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Diploma in Pharmacy 2nd Year
Hospital & Clinical Pharmacy
Experiment

To fill up IPC's ADR reporting form and perform causality assessments using various scales.

Aim:

To fill up IPC's ADR reporting form and perform causality assessments using various scales.

Reference :

‘ Dr. Gupta G.D. , Dr. Sharma Shailesh, Dr. Sharma Anshu, “Practical Manual of Hospital & Clinical Pharmacy” Published by Nirali Prakashan, Page no 13 - 18

Theory :

Suspected Adverse Drug Reaction Reporting Form

For documenting adverse drug reactions, the NCC has designed a "Suspected Adverse Drug Reaction Reporting Form". There are several forms for recording adverse reactions to blood transfusions, blood-related products, and Adverse Event Following Immunization (AEFD)

ICSR is a report that includes details about a suspected Adverse Drug Reaction (ADR) associated with the administration of one or more medications to a specific patient. The points listed below should be completed on an ADR form:

A) Patient Information

1) **Patient Initials**: The initials of a patient should be written instead of full name. For example, Madhu Gupta should be written as MG.

2) **Age at Time of Event or Date of Birth:** Either the date of birth or age of the patient should be written when the event or reaction has occurred.
3) **Sex:** The gender of the patient should be mentioned.
4) **Weight:** The weight of the patient should be mentioned.

B) Suspected Adverse Reaction

5) **Date of Reaction Started:** The date on which the reaction initially appeared should be mentioned
6) **Date of Recovery:** If the reaction recovered, the patient's recovery date from the reaction should be reported.
7) **Describe Reaction:** Description of the reaction, including its type. location, etc. should be provided. For example, an erythematous maculopapular rash appeared on the patient's upper and lower limbs.

C) Suspected Medications

8) The reporter should provide information about any suspected medications, including the drug name (brand or generic name), manufacturer, batch number or lot number, expiry date, dose used, route of administration, frequency, dates of therapy started and ended, and indication.
9) **Dechallenge Details:** The status on dechallenge should be mentioned as:
   i) **'Yes':** If the reaction subsides after dechallenge
   ii) **'No':** If the reaction does not subsides after der hallenge
   iii) **'Unknown':** If effect of dechallenge is not known.
   iv) **"Not Applicable' or 'NA':** When dechallenge is unnecessary, as it is when it comes to things like vaccines, anaesthesia, the delivery of only one dose, patient death, or the end of therapy before a reaction or occurrence.
   v) **'Reduced Dose':** If dose at which the reaction occurred is reduced.

Note: Reduced dose and date should also be mentioned

10) **Re-challenge Details:** The status on re-challenge should be mentioned as
    i) **'Yes':** If reaction reappeared after re-challenge.
    ii) **'No':** If reaction does not reappear after re-challenge.
    iii) **'Unknown':** If effect of re-challenge is not confirmed.
    iv) **Not Applicable' or 'NA':** If re-challenge is not applicable as in case of anaphylaxis reaction.
    v) **Re-Introduced Dose':** Mention the dose and date of re-challenge The dose and date or re-challenge should be mentioned.
11) **Concomitant Drugs:** The details of all concurrent drugs including self- medication, OTC medication, herbal remedies with therapy dates should be recorded.
12) **Relevant Tests/Laboratory Data:** All the laboratory data (if available) that are related to the reaction should be mentioned.
13) **Other Relevant History:** The related history of patient including pre- existing medical condition (such as, allergies, pregnancy, smoking. alcohol use, hepatic/renal dysfunction) and concurrent condition should be noted.
14) **Seriousness of the Reaction:** The relevant cause for seriousness should be marked if any reaction is serious in nature:
    i) **'Death':** If a negative incident caused the patient's death Note: The cause and date of the death should be mentioned in the seriousness of the reaction.
    ii) **'Life-Threatening':** If the patient was at serious risk of dying when the adverse event occurred.
    iii) **'Hospitalisation/Prolonged':** If the adverse event extended the patient's hospital stay or caused hospitalisation.

iv) **'Disability':** If adverse event caused a person's ability to carry out regular living functions to be significantly disrupted.

v) **'Congenital Anomaly':** If taking drugs during or before would have harmed the unborn child. pregnancy

vi) **'Required Intervention to Prevent Permanent Impairment/Damage':** If a body function or structure needed to be protected against permanent impairment through medical or surgical intervention

vii) **'Other':** When the conditions do not fulfil the criteria above, yet it could still be dangerous for the patient and require a surgical or medical procedure to avoid one of the above conditions.
For example, severe blood dyscrasias (blood disorders), non-hospitalised seizures or convulsions, the emergence of drug dependence, or drug addiction.

