How to fill ADR Reporting Form and Causality Assessment

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ADR Reporting Forms

- Suspected Adverse Drug Reaction Reporting Form
 (For voluntary reporting of Adverse Drug Reactions by Healthcare Professionals)
- ADR Reporting Form for Consumer
- Transfusion Reaction Reporting Form (TRRF)
 (Haemovigilance Program of India)
- Medical Device Adverse Event Reporting Form (Materiovigilance Program of India)

Who can report?



Doctor



Dentist



Pharmacist



Patient



Nurse

Where to report

- Nearest ADR Monitoring Center (AMC)
 - AIIMS Raipur
 - Pt. JNMC, Raipur
- Directly to NCC, IPC Ghaziabad
- <u>pvpi.ipcindia@gmail.com</u>
 <u>pvpi@ipcindia.net</u>
- Toll free no. 1800 180 3024
- ADR Reporting Android app



What to report?

- Serious or Non-serious ADR
- Known or Unknown ADR
- Frequent or Rare
 - Related to medicine, vaccine, herbal products



SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by Healthcare Professionals

INDIAN PHARMACOPOEIA COMMISSION						FOR AMC/NCC USE ONLY				
	ordination Centre-F try of Health & Fam Sector-23 , Raj N	ily Welfare, 6	Government	of India	0	AM	AMC Report No. :			
Depot Type - Ini	tial — Fallana					Wo	rldwide Uniq	ue No. :		
A. PATIENT INFOR	MATION					12.1	Relevant tests	/ laboratory da	ta with dat	es
Patient Initials	at ient Initials 2. Age at time of Event or Date of 3. M □ F □ Other □									
12 To	Birth		4. Weigh	tI	Kgs					
B. SUSPECTED AD	VERSE REACTI	ON								g. allergies, rac
5. Date of reaction :	tarted (dd/mm/	(yyyy)				bres	gnancy, smok	ng, arconoruse,	, nepatic/re	enal dysfunction
6. Date of recovery	(dd/mm/	(vvvv)								
Describe reaction	orproblem									
						□ 1 □ 1 □ 5.0 □ 1	Death (dd/min life threatenin Hospitalization Disability Outcomes Recovered	n/Prolonged Recovering	Require Preven impaire Other (s	ital-anomaly d intervention to t permanent nent/damage specify) □ Not reco
.No 8. Name (Brand/Gener	Manufactur				Route used	Frequenc (OD, BD etc.)	1555	py dates d Date stopped	Indicat	ion Caus Assess
H		31	33	- W - 3	32 33		26	75		
iii .	_	_					-			
N Action Taken	(alassa tisk)					10 Boss	tion reasons	and after releater	duction (a)	lonen tiekt
No 9. Action Taken	(please tick)	Dose	Dose not	Not	Unkn	ID. Reac	tion reappear	ed after reintro	duction (pi	lease tick)
	se increased	reduced		applicable		Yes	N	o Effect	Effect unknown	
ii .										
101	7.1			\$ 3			23-12	8		
iv	11. Concomitant medical product including self-medication S.No Name (Brand/Generic) Dose used Rou		on and herb ute used	Freq	uency		apy dates			
iv		Do se u			(OD, E	SD, etc.)			_	
11. Concomitant me No Name (Brand/		Do se u		1.1	(OD, E	sb, etc.)				
iv II. Concomitant me		Do se u			(OD, E	sD, etc.)				
iv I. Concomitant me No Name (Brand/	Generic)	Do se u			(OD, E					
iv I.I. Concomitant me No Name (Brand/	Generic)	Do se u			(OD, E	D. REPO	ORTER DETAI			
	Generic)	Do se u			(OD, E	D. REPO	DRTER DETA e and Profess E-n (with STD cod	LS ional Address:_ ail le)	ignature:_	
iv 11. Concomitant me No Name (Brand/	Generic)	Do se u			(OD, E	D. REPC 16. Nam Pin: Tel. No. Occupat	PRTER DETA e and Profess E-n (with STD codion:	LS ional Address:_ ail le)	ignature:	

constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.

National Coordination Centre Pharmacovigilance Programme of India Ministry of Health & Family Welfare, Government of India Sector-23, Raj Nagar, Ghaziabad-201002 Tel.: 0120-2783400, 2783401, 2783392 Fax: 0120-2783311

www.ipc.nic.in

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)

A. Patient Information

1 Patient Initials

2 Age at the time of Event or Date of Birth

Sex

Male Female Other

4 Weight (kg)

B. Suspected Adverse Reaction

- 5 Date of Reaction started (dd/mm/yyyy)
- 6 Date of recovery (dd/mm/yyyy)
- 7 Describe reaction or problem

Name (Brand and/or Generic) 8 Manufacturer (if known) Batch No. /Lot No.

