Expanding into Ambulatory Services: What a Hospital Pharmacist Needs to Know

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Speakers have no conflicts of interest to disclose

Learning Objectives for Pharmacists

• Distinguish which ambulatory pharmacist patient care services would yield the greatest organizational benefit & the optimal path for revenue generation for these services in order to develop a successful service proposal.
• Design a plan to integrate pharmacists into an ambulatory setting that is likely to be successful.
• Prepare for challenges, recognized successes based on knowledge learned from others’ experiences.

Learning Objectives for Technicians

• Describe a role for a pharmacy technician in managing the revenue from an ambulatory practice.
• Describe two roles a pharmacy technician may play in the workflow of an ambulatory clinic to support the work of the pharmacist.
• List three barriers to utilizing pharmacy technicians in an ambulatory program.
Perfecting Your Dive into Ambulatory Practice

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Chicago College of Pharmacy
Midwestern University

APC (Ambulatory Payment Classifications) Codes are used in which setting?
1. Hospitals or health-systems for “facility fee” services in their ambulatory clinics
2. Physician offices for diabetes education services
3. Assisted living and group homes for clinical provider services
4. For in-home services provided by Medicare Part B providers

Which one of the following statements is NOT a CMS criteria for billing incident to physician in a hospital-based outpatient clinic?
1. Must have an order/referral
2. Must have an eligible provider supervising in the suite
3. Must be an established patient of the supervising provider(s)
4. Must be considered a recognized provider
Why make the dive?

New Models of Care

Hospital Pressures

- High cost of hospitalizations (Kaiser Report of 2015 data average cost/day)

<table>
<thead>
<tr>
<th>Location</th>
<th>State/Government</th>
<th>Non-Profit</th>
<th>For-Profit</th>
</tr>
</thead>
<tbody>
<tr>
<td>National</td>
<td>$2,013</td>
<td>$2,413</td>
<td>$1,831</td>
</tr>
<tr>
<td>Illinois</td>
<td>$2,956</td>
<td>$2,422</td>
<td>$1,546</td>
</tr>
<tr>
<td>Missouri</td>
<td>$1,599</td>
<td>$2,353</td>
<td>$1,896</td>
</tr>
</tbody>
</table>

- Patient centeredness
The Readmission Penalty

Table 1. The first five years of the Hospital Readmission Reduction Program

<table>
<thead>
<tr>
<th>Year penalties applied</th>
<th>FY 2013</th>
<th>FY 2014</th>
<th>FY 2015</th>
<th>FY 2016</th>
<th>FY 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Performance measurement</td>
<td>June 2009</td>
<td>June 2010</td>
<td>June 2011</td>
<td>June 2012</td>
<td>June 2013</td>
</tr>
<tr>
<td>Diagnoses of initial hospitalization</td>
<td>Heart attack</td>
<td>Heart failure</td>
<td>Heart attack</td>
<td>Heart failure</td>
<td>Heart attack</td>
</tr>
<tr>
<td>Penalty percentage reduction in base payments on all Medicare patient admissions</td>
<td>1%</td>
<td>2%</td>
<td>3%</td>
<td>4%</td>
<td>5%</td>
</tr>
<tr>
<td>Maximum rate of penalty</td>
<td>6%</td>
<td>6%</td>
<td>7%</td>
<td>7%</td>
<td>7%</td>
</tr>
<tr>
<td>Average hospital inpatient adjustment (missing obtration)</td>
<td>0.37%</td>
<td>0.25%</td>
<td>0.49%</td>
<td>0.49%</td>
<td>0.58%</td>
</tr>
<tr>
<td>Average hospital penalty (spending per adjusted hospital stay)</td>
<td>0.42%</td>
<td>0.38%</td>
<td>0.53%</td>
<td>0.61%</td>
<td>0.74%</td>
</tr>
<tr>
<td>Percent of hospitals penalized</td>
<td>54%</td>
<td>60%</td>
<td>78%</td>
<td>78%</td>
<td>78%</td>
</tr>
<tr>
<td>Percent of hospitals at max penalty</td>
<td>8%</td>
<td>6%</td>
<td>1.2%</td>
<td>1.1%</td>
<td>1.1%</td>
</tr>
<tr>
<td>CMS estimate of total penalties</td>
<td>$300 million</td>
<td>$277 million</td>
<td>$308 million</td>
<td>$343 million</td>
<td>$338 million</td>
</tr>
</tbody>
</table>

http://files.kff.org/attachment/Issue-Brief-Fewer-Hospital-U-turns-The-Medicare-Hospital-Readmission-Reduction-Program

Care of Patients and Provider Workflow are Different!

Hospital
- Care for acute issues
- Controlled environment
- Team based?
- Global payment
- Provider “in-charge”
- 24 hour workflow

Ambulatory
- Care for chronic issues
- Uncontrolled and variable environment
- Team based?
- FFS $ global payment
- Patient in charge
- 15-30 minute workflow

Apples and Oranges
Patient Care Services Hospital

- Rounds
- Orders made
- Orders implemented
- Respond to acute changes
- Follow up

Patient Care Services Ambulatory

- Patient check in
- 15-30 minute visit
- Plan created
- Documentation
- Follow up

Health Care Team: Complex Adaptive System

- Diverse individuals who learn together defined by interdependent connections that vary in intensity and may be inconsistent

Mindfulness

- How members think
- How members work
- How members respond

Meaningful interactions

- Information exchange
  - problem-solving & dissolving
- Eliminate variation in training and status
- Learning & action occur together without hierarchy or excessive time

Strategies for Optimal Ambulatory Workflow

- Collect required patient information once.
- Minimize how often a patient is moved.
- Use evidence-based practices to reduce any disagreements in patient management.
- Eliminate unneeded or excessive activities.
- Eliminate any duplicative communication.
- Provided concise, consistent and clear information to the patient
**Evidence Based Workflow Design**

- Team practicing at highest skill level
- Pre-visit planning
- Pre-visit laboratory testing
- Sharing or splitting the documentation
- Specific patient care delegated to team members
- Flexible scheduling for ebbs & flows of patient demand

**Improved communication**

- Internally amongst providers
- Between patients and clinic providers & staff
- Between external providers and clinic

Quality improvement projects around clinician concerns

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**Understanding Payment in the Ambulatory Space**

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**Payment Models**

- Category 1: Fee for Service – No Link to Quality & Value
- Category 2: Fee for Service – Link to Quality & Value
- Category 3: At Risk Built on Fee for Service Architecture
- Category 4: Population-Based Payment

https://hcp-lan.org/ - Health Care Payment Learning and Action Network
Payers and Payer Mix

Focus on Medicare

Sets the industry standard

Is the largest single payer

Benefits created through legislation
Social Security Act in 1965         MACRA 2015

CMS is the benefit administrator

CMS: Center for Medicare and Medicaid Services

Payment

Hospital

Medicare Part A
• Universal benefit
• Covers
• Hospitals, Health Systems
• Long term care
• Hospice and Home Health

Medicare Part B
• Must Opt out
• Must have contributed to Social Security
• Covers outpatient services

Medicare Part C
• May opt in
• Medicare Advantage
• Administered by commercial payers

Medicare Part D
• May opt in
• Administered by commercial payers (PDPs)

Commercial Payers

PDPs
Medicare Part A
• IPPS (Inpatient Prospective Payment System)
• MS-DRGs (Medical Severity Diagnosis Related Groups)
• Revenue Codes

Medicare Part B
• PPS (Physician fee schedule)
• MACRA Quality Payment Program
• HOPPS (Hospital Outpatient Prospective Payment System)
• Eligible providers

Medicare Part C
• all Part A and Part B services, may provide Part D
• Rules on relationships with providers
• CMS Call Letter
• Payment fixed per-member-per month

Medicare Part D
• CMS Call Letter
• CY 2017 Medication Therapy Management Program Guidance Memo
• Payment a direct subsidy payment per enrollee

Where do Pharmacists Fit?

Auxiliary Personnel

Pharmacist scope of practice

State

Insurance Regulations

Medical scope of practice

Understanding the Language of Healthcare Billing
Basic structure of health care services payment

Language of Medicare Reimbursement

Medicare Coding System
- HCPCS (Healthcare Common Procedure Coding System)
  - Level 1 – CPT (Current Procedural Terminology codes)
    - 5 numeric digits ex. 99605
  - Level 2 – Codes for product supplies and services not covered under CPT (ambulance and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) when used outside a physician’s office)
    - Single alphabetical letter followed by 4 numeric digits

CPT: Current Procedural Terminology codes

Nomenclature to report medical services & procedures for payment
Maintained and owned by the AMA

Category 1 (3 categories)
- Evaluation and management (E&M): 99201–99499
  - Anesthesia: 00100–01999; 99100–99150
  - Surgery: 10000–69990
  - Radiology: 70000–79999
  - Pathology and laboratory: 80000–89398
  - Medicine: 90081–99099; 99151–99199; 99500–99607
    - Example 99505–99567 medication therapy management services
Level 2 HCPC codes

A-codes: Transportation, Medical Supplies, Misc. & Experimental
B-codes: Enteral & Parenteral tx
C-codes: Temporary Hospital Outpatient Prospective Payment System
D-codes: Dental Procedures
E-codes: Durable Medical Equip. (DME)
G-codes: Temporary Procedures & Professional Services
H-codes: Rehabilitation Services
J-codes: Drugs Administered Other Than Oral Method, Chemotherapy Drugs
K-codes: Temporary Codes for DME Regional Carriers
L-codes: Orthotic/Prosthetic Procedures
M-codes: Medical Services
P-codes: Pathology and Laboratory Codes
Q-codes: Temporary
R-codes: Diagnostic Radiology Services
S-codes: Private Payer Codes
T-codes: State Medicaid Codes

ICD-10 Codes: International Classification of Diseases, 10th Revision

- For classifying diagnoses and reason for visits in all health care settings.
- Codes may be 3, 4, 5, 6 or 7 alpha/numeric characters
- Code or codes from A00.0 through T88.9, Z00-Z99.8
- 69,000 codes

NPI number: National Provider Identifier

- A unique 10-digit identification number issued to health care providers

Resource-based Relative Value Scale (RBRVS)

A system for describing, quantifying, and reimbursing physician services relative to one another.

- Physician work (time, technical skill & effort, judgment & stress)
- Practice expense (rent, wages)
- Professional liability insurance

Relative value unit (RVU) is assigned to each billing code

RVU's are determined by AMA Committee from physician survey

Based on conversion factor that estimates the sustainable growth rate (SGR) and Geographic Practice Cost Index

Repealed by MACRA but still used by Commercial Payers
Why are RVUs important

Work RVU x GPCI + Practice expense RVU x GPCI + Prof liability RVU x GPCI = Total RVU.

Total RVU x conversion factor = $ for a CPT code.

RVU: Relative Value Unit
GPCIs: Geographic Practice Cost Indices

Basic structure of health care services payment

What you did, HCPCS code

Why you did it, ICD-10

Who did it, NPI number

Coding for billing

Billing Forms

PFS
- 837P
- CMS-1500

HOPPS
- 837I
- CMS-1450
Billing Codes

Payable to the Institution

- Facility Fee APC code

Payable to the Institution or the Eligible Provider

- Transition Care Management Codes (TCM) – Medicare only
- Chronic Care Management Codes (CCM) – Medicare only
- Complex Chronic Care Management Codes – Medicare only

Payable to the Eligible Provider

- E/M established patient codes
- Annual Wellness Visits – Medicare only

Payable to Pharmacists

- MTM codes
- Diabetes self-management training (DSMT)

APC (Ambulatory Payment Classifications) Codes for HOPPS

Pays for most clinic and emergency department visits

Outpatient payment groups based on HCPCS codes

- Similar clinical services
- Similar resource consumption

APC for Outpatient E/M service

- Describe use of space and supplies
- Describe involvement of hospital employees
- Example: APC code 5012 (was 0634) with HCPCS code G0463

<table>
<thead>
<tr>
<th>Billing Options</th>
<th>CPT billing codes</th>
<th>Practice Setting</th>
<th>2017 Medicare Payment Chicago, IL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes self-management training (DSMT)</td>
<td>00108 (individual visit) 00109 (group visit)</td>
<td>PB</td>
<td>G0108 - $67.05 (HP) G0109 - $55.36 (HP)</td>
</tr>
<tr>
<td>CLIA-Waived Lab</td>
<td>variable per POC test</td>
<td>all</td>
<td>Hand per CPT code</td>
</tr>
<tr>
<td>Medication Therapy Management (MTM)</td>
<td>99605, 99660, 99607</td>
<td>pharmacy, employer, health plan, PB</td>
<td>variable per payer</td>
</tr>
<tr>
<td>Incident to physician Office visit in a physician-based (non-hospital) clinic</td>
<td>99211-99215 (PB)</td>
<td>PB</td>
<td>99211 = $21.37 99212 = $46.66 99213 = $78.11 99214 = $114.72 99215 = $154.92</td>
</tr>
<tr>
<td>Incident to physician Office visit in a hospital-based (hospital outpatient clinic visit)</td>
<td>APC code 5012 (was 0634) with HCPCS code G0463</td>
<td>HP</td>
<td>G0108 - $55.36 (HP)</td>
</tr>
<tr>
<td>Incident to physician Transitional Care Management (TCM) &amp; RPh part of team</td>
<td>99496 (within 7d D/C) 99495 (within 14d D/C) APC 5012</td>
<td>HP, PB</td>
<td>99496 = $171.81 (HP) 99495 = $82.41 (HP)</td>
</tr>
<tr>
<td>CMS Annual Wellness Visit (AWV)</td>
<td>99405 (initial, annual) 99406 (annual) 99407 (60 mins/month) 99408 (90 mins/month) 99409 (90 mins additional service to 99407)</td>
<td>PB, HP, FQ</td>
<td>99405 = $102.36 (HP) 99406 = $216.02 (HP)</td>
</tr>
<tr>
<td>Chronic Care Management (CCM)</td>
<td>99490 (20 minutes/month) 99497 (60 mins/month) 99489 (with additional service to 99491)</td>
<td>PB, HP, FQ</td>
<td>99490 = $44.61 (HP) 99491 = $15.61 (HP) 99489 = $28.00 (HP)</td>
</tr>
<tr>
<td>Complex Care Management</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Incident to Services Requirements

<table>
<thead>
<tr>
<th>Physician Office Services</th>
<th>Hospital Outpatient Services</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CPT E/M Codes</strong></td>
<td><strong>APC 5012</strong></td>
</tr>
<tr>
<td>Direct supervision by an eligible practitioner within the suite or office space &amp; immediately available for assistance</td>
<td>Direct supervision by an eligible practitioner who is present on the campus where the services are provided or present within the off-campus department if setting is off-campus, and immediately available for assistance.</td>
</tr>
<tr>
<td>Patient is established patient with the eligible provider. A prior face-to-face visit &amp; established plan of care.</td>
<td>Same</td>
</tr>
<tr>
<td>Service is integral though incidental part of the eligible provider’s services</td>
<td>Same</td>
</tr>
<tr>
<td>The services are commonly part of the provider’s bill</td>
<td>Same</td>
</tr>
<tr>
<td>The services are commonly furnished and appropriate to be provided in a physician’s offices or clinic.</td>
<td>Same</td>
</tr>
</tbody>
</table>

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### Incident to Services Requirements

<table>
<thead>
<tr>
<th>Physician Office Services</th>
<th>Hospital Outpatient Services</th>
</tr>
</thead>
<tbody>
<tr>
<td>The service must be medically necessary, authorized &amp; documented.</td>
<td>Same</td>
</tr>
<tr>
<td>The authorized provider must provide subsequent services at a frequency that reflects active participation in managing the patient and plan of care.</td>
<td>Same</td>
</tr>
<tr>
<td>A financial relationship must exist between the auxiliary personnel and the eligible provider</td>
<td>An employee relationship must exist with the hospital as an employee, leased employee, or independent contractor</td>
</tr>
<tr>
<td>Services provided are within the scope of practice for the auxiliary personnel as dictated by the State practice act</td>
<td>Same</td>
</tr>
</tbody>
</table>

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**Medicare Learning Network**

CMS General Rules

“Medically necessary” as “services or supplies that are proper and needed for the diagnosis or treatment of a medical condition and are provided for the diagnosis, direct care, and treatment of the medical condition, meet the standards of good medical practice in the local area, and are not mainly for the convenience of the patient or the provider.”

“Usual /Customary/Reasonable” is the amount paid for a medical service in a geographic area based on what providers in the area usually charge for the same or similar medical service.

Any enrolled provider accepting Medicare and Medicaid may not discriminate against Medicare/Medicaid patients, including providing a different service level between Medicare and commercial patients using the same billing code.

It is all changing!

Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)

• Repeals the Sustainable Growth Rate (SGR) Formula
• Changes the way that Medicare rewards clinicians for value over volume
• Streamlines multiple quality programs under the new Merit Based Incentive Payments System (MIPS)
• Provides bonus payments for participation in eligible Alternative Payment Models (APMs)

MIPS Value Based Payment

Performance Categories
Quality, Cost, Improvement Activities, Advancing Care Information

Performance year submit feedback available adjustment
2017 March 31, 2018 Feedback January 1, 2019

Quality Payment Program https://qpp.cms.gov/resources/education
MIPS Value Based Payment

Transition Year Weights

<table>
<thead>
<tr>
<th>Component</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality</td>
<td>60%</td>
</tr>
<tr>
<td>Cost</td>
<td>0%</td>
</tr>
<tr>
<td>Improvements</td>
<td>15%</td>
</tr>
<tr>
<td>Advancing Care</td>
<td>25%</td>
</tr>
</tbody>
</table>

Pick your path in MIPS: If you choose the MIPS track of the Quality Payment Program, you have three options.

- Don’t Participate
- Submit something
- Submit a Partial Year
- Submit a Full Year

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Quality Component

Most participants: Report up to 6 quality measures, including an outcome measure, for a minimum of 90 days.

Groups using the web interface: Report 15 quality measures for a full year.

Groups in APMs qualifying for special scoring under MIPS, such as Shared Savings Track 1 or the Oncology Care Model: Report quality measures through your APM. You do not need to do anything additional for MIPS quality.

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Quality Measures

- 168 Measures

Select Measures

Search All by keyword: SEARCH

Filter by:
- High Priority Measure
- Data Submission Method
- Specialty Measure Set

Example of measures:

- Use of high-risk medications in the elderly
- Medication management for people with asthma
- Documentation of current medications in medical record
- Adherence to antipsychotic medications

ICHIP/MSHP 2017 SPRING MEETING
Improvement Component

- Most participants: Attest that you completed up to 4 improvement activities for a minimum of 90 days.
- Groups with fewer than 15 participants or if you are in a rural or health professional shortage area: Attest that you completed up to 2 activities for a minimum of 90 days.
- Participants in certified patient-centered medical homes, comparable specialty practices, or an APM designated as a Medical Home Model: You will automatically earn full credit.
- APMs not in advanced AMP automatically earn credit.

Examples of Improvement Activities

Population Management
- Participation in CMMI models such as the Million Hearts
- Participation in research that identifies interventions, tools or processes that can improve care of a targeted patient population.
- Manage medications to maximize efficiency, effectiveness and safety by:
  - Reconcile and coordinate medications and provide medication management
  - Integrate a pharmacist into the care team
  - Conduct periodic, structured medication reviews

Coordination of Care
- Implementation of practices/processes to develop regularly updated individual care plans for at-risk patients

Behavioral and Mental Health
- Depression screening and follow-up plan
- Tobacco use

Advancing Care Information Component

- Fulfill the required measures for a minimum of 90 days:
  - Security Risk Analysis
  - e-Prescribing
  - Provide Patient Access
  - Send Summary of Care
  - Request/Accept Summary of Care
- Choose to submit up to 9 measures for a minimum of 90 days for additional credit.
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References for work-flow and Teamwork Improvement

Ambulatory Care:
Becoming a Top Diver on the Team

Brooke L. Griffin, PharmD, BCACP
Professor of Pharmacy Practice
Vice Chair of Clinical Services
Midwestern University
Chicago College of Pharmacy
3.31.17

Selection of Midwestern University's Ambulatory Care Models

- Health-system/Outpatient Clinics
  - DuPage Medical Group - MTM
  - Advocate Medical Group – Anticoag, DM, HF, Lipids, Wellness
  - Dreyer Medical Group – DM, Lipids
- Hospital-affiliated
  - Swedish Covenant – Discharge counseling/Med Rec
  - Mercy Hospital – Anticoag, SC, Osteo
  - Norwegian Hospital – DM
  - Mt Sinai – Med rec, DM management, Immunizations
- VA-affiliated
  - NCVA – Pulmonary, WH
- MWU Clinic - Dental

Mercy Hospital and Clinics

- First outpatient clinical pharmacist
- Services:
  - Anticoagulation
  - Smoking Cessation
  - Osteoporosis
  - Outpatient “Rounds”
  - Maternal and Child Health
- Grew to three pharmacists
- Hired their own FTE
Dupage Medical Group
BreakThrough Care Center

- Partnership between a private physician owned medical group (DuPage Medical Group) and a payer (Humana)

- Goals of the BCC Model
  - Provide patient-centered care for high-risk Medicare patients in one facility
  - Improve medical outcomes
  - Improve accessibility to necessary services
  - Lower health care costs

### BCC Team Members and Roles

<table>
<thead>
<tr>
<th>Team Member</th>
<th>Roles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician</td>
<td>PCP for BCC patients, on call after hours</td>
</tr>
<tr>
<td>Nurse Practitioner</td>
<td>Works alongside MD, initial and follow-up visits, on call after hours</td>
</tr>
</tbody>
</table>
| Health Coaches (RN, LPN) | Primary contact between patient and team  
Assist in the care of patients with psychiatric conditions, help coordinate transportation, and overall access to care |
| Social Worker        | Awaits in the care of patients with psychiatric conditions, help coordinate transportation, and overall access to care |
| Pharmacist           | Medication Therapy Management (MTM)                                  |
| Dietitian            | Establish dietary goals, patient education                          |
| PT and Trainer       | Working with patients on exercise/mobility goals                     |

### The Pharmacist’s Role

**Medication Therapy Management (MTM)**

- Comprehensive medication review (CMR)
- Identify drug-related problems (DRPs)
- Work with patient to set goals
- Maintain patient’s medication list
- Assess adherence
- Address access issues
- Provide drug therapy recommendations
- Provide action plan for patient
- Patient follow-up between MD/NP visits
- Fill pill boxes, if needed
- Education
  - Staff, patients, caregivers
  - Patient seminars
  - Drug information
- Precepting
  - Students and residents

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ICHM/MSHP 2017 SPRING MEETING
A Typical Day…

MTM
Initiates med changes, then PharmD implements plan, provides education, monitors therapy

Social Worker
Assess barriers to adherence and access

Dietician
Dietary issues often identified by MTM; shared education

Health Coach
Obtains info from patient during wellness checks
MTM evaluates and provides plan

PT/Trainer
Follow up on exercise goals and monitor for ADRs (i.e. falls)

Lab
Point of care results available for efficient med monitoring

PT/Trainer
Follow up on exercise goals and monitor for ADRs (i.e. falls)
Communication ➔ Collaboration

• Improved utilization of team resources
  – Increased referrals among the group
  – Team huddle
  – Team visits
  – Curbside consults
  – TEAMWORK!

• Improved utilization of pharmacist
  – Referrals for medication access issues, chronic disease management, nonadherence, etc.
  – Drug information questions
  – Patient education

Next Steps

• Ok, you’ve convinced me – I’m ready to hire an Ambulatory Care Pharmacist...

• What should I look for in the candidates?

Pharmacists’ Role

“Clinical Connection”
between patients and providers!

• Advanced patient interviewing/counseling skills
• Drug therapy expertise
• Ability to monitor drug therapy outcomes
• Compassion for patient well-being
What are the components of standard Ambulatory Care Practice?

- Leadership
- Patient Care
- Medication Management

Seven Standards of Ambulatory Patient Care

1. Interviewing patients and caregivers
2. Assessing legal and clinical appropriateness of medications
3. Identifying, resolving, and preventing drug-related problems
4. Participating in pharmacotherapy decision making
5. Educating patients and caregivers on disease, medications, adherence and preventative health
6. Monitoring the medication effects and outcomes
7. Maintaining medication profiles and other documents

Medication Management
Example Job Description

- Medication Therapy Management (MTM)
  - Perform or obtain necessary assessments of the patient's health status
  - Formulate a medication treatment plan
  - Select, initiate, modify, or administer medication therapy
  - Monitor and evaluate the patient's response to therapy, including safety and effectiveness
  - Perform a comprehensive medication review to identify, resolve, and prevent drug-related problems, including adverse drug events

Adapted from Table 1-2 in Kliethermes 2012. Building a Successful Ambulatory Care Practice: A Complete Guide For Pharmacists
Other Imperative Skills

- Proactive Communication
- Listening Skills
- Innovative Spirit
- Creativity
- Maintain Enthusiasm
- Strong Work Ethic
- Adapt to Change

What services should the pharmacist provide?

Needs Analysis

**Needs Analysis**
1. What do patients need?
2. What do providers need?
3. Where are the gaps in care?

**Research**
- What similar programs already exist?
- What can you learn from their experience?
- Does this impact your strategy for implementation?

**Recruitment**
What types of patients should be a part of this new service? Referred or self-referral?
Examples of Pharmacist-Managed Ambulatory Care Clinics and Programs

Anticoagulation Clinic
Pain Management
Mental Health Clinic
MTM
Pharmaco therapy
Cardiovascular Clinic
HTN Clinic
HF Clinic
DM Clinic
Dyslipidemia Clinic
Hem/Onc
HIV/AIDS
Geriatrics
Women's Health

Thyroid Clinic
H. Pylori Clinic
Transplant Clinic
Neurology Clinic
Hep C Clinic
Smoking cessation
Weight Management
Fall prevention
Immunization
Emergency Preparedness
Substance Abuse
Discharge Clinic
Pediatrics

Barriers to Service Implementation

• Stakeholder Buy-In
• Work load issues
• Budgetary considerations
• Recruitment Issues
• Licensure and regulatory barriers
• Reimbursement and pricing issues
• Staff competency

Reimbursement

• It's possible!
• Depends on state laws and insurance policies
• Fee-for-service
• Incident-to billing
• Cost avoidance
• Improved care efficiency
• Grants
• Co-fund with academia
• Contact your compliance officer or billing specialist
Collaborative Drug Therapy Management Agreements (CDTM)

- Defined as an agreement between one or more physicians and pharmacists where pharmacists work within professional responsibility to: perform patient assessments, order drug-therapy lab tests, administer drugs, and select, initiate, monitor, continue and adjust medication regimens
- Language differs by state

Advanced Ambulatory Care Practice

Successes and Challenges

BreakThrough Care Center Outcomes:
5 months

<table>
<thead>
<tr>
<th>Measure</th>
<th>Before BCC</th>
<th>After BCC</th>
<th>Percent change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Pressure</td>
<td>128/73</td>
<td>124/70</td>
<td>‐3.13</td>
</tr>
<tr>
<td>Patients flagged through 3/31</td>
<td>127/73</td>
<td>123/70</td>
<td>‐3.15</td>
</tr>
<tr>
<td>Average A1c (out of control: Average A1c &gt;8%)</td>
<td>154.86</td>
<td>133.43</td>
<td>‐27.14</td>
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<td>133.43</td>
<td>‐27.14</td>
</tr>
</tbody>
</table>
Challenge: Patient Costs

- Billing and copay issues are still a challenge
  - Tried to use MTM codes
- Copays for clinic resources (PT, dietician, MD, etc.) can be a deterrent for utilization
  - Reduce or eliminate copays
  - Need people to assist patients with financial hardship applications when appropriate to reduce or eliminate copays
- Pharmacists work to reduce drug costs
  - Generics
  - PAPs
  - Samples
  - DM testing supplies – formulary changes

What We Have Learned:

Common Themes to Patient Care in Ambulatory Care

- Disease state education – start from the beginning
  - Regardless of when they were diagnosed, incorporate this into your initial visits
- Offer pill box filling
  - You may be surprised on who will accept your offer
- Ask every patient about cost
  - Research lower cost alternatives, find coupons, and print patient assistance forms before the patient arrives
- Be willing to make multiple phone calls on their behalf
  - Mail order pharmacy, local pharmacy, insurance company
- Trust other team members
  - Everyone is bringing their strengths to the team

Completing the Dive:

Practitioners’ Views
SSM Health – St. Clare Hospital
Fenton, MO

Kristina Bryowsky, PharmD, MBA, BCPS
Director of Pharmacy
Lauren Odum, PharmD, BCPS
Ambulatory Care Clinical Pharmacist
SSM Health – St. Clare Hospital

Justifying the Position

• 100% funded by Department of Pharmacy
• Support new PGY1 residency program, added depth and breadth
• Graduate Medical Education funding
• May be reimbursed for some School of Pharmacy APPE students
• Quality improvement
Hiring the Pharmacist

• Ideal candidate has at least 3 years of experience as an ambulatory care clinical pharmacist and/or a PGY2 residency in ambulatory care and has started other clinics
• Ideal candidate is approachable, knowledgeable, independent
• Advertise the position through ACCP and ASHP; consider interviewing at Midyear
• Include physicians who will work with the pharmacist in the interview and selection process
• How will this pharmacist be supported in maintaining skills/knowledge base, especially without other ambulatory care pharmacists on site?

Before Arrival of the Pharmacist

• Establish rapport with key administrators on the ambulatory side
• Identify which physicians the pharmacist will collaborate with
  • Collaborative
  • Worked with pharmacists during training and had positive experiences
• Identify space and resources for the pharmacist
  • Office or desk space
  • Patient exam room space
  • Computer
  • Phone

Ambulatory Care Pharmacy Service

• 1 pharmacist working with 5 family medicine physicians and 1 nurse practitioner
• Average 70 patients per day
• Main activities
  • Patient referrals by PCP
  • Reason for many referrals: HTN, DM, polypharmacy
  • Patient chart review
  • Drug-related problems identified and discussed with PCP prior to patient visit
  • Drug information resource
  • Preceptor for pharmacy residents and students
  • Smoking cessation clinic
Establishing the Role

• Do not take students or residents during the first 6 months
  • Important time to establish relationships
• Shadowed physicians and medical assistants
  • Rapport building
  • Learned workflow and roles
  • Identified prescribing patterns
  • Identified areas of strength and weakness
• Chart reviews and recommendations
  • Rapport building
  • Allowed them to understand my thought process and knowledge base

Establishing the Role

• Determine what the health system and physicians value the most and what quality measures need to be improved
  • Dashboard
  • How do your physicians get paid?
• Avoid becoming a patient assistance program or duplicating a pharmacist clinic that already exists
• Write a collaborative practice/protocol agreement
  • Follow state laws
  • Review examples of others within your state
  • Broad versus narrow scope?
  • Discussing with physicians that only patients who are referred to a pharmacist will have medication adjustments by the pharmacist

Establishing the Role

• Identify focused quality measures
  • BP, A1C, polypharmacy
• Scan patient charts or request an EPIC report of patients outside of these parameters
  • BP over 150/90 mmHg
  • A1C over 8%
  • Taking over 10 medications
• At patient’s visit, ask for the referral
EPIC Support

• Schedule built in EPIC for patient visits
  • 30 minutes per patient visit
  • “Pharmacist visit type” created in EPIC
    • Currently not attached to a bill

• Referral and referral report created
  • “Amb referral to medication management”

Measuring Success

• Workload
  • In first 9 months, ~150 referrals
  • In ~3 months, 230 phone calls, 45 patient visits, 115 MyChart messages
• Importance of early, measurable success
  • Example: Reducing a patient’s A1C to goal
• Share success with P&T
  • A1C goals attained
  • A1C reduction
  • BP goals attained
  • BP reduction
  • Polypharmacy medication reduction
• Consider keeping track of interventions to describe the position
• Compare to “usual care”
• Strive to constantly refine the clinic/role

Barriers

• Billing
  • Charges passed onto patient?
  • May limit referrals, especially for patients with highest need/financial limitations
  • Physical location of pharmacist changes “rules” for reimbursement and reimbursement rates
    • Hospital based versus physician based clinic
Why Ambulatory Pharmacy?

Dawn Hunsberger, PharmD
Ambulatory Care Pharmacist
Merchyhealth System

Apply skills and knowledge

Physician Feedback

“The Ambulatory Pharmacists really care about the patients in my practice. They shed light on complex and difficult situations. This allows me to practice more medicine.”

-Arthur S Rone, MD Internal Med
Team Work

- Patients
- Physicians
- NP
- RN
- Care Coordinator

Patient Feedback

The Clinic Pharmacists get me to the right people. They helped me get my medication and learn how to take it properly.”

BF, RMB Internal Med Patient

“The Clinic Pharmacists keep me focused on things that are important. They do a good job explaining information about my medicine. They take time to follow up with me.”

