman, PharmD Candidate	**Original - Research in Progress**
18	Antifungal prophylaxis consideration in patients being treated with blinatumomab for Philadelphia chromosome-negative relapsed or refractory b-cell acute lymphoblastic leukemia: a case report.	Margaret Lee, PharmD Candidate	**Encore**
19	Differences in Clostridium difficile infection outcomes between guideline concordant and discordant therapy	Surafel Mulugeta, PharmD / MS Candidate	**Encore**
20	Implementation of decentralized pharmacy technicians to improve medication delivery and nursing satisfaction	Whitnee Caldwell, PharmD	**Encore**

	Poster Session II, Saturday, April 9, 2016 9:30-10:30am, Fon Du Lac DEF	ACPE UAN: 0121-0000-16-047-L04- P 0121-0000-16-047-L04-T	as of March 25, 2016
21	Effectiveness of Pharmacy Practice Model Initiative Competency	Saba Mohiuddin, PharmD Candidate	**Student - Research Complete**
22	A Proposal for Interprofessional Home Visits for the Elderly in Rural Communities	Katarzyna Plis, PharmD Candidate Danielle Cilano, PharmD Candidate Sarah Bay, PharmD Candidate Rimple Patel, PharmD Candidate	**Student - Research Complete**
23	Comparison of oral morphine equivalent doses vs. PHQ9 scores in a family practice setting	Lauren A. Kirkpatrick, PharmD Candidate	**Student - Research in Progress**
24	Desmopressin (DDAVP) Dose Changes Post Discharge in Pediatric Patients with Diabetes Insipidus Receiving Oral DDAVP Compounded from Nasal Spray Inpatient	Gennaro A. Paolella, BS, PharmD Candidate	**Student - Research in Progress**

Poster #: 13 **Poster Session II, Saturday, April 9, 2016**

Category: Original - Research Complete

Title: Calcium and Vitamin D co-supplementation in Gestational Diabetes Mellitus

Abstract:
PURPOSE: The purpose of this poster is to examine if vitamin D and calcium supplementation is an effective intervention during pregnancy to improve maternal outcomes in patients with gestational diabetes. Diabetes is a significant cause of morbidity and mortality in the US, and an important economic burden. The CDC estimates up to 9.2% of pregnancies are affected by GDM. A 2012 study estimated the costs associated with GDM at about $1.3 billion. Available studies examining the relationship between Vitamin D deficiency and insufficiency in patients with GDM and associated maternal outcomes are inconsistent in their findings. Although the mechanism of effect is unclear there a few studies of Vitamin D and calcium co-supplementation reporting promising results.

METHODS: A systematic review was conducted using EMBASE, PubMed, and MedLine databases between October and December 2015. Search terms included: Calcium, Vitamin D, Gestational Diabetes. Studies written in English and published in the last 5 years were included in this review. As there are so few studies on co-supplementation with calcium and vitamin D, CEBM level of evidence 4 or greater were included. Studies that did not examine gestational diabetes or did not examine co-supplementation of calcium and vitamin D were excluded. Under these inclusion and exclusion criteria a total of 3 eligible studies were identified.

RESULTS: Karamali in a randomized placebo controlled trial of 60 patients found that Vitamin D and calcium co-supplementation in women with gestational diabetes decreased the rates of many maternal and neonatal outcomes. There was a significant reduction in cesarian rates from 63% to 23% the number needed to treat (NNT) estimated as 2.5, and for maternal hospitalization from 13% to 0 (NNT=7). For neonatal hyperbilirubinema the NNT=2.7, neonatal hospitalization was reduced from 57% to 20% (NNT = 2.7), and macrosomia NNT = 3. Asemi in a randomized placebo controlled trial of 56 patients found statistically significant improvement in laboratory values for fasting plasma glucose, serum insulin, HOMA-R, LDL cholesterol, total cholesterol:HDL cholesterol, HDL cholesterol, GSH, and MDA. Clinical outcomes were not measured in this trial. Whitelaw in a cross-sectional study of 1467 patients found a weak inverse association for laboratory values with FPG and 25-hydroxyvitamin D at 0.99 (0.98, 0.99) and p-value <0.001. They found a strong association between serum calcium and fasting insulin (ratio of Geometric means 1.06 at 95% CI 1.03, 1.08, p<0.001), post challenge glucose (RGM 1.03, CI 10.01, 1.04, p<0.001), and GDM (Odds ratio 1.33, 95% CI 1.06, 1.66, p = 0.012).

CONCLUSION: These early studies indicate that co-supplementation with Vitamin D and calcium could be an inexpensive and safe intervention to help reduce undesirable maternal outcomes in patients with gestational diabetes. The cross-sectional study's results find only a weak association with laboratory outcomes for vitamin D supplementation, but find strong associations with calcium. This is the weakest study design examined and it also it did not examine the combined effects of calcium and vitamin D supplementation, rather it examined their effects independent of one another. The two RCTs examined in this systematic review found co-supplementation with calcium and vitamin D improved maternal laboratory results and improved maternal outcomes. There are other limitations to note: studies are small, two were conducted in the middle east and may lack external validity, and only a single small trial

measured clinical outcomes. Further well-designed, randomized controlled trials investigating the impact on maternal and fetal outcomes are necessary. If a positive effect is established, future studies can focus on the optimal amount of supplementation and the timing during pregnancy.

Submitting Author: Michael Fotis

Organization: Northwestern University Feinberg School of Medicine

Authors: Primary Author: Christina Hill PA-S2; Master of Medical Sciences Candidate; Northwestern University Feinberg School of Medicine

Poster #: 14 **Poster Session II, Saturday, April 9, 2016**

Category: Original - Research Complete

Title: Sacubitril; Losartan the next treatment for heart failure?

Abstract:
PURPOSE: Congestive heart failure (CHF) is a leading cause of morbidity and mortality for which there are few recent improvements in treatment. Over one million US patients on optimized drug therapy are hospitalized each year. These patients are at high mortality risk and are likely to be readmitted within 2-3 months. Identification of neurohormonal mechanisms that do not overlap with existing therapies are needed. The enzyme Neprilysin impairs endogenous vasoactive compounds, including natriuretic peptide leading to diuresis, natriuresis, and vasodilation. Sacubitril, a neprilysin inhibitor in combination with valsartan is the first of these treatments to show a morbidity and mortality benefit compared to enalapril, as reported in the PARADIGM-HF trial. The purpose of this study is to analyze the safety and efficacy data available on Sacubitril; valsartan and to determine if there is a role for the drug in the clinical treatment of CHF. This poster summarizes the findings from the Northwestern University's Physician Assistant program's capstone project.

METHODS: A systematic review of the databases PubMed, MedLine, and EMBASE was performed up to December of 2015. The following keywords were used: Heart Failure, Neprilysin, ACE-I, ARB, Sacubitril, vasopeptidise inhibitor, PARADIGM-HF. Evidence from RCT, systematic reviews, and retrospective cohort studies was examined. Inclusion criteria was specified by the PICO approach and included: 1) adult patients with NYHA class II-IV HF with ejection fraction <40% 2) treatment with Sacubitril; valsartan 3) direct comparison to recommended treatment with an ACE-I 4) inclusion of morbidity, mortality, and safety outcomes 5) CEBM level of evidence 2b or greater. Three studies met all inclusion criteria.

RESULTS: Clinical trials (ASCEND-HF, IMPRESS, OVERTURE) support a logical progression to the development of Sacubitril, based on clinically objective outcomes, including safety and tolerability. Specifically, combining a neprilysin inhibitor with an ARB reduces the risk of increased peripheral vascular resistance seen when used in isolation, or angioedema when used in combination with an ACEI. The use of Sacubitril; Valsartan compared to enalapril in the treatment of HF was found to significantly reduce the risk of death (17% vs 19.8% NNT 36) from any cause and (13.3% vs 16.5% NNT 31) from cardiovascular causes, and time to first hospitalization for CHF (12.8% vs 15.6% NNT 36). Safety data for Sacubitril; Losartan found patients experiencing significantly less angioedema, renal impairment, or adverse events leading to discontinuation compared to enalapril. However a significant (18% vs 12%; NNH 17) increase in hypotension was found for patients on Sacubitril; Losartan compared to enalapril.

CONCLUSION: Clinical evidence supports a modest benefit of Sacubitril; Losartan in eligible patients for the treatment of CHF. However, this evidence should be examined in light of a number of limitations that may overestimate effectiveness when used in the general population. First, there is only a single RCT directly comparing Sacubitril; Losartan to guideline therapy. The study population is dominated by white males. Other limitations include: a run-in period, which may have led to an underestimation of the rate of angioedema as these patients were excluded from randomization; and a dose related disparity between groups (max dose of Sacubitril; Losartan versus 10 mg enalapril). Twelve percent (12%) of patients dropped out of the "run-in" phases because of side effects; reported adverse reaction rates are

thus likely lower than would be expected in practice. Publication bias is also a safety concern. Nesiritide a natriuretic peptide agonist has restricted indications due to insufficient evidence to demonstrate benefit and findings of increased mortality. Treatment with Sacubitril; Losartan may cost 10 times more than generic ACE/ARB regimens. Clinicians should interpret these findings cautiously as more research is needed.

Submitting Author: Michael Fotis

Organization: Northwestern University Feinberg School of Medicine

Authors: Primary Author: Tara Marcus PA-S2; Master of Medical Sciences Candidate; Northwestern University Feinberg School of Medicine

Poster #: 15 **Poster Session II, Saturday, April 9, 2016**

Category: Original - Research in Progress

Title: Digoxin and Time to Cardiac-Related Hospitalizations: A Retrospective Cohort Study

Abstract:
Purpose: The purpose of this study is to evaluate the safety of digoxin therapy in patients with atrial fibrillation with and without heart failure. The time to first cardiac-related hospitalization will be documented comparing patients with atrial fibrillation with and without digoxin therapy. Additionally, the safety of digoxin will be further analyzed by evaluating the length of digoxin therapy prior to first cardiac-related hospitalization and digoxin serum concentrations. Finally, a sub-group analysis of patients with and without heart failure will be conducted to determine if concomitant heart failure has any impact.

Methods: This study is a retrospective cohort study with two groups of patients: patients with atrial fibrillation receiving digoxin therapy and patients with atrial fibrillation not receiving digoxin therapy. Cardiac event is defined as any of the following: cardiac arrhythmia, acute myocardial infarction, unstable angina, cardiac arrest, hypertensive urgency/emergency, and cardioembolic stroke. Patients included in the study are those who are 18 years of age and older, with one or more inpatient admission with a primary discharge diagnosis of atrial fibrillation or two or more outpatient, nonemergency department encounters for atrial fibrillation. Patients must also have at least one primary care or cardiology clinic visit. The following data will be collected for each patient: initial diagnosis of atrial fibrillation, patient age and gender, past medical history, start date of digoxin therapy, concurrent medications, date of initial hospitalization with a cardiac primary admission diagnosis, primary admission diagnosis, length of hospitalization, admission to ICU or general acute medicine floor, serum digoxin level, admission renal function, troponin, potassium, magnesium, and most recent height and weight. The data collected will be used to assess the time to first hospitalization in patients with atrial fibrillation with or without digoxin therapy. The time to initial hospitalization will be reported in number of days since atrial fibrillation diagnosis, and will be analyzed using a Cox proportional hazards regression. The secondary endpoints for continuous variables will be reported as percentages, means, and standard deviations, and assessed using a student t-test.

Results: Research in Progress

Conclusions: Research in Progress

Submitting Author: Stephanie Dwyer, PharmD

Organization: Captain James A. Lovell Federal Health Care Center

Authors: Sherri Stoecklein, PharmD, BCPS Informatics Pharmacist Captain James A. Lovell Federal Health Care Center

Poster #: 16 **Poster Session II, Saturday, April 9, 2016**

Category: Original - Research in Progress

Title: Evaluation of fall risk in dementia patients on an atypical antipsychotic in the VA population

Abstract:
Purpose: Antipsychotics are widely used as off-label treatment for behavioral symptoms in dementia patients. It is recognized that antipsychotics can increase the risk for falls in the elderly population. When used in dementia patients, this risk is further increased, since dementia itself is an independent risk factor for falls. A study on the use of antipsychotics in the Veterans Affairs (VA) Community Living Centers (CLC) found that veterans residing in the dementia special care units were more likely to receive an antipsychotic, more commonly atypical antipsychotics. The purpose of this study is to determine whether atypical antipsychotics increase fall risk in dementia patients.

Methods: This study was approved by the Institutional Review Board. This study will be a retrospective cohort study comparing two groups in the VA population: dementia patients receiving atypical antipsychotics versus dementia patients not receiving atypical antipsychotics. The primary endpoint is the difference in the incidence of falls between the two cohort groups. The secondary endpoints are the differences in the incidence of falls between subtypes of dementia, different atypical antipsychotics, and different fall risk as defined by the Morse Scale. Primary endpoint will be analyzed using unpaired t-test, while secondary endpoints will be analyzed through descriptive analysis. The following data will be collected: age, gender, number of other Fall Risk Increasing Drugs (FRIDs), comorbid conditions that can also increase fall risk, subtype of Dementia, type of atypical antipsychotics, fall risk as defined by Morse Scale, and the documented fall. Each patient's chart will be reviewed from admission and up to 6 months, or patient's discharge, or patient's death whichever is the earliest to determine if a documented fall has occurred during that time. Determining fall risk in the dementia population receiving atypical antipsychotics can help prevent inappropriate prescribing of these agents for treatment of behavioral symptoms, leading to decreased fall risk.

