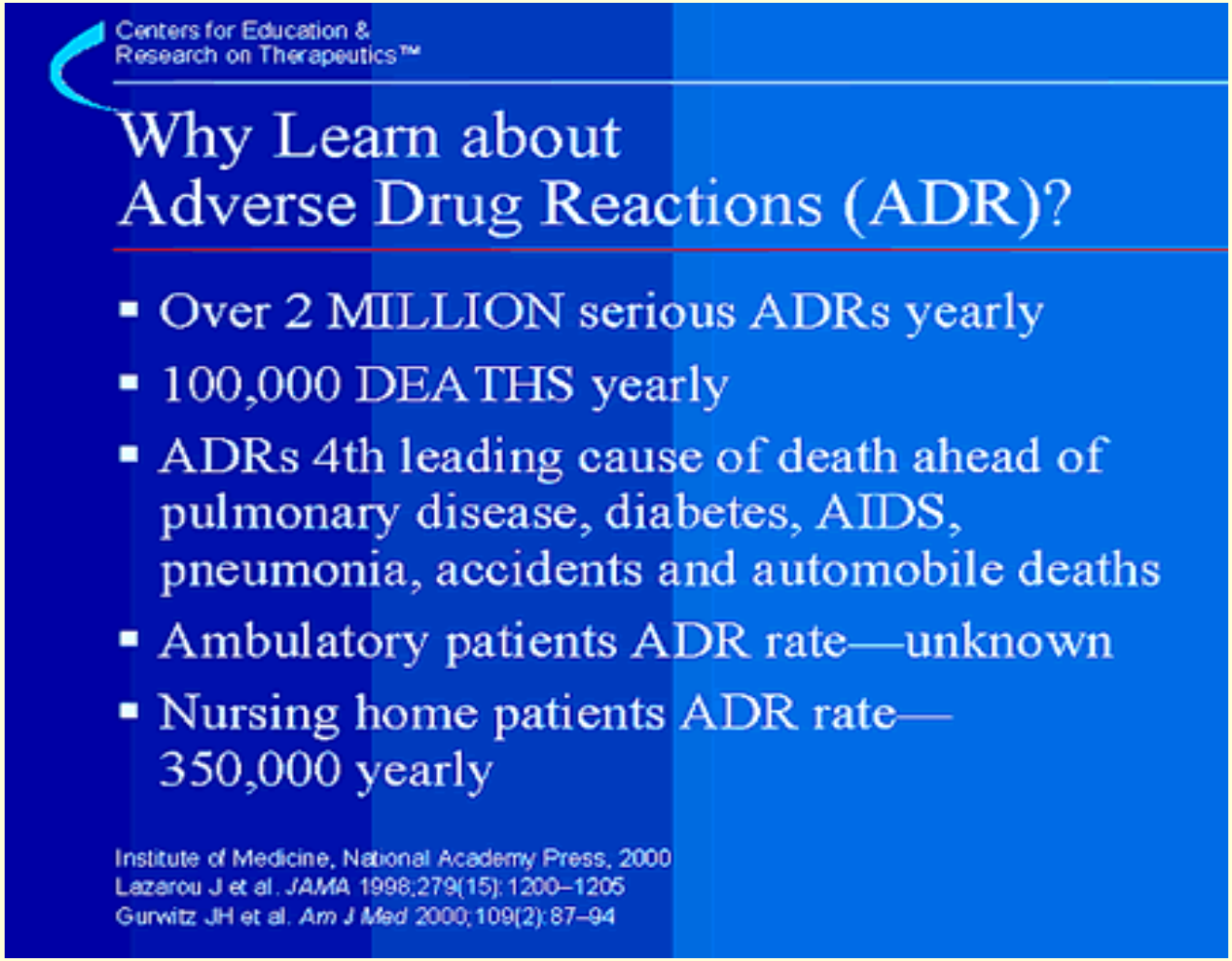
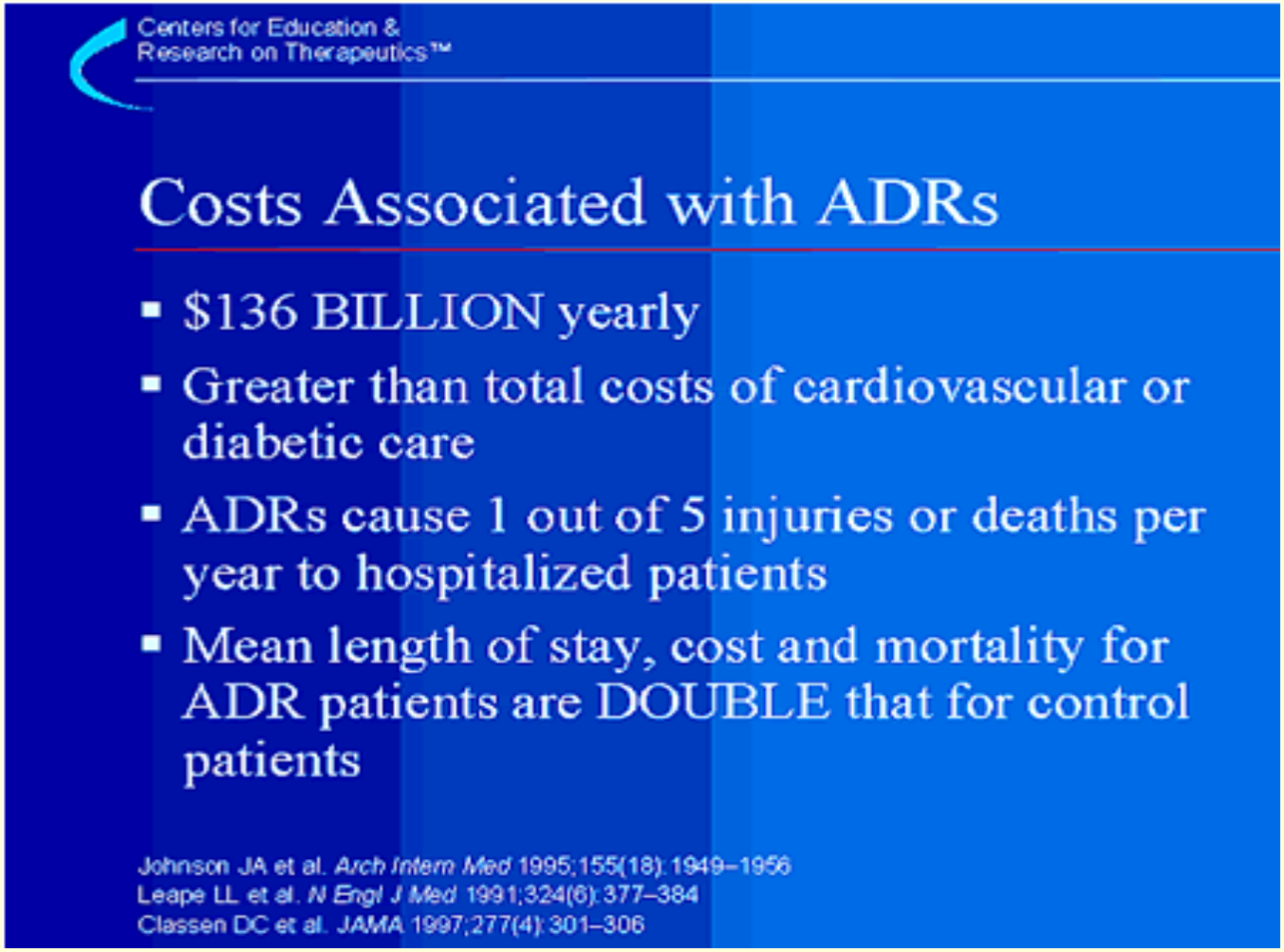
Implementation of a decision-support system (SafeRx) for safer drug therapy

