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

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Areas of discussion

H M Patel Centre for Medical Care & Education

- Purpose and range of Pharmacovigilance
- Medical college set up
- Problems/ Challenges

The World Health Organization

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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

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- 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

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- 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

(2) S, Soulaymani, Bencheikh R (2012) Safety monitoring of herb-drug interactions: a component of Pharmacovigilance.

Our set up (Medical College Perspectives)

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Milestones:

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- 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 t Pharmacovigilance

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

Milestones

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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?

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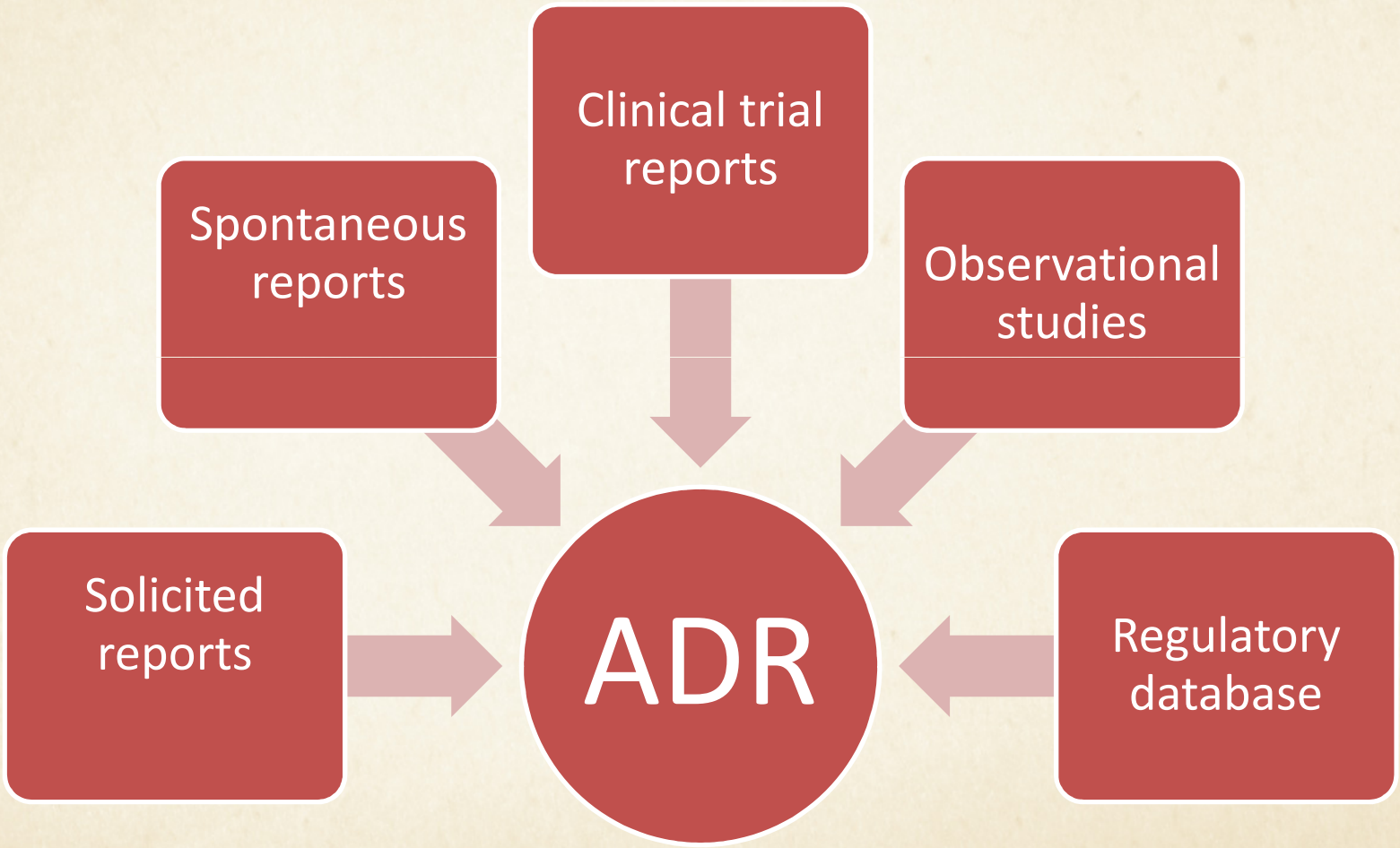
- In the list of PVPI, NCC, Ghaziabad !
- How much it could contribute in PV per se?
- No of ADR reported : ONLY 37 over a period of 4 months
- **What are the problems?**

What are the **problems or challenges ?**

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

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Awareness &/or alertness

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- 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**

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- 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

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- 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**

DOCUMENTATION

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A critical challenge

- Case files
- Prescriptions

- ……..Lack of clinical details and
- ….. Difficulty in obtaining required details

are important limitations.

OBSERVATIONAL STUDIES

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- 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

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- Missing data……

Herbal Medicines

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- 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 interractions
- **Only possible through observational studies**

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

Manpower

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- ***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

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- High work load
- Patient load
- Not well addressed

Therefore Missing data……

Way Ahead…..

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- 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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THANK YOU