



## KNOWLEDGE AND ATTITUDES OF DOCTORS TOWARD ADVERSE DRUG REACTION REPORTING AND MONITORING IN THE HOSPITAL: A PILOT STUDY

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## Adverse Drug Reaction



A response to a drug that is noxious and unintended and occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease, or for modification of physiological function.

*World Health Organization*

## Background



- Adverse drug reactions (ADRs) are known to be a major cause of morbidity and mortality.
- The 4<sup>th</sup> to 6<sup>th</sup> leading cause of death in the USA (Green et al, 2001)
- ADR incidents in hospitalised patients (Lazarou et al, 1998)
  - 6.7% serious ADRs
  - 0.32 % fatal ADRs

## Background



- Only a small proportion are reported.
- ADR reporting is the cornerstone of drug safety after the release of a drug into the market.
- It has been shown over the years that ADR reporting has provided early warning in drug safety
- An increase in the number and quality of reports by improving ADR reporting system in hospitals, could improve patient outcomes and save healthcare costs.

## ADRs Reporting in Indonesia



- Indonesia monitor ADRs through a **spontaneous reporting scheme** which is coordinated by:  
**National Agency of Drug and Food Control**  
(Badan Pengawasan Obat dan Makanan RI)  
Jl. Percetakan Negara No. 23  
Kotak Pos No. 143 Jakarta 10560
- The system invites reporting from all health professionals

## Spontaneous Reporting Scheme




- **The advantages:**
  - Simple to operate
  - Effectively identify new ADRs
  - Cost-effective because health professionals are unpaid to do the reporting and it involves all drugs (newly marketed and old drugs).
  - The spontaneous reporting scheme is dependent solely on individuals to detect, evaluate and send a report to the collating agency.
- **Limitations:**
  - Problems with motivating individuals to complete reports
  - Long latency reactions may be missed
  - Data is often incomplete
  - Causality is difficult to assess
  - Reactions are under reported


## What to Report?

- The committee encourages reporting of all suspected reactions to drugs
- However, NA DFC particularly asks for reports of:
  - All suspected reactions to a drug, especially a new reaction that has never been known to be related to the drug
  - All suspected drug interactions
  - All serious reaction
  - All dependence reaction

## The Form


PENDERITA		Umur :	Sex :	Berat badan :	Pekerjaan :		
Nama (singkatan) : .....							
Kedahlan (beri tanda X) :		Penyakit utama :		Kedahlan (beri tanda X) :			
Fils .....				<input type="checkbox"/> Sembah.			
Wanita .....				<input type="checkbox"/> Menegep.			
Hamil .....				<input type="checkbox"/> Sembah dengan gejala asa.			
Tidak hamil .....				<input type="checkbox"/> Baku semah.			
Tidak tahu .....				<input type="checkbox"/> Tidak tahu.			
Penyakit/Kemala lain yang menyerta :		Gejala/Gejala lain yang menyerta :		Gejala/Gejala lain yang menyerta :			
<input type="checkbox"/> Gangguan ginjal.		<input type="checkbox"/> Gangguan hati.		<input type="checkbox"/> Kerdahlan medik lainnya.			
<input type="checkbox"/> Tidak tahu.		<input type="checkbox"/> Adanya.		<input type="checkbox"/> Faktor induksi, perantaraan, klonis dan lain-lain.			
EFEK SAMPING OBAT (E.S.O.)							
Bentuk/manifestasi E.S.O. yang terjadi :		Sifat/Tanggap mula terjadi :		Kedahlan E.S.O. (beri tanda X) :			
				Tanggal .....			
				<input type="checkbox"/> Sembah.			
				<input type="checkbox"/> Menegep.			
				<input type="checkbox"/> Sembah dengan gejala asa.			
				<input type="checkbox"/> Baku semah.			
				<input type="checkbox"/> Tidak tahu.			
Bentuk E.S.O. yang pernah dialami :							
OBAT							
No.	Nama (Nama Dagang/Pabri)	Bentuk sediaan	Dosis/Kepek	Frekuensi			Indikasi penggunaan
				Cara	Dosis/Waktu	Tgl. mula	
1.	.....	.....	.....	.....	.....	.....	.....
2.	.....	.....	.....	.....	.....	.....	.....
3.	.....	.....	.....	.....	.....	.....	.....
4.	.....	.....	.....	.....	.....	.....	.....
5.	.....	.....	.....	.....	.....	.....	.....
6.	.....	.....	.....	.....	.....	.....	.....
7.	.....	.....	.....	.....	.....	.....	.....
8.	.....	.....	.....	.....	.....	.....	.....
9.	.....	.....	.....	.....	.....	.....	.....
10.	.....	.....	.....	.....	.....	.....	.....
Keterangan: tambah/mulanya, keparasan timbulnya Efek Samping Obat, apakah efek samping yang timbul dibantu.						Data Laboratorium (jika ada).	
						..... 19.....	
						Tanda Tangan penerap,	
						.....	





