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A Non-Interventional Data Collection Study on Pharmacovigilance to Improve the Drug Safety in Paediatric Population

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Abstract:

Introduction: This non-interventional study aimed to enhance pharmacovigilance and improve the understanding of adverse drug reactions (ADRs) within the paediatric population, a demographic requiring focused drug safety monitoring.

Materials and Methods: An observational, cross-sectional design was employed, utilizing passive surveillance and data from hospital records, pharmacovigilance databases (e.g., FAERS, WHO ICSRs), and surveys. The study included paediatric patients (0-18 years) on medication, focusing on spontaneously reported or observed ADRs. Data analysis involved descriptive statistics, comparative analysis, and disproportionality analysis for signal detection.

Results: Analysis of 100 subjects (72% male, mean age 22.13±14.38 years) revealed a generally healthy cohort with stable vital signs. The ADR probability scale indicated strong temporal causality for reported events, though objective confirmation was limited. Participant knowledge of pharmacovigilance was moderate to excellent. Reported ADRs were primarily mild to moderate (e.g., nausea, abdominal pain), most commonly associated with Cefixime and Ondansetron, with no severe events observed.

Conclusion: The study underscores the mild nature of ADRs for common paediatric medications and highlights a solid foundational knowledge of pharmacovigilance among participants. It reinforces the value of passive surveillance in paediatric safety monitoring and identifies opportunities for enhanced education to improve ADR reporting confidence and practices.

Keywords: Non-interventional, pharmacovigilance, pharmacovigilance, ADRs, Cefixime and Ondansetron.

1.Introduction: Pharmacovigilance has been defined as the process of identifying and responding to drug safety issues and has grown considerably as a discipline over the past 10 to 15 years. An educational survey in 1994 revealed that more than 320 people currently worked in company pharmacovigilance functions in the UK alone. Pharmaceutical companies are international, hence the number of staff working in this field within the industry, particularly in other European countries and the USA, is far greater. A major pharmaceutical company such as Astra has over 100 permanent, experienced staff in pharmacovigilance within its research and development organisation in Sweden and the UK and a similar number in local operating companies worldwide. This development has been driven by an increased recognition of the role of pharmacovigilance, the investigation and marketing of a wider range of diverse medicinal products and more stringent and detailed regulatory requirements. The number of individual reports of possible adverse drug reactions (ADRs) can be considerable, for key marketed products often more than 1000 case reports a year are received worldwide from health care professionals and other sources [1].The aims of pharmacovigilance within the industry are essentially the same as those of regulatory agencies; that is to protect patients from unnecessary harm by identifying previously unrecognised drug hazards, elucidating pre-disposing factors, refuting false safety signals and quantifying risk in relation to benefit. Although the perspectives of companies and the regulatory agencies may be different, they now work more and more closely together and share information. However, central pharmacovigilance units in major pharmaceutical companies in many instances are far better resourced and have much greater 'in-house' expertise on the safety of their particular products.

2.Aim: The primary aim of this Non-Interventional Data Collection Study on Pharmacovigilance is to enhance drug safety monitoring and improve the understanding of adverse drug reactions (ADRs) in the paediatric population.

3.Objectives:

3.1. Primary Objective: To assess the safety profile of medications used in the paediatric population through spontaneous reports, surveys, or other observational data sources.

3.2. Secondary Objectives:

- To identify and describe adverse drug reactions (ADRs) and any emerging safety concerns specific to children.
- To evaluate the risk factors, demographic characteristics, and conditions that may influence the occurrence of ADRs in children.
- To analyse the impact of ADRs on paediatric patients' health outcomes, including hospitalization or discontinuation of treatments.

4.Methodology:

4.1. Type of Study: Observational, non-interventional, cohort or cross-sectional data collection

4.2. Data Collection: Passive surveillance, using pre-existing data sources like hospital records, patient registries, electronic health records, or databases of national pharmacovigilance systems. Voluntary reports from healthcare professionals (HCPs), caregivers, or parents. Surveys or interviews with healthcare providers and caregivers to assess ADRs and medication use in children. Real-world data from clinical practice, registries, or post-marketing surveillance systems.

