PATTERN OF ADVERSE DRUG REACTIONS AMONG PATIENTS ADMITTED IN A TERTIARY CARE TEACHING HOSPITAL: A PROSPECTIVE OBSERVATIONAL STUDY

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Introduction

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

- 2.9-5.6% of all hospital admissions are caused by ADRs.

- 35% of hospitalized patients experience an ADR during their hospital stay.

- An incidence of fatal ADRs is 0.23 - 0. 41%.

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- Essential to have constant surveillance, collection & analysis of data regarding adverse drug reaction in a systematic manner.

- For assessing the safety of drugs in a hospital setting.

- Prolongs Hospital stay & financial burden on the patient.

Objectives

- To monitor and study the pattern & frequency of Adverse drug reactions.
- Assess the causality.
- Assess the severity.

Materials and Methods

- Study conducted based on ADRs reported between November 2013 and April 2014 (6 months) to the ADR reporting unit of S.S.Institute Of Medical Sciences & Research Centre, Davangere.

- Suspected Adverse Drug Reaction Reporting Form.

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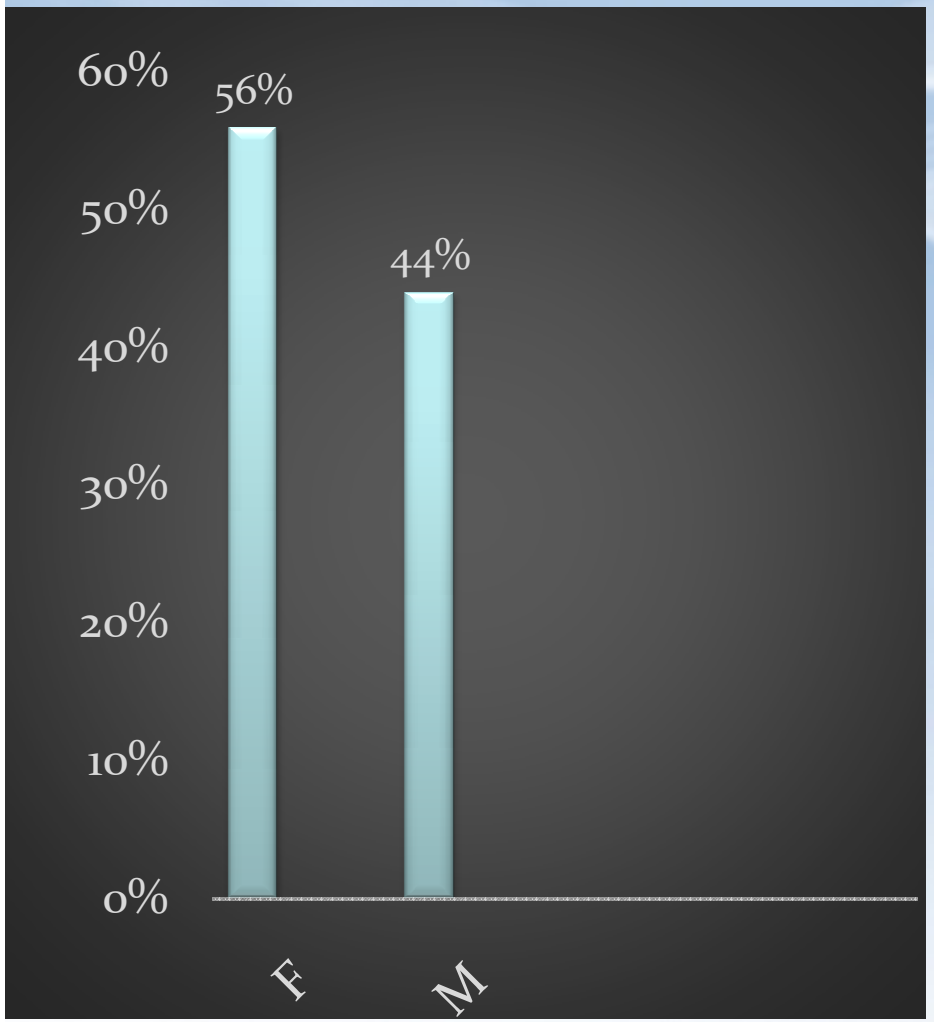
- **Details collected in the ADR reporting form:**

