PHARMACOVIGILANCE (BP803ET)
UNIT 1
CASE STUDY AND PUZZLES

a) Pharmacy and Therapeutic Committee

Puzzle Questions

1. **Formulary Inclusion Efficiency** The PTC reviews 200 drug requests annually, approving 60% based on evidence and cost (e.g., drug A costs $10/dose vs. alternative $15, saving 33%). For 50 new requests, calculate approvals: 30 (60% of 50). Policies: Require RCT data for inclusion; automatic stop orders for antibiotics after 7 days to prevent resistance.
2. **Prescription Management** Hospital processes 1,000 inpatient prescriptions/week, with 10% outpatient. Implement automatic stop order: Reduces prolonged use by 20% (200 prescriptions affected). Emergency list: 20 drugs, preparation time 10 hours/committee meeting. Organization: Chair (physician) + 5 members (pharmacists, nurses).
3. **Emergency Drug List Optimization** Current list has 30 drugs, but usage data shows 40% underutilized. Revision: Delete 12, add 8 new based on incidents (e.g., epinephrine for anaphylaxis). Functions: PTC meets quarterly; policies ensure list availability in crash carts, reducing response time by 15% (from 5 min to 4.25 min).

Case Study Questions: Inefficient Formulary Management in a Tertiary Hospital

1. **Assessment of PTC Organization** Organization fragmented with no pharmacist chair, leading to 25% delayed approvals. Improvements: Appoint multidisciplinary team (physicians, pharmacists, admins); functions include quarterly reviews for formulary updates.
2. **Policies for Prescriptions and Orders** Inpatient: Require e-prescriptions with checks; outpatient: Counseling mandatory. Automatic stop: For narcotics after 48 hours. Emergency list: Include antidotes, prepared via evidence review.
3. **Improvement Plan** Train on policies; integrate software for tracking; monitor via audit (aim 95% compliance), reducing off-formulary use by 30%.

b) Drug Information Services

Puzzle Questions

1. **Query Handling Capacity** Centre handles 500 queries/month from sources like Micromedex. Computerised: 70% via database, retrieval time 2 min/query. For 100 poison queries, calculate time: 200 min. Storage: Cloud-based, with backup reducing loss risk to 1%.
2. **Poison Information Efficiency** 200 poison calls/year, 40% resolved via primary sources (books). Add computerised service: Increases resolution to 80% (160 cases).

Methods: Keyword search for retrieval, cutting response time by 50% (from 10 min to 5 min).

3. **Information Retrieval Optimization** Database has 10,000 entries; search algorithm finds 90% relevant in 1 min. For 50 complex queries, add AI: Improves to 95%, saving 25 min total. Sources: Include journals, websites; centre staff: 3 pharmacists.

Case Study Questions: Overloaded Drug Information Centre in a Hospital

1. **Evaluation of Services** Overload from manual sources causes 20% unanswered queries. Improvements: Expand to poison centre with hotlines; sources: Integrate PubMed, UpToDate.
2. **Computerised Services Analysis** Current: Basic database, slow retrieval. Enhance: EHR integration for real-time info; storage via indexed systems for quick access.
3. **Management Plan** Train on sources; monitor query resolution (target 95%); implement backup for data security.

c) Patient Counseling

Puzzle Questions

1. **Counseling Session Timing** 300 patients/day, each session 5 min (25 hours total). Steps: Assess (1 min), inform (2 min), verify (2 min). Special cases: Elderly (add 2 min for polypharmacy), reducing non-adherence by 15%.
2. **Special Case Handling** 20% patients are pediatric; require pharmacist for dose explanations. Definition: Interactive advice. For 100 cases, special: 20, with steps including visual aids, improving understanding by 30%.
3. **Adherence Impact Calculation** Non-adherence 40%; counseling reduces by 25% (to 30%). Steps: 5 (greet, explain, questions, summarize, follow-up). Special: Pregnancy (avoid teratogens), time added 3 min/case.

Case Study Questions: Poor Counseling Leading to Non-Adherence

1. **Definition and Steps Evaluation** Definition inadequate, missing interaction. Improvements: Standardize steps (assess needs, provide info, confirm).
2. **Special Cases Analysis** Cases like dialysis patients need tailored advice (e.g., timing with meals). Pharmacist role: Identify risks, educate on side effects.
3. **Plan** Implement checklists; train on specials (e.g., pediatrics); measure via surveys (aim 90% satisfaction).

d) Education and Training Program in the Hospital

Puzzle Questions

1. **Training Program Coverage** Internal: 200 staff/year, 10 hours each (2,000 hours). External: 50 from clinics. Pharmacist role: Lead sessions, reducing errors by 20%. Code of ethics: Emphasize confidentiality.
2. **Interdepartmental Communication** 100 meetings/year, pharmacist facilitates 40%. Services to nursing homes: Consults, cutting readmissions 15%. Community education: 5 programs/year on health (e.g., vaccination).

3. **Ethics and Communication Impact** Code violations 10%; training reduces to 5%. Internal vs. external: Internal on-site, external webinars. Role: Pharmacist in communication improves coordination by 25% (e.g., fewer med errors).

