Medication error reporting and learning, and pharmacovigilance systems at the national and organizational level

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Pharmacovigilance systems at the national and organizational level – Botswana experience

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Outline of Presentation

• Baseline assessment
• Building foundation for establishing national PV program
• A system for spontaneous reporting of suspected ADRs
• Stakeholder Engagement
• Establishing ADR Monitoring Centres at Hospitals
• Achievements
Baseline assessment

- The national PV system in Botswana did not meet the WHO minimum criteria for a functional PV system
- The importers count on the parent companies to take the responsibility of monitoring safety of their products
- None of the hospitals have a functioning Adverse Drug Reaction Reporting and Monitoring System – culture of reporting ??
- PV activities are not included in the strategic and/or annual operational plans of Public Health Programs
- The skill and competence amongst the University faculty members to train students in PV is absent
Initiation

• A functional PV centre
• A system for spontaneous reporting of suspected ADRs
• A national database for managing ADR reports
• A national PV advisory committee
• A clear communication strategy
System for reporting of suspected ADRs

• ADR Reporting Forms (paper based)
• E-Reporting (web based, Smartphone – MedSafety App)
• E-mail
• WhatsApp
• Toll free Telephone
Stakeholder Engagement

• Key stakeholders identified
  • HCPs, PHPs, District Health Management Teams

• Healthcare Practitioner Education Program on Medicines and Vaccines safety issues

• Public Engagement
Establishing ADR Monitoring Centres at Hospitals

• Awareness and sensitization programme on continuous basis

• Work with hospital administration, Drugs & Therapeutic Committees and Healthcare Professionals

• Conduct Monthly CMEs on PV for HCPs practicing in the hospital and private practitioners in the community

• Work with DHMT for the effective implementation of the national pharmacovigilance programme at grassroots level
Establishing ADR Monitoring Centres at Hospitals

• Liaise with National Public Health Programs to promote PV
• Ensuring that all ADR reporting tools are available to HCPs
• Train HCPs adequately to facilitate ADR reporting
• To provide thank you notes to reporters
• To attend to inpatient and outpatient wards on daily basis for collection of ADR reports while promoting pharmacovigilance program
• Medication Error reporting / Quality defects reporting
Achievements

• WHO minimum criteria for a functional PV system

• Increase in quantity and quality of reports

• Benchmarking of 200 ADR reports/million population

• TB Preventive Therapy in HIV Patients – INH induced Hepatitis
Achievements

ICSR since 2018

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Look Alike Medications
Achievements

- Vaccines Safety Monitoring
- PV in Mass Drug Administration (Praziquantel)
- Published Factsheets, Safety Alerts, DHCP Letters
- PV Curriculum in UG teaching
Achievements
THANK YOU