Objectives

- Define the terms formulary and formulary system
- Explain the purpose of a formulary system
- Define key terms in formulary management
- Explain the Pharmacy & Therapeutics Committee’s role in the formulary system
- Describe management and maintenance of a formulary system
- Describe the role of a pharmacist and pharmacy technician in formulary management
- Discuss how drug shortages affect formulary management and pharmacy practice

History of Formularies

<table>
<thead>
<tr>
<th>Decade</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1940s</td>
<td>Rudimentary drug lists</td>
</tr>
<tr>
<td>1950s</td>
<td>Policies to support generic substitution</td>
</tr>
<tr>
<td>1960s</td>
<td>Hospitals developed formulary policies</td>
</tr>
<tr>
<td></td>
<td>American Society of Health-System Pharmacists and American Hospital Association released joint guidelines on the legality of formularies</td>
</tr>
<tr>
<td></td>
<td>Reimbursement eligibility and accreditation requirements</td>
</tr>
<tr>
<td>1980s</td>
<td>Literature described clinical and economic value</td>
</tr>
<tr>
<td></td>
<td>Hospital formulary concept accepted</td>
</tr>
<tr>
<td>1990s</td>
<td>American Medical Association published policy on drug formularies</td>
</tr>
</tbody>
</table>

References

Formulary

• Medications
• Medication-associated products or devices
• Medication use policies
• Ancillary drug information
• Decision support tools
• Organizational guidelines

Formulary System

“A formulary system is the ongoing process through which a health care organization establishes policies regarding the use of drugs, therapies, and drug-related products and identifies those that are most medically appropriate and cost-effective to best serve the health interests of a given patient population.”

- ASHP Guidelines on the Pharmacy and Therapeutics Committee and the Formulary System

Purpose of a Formulary System

Safe, effective and cost-effective medication use practices

• Compare benefits vs. risk vs. cost information
• Compare efficacy
• Complete safety reviews
• Decrease bias/conflict in decision making
• Identify potential for misuse
• Provide expert review
• Provide practice experience
• Provide guidance, warnings, education
• Recommend monitoring for institutional use
• Recommend guidance for resource allocation
### Purpose of a Formulary System

- Improved outcomes
  - Prevent adverse medication events
- Cost containment
  - Appropriate use of resources
- Opportunities
  - Evaluate practices and increase staff knowledge
- Education
  - All healthcare staff

### Formulary Management Terms

- F&I committee – Pharmacy & Therapeutics Committee
- Drug monograph – unbiased evaluation of a specific medication
- FMEA form – evaluation of risks involved with medication use
- Formulary tools
  - Restrictions – limits on use of a specific medication
  - Order entry rules – logic built within the information system to direct providers
  - Stop orders – medication orders that automatically terminate
- Closed formulary – limitations
- Open formulary – no limitations
- Therapeutic Class Review – review of similarities and differences within a drug class
- Therapeutic Interchanges – approved exchanges due to previously established guidelines

### Formulary Management

- Evidenced based decisions
  - National guidelines
  - Standards of care
- Process to evaluate
  - New requests
  - Deletion requests
  - Restriction amendments
  - Service, physical, location
  -off label use
  - Non-formulary requests
  - Costs of medications
Formulary Management

Medication Use Policies
- guidelines
- methods for ordering, preparation and dispensing of medications
- selection of manufacturers
- new formulary processes
- drug shortages
- recalled medications

Committees
- Pharmacy & Therapeutics Committee (P&T)
- subcommittees of P&T

Pharmacy & Therapeutics Committee

- reports to a medical executive committee
- Committee membership
  - physicians
  - pharmacy
  - nursing administrators
  - hospital administrators
  - risk/quality management

CHASE, KA. (2010). INTRODUCTION TO HOSPITAL AND HEALTH-SYSTEM PHARMACY PRACTICE. BETHESDA, MD: AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS.
Pharmacy & Therapeutics Committee

- Responsibilities
  - medication selection
  - medication use policy review
  - adverse drug event monitoring
  - drug therapy guideline development
  - staff education
  - formulary system maintenance

- Subcommittees
  - pharmacy nursing committee
  - medication error reporting

Regulatory Requirements

The Joint Commission Certification
- performance standards
Medication Management Chapter
- critical processes
- medication safety

Medication Management Standards

- Planning
- Selection and procurement
- Storage
- Ordering
- Preparation and dispensing
- Administration
- Monitoring
- Evaluation
Pharmacy and Medication Management

- **Formulary Management**
  - drug information
  - safety information

- **Formulary Maintenance**
  - updates to the formulary
  - updates to medication use policies

- **Regulatory Requirements**
  - dynamic rules, regulations and accreditation requirements

- **Education**
  - formulary information
  - process information

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Pharmacist’s Role

- Provides information to guide medication practice
  - all pharmacists

- Creating and maintaining resources
  - drug information
  - formulary information

- **Education**
  - access to the formulary
  - formulary restrictions

- **Quality Improvement**
  - process for non-formulary requests
  - visually inspecting medications

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Pharmacy Technician’s Role

- **Current processes**
  - procurement
  - storage
  - preparation
  - delivery

- **Changes in processes**
  - improvement
  - deterioration

- **Standardization**
  - increased safety
  - better outcomes

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Formulary Maintenance

• Medication list
  • annual review based on evolving safety and efficacy information

• Medication use policies
  • regular review

• Formulary updates
  • monthly
  • changes to formulary database
  • changes to healthcare software
  • alerts for pharmacy, nursing and physicians

Formulary Maintenance Tools

• Formulary management tool
  • stores and organizes information

• Commercial formulary management tool (CFMT)
  • within a commercial medication information database

• Information management system
  • editing tool within the CFMT for customizing records

• Health system formulary
  • formulary information for all locations in a health system (hospitals, clinics, pharmacies)

Drug Shortages

• Interruption in supply due to:
  • changes in product formulations
  • discontinued production
  • lack of available raw or bulk materials
  • manufacturing difficulties
  • natural disasters
  • regulatory issues
  • recalls of the affected or related products
History of Drug Shortages

January 1996 to June 2002
- Drug Information Service at University of Utah reported 224 drug shortages
  - 2007: 129 new drug shortages
  - 2009: 166 additional new shortages
  - 2010: 211 shortages, the highest recorded in a single year to date
  - 2013: 294 shortages reported in the first 10 months

Drug Shortage Strategies

- Supply
  - Wholesalers
  - Manufacturers
  - Direct Orders
  - Emergency Supply
  - Alternate products
- Protocols to Conserve Use
  - Criteria for Use / Algorithms
  - Alternate Products
- Temporary Restrictions
  - Faculty or Department Approval

Impact of Drug Shortages

- Pharmacy time dedicated to managing shortages
  - labor costs
  - workflow efficiency
- Increased risks
  - adverse events
  - second line agents
  - medication errors
- Demand for alternative agents
  - multiple shortages in one drug class
  - restriction of allocated supplies
Drug Shortage Communication

- Ordering Providers
  - Order Entry Alerts
  - Report to P&T Committee

- Pharmacy Staff
  - Email communication

- Nursing Staff
  - Pharmacy Alerts

- In-services for Alternative Products

Drug Shortage Resources

Food and Drug Administration

https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm

American Society of Health-System Pharmacy

https://www.ashp.org/drug‐shortages/current‐shortages/drug‐shortages‐list?page=CurrentShortages

References

References