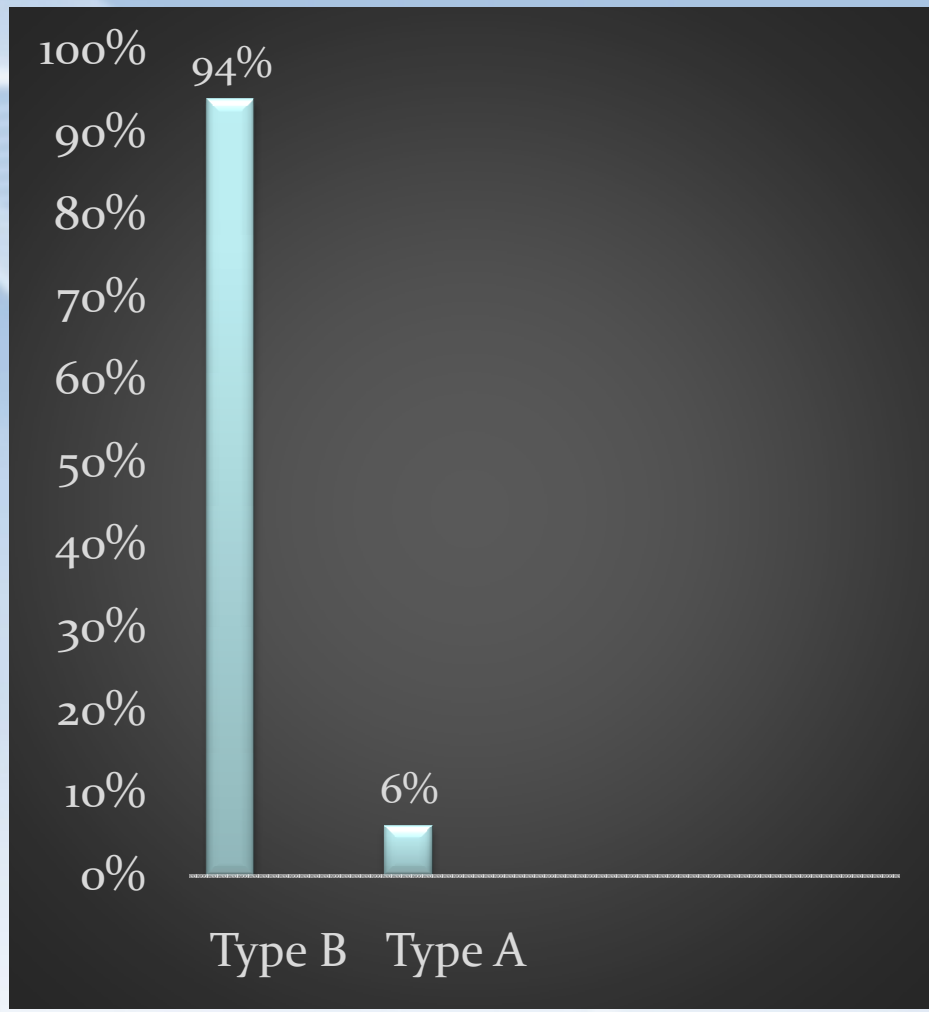
- Patient profile - Age, sex and weight.
- Patient medication details (generic name of the medicine, dose frequency, strength, date of start & stop).
- Description of the adverse event.
- Onset and ablation of adverse event.
- Other relevant history including pre-existing medical conditions.

Analysis

- Total of 71 ADRs were reported during study period.
- Descriptive analysis of the ADR data collected was done by Microsoft Excel software and expressed as percentage comparison.
- Causality assessment done using Naranjo Probability Scale.
- Severity assessment done using Modified Hartwig and Siegel scale.

