J Pharma Care Health Sys 2016, 3:4(Suppl)
http://dx.doi.org/10.4172/2376-0419.C1.018

Spontaneous adverse drug reactions reporting by patients in Canada: A multi-method study

Rania Al Dweik
University of Ottawa, Canada

Aim: The objective of this study is to evaluate the importance of patient ADR reporting on Pharmacovigilance activities.

Method: Phase-I is systematic review to identify factors influencing patients reporting. Phase II is descriptive analysis of all ADRs reports received by Health Canada over the last 10 years. Phase III, an interpretative descriptive will be used to explore usability of the Canadian Vigilance systems by patients.

Results: Of 1435 citation reviewed, 22 studies published in 26 papers were appraised. These studies mainly focused on factors affecting patients reporting of ADRs. None of these studies conducted at North America. Sixteen out of 22 reviewed studies described barriers to the reporting process included: Poor awareness of ADR reporting systems; difficulties with reporting procedure and forms; lack of feedback to ADRs submitted by the patients; confusion as to who reports ADRs and to whom they are reported; poor economic status; ADRs resolved; and prior negative reporting experience. Another 11 out of the 22 reviews studies described the motives for reporting ADRs by patients and those included: prevent others from similar ADRs; inform regulatory bodies, drug manufacturer, HCPs, and public; improve drug safety and medication leaflet and enhance scientific knowledge; improve HCP practices; failure of HCPs to report their ADRs; asked to report ADRs by HCPs; it was serious ADRs; and desire for personal feedback and want more information about the ADRs.

Conclusion: Findings from this research anticipate to make three significant contributions: highlight the role of patients in directly reporting ADRs; provide new information that may help us provide guidance to streamline and optimize patient ADR reporting; and provide policy makers, public health officials, and regulatory agencies with this critical information in order to improve medication safety in Canada.

raldw034@uottawa.ca

Design of pediatric sprinkle capsule formulation for delivery of antimalarial combination in treatment of malaria

Shrikant Y Charde[1], Prashant P Raut[2], Pradeep Bishnoi[2] and Hiren Savani[2]
[1]Birla Institute of Technology and Science Pilan-Hyderabad Campus, India
[2]Birla Institute of Technology and Science Pilani, India

For pediatric patients, it is necessary to consider the use of dosage forms which are easy to swallow, disintegrate rapidly in the mouth, offer dose flexibility and which have pleasant taste and appearance. Therefore, study was aimed to design multi-unit particulate drug delivery system (Mini-tablets) of amodiaquine hydrochloride (AQ) and artesunate (AS) for treatment of malaria, which can be encapsulated or filled into primary packs such as sachets. Individual minitablets of AS and AQ were manufactured by direct compression and dry granulation technique respectively, using 1.5 mm punches on tablet compression machine (Minipress, Rimek). The designed tablets were evaluated for weight variation, content uniformity and *in vitro* drug release. Drug release studies were carried out using USP type II apparatus. Dissolution media used during the study was sodium acetate buffer (500 mL, p^H 5.5). Paddle rotation was kept at 100 rpm. Further, accelerated stability studies of designed formulations were performed for 6 months. Weight variation, drug content and other physical characteristics of designed tablets were found to be acceptable indicating suitability of technique used for manufacturing tablets. Further, all dissolution study profiles met pharmacopoeial requirements for rapid drug release (i.e. >75% drug released in 45 min). Further, designed formulations were found to be stable at accelerated conditions. It can be concluded that the designed formulations can provide flexibility of dose selection for different age groups. It may also provide fast disintegration which can be exploited through dispersion in water prior to dosing or through oro-dispersion as a mean of administration.

shrikant@hyderabad.bits-pilani.ac.in