DRUG SAFETY JOURNAL

COHORT EVENT MONITORING: EXPERIENCES AND LESSONS LEARNT FROM IMPLEMENTATION IN FOUR (4) AFRICAN COUNTRIES

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DATA COLLECTION QUESTIONNAIRE

Please answer all questions by typing in the shaded area. Where tick boxes are provided, please click on the box next to your selection to mark it with a cross.

SECTION 1: BACKGROUND INFORMATION ON COUNTRY, PV PROGRAMME AND CEM

Country Details

1. Country:
2. Population:
3. Urban-rural distribution of population:

   Urban % Rural %

Health System

4. Brief description of health system:

Pharmacovigilance

5. Year Pharmacovigilance activities began in your country:
6. Year of becoming full member of WHO Programme for International Drug Monitoring:
7. Which organization is responsible for national coordination of Pharmacovigilance activities? (Tick appropriate)

   - ☐ National Drug Regulatory Authority
   - ☐ Ministry of Health
   - ☐ Designated tertiary healthcare institution
   - ☐ A university or other scientific/research based institution
   - ☐ Other. Please specify:

8. In addition to the National Pharmacovigilance Centre, does your country have Regional Pharmacovigilance Centres:

   ☐ No ☐ Yes. Please specify number:

9. Number of staff at National Pharmacovigilance Centre:
10. Number of staff at each Regional Pharmacovigilance Centres (provide range if number varies):
11. Number of ADR reports received so far this year: (to date: / /2013)

12. Number of ADR reports received in each of past 5 years:

Year	Number of ADR reports
2012	
2011	
2010	
2009	
2008	

13. Number of ADR reports submitted to WHO Programme for International Drug Monitoring (Uppsala Monitoring Centre) so far this year: (to date: / /2013)

14. Number of ADR reports submitted to WHO Programme for International Drug Monitoring (Uppsala Monitoring Centre) in each of the past 5 years:

Year	Number of ADR reports
2012	
2011	
2010	
2009	
2008	

CEM

15. Which organization was primarily responsible for implementation and coordination of CEM?

16. How many CEM programmes have been implemented in your country?

PLEASE GO TO SECTION 2

SECTION 2: CEM PRE IMPLEMENTATION ISSUES/ACTIVITIES/EXPERIENCES

NOTE: If your country has implemented more than one CEM programme, kindly MAKE A COPY and COMPLETE THIS SECTION FOR EACH CEM PROGRMME, as the experiences may differ between programmes.

17. Name of CEM programme:

Rationale for implementing CEM

18. What is the disease focus of the CEM programme?

19. What is the prevalence and/or incidence of the disease in the population?

    a) Prevalence: /100 000 population. Source of information:

    b) Incidence: /100 000 population. Source of information:

20. What was the rationale for implementing the CEM programme?

21. What medicines were monitored by CEM programme?

22. What informed the choice of medicines to be monitored?

Ethical approval

23. Was ethical clearance/approval required prior to implementing CEM?

    ☐ Yes ☐ No (Please go to Question 27)

24. How long did it take from application to granting of ethical approval?

25. Briefly describe the process of obtaining ethical approval:

26. Were there any difficulties in obtaining this approval?

    ☐ No ☐ Yes. Please describe:

27. What were the requirements for patient consent?

    ☐ Written informed consent
    ☐ Verbal informed consent
    ☐ Universal enrolment with 'opt-out' clause
    ☐ Other. Please specify

Stakeholders and Funding

28. What was the total budget for implementing CEM? (Please include currency)

29. What were the sources of funding for CEM?

30. Who were the stakeholders involved in the CEM programme? Please provide the name of organizations or positions of individuals and describe the extent of each stakeholder's involvement in planning and implementing the programme:

Stakeholder	Role in planning and implementing the CEM programme

31. How was consultation with stakeholders undertaken?

Programme Tools

32. What documents/tools were developed for implementation of the programme? Please list the documents/tools below.

33. Were the documents/tools that were developed for the CEM study pre-tested prior to implementation?

☐ Yes ☐ No (Please go to Question 36)

