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# Clinical Outcomes Among Patients Hospitalized Following Suspected Exposure to Substandard and Falsified Medicines in a Regional Hospital in Mali: A Retrospective Study

**Kadidiatou Diarra[1,2]*, Abdoulaye Kissima Traoré[3], Ousmane Haidara[3]**

[1]Department of Preventive Medicine and Public Health, Faculty of Medicine, Pharmacy, and Dentistry, Cheikh Anta Diop University, Senegal

[2]Institute of Health and Development (ISED), Cheikh Anta Diop University, Senegal

[3]Department of Cardiology, Sikasso Regional Hospital, Mali

**Research Article**

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***Corresponding author:** Dr. Kadidiatou Diarra, Department of Preventive Medicine and Public Health, Faculty of Medicine, Pharmacy, and Dentistry, and Institute of Health and Development (ISED), Cheikh Anta Diop University, Dakar, Senegal; ORCID: https://orcid.org/0009-0001-3651-0462

## Abstract

Background: Substandard and falsified (SF) medicines remain a major public health concern in West Africa, yet their clinical consequences are poorly documented. This study described clinical outcomes following suspected exposure to SF medicines and identified factors associated with unfavorable outcomes.

**Materials and Methods:** A retrospective descriptive and analytical study was conducted at Sikasso Regional Hospital, Mali, using medical records from November 2022 to October 2023. Medical records of all patients admitted with suspected exposure to SF medicines were included (n=36). Sociodemographic, clinical, and biological data were extracted. Multiple correspondence analysis (MCA) and bivariate and multivariable logistic regression were performed using R 4.4.2.

**Results:** Among the 36 patients represented in the included records, mean age was 41.6±15 years and 66.7% were male. Unfavourable clinical outcomes occurred in 69.4%. MCA showed that favorable outcomes clustered with younger age, cardiorespiratory conditions, and urban residence. Age ≥45 years was independently associated with unfavorable outcomes (aOR=6.7; 95% CI: 1.2–38.1; p=0.02).

**Conclusion:** Unfavorable clinical outcomes were frequent among patients with suspected exposure to SF medicines, particularly those aged ≥45 years. Strengthening pharmaceutical regulation and public awareness may help reduce associated health risks.

**Keywords:** Substandard and Falsified Medicines; Clinical Outcomes; Pharmacovigilance; Mali; West Africa

## Abbreviations

SF: Substandard and Falsified; MCA: Multiple Correspondence Analysis; WHO: World Health Organization; EG/DEG: Ethylene Glycol or Diethylene Glycol; STROBE: Strengthening the Reporting of Observational Studies in Epidemiology.

## Background

The circulation and use of substandard and falsified (SF) medicines represent a major public health challenge, particularly in West Africa. According to the World Health Organization (WHO), at least one in ten medical products circulating in low- and middle-income countries is either substandard or falsified, resulting in serious clinical consequences, including treatment failure, toxicity, and death, as well as a substantial economic burden on health systems [1]. In Africa, a recent meta-analysis estimated that approximately 22.6% of tested medical products were substandard or falsified. The highest prevalence was reported in informal distribution channels and among widely used medicines, particularly antibiotics, antimalarials, and antihypertensive drugs [2]. The direct health consequences include preventable illness and death, the emergence of antimicrobial resistance, and reduced public confidence in healthcare systems [3]. Recent incidents highlight the severity of this threat. In 2022, pediatric syrups contaminated with ethylene glycol and diethylene glycol were linked to acute kidney injury and deaths among children in The Gambia, prompting global health alerts [4-6].

Several studies have documented the health risks associated with SF medicines, including treatment failure, antimicrobial resistance, and a range of adverse effects such as cardiovascular complications and kidney toxicity related to ethylene glycol or diethylene glycol (EG/DEG) contamination [3,7]. However, evidence on the clinical outcomes of patients exposed to these products in hospital settings remains limited, particularly in West Africa. This study aimed to describe the clinical outcomes of patients hospitalized in Sikasso with suspected exposure to SF medicines and to identify factors associated with unfavorable clinical outcomes.

