International Journal of Pharmacy and Chemistry
2021; 7(6): 125-127
http://www.sciencepublishinggroup.com/j/ijpc
doi: 10.11648/j.ijpc.20210706.14
ISSN: 2575-5730 (Print); ISSN: 2575-5749 (Online)

Classifying Causality of an Adverse Drug Reaction: Naranjo Algorithm

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To cite this article:
Gudisa Bereda. Classifying Causality of an Adverse Drug Reaction: Naranjo Algorithm. *International Journal of Pharmacy and Chemistry.* Vol. 7, No. 6, 2021, pp. 125-127. doi: 10.11648/j.ijpc.20210706.14

Received: December 7, 2021; **Accepted**: December 29, 2021; **Published**: December 31, 2021

Abstract: The Naranjo adverse drug reaction likelihood scale was elaborated to assist standardizes apprehensiveness of causality for entire adverse drug reaction.). Adverse drug reaction is an unpleasant or detrimental reaction proficiency pursuing the administration of a medication or combination of medications under usual circumstances of usage, which is doubted to be affiliated to the medicine. Causality delineated as the likelihood that a specific medication is accountable for a secluded consequence or adverse drug reaction. Certain (doubtful) causality if the total score is zero or lower. Possible causality delineated as if the total score is one to four. When a medical circumstances happens with a consequent time resultant to medication uptake, but which could be described by coincident malady or distinctive medication uptake. Probable or likely causality delineated as if the total score is five to eight. When a medical circumstance happens with a well-founded time consequence to medication uptake and is questionably to be owing to every coincident infirmity or disparate medication uptake. When a medical circumstances enclosing laboratory parameters anomaly happens in a presumptive time consociated to medication administered to the patients and cannot be described by coincident malady or distinctive medications or pharmaceutical products; administer of the mediation redundantly antecedents a connate response or reaction to discontinuation presumptive (a medicines qualities consequences, and relating to the study of malady).

Keywords: Adverse Drug Reaction, Causality, Naranjo Algorithm

1. Introduction

Adverse drug events (ADEs) can happen in any health care setting, enclosing inpatient (e.g., acute care hospitals), outpatient, and institutional and non-institutional long-term care (LTC) settings (e.g., nursing homes, group homes). Adverse drug reaction is an unpleasant or detrimental reactions proficiency pursuing the administration of a medication or combination of medications below usual circumstances of usage, which is doubted to be affiliated to the medicine. The reactions perhaps has familiar side effect of the medicine or it perhaps fresh and formerly un-recognised. Hast determination and documenting of adverse drug reactions is crucial so that imminences are distinguished quickly and applicable adjustment effect is received to guarantee that medications are used securely. Doubted adverse drug reactions to entire medicinal agent should be narrated, enclosing medications (over the counter (OTC) as well as that physician prescribe medications), blood products, vaccines, and radiographic contrast media, complementary and herbal products [1, 2]. Causality delineated as the likelihood that a specific medication is accountable for a secluded consequence or adverse drug reaction.

2. Classifying Causality of an Adverse Drug Reaction

Naranjo Algorithm: One ubiquitously used algorithm is the adverse drug reaction probability scale developed in 1981 by Naranjo and colleagues to standardize causality assessments [3]. The key advantage of the Naranjo score is its simplicity of use and clarity [4]. Furthermore, the Naranjo score sequences in a significant increase in inter- and intra-rater agreement compared with global introspection alone [4, 5]. However, algorithms alone lack the ability to accurately provide a quantitative assessment of the probability of the causal relationships [6]. An essential detrimental in

pharmacovigilance is that consummate case reports concern suspected adverse drug reactions. Adverse reactions are rarely specific for the drug, diagnostic tests are ordinarily absent and a rechallenge is rarely ethically justified [7]. The Naranjo adverse drug reaction likelihood scale was elaborated to assist standardizes apprehensiveness of causality for entire adverse drug reaction. The adverse drug reaction likelihood scale contains of ten interrogative that are responded as either Yes, No, or Do not know. Distinctive point values (-1, 0, +1 or +2) are ascribed to every response [8]. A simplified interpretation of the ten interrogations is furnished beneath and also the concrete adverse drug reaction likelihood scale form and directions on how it is filled furnished beneath.

