Formulary Hot Topics
Panel Discussion

Ohio Society of Health System Pharmacists
77th Annual Meeting
FRIDAY, April 22, 2016
8:30-9:30 AM
Bexley Ballroom II
## Panel Speakers & Case Facilitators

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<td>Indrani Kar, PharmD</td>
<td>University Hospitals</td>
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Disclosures

The panel speakers have nothing to disclose.
Learning Objectives

• Evaluate differences between formulary structures
• Identify standard elements for formulary evaluation
• List operational components of formulary management
• Describe hot topics in formulary management
Formulary Structure

When you have seen one structure, you have seen one structure.
Poll - Locations

By a show of hands, what city do you practice in?
1. Cleveland
2. Akron
3. Columbus
4. Dayton
5. Cincinnati
6. Toledo
7. Other
Cleveland Clinic Foundation (Cleveland)

Mandy Leonard, PharmD, BCPS – System Director, Drug Use Policy and Formulary Management

Name
CCHS Medical Staff P&T Committee

Physician Chair
Oncologist

Members
• Chair of each Formulary Specialty Panel
• Chair of each Hospital’s P&T Committee
• Nursing representative
• Chief Pharmacy Officer (Secretary)
• Medication Safety Officer
• System Director for Formulary Management

Panels
• Cardiovascular
• Critical Care
• Hem/Onc
• Internal Medicine
• NeuroSciences
• Pediatrics
• Med Policy/Procedure
• Transplant

Tasks
• Formulary evaluations
• Medication policies/guidelines/protocols
• MUE’s
• Cost containment initiatives
Name
Ohio State University Health System P&T Committee

Physician
Chair Internal Medicine

Members
- Physicians - IM, Surgery, Transplant, Hematology, Critical Care, Anesthesia
- Pharmacy - Director (Secretary), Subcommittee Chairs, Pharmacy Leaders
- Nursing/Nursing Education
- Hospital Administration
- Respiratory Therapy
- Laboratory
- Informatics

Subcommittees
- Antithrombotic/Thrombosis/Hemostasis
- Antibiotic
- Formulary
- Hematology/Oncology
- Medication Safety & Policy

Tasks
- Formulary evaluations
- Medication policies/guidelines/protocols
- IV guidelines
- MUE’s
- CPOE prioritization
- Quality and safety
- Cost containment initiatives
Mercy Health (Cincinnati)
Susan Marx Mashni, PharmD, BCPS – Chief Pharmacy Officer

Single System Committee:
- 23 hospitals across Ohio and Kentucky
- 1 EMR affiliate

Corporate Structure:
• Committee organized by Director of Drug Use Policy
• Originally chaired by CMIO; now chaired by a Regional CMO
• Continuous quality improvement process

Members
• Physicians -
  • Each market (hospital) represented via allocation
  • IM, Surgery, Emergency, Cardiology, Infectious Disease, Nephrology, Oncology/Hematology, Critical Care, and Anesthesia
• Pharmacy – Chief Pharmacy Officer (Secretary)
• Nursing

Working Group
• Pharmacy ran system-wide committee
• Members include Clinical Coordinators from each site
• Review formulary requests and provide recommendations to formulary committee

Tasks
• Formulary evaluations
• Medication policies
• IV guidelines
• MUE’s
• Clinical Content for EMR
• Quality and safety
• Cost containment initiatives
OhioHealth (Columbus)
Amy Beatty, PharmD, BCPS – Clinical Director, Pharmacy Services

**Corporate Structure**
“OhioHealth System P&T Committee”

**Physician Chair**
Infectious Disease Physician

**10 hospitals**
- Site P&T committees “endorse” and MECs “approve”
- Membership = Site P&T chairs and site & system pharmacists

**Supportive vetting entities**
- Clinical Guidance Councils – physician-led, discipline-specific
- System AMS
- Medication Safety
- Pharmacy Nursing Committee

**Tasks**
- Formulary, Guideline, and Policy Approvals
- Future state: P&T oncology subcommittee
UC Health (Cincinnati)
Sheila Takieddine, PharmD, BCPS – Drug Policy Development Specialist

Corporate structure

Physician Chair (Family Medicine Practitioner)

Voting members
- Physicians (Internal Medicine, General Surgery, Anesthesiology, Emergency)
- Pharmacy Directors
- Nurses

Subcommittees
- Anti-Infective
- Chemotherapy and Biologics
- Formulary
- Medication Safety
- Medication Administration

Tasks
- Formulary evaluations
- Medication management policies
- Guidelines, protocols
- MUEs
- Cost-savings initiatives
Mount Carmel Health System (Columbus)
Virginia Ruef, PharmD – Pharmacy Regional Manager, Clinical Practice