JW, Alpine Internal Med Patient
Highlights

• D-dedication
• I-innovative
• V-validate
• E-enthusiasm

Go For It!
Expanding into Ambulatory Services

Pharmacy Technician Self-Assessment Questions:

Opportunities for pharmacy technicians’ roles in revenue generation include:
A. Auditing clinic bills for accurate coding.
B. Managing revenue accounts.
C. Analytical management of attributable outcome measurement.
D. All of the above

Which of the following is the most common clinical role for pharmacy technicians in the ambulatory setting?
A. Pill box filling and management
B. Medication reconciliation
C. Patient Education
D. Rooming patients

The greatest barrier to using pharmacy technicians in the ambulatory setting is:
A. Lack of adequate training
B. Lack of a reimbursement mechanism
C. Lack of space for additional personnel
D. State laws do not support this service

Answers: D, A, B
Developing Your Leadership Pipeline to Feed Innovation

Michael F. Powell, MS, FASHP
Executive Director, Pharmacy & Nutrition Services, Nebraska Medicine
& Associate Dean for Hospital Affairs, UNMC COP

Speaker has no conflicts of interest to disclose

Developing Your Leadership Pipeline

• Compare and contrast replacement planning, succession planning, and succession management in building a leadership pipeline for a pharmacy service.

• Explain the benefits and challenges of succession management in building leadership continuity for an organization.

• Identify both internal and external resources for developing leadership skills in an organization.

• Describe the leadership skills and strategies necessary for stimulating innovation.

• Discuss the linkage between leadership and becoming an innovative organization.

Nebraska Medicine – Fast Facts

• $1.2 billion academic health system
• Two hospitals, anchored by an academic medical center, Nebraska Medical Center
• More than 1000 affiliated physicians across all specialties
• 39 ambulatory clinics
• One of only nine health systems in the U.S. with transplant programs for all solid organs: liver, intestine, kidney, pancreas, lung and heart
• 7,800 employees
• Partial ownership of two rural hospitals and one specialty hospital
• Primary clinical partner of UNMC
• 606 beds
• 27,981 discharges
• 426,923 outpatient visits
• 77,544 ER visits
Nebraska Medicine – Pharmacy Facts

- Acute Pharmacy
  - Centralized UD to nurse servers, Sterile IV production
  - Team-based rounding
  - 24 hour ED services
  - Own discharge medication reconciliation; release all discharge Rx
  - Pharmacokinetic dosing; renal dose monitoring; antimicrobial, anticoagulation and diabetic stewardship programs; personalized medicine
- Community-based services
  - Specialty pharmacy-financial counselors
  - 3 retail pharmacies
- Transitional Care Services
  - PCMH
  - Bedside Medication delivery
  - Post discharge surveillance

What is Innovation?

- Innovation Can refer to new technology, new products, new ideas
  - Can reflect a new way of using an existing technology, product, ideas or even people
  - Example: One might say that the first telephone was an invention, the first cellular telephone either an invention or an innovation, and the first smartphone an innovation

Why is Leadership Critical to Innovation?

- Innovation is a critical driver of growth.
  - Few leaders include innovation as a part of their strategic agenda.
  - Few leaders create culture supportive of innovation.
- Innovation directly associated with change.
  - Employees associate change with risk
  - Leadership is essential to win the hearts and minds of employees
  - Leadership is essential in creating a culture of change
Case Study

- After 25 years and academic medical center implemented an electronic health record. Unit based pharmacists were responsible for verifying medication orders entered by physicians. After 6 months, the nursing staff complained of increased turn around time on inpatient and discharge medication deliveries. Pharmacy leadership team charged a team of pharmacists to develop a plan to improve service. The solution was to establish a team based rounding service. The pharmacists found that they were catching order problems and discharge plans earlier in the process. This is an example of:
  1. Invention
  2. Innovation

What is Essential for Innovation?

- Innovation is not random
  - Depends on culture
  - Culture depends on leadership
- Focus on an innovation process – innovation requires:
  - Structured activity
  - People with innovative mindsets working together
  - Clarification of challenges
  - Define innovation driving growth
  - Innovation to formal agenda at regular leadership meetings
  - Performance metrics and targets for innovation

What is Essential for Innovation?

- Identify and leverage different contributions to innovation
- Leaders can see how different skills and contributions are needed
- Four sets of preferences and perspectives contributing to innovation:
  - Clarifiers
  - Ideators
  - Developers
  - Implementers
What is Essential for Innovation?

• Work across boundaries
• Multidisciplinary, cross boundary activity
• Leaders must work across boundaries to connect:
  — Ideas with ideas
  — Ideas with people
  — People with people

What is Essential for Innovation?

• Embrace polarities
• Innovation comes from embracing paradoxes, conflicting priorities rather than a problem solving mindset

Roles and Capabilities to lead innovation

• Leading Self: Ideating and creating
  — Seeking and generating novel solutions and approaches
  — Participating on innovation teams
  — Pushing across boundaries and systems
Roles and capabilities to lead innovation

- Leading Others: Innovation project leader
  - Leading group innovation processes
  - Effective team leader and flexible project manager
  - Finessing resources from outside their unit

Roles and Capabilities to lead innovation

- Leading Managers: Connecting and championing
  - Supporting and protecting the innovation team from other parts of the organization.
  - Building a case for grass roots innovations.
  - Facilitating constructive cooperation between groups working on similar opportunities.

Roles and capabilities to lead innovation

- Leading the function: Managing innovation portfolio and pipeline
  - Helping develop an innovation strategy that bridges silos
  - Initiating strategic and structural changes to facilitate promising innovation
  - Managing pipeline to insure right mix of innovation bets – including managing competition for resources
Roles and capabilities to lead innovation

- Leading the organization: Shaping culture and strategy
  - Setting innovation strategy for the organization
  - Shaping culture to support innovation (support for new, different, disruptive ideas throughout the organization)
  - Find ways to view concepts not filtered or de-risked through layers of management
  - Modeling behavior
  - Communicating the vision of innovation

Leadership in a culture of Innovation

1. Demonstrates Excellent Strategic Vision
2. Shows strong customer focus
3. Create a climate of reciprocal trust
4. Displays fearless loyalty to doing what’s right for the organization and customer
5. Puts faith in a culture that magnifies upward communication
6. Are persuasive
7. Excels at setting stretch goals
8. Emphasizes speed of play
9. Candid in their communications
10. Inspires through action

How does succession management contribute to a culture of innovation

- Innovation
- Culture
- Leadership
How do leadership planning, succession planning and succession management contribute to a culture of innovation

• Add breadth to leadership
• Creates a culture of engagement & loyalty
• Creates an environment of trust
• Magnifies upward communication
• Assures sharing of vision

ICHM/MSHP 2017 SPRING MEETING

Which of the following is not a capability necessary for leading a function for innovation?

1. Helping develop an innovation strategy that bridges silos
2. Setting innovation strategy for the organization
3. Initiating strategic and structural changes to facilitate promising innovation
4. Managing pipeline to insure right mix of innovation bets – including managing competition for resources

ICHM/MSHP 2017 SPRING MEETING

Leadership Pipeline

• What started us down this path?
  – Stage of my career
  – Lack of leadership bench depth
  – Desire to broaden the traditional candidate pool
  – Desire to assure continuity
  – Building talent from within
  – Desire to accelerate innovation
  – Need to increase engagement
  – Recruitment barriers

ICHM/MSHP 2017 SPRING MEETING
Defining Replacement Planning

- Planning for retirement, unanticipated departures, unexpected deaths
- Defines who can move into key roles assuming the organizational chart does not change
  - Focuses on identifying (usually) multiple, key individuals who can fulfill a role
  - Frequently an interim assignment
  - Should be a written plan

Three Key Principles

1. Differs from leader development
2. Not every leader needs a succession plan
3. A comprehensive approach is not always the right approach

Defining Succession Planning

- ACHE: “A structured process involving the identification and preparation of a successor for a given organizational role that occurs while that role is still filled.”
Defining Succession Planning

- Focuses on developing people rather than merely naming them as replacements
- Goal:
  - Create bench depth
  - Generate as many qualified replacement candidates as possible
  - Build long-term sustainability and viability of an organization

Differentiating Leadership Development

<table>
<thead>
<tr>
<th>Succession Planning</th>
<th>Leadership Development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scope</td>
<td>Critical positions, high potential leaders</td>
</tr>
<tr>
<td>Objective</td>
<td>Prepare leaders for next-level role</td>
</tr>
<tr>
<td>Typical Development Methods</td>
<td>Hands-on project work</td>
</tr>
</tbody>
</table>

Challenges

- Reliance on averages masks most urgent retirement risks
- Missing critical roles below executive ranks
- Unreliable measurements of performance
- Flawed understanding of potential
  - Mini-me
  - Old faithful
  - Ivy league
Four Step Succession Management Process

• Pinpoint future leadership gaps
• Identify top talent
• Customize high potential development
• Personalize on-boarding for new hires.

Finding the Highest-Potential Successors

• Identify high performing staff
• Vet top selections
• Final pool of potential successors

Perceived Barriers to Implementing a Succession Management Plan

• Culture of “haves” and “have-nots”
• Success hiring people externally- search firms
• Reluctance to invest in staff- fear of being replaced
• Develop for jobs that don’t exist
• Boomers dominate management
• Artificially narrowed talent pool
Trustworthy Performance Appraisals

- Equip managers to rate more accurately
  - Empower managers to lead difficult performance conversations
  - Provide managers visibility into how they grade
  - Make managers back up their ratings

Nebraska Medicine Process

- Quarterly Talent Review
  - Leadership group
  - Direct reports
- Engaging potential leaders
  - Interview
  - Define commitment
  - Define resources
  - Personal development plan
  - Engage mentor or sponsor

Employee Development Ideas

- Fundamental Concepts
  - Attendance at meetings: When appropriate, include employees in organizational or project related meetings that will help them develop in areas outlined in their development plan. Giving employees exposure to strategic projects and initiatives is helpful because it provides them with knowledge that often enables them to better align their work to the strategic priorities of the organization.
  - Preparing Reports and/or Presentations: Involve employees in the analysis and preparation of reports or presentations your department may be involved in. This will help sharpen their analytical and writing skills.
  - Giving Feedback: One of the best development actions you can take on behalf of your employees is giving them timely and specific feedback. Feedback and coaching are essential to growth and development
Employee Development Ideas

• Intermediate Steps
  – Exposure to the Budget: Although many employees do not control or manage the expenditures of the department, why not have them understand the practicalities of managing the overall budget of the department, especially if they have career aspirations to reach the management level.
  – Job Rotation: When possible, consider rotating people in and out of positions in your department which will give them the opportunity to gain a deeper understanding of the department, and keep them in a learning curve, which is important for high performers who are constantly looking for that.
  – Giving Presentations: This is a critical career skill that your employees can develop or enhance. Be sure to give them plenty of coaching and feedback before and after the presentation to help their learning.

• Formalized Leadership Development
  – Project Ownership: Give employees projects that they can own from start to finish. This will accelerate their learning in project management, communication, and execution skills.
  – Internal Training Courses: Encourage employees to take advantage of relevant training courses that are offered internally at the organization.
  – External Training/Seminars: Budget permitting, external seminars that will expose the employee to skill building opportunities for their current position can be a great development action.
  – Mentoring Relationships: Based on the employee’s career aspirations, encourage them to take the initiative to develop informal mentoring relationship with leaders in the organization they admire. It can be as simple as asking them to have lunch or coffee with them once a quarter.

Development Activities

• ASHP Leadership Academy
• ASHP: Leaders Innovation Master Series
Resources: Personal Development Plan

Name: ____________________________

Use the following questions and tables to list three professional development goals for FY__.

1. List at least one professional development goal targeting advancement in your role related to current work of the department.

2. List any professional development goals related to your role/leadership in guiding the future work of the department.

3. List any professional development goals related to your future professional aspirations.

---

External Resources

- ASHP Leadership Academy
- ASHP Leaders Innovation Master Series
- Advisory Board Executive Fellowships
- Academic Programs (MHA, MBA, MPH)
- Residency Programs
  - Nontraditional

---
The Final Elements

- Mentorship
- Sponsorship

Scenario 1

- Pharmacist clinician with 17 years of experience in oncology. Highly valued by medical staff, advanced practice providers. Demonstrates exceptional skill at influencing other clinicians. Performance appraisals consistently in the outstanding range. Active personal life raising 3 sons active in sports. Husband is an architect.
- Situation: Developing a stand alone cancer hospital in a multihospital system

Development Pathway

- ED approached pharmacist about future goals
  - Interest in leadership
- Discussed development pathway
  - ASHP Leadership Academy
  - Project
    - Staffing model redesign
    - Association roles
    - Non traditional residency
    - Monthly coaching sessions
- Personal development plan
Scenario 2


- Situation: Medication safety manager accepts Clinical manager role for Internal Medicine.

Development Pathway

- ED approached pharmacist about future goals
  - Interest in leadership

- Launched development pathway
  - ASHP Leadership Academy
  - Clinical manager position
  - Director Inpatient Pharmacy
  - Project Lead – Pharmacy EHR

- Executive MBA

- Executive Director, Enterprise Applications

Scenario 3

- Pharmacist clinician with residency training practicing in emergency medicine. Left role in pharmacy to pursue role in EHR implementation, coordinating Provider Order Entry build. Demonstrated exceptional skills influencing and training providers and exceptional comprehension of process design. Active personal life raising 3 daughters active in sports and clubs. Husband police officer.

- Situation: Unexpected resignation of clinical manager followed at one-year by resignation of pharmacy director.
Development Pathway

- ED approached pharmacist about future goals
  - Interest in leadership
- Discussed leadership opportunities
  - Manager, Medication Safety
  - Biweekly coaching sessions
    - Co-chair medication management committee
    - Manager, Critical Care & Emergency Services
- Development opportunities
  - ASHP Leadership Academy
  - ASHP Leaders Innovation Master Services
  - Personal Development Plan
- Executive Director, Enterprise Applications

Case Study

- Your leadership team conducts a quarterly assessment of your staff for leadership potential. Identified staff have been given projects; have been enrolled in the ASHP leadership academy; and have been assigned projects to lead, though no leadership vacancies exist. This is an example of?
  1. Replacement planning
  2. Succession Planning
  3. Succession Management

Case Study

- A manager for the central pharmacy submits her resignation. Her spouse has accepted a fellowship in critical care medicine at an academic medical center across the country. You name an interim manager from her staff. This is an example of:
  1. Replacement planning
  2. Succession Planning
  3. Succession Management
Case Study

- Your Chief Pharmacy Officer has informed the CEO and COO of his intent to retire within two years. During that time he has been sponsoring an area Director by assigning her increasing leadership responsibilities representing the pharmacy service with the medical staff and executive leadership. This is an example of?

  1. Replacement planning
  2. Succession Planning
  3. Succession Management
A Review of 340B Program Landscape, Risk, and Software Optimization

William Pong, PharmD, MBA
Administrative Director, Pharmacy Services
Loyola University Health System
March 31st, 2017

Objectives

- Review the 340b program landscape complexity
- Identify and focus on high risk areas
- Discuss opportunities to improve operations and procurement savings
- Explain strategies to maximize regulatory compliance
- Describe functionalities that enhance program performance

I have no actual or potential conflict of interest in relation to this program/presentation

Background

Loyola University Medical Center is an 570 bed academic medical center located in Maywood, IL, 20 minutes west of Chicago.

On campus:
- Main Hospital
- Ambulatory clinics & surgical centers
- Outpatient oncology center
- Outpatient retail pharmacy

Off campus:
- Ambulatory specialty clinics
- Outpatient oncology centers
- Home infusion pharmacy

340B program Landscape

- Cover Entity (CE) – Disproportionate share hospital
- Child sites – Outpatient clinics or centers
- Contract Pharmacy – National or single Vendors
- In house Pharmacy – within the hospital

LUMC 340B Program Landscape

Landscape Key Elements

- Eligibility
- Diversion
- Duplicate discount
- Risk and Compliance
Landscape – Eligibility

- Medicare cost report (MCR)
- HRSA OPA database registration
- Patient definition
- Cover Entity – Vendor contracts
- Accumulation methodology (Software/Manual)

Eligibility Risk Areas

- MCR (annually) – DSH percentage, qualifying lines, child site listings, changes (additions, deletion, relocations, etc.)
- HRSA OPA Database (quarterly) – Child sites and/or contract pharmacy changes
- Patient definition – Prescriber, clinic, and/or contract changes

Eligibility Risk Areas

- Cover Entity Vendor Contracts – Retail store accuracy in database, contract, and operations. Registration changes and eligibility identification.

Landscape – Diversion

- Definition – *Diversion* of 340b drugs to individuals who are not patients of the covered entity.
- Does violation in eligibility result in diversion?
**Diversion Risk Areas**

<table>
<thead>
<tr>
<th>Eligibility Key Elements</th>
<th>Example Violations</th>
<th>Results</th>
<th>Diversion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicare cost report (MCR)</td>
<td>Provided drugs to child site not on current MCR</td>
<td>We not 340b eligible</td>
<td>yes</td>
</tr>
<tr>
<td>HRSA OPA database</td>
<td>Provided drugs to child site not in MCR but not registered and listed in HRSA OPA database</td>
<td>We not 340b eligible</td>
<td>yes</td>
</tr>
<tr>
<td>Patient definition</td>
<td>340b accumulations from a drug dispensed/administered to a patient prescribed by a non-employee or contracted provider</td>
<td>Accumulation is not 340b eligible</td>
<td>for replenishment</td>
</tr>
<tr>
<td>CE - Vendor Contract</td>
<td>Retail contract pharmacy listed on the contract but not registered and listed in HRSA database processed 340b prescriptions for the CE</td>
<td>Contract pharmacy is not eligible to participate</td>
<td>yes</td>
</tr>
<tr>
<td>Accumulation methodology</td>
<td>Inpatient drugs charges incorrectly coded as outpatient in the EMR patient encounter feed</td>
<td>Accumulation is not 340b eligible</td>
<td>for replenishment</td>
</tr>
</tbody>
</table>

**Diversion Risk - Data**

- EMR data accuracy (Charges, encounter feed, prescribers)
- Split billing software accuracy (Crosswalk and filters)
- Purchase data accuracy (Wholesalers, direct purchases)
- Retail pharmacy data accuracy (adjudication vs. sale, returns)

**Review Question 1**

According to HRSA OPA 2015 Audits, what was the most prevalent violation finding?

A. Diversion  
B. No adverse findings  
C. Incorrect database  
D. Duplicate discount  
E. Contract pharmacy violations

**Review Question 2**

A CE provided 340b drugs to a new clinic that is not listed on the current MCR and not registered with HRSA. What areas did the CE violate?

A. Diversion  
B. Eligibility  
C. Incorrect database  
D. A and B  
E. All of the above

**Landscape - Duplicate Discount**

- **Duplicate Discount Prohibition**: 42 USC 256b(a)(5)(A)(i) prohibits duplicate discounts; that is, manufacturers are not required to provide a discounted 340B price and a Medicaid drug rebate for the same drug. Covered entities must have mechanisms in place to prevent duplicate discounts.
Landscape - Duplicate Discount

- Carve in – CE bills Medicaid for outpatient drugs at 340b acquisition cost.
- Carve out – CE does not bill Medicaid for outpatient drugs at 340b acquisition cost.

Duplicate Discount – Risk Areas

- Medicaid rules vary from state to state
- Carve in vs. carve out (CE services, contract pharmacies)
- UD modifier accuracy (Cover entity and child sites)
- Medicaid Fee for service & MCO Plan accuracy (Retail)
- Contract pharmacy vendor (Data transparency)

Landscape - Compliance

- Policy and procedures (Established, following)
- Eligibility audit (340b prescriptions or orders)
- Database audit (child sites, cost report, contracts)
- Dispense vs. purchase audit (Virtual, physical)
- Duplicate discount audit (340b prescriptions / orders)
- GPO prohibition

Compliance - Risk Areas

- Auditable records
- Charge and dispense accumulations
- 340B Drug purchases
- Patient medical record
- Vendor contracts
- Vendor data (dispense, accumulations, purchases)
- Self audit results and record keeping
- Material breach (acceptable threshold)

Review Question 3

Which of the following areas should be included for routine audits to ensure 340B program compliance?

A. Eligibility  
B. Database  
C. Duplicate discount  
D. A and C  
E. All of the above

Improve Operational Methodologies and Procurement Savings

Case # 1 background:

- Relates to mixed use practice area
- GPO prohibition regulation
- Charges & accumulations capture
- Data analytics
- Report functionalities
What Happened?
The call for pharmaceutical cost savings???
Top 10 drug spend.....

How it was found?
The use of Wholesaler Reports:
- Top 10 drug spends
- Assumes utilization problem
- Requires further investigation
- Manipulation of 340b/WAC/GPO purchases
- Limited value

“ISUPREL” Story
- Big dollar spend NDC & recent price hike impact
- $210 to $1,670 per vial
- Average (GPO+WAC) month spend of $100,000
- Initial goal to address appropriate usage and/or identify alternatives

Investigation
- Confirmed 90% of Cath/EP Lab are outpatients & missing charges
- Confirmed the cost difference between 340B, GPO, and WAC

“WAC GPO Negative Savings” or “340B missed opportunities” Reports
- Consolidates all purchase data
- Calculates WAC / GPO to 340b savings (-/+) 
- Identifies date and time of purchases
- Identifies NDCs with WAC, GPO, 340B cost
- Identifies high volume & high cost purchased NDCs

Example Report
Resolution

- Engage Cath/EP Lab leader, establish charge capture process and ongoing monitoring
- I.T. Manager & 340B specialist monitor and confirm charge capture in split billing software accumulation
- Biweekly outpatient charges to 340B accumulations reconciliation
- Process hardwired and sustained after 3 months

Savings Results

- Isuprel Purchasing Savings (Jan - June 2016)
  - $133,660
  - $133,650
  - $133,660
  - $133,650
  - $133,660
  - $133,650
  - $133,660

Review Question 4

Accurate drug charge capture and review of a 340B program “missed opportunities” report can improve operations and procurement savings?

A. True
B. False

Splitting Billing Software (SBS) Reports Considerations

- Identifying reporting needs
- Standard vs. custom reports
- Accessibility
- Meeting objectives / goals
- Unique advantages
- Review frequency
- Optimize performance and/or compliance

SBS Functionalities that enhance program performance & compliance

Case #2
- Contract & hospital retail Pharmacies
- Split billing software (SBS) system filters
- Patient encounter feed (diagnosis code match)
- Charge capture feed (depts, cdms)
- Prescriber list
- Capture rate, Lost savings, Compliance

Patient Encounter Feed

- ICD 9 to ICD 10
- Software requirements
- Data feed acceptance / modifications
- Character alignment
- Test to production
- Impacts prescription eligibility, capture volume, and savings
Data Feed Optimization Considerations

- Separate mixed used & retail data feed
- Contract pharmacy & retail data feed accurate locations (i.e. hospital units, clinics, etc.)
- Automated surveillance mechanism – ensure charge / dispense data deliver to split billing software
- Determine optimal upload frequency (i.e. daily)

Why is it important ???

ICD 10 Feed Impact on Contract Pharmacy Performance

- Patient MRN#
- Diagnosis code
- Date of Service
- Patient location
- Patient status
- Providers

Post ICD 10 Feed Fix – impact on a contract pharmacy

Program Filters

- Are they important ???
**Split Billing Software Filters**

- Prescribers
- Diagnosis code
- Medicaid
- Drug class specifications
- Non-covered drug rules

**How does it work…….**

**Example Filters**

**Prescriber list**

- Accuracy
- Frequency
- System format to upload
- Test NPI, DEA, or both
- Impacts prescription eligibility, capture volume, savings, and compliance

**ICD 10 Diagnosis Code Match**

- Diagnosis code matching
- Confirms visit association
- Default days
- Specific match (i.e. pain meds, antibiotics)
- Balance between restrictive & loose
- Impacts volume capture, compliance

**Split Software Filters – Program Impacts**
NPI/DEA & Code Match Impact on volume, compliance and performance

Review Question 5
Which of the following data elements are critical to an effective 340B split software system?

- Prescriber list (DEA / NPI)
- Wholesaler purchases
- Patient encounter feed
- Program filters
- A, C, and D
- A, B, C, and D

Review Question 6
The effective use of prescriber DEA and diagnosis code match in the 340B split software system can improve program compliance and/or performance.

- True
- False

Optimization Take-aways
- Actionable reports
- Filters
- Data feeds
- Data integrity
- Compliance, performance, & savings

Contact William Pong at wpong@lumc.edu for more information.
Pharmacy's Role in National Medication Safety Initiatives

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The speakers have no conflict of interest to disclose.

Today's Objectives

2. Discuss the mission, purpose, and goal of the Illinois Medication Safety Coalition.

National ADE Action Plan

The three initial targets of the ADE Action Plan are:
1. Anticoagulants
2. Diabetes agents
3. Opioids

The ADE Action Plan suggests a four-pronged approach to reduce patient harms from these three ADEs:
1. Surveillance
2. Prevention
3. Incentives and Oversight
4. Research


Adverse Drug Event (ADE) Action Plan

Key Players:
- The Office of Disease Prevention and Health Promotion (ODPHP)
- Federal Interagency Steering Committee
- Workgroups for ADEs

Purpose:
- Identify high-priority ADE targets
- Identify and implement high-priority strategies and opportunities to reduce ADEs
- Engage and inform stakeholders and consumers
- Provide safe and higher quality healthcare services, reduce healthcare costs, and improve health outcomes.

Drug-Related Harm Terms

- Definitions:
  - Adverse Drug Event: an injury resulting from medical intervention related to a drug.
  - Medication Error: inappropriate use of a drug that may or may not result in harm.
  - Adverse Drug Reaction: harm directly caused by a drug at normal doses.

Adverse Drug Event (ADE) Prevention is a Patient Safety Priority

- 82% of the US population reported using at least 1 prescription medication or OTC medication, and 29% reported using ≥ 5 prescription medications.
- Of the elderly population, 57-59% reported taking 5-9 medications and 17-19% reported taking ≥ 10 over the course of the year.
- ADEs incurred $5.6 million in excess hospital costs.
- ADEs contributed to $3.5 billion US healthcare costs.
- Elderly experience ADEs that result in ED visits and are 7 times more likely than younger persons to have an ADE that requires hospitalization.

Hospital ADE Contribution

Inpatient settings:
- ADEs are among the largest contributors to hospital-related complications according to research.
- ADEs comprise ~ 1/3 of hospital adverse events, affecting ~ 2 million hospital stays annually, and prolonging hospital length of stay by 1.7 to 4.6 days.

ADE High Priority Targets

Three types of ADEs were considered to be common, clinically significant, preventable, measureable, and were therefore selected as high-priority targets of the ADE Action Plan.
- Anticoagulants (primary ADE of concern: bleeding)
- Diabetes agents (primary ADE of concern: hypoglycemia)
- Opioids (primary ADE of concern: accidental overdoses/oversedation/respiratory depression)

Outpatient ADE Contribution

Outpatient Settings:
- ADEs account for ~3.5 million physician office visits
- An estimated 1 million emergency department visit
- ~125,000 hospital admissions each year.

ADE Reduction Approach

1. Surveillance—Coordinate existing Federal surveillance resources and data to assess the health burden and rates of ADEs.
3. Incentives and Oversight—Explore opportunities, including financial incentives and oversight authorities, to promote ADE prevention.
4. Research—Identify current knowledge gaps and future research needs (unanswered questions) for ADE prevention.

Anticoagulation: Prevention Strategies-Inpatient

Safer Care
- Improve anticoagulation management provider education
- Improve provider accessibility to evidence-based anticoagulation management strategies/tools
- Address gaps in provider knowledge by developing guidelines for managing NOAC safely.

Effective Communication and COC
- Improve EHR tools to enable provider access to real-time laboratory results
- Integrate anticoagulation-specific targets into currently existing care transition models

Science-Driven Prevention and Treatment
- Promote a multidisciplinary and systematic approach to anticoagulation management.
- Address safe use of anticoagulants commonly utilized in inpatient settings.

Promotion of Best Practices Within Communities
- Identify and promote adoption of anticoagulation management standards.
- Improve sharing of quality-improvement anticoagulation ADE prevention learning initiatives among healthcare systems.

Anticoagulation: Prevention Strategies-Outpatient

Safer Care
- Improve provider education of high-quality outpatient anticoagulation management.
- Address provider concerns with sub/supratherapeutic INRs.
- Address gaps in provider knowledge by developing guidelines for managing NOAC safely.

Effective Communication and COC
- Integrate anticoagulation-specific targets into currently existing care transition models.

Science-Driven Prevention and Treatment
- Address factors contributing to variability in anticoagulation services within facilities.
- Address gaps in guidelines to identify patients at high risk for bleeding events.

Promotion of Best Practices Within Communities
- Identify and promote adoption of high-quality anticoagulation management standards.
- Improve distribution and sharing of quality-improvement anticoagulation ADE prevention learning initiatives among healthcare systems.

Patient and Family Engagement
- Improve and incorporate patient education and education tools of anticoagulation-specific patient management.
### Diabetes: Prevention Strategies-Inpatient

**Patient and Family Engagement**
- Individualized target setting
- Use teach-back method to educate patients on self-management implications of changes to insulin
- Educate patients on low blood glucose products
- Provide patients with hypoglycemia materials

**Effective Communication and COC**
- Multidisciplinary coordination and collaborative healthcare professional partnerships
- Provider education on the importance of effective communication and coordination of care
- Engagement with pharmacists, nurses, dietitians, and other health care professionals at the time of discharge
- Support development of tools

**Science-Driven Prevention and Treatment**
- Consider individual patient characteristics in selecting diabetes agents and glycosic targets
- Use protocols assume and measure risks
- Support development of standard tools for insulin administration
- Use standardized and ensure consistency in order sets
- Capture critical information and conduct KCA of hypoglycemic events

**Promotion of Best Practices Within Communities**
- Encourage multidisciplinary care coordination
- Consider individual patient circumstances
- Ensure professional supervision during any medication changes

---

### Diabetes: Prevention Strategies-Outpatient

**Safer Care**
- Coordination of real time and blood glucose testing
- Care coordination across all healthcare professionals
- Medication reconciliation of diabetes medications
- Caution against use of sliding scale in high-risk patients
- Incorporation patient glucometer data into the EHR

**Effective Communication and COC**
- Provider tracking on effective use of decision aids
- Provider education in the importance of effective communication and coordination of care
- Integration of databases with patient education of lifestyle changes

**Science-Driven Prevention and Treatment**
- Development and enhancement of decision aids
- Adressing inaccuracy of self-monitoring of blood glucose with patients and caregivers

**Promotion of Best Practices Within Communities**
- Multidisciplinary care coordination
- Consideration of individual patient circumstances

**Patient and Family Engagement**
- Establish individual patient goals
- Shared decision making
- Provide patient education using teach back
- Understand patient complaints/adherence to medication barriers
- Address cultural competency and health literacy barriers
- Education on hypoglycemia and how to treat

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### Opioid: ADE Prevention Strategies-Inpatient

**Safer Care**
- Expand dissemination of evidence-based opioid guidelines/protocols

**Effective Communication and COC**
- Develop more optimal and integrated health IT opioid management tools
- Coordinate care through practices such as medication reconciliation and discharge counseling

**Science-Driven Prevention and Treatment**
- Promote systematic and coordinated care
- Promote safe practices at point of initiation of inpatient opioids
- Promote the use of evidence-based tools for morphine equivalent dose (MED) and transitions between formulations

**Promotion of Best Practices Within Communities**
- Use metrics to monitor the use of opioid safety "best practices"
- Promote the use of evidence-based guidelines for monitoring

**Patient and Family Engagement**
- Promote patient education to improve safety of care transition

---

### Opioid: Prevention Strategies-Outpatient

**Safer Care**
- Develop more optimal and integrated health IT opioid management tools
- Integrate opioid-specific targets into care transition models

**Effective Communication and COC**
- Promote systematic and coordinated care
- Promote the use of evidence-based strategies for managing risk factors associated with opioid overdoses
- Increase availability of mental health and substance use disorder treatment for patients on opioids

**Science-Driven Prevention and Treatment**
- Use metrics to monitor the use of opioid safety "best practices"
- Promote effective strategies identified by Federal Agencies that engage in patient care

**Promotion of Best Practices Within Communities**
- Educate patients and their families to recognize early signs of dependence
- Spread public health messages promoting safe opioid storage, use, and disposal

**Patient and Family Engagement**
- Educate patients and their families to recognize early signs of dependence
- Spread public health messages promoting safe opioid storage, use, and disposal

---

### Post Assessment Question 1:

All of the following are examples of ADE prevention strategies/tools pharmacists can adopt to improve patient and family engagement in diabetes management except:

A. Educating the patient on s/sx of hypoglycemia and the rule of 15/15 in the event that their blood glucose is < 70 mg/dL and they are symptomatic or their blood glucose is < 70 mg/dL.

