PHARMACOVIGILANCE (BP803ET)
UNIT 3
CASE STUDY AND PUZZLES

a) Hospital and Its Organization
Puzzle Questions

1. Upgrading to Tertiary Hospital
The hospital needs to handle 500 patients with a 10:1 patient-to-specialist ratio, requiring 50 specialists (500 / 10). With 15 current specialists, 35 additional specialists are needed. Organizational changes: Introduce a board of directors for oversight, add department heads for cardiology and ICU, and create multidisciplinary teams reporting to the medical director for better coordination.

2. **New Radiology Department**
New hierarchical structure: CEO at top, with medical director below; department heads for surgery, pediatrics, nursing, and radiology (new) reporting to the medical director; radiology head oversees three technicians. For 300 beds at 2:1 staff-to-bed ratio, 600 total staff are needed. Adding 1 head + 3 technicians = 4 additional staff.

3. **Adding Surgical Unit**
Referrals: 20% of 100 patients = 20 referrals monthly. Adding surgical unit (2 surgeons + 4 nurses) allows handling these cases internally, reducing referrals to 0 (assuming full capacity). Reorganization: Shift general physicians to pre/post-op care, integrate surgeons into medical staff under the medical director, and assign nurses to surgical rotations for efficient workflow.

Case Study Questions: Expansion of a Rural Primary Hospital
1. **Feasibility of Upgrading**Feasible, as primary hospitals focus on basic care, while secondary add specialties like pediatrics/radiology. Key changes: Clinical – add specialists (e.g., pediatricians, radiologists) and equipment; Non-clinical – establish a board of directors, upgrade infrastructure (e.g., labs, wards), and enhance administrative support for increased load.

2. Revised Organizational Structure
o CEO: Overall management and expansion oversight.

o Board of Directors: Strategic decisions and funding.

o Medical Director: Supervise clinical operations, including new departments.

o Department Heads: Pediatrics (specialist consultations), Radiology (diagnostic services), Nursing (patient care coordination).

o Support Staff: Add administrative roles for billing/logistics. Medical staff functions: General physicians handle referrals; specialists provide targeted care; nurses focus on maternity/pediatrics.

3. **Challenges in Integrating New Staff**Challenges: Resistance to change, training gaps, rural recruitment difficulties. Alignment: Train on hospital goals (e.g., improved access); integrate via cross-department teams; monitor via performance metrics to ensure expanded services meet population needs.

b) Hospital Pharmacy and Its Organization

Puzzle Questions

1. **Improving Efficiency**At 50% efficiency, current output: 1,000 prescriptions. To reach 100% (2,000 potential), but actual need is 1,000, so focus on staff. Each staff handles 200/day; 3 staff handle 600. For 1,000: Need 5 total staff (1,000 / 200 = 5), so 2 additional. New layout: Circular design with separate stations for intake, compounding, dispensing, and counseling to streamline workflow.

2. **Processing IV Admixtures**500 admixtures at 10 min each = 5,000 min (83.33 hours) daily. 4 staff (1 pharmacist + 3 technicians) at 8 hours each = 32 hours. Insufficient; need overtime or more staff. Additional technicians: (83.33 - 32) / 8 ≈ 6.4, so 7 more to avoid overtime.

3. **Reducing Delivery Time**New location: Satellite pharmacy near ICU. Layout: Zoned areas for storage, dispensing, and urgent prep to cut time to 7.5 min. Impact: For 30 urgent patients (10% of 300), time saved = 225 min daily, improving care efficiency by faster response (e.g., reduced adverse events).

Case Study Questions: Inpatient Medication Error in a Tertiary Hospital

1. **Assessment and Improvements**Structure is centralized but linear layout causes bottlenecks. Improvements: Relocate to a modular layout with parallel stations; add 2-3 technicians for shortages; integrate EHR for real-time checks to prevent errors like mislabeling.

2. Responsibilities of Hospital Pharmacist

o Monitor drug interactions and allergies.
o Conduct drug utilization review (e.g., assess antibiotic appropriateness).
o Role in safety: Error reporting, counseling, and collaboration with physicians to avoid reactions.

3. Plan to Enhance Functions

o Integrate EHR for automated alerts and workflow.
o Staff training: Regular sessions on error prevention and compounding.
o Monitor outcomes: Reduce overtime via staffing, track error rates post-implementation.

c) Adverse Drug Reaction

Puzzle Questions

1. **Improving Detection**Reported: 50/month. Missed 30%: Total estimated = 50 / 0.7 ≈ 71.43/month. Method: Implement record linkage studies to cross-reference patient records with pharmacy data for comprehensive detection.
2. **New Monitoring System**Current: 100/year. +25% detection: New count = 125/year. Additional 25 cases: Assume proportional – 10 allergic (40%), 7.5 excessive (30%), rest others.
3. **Combined Probability**Combined probability (independent): 1 - (1 - 0.0001)^3 ≈ 0.0003 (0.03%). Confirmation: Spontaneous reports for initial flags; record linkage to analyze patterns and causality.

