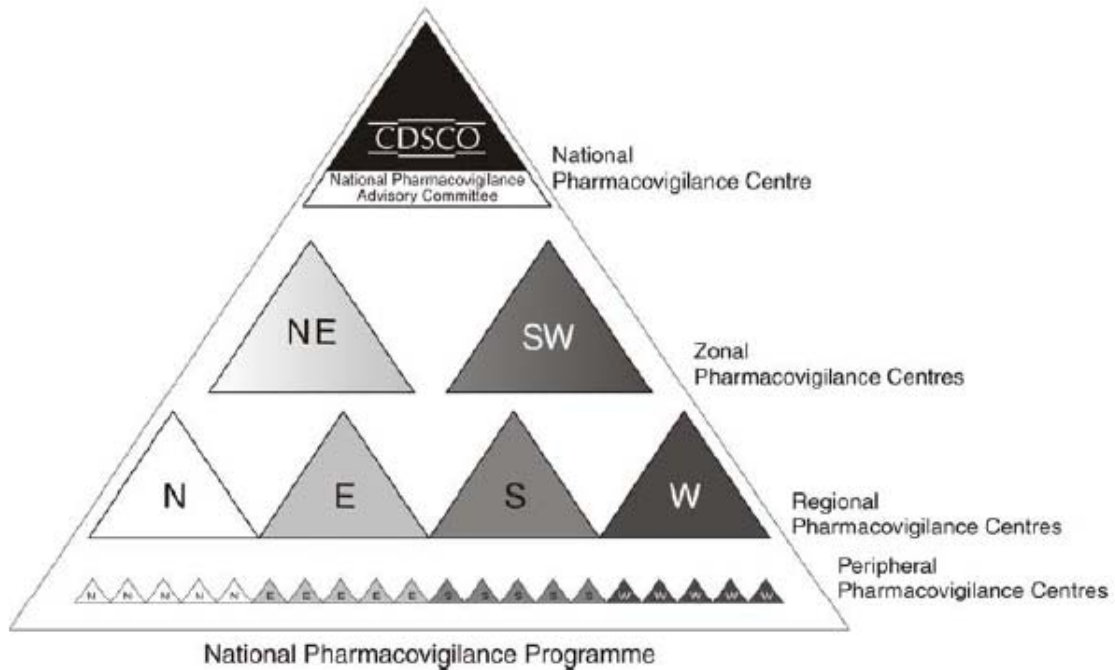




# **National Pharmacovigilance Programme Annual Stocktaking Meeting All India Institute of Medical Sciences Zonal Centre**

**Dr. Madhur Gupta**



Hierarchical Structure of the Proposed Centres

Collection / Maintenance a log of  
all ADE notification forms received  
and forwarded

Total No. of ADE Report forms  
received - 4489

North - 845

East - 1801

# North East Zonal Centre AIIMS

Total ADE Report Forms Received- 4489

<b>North Region</b>	<b>Centre No.</b>	<b>Number of ADE Report Forms</b>
<b>AIIMS, New Delhi</b>	<b>200</b>	<b>222</b>
<b>LHMC, New Delhi</b>	<b>210</b>	<b>109</b>
<b>V.P.Chest Institute</b>	<b>211</b>	<b>170</b>
<b>Apothecaries Foundation</b>	<b>212</b>	<b>66</b>
<b>MAMC, New Delhi</b>	<b>213</b>	<b>72</b>
<b>Chhatrapati Shivaji Subharati Hospital</b>	<b>214</b>	<b>193</b>
<b>Era's Lucknow Medical College, Lucknow</b>	<b>215</b>	<b>13</b>

