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Cheering Adverse Drug Reactions Reporting By Health Care Employees: Reasons For Under-Reporting: A Review

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Abstract: With the flourishing population, demand of drugs has increased too. People prefer taking medicines over the counter rather than consulting physicians. Sudden occurrence of new disease like recently seen in COVID-19,different types of flu's, has put so much burden on pharmaceutical companies. Yet, being an individual there are so many ways the burden on them can be abridged, are of the way is filling the ADR form.

Keywords: ADR,Pharmacovigilance, AMC, HLA,HCP

Introduction

Medication related adverse events are the harmful events caused by any medication. It is one of the rising causes of morbidity and mortality both nationally and internationally. Adverse drug reactions (ADRs) cause significant morbidity and mortality across diverse populations worldwide and have an economic impact upon the healthcare system [1].

Since, the use of drugs has significantly increased over a past few decades, ADRs has been seen increasing day by day. The seriousness is not just limited to rashes, headache but can be life threating, it may cause disability or congenital abnormalities. It has been seen that ADR's increase exponentially. With four or more medications and also by consuming. advanced new complex drugs. One in ten people in the United States suffers from it, nearly same picture is observed in our Indian context. So, does that mean we stop consuming modern drugs? The World Health Organization (WHO) monitors spontaneous ADR reporting in the majority of countries. A common problem is **under-reporting** [2].

With the boom in population, demand of drugs has increased too. People prefer taking medicines that are more potent and faster acting, rather than "plant based (herbal) slow medication. Sudden occurrence of new disease like recently seen in COVID-19, has put so much pressure on pharmaceutical companies. Yet, being an individual there are so many ways the burden on them can be reduced, are of the way is filling the ADR form. All healthcare Professionals (clinicians, dentist, pharmacist, nurses) and patients/consumers con report ADRs to NCC as. AMC (ADR monitoring centre) It is estimated that only 5–10% of ADRs are reported [3].

Even after the careful analysis of trials (drug clinical trial) sometimes the drug reaction does not appear on the selected individual of trial but rather on a consumer who had no idea about its adverse effects. In such cases we fill the ADR form. With the help of this, we can predict the hazardous event of a drug for future administration and search for prevention or a specific treatment to it. it also generate signal worldwide for which fda can generate black box warning and alert physicians world wide to such effects of drugs. Pharmacogenetics and Pharmacogenomics plays a crucial role in

identification of HLA or corresponding genes which is present in same individuals due to which such ADR reactions occurs in only few people with specific genotype. Although there is no estimate of patient reporting, 95% of healthcare professionals (HCPs) do not report ADRs [4].

Serious, unexpected reactions that are not fatal or life threatening must be filled as soon as possible but not later than 15 calendar days. According to the reports the percentage distribution of the ADR's is gynaecology 22%, oncology 26%, medicine 15%, ART 9%, neurology 4%. So, if we know the cause and the solution to it why so many cases are not being acknowledge by the healthcare system? The answer to it mainly lies on the root level. Many people prefer to take direct medicine from the pharmacist. The pharmacist not being to take some effort doesn't give more importance to it. It can be also possible that same healthcare professionals have no idea of the ADR reporting system. In 1976, a British physician, *Inman*, was the first to publish reasons for under-reporting by HCPs [5], including:

- **Complacency** (be certain of that serious ADRs are well documented when the drug is released on the market)
- **Fear** of being tangled in a lawsuit
- **Guilt** for having been accountable for damage observed in a patient;
- **Ambition** to publish a case series or financial benefit
- **Lack of awareness** of the notification process
- **Insecurity** about reporting qualms of an ADR; and
- **Indifference**

These factors were subsequently confirmed in two systematic reviews of barriers and motives to HCP reporting of ADRs [1, 2].

Other causes are:

1. Unsure how to fill the form and where to send
2. Difficult to admit harm done to patient
3. Fear of facing legal problems
4. Lack of information provided by the patients
5. Being busy/ignorant to fill ADR
6. Unsure of which drug caused the ADR

ADR is a very important subject and forms the core of the future of pharmacology. We need more and more participations of individuals. Encouraging healthcare professional might work. The curriculum of MBBS & MD, DM should have an essential (must know) & elaborate discussion about it. One can have ADR related exams and ADR should be included in practical too. Even school curriculum must have first aid teaching & basic knowledge about such untoward drug reactions and how to respond to it.

