How Can Pharmacy Staff Add to the Accountability of ACO's?

Sandra Van Trease
Group President, BJC HealthCare
President, BJC HealthCare ACO, LLC

The speaker has no conflict of interest to declare.

Objectives

1. Describe what an Accountable Care Organization (ACO) is and how it can reduce health care costs
2. List areas of cost savings where pharmacy staff may be directly involved in an ACO
3. Describe steps pharmacists should take to make sure they have a place at the ACO table.

ACO Overview

- Patient Protection and Affordable Care Act (ACA) 2010
- CMS began contracting with ACOs in January 2012
- Government is targeting $1B in Medicare savings over 4 years across entire continuum of care (office/home, hospital, post acute)
- "Savings" (Hospital and Professional fee)
  - Reduced re-admissions
  - Reduced admissions
  - Reduced ED visits, unnecessary tests/procedures
- Solution: Accountable Care Organizations (ACOs)

BJC HealthCare ACO

What are we doing?: We are taking better and more coordinated care of seniors

Why it's important now: Seniors are a growing part of our population and utilize the most care. We have a time limited opportunity provided by Medicare that is going to give us tools and remove barriers to provide better care at a lower cost. We believe these tools are essential for our future success.

Where we're headed: When we are successful, patients will experience better health, our community will have better healthcare and we will be providing better value. We will have a healthcare system that others will want to emulate or join.

BJC HealthCare ACO

Beneficiary Attribution	
• Beneficiaries:	42,114
• Opt out of Data Sharing:	1,396
• % Remaining since MSSP Start:	70.1%
Physician Participation	
• Employed – 262	
• Private – 182	
Shared Savings Target	**2.4%**
12 Month Spend	**$255M**

Care Management	Transitional Care Program
	High Risk Patient Care Management
	Skilled Nursing Program
Physician Operations	Patient Access
	Patient Alerts
	After hours call triage
Clinical Data Sharing	Clinical/Financial Data Analytics
	Electronic Data Sharing Amongst Providers

As a pharmacist, what is your current status regarding your participation with an ACO?

1. Participant
2. Non-participant
3. Planning phase
4. Don't know

What areas of Pharmacists' expertise are of particular relevance to improving the quality of primary care?

- Medication reconciliation
- Pharmacotherapy management and monitoring
- Care coordination related to drug therapy

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ACO Status Today

- Nearly 480 private ACOs in existence
- 360 Medicare Shared Savings Program ACOs
  - 11 ACOs in Illinois (including Walgreens)
- Tremendous variation amongst ACOs
- Growing number use pharmacists to provide medication management as a core element

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Walgreens Participation in ACOs

- Participate in 3 Medicare ACOs nationwide
- First national pharmacy chain to participate
- Partnered with hospitals and physician groups
- *Services:* immunizations, screenings, wellness programs, medication adherence, in-store clinics (nurse practitioners), disease management (pharmacists), MTM, care transitions

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Medication-Related Problems

Approximately 75% of medication problems in primary care are related to:

- Clinician-influenced gaps in care
- Inappropriate or ineffective prescribing
- Lack of care coordination
- Inconsistent monitoring of drug therapy
- Patient factors account for remaining 25%

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Medication Reconciliation Problems

- 50% discrepancies result from discontinued medications
- 35% due to differences between patient-reported use and the EHR medication list
- Only 45% of Medicare patients bring their medication list to physician appointments

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Medications During Care Transitions

- Discrepancies at hospital admission range from 30-70%
- Poor communication results in:
  - 50% of medication errors in the hospital
  - 20% of adverse drug events

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Components of Integrated Care

- Multidisciplinary care team members (including patients and care-givers)
- Reciprocal interdependency
- Handovers (receipt of information)
- Coordinated outcomes (shared goals)
- Continuous outcomes (patient progress from visit to visit)

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Comprehensive Medication Management

Core elements of patient-centered medication use and safety:

1. Gold standard medication list
2. Regular assessment of medication appropriateness (each drug on the list)
3. Personal medication action plan
4. Documentation and communication of recommendations to patient and providers

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Pharmacist's Recommendations

- Avoid medication errors
- Resolve inappropriate medication prescribing (omission, duplication, unnecessary drug, dose-optimization, drug interactions, ADRs, non-adherence)
- Address health literacy
- Reduce costs for patient and health system

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Virtual Care Teams

- ACO partners with external pharmacists in the community to provide coordinated services
- ACO identifies highest priority needs
- ACO pinpoints gaps in medication management
- Successful implementation requires data-sharing (health records) and communication
- Provider and patient engagement are key

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ACO Quality Measures

33 quality measures in 4 domains:

- Better care for individuals
  - Patient/caregiver experience
  - Care coordination/patient safety
- Better health for populations
  - Preventive health
  - At risk populations

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ACO Quality Measures

Selected measures impacted by pharmacists:

#5	Health promotion and education
#8	Risk standardized all condition readmission
#9	Ambulatory Sensitive Conditions Admissions: COPD or Asthma in Older Adults
#10	Ambulatory Sensitive Conditions Admissions: Heart failure
#12	Medication reconciliation
#13	Falls: Identification of medications that increase risk for falls

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ACO Quality Measures

Selected measures impacted by pharmacists:

#14	Influenza Immunization
#15	Pneumococcal Vaccination for Patients 65 Years and Older
#17	Tobacco Use: Screening and Cessation Intervention
#22	Diabetes Composite (All or Nothing Scoring): Diabetes Mellitus: Hemoglobin A1c Control (8 percent)
#23	Diabetes Composite (All or Nothing Scoring): Diabetes Mellitus: Low Density Lipoprotein Control

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Pharmacist Collaboration Levels

Level	Description
Coordinated Care	Minimal to basic collaboration, limited communication with physician – usually with office staff
Co-Located Care	On-site care, access to health records, part-time or full-time, opportunity for patients to meet with pharmacist
Integrated Care	Pharmacist services embedded into routine practice workflow, collaborative practice agreements

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Opinion Poll: "I believe that I could help an ACO improve their quality measures."

1. Agree
2. Disagree

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Integrated Care Teams

- *"Patient care that is coordinated across professionals, facilities, and support systems; continuous over time and between visits; tailored to the patients' needs and preferences; and based on shared responsibility between patient and caregivers for optimizing health."*

  Sara Singer et al., Medical Care Research and Review, 2011

- No mention of health care professional's place of work
- Seamless patient-centered care
- Shared responsibility for care (patient + all health care professionals)
- Continuous over time and between visits

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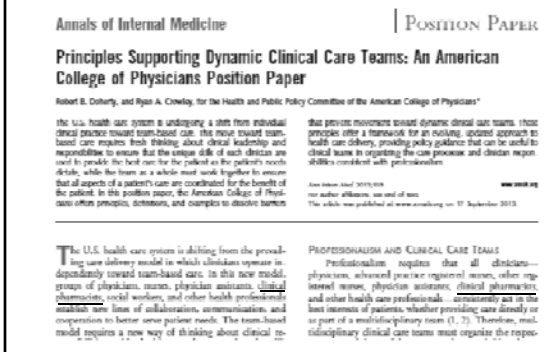
Clinical Care Teams: ACP Position*



Annals of Internal Medicine | Position Paper

Principles Supporting Dynamic Clinical Care Teams: An American College of Physicians Position Paper

Robert B. Doherty, and Ryan A. Crowley, for the Health and Public Policy Committee of the American College of Physicians*

the U.S. health care system is undergoing a shift from individual clinical practice toward team-based care. this move toward team-based care requires fresh thinking about clinical leadership and responsibilities to ensure that the unique skills of each clinician are used to provide the best care for the patient as the patient's needs dictate, while the team as a whole must work together to ensure that all aspects of a patient's care are coordinated for the benefit of the patient. In this position paper, the American College of Physicians offers principles, definitions, and examples to dissolve barriers that prevent movement toward dynamic clinical care teams. these principles offer a framework for an evolving, updated approach to health care delivery, providing policy guidance that can be useful to clinical teams in organizing the care processes and clinician responsibilities consistent with professionalism.

The U.S. health care system is shifting from the prevailing care delivery model in which clinicians operate independently toward team-based care. In this new model, groups of physicians, nurses, physician assistants, clinical pharmacists, social workers, and other health professionals establish new lines of collaboration, communication, and cooperation to better serve patient needs. The team-based model requires a new way of thinking about clinical re-

Professionalism and Clinical Care Teams

Professionalism requires that all clinicians—physicians, advanced practice registered nurses, other registered nurses, physician assistants, clinical pharmacists, and other health care professionals—consistently act in the best interests of patients, whether providing care directly or as part of a multidisciplinary team (1, 2). Therefore, multidisciplinary clinical care teams must organize the respec-

** "Clinical Pharmacist" specifically named*

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Potential Pharmacist Roles: BJC ACO

- Case management rounds (multidisciplinary team)
- Virtual comprehensive medication management (high-risk patients)
- Care transition pharmacist (hospital)
- Pharmacotherapy-related professional development for clinicians (seminars, webinars, newsletters, etc.)

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Pharmacists in ACOs: *Challenges*

- Pharmacist training (and retraining)
- Business model (organizational alignment) and payment reform
- Workflow integration (practice)
- Workflow integration (pharmacy)
- Measurement of impact on quality and on savings

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Scalability and Sustainability

Workforce Development:

- Credentialed pharmacists for direct and indirect patient interactions
- Pharmacist enthusiasm is not only qualification
- Competency-based training opportunities
- Interdisciplinary training opportunities

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Key References

1. Smith M, Bates D, et al. Pharmacists belong in accountable care organizations and integrated care teams. Health Affairs 2013;32:1963-70.
2. AMCP. Pharmacists as vital members of accountable care organizations. 2011.
3. Schnur ES, et al. PCMHs, ACOs, and Medication Management: Lessons Learned from Early Research Partnerships. JMCP 2014;20:201-5.

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What effect has your participation in this program had on your personal interest in partnering with an ACO?

1. Increased
2. Decreased
3. No change

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Practical Applications of MedWatch Updates

Jennifer Phillips, PharmD, BCPS
Kim Janicek, PharmD, CPPS

The speakers have no conflict of interest to declare.

Objectives

- Discuss the MedWatch Program and future safety initiatives (P, T)
- Describe the content of recently issued MedWatch Safety Alerts (P, T)
- Apply specific MedWatch information to simulated patient cases (P)
- Utilize specific MedWatch Alert information to develop or modify policy and guidelines (P)
- Demonstrate how to navigate safety information on the FDA website (P, T)

Overview

- Speaker #1 (Jen Phillips)
  - Introduction
- Speaker #2 (Kim Janicek)
  - Review of regadenoson (Lexiscan) and Adenosine (Adenoscan)
  - Review of rosiglitazone (Avandia)
  - Review of sodium phosphate products
- Speaker #3 (Jen Phillips)
  - Discussion

Introduction

- MedWatch is an on-line database of FDA safety alerts for drugs, devices, biologics, and dietary supplements.
- Many safety alerts are issued for drugs and biological products each year.
  - A total of 83 issued in 2013
- Staying up-to-date on safety information is challenging!

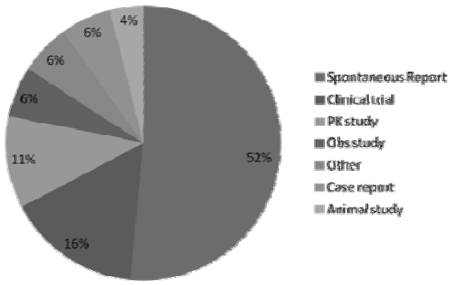
Sources of Safety Information

- Clinical trials
- Post-marketing surveillance
  - Industry reporting
    - Required to report all ADRs.
  - Voluntary reporting
    - Consumers and healthcare professionals
  - Adverse Event Reporting System (AERS)
    - Computerized database of ADRs
- Other strategies

FDA Safety Actions

- Changes to product labeling
  - Changes to contraindications, warnings, precautions
- Recall
  - Removal of certain lots of the product due to quality issues
- Drug withdrawal from the market
  - Change in approval status

Evidence Sources for Labeling Changes



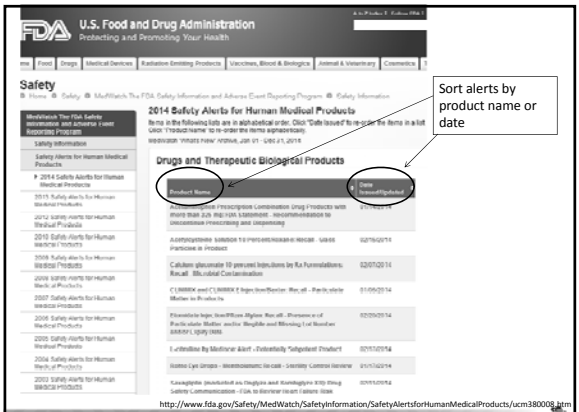
Pharmacoepidemiol Drug Saf 2013; 3: 302-5.

Navigating the MedWatch Site

- Active Learning Demonstration
  - http://www.fda.gov/Safety/MedWatch/default.htm
  - Links to safety alerts and drug safety communications
  - Links to drug safety labeling changes
  - MedWatch Learn
  - Subscription options
  - Reporting events

Drug Safety Communications

- Purpose
  - Provide actionable information to patients and healthcare professionals on new safety information
- Sections
  - Safety Announcement
  - Additional Information for Patients
  - Additional Information for Healthcare Professionals
  - Data Summary



http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm380008.htm

Drug Safety Communications

http://www.accessdata.fda.gov/scripts/MedWatchLearn/

MedWatch Learn

- Interactive tutorial on how to report problems to the FDA
  - Students
  - Healthcare professionals
  - Consumers
- Includes interactive case studies

Subscription Options

- Listservs
  - Hyperlinked summaries of the MedWatch alerts
- Twitter
  - @FDAMedWatch
- RSS feeds
  - Alerts delivered to your webpage or desktop

Reporting Events

- Can submit reports of ***serious*** adverse effects or quality problems related to:
  - Prescription or OTC products
  - Biologics
  - Medical devices
  - Nutritional products
    - Dietary supplements, infant formulas, medical food
  - Cosmetics
  - Food/beverages

Reporting Events

- What ***not*** to report to MedWatch
  - Vaccines
    - Report to Vaccine Adverse Event Reporting System (VAERS)
    - https://vaers.hhs.gov/esub/step1
  - Investigational drugs
    - Refer to study protocol for contact person
  - Veterinary Medicine Products
    - http://www.fda.gov/animalveterinary/safetyhealth/reportaproblem/ucm055305.htm

Recent FDA Alerts

- Regadenoson (Lexiscan) and adenosine (Adenoscan): 11-20-13
- Rosiglitazone (Avandia): 11-25-13
- Sodium Phosphate Products: 1-6-14

Regadenoson and Adenosine

Regadenoson and Adenosine

JG is a 69 year old Caucasian male scheduled to undergo an elective hip replacement. Prior to surgery, a cardiac clearance is required. JG's cardiologist contacts you regarding a recent alert he heard that was issued by the FDA about nuclear stress agents.

The physician is asking for further clarification of the alert and a recommendation from you on what he should do.

Regadenoson and Adenosine

- Basis of alert:
  - Medical literature
  - Spontaneous reports (FAERS)
- Current status:
  - Avoid use in patients with
    - Signs or symptoms of unstable angina
    - Cardiovascular instability
  - Unable to discern a difference between regadenoson and adenosine

http://www.fda.gov/Drugs/DrugSafety/ucm375654.htm

Regadenoson and Adenosine: Literature

- In 4 published studies, no increase in CV events were noted with regadenoson vs. adenosine
- There are 2 case reports of MI reported in the medical literature for regadenoson
- There are 4 case reports of MI in the literature for dipyridamole and 4 case reports for adenosine

http://www.fda.gov/Drugs/DrugSafety/ucm375654.htm

Regadenoson and Adenosine: Spontaneous Reports

- The FDA Adverse Event Reporting System (FAERS) database search
  - 6/24/08 – 4/10/13 for regadenoson
  - 5/18/95 – 4/10/13 for adenosine

	Death	MI
Regadenoson	29	26
Adenoscan	27	6

http://www.fda.gov/Drugs/DrugSafety/ucm375654.htm

Regadenoson and Adenosine: Spontaneous Reports

- Timing of deaths or MIs were not always specified in reports
  - When reported, events tended to occur within 6 hours of administration
- A few deaths occurred when regadenoson or adenosine were administered with exercise stress testing
  - Not FDA approved indication

http://www.fda.gov/Drugs/DrugSafety/ucm375654.htm

Back to the case…

JG is a 69 year old Caucasian male scheduled to undergo an elective hip replacement. Prior to surgery, a cardiac clearance is required. JG's cardiologist contacts you regarding a recent alert he heard that was issued by the FDA about nuclear stress agents.

The physician is asking for further clarification of the alert and a recommendation from you on what he should do.

Regadenoson and Adenosine: Interactive Application

Some more info on JG:

Ht: 5'10" , **Wt**: 225 lbs

Allergies: NKDA

PMH: Hypertension, Diabetes Mellitus, Gout, Multiple Sclerosis, Osteoarthritis, Renal Insufficiency

SH: Occasional ETOH use, smokes 1-2 cigars per week. Retired, lives at home with wife

Cardiologist Note: Recent travel to Europe with a moderate amount of walking. Patient reports that after eating, would experience "chest tightness" that was relieved by rest. Episodes lasted less than 5 minutes and typically were precipitated by a large meal.

Interactive Application

- Form groups of 3-5
- Review case and FDA alert on the FDA website
- What would you recommend?
  - Is it safe for this patient to receive regadenoson?
  - Is it safe for this patient to receive adenosine?
  - If not, what would you recommend instead?

Rosiglitazone (Avandia)

Rosiglitazone: Historical Perspective

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm376683.htm

Rosiglitazone

- FDA Safety Announcement
  - Use of rosiglitazone-containing products does *not* increase the risk of heart attack compared to standard drugs used to treat type 2 diabetes mellitus (i.e., metformin and sulfonylureas)
- Basis of Alert:
  - Meta-analysis of trials and observational studies (2010)
    - RECORD Trial
  - Expert Re-evaluation of data conducted by Duke Clinical Research Institute (DCRI)

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm376683.htm

Rosiglitazone

- Current Status:
  - Distribution no longer restricted
  - Health care professionals, pharmacies and patients no longer required to enroll in REMS
  - Prescribing information and medication guide updated

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm376683.htm

Rosiglitazone: Interactive Application

- Form groups of 3-5
- Review information found in the handouts at your table and the safety information listed on the FDA website.
- Make your recommendation, including rationale, to the Pharmacy and Therapeutics Committee as to the formulary status of rosiglitazone
  - ADD rosiglitazone to formulary?
  - Do NOT ADD rosiglitazone to formulary?
  - ADD with restrictions?

OTC Sodium Phosphate Products

Sodium Phosphate OTC Products

- History:
  - Previous alert issued in 2008 warned against use of high-dose oral sodium products prior to colonoscopy
- Current Alert:
  - Use of ≥ 1 dose in 24 hours can cause serious complications including acute kidney injury, arrhythmias, or death
  - Do not use oral in children ≤ 5 years or rectal in children ≤ 2 years without consulting healthcare provider

http://www.fda.gov/Drugs/DrugSafety/ucm380757.htm

Sodium Phosphate OTC Products

- Current Alert (cont.)
  - Use with caution in patients:
    - Older than 55 years of age
    - Kidney disease
    - Bowel inflammation or obstruction
    - Heart or kidney failure
    - Taking certain medications (ACEI, ARB, or NSAIDs)

http://www.fda.gov/Drugs/DrugSafety/ucm380757.htm

Sodium Phosphate OTC products

- Basis of Alert
  - FAERS database from 1969-2012 and Medical Literature 1957-August 2013
    - 54 cases of serious adverse events
      - 10 FAERS
      - 44 published case reports
- Reported Events:
  - Dehydration and/or electrolyte disturbances (Ca, Na, Phos)
  - Fatalities
    - 12/25 adults
    - 1/29 pediatric cases

http://www.fda.gov/Drugs/DrugSafety/ucm380757.htm

Sodium Phosphate OTC products

- Most complications occurred with
  - A single, larger than recommended dose - OR -
  - Multiple doses per day
- Individuals at higher risk for adverse events:
  - Young children
  - ≥ 55 years of age
  - Dehydration
  - Kidney disease, bowel obstruction, bowel inflammation
  - Concomitant use of ACEI, ARB, or NSAIDs

http://www.fda.gov/Drugs/DrugSafety/ucm380757.htm

Sodium Phsopahte: Patient Case

- BP is a 4 year old male with constipation s/p hernia repair surgery and post-op opioid usage for pain control in PACU. Patient is now being discharged home. PMH includes chronic constipation and chronic ear infections with recent bilateral tympanostomy tube insertion. Current medications include a daily peds MVI, daily peds fiber supplement and ibuprofen 10 mg/kg for pain control. Wt: 42 lbs
- Mother would like to know if it is OK to use Fleets pediatric enema to manage patient's constipation.

Sodium Phosphate: Interactive Application

- Form groups of 3-5
- Review patient case and information found on the FDA MedWatch website.
- Make your recommendation on the appropriateness of using sodium phosphate in this patient.
  - If appropriate, what dose and product would you recommend?
  - If not appropriate, what other product would you recommend?

Other Recent FDA Safety Alerts

Recent Alerts

- FDA evaluating risk of stroke, heart attack and death with FDA approved testosterone products *(issued 1/31/14)*
  - Alert issued based on two observational studies
  - No label changes at this time
- FDA to review heart failure risks with saxagliptin *(issued 2/11/14)*
  - Alert issued based on a single, randomized placebo controlled trial (n=16,492)
  - No label changes at this time
  - FDA requested clinical trial data from the manufacturer

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm384225.htm
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm385471.htm

What is the impact of FDA Drug Risk Communications?

Impact of FDA Communications

- Systematic review (2012)
  - Reviewed 49 published studies from 1990-2010
  - Data sources
    - Medical/pharmacy claims
    - Surveys/focus groups
    - Medical records
    - Prescribing audits
    - Vital statistics
  - Analyzed the impact of FDA risk communications on drug utilization, health care services, and health outcomes
  - Analyzed intended and unintended consequences

Dusetzina SB, et al. Med Care 2012;50:466-78.

Impact of FDA Communications

Type	Result	Examples
Increased monitoring	No evidence of a large or sustained impact	Anti-psychotics: glucose Troglitazone: LFTs
Drug-drug interactions	Clinical practice responds slowly; multiple alerts required	Cisapride, terfenadine, tramadol
Sub-population	"Spill-over" effect to unintended sub-populations	Telithromycin Atypical anti-psychotics
General Caution	Varied impact on clinical practice	Rosiglitazone LABAs

Dusetzina SB, et al. Med Care 2012;50:466-78.

Impact of FDA Communications

- Conclusions
  - Risk communications involving increased monitoring did not have a large or sustained impact on clinical practice.
  - Warnings appear to be implemented more quickly for new users vs. continuing users.
  - Most prescribers were aware of safety alerts, although not all agreed with them.
  - Warnings are more effective when they are specific and the messaging is reinforced over time.
  - With a projected increase in the amount of safety communications, continued assessment of their impact on clinical practice is needed.

Dusetzina SB, et al. Med Care 2012;50:466-78.

The Sentinel Initiative and Mini-Sentinel Pilot

Sentinel Initiative

- Food and Drug Administration Amendments Act of 2007
  - Required collaboration with public, academic, and private sectors
  - Collect, link, and analyze data from multiple electronic data sources
- Sentinel Initiative launched in 2008
  - Multi-year effort to create a national, electronic safety monitoring system
  - "Active" vs. "passive" surveillance
  - Goal: Data from 100,000,000 patients by July 2012
  - Mini-Sentinel Pilot in progress

http://www.fda.gov/downloads/Safety/FDAsSentinelInitiative/UCM274548.pdf

Sentinel Initiative

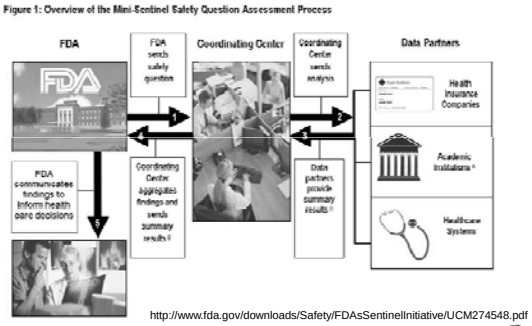
- Mini-Sentinel Pilot
  - Sophisticated statistical systems analyze patterns in defined patient populations (insurance claims, EHR)
  - Focuses on drugs, vaccines, biologics, and medical devices
  - Types of assessments
    - Exposure to medical products
    - Occurrence of diagnoses/medical procedure
    - Health outcomes based on exposure
    - Impact of FDA's regulatory actions or interventions

http://www.mini-sentinel.org/

Mini-Sentinel

- Allows for rapid response to FDA queries
  - Results to queries are in the public domain
- 18 partnering organizations as of 12/2012
  - 130,000,000 million individuals
- Being used in combination with data from other sources to help the FDA make decisions
- For more information:
  - http:///www.mini-sentinel.org

Mini-Sentinel Program



http://www.fda.gov/downloads/Safety/FDAsSentinelInitiative/UCM274548.pdf

Mini Sentinel Controversies

- Results from the Mini-Sentinel program have contradicted published meta-analyses
- Example: dabigatran and bleeding risk
  - Meta-analysis
    - GI tract bleeding with dabigatran vs. warfarin
    - RR 1.41 [95% CI 1.29-1.55], p<0.001
  - Mini-Sentinel
    - Bleeding rate 1.6 with dabigatran (per 100,000 days at risk)
    - 3.5 with warfarin (per 100,000 days at risk)

JAMA Intern Med 2014;174(1):150-1

Summary

- Keeping up to date on safety information is a challenge
- Impact of risk communication on clinical practice is variable
- Future initiatives of the FDA may help capture impact on clinical practice in "real-time" but should be interpreted in the context of other data.

Questions and Comments?

Practical Applications of MedWatch Updates

Kim Janicek, PharmD
Jen Phillips, PharmD, BCPS

0121-0000-14-016-L05-P
0121-0000-14-016-L05-T

Learning Assessment Questions:

1. The evidence for most safety-related labeling changes comes from:
    a. Clinical trials
    b. Animal studies
    c. Spontaneous Reports

2. All of the following information should be reported to the FDA MedWatch program except:
    a. Serious adverse events related to the use of a newly approved drug
    b. Serious adverse events related to the use of an over-the-counter product
    c. Serious adverse events related to the use of a dietary supplement
    d. Serious adverse events related to the use of vaccines

3. Published analyses of bleeding associated with dabigatran from the Mini-Sentinel program correlate with findings from:
    a. Meta-analyses
    b. Clinical Trials
    c. Case reports
    d. None of the above

4. Based on a recent safety alert issued by the FDA, patients with signs or symptoms of (fill in the blank) _____ should not use adenosine or regadenoson.
    a. Unstable angina
    b. Renal insufficiency
    c. Constipation
    d. Gastroesophageal reflux disease

5. A recent safety alert issued by the FDA on rosiglitazone recommends which of the following?
    a. Removal of rosiglitazone distribution restrictions
    b. Creation of a REMS program for rosiglitazone
    c. Removal of rosiglitazone from the market

Platform Presentations

Comparison of zolpidem to other drugs associated with falls in hospitalized patients

Ed Rainville, MSPharm.