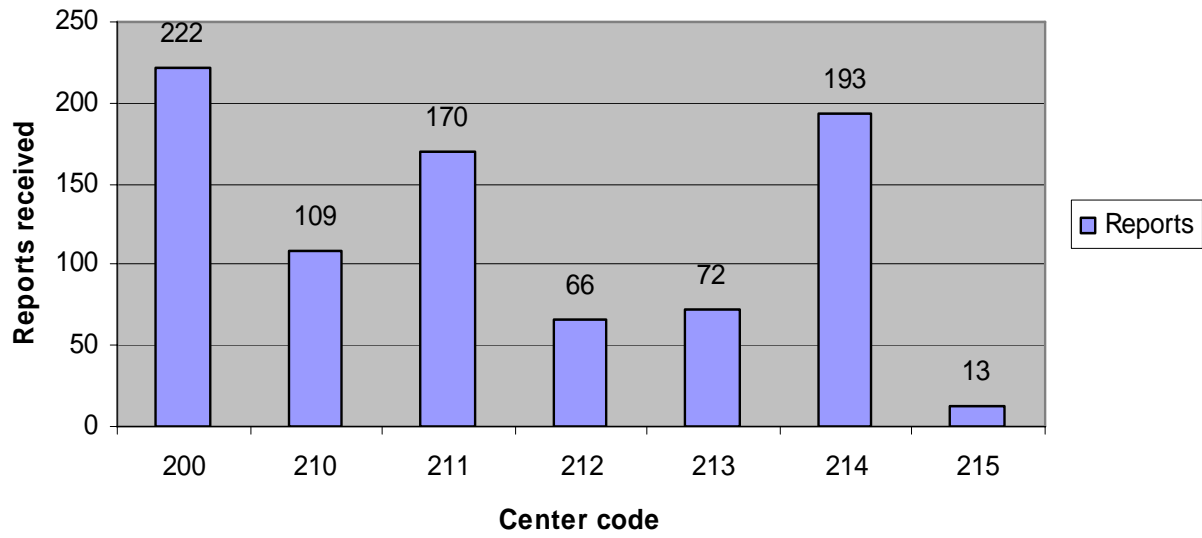
# North East Zonal Centre AIIMS

## Total ADE Report Forms Received- 4489

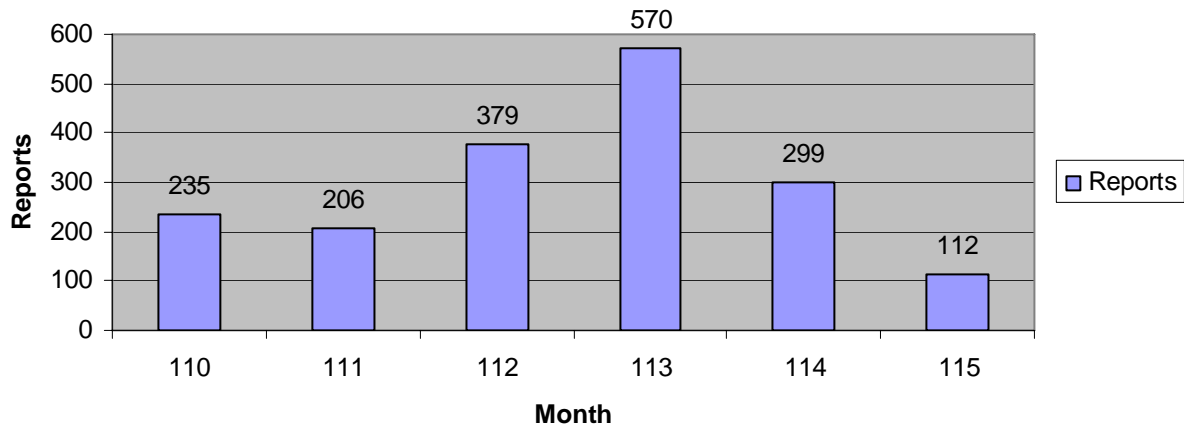
North Region	Centre No.	Number of ADE Report Forms
NRS Medical College & Hospital IPGMER -SSKM Hospitals, Kolkata	110	235
S.C.B. Medical College, Orissa	111	205
IPGMER, Kolkata	112	379
IPGMER, Kolkata	113	570
Gauhati Medical College	114	299
Dr. BC Roy Memorial Hospital for Children, Kolkata	115	112

