Available online www.jocpr.com

Journal of Chemical and Pharmaceutical Research, 2015, 7(10):915-923

Research Article

ISSN : 0975-7384
CODEN(USA) : JCPRC5

Writing an Observation of Pharmacovigilance in the Clinical Pharmacology and Toxicology Department of the UHC Ibn Rushd of Casablanca

Hakim EL ALAMA [1,2 *], Houda FILALI [1,2], Imane RAHMOUNE [1,2], Abdelwahab TAZI [1,2], Farid HAKKOU [1,2]

[1] *: Laboratory of Pharmacology and Toxicology, Faculty of Medicine and Pharmacy of Casablanca, Hassan II University, 19, rue Tarik Ibn Ziad, Casablanca, Morocco*
[2] *: Clinical Pharmacology and Toxicology Department, Ibn Rushd Hospital, University Hospital Center Ibn Rushd of Casablanca, 1, Rue des Hôpitaux, Casablanca, Morocco*

ABSTRACT

Observation of pharmacovigilance is a descriptive and analytical study of a drug side effect. This is a multidisciplinary, multifactorial work in which the pharmacologist determines the nature of the adverse effect, classifies drugs according to the order incrimination and advises on the management of the side effect drug, based on the updated version of the French method of accountability and knowledge in clinical and pharmacology. The method of writing a pharmacovigilance observation accredited by Clinical Pharmacology and Toxicology department of the UHC Ibn Rushd of Casablanca allows to study the adverse effects as a whole and based on certain concepts that are often ignored such excipients effect notorious drug interactions or occurrence mechanism of adverse drug reactions.

Keywords: Writing, Observation, Pharmacovigilance, Adverse Drug Reaction, French Accountability.

INTRODUCTION

According to the National Security Agency for Medicines and Health Products (ANSM); Pharmacovigilance is the monitoring of drugs and the prevention of adverse reaction risk resulting from their use, this risk is either potential or benign [1].
Adverse drug reaction (ADR) is defined by the World Health Organization (WHO) as a noxious and unintended response to a drug which occurs at doses normally used in humans for prophylaxis, diagnosis or treatment of a disease or for the restoration, correction or modification of physiological function [2].
Method proposed and approved by the Clinical Pharmacology and Toxicology department of the UHC Ibn Rushd of Casablanca is a critical and thorough study of the actors involved in the development of ADR, it helps to understand the causal link between the use of drug and the occurrence of ADR.

OBJECTIVES

Analytical and descriptive study of the method of preparation of a pharmacovigilance observation allows determining the role, impact and interactions between different parts of each element of observation.
Pharmacovigilance observation allows charging the offending drug in the occurrence of the adverse effect and consequently to give notice pharmacologist can be a final discontinuation of the drug, dose adjustment, substitution or other.

OBSERVATION OF PHARMACOVIGILANCE

Observation of pharmacovigilance is constituted of the following in chronological order (**Annex**):

1- Identity: Identity information is an element of guidance and analysis (eg: age may be a predisposing factor, profession used to evaluate the risk of exposure to certain elements, region allows identify endemic areas, etc.).

2- Reason for hospitalization (RFH): This is the reason (disease, accident, poisoning, etc.) to which the patient is hospitalized, in some cases the patient is hospitalized for adverse reactions (eg: Lyell's syndrome) in this case the RFH is the same as ADR.

3- ADR: ADR nomenclature must meet some clinical and / or para-clinical criteria for diagnosis, it must be also limited to the descriptions (rise, decline, defect, damage, deterioration) and not abuse of terms like hepatitis, cytolysis, steroid-induced diabetes, etc.

4- Background: Background to assess the prescription and analyze the medical act and in conjunction with ADR, they may have against a possible indication for certain drugs, some employment or orientation precautions to the genetic component. The background can be personal, surgical or family.

5- History of drug adverse reaction (HDAR): HDAR must be written in a harmonious way by including the information in any event and date of occurrence.

6- Clinical examination: Clinical examination is a diagnostic and guidance element; sometimes it is a confirmation for some effects of a purely clinical diagnosis among these exams were general clinical examination, cardiovascular, neurological, pulmonary, etc.

7- Diagnosis to evoke: In pharmacovigilance, we study first non-drug causes that may be causing the effect; the elimination of these causes is based on the arguments in favor and those against it. Drug causes are determined using a simple literature search.

8- Para-Clinical examination: It is a biological and radiological examination.