34. Briefly describe how each of the documents/tools was pre-tested:

35. What did you learn from the pre-testing of each document/tool?

Site Selection

36. How many sites were involved in patient enrolment?

37. How were the sites selected?

38. Was it necessary to pay an advocacy visit to the sites prior to implementation?

☐ Yes ☐ No

Please explain your answer:

39. What was the nature and level of healthcare delivery offered by the sites? Please tick all the apply

- ☐ Public sector tertiary level hospital or its equivalent such as a national hospital, etc
- ☐ Public sector secondary level hospital or its equivalent such as a provincial hospital
- ☐ Public sector primary level hospital or its equivalent such as a district hospital, community healthcare centre, etc
- ☐ Private sector hospital/clinic
- ☐ Community pharmacy
- ☐ Other (please specify)

40. What was the distribution of sites in terms of urban/rural location:

Urban % Rural %

Training

41. Were the healthcare providers at the monitoring sites trained in relation to CEM prior to implementation?

☐ Yes ☐ No (Please go to Section 2, Question 44)

42. How was this training carried out?

43. Who was responsible for training the healthcare providers?

PLEASE GO TO SECTION 3

SECTION 3. IMPLEMENTATION PROCESS

NOTE: If your country has implemented more than one CEM programme, kindly MAKE A COPY and COMPLETE THIS SECTION FOR EACH CEM PROGRMME, as the experiences may differ between programmes.

44. Name of CEM programme:

Human Resources

45. What professions were involved?

- ☐ Doctors
- ☐ Nurses
- ☐ Pharmacists
- ☐ Clinical assistants
- ☐ Clerical staff
- ☐ Other (please specify):

46. For each of the sites that were involved in CEM, please provide the total number of personnel required to implement **all aspects** of CEM at that site. Please also provide the number for each of the professions/positions e.g. doctors (2), nurses (3), pharmacists (1) clerical staff or assistant (1), data entry (5), etc? Indicate all that apply:

Site	Total Staff	Number of each profession
National Centre		
Regional Centres		
Clinics		
Other		

47. How would the sites best describe the additional workload associated with CEM?

- ☐ Fitted well into routine work
- ☐ Interfered to small extent with routine work
- ☐ Interfered to large extent with routine work
- ☐ Other (please describe)

48. In general, how would you describe the level of enthusiasm and co-operation of the health care providers at the monitoring sites in relation to CEM activities?

- ☐ Enthusiastic/ cooperative
- ☐ Neutral
- ☐ Reluctant/ uncooperative
- ☐ Other (please describe)

49. How would you rate understanding of the methodology and adherence to protocol by the site personnel?

- ☐ The methodology was generally well understood with good adherence to protocol at all sites
- ☐ The methodology was understood but there were minor deviations from protocol at some sites
- ☐ The methodology was not well understood and there were deviations from protocol at many sites
- ☐ The methodology was poorly understood and there were major deviations from protocol at most sites
- ☐ Other (please describe):

50. Were incentives used for HCPs

☐ Yes ☐ No (Please go to Question 54)

51. What was the rationale for providing incentives for HCPs?

52. What was the nature and quantity of incentive(s) for HCPs and how was this determined?

53. In your opinion, would it have been possible to undertake a CEM programme in your country without the use of incentives for HCPs?

☐ Yes ☐ No

Please explain your answer:

Patient Enrolment

54. How would you rate the willingness of patients to participate in the programme?

- ☐ Very willing to participate (> 90 % participation)
- ☐ Fairly willing to participate (< 90 % > 60 % participation)
- ☐ Not willing to participate (< 60 % participation)

55. Who was responsible for obtaining informed consent from patients (if applicable)?

56. Were there any challenges in obtaining informed consent from patients?

☐ Yes ☐ No. (Please go to Question 58)

57. What were the challenges in obtaining informed consent from patients?

58. Were incentives used for patients

☐ Yes ☐ No (Please go to Question 62)

59. What was the rationale for providing incentives for patients?

60. What was the nature and quantity of incentive(s) for patients and how was this determined?

61. In your opinion, would it have been possible to undertake a CEM programme in your country without the use of incentives for patients?