B. Setting/recommending an A1c goal of < 8.0% instead of < 7.0% because the patient is 70 years old and has a history of hypoglycemia.

C. Capturing critical information association with a hypoglycemic event and conducting a root cause analysis.

D. Discussing daily barriers with adhering to a low sugar/low carb diet and oral medication schedule.

---

### Post Assessment Question 2:

All of the following are examples of Anticoagulant ADE prevention strategies in an outpatient setting except:

A. Improve incorporation of anticoagulation-specific patient management into chronic disease education programs.

B. Supporting development of an electronic flow-sheet that displays trends in daily INR labs during the patient’s hospital stay.

C. Promoting a multidisciplinary, coordinated, and systematic approach to inpatient anticoagulation management, by including pharmacist/nurse on daily rounds or in anticoagulation stewardship initiatives.

D. Addressing safe use of Heparin (IV) or other anticoagulants commonly utilized inpatient settings.
CMS Partnership for Patients
Hospital Engagement Network
National Initiative

"The Hospital Engagement Network (HEN) will engage the hospital, provider and broader caregiver communities to quickly implement well-tested, evidence-based harm and measured best practices... the end result of the overall initiative shall be reduction in hospital-based harm and preventable readmissions."

- HEN 1.0: January 2012 – December 2014
- HEN 2.0: September 2015 – August 2016
- HIIN: September 2016 – August 2018 or 2019

Who's Participating?
More than 4,000 Hospitals!

- Carolinas Healthcare System
- Iowa Healthcare Collaborative
- Dignity Health
- Michigan Health & Hospital Association
- *IL – HEN 2.0 & HIIN
- Healthcare Association of New York State
- Minnesota Hospital Association
- HealthInsight
- Ohio Children's Hospitals' Solutions for Patient Safety
- The Hospital and Healthsystem Association of Pennsylvania
- Ohio Hospital Association
- American Hospital Association Health Research and Educational Trust
- *IL – HEN 1.0, MO – HEN 1.0, 2.0, & HIIN
- HRET of New Jersey
- Premier, Inc.
- Health Services Advisory Group
- Washington State Hospital Association

Closer to Home
Orphan (non-HIIN participating) Hospitals in Illinois
84% (171/203) Participation, 32 orphans

<table>
<thead>
<tr>
<th>Hospital Name</th>
<th>City</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abraham Lincoln Memorial Hospital</td>
<td>Carthage</td>
</tr>
<tr>
<td>Anderson Hospital</td>
<td>Springfield</td>
</tr>
<tr>
<td>Captain James A. Lovell Fed Health Care Ctr</td>
<td>North Chicago</td>
</tr>
<tr>
<td>Community Memorial Hospital</td>
<td>NorthShore University Health System</td>
</tr>
<tr>
<td>Edward Hines, Jr. Veterans Affairs Hospital</td>
<td>Pana Community Hospital</td>
</tr>
<tr>
<td>Genesis Medical Center, Hln Campus</td>
<td>Passavant Area Hospital</td>
</tr>
<tr>
<td>Harrisburg Medical Center</td>
<td>President Hospital of Cook County</td>
</tr>
<tr>
<td>Hospital Medical Complex</td>
<td>Richard Memorial Hospital</td>
</tr>
<tr>
<td>Illinois Valley Community Hospital</td>
<td>Richmond Community Hospital</td>
</tr>
<tr>
<td>Ingalls Memorial Hospital</td>
<td>Chicago Regional Medical Center</td>
</tr>
<tr>
<td>Jackson Park Hospital and Medical Center</td>
<td>South Shore Hospital</td>
</tr>
<tr>
<td>Jesse Brown Veterans Affairs Medical Center</td>
<td>Swedish Covenant Hospital</td>
</tr>
<tr>
<td>Lawrence County Memorial Hospital</td>
<td>Vandalia Memorial Hospital</td>
</tr>
<tr>
<td>Marion Veterans Affairs Medical Center</td>
<td>Thorek Memorial Hospital</td>
</tr>
<tr>
<td>Marshall Browning Hospital</td>
<td>University of Chicago Medical Center</td>
</tr>
<tr>
<td>Massac Memorial Hospital</td>
<td>Veterans Affairs Illinois Health Care System</td>
</tr>
</tbody>
</table>

Closer to Home
Orphan (non-HIIN participating) Hospitals in Missouri
82% (84/103) Participation, 18 orphans

<table>
<thead>
<tr>
<th>Hospital Name</th>
<th>City</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belton Regional Medical Center</td>
<td>Mercy Hospital Aurora</td>
</tr>
<tr>
<td>Cameron Regional Medical Center</td>
<td>Mercy Hospital Cassville</td>
</tr>
<tr>
<td>Centerpoint Medical Center</td>
<td>Mercy Hospital Leland</td>
</tr>
<tr>
<td>Freeman Memorial Hospital</td>
<td>St. Francis Hospital</td>
</tr>
<tr>
<td>General John J. Pershing Memorial Hospital</td>
<td>Ozarks Community Hospital</td>
</tr>
<tr>
<td>Harry S. Truman Memorial Veterans Hospital</td>
<td>Parkland Health Center-Bonne Terre</td>
</tr>
<tr>
<td>Hebrew Medical Center</td>
<td>Putnam County Memorial Hospital</td>
</tr>
<tr>
<td>John J. Pershing Veterans Affairs Medical Center</td>
<td>Veterans Affairs St. Louis Health Care System</td>
</tr>
<tr>
<td>Kansas City Veterans Affairs Medical Center</td>
<td>Wright Memorial Hospital</td>
</tr>
</tbody>
</table>
HEN & HIIN AIMS

- Support the Partnership for Patients campaign for national improvement
- Help hospitals implement best practices to reduce harm and readmissions, provide education and improvement support
- Improve clinical harms and safety culture
- Goals: 40/20 HEN & 20/12 HIIN

HEN / HIIN Goals

<table>
<thead>
<tr>
<th>HEN 1.0 &amp; 2.0 (2012-2016)</th>
<th>HIIN [2017-2018 or 19]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduce Hospital Acquired Conditions by 40% &amp; Readmissions by 20%</td>
<td>Reduce Hospital Acquired Conditions by 20% &amp; Readmissions by 12%</td>
</tr>
<tr>
<td>Adverse drug events (ADE) - opioid safety, anticoagulation, and glycemic management</td>
<td>Same – no change</td>
</tr>
<tr>
<td>Catheter-associated urinary tract infections (CAUTI)</td>
<td>Same – no change</td>
</tr>
<tr>
<td>Central line-associated bloodstream infections (CLABSI), in all hospital settings</td>
<td>Same – no change</td>
</tr>
<tr>
<td>Injuries from falls and immobility</td>
<td>Same – no change</td>
</tr>
<tr>
<td>Pressure ulcers</td>
<td>Same – no change</td>
</tr>
<tr>
<td>Obstetrical adverse events, early elective delivery, obstetrical hemorrhage, and preterm infant treatment and management</td>
<td>Replaced with ( \text{Clostridium difficile / Antibiotic Stewardship} )</td>
</tr>
<tr>
<td>Surgical site infections, hip/knee replacements, colon surgery, &amp; hysterectomy</td>
<td>Same – no change</td>
</tr>
<tr>
<td>Ventilator‐Associated Events (VAE)</td>
<td>Same – no change</td>
</tr>
<tr>
<td>Preventable Readmissions</td>
<td>Changed to All-Cause Readmissions</td>
</tr>
</tbody>
</table>

Benefits of Participation

IHA IL HIIN Programming for 2017-2018

Resources

- Starter Packs
- Peer-to-Peer Learning Network
- Improvement Action Networks
- Improvement Calculator

Training

- Quality Improvement Fundamentals
- QuoST
- Safety Sessions
- Simulations
- Project ECHO

Innovation

- Quality Awards
- Quality Advocacy Showcase
- Innovation Challenge

The Hard Work is Paying Off!

HEN (over 4 years)
Nationally: Substantial progress through 2014, compared to 2010 baseline
- 17% reduction in overall harm
- 39% reduction in preventable harm
- 87,000 lives saved
- $18.88 in cost savings from harm avoided
- 2.1M fewer harms over 4 years

IL: IL HNA HEN hospitals prevented 15,887 instances of patient harm for a cost savings of $161.8 million
MO: Participating Missouri hospitals prevented 10,600 harms and saved $98.4 million

What Pharmacists and Technicians can do to advance the work of the HIIN and medication safety
Excessive Anticoagulation

Determine how to easily collect this data & team up to reduce the occurrence

<table>
<thead>
<tr>
<th>Measure type</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Numerator</td>
<td>Number of inpatients experiencing excessive anticoagulation with warfarin</td>
</tr>
<tr>
<td>Denominator</td>
<td>Number of inpatients receiving warfarin anticoagulation therapy</td>
</tr>
</tbody>
</table>

Exclusions
- Patients with INR greater than 6 on admission

Data source
- Hospital Reported: Submit to Keystone Data System (KDS)

Baseline period
- Returning HEN 2.0 Hospitals: 2016 Q4
- New GLPP HIIN Hospitals: 2016 Q4

Data collection period
- Monthly, beginning 2016 Q4

Hypoglycemia Due to Insulin

Determine how to easily collect this data and team up to reduce the occurrence

<table>
<thead>
<tr>
<th>Measure type</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Numerator</td>
<td>Number of patients experiencing a hypoglycemia event (e.g., plasma glucose concentration of ≤50 mg/dL)</td>
</tr>
<tr>
<td>Denominator</td>
<td>Number of inpatients receiving insulin identified as warranted</td>
</tr>
</tbody>
</table>

Exclusions
- Patients with hypoglycemia present on admission

Specifications/definitions
- Patients with multiple blood glucose levels ≤50 mg/dL or less during an admission count only once.

Datasource(s)
- Hospital Reported: Submit to MHA Keystone Data System (KDS)

Baseline period
- Returning HEN 2.0 Hospitals: 2016 Q4
- New GLPP HIIN Hospitals: 2016 Q4

Data collection period
- Monthly, beginning 2016 Q4

Opioid Overdose

Determine how to easily collect this data and team up to reduce the occurrence

<table>
<thead>
<tr>
<th>Measure type</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Numerator</td>
<td>Number of patients treated with opioids (any route) who received a reversal agent (naloxone)</td>
</tr>
<tr>
<td>Denominator</td>
<td>Number of patients who received an opioid</td>
</tr>
</tbody>
</table>

Exclusions
- Obstetric Patients, Emergency Department, and Independent Surgery Centers

Specifications/definitions
- Comprises all inpatients (exclusion OB) and Outpatient Surgery and Endoscopy (excluding Emergency Department). Multiple doses of naloxone to the same patient during a hospital stay count as one event.
- Verification of indication is not required

Data source(s)
- Hospital Reported: Submit to MHA Keystone Data System (KDS)

Baseline period
- Returning HEN 2.0 Hospitals: 2016 Q4
- New GLPP HIIN Hospitals: 2016 Q4

Data collection period
- Monthly, beginning 2016 Q4

And provide medication expertise on all other applicable HIIN clinical topics – thank you!

For resources and more information, check out: www.alliance4ptsafety.org/HIIN

Switching gears.....

If Tennessee Can Do It, So Can Illinois!

Announcing......

The ILLINOIS MEDICATION SAFETY COALITION!

For all Healthcare Providers with a passion for medication safety
IMSC’s Principles

Our Vision
An environment free of medication-related harm

Our Mission
Improving medication safety in Illinois through pharmacist-led collaboration for every patient, every time

Our Purpose
• Inspire Pharmacists’ engagement as quality improvement partners
• Collaborate to spread innovations and best practices
• Provide resources/opportunities for healthcare professionals and patients
• Instill medication safety as a top core value of the pharmacy profession in Illinois
• Recognize pharmacists as trusted leaders in medication safety

Current Initiatives & Participation Opportunities

1. Adverse Drug Event Prevention
   - Anticoagulants, Insulin, Opioids
2. Medication Safety Awareness Campaign
3. Transitions of Care: Hospital to Long-Term Care
4. Advocacy sounding board

Participation Opportunities
- Monthly conference calls
- Provide input/shape the coalition
- Speaker; project lead; best practice, guideline, resource expert/reviewer

IMSC Website
www.Alliance4PtSafety.org

Thank You!

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Patient Safety and Pharmacy Workload: One Snapshot

Scott A. Meyers, RPh, MS, FASHP
Executive Vice President

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

1. Describe how workload issues can create patient safety concerns.
2. Discuss potential solutions for workload related patient safety concerns.

The speaker has no conflicts to disclose.

Filled Without Warning
• The article appeared on the front page on Sunday, December 18th.
• 255 pharmacies visited
• 52% failed to counsel on serious interactions
• 63% of CVS pharmacists failed to counsel
• 30% of Walgreens
• 72% of independent pharmacists failed too!

Serious Combinations?
• Combinations could cause:
  – Kidney Failure
  – Stroke
  – Unexpected pregnancies with possible birth defects
• Several of the combinations are rarely seen

The Study
• “Safety laws are not being followed”
• Computer alerts don’t work or are ignored
• Pharmacies emphasize fast service over patient safety.
• Assembly-line conditions
• 30 stores from each of 7 chains
• Chicago, Indiana, Wisconsin and Michigan
• Numerous independent pharmacies

The Responses
• The Governor asked the Department of Financial and Professional Regulation to draft new patient safety rules.
  – Mandatory counseling on new prescriptions
  – Mandatory counseling on prescriptions for new patients
  – Mandatory counseling on changes to existing prescriptions:
    • Dose, frequency, route of administration
More from IDFPR

- Mandatory Counseling on prescribed OTCs
- Mandatory signage regarding patient’s rights to counseling clearly posted in every pharmacy.
- All counseling must be done by the pharmacist or student pharmacist.

From the Legislature

- HB2392 – Rep. Mary Flowers, D, Chicago
- 10 prescriptions/hour/pharmacy
- 8-hour work shift maximum per pharmacist
- Two 15-minute breaks and 30-minute meal per day
- At least one pharmacy technician on duty whenever the practice of pharmacy takes place.

HB2392 continued

- Comfortable breakroom with table and chairs on premises.
- If a break is interrupted or not provided, triple pay for the entire day.
- Any medication error must be recorded and maintained for 5 years.
- Whistleblower protection for any individual that reports violations.

Current Illinois Law

- 820 ILCS 140/3 – Every employer shall permit its employees who are to work for 7½ continuous hours or longer, except those specified in this Section, at least 20-minutes for a meal period beginning no later than 5 hours after the start of the work period.
- This Section does not apply to employees for whom meal periods are established through the collective bargaining process.

So How Do We Solve The Problem?

- Will mandatory counseling fill the gap? – Completely or partially?
- What else could be done?
- Are the limits set by HB2392 reasonable?
- What would implementation of those limits end up costing?
- Who would feel the biggest impact?

Barriers to Patient Safety

- Computer systems?
- Drive up windows?
- Pharmacy designs?
- Workload?
- Performance metrics?
- Patient expectations?
- How do we change all of these?
What did you learn today?

What are you taking back to work on in your facility?

Questions/Comments

scottm@ichpnet.org
With Great Power Comes Great Responsibility: Antimicrobial Stewardship in the Age of Super Bugs

Ashley Evans, Pharm.D.

Disclosures

- The speaker has no actual or potential conflicts of interest to disclose.

Objectives

- Define the burden of antimicrobial resistance.
- Recognize factors contributing to the development of antimicrobial resistance.
- State recommendations for antimicrobial stewardship across the continuum of care based on available data and guidelines.

Superbug:

- A pathogenic microorganism, especially a bacterium that has developed resistance to the medications normally used against it.

Annual Impact- United States

- 2 million infections
- 23,000 deaths
- $20 billion in direct healthcare costs
- $35 billion in additional costs to society

Impact

ANTIMICROBIAL RESISTANCE
CONTRIBUTING FACTORS

Bacterial Resistance Mechanisms

- Mutated or acquired bacterial genetic material
- New or altered gene products
- Functional proteins that confer antimicrobial resistance

Discovery of Antibiotic Classes

- **Beta Lactams**
- Aminoglycosides
- Cephalosporins
- Macrolides
- Glycopeptides
- Oxazolidinones
- Ansamycins
- Quinolones
- Streptogramins
- Lipopeptides

Antibiotic Use in Agriculture

Antimicrobial Use in U.S. Acute Care Hospitals
Multistate Point-Prevalence Survey of Health Care–Associated Infections

11,282 Patients (183 Hospitals)

4504 Patients Receiving ABX for Active Infection or No Documented Reason

452 Patients had at Least 1 Health Care Associated Infection


Discussion Question

• Approximately what percentage of US antibiotic expenses for humans are related to outpatient care?
  A. 20%
  B. 40%
  C. 60%
  D. 80%


Prevalence of Inappropriate Antibiotic Prescriptions Among US Ambulatory Care Visits

Ambulatory visits resulting in antibiotic prescriptions: 12.6%

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Antibiotic Prescriptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sinusitis</td>
<td>56/1000</td>
</tr>
<tr>
<td>Suppurative Otitis Media</td>
<td>47/1000</td>
</tr>
<tr>
<td>Pharyngitis</td>
<td>43/1000</td>
</tr>
<tr>
<td>Acute Respiratory Conditions (Combined)</td>
<td>221/1000</td>
</tr>
<tr>
<td>All Conditions (Combined)</td>
<td>506/1000</td>
</tr>
</tbody>
</table>

Estimated appropriate prescriptions: 363/1000


Broad-Spectrum Agents in Ambulatory Setting

Percentage of antibiotics prescribed according to antibiotic classes for adult ambulatory visits, 2007–14.

Antimicrobial Stewardship

• Improve prescribing by clinicians
• Improve use by patients
• Minimize missed or delayed diagnoses leading to underuse
• Ensure correct drug, dose, duration

Discussion Question

- In what settings have you seen antimicrobial stewardship activities?
  A. Acute Care Hospital
  B. Nursing Care Center
  C. Ambulatory Surgery Center
  D. Ambulatory Care Center

Required Antimicrobial Stewardship

- CMS Proposed Condition of Participation
  - Pending Publication
- The Joint Commission Accreditation Standard
  - Effective January 1st, 2017
- Missouri Senate Bill 579
  - Effective August 28th, 2017

What is required?

Organizational priority with budget plans
Multidisciplinary stewardship
Documentation of activities
Data collection, analysis, and reporting
Communication and collaboration on antimicrobial-use issues
Continuous improvement & strategic planning
Provider training and education
Patient and Family Education
Infection Prevention

Antimicrobial Stewardship: General Approaches

Front-End Stewardship Activity
Antimicrobial Prescription
Back-End Stewardship Activity

Infectious Disease Society of America Stewardship Guidelines

- Evidence based guideline for acute care hospitals

<table>
<thead>
<tr>
<th>Education</th>
<th>Guideline/Clinical Pathways</th>
</tr>
</thead>
<tbody>
<tr>
<td>Combination Therapy</td>
<td>Streamlining or De-escalation</td>
</tr>
<tr>
<td>Dose/Duration Optimization</td>
<td>IV to PO</td>
</tr>
<tr>
<td>Pharmacokinetic Monitoring</td>
<td>Reduce Use of Agents w/ High Risk of CDI</td>
</tr>
<tr>
<td>Routine Prescriber Review of Regimens</td>
<td>Alternative Dosing Strategies</td>
</tr>
<tr>
<td>Clinical Decision Support</td>
<td>Development of Antibiotics</td>
</tr>
<tr>
<td>Selective Susceptibility Reporting</td>
<td>Beta-Lactam Allergy Testing</td>
</tr>
<tr>
<td>Rapid Diagnostic Testing</td>
<td>Procalcitonin Testing *</td>
</tr>
</tbody>
</table>

Core Elements of Outpatient Antibiotic Stewardship

- Centers for Disease Control and Prevention
- November 2016
- Recommendations and Reports
  - Clinics, Emergency Departments, Urgent Cares, Dental Clinics

*Procalcitonin Testing is not currently recommended in the Infectious Disease Society of America Stewardship Guidelines.
Core Elements of Outpatient Antibiotic Stewardship

- Identify high priority condition(s)
- Identify barriers leading to deviations from best practices
- Establish standards for antibiotic prescribing
- Reinforce or modify strategies
- Audit and feedback
- Implement stewardship strategies


Stopping Antibiotic Overprescribing: What Works?

" Doctors already know that every antibiotic prescription increases the chances of developing resistance. But when faced with a suffering patient, they disregard concerns for the population and...

Patient Education

Prescriber Education

Reduction in Prescribing?

Denver Health Medical Center Walk-in Clinic
1-Hour Physician Education on Antibiotic Use in URIs
Posters in Clinic Exam Rooms Explaining Lack of Effectiveness of Antibiotics for Certain Diagnoses
Computer Based Patient Education (~17min)

% of Bronchitis Patients Given Antibiotics Decreased from 58% to 24%

Multiple Approaches

Behavior Modification

Baseline: Prescribing Antibiotics at 20-24% of Visits

Control Group
Alternatives suggested by e-prescribing software
11% Decline in Prescribing
16%
Not Statistically Significant

Prompt to enter justification for prescribing
18%
Statistically Significant

Periodic emails comparing prescribing rates among colleagues
16%
Not Statistically Significant

Multiple Approaches

Patient Education + Prescriber Education + Reduction in Prescribing?

9.7% reduction in prescribing rates

No significant differences between strategies

Slightly stronger effects of active clinician education

Targeting all ARIs led to a greater reduction than focusing on specific ARIs

Systematic Review of QI Strategies
Systematic Review

Medium-Strength Evidence

- Communication Skills Training
- Laboratory Testing

Patient-Centered Outcomes

- Not adversely affected
- Rarely reported

American Academy of Family Physicians Suggested Approach

Tentative Diagnosis

Determine if Antibiotic Therapy is Needed

Select Individual Agent Based On: spectrums of activity, clinical trial results, side effect profiles

When Antibiotics Are Withheld

Shared Decision Making

- Explain viral nature and lack of benefit from antibiotics
  “Negative treatment recommendations”
- Explain potential for harm from antibiotic therapy
- Empathize with patients about their symptoms
- Provide education materials
- Prescribe therapies for symptoms
  “Positive treatment recommendations”
- Contingency plan or delayed prescription

Knowledge Question

- Antimicrobial resistance leads to approximately how many infections annually in the US?
  A. 1 million
  B. 1.5 million
  C. 2 million
  D. 3 million

Knowledge Question

- In what decade was a novel class of antimicrobial agents last discovered?
  A. 1970’s
  B. 1980’s
  C. 1990’s
  D. 2000’s
Knowledge Question

- Prescribing or recommending therapies for symptom treatment in viral respiratory tract infections is an example of a:
  A. Delayed prescription
  B. Audit and feedback
  C. Negative treatment recommendation
  D. Positive treatment recommendation

Action Items

- Help educate patients and the public on when antibiotics are not appropriate.
- Provide recommendations for treatment of symptoms for viral illness.
- Review treatment guidelines and provide resources and education for prescribers.

References, continued

- Martinez J, Baquero F. Mutation Frequencies and Antibiotic Resistance. Antimicrobial Agents and
- Sanchez G, Fleming K, Roberts R, Hicks L. Core Elements of Outpatient Antibiotic Stewardship. MMWR.
  Nov 2016. 65(49):1427-1430.
- Thompson C. Antimicrobial Stewardship in Hospitals to Become National Requirement. Pharmacy News. ASHP.
- Department of Health and Human Services. Medicare and Medicaid Programs; Hospital and Critical Access
Dual Antiplatelet Therapy: What is the optimal duration?

Andrew Smith, Pharm.D., BCPS, AQ Cardiology
UMKC School of Pharmacy
TMC- Hospital Hill

Objectives

Pharmacists
• List the risks and benefits of extended duration dual antiplatelet therapy.
• Recognize a patient's risk/benefit for extended duration dual antiplatelet therapy using the DAPT score.
• Recall the optimal duration of dual antiplatelet therapy based on patient clinical parameters.

Technicians
• List the risks and benefits of extended duration dual antiplatelet therapy.
• Name the currently available antiplatelet medications.
• Describe the appropriate dosing of antiplatelet agents discussed.

Disclosure

• No conflicts of interest to disclose

Coronary Heart Disease

• Estimated 15.5 million Americans ≥ 20 years old have CHD
• Every 42 seconds an American has an MI
  – 550,000 new attacks
  – 200,000 recurrent attacks
• Average age for first MI is 65.1 years in men and 72.0 years in women

DAPT= dual antiplatelet therapy; PCI= percutaneous coronary intervention; SIHD= stable ischemic heart disease

2016 ACC/AHA Guideline Focused Update on Duration of Dual Antiplatelet Therapy in Patients With Coronary Artery Disease

J Am Coll Cardiol 2016;68:1082–115
ACC= American College of Cardiology
AHA= American Heart Association

Dual Antiplatelet Therapy

• Treatment with aspirin 81mg daily + a P2Y<sub>12</sub> inhibitor such as:
  – Clopidogrel 75mg daily
  – Ticagrelor 90mg BID
  – Prasugrel 10mg daily
• DAPT is indicated:
  – Following elective PCI for SIHD
  – Acute coronary syndrome
2016 DAPT Focused Update

Guidelines updated
- 2011 Percutaneous Coronary Intervention
- 2011 Coronary Artery Bypass Grafting Surgery
- 2012 Stable ischemic heart disease
- 2013 ST-segment elevated myocardial infarction
- 2014 Non ST-segment elevated ACS
- 2014 Perioperative cardiovascular evaluation

DAPT= dual antiplatelet therapy; ACS= acute coronary syndrome

DAPT Duration Literature

- Studies of Shorter duration DAPT (3-6 months vs. 12 months)
  - 5 RCTs following “elective” DES
- Studies of Longer duration DAPT (total 18 to 48 months)
  - 6 RCTs predominately “elective” DES
- Studies DAPT > 1 year after MI (median duration 18-33 months)
  - CHARISMA, PEGASUS TIMI 54, and DAPT study

DAPT= dual antiplatelet therapy; RCT= randomized controlled trial; DES= drug eluting stent

2016 DAPT Focused Update

Three Key Questions

1. Is 3-6 months of DAPT as effective as 12 months in patients with SIHD treated with “newer” DES?
2. Is > 12 months of DAPT more effective in patients treated with “newer” DES?
3. In patients with ACS does continuing DAPT > 12 months improve outcomes?

DAPT= dual antiplatelet therapy; SIHD= stable ischemic heart disease; DES= drug eluting stent; ACS= acute coronary syndrome

DAPT Duration

Ischemic Risk

Bleeding Risk

OPTIMAL DURATION

Shorter Duration
- Higher Ischemic Risk
- Lower Bleeding Risk

Longer Duration
- Higher Ischemic Risk
- Higher Bleeding Risk

Mortality rate

Patient Factors Associated with Increased Ischemic Risk

- Advanced Age
- Acute coronary syndrome
- Multiple prior MI
- Extensive CAD
- Diabetes mellitus
- Chronic kidney disease

Increased Risk of Stent Thrombosis

- Acute coronary syndrome
- Diabetes mellitus
- LVEF < 40%
- First generation DES
- Stent underdeployment
- Small stent diameter
- Longer stent length
- In-stent restenosis
- Bifurcation stents

Increased Ischemic Risk

Patient Factors Associated with Increased Bleeding Risk

- History of Bleeding
- Oral anticoagulant therapy
- Chronic steroid or NSAID therapy
- Female sex

- Low body weight
- Anemia
- Diabetes mellitus
- Advanced age
- CKD

NSAID= nonsteroidal anti-inflammatory drug; CKD= chronic kidney disease
Overriding Concepts of DAPT Duration

- **Patient with: ↑ Bleeding risk and ↓ Ischemic risk**: Shorter duration of DAPT
- **Patient with: ↓ Ischemic risk and ↑ Bleeding risk**: Longer duration of DAPT

Balancing Risk vs. Benefit DAPT Score

<table>
<thead>
<tr>
<th>Variable</th>
<th>Points</th>
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</thead>
<tbody>
<tr>
<td>Age ≥ 75 years</td>
<td>-2</td>
</tr>
<tr>
<td>Age 65 to &lt; 75 years</td>
<td>-1</td>
</tr>
<tr>
<td>Current cigarette smoker</td>
<td>1</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>1</td>
</tr>
<tr>
<td>MI at presentation</td>
<td>1</td>
</tr>
<tr>
<td>Prior PCI or MI</td>
<td>1</td>
</tr>
<tr>
<td>Stent diameter ≤ 3mm</td>
<td>1</td>
</tr>
<tr>
<td>Paclitaxel-eluting stent</td>
<td>1</td>
</tr>
<tr>
<td>CHF or LVEF &lt;30%</td>
<td>2</td>
</tr>
<tr>
<td>Saphenous vein graft PCI</td>
<td>2</td>
</tr>
</tbody>
</table>

- DAPT ≥ 2 risk/benefit favors extended duration
- DAPT < 2 unfavorable risk/benefit ratio

Drug Selection

**Recommendation COR LOE**

- In patients with ACS treated with DAPT (medical management or after PCI) it is reasonable to use **ticagrelor** in preference to **clopidogrel** for maintenance P2Y12 inhibitor therapy  
<table>
<thead>
<tr>
<th>CR</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>IIA</td>
<td>B-R</td>
</tr>
</tbody>
</table>

- In patients with ACS treated with DAPT after PCI who are not at high risk for bleeding complications and without a history of stroke or TIA, it is reasonable to choose **prasugrel** over **clopidogrel** for maintenance P2Y12 inhibitor therapy  
  | CR | LOE |
  | IIA | B-R |

- Prasugrel should not be administered to patients with a prior history of stroke or TIA  
  | CR | LOE |
  | III | B-R |

- In patients treated with DAPT, a daily aspirin dose of 81 mg (range, 75 mg to 100 mg) is recommended  
  | CR | LOE |
  | I   | B-NR |

- ACS=acute coronary syndrome; DAPT=dual antiplatelet therapy; PCI=percutaneous coronary intervention; TIA=transient ischemic attack

Stable Ischemic Heart Disease

**Recommendation COR LOE**

- After BMS implantation, P2Y12 inhibitor therapy (clopidogrel) should be given for a minimum of 1 month  
  | CR | LOE |
  | I   | A   |

- After DES implantation, P2Y12 inhibitor therapy (clopidogrel) should be given for at least 6 months  
  | CR | LOE |
  | I   | B-R |

- Patients who have tolerated DAPT without a bleeding complication and who are not at high bleeding risk continuation of DAPT with **clopidogrel** for longer than 1 month (BMS) or longer than 6 months (DES) may be reasonable  
  | CR | LOE |
  | IIb | A   |

- Patients who develop a high risk of bleeding, are at high risk of severe bleeding complication, or develop significant overt bleeding, discontinuation of P2Y12 inhibitor therapy after 3 months (DES) may be reasonable  
  | CR | LOE |
  | IIb | C-LD |

- Patients without prior history of ACS, coronary stent implantation, or recent (within 12 months) CABG, treatment with DAPT is not beneficial  
  | CR | LOE |
  | III | No benefit |

- BMS=bare metal stent; DES=drug eluting stent; DAPT=dual antiplatelet therapy

Acute Coronary Syndrome treated with PCI

**Recommendation COR LOE**

- After BMS or DES implantation, P2Y12 inhibitor therapy (clopidogrel, prasugrel, or ticagrelor) should be given for at least 12 months  
  | CR | LOE |
  | I   | B-R |

- Patients who have tolerated DAPT without a bleeding complication and who are not at high bleeding risk, continuation of DAPT (clopidogrel, prasugrel, or ticagrelor) for longer than 12 months may be reasonable  
  | CR | LOE |
  | IIb | A   |

- After DES implantation patients who develop a high risk of bleeding, are at high risk of severe bleeding complication, or develop significant overt bleeding, discontinuation of P2Y12 inhibitor therapy after 6 months may be reasonable  
  | CR | LOE |
  | IIb | C-LD |

- BMS=bare metal stent; DES=drug eluting stent; DAPT=dual antiplatelet therapy; PCI=percutaneous coronary intervention
Acute Coronary Syndrome treated with Medical Management

Recommendation | COR | LOE
---|---|---
Patients are managed with medical therapy alone and treated with DAPT, P2Y12 inhibitor therapy (clopidogrel or ticagrelor) should be continued for at least 12 months. | I | B-R

PPI and DAPT

Recommendation | COR | LOE
---|---|---
PPIs should be used in patients with a history of prior gastrointestinal bleeding who require DAPT. | I | C

Patient case discussion

Case #1

SS is a 67 year old female admitted for NSTEMI who went emergently to the cath lab and received a DES to her LAD artery. She received ticagrelor 180mg X1 dose and is now on 90mg PO BID. She is doing well.