Case Study Questions: Inadequate Training in a Community Hospital

1. **Role of Pharmacist Assessment** Limited to dispensing; expand to training lead. Internal: Workshops; external: Online modules.
2. **Services and Ethics Analysis** Nursing homes: Lack drug reviews. Code: Add integrity clause. Communication: Weekly rounds.
3. **Improvement Plan** Schedule programs; include community health (e.g., diabetes talks); monitor via feedback.

e) Prescribed Medication Order and Communication Skills

Puzzle Questions

1. **Order Interpretation Efficiency** 400 orders/day, 10% errors from misinterpretation. Legal: Require signatures. Communication: Clarify with prescribers, reducing errors 50% (to 20/day).
2. **Communication with Patients** Skills: Active listening, empathy. For 200 patients, poor skills cause 30% confusion. Improve: Training, adding 1 min/order, enhancing satisfaction by 40%.
3. **Legal Compliance Calculation** Non-compliant 15%; audits reduce to 5%. Interpretation: Check allergies. Skills: Use teach-back, for prescribers: SBAR method.

Case Study Questions: Communication Breakdown in Prescription Handling

1. **Order Interpretation and Legal** Misreads lead to ADRs. Improvements: Standard forms; legal: Retain records 5 years.
2. **Communication Skills Analysis** With prescribers: Incomplete queries. Patients: No explanations. Enhance: Role-playing training.
3. **Plan** Protocol for orders; skills workshops; monitor compliance (target 98%).

b) Hospital Formulary

Puzzle Questions

1. **Formulary Revision** Current formulary has 500 drugs; add 50 new, delete 30 outdated. Revision process: Committee reviews evidence, cost (e.g., new drug saves 20% on alternatives). Differentiation: Formulary includes guidelines, drug list is basic inventory. Contents: Generic names, dosages, indications.
2. **Addition/Deletion Criteria** For addition: Drug X efficacy 90%, cost $5/dose vs. alternative $8. Probability of approval: If >20% savings and evidence-based, 80%. Deletion: If usage <5% annually (e.g., 10 prescriptions/year out of 10,000), remove to cut costs by $2,000.
3. **Preparation Cost Analysis** Preparation: 20 committee hours at $50/hour = $1,000. Revision annually: Add/delete 10% of 600 drugs. Impact: Standardized prescribing reduces variations by 30%, saving $15,000 in procurement.

Case Study Questions: Outdated Formulary in a Tertiary Hospital

1. **Assessment and Differentiation** Formulary outdated, missing 15% new drugs. Diff from drug list: Formulary has therapeutic equivalents, list is alphabetical. Improvements: Digital version with updates; include contents like contraindications.
2. **Preparation and Revision Process** Steps: Gather requests, evaluate (efficacy, cost), vote. Addition: Evidence from trials; deletion: Low usage or safety issues. Role: Pharmacist leads evaluation.
3. **Management Plan** Annual revisions; train on changes; monitor adherence via audits to ensure 95% compliance.

c) Therapeutic Drug Monitoring

Puzzle Questions

1. **TDM Optimization** For drug Y (narrow index), monitor 100 patients. Need: Prevent toxicity (30% risk without TDM). Factors: Age (elderly adjust dose 20% lower), renal function. Indian scenario: Limited labs, but PvPI monitors nationally.

2. **Factor Impact Calculation** Patient Z: Clearance reduced 50% due to liver issue, dose halve from 100mg to 50mg. Indian: 40% non-adherence due to cost; TDM coverage in urban 60%, rural 20%.
3. **Scenario Analysis** In India, TDM for antibiotics: Factors like genetics (CYP variations). Need: For 200 cases, TDM reduces resistance by 25% (from 80 to 60 cases).

Case Study Questions: Vancomycin Overdose in Renal Patient

1. **Need and Factors** Need: Narrow therapeutic window. Factors: Renal clearance, age, co-meds. Indian: Reliance on government labs, challenges in rural access.
2. **Monitoring Methods** Assays for levels; adjust based on troughs. Indian scenario: PvPI reporting, but underutilized (only 10% cases monitored).
3. **Plan** Educate on factors; implement protocol for high-risk; track via EMR in Indian context.

d) Medication Adherence

Puzzle Questions

1. **Non-Adherence Reduction** 40% non-adherence in 500 patients = 200 cases. Causes: Forgetfulness (50%), cost (30%). Pharmacist role: Counseling reduces by 25% (to 150 cases).
2. **Monitoring Efficiency** Methods: Pill counts for 300 patients, 20 min each = 100 hours. Digital apps cut time 50% to 50 hours. Pharmacist: Reminders via SMS.
3. **Impact Calculation** Monitoring weekly: Adherence rises 15% (from 60% to 75%), reducing hospitalizations by 10 (from 50).

Case Study Questions: Non-Adherence in Diabetic Patient

1. **Causes Analysis** Causes: Complexity, side effects. Pharmacist: Simplify regimens, educate.
2. **Role and Monitoring** Role: MTM sessions. Methods: Self-reports, refill rates.

3. **Improvement Plan** Tools like adherence aids; follow-up calls; measure via HbA1c improvements.

e) Patient Medication History Interview

Puzzle Questions

1. **Interview Efficiency** 150 interviews/day at 10 min = 25 hours. Forms: Standardize to cut 20% time (to 20 hours). Need: Identify 15% interactions.
2. **Form Components** Forms include allergies, OTC use. For 200 patients, detect 40 issues (20%).
3. **Special Cases** Elderly: 30% more questions on polypharmacy. Need: Prevent 10% errors.

Case Study Questions: Incomplete History Leading to Interaction

1. **Need Evaluation** Need: Avoid ADRs (25% preventable). Improvements: Structured forms.
2. **Interview Forms Analysis** Components: Current meds, allergies, adherence. Use open-ended questions.
3. **Plan** Train on interviewing; integrate into EMR; monitor via error rates.

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