Special Acknowledgment to Daniel Ricci, PharmD.
for his work on this project

March 28, 2014

Conflict of Interest Statement:

The speaker has no conflict of interest in relation to this presentation.

Objective of Study

- Indicate the risk of falls in hospitalized patients associated with the use of zolpidem as compared with other medications commonly associated with this risk.

Background


LawyersandSettlements.com
THE BLOG

Mayo Clinic Phasing out Ambien after Slip and Fall Study

AMBIEN
ZOLPIDEM TARTRATE/SC

The Mayo Clinic has decided to phase out use of Ambien, the prescription sleeping pill, over concerns that patients on the drug have a higher rate fall rate than those who are not on it.

In a study conducted by the Mayo Clinic in Rochester, MN and published in the Journal of Hospital Medicine (11/19/12), researchers reviewed fall data from more than 16,000 patients who were hospitalized. The study found that patients who were given Ambien while hospitalized experienced falls more than four times greater than those who were not given Ambien. According to the study, the fall rate for

- Reference: Lawyersandsettlement.com. November 20, 2012. Available from: URL: http://www.lawyersandsettlements.com/blog/mayo-clinic-phasing-out-ambien-after-slip-and-fall-study-010966.html

Background

- "*Zolpidem is independently associated with increased risk of inpatient falls.*"
  - 41,947 adult admissions
  - 16,320 prescribed zolpidem
  - Comparison: 4,962 received zolpidem vs. 11,358 control group (patients who were prescribed zolpidem but did not receive it)
  - Fall rate: 1.42/100 zolpidem patients vs. 0.71/100 control group
- Reference: Kola BP, Lovely JK, Mansukhani MP, Morgenthaler TI. Zolpidem is independently associated with increased risk of inpatient falls. *J Hosp Med.* 2013;8:1-6.

Background

- Further analyses of fall risk:
  - Age (p=0.07)
  - Antidepressant (*NS*)
  - Antipsychotic (*NS*)
  - Antihistamine (*NS*)
  - Sedative antidepressant (*NS*)
  - Benzodiazepine (*NS*)
  - Opioid (*NS*)

Background

Authors Conclusion:

"Zolpidem thus appears to increase the risk of falling beyond that attributable to other medications in hospitalized patients."

Study Method

- Retrospective chart review from October 2012 to January 2013 (4 months)
- Patients identified through electronic reporting system for inpatient falls.
- This study had the requisite institutional review board approval

Study Method

- Patient data:
  - Age
  - Gender
  - Select medications taken within 24 hours prior to fall:
    - Zolpidem
    - Sedative antidepressants (trazodone, mirtazapine)
    - Other antidepressants
    - Antipsychotics
    - Antihistamines
    - Benzodiazepines
    - Opioid analgesics

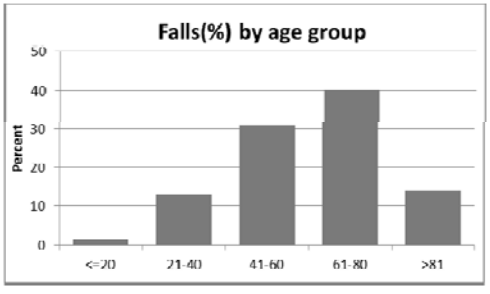
Study Method

- Exclusions
  - Pediatrics (less than 18 years old)
  - Falls occurring in the Emergency Department

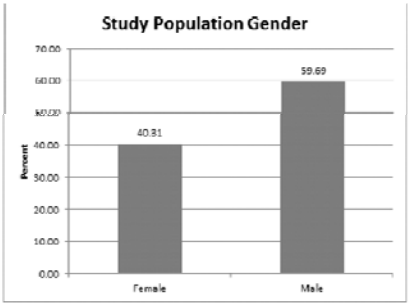
Results

- 152 Falls Reported in 4 months
- 23 Falls excluded (14 – ED, 9 – Peds)
- 8 Patients with multiple falls
  - 7 patients with 2 falls, 1 patient with 3 falls
- 129 Falls (120 patients) included in analysis
- 41,676 patient days
- 347 average daily census

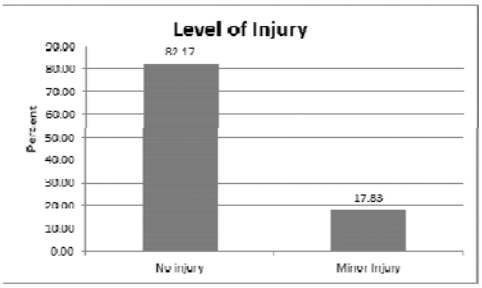
Results (N = 120 patients)



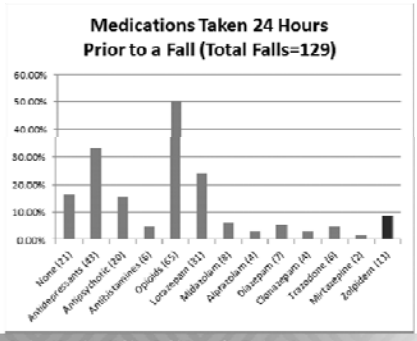
Results (N = 120 patients)



Results (N = 120 patients)



Results



Limitations

- Documentation of falls was voluntary.
- Other contributing factors (other medications, condition of patient, etc.) were not included.
- Doses used was not analyzed.
- Combination of medications was not studied.

Conclusions

- Zolpidem is a risk factor for patient falls.
- Other medications pose at least equal or greater risk in contributing to patient falls.

Based upon the results of this study, what is the best action to reduce the risk of patient falls related to zolpidem?

A. Remove zolpidem from the formulary and provide a substitution to a benzodiazepine.
B. Do nothing, zolpidem is not a risk to patient falls.
C. Restrict the use of zolpidem to patients younger than 80 years old.
D. Reduce the use of zolpidem and other medications associated with risk of falls.
E. Remove zolpidem from the formulary and do nothing else.

Platform Presentations

Chronic Obstructive Pulmonary Disease (COPD) Exacerbation Inpatient Treatment: A Retrospective Chart Review

Jennifer Arnoldi, Pharm.D., BCPS
Clinical Assistant Professor
SIUe School of Pharmacy
jearnol@siue.edu

I have no conflicts of interest to disclose.

Pharmacist Objective

- Discuss evidence-based inpatient treatment of COPD exacerbations.

Background

- COPD exacerbation[1]
  - Acute worsening in underlying COPD
  - Increase in cardinal symptoms
    - Shortness of breath
    - Sputum volume
    - Sputum purulence
  - Warrants a change in management

GOLD 2013

Impact of COPD

- Cost of hospitalization accounts for almost 50% of total COPD expenses[2]
- A 2006 study of 127 patients over one year
  - 77% of COPD patients experienced an exacerbation[3]
  - The average cost for an exacerbation-related hospital admission was $7,100[4]
- 2003-2004 Medicare data[5]
  - COPD-related 30-day readmission rates were 22.6%
  - Cost increases of $8,400 to $11,100 found in second admission

2. Hilleman et al. *Chest* 2000.
3. O'Reilly et al. *Prim Care Respir J* 2006.
4. Elixhauser et al. Statistical Brief #121: Readmissions for Chronic Obstructive Pulmonary Disease, 2008.
5. Jencks et al. *N Engl J Med* 2009.

Inpatient Exacerbation Management

- **G**lobal Initiative for Chronic **O**bstructive **L**ung **D**isease (GOLD) Guidelines
  - Controlled oxygen therapy
  - Bronchodilator therapy
  - Glucocorticoids
  - Antibiotics

GOLD 2013: Steroids

- Benefits
  - Shorten recovery time
  - Improve lung function
  - Reduce risk of early relapse and treatment failure
- Prednisone 30-40mg/day for 10-14 days
  - 2014: Prednisone 40mg/day for 5 days

GOLD 2013: Antibiotics

- Place in therapy:
  - 3 cardinal symptoms present or mechanical ventilation needed
  - 2 of 3 cardinal symptoms (if ↑ sputum purulence is present)
- Common pathogens
  - Viruses
  - *H. influenzae, S. pneumoniae, M. catarrhalis*
  - GOLD 3 and GOLD 4, consider *P. aeruginosa*

GOLD 2013 Empiric Antibiotics

- Amoxicillin ± clavulanate, macrolide or tetracycline
- Consider broader coverage ± sputum cultures if:
  - Frequent exacerbations
  - Severe airflow limitation
  - Mechanical ventilation
- Duration of therapy 5-10 days

Study Aim

- To evaluate current inpatient treatment of COPD exacerbations in a teaching hospital
- To compare the treatment of COPD exacerbations in clinical practice with recommendations from the GOLD 2013 guidelines

Methods

- Retrospective chart review
- Patient selection
  - 18 to 89 years of age
  - Hospitalized for COPD exacerbation
  - Exclusions
    - Received antibiotic or systemic corticosteroid therapy for any reason other than a COPD exacerbation

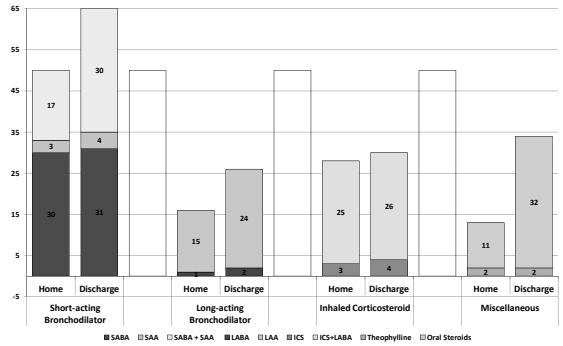
Data Collection

- Disease
  - Smoking history
  - Cardinal symptoms
  - Documentation of baseline COPD severity
- Treatment
  - COPD medication therapy (acute and chronic)
  - Inpatient vaccination screening and administration
- Readmission
  - Time to hospital readmission
  - Reason for hospital readmission

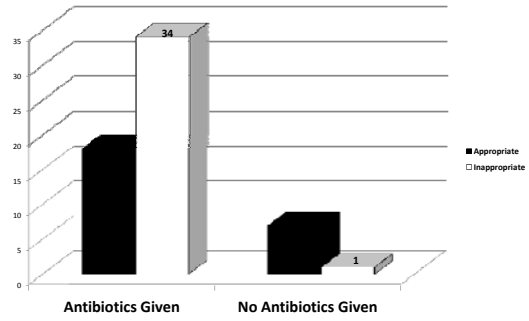
Patient Characteristics

Total Patients	N=60
Age (years)	
Range	30-89
Mean	70
Race	
Caucasian	57 (95%)
African American	3 (5%)
Gender	
Male	30 (50%)
Female	30 (50%)
Smoking Status	
Current	30 (50%)
Former	22 (37%)
Never	2 (3%)
Undocumented	6 (10%)

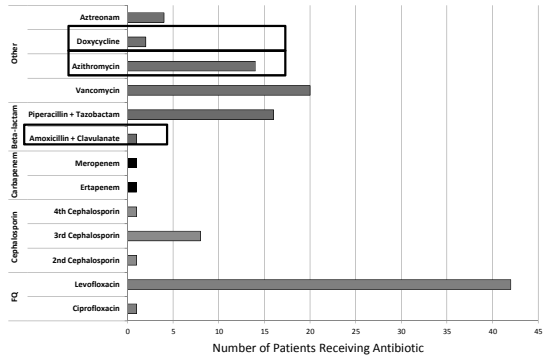
COPD Medication Therapy



Antibiotic Use

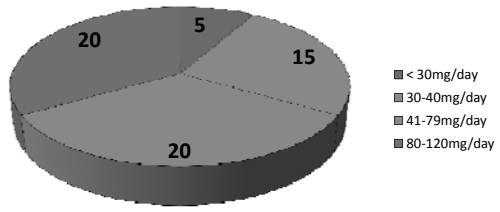


Choice of Antibiotic



Steroid Dosing

N=60



Limitations

- Retrospective chart review
  - ICD-9
  - Differential diagnoses
- Single site
- Small number of patients
- Lack of information
  - Baseline COPD status and severity
  - History of exacerbations

Summary

- Opportunities for improvement
  - Symptom-driven antibiotic use
  - Antimicrobial selection
  - Oral corticosteroid regimens
  - Assessment of baseline disease severity
- Future direction

Assessment

In which of the following patients, hospitalized for a COPD exacerbation, would it be most appropriate to recommend an antibiotic?

a. A 66 year old male with a cough
b. A 72 year old female with shortness of breath and copious clear sputum production
c. A 54 year old female with copious sputum production that is thick and green-colored
d. A 63 year old male with cough and shortness of breath

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Chronic Obstructive Pulmonary Disease (COPD) Exacerbation Inpatient Treatment: A Retrospective Chart Review

Jennifer Arnoldi, Pharm.D., BCPS
Clinical Assistant Professor
SIUe School of Pharmacy
jearnol@siue.edu

Pharmacy Practice Pearls

Clinical Impact of a Pharmacist in Discharge Medication Reconciliation

Teresa Chu, PharmD
Swedish Covenant Hospital
Chicago, Illinois

Objectives

1) Describe the clinical role of a pharmacist performing discharge medication reconciliation.

2) Explain the impact a pharmacist can have on readmission rates with medication reconciliation, clinical, and prescription-related interventions.

I have no potential/actual conflict of interest to declare

Medication Reconciliation

Reconcile medication profiles from each transition of care (ie: home → inpatient → discharge). (61% incomplete med hx on admission, 33% discharged pts with med-related problems)[1]
Provide the patient an updated medication list.
Counsel the patient on new and continued home medications.
Check prescriptions to ensure all legal requirements are met.

Going Beyond Med Recon.

- At discharge, go beyond medication reconciliation and prescription-interventions
- Take steps toward making **clinical**-interventions:
  - Maintain open communications with prescribers
  - Maintain open communications with nurses
  - Update ourselves on current treatment guidelines

Clinical Interventions

1) Review the patient's chief complaint and the resolution of acute issues.

2) Evaluate the continuum of care patient received from one level of triage to another, including the discharge plan

3) Intervene when prescribed discharge medication regimen is suboptimal according to evidence-based recommendation standards.

Clinical Interventions (cont.)

Are the discharge medications prescribed appropriate? Are continued home medications appropriate? Are prophylactic drugs included?	Match the drug with patient's problem list. Prescribing should be evidence-based.
Are all medications at optimal/ target doses? 52.2% of discharge medication profiles require dose adjustments[2]	Medications should be dosed according to the most current treatment guidelines.

Clinical Interventions (cont.)

Recommend to discontinue medications without appropriate indications.	Eliminate duplications and reduce risk for drug-induced adverse events.
Recommend to add omitted medications if indicated.	For disease-state management and prevention of co-morbidities.
20% of discharge medication profiles requires the discontinuation or addition of medication(s)[2]	

Impact of a D/C Pharmacist

- PHARMACISTS *can* potentially increase medication compliance and reduce adverse drug events.[3*]
- PHARMACISTS *may* impact readmission rates.[4*]
- Quality-of-care improvement*
- Cost-saving interventions (stream-lining to less expensive therapy, d/c unnecessary meds, route modifications) can lower drug cost by 41%.[5]

* Hypothesis generated for future randomized studies to confirm results

Zadeh MD, Chu T. Impact of Pharmacist Discharge Counseling on Medication Adherence and Hospital Readmission Rates

Swedish Covenant Hospital[4]

- A prospective, randomized study; currently in progress

Primary Objective: To evaluate whether discharge medication reconciliation and counseling by pharmacists can increase a patient's medication adherence and reduce hospital readmission rates

Secondary Objective: To assess and compare the patient's medication adherence 1-2 weeks vs. 30-45 days post-discharge

Inclusion Criteria: New onset or history of CHF and/or COPD

Exclusion Criteria: Not being discharged home, pre-planned hospital readmission

Zadeh MD, Chu T. Impact of Pharmacist Discharge Counseling on Medication Adherence and Hospital Readmission Rates

Swedish Covenant Hospital (cont.)

- Subjects divided into 2 groups:
  - Control: non-pharmacist involved discharge process
  - Intervention: med reconciliation and counseling by pharmacist at discharge
- All patients were contacted via phone for follow-up interviews
  - 1-2 weeks post-discharge: med compliance assessment (MMAS questionaire[6])
  - 30-45 days post-discharge: hospital readmission assessment and med compliance assessment (MMAS questionaire[6])
- Results and data evaluation in progress

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Pharmacy Practice Pearls

Clinical Impact of a Pharmacist in Discharge Medication Reconciliation

Teresa Chu, PharmD

0121-0000-14-018-L04-P

Learning Assessment Questions:

1. All of the following are procedures involved in the medication reconciliation process, except:

    a. Communicating with the physician when a dosing regimen is suboptimal or not indicated.
    b. Including herbal and homeopathic medications as part of the home medication history for reconciliation.
    c. Reconciliation of the patient's home medications and discharge medications is sufficient.
    d. Recommending prophylactic drugs to the physician for long-term disease state management during discharge.

2. All of the following results can be objectively measured when a pharmacist is included in the reconciliation process, except:

    a. Improvement in quality-of-care
    b. Lowering readmission rates
    c. Lowering drug costs
    d. Reduction of adverse drug events

Pharmacy Practice Pearls

Innovative Use of Integrated Technology to Prevent Human Error in Providing Medications from the Point of Prescription to the Patient's Bedside

Alicia Juska, PharmD, BCPS
Swedish Covenant Hospital
Chicago, IL

Conflict of Interest Disclosure

- Alicia Juska, the speaker, has no actual or potential conflict of interest in relation to this presentation.

Objectives

- Explain how integration of robotics, automation, and technology can reduce potential medication errors for patient specific drug selection, packaging, dispensing, and administration of bar coded unit doses.
- Identify ways that implementation of a centralized medication storage and dispensing robot with pass through access to the clean room can reinforce compliance with Chapter 797 guidelines and improve the environment for compounded sterile products (CSPs).

Medication Error Data

- Medication errors are 1 of the 6 leading avoidable costs in U.S. health care[1]
  - Avoidable cost opportunity from medication errors is $20 billion (range $15-28 billion)[1]
- 450,000 adverse drug events occur annually[2]
  - 25% of these medication errors are preventable[2]
- Technology has been introduced to improve accuracy of the medication use system[2]

National Data for Use of Technology in Hospitals

- 30% use computerized provider order entry[3]
- 50% use barcoded medication administration[3]
- 65% of clean rooms were compliant with Chapter 797 guidelines for CSPs[4]
- 11% use robots[4]
- 18% use carousels[4]

How many of you currently use the following in your inpatient pharmacy?

A. Computerized Prescriber Order Entry (CPOE)
B. Bedside Medication Verification (BMV)
C. Electronic Medication Administration Record (EMAR)
D. Robotics (Boxpicker, Carousel, etc)

Swedish Covenant Hospital

- Overview
  - 300 bed hospital on the Northwest Side of Chicago
  - Community, non-profit, independent, teaching hospital
  - Decentralized pharmacy model with one central pharmacist to oversee distribution
- Technology (at SCH in 2012)
  - Pharmacy redesign and robotic installation
  - CPOE, EMAR, and EHR in place
  - BMV in progress

SCH Inpatient Pharmacy Pre-Remodel

Oral Solid Medication Storage

Pharmacist Work Stations

Remodeled SCH Inpatient Pharmacy

Overview with Centralized Med Storage & Dispensing Robot

Pharmacist Work Stations

System-wide National Drug Code (NDC) Linked Barcode Technology

- From computerized prescriber order entry (CPOE)
- To pharmacist order verification
- To dispensing a unit dose
  - 10% from a centralized medication storage and dispensing robot or
  - 90% via decentralized automated dispensing cabinets (ADCs)
- To bedside medication verification (BMV) with electronic charting on the medication administration record (EMAR)

Medication Use System Control

- All medications must be barcoded when received from the wholesaler
  - New NDCs (change in manufacturer, backorder item replacement) must be entered in the system
- All medications must be assigned an NDC linked barcode prior to being filled in the:
  - Centralized medication storage and dispensing robot
  - Unit dose packager
  - Decentralized ADCs
- Above steps ensure a nurse will be able to scan the medication on the floor

Barcoded Unit Dose

From Robot

From Prepackaging Machine

How many times does a technological double check (barcode scan) occur prior to a dose being administered to a patient at bedside?

A. 2
B. 4
C. 6
D. 8

Barcode Scan Throughout the Medication Use System

- Filling robot with daily shipment received
- When removing and/or refilling robot with barcoded unit doses made by the automated prepacking machine
- When removing a dose from the robot an individual label with a barcode is printed
- Prior to any ADC refill
- When the nurse removes a dose from the ADC
- During BMV, prior to patient administration, and for concurrent EMAR documentation

Benefits of Technological "Double-Checks" Using System-wide Barcodes

- Prevent human errors and decrease medication errors
  - Reinforce appropriate preparation of unit doses
  - Increase level of accurate dispensing of unit doses for both oral and intravenous medications and restocking of ADCs
  - Decrease number of missing doses
  - Streamline pharmacy workflow
  - Tighten control of pharmacy inventory for both oral and injectable medications
- Free pharmacists' time from dispensing duties to allow for more clinical patient-care activities
  - Future "tech check tech" possibilities
- Increase patient safety

Changing Gears and On to the IV Side

Aseptic Garbing, Hand Washing, Gowning, and Gloving Practices of Compounding Personnel[5,6]

- To enter, compound, and leave the IV room correctly takes 21 steps
- Highlights include:
  - Putting on shoe covers one at a time, crossing into the clean ante-area of the IV room
  - Putting on a head cover, beard mask, face mask
  - Hand washing and drying
  - Gowning
  - Collecting compounding items (drugs, needles, syringes)
  - Disinfecting hands with a waterless, alcohol-based surgical hand scrub
  - Gloving

What is the most appropriate process for entering the IV room?

A. gown, shoe covers, wash hands, gloves, hair cover, alcohol-based surgical hand scrub
B. shoe covers, wash hands, gloves, gown, hair cover, alcohol-based surgical hand scrub
C. hair cover, gown, shoe covers, wash hands, gloves, alcohol-based surgical hand scrub
D. shoe covers, hair cover, wash hands, gown, alcohol-based surgical hand scrub, gloves

Chapter 797 Environmental Control Requirements[5,6]

- Designated, separate, well-light area
- 68ºF or cooler
- Relative humidity 30-60%
- HEPA filtered air
  - Unidirectional flow
  - Sufficient velocity to sweep particles away from compounding area
  - Introduced at ceiling with returns mounted low on the walls

Chapter 797 Environmental Control Requirements[5,6]

Clean Room	ISO Class
Ante Area	ISO Class 8
Buffer Area	ISO Class 7
Direct Compounding Area	ISO Class 5
Laminar Airflow Workbench (LAFW) or Compounding Aseptic Containment Isolator (CACI)	ISO Class 5

Chapter 797 Recommended Action Levels for Microbial Contamination[5,6]

ISO Class	Surface Sample (Contact Plate) (cfu per plate)
8	> 100
7	**> 5**
5	**> 3**

Surface sampling to be conducted every 6 months

Clean Room Pre-Remodel

Ceiling with Dust Pockets

Cooling and Air Filtration System

Remodeled Clean Room

Sealed Ceiling Tiles and Floor Molding, HEPA Filters in Ceiling, Low Vent Returns, Closed Door to Direct Compounding Area

Clean Air Room Access Comparison

Door of Ante Room Leading into Buffer Room Entrance (Full garbing)

Pass Through Window (No garbing)

Pass Through Window

- Advantages
  - Decrease traffic in and out of IV room
    - Personnel
    - Carts (wheeled through pharmacy past front door)
  - Save personnel time to garb
  - Decrease $ spent on garbing/gowning supplies to enter IV room
  - Pharmacist can check stat medication quickly

Compounding Supplies Pre-Remodel

IV Room Supplies in Pharmacy Storage Area

Supplies in Ante Room

Remodeled Compounding Supplies

IV Room View

Supplies in Ante Room

Pharmacy Automation

Inside Centralized Med Storage (Drug Bins & Robot)

Med Pick Station

Robot & Refrigerated Compartment Inside Centralized Med Storage

Additional Med Pick Station in IV Room

- Advantages
  - Allows IV technician access to IV medications without leaving IV room
    - Room temperature medications AND
    - Refrigerated medications
  - Improves workflow and technician efficiency
  - Requires technician to barcode scan each drug removed for compounding
  - Maintains inventory count for IV medications without requiring entry of buyer into the IV room

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Questions?

ICHP 2014 Spring Meeting: Taking Bold Steps for Patient Care

Pharmacy Practice Pearls:

Innovative Use of Integrated Technology to Prevent Human Error in Providing Medications from the Point of Prescription to the Patient's Bedside

Alicia Juska, Pharm D, BCPS

0121-0000-14-018-L04-P

Learning Assessment Questions

Choose the best answer:

1. What is the benefit of using a barcoded medication administration system?
   A. Print a report for drug recalls on a specific lot of a drug given to a patient
   B. Intercept potential medication errors prior to patient administration
   C. Start allowing technicians to check technician prepared doses to send to floors
   D. Save time on restocking shelves when drugs are received from the wholesaler

2. According to the USP Chapter 797 guidelines, what is the recommended action level for surface sample microbial contamination of the laminar airflow work bench?
   A. Greater than 100
   B. Greater than 10
   C. Greater than 5
   D. Greater than 3

Pharmacy Practice Pearls

Drug Choice and Dosing in the Patient with Advanced Liver Disease

Mia Schmiedeskamp-Rahe
PharmD, PhD, BCPS

There are no conflicts of interest to declare

Objectives

- Identify patients with advanced liver disease requiring dose adjustments of medications.
- Discuss the principles of selecting medications appropriate for patients with advanced liver disease.

The problem

- Liver disease is 12th leading cause of death
- 5th leading cause in 45-64 year olds
- Studies often omit severe liver disease
- Little information in disease-state guidelines
- Little information in package inserts

The problem

- The resulting risk is neglect of liver disease
  - When selecting medications
  - When dosing medications
- Those with severe liver disease are vulnerable
  - Liver is key site of drug metabolism
  - Severe liver disease increases side effect risk

The goal

- Recognize patients with advanced liver disease
- Account for advanced liver disease
  - When selecting medications
  - When dosing medications

Identifying patients with advanced liver disease

- Patients with cirrhosis that is decompensated
  - presence of jaundice
  - ascites
  - hepatic encephalopathy
  - large esophageal or gastric varices
- Patients with Child-Pugh class B or C cirrhosis

The Child-Pugh score

	1 point	2 points	3 points
Total bilirubin (mg/dl)	< 2	2 – 3	> 3
INR	< 1.7	1.7 – 2.3	> 2.3
Albumin (g/dl)	> 3.5	2.8 – 3.5	< 2.8
Ascites	none	controlled	refractory
Hepatic encephalopathy	none	mild	poorly controlled

Applicable to those with cirrhosis
Score ranges from 5 to 15

The Child-Pugh score

Points	Class	1-year survival	2-year survival
5 - 6	A	100%	85%
7 - 9	B	81%	57%
10 -15	C	45%	35%

Patients with class B and C cirrhosis
have advanced (decompensated) liver disease

Patient case #1

- A patient diagnosed with cirrhosis has the following:
  - No ascites
  - No hepatic encephalopathy
  - INR = 2.0
  - Tbil = 1.1 mg/dl
  - Albumin = 2.0 g/dl
  - Large esophageal varices
- Does this patient have advanced liver disease?

