

**Original Research Article****To monitor the adverse drug reactions and safety of medicines commonly prescribed at obstetrics and gynaecology unit in a tertiary care hospital**Kavita Dhar<sup>1\*</sup>, Shalu Chauhan<sup>2</sup>, Jyotsna Sharma<sup>1</sup>, Preeti Gaur<sup>1</sup>, V.S. Chopra<sup>3</sup>, Umakant Bajaj<sup>4</sup><sup>1</sup>Assistant Professor (Pharmacology), Santosh Medical College and Hospitals, Santosh University, Ghaziabad, India<sup>2</sup>Krishna Institute of Engineering & Technology, Ghaziabad, India<sup>3</sup>Professor & Head (Pharmacology), Santosh Medical College and Hospitals, Santosh University, Ghaziabad, India<sup>4</sup>Principal, Krishna Institute of Engineering & Technology, Ghaziabad, India**ARTICLE INFO:****Article history:**

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Adverse drug reactions are the recognized hazards of drug therapy and they can occur with any class of drugs. Any substance that is capable of producing a therapeutic effect can also produce unwanted or adverse effects. Adverse Drug Reactions result in increased healthcare cost due to the need of some interventions and increased hospital stay. The study was undertaken to monitor the adverse drug reactions to medicines commonly prescribed at obstetrics and gynaecology unit in a tertiary care hospital, to establish ten most commonly prescribed medicines in this unit that gave maximum adverse drug reactions and to determine the list of commonly affected organ systems and assess their causality. In this Retrospective, non-interventional study a total of 63 adverse drug reaction reports were collected from 249 patients. The most common medicine that caused maximum ADRs was Oxytocin 10 (15.87%). Other frequently used drugs were Amikacin, Methylethylgometriner, Mifepristone+Misoprostol, Levonorgestrel+Ethinylestradiol, Cefotaxim+sulbactam, Cefixime+Ofloxacin, Mifepristone alone, Clomifene citrate, Tramadol. The most commonly affected organ system was cardio-vascular system 12 (19.04%). The assessment by Naranjo's scale showed that out of 63 ADRs, 41 (65.07%) ADRs were probably related to drugs, 21 (33.33%) ADRs were possibly related to drugs and 1 (1.58%) ADR was doubtful. WHO causality assessment scale revealed that out of 63 ADRs, 51(80.95%) ADRs were probable or likely, 12(19.04%) ADRs were possible. It was observed that safe medicines were prescribed in obstetrics and gynaecology department as per FDA category A with no banned drugs. However, there is a need to sensitize the doctors to prescribe rationally and emphasize this aspect in under and post graduate medical teaching as well. The health system needs to promote spontaneous reporting of Adverse Drug Reactions from all health care professionals and the public at large in a well structured programme to build synergies for monitoring ADR in the country. Also proper documentation and periodic reporting to regional pharmacovigilance centres should be encouraged to arrive at meaningful conclusion on safety issue of medicines and thereby reduce considerably social and economic consequences of ADRs.

**Introduction**

WHO's definition of an adverse drug reaction, "*a response to a drug that is noxious and unintended and occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease, or for modification of physiological function*". [1] However, the terms "adverse effect" and "adverse reaction" must be distinguished from "adverse

event". An adverse effect is an adverse outcome that can be attributed to some action of a drug; an adverse event is an adverse outcome that occurs while a patient is taking a drug, but is not necessarily attributable to it[1]. Adverse drug reactions caused by immune and non-immune mechanisms are a major cause of morbidity and mortality worldwide. They are

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