Challenges of pharmacovigilance in our set up
(medical college perspectives)

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Areas of discussion

• Purpose and range of Pharmacovigilance

• Medical college set up

• Problems/ Challenges
Pharmacovigilance as

To identify, review and understand drug adverse effects and taking required precautionary actions to curtail these drug linked problems

The importance of Pharmacovigilance- Safety Monitoring of Medicinal Products (2002)  WHO
Purpose

• To improve **scientific understanding of safety profile** of drugs and advise regulatory authorities.

• It has been limited to **detection of unidentified adverse drug effects** and

• Support public health by **providing reliable scientific information**.
Recent range of Pharmacovigilance

• Expands to include, herbals medicines, blood products, biologics, medical devices and vaccines (1)

• Additionally traditional/herbal medicines causing potential adverse interaction (2)

(1) Shaw et al 2012: Pharmacovigilance of herbal medicine
Our set up (Medical College Perspectives)
Milestones:

- The Department was selected as one of the peripheral centres for 'National Pharmacovigilance Programme of India' implemented from January 2005 by CDSCO, Government of India.

- Adverse Drug Events Reporting:
  Total of 210 adverse drug events were collected / reported at our centre during the period of 2005 to 2008

.........LESS????
Activities related to Pharmacovigilance

- CMEs for clinicians
- Workshop for post graduate students & paramedical staffs
- Conference involving Clinicians, Academia and Industry
Milestones

Pharmacovigilance Program of India

• To monitor Adverse Drug Reactions (ADRs) in Indian population
• To create awareness amongst health care professionals about the importance of ADR reporting in India
• To monitor benefit-risk profile of medicines
• Generate independent, evidence based recommendations on the safety of medicines
• Support the CDSCO for formulating safety related regulatory decisions for medicines
• Communicate findings with all key stakeholders

Recognized as a centre in early part of this year
How much we could achieve?

• In the list of PVPI, NCC, Ghaziabad!

• How much it could contribute in PV per se?

• No of ADR reported: ONLY 37 over a period of 4 months

• What are the problems?
What are the **problems or challenges**?

- Awareness, alertness
- Reporting - who, what and to whom
- Documentation
- OTC medicines
- Herbal medicines
- Manpower
Spontaneous reports

Clinical trial reports

Observational studies

Solicited reports

Regulatory database
Awareness &/or alertness

• Clinicians – Well aware but not alert

• Patients – Alertness is perhaps proportional to Awareness of reporting

• Paramedical staffs – Partially aware & alert

• Requires to be addressed aggressively (one of the objectives of PvPI)
Reporting By PHYSICIAN/CLINICIAN

- Trivial - on non-serious cases
- Preferences - priority is on disease, not on drugs & data
- Lack of time – way of reporting goes mostly to Dermatology for treatment, if not for data compilation
- Non rewarding – Lack of motivation
- Drug Information not readily available & not were well trained in medical curriculum

**Solution:** Include drug safety in curriculum at various levels
Patient reporting

- Very less patient reporting.
- Less awareness on extent and nature of ADR & thereby reporting.
- Wider use of OTC and left over medicines.
- Increasing patient awareness program.
A critical challenge

- Case files
- Prescriptions
- ..........Lack of clinical details and
- ..... Difficulty in obtaining required details

are important limitations.
OBSERVATIONAL STUDIES

- Data or findings are not reported to ADR monitoring centre.... not centralized

- Come out as Publication of reports

- Long lag time between first detection of a signal by the researcher and publication of a report
OTC drugs

- Missing data.........
Herbal Medicines

• Common belief that “herbal” means “safe” medicine & long-term use of traditional medicine assures its efficacy and safety.

• Irrational use of herbal and traditional medicines raises serious concerns about safety.

• Self-medication by common people further increases the risk…. Drug interactions.

• **Only possible through observational studies**

……..Shaw et al (2012) Pharmacovigilance of herbal medicine
Manpower

• *Trained persons* – is there an adequate number to take care of various aspects of Pharmacovigilance in any centre?

  Mostly all shared activities.
Primary Health Centres

- High work load
- Patient load
- Not well addressed

Therefore Missing data......
Way Ahead…..

• Not the challenges of a particular medical college only but CHALLENGES AT LARGE!

• There is a need for better integration of pharmacovigilance into clinical practice and public policy

• Incorporated into II, III MBBS Medical Curriculum … but the out come may not be immediate.
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