Patient case #1

Attribute	Child-Pugh points
No ascites	1
No hepatic encephalopathy	1
INR = 2.0	2
Tbil = 1.1 mg/dl	1
Albumin = 2.0 g/dl	3
Large esophageal varices	NA

Child-Pugh score is 8 and class is B: advanced liver disease
The large varices also indicate decompensated liver disease

Patient case #2

- A patient diagnosed with cirrhosis is starting interferon, ribavirin and sofosbuvir for hepatitis C.
  - No ascites
  - No hepatic encephalopathy
  - INR = 1.3
  - Tbil = 0.9 mg/dl
  - Albumin = 3.8 g/dl
  - No varices
- Does this patient have advanced liver disease?

Patient case #2

Attribute	Child Pugh points
No ascites	1
No hepatic encephalopathy	1
INR = 1.3	1
Tbil = 0.9 mg/dl	1
Albumin = 3.8 g/dl	1
No varices	NA

Child-Pugh score is 5 and class is A, with no signs of decompensation: this is not advanced liver disease

Strategy for choosing drugs in advanced liver disease

- Several recent articles delineate concerns and underlying principles
- Strategy should be systematic and straightforward
- Should be usable by general practitioners

Step #1: Avoid hepatotoxins

- Consider if the drug has a well-established risk of liver failure
- livertox.nih.gov is a helpful resource

Examples:

- Avoid isoniazid in favor of a fluoroquinolone
- Avoid phenytoin, carbamazepine in favor of levetiracetam
- Avoid darunavir in favor of other options for HIV

Step #2: Avoid nephrotoxins

- Advanced liver disease predisposes to renal failure
- Avoid medications with high nephrotoxic potential
- Examples:
  - Avoid NSAIDS
  - Avoid aminoglycosides unless only option
  - Monitor vancomycin to avoid supra-therapeutic levels
  - Expect that contrast dye will precipitate renal failure

Step #3: Determine if drug will accumulate

- Drugs metabolized in the liver will accumulate
  - Oxidation is more affected
  - Conjugation is less affected
  - In the most advanced cases this distinction is less prominent
- These patients often have brittle renal function
  - Those who regularly experience acute kidney injury are at risk to accumulate renally-cleared drugs
  - Example: avoid glyburide in favor of glipizide

Step #4: If drug accumulates, can this be monitored?

- If the drug is expected to accumulate, this can be managed by therapeutic drug monitoring
- Examples:
  - Warfarin
  - Tacrolimus and cyclosporine
  - Antiarrhythmics

Step #5: Will unmonitored accumulation present a risk?

- If side effects of undetected high levels are unacceptably dangerous, best to avoid
- Examples would include arrhythmias, seizures, bleeding
  - high-dose tricyclic antidepressants
  - bupropion
  - dipyramidole

Step #6: Is the drug likely to worsen encephalopathy?

- Many drugs precipitate hepatic encephalopathy
- Examples:
  - Avoid benzodiazepines except when absolutely necessary
  - Avoid hypnotic drugs like zolpidem, eszopiclone
  - Avoid opioids if a less-sedating drug works (e.g. tramadol, < 2 g/day acetaminophen)
  - Minimize other sedating drugs such as TCA for neuropathic pain

Choosing doses with package insert

- Package inserts may offer guidance
- Usually based on Child-Pugh score
- Example: Tigecycline
  - Mild to moderate hepatic impairment (Child-Pugh class A or B): No dosage adjustment necessary
  - Severe hepatic impairment (Child-Pugh class C): Initial: 100 mg single dose; Maintenance: 25 mg every 12 hours

Strategy for choosing doses without guidance from package insert

- Examples: glipizide XL, propranolol
  - No dose recommendations for hepatic impairment in manufacturer's labeling
- Strategy: Start low and go slow
  - Start at or near lowest available dose
  - titrate slowly
  - monitor parameters that can reveal accumulation

Patient case #3

- A cirrhotic patient with ascites, large varices, hepatic encephalopathy and INR = 3.0 is newly started on the following drugs:
  - isoniazid for treatment of latent tuberculosis
  - ibuprofen for mild back pain
  - bupropion for smoking cessation
  - lorazepam for anxiety
  - propranolol 20 mg bid for varices

Which one of the newly started drugs is most appropriate for this patient with advanced liver disease?

A. Isoniazid
B. Ibuprofen
C. Bupropion
D. Lorazepam
E. Propranolol

Questions?

Reading list

1. Centers for Disease Control and Prevention. National Vital Statistics Reports: Deaths: Final Data for 2010. Available at http://www.cdc.gov/nchs/data/nvsr/nvsr61/nvsr61_04.pdf. Accessed February 15, 2014.

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Reading list

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6. Lin S, Smith BS. Drug dosing considerations for the critically ill patient with liver disease. Crit Care Nurs Clin N Am. 2010;22:335-340.

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Pharmacy Practice Pearls:
Drug Choice and Dosing in the Patient with Advanced Liver Disease
Mia Ruth Schmiedeskamp-Rahe, PharmD, PhD, BCPS
0121-0000-14-018-L04-P

Learning Assessment Questions

1. For a patient with chronic liver disease due to hepatitis C, which finding would be sufficient to indicate decompensated liver disease?

A. Cirrhosis on liver biopsy
B. Serum albumin 3.0 g/dl
C. Refractory ascites
D. Total bilirubin 2.2 mg/dl

2. A 55 year-old patient with Child-Pugh class C liver disease (weight 60 kg, serum creatinine 0.8 mg/dl) is prescribed medications for hospital discharge, including furosemide 40 mg po daily, spironolactone 50 mg po daily, levetiracetam 500 mg po q12h, propranolol 20 mg po q12h and ibuprofen 400 mg po q6h prn mild pain.

Which medication should be challenged by the clinical pharmacist on the basis it should not be used in patients with severe liver disease?

A. Spironolactone
B. Levetiracetam
C. Propranolol
D. Ibuprofen

Pharmacy Practice Pearls

Colistin Dosing: A Literature Review

By:
Kanan Shah, Pharm.D.
Hee Jung Kang, Pharm.D., BCPS

Conflict of Interest Declaration

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

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Learning Objectives

- Discuss the risks and benefits of the different dosing strategies available in the current literature.
- Explain colistin's role in combination regimens for multidrug resistant gram negative infections.

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Colistin: The Basics

- Colistin methanesulfonate (CMS) IV form
- CMS inactive prodrug for colistin base (CBA)
- Polymyxin E
- Bactericidal
  - disrupts outer cell membrane → intracellular component leakage → cell death
- Last-line treatment of multi-drug resistant gram negative bacteria

MacLaren G, Spelman D. Colistin: an overview. In: *UpToDate, Hooper DC (Ed), UpToDate, Waltham, MA, 2005.*

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Colistin Potency

- 1 IU of colistin = amount of colistin that inhibits growth of Escherichia coli 95 I.S.M. in 1 ml broth of pH 7.2
- 1 mg colistin base activity (CBA) = 2.4 mg CMS
- 12,500 IU = 1 mg CMS
- 30,000 IU = 1 mg CBA

Falagas ME. Use of international units when dosing colistin will help decrease confusion related to various formulations of the drug around the world. *Antimicrob Agents Chemother*. 2006;50 (6):2274-2275.

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What is the dose of colistin in CBA that corresponds to 9 million IU of colistin?

A. 100 mg
B. 150 mg
C. 300 mg
D. 720 mg

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Manufacturer Recommended Dosing

USA Colistimethate (expressed in mg CBA)

	Normal Renal Function	Mild Renal Impairment	Moderate Renal Impairment	Considerable Renal Impairment
Plasma Creatinine (mg/100mL)	0.7 – 1.2	1.3 – 1.5	1.6 - 2.5	2.6 - 4
Urea Clearance (% normal)	80 - 100	40 - 70	25 - 40	10 - 25
Unit Dose CMS (mg)	100 - 150	75 - 115	66 - 150	100 - 150
Frequency (times/day)	4 - 2	2	2 - 1	Every 36 hours
Total Daily Dose (mg)	300	150 - 230	133 - 150	100
Approximate Daily Dose (mg/kg/day)	5	2.5 - 3.8	2.5	1.5

Colistimethate for injection [package insert]. Big Flats, NY: X-gen Pharmaceuticals Inc; 2010.

Manufacturer Recommended Dosing USA Colistimethate

- Dosing Strategies
  - Direct Intermittent Administration
    - Half daily dose over 3-5 minutes every 12 hours
  - Continuous Infusion
    - Half daily dose over 3-5 minutes
    - After 1-2 hours administer remaining daily dose over 22-23 hours

Colistimethate for injection [package insert]. Big Flats, NY: X-gen Pharmaceuticals Inc; 2010.

Do you have a protocol at your institution that adheres to this regimen?

A. Yes – exactly
B. Yes – modified
C. No

Resistance Breakpoints

	CLSI*	EUCLAST§
Acinetobacter spp.	≥4 mg/L	>2 mg/L
Pseudomonas aeruginosa	≥8 mg/L	>4 mg/L

*Clinical and Laboratory Standards Institute § European Committee on Antimicrobial Susceptibility Testing

European Committee on Antimicrobial Susceptibility Testing. Colistin: Rationale for the clinical breakpoints, version 1.0, 2010. http://www.eucast.org.
Biswas S, Brunel J, Dubus J, Reynaud-Gaubert M, Rolain J. Colistin: an update on the antibiotic of the 21st century. *Expert Rev Anti Infect Ther.* 2012;10(8):917-934.

Plachouras et al.

- Dosing regimen
  - 100 mg CBA Q8H if CrCl ≥ 50
  - 67mg CBA Q8H if CrCl < 50
- Modeled serum colistin levels based on PK data from 18 subjects

Plachouras D, Karvanen M, Friberg LE, et al. Population pharmacokinetic analysis of colistin methanesulfonate and colistin after intravenous administration in critically ill patients with infections caused by gram-negative bacteria. *Antimicrob Agents Chemother.* 2009;53(8):3430-3436.

Plachouras et al.

Dosing Strategy	Time to Reach Peak >2mg/L
100 mg (15 min infusion) Q8H	>36 hrs
300 mg (15 min or 2 hr infusion) X1 dose then 150 mg (15 min infusion) Q12H	>12 hrs
400 mg (15 min or 2 hr infusion) X1 dose then 15 0mg (15 min infusion) Q12H	<12 hrs

Plachouras D, Karvanen M, Friberg LE, et al. Population pharmacokinetic analysis of colistin methanesulfonate and colistin after intravenous administration in critically ill patients with infections caused by gram-negative bacteria. *Antimicrob Agents Chemother.* 2009;53(8):3430-3436.

Garonzik et al.

- Open-label population PK study in critically ill patients
- n=105
- 851 serum samples
- 12 patients on HD
- 4 patients on CRRT

Garonzik SM, Li J, Thamlikitkul V, et al. Population pharmacokinetics of colistin methanesulfonate and formed colistin in critically ill patients from a multicenter study provide dosing suggestions for various categories of patients. *Antimicrob Agents Chemother*. 2011;55(7):3284-3294.

Garonzik et al.

	Median	Range
CrCl (ml/min/1.73m^2)	28.7	0 - 169
Daily CBA dose (mg)	200	75 - 410
$C_{ss,avg}$ [1] (mg/liter)	2.36	0.48 - 9.38

1. Average steady-state plasma concentration

Garonzik SM, Li J, Thamlikitkul V, et al. Population pharmacokinetics of colistin methanesulfonate and formed colistin in critically ill patients from a multicenter study provide dosing suggestions for various categories of patients. *Antimicrob Agents Chemother*. 2011;55(7):3284-3294.

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Garonzik et al.

Dose	Patient Population	Dose calculation[2]
Loading	All patients	CBA (mg) = colistin $C_{ss\text{-}avg}$ target X 2 X body wt (kg) Max: 300mg CBA
Maintenance Dose (24hr after loading dose)	No renal replacement	Daily dose CBA (mg)[1] = colistin $C_{ss\text{-}avg}$ target X (1.5 X CrCL[2] +30) Max: 300mg CBA
	Intermittent HD	Daily dose CBA (mg)[3] = colistin $C_{ss\text{-}avg}$ target X 30 Supplemental dose: Add 50% daily dose if admin last hour of HD OR 30% daily dose if admin after HD
	CRRT	Daily dose CBA (mg)[4] = colistin $C_{ss\text{-}avg}$ target X 192

1. Interval for CrCl<10ml/min/1.73m2 dose every 12 hours; for CrCl 10-70ml/min/1.73m2 dose every 8-12 hours; CrCl >70ml/min/1.73m2 dose every 8-12 hours
2. CrCl calculated using Jelliffe equation
3. Twice daily dosing recommended
4. Dosing every 8 – 12 hours recommended

Garonzik SM, Li J, Thamlikitkul V, et al. Population pharmacokinetics of colistin methanesulfonate and formed colistin in critically ill patients from a multicenter study provide dosing suggestions for various categories of patients. *Antimicrob Agents Chemother*. 2011;55(7):3284-3294.

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Dalfino et al.

- n=28
- Septic patients (bloodstream infections (64.3%) and ventilator-associated pneumonia (35.7%))
- Colistin MICs 0.19 – 1.5 mg/L
- Dosing (infused over 30 minutes)
  - Loading dose (LD) CMS 300 mg CBA
  - CrCl >50 150 mg CBA every 12 hours
  - CrCl 20-50 150 mg CBA every 24 hours
  - CrCl <20 150 mg CBA every 48 hours

Dalfino L, Puntillo F, Mosca A, et al. High-dose, extended-interval colistin administration in critically ill patients: is this the right dosing strategy? A preliminary study. *Clin Infect Dis.* 2012;54(12):1720-1726.

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Dalfino et al.

- Clinical cure 82.1% (23/28)
- Bacteriological clearance 73.9% (17/28)
- No deterioration of renal function 82.1% (23/28)
- Acute kidney injury in 17.8% after ~7 days of therapy
  - No renal replacement therapy needed in any patients

Dalfino L, Puntillo F, Mosca A, et al. High-dose, extended-interval colistin administration in critically ill patients: is this the right dosing strategy? A preliminary study. *Clin Infect Dis.* 2012;54(12):1720-1726.

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Comparison Dosing Regimens

Manufacturer US	Garonzik et al.	Dalfino et al.
No loading dose for intermittent infusion	Loading dose recommended	Loading dose recommended
N/A	Loading dose based on weight / CrCl (max 300mg CBA)	Fixed loading dose (300mg CBA)
No HD/CRRT recommendations	HD/CRRT recommendations	No HD/CRRT recommendations
Intermittent dose - ranges	Calculated intermittent dose	Fixed intermittent dose
Frequency modified based on renal function - ranges	Frequency modified based on renal function – ranges	Frequency modified based on renal function

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Combination Therapy

- Synergistic bactericidal activity
- Prevent bacterial regrowth
  - Seen shortly after initial exposure to colistin
- Optimal dosing strategies unestablished
  - Lower dose versus high dose
  - Intermittent versus continuous infusion
- Choice of combination agent
  - Multiple agents studied

Poudyal A, Howden BP, Bell JM, et al. In vitro pharmacodynamics of colistin against multidrug-resistant Klebsiella pneumoniae. *J Antimicrob Chemother.* 2008;62(6):1311-1318.

Activity Instructions

- Think of one positive and one negative aspect of the dosing strategies in the two trials presented above.
- Think of one reason why combination therapy is advantageous for patients receiving colistin.
- Share and discuss with partner.

THANK YOU

Pharmacy Practice Pearls
Colistin Dosing: A Literature Review
Kanan Shah, PharmD
0121-0000-14-018-L04-P

Learning Assessment Questions

1. In the study by Garonzik et al., what is the risk of using the recommended dosing strategy?
    a. Dosing strategy has not been validated to achieve clinical cure
    b. Dosing strategy has been validated to achieve microbiological eradication
    c. Dosing strategy will achieve Css-avg above 10 mg/L
    d. Dosing strategy is based on >800 colistin blood samples

2. Combination therapy with colistin may be advantageous over colistin monotherapy because
    a. colistin monotherapy serum level above MIC are reliably achieved in most patients
    b. combination therapy with colistin may prevent bacterial regrowth
    c. dosing strategies for colistin are well established in combination therapy regimens
    d. dosing strategies for colistin are well established in monotherapy regimens

Student Involvement in Attaining Core Measures in a Safety-Net Institution

Antoine T. Jenkins, PharmD, BCPS
Asst. Professor of Pharmacy Practice
Chicago State University
Internal Medicine Clinical Pharmacist
Norwegian American Hospital

Financial Disclosures

Nothing to disclose

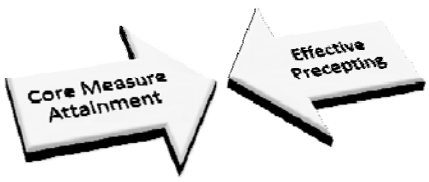
Learning Objectives

- Describe appropriate practice-based learning activities for students in relation to institution core measures.
- Summarize the importance of balancing precepting responsibilities with daily pharmacy practice duties
- Describe potential barriers to incorporate students in participating in hospital performance measures
- Explain how to successfully integrate students into the core measure activities

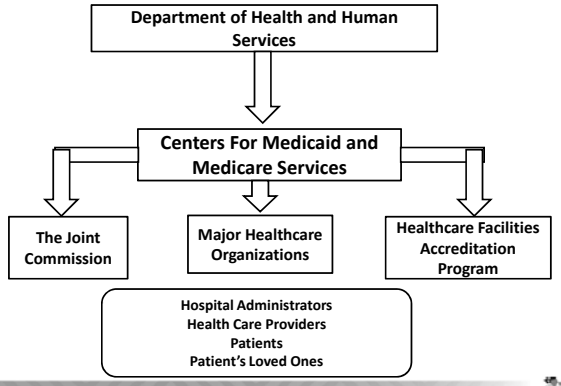
Imagine This…

What is your internal voice saying?

Important Merger



Quality Health Care… Who Cares??



Institutional Core Measures: Main Concepts

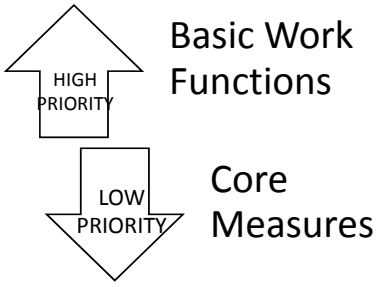
- Core Measures:
  - Been around for more than 10 years.
  - Measure or quantify.
  - Centered around quality patient care.
  - Stem from evidence-based data.
  - Continues to drive quality and safety
    - Hospitals must now submit data for six selected core measure sets.
    - IL Department of Public Health---Hospital report cards.
  - Every patient, every time!!

http://www.jointcommission.org/core_measure_sets.aspx. Accessed Mar 1, 2014
http://www.healthcarereportcard.illinois.gov/

Institutional Core Measures: Let's Discuss Reality…

- Shifts when you are working short-staffed
  - Pharmacists
  - Nurses
- The culture of the institution
  - Variability in work ethics
- Turnover rates
  - Staff
  - Administrators

Institutional Core Measures: Let's Discuss Reality…



Institutional Core Measures: Better Prioritizing Daily Duties

- Core measures SHOULD be included in basic work functions.
- Quality health care should be an expectation, not a privilege.
- Who is ultimately responsible?
- Who can assist in keeping core measures on the forefront? STUDENTS

Institutional Core Measures: Existing Opportunities

2014 Joint Commission Core Measures	
Perinatal Care	Tobacco Treatment
Stroke *	Pneumonia
Venous Thromoboembolism*	**Inpatient Immunizations***
Heart Failure*	**Acute Myocardial Infarction***
Emergency Department	Children's Asthma Care
Surgical Care Improvement Project*	**Hospital-Based Inpatient Psychiatric Services***
Substance Abuse	Hospital Outpatient Department

http://www.jointcommission.org/core_measure_sets.aspx. Accessed Mar 2, 2014.

Institutional Core Measures: Specific Practice-Based Activities

- Heart Failure
  - Continues to have a major impact on health care dollars
  - Readmissions continue to an issue for many institutions

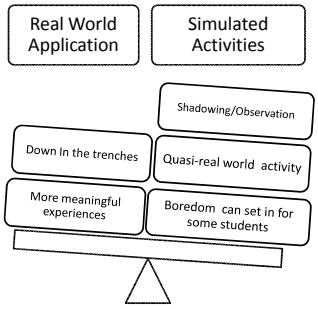
Heart Failure Core Measure Set	
Set Measure ID	**Measure Short Name**
HF-1	Discharge Education
HF-2	Evaluation of left ventricular function
HF-3	ACEI or ARB for left ventricular dysfunction

http://www.jointcommission.org/core_measure_sets.aspx. Accessed Mar 2, 2014

Institutional Core Measures: Student Involvement

- Any pharmacy student can be integrated into this process:
  - IPPE---Real life practice as they learned specific didactic concepts
    - 2nd Year CSU-COP students and immunizations at NAH
  - APPE—Consistent application of real world issues on a daily basis
- Can be done at any institution

Institutional Core Measures: Student Involvement



Institutional Core Measures: Student Involvement

- Questions to ask your when integrating students into specific core measure activities
  - Exactly what will the students do during the experience?
  - How will the model look?
  - Who will supervise their daily activities?

Doty, Randell. Integrating Your Student Into Practice. Getting Started as a Pharmacy Preceptor

Institutional Core Measures: Student Involvement—Heart Failure

- **Exactly what will the students do during the experience?**

  APPE student activities = Pharmacist activities
- Heart failure patients
  - Completely work-up each patient
  - Evaluate appropriateness of current treatment regimens
    - Contact prescribers with specific recommendations
      - ACEI or ARB
      - Search for documentation for contraindication/severe intolerance for above agents
      - Provide documentation if not present
  - Patient education
  - Documentation of patient education

Institutional Core Measures: Student Involvement—Heart Failure

- **How will the model look?**
  - Ensure buy-in from key leaders at your institutions
  - At Norwegian American Hospital (NAH)
    - Daily list of core measure patients emailed to pertinent stakeholders
    - Managers provides list of patients to front-line staff
      - Pharmacist provides list to students
      - Divide and conquer!
    - Work-up patient as per prior slide
    - Patient education
      - "Observe-then-do" approach
      - Mock session with preceptor, then "do" with real patient

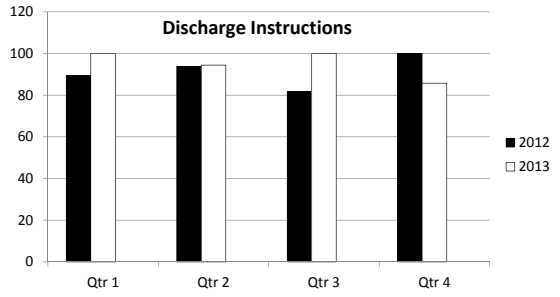
Institutional Core Measures: Student Involvement---Heart Failure

- **How will the model look?**
  - Document the interaction
    - Obtain signature of provider-to-patient educational session form
    - Place for in the chart
    - Document the clinical intervention in Meditech as "core measure"
  - Other recommendations
    - Beta blocker for systolic heart failure patients prior to discharge
    - Other important items
  - Visit patient the next day for any follow-up questions/concerns

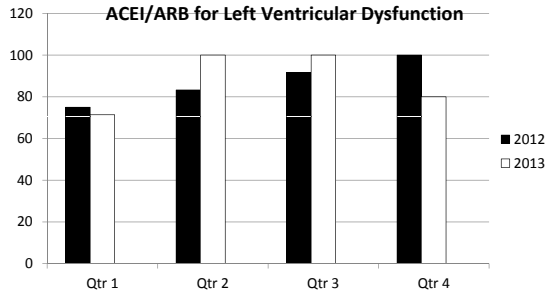
Institutional Core Measures: Student Involvement—Heart Failure

- **Who will supervise the process?**
  - Primary preceptor only?
  - Primary preceptor of record, but others will assist in precepting the students?

Institutional Core Measures: Student Involvement—Heart Failure

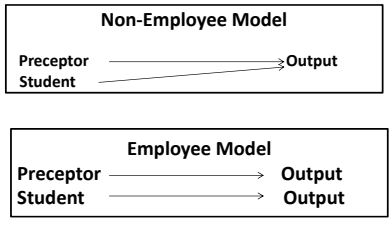


Institutional Core Measures: Student Involvement—Heart Failure



Institutional Core Measures: Student Involvement

Experiential Education Models
Effects on Productivity



Slack MK, Draugalis JR. Am J Hosp Pharm 1994; 51 (4) 525-30.

Institutional Core Measures: Student Involvement

- Specific challenges for student integration
  - Unmotivated individuals
  - Initial training could be time consuming
  - Student who has not bought-into the specific core measure
  - Coverage for particular service will not be continuous

Institutional Core Measures: Other Activities

- Other core measure activities at NAH where students are involved:
  - AMI patients
  - SCIP
  - Inpatient immunizations

Institutional Core Measures: Benefits of Involving Students

- Patients
  - Receive quality health care
- Site
  - Joint Commission is happy and CMS is reimbursing, the site is happy
- Preceptors
  - Increase in productivity
- Students
  - Gain REAL WORLD experience
  - Helps to become competent practitioners

Institutional Core Measures: Conclusions

- Core measures
  - Continue to be a vital part of an institution's overall strategic plan.
  - Must be interwoven in our daily work.
  - Can be easily and effectively become apart of an IPPE or APPE students activities.

Pharmacy Student Driven Immunization Program: The missing link?

Norwegian American Hospital
Charlene A. Hope, PharmD, BCPS, CPHQ, CPPS
Director of Pharmacy

The speaker has no conflict of interest to declare.

Norwegian American Hospital

- 200-bed, Community safety-net hospital
- Affiliated Family Practice Residency program
- Patient Population: Acute care services (general medicine and telemetry), Surgery, ICU, Women's health services (OB, mother-baby) Behavioral Medicine (adults, geriatrics, detoxification units)
- Inpatient Pharmacy: 6 full-time pharmacists, 2 co-funded pharmacy faculty providing services 6:30a-11p 7days/week, unit-based pharmacy model M-F, 9a-4p
- Experiential education site for 3 colleges of pharmacy offering Introductory and Advance Pharmacy Practice (APPE) Experiences

Why the focus on Inpatient Immunization?