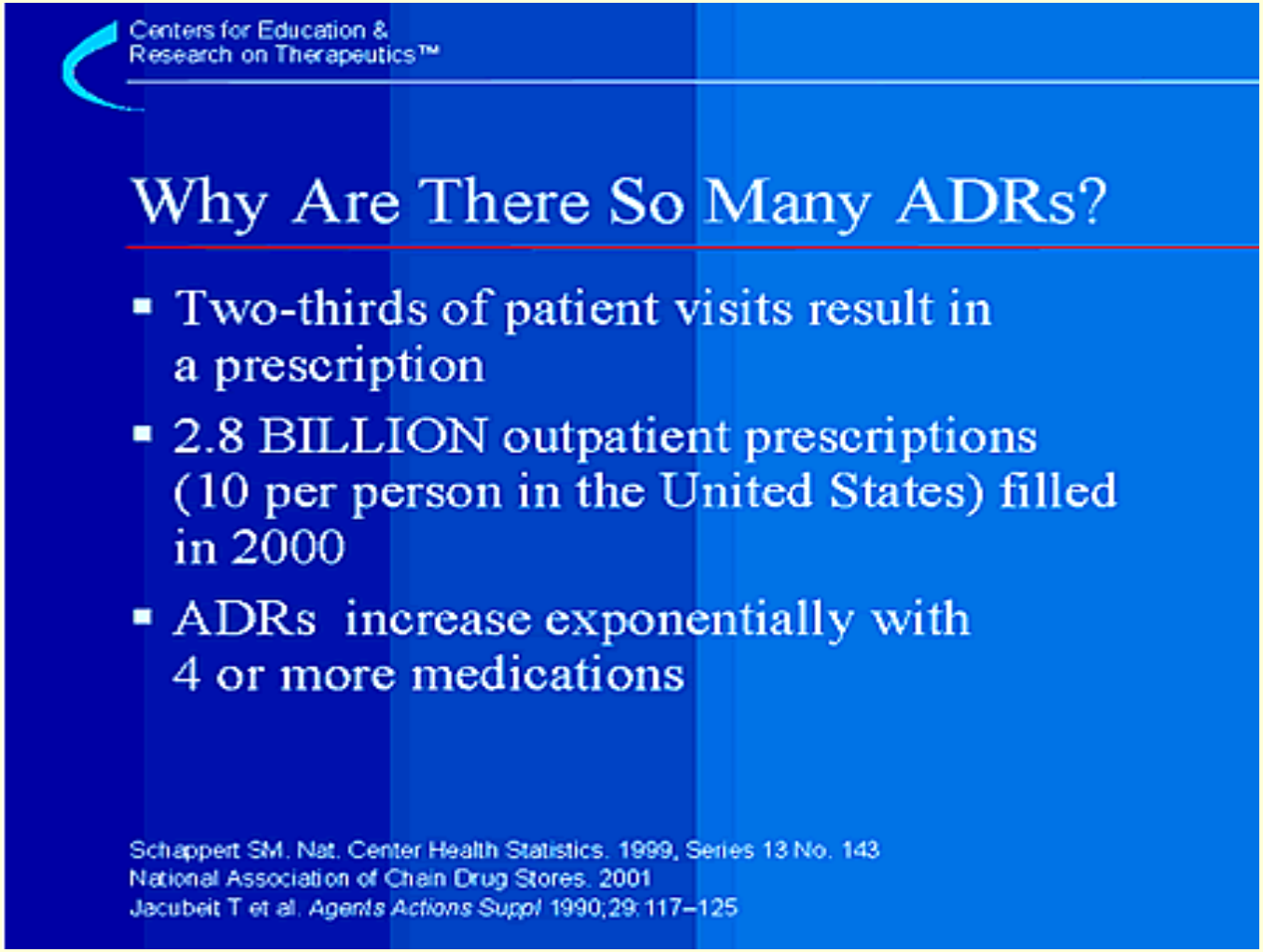
Background


Centers for Education & Research on Therapeutics™
Why Learn about Adverse Drug Reactions (ADR)?
Over 2 MILLION serious ADRs yearly
100,000 DEATHS yearly
ADRs 4th leading cause of death ahead of pulmonary disease, diabetes, AIDS, pneumonia, accidents and automobile deaths
Ambulatory patients ADR rate—unknown
Nursing home patients ADR rate—350,000 yearly
Institute of Medicine, National Academy Press, 2000
Lazarou J et al. JAMA 1998;279(15):1200–1205
Gurwitz JH et al. Am J Med 2000;109(2):87–94

Background


Centers for Education & Research on Therapeutics™
Costs Associated with ADRs
$136 BILLION yearly
Greater than total costs of cardiovascular or diabetic care
ADRs cause 1 out of 5 injuries or deaths per year to hospitalized patients
Mean length of stay, cost and mortality for ADR patients are DOUBLE that for control patients
Johnson JA et al. Arch Intern Med 1995;155(18):1949–1956
Leape LL et al. N Engl J Med 1991;324(6):377–384
Classen DC et al. JAMA 1997;277(4):301–306

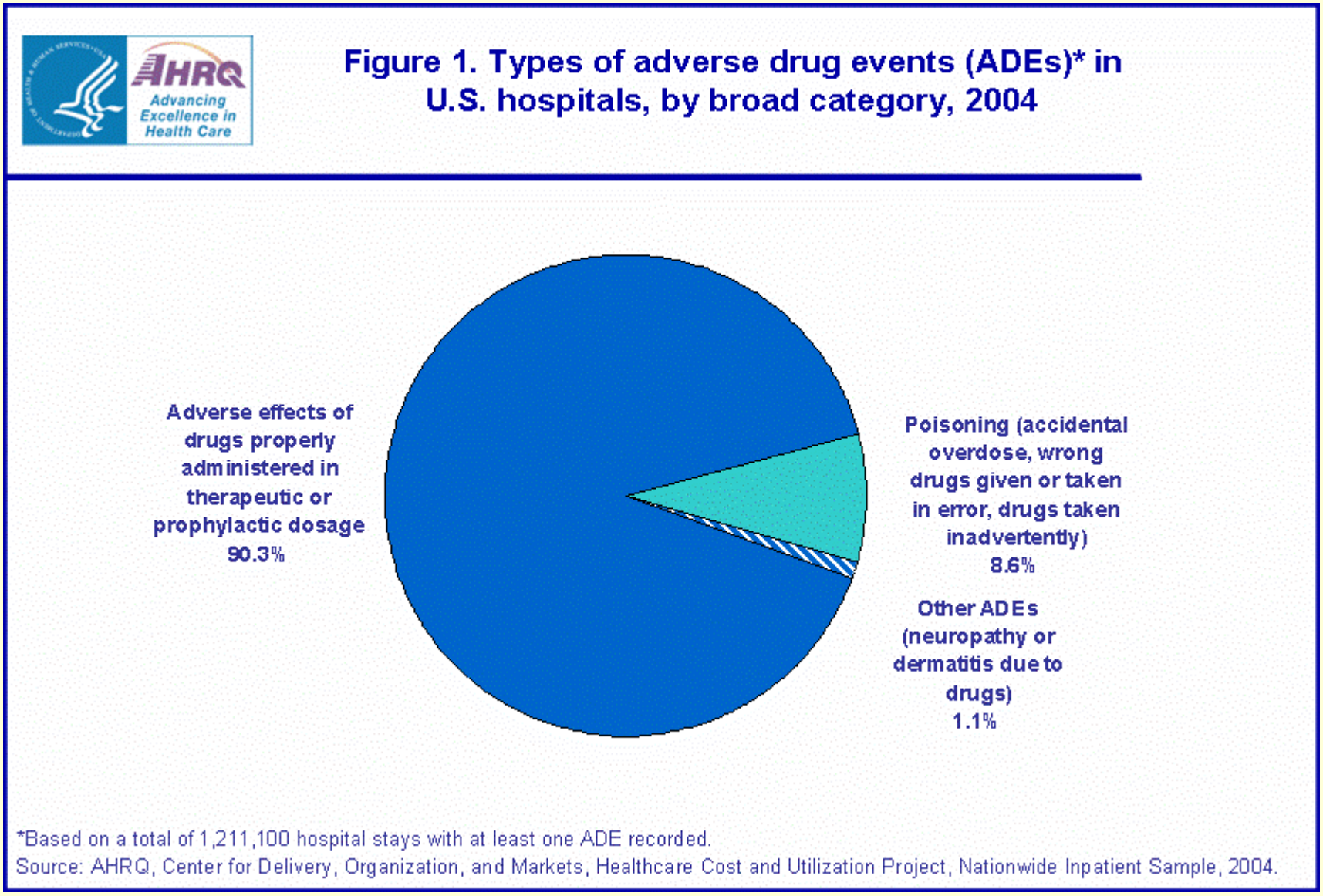
Background


Centers for Education &
Research on Therapeutics™
Why Are There So Many ADRs?
Two-thirds of patient visits result in a prescription
2.8 BILLION outpatient prescriptions (10 per person in the United States) filled in 2000
ADRs increase exponentially with 4 or more medications
Schappert SM. Nat. Center Health Statistics. 1999, Series 13 No. 143
National Association of Chain Drug Stores. 2001
Jacubeit T et al. Agents Actions Suppl 1990;29:117–125