Results: Research in Progress

Conclusions: Research in Progress

Submitting Author: Lianna Serbas

Organization: Captain James A. Lovell FHCC

Authors: Lianna Serbas, PharmD PGY1 Pharmacy Resident Capt. James A Lovell FHCC Yinka Alaka, PharmD Pharmacy Clinical Specialist Capt. James A Lovell FHCC

Poster #: 17 **Poster Session II, Saturday, April 9, 2016**

Category: Original - Research in Progress

Title: Oral lorazepam for seizure prophylaxis in adult patients treated with high dose intravenous busulfan before hematopoietic stem cell transplantation: A retrospective study

Abstract:
Purpose: To determine the efficacy of oral lorazepam in preventing seizures in adult patients receiving high dose intravenous busulfan prior to allogeneic hematopoietic stem cell transplant (HSCT).

Methods: This is a single center study conducted at Rush University Medical Center (RUMC) located in Chicago, Illinois. • This retrospective study was approved by the Institutional Review Board prior to data collection. • A stem cell transplant database was used to identify patients who have received allogeneic HSCTs from January 1, 2009 to March 31, 2015. • Patients were included if they were ≥ 18 years old, received intravenous high dose busulfan, received oral lorazepam for seizure prophylaxis. • Patients were excluded only if they received concomitant phenytoin. • RUMC's electronic medical record system and the stem cell transplant database will be used to collect the following: age, sex, race, underlying malignancy, type of transplant, conditioning regimen, dates of busulfan administration, fever during busulfan administration. • Medication charts were reviewed for past medical history of seizures, illegal drug use, AIDS, and CNS malignant disease involvement at or during diagnosis. • The primary endpoint is the occurrence of seizures from the start of busulfan until 72 hours following the completion of busulfan. • Per RUMC policy, patients receive oral lorazepam 0.5 mg every 6 hours starting 24 hours prior to busulfan administration and continuing for 48 hours after the completion of busulfan. • Categorical variables will be analyzed using Chi square or Fischer's Exact test.

Results: Research in progress

Conclusions: Research in progress

Submitting Author: Monica Timmerman

Organization: Midwestern University Chicago College of Pharmacy and Rush University Medical Center

Authors: Lisa M. DiGrazia, PharmD, BCPS, BCOP; Amanda N. Seddon, PharmD, BCPS, BCOP; Annette Gilchrist, PhD

Poster #: 18 **Poster Session II, Saturday, April 9, 2016**

Category: Encore

Title: Antifungal prophylaxis consideration in patients being treated with blinatumomab for Philadelphia chromosome-negative relapsed or refractory b-cell acute lymphoblastic leukemia: a case report.

Abstract:
PURPOSE: The purpose of this case is to illustrate why antifungal prophylaxis should be considered for patients being treated with blinatumomab for Philadelphia chromosome-negative relapsed or refractory B-cell acute lymphoblastic leukemia (ALL). Based on the National Comprehensive Cancer Network (NCCN) guidelines, consideration of antibacterial, antiviral, and antifungal prophylaxis should be considered for ALL patients being treated with chemotherapy. In this case, AL, a 24-year-old female, upon first diagnosis of B-cell acute lymphoblastic leukemia, was initiated on induction chemotherapy with Cancer and Leukemia Group B (CALGB) 10403 protocol. After four cycles, a bone marrow biopsy was performed and her results were consistent with remission. Two months later, during a routine follow-up visit, AL was noted to have worsening pancytopenia. Her bone marrow biopsy results were consistent with relapsed B-cell ALL involving 80% of the marrow space. The patient was then admitted to the hospital to begin re-induction therapy with newly approved blinatumomab. Blinatumomab is a novel agent that activates T cells by binding to both CD19 expressed on B cells and CD3 expressed on T cells, which results in lysis of the CD19 cells. It is recommended that the first 9 days of the first cycle be administered in the hospital to monitor for cytokine release syndrome (CRS). In addition to CRS, other side effects include neurological toxicities, infections, and elevated liver enzymes. As part of her supportive care regimen, AL continued acyclovir for antiviral prophylaxis and was initiated on levofloxacin for antibacterial prophylaxis. Due to patient's pancytopenia, antifungal prophylaxis with an azole antifungal was considered, but due to concern for elevated liver enzymes reported with both blinatumomab and azole antifungals, antifungal prophylaxis was held. AL received the first 9 days of blinatumomab induction therapy inpatient as recommended to monitor for CRS. AL tolerated treatment without any issues and was discharged from the hospital to continue the remainder of blinatumomab therapy at home. One month after the initial induction of blinatumomab, AL was admitted to the emergency department with abdominal pain and headache. AL was afebrile upon admission and blood cultures were obtained. Blood culture results revealed growth of budding yeasts, which was later identified as candida krusei. AL began treatment with micafungin and blinatumomab therapy was discontinued. An infectious disease (ID) team was consulted and due to persistently positive cultures for budding yeast, AL's central line was removed. Cultures of the line were negative. In addition, a transesophageal echocardiogram was obtained, which was negative for valvular vegetation. After five days of failed treatment with micafungin, persistent fever and now newly hypotensive, AL was transitioned to liposomal amphotericin and flucytosine per ID's recommendations and also transferred to the medical intensive care unit (MICU) for sepsis. The following day, AL went into respiratory distress and was intubated. Two days after, liposomal amphotericin and flucytosine was discontinued and voriconazole was initiated. Cultures remained positive for 13 days with fungemia. Given the progressive decline in her condition and poor prognosis, she expired 21 days from when she was transferred to the MICU. As with any new cancer drug, supportive care treatment is not well defined. Although more experience is needed to draw a definitive conclusion, the purpose of this case report is to share our experience and generate discussion about the need for antifungal prophylaxis, and if so which antifungal agent, in patients receiving blinatumomab therapy.

METHODS: n/a RESULTS: n/a CONCLUSION: n/a

Submitting Author: Margaret Lee

Organization: Midwestern University Chicago College of Pharmacy

Authors: Margaret Lee, PharmD Candidate, Midwestern University Chicago College of Pharmacy, Downers Grove, IL; Lisa M. DiGrazia, PharmD, BCPS, BCOP, Amneal Biosciences, Bridgewater, NJ; Amanda N. Seddon, PharmD, BCPS, BCOP, Rush University Medical Center, Chicago, IL

Poster #: 19 **Poster Session II, Saturday, April 9, 2016**

Category: Encore

Title: Differences in Clostridium difficile infection outcomes between guideline concordant and discordant therapy

Abstract:

Purpose: Clostridium difficile infection (CDI) is currently the leading cause of nosocomial infection in the U.S. Treatment modality and prognosis is often based on infection severity; however, severity classifications differ widely among guidelines/severity indices. This study aimed to evaluate the outcomes in guideline concordant and discordant therapy for CDI by defining severity according to IDSA/SHEA (ID), Zar, and modified-ESCMID (ED) severity indices.

Methods: Retrospective, single center study from a 495-bed tertiary medical center evaluating patients admitted with CDI between June 2006 and September 2010. CDI was defined as at least 3 loose stools within a 24-hour period plus a positive diagnostic assay (EIA or PCR). Severe CDI was defined according to the ID, Zar, and ED severity indices. Severe CDI cases treated with vancomycin 125 mg Q6 hours or non-severe CDI cases treated with metronidazole 500 mg Q8 hours were classified as guideline concordant therapy. Other treatment modalities were classified as guideline discordant therapy. Poor outcome (PO) was defined as: recurrent CDI (new-onset of CDI <8 weeks after a previous, successfully treated CDI), treatment failure (requiring treatment modification while on active therapy), or death during admission (all-cause mortality). Significant confounders for PO were identified via bivariate analysis ($p<0.05$) and multivariate logistic regression was used to control for these variables. Goodness-of-fit was assessed via Hosmer-Lemeshow. Statistical analysis was performed via Stata 12.0®. This project has been reviewed and approved by UIC's IRB committee.

Results: A total of 97 CDI cases were included. According to ID, Zar, and ED severity indices, 21%, 42%, and 86% of the cases were classified as severe CDI, respectively. 43%, 34%, and 18% of all cases were treated in concordance with the Zar, and ED indices, respectively. Overall, 24% of patients experienced a PO. Corticosteroid use and duration, current antifungal use, length of stay, baseline white blood cell count, and baseline serum creatinine were considered confounders to PO. Controlling for confounders, the odds of experiencing a PO in the ID-guideline concordant group was 16% (95%CI, -3.26 to -0.04, P=0.044) less than the discordant group. Similarly, the odds of experiencing a PO in the Zar-guideline concordant group was 19% (95%CI, -3.39 to -0.34, P=0.044) less than the discordant group. However, there was no significant difference in PO between ED-guideline concordant and discordant group (OR= -0.59. 95%CI: -2.18 to 0.99, P=0.461). The Hosmer-Lemeshow test showed reliable goodness-of-fit and all models showed good discriminatory ability (AUC>76%).

Conclusions: This is the first study to compare differences in patient outcomes among major severity indices as stratified by guideline concordant and discordant therapy. Adherence to severity classifications and treatment recommendations within the ID and Zar criteria was associated with a decreased risk of PO. In contrast, concordance with the ED guideline did not affect patient outcome. Dictating the treatment of CDI based on the ID or Zar severity index may more reliably predict patient outcomes compared to the ED guideline.

Submitting Author: Surafel Mulugeta

Organization: University of Illinois at Chicago

Authors: 1. Surafel Getachew Mulugeta, PharmD/MS Candidate(1) 2. Eric Wenzler, PharmD, BCPS(1) 3. Melinda M. Soriano, PharmD, BCPS(2) 4. Fred Zar, MD(3) 5. Larry Danziger PharmD, FIDSA(1),(3) (1)Pharmacy Practice, University of Illinois at Chicago, Chicago, IL, (2)Merck Research Labs, Upper Gwynedd, PA, (3)College of Medicine, University of Illinois at Chicago, Chicago, IL

Poster #: 20 **Poster Session II, Saturday, April 9, 2016**

Category: Encore

Title: Implementation of decentralized pharmacy technicians to improve medication delivery and nursing satisfaction

Abstract:
Purpose: To assess the impact decentralized pharmacy technicians (DPTs) can have on the medication delivery process and on nursing satisfaction with the pharmacy service

Methods: A two-week prospective study on one general medicine floor and two intensive care units was conducted between September and October 2015. One decentralized pharmacy technician was assigned to each of these locations Monday through Friday from 9:00 am to 5:30 pm to improve medication availability through timely communication with nursing staff regarding medication procurement issues. Each study floor served as its own control in that data pertinent to the study outcomes was collected in a two-week period preceding the intervention period. The number of medication requests sent to the central pharmacy and the number of medications that required physical pick-up by nurses during the intervention period and the control period were recorded. Nursing satisfaction was surveyed prior to the intervention period and immediately following the intervention period.

Results: Nursing workflow interruptions due to medication retrieval were decreased by 74%. Post-intervention, mean scores for each nursing satisfaction survey question were significantly higher than the pre-intervention period survey ($P < 0.01$ for all five questions). Electronic medication requests sent to central pharmacy did not decrease significantly, 463 and 453 requests were sent during the pre-intervention and intervention periods respectively.

Conclusion: The decentralized pharmacy technician model significantly reduced nursing workflow interruptions and improved nursing satisfaction.

Submitting Author: Whitnee Caldwell

Organization: Northwestern Memorial Hospital

Authors: Whitnee Caldwell, PharmD; Bryan Shaw, PharmD; Fuwang Xu, PharmD; Noelle Chapman, PharmD; Ana Fernandez, CPhT All from Northwestern Memorial Hospital

Poster #: 21 **Poster Session II, Saturday, April 9, 2016**

Category: Student - Research Complete

Title: Effectiveness of Pharmacy Practice Model Initiative Competency

Abstract:

Purpose: The Pharmacy Practice Model Initiative (PPMI) is a national initiative started by the American Health Systems Pharmacists (ASHP) in 2008 to encourage the most effective use of pharmacists allowing for overall advancement in patient care. With regards to pharmacy education, there is a lack of literature discussing PPMI. Such literature would be beneficial for schools of pharmacy in order to assess the best approach to teaching students regarding PPMI. Education of pharmacy students regarding PPMI and the professional goals of advancing patient care can impact healthcare reform and encourage them to advocate for patient care at all stages in their career. In 2013, Pharmacy Practice Model Initiative (PPMI) components were incorporated into Southern Illinois University Edwardsville School of Pharmacy's curriculum. Students partook in an educational activity to learn more about PPMI during their Advanced Pharmacy Practice Experience (APPE) preparatory course in their 3rd year. Additionally, a competency requirement on PPMI was developed for students to complete during their Hospital (APPE). This study's primary objective is to determine the effect of the PPMI competency on students' understanding and discussion of PPMI during their Hospital (APPE).

Methods: A survey of SIUE preceptors who taught hospital APPE rotations was determined to be the most practical approach to obtaining the necessary information regarding student knowledge base of PPMI. A survey was created consisting of primarily short answer questions and yes/no options. The 20 question survey collected the following information: hospital and preceptor demographics, staffing model, staff training, automation/technology systems, pharmacy involvement in PPMI initiatives, and student understanding and discussion of PPMI during the rotation. Inclusion criteria were: Illinois or Missouri SIUE preceptors, taught ≥ 6 hospital APPE students for the academic school year, and agreed to the interview. Exclusion criteria included: those who did not respond or complete the interview. Only one preceptor was selected from each hospital site. Seven preceptors were selected based on the criteria that were eligible to partake in the survey and were subsequently contacted. Preceptors who taught from May 2013-May 2014 were selected to participate.

Results: Six out of the seven preceptors contacted responded and completed the interview. All preceptors interviewed answered every question on the survey. When asked about the average baseline knowledge of their SIUE Hospital APPE rotation students with regards to PPMI on a numerical scale, the responses ranged from 4 to 8.5 (mean ± S.D., 6.4±1.65).When asked about the impact of PPMI within the hospital after discussion with SIUE APPE hospital students, 5 out of 6 preceptors stated that no changes were made based on these discussions. One preceptor noted that three specific ideas for implementing the goals of PPMI were initiated by SIUE APPE students during their hospital rotation. These ideas included: technicians checking the work of other technicians (tech-check-tech), pharmacists managing insulin titrations until physician champion is set, and medication reconciliation done by pharmacy technicians. Another preceptor stated that since there were no changes implemented after student discussions within the 2013-2014 school year, the site decided to adjust the discussion of PPMI to include students filling out the ASHP hospital PPMI survey which allows hospitals to see how well they are doing in terms of implementing PPMI goals.

