

Pharmacovigilance in Public Health Programmes

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Essential Medicines and Health Products

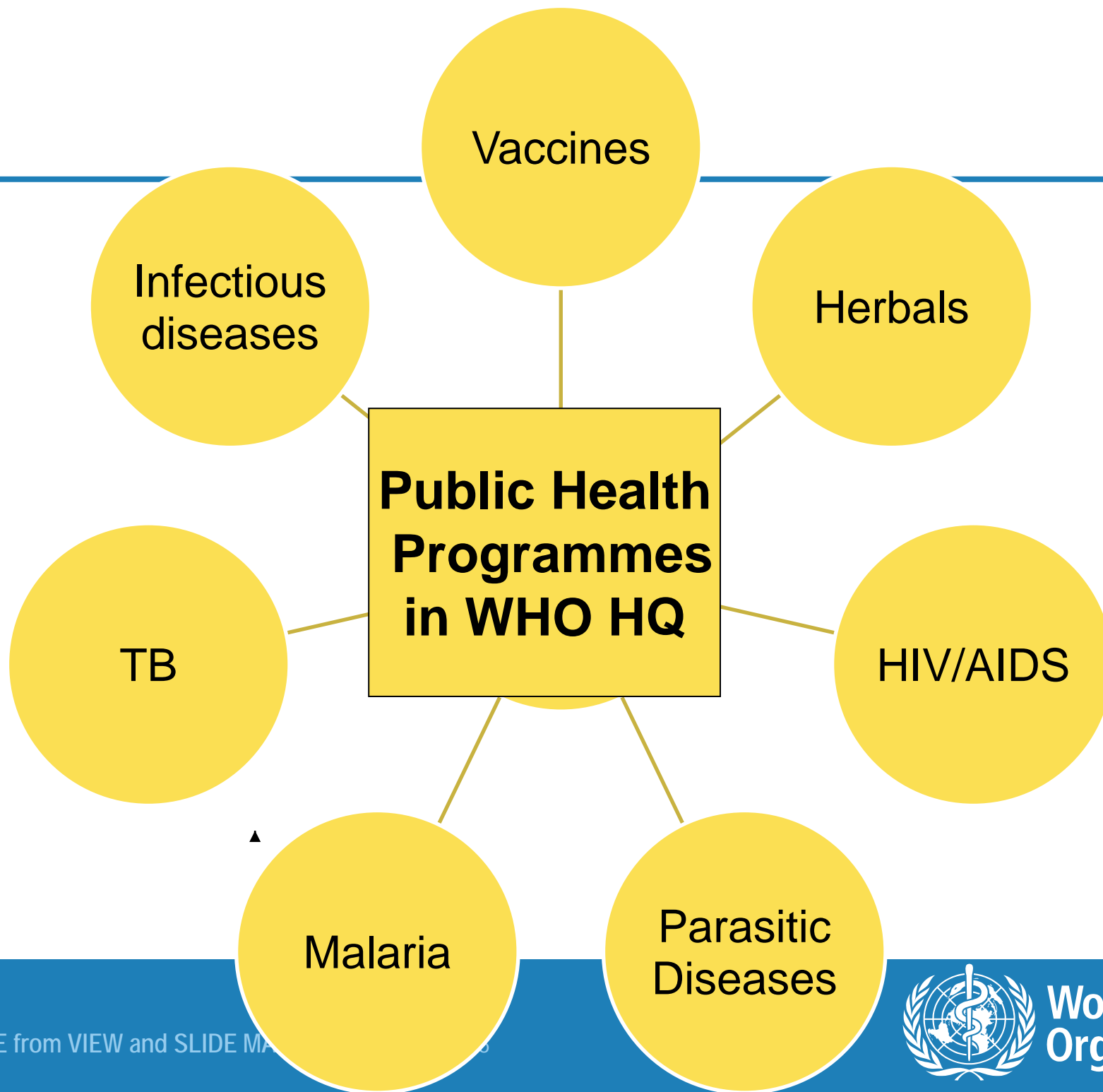


World Health
Organization

Public Health Programs (PHP)

- Objective – **promote**, **protect**, and **restore** health
- Components – education, environment, nutrition, lifestyle/behavior, prevention (immunization), pharmacotherapy
- Priority in developing countries – reducing morbidity and mortality of major common diseases





Priority PHP

- Prevent, treat and control infectious diseases: malaria, TB, HIV/AIDS
- Immunization programmes
- Mass distribution of free medicines
 - national MOH
 - donors: WHO, UNICEF, GF, USAID, etc.



PV is at the heart of public health

To:

- ✓ prevent harm and cost of medicines
- ✓ improve clinical practice
- ✓ promote rational use of drugs
- ✓ participate in research and education



Arguments for PV of 'old' medicines in Public Health Programmes

- It is not always the product that determines medicine safety but how it is used
- There is a high risk of misuse of drugs: presumptive treatment
- Urgent need to educate staff in public health programmes on the need for PV

Medicines in priority diseases: HIV, TB, Malaria

We are accelerating the use of new drugs in new environments, which are mostly devoid of pharmacovigilance activities

- Faster scale up of public health programs due to availability of new funding from major donors such as the Global Fund, World Bank, PEPFAR, PMI, etc
- New drugs are reaching developing countries in greater numbers and more quickly because of new funding from several donors, including the Bill and Melinda Gates Foundation



Importance of pharmacovigilance

Cannot extrapolate data from developed countries:

- Type of drug use is different
 - Do not use the co-formulated ARVs
 - Minimally use anti-TB, anti-malarial and anti-diarrhoeal drugs
- Patient genotype, phenotype, social and economic conditions are markedly distinct
 - Large number of malnourished patients
 - Patients with concomitant diseases
 - High rates of illiteracy and poverty, increases likelihood of inappropriate use by pregnant women, breast feeding mothers, young children, elderly
 - Large number of patients using herbal and other traditional medicines



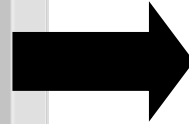
Background

- Global Drug Facility (GDF):
 - procurement agency;
 - in 2009 delivered over 2.4 million patient treatments
 - In 2011 brought upwards of 60,000 additional MDR-TB patients to treatment



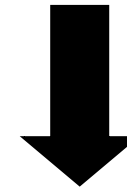
Large-scale interventions

Lymphatic filariasis
Onchocerciasis
Schistosomiasis
Soil-transmitted Helminthiasis
Trachoma



Albendazole
Azithromycin
Diethylcarbamazine

Ivermectin
Mebendazole
Praziquantel



in 2008

668 070 259



Impact of ADRs on PHP

- Significant cause of morbidity and mortality
- Affect treatment adherence
- Increase risk of drug resistance
- Public confidence in PHP
- Wasted financial resources



In most settings PV and PHPs operate in isolation, as independent vertical programmes



Urgent need for synergistic collaboration

PHP

- ✓ Financially well-supported
- ✓ Offer a cohort of patients under controlled conditions
- ✓ But usually no PV capacity
- ✓ Conflict of interest

PV centres

- ✓ detect , evaluate, and prevent adverse events
- ✓ Good expertise, capacity
- ✓ Independence
- ✓ But little funds



SHARED RESPONSIBILITIES

Natl-PV

Trachomatis
Filariasis
Tuberculosis
Malaria
Vaccines

PHP
PROGRAMMES

- PV centre support PHP by
- Initiating, organizing, carrying, advising and guiding safety monitoring
- PHPs funding the PV activities
- Best practices in PHP; National PV offices strengthened through service provided



Benefit of Pharmacovigilance—beyond Safety

