Wa'ad H. Al-Kathiri, Clinical Pharmacist (SBAHC),KSA *(Project Leader)*
Thamir M. Al-Shammari, Dean of pharmacy college (HU), KSA
Hisham S. Al-Jadhey , Vice Dean for Graduate Studies and Research,(KSU), KSA

Department of Clinical Pharmacy

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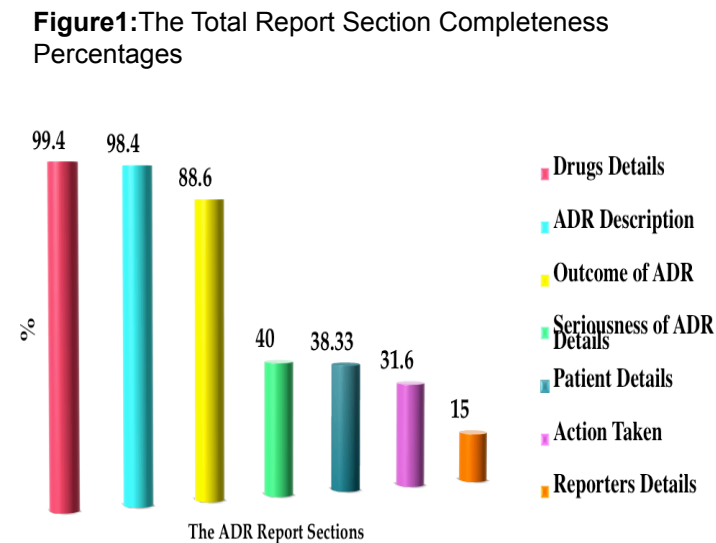# Saudi Adverse Event Reporting System (SAERS);Completeness and Quality

BACKDROUND:SAERS is a part of the SFDA pharmacovigilance system for monitoring the safety of medications. The completeness and the accuracy of data sent to the SAERS will help the evaluators to investigate if there is a signal between the drug and the adverse event.

AIM: To assess the completeness and quality of the Saudi Adverse Event Reporting System (SAERS), and perform a descriptive statistics for all elements of SAERS.
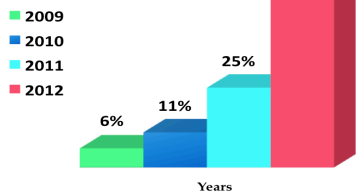
METHOD: Reports that have been received during the period of December 2009 until June 2012 in the SAERS were reviewed. The completeness was assessed by reviewing the components of the ADR form and how many of these fields were filled. For quality; two independent reviewers reviewed randomly selected reports to assess the quality of the information describing the adverse event. The adequacy of these reports was based on the criteria of good quality report. Descriptive analyses of the SAERS components ADRs form components were carried out. The Statistical Package for Social Science (SPSS), (Version 20.0) was used to perform these analyses.

TEAM:
Thamir M. Al-Shammari , Ph.D, M.S Dean of pharmacy college , Hail University, Hail, KSA.
Hisham Aljadhey, PharmD, PhD Vice Dean for Graduate Studies and Research, Director of Medication Safety Research Chair, King Saud University, Riyadh, KSA

PROJECT SPONSOR:
▪ Non

COACH
Wa'ad Hasan Al Kathiri, MSc.
Clinical Pharmacist, Sultan bin Abdulaziz Humanitarian City, Riyadh , KSA
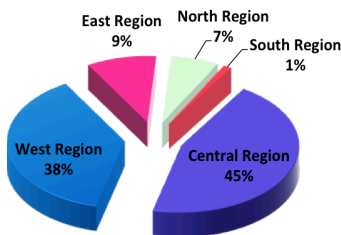
RESULTS: Total reports received were 14783 report.

Figure1: The Total Report Section Completeness Percentages

Figure 2: The tendency of reporting at each year of the study period time

Figure 3: The Regional Percentages of the Local Institution

CONCLUSIONS:
◆ This is the first study assessing the completeness and quality of SAERS.
◆ SAERS showed an increasing tendency of reporting over time.
◆ Although the system is considered new, it has a high number of reports
◆ Based on the results of this study, it is relatively considered of a good quality of data.
◆ However, the SFDA is required to perform more awareness campaigns to educate and train the HCPs about their reporting system to improve the HCPs response in filling the ADR reports, especially for ministry of health hospitals, and the south and north regions duo to low number of reports received.
◆ SFDA staff need more training in using MEDRA coding system.