RESULTS





Genderwise ADR distribution

Typewise ADR distribution

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Age-wise ADR Distribution

AGE- GROUP	PERCENTAGE OF ADRs
0-18 Years	16%
19-59 Years	70%
> 60 years	14%

Causality assessment based on Naranjo Scale

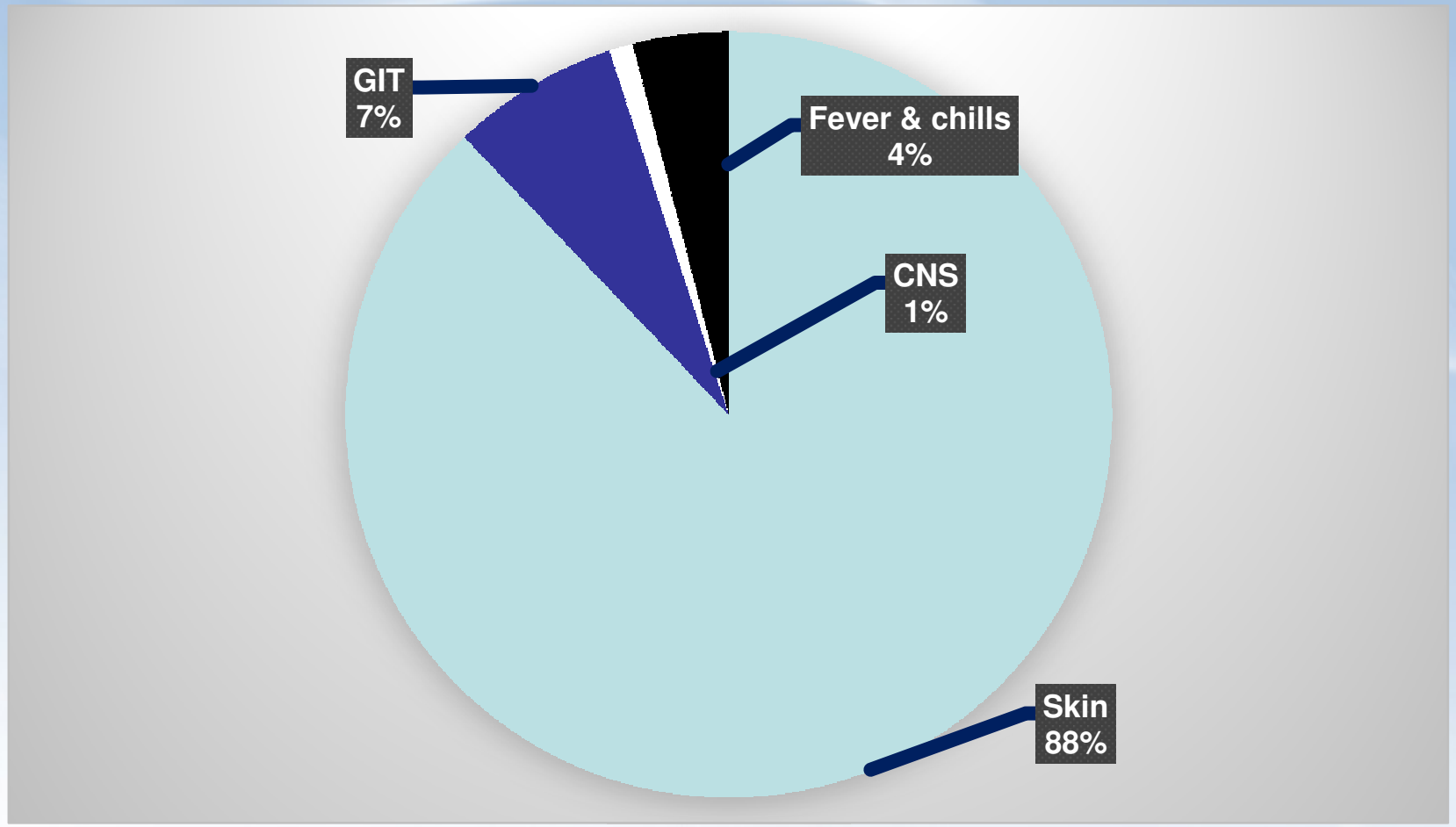
CAUSALITY	PERCENTAGE OF ADRs
Possible	67%
Probable	33%