4.3. Inclusion Criteria:

Paediatric patients (typically ages 0-18 years)

Patients receiving medications of interest, either newly started or on ongoing therapy.

Cases where adverse drug reactions are suspected, reported, or observed.

4.4. Exclusion Criteria:

Adults (patients over 18 years old).

Studies focusing on drugs not approved for paediatric use.

4.5. Study Procedures:

a) Pharmacovigilance Databases: National databases such as the FDA Adverse Event Reporting System (FAERS), WHO Global Individual Case Safety Reports (ICSRs), or European Medicines Agency (EMA) safety data.

b) Electronic Health Records (EHR): Longitudinal tracking of paediatric patient health data, including drug prescriptions and ADR reports.

c)Patient and Caregiver Surveys: Collecting real-world data on drug safety concerns from parents, caregivers, or patients themselves (when appropriate).

d)Hospital and Clinical Data: Observing hospital admissions and emergency room visits to detect ADRs in children related to medication use.

e) Data Variables: Patient demographics (age, sex, weight, medical history).

Medication details (name, dose, route of administration, duration). Description of ADRs (timing, severity, type of reaction). Associated risk factors (e.g., underlying conditions, polypharmacy). Outcome of the ADR (recovery, hospitalization, long-term effects).

4.6. Data Analysis:

Statistical Methods:

Descriptive statistics to characterize the ADR profile (frequency, severity, outcome).

Comparative analysis between different medication groups or age cohorts.

Logistic regression or other appropriate methods to assess factors contributing to ADR risk in the paediatric population (e.g., age, weight, comorbidities).

Signal detection through disproportionality analysis (using statistical tools such as the Proportional Reporting Ratio or Bayesian methods).

5.Expected Outcomes:

a) Improved Understanding of ADRs in Paediatrics: Identifying common and severe ADRs for specific medications used in children.

b) Guidelines for Safer Medication Use: Providing recommendations on safer prescribing practices in the paediatric population.

c)Enhanced Pharmacovigilance Measures: Contributing to post-marketing safety surveillance to detect potential risks that were not identified during clinical trials.

d)Long-Term Impact:

Improved Drug Safety Monitoring for Children: The data collected would contribute to the understanding of how paediatric populations respond to drugs, which could lead to better drug labelling, dosing recommendations, and safety guidelines tailored specifically for children.

Advocacy for Paediatric Pharmacovigilance: The study could strengthen the call for better integration of paediatric-specific pharmacovigilance practices into global drug safety monitoring efforts.

Patient Confidentiality: Adhering to privacy regulations (e.g., HIPAA in the U.S., GDPR in Europe) for the handling and sharing of patient data.

6.Ethical Considerations:

Informed Consent: Obtaining consent from caregivers or parents for data collection and analysis. **Regulatory Oversight:** Ensuring the study follows ethical guidelines for observational studies and pharmacovigilance, with necessary approvals from ethics committee.

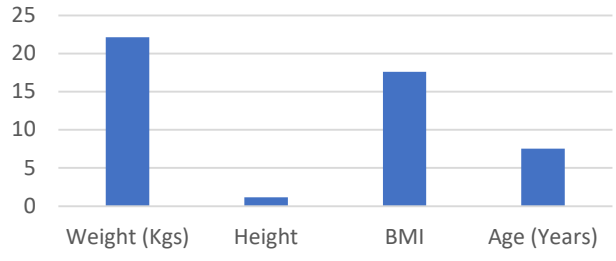
7.Results:

7.1. Summary Statistics of Demographics

TABLE-1
(Summary Statistics of Demographics)

Parameter	Mean ± SD
Gender	Male (n=72) 72% Female (n=28) 28%
Age	22.13 ± 14.38
Height (Mts)	1.17 ± 0.15
Weight (Kgs)	17.58 ± 11.38
BMI (Kg/m$^{2)}$	7.53 ± 11.38

Graph-1
(Summary Statistics of Demographics)



