

WHO Pharmacovigilance Indicators

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Scope of presentation

- Sensitization of Coordinators, Co-coordinators, Pharmacovigilance Associates on WHO Pharmacovigilance Indicators
- Indicators useful at AMC level
 - Core Indicators
 - Supplementary indicators

Pharmacovigilance

“The science and activities related to the detection, assessment, understanding and prevention of adverse drug effects or any other possible drug-related problem”

Indicators

Specific **objective** measures that allows the evaluation of the **baseline situation** and **progress** in the systems and assessment of services and interventions

S

- Simple, Specific

M

- Measurable

A

- Achievable

R

- Reliable, Reproducible

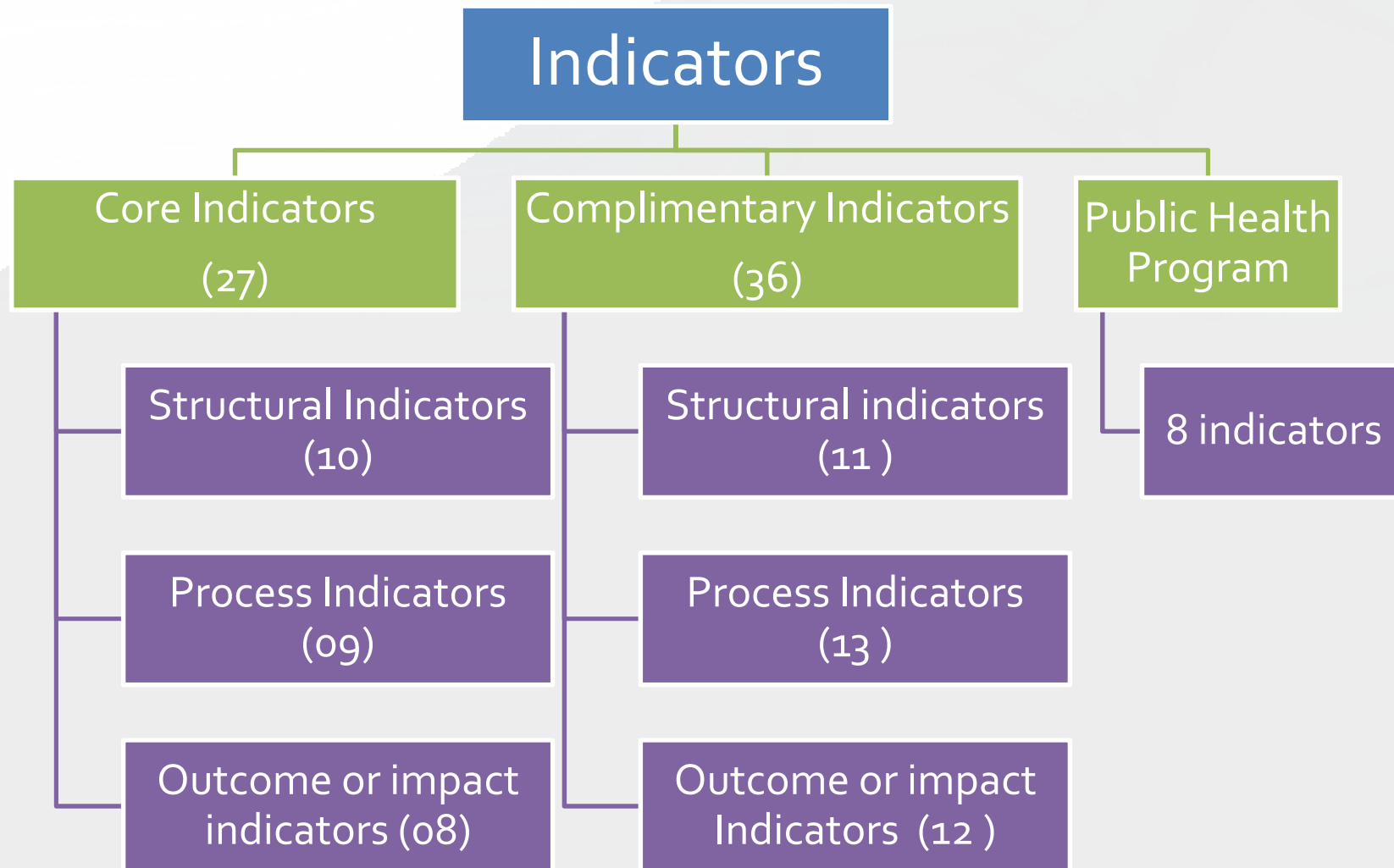
T

- Time-bound, Trackable

Need of Pharmacovigilance indicators

- Assessment of pharmacovigilance activities at various level
 - Local, National, International
- Identification strength and weaknesses
- Tool for
 - Monitoring and supervision
 - Measure impact
 - Education
 - Feedback to funding agency, Government
- Comparison of pharmacovigilance activities