Case Study Questions: Polypharmacy in an Elderly Patient

1. Classification and Mechanisms

o Excessive effects: Ibuprofen worsening hypertension (pharmacodynamic).
o Drug interaction: Ibuprofen reducing metformin efficacy (pharmacokinetic).
o Idiosyncratic: Mild NSAID reaction (unpredictable). Beneficial interactions: None here; adverse dominate via competition/enhanced effects.
2. **Detection and Management Methods**Methods: Spontaneous reporting for immediate flags; record linkage for pattern analysis. Reporting process: Document via hospital form, submit to regulatory body (e.g., FDA) with details on drug, reaction, and patient.

3. Management Plan

o Dose adjustments: Reduce ibuprofen or switch to alternative.
o Monitoring: Regular BP/glucose checks.
o Education: Inform patient on symptoms, interactions; provide written guides.

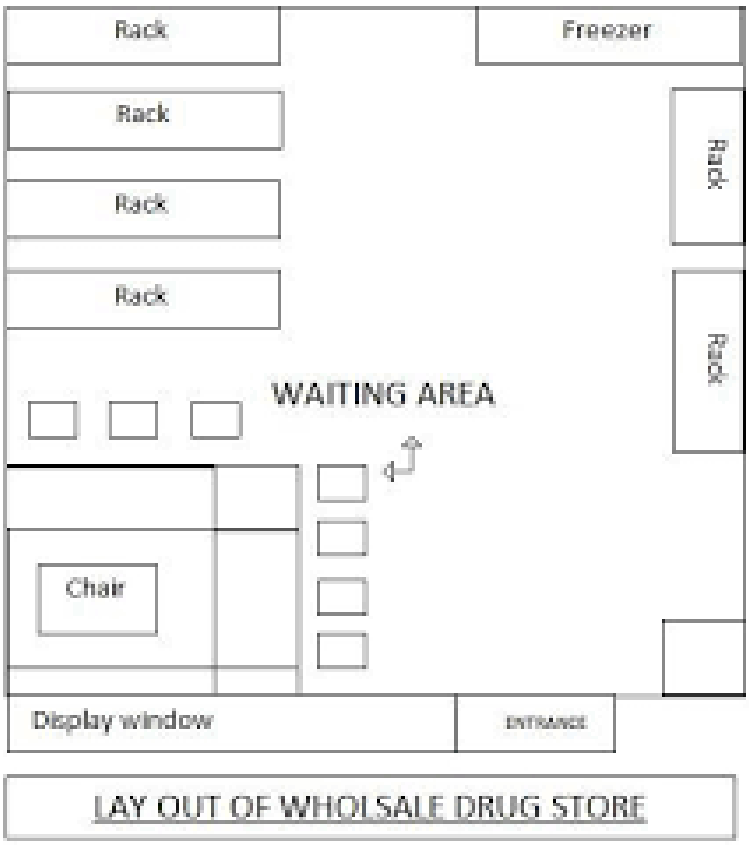
d) Community Pharmacy

Puzzle Questions

1. **Staff and Records**200 prescriptions at 5 min each = 1,000 min (16.67 hours) daily. 2 pharmacists at 6 hours each = 12 hours. Need additional staff: (16.67 - 12)/6 ≈ 0.78, so 1 more. System: Digital ledger for proprietary products, tracking batch/sales per legal standards.

2. **Compliance for Wholesale**Temperature-sensitive: 200 units/week. Monitoring: 2 hours/day = 14 hours/week. Staff needed: 14/40 (full-time week) ≈ 0.35 FTE, so 1 part-time. Layout: Dedicated cold storage zone with logs and alarms.

3. **Reducing Errors**New design: Separate locked storage for controlled substances. Error reduction: From 10% to 5%. For 5,000 transactions: Errors drop from 500 to 250, improving accuracy to 95%.



Case Study Questions: Compliance Issues in a Retail Drug Store

1. **Evaluation and Improvements**Structure mixes retail/wholesale without separation. Improvements: Add partitions for controlled storage; ensure temperature-controlled areas; redesign for compliant maintenance per legal standards.

2. **Dispensing Process Analysis**Violations: No prescription for antibiotics (Schedule H); incomplete records. Retail: Maintain purchase/sale registers; Wholesale: Bulk order logs with verification.

3. Compliance Plan

o Training: Sessions on laws, dispensing, records.

o Maintenance: Digital registers for accuracy.

o Redesign: Separate counters/sections for retail/wholesale to minimize errors.