Pharmacovigilance

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Outline

- What is pharmacovigilance?
- Why is pharmacovigilance important?
- Types of reports
- How to report

What is Pharmacovigilance?

Pharmacovigilance is the science of **collecting**, **monitoring**, **researching**, **assessing** and **evaluating** information from healthcare providers and patients on the adverse effects of medicines, biological products, herbals and traditional medicines, with the view to: (WHO)

- Identifying new information about hazards,
- Preventing harm to patients."

In simple terms……..

- Is the process of evaluating and improving the safety of marketed medicinal products and devices
- The key players are
  - ✓regulatory bodies,
  - ✓Public health programs,
  - ✓pharmaceutical companies and
  - ✓healthcare professionals
  - ✓patients

Medicinal products and devices

- ✓ Medicines
- ✓ Biological products e.g. vaccines, blood , blood components
- ✓ Herbal medicines
- ✓ Medical devices
- ✓ Cosmeceuticals

Why Pharmacovigilance?

- During drug development, only a **small number** of patients are exposed to the medicinal product
- On registration, **many more patients** are exposed to the medicinal product, so rare ADRs are bound to be observed
- Comorbidities and drug interactions
- Patient groups- children, elderly, pregnant women are not included in clinical trials

Goals of pharmacovigilance

To :

- Improve patient care and safety
- Improve public health and safety
- Detect problems related to the use of medicines and communicate the findings in a timely manner

What to report

- Suspected adverse drug reactions
- Poor quality medicinal products
- Adverse effects following immunizations
- Transfusion reactions
- Medical device incident reporting form
- Medication Errors

1.Suspected adverse drug reactions (ADRs

ADR- a response to a drug which is **harmful and unintended** and which occurs at **doses normally** used in humans for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function.

Examples: vomiting, respiratory depression, headache, Steven Johnson syndrome, itchiness, etc

Serious adverse drug reaction

- Adverse drug reactions are considered serious if
  - Life-threatening
  - Results in hospitalisation/prolonged length of stay
  - Results in disability
  - Congenital anomaly
  - Death

Suspected adverse drug reactions (ADRs

- ✓ Report **all suspected adverse effects** of concern to the patient.
- ✓ Report adverse effects, whether **mild**, **moderate** or **severe**
- ➢ Report using **Yellow form**

2. Poor quality medicinal products

- These can be
  - Medicines
  - Blood and blood products
  - Herbal products
  - Medical devices
  - Vaccines
  - Cosmeceuticals
  - others

Examples of what to report…

- Colour change, caking
- Moulding
- Therapeutic ineffectiveness
- Incomplete packs
- Mislabeling
- Devices- electrical, mechanism, readings, calibration issues
- Report with **pink form**

Examples

3. Adverse effects following immunizations(AEFIs)~ Types by cause

- **Vaccine product-** inherent properties of vaccine & excipients-DPT-limb swelling
- **Vaccine quality defect-** paralytic polio- incomplete inactivation polio vaccine
- **Immunization anxiety** -anticipation of or as a result of injection e.g. fainting, hyperventilation, convulsions

Type of AEFIs by cause

- **Immunization error-** poor handling, storage or administration

- **Coincidental event** - For example, fever after immunization in a patient with malaria

Classifications of AEFIs

- **Minor**- occurs within a few hours, resolves after a short time and poses little danger. i.e. pain, swelling, fever, malaise, headache, nausea
- **Severe**- seizures, prolonged crying, thrombocytopenia, paralysis, high fever, injection site abscess- **must be reported**
  - **Serious reactions**- life-threatening, causes hospitalization, disability or death

4. Adverse Transfusion reactions

- Unfavorable and harmful transfusion-related events occurring during or after transfusion with blood or components
- Due to
  - ✓Misidentification of patient
  - ✓Improper sample identification
  - ✓Wrong blood issued
  - ✓Administration error
  - ✓Technical error
  - ✓Storage error

Adverse Transfusion reactions

- Reported for Donor & Patient
- Types of reactions
  - ✓General -fever, chills, nausea
  - ✓Dermatological- rashes, urticaria
  - ✓Cardiac/respiratory -dyspnea, chest pain, hypotension, tachycardia
  - ✓Renal- hemoglobinuria, anuria
  - ✓Hematological- unexplained bleeding

Adverse transfusion reactions……

- Reporting Details
  - Patient details history
  - Type of reactions
  - Vital signs
  - Lab investigation
  - Report **errors, near misses** and **other incidents**
    - Report using **beige form**

5. Medical device incidents

- Can occur among Invitro devices, implants, diagnostics devices(rapid diagnostic tests), etc.
- Reporting elements
  - ✓Patient details
  - ✓Details of the medical device- name, model, manufacturer
  - ✓Description of event
  - ✓Event classification- fatal, serious, moderate, mild, unknown

Examples-Reportable events

- Inadequate labelling leading to injuries
- Device malfunction
- Inadequate instructions
- Deterioration in device performance
- Lead to death or serious deterioration of health

- Report using **green form**

6. Medication errors

- Categories of process errors
  - Prescribing
  - Dispensing
  - Administration
  - Transcribing

Medication Error examples

- Wrong (drug, dose, frequency, duration, route, patient) inappropriate drug,
- Omission error
- Illegible prescription

  - Report using **Blue form**

How to report?

- Fill the forms online- www.pv.pharmacyboardkenya.org

"You need not be certain…

Just be suspicious"