Development of Computerized Adverse Drug Event Surveillance System in Korea

: Retrospective and Prospective Patient Medical Record Review

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Introduction

- Medication errors and health care costs
  - Common and expensive medication errors
  - Known issues on patient safety and health care costs
- Preventable medication errors & CDSS
  - Many medication errors known to be preventable
  - Many studies on medication errors and medication CDSSs in US and other countries
- However, still significant
  - In 2006 IOM reports, medication errors are reported still significant and costly
  - Few studies in Korea, very early stage of medication CDSSs
  - Need more opportunities to show how it works and it is effective to prevent with CDSS.

Methods (1/3)

- Computerized Adverse Drug Event Surveillance Program (CADESS)
  - Using 46 ADE signals including lab test, drug level, medication, & diagnosis codes
  - Screened EMR for patients with ADE signals checked
  - 6 pharmacists reviewed electronic medical records of ADE signal monitored patients to identify ADE occurrence
  - ADE identified patients data was recorded in a structured format to collect data for the statistical analysis

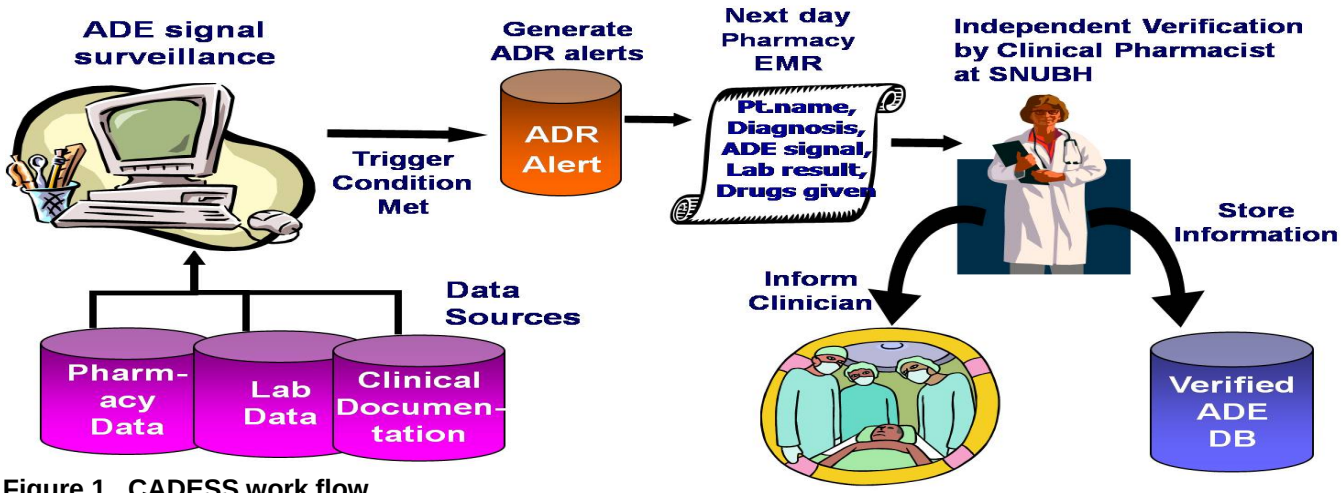


Figure 1. CADESS work flow

Methods (2/3)

- *Study settings*
  - Seoul National University Bundang Hospital, Korea
  - 990-bed, secondary, academic hospital
  - Advanced electronic medical record system and medication related CDSS in operation (order duplication checking, drug-drug interaction, contraindications, etc.)
- *Medical Record Reviews*
  - Training of reviewers & reliability test in advance of study
  - Retrospective & Prospective chart review for 1 month each
  - By 6 pharmacists under the supervision of clinical pharmacists and physicians
- *Statistical analysis*
  - SAS, SPSS ver.12.0
  - Descriptive analysis, kappa value for reliability test

Methods (3/3)

Reviewer's training

- ADE review manual & study reviews
- 6 reviewers reliability test
- Reviewed 30 randomly selected inpatients w/ ADE signals

Retrospective EMR review

- April. 2005 inpatients for a month
- EMR Reviewed by 6 pharmacists for suspected ADE
- Supervised by clinical pharmacists & physicians
- ADE identified

Prospective EMR review

- 7/18/2006 ~ 8/17/2006 inpatients for a month
- EMR Reviewed by 6 pharmacists for suspected ADE
- Supervised by clinical pharmacists & physicians
- ADE identified daily

Data Analysis

- Data collected in a structured format
- Kappa value for reliability test using SAS
- Descriptive statistics using SPSS 12.0