Pharmacovigilance Indicators



Data Sources

- Pharmacovigilance Center
(Local/Regional/National/International)
- Hospital
- National database (Census, registry)
- Pharmaceutical database
- Survey

Core **Structural** Indicators

Existence of

1. Pharmacovigilance centre, department or unit with a standard accommodation
2. Any regular financial provision (e.g. statutory budget) for the pharmacovigilance centre
3. Human resources to carry out its functions properly
4. Standard ADR reporting form in the setting
5. A place for collection, recording and analysis of ADR reports
6. Pharmacovigilance into the national curriculum of the various health care profession
7. Newsletter, information bulletin or website (a tool for pharmacovigilance information dissemination?)

Core **Process** Indicators

1. Total number of ADRs received in previous year

Calculation:

- Absolute number of reports
- Number of reports per 100,000 population

2. Current total number of reports in national/regional/local database(Cumulative indicator)

Calculation:

- Absolute total number of reports

Core **Process** Indicators

3. Percentage of total annual reports acknowledged/issued feedback

$$\frac{\text{No. of reports provided with feedback during one-year period}}{\text{Total no. of reports received during one-year period}} \times 100$$

4. Percentage of reports subjected to causality assessment in previous year

$$\frac{\text{No. of reports subjected to causality assessment in the year}}{\text{Total no. of reports received during same year}} \times 100$$

Core **Process** Indicators

5. Percentage of total annual reports satisfactorily completed and submitted to National Pv Center in previous calendar year

No. of reports filled satisfactorily during the year

X 100

Total no. of reports received during same year

No. of reports filled in satisfactorily **AND** committed to
National Database during the year

X 100

Total no. of reports received during same year

Core **Process** Indicators

6. Number of active surveillance activities initiated, ongoing or completed in the past five calendar years
 - Phase IV Clinical trials, **Cohort Event Monitoring**, (CEM), **Targeted Spontaneous Reporting** (TSR),
 - **Calculation:** Absolute number

Core **Outcome** Indicators

1. Number of medicine-related hospital admissions per 1000 admissions

No. of people admitted owing to a medicine-related illness

X 1000

Total number of people admitted to same hospital or setting

2. Number of medicine-related deaths per 1000 people served by the hospital per year

No. of medicine-related hospital death
(Outpatient and Inpatient)

X 1000

Total number of outpatient and inpatient of the hospital
during the period

Core **Outcome** Indicators

3. Average duration (days) of medicine related extension of the hospital stay

Complementary **Structural** Indicators

1. Dedicated computer for pharmacovigilance activities
2. Source for data on consumption and prescription of medicine
3. Functioning and accessible communication facilities at pharmacovigilance center
4. Library or reference source for drug-safety information
5. Computerized case report management system
6. Essential medicine list in use

Complementary **Structural** Indicators

7. Consideration of pharmacovigilance data while preparing Standard Treatment Guidelines
8. Organization of training courses for healthcare professionals, general public
9. Web-based pharmacovigilance training tool for healthcare professionals, general public

Complementary **Process** Indicators

1. Percentage of health-care facilities that had a functional pharmacovigilance unit (i.e. submits ≥ 10 reports annually to the pharmacovigilance centre)
 - Whether AMC functional last year (≥ 10 reports)
2. Percentage of total reports sent in the previous year by the different stakeholders: Medical doctors, Dentists, Pharmacists, Nurses, General Public
3. Percentage of health-care providers aware of and knowledgeable about ADRs per health facility
 - Level of awareness of healthcare professionals about ADRs

Complementary **Process** Indicators

4. Percentage of patients leaving a health facility aware of ADRs
5. Number of face-to-face training sessions conducted on pharmacovigilance in previous year, for healthcare professional and general
6. Number of healthcare professionals and individuals from general public received face-to-face training in pharmacovigilance

Complementary **Outcome** Indicators

1. Percentage of preventable ADRs out of the total number of ADRs reported in the preceding year
2. Number of medicine-related congenital malformations per 100,000 births
3. Number of patients affected by a medication error in hospital per 1000 admissions in the previous year
4. Average number of medicine per prescription
5. Percentage of prescriptions with medicines exceeding recommended dose

Complementary **Outcome** Indicators

6. Percentage of prescriptions containing medicines with potential for interaction
7. Number of medicine-related congenital malformations per 100,000 births
8. Percentage of patients receiving information on the use of their medicines and on potential ADRs associated with those medicines

Utility at AMC Level

- Assessment of progress of AMC
- Identification of areas which require improvement
- Prepare Annual Report in a systematic way
- Educational intervention
- Teaching tool
 - Undergraduate, Postgraduate

Thank you...!