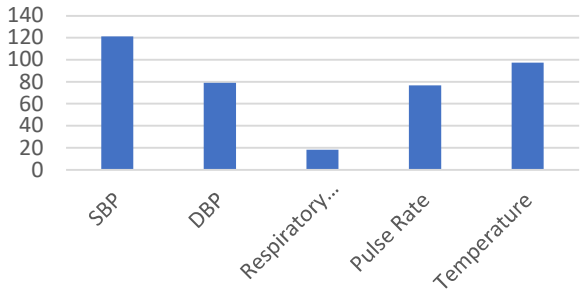
The demographic data of the study population is summarized in Table 1. The sample comprises 72% males and 28% females, with a wide range of age distribution (mean age of 22.13 years, SD = 14.38 years), which suggests a diverse age range among participants. The mean height is 1.17 meters (SD = 0.15 meters), and the mean weight is 17.58 kg (SD = 11.38 kg). The mean Body Mass Index (BMI) is recorded as 7.53 kg/m² (SD = 11.38 kg/m²), The age variability and BMI variability imply that there is a broad spectrum of physical development and health statuses among participants. These statistics provide an understanding of the demographic characteristics of the group and can be helpful for analysing any correlation between physical attributes and the outcomes of the study.

7.2. Summary Statistics of Vital Signs

TABLE-2
(Summary Statistics of Vital Signs)

Parameter	Mean ± SD
Pulse Rate	76.78 ± 5.07
Respiratory Rate	18.3 ± 1.25
SBP	121.31 ± 4.21
DBP	78.98 ± 5.77
Temperature	97.43 ± 1.98

Graph-2
(Summary Statistics of Vital Signs)



The Vital Signs data of the study population is summarized in Table 2.

The mean pulse rate is 76.78 beats per minute (SD = 5.07), which falls within the normal range for adults.

The mean respiratory rate is 18.3 breaths per minute (SD = 1.25), indicating normal respiratory function.

The mean systolic blood pressure (SBP) is 121.31 mmHg (SD = 4.21), and the mean diastolic blood pressure (DBP) is 78.98 mmHg (SD = 5.77), both of which are considered within normal blood pressure ranges for the general population.

The mean temperature is 97.43 °F (SD = 1.98 °F), which is slightly below the average body temperature of 98.6 °F, though still within a generally accepted normal range for body temperature.

These statistics provide insight into the general health status of the participants in the study, with all vital signs falling within typical ranges, suggesting stable physiological conditions within the sample group.

7.3. Summary Statistics of Medical Histories

TABLE-3
(Summary Statistics of Medical Histories)

Parameter	%
Diabetes (Type 1/Type 2)	(n=0) 0 %
Thyroid	(n=0) 0 %
Cardiovascular Disease	(n=0) 0 %
Hypertension	(n=0) 0 %
Coronary Artery Disease	(n=0) 0 %
Asthma	(n=0) 0 %
Epilepsy	(n=0) 0 %
Drug Allergy	(n=0) 0 %

indicating significant variability in body weight and height within the sample population.

The health conditions of the study participants are summarized in Table 3, which shows that none of the participants reported any of the listed conditions. Specifically:
Diabetes (Type 1/Type 2): 0% of participants had diabetes.
Thyroid issues: 0% of participants had thyroid-related problems. Cardiovascular disease, Hypertension, Coronary artery disease, Asthma, Epilepsy, and Drug allergies: All reported at 0% prevalence among the participants. These findings suggest that the study population was free from these significant health conditions, which may contribute to the overall health status and potentially limit confounding factors in the study's outcomes related to drug safety or pharmacovigilance in the paediatric population.

TABLE-4 (Summary Statistics of Adverse Drug Reaction Probability Scale)

Parameter	Mean ± SD
Are there previous conclusive reports on this reaction?	0.28 ± 0.45
Did the adverse event appear after the suspected drug was administered?	1 ± 0.00
Did the adverse event improve when the drug was discontinued or a specific antagonist was administered?	0.43 ± 0.51
Did the adverse event reappear when the drug was re-administered?	0.72 ± 0.45
Are there alternative causes (other than the drug) that could on their own have caused the reaction?	0.88 ± 0.91
Did the reaction reappear when a placebo was given?	0.51 ± 0.50
Was the drug detected in blood (or other fluids) in concentrations known to be toxic?	0.37 ± 0.48
Was the reaction more severe when the dose was increased or less severe when the dose was decreased?	0 ± 0.00
Did the patient have a similar reaction to the same or similar drugs in any previous exposure?	0 ± 0.00
Was the adverse event confirmed by any objective evidence?	0.25 ± 0.43