Figure 2. Study flow

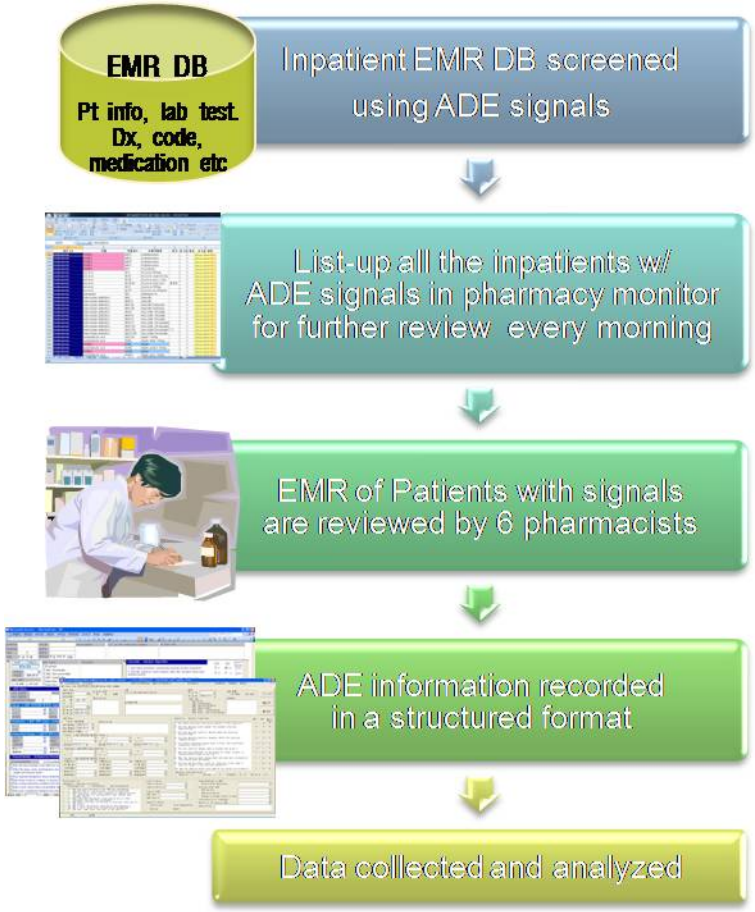


Figure 3. ADE identification process

Results (1/4)

- Reliability test among reviewers
  - Kappa value was .87 which meant almost perfect agreement among reviewers.
  - For 30 patients sample reviewed by 6 pharmacists
- Summary of study results

Methodology	Retrospective	Prospective
Study period	2005. 4/1~4/30	2006.7/18~8/18
total inpatients	3608	3510
Signal screened patients	457	478
Signal screened rate among inpatients	12.7%	13.6%
# of Signals detected	609	698
# of ADE during the study	145	120
ADE incidence among inpatients	4.0%	3.4%
PPV of ADE signal	23.8%	17.2%

Table 1. Summary of study results

Results (2/4)

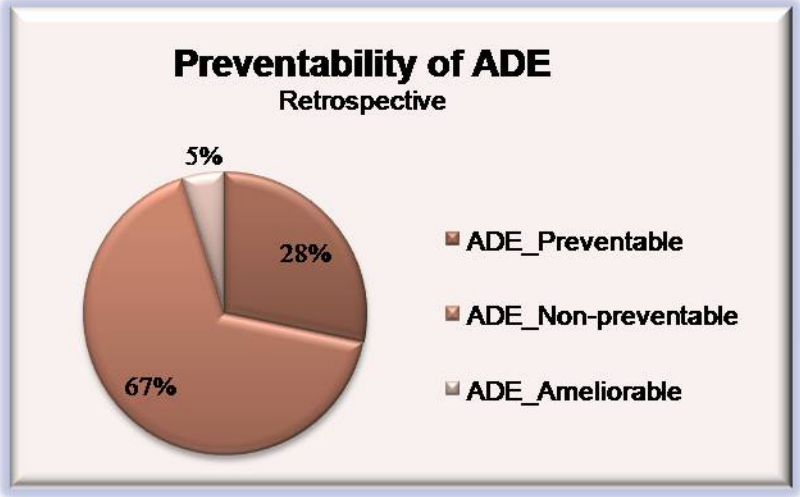
ADE signals with high frequency			
Retrospective		Prospective	
Antihistamine	116	Antihistamine	136
Antidiarrhea	74	Antidiarrhea	117
Glucose, fasting	82	Methlprednisolone	62
Methlprednisolone	56	ALT	46
ALT	32	AST	44
Anti-emetics	30	WBC count, Blood	38