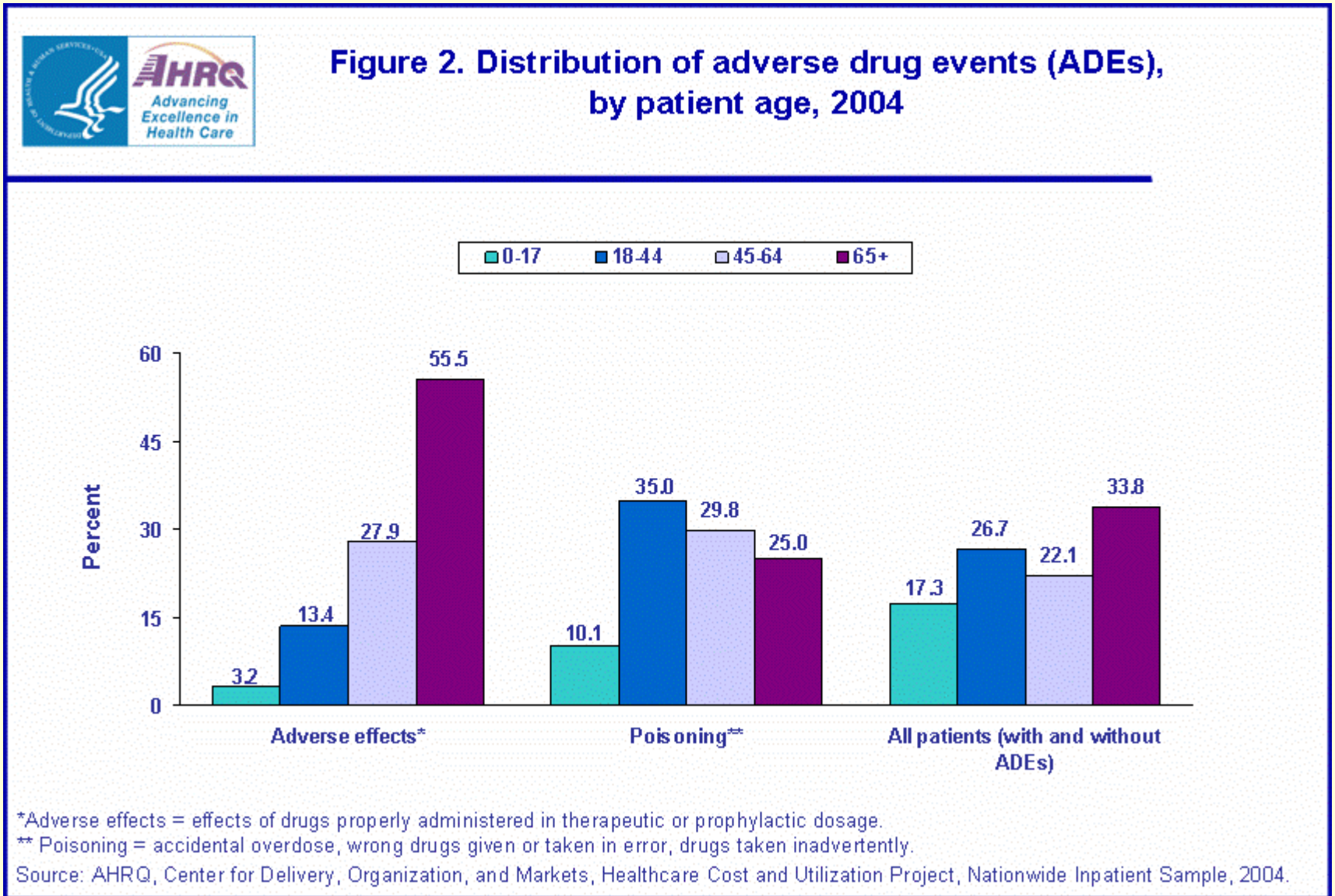
Background


Centers for Education & Research on Therapeutics™
Characterization of New Drug's Safety Profile Before Marketing
Most drugs approved by FDA with average of 1500 patient exposures
Some drugs have rare toxicity profiles (bromfenac hepatotoxicity 1 in 20,000 patients)
For drugs with rare toxicity, more than 100,000 patients must be exposed to generate a signal i.e. after drug is marketed
Friedman MA et al. JAMA 1999; 281(18):1728–1734

Background

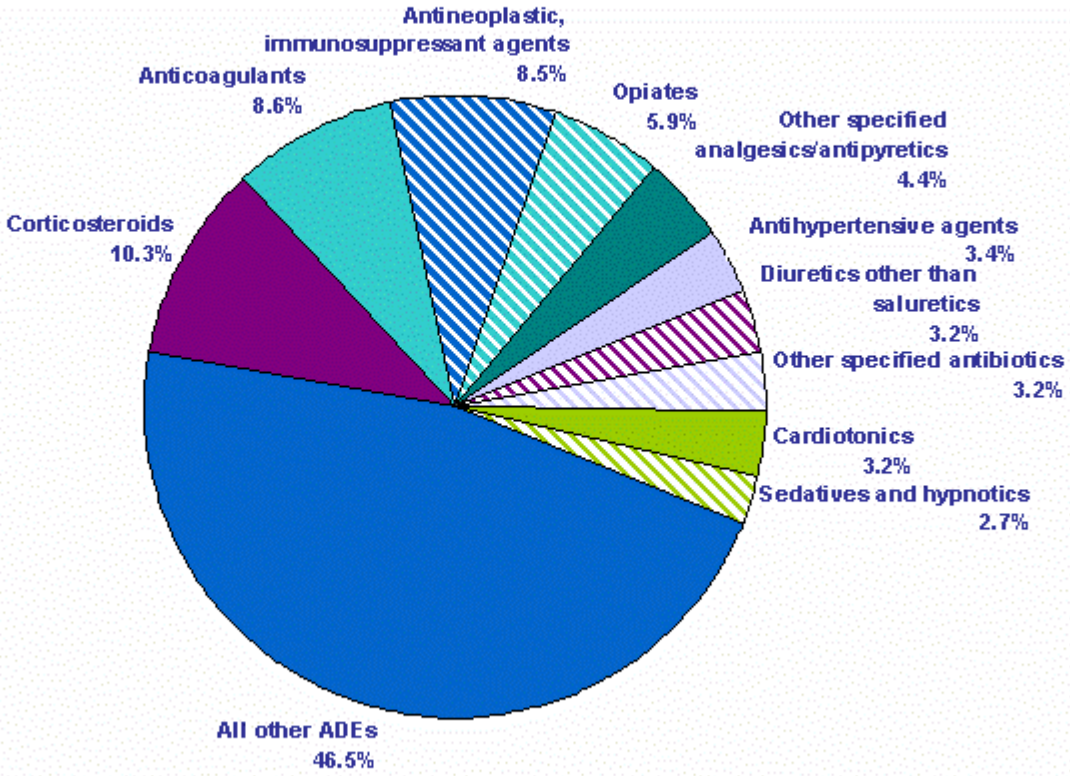

AHRQ
Advancing Excellence in Health Care
Figure 1. Types of adverse drug events (ADEs)* in U.S. hospitals, by broad category, 2004
Adverse effects of drugs properly administered in therapeutic or prophylactic dosage 90.3%
Poisoning (accidental overdose, wrong drugs given or taken in error, drugs taken inadvertently) 8.6%
Other ADEs (neuropathy or dermatitis due to drugs) 1.1%
*Based on a total of 1,211,100 hospital stays with at least one ADE recorded.
Source: AHRQ, Center for Delivery, Organization, and Markets, Healthcare Cost and Utilization Project, Nationwide Inpatient Sample, 2004.

Background


AHRQ
Advancing Excellence in Health Care
Figure 2. Distribution of adverse drug events (ADEs), by patient age, 2004
0-17
18-44
45-64
65+
Percent
60
45
30
15
0
3.2
13.4
27.9
55.5
10.1
35.0
29.8
25.0
17.3
26.7
22.1
33.8
Adverse effects*
Poisoning**
All patients (with and without ADEs)
*Adverse effects = effects of drugs properly administered in therapeutic or prophylactic dosage.
** Poisoning = accidental overdose, wrong drugs given or taken in error, drugs taken inadvertently.
Source: AHRQ, Center for Delivery, Organization, and Markets, Healthcare Cost and Utilization Project, Nationwide Inpatient Sample, 2004.