15) **Outcomes:** The outcome of the event should be marked:

i) **'Fatal':** If the patient dies

ii) **'Continuing':** If the patient is continuing to experience the reaction.

iii) **'Recovering':** If the patient is recovering from the reaction.

iv) **'Recovered':** If the patient has completely recovered from the reaction (mention the date of recovery).

v) **'Unknown':** If the outcome is not known.

D) Reporter

16) **Name and Professional Address**: The patient name and address should be mentioned on the form by the reporter. The identity of the reporter should be maintained

17) **Causality Assessment:** If trained, the reporter should determine the causality and support the determination.

18) **Date of Report:** The date on which he/she reported the adverse event should be mentioned.

All the required information should be collected to fill in suspected ADR reporting form. All the Essentially Required Items (ERI) should be filled for quality ICSR if complete information is not available. It should be ensured that the form must include all the mandatory fields if ERI is not available.

Mandatory Fields	Essentially Required Items
Initials of the patient, age at response onset, reaction term(s), and date of reaction onset, suspected medication, and reporter s details should be filled.	Patient initials, age at onset of reaction. gender, reaction term(s), date of onset of reaction, suspected medication(s), dose. date of therapy started, indication of use, seriousness, outcome, dechallenge and rechallenge details, reporter's information and date of report should be filled.

Note: For a valid case report mandatory fields are the minimum requirement

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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 impairment/damage
☐ Hospitalisation/Prolonged
☐ 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 Assessments
								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	Unknown	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.

Case Study

On 12.01.2016, 65-year-old Madan Lal was taken to the hospital after experiencing upper stomach pain and nausea for the last 5 days. A yellowish discoloration in the nail bed, conjunctiva, and hand was discovered during a physical examination. His weight was 72 kg.

He experienced a few psychotic attacks, for which he has been receiving chlorpromazine medication for the last four weeks. When questioned, he told that he was taking 4 Tab. of Largactil (Chlorpromazine) 100 mg pills before bed. Before being admitted to the hospital, he was also taking Tab. Diclofenac 50 mg twice day for three days due to gastrointestinal pain. On the day of admission, he was examined for the following laboratory parameters:
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)

Treatment with Diclofenac and chlorpromazine was stopped on admission. The level of pain decreased after stopping the medication for 7 days. Additionally, he was re-examined for above parameters as indicated above:
Alkaline Phosphatase = 110 IU/L
ALT=98 Units/L
Total Bilirubin = 1.8 mg/dL

Note: Tab Chlorpromazine
Brand Name: LARGACTIL,
Manufacturer: Wedley labs 1
Batch number: LGL088 **Expiry date:** Dec 2018

A. Patient Information

1	Patient Initials - ML
2	Age at the time of Event or Date of Birth-65 years
3	Sex 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):
7	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 Patient was admitted on 12.01.2016 and investigated. Live function tests indicated raised serum bilirubin, ALT and alkaline phosphatase Drugs were discontinued.On discontinuation of drug, reaction subsided in one week

C. Suspected Medication

8	Name (Brand and/or Generic): Tab. Chlorpromazine (Largactil) Manufacturer (if known): Wedley labs Batch No/Lot No: LGL0881 Exp. Date (if known): Dec 2018 Dose used: 400 mg Route used: Oral Frequency (OD, BD, etc): OD Therapy dates Date Started 12.12.2015 Date Stopped 12.01.2016 Indication: Psychosis Causality Assessment: Probable

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)**			
	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)

11	Name (Brand/Generic)	Dose used	Route Used	Frequency (OD, BD, etc.)	Therapy dates		Indication
					Date Started	Date Stopped	
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	**12.01.2016**	**19.01.2016**
	Alkaline Phosphatase = 180 U/L	Alkaline Phosphatase = 110 U/L
	ALT = 205 U/L	ALT = 98 U/L
	Total Bilirubin = 5.0 mg/dL	Total Bilirubin = 1.8 mg/dL

Relevant medical/medication history

13 (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)
Life threatening
✓ Hospitalisation (initial or prolonged)
Disability
Congenital anomaly
Required intervention to prevent permanent impairment/damage
Other (specify)

Table 4: Causality Assessment – ADR Case 1

Categories	Time Sequence	Other Drug Disease Ruled Out	Dechallenge	Rechallenge
Certain	Yes	Yes	Yes	Yes
Probable	Yes	Yes	Yes	No
Possible	Yes	No	No	No
Unlikely	No	No	No	No

Result :

IPC's ADR reporting form was filled and causality assessments using various scales was performed.

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