EVALUATION OF CAUSALITY ALGORITHMS OF ADVERSE DRUG REACTIONS

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Introduction

Determining the causal link between an adverse event and the use of medication is one of the main analysis steps to establish the occurrence of an adverse reaction. There are different analytical tools for the causality of adverse drug reactions (ADRs), the most direct and accessible of which are algorithms, such as those developed by Naranjo and collaborators in 1981 and Karch and Lasagna in 1977. However, there is still no consensus in the scientific literature on which causality method is most effective and reproducible[1,2]. The objective of this work is to evaluate the agreement between the results obtained by applying different ADR causality analysis algorithms in a highly complex hospital unit.

Material and Methods

The selected methodology was applied to reports of adverse drug reactions by different pharmacists. To apply the causal analysis, a concise form was created that brings together two causality methods, allowing a greater number of notifications to be evaluated in less time. All evaluators received theoretical and practical training, in addition to participating in the process of optimizing the data collection tool. The expectation of the result of this work is that it will be possible to list which of the AMR causality analytical tools used will demonstrate greater reproducibility.

Results and Discussion

We collected 51 ADR reports notified to the National Health Surveillance System, referring to the year 2022, which generated 656 causality analyses, with an average time to complete the analysis form of 3 minutes for each case, without considering prior consultations to the literature on medications for each suspected ADR. Among the four classes of causality established as Definite, Probable, Possible and Doubtful/Conditional, the Possible result was the most found by the methods used. The majority of reported adverse reactions (89.3%) had an antimicrobial as the suspected drug, with 30.8% (101) of these being vancomycin. The simple disagreement between the two methods was 89.94% (295), with the majority of analyzes by Karch & Lasagna being unclassifiable (64.63%), contributing to the disagreement. Even without results considered “unclassifiable”, disagreement remains high (71.55%).

Conclusion

The results obtained from the application of two different methods for causality analysis demonstrated variation between the three professional evaluators, corroborating the disagreement between authors in the scientific literature regarding the establishment of a standard method. Although the occurrence of cases not classifiable by the Karch & Lasagna method is a limitation for the study, the number of ADR case analyzes made it possible to compare the methodologies studied. Causal analysis methods based on an algorithm of objective questions allowed the evaluation of each case quickly and dynamically, however, they demonstrated differences in ADR classification when used by different professionals, showing fragility in reproducing this classification. The findings of this work may contribute to the

establishment of a standard causal analysis tool in the future, or even the creation of a method that addresses the causality of adverse reactions in the hospital context with greater reproducibility and effectiveness.

Acknowledgments

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