Background

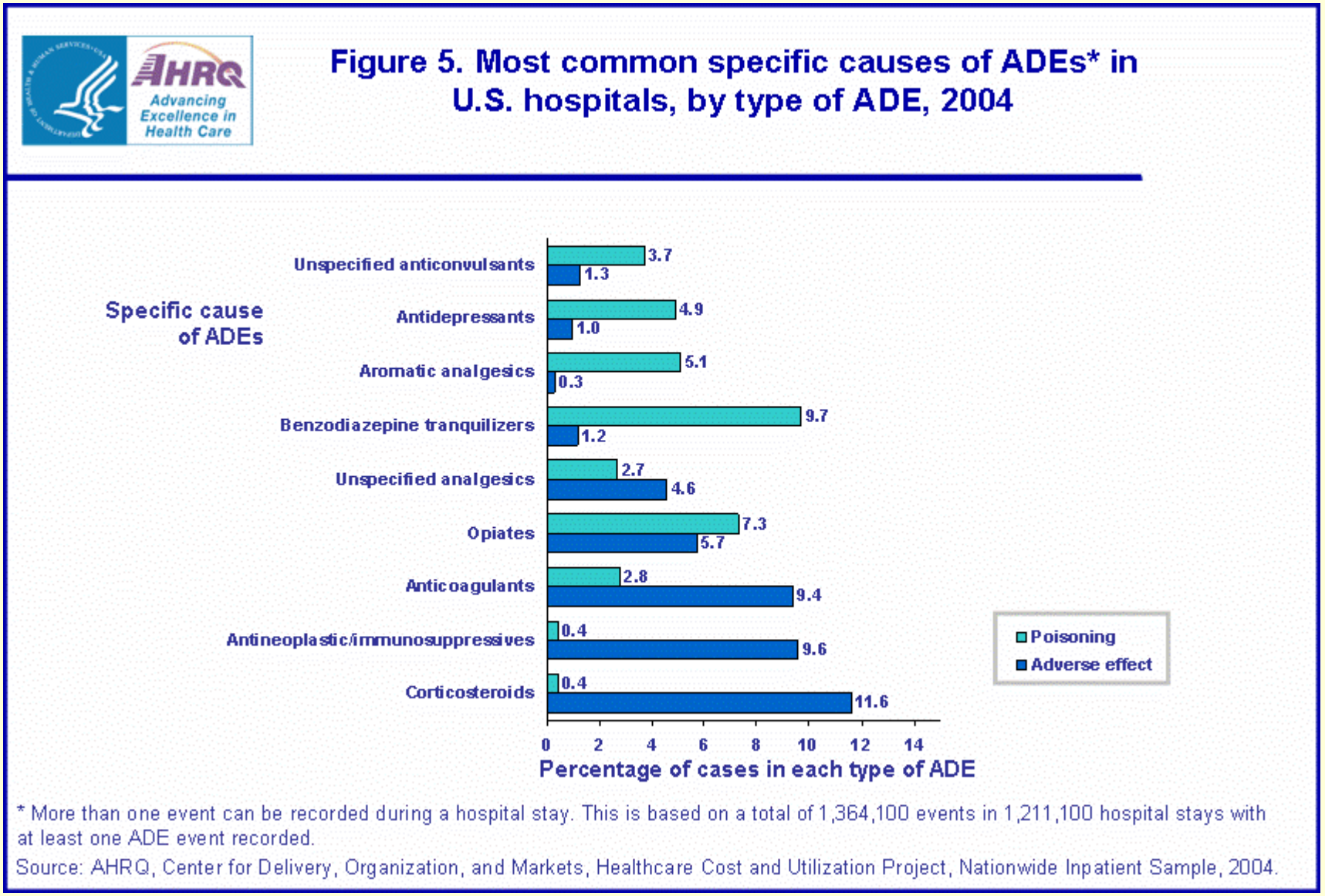
Figure 4. Most common specific causes of adverse drug events (ADEs)* in U.S. hospitals, 2004



* More than one event can be recorded during a hospital stay. This is based on a total of 1,364,100 events in 1,211,100 hospital stays with at least one ADE event recorded.

Source: AHRQ, Center for Delivery, Organization, and Markets, Healthcare Cost and Utilization Project, Nationwide Inpatient Sample, 2004.

Background


AHRQ
Advancing Excellence in Health Care
Figure 5. Most common specific causes of ADEs* in U.S. hospitals, by type of ADE, 2004
Specific cause of ADEs
Unspecified anticonvulsants
3.7
1.3
Antidepressants
4.9
1.0
Aromatic analgesics
5.1
0.3
Benzodiazepine tranquilizers
9.7
1.2
Unspecified analgesics
2.7
4.6
Opiates
7.3
5.7
Anticoagulants
2.8
9.4
Antineoplastic/immunosuppressives
0.4
9.6
Corticosteroids
0.4
11.6
0
2
4
6
8
10
12
14
Percentage of cases in each type of ADE
Poisoning
Adverse effect
* More than one event can be recorded during a hospital stay. This is based on a total of 1,364,100 events in 1,211,100 hospital stays with at least one ADE event recorded.
Source: AHRQ, Center for Delivery, Organization, and Markets, Healthcare Cost and Utilization Project, Nationwide Inpatient Sample, 2004.

Computerized physician order entry - CPOE

CPOE BENEFITS

CPOE Eliminates:

handwriting errors

Rx order travel time to pharmacy

CPOE

CPOE BENEFITS

CPOE Eliminates:

abbreviation errors

transcription errors

CPOE

CPOE BENEFITS

CPOE Facilitates

ID of prescribing MD

integration of CDSS

integration with Pt. record

CPOE

CPOE BENEFITS

CPOE facilitates:

Analysis of patient and Rx data

CPOE

Medscape® www.medscape.com

Cause of Error	No. Errors (No. per Pt. Discharge) Before CPOE System	After CPOE System	*p*
Prescribing	38 (0.014)	13 (0.008)	0.06
Unit order processing	40 (0.014)	30 (0.018)	0.40
Pharmacy order processing	74 (0.027)	90 (0.053)	<0.01
Computerized order entry	NA[a]	17 (0.010)	NA
Preparation	1 (<0.001)	0 (0.000)	0.43
Dispensing	9 (0.003)	2 (0.001)	0.17
Delivery	13 (0.005)	4 (0.002)	0.22
Administration	54 (0.019)	42 (0.025)	0.24
Clinical monitoring	4 (0.001)	1 (0.001)	0.41

[a]NA = not applicable.

Types of Unintended Consequences of Computerized Provider Order Entry Systems

- More or new work for clinicians
- Unfavorable workflow issues
- Never-ending system demands
- Problems related to persistence of paper orders
- Unfavorable changes in communication patterns and practices
- Negative feelings toward the new technology
- Generation of new types of errors
- Unexpected changes in an institution's power structure, organizational culture, or professional roles
- Overdependence on the technology

Clinical decision support system-CDSS

- A clinical decision support system (CDSS) links health observations with medical knowledge in order to assist clinicians in decision making.
-
- The embedding of a CDSS into patient care workflow offers opportunities to reduce medical errors as well as to improve patient safety, to enhance drug selection and dosing, and to improve preventive care. It is less certain whether a CDSS can enhance diagnostic accuracy.

- A CDSS can assist clinicians in reducing some errors and costs.

Clinical decision support systems-CDSS

- *1. Access to accurate clinical data*.
- *2. Access to pertinent medical knowledge.*
- *3. Ability to use appropriate problem solving skills*.