## Key Studies

- Green CF, et al (BJCP 2001; 51:81-6)
  - Sample: 600 randomly selected hospital pharmacists from 7,000 hospital pharmacists in UK
  - Response rate of 53.7% (322/600)
  - Attitudes toward ADR reporting
  - Hypothetical ADRs
- Eland A, et al (BJCP 1999; 48: 623-7)
  - Netherlands medical practitioners
  - Sample: 10% medical practitioners
  - Response rate of 73% (1442/1984)
  - Attitudes towards ADR reporting
  - Hypothetical ADRs



## Key Studies

- Yunita, et al (JPPR 2005; 35: 9-14)
  - Sample: 1323 hospital pharmacists from the entire membership of SHPA, 803 doctors in WA
  - Response rate of 43% and 35%
  - Knowledge and Attitudes toward ADR reporting
  - Hypothetical ADRs

## Aim of the Study




- To evaluate involvement in, understanding of and reasons for reporting ADRs

## Methods




- Cross sectional – observational study
- Study was done in the Ophthalmic Department, Dr. Soetomo Hospital
- Sampling of 37 doctors was chosen by purposive sampling method
- The instrument utilized was a questionnaire that has been validated through validity and reliability test.



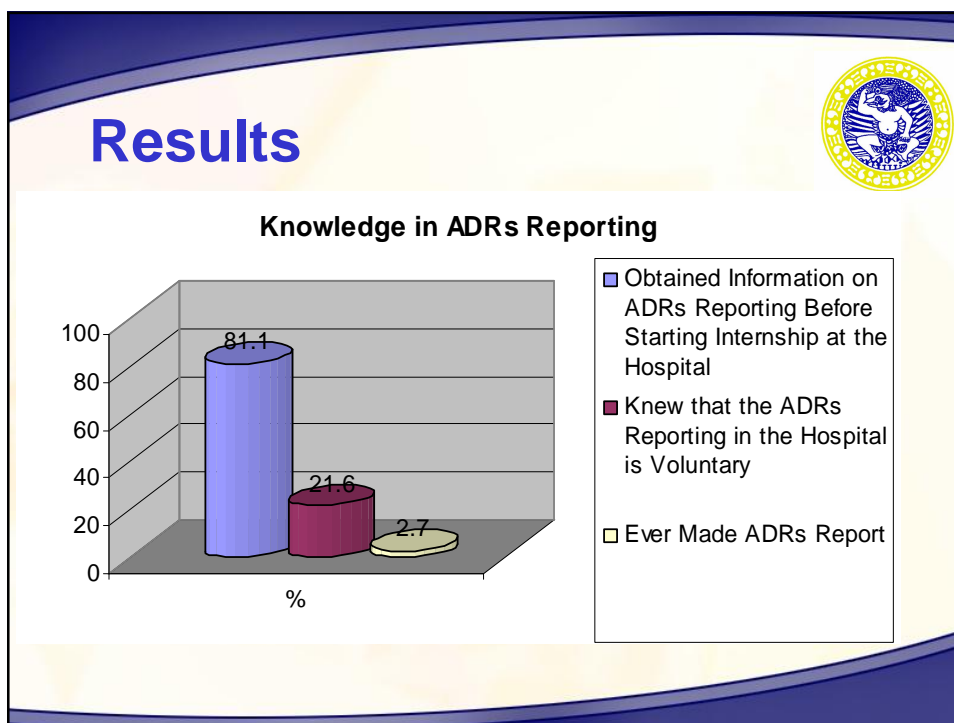
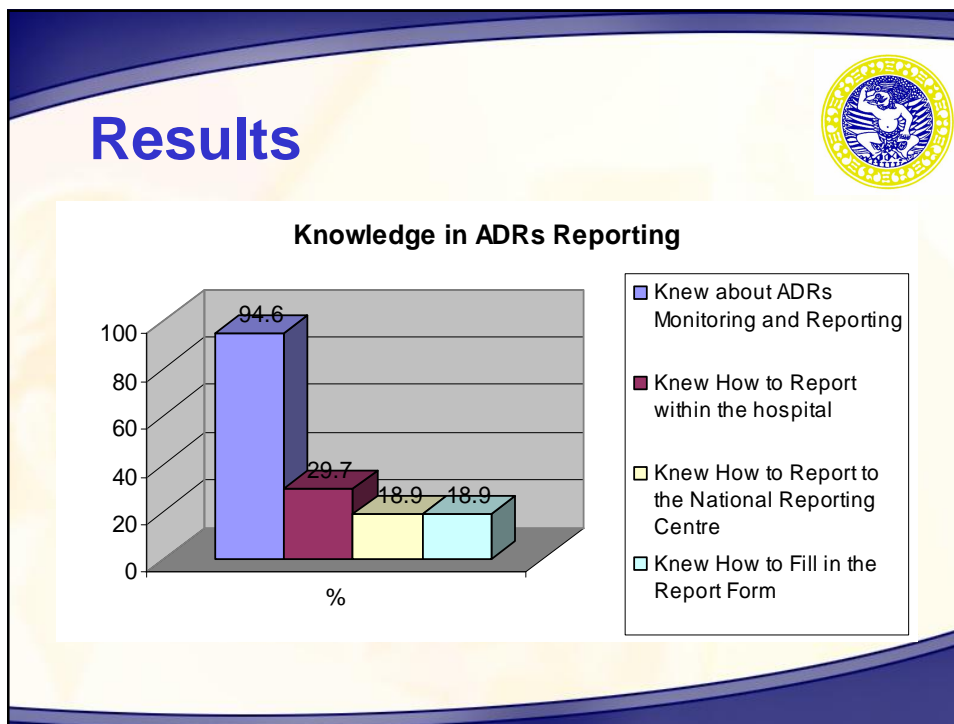
## Questionnaire

- Characteristic of respondents
  - Age & Gender