Exp. Date (if known)

Dose used

Route used

Frequency (OD, BD, etc)

Therapy dates **Date Started**

Indication

Causality Assessment

Date Stopped

9	Action Taken (Please tick)							
	Drug Withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown		
i								
ii								
iii								
iv								

10

Reaction reappeared after reintroduction (please tick)

TO	>1			
	Yes	No	Effect unknown	Dose (if reintroduced)
i				
ii				
iii				
iv				

Concomitant medical products

Including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

	Name	Dose	Route	Frequency	Therap		
	(Brand/ Generic)	used	Used	(OD, BD, etc.)	Date Started	Date Stopped	Indication
i							
ii							
iii							
iv							

Relevant tests/laboratory data with dates 12 Relevant medical / medication history (e.g. allergies, race, pregnancy, smoking, 13 alcohol use, hepatic/renal dysfunction etc.) Seriousness of the reaction:

No If Yes (Please tick anyone)

Death (dd/mm/yyyy)
Life threatening
Hospitalization (initial or prolonged)
Disability
Congenital anomaly
Required intervention to prevent permanent impairment / damage
Other (specify)

15 Outcomes

Recovered
Recovering
Not recovered
Fatal
Recovered with sequelae
Unknown

D. Reporter Details

Name and Professional Address **Email** Pin Tel. No. (with STD Code) Occupation Signature

Date of this report (dd/mm/yyyy)

Mandatory Fields for Suspected ADR Reporting Form

- Patient initials
- Age at onset of reaction
- Date of onset of reaction
- Reaction term(s)
- Suspected medication
- 16, 17 Reporter information

Safety Database

• Vigiflow software



home

Welcome to VigiFlow!				
User name				
Password				
	Change password			
	Login			

VigiFlow 5.3

(Released on April 13, 2015)

VigiFlow 5.3 release included addition of ICD-10 in Spanish and keeping the language for the session for the terminology chosen for WHO-ART and ICD-10.

Monthly VigiFlow webinars

We are happy to announce that the past VigiFlow webinars are available on YouTube! To find them, please follow this link.

Service on VigiFlow servers

Service activities will be made on VigiFlow servers the third Wednesday of each month from 19.00 to 22.00 CET. During this time access to VigiFlow may be unstable.

Safety Database

• Vigiflow software

CENTRE	new report send report list reports
•	home
english ▼	no id - no header
contacts	
user guide	Report information - standard case
	report Id
O. report info	report title
1. patient	type of report spontaneous
2. tests and procedures	serious O yes O no <u>clear</u> ?
3. relevant medical history	death life-threatening ?
4. relevant past drug therapy	□ hospitalization/prolonged □ disabling □ congenital-anomaly □ other medically important condition
5. reactions	country of occurrence country of primary source
6. drugs	India ▼ India ▼
7. assessment	does this case fulfill local criteria oyes ono clear
8. overview	for an expedited report additional documents held by sender and selection and selecti
9. save	yes 5 110 <u>c/ca/</u>
A. print report	was the case medically confirmed open on clear ?
	Information on sender
	type of sender pharmaceutical company regulatory authority other health professional regional pharmacovigilance center other
	date first received at regional centre (dd mm ccyy)
	sender AIIMS, Chhattisgarh
	person responsible Suryaprakash Dhaneria
	regional centre report Id
version 5.3	Other case identifiers in previous transmissions



Madan Lal, a 65-years old male patient admitted to hospital on 12.01.2016 with chief complaints of pain in upper abdomen and nausea since last 5 days. On physical examination, he had yellowish discoloration of palm, conjunctiva and nail bed. His weight was 72 kg.

He had few episodes of psychotic attacks, for which he was on Chlorpromazine therapy since last 4 weeks. On enquiry, he told that he was taking Tab. Largactil (Chlorpromazine) 100 mg, 4 tablets at bed time.

He was also taking Tab. Diclofenac 50 mg twice-a-day (self-medication) for abdominal pain for three days before admitting to hospital. He was investigated on the day of admission for laboratory parameters which are as follows:

- Alkaline Phosphatase = 180 U/L (Normal range: 25 100 U/L)
- ALT = 205 U/L (Normal range: 10 40 Units/L)
- Total Bilirubin = 5.0 mg/dL (Normal range: 0.8 1.2 mg/dL)

On admission, Chlorpromazine and Diclofenac therapy was stopped. After 7 days of stopping the medications, the intensity of pain decreased. Also, he was re investigated for above parameters which are as follows:

- Alkaline Phosphatase = 110 IU/L
- ALT = 98 Units/L
- Total Bilirubin = 1.8 mg/dL
- Note: Tab Chlorpromazine

Brand Name: LARGACTIL, Manufacturer: Wedley labs
Batch number: LGL0881, Expiry date: Dec 2018

A. Patient Information

Patient Initials – ML

2 Age at the time of Event or Date of Birth – 65 years

Male Female Other

4 Weight (kg) - 72 kg

B. Suspected Adverse Reaction

- 5 Date of Reaction started (dd/mm/yyyy): **07.01.2016**
- 6 Date of recovery (dd/mm/yyyy):

Describe reaction or problem

Patient was taking Chlorpromazine since 12.12.2015. He developed pain in abdomen and nausea since 07.01.2016. Examination revealed yellowish discoloration of conjunctiva, palm and nails. Pt. was admitted on 12.01.2016 and investigated. Liver function tests indicated raised serum bilirubin, ALT and alkaline phosphatase. Drugs were discontinued. On discontinuation of drug, reaction subsided in one week.