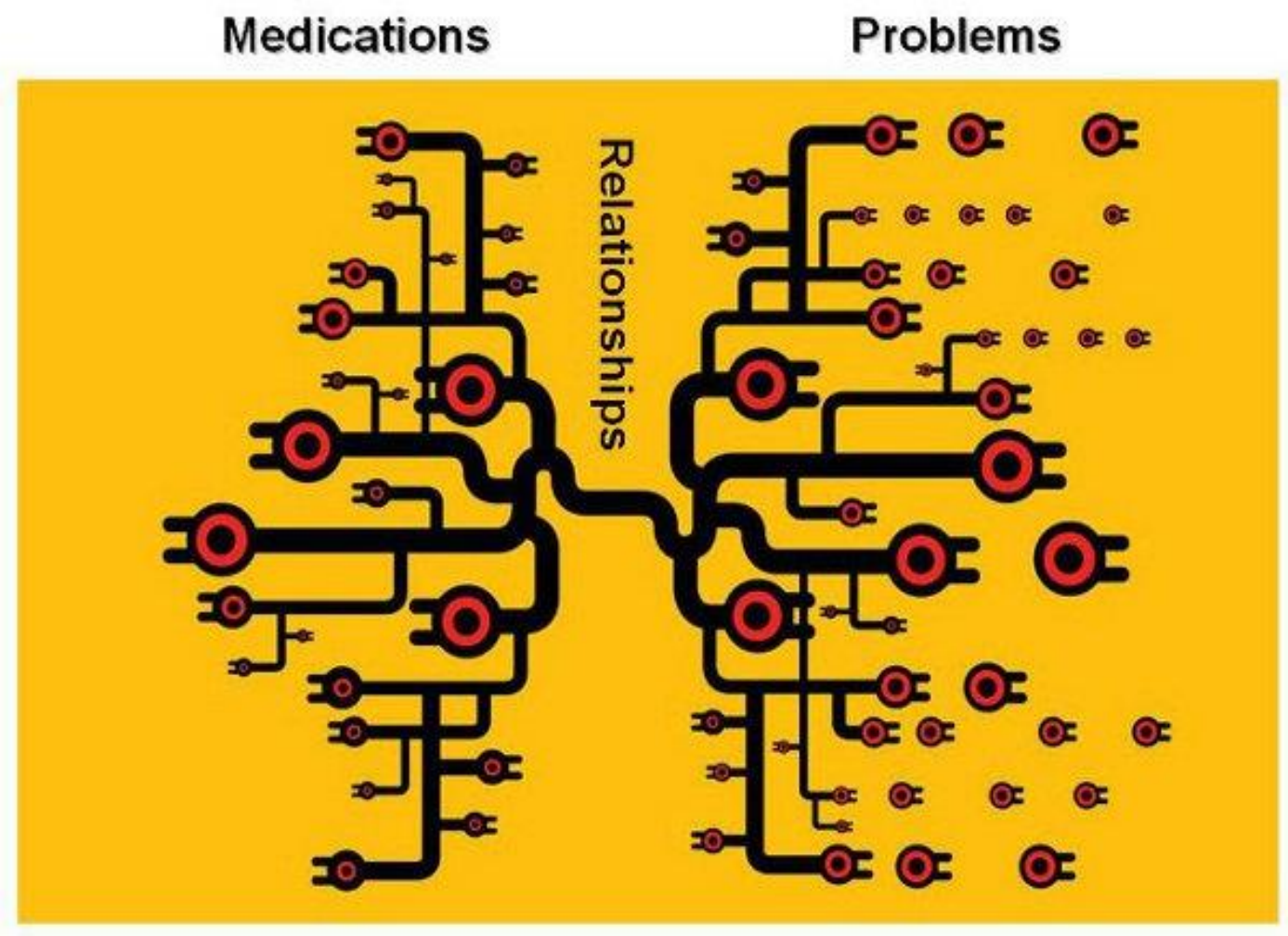
CDSS

- An effective CDSS involves six levels of decision making: alerting, interpreting, critiquing, assisting, diagnosing and managing.
- Alerts are a vital component of a CDSS. Automated clinical alerts remain an important part of current error reduction strategies that seek to affect the cost, quality, and safety of health care delivery

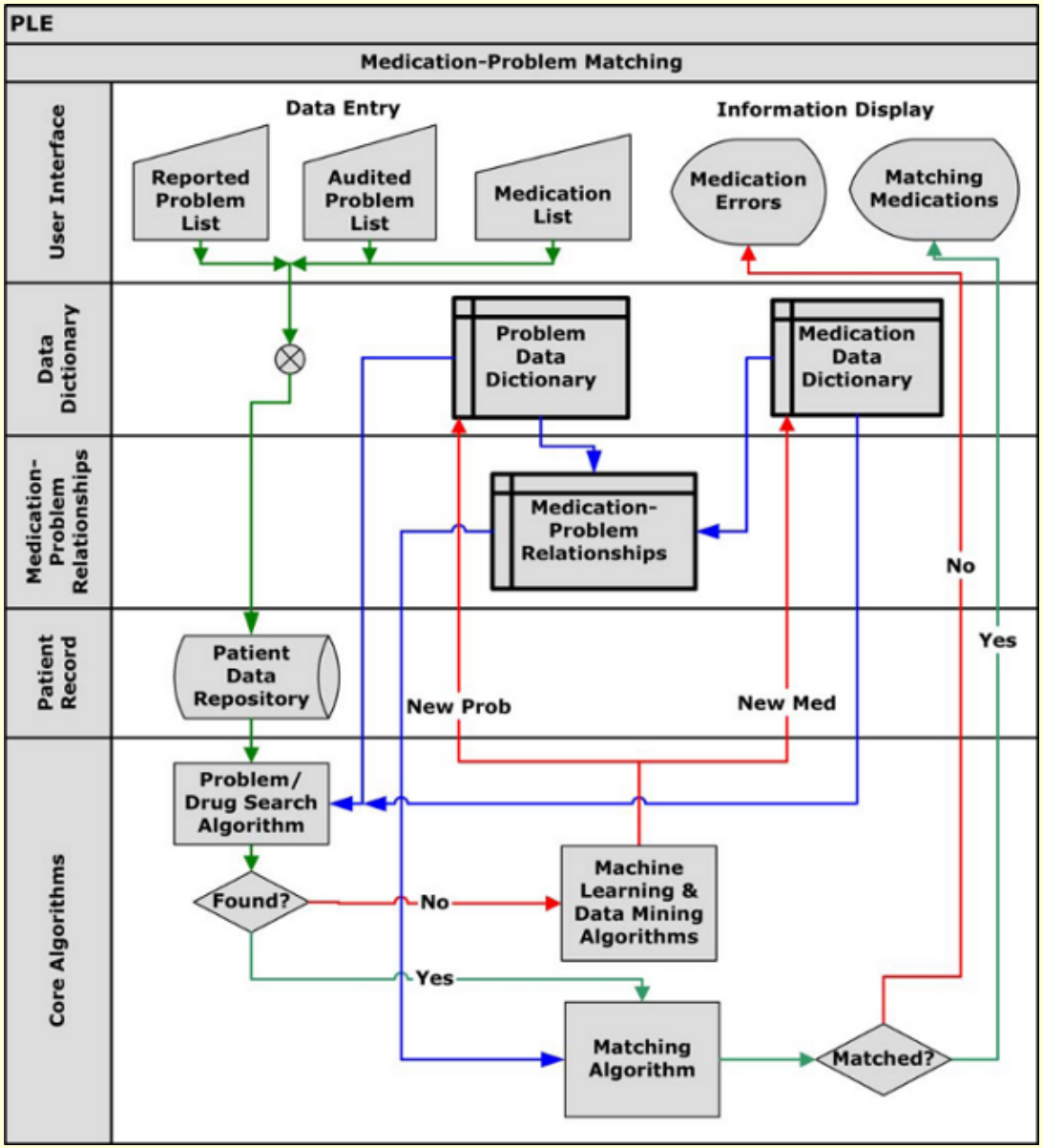
CDSS

- Several practical factors contribute to the success of a CDSS:
- considering the potential impact on clinical workflow.
- creating an intuitive and configurable user interface.
- delivering decision support in real time at the point of care.
- providing actionable alerts/reminders/recommendations that are succinct and relevant to patient care.

CDSS



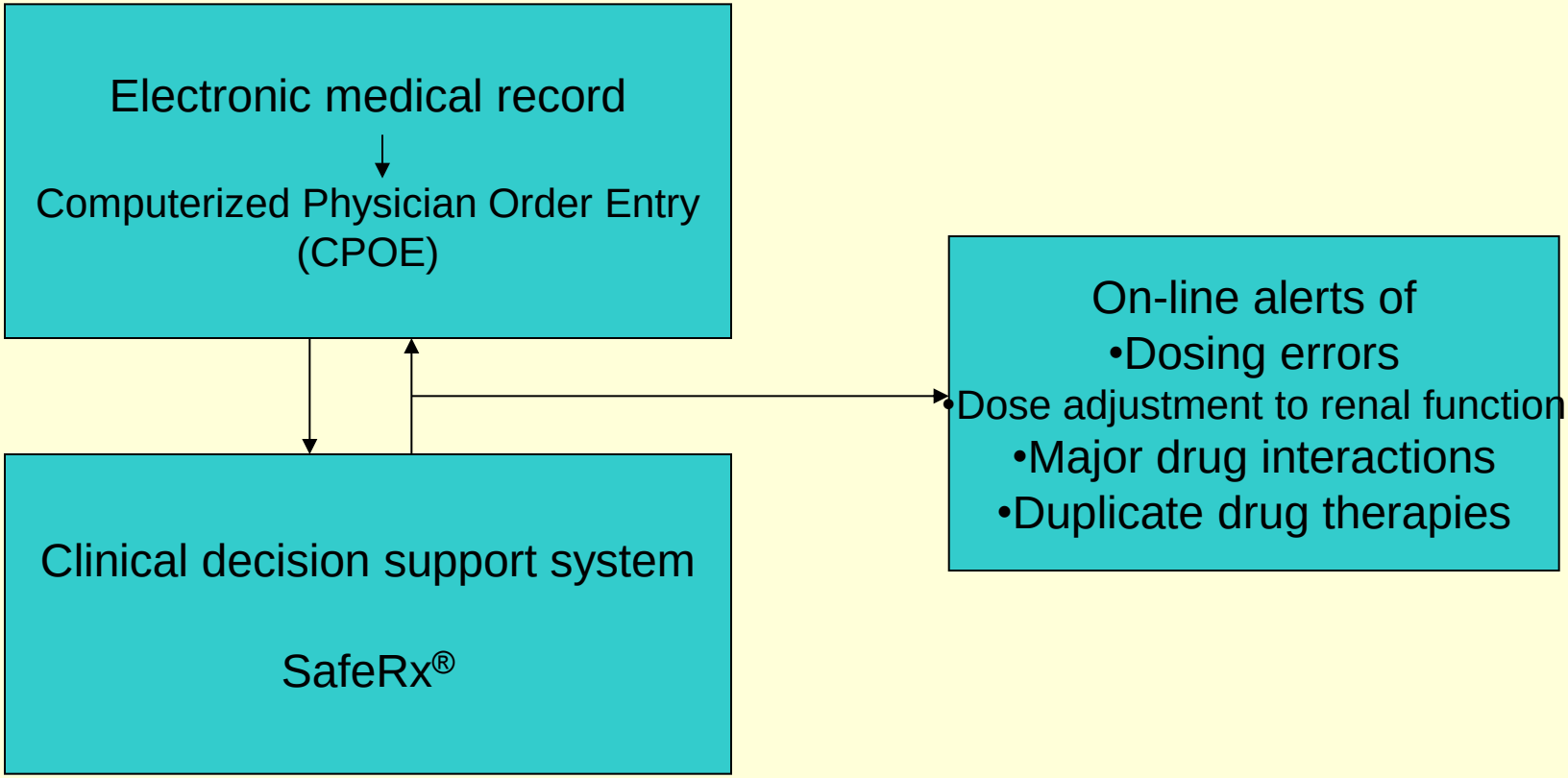
CDSS


PLE
Medication-Problem Matching
User Interface
Data Entry
Information Display
Reported Problem List
Audited Problem List
Medication List
Medication Errors
Matching Medications
Data Dictionary
Problem Data Dictionary
Medication Data Dictionary
Medication-Problem Relationships
Medication-Problem Relationships
Patient Record
Patient Data Repository
New Prob
New Med
No
Yes
Core Algorithms
Problem/ Drug Search Algorithm
Found?
No
Machine Learning & Data Mining Algorithms
Yes
Matching Algorithm
Matched?