## Materials and Methods

### Design and Study Setting

The study was conducted at Sikasso Regional Hospital, the main public referral hospital serving the Sikasso region in southeastern Mali. The hospital provides a wide range of services, including diagnosis and treatment, emergency care, patient referral and transfer services, as well as training and research activities [8]. The hospital includes 15 departments, has a capacity of approximately 163 beds, and is staffed by a multidisciplinary team of around 253 healthcare and support personnel [8,9].

A retrospective study was conducted using data collected between November 2022 and October 2023. The study was designed and reported in accordance with international recommendations for observational studies, including the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.

### Study Population

The study population consisted of hospital records from Sikasso Regional Hospital covering the period from November 2022 to October 2023. All records documenting suspected exposure to at least one substandard or falsified medicine were considered for inclusion. An exhaustive sampling approach was used.

### Inclusion Criteria

Hospital records were eligible when suspected exposure to a potentially substandard or falsified medicine was documented based on at least one pharmaceutical criterion, including lack of marketing authorization, suspicious or non-compliant packaging, uncertain origin, or purchase through an informal market. Records containing the clinical and biological information required to assess the study outcomes were included.

### Assessment of Suspected SF Medicine Exposure

Suspected exposure to SF medicines was identified based on information documented in hospital records, including pharmaceutical characteristics such as lack of marketing authorization, suspicious or non-compliant packaging, uncertain origin, or purchase through an informal market. When available, information from the assessment of the suspected medicine was also recorded. The temporal relationship between reported medicine exposure and the onset of clinical manifestations was documented. These manifestations included cardiorespiratory symptoms, lower-limb edema, dyspnea, vomiting, cough, and fever.

## Sampling and Data Collection

All hospital records available during the study period were screened according to predefined eligibility criteria. A total of 36 hospital records meeting these criteria were included in the study. Data were retrospectively extracted from the eligible hospitalization records using a standardized data-collection form. The selected variables were entered into a Microsoft Excel database by a member of the research team. The completed data-collection forms and database



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entries were reviewed for completeness and internal consistency before analysis. Any unclear or inconsistent information was checked against the corresponding hospital record.

### Variables Studied

The dependent variable was the clinical outcome during hospitalization, classified as favorable or unfavourable. Independent variables included sociodemographic and socioeconomic characteristics (age, sex, place of residence, occupation, and ethnic background); clinical characteristics (mode of admission, therapeutic class and route of administration of the medicines used, diagnoses, and affected organs); and biological parameters (electrolyte profiles, glomerular filtration rate, and cardiac biomarkers).

### Operational Definition

Clinical Outcome: Clinical outcome was defined as the patient's status at discharge or at the end of hospitalization. A favorable outcome was defined as complete recovery or cure. An unfavorable outcome was defined as death, the need for dialysis, or referral to another health facility for specialized management.

## Statistical Analysis

All analyses were performed using R software (version 4.4.2). Categorical variables were summarized using absolute and relative frequencies with 95% confidence intervals. Continuous variables were described using means and standard deviations or medians, depending on their distribution.

Multiple correspondence analysis (MCA) was conducted to explore relationships between patient characteristics and clinical outcomes. Bivariate analyses were performed, followed by multivariable logistic regression including variables with a p-value<0.25 in the bivariate analysis. Statistical significance was set at $p<0.05$. Model fit was assessed using the Hosmer-Lemeshow goodness of fit test.

## Ethical Approval

The study was conducted in accordance with the principles of the Declaration of Helsinki. Authorization to conduct the study and access hospital records was obtained from the administration of Sikasso Regional Hospital. Given the retrospective nature of the study and the use of anonymized routinely collected hospital data, no direct contact with patients occurred during the research process.

All data were anonymized before analysis, stored securely, and used exclusively for scientific purposes in accordance with applicable data protection and confidentiality requirements.