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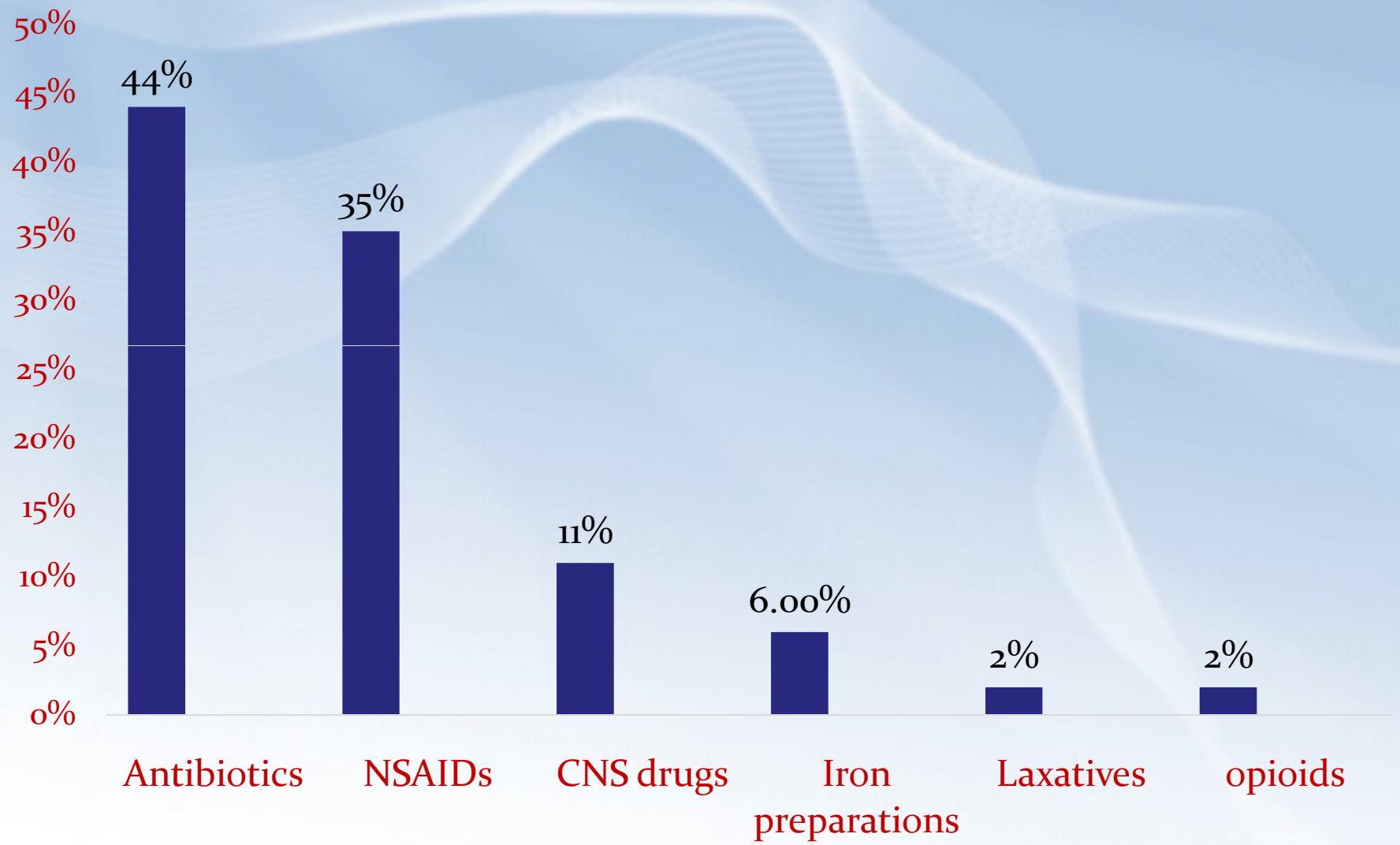
Severity assessment based on Modified Hartwig and Siegel scale