IT preparation for hospital-wide CPOE

Request to revise current immunization assessment screen

ASHP Mentored Adult Inpatient Immunization Program

Call for Application to Participate

Immunization Core Measures

- Beginning of January 2012 – Two immunizations measures became effective for discharges:
  - IMM-1a Pneumococcal Immunization (PPV23) – Overall rate
  - IMM-1b Pneumococcal Immunization (PPV23) – Age 65 and Older
  - IMM-1c Pneumococcal Immunization (PPV23) – High Risk Populations (Age 6 through 64 years)
  - IMM-2 Influenza Immunization

ASHP Project Impact: Contemporary Strategies for Improving Immunization Rates across the Health-system

Information Technology (IT)	Pharmacy	Nursing
Administration documentation screen was developed	A MAR comment was added remind the RN to document their vaccination administration in Meditech (new paperless process)	Combination of one-on-one and group in-service training on the new administration process.
Immunization screening documentation fields improved to capture patient education and VIS distribution	Vaccinations were profiled and remained on the MAR for a total of three days	Created a training program for learning management system
Electronic access the VIS statements	Addition of vaccines to the Omnicell machines	Hosted an immunization booth providing nursing staff instruction on how to complete the screening and documentation of the administration process in Meditech

ASHP Project Impact: Contemporary Strategies for Improving Immunization Rates across the Health-system

- Despite the numerous changes made within Meditech and education provided, there were minimal improvements gained in the key measures that were tracked.
- Key barriers were identified:
  - Lack of full implementation of workstations on wheels (WOWs)
  - Time currently needed to collect and document screening and administration information in the HIS
  - Inpatient Immunization still remains low priority for nursing staff

ASHP Project Impact: Contemporary Strategies for Improving Immunization Rates across the Health-system

MANUAL PROCESS	• Patient responses to screening questions and information collected at the time of administration still require nursing staff to write down and enter information into the computer at a later time.
TIME-CONSUMING	• Transfer of the information to the HIS, actually added more time to inpatient immunization process.
INCOMPLETE	• As a result, documentation in the HIS either was incomplete or there was no documentation and occasionally could be found in the paper MAR.
POOR OUTCOME	• This is especially apparent for our acute care units where there was a noted decreased in immunization rates post intervention.

Plan-Do-Study Act (PDSA) Cycle: Pharmacy Student Run Immunization Service

- Team utilized Rapid Plan-Do-Study-Act (PDSA) cycles were performed through the intervention period to address barriers.
- One PDSA of particular interest was the potential to use pharmacy students to provide inpatient immunization services.

PDSA Cycle: Pharmacy Student Run Immunization Service

PLAN

- The immunization service consisted of initial screening and re-screening of patients immunization status, providing education and for those patients that qualified and agreed to be immunized, administration of the vaccine.
- Two APPE students completing their hospital rotation at our site provided this service for a total of 10 days on the medical-surgical unit.
- Data was collected for this unit and compared to the telemetry unit for which there was no student involvement.

Study

A total of 82 patients were seen on each nursing unit

	Medical Surgical	Telemetry
% of patients with complete documentation of screening for influenza vaccination	90% (n=74)	76% (n=62)
% patients with complete documentation of screening for pneumonia vaccination	90% (n=74)	78% (n=64)
% of patients 65 years of age or older, with complete documentation of screening for pneumonia	81% (18/21)	57% (12/21)

The student run service; resulted in a 12% increase in completed documentation
These results agree with the above prediction.

Study

	Medical Surgical	Telemetry
Number of Patients Eligible for Vaccination	Influenza = 25 Pneumococcal=29	Influenza = 28 Pneumococcal=30
Pharmacy Student Administration	Influenza = 83% (19) Pneumococcal=92% (24)	Influenza=0% (0) Pneumococcal=0% (0)
Nursing Administration	Influenza = 17% (4) Pneumococcal=8 % (2)	Influenza=100% (1) Pneumococcal=100% (3)
Missed Opportunities	Influenza = 2 Pneumococcal=3	**Influenza = 27** **Pneumococcal=27**

Act

- The pharmacy student run inpatient immunization service pilot was very successful
  - Results reported to nursing leadership
  - Team decided to move forward with implementation of this program

Advantages of the student run program include:

- Students had completed the APhA Pharmacy-based Immunization Training Delivery Training Program and provided consistency in delivery of the service. This also established that they had the skills to perform the service.
- Students had the time to dedicate to screening, education and administration of patients. This also involved working closely with the nursing staff which promoted interprofessional interaction.
- This small pilot demonstrated the impact the students have on improving patient outcomes as it relates to inpatient immunization.

Student –run Immunization Program
Service Description

- Education
- Screening
- Offer
- Administration
- Activity Documentation

Education

Student utilize the Influenza and the Pneumococcal Vaccine Information Statement (VIS) to provide the patient or their family members education

Key step:
Addressing Health-care disparities
Health Literacy

Screening

Student perform immunization assessment.
Translator phone service is available
Spanish speaking patients
Documented on a paper form.

Offer

If patient is eligible, offer is made to receive the immunization

Administration

Student prepares vaccination in the main pharmacy

Vaccine preparations are verified by the central pharmacist prior to administration

Decentralized pharmacist or the floor nurse provides oversight on the nursing unit.

Activity Documentation

Student communicates with the patient's nurse

- Administration is documented as given in the e-MAR

Administration Assessment form is completed in Meditech

Clinical Intervention documentation of any immunization activity: screening, education or administration

Key Elements for Success

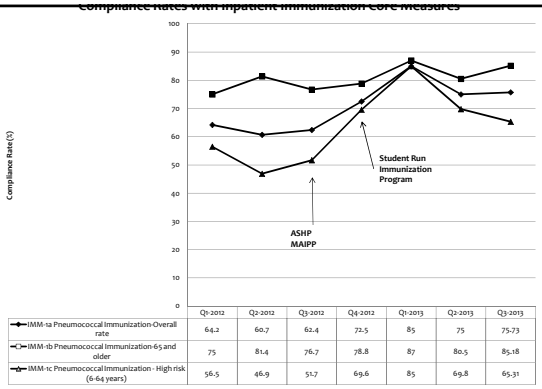
- Nursing staff Buy-in
- Student Orientation to the Site
  - Set Expectations on Day #1
- Student Orientation to the Program
  - Preceptor
  - Another APPE student
- Ability for students to document patient care interactions in the electronic HIS.

Potential Barriers

- Limited to 5 days per week; no weekend coverage
- Maintain continuity of the program between modules
  - Experience a one-week lag during the first week of the rotation
- Different comfort levels of students to interact with different patient populations
  - Detox, Mother-Baby and Behavior Medicine

What you need to get started

- Designated area in the pharmacy
  - Pneumococcal and Influenza VIS statements
    - English and Spanish
  - Syringes, needles
  - Rest of supplies (alcohol swabs, band-aids) are obtained on the nursing unit.



	Q1-2012	Q2-2012	Q3-2012	Q4-2012	Q1-2013	Q2-2013	Q3-2013
IMM-1a Pneumococcal Immunization-Overall rate	64.2	60.7	62.4	72.5	85	75	75.73
IMM-1b Pneumococcal Immunization-65 and older	75	81.4	76.7	78.8	87	80.5	85.18
IMM-1c Pneumococcal Immunization - High risk (6-64 years)	56.5	46.9	51.7	69.6	85	69.8	65.31

Student Assessment

Knowledge
- Immunization screening (inclusion, exclusion criteria, contraindications)
- Vaccine (storage, preparation)

Skill
- Patient Education
- Vaccine Preparation (Vial, syringe manipulation)
- Vaccine Administration

Attitudes
- Cultural Competency
- Addressing low literacy
- Perceptions of providing care with mental health issues

Teachable Moments

- Post Activity Debriefing
  - Occurs throughout the immunization program process
  - Preceptors discuss the patient interaction
    - What went well?
    - Patient's Disposition
    - Explore patient refusal of immunization
  - Challenge perceptions of providing direct care to more challenging patient populations
    - Detox, Behavioral Medicine patients
  - Support and build upon students confidence through the rotation

Lessons Learned

- Great activity to engage students regardless of what they plan to do after graduation.
- Develop interprofessional communication skills, program requires that they work with the nursing staff.
- Opportunity to practice a skill after completion of initial immunization training at the college.
- Develop autonomy over their daily assignments

Considerations for other hospitals

1. Great opportunity for smaller community hospitals
2. Focus program on one core measure element
3. Pilot your program

Building the foundation to INSPIRE

INvolvement of Student Projects In Research and Education

Milena McLaughlin,
PharmD, MSc, BCPS, AAHIVP
Assistant Professor
Midwestern University CCP
HIV/ID Clinical Pharmacist,
Northwestern Memorial Hospital
Chicago, Illinois

Scott Bergman,
PharmD, BCPS (AQ ID)
Associate Professor
SIUE School of Pharmacy
PGY2 Infectious Diseases Pharmacy
Residency Program Director
St. John's Hospital – Springfield, IL

Conflicts of Interest

- Dr. McLaughlin reports that she does not have any actual or potential conflicts of interest associated with this presentation.
- Dr. Bergman reports that he does not have any actual or potential conflicts of interest associated with this presentation.

Objectives

1. Discuss the who/what/where/when/why of student involvement in research
2. Describe the student involvement in research at Midwestern University/Northwestern Memorial Hospital as an illustrative example
3. Review a clinical pearl on submitting research with students

Audience Poll

Do you currently have a research program?

How many students do you have in your program?

Background

- ACPE and AACP suggest PharmD curricula and residency training include clinical research skills
- ACCP Task Force on Research in the Professional Curriculum recommendations
  - Courses in research ethics, methodology, biostatistics, and literature evaluation
  - Increase number of students in programs
  - Strive for peer-reviewed publication

ACPE= Accreditation Council on Pharmacy Education
AACP= American Association of Colleges of Pharmacy
ACCP= American College of Clinical Pharmacy

WHO, WHAT, WHERE, WHEN, AND WHY OF STUDENT INVOLVEMENT IN RESEARCH

Who?

Any professional year

Funding
- Elective credit
- Federal Work Study
- Grant
- Volunteer

Student interest meeting at College of Pharmacy

What?

Training
- CITI training
- Research contract

Research Projects
- Literature Search
- IRB
- Data Collection
- Manuscript preparation (Endnote®)

Drug Use Evaluations
- Departmental needs for P&T Committee

Where?

Clinical Site
- Patient data collection
- Site requirement considerations

University
- Education research
- Meet with faculty

Self Study
- Literature search
- Writing

When?

Academic Year

Longitudinal

Summer

Why?

- Extension of faculty member/clinical pharmacist
  - Involves time commitment up front but student becomes independent
  - Make "what you do anyway" into research
- Students gain research experience and skills

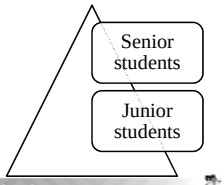
Pharmacy Knowledge	Writing Skills	Presentation Skills	Independence

STUDENT RESEARCH PROGRAM

Midwestern University and Northwestern Memorial Hospital

Logistics – Students

- Training
  - Grant student – summer going into P-II year
  - Trained by previous grant student (going into P-III year)
- One day orientation, same as for P-IV students
  - Tour of hospital
  - Learn EMR
  - ID badge



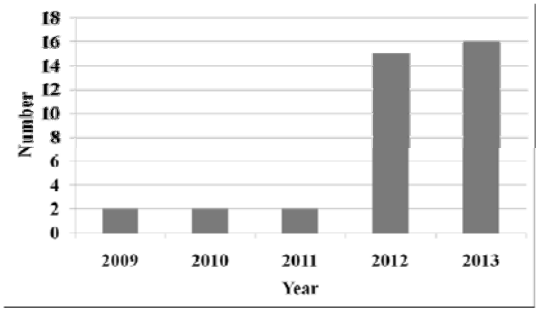
Logistics – Preceptors and Projects

Solicit projects from preceptors in Pharmacy Department

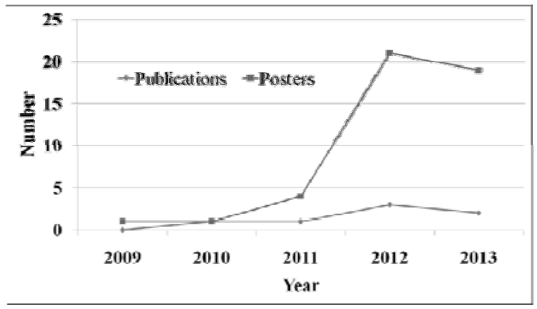
Commitment of preceptor to mentor student (Midyear project and Kenneth Suarez Day Presentation at MWU)

ID Trainees (PGY-2/Fellow) as coordinating preceptors

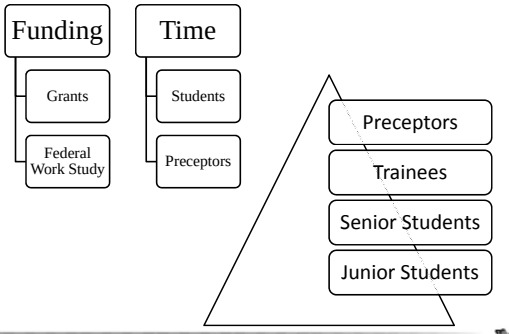
Growth of Student Involvement

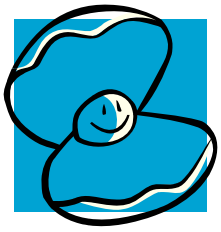


Growth of Publications and Posters



Barriers





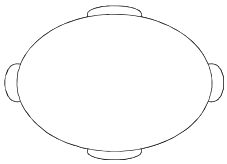
"CLINICAL" PEARLS

Conducting Research with Students

- Follow-up is key
- Set deadlines
  - Choose a mutual goal
- Meet regularly
  - Weekly meetings suggested
- Accountability
  - Reference letters

Submitting Research with Students

- Match purpose, objectives, results and conclusion
- Abstract needs to be short and to the point
  - Background/Introduction should not be more than 2 sentences
  - Make sure purpose is clearly stated
  - Don't forget to interpret what you found



QUESTIONS AND ROUND TABLE DISCUSSIONS

Facilitators

- **Milena McLaughlin (Inf. Dis., Midwestern)**
- **Scott Bergman (Infectious Diseases, SIUE)**
- Jen Phillips (Drug Information, Midwestern)
- Carrie Vogler (Internal Medicine, SIUE)
- Jennifer Roselli (Ambulatory care, SIUE)
- Michaela Doss (Emergency Medicine/ICU & New Practitioner, OSF Peoria)

INSPIRE Involvement of Student Projects in Research and Education

Scott Bergman, PharmD, BCPS (AQ-ID)
Milena McLaughlin, PharmD, MSc, BCPS, AAHIVP

0121-0000-14-020-L-4-P

Learning Assessment Questions

1. Which of the following suggestions will best assist pharmacists in identifying potential student researchers?
    a. Ask APPE students on rotation if they are interested
    b. Attend student research poster presentations
    c. Hold an interest meeting at a local college of pharmacy
    d. Identify one research student and use word of mouth

2. Which of the following is most likely to help sustain a student research program?
    a. Conduct research longitudinally with the same student(s)
    b. Keep students separate to allow them to be more efficient
    c. Make projects for the largest number of students possible
    d. Use multiple coordinators so more students can participate

Clinical Updates – His, Hers and Ours

Men's Health

Kelly A. Lempicki, PharmD, BCPS

This speaker has no actual or potential conflict of interest in relation to this presentation.

Objectives

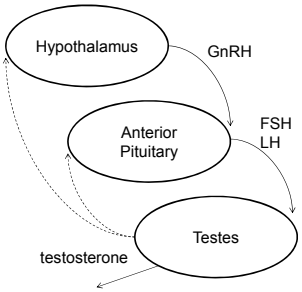
- Pharmacists
  - Review the condition of low-testosterone
  - Describe therapies available for the treatment of low-testosterone
  - Identify current "hot topics" in men's health
- Technicians
  - Explain the condition of low-testosterone and its associated signs and symptoms
  - Recognize medications that are used to treat low-testosterone

Meet Mr. T

- 67 yo man reports decreased libido and hot flushes for several months
  - Also c/o decreased energy and muscle strength and increased body fat
- PMH: HTN, hyperlipidemia
- Medications: lisinopril, simvastatin
- (-) tobacco, (+) EtOH – 1 glass wine daily
- No regular activity since retiring 2 years ago
- DRE WNL
- Labs
  - CBC, LFTs, BMP, PSA - normal
  - Testosterone 230 ng/dl, repeat 220 ng/dl

What is Low-Testosterone?

- Hypogonadism
  - Clinical syndrome resulting from subphysiologic testosterone levels caused by disruption of the hypothalamic-pituitary-gonadal (HPG) axis



1. Bhasin S, et al. *J Clin Endocrinol Metab* 2010;95:2536-2559.

Diagnosis

- Two components
  - Consistent signs and symptoms of androgen deficiency
  - Consistently low serum testosterone levels

1. Bhasin S, et al. *J Clin Endocrinol Metab* 2010;95:2536-2559.
2. Dohle GR, et al. *Guidelines on male hypogonadism* 2012.

Androgen Deficiency S/Sx

- Delayed puberty
- ↓ sexual desire (libido) and activity
- ↓ spontaneous erections
- Breast discomfort, gynecomastia
- ↓ body hair or need for shaving
- Small (<5 ml) or shrinking testes
- Infertility
- ↓ BMD, low trauma fracture, height loss
- Hot flushes, sweats

1. Bhasin S, et al. *J Clin Endocrinol Metab* 2010;95:2536-2559.
2. Dohle GR, et al. *Guidelines on male hypogonadism* 2012.

Less Specific S/Sx

- ↓ energy, motivation, initiative, self-confidence
- Depressed mood
- Poor concentration and memory
- Sleep disturbances (↑ sleepiness)
- Mild anemia
- ↓ muscle mass and strength
- ↑ body fat, ↑ BMI
- ↓ physical or work performance

1. Bhasin S, et al. *J Clin Endocrinol Metab* 2010;95:2536-2559.
2. Dohle GR, et al. *Guidelines on male hypogonadism* 2012.

Which of Mr. T's symptoms are more specific for androgen deficiency?

1. Hot flushes
2. Decreased energy
3. Decreased muscle strength
4. Increased body fat

Testosterone Level

- Specific cut-offs for low testosterone have not been established
  - Generally less than 280-300 ng/dl
- Recommend checking *at least two* total testosterone levels
  - Morning level
  - Not acutely ill

1. Bhasin S, et al. *J Clin Endocrinol Metab* 2010;95:2536-2559.
2. Dohle GR, et al. *Guidelines on male hypogonadism* 2012.

When to Use Testosterone Therapy

- Treatment with testosterone is recommended when:
  - The patient has symptoms of androgen deficiency

    AND
  - The testosterone level is consistently low

1. Bhasin S, et al. *J Clin Endocrinol Metab* 2010;95:2536-2559.
2. Dohle GR, et al. *Guidelines on male hypogonadism* 2012.

When to Avoid Testosterone Therapy

- Prostate cancer
- Breast cancer
- Unevaluated prostate nodule or induration
- PSA >4 ng/ml
  - >3 ng/ml if at high risk for prostate cancer (African American, 1st degree relative with prostate cancer)
- Hematocrit >50%
- Uncontrolled heart failure or sleep apnea
- Male infertility
- Severe lower urinary tract symptoms due to BPH

1. Bhasin S, et al. *J Clin Endocrinol Metab* 2010;95:2536-2559.
2. Dohle GR, et al. *Guidelines on male hypogonadism* 2012.

Would Mr. T be an appropriate candidate for testosterone therapy?

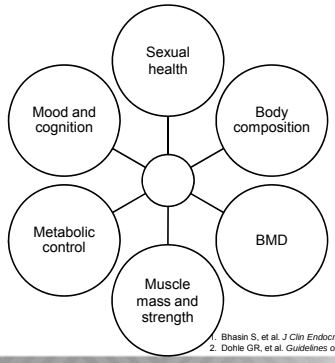
1. Yes
2. No

Goals of Therapy

- Improve quality of life and sense of well-being
- Improve sexual function
- Improve BMD
- Increase testosterone to a level that is mid-normal for young healthy men

1. Bhasin S, et al. *J Clin Endocrinol Metab* 2010;95:2536-2559.
2. Dohle GR, et al. *Guidelines on male hypogonadism* 2012.

Benefits of Testosterone Therapy



1. Bhasin S, et al. *J Clin Endocrinol Metab* 2010;95:2536-2559.
2. Dohle GR, et al. *Guidelines on male hypogonadism* 2012.

Adverse Effects

- Erythrocytosis
- Oily skin, acne
- Growth of prostate cancer
- ↓ spermatogenesis and fertility
- Potential for abuse/dependence
  - Schedule III
- Cardiovascular events?

1. Bhasin S, et al. *J Clin Endocrinol Metab* 2010;95:2536-2559.
2. Dohle GR, et al. *Guidelines on male hypogonadism* 2012.

Available Products

- Transdermal
  - Gel (AndroGel, Fortesta, Testim)
  - Solution (Axiron)
  - Patch (Androderm)
- Injectable
  - Cypionate (Depo-Testosterone)
  - Enanthate (Delatestryl)
- Implantable pellet (Testopel)
- Buccal bioadhesive tablet (Striant)

Testosterone Gel

- Directions
  - Apply once daily in the morning to clean, dry, intact skin

Product	Application Site
AndroGel	Shoulders, upper arms, abdomen
Fortesta	Thighs
Testim	Shoulders, upper arms

1. Bhasin S, et al. *J Clin Endocrinol Metab* 2010;95:2536-2559.
3. Lexicomp 2014

Testosterone Gel

- Adverse effects
  - Skin irritation
  - **Boxed warning**: transfer through skin-to-skin contact
    - Cover application site with clothes
    - Wash hands with soap and water after application

1. Bhasin S, et al. *J Clin Endocrinol Metab* 2010;95:2536-2559.
3. Lexicomp 2014

Testosterone Solution

- Directions
  - Apply to the axilla at the same time each morning
    - 1 pump per application
- Adverse effects
  - Skin irritation
  - **Boxed warning**: transfer through skin-to-skin contact
    - Cover application site with clothes
    - Wash hands with soap and water after application

1. Bhasin S, et al. *J Clin Endocrinol Metab* 2010;95:2536-2559.
3. Lexicomp 2014

Testosterone Patch

- Directions
  - Apply every evening to clean, dry skin
    - Back, abdomen, upper arms, thighs
      - Areas without prolonged pressure
    - Rotate sites daily
      - Allow 7 days before returning to a site again
- Adverse effects
  - Skin irritation
    - May apply topical hydrocortisone cream after removal or triamcinolone 0.1% cream under the patch

1. Bhasin S, et al. *J Clin Endocrinol Metab* 2010;95:2536-2559.
3. Lexicomp 2014

Injectable Testosterone

- Directions
  - Inject IM every 1-4 weeks
    - Gluteal muscle
- Adverse effects
  - Peaks and troughs in testosterone levels
    - Fluctuations in mood or libido
  - Pain at injection site
  - Excessive erythrocytosis (especially in elderly)
  - Cough

1. Bhasin S, et al. *J Clin Endocrinol Metab* 2010;95:2536-2559.
3. Lexicomp 2014

Testosterone Pellet

- Directions
  - Implant subcutaneously every 3-6 months
  - Requires surgical incision for insertion
- Adverse effects
  - Infection
  - Expulsion of pellet

1. Bhasin S, et al. *J Clin Endocrinol Metab* 2010;95:2536-2559.
3. Lexicomp 2014

Buccal Testosterone

- Directions
  - Apply to the gum above the incisor tooth every 12 hours
- Adverse effects
  - Taste alteration
  - Gum irritation

1. Bhasin S, et al. *J Clin Endocrinol Metab* 2010;95:2536-2559.
3. Lexicomp 2014

Which testosterone product would you recommend for Mr. T?

1. Gel
2. Patch
3. Implantable pellet
4. Buccal tablet

Monitoring

	Baseline	3 months	6 months	12 months	Annually
Symptoms	X	X	X	X	X
Testosterone level	X	X	X	X	X
Hematocrit		X	X	X	X
DRE/PSA	X	X	X	X	X

- BMD – every 1-2 years (if abnormal at baseline)

1. Bhasin S, et al. *J Clin Endocrinol Metab* 2010;95:2536-2559.
3. Lexicomp 2014

Timing of Testosterone Level

- Gel
  - AndroGel, Testim - √ in the morning after 14 days of use
  - Fortesta - √ 2 hrs after application, after 14 days of use
- Solution
  - √ 2-8 hrs after application, after 14 days of use
- Patch
  - √ 3-12 hrs after application, after ~ 14 days of use

1. Bhasin S, et al. *J Clin Endocrinol Metab* 2010;95:2536-2559.
3. Lexicomp 2014

Timing of Testosterone Level

- Injection
  - √ midway between injections
- Implantable pellet
  - √ at the end of the dosing interval
- Buccal bioadhesive tablet
  - √ immediately before or after application

1. Bhasin S, et al. *J Clin Endocrinol Metab* 2010;95:2536-2559.
3. Lexicomp 2014

Testosterone Controversy

- Is testosterone therapy associated with an increased risk of cardiovascular events?

Adverse events associated with testosterone administration[4]

The Testosterone in Older Men with Mobility Limitations (TOM) Trial

Basaria 2010

Design	Randomized, double-blind, placebo-controlled trial
Subjects	Men ≥ 65 yo with low testosterone and limitations in mobility (n=209)
Intervention	100 mg testosterone gel vs placebo applied once daily x 6 months
Results	Cardiovascular-related events: 23 (testosterone) vs 5 (placebo) [OR 5.4; 95% CI 2.0-14.9]
	Atherosclerosis-related events: 7 (testosterone) vs 1 (placebo) [OR 7.2; 95% CI 0.9-59.7]

Association of testosterone therapy with mortality, myocardial infarction, and stroke in men with low testosterone levels[5]

Vigen 2013

Design	Retrospective cohort study in the Veterans Affairs system
Subjects	Men who underwent coronary angiography and had a total testosterone level < 300 ng/dl (n=8709)
Cohorts	Men prescribed testosterone therapy vs men with no prescription
Primary end point	Time to all-cause mortality or hospitalization for MI or ischemic stroke

Vigen 2013

Results	Testosterone group (n=1223): 67 died, 23 MIs, 33 strokes
	No testosterone group (n=7486): 681 died, 420 MIs, 486 strokes
	Testosterone use was associated with an increased risk of all-cause mortality, MI, and stroke HR 1.29; 95% CI 1.05-1.58; p=0.02

Increased risk of non-fatal myocardial infarction following testosterone therapy prescription in men[6]

Finkle 2014

Design	Retrospective cohort study
Cohorts	Men with a first prescription for testosterone (n=55,593) vs men with a first prescription for a PDE5 inhibitor (n=167,279)
Outcome	Incidence of acute MI in the 90 days post-prescription compared to the 1 year pre-prescription

Finkle 2014

Results	Pre- vs post-prescription: 193 vs 65 events
	Rate ratio post/pre: 1.36; 95% CI 1.03-1.81

	Age < 65 years (n=48,539)		**Age ≥ 65 years (n=7,054)**	
Rate ratio (post/pre) (95% CI)	1.17 (0.84-1.63)		2.19 (1.27-3.77)	
	Heart Disease (n=4,006)	**No Heart Disease (n=44,533)**	**Heart Disease (n=2,047)**	**No Heart Disease (n=5,057)**
	2.9 (1.49-5.62)	0.90 (0.61-1.34)	2.16 (0.92-5.10)	2.21 (1.09-4.46)

Testosterone therapy and cardiovascular events among men: a systematic review and meta-analysis of placebo-controlled randomized trials[7]

Xu 2013

Design	Meta-analysis
Study selection	Randomized, placebo-controlled trials which reported cardiovascular-related events by study arm (n=27)
Results	Included 2,994 men who experienced 180 cardiovascular-related events
	Testosterone therapy was associated with an increased risk of cardiovascular-related events OR 1.54; 95% CI 1.09-2.18

FDA Statement

- Released 1/31/14
- Evaluating data about risk of death, MI, and stroke associated with testosterone therapy
  - No final conclusion or recommendation yet
- Patients should discuss concerns with health care professionals
- Health care professionals should consider risks vs benefits of testosterone therapy

8. Food and Drug Administration 2014

How would you respond to Mr. T's question about the safety of testosterone therapy?