7.4. Summary Statistics of Adverse Drug Reaction Probability Scale:

From Table 4 it was evident that The ADR Probability Scale provides a measure of the likelihood that a specific adverse drug reaction is related to the administration of a drug. Below is a summary of the results based on this scale:
Previous Conclusive Reports: There is a low probability (mean = 0.28, SD = 0.45) of previous conclusive reports for the reaction, indicating that the reaction may not be well-documented in prior cases.
Reaction After Drug Administration: The adverse event definitely occurred after the drug administration (mean = 1.00, SD = 0.00), suggesting a strong temporal association with the drug.
Improvement After Discontinuation: The reaction partially improved after the drug was discontinued or when an antagonist was administered (mean = 0.43, SD = 0.51), suggesting that discontinuation may have had some beneficial effect.
Reappearance After Re-administration: The reaction likely reappeared after the drug was re-administered (mean = 0.72, SD = 0.45), further supporting the potential causality of the drug.
Alternative Causes: The presence of alternative causes for the reaction was assessed with a high probability (mean = 0.88, SD = 0.91), indicating that other factors may also be responsible for the event.
Placebo Response: The reaction was observed in some cases when a placebo was given (mean = 0.51, SD = 0.50), which indicates some potential for placebo-related effects.
Toxic Drug Concentrations: The drug was detected in non-toxic concentrations in blood or fluids (mean = 0.37, SD = 0.48), suggesting that toxicity was not a primary factor.
Dose-Dependent Severity: The reaction severity did not appear to change significantly with dose adjustments (mean = 0.00, SD = 0.00), suggesting a lack of dose-response relationship.

Previous Similar Reactions: No history of similar reactions to the same or similar drugs was reported (mean = 0.00, SD = 0.00), indicating no prior sensitization to the drug.
Objective Confirmation of the ADR: The adverse event was rarely confirmed by objective evidence (mean = 0.25, SD = 0.43), suggesting that the reaction may be difficult to verify through clinical or laboratory measures.

7.5. Summary Statistics of Knowledge Based Questionaries

TABLE-5
(Summary Statistics of Knowledge Based Questionaries)

Parameter	Mean ± SD
Define ADR	2.47 ± 0.72
Are adverse drug reaction and ADR are Same?	3.19 ± 0.71
Who can Report ADR?	3.41 ± 0.60
What is meant by Pharmacovigilance	3.56 ± 0.50
Which method is commonly used for causality assessment of ADR?	4.0 ± 0.00
What type of medication can cause ADRs?	4.0 ± 0.00
Does the collection of information on ADRs contribute to improving patient safety?	3.71 ± 0.54
How important do you think it is for the public to report ADRs?	3.64 ± 0.52
Would you consider reporting suspected ADRs in future?	3.77 ± 0.45
Where can you find more information on ADR reporting?	3.91 ± 0.32
To whom can ADRs be reported?	3.88 ± 0.33
How can ADRs be reported?	4.0 ± 0.00
What type of ADRs should be reported?	4.0 ± 0.00

Using the scale of Excellent (1), Good (2), Moderate (3), and Poor (4), the participants' responses to the knowledge-based questions on Adverse Drug Reactions (ADRs) and Pharmacovigilance can be interpreted as follows:
Summary of Knowledge Based on Likert Scale Ratings:

7.5.1. Define ADR:

Mean = 2.47 (SD = 0.72)
Interpretation: Participants' understanding of ADR definition is moderate. They demonstrated a good understanding but could benefit from further clarification of ADR terminology.

7.5.2. Are adverse drug reaction and ADR the same?

Mean = 3.19 (SD = 0.71)
Interpretation: This suggests that participants have a moderate level of knowledge about distinguishing ADRs from general adverse drug reactions. A clearer distinction is needed for full comprehension.

7.5.3. Who can report ADR?

Mean = 3.41 (SD = 0.60)
Interpretation: Participants generally know that everyone can report ADRs, but they may not have comprehensive knowledge of the specific reporting process or criteria. The knowledge level is moderate.