South Region	Centre No.	Number of ADE Report Forms
JIPMER, Pondicherry	220	157
PSG Institute of Medical Sciences, Coimbatore	221	79
MAHE, Manipal	222	268
Al-Ameen College of Pharmacy, Bangalore	223	197
Amortha Institute of Medical Sciences , Kochi	224	158
Annamalai University	225	209
Sri Devaraj URS Medical College	226	87
JSS Medical College and Hospital	227	541
JSS College of Pharmacy	228	147

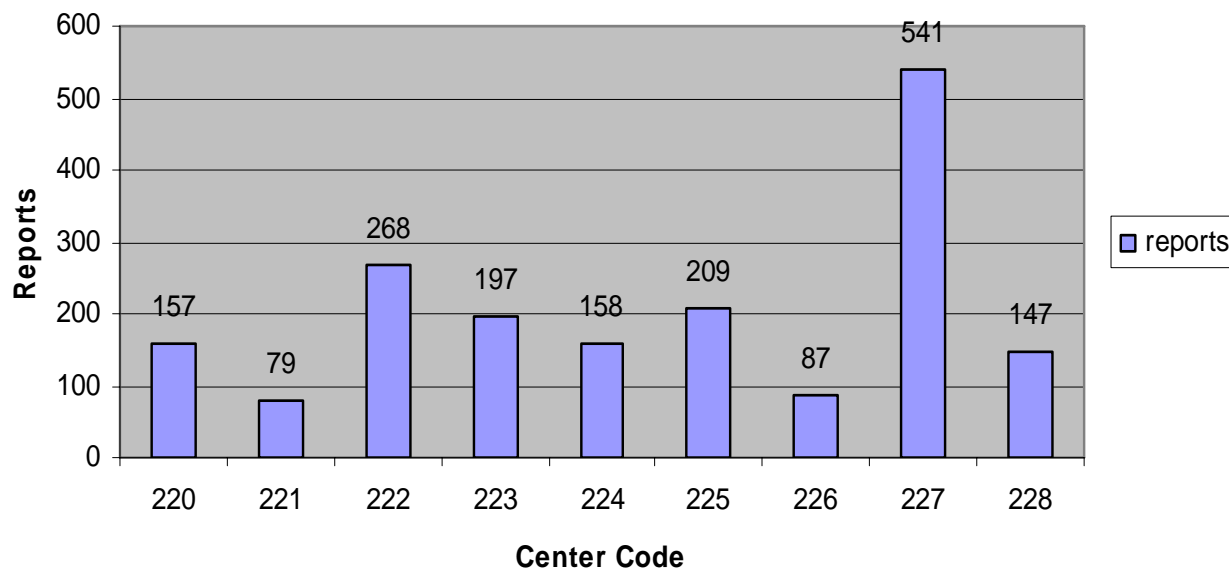
### Reports from North Zone



**Number of Reports from East Zone**



### Reports from South Zone



\* South Region was reporting to NE Zonal Centre till April'2006

# Total Adverse Drug Event Report Forms Received by North East Zonal Centre

4489



Received after  
Causality  
Assessment- 3813

Received without  
Causality  
Assessment-676



Random Check by N-E  
Zonal Centre-96  
(Target 5%)

## Some Observations

- Lot No. (Batch) of Suspected Medication Missing – 1762
- Concomitant Medications- 2432

# Some Observations

- Diagnosis – 2478
- Dose - 2312
- Frequency - 3212
- Route - 1523
- Dates - 652

# Some Observations

- Relevant tests /laboratory data - 2143
- Duration of Event - 1017
- Dechallenge / Rechallenge information - 2812