Conclusions: Based on the study results, the PPMI competency has been shown to be effective due to the majority of students having an appropriate understanding of PPMI according to their preceptors. Future directions could include studying the long term impact of student discussion on PPMI a few years after the rotations and surveying alumni to see how/if the competency impacted their own practice of pharmacy.

Submitting Author: Saba Mohiuddin

Organization: Southern Illinois University Edwardsville School of Pharmacy

Authors: Saba Mohiuddin, PharmD candidate Lisa Lubsch, PharmD, AE-C Jinyang Fan, PharmD, BCPS Dr. Lubsch and Dr. Fan are employed by Southern Illinois University Edwardsville School of Pharmacy.

Poster #: 22 **Poster Session II, Saturday, April 9, 2016**

Category: Student - Research Complete

Title: A Proposal for Interprofessional Home Visits for the Elderly in Rural Communities

Abstract:
Purpose; An assessment of elderly care was conducted in order to recognize the need of reducing cost and increasing quality and access of medical care among elderly patients living in rural counties.

Methods: According to a literature review conducted by pharmacy students, the market analyses indicates that the quality, cost, and access of care for the elderly living in rural Illinois is lower than in urban Illinois.The target area of research was Peoria and Fulton Counties in Illinois. In 2013, Peoria County consisted of 187,000 residents and Fulton County consisted of 36,346 residents. The counties in this study are categorized as rural.

Results: Based on a five star ranking of quality of care, which consists of quality measures, health inspections, staffing ratios and specialty. The overall ranking considers occurrences of bedsores, staff to patient ratio, and amount of specialized personnel. Service ratings in rural resident homes are often poor. This indicates that the need for interprofessional team is required, in order to improve care for rural elderly patients. Rural elderly residents are more likely to go without needed care, which increases their total medical costs due to future hospital or specialty care. Rural residents spend more on out of pocket health care than their urban counterparts. On average, rural residents pay 40 percent of their health care costs out-of-pocket compared to the urban share of 33 percent. Lack of access to healthcare providers for rural patients has been reported to be the biggest barrier, 31 percent were lacking transportation and 37 percent missed their appointments due to transportation issues. The average distance for an elderly person in Illinois to locate a community pharmacy was 0.9 miles in urban areas, but it was six times more (5.9 miles) in rural areas. At least 10 percent of the rural elderly had to travel more than 12 miles to find a community pharmacy.

Conclusions: Based on the review of the literature, our proposal is to incorporate pharmacists and other healthcare workers into interprofessional teams for home visits to the elderly living in rural areas. This team will be composed of physicians, pharmacists, nurses, and social workers who travel to patients. The team will propose a healthcare plan for each patient, and based on diagnosis, can determine a plan of action. Additionally, we propose for these interprofessional teams to offer general medical needs, such as blood glucose screenings, medication therapy reviews and patient counseling. This can be conducted in city centers or central points of counties that are easily accessible and open to elders living in that county. Our proposed services would help lower medical cost and increase access and quality to the elderly population in rural areas.

Submitting Author: Katarzyna Plis

Organization: Roosevelt University College of Pharmacy

Authors: Katarzyna Plis, Danielle Cilano, Sarah Bay, Rimple Patel, PharmD Candidates at Roosevelt University College of Pharmacy Abby Kahaleh, BPharm, MS, PhD, MPH Faculty at Roosevelt University College of Pharmacy

Poster #: 23 **Poster Session II, Saturday, April 9, 2016**

Category: Student - Research in Progress

Title: Comparison of oral morphine equivalent doses vs. PHQ9 scores in a family practice setting

Abstract:
Purpose: Determine if a pharmacist is able to decrease opioid use without worsening PHQ9 scores.

Methods: This retrospective chart review evaluates a sample size of 271 patients receiving pain management by a pharmacist in a family practice setting in southern Illinois. The primary outcome is to determine if decreasing oral morphine equivalent doses increases PHQ9 scores. Opioid use (measured by the oral morphine dose) and depression (measured by PHQ9 scores) were calculated for each patient visit and compared over a two year time frame.

Results: Research in Progress

Conclusions: Research in Progress

Submitting Author: Lauren Kirkpatrick

Organization: Southern Illinois University Edwardsville

Authors: Lauren Ashley Kirkpatrick, PharmD candidate 2016, Southern Illinois University Edwardsville
Chris Herndon, PharmD, BCPS, CPE, FASHP Southern Illinois University Edwardsville

Poster #: 24 **Poster Session II, Saturday, April 9, 2016**

Category: Student - Research in Progress

Title: Desmopressin (DDAVP) Dose Changes Post Discharge in Pediatric Patients with Diabetes Insipidus Receiving Oral DDAVP Compounded from Nasal Spray Inpatient

Abstract:

Purpose: The purpose of this study is to evaluate desmopressin (DDAVP) dose changes among diabetes insipidus (DI) pediatric patients receiving oral DDAVP solution formulated using DDAVP nasal spray. DDAVP is not commercially available as an oral liquid in the United States.1 This is problematic for pediatric patients unable to swallow whole tablets. Consequently, many caregivers must resort to extemporaneously compounding a DDAVP solution prior to immediate use. Comparing the effect of both formulations, oral tablets and solution compounded from tablets, on decreasing urine volume and increasing urine osmolality have produced equivalent results.2 However, many institutions utilize a compounding recipe that uses desmopressin nasal spray to produce an oral solution that has a 30 day shelf life.3 Following the inpatient administration of this formulation, however, the Pediatric Endocrinology service at the University of Chicago observed that preadmission desmopressin doses were no longer adequate post discharge. 1. Desmopressin. Micromedex 2.0. Truven Health Analytics, Inc. Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed December 20, 2015. 2. Argenti D, Ireland D, & Heald DL. A pharmacokinetic and pharmacodynamics comparison of desmopressin administered as whole, chewed, and crushed tablets, and as an oral solution. J Urol. 2001;165(5):1446-51. 3. Michigan Pediatric Safety Collaboration to Standardize Compounded Oral Liquids. University of Michigan College of Pharmacy. Available at: http://www.mipedscompounds.org. Accessed December 21, 2015.

Methods: This single center retrospective study evaluated the medical records of pediatric patients who received DDAVP oral solution compounded from DDAVP nasal spray. The observation period took place between January 1, 2013 and August 7, 2015. Only patients who received oral desmopressin before admission and after discharge were included in the study. Additionally, a two-month refill history of oral desmopressin tablets with instructions for extemporaneous compounding before and after discharge was required. Patients undergoing neurosurgical procedures and displaying acute renal impairment were excluded. Doses were then tabulated and analyzed using descriptive statistics.

Results: Research in Progress

Conclusions: Research in Progress

Submitting Author: Gennaro Paolella

Organization: University of Chicago

Authors: Gennaro Anthony Paolella, BS Pharmacy Student, University of Illinois at Chicago Pharmacy Student - Technician, University of Chicago Shannon Rotolo, PharmD, BCPS Clinical Pharmacist - General Pediatrics University of Chicago

Successfully Leading Change in Healthcare Organizations

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The speakers have no conflicts of interest to disclose.

Successfully Leading Change in Healthcare Organizations

Major Change Drivers in Healthcare Organizations

Ryan Loudermilk, MHA, R.T.(R)(T)
Performance Improvement Specialist
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What are Major Change Drivers in Healthcare?

- o EMR Implementation/Changes
- o Joint Commission standard changes
- o Legislative changes
- o Patient Safety
- o Cost
- o Others?

What are the Risks to Change?

- ⇨ FAILURE IS EXPENSIVE 
- ⇨ Wasted Time/Money/ People 
- ⇨ Loss of Morale 
- ⇨ Missed Opportunities
- ⇨ Decreased chance for other changes 

Why is Change often Difficult?

"There is nothing more difficult to take in hand, more perilous to conduct, or more uncertain in its success, than to take the lead in the introduction of a new order of things" – *Niccolo Machiavelli*

- Fear of the unknown
- Previous failures
- It's challenging
- Easier to stay the same
- Often unpopular
- Other?

Various Roles of Change Management

- Change Sponsors
- Change Agents ⇨
- Change Liasons
- Change Targets

Burning Platform

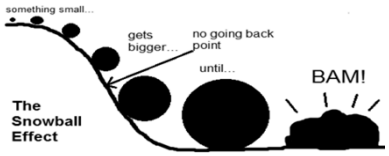
- Define why the change needs to happen
  - What's the pain?
  - Why move?
  - What's the benefit?

Communication

- 1st Priority when beginning a change
- Have a communication plan labeling various stakeholders
- Update plan as needed

Resistance

- Resistance can be viewed as a snowball- if left unchecked it can grow too large to control



Successfully Leading Change in Healthcare Organizations

Communications and Stakeholders in Change Management

Michelle M Smith, PharmD, FACHE

Goals

- Understand why communication is a key to Change Management
- Identify the tips and pitfalls to communication
- Review who the key players are in delivering and receiving communication to support a successful change process

Communicating Change

Example #1

- Creating a two-state System Pharmacy and Therapeutics Committee
  - Key to standard EHR implementation and various standardization processes
  - What is the communication
  - Who is involved

System P&T Example

- The process was identified, but what were the critical steps to getting this together?
  - ✓Who were the key people that needed to be involved?
  - ✓Who should be making the request
  - ✓What were the best ways to communicate the ask and then the process

Tips for Communicating Change

- There is no “perfect” way to communicate
- Start by asking what is changing and why
- Know what results you want from initiative and communication
- Include Communication leaders if the change is related to Strategy
- Share information with employees as soon as possible
- Quantity vs. Quality and Consistency
- Use a variety of communication vehicles
- Don’t confuse the process with communication
- Allow opportunities for concerns, questions and alternate ideas and consistently follow-up with answers and updates

Strategies Used in the Past

- Spray and Pray – give information and hope it would be sifted to employees
- Tell and Sell – give out only what management considers relevant
- Underscore and Explore – give out basic info and give employees freedom to figure out the puzzle
- Identify and Rely – wait on concerns of workers and address appropriately
- Withhold and upload – withhold information as much as possible, then when confronted with questions / rumors uphold the official position

Key Principles

- Effective communication is the single most important tool in facilitating organizational change
- Stakeholder acceptance and buy-in cannot happen with out effective communication
- Effective Communication is a two-way dialogue and alignment of interests
- It is more than sending out e-mails and holding a meeting

System P&T Example

- Review concept with 14 Pharmacy Directors
- Recommendation made to System Leadership Team due to System Standard build of EHR
- Individual Calls with Division Presidents and Chief Physician Executives
- What was the most effective method of communicating?

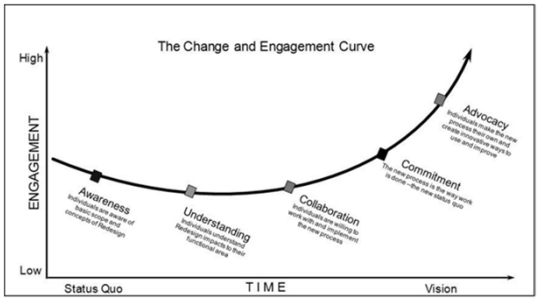
System P&T Example

- What were we communicating
- Why was it important
- How deep in the organization did we need to communicate
- What were the barriers to getting this process put in place

Effective Change Communication Includes:

- Overall strategy – pulls people along the change curve, gives them information before they realize the need or want it
- Coordination – across content and timing
- Effective mix of mediums
- Targeting messages to specific audiences
- Using key leaders to convey details and concerns
- The ability to gather input, feedback and concerns from the organization

The Change Curve



Question

- **What is the Role of Communications during change?**

A) Explain why change is happening
B) Show people where they are going
C) Show people how they will get there
D) All of the above

Basic Communication Strategies

- Communicate through managers / supervisors and to direct end users
- Target influential people – identify change leaders and early adopters in the field
- Establish two way communication so that everyone feels valued and create buy-in
- Fulfill information needs of various stakeholders and end users by pulling them along the change curve

Lean Communications Planning Matrix

CHANNEL	BEGINNING Rollout	MIDDLE PHASE Manage Expectations	IMPLEMENTATION Detailed Information	LESSONS LEARNED / FEEDBACK Monitor Progress
WRITTEN:				
Email				
Newsletter				
Bulletin Board				
Memo				
ORAL:				
One-on-One Meetings				
Group Meeting				
Focus Group / Surveys				

Elevator Speech

Target Audience	Message
Leadership	
Colleagues	

Who are the Stakeholders

- Project Sponsors / Steering Teams
- Executive Staff
- Functional Directors / Dept Managers
- Change agents / influencers
- End users
- External Stakeholders*

Why are the Stakeholders Important

- Stakeholders
  - Ensure active support and change leadership from appropriate senior management
  - Increase business involvement
  - Engage critical management levels
  - Target key messages to different groups
  - Maximize buy-in and ownership prior to GO LIVE of the project

Question

- What is NOT the role of the Leader?

A) Organize meetings and delegate work
B) Provide direction and reassurance
C) Communicates regularly and timely
D) Listens to people's concerns

Communication vs. Engagement

- Communications are things that are published, spoken or sent mainly passively and on occasion unidirectional messages
- Engagement activities are dynamic interactions between two or more people
- Both are needed for effective change management

Communication vs. Engagement

- E-mails
- Videos
- Newsletters
- Handouts
- Intranet postings
- Voicemail messages
- Bulletin board posts
- Large scale conference calls
- Presentation materials
- Meetings and work sessions
- Q&A sessions
- Interviews / Focus groups
- Town-hall meetings
- Phone conversations
- Lunch and Learn events
- Small scale meetings / virtual meetings
- Informal drop by / hallway conversations

Some fun with Communication

Successfully Leading Change
in Healthcare Organizations

What's so Challenging about Change?