Table 1. *Naranjo adverse drug reaction likelihood scale interrogative [9].*

Interrogation	Yes	No	do not know
Are there previously confirmed reports of reaction?	+1	0	0
Did the adverse event appear after the drug was used?	+2	-1	0
Did the adverse reaction improved when the medicine was withdrawn or a specific antagonist was used?	+1	0	0
Were there other feasible causes for the reaction?	-1	+2	0
Did the adverse reaction appear again upon administration of placebo?	-1	+1	0
Was the medicine determined in the blood or other fluids in toxic concentrations?	+1	0	0
Was the reaction worsened upon increasing the dose? Or was the reaction lessened upon decreasing the dose?	+1	0	0
Did the adverse reaction appear again upon re-administering the drug?	+2	-1	0
Did the patient have an identical reaction to the medicine or a related agent in the past?	+1	0	0
Was the adverse event confirmed by any other objective evidence?	+1	0	0

The Naranjo criteria classify the probability that an adverse event is affiliated to medication therapy depend on a list of weighted interrogations, which demonstrate agents such as the temporal consociation of medication administration and event incidence, optional causes for the event, medication levels, dose response relationships and former patient experience with the medicine. The overall scores range from negative four to positive thirteen; the reaction is thought-out unlikely if the score is nine or greater, likely if five to eight, possible if one to four, and doubtful if zero or lower [10]. (1) Certain (doubtful) causality delineated as if the total score is 0 or lower. When a medical circumstances enclosing laboratory parameters anomaly happens in a presumptive time associated to medication administered to the patients and cannot be described by coincident malady or distinctive medications or pharmaceutical products; administer of the mediation redundantly antecedents a connate response or reaction to discontinuation presumptive (a medicines qualities consequences, and relating to the study of malady). The circumstances definitive are a medicines qualities consequences or relating to phenomenalism (an observational and peculiar related to the treatment of infirmities). Back to an original condition is agreeable, if mandatory [11]. (2) Possible causality delineated as if the total score is 1–4. When a medical circumstances happens with a consequent time resultant to medication uptake, but which could be described by coincident malady or distinctive medication uptake. Circumstances of laboratory parameters anomaly, with consequent time association to medication uptake and described by malady or distinctive medications. Documented data on medication discontinuation is dearth [12]. (3) Probable or likely causality delineated as if the total score is 5–8. When a medical circumstance happens with a well-founded time consequence to medication uptake and is questionably to be owing to every coincident infirmity or disparate medication uptake or circumstance or laboratory parameters anomaly, with well-founded time association to medication uptake. Likely causality also questionably characterized to malady or distinctive medications and reaction to discontinuation medically questionable. Back to an original condition is not compulsory [13]. (4) Unlikely (definitely) causality delineated as if the total score is ≥ 9. When a medical circumstances enclosing laboratory parameters anomaly happens in temporal association to medication uptake that creates a unanticipated association to questionable, and when disparate medications, pharmaceutical products, or fundamental malady furnish presumptive elucidations. Circumstance to laboratory parameters anomaly, with a time to medication that creates an association is not probable (but not unattainable) [14].

Table 2. *The adverse drug interaction is assigned to a probability category from the total score as follows [15].*

Naranjo algorithm probability category	Naranjo score
Definite/Unlikely	If the score is collectedly greater than nine (>9)
Likely/Probable	If the score is collectedly from five to eight (5-8)
Possible	If the score is collectedly from one to four (1-4)
Doubtful/Certain	If the score is collectedly zero or negative (equal to zero or less)

The Naranjo criteria do not take into account drug-drug interactions. Drugs are evaluated individually for causality, and points deducted if another factor may have resulted in the adverse event, thereby weakening the causal association [16].

3. Conclusion

The Naranjo adverse drug reaction likelihood scale was

elaborated to assist standardizes apprehensiveness of causality for entire adverse drug reaction. Certain (doubtful) causality delineated as if the total score is 0 or lower. When a medical circumstances enclosing laboratory parameters anomaly happens in a presumptive time associated to medication administered to the patients and cannot be described by coincident malady or distinctive medications or pharmaceutical products. Possible causality delineated as if the total score is 1–4. When a medical circumstances happens with a consequent time resultant to medication uptake, but which could be described by coincident malady or distinctive medication uptake. Probable or likely causality delineated as if the total score is 5–8. Unlikely (definitely) causality delineated as if the total score is greater than or equal to nine. When a medical circumstances enclosing laboratory parameters anomaly happens in temporal association to medication uptake that creates a unanticipated association to questionable, and when disparate medications, pharmaceutical products. When a medical circumstance happens with a well-founded time consequence to medication uptake and is questionably to be owing to every coincident infirmity or disparate medication uptake or circumstance or laboratory parameters anomaly, with well-founded time association to medication uptake.

Acknowledgements

The author acknowledged those who support him during this manuscript preparation.

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