## Results

### Descriptive Results

#### Sociodemographic and Clinical Characteristics

A total of 36 hospital records were included in the analysis. The corresponding patients had a mean age of 41.6±15.0 years and a median age of 42 years. Ages ranged from 13 to 78 years, with a first quartile of 30 years and a third quartile of 50.3 years. Patients aged 13-44 years accounted for 52.8% (n=19). Men represented 66.7% of patients (n=24), and 63.9% (n=23) lived in the city of Sikasso. The Senoufo-Mianka ethnic group was the most represented (30.6%, n=11). Farmers were the largest occupational group (44.4%, n=16), followed by homemakers (30.6%, n=11).

Clinically, cardiorespiratory conditions were the most common reason for hospital admission (63.9%, n=23). Before or during hospitalization, 44.4% of patients (n=16) had used antibiotics and 38.9% (n=14) had used anti-inflammatory drugs. Oral administration was the most common route of medicine use (86.1%, n=31). Renal failure was the most frequently reported diagnosis, affecting 50.0% of patients (n=18) (Table 1).

| Variables/ Categories | Absolute Frequency (n) | Relative Frequency (%) | 95% CI |
|---|---|---|---|
| Sociodemographic and Economic Characteristics | | | |
| Age Group (n =36) | | | |
| 13-44 years | 19 | 52.8 | [36.5 - 69.1] |
| ≥ 45 years | 17 | 47.2 | [30.9 - 63.5] |
| Sex (n =36) | | | |
| Female | 12 | 33.3 | [17.9 - 48.7] |
| Male | 24 | 66.7 | [51.3 - 82.1] |
| Origin (n =36) | | | |



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| | | | |
|---|---|---|---|
| Sikasso City | 23 | 63.9 | [48.2 - 79.6] |
| Outside Sikasso City | 13 | 36.1 | [20.4 - 51.8] |
| Profession (n =36) | | | |
| Homemaker | 11 | 30.6 | [15.5 - 45.6] |
| Farmer | 16 | 44.4 | [28.2 - 60.7] |
| Other | 9 | 25 | [10.9 - 39.1] |
| Ethnicity (n = 36) | | | |
| Bambara | 9 | 25 | [10.9 - 39.1] |
| Peulh | 9 | 25 | [10.9 - 39.1] |
| Senoufo–Mianka | 11 | 30.6 | [15.5 - 45.6] |
| Other | 7 | 19.4 | [6.5 - 32.4] |
| **Clinical Characteristics** | | | |
| Mode of admission (n = 36) | | | |
| Cardiorespiratory | 23 | 63.9 | [48.2 - 79.6] |
| Lower Limb Edema | 6 | 16.7 | [4.5 - 28.8] |
| Other | 7 | 19.4 | [6.5 - 32.4] |
| Drug Class (n =36) | | | |
| Antibiotics | 16 | 44.4 | [28.2 - 60.7] |
| Anti-Inflammatory | 14 | 38.9 | [23.0 - 54.8] |
| Other | 6 | 16.7 | [4.5 - 28.8] |
| Route of administration (n =36) | | | |
| Oral | 31 | 86.1 | [74.8 - 97.4] |
| Intravenous | 5 | 13.9 | [2.6 - 25.2] |
| Diagnosis (n =36) | | | |
| Cardiovascular | 8 | 22.2 | [8.6 - 35.8] |
| Kidney Failure | 18 | 50 | [33.7 - 66.3] |
| More than One Disease | 10 | 27.8 | [13.1 - 42.4] |
| Affected Organs (N =36) | | | |
| Heart | 5 | 13.9 | [2.6 - 25.2] |
| Kidney | 8 | 22.2 | [8.6 - 35.8] |
| Mixed | 23 | 63.9 | [48.2 - 79.6] |

Note: Data are presented as counts (n) and percentages (%). Other occupations included trader, shepherd, blacksmith, student, child, and butcher. Other ethnic groups included Sarakolé, Dogon, and Malinké. Other reasons for admission included anemia, dyspnea, vomiting, cough, diabetes, and fever. Other drug classes included sildenafil, antihypertensive drugs, diuretics, and paracetamol.