☐ Yes ☐ No

Please explain your answer:

62. Who filled out the data collection forms at enrolment (pre-treatment)?

63. How many patients were enrolled into the cohort?

Actual Target

64. How long did it take to enrol all patients into the cohort?

Actual Expected

65. If enrolment took longer than expected, what reasons were identified?

Patient Follow-up

66. Who filled out the data collection forms at follow-up?

67. How were patients followed-up and by whom?

68. Were any difficulties encountered in following up patients?

☐ Yes ☐ No (Please go to Question 70)

69. Describe some of the challenges encountered in following up patients:

70. What percentage of enrolled patients was lost to follow-up? %

71. What measures were taken to minimize loss to follow-up?

Data Management

72. How was data collected?

☐ On paper Data Collection Forms

☐ Directly into data management software programme (Please go to Question 75)

73. Where was the data entered into the data management software programme?

☐ At the clinics (monitoring sites) (Please go to Question 75)

☐ At the Regional PV Centre

☐ At the National PV Centre

☐ Other (please specify):

74. How were the Data Collection Forms transmitted from the monitoring site (clinics) to the point of data entry?

☐ Post

☐ Courier

☐ Collected by PV Centre staff member and taken to PV Centre

☐ Delivered to PV Centre by Monitoring Site staff member

☐ Other (please specify):

75. What data management software was used?

☐ CemFlow

☐ Other. Please specify

76. Who was responsible for data entry?

- ☐ Data entry personnel
- ☐ PV Centre staff
- ☐ Healthcare Providers (Doctors, Nurses, Pharmacists) at monitoring sites
- ☐ Clerical staff at monitoring sites
- ☐ Other (please specify):

77. How many personnel were required (or are planned) for data entry?

78. What training was provided in relation to data entry software?

79. What was the time taken to enter all collected CEM data (or anticipated time required if data entry is ongoing)?

80. What were your impressions regarding the data entry process? (What worked or did not work and what changes you would like to see in the future to enhance data entry?)

81. Was Causality Assessment undertaken on each event?

☐ Yes ☐ No (Please go to Question 83)

82. Who was responsible for Causality Assessment of events?

Monitoring and Evaluation

83. How was the implementation of CEM monitored?

84. What was the total financial cost of implementing CEM? (Please include currency)

Actual Projected

85. Were additional resources, beyond what was budgeted, required to implement the CEM?

☐ Yes ☐ No (Please go to Question 87)

86. What additional resources were utilized to implement the CEM project?

Challenges

87. What were the major challenges encountered in implementing the CEM programme?

88. How were these challenges addressed?

89. If any challenges were not addressed, what were the reasons?

Lessons learnt

90. What lessons did you learn as a result of implementing the CEM methodology in your country?

91. In your opinion did CEM affect spontaneous reporting practices (positively or negatively)?

92. What was the added value (if any) of CEM? (For example, PV advocacy/sensitization, setting up of patient / pregnancy registers)?

93. Please provide any other comments you may have on your experience with CEM implementation?

94. Based on your experience of implementing CEM in your country, would your PV centre be interested in carrying out other CEM studies?

☐ Yes ☐ No

THANK-YOU FOR FILLING OUT THE QUESTIONNAIRE.

PLEASE RETURN THE COMPLETED FORM TO:

Comfort Suku: kunacom@yahoo.com

Cc: Geraldine Hill: geraldine.hill@who-umc.org

PLEASE ATTACH A COPY OF EACH OF THE FOLLOWING CEM DOCUMENTS:

Document	**Attached**
Treatment Initiation Form	☐
Treatment Review Form	☐
CEM Enrolment card	☐
Other(s)	☐ Please specify: