ADVERSE DRUG REACTION REPORTING- A RETROSPECTIVE ANALYSIS

BY

Ibel C Fredy

Pharm D (Doctor of Pharmacy)

Intern , PES College of Pharmacy,

Bangalore, Karnataka, India

CASE STUDY

Steven Johnson Syndrome (SJS/TEN)

A seven year boy admitted to hospital with skin blisters and eruptions followed by necrosis of the epidermal tissue

History:

k/c/o Trabeculoma in brain with c/o seizures and prescribed with carbamazepine ,Started on ATT 9 days back, skin reactions observed on the 9th day

Various reactions

Fixed drug eruptions

Utricaria

examples

- **Urticaria**

NSAIDs, antimicrobials, anticancer drugs, ACE inhibitors, corticosteroids

- **Fixed-drug eruptions**

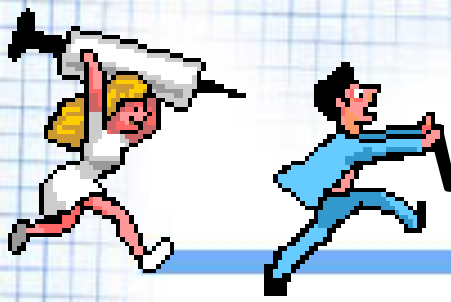
Tetracyclines, barbiturates, sulfonamides, codeine, carbamazepine, acetaminophen, NSAIDs

- **SJS and TEN**

Antibacterial sulfonamides, anticonvulsants, oxicam NSAIDs, allopurinol, nevirapine

Introduction

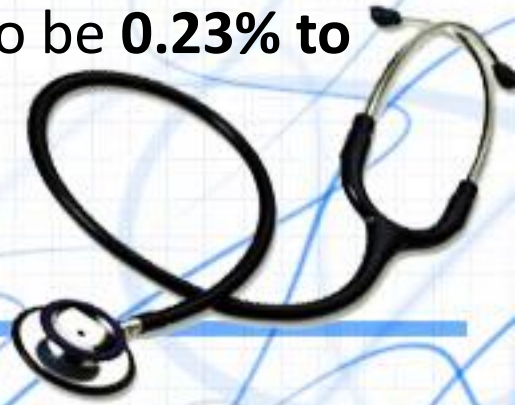
The World Health Organisation (WHO) defines an ADR as **"a response to a drug that is noxious and unintended and occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease, or for modification of physiological function"**



WHY ? monitoring ADRs

- Worldwide incidence of ADRs is steadily increasing

  - Up to **35% of hospitalized patients** experience ADRs
  - Approximately **5% to 10%** of all hospital admissions are due to ADRs
  - The incidence of **fatal ADRs** is estimated to be **0.23% to 0.41%**



- Adversely affect patients' **quality of life**
- ADRs are one of the leading causes of **morbidity and mortality**
- Cause patients to **lose confidence** in their doctors
- **Increase costs** of patient care

Objective of study

- Assess the incidence and pattern of reported ADRs
- Assess causality and offending drugs that caused ADRs
- Assess the severity and preventability of reported ADRs

Methodology

- **Study Site:** A Tertiary Care Hospital, Bangalore
- **Study Design:** Retrospective observational study
- **Source of Data:** Documented ADRs 2009-2015
- **Data Analysis:** Microsoft Excel

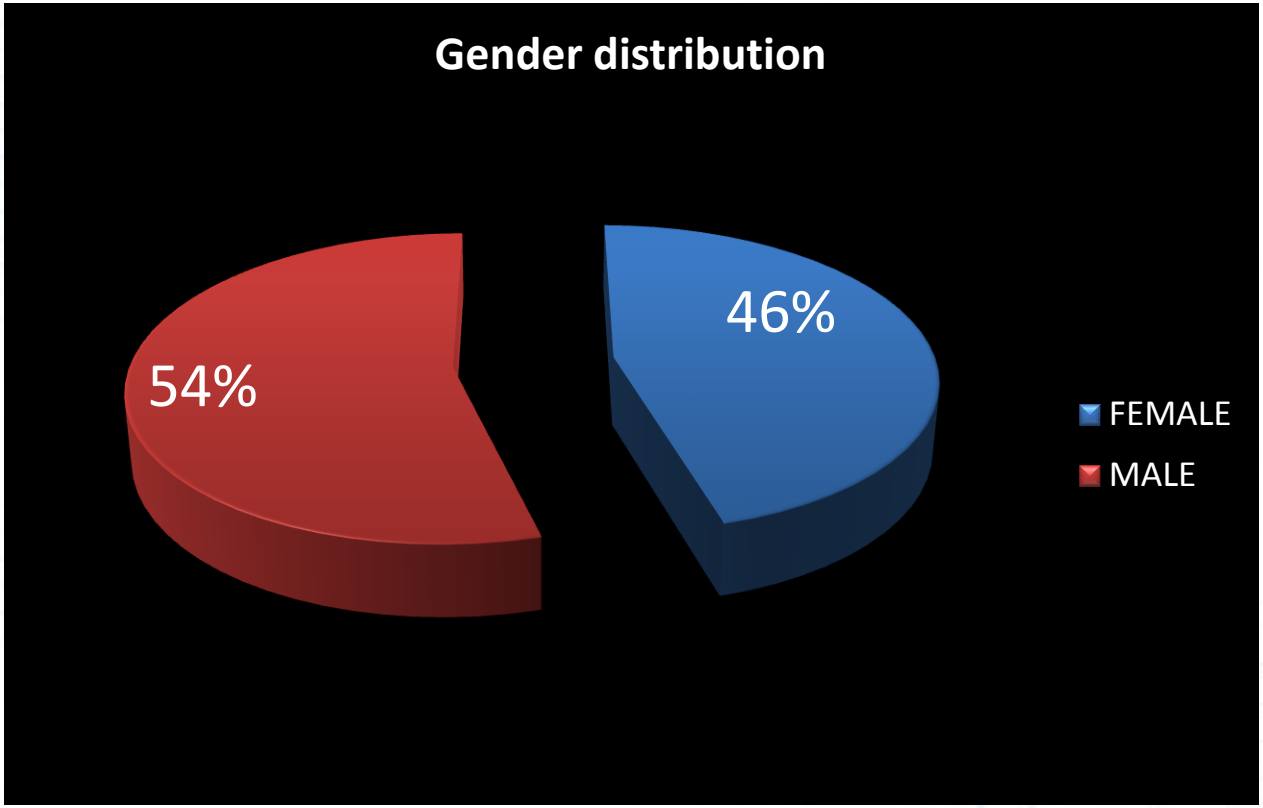
Documented ADRS from 2009-2015 were collected

Causality, Severity, preventability were assessed using different scales

Results were analyzed using MS Excel

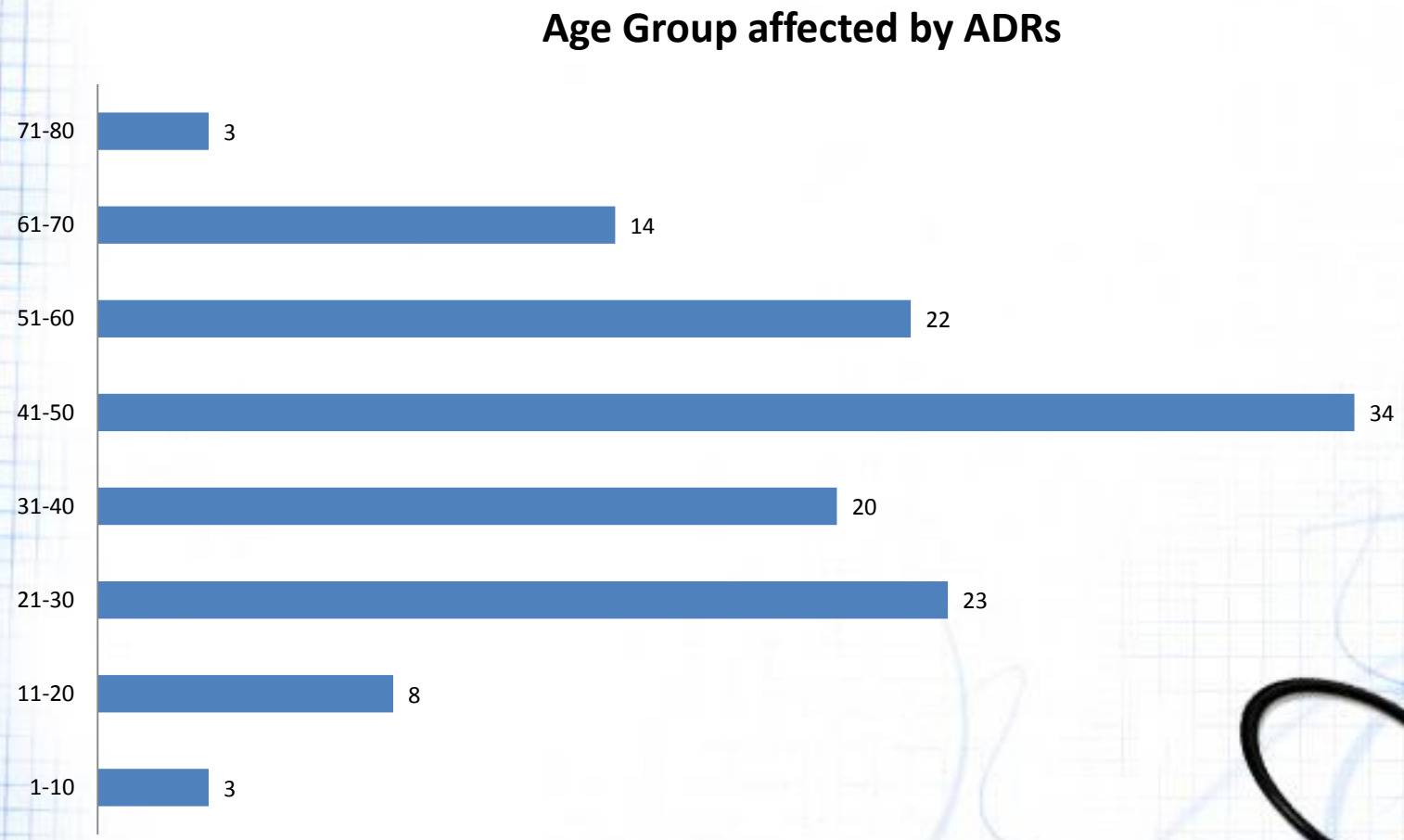
Results and Discussion

Gender distribution

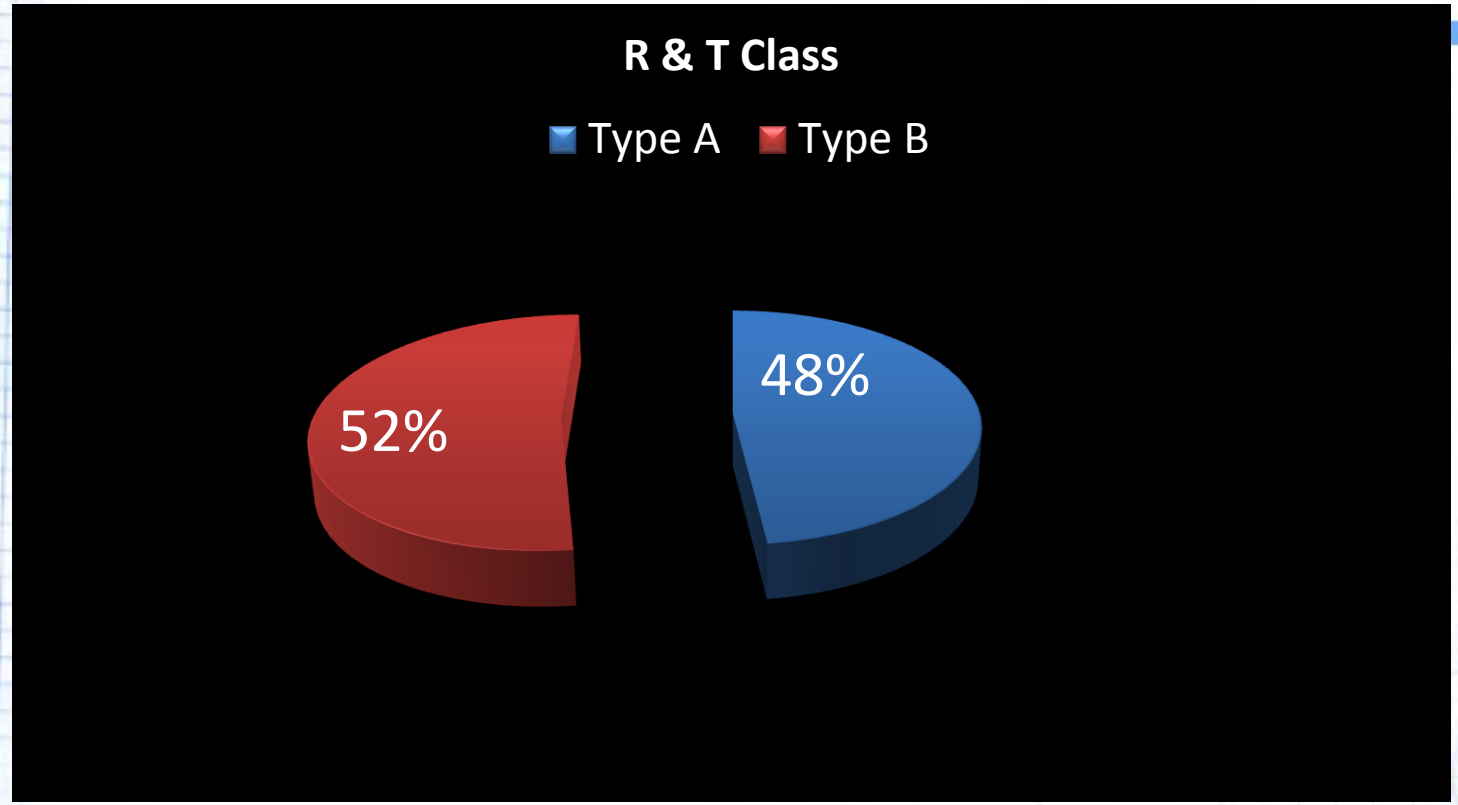


FEMALE	58
MALE	69

Age group

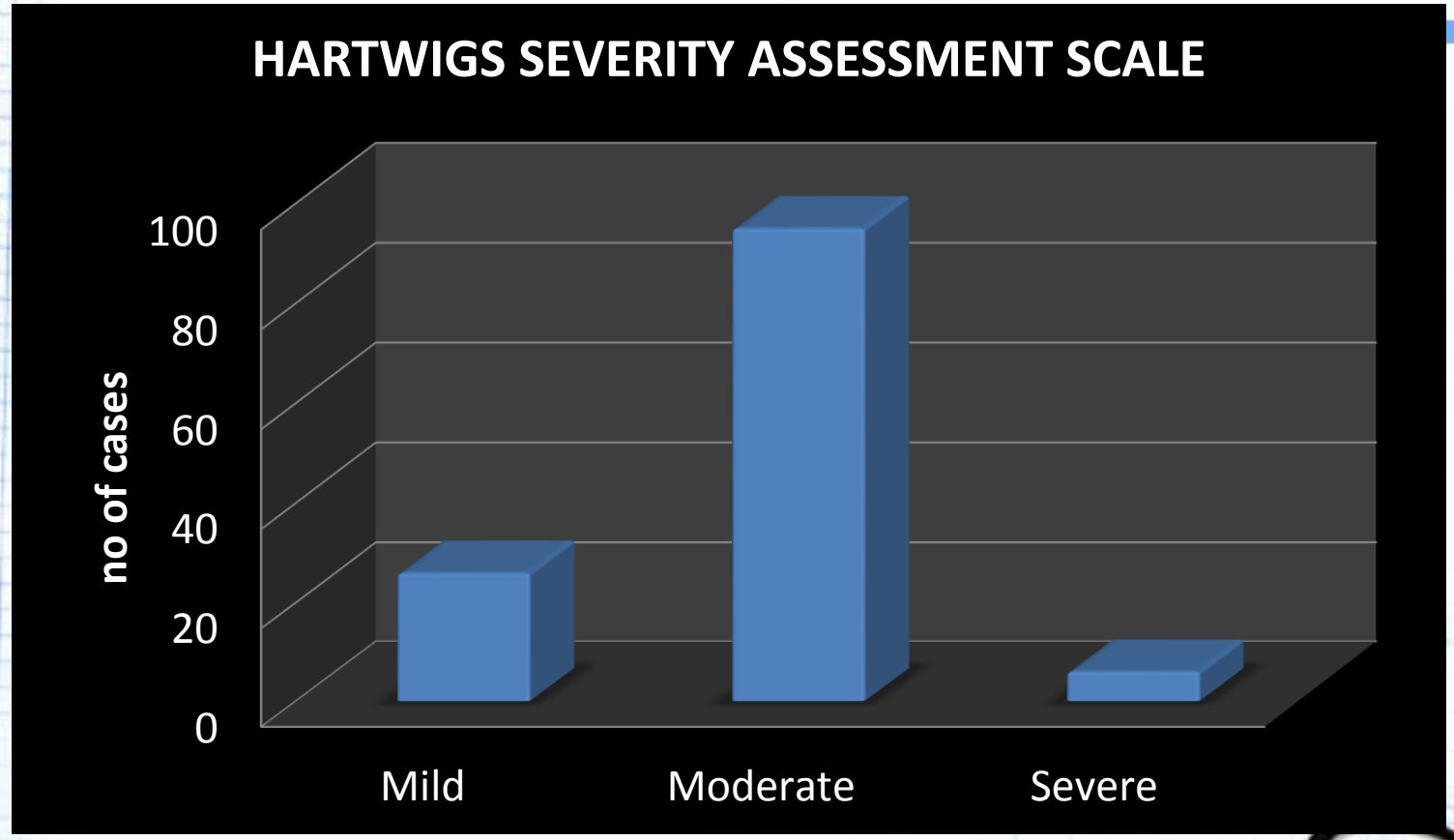

Age Group affected by ADRs
71-80
3
61-70
14
51-60
22
41-50
34
31-40
20
21-30
23
11-20
8
1-10
3

Rawling's and Thompson Classification



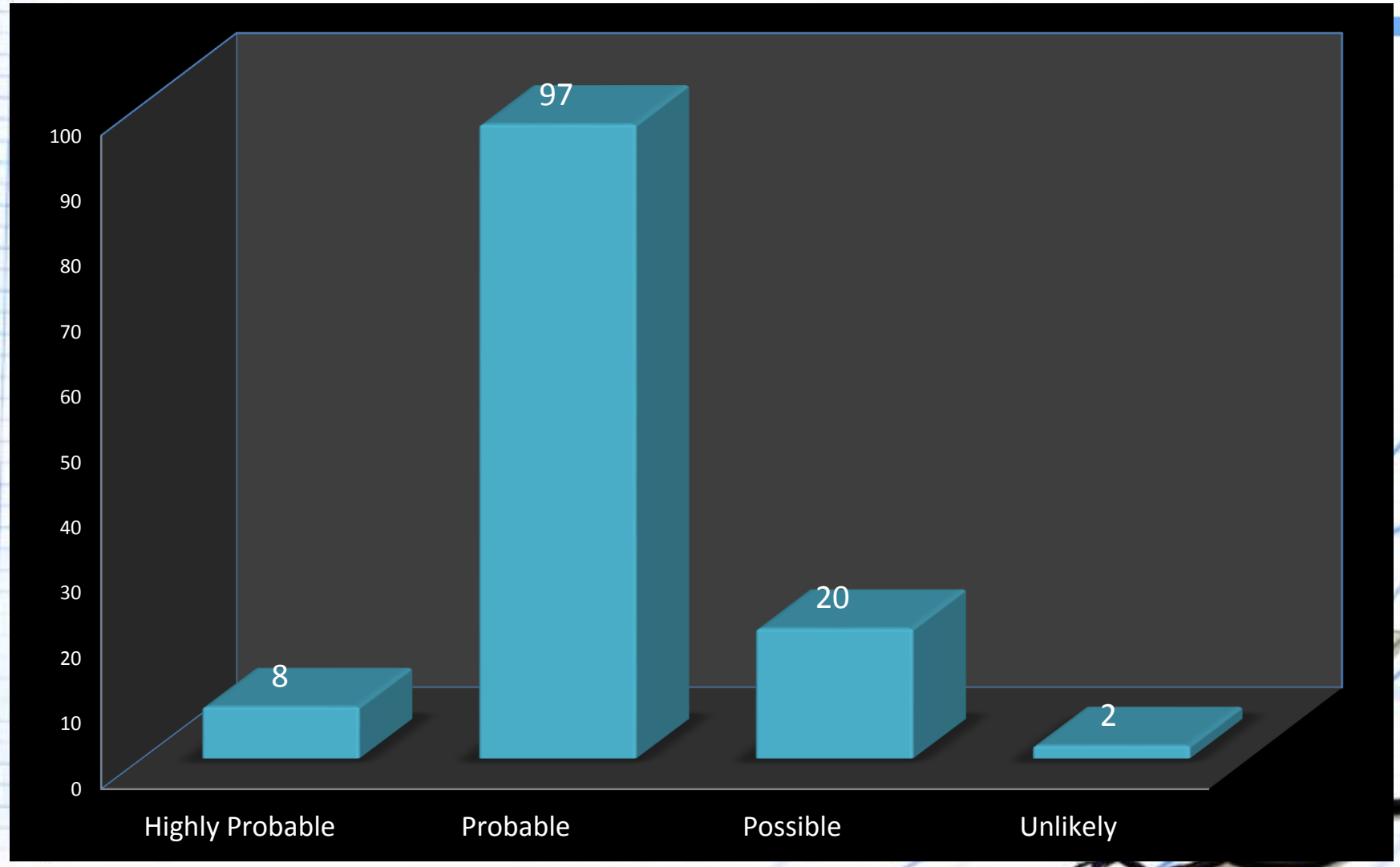
Type A	61
Type B	66

Severity Assessment

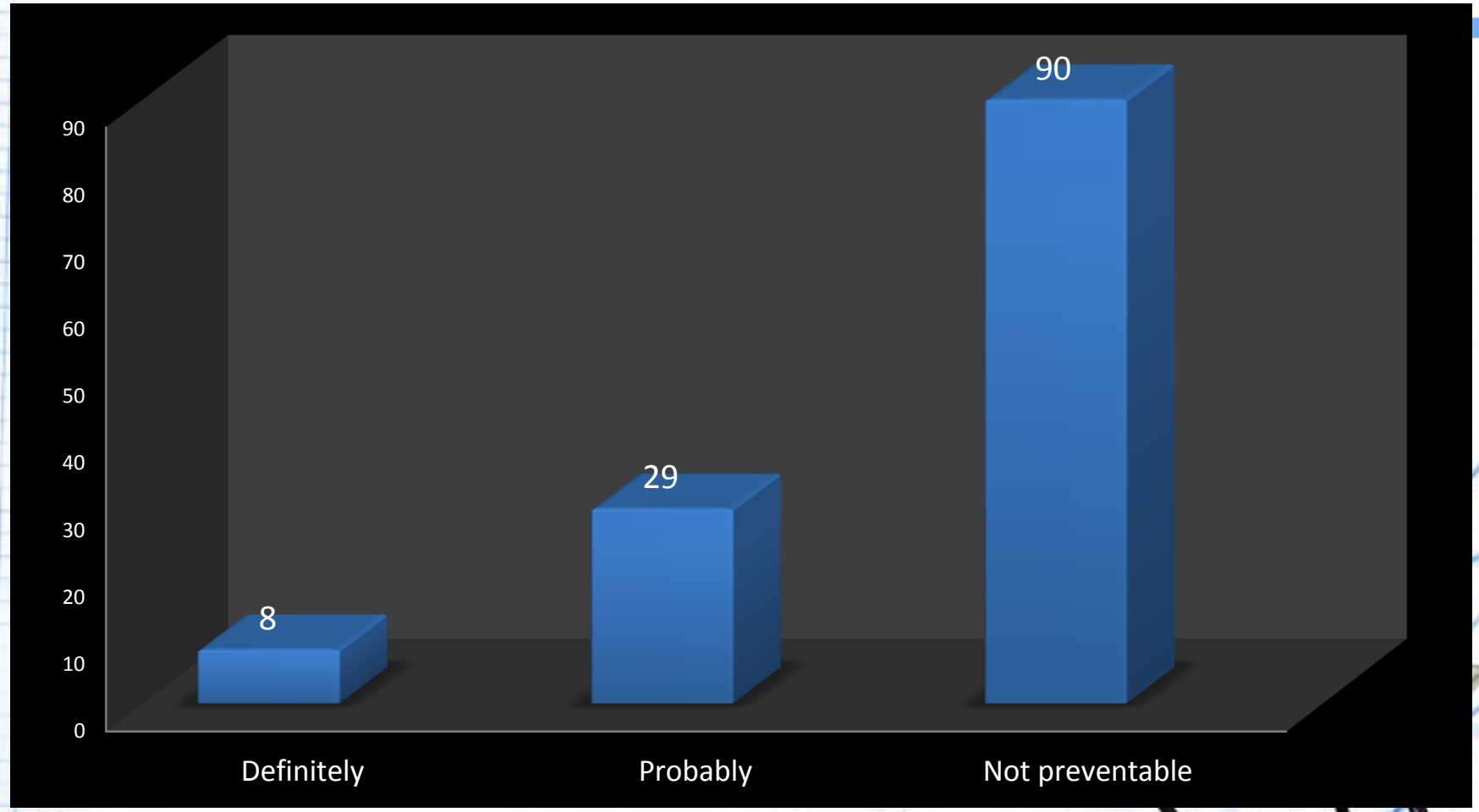


Mild	26
Moderate	95
Severe	6

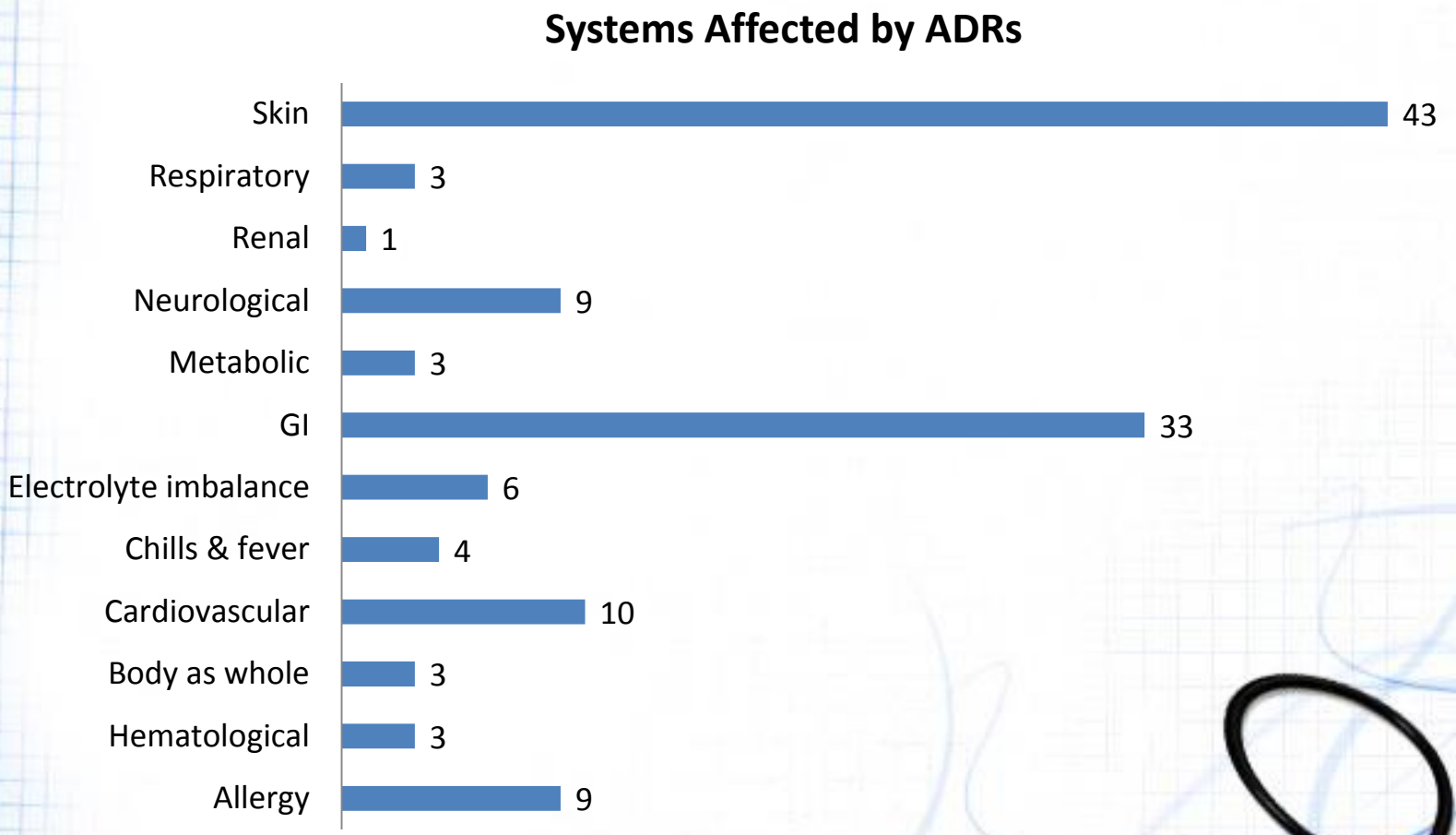
Causality Assessment



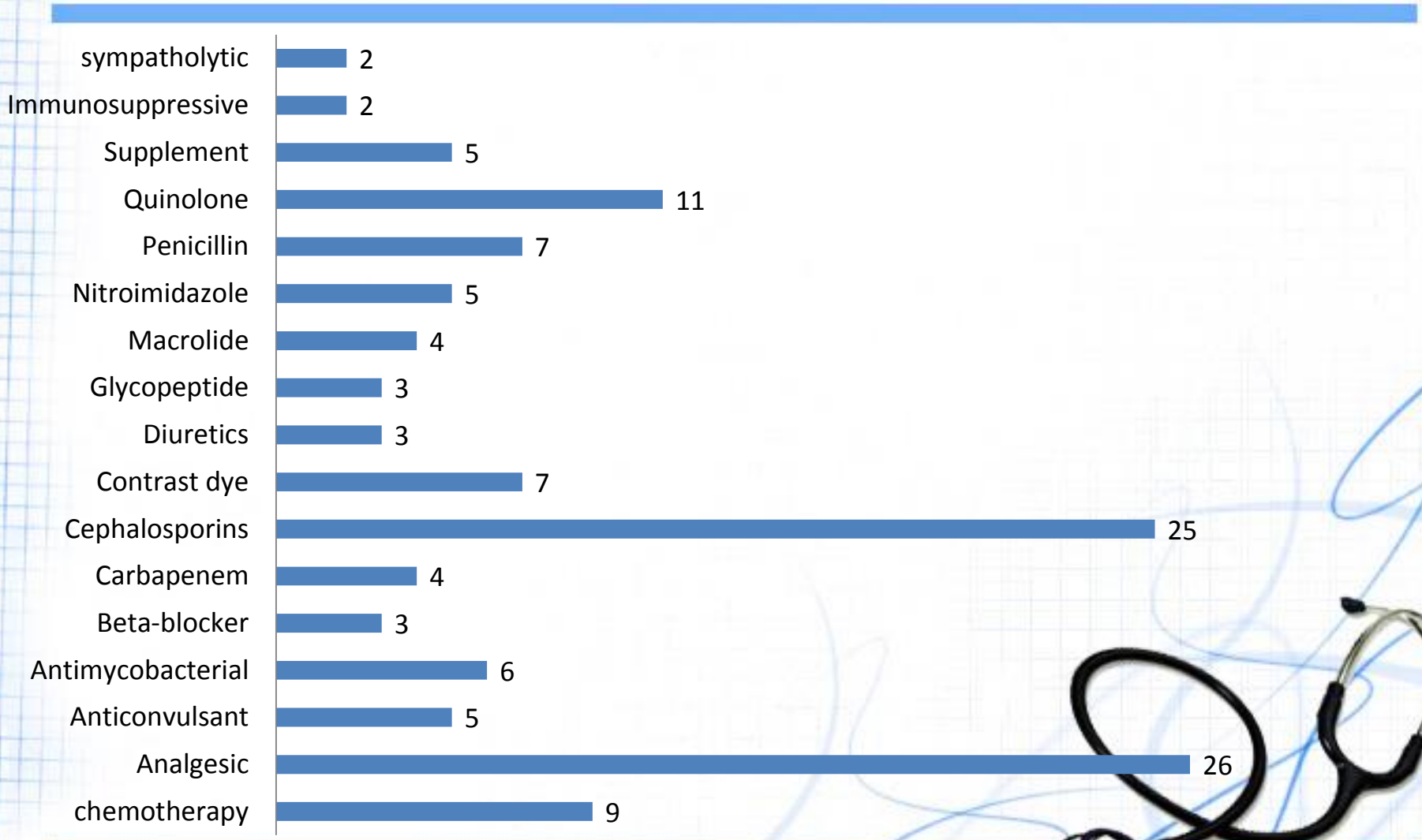
Preventability assessment



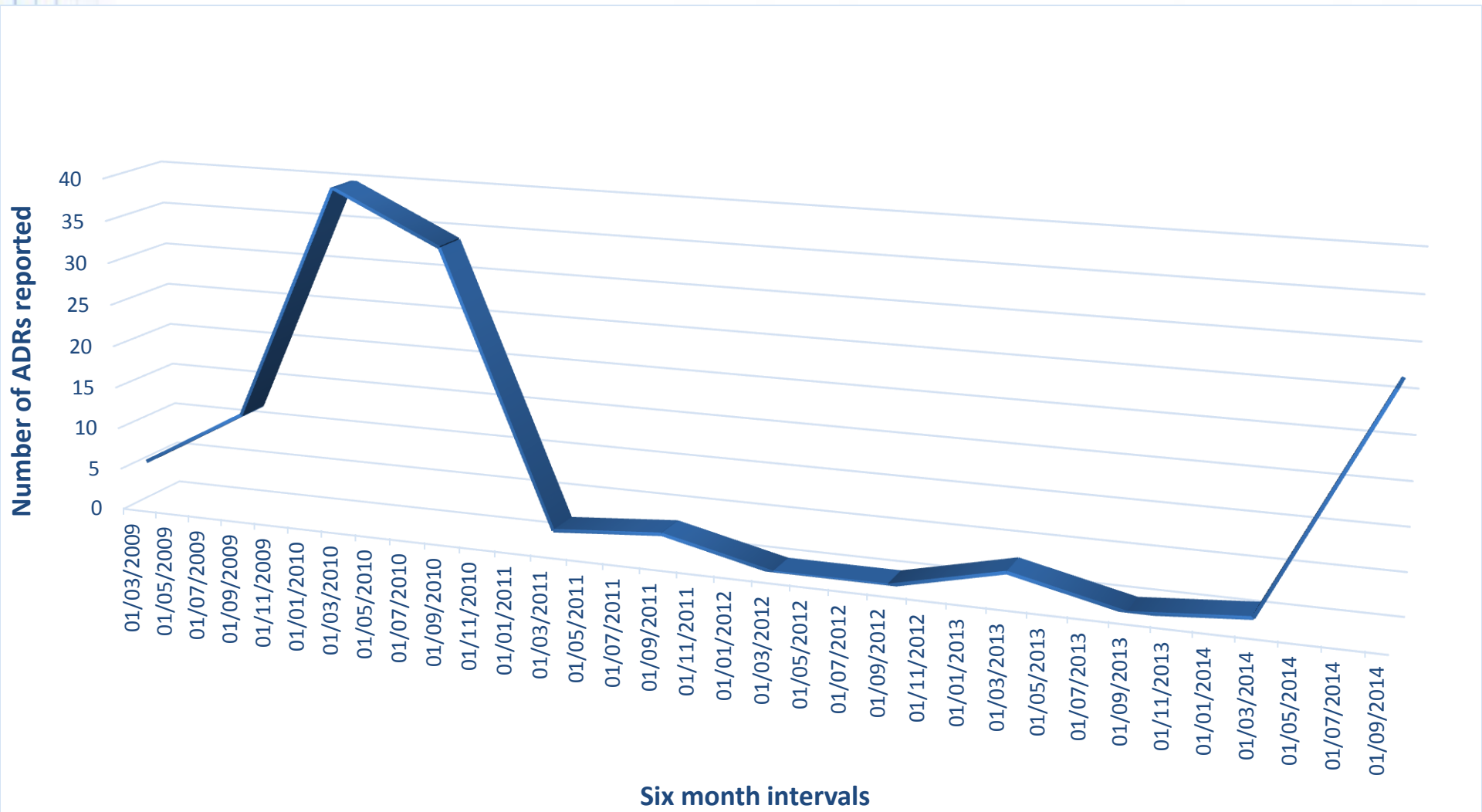
Systems Affected by ADRs



Class of Drugs associated with ADRs



Frequency of ADRs from 2009-2015



Conclusion

- Need for streamlining hospital based ADR reporting and monitoring
- Need for HCPs involvement.
- Conducting educational classes for HCPs
- Electronic documentation of medication history
- Encouraging ADR based studies
- Computerized reporting system

LIMITATIONS

- Under reporting by health care professionals.
- Lack of awareness of where and how to report.
- Study was not conducted on neonates and pregnant women.
- Inadequate knowledge about importance of reporting ADRs.
- Inconclusive submission of ADR forms.

FUTURE DIRECTIVES

- Provide patient counselling with emphasis on drug utilization.
- ADR assessing studies along with feedback.
- Provision of CMEs for HCPs on ADRs.
- To implement computerized reporting system in hospital setup to hasten reporting of ADRs in more efficient manner.

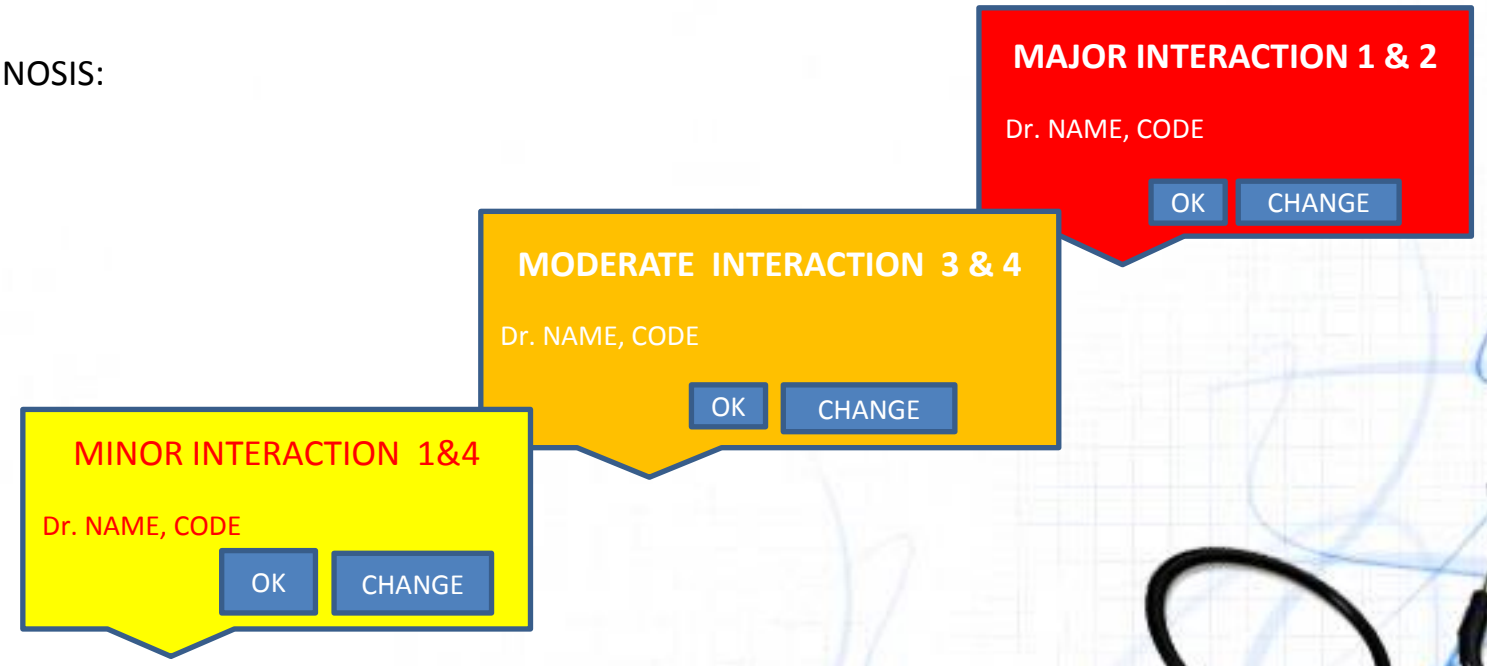
Future directives

– Computerized identification system

NAME: AGE: SEX:

DIAGNOSIS:

RX
1.
2.
3.
4.



Dr. XYZ
CODE

Take home message

“ADR VIGILANCE SAVES”

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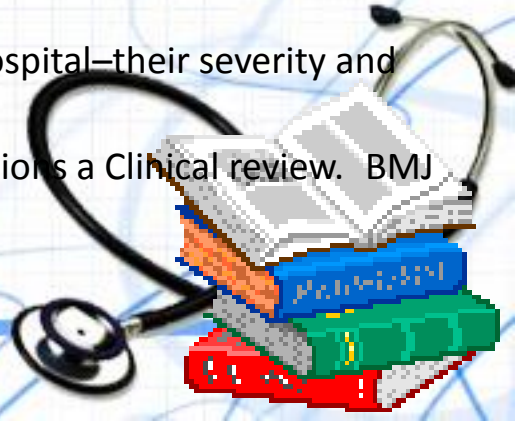

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WHO
WHAT
WHERE
WHEN
WHY
HOW
QUESTIONS
ANSWERS

Thank you