SafeRx system – for safer drug therapy

- Objectives: To improve the safety of drug therapy in Sheba Medical Center by implementing a clinical decision support system that provides on-line alerts with respect to different aspects of drug errors.

SafeRx- for safer drug therapy



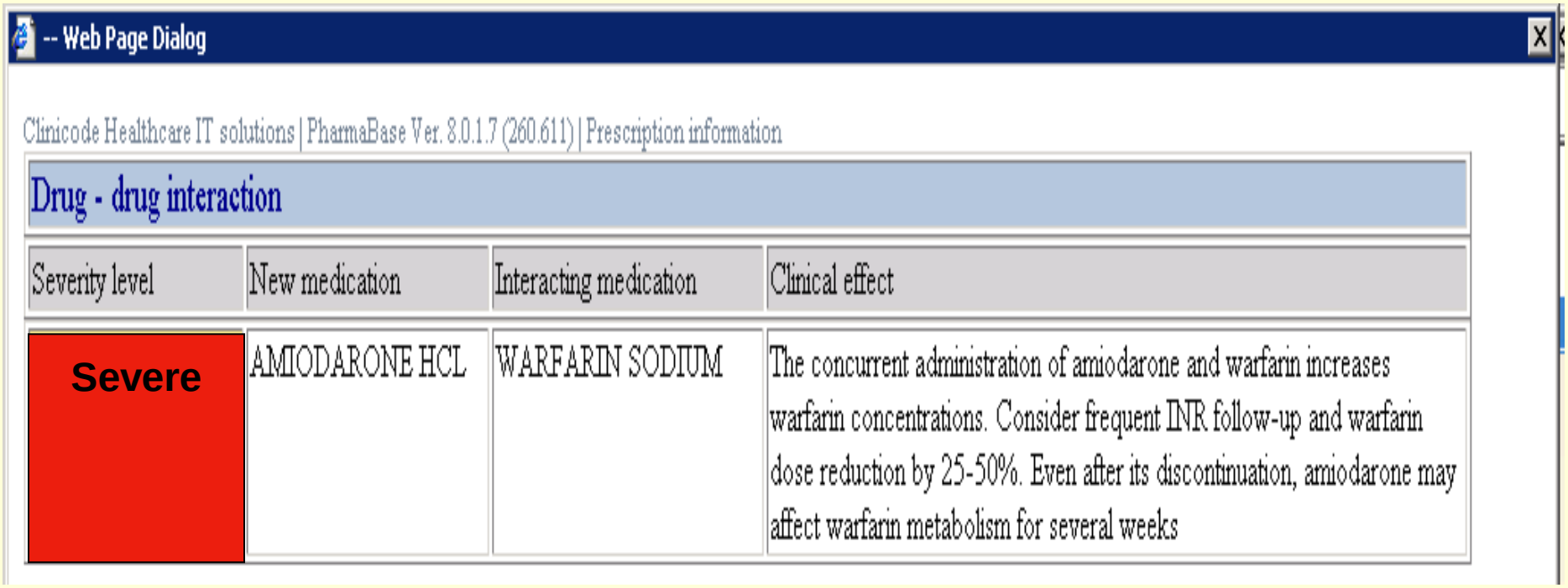
SafeRx –for safer drug therapy

- The SafeRx system interfaces with Chameleon and iMD soft electronic medical records.
- The system database relates to the updated Sheba drug catalogue. Data source: Micromedex® and Lexicomp®, FDA alerts and drug leaflet (manufacturer).
- The system database is constantly updated by clinical pharmacists supervised by a team of Sheba clinical pharmacologists.
- The alerting system is flexible and can be adjusted to the specific needs of each department.

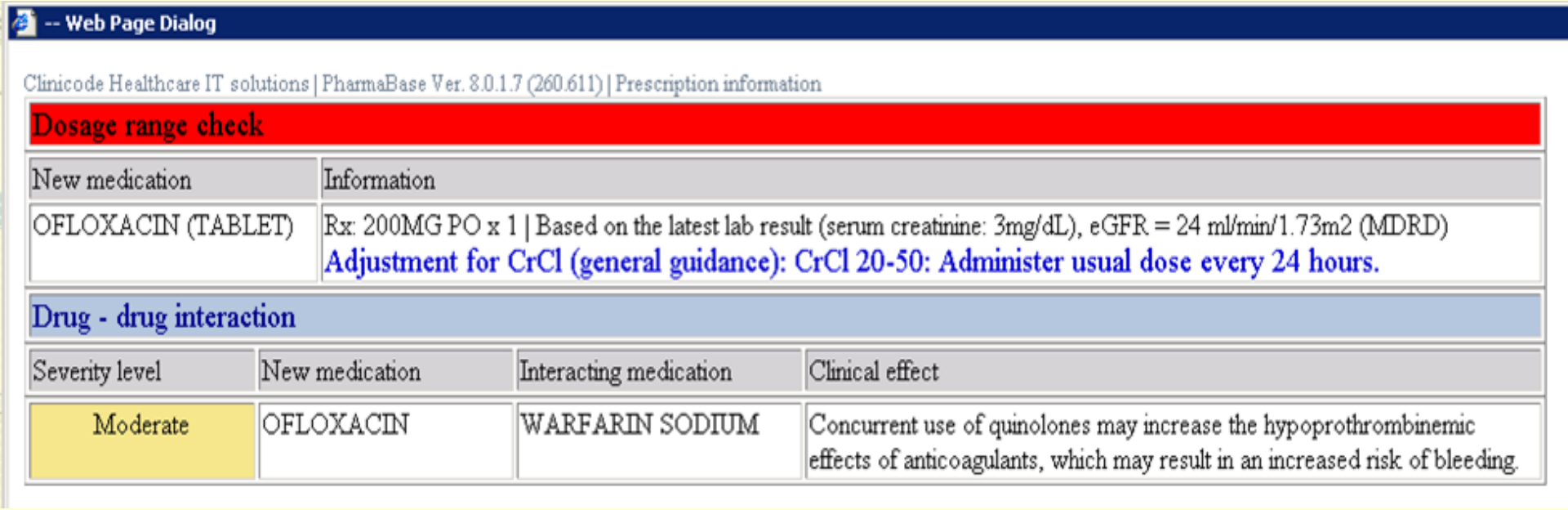
SafeRx – for safer drug therapy

- For each new department: introduction of the system in a “silent mode” (alerts are not presented to the users)
- Primary analysis of provided alerts after 4 weeks of “silent mode” operation.
- Alerts customization to specific user according to his needs coupled with recommendations by the steering committee of clinical pharmacologists and pharmacists.
- Operation of the system with alerts presented to all users.
- Primary feedback from all users after 4 weeks of operation.
- Continuous re-adjustment of alerts provided according to needs.

Example: Drug-drug interaction



Example: Dose-adjustment



-- Web Page Dialog

Clinicode Healthcare IT solutions | PharmaBase Ver. 8.0.1.7 (260.611) | Prescription information

Dosage range check

New medication	Information
OFLOXACIN (TABLET)	Rx: 200MG PO x 1 | Based on the latest lab result (serum creatinine: 3mg/dL), eGFR = 24 ml/min/1.73m2 (MDRD) **Adjustment for CrCl (general guidance): CrCl 20-50: Administer usual dose every 24 hours.**

Drug - drug interaction

Severity level	New medication	Interacting medication	Clinical effect
Moderate	OFLOXACIN	WARFARIN SODIUM	Concurrent use of quinolones may increase the hypoprothrombinemic effects of anticoagulants, which may result in an increased risk of bleeding.