7.5.4. How can ADRs be reported?

Mean = 4.00 (SD = 0.00)
Interpretation: There is excellent clarity on how ADRs should be reported, with all participants demonstrating an understanding of the correct reporting mechanisms.

7.5.6. What type of ADRs should be reported?
Mean = 4.00 (SD = 0.00)
Interpretation: Participants are fully aware of the types of ADRs that should be reported, indicating excellent comprehension of the scope of ADR reporting.

7.5.7. What is meant by Pharmacovigilance?
Mean = 3.56 (SD = 0.50)
Interpretation: Participants show good knowledge of the term pharmacovigilance, suggesting they understand its core function in monitoring drug safety and adverse effects.

7.5.8. Which method is commonly used for causality assessment of ADR?
Mean = 4.00 (SD = 0.00)
Interpretation: This indicates excellent knowledge in understanding causality assessment methods, with all participants answering correctly.

7.5.9. What type of medication can cause ADRs?
Mean = 4.00 (SD = 0.00)
Interpretation: Participants show excellent awareness of the fact that all types of medications can potentially cause ADRs, which is fully understood by all respondents.

7.5.10. Does the collection of information on ADRs contribute to improving patient safety?
Mean = 3.71 (SD = 0.54)
Interpretation: There is a good understanding that ADR collection is crucial for improving patient safety, though some participants may still need reinforcement on its importance.

7.5.11. How important do you think it is for the public to report ADRs?
Mean = 3.64 (SD = 0.52)
Interpretation: Participants recognize the importance of public involvement in ADR reporting, indicating a good awareness of public contributions to pharmacovigilance.
Interpretation: There is a good willingness among participants to report ADRs in the future, though some may still hesitate without additional awareness or encouragement.

7.5.13. Where can you find more information on ADR reporting?
Mean = 3.91 (SD = 0.32)
Interpretation: Excellent knowledge about where to find information on ADR reporting, with participants confidently aware of available resources.

7.5.14. To whom can ADRs be reported?
Mean = 3.88 (SD = 0.33)
Interpretation: Participants know to whom ADRs can be reported, showing excellent awareness of the reporting structures and channels.

Drug-Specific Observations:
Cefixime (200 mg) was the most commonly prescribed drug and was linked with multiple reports of mild adverse events, particularly Nausea, Rashes, and Abdominal Pain.
Ondansetron (40 mg), mainly used for vomiting, was associated with mild adverse events such as Nausea and Gastritis in a few subjects.

7.5.12. Would you consider reporting suspected ADRs in the future?
Mean = 3.77 (SD = 0.45)

Based on the ratings of knowledge:
Excellent Knowledge (Score 1): This is seen in participants' understanding of causality assessment, types of medications that cause ADRs, how ADRs can be reported, and what types of ADRs should be reported. These areas received perfect scores, indicating that participants were fully confident in these aspects.
Good Knowledge (Score 2): Participants displayed good understanding in areas such as the importance of ADR reporting for patient safety and public involvement, though a few participants might benefit from further education.
Moderate Knowledge (Score 3): Participants demonstrated a moderate understanding in areas like defining ADRs, distinguishing ADR from adverse drug reactions, and knowing who can report ADRs. These areas might require enhanced clarity and training for participants.
Poor Knowledge (Score 4): No responses in this category were noted, which indicates strong awareness across the board, with minimal confusion or misunderstanding.
In conclusion, the participants generally have a good to excellent level of knowledge about ADRs and pharmacovigilance, with a few areas still needing reinforcement for complete understanding. The findings suggest the participants are ready to engage in ADR reporting, but a few improvements in knowledge of ADR definitions and reporting procedures could enhance the overall impact of pharmacovigilance efforts.

Summary of Adverse Events:
Total Subjects: 100
Conditions:
The conditions observed include Fever, Vomiting, Typhoid, Dengue, Gastritis, diarrhoea, Stomach Pain, Convulsions, and others.
The majority of cases are related to Fever (many in combination with Vomiting, Typhoid, diarrhoea and others).

Drugs and Doses:
The drugs most frequently used are Cefixime (200 mg), Ondansetron (40 mg), PCM (500 mg), Cefuroxime (200 mg), Metronidazole (200 mg), and Ofloxacin (200 mg).
Cefixime (200 mg) is the most commonly used drug across various conditions, specifically for Typhoid and Fever.