1. Advise Mr. T to contact his doctor
2. Discuss the recent safety literature with Mr. T so he can make an informed decision
3. Encourage Mr. T to continue testosterone since the safety concerns do not apply to him

Summary

- Hypogonadism is diagnosed based on consistent symptoms of androgen deficiency and consistently low testosterone levels
- Testosterone therapy is available in many dosage forms
- Evidence suggesting an association between testosterone therapy and cardiovascular events continues to grow

References

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Clinical Updates – His, Hers and Ours
Men's Health
Kelly Lempicki, PharmD, BCPS
0121-0000-14-021-L01-P
0121-0000-14-021-L01-T

Learning Assessment Questions

1. Which of the following potential symptoms of hypogonadism is more specific for androgen deficiency?
    a. Decreased libido
    b. Decreased muscle strength
    c. Increased body fat
    d. Increased sleepiness

2. Which of the following testosterone products is administered twice daily?
    a. Buccal tablet
    b. Implantable pellet
    c. Patch
    d. Solution

3. Which statement most accurately describes the findings of recent literature evaluating the association between testosterone therapy and cardiovascular events?
    a. Testosterone therapy does not impact the risk of cardiovascular events
    b. Testosterone therapy increases the risk of cardiovascular events in older men and decreases the risk in younger men
    c. Testosterone therapy is associated with a decreased risk of cardiovascular events
    d. Testosterone therapy is associated with an increased risk of cardiovascular events

Clinical Updates – His, Hers and Ours

Women's Health

Alicia B. Forinash, Pharm.D., FCCP, BCPS, BCACP
St. Louis College of Pharmacy
Maternal Fetal Care Center at SSM St. Mary's

Conflicts

- I have no conflicts of interest to disclose.

ICHP 2014 Spring Meeting: Taking Bold Steps for Patient Care

Objectives

- **Pharmacists**
  - Identify current topics in post-menopausal women's health
  - Describe new pharmacologic agents for use in post-menopausal women's health-related disease states
- **Technicians**
  - Identify current topics in post-menopausal women's health
  - Recognize medications that are used in post-menopausal women's health and relate them to their respective disease states.

ICHP 2014 Spring Meeting: Taking Bold Steps for Patient Care

Abbreviations

- ET = Estrogen therapy
- HT = Hormone therapy
- EAA = Estrogen Agonist/Antagonist
- SERM = Selective estrogen receptor modulator
- UTI = Urinary tract infection
- TAH = Total abdominal hysterectomy
- BSO = Bilateral salpinoophorectomy
- CAD = Coronary artery disease
- MI = Myocardial infarction
- CVA = Cerebrovascular accident
- DVT = Deep vein thrombosis
- Wk = Week
- MOA = Mechanism of action
- ADR = Adverse Drug Reaction

ICHP 2014 Spring Meeting: Taking Bold Steps for Patient Care

Case

- A 50 yoF is at the pharmacy and states her doctor said she is post-menopausal. She starts getting teary-eyed and says that she doesn't need her Ovcon-35 anymore. She states she doesn't feel any different and asks what are symptoms of menopause.
- What are the most common symptoms of menopause?

A. Vasomotor symptoms
B. Insomnia
C. Vaginal dryness
D. Irritability

Which of the above symptoms will not get better with time?

ICHP 2014 Spring Meeting: Taking Bold Steps for Patient Care

Definitions

- **Menopause** is the loss of ovarian function leading to a state of permanent amenorrhea
  - Occurs after 12 consecutive months of amenorrhea
  - TAH vs. TAH/BSO
- **Perimenopause** is the transition period to nonreproductive life characterized by irregular menses

ICHP 2014 Spring Meeting: Taking Bold Steps for Patient Care

Menopausal symptoms

- Vasomotor
  - Hot flushes/sweating
- Insomnia/fatigue
- Irritability
- Forgetfulness and ↓ concentration
- Osteoporosis
- Atherosclerosis
- Urogenital atrophy
  - Vaginal dryness
  - Dysparenia
  - Decreased libido
  - Increased risk for UTI
  - Urinary incontinence
- Dry Skin
- Dysfunctional uterine bleeding during perimenopause

Menopause

Estrogen (ET) and Estrogen plus Progestin (HT or E+P)

- Indications
  - Moderate to severe symptoms associated with menopause
  - Moderate to severe vulvar and vaginal atrophy associated with menopause
  - Prevention of postmenopausal osteoporosis

Menopause Symptoms

- Vasomotor: systemic therapy
  - Cochrane Review of 24 trials (3,329 pt)
    - HT decreased frequency by 75% and severity
- Urogenital symptoms: Estrogens (any route)
  - Urogenital atrophy, Vaginal dryness, Dyspareunia
- ↓ risk of UTI
  - Only local estrogen

ACOG Obstet Gynecol 2014;123:202-16.
USPTFS. Ann Pharmacother 2012;157;1-11.
Cochrane Database Syst Rev 2004;4:CD002978

Benefits

- Osteoporosis prevention
- Quality of life
  - Mood stability
  - Fatigue
  - Insomnia

ACOG Obstet Gynecol 2014;123:202-16.
USPTFS. Ann Pharmacother 2012;157;1-11.
Cochrane Database Syst Rev 2004;4:CD002978

Risks

- Cardiovascular risk
  - HT primary prevention (WHI)
    - No overall increase in CV events or death
    - Absolute risk: 7 per 10,000 person-years
  - HT secondary prevention (HERS)
    - ↑ risk MI in 1st year
  - ET primary prevention (WHI-ET)
    - No overall increase in CV events or death
- Consider age and time since menopause

Anderson et al. jAMA 2004;291:1701-12.
Manson et al. N Engl J Med 2007;356:2591-602.
Manson et al. JAMA 2013;310:1353-68.
Hulley et al. JAMA 1998;280:605-13.
Grady JAMA 2002;288:49-57.
Writing group WHI. JAMA 2002:288;321-33.

Risks

- Cerebrovascular risk
  - HT (WHI)
    - Absolute risk of 8 per 10,000 person-years
  - ET (WHI-ET)
    - Absolute risk of 12 per 10,000 person-years

Hulley et al. JAMA 1998;280:605-13.
Grady JAMA 2002;288:49-57.
Writing group for the women's health initiative investigators. JAMA 2002:288;321-33.
Anderson et al. jAMA 2004;291:1701-12.

Risks

- Thromboembolism
- Breast cancer
  - HT (WHI):
    - Non-significant ↑ 15% with use <5 years of use
    - Significant ↑54% with ≥ 5 years of use
  - ET: ↑ after 10–15 years of use
- Endometrial cancer
  - Role of Progestogens

Hulley et al. JAMA 1998;280:605-13.
Grady JAMA 2002;288:49-57.
Writing group for the women's health initiative investigators. JAMA 2002:288;321-33.
Anderson et al. jAMA 2004;291:1701-12.

Risks

- Gallbladder dysfunction
- Cognitive decline (WHIMS)
  - HT: ↑ risk for dementia in women ≥65 years
- Ovarian cancer
  - ET/HT: Meta-analysis, case-control, and cohort trials
  - 1 RCT did not show increased risk.

Shumaker et al. JAMA 2003;289:2651-62.
NAMS Menopause 2012; Menopause 2012;19:257-71.

Case

- A 54yoF is complaining of intolerable hot flashes. She states it's embarrassing at work to sweat so much that she needs to change clothes or being unable to concentrate during a meeting because of them. She wakes up a couple times a night from them, too. She said her primary care doctor refused to give her hormones because he doesn't want the liability. She wants to know what she should ask her Ob/Gyn to prescribe. Last menstrual period 13 months ago. PMH: hypertension, DVT (10 years ago on contraceptives), obesity. What is the best recommendation?

A. 17-B estradiol patch
B. Ospemifene
C. Conjugated equine estrogens + bazedoxifene
D. Paroxetine

CEE + Bazedoxifene

- Conjugated equine estrogens (CEE) 0.45mg + bazedoxifene 20mg (Duavee®) daily
- Estrogen + Estrogen agonist/antagonist (EAA)
- Indications
  - Treatment of moderate to severe vasomotor symptoms
  - Prevention of osteoporosis

Duavee Package Insert. Pfizer, 2013.

CEE + Bazedoxifene

- Contraindications
  - Undiagnosed abnormal uterine bleeding
  - Breast cancer
  - Known/Suspected estrogen dependent noeplasia
  - Thromboembolism, thrombophilias
  - Hypersensivity
  - Hepatic impairment or disease
  - Pregnancy or lactation

Duavee Package Insert. Pfizer, 2013.

CEE + Bazedoxifene

Randomized, Controlled, Double-blind, Multi-center Trial
-Postmenopausal females
-Experiencing mod/sev vasomotor symptoms

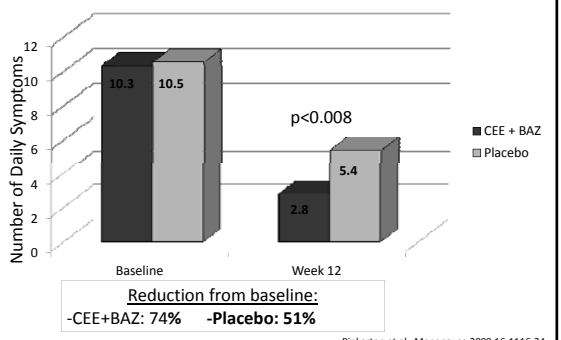
Daily Vasomotor Symptoms Severity
(0 = None, 1= Mild, 2=Moderate, 3=Severe)
(# of Mild x1) + (# of Moderate x2) + (# of Severe x3) = Score

CEE + Baz x 12weeks (n=122)	Placebo x 12 weeks (n=63)

- **Baseline Severity: 2.3**
- **Baseline Frequency: 10.4 Moderate-Severe Symptoms per day**

Pinkerton et al. Menopause 2009;16:1116-24.

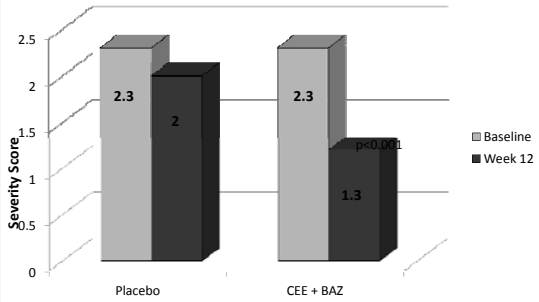
Vasomotor Frequency



Reduction from baseline:
-CEE+BAZ: 74% **-Placebo: 51%**

Pinkerton et al. Menopause 2009;16:1116-24.

Severity of Vasomotor Symptoms



Symptoms at week 12

Pinkerton et al. Menopause 2009;16:1116-24.

CEE + Bazedoxifene

ADR	CEE + Bazedoxifene	Placebo
Nausea	8%	5%
Diarrhea	8%	5%
Dyspepsia	7%	6%
Upper abdominal pain	7%	5%
Muscle spasms	9%	6%
Neck pain	5%	4%
Dizziness	5%	3%
Oropharyngeal pain	7%	6%

Duavee Package Insert. Pfizer, 2013.

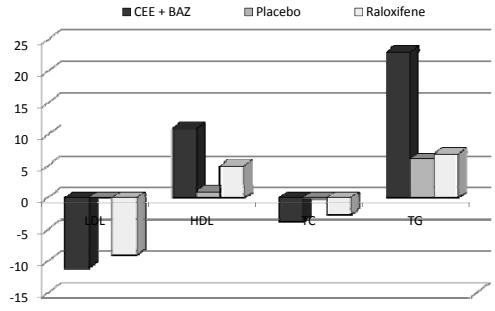
Other Effects

- Vasomotor Symptoms (up to 24 months)
  - Other studies decrease severity and frequency
- Vulvovaginal atrophy (12 weeks)
  - Improves cell lining, pH, symptoms, QOL
- Bone (at 24 months)
  - Prevent loss in women with normal bone density
  - No fracture data
- No difference
  - FBS, fasting insulin, c-reactive protein

Lindsay et al. Fertil Steril 2009;92:1045-52.

Lobo et al. Fertil Steril 2009;92:1025-38.
Kagan et al. Menopause 2010;17:281-9.

Cholesterol Changes



Lobo RA et al. Fertil Steril 2009;92:1025-38.

Serious Adverse Events

	CEE + BAZ	ET	HT
DVT	0.76 per 1000 pt years	0.7 per 1000 pt years	1.8 per 1000 pt years
CAD	CAD + Coronary insufficiency: 2.02 per 1000 MI: 1.56 per 1000	0.8 per 1000 pt years	0.5 per 1000 pt years
CVA	---	1.1 per 1000 pt years	0.8 per 1000 pt years

Lobo RA et al. Fertil Steril 2009;92:1025-38.
NAMS Menopause 2012; Menopause 2012;19:257-71.

Serious Adverse Events—2 years

- Vaginal bleeding
  - No difference vs. placebo and raloxifene
- Endometrial Protection
  - No difference vs. placebo endometrial events, cervical events, ovarian cysts, hyperplasia
- Breast
  - No difference vs. placebo in breast density

Pickar et al. Fertil Steril 2009;92:1018-24.
Archer Fertil Steril 2009;92:1039-44.
Harvey et al. Menopause 2012;20:138-45.

CEE + Bazedoxifene Summary

- Indication: vasomotor sx and osteoporosis prevention
  - Other options for osteoporosis prevention
  - Still need to have a uterus
  - ↓ frequency (50-80%) and severity
- Similar risks to HT
  - Alternative if intolerable ADR to HT

Case

- A 54yoF is complaining of intolerable hot flashes. She states it's embarrassing at work to sweat so much that she needs to change clothes or being unable to concentrate during a meeting because of them. She wakes up a couple times a night from them, too. She said her primary care doctor refused to give her hormones because he doesn't want the liability. She wants to know what she should ask her Ob/Gyn to prescribe. Last menstrual period 13 months ago. PMH: hypertension, DVT (10 years ago on contraceptives), obesity. What is the best recommendation? Is C correct?

A. 17-B estradiol patch
B. Ospemifene
~~C. Conjugated equine estrogens + bazedoxifene~~
D. Paroxetine

Paroxetine

- Paroxetine (Brisdelle™) 7.5 mg daily
- MOA: Selective Serotonin Receptor Antagonist
- Indication: moderate to severe vasomotor symptoms
- Contraindications:
  - MAO-I (within 14 days), thoridazine, pimozide
  - Hypersensitivity
  - Pregnancy

Brisdelle Package Insert. Noven, 2013.

Paroxetine

Randomized, placebo controlled
-Experiencing >7-8 mod/severe symptoms/day or 50-60/week
1° Outcome: Frequency and Severity of vasomotor symptoms

12 day Placebo, Single-blind run-in

12 Week Study		24 Week Study	
Paroxetine 7.5mg QHS (n=297)	Placebo (n=302)	Paroxetine 7.5mg QHS (n=285)	Placebo (n=285)

Simon JA et al. Menopause 2013;20:1027-35.

Methods

Calculations:

- Total weekly moderate and severe hot flashes at baseline = [(x on day 1 + x on day 2 … + x on day n) / (n-1)] x 7,
  - X = number of hot flashes
  - n = number of days in the run-in period
- Weekly hot flash score = $(2F_m + 3F_s) / (F_m + F_s)$
  - F_m and F_s = frequency of moderate and severe hot flashes during the study week

Baseline Mean Vasomotor: frequency 11.3/d and Severity 2.53

Simon JA et al. Menopause 2013;20:1027-35.

Baseline Mean Vasomotor: frequency 11.3/d and Severity 2.53

Mean Vasomotor sx per week	12 Weeks			24 Week s		
	Paroxetine	**Placebo**	**p-value**	Paroxetine	Placebo	p- value
Frequency (wk 4)	**-33.0**	**-23.5**	**<0.0001**	-28.9	-19.0	<0.0001
Composite score (wk 4)	**-0.09**	**-0.05**	**0.0048**	-0.09	-0.06	0.0452
Frequency (wk 12)	**-43.5**	**-37.3**	**0.009**	-37.2	-27.6	0.0001
Composite score (wk 12)	**-0.10**	**-0.5**	**0.2893**	-0.12	-0.07	0.0114

Effects sustained at 24 weeks

Simon JA et al. Menopause 2013;20:1027-35.

Adverse Events

- No difference in ADR
  - Mild-Moderate: 50.3% paroxetine vs. 46.7% placebo
  - Severe: 3.9% paroxetine vs. 3.1% placebo
  - Discontinuation: 4.4% paroxetine vs 3.6% placebo
- ADR >2% and twice as often as placebo
  - Nausea (paroxetine 3.8%, placebo 1.4%)
    - Fatigue (paroxetine 3.4%, placebo 1.5%)
    - Dizziness (paroxetine 2.0%, placebo 0.8%)

Simon JA et al. Menopause 2013;20:1027-35.

Off-label information

Paroxetine vs. Other Antidepressants

- Dosing
  - Subtherapeutic vs. therapeutic antidepressant
- Similar Efficacy in decreasing frequency
  - Paroxetine -50% vs. Venlafaxine -60% vs. other SSRI -50%
- Improved tolerability
- FDA indicated vs. off-label
- Cost

Case

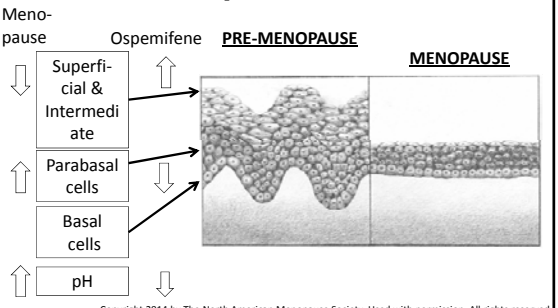
- A 62 yoF is complaining about vaginal dryness, itching all the time that also causes painful intercourse. She states the replens made her feel "leaky" sometimes. FH: CAD (father), breast cancer (sister). PSH: TAH (15 years age 2/2 fibroids). PMH: Hypertension, Hyperlipidemia, Osteoarthritis, diabetes type 2.
- What is the best recommendation?
  A. Estradiol vaginal cream
  B. Raloxifene
  C. Bremelanotide
  D. Ospemifene

Ospemiphene

- Ospemifene (Osphena®) 60mg daily with food
- Indication: moderate to severe dyspareunia
- MOA: EAA
- If pt has a uterus, still need a progestogen
- Contraindications
  - Undiagnosed vaginal bleeding
  - Pregnancy
  - Thromboembolism, MI, CVA
  - Estrogen dependent tumors

Ospemifene Package Insert. Shionogi, 2013.

Ospemifene



Ospemifene

Randomized, Controlled Trial
1: Safety and Efficacy of Ospemifene

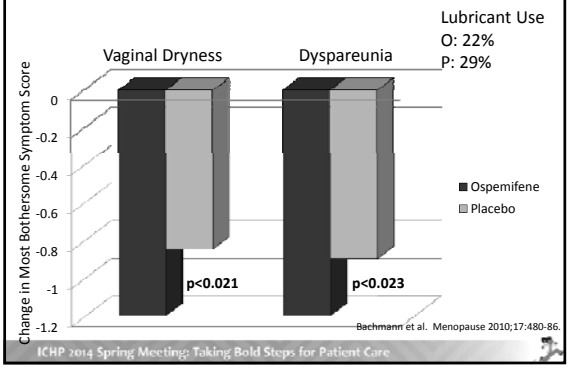
Ospemifene 60mg Qday x12 weeks (n=276)

Placebo x12 weeks (n=268)

Efficacy: Most Bothersome Symptom Score
(0 = None, 1= Mild, 2= Moderate, 3 = Severe)
- **Baseline Score for Vaginal Dryness: 2.4**
- **Baseline Score for Dyspareunia: 2.7**

Bachmann GA et al. Menopause 2010;17:480-86.

Ospemifene—12 weeks



Bachmann et al. Menopause 2010;17:480-86.

Ospemifene

Adverse Event	Ospemifene	Placebo
Vasomotor	7.5%	2.6%
Vaginal discharge Genital discharge	3.8% 1.3%	0.3% 0.1%
Muscle Spasms	3.2%	0.9%
Hyperhidrosis	1.6%	0.6%

Ospemifene Package Insert. Shionogi, 2013.

Ospemifene Risks

	Ospemifene	Placebo
DVT	1.45-2.12 per 1000	1.03-3.06 per 1000
Thromboembolic CVA	0.72 per 1000	1.04 per 1000
Hemorrhagic CVA	**1.45 per 1000**	0 per 1000
Endometrial thickening (≥5mm)	**60.1 per 1000**	21.1 per 1000
Endometrial Proliferation	**86.1**	13.3
Uterine Polyps	**5.9**	1.8

❖ Risk unknown with adding progestogen

Ospemifene Package Insert. Shionogi, 2013.

Case

- A 62 yoF is complaining about vaginal dryness, itching all the time that also causes painful intercourse. She states the replens made her feel "leaky" sometimes. FH: CAD (father), breast cancer (sister). PSH: TAH (15 years age 2/2 fibroids). PMH: HTN, Hyperlipidemia, OA, DM.
- What is the best recommendation?
  - A. Estradiol vaginal cream
  - B. Raloxifene
  - C. Bremelanotide
  - D. Ospemifene

Ospemifene Role

- Moderate to Severe dyspareunia
  - Significantly improved symptoms (mod/sev to none/mild)
- Generally well tolerated
- Same risks as systemic estrogen
- Still needs a progestogen
- Alternative to estrogen (topical, systemic)
  - No advantage, same risks

Who should receive ET/HT?

Do not use ET/HT

Vasomotor or UG Sx?

Yes

No

Any Contraindications?

Absolute	Relative
-Venous thromboembolism	-Uterine leiomyoma
-Known or suspected pregnancy	-History of migraines
-Undiagnosed vaginal bleeding	-Seizure disorder
-Suspected breast or endometrial cancer	-Hypertension
-Active liver disease	-FH of breast cancer
-CAD	
-CVA or TIA	

Yes. Do not use ET/HT

No. Consider ET/HT

Who should receive ET/HT?

No (CI)

Vasomotor: Antidepressants*, gabapentin, B-blockers, clonidine

Vaginal: Lubricating gels

Mild-Mod Non-estrogen alternatives

Mod-Severe ET/HT * Try to D/C by 5 years

Consider age and time since menopause

Step 1: Deciding on ET or HT/E+EAA

TAH or TAH/BSO?

Yes. Give ET

No. Give HT/E+EAA

Estrogen only

Estrogen + Progestogen (HT)

Estrogen + EAA

Step 2: Deciding a Route

Location of symptoms

Vasomotor Symptoms +UG?

UG Sx only?

Oral, Transdermal, Topical, Femring

Vaginal, Ospemifene (not Femring)

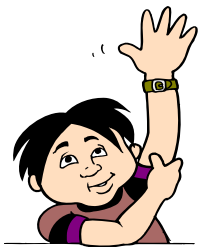
ADR due to po route? (GI intolerance, ↑TG)
Oral CI: ↑TG, liver disease, gallbladder disease
Choose non-oral route

Case

- A 54yoF is complaining of intolerable hot flashes. She states it's embarrassing at work to sweat so much that she needs to change clothes or being unable to concentrate during a meeting because of them. She wakes up a couple times a night from them, too. She said her primary care doctor refused to give her hormones because he doesn't want the liability. She wants to know what she should ask her Ob/Gyn to prescribe. Last menstrual period 13 months ago. PMH: hypertension, DVT (10 years ago on contraceptives), obesity. What is the best recommendation?

A. 17-B estradiol patch
B. Ospemifene
C. Conjugated equine estrogens + bazedoxifene
D. Paroxetine

Questions?



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9. Duavee Package Insert. Pfizer, 2013.
10. Brisdelle Package Insert. Noven, 2013.

ICHP 2014 Spring Meeting: Taking Bold Steps for Patient Care

Clinical Updates – His, Hers and Ours
Women's Health
Alicia Forinash, FCCP, BCPS, BCACP
0121-0000-14-021-L01-P
0121-0000-14-021-L01-T

Learning Assessment Questions

1. Which of the following is the best recommendation for treating vasomotor symptoms? Past medical history includes stroke (6 months ago).
    a. Ethinyl estradiol + drospirenone
    b. Conjugated equine estrogens + bazedoxifene
    c. Venlafaxine
    d. Paroxetine

2. Which new menopausal agent should you educate your patient on needing to take with food?
    a. Ospemifene
    b. Paroxetine
    c. Conjugated equine estrogens + bazedoxifene
    d. Bremelanotide

3. Which new product decreases the risk of endometrial hyperplasia in women who still have a uterus?
    a. Conjugated equine estrogens
    b. Bazedoxifene
    c. Ospemifene
    d. Paroxetine

4. Which new product is the best recommendation relieving symptoms in a patient only experiencing vulvovaginal atrophy? Past surgical history: total abdominal hysterectomy and bilateral salpingo-oopherectomy (TAH/BSO)
    a. Conjugated equine estrogens tablet
    b. Conjugated equine estrogens + Bazedoxifene tablet
    c. Ospemifene table
    d. Ospemifene tablet + medroxyprogesterone tablet

5. Which therapy helps prevent against osteoporosis?
    a. Ospemifene
    b. Paroxetine
    c. Conjugated equine estrogens + bazedoxifene
    d. Bremelanotide

Clinical Updates – His, Hers and Ours

Inflammatory Bowel Disease

Nehrin Khamo
Clinical Pharmacist/ Specialty Pharmacy Services
University Of Illinois
Hospital & Health Sciences System

Conflict of Interest

- The Speaker has no Conflict of Interest in relation to this presentation.

