

Medication errors in pediatric population: Magnitude and interventions

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Medication errors are an important cause of iatrogenic morbidity and mortality. There is limited evidence to indicate that children may be more vulnerable to medication errors because of the need for a weight-based dosing approach and the increased sensitivity of children to relatively small dosing errors. Polypharmacy, the lack of effective communication between children and healthcare personnel as well as prescribing errors for example incomplete or illegible prescription, incorrect route or incorrect intravenous infusion are common errors. Off-label or unlicensed use in pediatric population also contribute to medication errors. As medication errors are preventable errors, these require special attention. Multifaceted interventions including all members of healthcare team, i.e. physician, nurses, pharmacists as well caretakers are required. Interventions to prevent medication errors include computerization of prescriptions, electronic medical records, voluntary and triggered reporting. As the incidence and type of medication errors vary widely with hospitals, local evaluation of the type, frequency and root cause of various medication errors as well as customization of corrective measures may be desirable. Magnitude of medication errors in pediatric population, their impact on society and interventions to reduce medication errors have been discussed in this presentation.

Biography

Deepa Arora is a Physician having more than 15 years of experience in drug safety and clinical development in pharma industry and in academia. She has been in leadership and strategic roles in MNCs and Indian Pharma companies and successfully set up systems, developed teams and interacted with regulatory agencies in different regions including US, Europe, India and Australia. She has played an active role in developing awareness and skills of pharmacovigilance in the region by designing teaching modules for safety in medical institutions and training in pharmacovigilance workshops and courses. She is the author of the book "*Pharmacovigilance- An Industry Perspective*".

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Regulatory perspectives on drug dissolution testing

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Dissolution is considered to be surrogate parameter for in vivo release of drug product and for the bioavailability of the active ingredient and finally for therapeutic efficacy. Dissolution testing is an official test used by pharmacopeias for evaluating drug release of solid and semisolid dosage forms. Dissolution testing is used as regulatory tool to review the lot-to-lot quality of a drug product (Quality control), developing IVIVC and to ensure continuing product quality and performance after certain changes, such as changes in the formulation, the manufacturing process, the site of manufacture, and the scale-up of the manufacturing process. For majority of regulatory body's dissolution testing is critical to grant BCS based bio waiver and to check alcohol-induced dose-dumping of generic modified release oral drug products. Both US FDA and EMA emphasize on the need for an early identification of formulation and manufacturing factors that are important for setting satisfactory specification limits for the dissolution rate of an active substance from a dosage form. Thus dissolution test is expected to be an appropriate tool to detect deviations in those formulation factors that are defined to be critical in respect to drug absorption.

Biography

Deepika Agarwal has done her PhD from Panjab University, Chandigarh in field of pharmaceuticals and postdoctoral studies from Medical College of WI, USA. She is working in Dr Reddy's Laboratories Pvt Ltd as Sr Manger. She has about 20 publications and presentations in reputed journals and conferences.

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