Sheila Fain, RN, MS
Director, Consulting Services
LaMarsh Global

Image of pie. Retrieved from http://shannondonnelly.com/2012/04/23/cliches-easy-as-pie/

Notice of Disclosure

Planners and presenters of this professional development educational series offered through the ICHP – IL and ACHE have indicated they have no conflicts of interest.

Conflict of Interest: The presence of any potentially biasing relationship of a financial, professional or personal nature

**A conflict of interest Disclosure Statement has been submitted to the ICHP - IL*

Objectives

- Identify the challenges the change process will present to the organization and those it serves.
- Discuss how to sustain organizational change in the short term and long term.

WHAT ARE WE TRYING TO CHANGE?

R = Qs x A
Results = Quality of Solution x Its Acceptance

People and their behaviors are responsible for over 50% of project failures or delivery shortcomings!

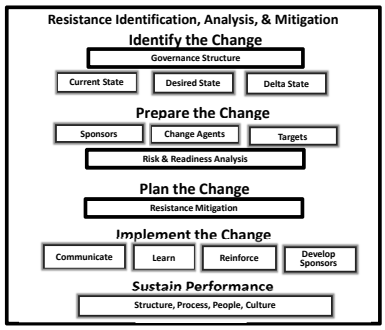
MANAGE RESISTANCE TO MANAGE CHANGE

- Resistance
  - Resistance is:
    - Natural
    - Normal
    - Logical
  - It is predictable
  - It can be reduced

Image of girl and pony. Retrieved from http://breatheandsmile.org/move-towards-resistance/

CHALLENGES

Managed Change™ Model



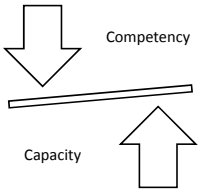
CHALLENGES

- Capability
  - Capacity + Competency
- Planning
  - Underestimating effort
  - Fail to manage distractions
  - Fail to understand impact on business
- Leadership
  - Alignment
  - Engagement/Commitment
  - Culture
- People
  - Engagement/commitment
  - Culture

Image citations on following slides

CHALLENGES - CAPABILITY

- Identify resources
  - Project Management
  - Change Management
  - Leadership
  - Subject Matter Experts
  - Employees
  - Performance Improvement, IT, HR, Communications, Learning
- Match the skill level of resources to project needs
- Clear schedules of project resources



CHALLENGES - PLANNING

- Estimate the effort
  - Impact Assessment
  - Risk and Readiness Assessment
    - 13 Critical Success Factors
- Manage competing priorities
  - Other change efforts
- Understand impact on business
  - Delta Dip
  - Compounding impact of changes

Image of plan. Retrieved from http://www.wtdynamics.co.uk/Blog/ArticleID/70/Time-to-Plan

CHALLENGES - LEADERSHIP

- Executive Sponsor
- Sponsor Alignment
  - Target issues
- Engagement/Commitment
- Culture
  - Availability
  - Listening
  - Targeted interventions

Image of leadership. Retrieved from http://www.thelivingleader.com/wp-content/uploads/leadership.jpg

What Am I Listening For?

"Most people do not listen with the intent to understand; they listen with the intent to reply."

Stephen Covey

Image of boy listening. Retrieved from https://onewildword.files.wordpress.com/2012/05/little-boy-listening.jpg

CHALLENGES – PEOPLE

- Understand the change
  - Why? What? How?
  - Impact on me
  - What's in it for me?
  - History
  - Culture
- Engagement/commitment
- Culture
  - Victim mentality
  - Feedback
  - Reinforcement

Organizations change because individuals change

Image of people. Retrieved from http://img.bllcdn.com/images/people/bayt-people-home.jpg

SUSTAINING THE CHANGE

Sustainment

- Starts when Desired State is achieved i.e. the goals of the change have been met not that the solution has been installed
- Requires planning, structure and effort
- Plan for sustainment at the beginning of the change effort
- Owned by operations, not the project team
- Targeted effort lasts for at least 6 months

Short Term Requirements

- Operations owns the Desired State, not the project team
- All stakeholders are aligned to the new normal
- There is a plan to ensure the organization does not revert back to the previous state
- Responsibility for any unfinished project or change work has been assigned to the business

Image of signs. Retrieved from http://fm.cnbc.com/applications/cnbc.com/resources/img/editorial/2014/10/15/102091053-short-term-long-term.1910x1000.jpg

Long Term Requirements

- Leadership is aligned to and fully capable of maintaining the new normal
- Employees are aligned to and fully capable of working in the new normal
- All performance related issues associated with people choosing not to change have been resolved
- The sustainment plan includes a mechanism to detect the need for future improvements
- HR and managers are able to hire, select, develop and promote employees that will flourish in the new normal
- Unfinished project or change work is complete

Image of signs. Retrieved from http://fm.cnbc.com/applications/cnbc.com/resources/img/editorial/2014/10/15/102091053-short-term-long-term.1910x1000.jpg

Today's competitive edge is an organization's ability to manage and leverage change effectively

Question

- Organizations change because:

A) People change
B) Leadership tells them to
C) They like making changes
D) It's easy

Question

- Once the goals of a change have been met you have reached the Desired State and are ready to move into sustainment. How long should the focus on sustainment last to ensure it becomes the new normal?

A) 1 month
B) 3 months
C) At least 6 months
D) 2 years

ANY QUESTIONS?

Image of question. Retrieved from http://abovethelaw.com/wp-content/uploads/2014/07/lawyer-question-mark-head.jpg

Resources

Videos Link to all resources
- Changing the Way Change Happens
- What Do You Do If You Don't Have Time for Change Management?
- 6 Lessons Learned from Failed Change Projects
- 3 Ways Change Management Improves Business Strategy

Blogs Link to all blogs
- 5 Pillars Needed to Build a Change Management Core Competency
- 7 Emotional Phases Employees Go Through During Change
- 6 Guidelines to Determine Change Management Scalability
- 4 Action Plans to Address Resistance to Change
- 4 Tips to Survive the Delta State
- 5 Critical Factors That Affect Whether or Not Change is Successful

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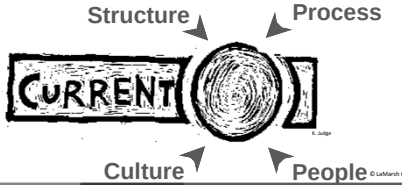
Appendix

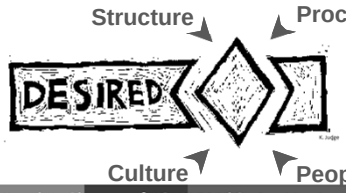
Resistance Source – Current State

- The people impacted by change need a clear understanding of the reasons why they need to change. Not just why the organization needs this change but, why they as individuals need to make the change.
- If targets of change do not understand and accept……not necessarily agree with but accept the reasons for change there will be resistance.
- Think resistance to leaving the Current State.



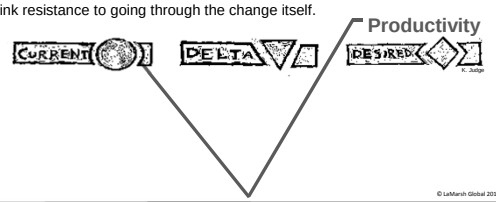
Resistance Source – Desired State

- Targets of change will have many questions about what the future will look like and specifically how it will impact their day to day activities. It is unlikely that you will have all of the answers at first.
- You must share what you do know as early as possible and continuously work to create that clear Desired State description and share it with targets.
- Think resistance to being in the Desired State.



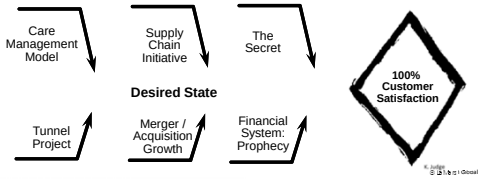
Resistance Source – Delta Dip

- As targets start to make the change in the Delta State, it is expected that performance, quality, productivity, etc. will take a dip.
- The change management team is responsible for predicting the impact of the change on the day-to-day business, understanding how much of a dip in key operational metrics the organization can absorb, mitigating the risk and monitoring and reacting to the impact as the change occurs.
- Think resistance to going through the change itself.



Resistance Source – Concurrent Changes

- Each project should be integrated with other changes impacting the targets of your change.
- The change management team is responsible for addressing conflicts between their change project and other projects. The Sponsor often plays a key role in addressing these conflicts.
- Think resistance due to too many changes at once.



Resistance Source – Key Roles

- When a person is impacted by a change, they will find themselves playing at least one of the Key Roles (Sponsor, Change Agent, Target). It is not uncommon to play multiple roles.
- If the role is not well understood and managed, resistance will result.
- Think:
  - the (perceived) lack of wiliness or ability of leaders to act as effective Sponsors
  - the (perceived) lack of willingness or ability of the Change Agents to do their job well
  - a natural reluctance on the part of any given Target or Target group to change

Change Sponsors

Change Agents

Change Targets

Resistance Source – History

- Our experience with past changes especially changes like the ones facing us right now frames our opinion about how the current change will be managed.
- Our perception of that experience is our reality.
- Think mistrust or concerns developed over time as a result of experience with past changes and how they were handled.

Targets have learned that change is either

MANAGED WELL

OR

MANAGED POORLY

Resistance Source – Culture

- The culture of an organization is the final source of potential resistance to change.
- Do current beliefs and behaviors support the change being proposed?
- Think the unwillingness to give up current beliefs and behaviors and adopt new ones thus change the culture
  - How we behave
  - What we believe
  - Rules we follow:
    - In rule book
    - Unwritten rules

Out with the old, in with the new: what essential updates in geriatrics should you learn in 60 minutes?

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I have no actual or potential conflicts of interest to disclose

Disclaimer

This presentation is based on the current literature and practice guidelines available at the time of slide preparation. I am not here as a representative of the VA and any opinions expressed are my own and do not necessarily represent the views of the Department of Veterans Affairs or the United States of America.

Learning Objectives for Pharmacists

1. Explain the basics of the Beers criteria such as the organization that compiles it, where to access it, and available companion papers.
2. Describe recent key changes to Beers criteria with focus on evidence and recommendations for nitrofurantoin, digoxin, proton pump inhibitors, insomnia medications, drug-drug interactions, and renal dosing tables.
3. Review recent changes to the pneumonia vaccination recommendations for older adults.

Learning Objectives for Pharmacy Technicians

1. Explain the basics of the Beers criteria such as the organization that compiles it, where to access it, and available companion papers.
2. Identify recent key changes to the Beers criteria.
3. Recognize recent changes to the pneumonia vaccination recommendations for older adults.

Beers Criteria History

Original Beers Criteria – 1991

– Explicit criteria for determining inappropriate medication use in nursing home residents

1997

– Expanded to all adults older than 65 years

2003

2012

– American Geriatrics Society took ownership

2015

What is the purpose of the 2015 Beers Criteria?

- Identify potentially inappropriate medications that should be avoided in many older adults
- Reduce adverse drug events and drug related problems
- Improve medication selection in older adults
- Designed for use in any clinical setting; also used as an educational, quality, and research tool
  - Not applicable to hospice and palliative care

Key Changes with Updates

2012 Update

- Rigorous evidence based approach
- Major expansion of drug-disease interactions
- Drugs to use *with caution*

2015 Update

- Dose adjustments based on renal function
- Drug-Drug Interactions
- Companion Papers
  - How to use the Beers criteria
  - Alternatives

2015 Criteria Literature Search

Initial search identified 20,748 citations

↓

Preliminary abstract review 6,719 citations

↓

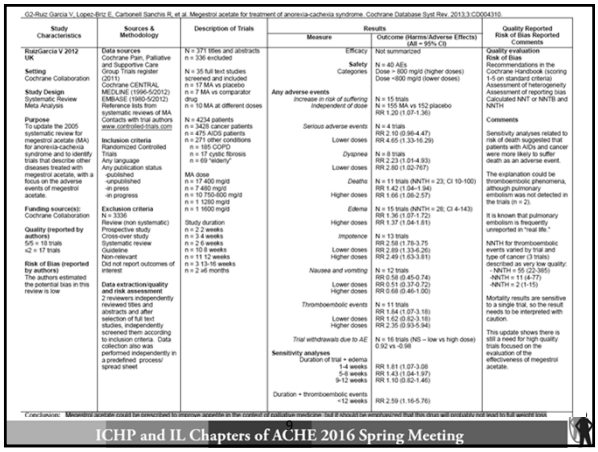
Reviewed by co-chairs 3387 citations

↓

Full panel review 1188 citations

↓

Creation of evidence tables 342 citations



Oz-Ruiz Garcia V, Lopez-Briz E, Carbonell Sanchis R, et al. Megestrol acetate for treatment of anorexia-cachexia syndrome. Cochrane Database Syst Rev. 2013;3:CD004310.

