



Session III. Pitfalls and Pearls in Resource-Limited Settings: Opening Remarks

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Context

- 35-year career commitment to the science, training, and application of pharmacoepidemiology
- Global pharmacovigilance work supported by:
 - Bill & Melinda Gates Foundation (2007-)
 - Strengthening Pharmaceutical Systems Partnership with MSH (2008-)
 - UW Department of Global Health (2010-)

The Pharmacovigilance Framework

People

Reporters

Doctors
Pharmacists
Nurses
Other Health Care Workers
Consumers

Evaluators

Medical Specialists
Clinical Pharmacologists
Pharmacists
Epidemiologists

Functions

Reporting (Detection and Generation)

Report suspected side effects, adverse events, quality concerns and errors

Data Collation (Evaluation)

Collate data, conduct initial analysis

Causality Analysis and Risk Determination

Establish causality or determine if further epidemiologic studies are required to establish association

Decision Making and Appropriate Action

Package insert amendments, warnings, scheduling changes, risk management, market withdrawal, product recall

Structures

Manufacturers
Hospitals/Institutions

Pharmacovigilance Center
Drug & Therapeutics Committees (DTCs)
Safety Advisory Committees

Regulatory Authority
Industry
Health Services
Professional Groups
Advisory Committees

Prevented medicine-related problems | Reduced morbidity and mortality

Pearls

1. Unprecedented interest in global pharmacovigilance and countries want their own data
2. Advances in methods - sentinel sites, active surveillance
3. Many examples of “signals to action”
4. Stage set for collaboration



Pitfalls = Challenges = Opportunities

1. No unified vision for pharmacovigilance in resource-limited settings
2. Greater translation of science to policy and practice is needed.
3. Limited resources & training given the need
4. Better metrics are needed



Personal Reflections on The Way Forward

- Define the question(s) for PV
- Mind the special populations
- Utilize most appropriate methods; no single approach can meet all needs – tool-kits needed.
- Disseminate successes and ‘non-successes’
- Collaborate, advocate, act, persistency
- Be good partners