Implementation of SafeRx in Sheba Medical Center-Current status

- Full operation:

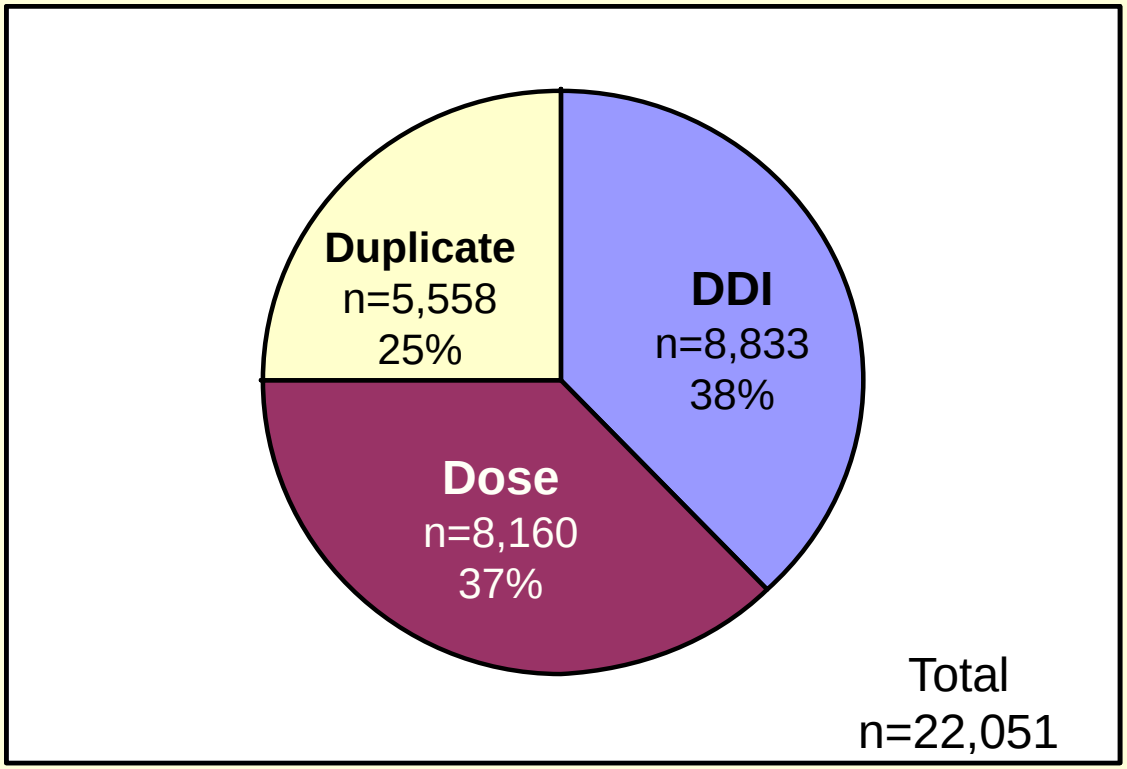
- Internal Medicine departments (6).
- Surgery departments (3).
- Orthopedic departments (2).
- Psychiatric departments (3).
- Neurology (1).
- Oncology (1).
- General ICU (1).
- Pediatric cardiac ICU (1).
- Plastic surgery department (1).
- Hemato-oncology department (1).
- Bone marrow transplantation department (1).

Implementation of SafeRx in Sheba Medical Center-Current status

- Silent mode operation
- Urology (1)
- Neurosurgery (1)
- Pediatric ICU (1)
- Emergency department (1)
- Dermatology (1).
- Geriatric rehabilitation department (2)

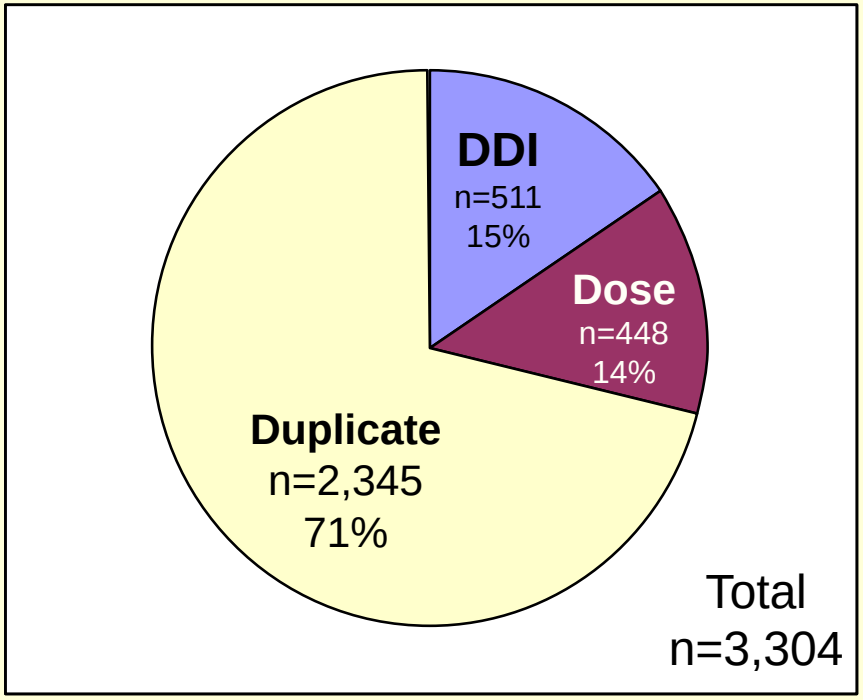
Interim analysis (Jan-Mar 2013)
Alerts in 6 Internal Medicine departments

- Total number of prescriptions: 56,701
- 18,431 prescriptions (32.5%) triggered a mean of 1.2 alerts



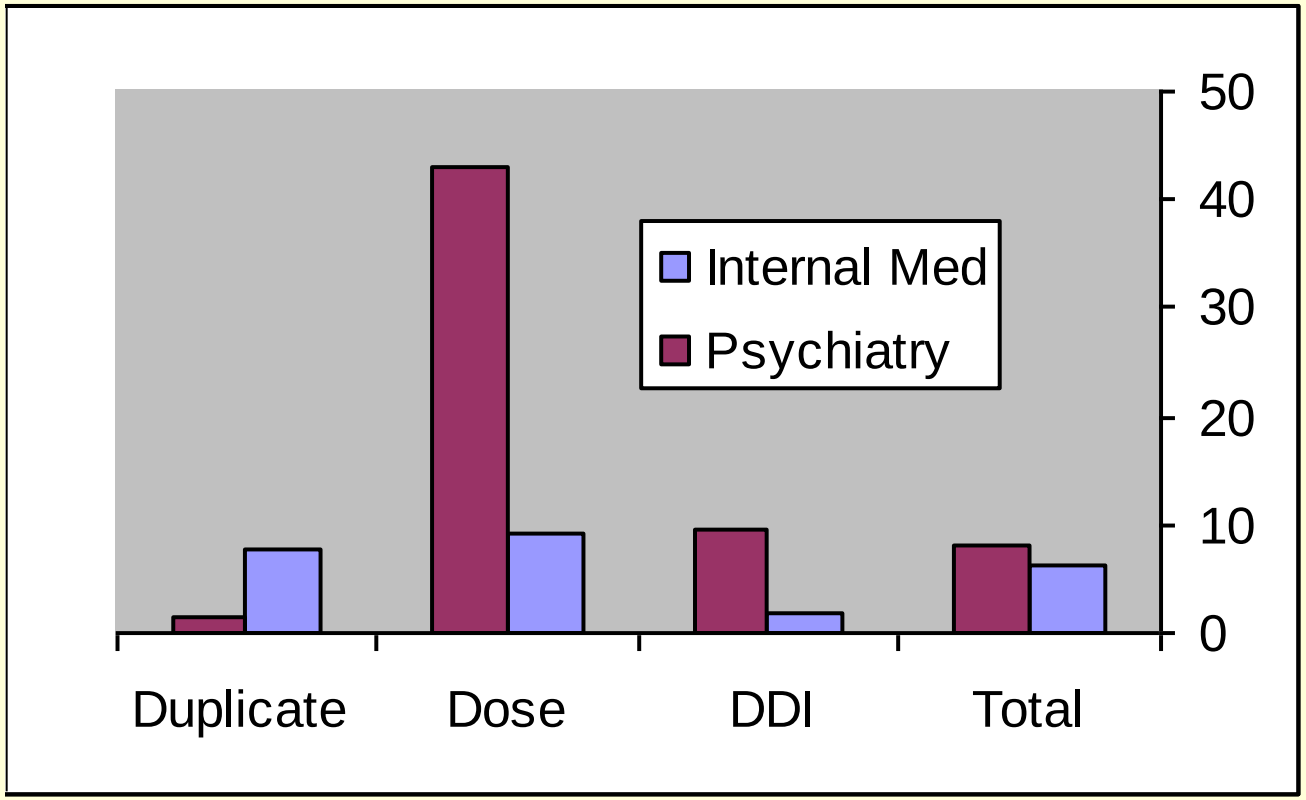
Interim analysis (Jan-Mar 2013)
Alerts in 3 Psychiatry departments

