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REVIEWER'S REPORT

Manuscript No.: IJAR-56549

Title: Pharmacovigilance and patient safety in a Moroccan University hospital,,

Recommendation:

Accept as it is .....

Accept after minor revision.....

Accept after major revision .....YES.....

Do not accept (*Reasons below*) .....

Rating	Excel.	Good	Fair	Poor
Originality		√		
Techn. Quality			√	
Clarity			√	
Significance		√		

Reviewer's ID: JPR-094

Detailed Reviewer's Report

1. Strengths of the Manuscript

1. **Relevant and Important Topic**

The manuscript addresses adverse drug reactions (ADRs) and pharmacovigilance, which are critical components of patient safety and healthcare quality.

2. **Use of Real-World Pharmacovigilance Data**

The study analyzes ADR reports collected from a regional pharmacovigilance center over a **five-year period (2013–2018)**, providing real clinical data.

3. **Comprehensive ADR Assessment**

The authors used multiple causality assessment methods including:

* WHO causality method

* Naranjo scale

* French method

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* Imbs method for avoidability

This strengthens the reliability of ADR evaluation.

4. **Identification of High-Risk Drug Classes**

The study highlights antimicrobials, analgesics/anti-inflammatory drugs, and cardiovascular drugs as the most frequently implicated medications.

5. **Clinical Case Analysis of Fatal ADRs**

The detailed description of fatal ADR cases adds clinical relevance and helps illustrate the real impact of pharmacovigilance.

6. **Contribution to Regional Pharmacovigilance Knowledge**

There is limited published data on pharmacovigilance systems in Morocco; therefore, the study contributes valuable regional information.

2. Weaknesses of the Manuscript

1. **Small Sample Size**

Only **140 ADR cases** were analyzed over five years, which limits statistical power and generalizability.

2. **Retrospective Study Design**

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The retrospective nature may introduce reporting bias and incomplete data.

3. **Underreporting Bias**

The study itself acknowledges severe underreporting of ADRs, which may significantly underestimate the real burden.

4. **Limited Statistical Analysis**

Only **bivariate analysis** was performed. Multivariate analysis could better identify independent risk factors.

5. **Language and Grammar Issues**

The manuscript contains several grammatical errors and formatting issues (e.g., spacing, punctuation, inconsistent percentages).

6. **Formatting Problems**

* Table formatting errors (e.g., *"Table Error! Main Document Only"*).

* Some tables lack clear titles and explanations.

7. **Methodological Clarifications Needed**

* Inclusion and exclusion criteria are not clearly defined.

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* Definition of ADR seriousness criteria could be better explained.

8. **Inconsistent Results Reporting**

Some percentages and numbers appear inconsistent across sections.

3. Significance of the Study

The study is significant because:

* It highlights **underreporting of ADRs in developing pharmacovigilance systems**.

* It demonstrates the **impact of ADRs on morbidity and mortality**.

* It identifies **high-risk drug classes**, which can guide clinicians and pharmacovigilance programs.

* It emphasizes the need for **improved ADR reporting systems and healthcare professional training**.

Overall, the study contributes to **patient safety improvement and pharmacovigilance strengthening in Morocco and similar healthcare settings**.

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4. Key Points of the Study

1. ADR reporting rate was **47 cases per million inhabitants per year**, indicating underreporting.

2. **66.4% of ADRs were classified as serious**.

3. **Mortality rate was 5.7%** among reported ADR cases.

4. **Antimicrobials were the most commonly implicated drugs (31.5%)**.

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5. Skin reactions were the **most frequent ADRs (66.4%)**.

6. **Allopurinol was implicated in several fatal cases**, mainly due to severe cutaneous reactions.

7. Approximately **50% of ADR-related deaths were potentially avoidable**, highlighting the importance of pharmacovigilance.

5. Recommendations for Authors

Major Recommendations

1. **Improve English language and grammar throughout the manuscript.**

2. **Clarify study methodology**, including:

* Inclusion and exclusion criteria

* ADR definition and classification criteria

3. **Perform multivariate statistical analysis** to better identify risk factors.

4. **Correct formatting issues in tables and figures.**

5. **Provide clearer discussion of study limitations.**

Minor Recommendations

1. Revise abstract for clarity and conciseness.

2. Standardize reference formatting according to journal guidelines.

3. Improve figure and table captions.

4. Reduce repetition in the discussion section.

5. Include more recent references on pharmacovigilance.

6. Final Recommendation

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Decision: Major Revision Required

Although the study addresses an important topic and provides valuable pharmacovigilance data, substantial improvements are needed in **language, methodology clarification, statistical analysis, and formatting** before the manuscript can be considered for publication.

Reviewer Justification for Major Revision

Manuscript Title: *Pharmacovigilance and Patient Safety in a Moroccan University Hospital*

Abstract Section

Line 6–8

Issue: Grammatical error and unclear sentence structure.

Justification: The sentence "The aim of this study were to calculate…" contains subject-verb disagreement and lacks clarity regarding study objectives. Scientific manuscripts require precise language.

Line 8–10

Issue: Objectives are not clearly structured.