**Table 1:** Sociodemographic and clinical characteristics of patients with suspected exposure to substandard and falsified medicines in Sikasso, Mali (n=36).

## Distribution of Clinical Outcomes

Death was the most frequent outcome (47.2%, n=17), followed by complete recovery (27.8%, n=10) and dialysis (19.4%, n=7). Cure and referral were each observed in 2.8% of patients (n=1) (Table 2).



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| Variables / Categories | Absolute frequency (n) | Relative frequency (%) | 95% CI |
|---|---|---|---|
| Detailed Hospitalization Outcomes (N =36) | | | |
| Cure | 1 | 2.8 | [0.5 - 14.2] |
| Complete Recovery | 10 | 27.8 | [15.8 – 44.0] |
| Death | 17 | 47.2 | [32.0 – 63.0] |
| Dialysis | 7 | 19.4 | [9.8 – 35.0] |
| Referral | 1 | 2.8 | [0.5 - 14.2] |

**Note:** Data are presented as counts(n) and percentages (%). Clinical outcomes were subsequently classified as favorable (cure or complete recovery) or unfavorable (death, dialysis, or referral) for analytical purposes.

**Table 2:** Detailed hospitalization outcomes among patients with suspected exposure to substandard and falsified medicines (n=36).

For analytical purposes, clinical outcomes were grouped into favorable and unfavorable categories. Overall, 69.4% (n=25) of patients experienced an unfavorable clinical outcome during hospitalization, whereas 30.6% (n=11) had a favorable outcome (Figure 1).

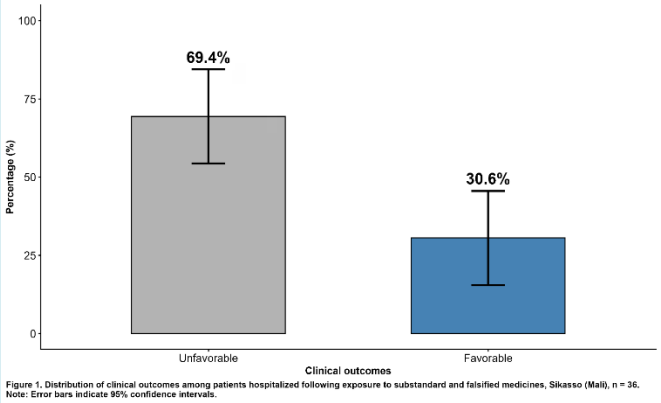



**Figure 1:** Distribution of clinical outcomes among patients hospitalized following exposure to substandard and falsified medicines, Sikasso (Mali), n=36.

## Analytical Results

### Bivariate Analysis

Bivariate analysis showed a statistically significant association between age group and clinical outcome ($\chi^2$=5.36; p=0.02). Patients aged ≥45 years had higher odds of an unfavorable clinical outcome than those aged 13-44 years (OR=6.8; 95% CI: 1.2-38.0). No statistically significant associations were observed for the other sociodemographic or clinical characteristics examined (Table 3).

| Variables / Categories | Clinical Outcomes | | $\chi^2$ | P value[2] | OR | 95% CI |
|---|---|---|---|---|---|---|
| | Favorable (n=11[1]) (n (%)) | Unfavorable (n=25[1]) (n (%)) | | | | |
| Sociodemographic and Economic Characteristics | | | | | | |
| Age Group | | | | | | |
| 13-44 years | 9 (81.82) | 10 (40.00) | 5.36 | 0.02 | Ref | - |
| ≥ 45 years | 2 (18.18) | 15 (60.00) | - | - | 6.8 | [1.2-38.0] |
| Sex | | | | | | |



