Sources of Pharmacovigilance data: current developments in WHO

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Methods supported by WHO

- 1. Spontaneous reporting
  - unsolicited communication of ADRs
  - By health care professionals or consumers
  - In a patient who was given one or more medicinal products
  - does not derive from a study or any organized data collection scheme
  - is “voluntary” reporting
  - will not provide rates and incidences of ADRs

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2. Cohort Event Monitoring (CEM)

- Prospective observation of a cohort of patients
- Collect ALL adverse events (before and after treatment)
- Actively pursue ALL patients in cohort
- ALL and everything
- Denominator and numerator: rates and frequencies
- Events and reactions
- New and old
-

('Hot pursuit')

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Ghana

- The budget for a one year active safety monitoring of ACTs, SPs and other antimalarials used in the health system in Ghana (cohort of 10 000) is estimated to be

  € 91,112.00.

Tanzania

S/N	DESCRIPTION	Total Cost
1.	Stationary & supplies and printing	10,000
2.	Allowances	70,000$
3.	Consultancy costs	20,000$
4.	Transport	5,000$
5.	Training cost	3000$
6.	Data base development	10.000$
7.	IT supplies &accessories	4000$
8.	IEC materials	5,000$
9	Running cost	5,000$
9.	**Grand Total**	**132.000$**

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When CEM?

1. New chemical entities or pharmacological class
2. Fast tracked approvals /products; conditional approvals
3. Best in early post-marketing phase

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3. Targeted Spontaneous Reporting (TSR)

- Middle of the road (between Spontaneous Reporting and CEM)
- Adapted to the safety question at hand.
  - the frequency of a **specific ,previously identified problem**
    - (e.g. vision disorders)
- Events likely to affect treatment outcomes
  - Treatment threatening toxicity
  - Poor adherence
- Less expensive than CEM because
  - part of routine care
  - Use existing cohort (eg TB cohort)
  - No baseline measurement

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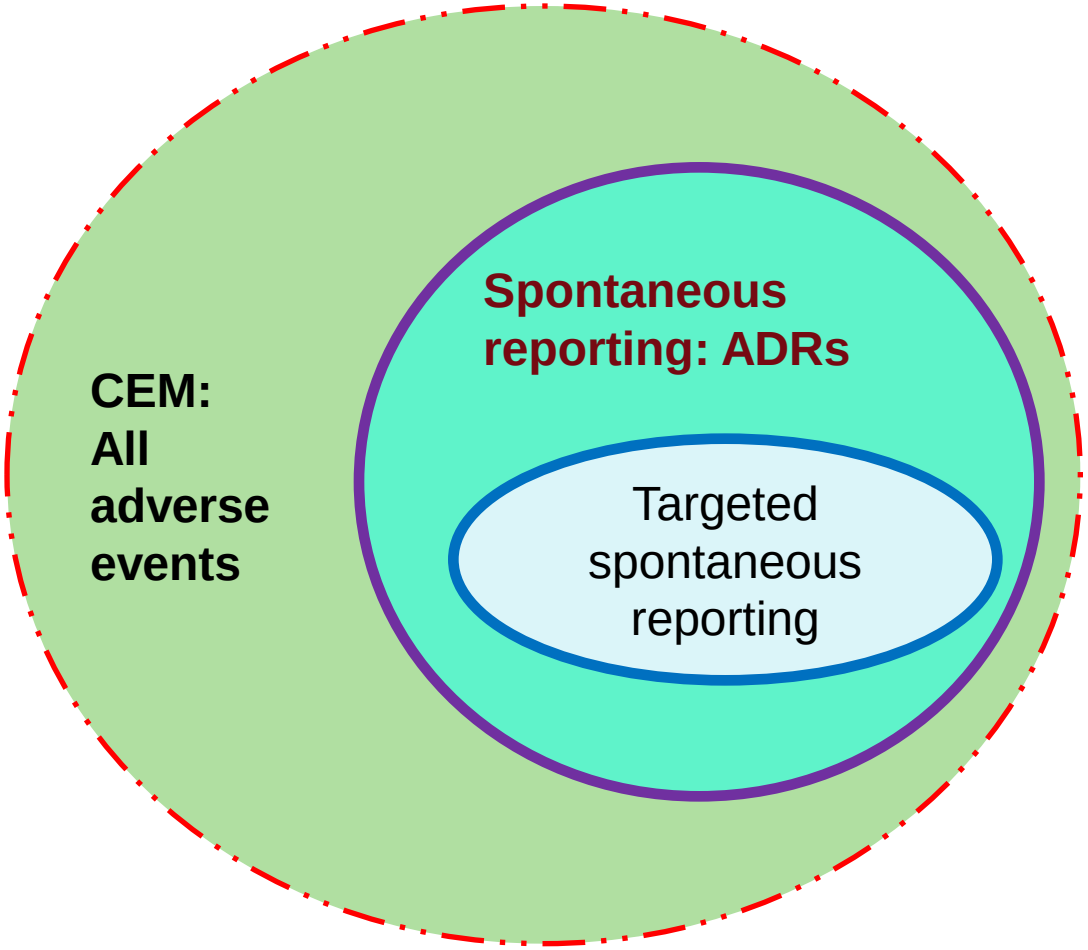

CEM: Ghana,Tanzania, Kenya, Nigeria, Zimbabwe

TSR: Belarus, Tanzania

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4. Electronic longitudinal patient records

- A complementary source of information on the real world use of medicinal products
- Data collected directly from the computer systems in which the doctors manage their patient records
- Listings *over time* for each patient of
  - Medical diagnoses
  - Drug prescriptions
  - Administrative information (test results, life style, …)

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Pregnancy registers

1. Quantify baseline risk of major congenital malformations in disease-endemic countries.
2. Quantify risk of major congenital malformations associated with exposure during pregnancy. (eg, to ACTs in 1st trimester of pregnancy)
3. Identify other factors that may contribute to risk of major congenital anomalies and other adverse birth outcomes

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The Minimum Requirements - I

1. A ***national pharmacovigilance centre*** with designated staff, stable basic funding, clear mandates, defined roles and collaborating with the WHO Programme for International Drug Monitoring
2. The existence of a ***national spontaneous reporting system*** with an ADR reporting form
3. A ***national database*** or system for collating and managing ADR reports
4. A national ADR or pharmacovigilance advisory committee
5. Clear communication strategy

- WHO website:
- www.who.int/medicines/en
  - Quality assurance and safety
    - Safety

- Email:
  - pvsupport@who.int

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