Question #1

Which of the following put SS at an increased ischemic risk?

a) Acute coronary syndrome presentation
b) Age
c) Dual antiplatelet therapy
d) Female gender
e) a and b
**Question #2**

What is the minimum duration of dual antiplatelet therapy for this patient?

- a) One month
- b) 6 months
- c) 12 months
- d) 30 months

Bonus question: What therapy should this patient be on to reduce her risk of GI bleeding?

**Question #3**

SS has completed her minimum duration of DAPT without adverse events. The physician asks your opinion regarding continuing her therapy for longer. You calculate her DAPT score as 3. What is your recommendation?

- a) Continue DAPT (benefit outweighs risk)
- b) Discontinue DAPT (risk outweighs benefit)

**Case #2**

SL is a 71 year old man with stable ischemic heart disease undergoing an elective PCI for progressive angina. He receives a BMS in his RCA and is started on prasugrel 10mg daily. He is preparing for discharge and you are doing his discharge medication reconciliation.

**Question #1**

You identify that prasugrel is NOT appropriate for patients following an elective PCI. What is the appropriate P2Y12 inhibitor and dose?

- a) Clopidogrel 75mg PO daily
- b) Clopidogrel 75mg PO BID
- c) Ticagrelor 60mg PO BID
- d) Ticagrelor 90mg PO BID

**Conclusion**

- DAPT is critical following PCI and in patients with ACS
- DAPT duration can range from 1-36 months depending on patient parameters
  - Shorter duration → ↓ bleeding but ↑ ischemic risk
  - Longer duration → ↓ ischemic risk but ↑ bleeding
- The DAPT score is a useful tool to evaluate risks vs. benefit
- Pharmacists can play a critical role in evaluating patients for DAPT duration
Questions

Andrew Smith, Pharm.D. BCPS (AQ Cardiology)
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816-235-5286
Dual Antiplatelet Therapy: What is the optimal duration?

Assessment Questions

Andrew Smith, Pharm.D., BCPS (AQ Cardiology)

Pharmacist Questions:

1. Extended duration of dual antiplatelet therapy would be expected to cause a:
   a. Decreased risk of bleeding with a decreased ischemic risk
   b. Decreased risk of bleeding with an increase ischemic risk
   c. Increase risk of bleeding with a decreased ischemic risk
   d. Increase risk of bleeding with no change in ischemic risk

2. Which of the following DAPT scores would indicate an **UNFAVORABLE** risk/benefit ratio to continue dual antiplatelet therapy for an extended duration?
   a. 1
   b. 2
   c. 3
   d. 4

3. A patient received a drug eluting stent during an elective percutaneous coronary intervention (PCI), what is the minimum duration of dual antiplatelet therapy for this patient?
   a. One month
   b. Six months
   c. Twelve months
   d. Thirty months

Answers: C, A, B
Dual Antiplatelet Therapy: What is the optimal duration?

Assessment Questions

Andrew Smith, Pharm.D., BCPS (AQ Cardiology)

Technician questions:

1. Extended duration of dual antiplatelet therapy would be expected to cause a:
   a. Decreased risk of bleeding with a decreased ischemic risk
   b. Decreased risk of bleeding with an increase ischemic risk
   c. Increase risk of bleeding with a decreased ischemic risk
   d. Increase risk of bleeding with no change in ischemic risk

2. Which of the following is **NOT** an antiplatelet medication?
   a. Clopidogrel
   b. Lisinopril
   c. Prasugrel
   d. Ticagrelor

3. Which of the following is the correct dosing for clopidogrel?
   a. Clopidogrel 10mg PO daily
   b. Clopidogrel 60mg PO BID
   c. Clopidogrel 75mg PO daily
   d. Clopidogrel 90mg PO BID

Answers: c, b, c
Objectives

• Define the effect chronic pain has on patients and health care providers
• Describe the different treatment options for chronic pain
• Explain the impact of the Centers for Disease Control’s recommendations regarding chronic pain management

Disclosure

• The speaker has no financial conflicts of interest
• Off label indications will be discussed and will be highlighted when done

Practice Site

• Family Medical Care Center
• Level 3 Patient Centered Medical Home
  – Diabetes, Depression, & Chronic Pain
• Cox Family Medicine Residency

Chronic Pain Definition\(^1,2\)

• In reference to non-cancer pain
  – Nociceptive, neuropathic, or mixed
  – Predominantly musculoskeletal pain conditions
• Variable definitions but generally lasts > 3-6 months or past the time of normal tissue healing

Chronic Pain Prevalence\(^3\)

• 11.2% Americans had daily pain according to a 2012 study
• Top 3 Most Common Disability Diagnoses:
  – Low back pain
  – Other musculoskeletal disorders
  – Neck pain
Types of Chronic Pain

- Osteoarthritis
- Rheumatoid Arthritis
- Neuropathy
- Complex Regional Pain Syndrome
- Gout
- Fibromyalgia

Chronic Pain Impact on Patients

- Estimated economic impact of pain from direct medical costs and loss of productive time ranges from $560-635 billion every year
  - Direct cost is $261-300 billion

Chronic Pain's Impact on Emotional State

- Depression
- Fear
- Anger
- Anxiety

Chronic Pain Impact on Providers

- Most clinicians have not been well trained in pain management
- Many quality metrics and reimbursements are based on patient satisfaction
- Many providers don’t feel comfortable prescribing long-term opioids

Chronic Pain Management Guides

- Various individual pain syndromes and patient population guidelines

Question

- What must be included in chronic pain management?
  A. Active patient engagement
  B. Interdisciplinary care
  C. Whole person care
  D. Multiple treatment approaches
Question

- What is the goal of any treatment?
  A. Be cured of chronic pain completely
  B. Return to a functional level
  C. Have a pain score of 0
  D. Improve pain score by 1

Question

- How many approaches are there to manage pain outside of medications?
  A. 1-5
  B. 6-10
  C. 11-15
  D. 16-20
  E. > 20

Active Patient Interventions

- Exercise
  - Pilates
  - Gyrotonics
  - Functional training
  - Tai Chi
  - Pilates
  - Feldenkrais
  - Postural retraining
  - Alexander technique

- Education
  - Education of expectations is key

- Relaxation
  - Graded motor imagery
  - Art & Music
  - Pet therapy

Passive Therapies & Physical Modalities

- Hyperbaric Oxygen
- Acupuncture
- Manipulation & Mobilization
- Electrical Stimulation
- Trigger Point Injections

Psychological & Behavioral Approaches

- Cognitive behavioral therapy to overcome negative beliefs
  - Somatic
  - Disability
  - Medication dependence
  - Catastrophic

- Mind-body interventions
  - Mindfulness-based stress reduction
  - Guided imagery
  - Biofeedback
  - Hypnosis

- Social support
  - Loved ones
  - Support groups
  - Healthcare providers

Invasive Interventions

- Intra-articular steroid injections
- Viscosupplementation
- Spinal cord stimulation
- Implanted targeted intrathecal drug delivery systems (pain pumps)
- Epidurals, nerve and facet blocks, and radiofrequency ablation
Other Considerations

- Sleep hygiene
- Alcohol avoidance
- Smoking cessation
- Avoid illicit substances

Medications

- Non-opioid pain relievers
- Antiarrhythmics
- Herbal medicine, supplements, & vitamins
- Antiepileptics
- Antidepressants
- Topical agents
- Muscle relaxants
- Opioids

Over-The-Counter (OTC) Relievers

<table>
<thead>
<tr>
<th>Name</th>
<th>Normal Dosing</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen</td>
<td>325-1000 mg every 4-6 hours as needed</td>
<td>MAX 3000 mg/day</td>
</tr>
<tr>
<td>Aspirin</td>
<td>325-1000 mg every 4-6 hours as needed</td>
<td>MAX 3900 mg/day</td>
</tr>
<tr>
<td>Ibuprofen</td>
<td>200-800 mg every 4-6 hours as needed</td>
<td>MAX 3200 mg/day</td>
</tr>
<tr>
<td>Naproxen</td>
<td>250-500 mg twice daily</td>
<td>MAX 1000-1500 mg/day</td>
</tr>
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</table>

NSAIDS: Increased risk of cardiovascular disease in patients with risk factors or prior history

Non-opioid Relievers

<table>
<thead>
<tr>
<th>Name</th>
<th>Dosing</th>
<th>Comments</th>
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<tbody>
<tr>
<td>Naproxen</td>
<td>100-400 mg daily</td>
<td>OFF-LABEL</td>
</tr>
<tr>
<td>Diclofenac</td>
<td>18-35 mg 3 times daily</td>
<td>OFF-LABEL</td>
</tr>
<tr>
<td>Ketorolac</td>
<td>10 mg every 4-6 hours as needed</td>
<td>MAX 40 mg/day x 5 days</td>
</tr>
<tr>
<td>Nabumetone</td>
<td>1000-2000 mg 1-2 times daily</td>
<td>OFF-LABEL</td>
</tr>
</tbody>
</table>

Beers criteria: all have potential to be inappropriate in older adults

Herbal Supplements

<table>
<thead>
<tr>
<th>Name</th>
<th>Dosing</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>White Willow Bark (Salix)</td>
<td>Various</td>
<td>OFF-LABEL</td>
</tr>
<tr>
<td>Devil’s Claw Root</td>
<td>1.5-3 g 3 times daily</td>
<td>OFF-LABEL</td>
</tr>
<tr>
<td>Alpha lipoic acid</td>
<td>200-600 mg 1-2 times daily</td>
<td>OFF-LABEL</td>
</tr>
<tr>
<td>Acetyl-L-carnitine</td>
<td>500-1000 mg/day</td>
<td>OFF-LABEL</td>
</tr>
<tr>
<td>Glucosamine/chondroitin</td>
<td>800-1200 mg 1-2 times/day/1500 mg/day</td>
<td>OFF-LABEL</td>
</tr>
<tr>
<td>Curcumin (Turmeric)</td>
<td>1.5-3 g daily</td>
<td>OFF-LABEL</td>
</tr>
<tr>
<td>Vitamins B &amp; D supplementation</td>
<td>Varies on extent of deficiency</td>
<td>OFF-LABEL</td>
</tr>
</tbody>
</table>

Medical Foods

- Metanx®
  - Targeted for neuropathy
- Theramine®
  - Targeted for pain and inflammation
- Limbrel®
  - Targeted for osteoarthritis
### Antidepressants²,⁶,⁷

<table>
<thead>
<tr>
<th>Class</th>
<th>Dosing</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tricyclic Antidepressants (TCAs)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Amitriptyline</td>
<td>25-150 mg at bedtime</td>
<td>Beers criteria; OFF-LABEL</td>
</tr>
<tr>
<td>- Doxepin</td>
<td>25-300 mg at bedtime</td>
<td></td>
</tr>
<tr>
<td>- Imipramine</td>
<td>100-150 mg at bedtime</td>
<td></td>
</tr>
<tr>
<td>- Desipramine</td>
<td>25-150 mg at bedtime</td>
<td></td>
</tr>
<tr>
<td>- Nortriptyline</td>
<td>10-150 mg at bedtime</td>
<td></td>
</tr>
<tr>
<td>Selective Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs)</td>
<td>30-60 mg/day</td>
<td></td>
</tr>
<tr>
<td>- Duloxetine</td>
<td>50 mg twice daily</td>
<td></td>
</tr>
<tr>
<td>- Milnacipran</td>
<td>15 mg twice daily</td>
<td></td>
</tr>
<tr>
<td>- Venlafaxine extended-release</td>
<td>17.5-225 mg daily</td>
<td>OFF-LABEL</td>
</tr>
</tbody>
</table>

### Antiepiletics²

<table>
<thead>
<tr>
<th>Name</th>
<th>Dosing</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbamazepine</td>
<td>200-1200 mg/day</td>
<td>Attempts to reduce the dose should be made at least once every 3 months to minimize side effects</td>
</tr>
<tr>
<td>Gabapentin</td>
<td>300-2400 mg/day</td>
<td>Abuse potential***</td>
</tr>
<tr>
<td>Pregabalin</td>
<td>150-450 mg/day</td>
<td>Controlled med</td>
</tr>
</tbody>
</table>

### Antiarrhythmics²

<table>
<thead>
<tr>
<th>Name</th>
<th>Dosing</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mexiletine²</td>
<td>600 mg/day</td>
<td>OFF-LABEL</td>
</tr>
<tr>
<td>Flecainide¹¹</td>
<td>50-100 mg twice daily</td>
<td>OFF-LABEL</td>
</tr>
</tbody>
</table>

### Topical Agents²,⁶,⁷

<table>
<thead>
<tr>
<th>Name</th>
<th>Dosing</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lidocaine/prilocaine</td>
<td>Applied to affected area daily</td>
<td>OFF-LABEL</td>
</tr>
<tr>
<td>Lidocaine patch</td>
<td>On for 12 hours, then off for 12 hours</td>
<td>Can place up to 3 patches simultaneously</td>
</tr>
<tr>
<td>Compounds</td>
<td>Multiple times per day</td>
<td>Various prescription products combined into one product but often not covered by insurances</td>
</tr>
</tbody>
</table>

### Muscle Relaxants²,⁶

<table>
<thead>
<tr>
<th>Name</th>
<th>Dosing</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carisoprodol</td>
<td>250-350 mg 4 times daily</td>
<td></td>
</tr>
<tr>
<td>Cyclobenzapine</td>
<td>5-10 mg 3 times daily or 15-30 mg at bedtime</td>
<td></td>
</tr>
<tr>
<td>Methocarbamid</td>
<td>4000 mg/day</td>
<td></td>
</tr>
<tr>
<td>Chlorzoxazone</td>
<td>500-750 mg 3 times daily</td>
<td></td>
</tr>
<tr>
<td>Orphenadrine</td>
<td>100 mg twice daily</td>
<td></td>
</tr>
<tr>
<td>Tizanidine</td>
<td>Up to 36 mg/day</td>
<td>Shouldn’t have as much tolerance develop so can be used for longer durations</td>
</tr>
<tr>
<td>Baclofen</td>
<td>Up to 80 mg/day</td>
<td></td>
</tr>
</tbody>
</table>

### Other Medications²,⁶

<table>
<thead>
<tr>
<th>Name</th>
<th>Dosing</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clonidine²</td>
<td>75-150 mg/day</td>
<td>OFF-LABEL</td>
</tr>
<tr>
<td>Botulinum toxins</td>
<td>Varies by the product</td>
<td>Migraine, spasticity</td>
</tr>
<tr>
<td>Memantine</td>
<td>10-30 mg/day</td>
<td></td>
</tr>
<tr>
<td>Dextromethorphan</td>
<td>40-450 mg/day</td>
<td></td>
</tr>
<tr>
<td>Naltrexone¹⁴</td>
<td>4.5 mg daily</td>
<td>Opioid dependence</td>
</tr>
</tbody>
</table>

---

²: References: 2, 6, 7

¹¹: OFF-LABEL

***: Abuse potential

---

ICHMP/MSHP 2017 SPRING MEETING
### Short Acting Opioids

<table>
<thead>
<tr>
<th>Name</th>
<th>Dosing</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Codeine</td>
<td>15-60 mg every 4 hours as needed</td>
<td></td>
</tr>
<tr>
<td>Oxycodone (+APAP combination)</td>
<td>5-15 mg every 4-6 hours as needed</td>
<td></td>
</tr>
<tr>
<td>Oxycodone (+ASA combination)</td>
<td>2.5-10 mg/325-650 mg every 6 hours as needed</td>
<td></td>
</tr>
<tr>
<td>Hydrocodone (+APAP combination)</td>
<td>4.8 mg/325 mg every 6 hours as needed</td>
<td></td>
</tr>
<tr>
<td>Tramadol</td>
<td>100-400 mg up to 4 times daily as needed</td>
<td>ODT product available</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>2-4 mg every 4-6 hours as needed</td>
<td></td>
</tr>
<tr>
<td>Oxycontin</td>
<td>25-100 mg every 4-6 hours as needed</td>
<td></td>
</tr>
<tr>
<td>Tapentadol</td>
<td>50-100 mg every 4-6 hours as needed</td>
<td></td>
</tr>
</tbody>
</table>

**Sustained-Release and Long Acting Opioids**

**For opioid tolerant patients only***

<table>
<thead>
<tr>
<th>Name</th>
<th>Dosing</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morphine - Avinza®, Kadian®, Morphabond™, MS Contin® - Arvyrom™</td>
<td>30+ mg every 24 hours</td>
<td></td>
</tr>
<tr>
<td>Oxycodone - X tampaz™, Oxy Contin® - Manipulon®</td>
<td>9+ mg every 12 hours</td>
<td>MANIPULATION RESISTANT</td>
</tr>
<tr>
<td>Oxymorphone</td>
<td>5+ mg every 12 hours</td>
<td></td>
</tr>
<tr>
<td>Hydrocodone - Vantrela™, Zohydror®</td>
<td>15+ mg every 12 hours</td>
<td></td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>8+ mg every 24 hours</td>
<td></td>
</tr>
<tr>
<td>Fentanyl</td>
<td>12+ mcg every 72 hours Transdermal</td>
<td></td>
</tr>
<tr>
<td>Tapentadol</td>
<td>50-250 mg every 12 hours</td>
<td></td>
</tr>
<tr>
<td>Methadone</td>
<td>2.5-10+ mg every 8-12 hours</td>
<td></td>
</tr>
</tbody>
</table>

### Opioid Adverse Effects

- Nausea
- Vomiting
- Constipation
- Thirst
- Fatigue
- Insomnia
- Irritability
- Hypersalivation
- Cough
- Respiratory depression
- Respiratory distress
- Prolonged Q-T interval
- Cardiac arrhythmias

### Question: Match Opioid Terms to Definitions

<table>
<thead>
<tr>
<th>Terms</th>
<th>Definitions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opioid-responsiveness</td>
<td>Need to increase when other factors are present</td>
</tr>
<tr>
<td>Addiction</td>
<td>Signs of discomfort when abruptly stopped</td>
</tr>
<tr>
<td>Physical Dependence</td>
<td>Developed as part of addiction</td>
</tr>
<tr>
<td>Withdrawal</td>
<td>Effects diminishes over time</td>
</tr>
<tr>
<td>Tolerance</td>
<td>Ability to achieve pain relief</td>
</tr>
<tr>
<td>Pseudotolerance</td>
<td>Pathologically pursuing response</td>
</tr>
<tr>
<td>Drug Misuse</td>
<td>Other than prescribed</td>
</tr>
<tr>
<td>Diversion</td>
<td>Incorrect use of medications</td>
</tr>
</tbody>
</table>

### Opioid Monitoring

8 A’s

- Prescription Drug Monitoring Programs (PDMPs)
- Opioid treatment agreements
- Urine drug tests (UDTs)

### Opioid Outcomes

- US counts for 4.6% of global population but used 69% of opioid supply in 2014
  - Opioid prescriptions ≠ opioid-related deaths
  - 28,647 deaths were related to opioids
    - 61% of all drug overdose death
    - 18,893 deaths were due to prescription opioids
- Risk Evaluation and Mitigation Strategies (REMS)
Naloxone

**INTRANASAL**

<table>
<thead>
<tr>
<th>Formulations</th>
<th>INTRAMUSCULAR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 mg/ml. Luer-Jet™ Luer-Lock needleless syringe; Nalox® 4 mg</td>
<td>0.4 mg/ml single-use 1 mL vial or 10 mL multi-dose vial; Eziject™ auto-injector 0.4 mg</td>
</tr>
<tr>
<td>Directions</td>
<td></td>
</tr>
<tr>
<td>Spray 1 mL, half of the syringe into each nostril</td>
<td>Inject 1 mL, in shoulder or thigh</td>
</tr>
<tr>
<td>Nalox® contents of one device (4 mg) into one nostril</td>
<td>Ezio: 0.4 mg SUCQ or IM in the thigh</td>
</tr>
<tr>
<td>Repeat after 3 minutes if no or minimal response.</td>
<td>Repeat after 3 minutes if no or minimal response.</td>
</tr>
<tr>
<td>Cost</td>
<td></td>
</tr>
<tr>
<td>Nalox® $25.50</td>
<td>Single use vial: $80</td>
</tr>
<tr>
<td>Nalox® ($150 2 units)</td>
<td>Eziject™: $$$$</td>
</tr>
</tbody>
</table>

Copy cards available for commercial insurance patients. Nalox® has a program for cash paying patient.

---

**Question**

- Which of the following is a valid resource for naloxone?
  A. Harm Reduction Coalition
  B. National Institute of Health: National Institute of Drug Abuse
  C. Opioid Overdose Prevention Kit
  D. Evzio™ and Narcan® websites

---

**Guidelines for Prescribing Opioids**

- Centers for Disease Control and Prevention’s (CDC) Guideline for Prescribing Opioids for Chronic Pain (2016)

---

**Washington Post-Kaiser Family Foundation National Poll of Long-Term Opioid Users (n=809)**

- 92% Feel their opioids make a significant difference in reducing pain at least somewhat well
- 53% opioids reducing pain very well
- 57% Report improved quality of life with opioid
- 20% Report a negative impact on mental health
  - 20% positive impact
  - 60% no difference

---

**CDC’s Key Clinical Questions**

- Effectiveness of long-term opioid therapy
- Risks of opioids
- Comparative effectiveness of opioid dosing strategies
- Accuracy of instruments for predicting opioid overdose, addiction, abuse, or misuse
- Effects of prescribing opioid therapy
**CDC Guideline Highlights**

- Opioids are not first-line therapy
- Establish goals for pain and function
- Discuss risks and benefits

**ASIPP Objectives**

- To provide guidance for the prescription of opioids for the management of chronic non-cancer pain
- To develop a consistent philosophy among many diverse groups with an interest in opioid use as to how appropriately prescribe opioids
- To improve the treatment of chronic non-cancer pain
- To reduce the likelihood of drug abuse and diversion

**ASIPP Summary of Recommendations**

### Initial Steps of Opioid Therapy
- Comprehensive assessment and documentation
- Screening for opioid abuse to identify opioid abusers
- Utilization of prescription drug monitoring programs
- Utilization of urine drug testing
- Establish appropriate physical diagnosis and psychological diagnosis if available
- Consider appropriate imaging, physical diagnosis, and psychological status to collaborate with subjective complaints
- Establish medical necessity based on average moderate to severe pain and/or disability
- Stratify patients based on risk
- Establish treatment goals of opioid therapy with regard to pain relief and improvement in function
- Obtain a robust opioid agreement, which is followed by all parties

### Assessment of Effectiveness of Long-Term Opioid Therapy
- Initiate opioid therapy with low dose, short-acting drugs with appropriate monitoring
- Consider up to 40 morphine milligram equivalent (MME) as low dose, 41-90 MME as moderate dose, and >91 MME as high dose
- Avoid long-acting opioids for the initiation of opioid therapy
- Recommend methadone only for use after failure of other opioid therapy and only by clinicians with specific training in its risks and uses, within FDA recommended doses
- Understand and educate the patients of the effectiveness and adverse consequences of long-acting opioids
- Similar effectiveness for long-acting opioids and short-acting opioids with increased adverse consequences of long-acting opioids
- Periodically assess pain relief and/or functional status improvement of >30% without adverse consequences
- Recommend long-acting or high dose opioids only in specific circumstances with severe intractable pain

### Monitoring for Adherence and Side Effects
- Monitor for adherence, abuse, and noncompliance by UDT and PDMPs
- Monitor patients on methadone with an electrocardiogram periodically
- Monitor for side effects including constipation and manage them appropriately, including discontinuation of opioids when indicated

### Final Phase
- May continue with monitoring with continued medical necessity, with appropriate outcomes
- Discontinue opioid therapy for lack of response, adverse consequences, and abuse with rehabilitation

**Question**

- What is not in common between the CDC and ASIPP recommendation?
  A. Avoid combining opioids and benzodiazepine
  B. Review PDMPs and UDTs
  C. Start with low-dose opioids
  D. Screen for abuse
Summary

- Different chronic pain syndromes plague millions of Americans
- There are several options including passive, active, invasive, and medication therapies
- National organizations like CDC and ASIPP have provided several key guidance statements in prescribing opioids for chronic pain

References

Methicillin-Resistant 
*Staphylococcus aureus*  
Nasal Swabs as a Tool in Antimicrobial Stewardship

Natalie R. Tucker, PharmD  
Antimicrobial Stewardship Pharmacist  
Tyson E. Dietrich, PharmD  
PGY2 Infectious Diseases Pharmacy Resident  
HSHS St. John’s Hospital

**Disclosures**

- N. Tucker: No actual or potential conflicts of interest to disclose  
- T. Dietrich: No actual or potential conflicts of interest to disclose  
- May be discussing off-label uses

---

**Objectives: Pharmacists**

- Identify patients at risk and recommended empiric therapies for MRSA pneumonia  
- Discuss the relationship between MRSA nasal swabs and MRSA pneumonia  
- Explain how using MRSA nasal swabs can be a beneficial tool in antimicrobial stewardship

---

**Objectives: Technicians**

- Describe the impact of MRSA pneumonia on patient care  
- Explain the purpose of using MRSA nasal swabs  
- Discuss the benefits of decreasing unnecessary vancomycin use

---

**Terminology**

- CAP = community acquired pneumonia  
- HAP = hospital acquired pneumonia  
- HCAP = healthcare associated pneumonia  
- VAP = ventilator associated pneumonia  
- MSSA = methicillin-susceptible *Staphylococcus aureus*  
- MRSA = methicillin-resistant *Staphylococcus aureus*  
- ICU = intensive care unit  
- MDR = multidrug resistant  
- PCR = polymerase chain reaction  
- PPV = positive predictive value  
- NPV = negative predictive value

---

**Evidence Behind MRSA Nasal Swabs in Predicting MRSA Pneumonia**
Significance of MRSA Pneumonia

- MRSA accounts for:
  - 20-40% of HAP & VAP, with 56% mortality
  - 27% of HCAP, with 20% mortality
- Increase in annual incidence of MRSA causing HAP & VAP:
  - 2008: 11.3 cases per 100,000 patient days
  - 2012: 15.5 cases per 100,000 patients days
- National prevalence survey reported 4.1% MRSA colonization in inpatients

Risk Factors for MDR Pathogens: 2016

<table>
<thead>
<tr>
<th>MDR HAP</th>
<th>MDR VAP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior IV antibiotics within 90 days</td>
<td>Prior IV antibiotics within 90 days</td>
</tr>
<tr>
<td>Septic shock at time of diagnosis</td>
<td>Septic shock at time of diagnosis</td>
</tr>
<tr>
<td>Acute respiratory distress syndrome preceding diagnosis</td>
<td>Acute respiratory distress syndrome preceding diagnosis</td>
</tr>
<tr>
<td>Hospitalization ≥ 5 days prior to diagnosis</td>
<td>Hospitalization ≥ 5 days prior to diagnosis</td>
</tr>
<tr>
<td>Acute renal replacement therapy prior to onset</td>
<td>Acute renal replacement therapy prior to onset</td>
</tr>
</tbody>
</table>

Empiric Treatment for MRSA

- Vancomycin
- Linezolid
- Strong recommendation, moderate quality evidence
Patient Case

• DW is a 67 year old male
  — Chronic obstructive pulmonary disease
  — End-stage renal disease on hemodialysis
• Presents with shortness of breath, productive cough with purulent sputum, and fever
• Recently prescribed oral azithromycin for bronchitis

Patient Case

• Chest x-ray with diffuse infiltrates
• Admitted with septic shock & pneumonia

<table>
<thead>
<tr>
<th>Tmax</th>
<th>RR</th>
<th>BP</th>
<th>HR</th>
<th>WBC</th>
<th>Scr</th>
<th>Lactate</th>
</tr>
</thead>
<tbody>
<tr>
<td>39.6</td>
<td>26</td>
<td>72/44</td>
<td>112</td>
<td>17.6</td>
<td>4.6</td>
<td>4.6</td>
</tr>
</tbody>
</table>

Assessment

Which of the following would indicate that DW requires empiric therapy for MRSA?

A. COPD  
B. Septic shock  
C. Hemodialysis  
D. Oral azithromycin within 90 days

Patient Case, cont.

• Upon admission, DW receives a nasal swab to screen for MRSA colonization

Current Use of MRSA Nasal Swabs

FDA Indication
• Detect MRSA colonization

Illinois Law
• MRSA Screening and Reporting Act

HSHS St. John’s Hospital Policy
• Screen on ICU admission

Chromogenic Agar

• Qualitative test for detection of MRSA
• Selective agents in agar suppress growth of all non-MRSA organisms
• Results in 18 – 24 hours
PCR Screening

- Qualitative diagnostic test for detection of MRSA DNA from nasal swabs in patients at risk for nasal colonization
- Uses PCR for MRSA DNA amplification and detection
- Results in 3 hours

Predictive Value of Screening

<table>
<thead>
<tr>
<th>Study Type</th>
<th>Chan 2012</th>
<th>Rimawi 2014</th>
<th>Dangerfield 2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objective</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interventions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patients</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Results</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Limitations</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Active MRSA Surveillance in ICU Patients with VAP

<table>
<thead>
<tr>
<th>Study Type</th>
<th>Prospective observational study in 388 VAP patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objective</td>
<td>Determine performance characteristics of active surveillance cultures as predictors of MRSA VAP</td>
</tr>
<tr>
<td>Intervention</td>
<td>Cultures on ICU admission, every 7 days, &amp; on ICU discharge: Nares, oropharynx, or trachea &amp; open wounds</td>
</tr>
<tr>
<td>Patients</td>
<td>Median days to VAP: 6; Mean days hospitalization: 39.4; MRSA colonization: 14%</td>
</tr>
<tr>
<td>Results</td>
<td>PPV: 48.1%; Sensitivity: 70.3%; NPV: 96.7%; Specificity: 92%</td>
</tr>
<tr>
<td>Limitations</td>
<td>VAP diagnostic criteria; Chromogenic agar</td>
</tr>
</tbody>
</table>

Negative PCR may not Rule Out MRSA Pneumonia?

<table>
<thead>
<tr>
<th>Study Type</th>
<th>Retrospective review in 275 MICU patients with pneumonia, 165 with MRSA pneumonia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objective</td>
<td>Investigate data on MRSA pneumonia in patients with MRSA nasal colonization</td>
</tr>
<tr>
<td>Patients</td>
<td>HCAP: 86%; CAP: 14%; MRSA colonization: 45%</td>
</tr>
<tr>
<td>Results</td>
<td>PPV: 97.4%; NPV: 54.3%</td>
</tr>
<tr>
<td>Limitations</td>
<td>No hospital-acquired pneumonias; High prevalence of MRSA CAP (17%) &amp; MRSA colonization</td>
</tr>
</tbody>
</table>

Putting the MRSA Nasal Swab to Work

<table>
<thead>
<tr>
<th>Study Type</th>
<th>Retrospective cohort of 435 confirmed pneumonia patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objective</td>
<td>Describe diagnostic characteristics of MRSA PCR in predicting culture-confirmed MRSA pneumonia</td>
</tr>
<tr>
<td>Intervention</td>
<td>MRSA PCR nasal swab</td>
</tr>
<tr>
<td>Patients</td>
<td>HCAP: 54.7%; CAP: 34.3%; HAP/VAP: 11%; ICU: 41.6%; MRSA colonization: 14.3%</td>
</tr>
<tr>
<td>Results</td>
<td>PPV: 35.4%; Sensitivity: 88%; NPV: 99.2%; Specificity: 90.1%</td>
</tr>
<tr>
<td>Limitations</td>
<td>Mix of sputum, BAL, &amp; blood cultures; MRSA PCR not standard of care at institution; May have larger immunocompromised population</td>
</tr>
</tbody>
</table>

A Not-So-Good Study

<table>
<thead>
<tr>
<th>Study Type</th>
<th>Retrospective study of 72 patients with MRSA nasal PCR + lower respiratory tract sample with S. aureus</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objective</td>
<td>Determine if absence of MRSA nasal colonization can predict absence of MRSA in lower respiratory tract secretions</td>
</tr>
<tr>
<td>Patients</td>
<td>ICU: 68.1%; Mortality: 30.6%; MRSA colonization: 38.9%</td>
</tr>
<tr>
<td>Results</td>
<td>PPV: 93.3%; Sensitivity: 93.3%; NPV: 95.2%; Specificity: 95.2%; 2 (4.8%) patients with negative PCR and positive cultures</td>
</tr>
<tr>
<td>Limitations</td>
<td>Excluded hospital acquired pneumonias; High MRSA colonization; High mortality not explained</td>
</tr>
</tbody>
</table>
HCAP & CAP Data

**Study Type**
Retrospective cohort of 165 MICU patients

**Objective**
Correlation between MRSA nasal swab and MRSA lower respiratory tract infection

**Intervention**
Nasal swab + respiratory culture within 24 hours of admission

**Patients**
HCAP risk factor(s): 44.8% CAP: 55.2%
MRSA colonization: 17%

**Results**
PPV: 28.6% Sensitivity: 80% NPV: 98.5%
2 (1.2%) patients with negative swab and positive cultures

**Limitations**
No hospital acquired pneumonias


More HCAP & CAP Data

**Study Type**
Retrospective cohort of 200 ICU & intermediate care patients with clinically confirmed pneumonia

**Objective**
Concordance between nasal PCR and respiratory cultures

**Patients**
CAP: 52.5% HCAP: 44% HAP/VAP: 3.5%
MRSA colonization: 27.5%

**Results**
PPV: 34.5% Sensitivity: 90.5% NPV: 98.6%
2 (1.4%) patients with negative swab and positive cultures
2 potentially preventable antibiotic days of therapy per patient

**Limitations**
Few nosocomial pneumonias


The Latest Data

**Study Type**
Retrospective study of 400 ICU patients with nosocomial pneumonia

**Objective**
Determine diagnostic performance characteristics of MRSA nasal PCR for prediction of MRSA pneumonia in critically ill

**Intervention**
Inservice presentations to ICU providers regarding MRSA nasal PCR as antimicrobial stewardship tool

**Patients**
HAP: 18% HCAP: 54% VAP: 28%
MRSA colonization: 22.8%

**Results**
PPV: 37.36% Sensitivity: 91.89% NPV: 99.03% Specificity: 84.3%
After 4th culture, NPV = 87.5%
Vancomycin de-escalated based on negative MRSA PCR: 42%


Summary of Trials

<table>
<thead>
<tr>
<th></th>
<th>PPV</th>
<th>NPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chan et al.</td>
<td>48.1%</td>
<td>96.7%</td>
</tr>
<tr>
<td>Rimawi et al.</td>
<td>97.4%</td>
<td>54.3%</td>
</tr>
<tr>
<td>Dangerfield et al.</td>
<td>35.4%</td>
<td>99.2%</td>
</tr>
<tr>
<td>Johnson et al.</td>
<td>93.3%</td>
<td>95.2%</td>
</tr>
<tr>
<td>Tilahun et al.</td>
<td>28.6%</td>
<td>98.5%</td>
</tr>
<tr>
<td>Giancola et al.</td>
<td>34.5%</td>
<td>98.6%</td>
</tr>
<tr>
<td>Smith et al.</td>
<td>37.4%</td>
<td>99%</td>
</tr>
</tbody>
</table>


Risks of Unnecessary Vancomycin

- Vancomycin resistance (ex: VRE)
- Nephrotoxicity
- Adverse reactions
- Trough monitoring & costs

Patient Case, cont.

