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P.V SCOPE TODAY

Adverse Drug reactions (ADR)

Inadequate/incorrect use

Medication errors

Dependence, abuse and poisoning

Antibiotic resistance

Product Quality Problems

Failing Good Manufacturing Practice

Substandard and counterfeit products

Lack of efficiency

Other Safety Challenges

E.g. Rumours during mass drug administration

DRUG SAFETY MONITORING IN MALAWI: N. Dzabala & F. Chimimba

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WHY PHARMACOVIGILANCE?

Humanitarian Concerns

ADRs calculated between 4th & 6th leading cause of death (USA)

Globally at least 10% of all hospital admissions are due to ADRs

6.5% (UK) hospital admission are due to ADRs

0.15% of patients admitted to hospital died from ADRs

In 1995, 2,500 people in Nigeria died due to a fake Meningitis vaccine. In the same year, 89 died in Haiti after taking cough syrup that was made from antifreeze.

Economic Concerns

\$15, 467.00: The total cost of treating 35 paediatric patients with ADRs in 1 hospital (Nigeria, 2011)

GBP 2 billion: Annual cost to the UK of treating patients with ADRs

\$30 billion: Annual cost of treating ADRs (USA, 2013)



Associate Member
Official Member

WHO PROGRAM FOR INTERNATIONAL DRUG MONITORING MEMBERS

As of last year, Malawi did not belong to this global community. However, this year, Malawi became an associate Member of the WHO international drug safety monitoring program.

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THE DRUG

Development Process

During clinical trials:

Very few clinical trials are conducted in Africa.

Not enough data is collected on medicine safety because:

Duration of the clinical trials is short,

Sample size is small

Mainly composed of healthier, less diverse, and more controlled subjects who take fewer medications concomitantly during the trials.

Subjects are closely monitored throughout the trial

What Happens when Marketed?

People using the drug in practice will be different from those in the trial

Different ages: children / elderly/pregnant

Have other disease states

Have different risk factors e.g. renal or hepatic function

Taking other medication

Only limited safety information: rare effects (<1 in 10,000) are unlikely to be identified

International differences

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WHAT CAN YOU DO TO HELP?

Be aware

Risk factors for ADRs: e.g. Older age, Lots of meds, High doses of meds, History of allergy, Other conditions (e.g. HIV)

If a patient presents with a new symptom consider if it could be ADR, especially if in high risk group

Be proactive

Counsel patients on new meds to seek help if any concerns

Clearly label ALL medicines

Avoid inappropriate prescribing and take prompt action when you see inappropriate prescribing (overdose, contraindicated drug, drug-drug interactions)

Be PV champions

Build confidence and encourage others

"You can reduce the suffering and save thousands of patients' lives by doing one thing: Report suspected ADRS" (WHO)

Champions make a difference