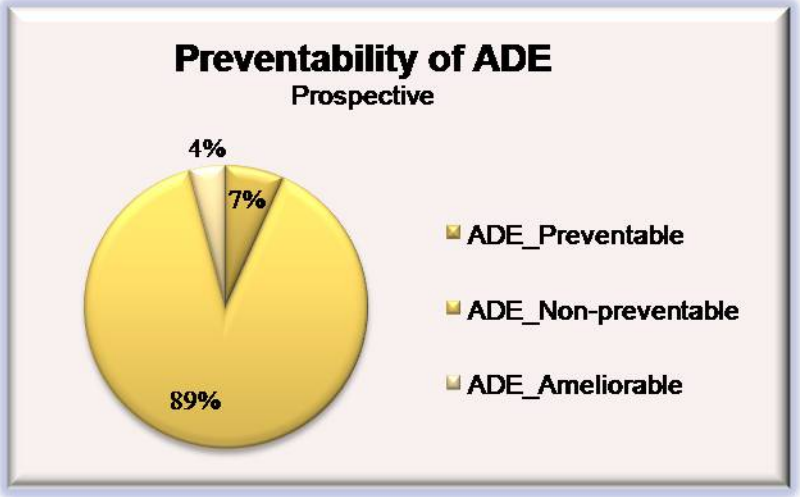
Table 2. ADE signals with high frequency (number of alerts)

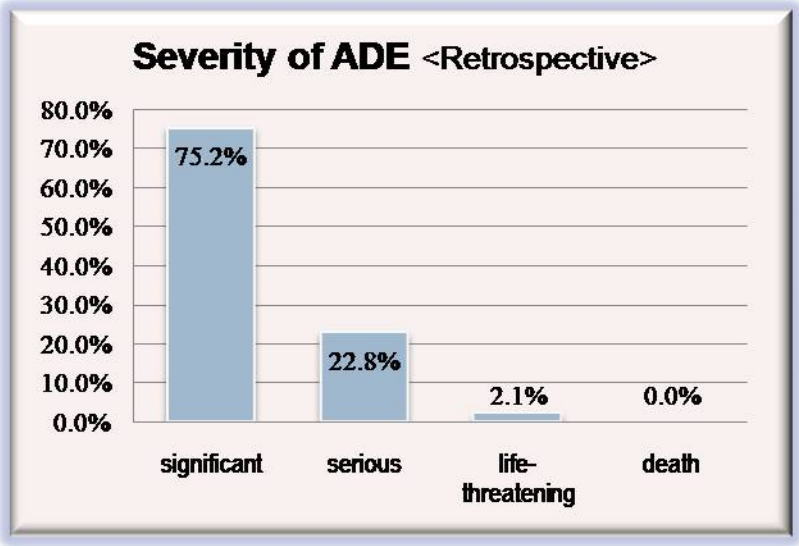
ADE signals with high PPV			
Retrospective		Prospective	
PT(INR)	100%	WBC count, Blood	45%
Vancomycin	100%	Anti-emetics	42%
Vitamin K	100%	ALT	41%
Methlprednisolone	100%	PT(INR)	33%
Naloxone	100%	Antihistamine	31%
Atropine	67%	Creatinine	26%
ALT	56%	AST	23%
Phenytoin	50%	Dextrose 50 & Glucose	20%

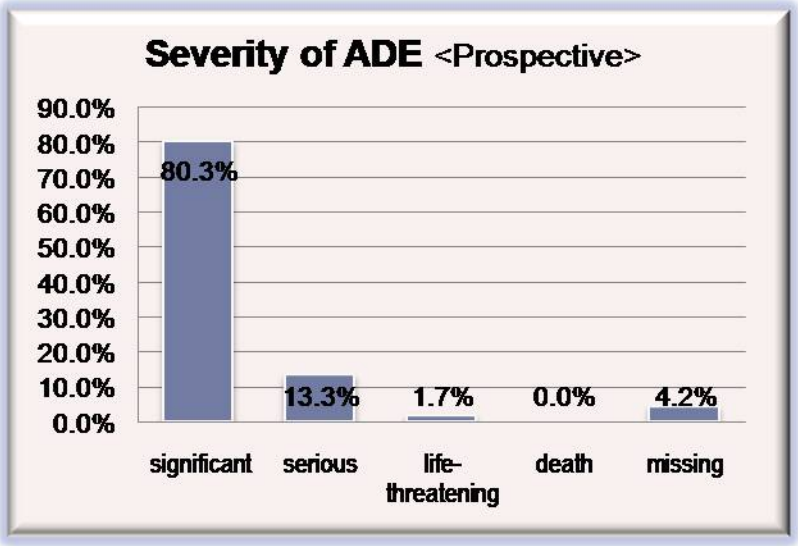
Table 3. ADE signals with high PPVs (percentage)

