
National Pharmacovigilance Programme

Progress Report

2005 - 2006

South-West Zonal Center

Department of Clinical Pharmacology, KEM Hospital

Coordinator- Dr. (Mrs.) Nilima A. Kshirsagar

Director (ME and H) & Dean, Seth GSMC & KEMH

Prof and Head, Department of Clinical Pharmacology

1. General Progress of the Centre

Numbers of ADR generated at the Zonal Center

Year	Jan- Dec 2005	Jan- Nov 2006
ADR reports	332	616

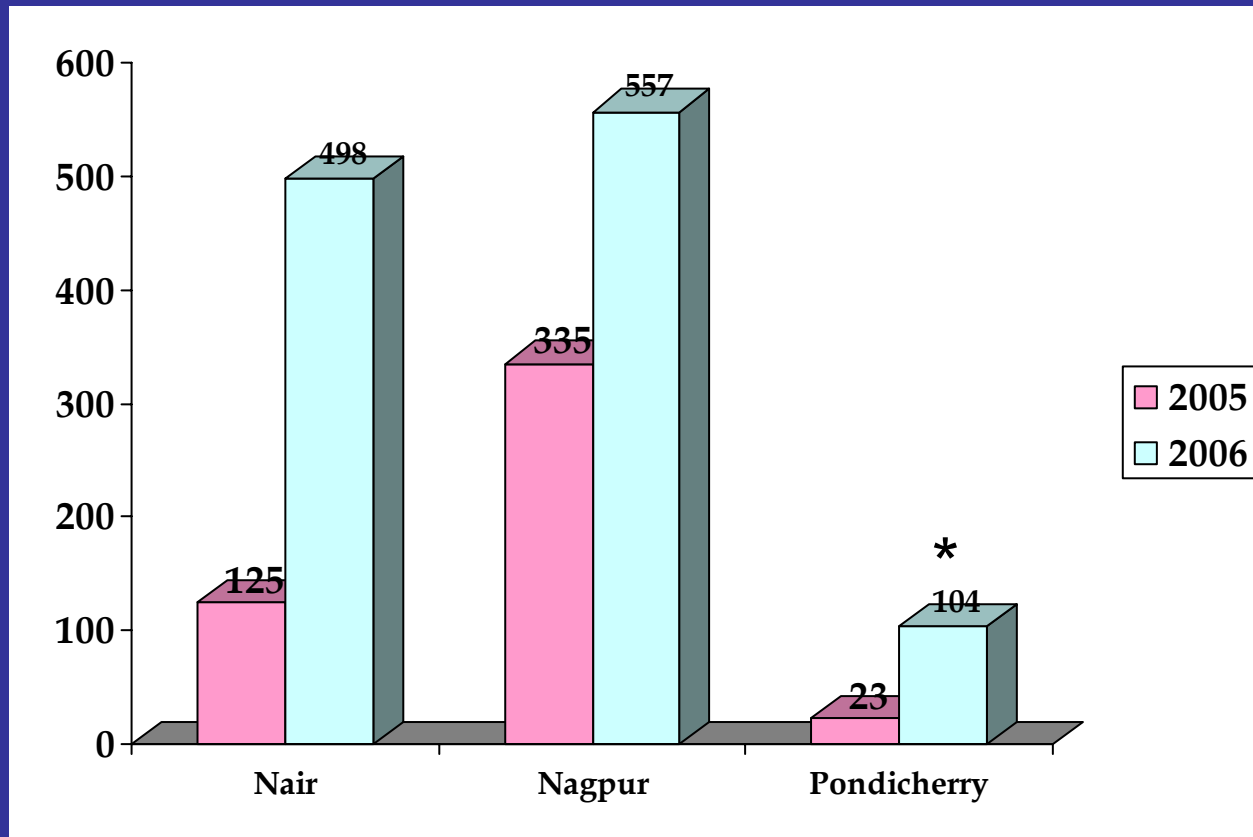
1. General Progress of the Centre

- Pharmacologist appointed on NPVP w.e.f.
February 2006
- Data entry operator appointed on NPVP w.e.f.
February 2006