- Upon admission, DW received a nasal swab to screen for MRSA colonization
- On day 2, DW’s MRSA nasal swab returns as negative
- On day 3, DW is much improved
- Sputum culture grows normal flora

Assessment

Based on DW’s improving condition and negative MRSA nasal swab, which of the following would you recommend?

A. Addition of second anti-MRSA agent
B. Continue current therapy
C. Convert to oral vancomycin
D. Discontinue vancomycin

Evidence Summary

• Majority of data in ICU patients with HCAP and CAP
• Negative MRSA nasal swabs show high NPV for MRSA pneumonia
  – Potential to use as antimicrobial stewardship tool

Impact of provider education on methicillin-resistant Staphylococcus aureus nasal swabs and antibiotic de-escalation

Tyson E. Dietrich, PharmD; Natalie R. Tucker, PharmD; Alexis L. Kasniunas, PharmD; Brandi D. Strader, PharmD, BCPS

Study Site

• HSHS St. John’s Hospital
  – Regional acute care medical center
  – Springfield, IL

• 38 Bed ICU
  – Closed unit
  – Providers ➔ physicians/nurse practitioner/pharmacists(n=10)

Purpose

Evaluate the impact of MRSA nasal swabs as an antimicrobial stewardship instrument to assist with the de-escalation of empiric vancomycin coverage in the ICU

Study Design

• Quasi-experimental pilot study
  – Initial phase
    • Pre-education electronic medical record review
      – November 1, 2014 to February 28, 2015
  – Intervention phase
    • Education of ICU providers
      – November 2016
  – Final phase
    • Post-education electronic medical record review
      – December 1, 2016 to February 28, 2017
Patient Criteria

Inclusion
- ≥18 years of age
- ICU patients
- Confirmed pneumonia
- MRSA nasal swab within 48 hours of ICU admission
- Vancomycin use
- *HSHS provider overseeing the care of the patient

Exclusion
- Concomitant infections requiring MRSA coverage
- Pregnancy

*Retrospective evaluated all ICU providers from Southern Illinois University and Springfield Clinic.

Outcomes

• Primary
  - Time to de-escalation of empiric vancomycin therapy

• Secondary
  - PPV and NPV of MRSA PCR
  - Development of MRSA pneumonia
  - Provider acceptance
  - Mortality

Provider Education

• Impact can vary depending on delivery
  - Ex. Didactic vs. interactive

• Davis et al.
  - Using both interactive and didactic methods were associated with a positive effect on practice
  - SES = 0.67 (95% CI, 0.01-1.45)

Education Intervention

• Comprehensive and summary handout

• Background
  - HAP/VAP 2016 guidelines
  - NPV/PPV of MRSA nasal PCR
  - De-escalation

• Small group
  - 10-15 minutes
  - 1:1 or 1:2

Statistics

• Descriptive
• Inferential
  - Two tailed t-test
• Power analysis
  - 80% power = 17 patients per group
• P-value ≤ 0.05

Results
Patient Selection

<table>
<thead>
<tr>
<th>Pre-education</th>
<th>Post-education</th>
</tr>
</thead>
<tbody>
<tr>
<td>53 patients identified</td>
<td>51 patients identified</td>
</tr>
</tbody>
</table>

Exclusions:
- Other infection (n = 15)
- No swab (n = 3)
- Vancomycin after MRSA PCR (n = 3)
- No ICU provider (n = 3)
- Vancomycin started post ICU (n = 3)

- Not HSHS provider (n = 24)
- Other infection (n = 4)
- Pre-operative/one time dose (n = 6)
- Vancomycin started post ICU (n = 2)

17 patients evaluated
14 patients evaluated

Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Pre-education (n = 17)</th>
<th>Post-education (n = 14)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median Age, years (IQR)</td>
<td>65 (51-81)</td>
<td>67 (60-72)</td>
<td>0.456</td>
</tr>
<tr>
<td>Male</td>
<td>11 (65%)</td>
<td>8 (57%)</td>
<td>0.679</td>
</tr>
<tr>
<td>Median APACHE II (IQR)</td>
<td>19 (16-22)</td>
<td>20 (12-23)</td>
<td>0.653</td>
</tr>
<tr>
<td>Underlying Lung Disease</td>
<td>7 (41%)</td>
<td>10 (71%)</td>
<td>0.098</td>
</tr>
<tr>
<td>History of MRSA</td>
<td>1 (6%)</td>
<td>1 (7%)</td>
<td>0.892</td>
</tr>
<tr>
<td>Mechanical Ventilation</td>
<td>13 (76%)</td>
<td>8 (57%)</td>
<td>0.474</td>
</tr>
<tr>
<td>HSHS Provider</td>
<td>5 (29%)</td>
<td>14 (100%)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Pneumonia Classification
- CAP 5 (29%)
- HCAP 7 (41%)
- HAP 4 (24%)
- VAP 1 (6%)

<table>
<thead>
<tr>
<th>Pneumonia Classification</th>
<th>Pre-education (n = 17)</th>
<th>Post-education (n = 14)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAP</td>
<td>5 (29%)</td>
<td>7 (50%)</td>
<td>0.456</td>
</tr>
<tr>
<td>HCAP</td>
<td>7 (41%)</td>
<td>5 (36%)</td>
<td>0.256</td>
</tr>
<tr>
<td>HAP</td>
<td>4 (24%)</td>
<td>2 (14%)</td>
<td>0.533</td>
</tr>
<tr>
<td>VAP</td>
<td>1 (6%)</td>
<td>0 (0%)</td>
<td>0.373</td>
</tr>
</tbody>
</table>

Median Time to PCR Collection (min)
- Pre-education: 0 (0-12)
- Post-education: 0 (0)

Median Time to PCR Result (hours)
- Pre-education: 22 (11-26)
- Post-education: 14 (10-20)

P-value: 0.257

Excluding Outliers

Median Hours of MRSA Coverage After Swab Result (IQR)
- Pre-education: 147 (72-186)
- Post-education: 48 (36-110)

P-value: 0.044

Time to De-escalation

<table>
<thead>
<tr>
<th>Time</th>
<th>Pre-education (n = 17)</th>
<th>Post-education (n = 14)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median Hours of MRSA Coverage After Swab Result (IQR)</td>
<td>101 (49-178)</td>
<td>38 (23-59)</td>
<td>0.054</td>
</tr>
<tr>
<td>Median Hours of MRSA Coverage (IQR)</td>
<td>168 (72-202)</td>
<td>48 (35-99)</td>
<td>0.023</td>
</tr>
</tbody>
</table>

Excluding Outliers

Median Hours of MRSA Coverage After Swab Result (IQR)
- Pre-education: 85 (48-151)
- Post-education: 38 (24-65)

P-value: 0.106

Predictive Value of MRSA Nasal Swab for MRSA Pneumonia

<table>
<thead>
<tr>
<th>Predictive Value</th>
<th>Retrospective (n=15)</th>
<th>Prospective (n=10)</th>
<th>Combined (n=25)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive (%)</td>
<td>95</td>
<td>8</td>
<td>95</td>
</tr>
<tr>
<td>Negative (%)</td>
<td>10</td>
<td>92</td>
<td>10</td>
</tr>
</tbody>
</table>

Provider Surveys

- To gage interest/involvement
- Initial
  - Given immediately after education
- Follow-up
  - Given 1 month after education
- Responses
  - Strongly agree - agree - neutral - disagree - strongly disagree

Provider Acceptance - Survey 1

- Found the information regarding MRSA nasal swabs as a de-escalation tool useful
  - Agreed
- Comfortable with implementing MRSA nasal swab in my practice
  - Agreed
- Will be implementing MRSA nasal swab in my practice
  - Agreed
- Already incorporated the use MRSA nasal swabs into my current practice
  - Neutral
- Typically wait for cultures to be finalized before de-escalation
  - Agreed
Provider Acceptance - Survey 2

• Using the education provided to help with de-escalation
  – Agreed

• Comfortable with implementing MRSA nasal swab in my practice
  – Agreed

Mortality and Development of MRSA Pneumonia

• No patient in either group developed MRSA pneumonia post de-escalation

• Mortality
  – 11/17 (65%) pre-education vs. 2/14 (14%) post-education (p=0.003)

Assessment Question

TH was admitted to your ICU 48 hours ago for respiratory failure and suspected pneumonia. His MRSA nasal swab is positive and cultures are still pending.

True or False

Based on his MRSA PCR result, antibiotics should continue because he will likely have MRSA pneumonia.

Limitations

• Differing provider groups
• Single center
  – Limits external validity
• Low patient numbers
• Potential for bias
• New guidelines
  – 2016 HAP/VAP guidelines

Conclusion

• Consistent with literature
  – PPV = 50%
  – NPV = 96%
• No development of MRSA pneumonia after de-escalation
• High provider acceptance
• MRSA nasal swabs can play a significant role in de-escalation

Future Implications

• Growth of MRSA nasal swab use
  – NOT just in “high risk” patients
  – Pharmacist interventions

• Expansion of education

• Continued data collection
  – Cost analysis
  – Patient harm
Methicillin-Resistant 
*Staphylococcus aureus* 
Nasal Swabs as a Tool in 
Antimicrobial Stewardship

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Tyson Dietrich, PharmD  
tyson.dietrich@hshs.org
Patient Safety for Pharmacy Technicians

Presenters:
- Grant Florer, PharmD
- Cora Housley, PharmD
- Sarah Cook, PharmD

Faculty Disclosure

- Dr. Grant Florer has nothing to disclose
- Dr. Cora Housley has nothing to disclose
- Dr. Sarah Cook has nothing to disclose

Learning Objectives

- Describe common technician roles and responsibilities related to medication safety
- Identify common errors or problems, challenges, and practices encountered by technicians that lead to medication errors
- Review medication safety best practices for pharmacy technicians
- List medication safety best practice principles that minimize poor outcomes

Introduction

- Pharmacy technicians play a major role in modern pharmacy practice
- As front-line staff, technicians play a crucial role in patient safety
- Patient safety includes identifying and preventing medication errors

Defining a Medication Error

- “A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.”

The Emily Jerry Story

- Emily Jerry was diagnosed with a yolk sac tumor at the age of a year-and-a-half old
- After chemotherapy treatment Emily’s tumor disappeared
- Physicians recommended to do one final three day round of chemotherapy to make sure there was no residual cancer cells remaining
- The pharmacy ran out of standard bags of 0.9% sodium chloride
What Happened Next?

- The pharmacy technician filled an empty bag with hypertonic saline vials and used that as the base solution.
- The pharmacy technician thought that she was doing the right thing: the concentration of that bag was 23.4%.
- Emily was found unconscious with little to no brain activity on the EEG.
- The decision was made to take Emily off of life support.


Medication Error Categorization

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Circumstances exist for potential errors to occur</td>
</tr>
<tr>
<td>B</td>
<td>An error occurred but did not reach the patient</td>
</tr>
<tr>
<td>C</td>
<td>Error reached the patient but did not cause harm</td>
</tr>
<tr>
<td>D</td>
<td>Patient monitoring required to determine lack of harm</td>
</tr>
<tr>
<td>E</td>
<td>Error caused temporary harm and some intervention</td>
</tr>
<tr>
<td>F</td>
<td>Temporary harm with initial or prolonged hospitalization</td>
</tr>
<tr>
<td>G</td>
<td>Error resulted in permanent patient harm</td>
</tr>
<tr>
<td>H</td>
<td>Error required intervention to sustain the patient's life</td>
</tr>
<tr>
<td>I</td>
<td>Error contributed to the patient's death</td>
</tr>
</tbody>
</table>


Learning Assessment #1

- Pharmacy technicians have a critical role in identifying and preventing medications errors
  A. True
  B. False

Opportunities for Error

- Automated dispensing cabinets
- Expiration dates
- Compounding
- Drug labeling/packaging
- Environmental factors
- Low-quality processes
- Continual approval of new drugs

Automated Dispensing Cabinets Filling Errors

- A common cause of drug errors in the hospital setting
- Employ vigilance during fills
- Suggest system factors to ensure stocking accuracy

Expiration Dates

- Prevention of deteriorated medication errors through:
  - Appropriate storage
  - Expiration date vigilance
Medication Quality Error

- Performing a basic visual examination when compounding or packaging medications
  - Correct color, texture, or consistency


Drug Labeling and Packaging

- 29% of dispensing errors due to incorrect medication
- Look-alike/sound-alike
- Labeling similarities
- Confirmation bias
  - Seeing what you expect to see
  - Not recognizing differences

Examples

Labeling Similarities

Sound-Alike

Environmental Factors

- Interruptions
- High workload
- Staffing levels
- Confined or cluttered spaces
- Poor lighting
- Noise

Less Obvious Environmental Factors

- Uncomfortable temperature
- Working while ill
- Unclear workflow
- Not taking breaks (i.e. lunch)
- Substitute/PRN staff
- Short staffing (vacations, call-ins)

Workload Errors

- Study of pharmacy staff
- Increased error rate during periods of low workload, compared to periods of high workload
  - Especially when going from a period of high volume to low
  - Boredom
  - Distraction
  - Lack of focus

The “Perfect Storm” of Environmental Factors

Bob is a technician who usually works retail full time, but today he is picking up an additional PRN shift at the hospital despite not feeling well. The hospital is renovating their IV room to be compliant with USP 797, so a temporary IV glove box is jammed into a hot, poorly ventilated, poorly lit closet right next to the loud construction. The hospital had a second technician call in sick, so Bob is now working in the IV room for the first time in months. Workload in the IV room is very high and Bob skips his lunch break and volunteers.

Low Quality Processes

- Lack of safety checks
- Poorly utilized technology – Incentivizes workarounds if not properly managed
- Inefficient workflow
- Lack of clear responsibilities

Focus on the System, not the Individual

- Humans are not perfect
- System failures allow opportunity for human error
- Redesign systems and processes that led to the error
- Recognize when you are working under high risk conditions
- Adopt best practices and guidelines

New Drugs

- There is continual approval of new drugs
- Take responsibility to assure you have the proper training to handle the materials you work with

Learning Assessment #2

Please match the following situations with their respective opportunity for error:

1. Sound a-like/look a-like drugs
   A. Double-checks (pharmacist check technician)
   B. Distinct packaging/distinct placement in pharmacy
   C. Adequate staffing (finding someone to cover your shift if you have to step away)

2. Compounded medications

3. High work load

Objective 3

Review medication safety best practices for pharmacy technicians
Drug Storage

- Areas must be thermostatically controlled within the temperature requirement(s) provided by the manufacturer or the latest edition of the United States Pharmacopeia (USP)
- Daily refrigerator and temperature logs/recordings must be completed and maintained

Storage Temperatures

- Frozen
  - -25°C to -10°C
- Refrigerated
  - 2°C to 8°C

Room Temperature Medications

- Room temperature: 20°C to 25°C
  - AKA: ambient temperature
  - Excursions from 15°C to 30°C remain compliant

Why Room Temperature?

- Unless otherwise stated by product labels, the majority of medications are stable and may be stored at room temperature
- Some agents are only stable under room temperature
  - Many creams/ointments

Considerations for Room Temperature Medications

- Keep in non-humid areas
- Avoid areas with direct sunlight exposure
- Keep thermometers in different areas where medications are being stored

Ways to Prevent Med Errors

1. Separate look-alike, sound-alike medications
   a. 33% of all medication errors
   Ex) hydrALAZINE vs. hydrOXYzine

A full list of confused drug names available through ISMP
Ways to Prevent Med Errors

2. Avoid organizing meds with similar packaging or labeling appearances in the same area

3. Segregate high-risk medications

<table>
<thead>
<tr>
<th>ISMP High Risk Medications in Acute Care Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epinephrine (subQ)</td>
</tr>
<tr>
<td>Mg sulfate injection</td>
</tr>
<tr>
<td>Opium tincture</td>
</tr>
<tr>
<td>Nitroprusside injection</td>
</tr>
<tr>
<td>K phosphate injection</td>
</tr>
<tr>
<td>Vasopressin (IV or IO)</td>
</tr>
</tbody>
</table>

High-risk medication classes: antithrombotics, antiarrhythmics, anesthetics, sedation agents, opioids/narcotics, neuromuscular blocking agent, TPNs

Learning Assessment #3

Which of the following statements regarding medication safety best practices is incorrect?

A. Daily refrigerator & temperature logs must be maintained
B. Medications stored at ambient temperatures may have excursions from 10°C to 35°C and remain compliant
C. Separating look-alike/sound-alike medications may reduce medication errors
D. Separating high-risk medications such as anticoagulants and opioids may reduce medication errors

Objective 4

List medication safety best practice principles that minimize poor outcomes

Labeling to Prevent Improper Storage

- Refrigerator/freezer items should be placed in a clearly labeled bag
- Refrigerator/freezer bulk or compounded items must have a sticker on the item or patient label

Preparing Improper Storage of Checked Medications

- Sort refrigerator, freezer, and room temperature items into separate marked bins
  - Place bin into the appropriate location until delivery to the floor
- Checked medications should be sorted into appropriate bins in a timely manner
Preventing Improper Storage of Returned Medications

- Returns should be immediately placed into marked return bins
- Bins should be placed in the appropriate storage location until the return can be completed

Utilizing Inspections to Prevent Improper Storage

- Required medication storage area inspections provide an optimal time to confirm check medications are being stored appropriately

Learning Assessment #4

Think – Pair - Share

- Your labeling practices for refrigerated, freezer, and room temperature items
- How your institution separates refrigerator, freezer, and room temperature items

Guide to Vaccine Storage: The Storage Units

- Use a dedicated refrigerator or freezer.
  - Post “Do Not Unplug” sign
- Optimal Temps for Vaccines:
  - Refrigerated: 40°F
  - Frozen: -58°F to 5°F
- Use water bottles or ice packs to keep the temperature consistent

Guide to Vaccine Storage: The Vaccines

- Unpack shipments immediately
- Place vaccines that expire first in front
- Keep in original boxes to protect from light
- Organize by vaccine type
Learning Assessment #5

Think – Pair - Share

• Your labeling practices that ensure proper storage of vaccines
• What temperature monitoring and tracking system you use and who monitors the refrigerator and freezer

Guide to Vaccine Storage Monitoring

• Temperature probe in center of unit
• Record twice a day:
  – Temperature
  – Date
  – Time
  – Initials
• Visually inspect for misplaced items
• Report/investigate out of range temperatures

Guide to Vaccine Storage Summary

• Each vaccine has specific storage requirements.
• Vaccine storage requires dedicated refrigerators/freezers.
• Vaccines stored incorrectly may not be usable.
• Storage temperature should be manually checked twice a day.

Questions?
A Tale of Two Specialty Pharmacies: Novel Models for Technician Incorporation

Renee Advincula, PharmD
Interim Manager, Specialty Pharmacy Services
Northwestern Medicine Specialty Pharmacy

Helen Sweiss, PharmD Candidate 2018
University of Illinois Hospital & Health Sciences System
Specialty Pharmacy Services, Prior Authorization Specialist

April 1, 2017

Disclosures

• The speakers have no actual or potential conflict of interest to the content of this presentation.

Objectives

1. Describe a specialty pharmacy setting and what classifies a medication as “specialty”.
2. Explain the model and function of two specialty pharmacies in an urban setting.
3. Describe technician roles within a specialty pharmacy practice setting.
4. List general challenges specialty pharmacies face, as well as technician-specific challenges.

What is Specialty Pharmacy?

<table>
<thead>
<tr>
<th>Average cost per prescription</th>
<th>Traditional Pharmacy</th>
<th>Specialty Pharmacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>$&lt;100</td>
<td>Diabetes</td>
<td>Multiple Sclerosis</td>
</tr>
<tr>
<td></td>
<td>Blood Pressure</td>
<td>Oncology</td>
</tr>
<tr>
<td></td>
<td>Pain/Inflammation</td>
<td>Hepatitis C</td>
</tr>
<tr>
<td></td>
<td>Heart Disease</td>
<td>Rheumatoid Arthritis</td>
</tr>
<tr>
<td></td>
<td>Asthma</td>
<td>Crohn’s Disease</td>
</tr>
<tr>
<td></td>
<td>Depression</td>
<td>Hemophilia</td>
</tr>
</tbody>
</table>

Examples of Diseases Treated

What Are Specialty Medications?

• Typically identified by their high cost and the complex disease states targeted
• Prescribed by a specialist
• Requires special handling
• Unique distribution management
• High touch/intense patient supervision

What Are Specialty Medications?

Traditional Prescriptions: Average cost per prescription*

<table>
<thead>
<tr>
<th></th>
<th>Diabetes</th>
<th>Pain</th>
<th>High Cholesterol</th>
<th>High Blood Pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$94.21</td>
<td>$38.36</td>
<td>$29.78</td>
<td>$10.48</td>
</tr>
</tbody>
</table>

Specialty Prescriptions: Average cost per prescription

<table>
<thead>
<tr>
<th></th>
<th>Hepatitis C</th>
<th>Cancer</th>
<th>Inflammatory Conditions</th>
<th>HIV</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$25,000</td>
<td>$6,100</td>
<td>$4,800</td>
<td>$1,800</td>
</tr>
</tbody>
</table>

Why is Specialty Pharmacy Important?

The Best Selling Drugs in the World

2014 Sales in Billions

<table>
<thead>
<tr>
<th>Drug</th>
<th>Sales (in Billions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Humira</td>
<td>$12.54</td>
</tr>
<tr>
<td>Sovaldi</td>
<td>$10.28</td>
</tr>
<tr>
<td>Remicade</td>
<td>$9.24</td>
</tr>
<tr>
<td>Rituxan</td>
<td>$8.68</td>
</tr>
<tr>
<td>Enbrel</td>
<td>$6.54</td>
</tr>
<tr>
<td>Lantus</td>
<td>$7.28</td>
</tr>
<tr>
<td>Avadex</td>
<td>$6.96</td>
</tr>
<tr>
<td>Humaclept</td>
<td>$6.19</td>
</tr>
<tr>
<td>Advair</td>
<td>$4.43</td>
</tr>
<tr>
<td>Creon</td>
<td>$5.67</td>
</tr>
</tbody>
</table>

Data Source: Genetics Engineering & Biotechnology News

Access to Specialty Medications is a Complex Process

Patients and clinical providers have to navigate this process on their own

Roles of Pharmacy Technician

<table>
<thead>
<tr>
<th>Role</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provide IT support</td>
<td>44%</td>
</tr>
<tr>
<td>Provide support for quality improvement</td>
<td>21%</td>
</tr>
<tr>
<td>Recept checking tech</td>
<td>18%</td>
</tr>
<tr>
<td>Dispension tasks</td>
<td>69%</td>
</tr>
<tr>
<td>Initiation of medication reconciliation</td>
<td>11%</td>
</tr>
</tbody>
</table>

Increase in demand for pharmacy technicians

- Increase in prescription volume
- Expanded access to healthcare
- Greater role in pharmacy operations

Employment:

- 2014: 372,500
- 2024: 407,200


ROLE OF THE PHARMACY TECHNICIAN
What does this look like for you?

<table>
<thead>
<tr>
<th>State</th>
<th>Employment</th>
<th>Employment per thousand jobs</th>
</tr>
</thead>
<tbody>
<tr>
<td>California</td>
<td>33,010</td>
<td>2.13</td>
</tr>
<tr>
<td>Texas</td>
<td>32,000</td>
<td>2.76</td>
</tr>
<tr>
<td>Florida</td>
<td>26,200</td>
<td>3.31</td>
</tr>
<tr>
<td>Illinois</td>
<td>19,160</td>
<td>3.27</td>
</tr>
<tr>
<td>New York</td>
<td>17,720</td>
<td>1.97</td>
</tr>
</tbody>
</table>

Practice Advancement Initiative (PAI)

- ASHP’s practice advancement initiative – formerly the Pharmacy Practice Model Initiative (PPMI)
- Partnership of ASHP and the ASHP foundation aims to integrate pharmacists into the healthcare team and capitalize on the expertise of pharmacy technicians to advance practice

Northwestern Medicine Specialty Pharmacy

With NM Specialty Pharmacy, all providers and information become connected and centered around the patient.

Impact on Clinic Practice

Making the prescribing process as easy as possible

- NM Specialty Pharmacy team takes care of the details
  - Pharmacy team delivers a quality clinical connection to ensure smooth transition from clinic to home
  - Timely prior authorization and patient assistance program enrollment
- Extension of the patient care team
  - Dedicated team gives a direct point of contact for specialty pharmacy services
  - Comprehensive patient education and specialized therapy management
  - Ongoing follow up and management of patients by pharmacy staff
  - Side effect management, adherence coaching
  - Coordinated refills
Overview of Specialty Medication Management Program

Prescriber e-prescribes prescription/s to "NW Medicine Specialty Pharmacy"

NM Specialty Pharmacist: assesses patient specific parameters for fulfillment: indication, labs, dose, drug interactions

Patient Care Advocate obtains prior authorization, patient assistance programs, and co-pay cards and documents in EHR and works with patient, pharmacist and healthcare team

Patient receives initial education and is introduced to specialty pharmacy services by NM Specialty Pharmacist within 24-48h after clinic visit (documents in EHR)

Medication is delivered to bedside, home, or clinic

Patient receives a follow up phone call from a NM Specialty Pharmacist within one week of starting therapy

Patient is contacted by Patient Care Advocate to coordinate refills monthly and monitors for side effects or adherence issues. Issues identified are triaged to the NM Specialty Pharmacist/clinic staff as appropriate.

Role of Pharmacy Technicians and Student Pharmacists

- Access
  - Referrals/benefit verification
  - Prior authorizations
  - Medication assistance
  - Scheduling and delivery
  - Cold chain shipping

- Clinical
  - Monthly clinical assessments

University of Illinois Hospital and Health Sciences System (‘UI Health’) Specialty Pharmacy Services

‘Layered Learning’ Practice Model

- A model designed to enhance pharmaceutical care delivery to patients
- Promotes the Practice Advancement Initiative (PAI)
- Transforms traditional clinical pharmacy practice by incorporating a layered fashion of learning among pharmacists, residents, and students

Coverage of Specialty Medications

- Prior Authorization:
  - A step that the prescription benefit plan requires for some medications before they pay for the medication
  - A cost-saving step for the insurance company to assist in ensuring the medication prescribed is appropriate for the patient
  - Prevents improper prescribing

- It is crucial to determine coverage and conduct benefit verification which includes getting an approval for prior authorization BEFORE starting the patient on a specialty medication
What Do Prior Authorizations Mean To Pharmacies?

- Medication will not be processed and filled if the prior authorization step is not completed and approved
- Someone in the pharmacy has to communicate to the doctor’s office that a prior is needed
- Patient has to wait in getting their medication until the prior is approved
- There is a chance that a prior authorization may be denied
- If denied, the doctor’s office can appeal the denial

Specialty Technician Challenges

Issues may arise at each step of the Specialty Pharmacy Service workflow

Prior Authorization Process of First Request

- Initiate PA
- Submit to Insurance
- Benefit Verification
- PA Approved
- PA Denied
- Initiate Appeal Process

Specialty Pharmacy Technician Challenges

- Pharmacy Benefit Determination
  - Determining Pharmacy benefit vs. Medical Benefit
- In-Network vs. Out-of-Network Patients
- Formulary Changes
  - Insurance specific changes in medication on formulary
- Prior Authorization Denial & Appeal
  - Quarterly changes in Insurance Criteria
- Prior Authorization Management
  - Coordination of expiring prior authorizations and renewal process
- Training and Clinical Support

Case #1

On October 19, 2016, you receive a new referral from the liver clinic for Zepatier + RBV 16 week treatment. BM is a Medicare Part D – Medicaid Dual patient. Upon calling Medicaid, you are informed that his United Healthcare Medicare Part D plan is not effective until November 1, 2016. What is your next step of action?

A. Initiate Prior Authorization and submit to insurance immediately
B. Wait until November 1st to submit the prior authorization
C. Do not submit any forms since the patient has no active coverage at this time
D. Both B & C
Case #2
- You are a technician in SPS and receive a referral for BW for a 12 week treatment of Harvoni 90mg/400mg tablets. A few days after submitting a prior authorization to BW’s pharmacy insurance, you receive a denial. What are some possible reasons for this denial?

Initiate PA and Submit to Insurance
PA Denied
Initiate Appeal Process

Case #3
BM is currently in week 8 of Zepatier + RBV treatment and switched insurance to CVS Caremark as of January 1, 2017. SPS submitted a prior authorization to CVS Caremark on January 5, 2017. Patient verbally understood situation and had enough medication until January 11, 2017. On January 9, 2017, you receive a denial letter from CVS Caremark stating the following:

BM is at risk of interruption of therapy. What is your next plan of action?
A. Submit an appeal with a letter of medical necessity STAT
B. Submit Merck Access Program Enrollment form to prevent interruption of therapy
C. Reach out to Medication Assistance Program (MAP)
D. All of the above

Initiate PA and Submit to Insurance
PA Denied
Initiate Appeal Process
Prior Authorization
Process of First Request

Pharmacy Technician’s Role
Financial Assistance
- Trained to navigate through complicated process of obtaining financial assistance
  - Gathering financial paperwork for submission to:
    - patient assistance network
    - disease state financial assistance foundations
    - free medication program through pharmaceutical company
  - Submission and follow up (may take at least 2 weeks to receive response)

Challenges: Financial Assistance
- Patients who have insurance, but have a high copay
  - Have an income that surpasses minimum requirements
- Medicare/Medicaid patients who are not eligible for patient assistance through copay cards foundations
- Pharmacy technicians are well trained to navigate through these barriers and communicates with clinical team/patient every step of the way

Challenges: Specialty Pharmacies
- Access to limited distribution drugs
- Contracting through pharmacy benefit managers and pharmaceutical manufacturers
- Accreditation
- Marketing to physician groups for prescription capture

Specialty Pharmacy & Pharmacy Technician Roles
- NM and UI Health are two health systems with one goal in mind: optimal patient care
- Pharmacy technicians play a vital role in the pharmacy practice setting to help patients navigate through the complex process of obtaining specialty medications
Acknowledgements

- Travis Hunerdosse, Director, NM Specialty Pharmacy
- JoAnn Stubbings, Assistant Director, Specialty Pharmacy Services, University of Illinois at Chicago College of Pharmacy
- Nehrin Khamo, Clinical Pharmacist, Team Lead, Managed Care Services (Specialty & Mail Order), University of Illinois at Chicago, Ambulatory Care Pharmacy Services College of Pharmacy

References

- The consensus of the Pharmacy Practice Model Summit. Am J Health-Syst Pharm. 2011;68:1148-52
Disclosures

• I have no conflicts of interest to disclose.