Pharmacist Objectives

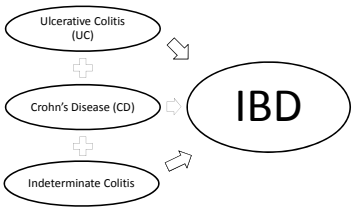
- Describe the pathophysiology and clinical features of Ulcerative Colitis & Crohn's Disease
- Identify optimal therapies for patients with Ulcerative Colitis or Crohn's Disease
- Recognize new treatment options for Ulcerative Colitis and Crohn's Disease

Pharmacy Technician Objectives

- Recognize signs or symptoms of Ulcerative Colitis & Crohn's Disease
- Identify common therapies for Ulcerative Colitis or Crohn's Disease

Inflammatory Bowel Disease (IBD)

IBD is a term that describes a group of chronic conditions that cause inflammation/ulceration in the GI tract



DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. *Pharmacotherapy: A Pathophysiologic Approach*, 9th Ed. New York: McGraw-Hill; 2014.

Inflammatory Bowel Disease

- **Etiology unclear**
  - Infectious triggers
  - Genetics
  - Environmental triggers
  - Immune defects
  - Other possible causes/triggers
    - Drugs, Diet, Stress, Depression, Sleep, Hormonal Influence

Ananthakrishnan AN. Environmental Risk Factors for Inflammatory Bowel Disease, *Gastroenterology & Hepatology. 2013;* Volume 9: 367-74.

Pathophysiology of IBD

Defect between the barrier function of the intestinal epithelium and the mucosal immune system

⇩

Dietary and bacterial antigens penetrate the intestinal wall

⇩

Immune system produces inflammation

⇩

IBD gut does not have controlled inflammation.
Acute inflammation can lead to chronic inflammation

Lakatos PL, Szamosi T, Lakatos L. Smoking in inflammatory bowel disease: good, bad or ugly? *World J Gastroenterol.* 2007; 13(46): 6134-6139.
Van Der Heide F, Dijkstra A, Weersma RK, et al. Effects of active and passive smoking on disease course of Crohn's disease and ulcerative colitis. *Inflamm Bowel Dis.* 2009;15(8):1199–207.

Inflammatory Bowel Disease

UC	CD
Limited to colon and/or rectum	Occurs anywhere in the GI tract, potentially from mouth to anus
Superficial mucosal inflammation	Transmural mucosal inflammation
Inflammation pattern is continuous	Inflammation pattern is patchy with cobblestone appearance
Nontransmural & crypt abscesses	Transmural lesions & granulomas

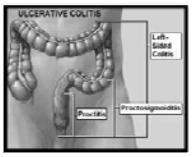
DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. *Pharmacotherapy: A Pathophysiologic Approach*, 9th Ed. New York: McGraw-Hill; 2014.

Assessment Question

Which of the following factors has the opposite effect in UC vs. CD?

a) Genetics
b) Infections
c) Smoking
d) Drugs
e) Immune defects

UC Disease Location



Ulcerative Proctitis	Proctosigmoiditis	Left Sided Colitis (Distal Colitis)	Pancolitis	Fulminant Colitis
• Inflammation of rectum only	• Inflammation of the rectum & sigmoid colon	• Continuous inflammation that begins in the rectum, sigmoid colon & descending colon	• Inflammation in the entire colon	• Inflammation in the entire colon, rare, life-threatening form of colitis

DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. *Pharmacotherapy: A Pathophysiologic Approach*, 9th Ed. New York: McGraw-Hill; 2014.
http://www.moondragon.org/health/disorders/ulcercolitis.html. Accessed February 19, 2014.

Ulcerative Colitis Severity

- **Mild Disease**
  - Fewer than four stools/day ± blood
  - No systemic disturbance
  - Mild abdominal pain
- **Moderate Disease**
  - Four to six stools/day ± blood
  - Minimal systemic disturbance
  - Mild abdominal pain/mild anemia

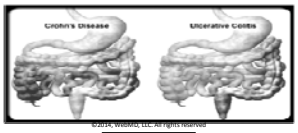
DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. *Pharmacotherapy: A Pathophysiologic Approach*, 9th Ed. New York: McGraw-Hill; 2014.

Ulcerative Colitis Severity

- **Severe Disease**
  - More than six stools/day containing blood
  - Systemic disturbance such as fever, anemia, and tachycardia
- **Fulminant Disease**
  - >10 stools/day, continuous bleeding
  - Severe pain, abdominal tenderness/distention
  - Toxic Megacolon

DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. *Pharmacotherapy: A Pathophysiologic Approach*, 9th Ed. New York: McGraw-Hill; 2014.

Crohn's Disease Location



Ileocolitis	Ileitis	Gastroduodenal Crohn's Disease	Jejunoileitis	Crohn's (Granulomatous) Colitis
• Affects the end of the small intestine (the ileum) and the large intestine (the colon)	• Affects the ileum	• Affects the stomach and the beginning of the small intestine(the duodenum)	• Affects the upper half of the small intestine (the jejunum)	• Affects the colon only

Beth Israel Deaconess Medical Center. Available at http://www.bidmc.org/Centers-and-Departments/Departments/Digestive-Disease-Center/Inflammatory-Bowel-Disease-Program/Crohns-Disease/What-are-the-types-of-Crohns-disease.aspx. Accessed February 19, 2014.

Crohn's Disease Severity

Mild to Moderate	Moderate to Severe	Severe Fulminant
Frequent diarrhea & abdominal pain	Failed treatment for mild to moderate disease	Persistent symptoms despite appropriate treatment for moderate to severe Crohn's disease
	Fever, significant weight loss, abdominal pain or tenderness, intermittent nausea, vomiting, and anemia	May experience high fever, persistent vomiting, evidence of intestinal obstruction, abscess, and severe weight loss

Stange EF, Travis SP, Vermeire S, et al. European evidence based consensus on the diagnosis and the management of Crohn's disease: definitions and diagnosis. *Gut*. 2006;55(suppl 1):i1-15.

Clinical Features of IBD

Disease Hallmark	• UC - Bloody diarrhea • CD - Can present in many ways
Laboratory Findings	• UC - ↓ Hgb, ↑ WBC, possible hypokalemia, elevated ESR, elevated LFT • CD - Mild decrease in Hgb, mild increase in WBC, elevated ESR
Nutrition Status	• Nutritional deficiencies based on location of disease • Vit B12, Folate, Iron, Calcium, Mg, other Vitamins
Dehydration Status	• Electrolytes • Albumin

DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. *Pharmacotherapy: A Pathophysiologic Approach*, 9th Ed. New York: McGraw-Hill; 2014.

Clinical Features of IBD

Complication	• UC - Perforation, Toxic Megacolon, risk of colon cancer • CD - Risk of ulceration, developing fistula, and fissures
Disease Manifestation	• UC - Usually no systemic involvement • CD - Systemic involvement: Dermatologic, Rheumatologic, Ocular, Hepatobiliary, and Hematologic
Disease Outcome	• UC - Potential Cure with surgery • CD - There is no cure . Surgery is reserved for those who have refractory disease

DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. *Pharmacotherapy: A Pathophysiologic Approach*, 9th Ed. New York: McGraw-Hill; 2014.

Assessment Question

Which of the following symptoms is considered a disease hallmark for UC?

a) Fever
b) Fatigue
c) Bloody diarrhea
d) Weight loss
e) Abdominal pain

Signs and Symptoms of IBD

- Symptoms range from mild to severe. They can be mild during remission and/or severe during relapse
- Common symptoms associated with UC & CD
  - Malaise/Fatigue
  - Fever
  - Rectal bleeding
  - Abdominal pain

DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. *Pharmacotherapy: A Pathophysiologic Approach*, 9th Ed. New York: McGraw-Hill; 2014.

IBD Treatment Goals

- Induce remission for acute flares/maintain remission
- Improve quality of life
- Prevent surgery
- Prevent and/or resolve complications
  - Fissures, fistulas, abscess formation, colon cancer
- Prevent and/or resolve systemic manifestations
  - Hepatobiliary complications, arthritis, uveitis, and skin lesions

Cosnes J, Cattan S, Blain A, et al. Long-term evolution of disease behavior of Crohn's disease. *Inflamm Bowel Dis.* 2002;8(4):244-50.
Engstrom PF, Goosenberg EB. *Diagnosis and Management of Bowel Diseases.* 3rd Edition. West Islip, NY: Professional Communications, Inc: 2007.

IBD Optimal Drug Therapies

- ***Drug factors to consider***
  - Severity of the disease
  - Location of the disease
  - Administration route
  - Side effects profile
  - Engage the patient with medication selection
  - Adherence
  - Effectiveness and safety profile
  - Cost

Categories of Medications for IBD

- Aminosalicylates (5-ASA)
- Corticosteroids
- Immunosuppressive agents
- Antimicrobials
- Biological agents

Baumgart DC, Sandborn WJ. Inflammatory bowel disease: clinical aspects and established and evolving therapies. *Lancet.* 2007;369(9573):1641-57.

Assessment Question

Which of the following statements is true?

a) Treatment options for UC & CD are based on clinical features
b) The location, severity, symptoms, and diagnostic testing can determine what medication(s) to choose to treat IBD
c) UC & CD are treated based on race, and age
d) To choose a medication for an IBD patient, cost should not be a factor to consider

5-Aminosalicylic Acid (5-ASA)

- Treat mild to moderate IBD
- Adjunctive treatment
- Mechanism of Action:

Anti-inflammatory	Immunosuppressive
• Inhibit prostaglandin production by blocking cyclooxygenase, lipoxygenase • ↓ platelet activating factors	• Stimulates release of adenosine • Impairs leukocyte function and activation • Interferes with cytokine synthesis, IL-1, IL-2, TNF-α cytokines needed to activate inflammatory process

DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. *Pharmacotherapy: A Pathophysiologic Approach*, 9th Ed. New York: McGraw-Hill; 2014.

5-Aminosalicylic Acid (5-ASA)

Sulfasalazine	Olsalazine	Balsalazide	Mesalamine
• Azulfidine®	• Dipentum®	• Colazal®	• Apriso® • Asacol HD® • Pentasa® • Rowasa® Enema • Canasa® Suppository • Delzicol® • Lialda ®

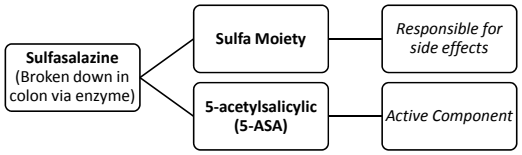
DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. *Pharmacotherapy: A Pathophysiologic Approach*, 9th Ed. New York: McGraw-Hill; 2014.

(5-ASA) Medications: Site of Action

Rectum	• Canasa® Suppository
Rectum & **Proctosigmoid**	• Rowasa ® Enema
Rectum, Proctosigmoid & **Colon**	• Azulfidine®, Dipentum®, Colazal®
Rectum, Proctosigmoid, Colon, &**Terminal Ileum**	• Asacol HD®, Delzicol®, Lialda ®
Rectum, Proctosigmoid, Colon, Terminal Ileum, **Ileum & Jejunum**	• Apriso®
Rectum, Proctosigmoid, Colon, Terminal Ileum, Ileum, Jejunum & **Duodenum**	• Pentasa®

DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. *Pharmacotherapy: A Pathophysiologic Approach*, 9th Ed. New York: McGraw-Hill; 2014.

Sulfasalazine (Azulfidine®)



Nielsen OH, Munck LK. Drug insight: aminosalicylates for the treatment of IBD. *Nat Clin Pract Gastroenterol Hepatol.* 2007;4(3):160-70.

Sulfasalazine: Points to Consider

- Dose related reactions
- Metabolism status
- Adverse events: Dyspepsia, nausea, fatigue, headache, and dizziness
- Stop if patient is allergic to Sulfa and Sulfonamide

DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. *Pharmacotherapy: A Pathophysiologic Approach*, 9th Ed. New York: McGraw-Hill; 2014.

Sulfasalazine: Points to Consider

- Sulfasalazine hypersensitivity reactions, not dose related
  - Fever
  - Arthralgias
  - Hepatic dysfunction
  - Rash – Stevens Johnson
  - Hematological Toxicity
- Male fertility
- Urine color change, may stain contact lenses

DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. *Pharmacotherapy: A Pathophysiologic Approach*, 9th Ed. New York: McGraw-Hill; 2014.

Newer (5-ASA) Agents

- Olsalazine, Balsalazide, Mesalamine
- Unlike Sulfasalazine, there is no sulfa moiety
- Alternative for patients with sulfa allergy
- Side Effects
  - Headache, nausea, diarrhea (Olsalazine), rash, hair loss, interstitial nephritis, pericarditis, pneumonitis, pancreatitis, paradoxical exacerbation of colitis, and hepatitis

DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. *Pharmacotherapy: A Pathophysiologic Approach*, 9th Ed. New York: McGraw-Hill; 2014.

(5-ASA) Optimal Dosing & Counseling Points

- *For oral formulations - swallow pill as a whole and consider pill burden and adherence*
  - Azulfidine® 3-6g/daily in divided doses
  - Dipentum® 1g/daily in divided doses
  - Colazal® 6.75g/daily in divided doses
  - Delzicol® 1.6-2.4 g/d in divided doses
  - Asacol HD® 4.8 g/d in divided doses
  - Lialda® 2.4-4.8g **daily**
  - Apriso® 1.5 g **daily**
  - Pentasa® 4g/d in divided doses

DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. *Pharmacotherapy: A Pathophysiologic Approach*, 9th Ed. New York: McGraw-Hill; 2014.

(5-ASA) Optimal Dosing & Counseling Points

- Canasa® 1000mg/day
  - **Peal off packaging & evacuate bowels first**
- Rowasa® 4g/day at bedtime
  - **Lay on left side. Leave in at least 8 hours. May stain clothes**

DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. *Pharmacotherapy: A Pathophysiologic Approach*, 9th Ed. New York: McGraw-Hill; 2014.

Assessment Question

Patient presents to the pharmacy a prescription for Pentasa®, what is an appropriate initial counseling tip for patient?

a) If allergic to Sulfa, don't take the medication
b) The importance of adherence considering pill burden
c) Don't take the medication if symptoms are controlled
d) Consider switching to another medication if symptoms don't resolve

ICHP 2014 Spring Meeting: Taking Bold Steps for Patient Care

Corticosteroids

- **Treatment of active UC or CD**
  - Induce remission rapidly
  - Does not maintain remission
- **Mechanism Of Action is unknown**
  - suppress immune system
  - inhibit cytokines
  - inhibit prostaglandins
  - decrease margination of monocytes and neutrophils

DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. *Pharmacotherapy: A Pathophysiologic Approach*, 9th Ed. New York: McGraw-Hill; 2014.

ICHP 2014 Spring Meeting: Taking Bold Steps for Patient Care

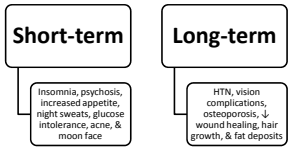
Corticosteroids Agents & Route of Administration

- Agents used
  - Budesonide (Entocort EC® Uceris®)
  - Hydrocortisone Rectal Preparations (Cortenema®, Colocort®, Cortifoam®)
  - Methylprednisolone
  - Prednisone
- Severe IBD
  - Parenteral
- Mild to Moderate IBD
  - Oral

DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. *Pharmacotherapy: A Pathophysiologic Approach*, 9th Ed. New York: McGraw-Hill; 2014.

ICHP 2014 Spring Meeting: Taking Bold Steps for Patient Care

Corticosteroids: Points to Consider



While on steroids, minimize bone loss

- Supplement with Calcium
- Use lower dose possible
- Life style modification

DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. *Pharmacotherapy: A Pathophysiologic Approach*, 9th Ed. New York: McGraw-Hill; 2014.

ICHP 2014 Spring Meeting: Taking Bold Steps for Patient Care

Immunosuppressive Therapy

- Place in Therapy
  - Steroid sparing
  - Combine with biological agents to reduce immunogenicity
- Slow onset of action
  - Azathioprine (AZA) (3 months)
  - 6-mercaptopurine (6-MP) (3 months)
  - Methotrexate (MTX) (2 to 8 weeks)
  - Cyclosporine (CSA), Tacrolimus (5-14days)

DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. *Pharmacotherapy: A Pathophysiologic Approach*, 9th Ed. New York: McGraw-Hill; 2014.

ICHP 2014 Spring Meeting: Taking Bold Steps for Patient Care

Immunosuppressive Optimal Dosing Therapy

- Azathioprine: 2-3 mg/kg/day
- 6-Mercatopurine: 1-1.5mg/kg/day
- Methotrexate: 25mg IM **weekly**
  - *Folate antagonist: supplement with folic acid*
  - *Pregnancy category X*
- Cyclosporine: 5mg/kg/day
- Tacrolimus 5mg BID

Hanauer, SB. Challenging Issues in Ulcerative Colitis. CME Podcast co-sponsored through University of Chicago Pritzker School of Medicine and Curation CME Institute; December 2008 – December 31, 2009.
Brynskov J, Freund L, Rasmussen SN, et al. A placebo-controlled, double-blind, randomized trial of cyclosporine therapy in active chronic Crohn's disease. *N Engl J Med*. 1989;321;845-850.

Immunosuppressive Therapy: Points to Consider

- Side effects
  - Bone marrow suppression
  - Infections
  - Pancreatitis
  - GI disturbances
  - Hypersensitivity reactions
  - Malignancy & Lymphoma
  - Hepatotoxicity
  - Pregnancy category (D, X)
- Nephrotoxicity, hypertension, paresthesia with Cyclosporine & Tacrolimus

Hanauer, SB. Challenging Issues in Ulcerative Colitis. CME Podcast co-sponsored through University of Chicago Pritzker School of Medicine and Curation CME Institute; December 2008 – December 31, 2009.

Assessment Question

What are some counseling tips to consider prior to the patient starting Methotrexate?

a) Discuss pregnancy category
b) Counsel patient on importance of folate intake
c) Address dosing directions and regimen
d) Discuss necessary labs that need to be done while on therapy
e) All of the above

Antimicrobials

- Crohn's patients with abscess or fistulas
- Symptoms related to bacteria
- Intestinal or perianal disease or pouchitis
- Mechanism Of Action: unknown
  - **Metronidazole**
    - Dose 10-20mg/kg/day, 250mg 2–3/ daily
    - Adverse events: nausea, metallic taste, disulfiram reaction, peripheral neuropathy
  - **Ciprofloxacin**
    - Dose 500mg 2x daily
    - Adverse Events: vaginitis, abdominal pain, distal neuropathy, and tendinopathy

DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. *Pharmacotherapy: A Pathophysiologic Approach*, 9th Ed. New York: McGraw-Hill; 2014.

Assessment Question

Which of the following medications is used to induce rapid remission in IBD?

a) Sulfasalazine
b) Azathioprine
c) Prednisone
d) Methotrexate
e) 6-Mercaptopurine

Biologic Response Modifiers (BRMs)

- Substances that stimulate the body's response to infection and disease
- Examples include monoclonal antibodies, interferon, and colony stimulating factors
- Indicated for chronic medical conditions such as Rheumatoid Arthritis (RA) and IBD
- Some have severe and potentially fatal adverse effects including increased risk for infections and cancer (Anti-TNF agents)

DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. *Pharmacotherapy: A Pathophysiologic Approach*, 9th Ed. New York: McGraw-Hill; 2014.

Categories of (BRMs)

- Anti-TNF agents
- T-Cell co-stimulation blocker
- Interleukin-6 receptor antagonist
- Monoclonal Antibody

Biological Agents

- **Agents used for IBD treatment**
  - Certolizumab (Cimzia®) Subcutaneous
  - Adalimumab (Humira®) Subcutaneous
  - Golimumab (Simponi®) Intravenous, subcutaneous
  - Infliximab (Remicade®) Intravenous only
  - Natalizumab (Tysabri®) Intravenous only
- **Dosing is standardized per package insert**

Baumgart DC, Sandborn WJ. Inflammatory bowel disease: clinical aspects and established and evolving therapies. *Lancet*. 2007;369(9573):1641-57.

Biological agents: Adverse Effects

- Infection
  - TB, Hepatitis B
- Malignancy
  - Lymphoma, leukemia, skin cancer
- Hepatotoxicity
- Lupus like syndrome
- Psoriasis (new or exacerbation)
- Heart failure (new or exacerbation)
- CNS demyelinating disorders/seizures (new or exacerbation)

Assessment Question

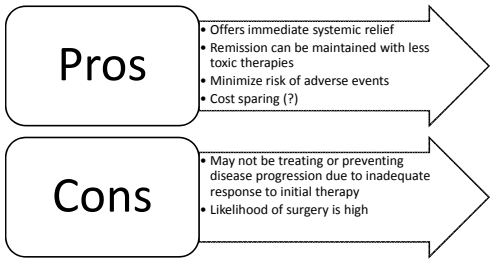
Which of the following needs to be assessed prior to start of therapy with biological agents?

a) Infections, risk of malignancy & laboratory testing
b) Eating habits
c) Patient's age
d) Psychological status
e) Pill burden

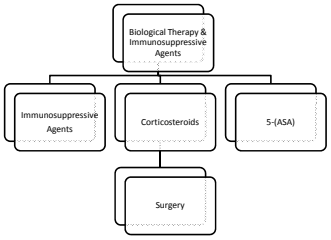
Conventional Therapeutic Algorithms (Bottom-up, Step-up)

- Mild
  - (5-ASA) Agents / Antibiotics
- Moderate
  - Corticosteroids
  - Immunosuppressive agents
- Severe
  - Anti-TNF
  - Natalizumab
  - Surgery

Bottom-Up Therapy



Top-Down (Step-Down) Therapy



D'Haens GR. Top-down therapy for IBD: rational and requisite evidence. *Nat Rev Gastroenterol Hepatol.* 2010;7(2):86-92.

Top-Down Therapy

Pros
- May delay disease progression
- Biological agents may stop inflammation and prevent complications

Cons
- Adverse events
- Toxicity
- Cost and coverage

New Potential Therapies

- **Janus kinase (JAK) inhibitor**
  - Xeljanz® (tofacitinib)
- **p40 subunit of interleukin 12/23**
  - Stelara® (Ustekinumab)
- **Chemokine Antagonists**
  - Novel mechanism that is under study
  - Specific to gut, reducing side effects
- **Adhesion molecule blockers**
  - Entyvio® (Vendolizumab)
  - Etrolizumab

Mayo Clinic. Available at http://www.mayoclinic.org/medical-professionals/clinical-updates/digestive-diseases/expanding-pipeline-inflammatory-bowel-disease-drugs. Accessed February 19, 2014

Summary

- Choosing optimal therapy is based on location of disease, clinical symptoms, and diagnostic testing
- Conventional vs. new algorithm therapy
- None of the drugs are considered curative for IBD; goal is disease management
- Consider the side effects profile, adherence, and monitoring parameters needed when choosing medications to manage IBD

Assessment Question

What potential classes of drugs are in the pipeline to treat IBD?

a) Janus kinase (JAK) inhibitors
b) Chemokine Antagonists
c) Adhesion molecule blocker, monoclonal antibody
d) All of the above

Reference

1. DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. *Pharmacotherapy: A Pathophysiologic Approach*, 9th Ed. New York: McGraw-Hill; 2014.
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3. Lakatos PL, Szamosi T, Lakatos L. Smoking in inflammatory bowel disease: good, bad or ugly? *World J Gastroenterol.* 2007; 13(46): 6134-6139.
4. Van Der Heide F, Dijkstra A, Weersma RK, et al. Effects of active and passive smoking on disease course of Crohn's disease and ulcerative colitis. *Inflamm Bowel Dis.* 2009;15(8):1199 –207.
5. http://www.moondragon.org/health/disorders/ulcercolitis.html. Accessed February 19, 2014.
6. Beth Israel Deaconess Medical Center. Available at http://www.bidmc.org/Centers-and-Departments/Departments/Digestive-Disease-Center/Inflammatory-Bowel-Disease-Program/Crohns-Disease/What-are-the-types-of-Crohns-disease.aspx. Accessed February 19, 2014.
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Transitions of Care Pharmacist: The Crucial Piece of the Discharge Puzzle

Amy Boblitt, BS, Pharm.D.
Michael Sheppard, Pharm.D.
Laura Jeffers, Pharm.D.
Jennifer Ratliff, RPh.
Manali Soni, Pharm.D.

Memorial Medical Center
Springfield, Illinois

The Care Transition Team has no conflicts of interest to disclose.

Objectives

- Pharmacist Objectives
  1. Describe the role of a care transition pharmacist.
  2. Identify opportunities for pharmacist intervention throughout a patient's hospital transition.
  3. List three reasons for using the teach-back methodology.
  4. Identify tools available to help improve health literacy.

Objectives

- Technician Objectives
  1. List three opportunities that may require pharmacist intervention during a patient's hospital transition.
  2. Recognize the importance of the teach-back methodology.
  3. Describe how a technician can help support a care transition pharmacist.

Background

- Team of 11 pharmacists
- Monday – Friday 8am -4:30pm
- Part of the interdisciplinary team
- BOOST involvement

Goals of Our Team

- Decrease hospital readmission due to preventable drug-related events
- Increase patient adherence
- Increase patient satisfaction
- Increase patient understanding
- Ensure accurate medication lists
- Reduce medication errors

Our Roles

- Medication Reconciliation Assistance
- Medication Therapy Evaluation
- Patient Counseling
- Core Measures
- Follow-up Phone Calls
- Hotline Phone Calls

Discharge Intervention Analyses[1]

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Discharge Intervention Analyses[1]

"Analyses of interventions at discharge made by a pharmacist care transition team in a community based hospital"

- Goal: To evaluate interventions to better define the role of pharmacists in educating and assisting patients and correcting medication errors at discharge.

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Discharge Intervention Analyses[1]

- **Methods:**
  - Consultations were initiated by: patient care facilitators, physicians, or pharmacists
  - Patient selection was based on criteria including: poly-pharmacy, health literacy concerns, high risk medications, multiple medication changes during admission, and primary diagnosis.
  - Eight weeks of data collected

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Discharge Intervention Analyses[1]

- Results:
  - 146 patients were evaluated
  - Successful teach-back was demonstrated by 79.1%
  - Pharmacist completed a prescription assistance action for 65.1% patients
  - At least one error was corrected for 51.4% patients
  - Two or more errors were corrected for 26% patients

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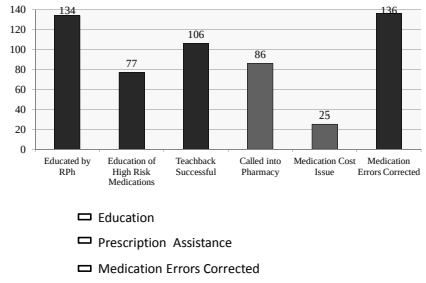
Frequency of Interventions Performed at Discharge[1]



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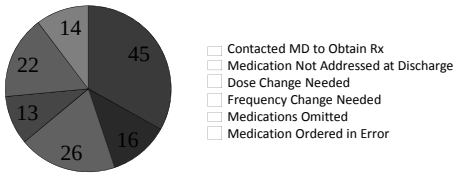
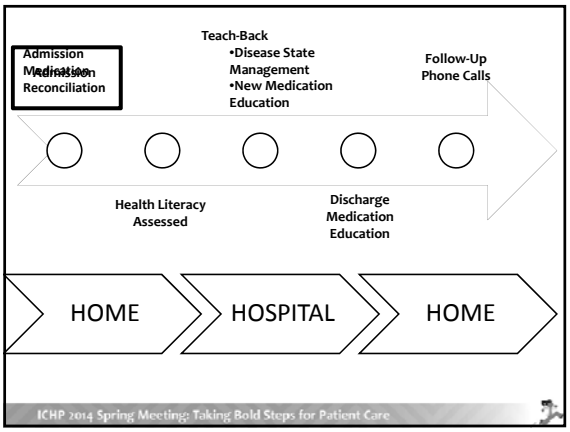
Medication Errors Corrected[1]



Conclusion: Pharmacists educated 134 patients using teach-back methodology and identified 136 discharge errors during the transition process. The results from the study show a pharmacist care transition team can offer reduction in medication errors by serving as an intermediary between patients and other healthcare professionals.



