CHAPTER 4
MATERIALS AND METHODS

4.1. Study Site and Approval

The present study was a retrospective study conducted at Konaseema Institute of Medical Sciences and Research Foundation, a 800 bedded tertiary care teaching hospital located at Amalapuram, Andhra Pradesh, India. The protocol of this study was approved by the Institutional Ethics Committee (IEC) of Konaseema Institute of Medical Sciences and Research Foundation.

4.2. Sample Size Determination

Sample size was determined by using the online sample size calculator. The sample size for this study was determined to be 784 cases, where the population size was 2957, at a confidence interval of 3 and at a confidence level of 95%.

4.3. Inclusion and Exclusion Criteria

Cases of both the genders and all the age groups (Pediatrics, Adults & Geriatrics) who were treated in the departments of General medicine, Pediatrics, Psychiatry, Gynecology & Obstetrics, Chest & Tuberculosis (TB) and Orthopedics were included in the study. The prescriptions with polypharmacy (>2 drugs) were taken into consideration during the screening process and the polypharmacy was classified into minor (3-5 drugs), moderate (6-8 drugs) and major (≥9 drugs) [60].

Case records that did not met the inclusion criteria along with the case records of ambulatory patients were excluded from the study.

4.4. Data Collection

Data was collected by reviewing the past six months inpatient case records (i.e., from November 2014 to April 2015) from the medical records department. Data was collected by using a previously designed standard data collection proforma for this specific project. Information collected from the case records include inpatient number, gender, age, department, date of admission, diagnosis, number of drugs prescribed, names of the drugs prescribed and date of discharge.
4.5. Prevalence Calculation

Prevalence of the patients who were observed with possible drug-drug interactions was calculated by dividing the number of cases with at least one drug-drug interaction with the total number of cases screened for possible drug-drug interactions. Prevalence is usually expressed in terms of percentages.

4.6. Identification and Severity Assessment of Possible Drug-Drug Interactions by Using Micromedex 2.0

Drugs prescribed in each prescription were entered into the software Micromedex 2.0 in order to analyze for the identification and severity assessment of possible drug-drug interactions. Drug combinations administered at different timings were excluded during the entry of drugs into the software. Micromedex was developed by Truven Health Analytics, an International Business Machines (IBM) company at present which can be used by the health care professionals like clinicians and clinical pharmacists to improve the patient outcomes by getting standard unbiased clinical information. This software has the adequate sensitivity for the identification of drug-drug interactions in a prescribed prescription was the main reason behind the usage of this software majorly in our study. Rarely, other literature sources were also taken into consideration in the screening process in order to get a supporting evidence accurately for a possible drug-drug interaction. Hospitals can use like this softwares to get better patient outcomes and also to prevent or mitigate avoidable drug events. \[61\].

4.7. Classification of Drug-Drug Interactions based on severity

Based on the severity, drug-drug interactions can be classified into minor, moderate and major. A minor interaction can be defined as an interaction which would have limited clinical effects and manifestations may include an increase in the frequency or severity of the side effects but usually would not require a major alteration in therapy. An interaction which may result in exacerbation of the patient’s condition and/or require an alteration in therapy is called as a moderate interaction and an interaction which may be life threatening and/or require medical intervention to minimize or prevent serious adverse effects is called as a major interaction \[62\].
4.8. Categorization of possible drug-drug interactions based on duration of stay and at various stages of treatment

The occurrence of possible drug-drug interactions were categorized at different stages of treatment into during admission (drugs prescribed in the first 24 hours of admission), during stay and at discharge. In inpatients, duration of stay plays a significant role and in this study, based on the duration of stay the possible drug-drug interactions were categorized at a 5 days class interval.

4.9. Plan of Work

**PHASE-I**
- Literature survey
- Preparation of the Protocol
- Protocol submission to the Institutional Ethics Committee for approval

**PHASE-II**
- Data collection
- Data evaluation by using the software MICROMEDEX 2.0
- Classifying the drug-drug interactions based on their severity

**PHASE-III**
- Interpretation of the Results
- Making Conclusions and Recommendations
- Publishing the work

4.10. Statistical Analysis

Statistical analysis was performed done by using the Statistical Package for the Social Sciences (SPSS) 21.0. Mean, standard deviation (SD) and percentages were calculated for the demographic data. Chi square test and one way analysis of variance were performed and all the p-values were obtained at 95% confidence interval in this study (p<0.05).