



MATA AMRITANANDA MAYI DEVI

PHARMACOVIGILANCE

TO ENSURE GLOBAL SAFETY OF MEDICINES

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SEE, HEAR AND TOUCH

- WHO 1966 --for the benefit of the recipient
- From the first day of medical school, we are taught “Primum Non Nocere”
- Mishaps do happen
- Thalidomide disaster – 1960 - 61 West Germany - an eye opener
- Millions of lives could have been saved if we were vigilant enough !!

PHARMACOVIGILANCE IS NOT ANYONE'S PERSONAL AGENDA

Pharmacovigilance Team

All Healthcare Professionals

Physicians, Surgeons, Dentists,
Pharmacists, Nurses, Health
Inspectors

GOALS AND MILESTONES

- **Step 1: Foster the Culture of Notification of ADEs**
Debriefing, Interaction & Training
- **Step 2: Data management**
Debriefing, Interaction, Training
- **Step 3: Data analysis**
Debriefing, Interaction, Training



THE FIRST STEP

- **December 1994 - Medical Director - Mandatory to report adverse events**
- **Spread the message - Hard copies and through internet message**
- **Doctors, Pharmacists, Nurses and Students**
- **Poster designed and pasted in the Nursing chamber**

FROWNED!

Mandatory ? Two Reasons

- 1. Accreditation - active involvement in Pharmacovigilance Programme**
- 2. Potential safety issues with marketed drugs – we must be ready to respond quickly**
- 3. Global database is a necessity**

THE CAMPAIGN

- **Lecture classes to students**
- **Orientation class to new comers**
- **Daily enquiries in the wards**
- **Thank you letters**
- **E- mail reminders**
- **Periodic presentation of statistics**
- **Safety alerts**

AUGUST AUDIENCE TARGETED

Presentations

- **Amrita academic meetings**
- **HOD meetings**
- **IMA meetings**
- **Article in Amrita Patrika – locally circulated**

THE COLD RESPONSE

- **Responses slowly trickled**
- **Definite lack of warmth**
- **Redesigned the notification form**
- **Made the procedure very simple**

MORALE BOOST

- **Be proud - AIMS the only Peripheral Pharmacovigilance Centre in Kerala**

Initiated by DCGI, Government of India, to maintain a close watch over the use of drugs and their effects on people as a part of WHO initiative for Global Safety of Medicines)

- **Amrita is Synonym for Global Service**
As Is Pharmacovigilance

AIMS To SWEDEN

Primary Peripheral Centre



Regional Centre (Causality analysis)



Zonal Centre (statistical analysis)



CDSCO (National database)



**WHO Uppsala Monitoring Centre in Sweden
(The Global Pharmacovigilance Database)**

NOTIFICATION FORM

FOR REPORTING

SUSPECTED ADVERSE DRUG REACTIONS /
INEFFECTIVE/DEFECTIVE MEDICINES /
ABUSE POTENTIAL/ INTERACTIONS /
DISPENSING ERRORS

**(To be sent to Head of the Department of Pharmacology
[Chairperson of PTC] for documentation and processing.
Phone 4008060 Ext. 8060 email: adr@aims.amrita.edu)**

Patient Details:

Name:.....

Age: **Sex:** M/F **MRD No:**.....

Nature of Suspected Event / Complaint

**Suspected drug reaction (known & unknown)/
Non responsiveness to medicine/ Unexpected experience /
Damaged package /Post expiry medicine/ Counterfeit
medicine/ Signs of deterioration / Dispensing error/
Sediments in the bottle or ampoule/ Any other**

.....
.....
.....

Product Information

Generic name.....

Brand name.....

Manufacturer & License No.....

Batch No:..... **Expiry date:**

Name of Notifier: Doctor / Nurse / Pharmacist / Any other

Dr/ Mr/ Ms.....

Specialty & Ward

Telephone No: **E-mail**

Date: **Signature of the notifier: ...**

(At AIMS it is mandatory to report all Adverse Drug Events)

GUIDELINES FOR SPONTANEOUS REPORTING

- ❖ **Who Can Report?**
 - **Any healthcare professional: Doctor, Dentist, Nurse, Pharmacist, Health Inspectors**

- ❖ **What To Report?**
 - **All suspected reactions, Lack of effect**
 - **Counterfeiting, Resistance**
 - **Interaction, Dependence and abuse**

- ❖ **Of Which To Report?**
 - **Allopathic medicines including OTC**
 - **Traditional Medicines, Biologicals like vaccines and sera**

When Is A Reaction Serious?

- **Death / life-threatening (real risk of dying)**
- **Hospitalization (initial or prolonged)**
- **Disability (significant, persistent or permanent)**
- **Congenital anomaly**
- **Required intervention to prevent permanent impairment or damage**

❖ **Report Even If:**

- **You're not sure of the product that caused adverse event**
- **You don't have all the details As soon as possible**

❖ **When To Report?**

- **As soon as possible**

- ❖ **What Happens To The Information Submitted:**
 - **The information in the form shall be handled in strict confidence.**
 - **Reporting does not indict the notifier or the manufacturer or the product**
 - **Stored in Database managed by WHO Uppsala Monitoring Centre in Sweden.**

UNDER PRESSURE??