The value of direct patient reports in pharmacovigilance can be summarized as follows:

1. They give more and better context than indirect reports from professionals
2. They commonly describe the impact on people's lives, which clinicians rarely note
3. Indirect and direct reports complement each other, generating multicultural knowledge
4. Knowledge of ADRs and their importance accumulates faster
5. Patients become active participants in their own care
6. Patients learn how to manage their medicines and to communicate better with professionals

Awareness regarding it should be reached to common public through online & offline portals. ADR filling might not directly help an individual but a serious condition can be prevented in future, saving lives of many innocent citizens.

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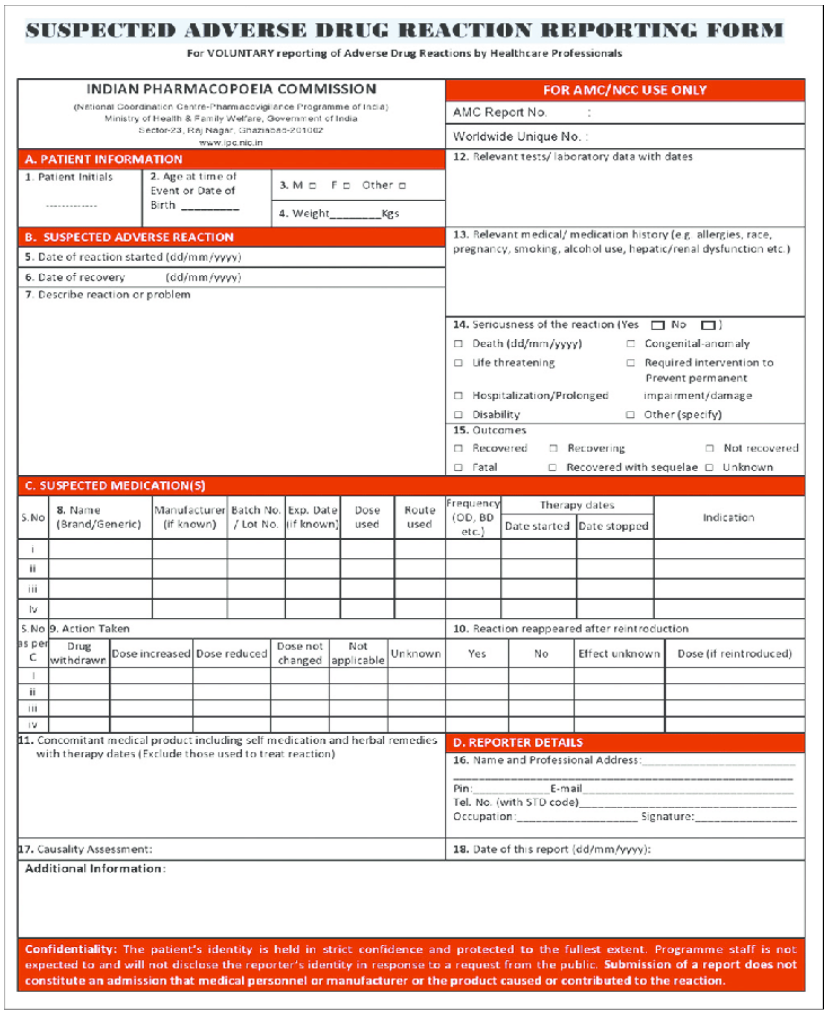

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

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
www.ipc.nic.in

FOR AMC/NCC USE ONLY
AMC Report No. :
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 (Yes ☐ No ☐)
☐ 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: Date started	Therapy dates: Date stopped	Indication
i										
ii										
iii										
iv										

S.No as per C	9. Action Taken: Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	10. Reaction reappeared after reintroduction: 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)

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

17. Causality Assessment:

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

Additional Information:

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.**

Fig: Suspected ADR form

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