Justification: Multiple objectives (reporting rate, mortality rate, risk factors, drug classes) are presented in one sentence without clarity. The objectives should be listed clearly and concisely.

Line 13–14

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Issue: Study design description is incomplete.

Justification: The authors mention a retrospective descriptive study but do not specify the study population, setting, or inclusion criteria.

Line 17–22

Issue: Results lack clarity and statistical interpretation.

Justification: Several p-values are presented without explaining the variables compared or the statistical tests used. Confidence intervals are also missing.

Line 26–30

Issue: Conclusion contains speculative statements.

Justification: Statements such as "insufficient knowledge of pharmacovigilance" are not supported by data from the study.

Introduction Section

Line 38–44

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Issue: Language and grammar problems.

Justification: Several sentences lack proper spacing and punctuation, reducing readability and scientific quality.

Line 45–48

Issue: Insufficient referencing for epidemiological claims.

Justification: Statements regarding hospitalization rates and pharmacovigilance development in Morocco require more recent and stronger references.

Line 49–50

Issue: Lack of contextual explanation.

Justification: The creation of the regional pharmacovigilance center in Oujda is mentioned but its relevance to the study design is not sufficiently explained.

Line 53–55

Issue: Research aim repetition.

Justification: The study objectives are repeated and still not clearly structured.

Materials and Methods Section

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Line 57–59

Issue: Study population not clearly defined.

Justification: The manuscript does not specify inclusion or exclusion criteria for ADR reports.

Line 60–64

Issue: Data collection description is vague.

Justification: The authors state that data were entered into two Excel files but do not explain data validation procedures.

Line 63–65

Issue: Causality assessment methods lack justification.

Justification: WHO, Naranjo, and French methods are mentioned without explaining why multiple tools were used.

Line 66–68

Issue: Statistical methods insufficiently described.

Justification: It is unclear whether data normality was assessed before choosing statistical tests.

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Line 69–70

Issue: Limited statistical analysis.

Justification: Only bivariate analysis was performed. Multivariate regression would provide stronger evidence for risk factors.

Line 71–73

Issue: Ethical approval description unclear.

Justification: The manuscript mentions approval from "our institution administration" but does not specify an ethics committee or approval number.

Results Section

Line 76–78

Issue: Formatting errors.

Justification: Table reference appears as "Table1summarizes", indicating formatting problems.

Line 79–84

Issue: Data interpretation unclear.

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Justification: The percentages reported for ADR seriousness and outcomes need clearer explanation and consistent denominators.

Line 85–86

Issue: Table references unclear.

Justification: "Table 2 and 3 (table 2 and 3)" indicates formatting errors.

Line 88–92

Issue: Causality results not adequately explained.

Justification: Reporting percentages without interpretation reduces the scientific value of the results.

Line 95–98

Issue: Drug classification unclear.

Justification: The authors list drug classes but do not explain the classification system used.

Discussion Section

Line 101–107

Issue: Excessive background repetition.

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Justification: The discussion repeats general ADR information already described in the introduction.

Line 108–113

Issue: Methodological limitation not clearly discussed.

Justification: Underreporting is acknowledged but not critically analyzed as a limitation of the study.

Line 124–128

Issue: Comparative discussion insufficient.

Justification: The authors compare reporting rates with other countries but do not discuss differences in healthcare systems.

Line 129–132

Issue: Weak interpretation of statistical findings.

Justification: The authors attribute non-significant results only to sample size without further analysis.

Line 133–156

Issue: Overly descriptive literature review.

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Justification: The discussion includes many unrelated literature examples instead of focusing on the study findings.

Fatal ADR Case Analysis

Line 179–193

Issue: Excessive clinical guideline description.

Justification: The section describing allopurinol prescribing guidelines is too detailed and not directly related to the study objectives.

Line 194–206

Issue: Case descriptions lack methodological integration.

Justification: Individual cases are described but not systematically analyzed.

Tables and Figures

Table Section

Issue: Major formatting error "Table Error! Main Document Only".

Justification: Indicates incorrect manuscript formatting and missing table linkage.

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Table 2 and Table 3

Issue: Statistical results poorly presented.

Justification: Confidence intervals and effect sizes are missing.

Table 4

Issue: Interpretation missing.

Justification: Causality assessment results are listed without explaining clinical relevance.

Table 6

Issue: Table formatting inconsistent.

Justification: Units, drug doses, and clinical descriptions are not standardized.

Conclusion Section

Conclusion Paragraph

Issue: Conclusion partially repeats results.

Justification: A conclusion should synthesize key findings rather than restate data.

Final Statements

Issue: Recommendations are general and not supported by study data.

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Justification: Suggestions such as prospective studies are generic and need clearer justification.

Overall Justification for Major Revision

Major revision is required because:

1. **Significant language and grammar issues** affect readability.

2. **Methodology description is incomplete** (population definition, data validation, ethics approval).

3. **Statistical analysis is limited** and lacks multivariate analysis.

4. **Tables and formatting contain major errors.**

5. **Discussion includes excessive literature review with limited focus on study findings.**

Addressing these issues will substantially improve the **scientific quality, clarity, and reliability** of the manuscript.