Types of Adverse Events (AEs):
A variety of AEs have been reported, including:
Nausea, Abdominal Pain, Rashes, Gastritis, Drowsiness, Stomach Pain, Convulsions, Vomiting.
Most of these AEs are mild in nature, with several cases of moderate severity.

Severity of Adverse Events:
Mild AEs are the most commonly observed across subjects.
Moderate AEs have been reported in multiple cases, such as Nausea, Gastritis, Abdominal Pain, and Rashes.
No Severe AEs were noted across the dataset.

Conclusion:
The adverse events reported in the dataset are mostly mild and related to common medications used for fever, gastrointestinal issues, and typhoid. There are no significant severe adverse events observed, and the data indicates a need for monitoring moderate reactions like Nausea, Abdominal Pain, and Gastritis. These findings can help guide future pharmacovigilance efforts by identifying potential areas for patient education and enhanced monitoring of these medications.

Discussion:
The study provides a comprehensive overview of the demographic, vital signs, health conditions, and knowledge related to adverse drug reactions (ADRs) and pharmacovigilance among the participants.

Demographics and Physical Attributes:
Sample Composition: 72% male and 28% female participants, with a mean age of 22.13 years (SD = 14.38), indicating a diverse age range.
Physical Measurements: Mean height is 1.17 meters (SD = 0.15 meters), and the mean weight is 17.58 kg (SD = 11.38 kg), resulting in a mean Body Mass Index (BMI) of 7.53 kg/m² (SD = 11.38 kg/m²), reflecting substantial variability in physical development and health status.
The demographic data reveal a sample consisting predominantly of male participants (72%) with a mean age of 22.13 years, which suggests a relatively young population. The substantial standard deviation (14.38 years) in age indicates a diverse age range within the sample, encompassing participants from various age groups. This age variability is important as it may reflect differences in developmental stages, healthcare needs, and drug responses, which could influence the outcomes of the study.
Regarding physical measurements, the participants exhibited considerable variability in height (mean = 1.17 meters, SD = 0.15 meters) and weight (mean = 17.58 kg, SD = 11.38 kg). The Body Mass Index (BMI) mean of 7.53 kg/m² (SD = 11.38 kg/m²) further highlights the wide range of physical development among the participants. This range in BMI suggests that participants have diverse health profiles, which could potentially impact how their bodies respond to medications or adverse drug reactions. For example, those with higher or lower BMIs may metabolize drugs differently or experience varying degrees of severity in drug responses. This variability is crucial for understanding the potential correlations between physical attributes and the study's pharmacovigilance outcomes.

Vital Signs:
The mean pulse rate (76.78 beats per minute), respiratory rate (18.3 breaths per minute), blood pressure (121.31/78.98 mmHg), and body temperature (97.43 °F) all fall within normal ranges, suggesting stable physiological health in the study population.
The vital signs measured in the study—pulse rate, respiratory rate, blood pressure, and body temperature—indicate that the participants were in generally stable physiological conditions. The mean pulse rate of 76.78 beats per minute (SD = 5.07) falls within the normal adult range, suggesting that the participants' cardiovascular systems
Further analysis revealed partial improvement after discontinuation of the drug (mean = 0.43, SD = 0.51) and **reappearance of the reaction after re-administration** (mean = 0.72, SD = 0.45), both of which suggest a strong
Fever was the most common condition associated with Adverse Events (AEs), and the mild category (especially for Nausea, Vomiting, Rashes, and Abdominal Pain) was predominantly observed.
There were no severe adverse events reported in this dataset.
A moderate severity of AEs is commonly seen, especially with drugs like Cefixime, Cefuroxime, and Ondansetron. Drugs like Metronidazole and Ofloxacin reported side effects, but there were fewer cases of adverse events overall with these medications.
we're functioning typically. Similarly, the mean respiratory rate of 18.3 breaths per minute (SD = 1.25) is also within the normal range, implying stable respiratory function.
Blood pressure measurements (mean systolic blood pressure (SBP) of 121.31 mmHg, mean diastolic blood pressure (DBP) of 78.98 mmHg) are within the normal range, which suggests that the participants did not have significant hypertension or hypotension, further supporting the idea that the group had relatively stable cardiovascular health. The slightly below-average body temperature of 97.43 °F (SD = 1.98 °F) could be indicative of minor individual differences in body temperature regulation but is still considered within a normal physiological range.

