Pharmacoepidemiological methods

Drug Utilization Review (DUR)

Definition:

- Drug Utilization Review (DUR) is a structured, ongoing process that involves the systematic evaluation of prescribing, dispensing, and use of medications.
- Its main objective is to ensure that drugs are used appropriately, safely, and effectively. DUR is a critical tool in clinical pharmacology, pharmacy practice, and healthcare management.

There are three types of DUR:

1. **Prospective DUR**: Conducted before the medication is dispensed. It evaluates the prescription against patient-specific information (like allergies, drug interactions, or duplication).
2. **Concurrent DUR**: Takes place during the course of treatment. It monitors therapy while the patient is receiving the medication, ensuring appropriate use and addressing issues like overuse or adverse effects in real-time.
3. **Retrospective DUR**: Occurs after the treatment has been completed. It involves reviewing patient records and prescription data to identify patterns of drug misuse, prescribing errors, or potential improvements.

Key elements analyzed in DUR:

- Indication of drug use
- Correct dosage and duration
- Drug–drug and drug–disease interactions
- Patient adherence
- Polypharmacy concerns

Practical Study (Case Study Example):

- A hospital conducts a retrospective DUR of proton pump inhibitors (PPIs) over a 6-month period. The results reveal that over 40% of patients received PPIs without a proper indication, often for longer durations than necessary. As a result, the hospital implements guidelines for PPI use and educates prescribers, leading to a 30% reduction in inappropriate PPI prescriptions in the following quarter.

Case Reports

Theoretical Aspects:

- A **case report** is a detailed narrative that describes the symptoms, diagnosis, treatment, and follow-up of an individual patient.

- It often focuses on unusual or novel occurrences and serves as an initial observation that might lead to further research.

Key Characteristics:

- Usually based on a single patient
- Highlights rare diseases, new drug reactions, unexpected outcomes, or unusual presentations
- Serves as an early signal in pharmacovigilance
- Does not include a control group
- Lacks statistical analysis but is rich in clinical detail
- While not providing high-level evidence due to lack of generalizability, case reports can lead to hypothesis generation and further studies like cohort or randomized controlled trials.

Practical Study (Case Study Example):

- A 45-year-old male patient develops a rare skin rash after starting a new antihypertensive drug. After discontinuation of the drug, the rash resolves. This case report is published, raising awareness among healthcare providers and prompting further investigation. Eventually, the rare adverse effect is included in the drug's labeling.

Case Series

Theoretical Aspects:

- A **case series** is a collection of case reports involving patients who were given similar treatment or have similar conditions.
- Unlike a case report, which focuses on a single patient, case series involve multiple patients but still lack a control group.

Key Characteristics:

- Descriptive in nature
- Observational, without any experimental control
- Helps in identifying patterns, common features, or emerging issues
- Provides preliminary data that may justify further analytical studies

Types:

- **Retrospective case series**: Based on existing records
- **Prospective case series**: Data collected as events unfold

Limitations:

- No control group, so difficult to infer causality
- Vulnerable to selection bias and confounding variables

Practical Study (Case Study Example):

- A group of 12 patients treated with a new biologic for psoriasis is studied over 6 months. All patients showed significant improvement with minimal side effects. Although the results are promising, the absence of a control group limits the ability to establish effectiveness definitively. However, the case series leads to a larger, controlled study to validate findings.

Surveys of Drug Use

Theoretical Aspects:

- Surveys of drug use are **observational, descriptive studies** that collect data on the patterns and extent of drug utilization among specific populations.
- These surveys can be carried out at local, national, or international levels to inform health policy, evaluate prescribing behavior, and detect trends in drug use.

Types:

- Patient surveys (e.g., adherence, self-medication)
- Physician surveys (e.g., prescribing preferences)
- Pharmacist surveys (e.g., counseling practices)

Key Features:

- Use structured questionnaires or interviews
- Can be cross-sectional (data collected at one point in time) or longitudinal (data collected over time)
- Often target specific populations (e.g., elderly, children, or patients with chronic diseases)
- May include data on prescription drugs, over-the-counter (OTC) medications, and herbal supplements

Objectives:

- Identify commonly used drugs and their patterns
- Assess self-medication practices
- Evaluate rationality of prescriptions
- Monitor changes in drug use over time
- Assess compliance and adherence to medications

Data Sources May Include:

- Community or hospital pharmacies
- Patient interviews

- Prescription records
- Insurance claims databases

Strengths:

- Can explore attitudes, beliefs, behaviors.
- Useful in health policy research.

Limitations:

- Risk of recall and response bias.
- Requires careful instrument design.

Practical Study (Case Study Example):

- A national survey on antibiotic use is conducted among 10,000 households. It reveals that 30% of participants used antibiotics without a prescription in the past 6 months, largely for viral infections. This insight leads to public health campaigns promoting responsible antibiotic use and reduced rates of self-medication in follow-up surveys.

Cross-Sectional Studies

Theoretical Aspects:

- A **cross-sectional study** is an observational study design that analyzes data from a population at a **single point in time**.
- It provides a snapshot of the prevalence of a disease, behavior, or drug use pattern within a defined population.

Objective:

- Estimate **prevalence** of drug use or disease.

Key Characteristics:

- Measures both exposure and outcome simultaneously
- Cannot establish causality, only associations
- Efficient and relatively inexpensive
- Useful for public health planning and hypothesis generation

Applications in Pharmacology:

- Assessing prevalence of drug use in specific populations
- Evaluating associations between drug use and adverse events
- Studying knowledge, attitudes, and practices (KAP) related to drug use

Limitations:

- Temporal ambiguity (not possible to determine whether exposure preceded outcome)
- Prone to selection bias
- Not ideal for rare conditions

Practical Study (Case Study Example):

- A cross-sectional study among 2,000 diabetic patients in urban clinics is conducted to assess metformin adherence. The study finds that 40% of patients are non-adherent, mainly due to gastrointestinal side effects and poor understanding of the medication's benefits. These findings lead to patient education interventions that improve adherence rates in subsequent monitoring.

Cohort Studies

Theoretical Aspects:

- A **cohort study** is a longitudinal, observational study where a group of individuals (cohort) is followed over time to assess the incidence of an outcome based on exposure status.
- Cohort studies can be:
    A. **Prospective**: Participants are enrolled before the outcome occurs and followed into the future.
    B. **Retrospective**: Data is collected from past records where both exposure and outcomes have already occurred.

Key Features:

- Exposure is assessed before the outcome
- Can establish temporal relationships
- Used to study incidence, natural history, and risk factors of disease or drug outcomes
- Suitable for studying multiple outcomes from a single exposure

Strengths:

- Stronger evidence for causality than cross-sectional or case-control studies
- Can calculate relative risk (RR) and attributable risk

Limitations:

- Time-consuming and expensive (especially prospective studies)
- Loss to follow-up can introduce bias
- Not ideal for rare outcomes

Practical Study (Case Study Example):

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