Regional Centres under KEM hospital

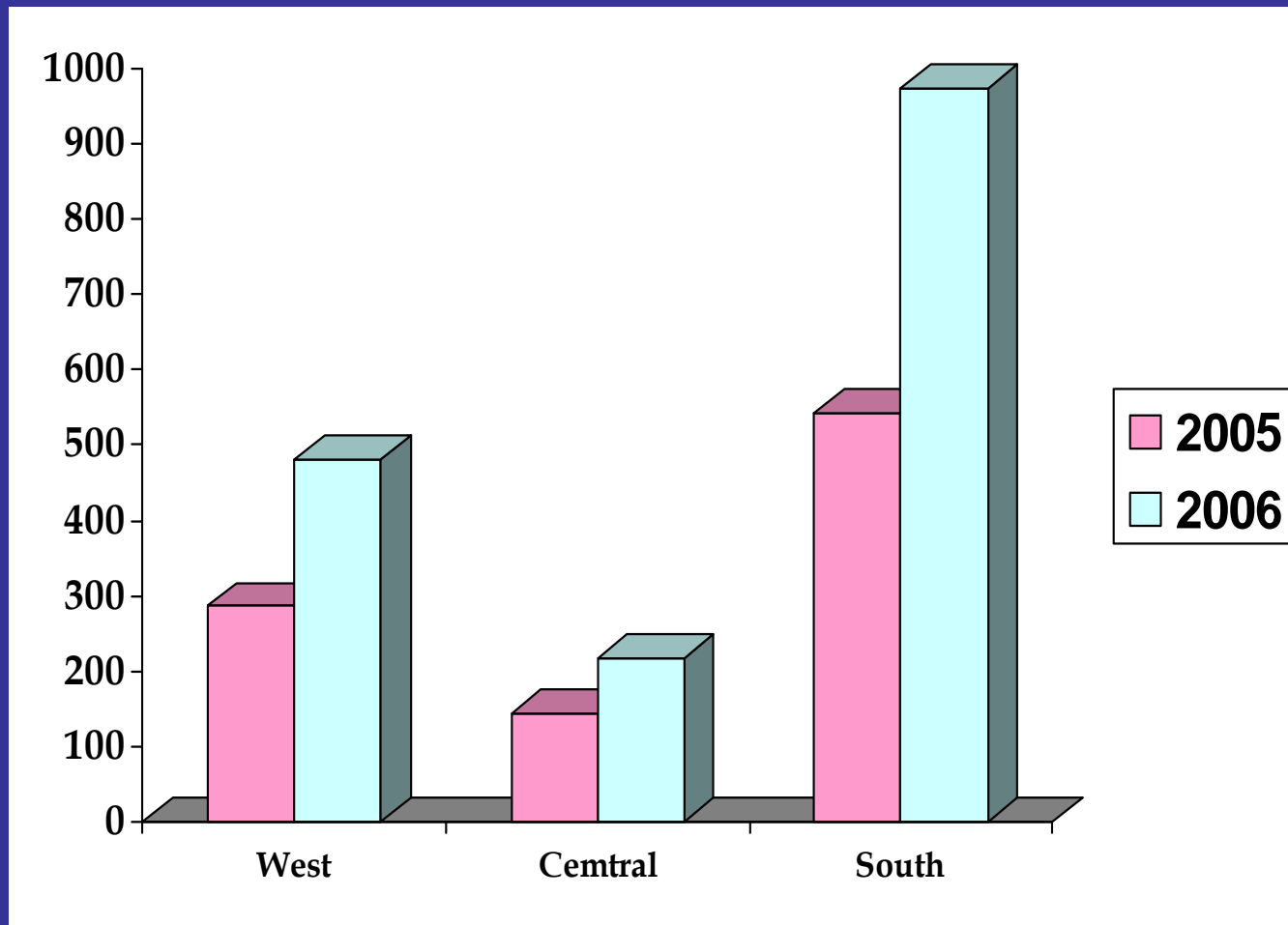
- Dr UM Thatte, TNMC & BYL Nair Ch. Hospital, Mumbai
- Dr. Meena Shrivastava, Indira Gandhi Medical College, Nagpur
- Dr. C Adithan, JIPMER, Pondicherry

Number of ADR received from Regional Centers in 2005 and 2006



* Data of some months submitted to AIIMS due to confusion as to the Zonal centre to report

Number of ADR received from Peripheral Centers in 2005 and 2006



Number of SAEs resulting in deaths

(2005 & 2006)

Name of the center	2005	2006
KEM	11 / 332 (3.31%)	7 / 654 (1.3%)
Mumbai [Including Peripheral centers]	4 / 419 (0.95%)	7 / 1397 (0.50%)
Nagpur [including Peripheral centers]	0 / 479 (0%)	1 / 768 (0.13)
Pondicherry [Including peripheral centers]	4 / 566 (0.70%)	3 / 1078 (0.28%)

2. Centers performance as per protocol benchmark

- a. **Periodic MIS report:** 11 Periodic MIS reports of 2006 & 1 consolidated MIS report of January – December 2005 submitted to National Centre
- b. **Number of AE report from KEM:** 2005- 332
2006- 654
- c. **Departments /clinicians sensitized about the pharmacovigilance Programme:**
 - Sensitization of Physicians (n= 41)
 - Advertising Programme
 - 'Quality of Health' workshop

**d. Therapeutic group allocated to the center is
Nimesulide**

**No. of ADR generated on Nimesulide since
notification on 27 March 2006: 16**

Pediatrics: 11

Geriatrics: 5

Major Finding : Hematuria in 7 pediatric patients

Other AEs – rash, backache, Abdominal pain

Therapeutic groups most commonly implicated to cause AEs (KEM)

Year 2006

Therapeutic Groups	AE generated (%) (Out of 654)
Antitubercular (AKT)	19.58 %
Anticoagulants (Warfarin)	11.76 %
Antiepileptic (Phenytoin, CBZ, Sodium Valproate)	17.28 %
Antiretroviral (ART)	4.20 %
Ayurvedic Medicines	2.46 %

Types of Adverse Drug Reactions in Zonal center

Sr. No	Types of ADR	Percentage (%)
1.	Dermatological	29.41
2.	Neuropsychiatry disturbances	17.6
3.	Hepatobilliary Disturbances	12.41
4.	GIT	17
5.	Metabolic disorder	4.2
6.	Diarrhoea	5.82
7.	Cardiovascular	2.94
8.	Hematological	5.88
9.	Genitourinary	1.1
10	Miscellaneous	3.39

Seriousness of AE

Year	Serious	Nonserious
2005	113	219
2006	162	492

3. Issues being faced by centers

- Financial
- Books not distributed to Centers
- Acknowledgement from national Center?

4. Specific success stories about Center's performance

'ADR of the month' presented on College website:

26 ADRs presented till date

Publications:

National: 22

International: 12