9- What to do (WTD): Various acts and decisions adopted to against adverse reaction by the service where the patient is hospitalized.

10-Chronology: Is to specify the date and the time between each event in connection with the drug side effect (first stopping treatment, reintroduction or substitution of one or more drugs, occurrence of ADR, consequences of ADR (regression complication, etc.), WTD, etc.

11- Accountability Study [3]: To study accountability, we refer to the updated version of the French method of accountability of adverse drug effects. This method is based on three elements which are:

a- Score of informativeness: This score is based on the availability of part of the appearance of the ADR period and secondly to stop / no stop or dose adjustment. Scores are either N0, N1 or N2 to the availability of previous notions.

b- Intrinsic Accountability: Based on the constituent elements and the case is subject to two types of criteria; chronological and semiological.

c- Extrinsic Accountability: This is a literature review at the summaries of product characteristics, reference books, journals or databases.

12- Mechanisms: Mechanisms of drug action and / or occurred ADR allow making the right decision (judgment, substitution, dose adjustment, etc.) depending on the nature of the mechanism:

Type A or pharmacological mechanism: Dose-dependent with the possibility of re-administration (dose adjustment).

Type B or immunoallergic / not immunoallergic mechanisms: Not dose-dependent with rechallenge is contraindicated.

Type C or chronic toxicity: Not dose-dependent with rechallenge is contraindicated.

13- Drug Interactions: When writing a pharmacovigilance observation it is imperative to identify the main drug interactions, clinical consequences (positive or negative), stress levels and modalities of prevention.

14- Known effect excipients: Excipients are components which are devoid of therapeutic activity which should be well tolerated; however some can cause intolerances or adverse reactions which determine certain stress levels.

15- Opinion of Pharmacologist: Based on the previous items, pharmacologist advises about the adverse effect concerning three crucial parts:

a- Nature of the effect: Deciding if it is a drug side effect or not, its frequency, its mechanism and its severity.

b- Ranking of drugs: Following their order of criminality based on intrinsic and extrinsic accountability scores.

c- What to do: Pharmacologist expressed against the ADR (drug withdrawal, substitution, dose adjustment, drug dosage, symptomatic treatment, or other clinical diagnostic tests, etc.).

16- Conclusion: Summary and classification of drugs in order of criminality.

CONCLUSION

Writing of a pharmacovigilance observation is a very sensitive instrument that requires rigorous work and mastery of the clinical tools and pharmacology. Diagnosis and management of drug adverse reactions require a multidisciplinary working and needs to be notified.

Acknowledgements: We thank those who participated in the development of this work.

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Observation of Pharmacovigilance

1-Identity:
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2-ADR :
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3-Antecedents :
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Personal :……
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Surgical :……..
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Familiy :……
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4-History of Adverse Reaction :

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5-Clinical examination:

General examination:

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Cardiovascular examination:

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Lung examination:

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Neurological examination:

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Other: ……
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6- Diagnosis to evoke:

Diagnosis	Arguments in favor	Arguments against

Remarks:
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7-Paraclinical examination:
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8-What To Do :

What To Do	Result	Remarks

Other:
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9-Chronology :

Date	Event

10- Study of Accountability:
a-Score informativity: ☐ NI 0 ☐ NI 1 ☐ NI 2
b-Intrinsic accountability:

Intrinsic accountability	**Parameter** / **Drug**							
CHRONOLOGY	Time limit of apparition of reaction							
	Evolution of the effect							
	Re-administration of medication							
	Chronological score							
SEMIOLOGY	Clinical and paraclinical semiology							
	Reliable specific additional examination (L) of torque adverse reaction / response to medication or a specific antidote:							
	Other non-drug cause(s)							
	Semiological score							
Intrinsic accountability score								

c- Extrinsic accountability:

Reference Drug	Vidal	Martindale	Meyler's	Other	Extrinsic accountability score

Supplement literature search:

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11- Excipient with known effect:

Drug	Excipient	Known effect

12- Drug Mechanism of action and / or occurrence of ADR:

Drug	Mechanism of action	Occurred mechanism of ADR

13- Drug Interactions and stress levels:

Association	Accordingly and stress level	WTD

Remarks :……
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14- Pharmacological advice :
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15- Conclusion :

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Trading name	INN	Dosage form	Dosage	Route of administration	Posology	Pharmacotherapeutic class	Short therapeutic indication	Duration treatment