Results (3/4)


Preventability of ADE
Retrospective
5%
28%
67%
ADE_Preventable
ADE_Non-preventable
ADE_Ameliorable


Preventability of ADE
Prospective
4%
7%
89%
ADE_Preventable
ADE_Non-preventable
ADE_Ameliorable


Severity of ADE <Retrospective>
80.0%
70.0%
60.0%
50.0%
40.0%
30.0%
20.0%
10.0%
0.0%
75.2%
22.8%
2.1%
0.0%
significant
serious
life-threatening
death


Severity of ADE <Prospective>
90.0%
80.0%
70.0%
60.0%
50.0%
40.0%
30.0%
20.0%
10.0%
0.0%
80.3%
13.3%
1.7%
0.0%
4.2%
significant
serious
life-threatening
death
missing

Results (4/4)

Table 4. Medications with high frequency of ADEs in retrospective chart review

Medications	Frequency	Percentage
antiinfectives	80	46.5%
NSAID	17	9.9%
anticonvulsant	14	8.1%
analgesic	14	8.1%
radiocontrast	14	8.1%
gastrointestinal	12	7.0%
cardiovascular	8	4.7%

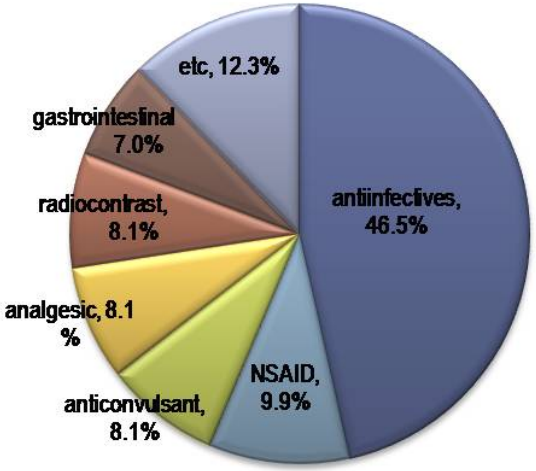
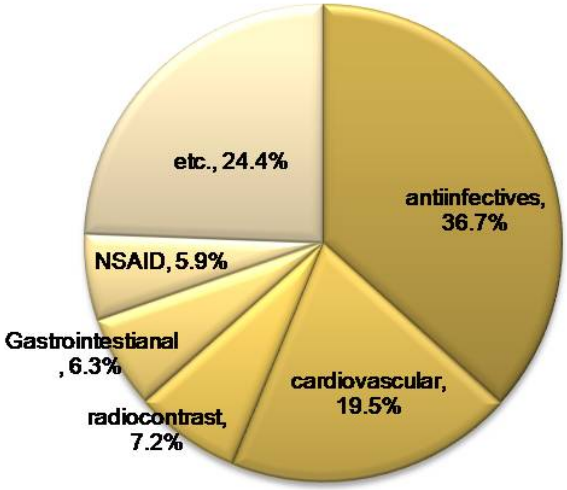


Table 5. Medications with high frequency of ADEs in prospective chart review

Medications	Frequency	Percentage
antiinfectives	81	36.7%
cardiovascular	43	19.5%
radiocontrast	16	7.2%
Gastrointestianal	14	6.3%
NSAID	13	5.9%
Diabetes medicatio	11	5.0%



Discussion

- Comprehensiveness of ADE signals
  - Lab and medication oriented signals
- Sample size of each signal
  - Statistically enough sample size for ADE incidence
  - However, not for each signal validation
- Technical errors
  - Missing signals in retrospective study
  - Signal errors by technical mistakes
- Medication CDSSs already in operation
  - Contraindications, drug-drug interactions, order duplication, etc in EMR system
- Methodology characteristics In nature
  - Since the care process was ongoing, ADE identification was ongoing in prospective chart review without conclusion.

Conclusions

- Failed to compare methodological differences
  - Better assumed to compare ADE reporting types
  - Not enough sample size to compare each signals
- Future direction for ADE surveillance system
  - ADE signals refined compared to previous studies
  - Model of ADE system for EMR hospitals to show what kind of EMR data collected in DB
- Further research needed
  - Evidence of clinical and economical benefits of the system
  - System usability
  - Physician attitudes to improve the practice patterns

- Acknowledgements

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