Learning Objective

• Identify and analyze patient specific characteristics to determine eligibility for nonionic iodinated contrast media in patients undergoing cardiac catheterization procedures.

Background

• Iodinated contrast agents (ICA) are used for opacification of vascular structures in cardiac catheterization procedures¹
  – Visipaque™ (Iodixanol)
  – Omnipaque™ (Iohexol)

• Clinical challenge of ICAs = nephrotoxicity
  – Contrast-Induced Nephrotoxicity (CIN)
  – Post-Contrast Acute Kidney Injury (PC-AKI)

• Visipaque™ (Iodixanol)²
  – Iso-osmolar contrast media (IOCM)
  – Osmolarity of 280 mOsm/L
  – 3-5x more expensive than Omnipaque™
  – Historically used more at Southeast Hospital

• Omnipaque™ (Iohexol)³
  – Low-osmolar contrast media (LOCM)
  – Osmolarity varying from 290-860 mOsm/L
  – Injections into peripheral arteries can be painful with increased osmolality⁴
**Background**

- **Safety** – No evidence strongly supports a serum creatinine (SCr) or estimated glomerular filtration rate (eGFR) level to avoid LOCM 4-6
- AHA/ACC and KDIGO7-8
  - CKD patients may have ↑ risk CIN
    - eGFR < 60 mL/min/1.73m² = IOCM
- The American College of Radiology (ACR)4
  - If a threshold has to be chosen for ↑ risk CIN
    - eGFR < 30 mL/min/1.73m² = IOCM

**Purpose**

- **Primary**
  - Apply a screening tool to identify and quantify patients that could have safely and appropriately received Omnipaque™ (iohexol) over Visipaque™ (iodixanol)
- **Secondary**
  - Calculate estimated annual cost savings after applying screening tool
  - Determine overall volume of ICA used and wasted

**Methods**

- Single center, retrospective chart review
- 100 randomly chosen patients who received ICA
  - January 1, 2016 to June 30, 2016
- Screening tool – two exclusion criteria for receiving Omnipaque™ (iohexol)
  1. eGFR < 30 mL/min/1.73m²
  2. Peripheral procedure

**Results**

<table>
<thead>
<tr>
<th>Demographics</th>
<th>n=100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (mean, range)</td>
<td>64, 54-73</td>
</tr>
<tr>
<td>&lt;65 years</td>
<td>54</td>
</tr>
<tr>
<td>≥65 years</td>
<td>46</td>
</tr>
<tr>
<td>Male</td>
<td>58</td>
</tr>
<tr>
<td>Female</td>
<td>42</td>
</tr>
<tr>
<td>White</td>
<td>90</td>
</tr>
<tr>
<td>Black</td>
<td>9</td>
</tr>
<tr>
<td>Asian</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Procedural Characteristics</th>
<th>n=100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central procedure</td>
<td>94</td>
</tr>
<tr>
<td>Peripheral procedure</td>
<td>6</td>
</tr>
<tr>
<td>eGFR ≥30</td>
<td>97</td>
</tr>
<tr>
<td>eGFR &lt;30</td>
<td>3</td>
</tr>
</tbody>
</table>

**Visipaque™ Usage In Cardiac Catheterization Procedures (6 months vs. Study Population)**

<table>
<thead>
<tr>
<th>Visipaque™ size</th>
<th>Number of Vials (n=765)</th>
<th>Number of Vials (n=100)</th>
</tr>
</thead>
<tbody>
<tr>
<td>200 mL</td>
<td>869</td>
<td>101</td>
</tr>
<tr>
<td>100 mL</td>
<td>122</td>
<td>2</td>
</tr>
<tr>
<td>50 mL</td>
<td>162</td>
<td>5</td>
</tr>
</tbody>
</table>

**Visipaque™ Usage (n=100)**

<table>
<thead>
<tr>
<th>Volume (mL)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Total dispensed</td>
<td>20750</td>
</tr>
<tr>
<td>Total used</td>
<td>10680 (51.5%)</td>
</tr>
<tr>
<td>Total wasted</td>
<td>10070 (48.5%)</td>
</tr>
</tbody>
</table>
**Results**

**Volume of Visipaque™ Used vs. Wasted**

- **Used**: 320
- **Wasted**: 170

<table>
<thead>
<tr>
<th>Volume (mL)</th>
<th>Average</th>
<th>Median</th>
<th>Maximum</th>
<th>Minimum</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>50</td>
<td>100</td>
<td>150</td>
<td>200</td>
</tr>
</tbody>
</table>

**Annual Estimated Amount and Cost of ICAs ± Screening Tool**

<table>
<thead>
<tr>
<th>Pricing: 40% GPO and 60% 340B</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ICA</strong></td>
</tr>
<tr>
<td>Visipaque™</td>
</tr>
<tr>
<td><strong>(-) Screening Tool</strong></td>
</tr>
<tr>
<td><strong>(+) Screening Tool</strong></td>
</tr>
<tr>
<td>Omnipaque™</td>
</tr>
<tr>
<td><strong>Total Cost ICAs</strong></td>
</tr>
<tr>
<td><strong>Cost Savings</strong></td>
</tr>
</tbody>
</table>

**Limitations**

- Data collected retrospectively
- Small sample size (n=100) vs. procedures performed annually (>1500)
- Estimated cost savings is based on study sample - percentage of patients who qualify for LOCM or IOCM may vary
- Estimated percentage of cases qualifying for GPO and 340B pricing may vary annually

**Conclusion**

- **With screening tool:**
  - ~90% patients could receive Omnipaque™
    - Eligible for Omnipaque™ = 91 patients
    - Eligible for Visipaque™ = 9 patients
  - ~70% cost savings for ICAs
    - (-) screening tool - Visipaque™ ~$110,000/year
    - (+) screening tool – ICAs ~$32,000/year
- **Implementation of a screening tool before procedures is beneficial and can decrease cost of ICAs**

**Future Implications**

- Application of screening tool
- Monitoring of ICA usage
  - Omnipaque™ vs. Visipaque™
  - Vial size (50 mL, 100 mL, 200 mL)
- Education for staff
  - Screening tool
  - Potential cost savings
  - Using smaller vials first to avoid waste

**Question**

Which of the following choices is the correct exclusion criteria for avoiding use of Omnipaque™ (iohexol) in cardiac catheterization procedures?

A. Central procedure and eGFR <60
B. Central procedure and eGFR <30
C. Peripheral procedure and eGFR <60
D. Peripheral procedure and eGFR<30
Insulin Portfolio Consolidation in an Academic Medical Center

Tony Huke, Pharm.D., BCPS
Melissa Gabriel, Pharm.D., BCPS
Susan Lewis, Pharm.D. Candidate
Allison Dodson, CPhT
Travis Myer, CPhT

Insulin is a Safety Risk!

• On the Institute for Safe Medical Practices (ISMP) High Alert Medications

Highlighted recommendations from the ISMP Safety Alert from February 21st 2013
A Clinical Reminder About The Safe Use Of Insulin Vials

• Dosing errors are common
  – Do not assume that all healthcare professionals are knowledgeable and skilled when it comes to measuring doses and recognizing doses that exceed safe limits

Learning Objective

• Identify increased safety and cost reduction opportunities through the consolidation of a health-system's insulin portfolio.

Questions?

References

Highlighted recommendations from the ISMP Safety Alert from February 21st 2013
A Clinical Reminder About The Safe Use Of Insulin Vials

• Dispense from pharmacy
  – To preserve an independent double-check, wherever possible, pharmacy should prepare, label, and dispense patient-specific insulin doses in insulin syringes, particularly for basal and other long-acting insulin

Highlighted recommendations from the ISMP Safety Alert from February 21st 2013
A Clinical Reminder About The Safe Use Of Insulin Vials

• Look-alike vials
  – ISMP still receives reports of serious mix-ups between insulin types and concentrations, and between insulin and other medications in similar-looking vials

Highlighted recommendations from the ISMP Safety Alert from February 21st 2013
A Clinical Reminder About The Safe Use Of Insulin Vials

• Stock the smallest vials
  – Consider stocking patient care units that require rapid-acting insulin with 3 mL vials of insulin to reduce the risk of catastrophic dosing errors

Highlighted recommendations from the ISMP Safety Alert from February 21st 2013
A Clinical Reminder About The Safe Use Of Insulin Vials

• Separate and verify drugs
  – If insulin vials are stored in ADCs, place each type of insulin in a separate pocket or lidded bin to help avoid mix-ups
  – If pharmacy-prepared, barcode-labeled syringes containing patient-specific insulin dose should be used

Timeline of events at TMC

• August 2014
  – Transitioned from the use of regular insulin (Novolin® R) to insulin lispro (Humalog®)
• January 2015
  – Transitioned from the use of insulin lispro (Humalog®) 10mL vials to 3 mL vials
• July 2015
  – Implemented therapeutic interchange of insulin lispro (Humalog®) for all rapid acting insulin orders

Timeline of events at TMC

• August 2015
  – Removed regular insulin (Novolin® R) and mixed insulins (Novolin® 70/30) from formulary
• March 2016
  – Transitioned from storing vials of NPH insulin (Novolin® N) and insulin glargine (Lantus®) in automated dispensing cabinets to dispensing patient-specific unit dose syringes from pharmacy
**Improved Safety**

- Only one insulin type (insulin lispro) readily available to nursing staff in automated dispensing cabinets
  - Decreased confusion
  - Eliminated look-alike vial error for nursing
- Unit dose, pharmacy-prepared syringes for long acting insulins
  - Aligns with ISMP recommendations
- Only 3 types of insulin stored system wide
  - NPH, Basal, ultra short acting
  - Decreased confusion risk

**Cost Savings**

- 3 mL vial size
  - Reduced waste and increased turnover
- Unit dose, pharmacy-prepared syringes for long acting insulins
  - Significant waste reduction and increased turnover
- Only 3 insulin types stored system-wide
  - Decreased shelf space

**Financial Impact**

- 2015 spend on all insulin products – $220,429
- Post consolidation annualized spend* – $148,613
- Annual cost savings – $71,816

*6 months actual data annualized

**Post Test Question**

Which of the following benefits can result from an insulin portfolio reduction within a health system pharmacy department?

- A. Improved safety
- B. Cost Savings
- C. Decrease Waste
- D. All of the above
Breaking Real and Perceived Barriers to Voluntary Reporting of Safety Events by Pharmacy Personnel in an Acute Care Institution

Lara K. Ellinger, PharmD, BCPS
Katie Gauen, PharmD
Tina Lertharakul, PharmD
Candidate (Midwestern University)

Objective

• List barriers to voluntary reporting of medication errors and adverse events.

Voluntary incident reporting

• Discloses adverse events and errors so patient safety and quality of care can be tracked and improved
• Crucial for error prevention
• Adverse events estimated to be underreported in healthcare systems at an annual rate of 50 to 96%


Barriers to reporting

• Fear of individual or organizational repercussion
• Belief that reporting errors can measure practitioner competence
• Legal concerns associated with error reporting
• Unclear
  – What should be reported
  – Process for reporting
  – Why reporting is important
• Time
• Complexity of form

Northwestern Event Tracking System (NETS) survey overview

• 17 question survey on background, awareness of, and concerns regarding the NETS
• Emailed September, 2016 to NMH Pharmacists and NMH Technicians listservs
• Survey was open for 2 weeks
• Response Rate of 40.3% (N=114 responders)

I have no real or potential conflicts of interest to disclose.
BACKGROUND AND AWARENESS QUESTIONS

NETS Survey

- Majority were
  - Pharmacists (72%)
  - Worked in inpatient setting (83%)
- Nearly all respondents were aware of the NETS (98%) and of how to access and submit reports (96%)
- Many claim they rarely (34%) or never (18%) report an event through the NETS

REPORTING CONCERNS QUESTIONS

I'm unclear on what should be reported.

- Strongly disagree: 17.5%
- Disagree: 21.4%
- Neutral: 3.5%
- Agree: 47.6%
- Strongly agree: 31.4%

I only submit a report if the event causes harm to the patient.

- Strongly disagree: 12.6%
- Disagree: 28.2%
- Neutral: 28.2%
- Agree: 9.7%
- Strongly agree: 9.7%

The event form requires too much detail and takes too long to complete.

- Strongly disagree: 17.1%
- Disagree: 7.8%
- Neutral: 12.0%
- Agree: 33.0%
- Strongly agree: 28.2%
Even though I don’t have to include my name on the report, I’m concerned that the information provided can be traced to me.

I don’t know who should be responsible for completing an event report.

I can just talk to my coordinator or manager instead of completing a report.

I am concerned that there will be a disciplinary action taken upon the person involved in the event based on my reporting.

I am concerned that my colleagues will distrust me if I submit a report for an event involving them.

My organization has not made it clear why reporting is important.
There is no follow-up or feedback on an event after an incident report is submitted.

Education and Process Improvements
- Staff meetings
  - Share process improvements in response to errors that have been reported
  - Plan to implement “good catch” award
- Education at team huddles
- Changed reporting form to require fewer fields
- Speaker on just culture for pharmacy leadership
- Medication safety position and NETS workgroup

Future Improvement Plans
- Addition of just culture information into new employee orientation
- Make safety event resources like the algorithm more easily available on intranet
- Introduce a just culture algorithm to management teams to help them resolve safety events involving employees
- Explore possibility of using frontline staff as medication safety representatives

NETS Reports
- Prior to this survey
  - December 2015 – February 2016:
    - 34 medication safety event reports were made by pharmacists
    - 3 were made by pharmacy technicians
- After this survey
  - December 2016 – February 2017:
    - 70 medication safety event reports were made by pharmacists
    - 8 were made by pharmacy technicians

Self Assessment Question
Which of the following is NOT a recognized barrier to incident reporting in health systems?
A. Fear of repercussion
B. Fear of having to help find a solution to the problem
C. Fear of losing colleagues’ trust
D. Fear of being viewed as incompetent or untrustworthy
References


Learning Objective

- Describe students’ use and perceptions of a virtual dispensing software in a required communications course.

Background

- ACPE requires verifying and dispensing be incorporated into didactic education
  – Not practiced in “real world” environment until Advanced Pharmacy Practice Experiences
- Simulating “real world” experience can help prepare students for future roles

Previous Studies

- European study assessed dispensing software use in 46 universities in 23 countries
  – 12 students (6.2%) at 6 universities
  – Positive experience (mean 4.6/5 Likert scale, SD 0.7)
  – 83.5% of non-users perceived potential benefits from use
- United Arab Emirates college study in second year students
  – 100% agreed/strongly agreed that MyDispense was useful
  – 97% felt it reinforced material from other courses

MyDispense

- Virtual dispensing software from Monash University
- Focuses on community/outpatient setting
- Incorporated into a required PS3 Healthcare Communications Course at MWU-CCP
  – 1 hour tutorial
  – 11 practice exercises
  – 5 quiz exercises

Student Attitudes and Behaviors on Utilization of a Virtual Dispensing Software in a Healthcare Communications Course

Michael Serlin, PharmD Candidate
Jennifer Mazan, PharmD
Kathy Komperda, PharmD, BCPS
Midwestern University Chicago College of Pharmacy

No conflicts of interest to disclose
Study Design

- Invitation to participate in questionnaire occurred after completion of quiz exercises
- Questionnaire components:
  - Usage of MyDispense
  - Perceptions of software
  - Demographics
- ~5 minutes to complete; ~10 questions
  - Administered during a required course session
- Mainly Likert scale questions

Results

Demographics (N=160)

<table>
<thead>
<tr>
<th>Female Gender n(%)</th>
<th>120(75)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median Age (years)</td>
<td>25</td>
</tr>
<tr>
<td>Highest degree prior to pharmacy school n(%)</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>71(44.4)</td>
</tr>
<tr>
<td>Associate</td>
<td>32(20.0)</td>
</tr>
<tr>
<td>Bachelor</td>
<td>30(18.8)</td>
</tr>
<tr>
<td>Master/Doctoral</td>
<td>6(3.7)</td>
</tr>
<tr>
<td>Current or prior work experience n(%)</td>
<td></td>
</tr>
<tr>
<td>Every week</td>
<td>37(23.1)</td>
</tr>
<tr>
<td>Most weeks</td>
<td>11(6.9)</td>
</tr>
<tr>
<td>Some weeks</td>
<td>100(62.5)</td>
</tr>
<tr>
<td>Rarely</td>
<td>6(3.7)</td>
</tr>
<tr>
<td>Never</td>
<td>3(1.9)</td>
</tr>
</tbody>
</table>

Use of MyDispense (N=160)

<table>
<thead>
<tr>
<th>Completion of practice exercises in MyDispense n(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Every week</td>
</tr>
<tr>
<td>Most weeks</td>
</tr>
<tr>
<td>Some weeks</td>
</tr>
<tr>
<td>Rarely</td>
</tr>
<tr>
<td>Never</td>
</tr>
</tbody>
</table>

Results

<table>
<thead>
<tr>
<th>I believe that MyDispense… (N=160)</th>
<th>SA/A* n(%)</th>
<th>N n(%)</th>
<th>SD/D* n(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Practice exercises prepared me for the quiz</td>
<td>130(81.3)</td>
<td>27(16.9)</td>
<td>3(1.8)</td>
</tr>
<tr>
<td>Practice exercises simulated realistic encounters</td>
<td>135(84.3)</td>
<td>19(11.9)</td>
<td>6(3.8)</td>
</tr>
<tr>
<td>Made me aware of the proper steps to follow for dispensing a medication</td>
<td>139(86.4)</td>
<td>15(9.4)</td>
<td>6(3.8)</td>
</tr>
<tr>
<td>Helped me understand the importance of the community pharmacist in the dispensing process</td>
<td>130(81.3)</td>
<td>22(13.7)</td>
<td>7(4.6)</td>
</tr>
<tr>
<td>Was a positive learning experience</td>
<td>136(85.0)</td>
<td>21(13.1)</td>
<td>3(1.9)</td>
</tr>
<tr>
<td>Will be able to apply what I learned to my future practice</td>
<td>133(83.3)</td>
<td>19(11.9)</td>
<td>7(4.6)</td>
</tr>
<tr>
<td>Should be used more in the pharmacy curriculum</td>
<td>127(76.9)</td>
<td>27(16.9)</td>
<td>6(3.8)</td>
</tr>
<tr>
<td>Should be used earlier in the curriculum</td>
<td>148(92.5)</td>
<td>16(10.0)</td>
<td>2(1.3)</td>
</tr>
</tbody>
</table>

*SA/A = Strongly Agree/Agree; N = Neutral; SD/D = Strongly Disagree/Disagree

Conclusions

- Software utilization rate was high
- Students viewed using virtual dispensing software as positive and beneficial
- Students gained benefit, despite majority having pharmacy work experience
- Potential for future implementation in different parts of the curriculum
Future Implications

- Exercises for other aspects of community practice
  - OTC section developed
- Implementation into other courses to reinforce concepts
  - Pharmacotherapeutics
- Institutional version
  - Available in Australia (Monash University)
  - Needs to be coded for US purposes

Review Questions

1. Even though the majority of students had pharmacy work experience, _______ of students perceived benefit from using MyDispense.

   A. less than half  
   B. half  
   C. majority

Questions?
2017 ASHP Proposed Policies: To Approve or Not to Approve, That is the Question
Nicole Allcock, PharmD, BCPS, FASHP
Noelle RM Chapman, PharmD, BCPS, FASHP
Joel Hennenfent, PharmD, MBA, BCPS, FASHP
Jen Phillips, PharmD, BCPS, FCCP
April 1, 2017

Disclosures

• The speakers have no conflicts of interest to disclose.

Learning Objectives

1. Explain the importance of ASHP policies to pharmacy professional practice.
2. Review controversial 2017 policies debated at this year’s House of Delegates (HOD).
3. Discuss Illinois and Missouri pharmacy perspectives for delegates to use in the HOD debate.
(Brief) Overview of the ASHP House of Delegates

Jen Phillips, PharmD, BCPS, FCCP
Associate Professor, Pharmacy Practice
Midwestern University Chicago College of Pharmacy

Policy Development Process

• Ideas begin at the member level
  – That’s YOU!
• 5 Councils submit policy recommendations to ASHP Board
  – Education and Workforce Development
  – Pharmacy Management
  – Pharmacy Practice
  – Public Policy
  – Therapeutics

• Policies approved by board go to House of Delegates for debate/approval
• Discussion opportunities:
  – Regional Delegates Conference (May)
  – ASHP Summer Meeting (June)
  – Open Forum for Members (June)
  – ASHP Connect
  – Formal/Informal contact with delegates
Policy Development Process

• 3 Voting opportunities
  – Virtual House in Spring, Fall
  – HOD session at summer meeting
• Non-delegates can submit recommendations or new business at 2nd session of the HOD

Resolutions

• Call for resolutions sent out in November
• Requires 2 ASHP active member sponsors
• Must be submitted 90 days prior to June HOD meeting

Who is the HOD?

• HOD votes on ASHP professional policies
• Membership:
  – Elected by affiliates or active members in each state (N=163)
  – Officers and directors of ASHP
  – Past presidents
  – Fraternal Delegates
    • US Army, Navy, Air Force, Public Health Service, and VA
House of Delegates Overview

Implications

- Delegates (that’s “us”) represent their constituents (that’s “you”) when voting
- Hearing your thoughts helps us represent you better!

Self-Assessment Question

- Which of the following is true regarding ASHP policy development?
  a. ASHP policies must be approved by the HOD and the ASHP board.
  b. There are 5 ASHP Councils who craft policy recommendations
  c. It is important for ASHP members to share their perspectives on ASHP policy development
  d. All of the above
Self-Assessment Question

- Which of the following is true regarding ASHP policy development?
  a. ASHP policies must be approved by the HOD and the ASHP board.
  b. There are 5 ASHP Councils who craft policy recommendations
  c. It is important for ASHP members to share their perspectives on ASHP policy development
  d. All of the above

2017 Policies: Council on Public Policy

CPuP1: Partial filling of Schedule II Rx

- "To advocate that state legislatures and boards of pharmacy create consistent laws and rules that discourage overprescribing by allowing partial filling of Schedule II drugs; further,
  - To advocate that public and private entities construct criteria for partial filling to minimize the additional practice burden on pharmacists and healthcare organizations; further,
  - To advocate that pharmacists educate prescribers and patients about options for filling prescriptions for Schedule II drugs, including the risks of overprescribing, while recognizing the patient or caregiver’s rights to make their own care and management decisions."
CPuP2: Restricted Drug Distribution

“To oppose restricted drug distribution systems that:
1. Limit patient access to medications; (2) undermine continuity of care
2. Impede population health management
3. Adversely impact patient outcomes
4. Erode patients' relationships with their healthcare providers, including pharmacists;
5. Are not supported by publicly available evidence that they are the least restrictive means to improve patient safety
6. Interfere with the professional practice of healthcare providers; or
7. Are created for any reason other than patient safety.”

CPuP2: Restricted Drug Distribution

- Would replace Policy 0714
- New policy:
  - Is considerably shorter than 0714
  - Is more strongly worded than 0714
  - Omits language regarding opinions on FDA's authority in this realm
  - Notes that restrictions should only be due to safety reasons

What do YOU think?
Open Microphone

- Please provide your thoughts on the CPuP Proposed Policies:
  - Partial filling of Schedule II Rx
  - Restricted drug distribution

Council on Therapeutics (CoT)

Joel Hennenfent, PharmD, MBA, BCPS, FASHP
Truman Medical Centers

COT 1: Therapeutic and Psychosocial Considerations of Transgender Patients

- To support medication and disease management of transgender patients as a part of care unique to this population; further,
- To advocate that transgender patients have access to pharmacist care to ensure safe and effective medication use; further,
- To promote research on, education about, and development and implementation of therapeutic and biopsychosocial best practices in the care of transgender patients; further,
- To encourage documentation of a patient’s birth sex and identified gender in the patient medical record.
COT 4: Weight-Based Drug Dosing

• To encourage pharmacists to participate in interprofessional efforts to ensure appropriate patient height and weight are recorded in the patient medical record to provide safe and effective drug therapy to patients who may fall outside normal weight parameters or experience clinically significant changes in weight in a short period of time; further,

• To encourage drug product manufacturers to conduct pharmacokinetic and pharmacodynamic research in pediatric, adult, and geriatric patients at the extremes of weight and weight changes to facilitate safe and effective dosing of drugs in these patient populations, especially for drugs most likely to be affected by weight; further,

• To encourage independent research on the clinical significance of extremes of weight and weight changes on drug use, as well as the reporting and dissemination of this information via published literature, patient registries, and other mechanisms; further,

• To advocate that clinical decision support systems and other information technologies be structured to facilitate prescribing and dispensing of drugs most likely to be affected by extremes of weight and weight changes.

COT 6: Pain Management

• To advocate fully informed patient and caregiver participation in pain management decisions as an integral aspect of patient care; further,

• To advocate that pharmacists actively participate in the development and implementation of health-system pain management policies and protocols; further,

• To support the participation of pharmacists in pain management, which is a multidisciplinary, collaborative process for selecting appropriate drug therapies, educating patients, monitoring patients, and continually assessing outcomes of therapy; further,
COT 6: Pain Management

• To advocate that pharmacists lead efforts to prevent inappropriate use of pain therapies, including engaging in strategies to detect and address patterns of abuse and misuse; further,
• To foster the development of educational resources on multimodal pain therapy, substance abuse and prevention of adverse effects, further
• To encourage the education of pharmacists, pharmacy students, and other healthcare providers regarding the principles of pain management.
• (Note: This policy would supersede ASHP policy 1106).

Open Microphone

• Please provide your thoughts on the COT Proposed Policies
  – Transgender patients
  – Weight-based Drug Dosing
  – Pain Management

Council on Pharmacy Practice (CPhP)

Noelle RM Chapman, PharmD, BCPS, FASHP
Northwestern Memorial Hospital
CPhP 1: Reduction of Unused Prescription Drug Products

• To recognize that unused prescription drug products contribute to drug misuse, abuse, and diversion; further,
• To advocate for research, education, and best practices to ensure appropriate quantities of prescription drug products are prescribed, including but not limited to partial fills or refills; further,
• To advocate that pharmacists take a leadership role in reducing excess quantities of unused prescription drug products.

CPhP 2: Ready-to-Administer Packaging for Hazardous Drug Products Intended for Home Use

• To advocate that pharmaceutical manufacturers provide hazardous drug products intended for home use in ready-to-administer packaging; further,
• To advocate that, when hazardous drug products intended for home use are not available from manufacturers in ready-to-administer packaging, pharmacists repackage those drug products to minimize the risk of exposure; further,
• To advocate that pharmacists provide education to patients and caregivers regarding safe handling of hazardous drug products intended for home use.

Open Microphone

• Please provide your thoughts on the CPhP Proposed Policies:
  – Unused Drug Products
  – Hazardous Drug Packaging
Council on Education and Workforce Development (CEWD)
Noelle RM Chapman, PharmD, BCPS, FASHP
Northwestern Memorial Hospital

CEWD 1: Workforce Diversity
• To affirm that a diverse and inclusive workforce contributes to health equity and health outcomes; further,
• To advocate for the development of a workforce whose background, perspectives, and experiences reflect the diverse patients for whom pharmacists provide care.

Open Microphone
• Please provide your thoughts on the CEWD Proposed Policies:
  – Workforce Diversity
Joint Council Task Force 1:
Medical Aid in Dying

Noelle RM Chapman, PharmD, BCPS, FASHP
Northwestern Memorial Hospital

JCTF 1: Medical Aid in Dying

• To affirm that a pharmacist’s decision to participate or
  decline to participate in medical aid in dying for
  competent, terminally ill patients, where legal, is one of
  individual conscience; further,
• To reaffirm that pharmacists have a right to participate
  or decline to participate in medical aid in dying without
  retribution; further,
• To take a stance of studied neutrality on legislation that
  would permit medical aid in dying for competent,
  terminally ill patients.
  • (This policy would supersede ASHP policy 9915.)

Open Microphone

• Please provide your thoughts
  on the Joint Council Task Force
  Proposed Policy:
  – Medical Aid in Dying
Council on Pharmacy Management (CPM)

Nicole Allcock, PharmD, BCPS, FASHP
Southeast Hospital
Cape Girardeau, Missouri

CPM 1: Any Willing Provider Status for Pharmacists and Pharmacies

• To advocate for federal and state legislation and regulations that will grant any willing provider status to pharmacists and pharmacies and improve patient care access and continuity of care; further,
• To support affiliated state societies in advocating that pharmacists and pharmacies be included in state any willing provider legislation or regulation.

CPM 2: Wholesaler and Manufacturer Requirements on Final use or Disposition of Drug Purchases

• To support drug distribution business models that meet the requirements of hospitals and health systems with respect to availability and timely delivery of products, minimizing short-term outages and long-term product shortages, managing and responding to product recalls, fostering product-handling and transaction efficiency, preserving the integrity of products as they move through the supply chain, and maintaining affordable service costs; further,
• To advocate that distributors not be permitted to make availability of drug products contingent on how those drugs products are used.
• (Note: This policy would supersede ASHP policy 1016.)
CPM 5: Controlled Substance Diversion Prevention

• To encourage healthcare organizations to develop policies that delineate the roles, responsibilities, and oversight of all personnel who handle controlled substances to ensure compliance with applicable laws and scopes of practice; further,
• To encourage healthcare organizations to ensure that all healthcare workers are appropriately screened for substance abuse prior to initial employment and monitored on a continuous basis to support a safe patient-care environment, protect co-workers, and discourage controlled substances diversion.

Open Microphone

• Please provide your thoughts on the CPM Proposed Policies:
  – Any Willing Provider Status
  – Wholesaler & Manufacturer Requirements on Final use or Disposition of Drug Purchases
  – Controlled Substance Diversion Prevention

Self-Assessment Question

• Which of the following is NOT the topic of an ASHP policy up for debate in 2017?
  a. Considerations for transgender patients
  b. Partial filling of CII prescriptions
  c. Workforce diversity
  d. Controlled Substance Diversion
  e. Medical marijuana
Self-Assessment Question

• Which of the following is NOT the topic of an ASHP policy up for debate in 2017?
  a. Considerations for transgender patients
  b. Partial filling of CII prescriptions
  c. Workforce diversity
  d. Controlled Substance Diversion
  e. Medical marijuana

Self-Assessment Question

• True or False: It is important for HOD delegates to discuss and consider constituents’ perspectives when voting on ASHP policies.
  – True
  – False

Self-Assessment Question

• True or False: It is important for HOD delegates to discuss and consider constituents’ perspectives when voting on ASHP policies.
  – True
  – False
Final Thoughts?

2017 ASHP Proposed Policies: To Approve or Not to Approve, That is the Question
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Noelle RM Chapman, PharmD, BCPS, FASHP
Joel Hennenfent, PharmD, MBA, BCPS, FASHP
Jen Phillips, PharmD, BCPS, FCCP
April 1, 2017
CPuP 1: Partial Filling of Schedule II Prescriptions
To advocate that state legislatures and boards of pharmacy create consistent laws and rules that
discourage overprescribing by allowing partial filling of Schedule II drugs; further,
To advocate that public and private entities construct criteria for partial filling to minimize the additional
practice burden on pharmacists and healthcare organizations; further,
To advocate that pharmacists educate prescribers and patients about options for filling prescriptions for
Schedule II drugs, including the risks of overprescribing, while recognizing the patient or caregiver’s rights
to make their own care and management decisions.

CPuP 2: Restricted Drug Distribution
To oppose restricted drug distribution systems that (1) limit patient access to medications; (2) undermine
continuity of care; (2) impede population health management; (3) adversely impact patient outcomes; (4)
erode patients’ relationships with their healthcare providers, including pharmacists; (5) are not supported
by publicly available evidence that they are the least restrictive means to improve patient safety; (6)
interfere with the professional practice of healthcare providers; or (7) are created for any reason other
than patient safety.
(Note: This policy would supersede ASHP policy 0714.)

CPuP 3: Collaborative Drug Therapy Management
To pursue the development of federal and state laws and regulations that authorize collaborative drug
therapy management by pharmacists; further,
To advocate expansion of federal and state laws and regulations that optimize pharmacists’ ability to
provide the full range of professional services within their scope of expertise; further,
To advocate for state laws and regulations that would allow pharmacists to transmit prescriptions
electronically under collaborative drug therapy management protocols; further,
To acknowledge that as part of these advanced collaborative practices, pharmacists, as active members
in team-based care, must be responsible and accountable for medication-related outcomes; further,
To support affiliated state societies in the pursuit of state-level collaborative drug therapy management
authority for pharmacists.
(Note: This policy would supersede ASHP policy 1217.)

