Impact of Structured Stimulated PV in tertiary hospitals: A review of Individual Case Safety Reports received at the TMDA

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A Decade of regulatory harmonization in Africa: Where are we? Where do we go from here?
OUTLINE

• Introduction
• A structured Stimulated PV Programme
• Comparative study
• Impact of the programme
• Way forward
• Conclusion

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INTRODUCTION (I)

• Detection and reporting of ADRs in clinical practice are the backbone of Pharmacovigilance.

• Under-reporting of ADRs by health-care professionals is a problem among African countries including Tanzania.

• Different efforts have been taken to overcome the problem of under reporting
Efforts undertaken to improve ADR reporting in Tanzania

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A STRUCTURED STIMULATED PV PROGRAMME

- A special program for detecting and reporting of ADRs
- Initiated at MNH – a tertiary Hospital
- Conducted a short training (Dec, 2018) on system rotation, collection of ADRs
- Use of intern pharmacists
- Programme works 24/7
COMPARATIVE STUDY

- **Objective**
  - To investigate impact of structured stimulated PV on ADRs reporting

- **Study Design**
  - Retrospective Comparative study

- ICSRs were received from MNH

- Data were generated in excel from Vigiflow/Vigibase

- Received ICSRs were divided into 2 groups
  - Data received by 31st Dec 2018
  - Data received after 31st Dec, 2019
RESULTS: Impact of Structured Stimulated PV (1)

No. of ICSRs from MNH Before 2018 and after 2018

163 ICSRs
C-consumers, D-clinicians, P-pharmacists, O-others

2006
Jan 2019
June 2019
2018
1,156 ICSRs

Trend of ICSRs from Tanzania sent into the Vigibase

VigiBase initial date

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Frequency of medicines accounted for most reported ADRs at MNH from 2016-2019

- 255 Reported Medicines
- 1,319 ICSRs
SUMMARY: Impact of Structured Stimulated PV

- Increased no. of ADR reports
- Be able to identify and prevent Medication errors (Vancomycin inj.)
- Signal detection
- Improved healthcare service
- Strengthening of MNH PV centre
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• Vigilant group at MNH

TMDA staff at KCMC
• Structured Stimulated Pharmacovigilance Programme:
  ❖ Should be instituted in all tertiary hospitals
  ❖ Framework of the programme should include all healthcare workers
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