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| | | | | | | |
|---|---|---|---|---|---|---|
| Male | 8 (72.73) | 16 (64.00) | 0.26 | 0.72 | - | - |
| Female | 3 (27.27) | 9 (36.00) | - | - | - | - |
| Origin | | | | | | |
| Sikasso city | 8 (72.73) | 15 (60.00) | 0.54 | 0.71 | - | - |
| Outside Sikasso city | 3 (27.27) | 10 (40.00) | - | - | - | - |
| Profession | | | | | | |
| Homemaker | 2 (18.18) | 9 (36.00) | 3.67 | 0.21 | - | - |
| Farmer | 4 (36.36) | 12 (48.00) | - | - | - | - |
| Other | 5 (45.45) | 4 (16.00) | - | - | - | - |
| Ethnicity | | | | | | |
| Bambara | 5 (45.45) | 4 (16.00) | 5.55 | 0.16 | - | - |
| Peulh | 1 (9.09) | 8 (32.00) | - | - | - | - |
| Senoufo–Mianka | 2 (18.18) | 9 (36.00) | - | - | - | |
| Other | 3 (27.27) | 4 (16.00) | - | - | - | - |
| **Clinical Characteristics** | | | | | | |
| Mode of Admission | | | | | | |
| Cardiorespiratory | 9 (81.82) | 14 (56.00) | 4.53 | 0.09 | - | - |
| Lower Limb Edema | 2 (18.18) | 3 (12.00) | - | - | - | - |
| Other | 0 (0.00) | 8 (32.00) | - | - | - | - |
| Drug Class | | | | | | |
| Antibiotics | 4 (36.36) | 12 (48.00) | 0.43 | 0.89 | - | - |
| Anti-Inflammatory | 5 (45.45) | 9 (36.00) | - | - | - | - |
| Other | 2 (18.18) | 4 (16.00) | - | - | - | - |
| Route of Administration | | | | | | |
| Oral | 9 (81.82) | 22 (88.00) | 0.24 | 0.63 | - | - |
| Intravenous | 2 (18.18) | 3 (12.00) | - | - | - | - |
| Diagnosis | | | | | | |
| Cardiovascular | 3 (27.27) | 5 (20.00) | 0.77 | 0.72 | - | - |
| Kidney failure | 6 (54.55) | 12 (48.00) | - | - | - | - |
| More than one disease | 2 (18.18) | 8 (32.00) | - | - | - | - |
| Affected Organs | | | | | | |
| Heart | 2 (18.18) | 3 (12.00) | 0.61 | 0.66 | - | - |
| Kidney | 3 (27.27) | 5 (20.00) | - | - | - | - |
| Mixed | 6 (54.55) | 17 (68.00) | - | - | - | - |

Note: Other occupations included trader, shepherd, blacksmith, student, child, and butcher. Other ethnic groups included Sarakolé, Dogon, and Malinké. Other reasons for admission included anemia, dyspnea, vomiting, cough, diabetes, and fever. Other drug classes included sildenafil, antihypertensive drugs, diuretics, and paracetamol.

Table 3: Factors associated with clinical outcomes among patients with suspected exposure to substandard and falsified medicines at Sikasso Regional Hospital, Mali: bivariate analysis (n=36).

## Multivariate Analysis

### Multiple Correspondence Analysis (MCA)

The MCA identified two contrasting profiles. Favorable clinical outcomes clustered with younger age (13-44 years), residence in Sikasso city, Bambara ethnicity, cardiorespiratory conditions, and oral anti-inflammatory drug use. In contrast, unfavorable clinical outcomes clustered with age ≥45 years, residence outside Sikasso city, Peulh and Senoufo-Mianka ethnicities, and multiple diagnoses (Figure 2).