CPuP 4: Greater Access to Less Expensive Generic Drugs
To support legislation and regulations that promote robust competition among generic pharmaceutical
manufacturers.
(Note: This policy would supersede ASHP policy 0222.)
• **CPuP 5: Drug Testing**

To recognize the use of pre-employment and random or for-cause drug testing during employment based on defined criteria and with appropriate testing validation procedures; further,

To support employer-sponsored drug programs that include a policy and process that promote the recovery of impaired individuals; further,

To advocate that employers use validated testing panels that have demonstrated effectiveness detecting commonly abused or illegally used substances.

(Note: This policy would supersede ASHP policy 9103.)

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**COUNCIL ON THERAPEUTICS (COT)**

• **COT 1: Therapeutic and Psychosocial Considerations of Transgender Patients**

To support medication and disease management of transgender patients as a part of care unique to this population; further,

To advocate that transgender patients have access to pharmacist care to ensure safe and effective medication use; further,

To promote research on, education about, and development and implementation of therapeutic and biopsychosocial best practices in the care of transgender patients; further,

To encourage documentation of a patient’s birth sex and identified gender in the patient medical record.

• **COT 2: Pharmacist’s Leadership Role in Glycemic Control**

To advocate that pharmacists provide leadership in caring for patients receiving medications for management of blood glucose; further,

To advocate that pharmacists be a member of the interprofessional healthcare team that coordinates glycemic management programs; further,

To encourage pharmacists who participate in glycemic management to educate patients, caregivers, prescribers, and other members of the healthcare team about glycemic control medication uses, metrics, drug interactions, adverse effects, the importance of adhering to therapy, access to care, and recommended laboratory testing and other monitoring.

• **COT 3: Drug Dosing in Diseases that Modify Pharmacokinetics or Pharmacodynamics**

To encourage research on the pharmacokinetics and pharmacodynamics of drugs in acute and chronic disease states; further,

To support development and use of standardized models, laboratory assessment, genomic testing, utilization biomarkers, and systemwide documentation of pharmacokinetic and pharmacodynamic changes in acute and chronic disease states; further,

To collaborate with stakeholders in enhancing aggregation and publication of and access to data on the effects of such pharmacokinetic and pharmacodynamic changes on drug dosing within these patient populations.
• **COT 4: Weight-Based Drug Dosing**
  To encourage pharmacists to participate in interprofessional efforts to ensure appropriate patient height and weight are recorded in the patient medical record to provide safe and effective drug therapy to patients who may fall outside normal weight parameters or experience clinically significant changes in weight in a short period of time; further,

  To encourage drug product manufacturers to conduct pharmacokinetic and pharmacodynamic research in pediatric, adult, and geriatric patients at the extremes of weight and weight changes to facilitate safe and effective dosing of drugs in these patient populations, especially for drugs most likely to be affected by weight; further,

  To encourage independent research on the clinical significance of extremes of weight and weight changes on drug use, as well as the reporting and dissemination of this information via published literature, patient registries, and other mechanisms; further,

  To advocate that clinical decision support systems and other information technologies be structured to facilitate prescribing and dispensing of drugs most likely to be affected by extremes of weight and weight changes.

• **COT 5: Pharmacist’s Leadership Role in Anticoagulation Therapy Management**
  To advocate that pharmacists provide leadership in caring for patients receiving medications for anticoagulant therapy management; further

  To advocate that pharmacists be responsible for coordinating the individualized care of patients receiving medications for anticoagulation therapy management; further,

  To encourage pharmacists who participate in anticoagulation therapy management to educate patients, caregivers, prescribers, and other members of the interprofessional healthcare team about anticoagulant medication uses, drug interactions, adverse effects, the importance of adhering to therapy, access to care, and recommended laboratory testing and other monitoring.

  (Note: This policy would supersede ASHP policy 0816.)

• **COT 6: Pain Management**
  To advocate fully informed patient and caregiver participation in pain management decisions as an integral aspect of patient care; further,

  To advocate that pharmacists actively participate in the development and implementation of health-system pain management policies and protocols; further,

  To support the participation of pharmacists in pain management, which is a multidisciplinary, collaborative process for selecting appropriate drug therapies, educating patients, monitoring patients, and continually assessing outcomes of therapy; further,

  To advocate that pharmacists lead efforts to prevent inappropriate use of pain therapies, including engaging in strategies to detect and address patterns of abuse and misuse; further,

  To foster the development of educational resources on multimodal pain therapy, substance abuse and prevention of adverse effects, further

  To encourage the education of pharmacists, pharmacy students, and other healthcare providers regarding the principles of pain management.

  (Note: This policy would supersede ASHP policy 1106).
• COT 7: Clinical Investigation of Drugs Used in Elderly and Pediatric Patients
To advocate for increased enrollment and outcomes reporting of pediatric and geriatric patients in clinical trials of medications; further,
To encourage drug product manufacturers to conduct pharmacokinetic and pharmacodynamic research in pediatric and geriatric patients to facilitate safe and effective dosing of medications in these patient populations.
(Note: This policy would supersede ASHP policy 0229.)

COUNCIL ON PHARMACY PRACTICE (CPHP)
• CPhP 1: Reduction of Unused Prescription Drug Products
To recognize that unused prescription drug products contribute to drug misuse, abuse, and diversion; further,
To advocate for research, education, and best practices to ensure appropriate quantities of prescription drug products are prescribed, including but not limited to partial fills or refills; further,
To advocate that pharmacists take a leadership role in reducing excess quantities of unused prescription drug products.

• CPhP 2: Ready-to-Administer Packaging for Hazardous Drug Products Intended for Home Use
To advocate that pharmaceutical manufacturers provide hazardous drug products intended for home use in ready-to-administer packaging; further,
To advocate that, when hazardous drug products intended for home use are not available from manufacturers in ready-to-administer packaging, pharmacists repackage those drug products to minimize the risk of exposure; further,
To advocate that pharmacists provide education to patients and caregivers regarding safe handling of hazardous drug products intended for home use.

• CPhP 3: Expiration Dating of Pharmaceutical Products
To support and actively promote the maximal extension of expiration dates of commercially available pharmaceutical products as a means of increasing access to drugs and reducing healthcare costs; further,
To advocate that the Food and Drug Administration implement procedures to allow pharmaceutical manufacturers to readily update expiration dates to reflect current evidence; further,
To advocate that regulators and accreditation agencies recognize authoritative data on extended expiration dates for commercially available pharmaceutical products.
(Note: This policy would supersede ASHP policy 9309.)

COUNCIL ON EDUCATION AND WORKFORCE DEVELOPMENT (CEWD)
• CEWD 1: Workforce Diversity
To affirm that a diverse and inclusive workforce contributes to health equity and health outcomes; further,
To advocate for the development of a workforce whose background, perspectives, and experiences reflect the diverse patients for whom pharmacists provide care.
• **CEWD 2: ASHP Guidelines, Statements, and Professional Policies as an Integral Part of the Educational Process**

To encourage all educators of the pharmacy workforce to use ASHP statements, guidelines, and professional policies as an integral part of education and training.

(Note: This policy would supersede ASHP policy 0705.)

**JOINT COUNCIL TASK FORCE**

• **JCTF 1: Medical Aid in Dying**

To affirm that a pharmacist’s decision to participate or decline to participate in medical aid in dying for competent, terminally ill patients, where legal, is one of individual conscience; further,

To reaffirm that pharmacists have a right to participate or decline to participate in medical aid in dying without retribution; further,

To take a stance of studied neutrality on legislation that would permit medical aid in dying for competent, terminally ill patients.

(This policy would supersede ASHP policy 9915.)

**COUNCIL ON PHARMACY MANAGEMENT (CPM)**

• **CPM 1: Any Willing Provider Status for Pharmacists and Pharmacies**

To advocate for federal and state legislation and regulations that will grant any willing provider status to pharmacists and pharmacies and improve patient care access and continuity of care; further,

To support affiliated state societies in advocating that pharmacists and pharmacies be included in state any willing provider legislation or regulation.

• **CPM 2: Wholesaler and Manufacturer Requirements on Final use or Disposition of Drug Purchases**

To support drug distribution business models that meet the requirements of hospitals and health systems with respect to availability and timely delivery of products, minimizing short-term outages and long-term product shortages, managing and responding to product recalls, fostering product-handling and transaction efficiency, preserving the integrity of products as they move through the supply chain, and maintaining affordable service costs; further,

To advocate that distributors not be permitted to make availability of drug products contingent on how those drugs products are used.

(Note: This policy would supersede ASHP policy 1016.)

• **CPM 3: Use of Patient’s Personal Technology Devices for Care**

To advocate that patients, physicians, pharmacists, and other healthcare professionals be involved in the approval, selection, and management of software applications (apps) used in patient care; further,

To advocate that decisions regarding the approval, selection, and management of patient-care apps should further the goal of optimizing patient care; further,
To provide resources to assist pharmacists in developing and assessing processes to safely and securely use medical apps; further,

To advocate that pharmacists be included in Food and Drug Administration evaluation and approval of mobile medical apps that involve medications or any aspect of medication therapy.

- **CPM 5: Controlled Substance Diversion Prevention**
  To encourage healthcare organizations to develop policies that delineate the roles, responsibilities, and oversight of all personnel who handle controlled substances to ensure compliance with applicable laws and scopes of practice; further,

  To encourage healthcare organizations to ensure that all healthcare workers are appropriately screened for substance abuse prior to initial employment and monitored on a continuous basis to support a safe patient-care environment, protect co-workers, and discourage controlled substances diversion.

- **CPM 6: Revenue Cycle Compliance and Management**
  To encourage pharmacists to serve as leaders in the development and implementation of strategies to optimize medication-related revenue cycle compliance, which includes verification of reimbursement, billing, finance, and prior authorization, for the healthcare enterprise; further,

  To advocate for the development of consistent billing and reimbursement policies and practices by both government and private payers; further,

  To advocate that information technology (IT) vendors enhance the capacity and capability of IT systems to support and facilitate medication-related billing and audit functions; further,

  To investigate and publish best practices in medication-related revenue cycle compliance and management.

  (Note: This policy would supersede ASHP policy 1205.)
Agenda
1) Review trends in healthcare landscape
2) Review the Pharmacy Forecast Report
3) Case study activities
4) Leadership pearls

Learning Objectives
1) Describe health-care imperative changes and impact on pharmacy practice
2) Review the Pharmacy Forecast and its role in strategic planning
3) Discuss the role of the Pharmacy Forecast on student professional development

Changing Healthcare Landscape
• US Healthcare System is the most expensive in the world
• US ranked last compared to other nations:
  – Quality care, Access, Efficiency, Equity, Healthy Lives
• Triple Aim Theory:
  – Health outcome
  – Patient experience
  – Cost
• Affordable Care Act and Bundle Payment
  – Shift from volume to value
  – Shift from acute care to preventative care

Changing Healthcare Landscape
• Increasing US health care spending (GDP ~17.7%)
• Aging population with extended lives
• Rising prevalence of adults with multiple chronic diseases
• Almost half of US population with least one chronic disease
  – ≥2 prescription drugs: 25-31%
  – ≥5 prescription drugs: 6-11%

Changing Healthcare Landscape
• Shortage of primary care
  – HRSA estimates ~7,000 additional primary care physicians needed in underserved areas
• Egregious drug price increases and shortages
• CMS 'Meaningful Use' requirements in information technology
• Big data analytics

References:

Number of People with Chronic Conditions

Use of Multiple Prescription Drugs By Age

Changing Healthcare Landscape

10 Challenges and Opportunities

Opportunities and Impact on Pharmacy Practice

10 Challenges and Opportunities

• Population health
• Shifting from volume- to value-based reimbursement
• Regulatory demands
• Infection control, especially in light of Ebola
• Demonstrating the value of M&A consumers
• Truly integrating systems
• Overspecialization of the physician workforce and questions over the physician shortage
• Hospital closures
• Reimbursement rate differences
• Data, data everywhere

Opportunities and Impact on Pharmacy Practice

• Population health management
  – Ambulatory clinics
  – Adherence packaging and mail order
  – Specialty Pharmacy
  – Partnerships
• Big data and predictive analytics
• Formulary management to mitigate impact due to drug price increases and shortages
American Society of Health-System Pharmacists (ASHP)

Vision:
• Medication use will be optimal, safe, and effective for all people all of the time.

Mission:
• The mission of pharmacists is to help people achieve optimal health outcomes. ASHP helps its members achieve this mission by advocating and supporting the professional practice of pharmacists in hospitals, health systems, ambulatory clinics, and other settings spanning the full spectrum of medication use. ASHP serves its members as their collective voice on issues related to medication use and public health.

ASHP’s Core Strengths
• Advocacy
• Career Services
• Continuing Education
• Drug Information
• Meeting and Conferences
• Professional Policies and Practice Standards
• Publishing
• Residency and Technician Training Accreditation

ASHP Research and Education Foundation

Vision:
• As the philanthropic arm of ASHP, our vision is that patient outcomes improve because of the leadership and clinical skills of pharmacists, as vital members of the healthcare team, accountable for safe and effective medication use.

Mission:
• The mission of the ASHP Foundation is to improve the health and well-being of patients through appropriate, safe and effective medication use.

ASHPF’s Core Strengths
• Leadership Program Development
• Clinical Training Program Development
• Research Designed to Support Practice Advancement
• Pharmacy Practice Tool Development
• Convening Consensus-Building Conferences

ASHP/ASHPF Collaboration

• 2004 Sara White Scholar-in-Residence
• 2005 AHP Article: Will There be a Leadership Crisis
• 2006 Center for H-S Pharmacy Leadership established in ASHPF
• 2007 Pharmacy Leadership Academy (PLA) established
• 2011 PLA recognized for graduate credit (MS, MHA, MBA)
• 2012 Visiting Leaders Program established
• 2012 Pharmacy Forecast established

Pharmacy Forecast

Purpose:
• To improve the effectiveness of leaders in hospital and health-system pharmacy practice

Overview:
• Predicts developments in eight domains likely to challenge pharmacy leaders in hospitals and health-systems
• Presents more than 40 authoritative, actionable strategic recommendations to pharmacy practice leaders
Pharmacy Forecast

Overview (continued):

• Reports survey results of trend watchers in health-system pharmacy and analyzes predicted trends
• Trend reports from ASHP Research and Education Foundation’s Center for Health-System Pharmacy Leadership
• Supported by the David A. Zilz Leaders for the Future Fund

Pharmacy Forecast

Methodology:

• Appointed Forecast Panel (FP) completes a questionnaire
• Survey asks likelihood of certain trends occurring over next five years
• Experts recruited to write a brief chapter for each domain
• Each chapters presents the survey results, authors assessment of predictions and strategic recommendations

Student Professional Development

How is this relevant for pharmacy students?

• Understand emerging trends and predicted challenges
• Promote thought provoking discussions and research
• Potential topic for journal clubs, rotational presentations and interview questions (i.e. internship, residency)

Forecast Panelist Questions

Forecast Question #1

More than 90% of health system will have strong financial incentives to keep their patients healthy and not in need of high-cost health care services, particularly inpatient care.

a) Very Likely
b) Somewhat Likely
c) Somewhat Unlikely
d) Very Unlikely
Forecast Question #2
Oral anti-factor Xa inhibitors (i.e., rivaroxaban, apixaban, edoxaban) will replace at least 25% of the current use of warfarin in the long-term management of thromboembolism and coagulation disorders.

a) Very Likely
b) Somewhat Likely
c) Somewhat Unlikely
d) Very Unlikely

Forecast Question #3
At least 25% of health systems will have a formal plan for including pharmacists, along with nurse practitioners or physician assistants (or both), in advanced roles that allow primary care physicians to care for more patients

a) Very Likely
b) Somewhat Likely
c) Somewhat Unlikely
d) Very Unlikely

Forecast Question #4
The number of ethical dilemmas experienced by health care professionals in health systems and referred to ethics committees for guidance will increase by at least 25%.

a) Very Likely
b) Somewhat Likely
c) Somewhat Unlikely
d) Very Unlikely
1. Healthcare Delivery and Financing

- Increasing cost of healthcare
- Pay-for-performance and healthcare reform
- Pressure to improve quality while reducing costs

Staying Ahead Of Intense Competition

- Expand services in outpatient clinics
- Ensure involvement in care-path development
- Centralize services to reduce costs across multi-hospital systems
- Pursue bilateral prescription data sharing partnerships
- Reduce charges for outpatient infusions (home infusion)
- Communicate impact of rising drug prices
- Ensure 340b integrity and compliance


2. Population Health Management

Aligning Incentives To Transform Care Delivery

- Payment reform reflected in savings-sharing between payers and providers
- Enhance training in behavioral health mediation
- Focus on formulary management
- Target panels of high-risk patients
- Annual wellness visits include evaluation of medications
- Provide medication-use education to long-term care facilities
- Post-discharge medication follow-up evaluations


3. Drug Development and Therapeutics

- 41 new pharmaceuticals were approved in 2014
- Breakthrough therapies accounted for 22%
- Novel new drugs has increased every year since 2011

Changing Practices In Response To New Technology

- Standardize and optimize antineoplastic use through technology
- Position pharmacy to lead pharmacogenomics implementation
- Integrate biosimilars and advocate for appropriate use
- Reconfigure warfarin clinics to address novel oral anticoagulants
- Expand the health system’s capacity to manage all specialty medications


Pharmaceutical Marketplace

Medication expenditures expected to increase 7-9% across all settings
Manufacturers positioned to control:
- Supply of raw materials
- Distribution of high-cost medications
- Price of generics


Following The Money

- Ensure appropriate care when using limited-distribution system
- Advocate against limited distribution systems
- Optimize approach to specialty pharmaceuticals
- Focus on patient’s best interest despite increasing medication expenditures


Data and Technology

- Continuing to expand implementation of the electronic health record (EHR)
- Centers for Medicare & Medicaid Services (CMS) meaningful use
  - Stage 2= 2015
  - Stage 3= 2018


Pharmacy Work Force

Aim to lower costs and improve patient outcomes
Optimize pharmacy work force in new models of care

Market Forces Stimulate Change In Pharmacy Practice Models

- Develop pharmacist privileging process to achieve health-system goals
- Maximize leveraging of all staff members (residents, technicians, students)
- Focus on staff development to meet future plans of department
- Advocate for provider status
- Acknowledge pharmacy technicians as essential members of the team
- Strategize to ensure adequate supply of PTCB-certified technicians

7. Patient Empowerment

- Shared decision-making & managing own healthcare
  - Facilitated by:
    - Federal Policy
    - Improving health outcomes
    - Providing cost-effective care
  - Patient health literacy

FROM PATERNALISM TO SHARED DECISION-MAKING

- Develop technology to facilitate medication-use empowerment
- Increase involvement where medication adherence is linked to outcomes
- Consider patient representation on clinical policy committees
- Assess success of pharmacy patient empowerment programs
- Develop patient assistance programs to lower cost of medications

8. Ethics

- Consolidation of payers and provider organizations
- Growing weight of business in healthcare
- Population health vs. Individual health
- Rising cost of medications

CHALLENGES TO PROFESSIONALISM IN HEALTHCARE

- Designate pharmacists to represent pharmacy on ethical issues
- Advocate for ethically sound policy for rationing medications
- Discuss pricing of medications that is out of line with patient benefit
- Collaborate with other professions to review ethical principles & professional autonomy

Role of PHARMACY FORECAST

- Strategic Planning
- C-Suite Education
Role of Pharmacy Forecast

- Preparing the Next Generation of Pharmacists
  - School of Pharmacy
  - Resident & Student Learning
  - Leadership Courses

Case Study

Forecast Panelist Responses

Forecast Response #1

Forecast Response #2

Forecast Response #3
Forecast Response #4

The number of ethical dilemmas experienced by health care professionals in health systems and referred to ethics committees for guidance will increase by at least 20%.

Take Home Message

- Landscape of pharmacy is changing
- Position pharmacy departments to keep pace with healthcare changes
- Prepare next generation of pharmacists to expect change in healthcare
- Equip next generation of pharmacists to manage change in healthcare

Special Acknowledgment to:

Long Trinh, Pharm.D., M.S., BCPS
Oregon Health & Science University
Inpatient, Operations Manager
(At time of program development Dr. Trinh was PGY2-Health System Pharmacy Administration Resident, Cleveland Clinic, OH)

Brian Kempin, Pharm.D.
PGY2-Health System Pharmacy Administration Resident
University of Virginia Health System
Section of Pharmacy Practice Managers' Advisory Group on Innovation Management

For their work in developing this program

THANK YOU!
Pharmacy Forecast Student Workshop

Goal of the Program:

The primary goal of the program is to promote student awareness of emerging trends in healthcare and opportunities within pharmacy practice.

Program Format:

This program will be conducted as a 2.5-hour session, and we would like to encourage all pharmacy student attendees to participate. The program uses several methods of teaching, including didactic lecture, case-based workshop, and an interactive voting session. The first half of the program will be didactic, covering emerging healthcare trends, impact on pharmacy practice; and an overview of ASHP, the ASHP Research and Education Foundation, and the Pharmacy Forecast. The second half of the program will be a workshop with small-group breakout sessions, whereby students will review one of three cases with facilitated discussion and a large group summary presentation on each topic discussed. The cases will cover a Pharmacy Forecast theme such as 1) Population Health Management, 2) Data and Technology, or 3) Pharmacy Workforce. In addition, an interactive student voting session will be conducted during the didactic lecture portion of the program, and results will be shared at the end of the workshop to compare the students’ votes to the responses of the Forecast panelists. Please refer to the Pharmacy Forecast Student Leadership Development Facilitator’s Handbook for additional details regarding the program format.

Program Description for Marketing Purposes:

Calling all future clinicians and leaders in the profession of pharmacy! This interactive session will expose you to emerging healthcare trends and enhance your understanding of the opportunities within pharmacy practice. The topics covered may serve as potential topics for journal clubs, rotational presentations, and interview questions with potential employers (i.e., internship, residency).

Learning Objectives:

- Describe healthcare imperative changes and impact on pharmacy practice.
- Review the Pharmacy Forecast and its role in strategic planning.
- Discuss the role of the Pharmacy Forecast in student professional development.
Population Health Management

A health system consisting of 15 hospitals with over 50 clinics and 20 retail pharmacies was engaged by a large pharmacy chain. The chain drugstore is seeking to partner with the health system to share data across the electronic health record (EHR). The bilateral prescription data-sharing capability with outside pharmacies offers the potential to improve safety, decrease unnecessary phone calls, and allow caregivers to view medication histories generated by third-party payers. The ultimate goal is to contribute to the management of population health, control cost, and improve quality.

General case questions:

1. If you were the pharmacy leader, understanding the preparedness of today’s workforce and pharmacy graduates, what opportunities do you see for a pharmacist in the role of population health management?
2. As the pharmacy leader, how would you determine which population to target? How will you operationalize your plan to allow pharmacists to impact population health?
3. What barriers do you anticipate pharmacists will face when trying to pursue a larger role in population health management than is currently practiced?
4. As a future pharmacist, how do you envision yourself to be more engaged in population health management?
Data and Technology

A large health system underwent the implementation of the EHRs to meet meaningful use requirements set by the Centers for Medicare & Medicaid Services (CMS). Other health systems across the United States have also adopted the EHRs to meet CMS requirements. The growth of EHRs will increase the quantity of clinical data (aka big data) available electronically, which presents the opportunity to analyze the data to make meaningful decisions. A data analytics organization engaged your health system, offering the ability to unlock the power of big data to allow you to control healthcare costs and improve quality of care.

General case questions:

1. How do you envision that big data combined with technology will enable healthcare professionals to best take care of patients in the future?
2. As a pharmacy leader, what opportunities do you envision for pharmacy practice with the advent of big data and technology?
3. What unintended consequences do you anticipate will be created by design and use related to EHRs across multiple settings?
4. As a pharmacist, what role do you envision big data, combined with healthcare devices, will play in the evolution of your future practice?

Pharmacy Workforce

Literature published suggests that the supply of pharmacists may exceed demand based on current pharmacy practices. In contrast, publication data also suggest that the demand of primary care exceeds the supply of primary care providers. To add to the scenario, healthcare payers have shifted the focus of reimbursement models from volume to value. Healthcare organizations are responding to payment reforms by redirecting their resources and capabilities toward population health management to improve access to quality care, while controlling cost. These factors create new opportunities for the pharmacy workforce.

General case questions:

1. What are your opinions about the factors influencing the pharmacy workforce, and how should student’s best prepare?
2. Where do you feel there are opportunities for pharmacists to expand their role to better align demand with the supply of pharmacists?
3. What are your thoughts related to pharmacists obtaining provider status and collaborative agreements?
4. What do you foresee are critical steps for new pharmacists to ensure that they are competent and capable practitioners as they seek employment in new patient care opportunities?
5. There remains to be a shortage of students receiving residency training. As pharmacy leaders, how should we evaluate pharmacists’ credentials as we hire them to practice in these advanced roles?

(Updated 092012016)
How to Write an Article for Publication
Kylie N. Barnes, Pharm.D., BCPS
University of Missouri – Kansas City
School of Pharmacy
April 1, 2017

Learning Objectives
1. Define a successful pathway for acceptance of a manuscript for publication in a professional journal.
2. Define a process to choose which professional journal would be appropriate for publication of your research.
3. Recognize the category of article which is best for your manuscript.

Learning Case: Preparing a Manuscript
You and your colleagues work for a school of pharmacy. You are working on a research project evaluating the efficacy of metformin in combination with glyburide compared to insulin alone in pregnant women with gestational diabetes. You have received approval on your research protocol from the IRB, and are ready to start researching.

What are the most appropriate steps to increase likelihood of acceptance for publication?
A. Complete all research before starting manuscript writing
B. Complete all manuscript writing before starting research
C. Create a timeline, with research and writing duties overlapping
D. Order of research and writing completion have limited impact

Learning Case: Preparing a Manuscript
Which journal is the most appropriate fit for the manuscript?
A. American Journal of Obstetrics and Gynecology (impact 4.8)
B. Diabetes Care (impact 8.7)
C. American Journal of Pharmaceutical Education (impact 2.5)
D. Journal of American Medical Association (impact 37.6)
Learning Case: Preparing a Manuscript

Which category of article is best for your manuscript?
A. Editorial
B. Meta-analysis
C. Clinical trial
D. Systematic review

Research in Pharmacy

- Successes
- Failures
- Best practices of medicine
- Case reports

Advance Practice

Stages of Manuscript Development

1. Planning the manuscript
2. Constructing the manuscript
3. Reviewing the manuscript
4. Submitting the manuscript

Planning the Manuscript

1. Create a timeline
2. Develop a manuscript team
3. Determine authorship
4. Develop manuscript outline
5. Select a target journal

Creating a Timeline

Figure 1: Manuscript timeline. IRB = institutional review board.

Developing a Manuscript Team

- Likely same members of the research team
- Set meeting dates throughout the manuscript timeline
  - Motivation to stay on tasks
  - Other aspects can be conducted through email as needed
Determining Authorship

- International Committee of Medical Journal Editors (ICMJE) recommended criteria:
  1. Substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data
  2. Drafting the article or revising it critically for important intellectual content
  3. Final approval of the version to be published

Many journals now require “contributory statement”
Appropriate to note significant contributions for those not meeting all criteria

Determine order of author list
Primary, or first
- Plans and executes the study, drafts the manuscript, ensures accuracy of data
Senior
- Assumes the same responsibilities of primary
Corresponding
- Communicates with the journal
Rest fall in line in descending order of contribution

Helps ensure all authors are in agreement with:
- Flow of the manuscript
- Individual responsibilities
Should be flexible
Clearly define deadlines
Helps prevent rewriting due to differing views regarding intent/flow

Early in the process, writing group should select a journal
Depends on:
- Content
- Professional focus / educational focus of the manuscript
Match the research work to the focus of the journal

Helpful to review published volumes or issues
If the article is focused in pharmacy education, and the journal’s focus is pharmacy practice, may not be a good match
Emailing the journal
- Pros and cons
Selecting a Target Journal

- Impact factor
  - Calculation representing how often articles from the journal are referenced or cited
  - Pharmacy-focused journals usually range from 1.5 – 3
  - Major medical journals can be as high as 50
  - Use is controversial
  - May not matter when priority is placed on getting the information to the right audience

- Other considerations
  - Peer reviewed?
  - Articles indexed on Pubmed? MEDLINE?
  - Journal use other methods to promote the article/journal? Podcasts? Ahead-of-print availability for hot topics?
  - If struggling to decide, consider reaching out to a medical librarian

Selecting a Target Journal

- Selecting type of article
- Review journal options
  - Original investigation
  - Clinical trial
  - Meta-analysis
  - Research letter
  - Systematic review (without meta-analysis)
  - Narrative Review
  - Viewpoint
  - Letter to the editor

Constructing the Manuscript

1. Selecting a title
2. Introduction
3. Methods
4. Results
5. Discussion
6. Conclusion

Writing the Introduction

- Important to use formal writing style
- Entire article should flow
- May consider writing introduction and methods section prior to starting research
  - Likely mirrors IRB submission
- Brevity is valuable! (1-2 paragraphs)
Writing the Introduction

1. What is known?

2. What is not known?

3. What questions need to be answered?

Writing the Methods Section

• Explains the project in sufficient detail; reader should be able to reproduce the study on their own

• Should include:
  – Description of research population
  – Inclusion and exclusion criteria
  – Materials used to conduct research
  – Procedures followed during the research
  – Plan for data analysis

• If using a well established protocol, cite it

• If using a complex protocol, an appendix prescribing the details may be required

  – Use tables, charts, and flowsheets to your advantage!

• If requires IRB approval, it is appropriate to list it has been obtained

• Registration information on a publicly funded trial is also listed

Writing the Results Section

• Start when completing research data analysis

• Present only data
  – Numbers supported in tables/figures
  – Text describes the findings
  – Interpretation of data reserved for discussion section
  – Cross-reference information presented in text, tables, and figures so it is complementary

• When determining the order of results, may consider:
  – Chronologically
  – Starting with most important finding
  – Starting with primary objectives, and moving the secondary
Writing the Discussion Section

1. A summary of the major research findings

2. The importance of the findings, particularly as they relate to previous research

3. Future directions for research in the topic area

Writing the Discussion Section

• May begin as “Our study showed…”
• Focus on writing a discussion – avoid restating results
• Help place the results in context with other pertinent studies
  – May cite other findings from similar studies here, or conflicting studies
• Section should answer “What do the findings mean?” for the reader

Writing the Discussion Section

• Address the strengths and limitations of the study
• Be careful to also note how the limitations may have also impacted the study results
• Changes in study design should also be explained here

Writing the Conclusion Section

• Some journals will require a separate conclusion section
• Generally short (1-2 sentence paragraph)
• Must be supported by data presented earlier in manuscript
• May be best to save this for the end

Reviewing the Manuscript

The actual review.
Then:
1. Writing the abstract
2. Selecting keywords

Reviewing the Manuscript

• Construction may take a few months, or even years
• Review for:
  – Cohesiveness
  – Update references / check references
  – Need for updated literature search
• Review by all members of the writing team
• Review original timeline
Reviewing the Manuscript

• Editing process
  – Ensure an organized and consistent manuscript
  – Verify all information directly supports the research and is accurate
  – Remedy differences in writing styles between authors
  – Ensure compliance with journal guidelines on syntax and usage
  – i.e., one vs 1

Writing the Abstract

• Structured with specific headings and formatting
• Clear and concise is key
  – Many journals restrict abstracts to > 300 words
• Easiest to write after the manuscript is complete
  – Allows for inclusion of all relevant data

Selecting Keywords

• Journal may request keywords to help with categorization
• Potential method:
  – Write a sentence about the article
  – Remove conjunctions and prepositions and search remaining terms in the Medical Subject Headings (MeSH) database and use those terms

Sample Abstract


Sample Keywords
Learning Case: Preparing a Manuscript

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D. Systematic review
References

Are You Privileged? The Essentials for Credentialing and Privileging Pharmacists.

Objectives

• Pharmacists
  – Define terms critical to this program: certification, competence, credential, credentialing and privileging
  – Explain the value of privileging pharmacists as part of the Medical Staff
  – Describe the process to attain Medical Staff privileges
  – Discuss any current laws regarding credentialing and privileging if they exist
  – Articulate a plan to privilege pharmacists as part of the Medical Staff at your health system

Objectives

• Technicians
  – Define terms critical to this program: certification, competence, credential, credentialing and privileging
  – Explain the value of privileging pharmacists as part of the Medical Staff
  – Describe the process to attain Medical Staff privileges
  – Discuss any current laws regarding credentialing and privileging if they exist
  – Describe how pharmacist credentialing and privileging will impact the duties of pharmacy technicians in health-systems.