Study Characteristics	Sources & Methodology	Description of Trials	Results: Measure	Results: Outcome (Harms/Adverse Effects) (All + 95% CI)	Quality Reported Risk of Bias Reported Comments
RuizGarcia V 2012 UK **Setting** Cochrane Collaboration **Study Design** Systematic Review Meta Analysis **Purpose** To update the 2005 systematic review for megestrol acetate (MA) for anorexia-cachexia syndrome and to identify trials that describe other diseases treated with megestrol acetate, with a focus on the adverse events of megestrol acetate. **Funding source(s):** Cochrane Collaboration **Quality (reported by authors)** 5/5 = 18 trials +2 = 17 trials **Risk of Bias (reported by authors)** The authors estimated the potential bias in this review is low	**Data sources** Cochrane Pain, Palliative and Supportive Care Group Trials register (2011) Cochrane CENTRAL MEDLINE (1966-5/2012) EMBASE (1960-5/2012) Reference lists from systematic reviews of MA Contacts with trial authors www.controlled-trials.com **Inclusion criteria** Randomized Controlled Trials Any language Any publication status -published -unpublished -in press -in progress **Exclusion criteria** N = 3336 Review (non systematic) Prospective study Cross-over study Systematic review Guideline Non-relevant Did not report outcomes of interest **Data extraction/quality and risk assessment** 2 reviewers independently reviewed titles and abstracts and after selection of full text studies, independently screened them according to inclusion criteria. Data collection also was performed independently in a predefined process/ spread sheet	N = 371 titles and abstracts n = 336 excluded N = 35 full text studies screened and included n = 17 MA vs placebo n = 7 MA vs comparator drug n = 10 MA at different doses N = 4234 patients n = 3428 cancer patients n = 475 AIDS patients n = 271 other conditions n = 185 COPD n = 17 cystic fibrosis n = 69 "elderly" MA dose n = 17 400 mg/d n = 7 480 mg/d n = 10 750-800 mg/d n = 1 1280 mg/d n = 1 1600 mg/d Study duration n = 2 2 weeks n = 3 4 weeks n = 2 6 weeks n = 10 8 weeks n = 11 12 weeks n = 3 13-16 weeks n = 2 ≥6 months	*Efficacy* **Safety** *Categories* **Any adverse events** *Increase in risk of suffering independent of dose* *Serious adverse events* *Lower doses* *Dyspnea* *Lower doses* *Deaths* *Higher doses* *Edema* *Higher doses* *Impotence* *Lower doses* *Higher doses* *Nausea and vomiting* *Lower doses* *Higher doses* *Thromboembolic events* *Lower doses* *Higher doses* *Trial withdrawals due to AE* **Sensitivity analyses** Duration of trial + edema 1-4 weeks 5-8 weeks 9-12 weeks Duration + thromboembolic events <12 weeks	Not summarized N = 40 AEs Dose > 800 mg/d (higher doses) Dose <800 mg/d (lower doses) N = 15 trials N = 155 MA vs 152 placebo RR 1.20 (1.07-1.36) N = 4 trials RR 2.10 (0.96-4.47) RR 4.65 (1.33-16.29) N = 8 trials RR 2.23 (1.01-4.93) RR 2.60 (1.02-767) N = 11 trials (NNTH = 23; CI 10-100) RR 1.42 (1.04-1.94) RR 1.66 (1.06-2.57) N = 15 trials (NNTH = 28; CI 4-143) RR 1.36 (1.07-1.72) RR 1.37 (1.04-1.81) N = 13 trials RR 2.58 (1.78-3.75 RR 2.89 (1.33-6.26) RR 2.49 (1.63-3.81) N = 12 trials RR 0.58 (0.45-0.74) RR 0.51 (0.37-0.72) RR 0.68 (0.46-1.00) N = 11 trials RR 1.84 (1.07-3.16) RR 1.62 (0.82-3.18) RR 2.35 (0.93-5.94) N = 16 trials (NS – low vs high dose) 0.92 vs -0.96 RR 1.81 (1.07-3.08 RR 1.43 (1.04-1.97) RR 1.10 (0.82-1.46) RR 2.59 (1.16-5.76)	**Quality evaluation** **Risk of Bias** Recommendations in the Cochrane Handbook (scoring 1-6 on standard criteria) Assessment of heterogeneity Assessment of reporting bias Calculated NNT or NNTB and NNTH **Comments** Sensitivity analyses related to risk of death suggested that patients with AIDs and cancer were more likely to suffer death as an adverse event. The explanation could be thromboembolic phenomena, although pulmonary embolism was not detected in the trials (n = 2). It is known that pulmonary embolism is frequently unreported in "real life." NNTH for thromboembolic events varied by trial and type of cancer (3 trials) described as very low quality: - NNTH = 55 (22-385) -NNTH = 11 (4-77) - NNTH = 2 (1-15) Mortality results are sensitive to a single trial, so the result needs to be interpreted with caution. This update shows there is still a need for high quality trials focused on the evaluation of the effectiveness of megestrol acetate.

Conclusions: Megestrol acetate could be prescribed to improve appetite in the context of palliative medicine, but it should be emphasized that this drug will probably not lead to full weight look.

Key Tables in the 2015 Criteria

- Table 2 – Potentially inappropriate drugs
  - Organized by organ system and therapeutic category
- Table 3 – Drug-Disease or Drug-Syndrome
- Table 4 – Medications to use with caution
- Table 5 – Drug-Drug Interactions (NEW)
  - Non anti-infectives
- Table 6 – Renal dosing table (NEW)
  - Non anti-infectives

Beers Criteria Changes - Nitrofurantoin

Organ System, Therapeutic Category, Drugs	Rationale	Recommendation	Quality of Evidence/ Strength of Recommendation
Anti-infective -Nitrofurantoin	Potential for pulmonary toxicity, hepatic toxicity and peripheral neuropathy	AVOID in patients with CrCl <30 ml/min AVOID long-term suppression 2012 Criteria: CrCl < 60 ml/min	Low/Strong

Beers Criteria Changes – Cardiovascular Drugs

Organ System, Therapeutic Category, Drugs	Rationale	Recommendation	Quality of Evidence/ Strength of Recommendation
Cardiovascular -Dronaderone	Worse outcomes reported in patients who have permanent atrial fibrillation, severe or recently decompensated heart failure	AVOID	Low/Strong
-Digoxin	For A. Fibrillation – may be associated with increased mortality	AVOID as first line therapy in atrial fibrillation	Moderate/Strong

Beers Criteria Changes - Digoxin

Organ System, Therapeutic Category, Drugs	Rationale	Recommendation	Quality of Evidence/ Strength of Rec.
Cardiovascular -Digoxin	Use in Heart Failure: ? Effects on risk of hospitalization and maybe associated with increased risk of mortality Higher doses – no additional benefit and may increase risk of toxicity Decreased renal clearance, may lead to ↑ risk of toxicity	AVOID as first line therapy for heart failure If used for A. Fib or heart failure, avoid >0.125 mg/d	Low/Strong Moderate/ Strong

Beers Criteria Changes – Antiarrhythmics

Organ System, Therapeutic Category, Drugs	Rationale	Recommendation	Quality of Evidence/ Strength of Rec.
Cardiovascular -Amiodarone	Amiodarone is effective for maintaining sinus rhythm but has greater toxicities than other antiarrhythmics	AVOID as first line unless patient also has heart failure or sig. LVH	High/ Strong
Antiarrhythmic drugs (Class Ia, Ic, III) : Avoid use as 1st line agents for A. Fib - 2012 Criteria. Removed in 2015 criteria, because new evidence and guidelines that suggest rhythm control may have equal or favorable outcomes compared with rate control.			

Assessment Question

- Which of the following is a medication related update in the 2015 Beers criteria?

A.) Amiodarone is definitely inappropriate to use in atrial fibrillation

B.) Nitrofurantoin can be considered for use if CrCl >30ml/min

C.) Digoxin should be avoided as 2nd line therapy for heart failure

D.) Digoxin should be avoided as 2nd line therapy for atrial fibrillation

Beers Criteria Changes – Non-Benzodiazepine Sedative Hypnotics

Organ System, Therapeutic Category, Drugs	Rationale	Recommendation	Quality of Evidence/ Strength of Rec.
CNS Medications: Nonbenzodiazepine, benzodiazepine receptor agonist hypnotics -Eszopiclone -Zolpidem -Zaleplon	Adverse events similar to those of BZDs in older adults (e.g., delirium, falls, fractures) Increased emergency room visits/hospitalizations Motor vehicle crashes Minimal improvement in sleep latency and duration	AVOID	Moderate/ Strong
Beers Criteria 2012: Avoid chronic use (>90 days) Also added to Table 3 to avoid with dementia or cognitive impairment			

Beers Criteria New Addition – PPI's and Desmopressin

Organ System, Therapeutic Category, Drugs	Rationale	Recommendation	Quality of Evidence/ Strength of Rec.
Gastrointestinal: Proton-pump inhibitors	Risk of C difficile infection , bone loss and fractures	Avoid use for > 8 weeks unless patient is considered high risk (corticosteroids or chronic NSAID use, Barrett's esophagitis, pathological hypersecretory condition, need for maintenance tx).	High/Strong
Genitourinary: Desmopressin	High risk of hyponatremia; safer alternative treatments	Avoid for treatment of nocturia or nocturnal polyuria	Moderate/ Strong

Beers Criteria Changes – SSI and Megestrol

Organ System, Therapeutic Category, Drugs	Rationale	Recommendation	Quality of Evidence/ Strength of Rec.
Insulin, Sliding scale	Higher risk of hypoglycemia without improvement in hyperglycemia management. Short or rapid acting insulins: Not to be used as a sole agent to manage hyperglycemia in the absence of basal or long-acting insulins	AVOID	Moderate/ Strong
Megestrol	Minimal effect on weight; Increases risk of thrombotic events and possible death	AVOID	Moderate/ Strong

Beers Criteria Changes – Drug-Disease Interactions

Disease or Syndrome	Drug(s)	Rationale	Recommendation Quality of Evidence/ Strength of Rec.
Delirium	Anticholinergics Antipsychotics BZDs Chlorpromazine Corticosteroids H2-receptor antagonists Meperidine Sedative hypnotics	-Potential to induce or worsen delirium -Avoid antipsychotic use for behavioral problems of dementia or delirium unless nonpharmacological interventions failed or not possible and the older adult is threatening substantial harm to self or others -Increased risk of CVA and mortality	AVOID Moderate/Strong

Beers Criteria Changes – Drug Disease Interactions

Disease or Syndrome	Drug(s)	Rationale	Recommendation Quality of Evidence/ Strength of Rec.
History of falls or fractures	Anticonvulsants Antipsychotics BZDs Nonbenzodiazepine, benzodiazepine receptor agonist hypnotics TCAs SSRIs Opioids	-May cause ataxia, impaired psychomotor functions, syncope, additional falls -Short-acting BZDs are not safer than long-acting BZDs Consider reducing use of other CNS active meds	-AVOID unless safer alternatives are not available -AVOID anticonvulsants except for seizure and mood disorders -AVOID opioids unless acute pain mgmt. due to fractures or joint replacement

Assessment Question

- Which psychotropic medication has recently been linked to the highest number of ED visits amongst older adults?

A.) Lorazepam
B.) Quetiapine
C.) Citalopram
D.) Zolpidem

Table 5: Drug-Drug Interactions

Object Drug/Class	Interacting Drug/Class	Rationale	Recommendation	Quality of Evidence/ Strength of Rec.
Alpha-1 blockers, peripheral	Loop Diuretics	↑ risk of urinary incontinence in older women	Avoid in older women, unless condition warrants both drugs	Moderate/ Strong
ACEIs	Amiloride or Triamterene	↑ hyperkalemia	Avoid routine use; reserve for hypokalemia on ACEI	Moderate/ Strong
Anticholinergic	Anticholinergic	↑ risk of cognitive decline	Avoid, minimize # of anticholinergic meds	Moderate/ Strong
Corticosteroids	NSAIDS	↑ risk of peptic ulcer disease / GI bleed	Avoid; if not possible, provide GI protection	Moderate / Strong

Table 5: Drug-Drug Interactions

Object Drug/Class	Interacting Drug/Class	Rationale	Recommendation	Quality of Evidence/ Strength of Rec.
Antipsychotic	2 or more other CNS drugs	↑ risk of falls	Avoid 3 or more CNS drugs, minimize # of CNS drugs	Mod. / Strong
Benzos and benzo receptor agonists	2 or more other CNS drugs	↑ risk of falls	Avoid 3 or more CNS drugs, minimize # of CNS drugs	High / Strong
Opioid Analgesics	2 or more other CNS drugs	↑ risk of falls	Avoid 3 or more CNS drugs, minimize # of CNS drugs	High / Strong
Antidepressant	2 or more other CNS drugs	↑ risk of falls	Avoid 3 or more CNS drugs, minimize the number of CNS drugs	Mod./ Strong

Table 5: Drug-Drug Interactions

Object Drug/Class	Interacting Drug/Class	Rationale	Recommendation	Quality of Evidence/ Strength of Rec.
Warfarin	Amiodarone	↑ risk of bleeding	Avoid when possible; monitor INR closely	Mod. / Strong
Warfarin	NSAIDS	↑ risk of bleeding	Avoid when possible; if used together – monitor closely for bleeding	High / Strong
Theophylline	Cimetidine	↑ theophylline toxicity	Avoid	Mod. / Strong
Lithium	ACEIs and Loop Diuretics	↑ toxicity	Avoid, monitor lithium concentrations	Mod./ Strong

Table 6: Renal Dosing Table

Medication	CrCl (ml/min) at which action is required	Rationale	Recommendation	Quality of Evidence / Strength of Rec.
Apixaban	<25	Increased bleeding	Avoid	Moderate/Strong
Dabigatran	<30	Increased bleeding	Avoid	Moderate/Strong
Rivaroxaban	30-50	Increased bleeding	Reduce dose	Moderate/Strong
	<30		Avoid	
Edoxaban	30-50	Increased bleeding	Reduce dose	Moderate/Strong
	<30 or >95	↑Bleed / ↓efficacy	Avoid	
Enoxaparin	<30	Increased bleeding	Reduce dose	Moderate/Strong
Fondaparinux	<30	Increased bleeding	Avoid	Moderate/Strong

Table 6: Renal Dosing Table

Medication	CrCl (ml/min) at which action is required	Rationale	Recommendation	Quality of Evidence/ Strength of Rec.
Duloxetine	<30	GI SE's (nausea, diarrhea)	Avoid	Moderate/ Weak
Gabapentin	<60	CNS SE's	Reduce dose	Moderate / Strong
Levetiracetam	≤80	CNS SE's	Reduce dose	Moderate / Strong
Pregabalin	<60	CNS SE's	Reduce dose	Moderate / Strong
Tramadol	<30	CNS SE's	IR: reduce dose; ER: avoid	Low / weak
H2 blockers (ranitidine, famotidine etc.)	<50	Mental status changes	Reduce dose	Moderate / strong

Table 6: Renal Dosing Table

Medication	CrCl (ml/min) at which action is required	Rationale	Recommendation	Quality of Evidence / Strength of Rec.
Amiloride	<30	Increased K+, Decreased Na+	Avoid	Moderate / Strong
Triamterene	<30	Increased K+, Decreased Na+	Avoid	Moderate / Strong
Spironolactone	<30	Increased K+	Avoid	Moderate / Strong
Colchicine	<30	GI, neuromuscular and bone marrow toxicities	Reduce dose; monitor for adverse effects	Moderate / Strong
Probenacid	<30	Loss of efficacy	Avoid	Moderate / Strong

Assessment Question

- According to the Beers criteria, which of the following is an accurate threshold in which action is required to dose adjust based on renal function?

