#### **Medication Without Harm**



**WHO Global Patient Safety Challenge** 





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

#### **Dr Parthasarathi Gurumurthy**

Director

Pharmacovigilance and Clinical trials
Botswana Medicines Regulatory Authority
(BOMRA)
Botswana









Dr Parthasarathi Gurumurthy
Director
Pharmacovigilance and Clinical Trials
pgurumruthy@bomra.co.bw





Promoting access to safe medicin

# 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 programe 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 programe 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

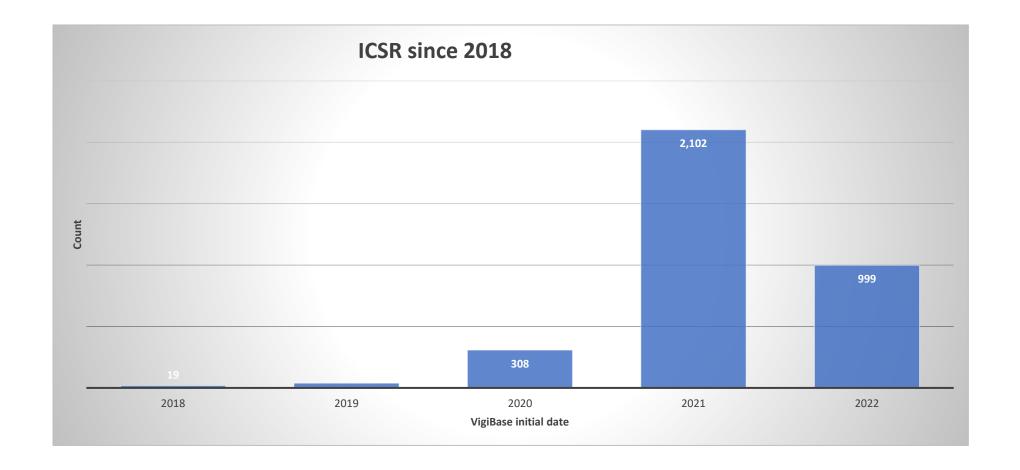




- WHO minimum criteria for a functional PV system
- Increase in quantity and quality of reports
- Benchmarking of 200 ADR reports/million population
- TB Preventive Therapy in HIV Patients INH induced Hepatitis











#### **Look Alike Medications**





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



















#### **THANK YOU**

- **♀** Plot 112, International Finance Park, Gaborone
- Private Bag 2, Gaborone Station, Botswana
- +267 373 1727/20
- Toll Free: 0800 600 216
- info@bomra.co.bw
- **f** Botswana Medicines Regulatory Authority
- www.bomra.co.bw





Promoting access to safe medicines