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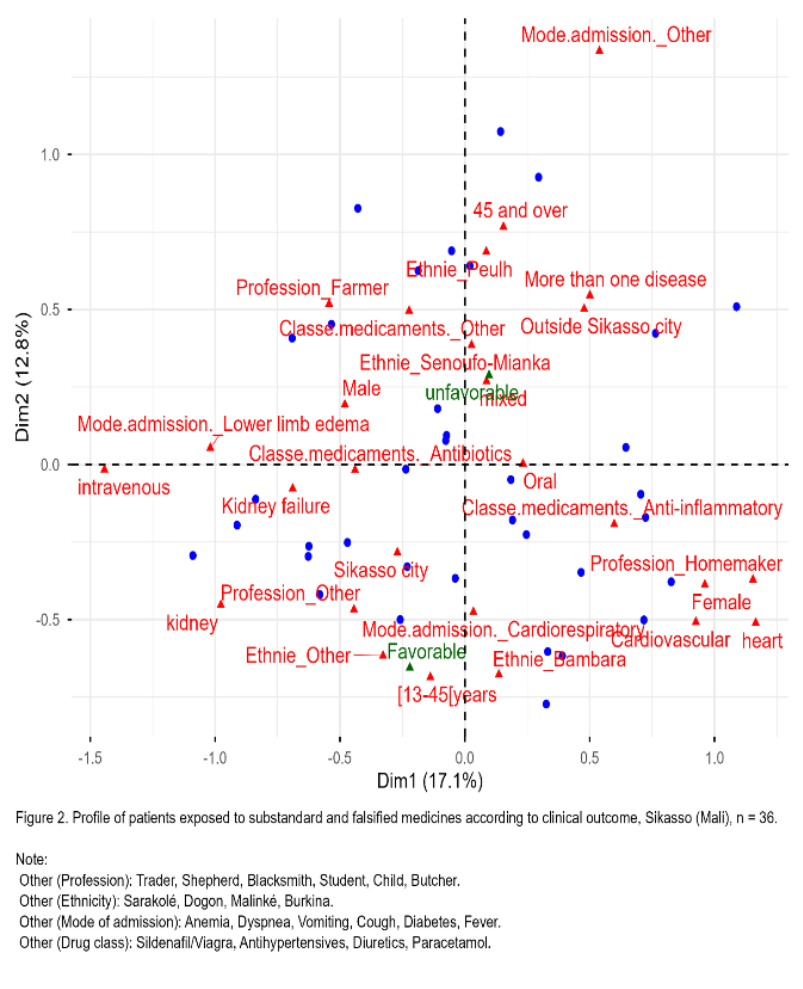



Figure 2. Profile of patients exposed to substandard and falsified medicines according to clinical outcome, Sikasso (Mali), n = 36.

Note:
Other (Profession): Trader, Shepherd, Blacksmith, Student, Child, Butcher.
Other (Ethnicity): Sarakolé, Dogon, Malinké, Burkina.
Other (Mode of admission): Anemia, Dyspnea, Vomiting, Cough, Diabetes, Fever.
Other (Drug class): Sildenafil/Viagra, Antihypertensives, Diuretics, Paracetamol.

**Figure 2:** Profile of patients exposed to substandard and falsified medicines according to clinical outcome, Sikasso (Mali), n = 36.

### Multivariable Logistic Regression

Age≥45 years was associated with higher odds of an unfavorable clinical outcome compared with age 13-44 years (aOR=6.7; 95% CI: 1.2–38.1; p=0.02) (Table 4).

| Co-Variables / Categories | aOR | 95% CI | P (LR-test) |
|---|---|---|---|
| Age Group | | | |
| ≥45 years vs 13–44 years | 6.7 | [1.2-38.1] | 0.02* |
| Sex | | | |
| Female vs Male | 1.5 | [0.3-7.9] | 0.64 |

**Table 4:** Final multivariable logistic regression model of factors associated with clinical outcomes among patients with suspected exposure to substandard and falsified medicines at Sikasso Regional Hospital, Mali (n=36).