Trinity Health
(corporate structure)
- Physicians and Pharmacists

Mount Carmel Health System P&T
- Physician Chair
- Members
  - Pharmacy Leaders, Physicians, Residents, Nurses
  - Ad Hoc/Resources: patient advocates, retail pharmacy, finance, respiratory

Standing Agenda Items
- Formulary evaluations
- Medication guidelines/policies/consult agreements
- MUEs
- IV guidelines
- Quality and safety assurance
University Hospitals (Cleveland)
Indrani Kar, PharmD – Clinical Pharmacy Specialist – Drug Policy/Formulary

System structure
- System Medication Safety & Therapeutics Committee (Adults)
- System Pediatric MST
- Entity MSTs

Physician Chair Infectious Disease

Members
- Subcommittee Chairs
- Entity CMOs
- Pharmacy: VP and directors
- Chief Nursing Officer
- Chief Quality Officer

Subcommittees
- Formulary
- Anti-infective
- Oncology
- Medication Safety
- Psychiatry
- High Reliability Medicine & Clinical Effectiveness

Tasks
- Formulary evaluations
- Policies & Guidelines
- MUE’s
- Order set collaboration
- Quality and safety
- Cost containment initiatives
Comparison of Formulary Structures

<table>
<thead>
<tr>
<th>Similarities</th>
<th>Differences</th>
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<td>• Health system or corporate management for system decisions</td>
<td></td>
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<tr>
<td>• Formulary Tasks</td>
<td>• Amount and type of subcommittees</td>
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<td>• Voting memberships</td>
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<td>• Sizes of hospitals and health system</td>
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Strength: System decisions decrease need for each individual hospital P&T from making decisions
Elements of Formulary Evaluation
Standard Elements of Formulary Evaluation

- Request
- Review
- Approval Process
- Operationalize
- Review of Use
Standard Elements of Formulary Evaluation

Request

• Electronic/Paper forms
• Requester type (MD, RPh, nurse)
• Expedited/Emergency situations
Standard Elements of Formulary Evaluation

Review

• Who conducts the review?
• Value based payment reform
• Development of drug use policy
• Similarities/Differences
Standard Elements of Formulary Evaluation

Approval Process

- Structure dependent
- System vs single institution
Standard Elements of Formulary Evaluation

Operationalize

• EMR and IT integration
• Smart Pumps
• Education (patient and clinicians)
• Product availability
• Addition/Removal from all systems
Standard Elements of Formulary Evaluation

Review of Use

• Standard post-approval medication use evaluations
• What automatically qualifies for post-formulary follow up?
• Cost savings
Complex Areas of Standard Formulary Evaluation

Impact on total cost of care
- Contracting
- Volume Projections
- Value rubrics/tools

FMEA
- Associated mitigation plans

Pipeline intelligence
- Internal
- External

Operational Plan for EMR
- One EMR
- Challenges with multiple

Multi-hospital system cost analysis
- 340B
- WAC
- GPO

Monitoring plans
- Objective rubric
- Determine 5Ws & How
Hot Topics in Formulary Management
# Hot Topics in Formulary Management 2016

- Timing to address new molecular entities and formulary review/addition
- **Biosimilars**
- Hospital based infusion clinical formulary process
- Multimodal pain management
- Managing drug shortages
- Cost savings initiatives and cost containment strategies for high cost medications
- **Staff education**
- White bag, Brown bag, Clear bagging
- Medication Assistance Programs
Timing to address New Molecular Entities (NME) and formulary review/addition

<table>
<thead>
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<th>What is it?</th>
<th>Why a hot topic?</th>
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<td>• A drug without a precedent among regulated and approved drug products</td>
<td>• Timing of FDA approval and formulary review - <strong>immediate versus delay</strong></td>
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<td>• FDA approved 45 NME’s in 2015</td>
<td>• Safety issues with non-formulary use of high risk NME’s</td>
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<td>• Formulary review process and time intensive to prepare</td>
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What is it?

- A drug without a precedent among regulated and approved drug products
- FDA approved 45 NME’s in 2015

Why a hot topic?