A.) Ranitidine when CrCl <50ml/min
B.) Edoxaban when CrCl <60ml/min
C.) Pregabalin when CrCl <30ml/min
D.) Levetiracetam when CrCl <60ml/min

How much do you like the 2015 Beers Criteria?

- Completely and totally fabulous!
- Pretty Good
- Good, but I have some issues with them
- Don't like them!

New Document

DRUGS & PHARMACOLOGY

Alternative Medications for Medications in the Use of High-Risk Medications in the Elderly and Potentially Harmful Drug–Disease Interactions in the Elderly Quality Measures

Joseph T. Hanlon, PharmD, MS,[a,b,c,d,e,f,g,h] Todd P. Semla, MS, PharmD,[i,j,k] and Kenneth E. Schmader, MD[l,m]

Alternatives to High Risk Medications

Therapeutic Class	High-Risk Medications	Alternatives
1st Generation Anti-histamine	Diphenhydramine (OTC) Hydroxyzine Doxylamine (OTC) Chlorpheniramine (OTC)	Intranasal normal saline 2nd generation antihistmane (e.g. cetirizine, loratadine, fexofenadine), Intranasal steroids (now OTC)
Parkinson's Disease	Benztropine, Trihexyphenidyl	Carbidopa/Levodopa
TCA's	Amitriptyline, Imipramine etc.	For depression – SSRI (except paroxetine), SNRI, bupropion For neuropathic pain – SNRI, gabapentin, pregabalin, lidocaine patch, capsaicin
Barbiturates	Phenobarbital, Butalbital, Pentobarbital etc.	For epilepsy – other anticonvulsants (e.g. lamotrigine, levetiracetam)

Alternatives to High Risk Medications

Therapeutic Class	High-Risk Medications	Alternatives
Non benzodiazepine sedative hypnotics (e.g. "Z" drugs)	Eszopiclone Zaleplon Zolpidem	None! Non-pharm interventions cited
Sulfonylureas, long-duration	Glyburide	Short acting sulfonylureas (e.g. glipizide), metformin
Skeletal Muscle Relaxants	Cyclobenzaprine, Methocarbamol, Carisoprodol, Metaxalone etc.	Acute mild-mod pain: APAP, non-acetylated salicylate (salsalate), propionic acid derivatives (ibuprofen, naproxen) if no HF or eGFR >30ml/min and given with PPI if used >7 days
Specific NSAIDS	Indomethacin, Ketorolac	See above for skeletal muscle relaxants
Opioids	Meperidine, Pentazocine	Tramadol, morphine, oxycodone

Alternatives to Meds in Drug-Disease Interactions

Disease	High-Risk Medications	Alternatives
Falls	Anticonvulsants	For epilepsy: lamotrigine, levetiracetam + Calcium/Vitamin D ± bisphosphonate; For neuropathic pain: SNRI, gabapentin, pregabalin, capsaicin, lidocaine patch
	Benzodiazepines; Non-Benzodiazepine hypnotics ("Z" drugs)	For anxiety: buspirone, SNRI For sleep: sleep hygiene
Falls or Dementia	TCA's, SSRI's (falls only)	For depression: SNRI, bupropion For neuropathic pain: SNRI, gabapentin, pregabalin, capsaicin, lidocaine patch
Falls or Dementia	Antipsychotics	For delirium: short term use if considered risk to self or others after non-pharm interventions fail For dementia: non-pharm approaches; low dose non-anticholinergic agent (risperidone or quetiapine) for short duration

Alternatives to Meds in Drug-Disease Interactions

Disease	High-Risk Medications	Alternatives
Dementia	H2 blockers	PPI
	Anticholinergics - e.g. 1st generation antihistamines and anti-parkinson agents	For allergies: 2nd generation antihistamine, nasal steroid For Parkinson's: levodopa / carbidopa
	Benzodiazepines	For anxiety: buspirone, SSRI, SNRI For sleep: sleep hygiene
	Non-benzodiazepine hypnotics ("Z" drugs)	Sleep hygiene
CKD (eGFR <30ml/min)	All non-aspirin NSAIDS (including COX-2 selective)	APAP, SNRI, topical capsaicin, topical lidocaine patch

Assessment Question

- Which of the following is an accurate pairing of an alternative to a high risk medication in the Beers criteria?

A.) Zaleplon instead of Lorazepam
B.) Acetaminophen instead of Cyclobenzaprine
C.) Fluoxetine instead of Venlafaxine
D.) Risperidone instead of Quetiapine

New Document

CLINICAL INVESTIGATIONS

How to Use the American Geriatrics Society 2015 Beers Criteria—A Guide for Patients, Clinicians, Health Systems, and Payors

Michael A. Steinman, MD,† Judith L. Beizer, PharmD, CGP,‡ Catherine E. DuBeau, MD,‖¶ ** Rosemary D. Laird, MD,†† Nancy E. Lundebjerg, MPA,‡‡ and Paul Mulhausen, MD, MHS§§*

7 Key Principles

The most important take home message is:

Use clinical common sense!

Key Principles

Medications in the AGS 2015 Beers Criteria are *potentially* inappropriate, not *definitely* inappropriate

- Unfavorable balance of benefits and harms for many older adults
  - Particularly in light of available alternatives
- But, there are some older adults in which use of Beers criteria meds can be appropriate

Key Principles

Read the rationale and recommendations statements for each criterion. The caveats and guidance listed there are important

- Medication appropriateness is not black or white
- Meds may be considered potentially inappropriate only in certain circumstances
- Example: digoxin in heart failure as a 1st line agent

Key Principles

Understand why medications are included in the criteria and adjust your approach to those medications accordingly

- Look at the "rationale" statements
  - This can help guide how stringent we should be in avoiding it
  - Example – medication that increases risk of falls
- Allows us to individualize decision making based on anticipated risk
  risk

Key Principles

Optimal application of the criteria involves …offering safer nonpharmacological and pharmacological therapies

- See alternative therapy document
- Often, the best alternatives involve non-pharmacologic strategies
  - Patient counseling and lifestyle changes

Key Principles

Access to medications included in the Beers criteria should not be excessively restricted by prior authorization and/or health plan coverage policies

- Judicious use through insurance design can be reasonable
- Onerous restrictions can disrupt care and hinder access to meds for patients that need them
- Programs that restrict access to meds should be carefully targeted and give clinicians efficient opportunities to justify use

Application of Key Principles - Clinicians

- Think of the Beers criteria as a *warning light*
  - Potentially unfavorable balance of benefits and harms
  - Why is the patient taking the drug?
  - Is this medication truly needed?
  - Are there safer or more effective alternatives?
  - Does this patient have characteristics that increase or mitigate the risk of this medication?
- This highlighted awareness should continue over time and prompt ongoing monitoring
- This highlighted awareness should continue over time and prompt ongoing monitoring

Application of Key Principles - Clinicians

- Actively inquire about symptoms that could be adverse drug effects, and assess whether these could be related to medications
- Don't automatically defer to colleagues
  - Just because another clinician prescribed a Beers criteria medication doesn't mean it is safe and effective
  - Use the opportunity to discuss with colleagues whether that medication is right for the patient

Beers Criteria Conclusions

- The success of the AGS 2015 Beers criteria depends on being applied in a thoughtful manner
- Utilizing these key principles and application strategies are intended to improve outcomes while minimizing unintended harms

To access all AGS 2015 Updated Beers Resources Visit

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Updates in Pneumococcal Vaccinations as Recommended by the Advisory Committee on Immunization Practices (ACIP) and the Center for Disease Control and Prevention (CDC)

Epidemiology of Pneumonia in Older Adults

- ~4,000 deaths and ~300,000 hospitalizations per year
- 2013 – estimated 13,000 cases of invasive pneumococcal disease (IPD) in elderly
  - ~10x more likely in older adults
- 20-25% of IPD cases and 10% of community acquired pneumonia cases are caused by vaccine preventable serotypes

Pneumococcal Vaccines

23-valent pneumococcal polysaccharide *(PPSV23)*	13-valent pneumococcal conjugate *(PCV13)*
• 1st marketed in 1983 • Protects against 23 serotypes – 12 also in PCV13 + 11 others • Most effective in adults and does not generate immunity in children under 2 years old	• 1st used in children in 2010 – expanded from PCV7 vaccine • Protects against 13 serotypes – 1 that is not in PPSV23 • Give before PPSV23 for better immune response

PCV13

- 0.5ml IM in deltoid x 1 lifetime dose
- Adverse effects: pain at injection site, redness, swelling at injection site, fatigue, headache
- Supplied: pre-filled syringe that does not contain latex

Timeline of PCV13

- FDA approved **2010** for children aged 6 weeks through 71 months (replaced PCV7)
- **Dec 2011** – FDA approved for prevention of pneumonia and invasive disease in adults >50 y/o
- **June 2012** – ACIP recommended for adults (≥19 y/o) with immunocompromising conditions with high risk of pneumococcal disease
- **August 2014** – ACIP recommended use for immunocompetent older adults
- **June 2015** – ACIP updates interval for the PCV13 → PPSV23 sequence for immunocompetent older adults

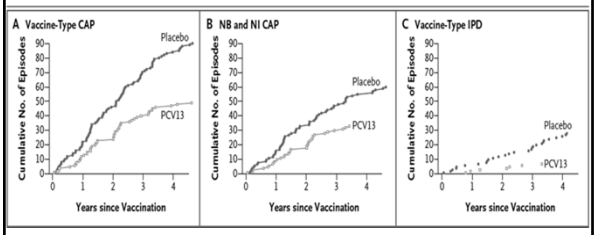
Immunogenicity Studies

- Adults 60-64 y/o with no prior vaccine hx.
  – PCV13 antibody titers to the 12 common serotypes comparable to or higher than PPSV23
- Adults ≥70 y/o with previous PPSV23 vaccine
  – PCV13 titers comparable for 2 and higher for 10 common serotypes

Immunogenicity Studies

- PCV7 → PPSV23 – better immune response than PPSV23 → PCV7
- PCV13 → PPSV23 – better immune response at 2, 6, and 12 months and at 3-4 years
  – 2nd vaccine given 1 year after 1st vaccine
- No study evaluated optimal interval between vaccines

CAPITA Trial



NB = Non-bacteremic
NI = Non-invasive

Indications for Vaccine

Indications for PCV13 and PPSV23 Administration for Adults Age 19 to 64 Years by Risk Group
Source: Centers for Disease Control and Prevention (CDC)[1]

Risk Group	Underlying Medical Condition	PCV13	PPSV23	
		Recommended	Recommended	Revaccination 5 years After First Dose
Immunocompromised persons*	Congenital or acquired immunodeficiency[†]	✔	✔	✔
	HIV	✔	✔	✔
	Chronic renal failure	✔	✔	✔
	Nephrotic syndrome	✔	✔	✔
	Leukemia	✔	✔	✔
	Lymphoma	✔	✔	✔
	Hodgkin disease	✔	✔	✔
	Generalized malignancy	✔	✔	✔
	Iatrogenic immunosuppression**	✔	✔	✔
	Solid organ transplant	✔	✔	✔
	Multiple myeloma	✔	✔	✔

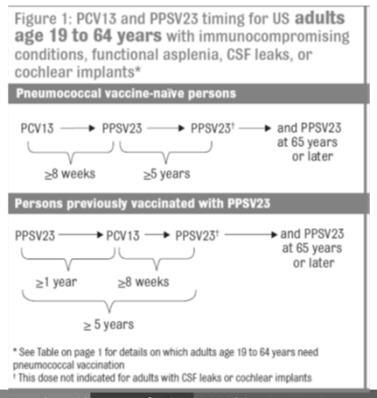
Indications for Vaccine

Indications for PCV13 and PPSV23 Administration for Adults Age 19 to 64 Years by Risk Group
Source: Centers for Disease Control and Prevention (CDC)[1]

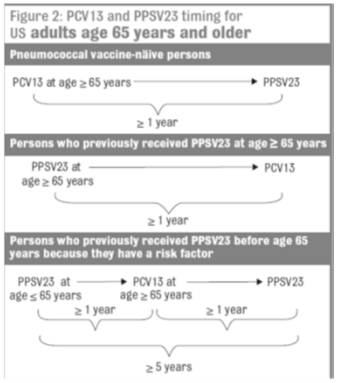
Risk Group	Underlying Medical Condition	PCV13	PPSV23	
		Recommended	Recommended	Revaccination 5 years After First Dose
Persons with functional or anatomic asplenia*	Sickle cell disease/other hemaglobinopathy	✔	✔	✔
	Congenital or acquired asplenia	✔	✔	✔
Immunocompetent persons*	Cerebrospinal fluid leak	✔	✔	
	Cochlear implant	✔	✔	
Immunocompetent persons	Chronic heart disease[†]		✔	
	Chronic lung disease[§]		✔	
	Diabetes mellitus		✔	
	Alcoholism		✔	
	Chronic liver disease, cirrhosis		✔	
	Cigarette smoking		✔	

Every Adult ≥ 65 y/o should get both PCV13 AND PPSV23!

