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Editorial

ADVERSE DRUG REACTION ASSESSMENT BY HEALTH CARE PROVIDERS: SAFETY PATIENT STRATEGY

Elisangela da Costa Lima

Reporting Adverse Drug Reactions (ADRs) is an important component for quality of care in hospitals, especially for accreditation programs[1,2] since ADR are plainly implicated in patient safety incident conception3. The manipulation and administration of medicines are a common factor for adverse event discussion. Nevertheless, the ADR avoidability assessment tool may have a relevant role for prevention of severe events in hospitals. This editorial will highlight factors contribute to the ADR assessment debate in Brazilian clinical settings.

Unfortunately, limited and fragmented definitions about ADR notion may hamper its identification and assessment at health services[3]. ADRs has been defined as, *"an appreciably harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, which predicts hazard from future administration and warrants prevention or specific treatment, or alteration of the dosage regimen, or withdrawal of the product"*[4].seems more precise, acceptable to pharmacologists and it has been used in several studies[5]. This concept is particularly interesting whereas that points the possibility of occurrence of adverse reactions due to medication errors[6].

ADRs are classified in as type A and B reactions. Whilst type A (augmented) reactions are generally dose related and preventable (from the known pharmacology), type B (bizarre) reactions are not dose related and unpredictable. Incidence and morbidity related type A reactions are high. On the other hand, type B reactions are regarded to have mortality[7]. This classification was expanded and detailed for more four types: C (chronic – some time after prolonged administration), D (delayed – sometime after use of drug), E (end of treatment – some time after withdraw of drug) and F (failure unexpected of therapy)[5]. This collection of sub-categories is useful to make health professionals aware about the stages leading up to ADRs.

ADR severity assessment ponders features related outcomes as (i) hospitalisation necessity or prolongation of hospitalisation, persistence or significant disability, life-threatening and death[5]. Severe ADR report may require fast action for understanding the problem and consequently motivate a local and/or global (regulatory authorities) intervention. Severe suspect ADR must be promptly recognize and assessment by hospital pharmacists.

The causality assessment (i.e. relationship between a suspect medicine and ADR) helps healthcare professionals to make decisions for upcoming therapy[8]. Aspects as such strength of the association and consistency of association, specificity, temporarity, biological gradient, plausibility, coherence, experimental evidence and analogy (in some circumstances) have been suggested by Bradford Hill[9] more than 50 years ago. Expert assessor judgement, structured guidance as algorithms and Bayesian statistical method are main ways used to causality assessment[10]. Scales and algorithms are largely used, especially the Naranjo algorithm, however, there are some difficulties for applying guidance for assessment[8].

All of the attributes above bring useful outlines to improve knowledge and clinical decision regarding risk and benefit of treatment. However, for the advancement of safety culture, the avoidability ADR assessment is pivotal for learning and preventing drugs related damage. A meta-analysis of ADR avoidability showed approximately half of the reactions in adults may be avoided[11].

There is no model for ADR avoidability assessments, but some scales grounded on treatment selection or prescribing appropriateness[12]. Thinking about Avoidability in hospitals, even in the absence of a suitable method is extremely important to improve health care since theses scales hold indicators about possibility of reaction prevention such as (i) proper drug and (ii) dose, route and frequency of administration suitable for patient`s and clinical condition, (iii) necessity of drug therapeutic monitory or other laboratory test before or during drug use, (iv) history allergy or prior reaction to the drug, (v) presence of drug-drug interaction, (vi) poor compliance or (vi) toxic serum drug level description[13].

Regardless of the limitations and difficulties associated with ADR assessments, we advise pro-activity of healthcare professionals, especially pharmacists, in facing these challenges when providing services. The Brazilian Program for Patient Safety[2] defines two ways for this: (i) production, systematization and dissemination of knowledge on patient safety and (ii) fostering the theme in technical, undergraduate and graduate programs in the area of healthcare.

Hopefully all health and education institutions realise these concepts as your duty and responsibility

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