National Pharmacovigilance Program

I was interested to read the informative communication by Bavdekar and Karande in the Viewpoint section of the Journal(1). The National Pharmacovigilance Program has been launched under the aegis of Directorate General of Health Services, Union Ministry of Health and Family Welfare. Surprisingly, most physicians seem to be unaware of this activity. This articles clearly mentions the definitions of adverse event and adverse reaction that may follow administration of a drug or a vaccine, or any other therapeutic agent, and the purposes of the National Program. Very ambitious plans have been made both at central as well as peripheral levels. The immediate objectives is "to foster a culture of notification not only among doctors but also amongst other health-care providers, *viz.*, pharmacists and nurses".

Whereas it would be useful to create awareness among non-medical health personnel about adverse drug reactions, it is extremely important that reports of such instances be accurate, reliable and subject to scrutiny. Anecdotal and ill-documented accounts need to be treated with caution. Since nurses and pharmacists do not prescribe medications, any side effects that they observe should be brought to the notice of the treating physician. The agency that receives the reports must ensure that various details are provided, including identity of the notifier. The IAP Clinical Pharmacology Cell has informed the IAP members that they could report adverse reactions to medications and vaccines etc on a proper form. Such information is to be examined and stored for rapid retrieval. The IAP cell could communicate with the National Committee.

The authors go on to make several "considerations for the future". They inform that the National Pharmacovigilence Committee does not have a pediatrician as its member. No wonder pediatricians have no knowledge of such a committee. It would be useful to know who are the members and from which source more information about this committee can be obtained.

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REFERENCE

1. Bavdekar SB, Karande S. National pharmacovigilence program. Indian Pediatr 2006; 43: 27-32.

(Pharmacovigilance Program) Reply

We are grateful to Dr. R.N. Srivastava for his interest in our article on the newly launched National Pharmacovigilance Program(l). He has raised a doubt regarding wisdom of permitting nurses and pharmacists to "independently" report an Adverse Event (AE). We believe that nurses and pharmacists play an important role in pharmacovigilance and that they should be encouraged to report AEs independently. Given their unique position in drug administration and recording observations on in-patients, nurses who form a large proportion of health-care staff in our vast country will contribute significantly to the spontaneous reporting of adverse events and adverse drug reactions. Since October 2002, nurses in the UK have been permitted to report AEs. On analyzing their inputs, it has been noted that their reports are valuable, both in number and in quality, and as complete as those from general practitioners and hospital doctors(2,3). Pharmacists too would play a major role in pharmacovigilance by reporting AEs to drugs prescribed in outpatient practice as they often receive valuable feedback from

their clients, information which may not reach the prescribing doctors. We would like to mention that up to 68 countries have already authorized pharmacists to report AEs and this has led to a substantial improvement of the international adverse drug reactions reporting system(4).

We fully endorse Dr. R.N. Srivastava's suggestion that the Clinical Pharmacology Cell of the Indian Academy of Pediatrics should liaison with the National Pharmaco-vigilance Program to improve the current unsatisfactory state of pediatric pharmaco-vigilance in our country. We reiterate our earlier demand that an expert pediatrician nominated by the Indian Academy of Pediatrics should be a member of the National Pharmacovigilance Advisory Committee. This would help in fostering the much-needed collaboration between the Indian Academy of Pediatrics and the National Pharmacovigilance Program and eventually improve awareness about the national program amongst its 16,000 members. Only collaborative efforts will ensure that a significant number of AEs get reported. This will lead to early identification of rare and life-threatening adverse drug reactions and help ensure that children in our country receive safe drugs.

Lastly, we wish to inform Dr. R.N. Srivastava and readers that detailed information about the national program, *viz.*, the AE reporting form, the protocol, list of centers, members of the National Pharmacovigilance Advisory Committee, *etc*. is available at the Central Drugs Standard Control Organization (CDSCO) website: http://cdsco.nic.in/html/pharmaco.html

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REFERENCES

1. Bavdekar SB, Karande S. National pharmaco-vigilance program. Indian Pediatr 2006; 43: 27-32.
2. Morrison-Griffiths S, Walley TJ, Park BK, Breckenridge AM, Pirmohamed M. Reporting of adverse drug reactions by nurses. Lancet 2003; 361: 1347-1348.
3. Ranganathan SS, Houghton JE, Davies DP, Routledge PA. The involvement of nurses in reporting suspected adverse drug reactions: experience with the meningococcal vaccination scheme. Br J Clin Pharmacol 2003; 56: 658-663.
4. van Grootheest K, Olsson S, Couper M, de Jong-van den Berg L. Pharmacists' role in reporting adverse drug reactions in an international perspective. Pharmacoepidemiol Drug Saf 2004; 13: 457-464.

Onset of Jaundice in G-6-PD Deficient Neonates

We read the letter by Drs. Murki and Dutta, in which they report on umbilical cord blood serum total bilirubin (STB) levels in glucose-6-phosphate dehydrogenase (G-6-PD)-deficient and-normal neonates, with great interest(1). In their study, cord blood bilirubin levels were similar in the G-6-PD deficient and control neonates, suggesting that, in the Indian neonates studied, G-6-PD deficiency associated