



## Boletín Médico del Hospital Infantil de México (English Edition)

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### EDITORIAL

## From suspicion to certainty: adverse drug reactions in our children

### De la sospecha a la certeza: reacciones adversas a medicamentos en nuestros niños

*“Children are not small adults when taking a drug”*

It is not coincidental that in the present issue of the *Boletín Médico de Hospital Infantil de México* two articles are published on adverse drug reactions (ADR) in children. In the article *“Do pediatricians detect adverse drug reactions even though they do not report them?”*, Morales-Ríos et al. of the Hospital Infantil de México Federico Gómez (HIMFG) address the subject of suspicion of ADR.<sup>2</sup> In the article *“DRESS syndrome associated with carbamazepine”* by Quintero-Martínez et al. (CMN del Occidente, IMSS), the authors report a clinical case of almost certain observation of an ADR.<sup>3</sup>

For those of us interested in pharmacology in general and, specifically, drug monitoring, it is beneficial for pediatric health that the topic of *adverse drug reactions* should always be emphasized. It is important for health personnel and family members of a sick child to immediately notify their suspicion of an ADR to a particular medication used as part of the child's medical therapy. Why then, since this seems to be common sense, are there few notifications of an ADR? I state the following about this topic:

1. Children comprise a highly vulnerable group in all senses, even in the field of ADR. Due to understandable ethical reasons, a drug is released to market without clinical studies carried out in children and adolescents. Diseases in children can be qualitatively and quantitatively different from equivalent processes observed in adults. Hence, the importance of drug monitoring in the pediatric field because children comprise a special population.
2. Strictly speaking, according to the general principles of pharmacovigilance, health personnel notice suspicion of an ADR, whereas the ad hoc committees of the national

pharmacovigilance systems are aimed at the identification, quantitative risk assessment and qualitative assessment of the clinical effects of acute or chronic use of drugs in the general population or in specific subgroups. Health personnel are qualified to establish causality between the drug and the observed reaction, whether or not the ADR is known, and whether it is mild or moderately severe based on the collection of notifications they receive about a drug, clinical trials, data from other national pharmacovigilance systems and applying an algorithm such as the famous Naranjo algorithm.<sup>4</sup>

3. When we mention “health professionals”, we are including physicians and, in the particular case of drug monitoring, pharmacists are also involved. However, it appears that insufficient emphasis is placed on the role that nursing plays on the detection of a suspected ADR, despite various scientific reports that have elucidated that it is nurses who by having more time and contact with hospitalized children detect more possible ADRs. For some reasons, they do not notify the physician verbally, although they could also notify the hospital's system of drug monitoring.<sup>5,6</sup>
4. It is clear that in the clinical case reported by Martínez-Quintero et al.,<sup>3</sup> the most important matter was to regain the health of the adolescent who was most probably a victim of carbamazepine toxicity. I state “most probably” because, as I mentioned previously, only a national system of drug monitoring could officially identify a rare and severe ADR to carbamazepine. However, once the patient's health is re-established, will the pediatrician remember to notify their almost certain suspicion of having observed an ADR to carbamazepine to the Drug Monitoring System of the IMSS High Specialty Medical Department of Pediatrics of the Occidente and to the IMSS General Regional Hospital

- No 1. "Dr. Carlos McGregor Sánchez Navarro" for follow-up? This is not a matter of bureaucracy but rather aimed at the health of our children. Drug monitoring monitors the drug, not the physician.
5. Finally, the majority of articles that deal with the reasons for the low rate of notification of suspicions of ADR arrive at the conclusion about the importance of strengthening education of health professionals so that everyone adheres to the policy. Despite this, in few articles it is clearly manifested that, in the case of children, parents and family members also have the obligation to notify any changes that have been observed in the child after the administration of medications. However, would they know that their opinion matters and that their observations can be very important?

In the end, as with most of the problems facing health professionals and lay persons, it is all a matter of education.

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