Patient Case

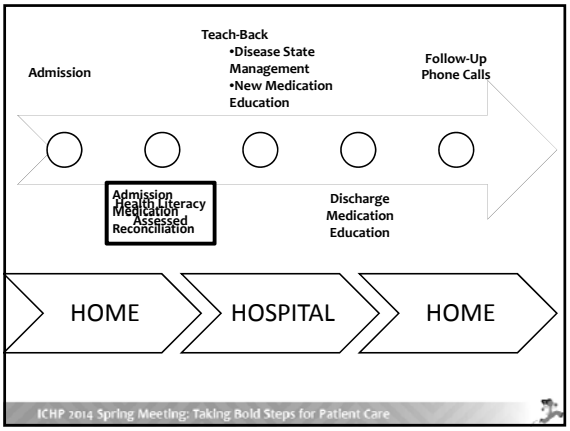
- RM is a 60-year-old male farmer admitted to general cardiac floor for worsening chest pain of 1 month duration
  - Patient scheduled for cardiac catheterization with possible Percutaneous Coronary Intervention (PCI)
- **Past Medical History**
  - Coronary Artery Disease (CAD) with Myocardial Infarction (MI) in 2011
  - Hypertension (HTN)

Patient Case Continued

- **Home Medications**
  - Metoprolol 50 mg by mouth once daily
  - Aspirin 325 mg by mouth twice daily
  - Nitroglycerin 0.4 mg under the tongue as needed
- Medication list obtained from hand-written scratch paper in patient's wallet
- Patient has informed you that he is not fond of taking medications

Patient Case Continued

- What tools should be used to help assess the patient's baseline understanding of medications?
- What possible interventions can the pharmacist make before and after discharge to increase health literacy?
- How can comprehension of education be assured?



Definition[2]

- "The degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions"

Prevalence[3]

- Approximately 9 out of 10 adults have difficulty using the everyday health information that is routinely available
- Only 12% of literate Americans are proficient in understanding health information

Importance

- Pharmacists desire successful patient outcomes
- Healthcare systems continue to be more complex
  - Increased number of medications
  - More tests and procedures
  - Complicated language
  - Multiple providers

Comparison[4]

- Pressure Float Mode
  - The height system will maintain the header height relative to ground pressure as specified by the working setting.
  - The height system will only run in the Auto state, if the feeder drive is on and the operator actuates the RESUME or SET #1 or SET #2 switch.
  - The feeder drive must be engaged to allow auto control. If the feeder is disengaged, auto control will stop immediately.
  - If the operator actuates the RAISE or LOWER switch, the system will go into Manual mode. To return to Auto mode, the operator momentarily presses the RESUME switch.
  - When a circuit fault is detected that affects the engaged auto mode, the height system will go into Manual mode.

Tools for Providers

- Numerous
  - Health Literacy Universal Precautions Toolkit[5]
  - National Action Plan to Improve Health Literacy[6]
  - "What Did the Doctor Say?:" Improving Health Literacy to Protect Patient Safety[7]

Tools for Patients

- Videos
- Charts
- Models
- Diagrams

Tools for Improving Medication Adherence/Accuracy

- Medication planners/organizers/alarms
- Medication lists
- Effective communication
  - Use "living room" language
  - Ask open-ended questions

Practice[8]

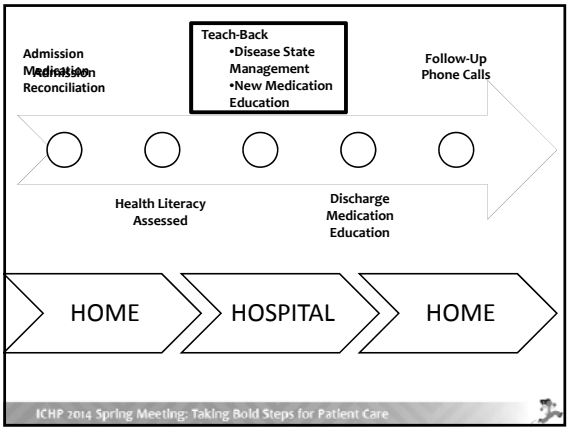
Medication	"Living Room" Language
Atorvastatin	
Clopidogrel	
Metoprolol	
Nitroglycerin	
Lisinopril	

Practice

Medication	"Living Room" Language
Atorvastatin	Lowers fats in the blood
Clopidogrel	Prevents blood clots
Metoprolol	Heart/blood pressure
Nitroglycerin	Chest pain
Lisinopril	Blood pressure

Patient Case Continued

- Patient was taking metoprolol tartrate once daily
- He was taking 2 aspirin tablets in the morning
- He was not able to tell us how to take his nitroglycerin



Background

"Studies have shown that 40-80 percent of the medical information patients receive is forgotten immediately and nearly half of the information retained is incorrect." [5]

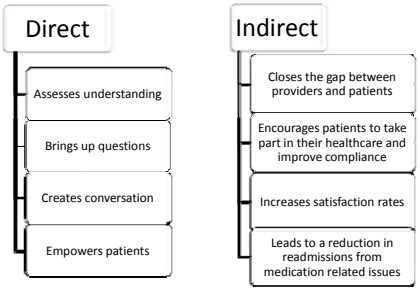
What is "Teach-Back"?[9]

- A method of communication that ensures understanding of information being shared
- Used between provider and patient/caregiver
- Incorporates asking the patient/caregiver to "teach back" what was said

How to use Teach-Back

- Only discuss 2-3 points at a time
- Use plain language and open-ended questions
- Cover the basics
  - Indication
  - Administration
  - Side Effects
  - Follow up

Teach-Back Benefits[11]



Is "Teach-Back" Associated With Knowledge Retention and Hospital Readmission in Hospitalized Heart Failure Patients?[10]

Objective:

To determine if patients educated with teach-back retain information and whether it's associated with fewer readmissions.

Methods:

- 276 patients; 13-month period
- Assessed recalled information in hospital and during follow-up.
- Readmissions confirmed through follow-up calls and review of medical records.

Results & Conclusions[10]

Results:

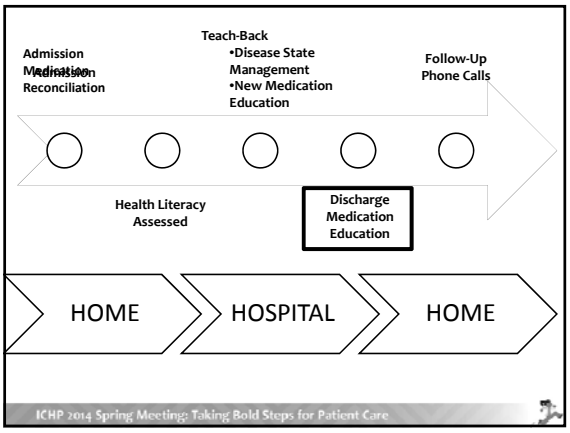
- Patients correctly answered 75%, of teach-back questions
  - 84.4% of the time while hospitalized
  - 77.1% of the time during follow-up telephone call
- Greater time spent teaching was significantly associated with correctly answered questions ($P < .001$).

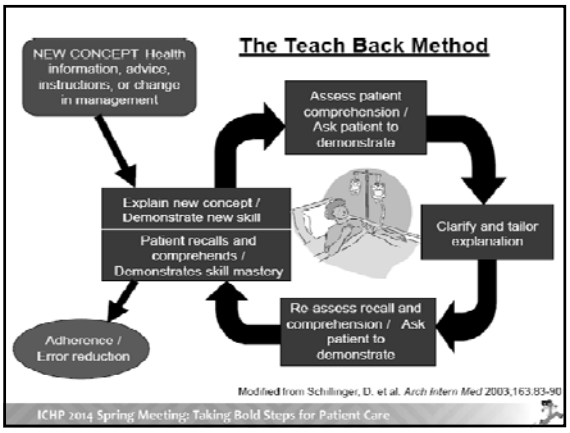
Conclusions:

- The teach-back method is an effective method used to educate and assess learning.
- Patients educated longer retained significantly more information than did patients with briefer teaching.

When is Teach-Back Most Applicable?[5]

- Medication changes
- Disease state education
- Injection administration
- Proper use of inhalers





Introduce the "New Concept"

- Review the discharge medication list
- Focus on changes
- Demonstrate techniques

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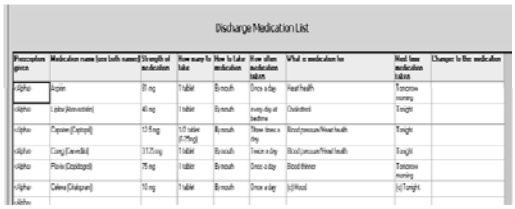
Discharge Medication List



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Assess Comprehension

- Ask the patient to attempt Teach-Back
- Focus on changes to previous routines
- Identify areas the patient lacks confidence

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Clarify and Tailor

- Use alternate words
- Use tools to offer visual examples
- Offer exact administration times

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Re-assess

- Continue to tailor instructions
- Ask patient to demonstrate a technique
- Observe patient filling a pill box

Similar Consultation Methods[12]

- Indian Health Service
  - What did your prescriber tell you the medication is for?
  - How did your prescriber tell you to take the medication?
  - What did your prescriber tell you to expect?

Patient Case

- RM is a 60-year-old male farmer admitted to general cardiac floor for worsening chest pain of 1 month duration
  - Patient scheduled for cardiac catheterization with possible Percutaneous Coronary Intervention (PCI)
- **Past Medical History**
  - Coronary Artery Disease (CAD) with Myocardial Infarction (MI) in 2011
  - Hypertension (HTN)

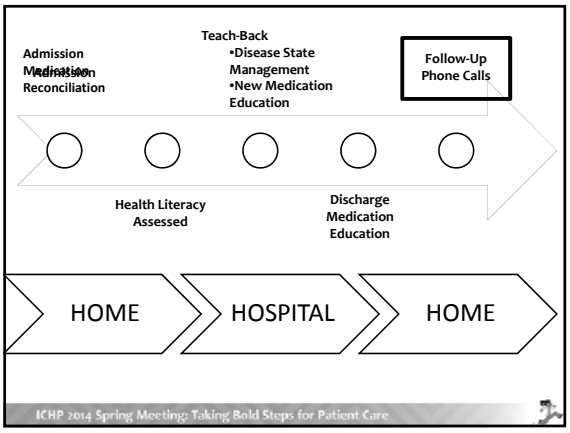
Patient Case Continued

- **Home Medications**
  - Metoprolol 50 mg by mouth once daily
  - Aspirin 325 mg by mouth twice daily
  - Nitroglycerin 0.4 mg under the tongue as needed
- Medication list obtained from hand-written scratch paper in patient's wallet
- Patient has informed you that he is not fond of taking medications

Patient Case Continued

- Discharge Medications
  - Metoprolol tartrate 50mg by mouth twice daily
  - Aspirin 81mg by mouth once daily
  - Nitroglycerin 0.4mg under the tongue as needed
  - Clopidogrel 75mg by mouth once daily
  - Atorvastatin 80mg by mouth at bedtime

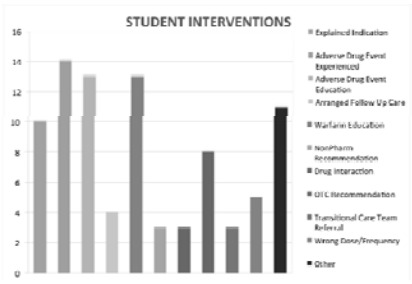
Discharge Medication List



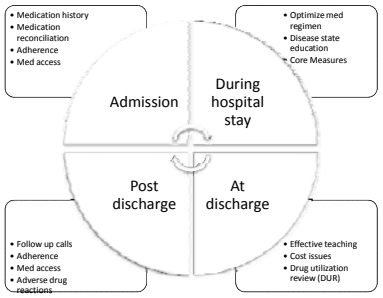
Follow -Up Phone Calls

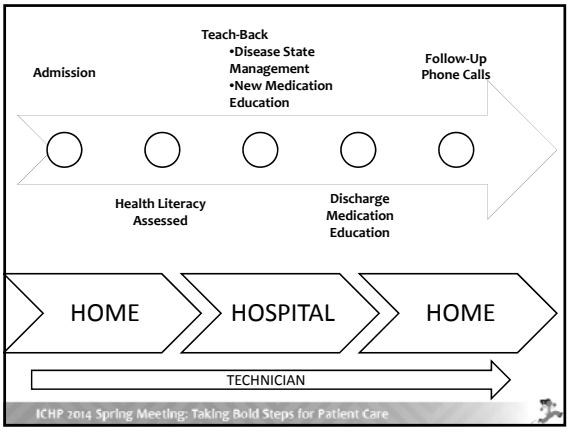
- Typically 3 to 7 days post-discharge
- Another opportunity to review medications utilizing teach back
- Answer patient questions, medication access problems, adverse drug reaction
- Hopefully increases patient satisfaction

Student interventions during follow-up phone calls[13]



Opportunities for Pharmacists





How to utilize a technician in transitions of care

Managing Referrals

- Time consuming, but very important
- Prioritizing
- New consult and discharge lists
- Discover discharge times
- Organize

Obtaining Medication List

- Gather medication list
- Investigate other sources
- Investigate compliance issues or cost issues
- Create personal medication record

Insurance

- Obtain insurance information
  - Check specific drug coverage
- Discuss medication cost
- Provide coupon card(s)
- Initiate prior authorization
- Report issues to the pharmacists

Patient Adherence

Technicians would be in the best position to discover adherence issues

- During patient interview
- When verifying refill history

Follow-Up

- Medication Access
- Hotline Phone Calls
  - Answering outside calls for pharmacists for drug-related questions
- Follow-up Appointments

Patient Case Continued

- Follow-up phone call to RM 4 days post-discharge
- Heartburn after large meals – started Prilosec OTC twice a day
- Interventions?

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Questions????

Contact Information

- Boblitt.amy@mhsil.com
- Sheppard.michael@mshil.com
- Jeffers.laura@mhsil.com
- Ratliff.jennifer@mhsil.com
- Soni.manali@mhsil.com

Memorial Medical Center

Discharge Medication List

Room/Bed: /

FIN: 226426310

Patient Name: INVESTIGATIONAL, PHARMACY

I need to pick up my medications at: Hometown Pharmacy – Highway 106

Medication Instructions were given to: Patient

Script Given	Medication Name	Strength of Med	How Many to Take	How to take	How Often Med is Taken	What is Medication for	Next time I take	Changes to this Medication
Script called to pharmacy	metoprolol tartrate (Lopressor)	50mg	1 tablet	By mouth	every morning and every evening	blood pressure/heart rate	tonight	*increased to two times a day*
Script called to pharmacy	nitroglycerin (Nitrostat)	0.4mg	1 tablet	Under the tongue (sublingual)	As needed every 5 minutes. Maximum of 3 tablets in 15 miuntes.	chest pain	only if needed	*call 911 after first dose* *keep in amber glass bottle*
Script called to pharmacy	clopidogrel (Plavix)	75mg	1 tablet	By mouth	Once a day	blood clots	tomorrow	*NEW medication *
Script called to pharmacy	atorvastatin (Lipitor)	80mg	1 tablet	By mouth	In the evening before bed	cholesterol	tonight	*NEW medication *

Memorial Medical Center

Discharge Medication List

Room/Bed: /

FIN: 226426310

Patient Name: INVESTIGATIONAL, PHARMACY

Script Given	Medication Name	Strength of Med	How Many to Take	How to take	How Often Med is Taken	What is Medication for	Next time I take	Changes to this Medication
Other: Over the Counter (OTC)	aspirin	81mg	1 tablet	By mouth	Once a day	heart health	tomorrow	*decrease in dose*

Stop these Home Medications
aspirin 325mg

Your Discharge Medication List was completed by: A Boblitt

If you have problems or questions about this medication list please call Memorial Medical Center at (217) 788 – 3000 and ask for the Pharmacy nursing unit.

In addition, if you have questions about your medications or prescriptions, you can call a pharmacist between the hours of 8:00 am – 4:00 pm, Monday – Friday, at (217) 788 – 4382

Transitions of Care Pharmacist: The Crucial Piece of the Discharge Puzzle

Amy Boblitt BS, PharmD
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Michael Sheppard, PharmD
Manali Soni-Talsania, PharmD

0121-0000-14-022-L04-P
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Learning Assessment Questions

1. Which one is a key component of teach-back?
    a.) Focusing on 2-4 key points at a time
    b.) Using medical terminology
    c.) Asking if the patient understands
    d.) Asking “yes” or “no” questions

2. When is teach-back appropriate?
    a.) Medication change education
    b.) Insulin administration education
    c.) Only when family members are present
    d.) Any time for any type of education

3. Which government agency developed a standardized patient counseling method to improve outcomes for the patient population they serve?
    a.) FDA
    b.) DEA
    c.) IHS
    d.) Affordable Care Act

4. Which of the following is a tool frequently used during teach back?
    a.) accurate discharge medication lists
    b.) closed ended questions
    c.) old medication lists
    d.) package inserts provided from the drug manufacturer

5. What is the ideal time to make discharge phone calls?
    a.) 1 day later
    b.) 30 days later
    c.) Depends on your institution and ideally on the specific patient
    d.) 365 days

6. Patient is being discharged on atrovastatin. Health literacy universal precautions are to be used for counseling purposes. Which of the following statements BEST describes atrovastatin's purpose using "living room language?"
    a) Inhibits HMG-CoA reducatse, the rate-limiting enzyme in cholesterol biosynthesis
    b) Lowers cholesterol to reduce the risk of cerebrovascular accidents and myocardial infactions
    c) Decreases cholester to reduce the risk of atherosclerotic cardiovascular disease
    d) Lowers fats in the blood to reduce the risk of strokes and heart attacks

Introduction

Quality Measures and Health-system Pharmacist: The Era of Accountability

Charlene A. Hope, PharmD, BCPS, CPHQ, CPPS
Director of Pharmacy
Norwegian American Hospital

The speaker has no conflict of interest to disclose.

Learning Objectives Pharmacists

- Discuss current efforts by PQA and ASHP PSAM Workgroup to develop and identify pharmacy sensitive measures.
- Explain the current challenges associated with developing and using pharmacy sensitive quality measures.
- Identify sources for selecting appropriate quality measures based on practice setting, payer mix and other organizational pressures.
- Describe three characteristics pharmacists should consider when selecting quality measures.
- Using information presented, choose 4 appropriate measures for your practice.

Learning Objectives Technicians

- Define pharmacy sensitive measures.
- Identify sources for quality measures used by health care organizations.
- Explain why certain measures may be chosen by an organization for use as a quality measure.
- Describe three characteristics pharmacists should consider when selecting quality measures.
- Assist pharmacists in screening appropriate sources for quality measures appropriate for the practice site.

Belief and Assumption:

A7. In the next 5–10 years, required quality measures related to medication use in hospitals and health systems will increase.

PPMI
PHARMACY PRACTICE MODEL INITIATIVE

Recommendation:

B7. Hospital and health-system pharmacists must be responsible and accountable for patients' medication-related outcomes

Recommendation:

B24f. Play a critical role in ensuring that the hospital or health system adheres to medication-related national quality indicators

The consensus of the Pharmacy Practice Model Summit Am J Health-Syst Pharm. 2011; 68:e110-4

Quality of Care: Dawn of a New Era

- Reimbursement Based on Quality
- Business Models
- Pharmacist Engagement
- Practice Models

Quality of Care: Dawn of a New Era

STRATEGIC RECOMMENDATIONS FOR PRACTICE LEADERS

1. Identify medication-related quality-of care measures within your institution and develop an action plan for the pharmacy department to improve performance on those measures.
   - Develop a pharmacy department dashboard of indicators that document pharmacists' contribution to improving the quality of care.
2. Develop a strategy for the pharmacy department to gain authority to manage all medication-related issues upon patient discharge.

Phelps PK, Pharmacy Forecast 2014-2018: Strategic Planning Advice For Pharmacies and Health-systems

Quality of Care: Dawn of a New Era

STRATEGIC RECOMMENDATIONS FOR PRACTICE LEADERS

4. Develop discharge hand-off plans for high-risk patients who may benefit from pharmacy follow-up. Develop a plan to refer such patients to medication therapy management programs after discharge

5. Develop a plan to interact with every patient in the hospital for medication histories, first-dose education, and discharge planning and follow-up.

6. Study the patient-care and financial implications associated with outsourced care-transition services and help your organization's executive leaders assess whether such services are in the best interests of patients and the institution.

Phelps PK, Pharmacy Forecast 2014-2018: Strategic Planning Advice For Pharmacies and Health-systems

Case Study: Pennsylvania Hospital

Pharmacists Help With CMS Core Measure Adherence

Program Details:

- Clinical Pharmacists screened patients for Core Measure diagnoses while doing their daily rounds.
- Patient-specific worksheets to keep track of medication-related core measure compliance.
  - Manual paper then transitioned to electronic.
- Clinical pharmacists document in the patient's permanent medical record
  - a contraindication if the patient was noncompliant with a medication due to contraindication
  - consult with the provider and recommend compliance if the patient was noncompliant and no contraindication was indicated.

Case Study: Pennsylvania Hospital

Pharmacists Help With CMS Core Measure Adherence

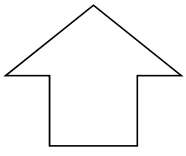
Results:

- Within 17 months of the core measure initiative 2742 patients were reviewed,
  - 218 documentations in patient charts
  - 224 recommendations (96% acceptance rate)
- The hospital improved its compliance in 9 targeted medication-related core measures and achieved 100% compliance in most of these measures.

Starting with the familiar

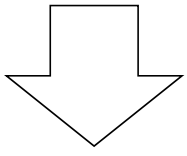
Medication-Related Core Measures	• **Venous Thromboembolism** • **Inpatient Immunization** • **Surgical Care Improvement Plan** • **Heart Failure** • **Acute Myocardial Infarction** • **Pneumonia** • **Stroke**
Medication Related HCAHPS questions	• Before giving you any new medicine, how often did hospital staff tell you what the medicine was for? • Before giving you any new medicine, how often did hospital staff describe possible side effects in a way you could understand? • When I left the hospital, I clearly understood the purpose for taking each of my medications.

Time to rethink? Clinical Intervention Report

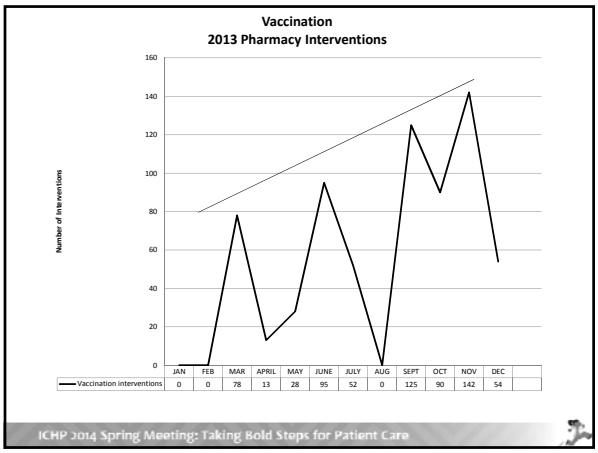


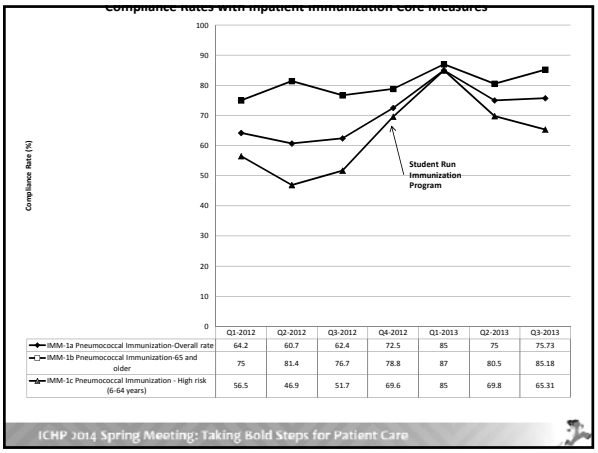
Quality Measure Dashboards

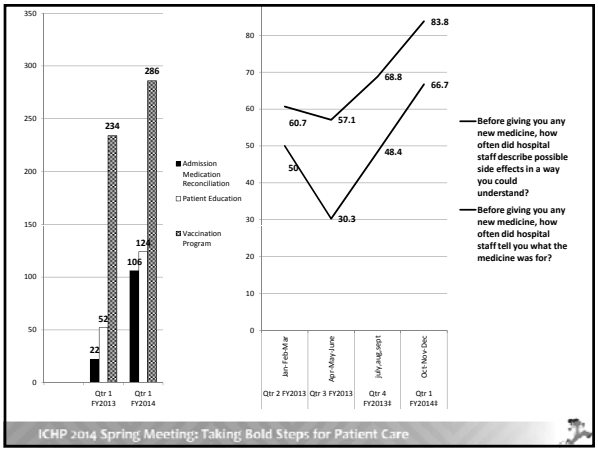
(Accountability)



Clinical Intervention Reporting (Productivity)



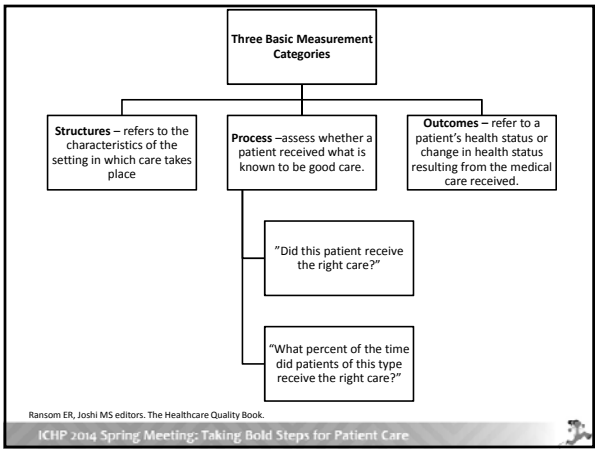


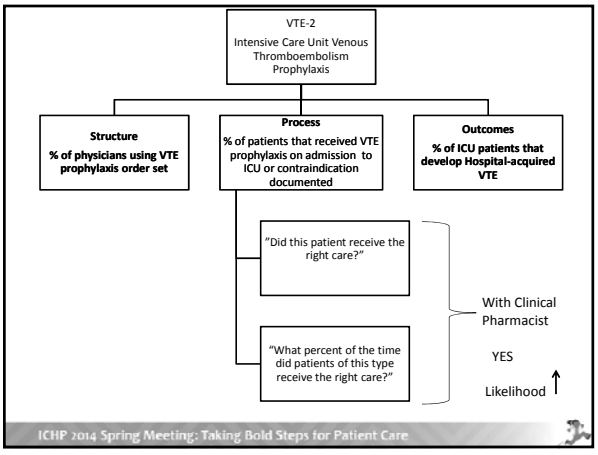


Quality Measurement Journey

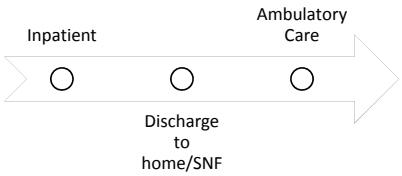
1. Develop a measurement philosophy
2. Identify concepts to be measured
   - Types and categories of measures
3. Select specific measures
4. Develop operational definitions for each measure
5. Develop a data collection plan and gather the data
6. Analyze the data
7. Use the analytic results (data) to take action (implement cycles of change, test theories, and make improvements)

Ransom ER, Joshi MS editors. The Healthcare Quality Book.