## Discussion

This retrospective study found that 69.4% of patients with suspected exposure to SF medicines experienced unfavorable clinical outcomes, including death, dialysis, or referral for specialized management. This high proportion highlights the potential clinical burden among patients hospitalized with suspected SF medicine exposure. However, because exposure was not systematically confirmed through pharmaceutical analysis, these outcomes cannot be directly attributed to SF medicines. Rather, the findings describe the clinical outcomes observed among patients with documented suspected exposure. Previous evidence has documented serious adverse effects, morbidity, and deaths associated with falsified medicines, although the available evidence remains heterogeneous and often relies on reported incidents rather than systematically followed patient cohorts [10].

Age≥45 years was associated with higher odds of unfavorable outcomes in the exploratory analysis. Older



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patients may be more vulnerable to severe clinical outcomes because of underlying comorbidities, reduced physiological reserve, and a potentially lower capacity to tolerate toxic effects or treatment failure. This finding has a practical implication for clinical care: older patients presenting with suspected exposure to SF medicines may require particularly careful clinical assessment and monitoring. Nevertheless, the wide confidence interval around the association indicates substantial statistical uncertainty, and this result should therefore be interpreted cautiously.

The MCA also identified contrasting patient profiles. Unfavorable outcomes clustered with older age, residence outside Sikasso city, Peulh and Senoufo-Mianka ethnicities, and multiple diagnoses, whereas favorable outcomes clustered with younger age, residence in Sikasso city, Bambara ethnicity, cardiorespiratory conditions, and oral anti-inflammatory drug use. Geographic differences may reflect disparities in access to healthcare, delays in reaching referral services, or greater reliance on informal medicine supply channels outside urban areas. However, these explanations remain hypotheses because these factors were not directly measured in this study. Similarly, the clustering observed for ethnicity should not be interpreted as indicating an independent effect of ethnicity. These MCA findings are descriptive and exploratory and require confirmation in larger studies. Their main implication is to highlight potentially relevant social, geographic, and clinical characteristics that should be investigated more systematically in future research.

The findings are consistent with the broader literature showing that SF medical products constitute an important public-health problem, particularly in settings where medicine-quality surveillance and regulatory systems remain limited [1-3]. Previous systematic evidence from low- and middle-income countries estimated an overall prevalence of 13.6% of poor-quality essential medicines, with a higher pooled prevalence of 18.7% in Africa [11]. More recent African evidence reported that approximately 22.6% of tested medical products failed at least one quality-control test [2]. In the present study, antibiotics were the most frequently reported drug class, although no statistically significant association between drug class and clinical outcome was observed. Previous evidence has also identified antibiotics among therapeutic classes affected by medicine-quality problems [2,3,12]. This finding does not establish that the antibiotics used by these patients were substandard or falsified, but it reinforces the relevance of medicine-quality surveillance for commonly used therapeutic products.

The substantial proportion of renal failure and the occurrence of dialysis among the patients also warrant attention. Previous reports have documented severe organ toxicity associated with contaminated medicines. The 2022 outbreak in The Gambia, involving pediatric syrups contaminated with ethylene glycol and diethylene glycol, was associated with acute kidney injury and deaths among children [4-6]. However, direct comparison should be made cautiously because the suspected products in the present study were not systematically subjected to pharmaceutical or toxicological testing. These findings highlight the value of incorporating pharmaceutical analysis of suspected products into pharmacovigilance investigations to better establish links between suspected exposure and observed clinical complications.

This study provides hospital-based evidence on a poorly documented public-health issue in Sikasso and combines descriptive statistics, MCA, and regression analyses to examine clinical outcomes and potential associated factors. Several limitations should be considered. The small sample size (n=36), resulting from the exhaustive inclusion of eligible hospital records available during the study period, limited statistical power and precision, as reflected by the wide confidence intervals, and increased the risk of type II error. Therefore, the observed associations should be interpreted cautiously and considered exploratory. In addition, the single-center design limits the generalizability of the findings. Suspected SF medicine exposure was based primarily on information available in hospital records and was not systematically confirmed by pharmaceutical analysis, creating a risk of exposure misclassification. The retrospective design also limits the completeness of available information and precludes causal inference between suspected SF medicine exposure and the observed clinical outcomes.