SEVERITY	PERCENTAGE OF ADRs
Mild	19%
Moderate	76%
Severe	5%

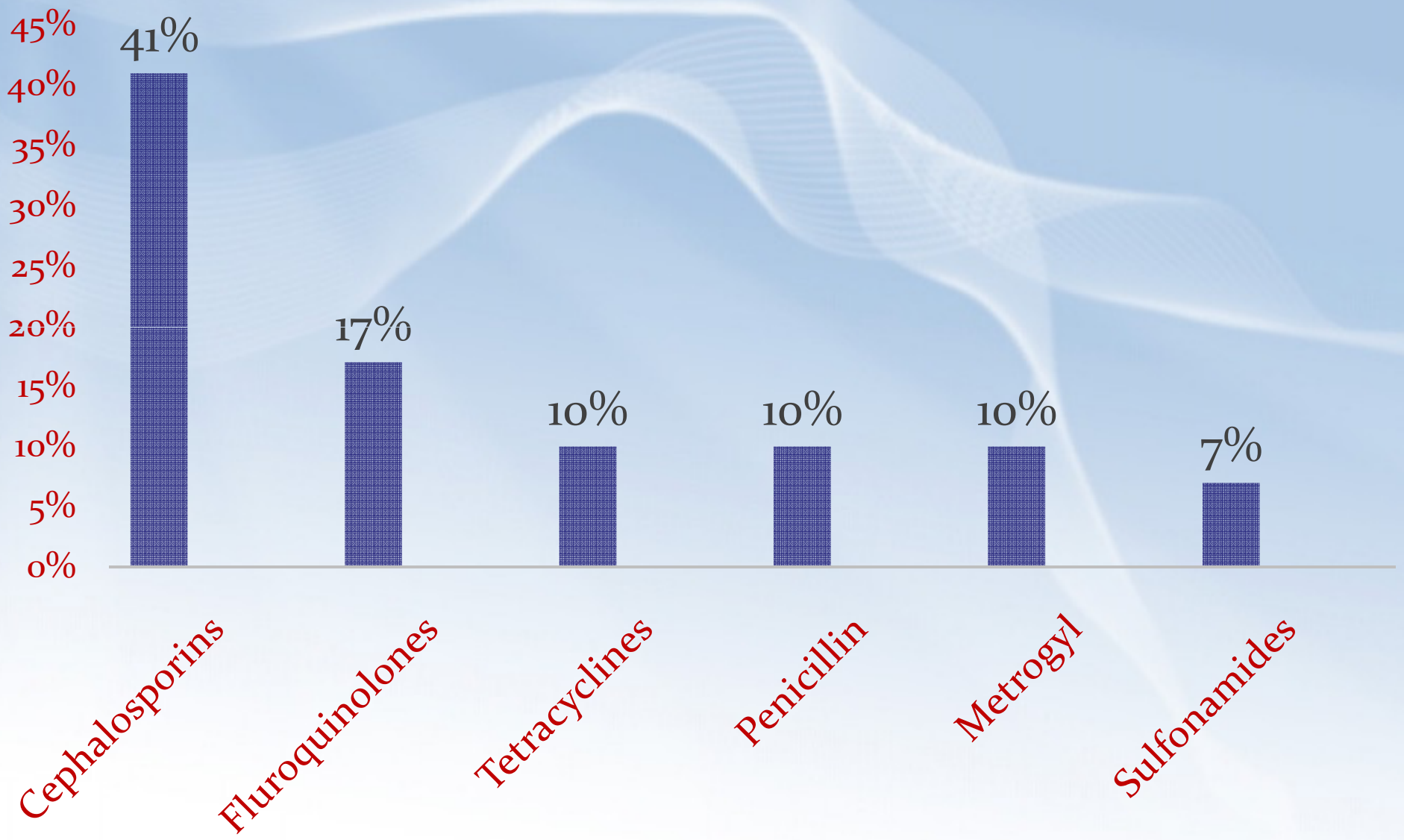
Systemwise ADR involvement



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50%
45%
40%
35%
30%
25%
20%
15%
10%
5%
0%
44%
35%
11%
6.00%
2%
2%
Antibiotics
NSAIDs
CNS drugs
Iron preparations
Laxatives
opioids

Contd…


45%
40%
35%
30%
25%
20%
15%
10%
5%
0%
41%
17%
10%
10%
10%
7%
Cephalosporins
Fluroquinolones
Tetracyclines
Penicillin
Metrogyl
Sulfonamides

DISCUSSION

- Demographic details of the present study showed female gender predominance over males for ADRs, this finding is similar to that of Singh et al.

- In the present study, a higher percentage of ADRs occurred in adult population (19-59 years)- similar to that reported by other studies.

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- Causality assessment revealed that most of the ADRs belonged to "possible" followed by "probable" category, this is consistent with that reported by Rao et al.

- The most common system associated with ADRs in our study were skin. Finding consistent with many studies which have reported a higher percentage of dermatological manifestations than others.

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- In our study, antibiotics were the most commonly involved drug classes in ADRs. This finding is consistent with previous study by Deepalatha et al.

- Amongst antimicrobial agents Cephalosporins accounted for the highest number of the ADR reports followed by fluoroquinolones. Other studies have also suggested similar findings.

CONCLUSION

- ADRs have proved a significant problem in healthcare.
- A wide clinical spectrum of ADRs was observed in our study and the majority of the causative drugs are antibiotics.
- Greater need for streamlining of hospital based ADR reporting and monitoring system to create awareness; and to promote the reporting of ADR among healthcare professionals of the country.

CONCLUSION

- Awareness programmes about the importance of ADR reporting for health care providers are essential to minimize drug related morbidity.

- The active initiation of Pharmacovigilance programme in all possible health care sectors will add further value in the protection of patient safety.

References

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