Quality Measures through Continuum of Care



ACCP White Paper
Process Indicators of Quality Clinical Pharmacy Services During Transitions of Care

Quality Measures and Health-system Pharmacist: The Era of Accountability

Mary Ann Kliethermes, BS, PharmD
Vice-Chair Ambulatory Care, Associate Professor
Chicago College of Pharmacy
Midwestern University
March 29, 2014

All conflicts were resolved through peer review.

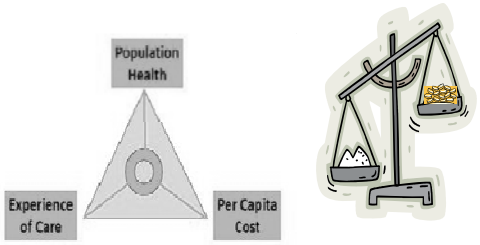
Defining Quality

The Institute of Medicine (IOM)

the degree to which health services for individuals or populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge

Institute of Medicine. Medicare: A Strategy for Quality Assurance. Washington, DC: National Academy Press; 1990

Proving Pharmacist Contribution to the Triple Aim



Quality Alphabet Soup

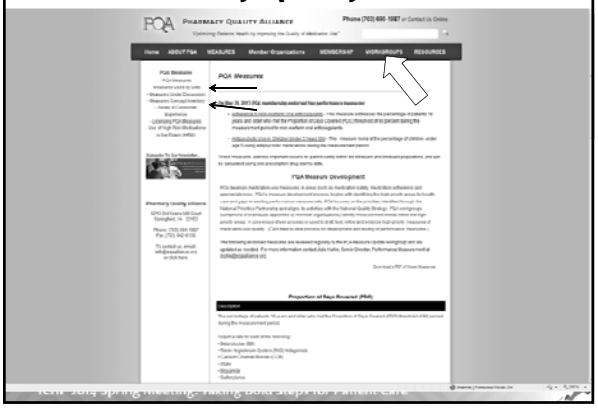
PQA	Pharmacy Quality Alliance
PCPI	Physician Consortium for Performance Improvement
NQF	National Quality Forum
AHRQ	Agency for Healthcare Research & Quality
PQRS	Physician Quality Reporting System
QIO	Quality Improvement Organizations
PSPC	Patient Safety and Clinical Pharmacy Collaborative
STAR **ACO**	Five-Star Quality Rating System (CMS) Medicare Shared Savings Program
NCQA	National Committee for Quality Assurance
HEDIS	Healthcare Effectiveness Data & Information Set
JC	Joint Commission
CPPA	Center for Pharmacy Practice Accreditation

your service, where will you go to find appropriate measures?

A. National Quality Strategy
B. HEDIS
C. Pharmacy Quality Alliance
D. Joint Commission
E. Star measures
F. I have no idea

Selecting Measures - Sources

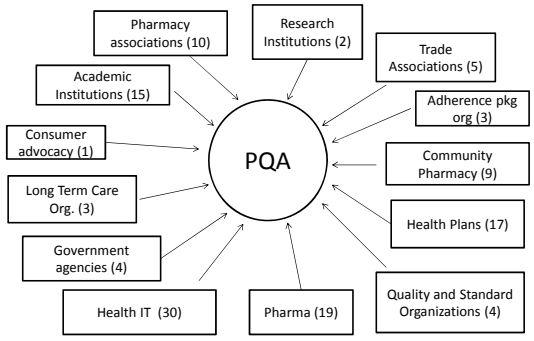
Pharmacy Quality Alliance



Other Quality Alliances

- Hospital Quality Alliance
  - Hospital Compare Program
  - http://www.qualitynet.org
  - http://www.medicare.gov/hospitalcompare
- Ambulatory Quality Alliance
  - Physician Quality Reporting System
  - http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html?redirect=/pqrs/
- Long Term Quality Alliance

Diverse Membership



PQA's Mission Statement

Improve the quality of medication management and use across health care settings with the goal of improving patients' health through a collaborative process to develop and implement performance measures and recognize examples of exceptional pharmacy quality.

PQA

Development of Measures

Workgroups identify measure concepts

Quality Metrics Expert Panel (QMEP) reviews/refines concepts

Specifications are drafted for high-priority measure concepts

QMEP reviews draft technical specifications and testing plan

PQA

Development of Measures

Health plan/PBM or other testing of draft technical specs

QMEP review of testing results; recommendation on endorsement

Membership vote on endorsement

Endorsed measures are reviewed and updated as necessary

PQA

CMS

Star Rating

Star Measures

Star PQA Measures: 2013 Average Rates

Part D Plan Rating	MA-PD	PDP
PDC – Diabetes	73.7 %	75.8 %
PDC - Hypertension	73.9 %	76.8 %
PDC – Cholesterol	69.0 %	71.0 %
Diabetes – RASA Use	84.3 %	82.3 %
High-Risk Medications	7.8 %	8.8 %

PDC = Proportion of Days Covered: the rate indicates the percent of persons on the target drugs who are highly adherent to the drug regimen.

Star PQA Measure Performance

Measure	2012		2013	
	MA-PD Average Star	PDP Average Star	MA-PD Average Star	PDP Average Star
High Risk Medication	2.7	3.1	3.1	3.1
Diabetes Treatment	2.9	2.9	3.0	2.8
Medication Adherence for Oral Diabetes Medications	3.1	3.1	3.1	3.3
Medication Adherence for Hypertension (ACEI or ARB)	3.1	3.0	3.0	3.2
Medication Adherence for Cholesterol (Statins)	3.0	3.2	3.1	3.2

http://regional.nacds.org/presentations/Using_Star_Ratings.pdf

Importance of Ratings?

Stars Rating	QBP Percentage for 2012/2013	QBP Percentage for 2014
Less than 3 stars	0%	0%
3 stars	3%	3%
3.5 stars	3.5%	3.5%
4 stars	4%	5%
4.5 stars	4%	5%
5 stars	5%	5%

•QBP is a percentage increase in payment to the plan above the standard rate. For plans with less than 5 stars, the standard rate may be capped at pre-ACA rates. For more details, https://www.cms.gov/MedicareAdvtgSpecRateStats/

http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Announcement2012final.pdf

Example of PQA Work 2013

- Measures developed to move forward in process
  1. Persons in a PCMH or other integrated care team model receiving a timely comprehensive medication review
  2. Drug therapy problem resolution in a MTM part D program
  3. Rate of drug therapy problem recommendations per MTMP enrollee (MTM Part D focus)
  4. Therapy initiation post MTM – treatment of hypertension for patients with diabetes (MTM Part D focus)
  5. Use of sedative hypnotic medications in the elderly
  6. Serious hypoglycemic events requiring hospital admission or ED visit associated with anti-diabetic medications
  7. Adherence to antihypertensive agents –RAS antagonists and therapeutic alternatives
- Measure submitted to the National Quality Forum (NQF)
  - Antipsychotic use in children under 5 years old.
  - 3 year review of adherence measures

2014 PQA Work

Task Forces and Panels
- Quality Metrics Expert Panel (QMEP)
- Measure Update Panel
- Measures for ACOs/Advanced Payment Models Task Force
- Specialty Pharmacy Measures Task Force

2014 PQA Work

Workgroups
- Adherence
  - Medication synchronization measure
- Long-term Care
  - Measures related to recommendation by the consultant RPH
- Medication Management for integrated care teams
  - Hypertension measure set
- Medication Use Safety
  - Severe hypoglycemic events, opioid utilization
- Mental Health
  - Use of multiple antipsychotic medications
- MTM Part D
  - CMS CMR action plan, SNOWMED codes

Example of a Measure concept

Adherence to Non-Warfarin Oral Anticoagulants

Description

The percentage of patients 18 years and older who met the Proportion of Days Covered (PDC) threshold of 80 percent during the measurement period for: Non-warfarin oral anticoagulants

Definitions

Non-warfarin anticoagulant medications: Dabigatran, rivaroxaban, apixaban*

*not to be included unless approved by FDA

Rationale

Adherence to all anticoagulants is important to ensure optimal patient outcomes. Warfarin was not included in this adherence measure due to frequent dosing adjustments to therapy, which makes an accurate calculation of adherence based on prescription claims improbable. Adherence to non-warfarin oral anticoagulants may be more critical to monitor, since there isn't a surrogate lab value such as INR.

Eligible Population

Ages: 18 years and older

Measure continued

Administrative Specification

Data Source: Prescription Claims Data

Denominator: Patients who filled at least two prescriptions for a non-warfarin oral anticoagulant (see medications under Definitions section) on two unique dates of service at least 6 months apart during the measurement period **AND** who received greater than 60 days supply of these medications during the measurement period.

Numerator:
The number of patients who met the PDC threshold during the measurement period

Exclusions:

Patients with one or more fills for warfarin, low molecular weight heparin (LMWH) or heparin during the measurement period

References

ASHP Pharmacy-Sensitive Accountability Measures Workgroup

Institutional	Ambulatory
• VTE: prophylaxis, therapy and education • Glycemic control: hypoglycemia • Ab utilization: surgery and CAP • Pain Management: Naloxone reversal, high risk opiods	• ATTR, management, • Glycemic control: HgA1c process and outcome • Ab utilization: Ab for bronchitis • Pain Management: high dose APAP, PRN long-acting opiods

DRAFT

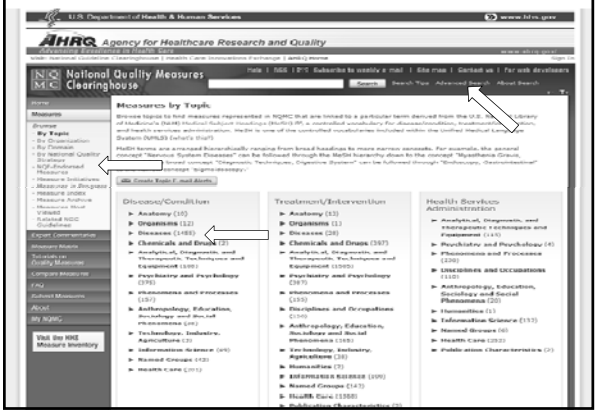
Health Care is A Team Sport

National Quality Strategy

Priority	Measure Focus	Measure Name/Description	Baseline Rate	Most Recent Rate	Aspirational Target
		ary needs			
4. Promoting the most effective prevention and treatment practices for the leading causes of mortality, starting with cardiovascular disease	Aspirin Use	Outpatient visits at which adults with cardiovascular disease are prescribed/maintained on aspirin	47%	51%	Increase to 65% by 2017
	Blood Pressure Control	Adults with hypertension who have adequately controlled blood pressure	46%	53%	Increase to 65% by 2017
	Cholesterol Management	Adults with high cholesterol who have adequate control	33%	32%	Increase to 65% by 2017
	Smoking Cessation	Outpatient visits at which current tobacco users received tobacco cessation counseling or cessation medications	28%	22%	Increase to 65% by 2017
5. Working with communities to promote best practices for healthy living	Depression	Percentage of adults who reported symptoms of a major depressive episode in the last 12 months who received treatment for depression in the last 12 months	68.2%	68.1% for 2011	Increase to 78.2% by 2020
	Obesity	Proportion of adults who are obese	35.7%	Update available in 2014	Reduce to 30.5% by 2020

2013 Annual Progress Report to Congress: National Strategy for Quality Improvement in Health Care http://www.ahrq.gov/workingforquality/nqs/nqs2013annlrpt.htm

http://www.qualitymeasures.ahrq.gov/browse/by-topic.aspx

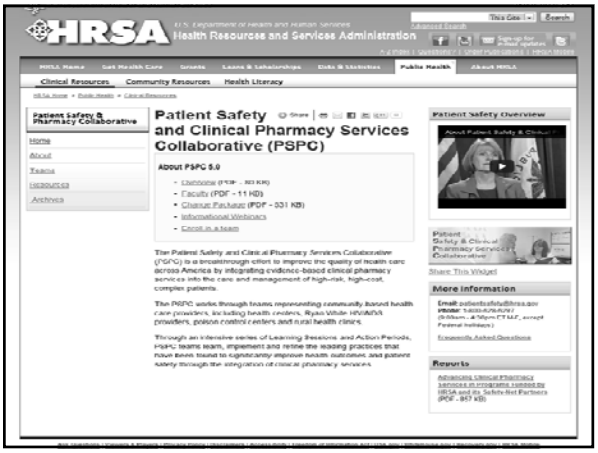


http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html

PQRS example measures

NQF #	PQRS #	National Quality Strategy Domain	Measure Description*	Measure Developer	Reporting Options
0059	1 GPRO DM-7	Clinical Process/ Effectiveness	Diabetes Mellitus: Hemoglobin A1c Poor Control: Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent hemoglobin A1c greater than 9.0%	NCQA	Claims, Registry, EHR, GPRO/ACO, DM Measures Group (DR)
0064	2	Clinical Process/ Effectiveness	Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control: Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent LDL-C level in control (less than 100 mg/dL)	NCQA	Claims, Registry, EHR, DM Measures Group (DR), Cardiovascular Prevention Measures Group (DR)
0061	3	Clinical Process/ Effectiveness	Diabetes Mellitus: High Blood Pressure Control: Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent blood pressure in control (less than 140/90 mmHg)	NCQA	Claims, Registry, EHR, DM Measures Group (DR)
0081	6	Clinical Process/ Effectiveness	Heart Failure: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD): Percentage of patients aged 18 years and older with a diagnosis of heart failure (if) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy either within a 12 month period when seen in the outpatient setting OR at each hospital discharge	AMA-PCPI/NCQA	Registry, EHR, HF Measures Group (R)

http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/MeasuresCodes.html



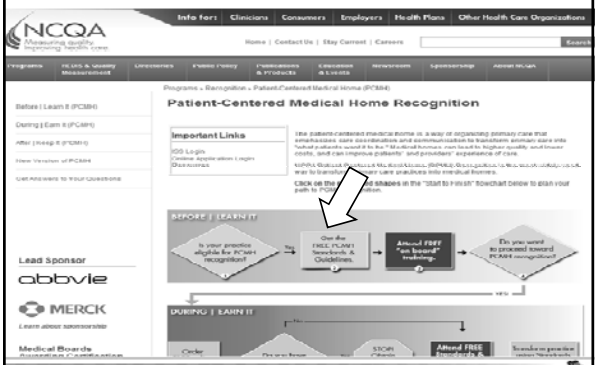
PCPS Sample Results

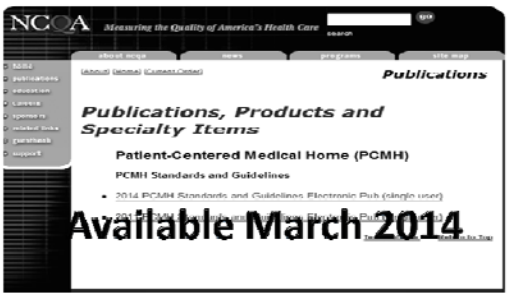
	Measures for Signaling Improvement		
	Health Status Condition	Marker For Improvement	Time To See Improvement
Health Outcome Signal	Anticoagulation	INR in Range	1-2 wk
	Diabetes	A1c < 7%; A1c < 8%	3 mo.
	Dyslipidemia	LDL at goal	3 mo.
	Hypertension	BP < 140/90 mm Hg DM, BP <130/80 mm Hg	3 mo.
	Depression	Status (accepted scale)	6 mo.
Clinical Process Signal	Asthma	On Controller Therapy	1-2 wks
	HIV/AIDs	On HAART	1-2 wks

http://pspcnationalperformancereport.files.wordpress.com/2012/03/pspc-national-performance-report-2011.pdf

NCQA PCMH Recognition

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



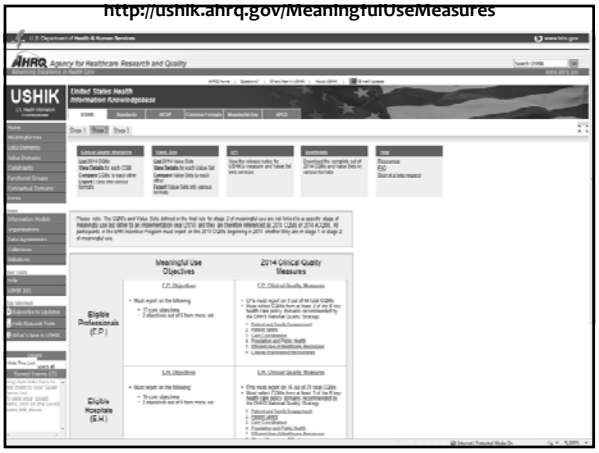


NCQA 2011 Measures

Domain	Element
Enhance Access and Continuity	• Access during office hours • Continuity
Identify and Manage Populations	• Use data for population management
Plan and Manage Care Management	• Care management • Identify high risk patients , Medication management
Provide Self-Care Support and Community Resources	• Support self care process
Track and Coordinate Care	• Referral tracking and follow up • Coordinate with facilities and care transitions
Measure and Improve performance	• Implement continuous quality improvement • Demonstrate continuous quality improvement • Measure patient/family experience • Measure performance

http://www.lafp.org/connect2014/images/content/NCQA/NCQA_Standards/2_NCQA_PCMH_2011_Standards_11.21.2011.pdf

http://ushik.ahrq.gov/MeaningfulUseMeasures



Meaningful Use Measures: CQMs for EPs

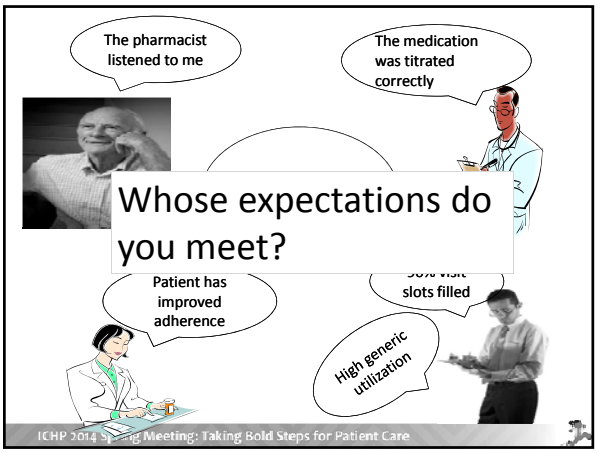
CMS eMeasure ID	NQF #	Measure Title	Measure Description	Numerator Statement	Denominator Statement	Measure Steward	Domain
CMS135v1	0081	Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD)	Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy either within a 12 month period when seen in the outpatient setting OR at each hospital discharge	Patients who were prescribed ACE inhibitor or ARB therapy either within a 12 month period when seen in the outpatient setting or at hospital discharge	All patients aged 18 years and older with a diagnosis of heart failure with a current or prior LVEF < 40%	American Medical Association-convened Physician Consortium for Performance Improvement ® (AMA-PCPI)	Clinical Process/ Effectiveness
CMS144v1	0083	Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)	Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12 month period when seen in the outpatient setting OR at each hospital discharge	Patients who were prescribed beta-blocker therapy either within a 12 month period when seen in the outpatient setting or at hospital discharge	All patients aged 18 years and older with a diagnosis of heart failure with a current or prior LVEF < 40%	American Medical Association-convened Physician Consortium for Performance Improvement ® (AMA-PCPI)	Clinical Process/ Effectiveness

http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/ClinicalQualityMeasures.html

Medicare Shared Savings Program
ACO – 33 Quality Measures

- Patient Satisfaction - 7 measures CAHPS
  - Education
- Care Coordination and Patient Safety - 6 measures
  - Hospital readmissions for COPD, HF and all conditions
  - Med reconciliation
- Preventive Health – 8 measures
  - Pneumococcal and Influenza vaccination
  - Obesity, Smoking
  - Depression, BP
- At Risk Populations – 12 measures
  - DM: HgA1c, LDL, BP, ASA, smoking
  - HTN: BP
  - Ischemic Vascular Dx: LDL, ASA or anti-thrombotic
  - HF: beta-blocker
  - CAD: LDL, ACE/ARB

http://www.scribd.com/doc/151412882/2013-ACO-Quality-Measures



ICHP 2014 Spring Meeting: Taking Bold Steps for Patient Care

Not easy!

"Measure tsunami"	Lack of alignment or harmonization	Poor IT utilization
Scientific merit or the strength of accuracy, reliability and validity	Different focus between clinicians, payers, patients	Lack of consensus –core measure sets?
Inconsistent data sources and specifications	Data transfer issues of privacy and ability to merge	

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Measure Commandments

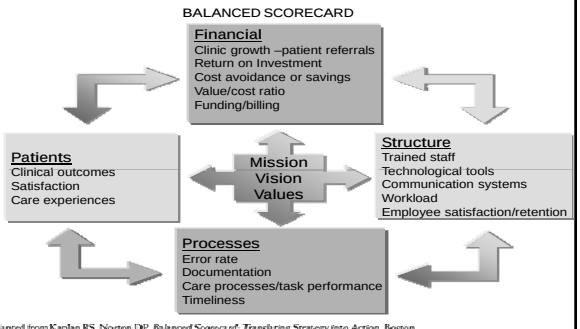
Measures must be meaningful

Measures must be feasible

Measures must be actionable

ICHP 2014 Spring Meeting: Taking Bold Steps for Patient Care

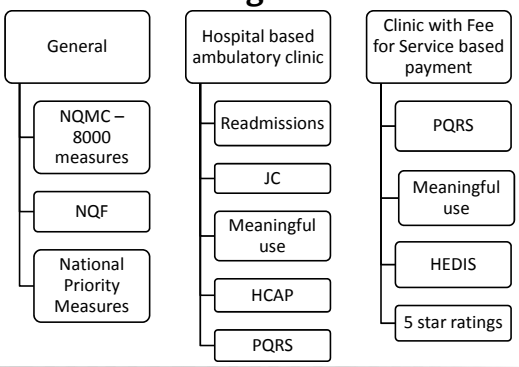
Choosing Measures: balanced scorecard



Adapted from Kaplan RS, Norton DP. *Balanced Scorecard: Translating Strategy into Action*. Boston, MA: Harvard Business School Press, 1996.

ICHP 2014 Spring Meeting: Taking Bold Steps for Patient Care

Selecting Measures



ICHP 2014 Spring Meeting: Taking Bold Steps for Patient Care

Selecting Measures

- Integrated models – PCMH/ACO
  - NCQA
  - ACO
  - Star ratings
  - H-Cap
- Managed Care
  - HEDIS
  - NCQA
  - PQA
  - Star ratings
  - URAC
- Community Pharmacy
  - CPPA
  - PQA
  - Star ratings
- Novice
  - PSPC
  - National strategy

Utilize Resources

AHRQ, IOM	• Guidance reports
QIOs	• Direct assistance and support
IHI	• Guidance reports and training
PCPCC	• Guidance reports
Pharmacy Associations	• Guidance reports and training

Tips for Successful Measure Collection

Availability of data

- Does it fit well into your process
- Will it disrupt care
- Use a % of the population
- Electronic versus manual if possible
- Use the least amount of resources and time

Accuracy of data

- Confidence in accuracy

Tips for Successful Measure Collection

Affordability

- Can you afford to collect this data

Actionable

- Can you interpret what you collect?
- Can you control or influence change based on what you collect?
- Do norms and benchmarks exist?

Integration Process

Lean

- Start with patient outcomes as a goal
- Focuses on processes to eliminate waste , non-value added activities
- Develop best sequence of services for efficiency and quality
- Structure and process measurement are the core

Six-sigma

- focused on reducing variation and defects within processes
- Series of steps
  - Identify and define what needs to be improved
  - Measure by collecting data
  - Analyze the results
  - Create solutions to improve
  - Control the process with policies, guidelines and strategies

PDSA Cycle

Patient Centered Quality

Patient data
- How well the provider listened and asked the right questions

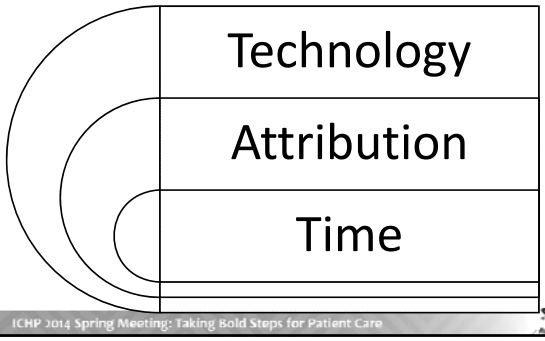
Patient as an Individual
- Patient culture, beliefs, circumstances and preferences considered

Patient as a person
- Open respectful, trusting relationship
- Informed decision making

Patient as a partner
- Plan understood and accepted by patient
- Patient motivated to execute
- Goals are understood and mutual
- Follow up plan understood

Kleinman LC, Dougherty D. Assessing Quality Improvement in Health Care: Theory for Practice. Pediatrics 2013;131;S110DOI:10.1542/peds.2012-1427n

Integration Challenges



The quality of your work, in the long run, is the deciding factor on how much your services are valued by the world.

Orison Swett Marden

(1850 - 1924) was an American inspirational author who wrote on success in life and how to achieve it

Active Learning (10 minutes)

- Using the balanced score card:
  - Structure
  - Process
  - Patient Outcomes
  - Financial Outcomes
- Using measurement commandments
  - Meaningful
  - Feasible
  - Actionable
- Using your specific setting
- Find the an optimal measure from the sources provided.