- Attitudes towards reporting and monitoring of ADRs
- Knowledge of ADR reporting
- Factors that encourage & discourage ADR reporting
- ADR reports in 2005



## Characteristics of Respondents

No	Data	Frequency
1	Age ≤ 30 years 31 – 34 years 35 – 40 years < 40 years	10 (27.0 %) 15 (40.5 %) 12 (32.4 %) 0 (0.0 %)
2	Gender Male Female	16 (43.2 %) 21 (56.8 %)
3	Graduation year (Medical Doctor) ≤ 1995 1996 – 2000 2001 – 2005	7 (18.9 %) 24 (64.8 %) 5 (13.5 %)
4	Year registered as student (Ophthalmic) 2000 - 2002 2003 – 2005	14 (37.8 %) 23 (62.1 %)
5	Duration of practice ≤ 5 tahun 6 – 10 tahun < 10 tahun	11 (29.7 %) 20 (54 %) 1 (2.7 %)



## Results



- Factors that encouraging report:
  - serious reaction (100 %)
  - rare reaction (70.3 %)
  - reaction to a new drug (86.5 %)
  - strong possibility of ADRs (83.8 %)
- Factor that discouraging report:
  - not knowing how to report (81.1 %)

## Results



- It was not found any number of ADRs report in the period of January-September 2005

## Conclusions



- Results showed that the level of knowledge on ADRs reporting should be improved.
- Strategy to improve ADRs reporting in Indonesia is important
- Further study need to be done

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