Selected special applications of pharmacoepidemiology

Studies of Vaccine Safety

Introduction

- Vaccine safety studies are a cornerstone of pharmacoepidemiology.
- They aim to detect, assess, and understand the occurrence of adverse events following immunization (AEFIs) in the general population.
- These studies are essential because vaccines are administered to healthy individuals, often on a mass scale, including vulnerable populations like infants and the elderly.

Objectives

- To monitor **short-term and long-term** adverse effects post-vaccination.
- To identify **rare or unexpected events** not detected in pre-licensure trials.
- To establish **causality** between vaccine exposure and adverse events.
- To maintain **public trust** by providing transparent safety data.
- To guide **vaccine policy decisions** and regulatory actions.

Methodologies Used:

1. **Passive Surveillance Systems:**
   - e.g., Vaccine Adverse Event Reporting System (VAERS) in the US.
   - Collect spontaneous reports of AEFIs from healthcare providers, patients, and manufacturers.
   - Limitations: underreporting, reporting bias, and lack of denominator data (how many doses were given).
2. **Active Surveillance Systems:**
   - e.g., Vaccine Safety Datalink (VSD), Post-Licensure Rapid Immunization Safety Monitoring (PRISM).
   - Uses linked electronic health records and administrative databases to proactively monitor safety.
3. **Cohort and Case-Control Studies:**
   - Identify and follow vaccinated and unvaccinated individuals to compare rates of adverse events.
   - Useful in establishing associations and estimating relative risks or odds ratios.
4. **Self-Controlled Case Series (SCCS):**
   - Each patient serves as their own control, comparing incidence of events during risk vs. non-risk periods.

- Efficient for studying rare events with transient risk periods (e.g., febrile seizures after MMR vaccine).

5. Signal Detection and Causal Inference:

- Use of statistical tools (e.g., disproportionality analysis, Bayesian models) to detect safety signals.
- Assessment of causality using tools like the Bradford Hill criteria and WHO-UMC causality framework.

Examples

- Monitoring myocarditis after mRNA COVID-19 vaccines.
- Evaluation of Guillain-Barré syndrome post-influenza vaccination.
- Assessment of febrile seizures after MMR (measles-mumps-rubella) vaccine.

Challenges

- Temporal association vs causal association.
- Differentiating between vaccine-induced effects and background incidence.
- Media coverage can cause bias reporting.
- Ethical concerns in conducting trials during public health emergencies.

Regulatory and Global Context

- WHO's Global Advisory Committee on Vaccine Safety (GACVS) oversees international vaccine safety.
- Pharmacovigilance planning (e.g., Risk Management Plans in Europe) is mandatory post-licensure.

Hospital Pharmacoepidemiology

Definition and Scope

- Hospital pharmacoepidemiology focuses on the use, outcomes, and safety of medications within hospital settings, including both inpatients and outpatients managed by hospital-based services.
- It applies epidemiologic principles to optimize drug utilization, minimize adverse drug events (ADEs), and improve patient outcomes.

Key Objectives:

- Monitor patterns of **drug utilization** in the hospital.
- Assess **adverse drug events (ADEs)**, their frequency, severity, and preventability.
- Support **antimicrobial stewardship** and combat resistance.

- Evaluate **compliance** with clinical guidelines and formularies.
- Optimize pharmacotherapy through **drug utilization review (DUR)** and **medication reconciliation**.

Methodologies Used:

A. Drug Utilization Studies (DUS):

- Quantify and evaluate drug prescribing, dispensing, and consumption.
- Identify trends (e.g., overuse of antibiotics, off-label use).

B. Prospective Surveillance Systems:

- Daily monitoring of medication charts and electronic prescribing systems to detect ADEs in real-time.

C. Retrospective Chart Review and Data Mining:

- Use of hospital information systems to identify ADEs, interactions, or dosing errors from past records.

D. Point Prevalence Surveys (PPS):

- Conducted on a specific day to assess antimicrobial use or drug-related problems across hospital units.

E. Signal Detection and Trigger Tools:

- Use of algorithms to detect patterns suggestive of ADEs (e.g., use of antidotes like naloxone indicating opioid overdose).

F. Pharmacovigilance Integration:

- Reporting serious ADEs to national authorities (e.g., FDA MedWatch, EudraVigilance).

Applications

- Identifying **high-alert medications** with high risk of causing harm (e.g., insulin, heparin).
- Assessing **off-label drug use** in critical care or pediatric settings.
- Guiding formulary decisions based on drug effectiveness and cost.
- Optimizing dosing in special populations (renal impairment, neonates).

Outcome Measures

- Reduction in adverse drug events (ADEs).
- Improved adherence to clinical guidelines.
- Economic evaluation of interventions (e.g., switch from IV to oral therapy).
- Reduction in antimicrobial resistance rates.

Technological Support

- Integration of Clinical Decision Support Systems (CDSS) within hospital Electronic Medical Records (EMR).
- Use of automated surveillance software for real-time ADR detection.

Challenges

- Fragmented documentation in large hospitals.
- Resistance from prescribers toward pharmacy-led interventions.
- Variability in ADR definitions and underreporting.
- Limited infrastructure in low-resource settings.

Examples

- Surveillance of nephrotoxicity from aminoglycosides in ICUs.
- Evaluation of sedative-hypnotic prescribing in psychiatric wards.
- Monitoring vancomycin dosing to maintain therapeutic drug levels.

Pharmacoepidemiology and Risk Management

Introduction

- This area of pharmacoepidemiology focuses on identifying, evaluating, minimizing, and communicating the risks associated with pharmaceutical products throughout their lifecycle.
- It plays a central role in risk management planning (RMP) and risk evaluation and mitigation strategies (REMS) to ensure that a drug's benefits outweigh its risks.

Purpose

- To **detect potential safety issues early**.
- To design **risk minimization strategies**.
- To enhance **post-marketing surveillance**.
- To ensure **regulatory compliance** and protect public health.

Key Components

1. Risk Identification:

- Conducted through clinical trials, observational studies, spontaneous reports.
- Includes detection of ADRs, misuse, medication errors, and drug interactions.

2. Risk Assessment:

- Evaluates frequency and severity of adverse events.
- Uses tools like Signal Detection Algorithms, disproportionality analysis (e.g., PRR, ROR).
- Involves causality assessments using methods like the Naranjo scale.

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