Name (Brand and/or Generic): Tab. Chlorpromazine (Largactil)

Batch No. /Lot No.: LGL0881

Frequency (OD, BD, etc): OD

Causality Assessment: Probable

Date Stopped 12.01.2016

Date Started 12.12.2015

Indication: Psychosis

Dose used: 400 mg

Route used: Oral

Therapy dates

Exp. Date (if known): Dec. 2018

Manufacturer (if known): Wedley labs

	Action Taken (Please tick)							
9	Drug Withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown		
i								
ii								
iii								
iv								

10

Reaction reappeared after reintroduction (please tick)

	Yes	No	Effect unknown	Dose (if reintroduced)			
i							
ii							
iii							
iv							

Concomitant medical products

Including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

	Name	Dose	Route	Frequency	Therapy dates		
	(Brand/ Generic)	used	Used	(OD, BD, etc.)	Date Started	Date Stopped	Indication
i	Tab. Diclofenac	50 mg	Oral	BD	09.01. 2016	12.01. 2016	Pain in abdomen
ii							
iii							
iv							

Relevant tests/laboratory data with dates 12.01.2016 19.01.2016 12 Alkaline Phosphatase = 110 U/L Alkaline Phosphatase = 180 U/L ALT = 205 U/L ALT = 98 U/LTotal Bilirubin = 5.0 mg/dL Total Bilirubin = 1.8 mg/dL Relevant medical / medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, 13 hepatic/renal dysfunction etc.)

Seriousness of the reaction:

No If Yes (P

If Yes (Please tick anyone)

	Death (dd/mm/yyyy)
	Life threatening
✓ f	Hospitalization (Initial or prolonged)
	Disability
	Congenital anomaly
	Required intervention to prevent permanent impairment / damage
	Other (specify)

15 Outcomes

	Recovered
√ 9	Recovering
	Not recovered
	Fatal
	Recovered with sequelae
	Unknown

D. Reporter Details

Name and Professional Address: Dr. A. K. Jain, Dept. of Medicine, AIIMS Raipur

Pin 492099

Email akjain@gmail.com

Tel. No. (with STD Code): 0771-2563452

Occupation Doctor

Signature 🙀



Date of this report (dd/mm/yyyy): 23.01.2016

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Causal	ity Assess	ment – AL	JR Case 1
		Other drug	

Yes

Yes

No

Probable

Possible

Unlikely

Time Dechallenge Rechallenge Categories disease sequence ruled out

Certain Yes Yes Yes Yes

Yes

No

No

Yes

No

No

No

No

No



Mr Sushant A Gupta, a 30-years old male with 68 kg weight was diagnosed as a case of bacterial meningitis. He was started empirically with Inj Ceftriaxone 1 g IV BD and Inj Vancomycin 500 mg IV QID on 12.01.2016. First dose of Inj. Ceftriaxone was given at 8 am and Inj. Vancomycin was given at 9 am on 12.01.2016. After 10 minutes of second drug administration, he started developing chills, rigors, fever, urticaria and intense flushing. He was treated with Inj. Pheniramine 25 mg IM, following which the reaction completely subsided. Inj. Ceftriaxone was continued. However, next doses of Inj. Vancomycin scheduled on day 1 were not given. On day 2, the Inj Vancomycin was re-introduced at 9 am to the patient. Similar symptoms developed again and quickly resolved after Inj. Pheniramine 25 mg IM.

Note:

- Inj Vancomycin
 - Brand Name: Vanzid
 - Manufacturer: SWACH Healthcare
 - Batch number: KKILo98
 - Expiry date: Mar 2016
- Inj Ceftriaxone
 - Brand Name: Taximax
 - Manufacturer: Wedley Labs
 - Batch number: OPO659
 - Expiry date: Dec 2016

Other drug	

Time

sequence

Yes

Yes

Yes

No

Categories

Certain

Probable

Possible

Unlikely

disease

ruled out

Yes

Yes

No

No

Dechallenge

Yes

Yes

No

No

Rechallenge

Yes

No

No

No



Will reporting have any negative consequences on the healthcare professionals or the patient?

- Submission of an ADR report does not have any legal implication on the reporter
- Confidentiality of the reporter and patient will be maintained
- The information is only meant for better understanding of medicines used in India and to safeguard the health of Indian Population

ADRs reporting is to evaluate benefit risk ratio of a medicine and there by ensuring safe use of medicines.

Thank you...!