Correspondence

Adverse Drug Reaction (ADR)

This is in connection with the query raised on Adverse Drug Reaction (ADR) to Cefipime and the reply(1).

It is often difficult to ascribe 'cause and effect' in case of ADR, but it should be objectively assessed and presented based on an acceptable 'Probability Scale'. The 'Naranjo ADR Probability Scale' is an internationally accepted one, by which ADR can be classified into highly probable, probable or doubtful(2). The scale is summarized in *Table I*. It is desirable to use an objective scale and document and report ADR in a systematic way for future reference.

TABLE I–*Naranjo ADR Probability Scale–Items and Score*

1. Are there previous conclusive reports on this reaction?
   Yes (+1) No (0) Don't know (0)
2. Did the adverse event appear after the suspected drug was administered?
   Yes (+2) No (–1) Don't know (0)
3. Did the adverse reaction improve when the drug was discontinued, or a specific antagonist was administered?
   Yes (+1) No (0) Don't know (0)
4. Did the adverse reaction reappear when the drug was re-administered?
   Yes (+2) No (–1) Don't know (0)
5. Are there alternative causes (other than the drug) that could on their own have caused the reaction?
   Yes (–1) No (+2) Don't know (0)
6. Did the reaction reappear when a placebo was given?
   Yes (-1) No (+1) Don't know (0)
7. Was the drug detected in the blood (or other fluids) in concentrations known to be toxic?
   Yes (+1) No (0) Don't know (0)
8. Was the reaction more severe when the dose increased, or less severe when dose was decreased?
   Yes (+1) No (0) Don't know (0)
9. Did the patient have a similar reaction to the same or similar drug in any previous exposure?
   Yes (+1) No (0) Don't know (0)
10. Was the adverse event confirmed by any objective evidence?
    Yes (+1) No (0) Don't know (0)

Interpretation; >9 = highly probable; >5 - 8 = probable; > 1 - 4 = possible; ≤ 0 = doubtful

Elizabeth K.E.,
Department of Pediatrics,
SAT Hospital, Govt. Medical College,
Thiruvananthapuram 695011, India.
E-mail: elizake@hotmail.com

REFERENCES

1. Fadnis VP, Unni J. Adverse drug reaction to cefipime. Indian Pediatr 2007, 44: 49-50.
2. Naranjo CA, Busto U, Sellers EM, Sandor P, Ruiz I, Roberts EA, *et al.* A method for estimating the probability of adverse drug reactions. Clinical Pharmacol Ther 1981, 30: 239-245.

Reply

Dr. Elizabeth has raised a valid issue regarding criteria for assessing ADRs. The widespread use of the Naranjo ADR Probability Scale (NADRPS) by journals assessing manuscripts submitted for publication as case reports, suggest that although no perfect solution exists for clinicians seeking to assess the likelihood of ADRs, this scale does provide a somewhat structured basis for assessment in a standardized and relatively reproducible format. However, several of the questions in NADRPS are difficult to apply. In some situations the scale requires modification to improve reliability, validity, and clinical usefulness(1). And more often than not, using NADRPS, we are only able to confirm that the cause and effect is either 'possible' or 'probable'(2). Another drawback of the scale is that even if none of the criteria are met, the cause and effect is categorised as 'doubtful' making it difficult to categorically rule out the possibility of ADR in any given case. But, because its inter-rater reproducibility is good, IP also would use this scale while reviewing articles related to ADRs.

Studies employing a computerized monitoring system to analyse laboratory data using the NADRPS or other suitably modified criteria have found that the detection rate of ADRs may almost be