Vaccine Intervals



Vaccine Intervals



So What Changed in 2015?

PCV13 → PPSV23

Age Groups	Underlying Conditions	2014 Interval Recs	2015 Interval Recs
≥ 19 years	• High-risk immunocompetent (CSF leak, cochlear implants) • Functional or anatomic asplenia • Immunocompromised	≥ 8 weeks	No change
≥ 65 years	N/A	6-12 months (minimum 8 weeks)	≥ 1 year

Why the Change?

- Confusion among healthcare providers
- Challenges in programming reminders in computerized programming
- CMS Policy
  - Medicare will only cover a different second pneumococcal vaccine after 1 year
- ACIP re-reviewed immunogenicity studies

Can I give PCV13 with Influenza Vaccine?

- Yes!
- The PCV13 labeling states that administration with inactivated flu vaccine was associated with diminished PCV13 antibody responses
  - Clinical significance of this data is unknown
- CDC still endorses giving at the same time

Let's Close with a Case!

- BD is a 66 y/o male with a PMH of COPD, DM, and HTN who received a PPSV23 vaccine 3 years ago. What pneumococcal vaccine(s) is he appropriate to receive and in what timeframe?
  - A.) PCV13 now only
  - B.) PCV13 now, then PPSV23 in 1 year
  - C.) PCV13 now, then PPSV23 in 2 years
  - D.) PPSV23 now, then PCV13 in 1 year

Questions??

References

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Dawn of an era in Hepatitis C management

Kushal Y. Shah, Pharm.D.
Clinical Pharmacy Specialist
Liver/Hepatitis C
April 2016

Disclosures

- The speaker has no actual or potential conflict of interest in relation to this presentation.
- I will discuss off-label use of medication, and medications that are not yet FDA approved.

Disclaimer: This presentation is based on the current literature and practice guidelines available at the time of slide preparation. I am not here as a representative of the VA and any opinions expressed are my own and do not necessarily represent the views of the Department of Veterans Affairs or the United States of America.

What is your primary practice site?

- Specialty pharmacy
- Hospital pharmacy
- Ambulatory care clinic
- Community pharmacy
- Other

Learning objectives

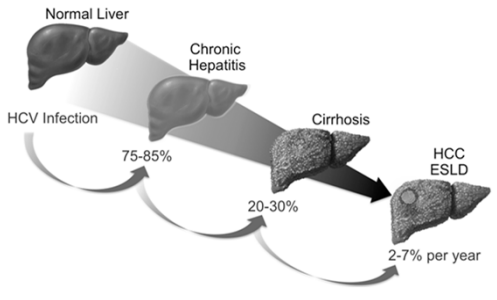
- Recognize direct acting antivirals (DAA) in hepatitis C (HCV) management
- Review the updated HCV treatment guidelines

Hepatitis C virus (HCV) overview

- Previously Non-A Non-B hepatitis (NANBH)
- Discovered as an independent virus in 1989
- 3.5 million infected in the US
- Risk factors
- No Vaccine for HCV

Edlin et. al. 2015; American Liver Foundation [Internet]. Available from: http://hepc.liverfoundation.org/.

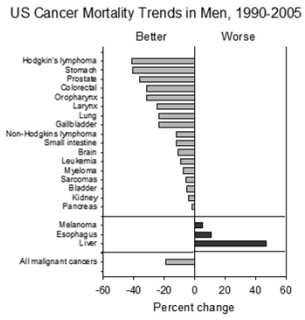
Natural history



http://www.hepatitisc.uw.edu/go/evaluation-staging-monitoring/natural-history/core-concept/all

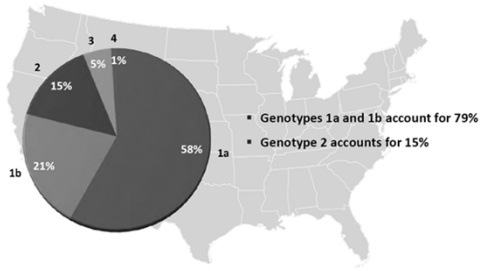
HCC

- At a time when most cancer mortality is decreasing, deaths from hepatocellular carcinoma (HCC) in the US are increasing
- Deaths from HCC are increasing faster than deaths from any other form of cancer



From Jemal, A. et al.
CA Cancer J Clin 2009;59:225-249.

HCV genotypes

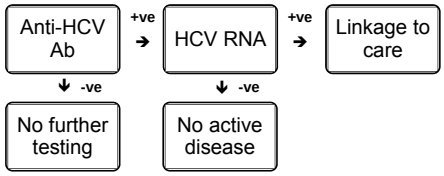


Zein NN, et al. Ann Intern Med. 1996;125:634-639.

Definition

- Quantitative HCV RNA
  - "Viral Load"
  - Determines the quantity of virus in the blood
  - Informs providers if the patient cleared the virus (20%) on their own or are chronically infected (80%)
- Sustained Virological Response (SVR)

Diagnostic testing

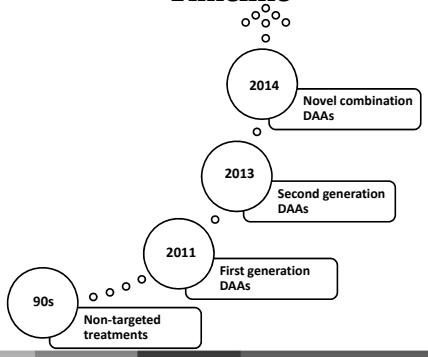


CDC. Testing for HCV infection: An update of guidance for clinicians and laboratorians. MMWR 2013;62(18).

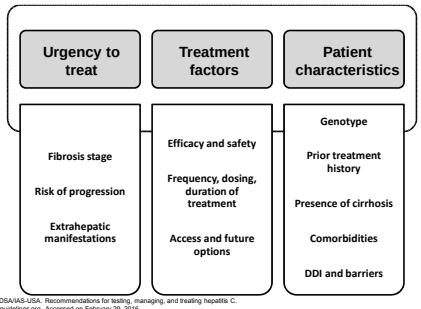
HCV life cycle and DAA targets

Adapted from Manns MP, et al. Nat Rev Drug Discov. 2007;6:991-1000.

Timeline



Consideration prior to initiating HCV treatment



AASLD/IDSA/IAS-USA. Recommendations for testing, managing, and treating hepatitis C. www.hcvguidelines.org. Accessed on February 29, 2016.

Benefits of achieving SVR

- Improved liver histology
- Improved clinical outcomes
- Viral eradication
- Mounting evidence for reduced all cause mortality in non-hepatic diseases
  - CAD, diabetes, cyroglobinemia/renal disease
- Decrease rate of decompensation, HCC, mortality

Yoshida EM, *et al.* Hepatology. 2015;61(1):41-45;
Van der Meer AJ, *et al.* JAMA. 2012;308(24):2584-2593.

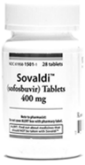
Basics of DAA

NS3/4A inhibitors	NS5A inhibitors	NS5B inhibitors
• Paritaprevir • Grazoprevir • Simeprevir	• Ledipasvir • Ombitasvir • Daclatasvir	• Sofosbuvir • Dasabuvir

- Shorten duration of treatment
- Improved tolerability
- Improved virological cure rates
- Pan-genotypic!

Sofosbuvir (SOF) (Sovaldi™)

- Dose:
  - 400 mg once daily
  - Used by itself (with ribavirin in G2) or in combination with other DAAs
- Side effects:
  - headache, fatigue, nausea
- DDI:
  - Anticonvulsants, rifampin, St. John's wort
  - HIV protease inhibitors
  - Amiodarone



Sovaldi™ [package insert]. Foster City, CA; Gilead Sciences, Inc., December 2013. (Revised 2015)

Ledipasvir (LDV)/Sofosbuvir (SOF) (Harvoni™)

- Dose:
  - ledipasvir 90 mg/sofosbuvir 400 mg once daily
  - 8, 12 or 24 weeks
- Side effects:
  - fatigue, headache, nausea, insomnia
- DDI:
  - PPI, antacids, H2 blockers, amiodarone, statins, phenytoin, carbamazepine… and more

Harvoni™ [package insert]. Foster City, CA; Gilead Sciences, Inc., October 2014.

PrOD (PTV/r/OBV+DSV) (Viekira Pak™)

- 3D regimen
- Dose:
  - 2 tablets of the co-formulated ombitasvir-paritaprevir-ritonavir (12.5/75/50 mg) once daily
  - 1 dasabuvir tablet (250 mg) twice daily, with food
  - 12 or 24 weeks
- Side effects:
  - fatigue, nausea, pruritus, other skin reactions, insomnia, and asthenia, rare/serious liver injury

Viekira Pak™ [package insert]. North Chicago, IL: AbbVie, Inc., December 2014.

PTV/r/OBV + RBV (Technivie™)

- Dose:
  - 2 tablets once daily
  - OBV/PTV/r (12.5/75/50 mg) with food + RBV
- Side effects:
  - fatigue, nausea, pruritus, other skin reactions, insomnia, and asthenia, serious liver injury

Technivie™ [package insert]. North Chicago, IL; AbbVie, Inc., July 2015.

PTV/r/OBV +/- DSV

- DDI:
  - Many DDI due to protease inhibitor and ribavirin
  - Not the same as Viekira due to removal of dasabuvir
- Use contraindicated-
  - CP*- B/C
  - Oral contraceptives
  - Anticonvulsant
  - Studied and indicated in HIV coinfection
    - Efavirenz contraindicated
  - Simvastatin, atorvastatin
  - Sildenafil (PAH)

*CP: Child-Pugh

SOF + Daclatasvir (DCV) (Daklinza™)

- Dose:
  - 2 tablets once daily (DCV 60 mg + SOF 400 mg)
  - 12, 16 or 24 weeks
- Side effects:
  - Fatigue, nausea, diarrhea, headache
- DDI:
  - DCV- substrate of CYP3A4
  - 3A4 inhibitors: decrease dose to 30 mg daily
  - 3A4 inducers: increase dose to 90 mg daily
  - Anticonvulsants

Daklinza™ [package insert]. Princeton, NJ; Bristol-Myers Squibb Company, July 2015.

Elbasvir (EBR)/Grazoprevir (GZR) (Zepatier™)

- Dose:
  - Elbasvir 50 mg/Grazoprevir 100 mg once daily
  - 12 or 16 weeks
- Key Points:
  - For renal impairment
  - Contraindicated: CP*-B/C
  - G1a requires resistance testing
- Side effects:
  - Fatigue, headache, nausea
- DDI:
  - Avoid use of strong CYP3A4 inhibitors/inducers
  - No interaction with amiodarone, PPI

Zepatier™ [package insert]. Whitehouse Station, NJ; Merck & Co., Inc., January 2016.

*CP: Child-Pugh

Ribavirin (Copegus®)

- Antiviral activity – not totally clear
- Dose based on weight and renal function
  - ≤75 Kg – 400 mg AM 600 mg PM
  - >75 Mg – 600 mg BID
- Major side effects include
  - Anemia
  - Teratogenic effects
  - Rash
- Extremely long half life

Hey guys… don't forget about me

- Interferon (pegIFN)
  - Once a mainstay of therapy
  - Rarely used currently
- Boceprevir & Telaprevir
  - First generation DAAs
  - Not available on the market anymore
- Simeprevir
  - Will be coming back for rescue!

Quiz time!

Which of the following DAA combination was recently FDA approved in patients with end stage renal disease and infected with HCV genotype 1 or 4?

A. Ledipasvir/Sofosbuvir
B. Paritaprevir/ritonavir/Ombitasvir + ribavirin
C. Sofosbuvir + Daclatasvir
D. Elbasvir/Grazoprevir

Resistance testing

- RAV – Resistance Associated Variant
- Resistance depends on
  - Prior DAA exposure
  - Virus/genotype
  - Patients
- When to consider?

Current recommendations

HCV Genotype	Regimen	Duration
1a/1b	Ledipasvir/Sofosbuvir	12-24 weeks
	Elbasvir/Grazoprevir +/- Ribavirin	12-16 weeks
	Daclatasvir + Sofosbuvir +/- Ribavirin	12-24 weeks
	PrOD + Ribavirin	12-24 weeks
	Sofosbuvir + Simeprevir +/- Ribavirin	12-24 weeks
2	Sofosbuvir + Ribavirin	12-24 weeks
	Daclatasvir + Sofosbuvir +/- Ribavirin	12-24 weeks
	Sofosbuvir + PegIFN + Ribavirin	12 weeks

AASLD/IDSA/IAS-USA. Recommendations for testing, managing, and treating hepatitis C. www.hcvguidelines.org. Accessed on February 29, 2016.

Current recommendations

HCV Genotype	Regimen	Duration
3	Daclatasvir + Sofosbuvir +/- Ribavirin	12-24 weeks
	Sofosbuvir + PegIFN + Ribavirin	12 weeks
	Sofosbuvir + ribavirin	24 weeks
4	Elbasvir/Grazoprevir +/- Ribavirin	12-16 weeks
	Ledipasvir/Sofosbuvir	12 weeks
	Ombitasvir/paritaprevir/ritonavir + Ribavirin	12 weeks
	Sofosbuvir + Ribavirin	24 weeks
	Sofosbuvir + PegIFN + Ribavirin	12 weeks

AASLD/IDSA/IAS-USA. Recommendations for testing, managing, and treating hepatitis C. www.hcvguidelines.org. Accessed on February 29, 2016.

