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# PHARMACOVIGILANCE IN A TERITIARY CARE HOSPITAL IN KASHMIR: A CALL FOR ACTION

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#### ABSTRACT

**Introduction:** In present era safety and efficacy of a drug is of paramount importance. Therefore, pharmacovigilance (PV) is an essential component to detect and present adverse drug reaction (ADRs) after marketing of a drug. Nevertheless, underreporting is a global issue creating health and economic burden on health care system. **Aim:** To assess the knowledge, attitude and practices (KAP) of doctor's nurses and pharmacists towards PV and ADRs reporting and to determine the factors limiting ADR reporting rates from the Healthcare Professionals (HCPs) point of view. **Methods:** The purpose and need of the study was explained to all HCPs (doctors, nurses and pharmacist) to whom a standard 30 inventories open-ended validate questionnaire was administered. All the responses were entered to Microsoft Excel sheet and analysed statistically through SPSS software version 27. **Results:** A total of 150 HCPs (98 doctors, 38 nurses and 14 pharmacists) participated in the study. Results reveal that doctors and nurses have equal knowledge and are updated about PV, ADRs and PVPI. All participants are of the opinion that periodic educational intervention and PV and ADR reporting training are necessary. **Conclusion:** The study in a broader perspective reveals that our HCPs have fairly good awareness of PV and ADR monitoring but regular and periodic sensitization and orientation of HCPs on PV would bring paradigm shift and improvement in ADR reporting rate.

KEYWORDS: Pharmacovigilance, Adverse drug reactions, Knowledge, Attitude, Practice.

#### INTRODUCTION

In the present era of evidence based medicine safety and efficacy of a drug is indeed a matter of concern. This has led to a pressing need of efficient post-marketing surveillance (pharmacovigilance) to optimize and take set of coherent actions to promote the use of drugs responsibly, appropriately and prudently. This will eventually maximize pharmacotherapeutic efficacy while minimizing adverse drug effects.( ADRs). ADRs are an inevitable consequence of modern drug therapy. They are an important cause of iatrogenic illness in terms of morbidity and mortality.<sup>[1]</sup> ADRs are most frequent cause of serious harm to the patients as well as carrying medico legal and economic consequences.<sup>[2]</sup> ADR reporting is the foundation of any pharmacovigilance (PV) system and the timely identification and reporting of ADRs to the regional or national drug regulatory authorities are critical. The world health organization (WHO) has

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defined ADR as a "response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis diagnosis or therapy of diseases or for the modification of physiological function".<sup>[3]</sup> ADRs have increasingly drawn worldwide attention accounting for significant morbidity and mortality and associated with increased health costs.<sup>[4,5]</sup> Recent estimates suggest that ADRs are the fourth major cause of death in United States of America (USA).<sup>[6]</sup> They are common and often preventable cause of hospital admissions. The world wide incidence of ADR's leading to emergency hospitalization varies from 0.2% to 41.3% while 28.9% of these ADRs are preventable.<sup>[7]</sup> A metaanalysis conducted in 2012 by Hakkarainen et al suggested that 52% of ADRs related emergency hospitalization and 45% of ADRs in patients were preventable.<sup>[8]</sup> This explicitly implies that there is insufficiency in recognizing and reporting of ADRs.<sup>[9,10]</sup>