Credentialing and Privileging: The Time is Now

Mark Woods, Pharm.D., FASHP, BCPS
Clinical Coordinator and PGY1 Pharmacy Residency Director
Pharmacy Department
Saint Luke's Hospital
Kansas City, Missouri

Disclosure

• Nothing to disclose

What best currently describes your organization’s approach to the credentialing and privileging of pharmacists?

☑ Been there, done that. Fully implemented.
☐ A work-in-progress.
☐ Thinking about it. That’s why I’m here today.
☐ Hoping if we wait long enough this might go away.
Credentialing and Privileging: Why?

- Driven by society's interest in:
  - Protecting the public's health
  - Liability law
  - Emergence of regulation
- Introduced in to accreditation procedures in 1989 by Joint Commission
- Sustained by Berwick's "triple aim" of health care
  - Efficient
  - Affordable
  - High quality

Essential Definitions

- Discussions about credentialing are complicated by lack of understanding around key terms and their context
- Essential to distinguish between:
  - Processes (credential) vs. titles (a credential)
  - Individual (credential/certificate) vs. organizations/programs (accreditation)
  - Required vs. voluntary

Credential

- Documented evidence of professional qualifications
  - Academic degrees
  - State licensure
  - Residency certificates
  - Board certifications

Three categories of credentials in pharmacy

- Credential to prepare for practice (Pharm.D. degree)
- Credential to enter and stay in practice (Licensure and re-licensure)
- Voluntary credentials to document specialized/advanced training (residency certificates, board certifications)

Credentialing

- The process of granting a credential (a designation that indicates qualifications in a subject or area) and
- The process by which an organization or institution obtains, verifies and assesses an individual's qualifications to provide patient care services

Accreditation

- The process whereby an association or agency grants public recognition to an organization, site or program that meets certain established qualifications or standards, as determined through initial and periodic evaluations.
- Examples: Joint Commission accreditation, Residency accreditation
Certification

- A voluntary process by which a nongovernmental agency or an association grants recognition to an individual who has met certain predetermined qualifications specified by that organization.
- Granted to designate to the public that this person has attained the requisite level of knowledge, skill, and/or experience in a well-defined, often specialized, area of the total discipline.
- Examples: Residency certificate, board certification

Privileging

- The process by which a health care organization, having reviewed an individual health care provider’s credentials and performance and found them satisfactory, authorizes that person to perform a specific scope of patient care services within that organization.

ASHP Professional Policy

Credentialing, Privileging and Competency Assessment (1415)

- To support the use of post-licensure credentialing, privileging and competency assessment to practice pharmacy as a direct-patient care practitioner; further
- To advocate that all post-licensure pharmacy credentialing programs meet the guiding principles established by the Council on Credentialing in Pharmacy; further
- To recognize that pharmacists are responsible for maintaining competency to practice in direct patient care.

ASHP Professional Policy

2010 Pharmacy Practice Model Initiative (PPMI)

- Item No. 140 – Hospital/health-system-level credentialing and privileging processes are necessary for pharmacists who provide drug therapy management
- Item No. 142 – Pharmacists who provide drug therapy management should be certified through the most appropriate Board of Pharmaceutical Specialties board certification process
- Item No. 138 – To support optimal practice models, pharmacists who provide drug therapy management must have completed an ASHP-accredited residency or equivalent.

What is the Joint Commission’s Position on Credentialing of Pharmacist?

- “There is no Joint Commission stance on credentialing of pharmacists. The overarching principle is whether the individual provides a medical level of care.”
- “Medical level of care involves making medical diagnosis and/or medical treatment decisions.”
- The following questions should be ask:
  - Is the individual credentialed/privileged in accordance with medical staff standards?
  - Is the individual who provides care a hospital employee?
  - Does it comply with relevant state laws/Scope of Practice acts?

So, how does this all fit together in practice today?
How might this fit together in BPS’s proposed future state?

Why Effective Credentialing/Privileging Processes are Important to the Profession?

- Pace of change/increasing complexity of patient care
- Expanding role of pharmacists in direct patient care
- Growing trend in specialty practice and need to document competence
- Need to assure public, payers and employers of competence
- Economic drivers (provider status)

Global Drivers to Practice Model Evolution

- Affordable Care Act (ACA) Goals
  - Expand access to healthcare insurance
    - Opportunity
      - Pharmacists as providers
      - Reduce costs
    - Opportunity
      - Implement Value Based Purchasing (VBP)
      - Reduce length of stay (LOS)
      - Provide quality data for Accountable Care Organizations
      - Provide patient protection against insurance company actions

Projected Total Physician Shortfall, 2013-2025
Pharmacists – as a Mid-Level Provider

- Mid-level practitioners, also referred to as advanced practice clinicians, are health care providers who have received different training and have a more restricted scope of practice than physicians and other health professionals.

Why Privilege?

- “…the ability to ensure the capabilities and competence of the health professionals, including pharmacists, who practice within an increasingly complex and sophisticated system has become both more relevant and essential.
- Assures stakeholders that the health care professional being considered for privileges has specific competencies and experience for specific services that the organization provides and/or supports.

Why Privilege?

- “…the ability to ensure the capabilities and competence of the health professionals, including pharmacists, who practice within an increasingly complex and sophisticated system has become both more relevant and essential.
- Assures stakeholders that the health care professional being considered for privileges has specific competencies and experience for specific services that the organization provides and/or supports.

Key Takeaways

- Key Takeaway #1
  - Understanding key terms related to credentialing and privileging is essential in establishing effective processes.
- Key Takeaway #2
  - ASHP policies and the PPMI strongly support the principles of pharmacists credentialing and privileging.
- Key Takeaway #3
  - Effective credentialing/privileging processes will protect the public health, healthcare organizations, providers and patients.

Key Takeaways

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Disclosure

- Nothing to Disclose
Illinois Pharmacy Practice Act
Section 225

- Section 225 ILCS 85/3 Section 3 (a) continued...
  - "Medication therapy management services" may also include patient care functions authorized by a physician licensed to practice medicine in all its branches for his or her identified patient or groups of patients under specified conditions or limitations in a standing order from the physician.
  - "Medication therapy management services" in a licensed hospital may also include the following:
    1. Reviewing and assessing the patients health status and
    2. Following protocols of a hospital pharmacy and therapeutics committee with respect to the fulfillment of medication orders.
  - (bb) "Pharmacist care" means the provision by a pharmacist of medication therapy management services, with or without the dispensing of drugs or devices, intended to improve patient health, quality of life, and comfort and enhance patient safety.

Advocate Health Care (AHC)
Current State

- Current site process for credentialing validation:
  - Job description variation across pharmacy positions within AHC
  - Variation in credentialing requirements for varies job duties
- Current site and system process for privileging
  - P&T approved policies, procedures, guidelines (site and system)
  - Collaborative practice agreements (site)
Advocate Pharmacy Credentialing / Privileging Journey

• Continuation of site/clinic specific hospital programs approved by the site P&T and MEC
  • Current pharmacist run MTM clinics with established collaborative practice agreements
• Looking ahead: establishing system strategy to outpatient clinic collaborative practice agreements with standard universal protocols
  • Utilizing technology based/remote services to expand agreements and enhance patient care

The Credentialing and Privileging Pathway of a Truman Medical Centers Pharmacist.

Joel A. Hennenfent, PharmD, MBA, BCPS, FASHP
Truman Medical Centers – Kansas City, Missouri

Truman Medical Centers
Kansas City, Missouri

<table>
<thead>
<tr>
<th>2 inpatient facilities</th>
<th>Level one Trauma Center</th>
</tr>
</thead>
<tbody>
<tr>
<td>547 beds</td>
<td>22,948 Acute admissions</td>
</tr>
<tr>
<td>51 clinics</td>
<td>3,403 ED visits</td>
</tr>
<tr>
<td>4K employees</td>
<td>85K+ Trauma admissions</td>
</tr>
<tr>
<td>610 medical staff</td>
<td>1,175</td>
</tr>
<tr>
<td>13K+ myTruHealth patient portal accounts</td>
<td>112,846 Behavioral Health outpatient visits</td>
</tr>
<tr>
<td>338K+ Acute admissions</td>
<td></td>
</tr>
</tbody>
</table>

Disclosure

• Nothing to Disclose
• Note:
  – Serve as Director-at-Large on ASHP Section of Clinical Scientists and Specialists Executive Board
  – Serve as Missouri Representative to ASHP House of Delegates

Are pharmacists at your institution privileged by the Medical Staff?

☑ Yes
☒ No
Missouri Pharmacy Practice History

- Hospital pharmacy practice based on protocols approved by the P&T committee and MEC of individual hospitals
- Medication Therapy Services (MTS) legislation required a written protocol between a pharmacist and physician
- MSHP advocated in partnership
  - Missouri Department of Health and Senior Services
  - Missouri Board of Pharmacy (MOBOP)
  - Missouri Hospital Association
  - Missouri Pharmacy Association

Missouri Statute Chapter 338

- Section 338.165.1 states that, “All pharmacists providing medication therapy services shall obtain a certificate of medication therapeutic plan authority as provided by rule of the board. Medication therapy services may be provided by a pharmacist for patients of a hospital pursuant to a protocol with a physician as required by section 338.010 or pursuant to a protocol approved by the medical staff committee.”

PharmacistCredentialing / Privileging Strategy

- TMC utilizes a criteria-based core privilege approach versus a specific list of privileges
- TMC non-core privileges for pharmacists are:
  - Modify and order medications by hospital protocol approved by the MEC
  - Protocol addition without adjusting the medical staff privileging process
  - Rapid implementation of new pharmacist-driven patient care programs
  - Provide MTS with pharmacist and physician protocol approved by the P&T committee and MEC

Which pharmacists should be privileged by the Medical Staff?

- Clinical Specialists
- Retail Pharmacists
- College of Pharmacy Faculty
- All Pharmacists

Pharmacist Credentialing / Privileging Goals

- TMC pharmacy team goal to create the pharmacist credentialing/privileging process
  - Compliant with state pharmacy practice statutes
  - Compliant with medical staff by-laws
  - Compliant with TJC
  - Similar to other medical staff privileged health care professionals in our institution
    - Application and form set up
    - PPPE and OPPE requirements
    - Metrics for OPPE

Preparation and Planning

- Designate a pharmacy team leader to research and understand the medical staff credentialing/privileging process
- Gain support of pharmacy team
- Gain support of the Chief Medical Officer and medical staff office team
- Develop a consistent credentialing/privileging process for all pharmacists in the organization to meet accreditation and regulatory requirements
Preparation and Planning

• Work with the medical staff office team to develop the necessary credentialing/privileging tools that are similar to what are used for physicians, advanced practice nurses, and physician assistants throughout the institution
• Obtain Medical Executive Committee (MEC) and Board of Directors approval

Establish Process for Pharmacy Team

• Complete application and submit documentation
• Pharmacy leadership team completed first
  – Provided full understanding and an estimate of time necessary
• Frequently asked questions (FAQs) document was created to assist the pharmacists with completing the paperwork

Establish Process for Pharmacy Team

• Pharmacy leadership team held multiple 2-hour help sessions at both campuses for the staff to answer questions
• Medical staff office team validated application information
  – Time-consuming process

Establish Ongoing Processes

• Develop OPPE and FPPE competence tools
  – Similar to other privileged health care professionals
• Identify performance metrics
  – Capture the necessary regulatory elements during first year of implementation
  – As your program becomes more robust, revise the OPPE documents to be similar to other mid-level practitioner requirements in your state
  – Create processes to monitor forward-looking metrics
    • Streamline pharmacist notes and clinical intervention documentation in the electronic medical record

Focused Professional Practice Evaluation (FPPE)

• What is FPPE?
  – Determination of initial competence
  – Focused Professional Practice Evaluation – the process through which the privilege-specific competence of a practitioner is evaluated. Completed when a practitioner is granted a privilege for the first time or for cause

Ongoing Professional Practice Evaluation (OPPE)

• What is OPPE?
  – Determination of ongoing competence
  – Peer review
  – Ongoing Professional Practice Evaluation – the process through which the organized medical staff conducts an ongoing evaluation of each practitioner's clinical competence and professional behavior in order to determine whether the practitioner's privileges should be continued, limited or revoked.

The Joint Commission – Intent of OPPE

• The intent of the standard is that organizations are looking at data on performance for all practitioners with privileges on an ongoing basis rather than at the two year reappointment process, to allow them to take steps to improve performance on a more timely basis.

The Joint Commission – Data Elements

• Who is responsible for reviewing performance data?
  – Department, Credentials, or Medical Executive Committee
• How often will data be reviewed?
  – The frequency can be defined by the organization
• What process is utilized to decide whether to continue, limit or revoke privileges?
  – Department chair, credentials committee chair, or MEC
• How will data be included in the credentials files?
  – Define a process to review the data and store in record

Example OPPE Metrics

• Failure to follow approved clinical practice guidelines
• Defined # of events occurring
• Defined # of individual peer reviews with adverse determinations
• Patient safety events
• Sentinel events
• Elevated infection rates
• Increasing LOS compared to others
• Patterns of unnecessary tests/treatments

OPPE Evaluation Methodologies

• Periodic chart review
• Direct observation
• Monitor diagnostic and treatment techniques
• Discuss with other individuals involved in the care of patients
  – Pharmacists
  – Physicians
  – Nurses
  – Administrators
(True or False) OPPE criteria must be specific and measurable

True
False

Credentialing, Privileging and Ongoing Professional Practice Evaluation

**Credentialing**
Process by which an organization or institution obtains, verifies and assesses an individual’s qualifications to provide patient care services.

**Privileging**
Process by which a health care organization, having reviewed an individual care provider’s credentials and performance and found them satisfactory, authorizes that individual to perform a specific scope of patient care services within that organization.

**Ongoing Professional Practice Evaluation**
Process through which the organized medical staff conducts an ongoing evaluation of each practitioner’s clinical competence and professional behavior in order to determine whether the practitioner’s privileges should be continued, limited or revoked.

Prior to Cerner engagement

- **Paper driven process**
- **New Cerner functionality**

**Lack of standards:**
- Clinical monitoring
- Documentation
- Reporting

**Medical staff credentialing and privileging:**
- Real time monitoring
- Standard workflows

Clinical Documentation

Clinical Monitoring

Automated Work Lists
What pharmacists should be credentialed and privileged by the Medical Staff?

- Clinical Specialists
- Retail Pharmacists
- College of Pharmacy Faculty
- All Pharmacists

Pharmacist Activities Dashboard

Pharmacy Clinical Interventions

Most Common Pharmacy Consults

Other Pharmacy Consultants
Pharmacy Uplift

Benefits

- Improved monitoring of high risk patients
- Increased efficiency in providing patient care
- Enhanced transparency to clinical activities
- Quantifiable clinical services

Next Steps

- Continuous advancement
- Quantify impact on patient care
- Billing for pharmacy services

Privileged by the Medical Staff

- The medical staff credentialing/privileging process is necessary for pharmacists to utilize MTS protocols and to implement hospital protocols approved by MEC

Privileged by the Medical Staff

- All pharmacists at TMC, regardless of role within the Department of Pharmacy Services, complete the medical staff credentialing/privileging process
- Pharmacists privileged by the medical staff at TMC
  - 54 employed pharmacists
  - 9 UMKC School of Pharmacy faculty members
  - 6 UMKC School of Medicine faculty members

Key Takeaways

- Prepare for the pharmacy profession gaining provider status
  - The Medical Staff credentialing and privileging process takes months to years to complete
  - Providers at our institution must be privileged by the medical staff to bill for services
  - Automate clinical documentation in EHR
- Start application process when employee accepts position
  - Require complete application received by the Medical Staff office within one week of hiring
  - Require residents to submit within one month of match

Are You Privileged? The Essentials for Credentialing and Privileging Pharmacists.
Navigating Illinois’ Legislative and Regulatory Process
Scott A. Meyers, RPh, MS, FASHP
Executive Vice President, ICHP
The Speaker has no conflicts of interest to disclose

Learning Objectives
- Describe proposed changes to the Pharmacy Practice Act (PPA) Rules related to compounding pharmaceuticals.
- Discuss potential changes resulting from the Sunset process of the PPA.
- List ways in which pharmacists, pharmacy technicians and pharmacy students can impact the creation or revision of pharmacy related laws.
- Describe which organizations weigh in on pharmacy related legislation and regulation and explain why.

Pre-test
- What USP Chapters are currently considered standards for compounding in Illinois?
  A. 797
  B. 800
  C. 81
  D. None of the above

The New Compounding Rules
- Coming soon to an Illinois Register near you!
- What we know so far:
  - USP Compounding Compendium will govern all standards.
    - Includes Chapters 795, 797 and 800.
  - A pharmacy may only dispense drugs pursuant to a patient-specific prescription.

The New Compounding Rules
- Sterile compounding for “office use” is prohibited unless the pharmacy is an “Outsourcing Facility” and wholesale drug distributor.
- Non-sterile compounded products may be delivered for “office use” under specific conditions.

The New Compounding Rules
- The pharmacy must maintain scales with sufficient accuracy for the products being compounded.
- An exclusive area if sterile compounding is undertaken.
- A logbook with lot numbers and Beyond Use Dates (BUDs).
- Current copy of the USP Compounding Compendium.
The New Compounding Rules

• The PIC is responsible for ensuring that all pharmacists, pharmacy technicians and pharmacy students who participate in compounding activities are adequately trained and documentation is maintained.
• Any pharmacy that chooses to add sterile compounding to the services provides must first be inspected and the compounding area approved by the Dept.

Pre-Test

• The current Illinois Pharmacy Practice Act (PPA) requires that the State employ at least how many pharmacy investigators?
  A. 7  
  B. 9  
  C. 4  
  D. None

Potential changes to the PPA

• Sunset requirement
• SB0902 – Sen. Dale Righter, R, Mattoon
• HB3462 – Rep. Mike Zalewski, D, Riverside
• Both created by IDFPR
• Changes definition of Electronic Transmission to Electronically transmitted.

Potential changes to the PPA

• Adds e-mail to “Address of Record” now requiring an e-mail address for every licensee and registrant.
• Increases the maximum fine for practicing pharmacy without a license from $5000 to $10,000.
• Technicians will now be licensed as register pharmacy technicians?

Potential changes to the PPA

• Removes Board of Pharmacy member per diems.
• Establishes that the public members may not be a health care professional.
• Removes the position of deputy pharmacy coordinator.
• Removes the requirement of employing at least 4 pharmacy investigators.

Potential changes to the PPA

• Increases the requirement of employing at least 4 pharmacy investigators.
• Adds new reasons for immediate revocation or suspension of licenses.
  — Interfering with the professional judgement of a pharmacist!
Other potential changes to the PPA

- **HB2392** – Rep. Mary Flowers, D, Chicago
  - We talked about this yesterday.
- **SB0636** – Sen. Terry Link, D, Gurnee
  - Originally intended to allow Baxter to distribute dialysate without a pharmacy.
- **SB1604** – Sen. Chris Nybo, R, Lombard
  - Would require pharmacies to fill generic prescriptions with brand name product when generic is unavailable but charge for the generic.

Other potential changes to the PPA

- **SB1907** – Sen. Steve Stadelman, D, Rockford
  - Would allow a pharmacist to fill an expired prescription if unable to reach prescriber.
- **SB2056** – Sen. Chapin Rose, R, Champaign
  - Would require all prescriptions to be electronically transmitted by Jan. 1, 2022.

Other potential changes to the PPA

- **HB0240** – Rep. Mary Flowers, D, Chicago
  - Prohibits transfer of patient information for commercial purposes.
- **HB2742** – Rep. Mike Zalewski, D, Riverside
  - Creates a new Section regarding Automated prescription refills.
  - Aimed at preventing auto-refills of discontinued medications.
  - Authorized IDFPR to write rules governing process.

Bills that might impact pharmacy without changing the PPA.

- **SB0073** – Ira Silverstein, D, Chicago
- **HB0239** – Rep. Mary Flowers, D, Chicago
  - Amends the Illinois Food, Drug and Cosmetic Act
  - Requires manufacturers to inform State purchasers of price increases
  - Brand name products increasing by more than 10 or 25% or $10,000 in a 12-month period.
  - generics with a price increase of more than $100
  - Provide the previous year’s marketing budget and justification for the increase.

Bills that might impact pharmacy without changing the PPA.

- **SB0625** – Sen. Iris Martinez, D, Chicago
- **SB0642** – Sen. Heather Steans, D, Chicago
- **HB0312 & HB0313** – Rep. Sara Feigenholtz, D, Chicago
  - Removes the requirement for a written collaborative practice agreement.
  - Provides for “Full practice authority”.


Bills that might impact pharmacy without changing the PPA.

- **SB0892** – Sen. Jil Tracy, R, Quincy
  - Would allow access to the PDMP to members of the staff of DCFS.
  - Opens the door to demands from other Departments and agencies in the State government.
  - The concern is abuse and neglect of children by parents taking controlled substances or theft of children's controlled medications.

- **HB2708** – Rep. Tom Demmer, R, Rochelle
  - Would allow access to the PDMP to members of the staff of DCFS.
  - Opens the door to demands from other Departments and agencies in the State government.
  - The concern is abuse and neglect of children by parents taking controlled substances or theft of children's controlled medications.

Bills that might impact pharmacy without changing the PPA.

- **SB1607** – Sen. Melinda Bush, D, Grayslake
  - Before prescribing any CS, prescribers or their agents would have to review the PDMP.
  - A prescriber who receives a 3-3-1 report from DHS must acknowledge when prescribing a CS.
  - Pharmacist suspecting that a patient was named in a 3-3-1 report must check PDMP.

- **SB1844** – Sen. Kwame Raoul, D, Chicago
  - Give Dept. of Insurance regulatory authority over PBMs
  - Regulates PBM audits
  - Allows for medication synchronization

Bills that might impact pharmacy without changing the PPA.

- **SB1944** – Sen. Chris Nybo, R, Lombard
  - Would repeal the Hypodermic Needle and Syringe Act
  - This is the Act that allows pharmacists to sell up to 20 needles and syringes to a patient without a prescription.
  - Senator indicates he will amend it to allow sale of up to 100 needles and syringes without a prescription.

- **SB2011** – Sen. Tim Bivins, R, Dixon
  - Would allow pharmacists to provide a partial fill on a CII prescription at the patient’s request.
  - Requires the pharmacist to notify the prescriber within 7 days.

- **HB0707** – Rep. Patricia Bellock, R, Westmont
  - Withholding information from a practitioner from whom a person seeks CS’s that has received same or similar in the last 30-days from another prescriber.
  - Obtaining CS’s for a person who has no medical need.
  - Providing CS’s to a person who has no medical need.
Bills that might impact pharmacy without changing the PPA.
- HB2511 – Rep. Sara Feigenholtz, D, Chicago
  - Amends the Public Aid Code
  - Removes the prior authorization after 4-drugs for long-term care patients.

Pre-test
- I know who my State Senator and State Representative are.
  A. True
  B. False
  C. Undecided
  D. Don’t care

How can you make a difference?
- To impact the making of statutes and regulations:
  1. Know who your legislators are.
  2. Get to know them personally.
  3. Contribute to their re-elections if they are supportive of pharmacy issues.
  4. Watch your e-mails for calls to action from ICHP and for articles in the KP.

How can you make a difference?
- Come to Legislative Day each year.
- Talk with your administrators.
- Become a member of the Government Affairs Division.
- Offer to help on healthcare issues.

Getting involved is easy!
- The Legislature is people!
- Treat them like you would want to be treated by your car mechanic or investment advisor?!
- They want to do a good job.

Does it look like they don’t care?
Does it look like they don’t care?

Pre-test

• When it comes to pharmacy issues which organization is most powerful in Springfield?
  A. Illinois State Medical Society
  B. Illinois Association of Trial Attorneys
  C. Illinois Department of Financial and Professional Regulation
  D. Illinois Retail Merchants Association

Who thinks pharmacy is their business?

Pharmacy has to stick together!

• We have to make lots of compromises in order to get things done. Why?
  – Pharmacists are outnumbered.
  – Most pharmacists are employees.
  – Most pharmacists don’t get involved politically.
  – Even fewer contribute to election campaigns.
  – Whether you agree or not, it’s the truth!

Post-test

• What USP Chapters are currently considered standards for compounding in Illinois?
  A. 797
  B. 800
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  D. None of the above

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Questions/Comments

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Missouri Board of Pharmacy Update
April 7, 2017

Tom Glenski, R.Ph.
Chief Inspector
Missouri Board of Pharmacy

Brian C. O’Neal, PharmD, MS, FASHP
Senior Director of Pharmacy and Biomedical Engineering
Children’s Mercy Kansas City

Program Objectives
• Discuss 2016 new and revised statutes and regulations
• Explain 2017 proposed legislation and regulations

2016 Enacted Legislation
• SB579
  – Telehealth/telemedicine
• SB865
  – Refill consolidation
  – Mandatory reporting
• SB875
  – Biosimilar substitution
• HB 1568
  – Naloxone protocol

SB 579
Telehealth/Telemedicine
• Defines telehealth/telemedicine
• Allows Missouri health care providers to provide telehealth/telemedicine services
• Contains requirements for prescriptions issued based on a telehealth/telemedicine examination

SB 579
Prescription requirements
Requires:
• Missouri licensed prescriber
• Valid physician-patient relationship
• Rx complies with state/federal
  • requirements
• Within the prescriber’s “scope of practice”
• Meet the applicable standard of care

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SB 579
Prescription requirements
Not valid if:
• Based solely on an internet questionnaire
• Based on a telephone examination without a previously established and ongoing prescriber-patient relationship
• No legitimate practitioner-patient relationship exists.

SB 579
Prescription requirements
• Requirement for a “physical examination” removed from BOP rule
• Controlled substances
  – DEA: Ryan Haight Act
  – BNDD

SB 865
Consolidation of refills
• Similar to Board’s previous interpretation
• Elements
  – Pharmacist “may” consolidate
  – Consolidate refills up to 90-day supply
  – Maintenance medication only
  – Prescriber can indicate no consolidation
  – No controlled substances
• Use professional judgment

SB 865
Consolidation of refills
Maintenance medication
• A medication prescribed for a chronic, long-term condition that is taken on a regular, recurring basis.
• 3 month period
• Consecutive period?
• Same pharmacy?

SB 865
Mandatory Reporting
• Licensee must report
  – Final adverse action taken by another licensing state, jurisdiction or governmental agency against any license that is also issued by the Board
  – Voluntary surrender while under disciplinary investigation
  – Exclusion from any state or federally funded health care program

SB 875
Biosimilars
Allows a pharmacist to substitute an interchangeable biological product for a prescribed biological product if substitution has been authorized by the prescriber.
SB 875
Biosimilars

“Interchangeable biological product”

FDA:
– Has licensed and determined meets the standards for interchangeability under 42 U.S.C. Section 262(k)(4)
– Has determined is therapeutically equivalent as set forth in the latest edition of or supplement to the Food and Drug Administration’s Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book)

SB 875
Biosimilars

Requirements

– Notification of substitution
  – Patient
  – Prescriber (within 5 days of dispensing)
– Compliance with other BOP laws/rules
  – Labeling
  – Recordkeeping
  – Two-line prescription format

HB 1568
Naloxone

• Authorizes Missouri licensed pharmacists to sell and dispense an “emergency opioid antagonist” without a prescription under protocol with an authorizing physician
• No additional Board license or certification required.
• No purchase restrictions (age, quantity, relationship)

HB 1568
Naloxone

• No specific protocol requirements
• This is not a MTS or immunization protocol
• Sample protocol on the Board’s website
• Protocol can be stricter than statute

HB 1568
Naloxone

• Document all sales/dispensing
• Should include:
  – Transaction date
  – Product name, strength and dosage form
  – Quantity
  – The names of the parties/entities (if known)
• Can use pharmacy dispensing system
2017 Legislation

- No Board-sponsored this year
- BOP proposals
  - Charitable pharmacy
  - Two line prescription format
  - Civil penalties
  - Pharmacist CE
  - Third party logistics (3PL) licensure
  - Rx Cares for Missouri Program

2017 Legislation

SB 139
- Rx Cares for Missouri Program
- Promote medication safety and to prevent prescription drug abuse, misuse, and diversion in Missouri
- BOP and DHSS

New/Revised Regulations

- 20 CSR 2220-2.200 Sterile Compounding
- 20 CSR 2220-2.095 Collection of Non-Controlled Medication for Destruction

20 CSR 2220-2.200 Sterile Compounding

- Revised
- Emergency rule 8/4/2016
- Final rule effective 1/30/2017
- Future revision following USP 797 revision

20 CSR 2220-2.200 Sterile Compounding

- Compounding definitions
  - Facilities/equipment
  - Risk levels
- Training
- Garbing
- Cleaning & disinfection
- Environmental monitoring
- End-preparation evaluation
- Remedial investigations/recalls
20 CSR 2220-2.200
Sterile Compounding
Educational program
• Webinar series
• Guidance document
• February newsletter
• Inspector Katie DeBold, PharmD

20 CSR 2220-2.095
Drug Take-Back
Collection of Non-Controlled Medication for Destruction
• New
• Effective 3/30/2017
• Return for destruction purposes only
• Does not affect return and reuse from LTCF rule

20 CSR 2220-2.095
Drug Take-Back
• Collection receptacle
  – Pharmacy
  – LTCF
• Mail-back program
  – No return to pharmacy
• Specific requirements for both
• Does not interfere with law enforcement collection programs

2017 Regulations
Rule review process underway
• All rules
  – Online comment submission
  – Two public hearings
    • April 19, 2017
    • July 12, 2017
• Specific rules
  – A set each Board meeting
  – Calendar online

Next rule revisions?
• Fees
• Pharmacy Standards of Operation
• Pharmacist-in-charge
• Standards of Operation for a Class J: Shared Services Pharmacy
• Administration of Vaccines Per Protocol
• Administration by Medical Prescription Order
**Board Activity Update**

- Technician Working Group
  - Recommendation to the Board
- Hospital Advisory Committee
  - Monthly meetings
  - Variety of topics
  - Recommendations to the Board

**Hospital Advisory Committee**

- Bert McClary (chairman)
- Daniel Good
- Jim Gray
- Colby Grove
- Kevin Kinkade
- Neil Schmidt
- Greg Teale

**Board Activity Update**

- Pharmacy Diversion Conference
  - May 5, 2017, Kansas City
- Missouri Pharmacy Practice Guide (12/2016)
- Class B Hospital Pharmacy Practice Guide
- New e-mail alert system: govdelivery.com
- Electronic inspections
  - All reports electronic
  - E-mailing reports

**MSHP Public Policy Committee Update**

**Selected Bills from 2017**

- Prescribing and dispensing of contraceptives
- Suicide prevention CE
- Medical cannabis
- Death with Dignity Act
- Opioid prescribing guideline accountability
- Prescription drug monitoring program

**Oral Hormonal Contraceptives**

- HB233 (Rep. Dogan)
- HB373 (Rep. Newman)
- Allows a pharmacist to prescribe and dispense oral contraceptives and patches
  - 18 years of age or older – with or without evidence of a previous prescription
  - Under 18 years of age – with evidence of a previous prescription
**Filling of Contraceptive Prescriptions**
- Requires a pharmacy to fill valid prescriptions for drugs or devices used to prevent pregnancy, without delay
- Includes emergency contraception

**Continuing Education**
- HB329 (Rep. Morris)
- Establishes the Tricia Leann Tharp Act that requires two hours of continuing education in suicide awareness and prevention
- Would be required for license renewal

**Medical Cannabis**
- HB437 (Rep. Neely)
- Medical cannabis registration cards
  - DHSS will publish list of indications for which a card can be issued
  - Card would allow possession of up to 20 ounces of medical cannabis
- Cultivation and production
- Investigational use by terminal patients

**Medical Cannabis**
- SB153 (Sen. Schaaf)
- Expands indications for use of medical marijuana to “serious conditions”

**Death with Dignity Act**
- HB524 (Rep. Ellington)
- Establishes the Missouri Death with Dignity Act
- Allows a person to request and obtain a prescription for a drug to end his or her life

**Opioid Prescribing Guidelines**
- SB72 (Sen. Schaaf)
- Act allows for those with prescriptive authority to be disciplined for failure to follow CDC Guidelines for Prescribing Opioids
Prescription Drug Monitoring Program

Multiple bills to establish a PDMP

MSHP Public Policy Committee

• Practice advancement work group
  – Aim to add prescribing authority for controlled substances to definition of practice of pharmacy in Statute 338.010.1
• Board of Pharmacy Technician Working Group
  – Advanced technician role

Post-Assessment Questions

1. A pharmacist may consolidate refills on a controlled substance prescription. T or F
2. The patient must be notified if the substitution with a biosimilar occurs. T or F
3. A naloxone protocol has the same requirements as a MTS or immunization protocol. T or F

Questions