Short Notes

Reporting of adverse drug reaction under Pharmacovigilance Programme of India

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During clinical trials series of Adverse Drug Reactions (ADRs) were not recorded due to lesser number of populations enrolled for the study. So, Pharmacovigilance is confined mainly to detection of adverse events that were previously either unknown or poorly understood. World Health Organizations (WHO) defines "Pharmacovigilance as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem". Thalidomide tragedy was the eye marker to introduce International Drug Monitoring system by WHO.[1] Looking towards the need, India also launched Pharmacovigilance Programme of India to promote patient safety and rational use of medicines available in India. Indian Pharmacopoeia Commission (IPC) is functioning as National Coordination Centre (NCC) for PvPI. Total 179 ADR Monitoring Centers (AMCs) are established under NCC-PvPI, all these AMCs are medical colleges & hospitals or corporate hospitals approved by Medical Council of India, public health programs. AMCs aims to collate, analyse and submit the ADRs to NCC. [2,3]

Healthcare professionals can report ADRs with all pharmaceutical products, herbals, vaccines, medical devices whether known or unknown, serious or non-serious and frequent or rare by filling the Suspected Adverse Drug Reactions Reporting Form (Figure-1) and submit to nearby AMC (available at www.ipc.gov.in). NCC-PvPI has also launched nationwide helpline (1800 180 3024) to provide assistance in ADRs reporting.[4] NCC has also introduced android mobile application to report ADRs in simple and quick way which will enhance the participation of private practitioners too.

The ADRs collected/gathered are put into the database, wherein analyzed and assessed for safety update and then finally sent to WHO-UMC.[5] The collected information is helps appropriate steps for detection of signals and reducing the risks associated with the drugs, also be used as an evidence as recommendation to national regulators, to assess benefit risk ratio, update prescribing information leaflet and promote rational use of medicines. The reporter will not have to face any legal action for reporting ADR and patient information will be kept confidential. The healthcare professionals are vitalize to report ADRs due to the use of any pharmaceutical drugs, vaccines, herbals and medical devices for patient safety in the Indian population.

Version-1.2

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by Healthcare Professionals

INDIAN PHARMACOPOEIA COMMISSION
(National Coordination Centre-Pharmacovigilance Programme of India)
Ministry of Health & Family Welfare, Government of India
Sector-23, Raj Nagar, Ghaziabad-201002

FOR AMC/NCC USE ONLY

AMC Report No. :

Report Type ☐ Initial ☐ Follow up

Worldwide Unique No. :

A. PATIENT INFORMATION

1. Patient Initials _____	2. Age at time of Event or Date of Birth _____	3. M ☐ F ☐ Other ☐
		4. Weight_____Kgs

12. Relevant tests/ laboratory data with dates

B. SUSPECTED ADVERSE REACTION

5. Date of reaction started (dd/mm/yyyy)

6. Date of recovery (dd/mm/yyyy)

7. Describe reaction or problem

13. Relevant medical/ medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction etc.)

14. Seriousness of the reaction: No ☐ if Yes ☐ (please tick anyone)

☐ Death (dd/mm/yyyy) ☐ Congenital-anomaly
☐ Life threatening ☐ Required intervention to Prevent permanent
☐ Hospitalization/Prolonged impairment/damage
☐ Disability ☐ Other (specify)

15. Outcomes

☐ Recovered ☐ Recovering ☐ Not recovered
☐ Fatal ☐ Recovered with sequelae ☐ Unknown

C. SUSPECTED MEDICATION(S)

S.No	8. Name (Brand/Generic)	Manufacturer (if known)	Batch No. / Lot No.	Exp. Date (if known)	Dose used	Route used	Frequency (OD, BD etc.)	Therapy dates		Indication	Causality Assessment
								Date started	Date stopped		
i											
ii											
iii											
Iv											

S.No as per C	9. Action Taken (please tick)						10. Reaction reappeared after reintroduction (please tick)			
	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unkn own	Yes	No	Effect unknown	Dose (if reintroduced)
i										
ii										
iii										
iv										

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S.No	Name (Brand/Generic)	Dose used	Route used	Frequency (OD, BD, etc.)	Therapy dates		Indication
					Date started	Date stopped	
i							
ii							
iii							

Additional Information:

D. REPORTER DETAILS

16. Name and Professional Address:_____
_____
Pin:_____E-mail_____
Tel. No. (with STD code)_____
Occupation:_____ Signature:_____

17. Date of this report (dd/mm/yyyy):

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.

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Pharmacovigilance Programme of India
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Pharmacovigilance Programme of India for Assuring Drug Safety

ADVICE ABOUT REPORTING

A. What to report

- Report serious adverse drug reactions. A reaction is serious when the patient outcome is:
  - Death
  - Life-threatening
  - Hospitalization (initial or prolonged)
  - Disability (significant, persistent or permanent)
  - Congenital anomaly
  - Required intervention to prevent permanent impairment or damage
- Report non-serious, known or unknown, frequent or rare adverse drug reactions due to Medicines, Vaccines and Herbal products.

B. Who can report

- All healthcare professionals (Clinicians, Dentists, Pharmacists and Nurses) can report adverse drug reactions

C. Where to report

- Duly filled Suspected Adverse Drug Reaction Reporting Form can be send to the nearest Adverse Drug Reaction Monitoring Centre (AMC) or directly to the National Coordination Centre (NCC).
- Call on Helpline (Toll Free) 1800 180 3024 to report ADRs.
- Or can directly mail this filled form to pvpi@ipcindia.net or pvpi.ipcindia@gmail.com
- A list of nationwide AMCs is available at:
  http://www.ipc.gov.in, http://www.ipc.gov.in/PvPI/pv_home.html

D. What happens to the submitted information

- Information provided in this form is handled in strict confidence. The causality assessment is carried out at AMCs by using WHO-UMC scale. The analyzed forms are forwarded to the NCC through ADR database. Finally the data is analyzed and forwarded to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Centre in Sweden.
- The reports are periodically reviewed by the NCC-PvPI. The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines.
- The information is submitted to the Steering committee of PvPI constituted by the Ministry of Health & Family Welfare. The Committee is entrusted with the responsibility to review the data and suggest any interventions that may be required.

E. Mandatory field for suspected ADR reporting form

- Patient initials, age at onset of reaction, reaction term(s), date of onset of reaction, suspected medication(s) and reporter information.

For ADRs Reporting Call on PvPI Helpline (Toll Free)

1800 180 3024

(9:00 AM to 5:30 PM, Working Days)

REFERENCES

1. WHO. The importance of Pharmacovigilance: safety monitoring of medicinal products. Geneva: WHO; 2002.
2. Kalaiselvan V, Surbhi S and Singh GN. Adverse reactions to contrast media: An analysis of spontaneous reports in the database of the Pharmacovigilance Programme of India. Drug Safety. 2014; 37: 703-10.
3. http://ipc.nic.in/showfile.asp?lid=414&EncHid assessed on 28th August 2015.
4. Kalaiselvan V, Mishra P and Singh GN. Helpline facility to assist reporting of adverse drug reactions in India, WHO South-East Asia Journal Public Health. 2014; (2)3: 194.
5. Kalaiselvan V, Saurabh A, Kumar R and Singh GN. Adverse reactions to herbal products: An analysis of spontaneous reports in the database of the Pharmacovigilance Programme of India, Journal of herbal medicine. 2015; 5: 48–54.