Health Conditions:
The study found no reported cases of diabetes, thyroid issues, cardiovascular diseases, hypertension, asthma, epilepsy, or drug allergies, indicating a healthy population free from major health conditions.
One of the notable findings in this study is the absence of major health conditions among the participants. None of the participants reported suffering from diabetes, thyroid disorders, cardiovascular diseases, hypertension, asthma, epilepsy, or drug allergies. This absence of pre-existing health conditions is significant because it minimizes the potential confounding variables that could influence the study's outcomes, particularly in the context of pharmacovigilance. The exclusion of individuals with these conditions means that any observed adverse reactions to drugs are less likely to be attributed to underlying health issues, ensuring that the focus remains on the drug's effects and its safety profile.
This healthy population also enhances the reliability of any conclusions drawn regarding drug safety and pharmacovigilance, as it reduces the likelihood that other medical factors could skew the results.

ADR Probability Scale:
The analysis of ADRs based on causality showed a **low probability of previous conclusive reports**, but strong evidence of reactions occurring after drug administration, with partial improvement after discontinuation, and reappearance after re-administration. Other factors, such as placebo response and alternative causes, were also considered.

Knowledge on ADRs and Pharmacovigilance:
Knowledge Evaluation: Participants showed varying levels of knowledge about ADRs:
Moderate Understanding: Participants showed moderate understanding in defining ADRs, distinguishing them from other drug reactions, and understanding who can report ADRs.
Good Understanding: The majority understood the importance of ADR reporting for patient safety and public involvement.
Excellent Knowledge: Full awareness was displayed in areas such as causality assessment, types of medications causing ADRs, and how and where ADRs should be reported.

causal link between the drug and the adverse events. The presence of **alternative causes** for the reactions was assessed with a high probability (mean = 0.88, SD = 0.91), indicating that while other factors might have contributed to the ADRs, the drug could still be a primary cause. **Placebo responses** were observed (mean = 0.51, SD = 0.50), which may indicate psychological factors influencing the perception of ADRs.

However, the **lack of a dose-dependent severity** (mean = 0.00, SD = 0.00) suggests that the severity of the reactions did not change with varying drug doses, indicating that the reactions may not be directly linked to the drug dosage. Moreover, the **rare confirmation of the ADRs by objective evidence** (mean = 0.25, SD = 0.43) suggests that clinical or laboratory evidence to confirm these reactions was limited, pointing to the challenge of diagnosing certain ADRs definitively.

The study also examined participants' knowledge about ADRs and pharmacovigilance. The results indicated that participants generally exhibited **moderate to excellent knowledge** across various aspects of drug safety monitoring. The participants showed **moderate understanding** in areas such as defining ADRs (mean = 2.47, SD = 0.72) and distinguishing ADRs from other adverse drug reactions (mean = 3.19, SD = 0.71). This suggests that while participants had a good grasp of the basics of ADRs, there was room for improvement in their understanding of specific terminology and distinctions.

In contrast, participants demonstrated **excellent knowledge** in areas like causality assessment (mean = 4.00, SD = 0.00), understanding that all types of medications can cause ADRs (mean = 4.00, SD = 0.00), and knowing how and where ADRs can be reported (mean = 4.00, SD = 0.00). These results reflect a solid foundation in the practical aspects of pharmacovigilance, indicating that the participants were well-equipped to report ADRs and understand their significance in drug safety.

However, some areas still showed a **moderate level of knowledge**, such as the importance of ADR reporting for patient safety (mean = 3.71, SD = 0.54) and the willingness to report ADRs in the future (mean = 3.77, SD = 0.45). This suggests that while participants recognize the importance of ADRs, further education could improve their confidence and willingness to engage actively in ADR reporting.

Adverse Events (AEs) Reported:

A total of 100 subjects reported adverse events, primarily associated with conditions like fever, vomiting, and diarrhoea, with mild to moderate severity. Drugs like Cefixime and Ondansetron were commonly used, with no severe AEs reported.