- Timing of FDA approval and formulary review - **immediate versus delay**
- Safety issues with non-formulary use of high risk NME’s
- Formulary review process and time intensive to prepare
# Biosimilars

## What is it?
- Regulatory term
- Highly similar
- No clinically meaningful differences in terms of safety, purity, and potency
- Same mechanism of action, same route, dosage form, and strength

## Why a hot topic?
- Interchangeability – NOT bioequivalent
- Extrapolation - indications
- Nomenclature – Vigilance & EMR
- Legislation
- Hospital Formulary Infrastructure
- Comparative Cost and Reimbursement
Hospital-based infusion clinic formulary process

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<td>• Pharmacy-operated outpatient infusion services</td>
<td>• Scheduling management</td>
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<td></td>
<td>• Addressing medical billing pieces</td>
</tr>
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<td>• Prior authorizations</td>
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<td></td>
<td>• Patient assistance and affordability</td>
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Image: http://www.qualitaspharmacy.com/isp-infusionservices.html
**Multimodal pain management**

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<td>• Inappropriate use of opioids = negative impact on quality and cost</td>
<td>• New alternatives - costly &amp; mixed evidence</td>
</tr>
<tr>
<td>• Minimize ADEs and improve pain control</td>
<td>• Nation-wide abuse epidemic (new CDC guidance)</td>
</tr>
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<td></td>
<td>• Physicians expect to have access for inpatient (reimbursement)</td>
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<td>• Pipeline competitors entering phase 3 trials</td>
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Managing drug shortages

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<td>• Lack of medications in adequate supplies to meet patient care needs</td>
<td>• Compromised safety and/or efficacy</td>
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<tr>
<td>• Supply chain, industry mergers, narrow profit margin for generic injectables, manufacturing compliance violations</td>
<td>• Cost and time intensive</td>
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<td>• Reactive approach, need for enforceable, proactive mitigation strategies</td>
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<td>• Impact on patient care</td>
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http://www.patientsbeforeprofit.com/news
Cost savings initiatives and cost containment strategies for high cost medications

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<td>• High costs of brands new to market</td>
<td>• The Ask from hospitals =</td>
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<tr>
<td>• Chronic hepatitis C agents</td>
<td>Reduce inpatient drug spend</td>
</tr>
<tr>
<td>• Chemotherapy and biologics</td>
<td>• Companies price certain drugs</td>
</tr>
<tr>
<td>• New increased costs of existing branded or generic drugs on</td>
<td>higher (e.g., nitroprusside), because hospitals previously could absorb the</td>
</tr>
<tr>
<td>market</td>
<td>increase</td>
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<td>• Drug company assistance programs</td>
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Cost savings initiatives and cost containment strategies for high cost medications

What can be done?

• Regulation on industry?
• Promotion of institutional pack sizes
• Formulary management
  • Operational
  • Clinical

Image: http://www.brukarinc.com/offshore-outsourcing-cost-savings/
Staff Education

**What is it?**
- Education of pharmacy staff, physicians, and nursing
- Requirements vary by specialty

**Why a hot topic?**
- Timing of education and approval
- Dissemination of education
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<td>• Expanding pharmacy practice</td>
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<tr>
<td>Brown</td>
<td>• Drug integrity</td>
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<tr>
<td>Clear</td>
<td>• Cost containment and revenue enhancement</td>
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<td></td>
<td>• Improve transitions of care and patient adherence</td>
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Medication Assistance Programs

What is it?
- Programs provide medications to patients at low or no cost

Why a hot topic?
- Acquisition of Medication assistance program medications poses concern
- License requirements of medication supplier to ship in Ohio

Image: http://earpenterprises.com/products/prescription-help/
340b Hospitals

**What is it?**

- Federal Program to enable safety-net entities to stretch scarce federal resources, reaching more eligible patients and providing more comprehensive services

**Why a hot topic?**

- Changes in federal regulations around program
- Impact on hospital-based ambulatory infusion centers

Image: [https://policyinterns.com/2015/03/18/issues-in-340b/](https://policyinterns.com/2015/03/18/issues-in-340b/)
Other formulary hot topics

Anticoagulant reversal agents

Hazardous drugs

Drug Supply Chain Security Act (DSCSA) – Track & trace
Audience Participation
Formulary Structure & Operational Questions

How many people have a system structure?

How many people have a structure not systematized?

What are some positives from a system structure?

What ideas are important take-aways for your institution?
Hot Topics Case 1
Managing biosimilars at transitions of care

Case details:

• Your system formulary committee recently approved filgrastim-sdnz (Zarxio) for addition to formulary and removal of Granix and Neupogen.

Audience question:

• When a patient is discharged, how will your institution manage transitions of care for patients receiving Zarxio?
• What is important to consider?
Hot Topics Case 2  
Rationing care due to national drug shortages

**Case details:**

- Your hospital has a critically low supply of IV proton pump inhibitors.

**Audience question:**

- How will you determine which patients receive drug or not?
- What is important to consider?
Summary

- System structure - Efficiency and strength
- More than one way to conduct a formulary process
- Standard elements of formulary evaluation take time
- Complex areas evaluation = multi-faceted management
- Many hot topics for hospitals to manage
Questions
Formulary Hot Topics Panel Discussion

Thank you for attending.
Special Thanks to our fantastic speakers.

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Address Questions to: Indrani.Kar@UHhospitals.org