- Total number of prescriptions: 5,156
- 3,023 prescriptions (58.6%) triggered a mean of 1.1 alerts



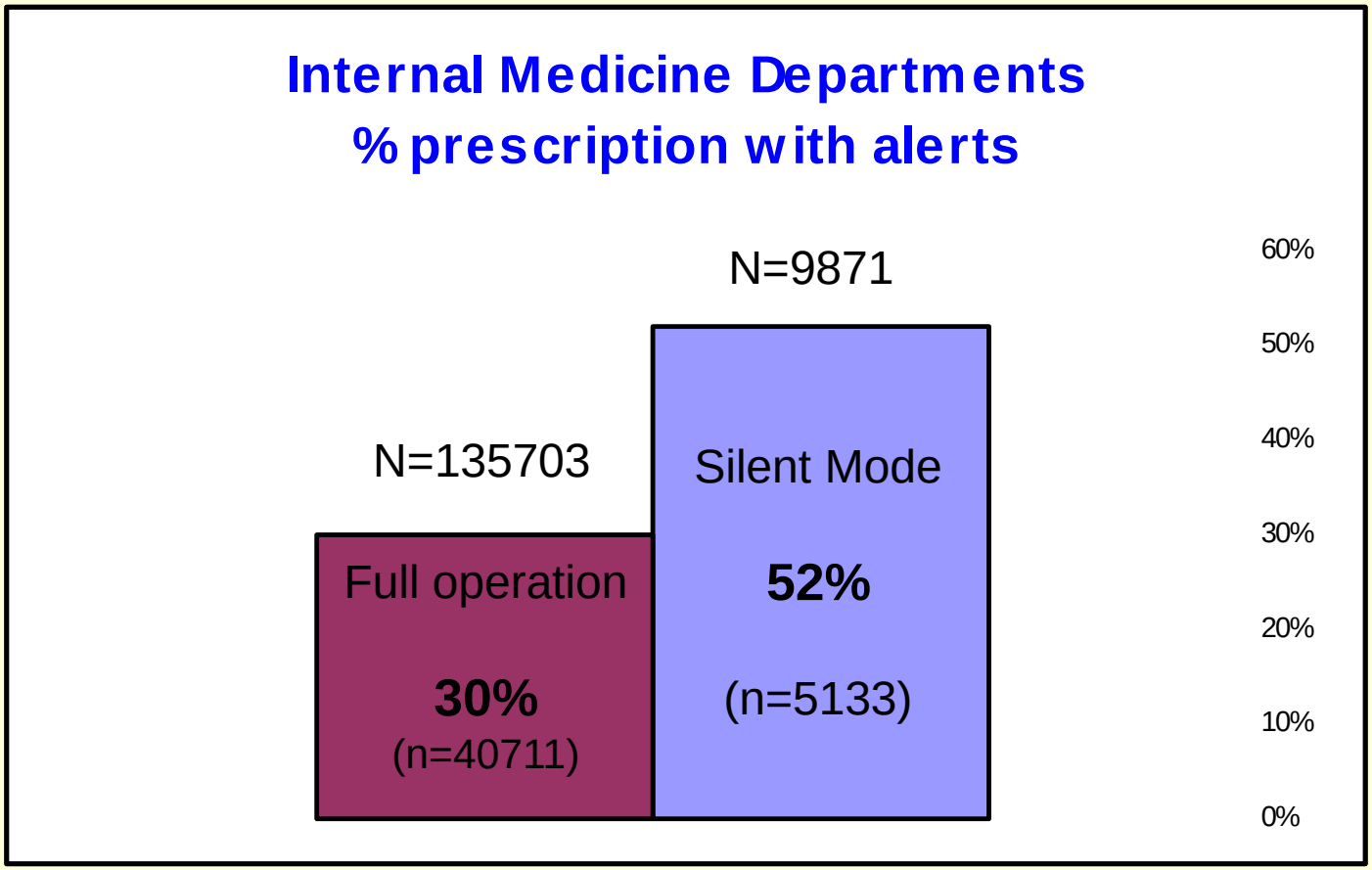
Acceptance rate

- 1,634 (6.4%) of 25,355 alerts were accepted by prescriber

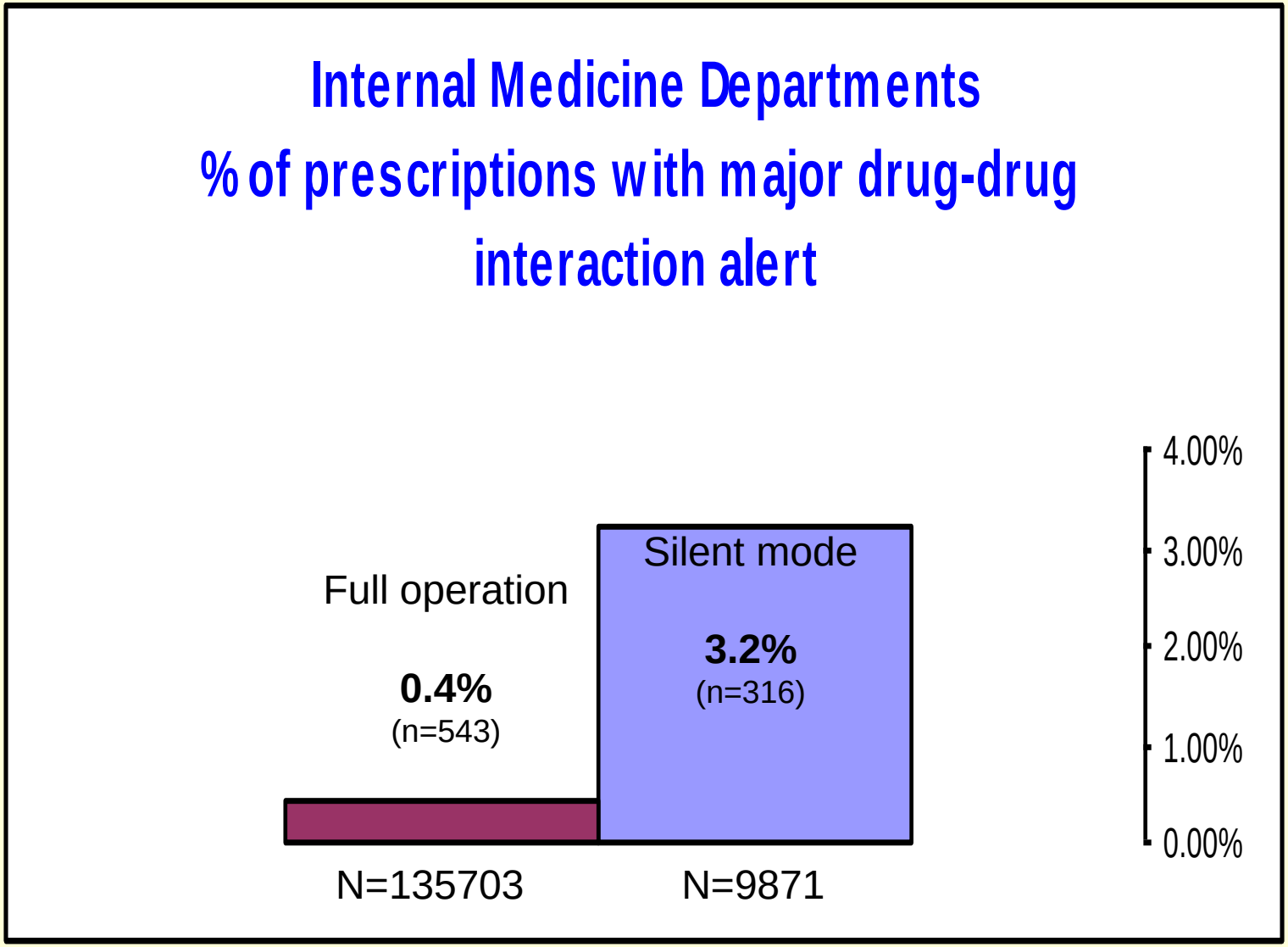


Acceptance rate (%) by alert type

Interim analysis of results



Interim analysis



Implementation of SafeRx in Sheba Medical Center- Future plan

- Full operation in all departments of the General hospital – End of 2013.
- Silent Mode in all departments of rehabilitation hospital obstetrics and gynecology and pediatric hospital- March 2014.
- Full operation in all departments of rehabilitation hospital obstetrics and gynecology and pediatric hospital- July 2014.
- Full operation in all outpatient clinics-End of 2014.

Implementation of SafeRx in Sheba Medical Center- Future plan

- Development of new modules:
- Drugs in pregnancy
- Drugs in lactation
- Allergy