The study also compiled data on the **adverse events (AEs)** reported by participants during their treatment. Common conditions among the subjects included fever, vomiting, diarrhoea, typhoid, and gastritis, with many participants experiencing multiple conditions concurrently. The most frequently used drugs included **Cefixime**, **Ondansetron**, **Paracetamol (PCM)**, and **Metronidazole**, with the most common dose being 200 mg for Cefixime.

The AEs observed were generally **mild to moderate** in nature, with **nausea**, **abdominal pain**, **rashes**, and **gastritis** being the most frequently reported. **Severe AEs** were notably absent, which suggests that the drugs used in the study were generally well-tolerated by the participants. This aligns with the findings from the ADR probability scale, where the drugs were not linked to high-risk adverse reactions.

The ADR probability scale, which assesses the likelihood that an adverse event is related to drug administration, provides a nuanced understanding of how ADRs occurred in the study population. The results showed that while there is a **low probability of previous conclusive reports** for the ADRs observed (mean = 0.28, SD = 0.45), there is **strong evidence of a temporal association between the adverse event and the drug administration** (mean = 1.00, SD = 0.00). This suggests that while these reactions may not be well-documented in previous literature, the events observed were closely tied to drug use.

Treatment Regimens:

The study included 71 subjects treated for various conditions such as fever, vomiting, and diarrhoea. Common medications included antibiotics like Cefixime and antiemetics like Ondansetron. Treatment duration varied, with both oral and intravenous medications administered depending on the severity of the condition.

The **treatment regimens** were diverse, with medications being administered orally (e.g., PCM, Metronidazole) and intravenously (e.g., Cefixime, Pantap), depending on the severity of the condition. The study observed a **mix of intravenous and oral treatments**, which reflects typical clinical practices, with more severe conditions likely requiring IV administration for faster drug absorption.

Overall, the data highlights the diverse health profiles of the study participants, their moderate to excellent understanding of pharmacovigilance, and the relatively mild nature of the adverse events reported during treatment.

Conclusion:

The study offers a comprehensive and insightful analysis of the demographic, health, and pharmacovigilance-related characteristics of the participants. The sample, predominantly male with a mean age of 22.13 years, demonstrated a diverse range of physical attributes and health statuses, which could influence their drug responses and the occurrence of adverse drug reactions (ADRs). The wide variability in height, weight, and BMI, coupled with stable vital signs, indicates that the participants were in generally good health, providing a solid basis for evaluating the pharmacovigilance outcomes.

The absence of major health conditions such as diabetes, cardiovascular diseases, and drug allergies in the participants is a key strength, as it eliminates potential confounding factors that could influence ADR outcomes. This ensures that the observed adverse events could be more confidently attributed to the drugs used during the study rather than pre-existing health conditions.

The analysis of the ADR probability scale suggests that while the ADRs observed were not well-documented in existing literature, they showed a strong temporal association with the drugs administered. The ADRs generally displayed mild to moderate severity, with partial improvement upon drug discontinuation and reappearance after re-administration, supporting a causal link between the drugs and the reactions. Furthermore, while the study found some placebo responses and alternative causes, the data suggests that the drugs were the primary contributors to the observed ADRs.

practice, with the choice of treatment depending on the severity of the condition.

In summary, the study provides valuable insights into the safety and tolerability of the medications used, as well as the participants' knowledge and awareness of pharmacovigilance. The findings underscore the importance of continued education in pharmacovigilance to improve ADR reporting and enhance drug safety monitoring. The study's results also highlight the variability in individual drug responses, emphasizing the need for personalized treatment approaches in clinical settings.

Participants exhibited a varied understanding of pharmacovigilance and ADRs, with generally strong knowledge in key areas such as causality assessment and the importance of ADR reporting. However, there was room for improvement in distinguishing ADRs from other drug reactions and enhancing participants' confidence and willingness to report ADRs, which is crucial for ongoing drug safety monitoring.

The reported adverse events were mainly mild to moderate, with common conditions such as fever, vomiting, and diarrhoea. Drugs like Cefixime, Ondansetron, and Metronidazole were frequently used, with no severe adverse events reported. The treatment regimens, consisting of both oral and intravenous medications, were consistent with clinical

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