# Clinical Departments Collated

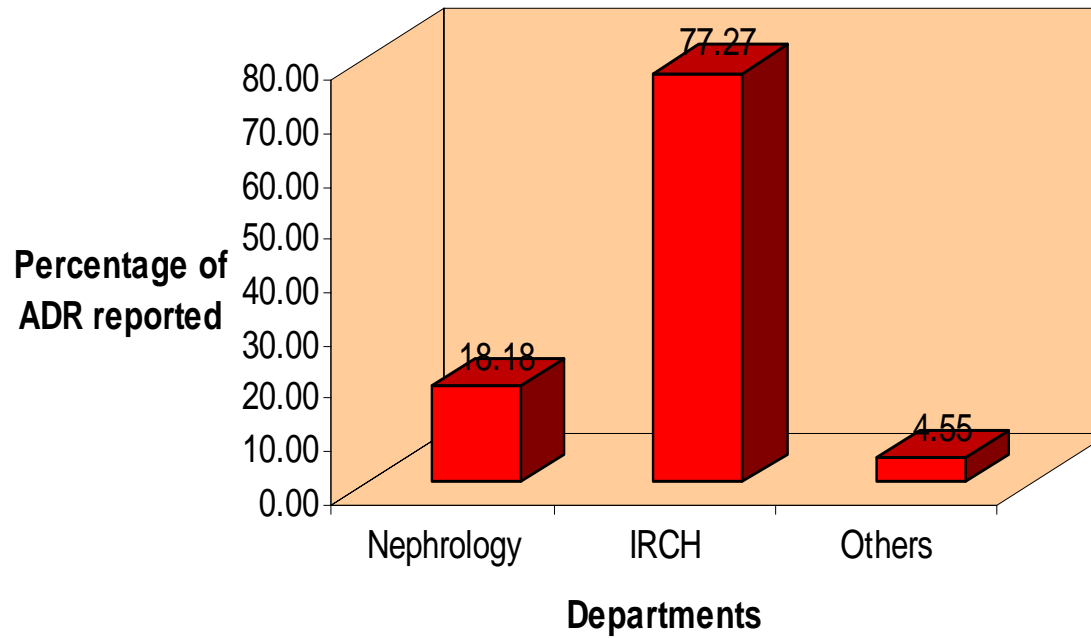
## Routinely Done

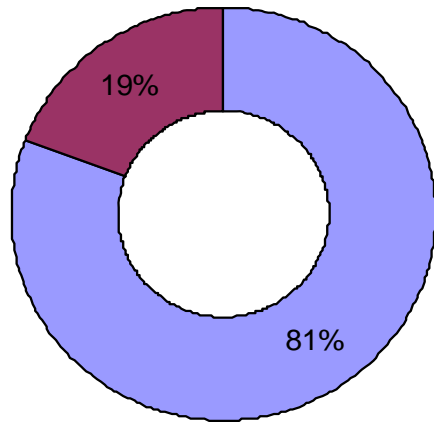
- Institute Rotary Cancer Hospital (Medical Oncology)
- Nephrology
- Medicine
- Pediatrics
- Ophthalmology

# Clinical Departments Collated

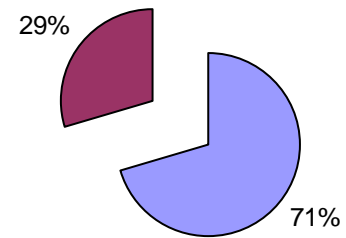
## Being Started

- Physical Medicine & Rehabilitation
- Casualty ( Adult & Pediatric)





■ Total AntiCancer ■ Others



■ Combination Chemotherapy ■ Individual Anticancer drugs

# Focussed Therapeutic Groups

- Statins- 26 reports collected
- AE- Headache, Nausea, Fever
- Incidence of rhabdomyolysis- None

# Issues needing attention

- Legibility
- Completeness of forms
- Causality done as best as possible by the regional centre
- MIS Form not attached with the reports.
- Timelines not adhered

# Issues needing attention

Serious AE

Deadlines of 48 hours to be followed

# Issues needing attention

- Communication
- CME activities by Peripheral/Regional Centre
- Supervision/monitoring by Regional Centre & Recommendations to be made.

# Thank you