- **Just write the minimum details and e-mail to Amrita Pharmacovigilance Team**

MRD Number of the patient

Name of the patient

Ward number and bed number

adr@aims.amrita.edu or call us at

8060/61/64/65

The TASK ACCOMPLISHED

- Reports include**

 - Allopathic medicines incl.OTC**

 - Traditional medicines**

 - Biologicals like vaccines and sera**

- Sildenafil – special drug**

DATA POOLED IN



- **Total # : 332 (ecl sil)**
- **Male : 166**
- **Female : 166**
- **Geriatrics : 121**
- **Paediatrics: 27**

ADVERSE DRUG EVENTS NOTIFIED

<p><u>Acute Renal Failure</u></p> <p>Vancomycin</p> <p>Gentamicin</p> <p>Amikacin</p> <p>Acyclovir, NSAID</p> <p>Ramipril</p> <p>Enalapril, Cisplatin</p> <p>Nimesulide</p> <p>Ciprofloxacin?</p>	<p>Seizure/ Encephalopathy</p> <p>Quetiapine</p> <p>Paclitaxel</p> <p>Valproate</p> <p>Warfarin</p> <p>Neutropenia</p> <p>Ceftazidime</p> <p>Pustular Rashes</p> <p>Pantoprazole</p>	<p>Gynaecomastia</p> <p>Spiro lactone</p> <p>Prox myopathy</p> <p>Prednisolone (Wysolone- Wyeth)</p> <p>Pedal edema</p> <p>Pioglitazone</p>
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**Steven Johnson/
Exfol dermatitis**
Carbamazepine
Ciprofloxacin
Chlorothiazide
Clarithromycin
Cotrimoxazole
Diclofenac
Levofloxacin
Phenytoin
Roxithromycin

Extreme Sedation
Loratadine
Cetirizine
Carboplatin
Anaphylaxis
Pancytopenia
Oxaliplatin
Electrolyte dist.
Cisplatin
Alendronate
GERD

Giddiness
Gabapentin
**Ovarian hyper-
stimulation**
FSH
AKT3/AKT4
Hepatitis
Urticaria
Polyarthralgia
Gouty arthritis
Allergic rashes
Ocular toxicity

Trastuzumab inj.

(Monoclonal antibody)

Chills and rigor

Paclitaxel

Dyspnoea

Seizure

Inj. Taxim

Chest pain

Etoricoxib

Oral ulcers

Gastritis

Methotrexate

Pancytopenia

L-Asparaginase

Myalgia

Prednisolone

Diabetes mellitus

Thalidomide

Postu hypotension

Streptokinase

GI bleeding

Amlodipine

Pedal edema

Cefuroxime

Rashes

Giddiness

Etoposide

Vomiting

Dapsone

Lepra reaction

Piperacillin

Chills, Nausea

Profuse sweating

Omeprazole

Malaise

Chills like feeling

Pruritis

Statins

Increase liver enzymes, Rashes

Pioglitazone

Pedal edema

Bleomycin

Interstitial lung disease

Meloxicam

Hyperkalaemia

Raloxifene

Palpitation

Hot flushes

Terazosin

Gastritis

Cisplatin

Alopecia

Vomiting

Nephrotoxicity

Leucopenia

Topiramate

Metabolic acidosis

Seizure/encephalopathy

Quetiapin

Valproate

Warfarin

Paclitaxel

Triamcinolone

Probenecid

fever

<p>Paroxymal dystonia</p> <p>Oxycarbazepine</p> <p>Myoclonic jerks</p> <p>Morphine</p> <p>Simvastatin</p> <p>Rhabdomyolysis</p>	<p>Ketamine</p> <p>Bradycardia</p> <p>apnoea</p> <p>(4months, 2yrs)</p> <p>Atorvastatin</p> <p>Alopecia</p> <p>Itching</p>	<p>Severe hypotension</p> <p>Omnipaque</p> <p>Donepezil</p> <p>Recurrent vomiting</p> <p>50 tab poisoning – symptomatic trt.</p>
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DATA ON SILDENAFIL

01 January 2006 – 30 November 2006

- Number of cases studied : 44
- Sex : Male – 16
Female – 28
- Age : > 60 : 1
21 to 60 : 30
02 to 20 : 09
> 2 years : 4
- ADR : Altered liver function tests –2
Treatment discontinued

THE SCENARIO AT AMRITA

- Very few both eyes and ears fully open –
cooperative
- Eyes tightly closed and ears fully blocked -
blissfully ignorant
- Some partially open - *Tactfully indifferent*
- Deliberately keep both of these closed –
arrogant and negligent

INTROSPECTION

Poor Performance ?

1. **Indifference because there is “No Immediate Reward”**
2. **Ego problem: Prophesied by a lesser grade person**

THE CRUSADE

- **Discharge Summary Scanning**
- **Case file In the Computer**
- **Constraint: Manpower**

PHARMACOVIGILANCE

**TO ENSURE GLOBAL SAFETY OF OF
MEDICINES**

PROOF

- 1. Trial Drugs – every physician has the time and inclination to fill up a two to three page form, photocopy and send it to the authorities concerned**
- 2. Rational Antibiotic Use: More listeners when the topic was presented by Dr. Mathai from Vellore**

**THANK YOU AND SEE
YOU AGAIN**





**AMRITA INSTITUTE OF MEDICAL SCIENCES , Kochi
(An ISO 9001 Certified Hospital)**