Overall, these findings support stronger pharmaceutical surveillance, pharmacovigilance, and control of informal medicine supply channels, together with improved recognition and reporting of suspected SF products by healthcare professionals. Larger prospective multicenter studies with sample sizes determined through an a priori calculation and adequate statistical power, incorporating physicochemical analysis of suspected medicines and longitudinal follow-up, are needed to confirm these exploratory findings and better characterize factors associated with clinical outcomes.

## Conclusion

This study found a high frequency of unfavorable clinical outcomes among patients with suspected exposure to SF medicines at Sikasso Regional Hospital. More than two-thirds experienced unfavorable outcomes, and age≥45 years was associated with higher odds of an unfavorable clinical outcome.



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These findings support strengthening pharmaceutical surveillance, regulation of medicine supply chains, and pharmacovigilance, particularly in settings where informal distribution channels remain important. Larger prospective multicenter studies with adequate statistical power and incorporating pharmaceutical analysis of suspected products are needed to confirm these exploratory findings and better characterize factors associated with clinical outcomes.

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## Funding

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## Conflicts of Interest

The authors declare no conflicts of interest.

## Ethical Approval

Authorization to conduct the study and access hospital records was obtained from the administration of Sikasso Regional Hospital. Given the retrospective nature of the study and the use of anonymized routinely collected hospital data, no direct contact with patients occurred. The study was conducted in accordance with the principles of the Declaration of Helsinki.

## References

1. World Health Organization (2024) Substandard and falsified medical products. World Health Organization.

2. Mekonnen BA, Yizengaw MG, Worku MC (2024) Prevalence of substandard, falsified, unlicensed and unregistered medicine and its associated factors in Africa: a systematic review. J Pharm Policy Pract 17(1): 2375267.

3. McManus D, Naughton BD (2020) A systematic review of substandard, falsified, unlicensed and unregistered medicine sampling studies: a focus on context, prevalence, and quality. BMJ Glob Health 5(8): e002393.

4. World Health Organization (2022) Medical Product Alert N°6/2022: Substandard (contaminated) paediatric medicines. The Gambia.

5. World Health Organization (2022) Medical Product Alert N°7/2022: Substandard (contaminated) paediatric liquid dosage medicines.

6. Bastani P, Jammeh A, Lamar F, Malenfant JH, Adewuyi P, et al. (2023) Acute Kidney Injury Among Children Likely Associated with Diethylene Glycol–Contaminated Medications- The Gambia, 2022. MMWR Morb Mortal Wkly Rep 72(9): 217-222.

7. Maffioli EM, Lu Y, Anyakora C (2025) Substandard and falsified antibiotics are associated with antimicrobial resistance: a retrospective country-level analysis. BMJ Glob Health 10(6): e017078.

8. Haidara DBS, Barre K, Cissouma A, Traore AK, Traore SA, et al. (2023) Evolution of the main hospital activity indicators in Sikasso Hospital, Mali, 2015-2021. Fortune J Health Sci 6(2): 210-214.

9. Haidara DBS, Kante M, Cissouma A, Traore M, Traore O, et al. (2023) Practical Knowledge and Attitudes of Caregivers Faced with Covid-19 At Sikasso Hospital - Mali. Fortune J Health Sci 6(2): 215-221.

10. Rahman MS, Yoshida N, Tsuboi H, Tomizu N, Endo J, et al. (2018) The health consequences of falsified medicines - A study of the published literature. Trop Med Int Health 23(12): 1294-1303.

11. Ozawa S, Evans DR, Bessias S, Haynie DG, Yemeke TT, et al. (2018) Prevalence and estimated economic burden of substandard and falsified medicines in low and middle-income countries: a systematic review and meta-analysis. JAMA Netw Open 1(4): e181662.

12. Antignac M, Diop BI, Macquart de Terline D, Bernard M, Do B, et al. (2017) Fighting fake medicines: First quality evaluation of cardiac drugs in Africa. Int J Cardiol 243: 523-528.



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