Special population

HCV Medication	Liver Transplant	HIV Coinfection
Sofosbuvir	Y	Y
Simeprevir	Y	Y
Ledipasvir/Sofosbuvir	Y	Y
PrOD*	Y	Y
Daclatasvir**	Y	Y
Elbasvir/Grazoprevir	N	Y

* If Metavir F0-F2 (no/compensated cirrhosis)
** no/compensated cirrhosis
- Decompensated cirrhosis: avoid use of simeprevir, PrOD, Elbasvir/Grazoprevir
- Close monitoring require for DDI, refer to resources for guidance

AASLD/IDSA/IAS-USA. Recommendations for testing, managing, and treating hepatitis C. www.hcvguidelines.org. Accessed on February 29, 2016.

Renal impairment

ESRD or CrCl <30 mL/min

HCV Genotype	Regimen	Duration
1a	Elbasvir/Grazoprevir	12 weeks
	PrOD + Ribavirin	12 weeks
1b	Elbasvir/Grazoprevir	12 weeks
	PrOD	12 weeks
2	PegIFN + Ribavirin	
3		
4	Elbasvir/Grazoprevir	12 weeks
5	PegIFN + Ribavirin	
6		

AASLD/IDSA/IAS-USA. Recommendations for testing, managing, and treating hepatitis C. www.hcvguidelines.org. Accessed on February 29, 2016.

Where are we going?

- SOF + Velpatasvir (VEL) (GS-5816)
- Daclatasvir/Asunaprevir/Beclabuvir
- EBR/GZR + SOF? (for prior EBR/GZR failures)
- ACH-3102 (Odalasvir)
- ABT-530
- MK-8408

Pharmacists role

- Hepatitis C screening
  - Birth cohort screening for patients born between 1945-1965
- Prevent interruption in HCV treatment
- Adherence
- DDI screening
- Treatment monitoring
- Preventative measures

BD Smith, RL Morgan, GA Beckett, et al. Recommendations for the identifi-cation of chronic hepatitis C virus infec-tion among persons born during 1945-1965. Morbidity and Mortality Weekly Report, Recommendations and Reports. 2012 Aug 17; 61(RR04):1-18.

Counseling points

- OTCs
  - APAP – safely use, but if cirrhotic limit to 2 g/24 hours
  - NSAIDs – generally safe unless cirrhotic
  - Iron – avoid excessive iron as some patients can 'store' it
  - Vitamin D – generally safe and most patients are deficient; need to be treated
- Substance abuse
  - Alcohol – gas on a fire!
  - Smoking – controversial
  - Marijuana – can accelerate cirrhosis/avoid

Summary

- The landscape of HCV treatment is changing rapidly
- Resistance testing may be helpful to guide initial and subsequent HCV treatments
- Competition had beneficial impact on cost
- Pharmacists can play an important role in educating patients and providers

Case

- TB is a 65 y/o Caucasian man. Identified with abnormal liver enzymes by his PCP. At this appointment, he was screened for HCV and HCV-Ab was positive.
- PMH: Diabetes, Hypertension, Depression, jaundice in his 30s
- Meds: metformin 500 mg po BID, lisinopril 10 mg po daily, omeprazole 20 mg po QAM
- Social history: Tattoo on his hand; denies alcohol, illicit drug use, incarcerated for 2 years

Case

- Labs:
  - HCV-Ab positive
  - Genotype: 1a, treatment naïve
  - HCV RNA: 5.2 million IU/mL
  - AFP: 15 (US negative for mass, normal texture)
  - HIV negative, HAV/HBV: Immune

WBC 5.9	HGB 15.5	PLT 209	AST 80	ALT 90	SCr 0.9	Alb 3.7

Quiz time!

Identify risk factors for TB's HCV infection:

A. History of incarceration
B. Tattoo
C. Hypertension
D. A,B and C
E. A and B

Quiz time!

Which of the following HCV treatment would you recommend for TB?

A. Ledipasvir/Sofosbuvir x 12 weeks
B. Paritaprevir/ritonavir/Ombitasvir x 12 weeks
C. Sofosbuvir + Daclatasvir x 24 weeks
D. Elbasvir/Grazoprevir x 16 weeks

Questions?

Kushal Y. Shah, Pharm.D.
Clinical Pharmacy Specialist
Liver/Hepatitis C
April 2016

Dawn of an era in Hepatitis C management

Self-assessment questions

Question 1:

Which of the following DAA combination was recently FDA approved in patients with end stage renal disease and infected with HCV genotype 1 or 4?

A. Ledipasvir/Sofosbuvir

B. Paritaprevir/ritonavir/Ombitasvir + ribavirin

C. Sofosbuvir + Daclatasvir

D. Elbasvir/Grazoprevir

Question 2: (Case)

- TB is a 65 y/o Caucasian man. Identified with abnormal liver enzymes by his PCP. At this appointment, he was screened for HCV and HCV-Ab was positive.
- PMH: Diabetes, Hypertension, Depression, jaundice in his 30s
- Meds: metformin 500 mg po BID, lisinopril 10 mg po daily, omeprazole 20 mg po QAM
- Social history: Tattoo on his hand; denies alcohol, illicit drug use, incarcerated for 2 years
- Labs:
    - HCV-Ab positive
    - Genotype: 1a, treatment naïve
    - HCV RNA: 5.2 million IU/mL
    - AFP: 15 (US negative for mass, normal texture)
    - HIV negative, HAV/HBV: Immune

WBC 5.9	**HGB** 15.5	**PLT** 209	**AST** 80	**ALT** 90	**SCr** 0.9	**Alb** 3.7

Which of the following HCV treatment would you recommend for TB?

A. Ledipasvir/Sofosbuvir x 12 weeks

B. Paritaprevir/ritonavir/Ombitasvir x 12 weeks

C. Sofosbuvir + Daclatasvir x 24 weeks

D. Elbasvir/Grazoprevir x 16 weeks

Question 3: (Case)

Identify risk factors for TB's HCV infection:

A. History of incarceration
B. Tattoo
C. Hypertension
D. A,B and C
E. A and B

WELCOME!

Crucial Conversations

HEALTHCARE OVERVIEW PRESENTATION

Ashley Dittmar

The speaker has no conflict of interest to declare.

PROBLEM Silence Kills.* Medical Mistakes cause over 195,000 deaths per year. Medication Errors affect more than 5 percent of patients. Nosocomial Infections are estimated at 3.5 million per year. Protocols, processes improvements, and new technologies are not enough!

SOLUTION Master Crucial Conversations skills to address the Seven Crucial Conversations for Healthcare.

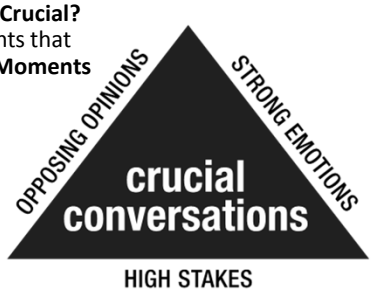
*For original sources, please see the Silence Kills study.

■ CRUCIALCONVERSATIONS

What's Wrong Here?

Let's watch an interaction in a working team.
Jackie has been asked to participate on a committee.
What different issues is this team facing in this conversation?

What Makes a Conversation Crucial?
Three elements that create **Crucial Moments**



Learning Assessment Question 1

What are Crucial Moments?

A-Moments that set us up to fail
B-Events comprised of high stakes, opposing opinions and strong emotions that change the trajectory of a crisis
C-Times when people speak up too abrasively within a Crucial Conversation

How Does She Do?

How do we typically respond to crucial conversations? Let's return to Jackie and see how she and the others do.

AMERICAN ASSOCIATION of CRITICAL-CARE NURSES

VitalSmarts

The Silence Kills Study

- Conducted numerous focus groups, interviews, and workplace observations
- Surveyed more than 1,700 healthcare professionals at hospitals across the U.S.
- Data came from nurses, physicians, clinical-care staff, and administrators at teaching, general, and pediatric hospitals

The *Silence Kills* Study

The study identified seven common and devastating crucial conversations—

- Broken Rules
- Mistakes
- Lack of Support
- Incompetence
- Poor Teamwork
- Disrespect
- Micromanagement

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ICHP and IL Chapters of ACHE 2016 Spring Meeting

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ICHP and IL Chapters of ACHE 2016 Spring Meeting

How About This Time?

Going to silence didn't work very well. Let's give this team another chance. Watch how they approach the crucial conversation this time.

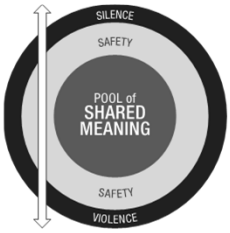
The Silence to Violence Continuum

We Make a Fool's Choice

When facing a crucial conversation, we often feel we have to choose between responding with silence or with violence.

We assume we can either share our honest opinion or be respectful.

We are blind to the dialogue option.



Drew from research on Fight or Flight—dating back to WWI.

Walter Cannon

Identifying Crucial Moments that have the potential to change the trajectory of a crisis…

So, we know "why" we toggle between silence and violence. But, "when" do we go to silence and violence?

- Common Crucial Moments we experience where people resort to silence or violence?
  - What are the consequences?

Learning Assessment Question 2

How does stress in critical moments impact our conversations?

A-Stress allows us to shift our focus in our Crucial Conversation to what matters the most
B-It forces us to be better self-monitors
C-Stress elicits responses in the forms of silence and aggressive or violent behavior

Crucial Conversations

Let's listen as Joseph Grenny, one of the authors of *Crucial Conversations*, introduces the research behind it.

When we start having these conversations effectively, we will see our issues get resolved and our bottom line improve.

Getting Unstuck

To see how the Crucial Conversations skills can help us get unstuck, let's watch as Jackie steps up to the right crucial conversation and uses several dialogue skills. How does this compare to her previous approaches?

Two Skills to be candid and respectful in Crucial Conversations:

Skill #1:
Unbundle with CPR

Skill #2:
Make it Safe

Skill: Unbundle with CPR

Content: a single instance of a problem. Not *always* the first instance, though it often is.

Pattern: a recurring problem—a pattern of behavior over time.

Relationship: how the problem is affecting your working relationship (trust, respect, competence)

Learning Assessment Question 3

What is the first skill utilized to dissect problems and understand underlying problems?

A-Addressing Silence and Violence
B-Reduce stress to combat fight or flight responses
C-Separate and prioritize issues by utilizing CPR

Skill: Unbundle with CPR

Scenario: You are a technician working with a pharmacist that is not following safety protocol. You have been working with this pharmacist for a while and this is not the first time you have seen this occur. You are worried about potential consequences for the patient if safety protocol is not followed correctly.

Content:
Pattern:
Relationship:

Skill: Unbundle with CPR

Scenario: You are a technician working with a pharmacist that is not following safety protocol. You have been working with this pharmacist for a while and this is not the first time you have seen this occur. You are worried about potential consequences for the patient if safety protocol is not followed correctly.

Content: The current violation of protocol
Pattern: The repeated violation of protocol
Relationship: The relationship with the patient as well as your relationship with the pharmacist based on the conversation

YOUR TURN!
Skill: Unbundle with CPR

Content: Current Issue
Pattern: Behavior Over Time
Relationship: Impact on the Relationship

Skill: Make It Safe

People rarely become defensive about *what* you're saying (**the content**).

People become defensive because of *why* they think you're saying it (**your intent**).

Skill: Make It Safe

Two things people need to feel safe with you:

Mutual Respect: I care about you as a human being and I respect you.

Mutual Purpose: I support you and want you to be successful.

Learning Assessment Question 4

There are two things you need to convey during a Crucial Conversation for people to feel safe with you:

A-Mutual Purpose and Mutual Respect
B- To convey the data and information you have to support your opinion
C- That you will address Silence and Violence

Contrasting

Contrast to Fix Misunderstandings

Don't: Explain what you don't intend; this addresses others' conclusions that you don't respect them or that you have a malicious purpose.

Do: Explain what you do intend; this confirms your respect or clarifies your real purpose.

**The *don't* is the more important part of Contrasting because it addresses misunderstandings that could put safety at risk.

No Help for the Newbie

You are a new pharmacist to the organization you work for. You are starting to get into the rhythm of your new position but realize there are sometimes questions that you have based on the new environment. The last two times you needed help, other pharmacists have told you they were busy and they would get back to you later, but they never did. You don't want to seem needy or take away people from their busy schedules. However, you have read and re-read policies to try to get answers to your questions to no avail. One of the other pharmacists in the organization just walked in and you would like to use contrasting with them to finally get to the bottom of your questions. You start the conversation with a contrasting statement by saying…

Don't want:

Do want:

No Help for the Newbie

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Don't want: I don't want to bother you or impact your day, I know that everyone is busy.

Do want: I would like some assistance and clarity around a few questions I have since I am new and am wondering if you wouldn't mind helping when you have a moment?

The supervisor who "plays favorites"

A manager who works for you has "favorite" employees. He's friends with some employees, but doesn't know others very well at all. You are concerned that his friends may have more influence with him than other employees do. Other employees are beginning to complain about favoritism.

You explain your concerns to him and he replies *"I don't think you should try to tell me who I can have as friends. I've known some of these people for more than ten years."*

Don't want:

Do want:

The supervisor who "plays favorites"

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Don't want: to impact the relationships you have fostered with employees throughout the years.

Do want: to ensure that all employees are treated similarly so that we can mitigate any issues that may arise with employees who aren't as well connected.

YOUR TURN!

Skill: Contrast

I don't want _____ (misunderstanding or disrespect)

~~**BUTs**~~

I do want ____ (guide the conversation where you want it to go).

Learning Assessment Question 5

Contrasting helps to:

A-Address misunderstandings
B-Foster respect
C-Serve as an outline to be candid and respectful
D-All of the above

Case Studies

Let's watch as two senior-level leaders talk about what happened to their key results when people learned to routinely employ Crucial Conversations skills.

What are two ways you
can apply the strategies we have
talked about today to begin
to foster more
candor and dialogue?

crucial conversations®

ICHP and IL Chapters of ACHE 2016 Spring Meeting